# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE
## Health Technology Appraisal

### Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (review of technology appraisal guidance 57)

**Responses to consultee and commentator comments on the ACD and to comments received through the NICE website**

| Comment from | Nature of comment | Response |
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| Clinical Expert 1 | I believe that the recommendations made in section 1 are sound and form a suitable basis for NHS guidance.<br>I welcome the introduction of the new categories of those people suitable for a trial of CSII, viz. those with type 1 diabetes in whom it has been impossible to maintain an HbA1c <8.5% on best MDI, and those children where MDI is considered to be inappropriate.<br>The Committee's consideration of the evidence in section 4.3 is balanced and well judged, particularly assessing the totality of evidence favouring reduction in HbA1c and severe hypoglycaemia on CSII, the better expected results in those with poor control on MDI, the Committee's view on the difficulties and differences of opinion on performing meaningful cost effectiveness studies, and the conclusion that CSII is an appropriate use of resources.<br>The proposed review of guidance in February 2011 is appropriate in my view. | Comment noted |
| Clinical Expert 1 | Section 4.1.8.<br>This section states that 'In summary, there is little evidence from RCTs of a significant difference between CSII and MDI therapy in terms of a decrease in HbA1c levels or in the rate of severe hypoglycaemic episodes in people with diabetes mellitus'. The Committee wisely later considers that 'the small number of RCTs cannot be relied upon to capture the benefits of CSII' (section 4.3.2). However, I believe that the conclusions of 4.1.8, and the discussion of the data in section 4.1.12 upon which the conclusions are based, need modification and rewording for the following reasons.<br>There are 5 RCTs comparing CSII with MDI based on long-acting insulin analogues (Doyle 2004, Maran 2005, Hirsch 2005, Bolli 2006 and Thomas 2007). The mean HbA1c was lower on CSII than MDI in 4 of the studies and equal in one. Meta-analysis shows that the mean HbA1c difference is significantly lower on CSII vs. MDI: 0.21 (95% CI 0.06 to 0.35%).<br>In three RCTs of CSII vs. MDI based on isophane insulin (Cohen 2003, Weintrob 2003 | The FAD contains a summary of the evidence that was placed before the Appraisal Committee and upon which the Appraisal Committee made its decision. The methods and results are detailed in the Assessment Report. |

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| | and Hoogma 2006), the mean difference in HbA1c is also 0.21 (0.03 to 0.39%) when meta-analysis is performed.<br>Thus, the evidence from RCTs suggests a small but significant difference in mean HbA1c and that the results are similar for MDI based on either isophane or long-acting analogues. However, the subjects in these trials were relatively well controlled, with a mean HbA1c of 7.5% on MDI. A pooled analysis of individual patient data from 3 RCTs comparing MDI vs CSII confirms what is known from observational studies - that the difference in HbA1c on switching to CSII is greatest in those worst controlled on MDI (Retnakaran R et al. Continuous subcutaneous insulin infusion versus multiple daily injections. The impact of baseline A1c. *Diabetes Care* 2004; 27: 2590-6). Thus, although the difference in HbA1c was 0.2% on average in RCTs, it was much larger in individual, poorly controlled subjects in RCTs.<br>No study using MDI based on long-acting analogues is suitable for analysis of severe hypoglycaemia (as the ACD notes), but there are 3 RCTs based on isophane that can be analysed (Cohen, Weintrob and Hoogma). The severe hypoglycaemia rate was reduced in all three studies (79, 66 and 60% reduction), with a mean rate ratio of 3.4. An HTA systematic review concludes that long-acting insulin analogues do not reduce severe hypoglycaemia compared with isophane MDI (Warren 2004).<br>Although, as the ACD correctly says, observational studies show an apparently greater improvement in HbA1c than RCTs, this is partly because the clinic-based subjects are more poorly controlled on MDI, and when statistical adjustment is made for HbA1c and age, the difference between RCTs and observational studies is very small (mean 0.2% HbA1c).<br>I therefore recommend that the Committee consider rewording the summary of the clinical evidence section as: 'There is good evidence from both a relatively small number of RCTs and from a larger number of observational studies that HbA1c and the frequency of severe hypoglycaemia are significantly reduced by switching from MDI to CSII'. | The Appraisal Committee agreed that the population in observational studies more closely resembled the population in normal clinical practice who would be considered for CSII therapy. |

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| Clinical Expert 1 | Minor point:<br>Section 3.1. The Starlet pump is not yet available. | FAD section 3.1 has been amended accordingly. |
| Clinical Expert 2 | Do you consider that all of the relevant evidence has been taken into account?<br>Yes, I think there has been a comprehensive review of the evidence | Comment noted |
| Clinical Expert 2 | Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?<br>I think the clinical effectiveness interpretation is reasonable. In terms of cost effectiveness it is difficult to know quite what cost to attribute to hypoglycaemia requiring hospitalisation, which should be at least be that of an A&E attendance, more than a simple out-patient cost but as stated in the ACD not the cost of an in-patient stay. Whether this makes a material difference to the cost-effectiveness analysis is questionable, since the major factor for hypoglycaemia related costs is the disutility of fear of hypoglycaemia. | Comment noted |
| Clinical Expert 2 | Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?<br>I think that the recommendations regarding use in children are excellent and will enable much more appropriate use of pump therapy for this patient group. The only issue with respect to this is the definition of the cut-off age - this would best be written as aged 12 and under, to encompass all primary school aged children, with children older than 12 then included with the adult guidance. As far as the latter is concerned the HbA1c cut-off appears arbitrary, although presumably reflects the view from the cost-effectiveness analysis that the ICER was only acceptable with a highish starting HbA1c and a significant drop on CSII. Whilst there is little doubt that this change to the guidance opens up access to CSII to a significantly larger adult population, the problem is that this HbA1c target does not reflect other NICE guidance. For example in the draft guidance | The age has been clarified in the FAD (see FAD sections 1.2 and 4.3.8).<br>The Appraisal Committee is not recommending a HbA1c of 8.5% as the target. This has been clarified in FAD sections 4.3.6 |

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| | for Diabetes in Pregnancy, there is a statement that CSII should be considered where MDI has failed to achieve the target HbA1c of 6.1% with no mention of hypoglycaemia. For consistency it would therefore read better if this guidance stated that CSII should be considered when the individual HbA1c target is not achieved<br>ie "it has been impossible for the individual to maintain their target haemoglobin A1c (HbA1c) level"<br>It would also be better if the following section read<br>" the person has experienced disabling hypoglycaemia ...."<br>as there are a number of patients who having once experienced disabling hypoglycaemia make every effort to avoid it in future to the detriment of their overall control as defined by HbA1c.<br>Finally as was alluded to at the Committee meeting there are a cohort of patients with type 2 diabetes who effectively become like a patient with type 1 diabetes in terms of intensified insulin therapy, and might be considered for CSII if MDI fails to optimise glycaemic control. Whilst I would not want to encourage CSII use in type 2 diabetes it might be reasonable to state "CSII is not routinely recommended for people with type 2 diabetes". | The Appraisal Committee was aware that patients who experience hypoglycaemia may accept poorer glycaemic control. The Appraisal Committee considered that avoiding the fear of hypoglycaemia did improve quality of life and make CSII cost effective.<br><br>The Appraisal Committee was not able to make a recommendation for type 2 diabetes due to lack of evidence of effectiveness and cost effectiveness (see FAD section 4.3.10) |
| Clinical Expert 2 | Are there any equality related issues that may need special consideration?<br>I think these have been adequately addressed in differentiating between children and adults. | Comment noted |
| Patient Expert 1 | I believe that the Committee considered all relevant evidence. | Comment noted |
| Patient Expert 1 | I think it was observed at the meeting that the cost effectiveness models are not applicable to paediatric use of CSII, as addressed in Section 4.3.7. I feel that the | The Appraisal Committee were aware of the |

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| | implications and resource impact on the NHS for paediatric use are inaccurate. However, the preliminary views are appropriate. | limitations of the model in its application to children (see FAD section 4.3.8). |
| Patient Expert 1 | I believe that the provisional recommendations are sound and suitable. The criteria for MDI failure is a welcome addition. Section 1.5 might benefit from more concrete parameters for continuation of CSII. I agree with [clinical experts name removed] suggestion in his response to the assessment report, that success of pump therapy might be better defined as a reduction of 1% in HbA1c and severe hypos reduced by 50% over a one year period. | Targets for improvements on CSII are to be decided on an individual patient basis in consultation with health professionals. |
| Patient Expert 1 | I see no equality related issues. | Comment noted |
| Patient Expert 2 | Do you consider that all of the relevant evidence has been taken into account?<br>No. In section 2.5 the report states that "Good control is indicated by a value of less than 7.5%..." yet in section 1.3, MDI is deemed to have failed to provide adequate control only is HbA1c is 8.5% or higher. That means that patients whose HbA1c is between 7.5% and 8.5% are considered to have sub-optimal control but will fall outside the criteria for getting a pump. The document does not make reference to any evidence to support a threshold HbA1c of 8.5%. | The Appraisal Committee has not recommended a target HbA1c level of 8.5%. It has made recommendations for when CSII can be used cost-effectively use. This has been clarified in FAD sections 4.3.6 |
| Patient Expert 2 | Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?<br>No. Section 4.1.3 states that observational studies were larger, of longer duration and more representative of people likely to be considered for CSII therapy, yet other sections repeatedly refer to the lack of statistically significant results in RCTs. This appears to weaken the document and gives the impression that NICE is rather reluctant in its | Section 4.1.3 is an accurate description of the available evidence. |

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| | approval of CSII. | |
| Patient Expert 2 | Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?<br>No. The Technology Appraisal issued in 2003 is already widely misinterpreted by PCTs and clinicians, and this review will simply add more confusion. The provisional recommendations seem to be a backward step from the earlier TA and it seems that patients will have an even harder battle to try to get this treatment. Please see further comments below. | The FAD attempts to be as clear as possible but cannot cover every particular circumstance and allows for the intervention to be tailored to an individual. |
| Patient Expert 2 | Are there any equality related issues that may need special consideration?<br>No. | Comment noted |
| Patient Expert 2 | Section 1.1 - Needs clarification. Would a child of 11 years and a few months fall within this category? | This has been clarified in FAD guidance section and section 4.3.9 |
| Patient Expert 2 | Section 1.5 - Cannot be applied in the long term, or this would appear to allow a pump to be taken away after control has been optimised. It needs to be noted that HbA1c will not always fall with improved control, as repeated hypoglycaemic episodes can keep the HbA1c artificially low. Although the paragraph allows for an alternative ("or a decrease in the rate of ...") I suggest that this second half will be disregarded and people who are established on pump therapy will find their PCTs are trying to take their pumps back. Further, the setting of any targets needs to include what the clinicians will do to achieve those targets, in terms of support and education. Patients are already being threatened with the removal of their pump if their control deteriorates, which suggests that some clinicians see pump therapy as a reward rather than a treatment. I cannot understand how removal of a treatment tool can help to improve a bad situation. This section will make the current situation worse. | The Appraisal Committee could not recommend continuation of an expensive treatment in the continuing absence of any evidence of benefit. The FAD does say that further support is required before withdrawal of CSII. |
| Patient Expert 2 | Section 1.6 - This is completely exclusive. This document should make allowance for individual cases whose clinician believes they would benefit from CSII to access it. | All NICE guidance comes with the caveat that an |

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| | | individual physician can allow for exceptions on clinical grounds. |
| Patient Expert 2 | Section 2.2 - It should be noted that Type 2 diabetes mellitus occurs MAINLY in adults, but there is an increasing number of younger people, including teenagers, being diagnosed with Type 2 diabetes. The long term implications of this in the individual may show greater cost effectiveness if CSII is adopted sooner rather than later. | Comment noted – included in FAD section 2.2 |
| Patient Expert 2 | It would be helpful if the document also made reference to how long it is reasonable to try to optimise control with methods other than CSII, after an initial approach about CSII. It should also be noted that whilst structured education is useful and helpful to many diabetics, education does not have to be delivered in a structured environment. In this way, a patient's existing knowledge and experience of carbohydrate counting and dosage adjustment can be taken into account. If the appraisal insists on structured education prior to commencement of CSII, then patients will continue to wait sometimes more than 18 months for a place on such a course. | The duration of trial of CSII is an individual decision for patients and health professionals (see FAD section 4.3.14). The importance of structured education had been stressed in the FAD, see section 4.3.12 and 4.3.15 |
| ABHI – Cross Industry | 1) Potential confusion of “mean baseline” and “minimum" HbA1c level<br>Recommendation 1.3 states that one parameter potentially indicating insulin pump use is that;<br>*“It has been impossible for the individual to maintain a haemoglobin A1c (HbA1c) level of less than 8.5%”.*<br>We are unclear how the minimum threshold of 8.5% has been arrived at. The economic analyses submitted by both the Assessment Team and as part of the industry submission demonstrated that insulin pump therapy in populations with a minimum threshold of 7.5% would be cost effective, taking in to consideration improved glycaemic control, the reduction in hypoglycaemic events and related quality of life benefits. The mean HbA1c baseline values used by industry and the Assessment Team were 8.1% | The Appraisal Committee does not recommend a target HbA1c level of 8.5% as a threshold. This is the level at which the use of CSII was judged cost-effective.<br>The assessment group did not model average population values. This was because the CORE model |

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| | and 8.8%, respectively. The appraisal Committee appears to have taken the mean starting "baseline" value as the absolute minimum value acceptable. Clearly shifting the minimum threshold to 8.5% would shift the population mean HbA1c up significantly. As indicated in the industry submission, epidemiological data from the HODaR database (Cardiff) indicates that in the population of type 1 diabetes whose HbA1c is >7.5%, the population mean HbA1c is 10.1%. Therefore, if NICE restricts access to those over 8.5%, the population mean will be significantly higher.<br>Summary: We request the Committee consider lowering the minimum HbA1c level to 7.5% as an indictor for the option of insulin pump therapy. | does not allow covariance between the baseline level of HbA1c and the drop on CSII. |
| ABHI – Cross Industry | 2) The use of the term "adequate control"<br>Without prejudice of the issue above, in Recommendation 1.2 – the wording;<br>"MDI therapy (including, if appropriate, the use of long-acting insulin analogues) has failed to provide adequate control of diabetes mellitus as defined in section 1.3"<br>We recommend that the word "adequate" be deleted, and the sentence read, "*MDI therapy has failed to provide control of diabetes mellitus as defined in 1.3*." We request this because 1.3 would effectively define "adequate control" as an HbA1c less than 8.5%. This is clearly not "adequate control" by any clinical definition. Whilst we propose that the evidence supports the use of insulin pumps as an option for anyone who cannot be controlled at an HbA1c <7.5%, if the Committee persists with 8.5% as the access threshold for insulin pump therapy, it should not imply that an HbA1c level below that is "adequate control".<br>Summary: We request the word "adequate" be dropped from paragraph 1.2. | This has been clarified in FAD guidance section |
| ABHI – Cross Industry | 3) Relative and Absolute lack of insulin in Type 2 Diabetics<br>We wish to draw to the Committee's attention the brief summary in Paragraph 2.1. The summary states;<br>"Type 2 diabetes mellitus is characterised by insulin resistance and is often associated with obesity. In type 2 diabetes mellitus, the pancreas initially responds by increasing | Comment noted and changed in FAD. |

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| | insulin production, but over time this excess production cannot be maintained, leading to a relative lack of insulin."<br>Though insulin resistance is clearly a very important contributing factor in the development of type 2 diabetes, the pathophysiologic description above does not take into account the well-described insulin secretory defect which results not only in a "relative" - but with time - in an "absolute" reduction of insulin. The United Kingdom Prospective Diabetes Study (UKPDS) clearly demonstrated that pancreatic islet function was about 50% of normal at the time of diagnosis and continued to decline with increasing duration of diabetes. This progressive decline occurred regardless of the treatment patients received.[1,2]<br>From a clinical perspective, patients with type 2 diabetes who are at the "end of the spectrum" with regards to beta-cell function (having an absolute insulin deficiency), are often very similar to patients with type 1 diabetes. These are patients that if not well controlled on multiple daily injections of insulin, can often benefit significantly from insulin pump therapy.<br>Summary: We request the Committee consider permitting access to uncontrolled patients with type 2 diabetes failing on MDI where it is clinically evident that the patient has absolute insulin deficiency. | The Appraisal Committee noted there are type 2 patients who may benefit from CSII but did not think that there was sufficient evidence to make a recommendation, see FAD section 4.3.10 |
| ABHI – Cross Industry | <u>4) Clarification on age cut-off for paediatrics</u><br>With respect to the definition of the child population in section 1.1, we believe that the wording should be changed from "as a treatment option for children younger than 11 years" to "as a treatment option for children up to 12 years of age". This would give clarity to pre and post secondary school children. The wording in section 1.2 would need to be amended accordingly to children older than 12 years of age. | This has been clarified in FAD guidance section |
| ABHI – Cross Industry | <u>Minor Comments</u><br>Finally, we have two comments on the response to our comments on the Assessment Report. We recognise the Assessment team has not accepted our cost of a severe | The study for costs was done on patients attending |

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| | hypo event. However they have not acknowledged the misquoted data referenced from TA53. We request this be acknowledged in any future monograph; otherwise the misquote could become fact in future citations. Furthermore, there is no acknowledgement of the additional evidence provided by the manufacturers who identified a new data source demonstrating that the fear of hypos resulted in a loss of utility of up to 4.7%. Whilst we are aware that there is no obligation to include this data in section four of the guidance, we feel it would add value as it allows the effect of fear of hypos to be quantified. | A&E and was not felt to be appropriate to all diabetics experiencing hypoglycaemia.<br>The figure from TA 53 was updated to bring it in line with costing in the rest of the report.<br>The Appraisal Committees recognised the importance of the effect of the fear of hypoglycaemic episodes on quality of life , see FAD sections 4.3.3 and 4.2.7 |
| Animas | In addition, we also have one specific comment to make as ANIMAS. We wish to advise the Institute that the details of the ANIMAS pump, detailed in paragraph 3.1, have recently changed. The ANIMAS IR1200 has been phased out, and replaced by the ANIMAS 2020. The mechanics of the pump are the same. The key differences being that the IR2020 is enhanced by being waterproof to a depth of 12m, and having a colour screen (aiding easier reading of alerts e.g. at night, or from a distance [such as a parent reading over the shoulder of their child]). The IR2020 was launched on 3rd December, at a list price £2,600, the same as the IR1200 it replaces. | The FAD has been amended accordingly. |
| Association of British Clinical Diabetologists | ABCD would support all these comments from Dr Hammond and commend NICE for a very helpful document.(Comments identical to clinical expert) | Comment noted |

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| British Dietetic Association | Do you consider that all of the relevant evidence has been taken into account?<br>We have no further evidence to add and generally agree with the interpretation of the evidence base given | Comment noted |
| BDA | Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?<br>We note in the conclusion of the assessment report (section 7.5) that "If (pump) use is expanded, there will be considerable educational need for both patient and healthcare professional. The education for patients should include structured education such as DAFNE"<br>We are disappointed that this part of the assessment report conclusion does not appear to have been incorporated into the main ACD guidance<br>The assessment report states that the cost per patient of a DAFNE course is about £240. Indeed NICE HTA 60 (section 3.5) states that the cost per patient of a DAFNE course is around £545 (though we understand this figure is out of date and £ 260 – 300 may be the most current figure.) This is not an insubstantial figure. Unfortunately, in many areas, PCTs have refused to commission these courses on the basis of their cost or on the basis that this education should be provided as part of the current service<br>We are disappointed that structured education for pump patients (and the cost implications of this) have not been given adequate coverage in the ACD. | The Appraisal Committee did not consider the evidence for structured education in a systematic manner as this was outside the remit for this appraisal. The importance of such education has been stressed in FAD section 4.3.12 and 4.3.15 |
| BDA | Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?<br>We welcome the change in guidance on hypoglycaemia to now include the persistent anxiety about recurrence of hypoglycaemia that is associated with adverse effects on quality of life.<br>We are concerned (section 1.4) that whilst the trained specialist team is defined as a | The Appraisal Committee did not hear evidence for |

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| | physician with a specialist interest in insulin pump therapy and a diabetes specialist nurse; the specialism of the dietitian in not mentioned. We strongly feel that the ACD should change the term “dietitian” to the term “advanced diabetes specialist dietitian.” This is important as general dietitians do not have the skills or experience necessary to manage patients on insulin pumps.<br>We feel ( section 1.2 ) that in addition to pump users and carers having the commitment and competence to use pump therapy effectively, there should be a statement added to the effect that pump users should also be free of major psychological and psychiatric problems ( Pickup and Keen 2001)<br>We are disappointed that the ACD does not make an attempt to more clearly define the term” high level of care” (section 1.3) in relation to the failure of MDI. The assessment report, in its conclusion states that “*The education for ( pump ) patients should include structured education such as DAFNE”* We are confused as to why this pivotal recommendation does not appear to feature in the main body of the ACD<br>We feel that the ACD should recognize structured education( as outlined in NICE HTA 60) or 1:1 interventions with detailed input around matching insulin to carbohydrate intake as being necessary before MDI can be said to have failed. | the exact composition of specialist teams for CSII. This will be a decision for the individual centre.<br><br>The FAD has been amended accordingly.<br><br>An attempt has been made to define this difficult term – the FAD suggests this should be as per NICE clinical guidelines, see FAD section 4.3.13. |
| BDA | Are there any equality related issues that may need special consideration?<br>We are unsure why a distinction has been made between adolescents and children < 11 years in terms of their eligibility for the pump. Indeed most of the research quoted seems to relate to both children and adolescents. One of the major reasons appears to be that adolescents are technically able to self inject at lunch time, thus giving them a reasonable shot at “good control on an MDI regimen.” We feel that many adolescents despite being *able* to inject at lunch time are prohibited from doing so by the stigma associated with injecting in front of peers or being singled out by being made to inject in a school medical room. We also feel that the erratic nature of blood sugar control during puberty should be a factor to consider when deciding whether this group should be | The Appraisal Committee heard evidence that children older than 12 should normally be able to adequately undertake a trial of MDI, see FAD section 4.3.9. |

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| | included for pump eligibility | |
| BDA | General comments<br>Section 2.4 appears to refer only to type 1 diabetes but this is not clear. In addition the section states that “daily life activities need to be arranged around an inflexible structure of meal times and insulin injections.” It is not clear whether this statement refers to traditional insulin regimens (including twice daily) or encompasses newer MDI regimens. This needs clarification. We feel the statement can only be said to apply to more traditional insulin regimens | The FAD has been amended accordingly. |
| BDA | Section 2.5 suggests that type 2 diabetes is always initially “managed by weight loss.” Some patients with type 2 diabetes are slim at diagnosis and do not need to lose weight. We would prefer the use of the term “lifestyle change to include weight loss if necessary.” | The FAD has been amended accordingly. |
| RCP | We are broadly supportive of the recommendations made in the ACD. | Comment noted |
| | The recommendations are essentially based on observational trials rather than randomised controlled trials. Some justification for this is made in the document but we find this a surprising basis for conclusions, out of step with most NICE strategies. As the RCTs are generally negative and the observational trails generally positive we feel that the conclusions should reflect this. | The FAD does note the available evidence and its strengths and weaknesses. |
| RCP | There is some inappropriate use of anecdotal evidence (e.g. on hypoglycaemia 4.3.3). | This evidence was presented to the Appraisal Committee and formed part of the considerations at the meeting. |
| RCPCH | We feel that the guidelines for children younger than 11 years of age are now much more appropriate, and the recommendation that they do not need to have failed a trial of multiple injection therapy before being considered for a subcutaneous insulin infusion pump is very welcome. | Comment noted |

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| RCPCH | For the children over the age of 11, it is a little disappointing that one of the definitions of failure of MDI is an HbA1 level as high as 8.5%. Since we are aiming for HbA1c levels less than 7.5%, this seems too high to allow children's levels to reach before an appropriate intervention. This seems to be based on the cost-effectiveness of using CSII to reduce HbA1c levels which is greatest when they start at high levels. However, it must be borne in mind that children will have a very long duration of diabetes and they should not be allowed to run at high levels if it can be avoided. The second criterion of failure of MDI in terms of hypoglycaemia is now very appropriate as it is often the persistent anxiety about the recurrence of hypoglycaemia that is the main issue. | The Appraisal Committee does not recommend a target HbA1c level of 8.5% as a threshold. This is the level at which the use of CSII was judged cost-effective.<br>. |
| RCPCH | I am particularly struck by the comments of the Department of Health 2007, in which it is stated that the key national issue is to reduce variation in access to CSII. It is crucial therefore that the implementation of these guidelines must be more consistent than previously, and that "the availability of CSII should be seen by every commissioner as an essential part of every service for Type 1 diabetes". This must be seen as the main aim of this Review.<br>I would therefore approve these guidelines as a fair and balanced review of the evidence, and find that they are a significant improvement on the current ones. | Comment noted |
| RCN | We consider that the relevant evidence & summaries of clinical effectiveness have been taken into account.<br>We agree with the provisional recommendations relating to children being offered CSII and agree that it is very difficult to manage the young child on alternative insulin regimens. | Comment noted |
| RCN | We note that MDI can be ‘by-passed’ if considered to be inappropriate which takes the child’s individual circumstances into consideration. This is a positive step. We agree with the statement that ‘those receiving the treatment and their carers have the commitment and competence to use the therapy effectively’. | Comment noted |
| RCN | With regards to paragraph 1.4, section 4-‘Evidence and interpretation’ (4.3.6), supports | Patients may receive CSII if |

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| | and explains the reason for setting the HbA1c level at 8.5%. Judging from clinical experience, for a cohort of people receiving CSII, this level of HbA1c would have excluded many of them from being eligible for CSII. There is a fear that this may open the flood gates for people wishing to receive CSII. However anecdotally, people who are interested in CSII are usually a small proportion of people with type 1 diabetes. There are no recommendations for how many people in terms of percentages of people with type 1 diabetes services who will be able to start or how much funding will be available for specialist teams. Some indication and guidance in respect of this would be very helpful. | their HbA1c remains high or if they experience hypoglycaemia in attempting to lower it.<br><br>The Appraisal Committee was not able to estimate the percentage of people would become eligible for CSII |
| RCN | It would also be helpful to label the two bullet points in paragraph 1.3 as either (a) or (b) and to highlight the 'or' as it could be easily missed. | The FAD has been amended accordingly. |
| RCN | 'Disabling hypoglycaemia-repeated and predictable occurrence and persistent anxiety about recurrence' etc- this criteria is probably the one that we can envisage being used more often with regards to eligibility for CSII and as the appraisal points out later, people who use CSII have highlighted and described the changes in hypoglycaemia that they have experienced on CSII. The question of measurability of the issues in this section is commented upon below in 1.5. | Comment noted |
| RCN | Paragraph 4.3.7 talks about 'CSII being recommended for children younger than 11 years' - does this imply that pump therapy can be offered at diagnosis? We consider that this needs to be clarified in order for the document to be able to guide the NHS. | The FAD clarified accordingly. |
| RCN | Paragraph 1.4 highlights the importance of CSII therapy being initiated only by trained teams. We strongly agree with this recommendation. However, the recommendation stresses that the physician should have a special interest in pump therapy but no mention is made of any requirements for the Clinical Nurse Specialist (CNS). We consider that there needs to be clarity about what a 'trained team' looks like - suggestions include having documented attendance at training days, being a 'certified | The exact composition of the specialised team is a decision for the treating centre. The Appraisal Committee did not hear evidence on this aspect of |

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| | pump trainer', evidence of starting a minimum number of children on a pump per year, clinic being able to demonstrate audited outcomes of the patients started on pump therapy. Specialist pump training, both initial and on going training of the specialist team needs to be factored in to this with regards to resources (both time and finance). | the delivery of care. |
| RCN | For paediatric health professionals, the main worry is always when the child is in the nursery or school setting. Based on experience of supporting pump therapy, this can work very well in this environment. However, if the child is not competent to do so themselves, an appropriate adult needs to be identified in this setting to support the child in the daily management of their diabetes. Therefore, there needs to be some thought about training and documentation for these specific carers, who are often teachers or identified support workers rather than school nurses. | This falls outside the remit of this appraisal. |
| RCN | Paragraph 1.5 - 'Improvement' is an important aspect to address. Not only should there be measurable biomedical improvements in glycaemic control but there should be quality of life improvements for the person using CSII for example a reduction in the frequency and severity of hypoglycaemia and a reduction in anxiety about recurrence. The quality of life improvements are difficult to measure. Will there be any guidance or recommendations as how to measure these- for example what tools/questionnaires etc? | The Appraisal Committee cannot give recommendations which will cover each individual situation and the targets for improvements need to be set for the individual patient in consultation with health care professionals |
| RCN | Further, as a trained specialist team is involved, it should be the specialist 'team' or a team member representing the specialist team (in discussion with the person receiving treatment and carer (as appropriate)) that is involved in setting the targets for improvement rather than just the responsible physician. | Comment noted |
| RCN | Section 4.3.11 of the appraisal consultation document states that if there are no demonstrable benefits seen within a 'reasonable time period' CSII would be withdrawn. It would be helpful to have an indication of what is considered a 'reasonable time | This decision is to be made on an individual basis. |

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| | period'- e.g. 6-12 months? | |
| RCN | We note that Accu-Chek DTron plus pump made by Roche does not appear on the currently available list of pumps. It uses pre-filled cartridges. | It has been added to the FAD. |
| RCN | In describing the technology, point 3.2 states that 'a higher infusion rate at meal time' can be delivered. This suggests that the pump delivers this automatically. Given the point above that there needs to be thought about pumps (or indeed any insulin therapy) in school settings, there needs to be clarity that additional insulin is given only when an individual button pushes. We suggest that this point is re-worded to read 'which are programmed in by the user with additional boluses of insulin at meal times'. This might help to clarify the difference between basal rates and boluses and will clear any potential confusion. | The FAD has been amended accordingly. |
| RCN | With regard to cannula changes, the maximum recommended time for them to be in use is 3 days. After 3 days (or more frequently if indicated) a new one should be used. Therefore saying the cannula is repositioned every 3 days is misleading. It suggests the same cannula is repositioned. | The FAD has been amended accordingly. |
| RCN | This final comment relates to equity. Currently there is real disparity in different geographical areas as to whether pump therapy is offered to young people or not. This seems to relate more to the interest of the particular team than to issues relating to funding. As a consequence families have to travel lengthy distances to be offered this mode of therapy. This should be born in mind in drawing up any implementation support tool. | Comment noted |
| RCN | The Appraisal Consultation Document appears to be a thorough and fair interpretation of the evidence available to date. The guidance as to how this is to be coasted and implemented would be imperative. | Comment noted |
| Diabetes UK | Diabetes UK believes that the recommendations as they stand will still restrict access to this technology for people with Type 1 diabetes over the age of 11 and people with Type 2 diabetes who would find it beneficial in terms of clinical and quality of life outcomes. | Comment noted |

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| Diabetes UK | Do you consider that all the relevant evidence has been taken into account?<br>Evidence relating to the quality of life benefits of pump therapy and glycaemic excursions has not been given adequate consideration.<br>Quality of Life<br>The quality of life benefits, as reported in Diabetes UK's submission, go beyond reducing hypoglycaemia and fear of recurrent hypoglycaemia and have not been given due consideration within this appraisal process. The use of this technology elicits strong responses from users with many not wishing to revert back to MDI Whereas we acknowledge that the Committee considered observational studies and evidence submitted, the evidence given by patient organisations and available in less "rigorous" studies must be given more weight (see reference below). The weakness of research in this area should not be used as a means to undervalue the important impact on quality of life of this technology, that has been identified by people with diabetes. Diabetes UK is calling for further research to be undertaken in assessing the quality of life benefits of CSII.<br>Quality of life improvements have been noted in various studies which include increased flexibility in food timing and diet, convenience, an increased sense of autonomy, particularly in children, improved social relations and improved sleep. Some of these improvements have also been identified by the carers of those using CSII.<br>Diabetes UK recommends that CSII should be made available to people with diabetes requiring insulin based on individual clinical need, patient choice and suitability. Suitability should consider the motivation and ability of an individual to use the insulin pump, and clinical need should take into consideration all quality of life benefits. | The Appraisal Committee was aware of quality of life issues and these were included into the Appraisal Committee's consideration of cost effectiveness, see FAD section 4.3.3 and 4.2.7. |
| Diabetes UK | Hba1c level<br>The use of Hba1c as the measure of control excludes consideration of glycaemic excursions. A person with diabetes can have good control as defined by their Hba1c level, but can be experiencing glycaemic excursions that impact negatively on their | The Appraisal Committee does not recommend a target HbA1c level of 8.5% as a threshold. This is the |

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| | health. CSII has been shown to improve fluctuations in glycaemic excursions but this has not been taken into account in the recommendations.<br>Diabetes UK disagrees with the whole premise that a person over the age of 11 years must have failed on MDI therapy before CSII is considered as a treatment option.<br>Diabetes UK questions the selection of 8.5 per cent as the decisional level. Good glycaemic control is recognised as being in the range between less than or equal to 6.5 and 7.5 per cent. The JBS2 guidelines identify that optimal control is less than or equal to 6.5 per cent, with an audit target of less than 7.5 It is important to consider that the optimal target may not be suitable for all people, impacting on quality of life in relation to hypoglycaemia , therefore a range is given. | level at which the use of CSII was judged cost-effective. |
| Diabetes UK | General comment<br>Section 2.5: When discussing good control it is important to acknowledge the benefits of the Hba1c range between 6.5 and 7.5, however targets should be individualised to take into account the importance of quality of life. | Comment noted |
| Diabetes UK | Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and the preliminary views on the resource impact and implications for the NHS are appropriate?<br>Diabetes UK is concerned that not enough weight has been given to quality of life benefits such as flexibility in food timing and diet, convenience, an increased sense of autonomy, particularly in children, improved social relations and improved sleep. In addition whilst the Committee discuss the benefits CSII can bring in relation to glycaemic excursions this is then ignored in the recommendations. Diabetes UK questions the use of QALYs in adequately assessing all quality of life benefits. | Quality of life benefits are considered and included in estimations of cost effectiveness, see FAD sections 4.3.3 |
| Diabetes UK | Cost effectiveness and Quality of life<br>Section 3.4: Some of the costs attributed to CSII would also be costs associated with MDI. All people with diabetes on insulin will require lancets, test strips, glucometers, education at initiation of insulin and ongoing education. This should be acknowledged. | The FAD has been amended accordingly. |

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| Diabetes UK | Section 4.2: Much of the cost effectiveness analysis is based on Hba1c levels and reductions in hypoglycaemia and fear of hypoglycaemia. Whereas these parameters are important they are not the only parameters to be considered. The QALY method of quantifying quality of life into a cost effectiveness calculation is not a sophisticated enough tool to be used to measure the quality of life benefits that can be achieved through CSII use. People with diabetes should not be penalised by restricted access to CSII because of the lack of available tools to adequately translate quality of life appropriately in terms of cost effectiveness. | Comment noted. The Appraisal Committee makes a decision based on the best available evidence. |
| Diabetes UK | Section 4.3.6: It appears inappropriate that all quality of life measures have been grouped together and considered within the three percent increment that is attributed to the avoidance of severe hypoglycaemia. The other quality of life benefits will not have the same "cost" as avoidance of hypoglycaemia.<br>The quality of life measures that appear not to have been considered are:<br>• Flexibility in food timing and diet<br>• Convenience<br>• An increased sense of autonomy, particularly in children<br>• Improved social relations<br>• Improved sleep | NICE methodology usually only considers health related quality of life. However in this appraisal the benefits of quality of life in general were acknowledged and included in consideration. |
| Diabetes UK | General comments regarding accuracy<br>Section 2.2: The statement about Type 2 diabetes fails to acknowledge the increasing numbers of children developing Type 2 diabetes. | The FAD has been amended accordingly. |
| Diabetes UK | Section 2.3: The sentence relating to the symptoms of severe hypoglycaemia needs to be amended to state "very occasionally *death*" | The FAD has been amended accordingly. |
| Diabetes UK | Section 2.5: Not all people with Type 2 diabetes will need to lose weight therefore it is better to refer to weight management than weight loss. | The FAD has been amended accordingly. |
| Diabetes UK | Section 3.2: For clarity please alter these statements as follows:<br>The pump can be programmed to deliver a *different* basal rate of insulin *each hour* | The FAD has been amended accordingly. |

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| | throughout the day, with higher infusion rates at meal times *which maybe a bolus or extended over a chosen period of time…* | |
| Diabetes UK | Section 4.3.6: What is appropriate in relation to long acting insulin analogues? | These decisions will need to be taken on an individual basis by the patient and health professionals. |
| Diabetes UK | Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?<br>CSII must be available as a choice of insulin administration for all people with diabetes who have the commitment and competence to use the technology. It should not be perceived as being reserved as a specialised treatment for those who are not achieving a particular level of control, and it should not be restricted on the basis of cost. This could be seen as creating a perverse incentive for poor control and limits the treatment choices available. This directly contravenes the government's agenda to increase choice for people with long term conditions to support self management. Choice of treatment is one of the key "choices" that people with diabetes wish to make on the basis of individual clinical need. | Comment noted. The Appraisal Committee is charged with recommending interventions that are a cost effective use of NHS resources. |
| Diabetes UK | Diabetes UK is concerned with the following with regards to the recommendations:<br>• The use of an Hba1c level to determine whether or not an individual should be considered for pump therapy will unfairly restrict access to CSII. The Hba1c level will exclude access to CSII for people with diabetes achieving an Hba1c of less than 8.5 per cent. The Hba1c level chosen does not reflect current evidence regarding good blood glucose control. It does not take account of individuals who will have an Hba1c within the range of 6.5 to 7.5 per cent, but who are experiencing significant fluctuation in their glycaemic excursions.<br>• The recommendations as they stand do not consider the quality of life benefits of CSII beyond reducing hypoglycaemia as stated in Diabetes UK's submission. | Comment noted. See above.<br><br>Quality of life benefits are |

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| | • The recommendations exclude people with Type 2 diabetes from accessing CSII<br>• The age cut off that requires those over the age 11 to have been failed by MDI therapy does not consider the clinical and quality of life benefits that pump therapy can bring. In addition the recommendation to make the age cut off 11 years of age is in appropriate and will particularly disadvantage adolescents (See Question iv).<br>• The recommendation regarding removing CSII where it is not deemed successful is problematic. It does not identify the need to review progress and provide support to address any issues before the removal of CSII is even considered. | included.<br>There was no evidence of benefit in this subgroup Clinical and quality of life benefits were considered and above this age a trial of MDI before CIII is a cost-effective use of resources.<br>The FAD refers to further support before removal. |
| Diabetes UK | Diabetes UK is also concerned that the details regarding the implementation tools have not been published with the appraisal document. This has restricted the ability of consultees to comment on how the recommendations will be implemented in practice and how implementation will be monitored.<br>Further recommendations regarding education and the competence of the specialist team are also made to ensure this is highlighted appropriately within the guidance and recommendations (see below). | Implementation tools are released with the FAD |
| Diabetes UK | Implementation<br>Section 5.3: Diabetes UK is disappointed that the details of the implementation tools cited in section 5.3 have not been published with the appraisal consultation document. This is not a transparent way of working, and has restricted the ability of stakeholders to comment effectively on the impact the guidance will have in practice. Organisations need to know how NICE intends to ensure that its guidance is implemented fairly and what audit criteria will be used otherwise there is the risk of another postcode lottery developing. The National Diabetes Support Team/Department of Health Insulin Pump working group document, supported by Diabetes UK, should be used as the basis to | See above |

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| | guide implementation. It is based on consensus of opinion from experts in the field. | |
| Diabetes UK | Education as part of implementation<br>Section 1.4:<br>It is important that the specialist team initiating people onto pump therapy are delivering education, and are competent to deliver this education. The pump therapy specialist team need to be working together with the individual's diabetes care team where they are not the same, and this should be explicitly referenced.<br>Section 1.4: The recommendation regarding the importance of the team members needed within the trained specialist team, should state "must comprise" rather than "should normally comprise". | Defining the exact composition of the team and specialisation of its members is outside the remit f this appraisal and is for an individual centre to determine. |
| Diabetes UK | Reviewing the effectiveness of CSII<br>Section 1.5/ 4.3.11: This recommendation does not identify the need to review progress and provide support to address any issues before removal of CSII is even considered. It is vital that a review that involves the individual with diabetes takes place. Diabetes UK also queries why adults and children over 11 years old have been singled out with regards to this recommendation as the safety implications would apply to all on CSII.<br>As a result, Diabetes UK recommends the recommendation is changed as follows:<br>Following initiation, CSII use should be reviewed with an individual (and where appropriate, their carers) where improvements in glycaemic control or quality of life are not apparent. Appropriate target improvements should be set by the responsible healthcare team in partnership with the individual (and where appropriate, their carers). The decision about whether to continue CSII therapy or not should be made in partnership based on individual clinical need and choice.<br>The decision about whether or not a person continues on CSII is a case by case consideration and should not be decided on the basis of national recommendations. Similarly the definition of a reasonable time period is for case by case consideration as a decision made by an individual in partnership with their healthcare professional team. | The FAD includes the need for further support before withdrawing CSII. |

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| Diabetes UK | Are there any equality related issues that may need special consideration?<br>Diabetes UK believes that some members of the diabetes community will be unfairly excluded from accessing CSII as a result of the recommendations as they stand. These concerns are outlined below.<br>People with Type 2 Diabetes<br>Section 1.6 and 4.3.9: The decision not to recommend CSII for people with Type 2 diabetes appears to have been made on cost effectiveness grounds owing to a lack of available evidence. However, by restricting access to CSII, this will potentially continue to limit the number of people with Type 2 diabetes using CSII therefore continuing to limit the evidence available. One small study has demonstrated that CSII improves the bioavailability of insulin which suggests that CSII would be a suitable option for people with severe insulin resistance.<br>The distinction between types of diabetes is also unhelpful when considering forms of insulin administration. What needs to be considered is where a person is physiologically and psychologically with their use of insulin. Some people with Type 2 diabetes have the same insulin requirements as people with Type 1 diabetes and therefore should be considered as eligible for CSII on the grounds of individual need, suitability and personal choice considering both quality of life and biological factors.<br>The demographics of people with Type 2 diabetes are also changing, with an increasing number of children being diagnosed with Type 2 diabetes. The impact of a younger population with Type 2 diabetes includes people having Type 2 diabetes for a longer duration, the possibility of more people progressing to insulin use at a younger age and more pregnant women with Type 2 diabetes. As a result to exclude people with Type 2 diabetes from the recommendations for CSII is to exclude many people who have a right to access a choice of treatment that may provide the best benefits for them. | The FAD acknowledges there are individual type 2 patients who may benefit but the Appraisal Committee was not able to recommend the CSII in type 2 diabetes due to a lack of evidence of benefit. |
| Diabetes UK | Hba1c level<br>The inclusion of a particular Hba1c level (8.5 per cent) as an indicator that MDI has | Quality of life benefits are considered. However for |

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| | failed is both unfair and restrictive. Having to *fail* to achieve an Hba1c level of 8.5 percent instantly restricts access to CSII for those individuals who are achieving good control and ignores the quality of life benefits that can be gained from CSII. Diabetes UK also questions the selection of 8.5 per cent as the decisional level. Good glycaemic control is recognised as being in the range between less than or equal to 6.5 and 7.5 per cent. The JBS2 guidelines identify that optimal control is less than or equal to 6.5 per cent, with an audit target of less than 7.5. It is important to consider that the optimal target may not be suitable for all people, impacting on quality of life in relation to hypoglycaemia, therefore a range is given. | patients who are well controlled on MDI, changing to CSII is not a cost-effective use of resources. |
| Diabetes UK | Age cut off<br><u>Section 4.3.6:</u><br>The decision to include an age cut off that requires those over the age of 11 to have been failed by MDI therapy will unfairly restrict access to CSII. It does not consider the clinical and quality of life benefits that can be achieved on CSII. Furthermore the choice of age 11 as a cut off is peculiar and based on a broad generalisation regarding the ability of child to use MDI at school. Not all children older than 11 will be able/ allowed to self inject an afternoon dose of insulin in school. The upheaval to the child and other family members caused by parents having to go into to school during the day to give an injection will not be adequately addressed by this generalisation. Many local paediatric services organise their clinics in age bands. The usual age bracket for juniors ends at age 12 not age 11.<br>This age cut off will particularly disadvantage adolescents who will be going through their transitional phase of life. The transitional phase is well recognised as a stage when many young people experience difficulties with their diabetes control and engagement with services. The quality of life benefits that CSII can bring, particularly in enabling more flexibility in the young person's routine make CSII a very valid treatment option for this age group. | See above. |

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| INPUT | 1.1 Clarify age group. Would it not be better to say children up the age of 12?<br>How will “commitment” be measured?<br>How will “competence” be assessed?<br>Benchmarks should be put in place to ensure consistent interpretation around the country, from clinic to clinic. | This FAD section has been changed |
| INPUT | 1.2 Obviously this would need to be changed to “older than 12.”<br>We question the phrase “adequate control.” We would suggest, “failed to achieve control.”<br>Again, how do we define and measure these? | This FAD section has been changed. |
| INPUT | 1.3 We have real issues with the new HbA1c guidance level of 8.5%. What was the basis for this decision? There is no approved medical guideline that says an A1c level of >7.5% constitutes control.<br>In the NICE Clinical Guidance for Type 1 diabetes (CG015) NICE state that 7.5% should be the target value for Type 1 diabetes (R44) and that those who seek to achieve an HbA1c of 7.5% should be given all appropriate support to achieve this. If one reads this new guidance in combination with CG015, NICE is giving conflicting messages.<br>Also, the IDDM European Study Group states that <7.5% is adequate control. This is also the level that the DCCT found was associated with a curvilinear increase in the progression and incidence of secondary complications associated with diabetes. The results of the DCCT Study prompted the American Diabetes Association (ADA) to recommend that an HbA1c level of less than 7.0% should be the goal for most patients. In 2002 the American Association of Clinical Endocrinologists (AACE) recommended that all patients with diabetes should strive for an A1C of 6.5%.<br>Under the guidance that we are revising, a patient with an HbA1c of 8.0% would be eligible for a pump in an area where pump uptake was less than 1-2%, but with the new suggested guidance they will not fit the guidance for a pump. In this sense the proposed guidance has become stricter! | The Appraisal Committee does not recommend a target HbA1c level of 8.5% as a threshold. This is the level at which the use of CSII was judged cost-effective. |

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| INPUT | 1.1. Team should be pump-trained, not a consultant with 'a special interest in pump therapy', as this limits the number of consultants prepared and available to take pump patients even more than it is already. Also 'specialist team's' indicates that specialist staff training is necessary. This will alienate diabetes teams who do not have many pump patients. ALL diabetes teams should be aware of pump therapy as a treatment option and should be able to offer advice on diet and lifestyle as they are still dealing with patients on insulin! | Defining the exact training requirements of the specialist team is outside the remit of this appraisal and is a decision for each centre. |
| INPUT | 1.5. As written, we will oppose this with every means at our disposal! Do any other chronic conditions have targets set? Do any other conditions have treatments withdrawn if targets are not met? If not, then this is clearly discriminatory! This section should be removed.<br>In its place we suggest implementing the Department of Health's Report, "Care Planning in Diabetes." This report is a key component of Standard 3 of the Diabetes National Service Framework (NSF) and incorporates all that is required.<br>*"Care planning, combined with structured education, can empower people with diabetes to make choices about how they manage their condition on a day-to-day basis.*<br>*Care planning can be defined as a process which offers people active involvement in deciding, agreeing and owning how their diabetes will be managed. It aims to help people with diabetes achieve optimum health through a partnership approach with health professionals in order to learn about diabetes, manage it and related conditions better and to cope with it in their daily lives.*<br>*Care planning is underpinned by the principles of patient-centredness and partnership working. It is an ongoing process of two-way communication, negotiation and joint decision-making in which both the person with diabetes and the healthcare professional make an equal contribution to the consultation. It differs from the 'paternalistic' or 'healthcare professional-centred' model of consulting, traditionally applied in acute settings." (Dept of Health 2006)* | Failure to show improvement on a treatment will lead to the withdrawal of almost all medical interventions. |

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| INPUT | 1.6. The blanket exclusion of patients diagnosed with type 2 diabetes from consideration for a pump is unfair to patients who may have been misdiagnosed initially, or whose diabetes is poorly controlled because of it has progressed to a point where they are totally insulin dependent. The US Medicare system allows coverage for insulin pump therapy for all patients who meet the low C-Peptide test result criteria set out in the document linked at: http://cms.hhs.gov/transmittals/downloads/R143CIM.pdf. This change was implemented in 2002, reversing the previous criteria that excluded patients with type 2 diabetes from receiving pump funding. If type 2s are excluded from receiving pump therapy until at least the next review of HTA57, the UK will be fully 10 years behind the US in its attitudes to diabetes care. Is it the intention of NICE to portray the UK as a backwards-thinking nation that disregards international standards for diabetes care? | The FAD acknowledges that some type 2 patients may benefit from CSII but the Appraisal Committee could not recommend it to all type to patients in the absence of evidence of benefit. |
| INPUT | 2.5. This section misrepresents the aetiology, disease processes, and long-term prognoses of both type 1 and type 2 diabetes. Proposed revision: “Type 1 diabetes mellitus requires life-long treatment with insulin. Type 2 diabetes mellitus is initially managed by diet and weight loss. As the disease inevitably progresses, oral glucose-lowering drugs are introduced. Over time, most type 2 diabetes patients will need insulin to control their blood sugar levels. Causes of beta-cell dysfunction in patients with type 2 are under investigation as the United Kingdom Prospective Diabetes Study (UKPDS) showed that seven years after diabetes diagnosis many patients produce only half as much insulin as non-diabetic individuals. Various types of exogenous (injected) insulin distinguished are by their speed of onset and duration of action. Insulin requirements change depending on food intake, hormonal changes, stress levels, exercise or illness. Insulins with varying times to onset and durations of action are usually combined in treatment regimens, which are then delivered by multiple injections timed to coincide with requirements. Many type 2 diabetes patients can achieve control of their diabetes using a basal insulin and oral medications but all type 1 diabetes patients and many type | This section has undergone modifications. |

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| | 2 diabetes patients require both bolus and basal insulin. The Diabetes Control and Complications Trial (DCCT) showed conclusively that in type 1 diabetes, achieving good control of blood glucose through an intensive regimen, including frequent self-monitoring of blood glucose (SMBG) reduces the risk of complications. The UKPDS showed similar findings in type 2 diabetes. Intensive insulin regimens attempt to mimic the normal secretion of insulin by the pancreas. However, exogenously administered insulin does not activate the feedback mechanism that the liver and pancreas use to regulate insulin and glucose secretion, whereby insulin production decreases and increases as blood glucose levels change. Therefore, people taking insulin need to check their blood glucose levels regularly, a minimum of 4 times per day, by using a monitor (glucometer). Frequent daily glucose measurements enable short-term control of blood glucose levels by allowing the patient or caregiver to adjust insulin doses. Long-term monitoring of control is achieved by measuring glycosylated haemoglobin (HbA1c) levels, which reflect average blood glucose levels over the preceding 6 to 9 weeks. According to the DCCT and the UKPDS, an A1C of less than 7.5% is associated with greatly reduced risk for long-term diabetes complications. (The normal A1C range for people who do not have diabetes is 4.5–5.5% according to most available assays' reference ranges)." | |
| INPUT | 3.2. The term "repositioned" with reference to cannula changes implies that the same cannula may be removed and reinserted in a different site. Let's keep it clear that the pump relies on disposable supplies to deliver insulin into the body. Also, it is important that the purposes of basal and bolus delivery (respectively) be explained. Many healthcare professionals in the UK whom we have encountered believe that patients wearing an insulin pump must also inject long-acting basal insulin (that is, they believe that the main advantage of a pump is not having to inject at mealtimes only, a belief that significantly misinterprets the technology). Proposed revision: "The pump is programmed to deliver basal rates of insulin throughout a 24-hour period, with boluses (doses) programmed separately at meal times and to correct glycaemic excursions. The main | The FAD has been amended accordingly. |

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| | advantage of modern insulin pumps is that they can deliver different basal rates of insulin at different times of the day and night. It is recommended that the disposable cannula is removed and replaced every 72 hours (3 days)." | |
| INPUT | 3.4. The reference to the requirement of "insulin, lancets, test strips and glucometers for monitoring" as originally worded implies that only insulin pump users need these things. ALL people with diabetes who take insulin require insulin, lancets, test strips, and glucometers. This need is not different between the MDI and pump using populations. The original wording implies that pumping is made more expensive or burdensome by these accoutrements when in fact these supplies are required no matter what form of insulin therapy patients' use. | The FAD has been amended accordingly. |
| INPUT | 4.1.7. It may be worthwhile to expand the statement regarding puberty as a time when diabetes is difficult to control. This difficulty is very often not any fault of the patient or his/her family. Rather, we propose that the statement be expanded to say: "The time of puberty was also identified as a difficult time to control diabetes because of fluctuations in sex and growth hormones, which dramatically affect insulin sensitivity throughout adolescence." | The FAD has been amended accordingly. |
| INPUT | 4.2.4. Surely the figure of £413 for a hospital stay resulting from hypoglycaemia is an underestimate as it does not factor in the lost productivity of a patient who is off work for a day or two following the incident? | The perspective of the appraisal is that of the NHS. |
| INPUT | 4.3.1. The Committee is described as "mindful of the need to take account of the effective use of NHS resources." We would like to see a broad survey of the way that NHS resources are used to deal with the long-term complications of poorly controlled diabetes, including retinopathy, neuropathy, nephropathy, etc. These conditions lead to significant costs across the NHS. | The economic model takes long term costs of complications into account |
| INPUT | 4.3.3. In addition to pump users experiencing more gradual onset of hypoglycaemia, we propose that the following statement be added to the paragraph: "Additionally, reduced frequency of hypoglycaemic events may help restore and maintain patients' | The Appraisal Committee felt that sufficient weight had been given to this |

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| | symptomatic responses to hypoglycaemia, reducing the risk that they will suffer from hypoglycaemia unawareness." | anecdotal evidence. |
| INPUT | 4.3.6. Understanding that the Committee has already drawn the conclusions reported in this paragraph, we propose a reconsideration of two aspects: 1) The A1C benchmark must be changed from 8.5% to 7.5%. 2) a proviso be added to the end of the paragraph: "for whom, despite a high level of care, it has been impossible to maintain a HbA1c level of less than 7.5%, or who experience disabling hypoglycaemia at an A1C below 7.5%" An A1C of 6.0% is no use to anyone if a patient who experiences persistent hypoglycaemia has a road accident because his or her A1C is "too good" to qualify for insulin pump therapy. | The CommitteeAppraisal Committee does not recommend a target HbA1c level of 8.5% as a threshold. This is the level at which the use of CSII was judged cost- effective. |
| INPUT | 4.3.10. The description of insulin therapy in general in this paragraph makes it sound onerous and burdensome rather than lifesaving and life-enhancing. Further, this paragraph makes pump therapy sound positively impossible for anyone with merely normal hygiene standards and intelligence. This is a gross misrepresentation: yes, life with insulin-dependent diabetes is a great balancing act but the sheer fact that millions of people around the world do it every day should suggest that it's not beyond the grasp of most mere mortals! We suggest the following revision to the statement that begins "Additionally, the use of effective insulin pump therapy…": "Additionally, the use of effective insulin pump therapy would require replacing the cannula every at least every 72 hours and programming the pump (similar degree of difficulty to operating a mobile phone)." | The FAD has been amended accordingly. |
| INPUT | 4.3.11. Reiterating our objection to Sec. 1.5 with regard to the targets to be set and met, we also object stridently to the Committee's conclusion that the "absence of such benefits within a reasonable time period should warrant a withdrawal of CSII therapy." More to the point, the absence of such benefits should warrant a review of the patient's diabetes care regimen, potentially including referral to a different diabetes care team, re-education, and increased support. If a patient is not succeeding on insulin pump therapy | The FAD states that increased support is required before CSII is withdrawn due to lack of benefits. |

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| | after having been prescribed the treatment because he or she was not doing well on injections, simply returning the patient to injection therapy hardly guarantees any better outcome! Surely patients who are sick deserve more and better care, not worse and less. | |
| INPUT | Finally we feel that it is appropriate to include the patients' view of insulin pump therapy. First introduced with somewhat crude technology in the late 1970s, the pump was designed by scientists and physicians in an effort to mimic the functions of a healthy pancreas. The first insulin pumps were actually adapted from similar pumps that were used to deliver constant medicine to treat cancer patients undergoing chemotherapy. Unfortunately, while the "theory" of pump therapy was sound, the initial practice of it was somewhat shaky. The technology to create a safe mechanical system was not yet in place; consequently, early pump users faced such challenges as not having adequate alarms to let them know when the pump was experiencing a technical malfunction.<br>From a lifestyle perspective, the pump required such unusual commitments as plugging it in every night and so not being able to move around while sleeping. Yet, many early pump users stuck with the system despite its flaws; they still achieved better blood sugar control on those pumps than they did with injection therapy. Two of our members have been using pumps for over 30 years and remember the early days.<br>Fortunately, times have changed and today's pumps are small, sleek, and safe and really do allow the user to "think like a pancreas" as the initial pump creators had envisioned. That is, just like a pancreas, an insulin pump releases small, continuous amounts of insulin into the body. In pump terminology, this is known as basal insulin and is pre-programmed into the pump to meet individual patient needs. And just as a pancreas produces insulin quickly to counteract carbohydrate intake, an insulin pump allows its wearer to dial in additional insulin to cover the amount of carbohydrates ingested. This insulin is known as bolus insulin. The combination of correct basal insulin rates with additional bolus insulin allows the person with diabetes to achieve the closest | Comment noted. |

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| | thing possible to a functioning pancreas. With over 35 years of technology behind them, insulin pumps are now pager-sized devices containing tiny computers, run on batteries. They are extremely safe, comfortable, and easy to wear.<br>Insulin is delivered through a thin tube that is connected both to the pump and the person wearing the pump, through a catheter, placed under the skin. The tube can easily detached for some activities, such as showering, that are easier to do without the pump on. Insulin pumps allow their users to continue any physical activity they're involved in – they don't inhibit sports, recreation, work, or sex. In fact because the pump user is able to lower the basal insulin rate during exercise or other activities that normally lower blood sugar, he or she will generally experience fewer hypoglycaemic episodes.<br>Certainly, any major change in diabetes treatment takes time to implement, and many people are involved in making that change occur; physicians, educators, manufacturers, and most important, the patients themselves. Anyone living with diabetes knows we must all act as our own advocates for getting the best health care possible, and it is very often the patient who must insist on making the switch to pump therapy. | |
| Insulin Dependent Diabetes Trust | Point 4.1.1<br>This states that the Assessment Group concluded that MDI based on long-acting insulin analogues is more efficacious than MDI therapy based on older insulins and therefore analogue-based MDI was used as a comparator for CSII therapy. I question whether this is a correct comparator for children. In young children under 6 years trials have not been carried out to demonstrate the safety or efficacy of insulin analogues in young children and whether it is appropriate in older children where only small trials of relatively short duration have been carried out. | The Appraisal Committee was aware of the limitations of evidence of effectiveness and cost effectiveness in young children. |
| Insulin Dependent Diabetes | In addition, the background of many studies state that the DCCT [1991] showed that intensive treatment with MDI results in better glycaemic control as measured by the HbA1c test but this study was carried out in highly selected adults with Type 1 diabetes | The Appraisal Committee was aware of the limitations of evidence in young |

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| Trust | and its findings cannot be extrapolated to children. Again this raises the question of whether it is correct to only compare only MDI with CSII, should a comparison with free mix twice daily also be compared with CSII? | children and was cautious in extrapolating findings in adult populations to the paediatric age group. |
| Insulin Dependent Diabetes Trust | There are two recently published studies that have investigated effects the effects of different regimes and insulins over 10 year periods in children that warrant inclusion and support the above concerns.<br>[1] Prevailing therapeutic regimes and predictive factors for prandial insulin substitution in 26,687 children and adolescents with Type 1 diabetes in Germany and Austria. Diabetic Medicine, October 2007.<br>In 26,687 children and adolescents treated from 1995 to 2005 in 152 clinics, 87% were treated with MDI or CSII and while this percentage increased over the period of the study, the HbA1c remained constant ie it did not improve. In addition, those using insulin analogues received up to 11% higher insulin doses per day compared with those treated with human insulin. | Comment noted. The results of these 2 studies would not alter the Appraisal Committee's recommendations. |
| Insulin Dependent Diabetes Trust | [2] Continuing stability of centre differences in pediatric diabetes care: do advances in diabetes treatment improve outcome? Diabetes Care, Vol 30, number 9, September 2007<br>21 paediatric diabetes centres investigated the influence of changes in insulin regimes, and other factors over 10 years, on HbA1cs, hypoglycaemia and ketoacidosis. 85.3% of the 2,269 children/adolescents were on one of 5 insulin regimes -the remaining 309 were on regimes that could not be classified. The HbA1c results for the different regimes were as follows: | Comment noted. |

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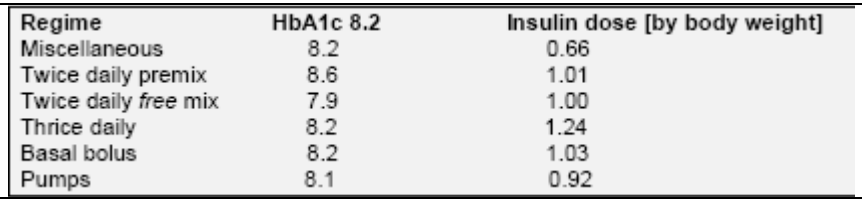
| |  | |

| Regime | HbA1c 8.2 | Insulin dose [by body weight] |
|---|---|---|
| Miscellaneous | 8.2 | 0.66 |
| Twice daily premix | 8.6 | 1.01 |
| Twice daily *free* mix | 7.9 | 1.00 |
| Thrice daily | 8.2 | 1.24 |
| Basal bolus | 8.2 | 1.03 |
| Pumps | 8.1 | 0.92 |

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| Insulin Dependent Diabetes Trust | Despite many changes over the past 10 years including increased use of insulin analogues, basal bolus regimes [4 injections + a day] and CSII those using twice daily free mix of soluble/regular plus NPH [intermediate-acting] and had lower HbA1cs than all other groups. HbA1cs on CSII were not significantly different from the total group even in centres where considerable numbers of patients were using them. The researchers concluded that despite major and continuing changes in insulin and insulin regimes, glycaemic control has not improved over a decade in these 21 international centres. Both these studies suggests that the so-called conventional regimes may be superior to modern intensive regimes and indeed CSII but also highlight the need to compare CSII with twice daily free mix soluble and NPH regimes. | Comment noted. |
| Insulin Dependent Diabetes Trust | Point 4.3.2 while agreeing that the lack of RCTs and lack of RCTs of longer duration requires evidence from observational studies, the statement that Committee 'was persuaded that the few, small trials [RCTs] of relatively short duration could not be relied on alone to capture the benefits of CSII therapy' is biased. It assumes that there will be benefits of CSII if more and larger trials are carried out when this may or may not be the case in all categories of people with type 1 diabetes. | Comment noted |
| Insulin Dependent Diabetes Trust | Bias<br>It is important that the final guidance does not mislead people and therefore I think stronger comment should be made about the possible/ probable bias of the studies involved in reaching these recommendations, Firstly, the selection bias in that studies are carried out in people who agree/want CSII treatment because they believe it to be a better form of treatment. Secondly, that people on CSII therapy generally receive better, | The Appraisal Committee was aware of the issues surrounding the interpretation of the results of observational studies, see FAD section 4.3.2 |

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| | more comprehensive and ongoing education on diet, exercise and adjusting insulin compared to people on MDl or twice daily injections and therefore the studies are not comparing like with like. | |
| Juvenile Diabetes Research Foundation | We are satisfied that all the relevant evidence has been taken into account.<br>We have no further comment about the summaries of clinical and cost effectiveness of CSII treatment<br>Whilst we concur with the main conclusions we have some reservations that are outlined below. We hope that these will be taken into consideration when preparing final guidance<br>There are no equality related issues that we believe need special consideration. | Comment noted |
| JDRF | Further comments<br>*Children*<br>Juvenile Diabetes Research Foundation is delighted to note the improved access to pumps for children which we believe will go some way to addressing the gap between levels of care for children with type 1 diabetes in the UK and those in Europe and the USA. This development has met with approval by all parents of children with type 1 diabetes who have taken part in JDRF's review process.<br>We would like NICE to consider changing the age limits to recommend insulin pump therapy as a treatment option for children up to 12 years old to ensure that CSII treatment is available for all children of primary school age. The current draft guidance could be interpreted to restrict this access to children of 10 and under.<br>We are concerned that there is no guidance about continuation of CSII use for children once they reach the cut off age. The current wording allows for interpretation and could be used to withdraw or refuse funding either as a child reaches 11 or on moving to practitioner who does not support pump use. It would be very alarming to the child and detrimental to blood glucose control to ask a child who has grown up using pump therapy to switch suddenly to MDI. We very much hope that any child who has been | The age has been clarified in FAD guidance section<br><br>The Appraisal Committee recommends a trial of MDI between the ages of 12 and 18, see FAD sections 1.2 and 4.3.9. |

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| | started on pump therapy will have the right to continue this method of treatment as long as they wish/it is suitable. | |
| JDRF | *HbA1c levels*<br>We are extremely worried about the increase in HbA1c levels needed for CSII therapy in children over 11 and adults. Medical guidelines in the UK give a target HbA1c level of 7.5% and this is even lower in other countries (the USA is moving towards levels of 6.5%). This increase will have three outcomes:<br>a) People who have improved their control through pump use may now not be eligible for CSII treatment.<br>b) This infers the message that HbA1c levels of 8.5% are adequate although evidence shows that the closer people with type 1 diabetes can get to normal blood sugar levels (range in people without the condition is usually 4-6.1), the smaller the risk of complications. Setting this higher level sends mixed messages.<br>c) People with type 1 diabetes struggling to maintain levels of 7.5% will be tempted to let their sugar levels 'float up' in order to qualify for a pump causing damage to their bodies during this period.<br>By setting levels at 8.5% these guidelines effectively tie the hands of practitioners and people struggling to achieve that final drop to recommended HbA1c levels. If medical guidance advises a certain target then people with type 1 diabetes who are engaged in achieving the recommended levels should have access to all technology and support to do so. | The Appraisal Committee does not recommend a target HbA1c level of 8.5% as a threshold. This is the level at which the use of CSII was judged cost-effective. |
| JDRF | *Hypoglycaemia*<br>JDRF would like to recommend a change in wording for point 1.3 to read:<br>The person *has experienced* disabling hypoglycaemia<br>This is because anecdotal evidence suggests that many people with type 1 diabetes who have experienced a traumatic hypoglycaemic episode may keep their blood sugars high in order to prevent the experience ever happening again. Thus they may run at 8- | The Appraisal Committee was aware that a consequence of hypoglycaemia was that patients accept poorer glycaemic control. The |

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| | 8.5% constantly without experiencing hypos but causing damage to their bodies and living with the acute and life affecting fear of hypoglycaemia. | Appraisal Committee agreed that avoiding the fear of hypoglycaemia improved the quality of life and improved the cost effectiveness of CSII |
| JDRF | *Targets*<br>JDRF would like NICE to further consider setting targets for implementation of CSII use in the UK. This is because past behaviour indicates that some diabetes practitioners do not keep up to date with technology developments and are unwilling to instigate pump use. We have examples of parents shifting their children's diabetes care centre because they are unable to access pumps although their child qualifies under current guidance. It has taken three years to reach the current NICE target of two percent of people with type 1 diabetes on pumps and removing this target may actually reduce this number. We would like to see a target figure of 15-20 percent of people with type 1 diabetes on CSII therapy to bring us in line with Europe and the USA. Furthermore we would ask that this be audited to ensure that the diabetes community is responding proactively. | The Appraisal Committee makes recommendations based on clinical and cost effectiveness. It is outside the remit of an appraisal to set target levels for the overall use of a technology in the NHS. |
| DAFNE | We do consider that the relevant evidence has been taken into account. | |
| DAFNE | We consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence but would make the following comments, which do carry resource implications:<br>We remain in agreement with the main findings of the HTA and the Appraisal Committee. We were particularly pleased that the report, and the Appraisal document, recognise the critical importance of patient education in safe and successful use of pump therapy. We would have liked to have seen even more emphasis laid on | Structured education has been emphasised in the FAD, see section 4.3.12 and 4.3.15 |

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| | education, which can often provide adult patients with Type 1 diabetes all the benefits they had assumed only to be deliverable by pump. It is our experience, if the education comes first, that those whose insulin requirements are really best delivered by pump therapy become manifest and they are well placed to take full advantage of the pump.<br>We would welcome an expansion of the description of "failure" of MDI, making it explicit that the "high level care" on offer had included delivery of accredited structured education in flexible insulin therapy. It needs to be recognised that such education is still not universally available to patients with Type 1 diabetes and is often underfunded, with unacceptable waiting lists. It would be wrong if pump therapy were to become a substitute for rather than an adjunct to proper patient education.<br>We are aware that there are few if any tried and tested models for structured education in flexible insulin therapy for children and adolescents and appreciate the ACD's differentiation of them. | |
| DAFNE | We do think the document covers the important issues for providing guidance for the NHS. We would wish to stress the importance of providing quality assured structured education, and the rarely used but important 24 hour support for troubleshooting for patients. We would like to see the training needs for the health care professionals providing pump services also be included. | Training of health professionals involved in delivering insulin pump services are decisions for the individual centres delivering services. |
| DAFNE | Re equality related issues:<br>We would however like to suggest that pregnant women, or women trying for pregnancy, with Type 1 diabetes, are also in a special situation. For them defining inadequate care as an HbA1c of > 8.5% may not be enough. We understand that this relatively high level has been selected because of the evidence for significant reduction in HbA1c above this level in general but we would wish to offer pump therapy to any woman who could not achieve the targets considered appropriate for pregnancy ($\leq$ 7% pre-pregnancy and $\leq$6.5% in pregnancy) for reasons likely to respond to pump. | The Appraisal Committee does not recommend a target HbA1c level of 8.5% as a threshold. This is the level at which the use of CSII was judged cost-effective.<br>There was no evidence of |

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| | | benefit from CSII in pregnant women available to the Appraisal Committee. |
| Assessment Group | I think all the relevant evidence has been considered. We used a wider than normal range of types of evidence in the assessment report. | Comment noted |
| Assessment Group | The current section 5 doesn't say anything on resource implications for the NHS. The previous guidance had an estimate that 1-2% of people with type 1 diabetes might be given CSII, and that caused problems. The ACD gives no such figure, preferring to rely on clinical description of those patients for whom CSII would be appropriate. But that means that the cost implication to the NHS is not estimated. I think a bit more detail is required.<br>The options include;<br>a) giving a semi-fixed estimate, perhaps something like "it is expected that not more than 5-10% of adults with T1DM would be treated with CSII", but 5-10% is still quite a wide range. And it is lower than in some comparable countries. The estimate for children might be nearer 25%?<br>b) trying to give more details of the criteria for using CSII, or the relative contra-indications. That would require trying to be explicit about who should get CSII, and those who should not, and that would be difficult. One problem is that some of those with classical contraindications (e.g. poor attendance at clinics) do well on CSII, and have a bigger improvement in Hba1c than those considered more suitable (partly because they have worse HbA1c to start with). References;<br>Rodrigues et al Diabetic Medicine 2005/22/842-9<br>Berkely et al diabetic medicine 2007/24./1496-7<br>So probably better to give broad outlines and then rely on clinical judgement. | The Appraisal Committee makes recommendations based on clinical and cost effectiveness. It is outside the remit of an appraisal to recommend what the expected proportion of people with diabetes who would go on to pumps should be. All patients who conform to the criteria within the recommendations should have the option of CSII. |
| Assessment Group | I think the provisional recommendations need some fine tuning - see more detailed comments which follow. | |

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| Assessment Group | Equality considerations - as we heard from INPUT and others, the main equality issue is geographical variation in funding amongst PCTs. | Comment noted |
| Assessment Group | I don't think the wording in the first bullet in para 1.1 is optimal. I think it would be better to say something like "MDI therapy has failed, or is considered to be impractical or inappropriate". The present wording could be misconstrued. What if MDI was considered appropriate but could not be delivered, for example in a primary school setting, because of problems with the lunchtime dose? | The FAD has been amended accordingly. |
| Assessment Group | I would add a new sentence somewhere: "The choice of pump in very young children should take into account the ability to deliver a very low basal rate". Some pumps are better for this than others. | The FAD has been amended accordingly. |
| Assessment Group | I was surprised at the inclusion of pregnancy in para 1.2. There is no evidence of benefit in pregnancy and occasional reports of harm from diabetic ketoacidosis (see assessment report). Paras 4.1.5 and 4.1.8 are correct. DKA could be disastrous for the baby. The foetus can cope well with hypoglycaemia but not ketoacidosis.<br>You could add something like “CSII should only be started in adults after an adequate period of intensification of education, self-management and MDI". | The FAD has been modified to make this point. |
| Assessment Group | It might be clearer if para 1.2 said 11 years and older. At present those aged 11 are not included. One problem with para 1.2 is that it doesn't say whether children who start CSII under age 11, should have a trial of MDI once they exceed that age. If they are doing well on CSII, it would be considered inappropriate to stop it, but if para 1.2 is applied to those over 11s, it suggests that to continue CSII, they would have to fail on MDI. | The age has been clarified in the FAD, see guidance section. |
| Assessment Group | Para 1.1. Perhaps "commitment and competence" should be defined, for example adherence to diet and other lifestyle measures, self-testing of blood glucose and self-adjustment of insulin doses. | The FAD has been changed. |
| Assessment Group | Similarly, does 2 high level of self care in para 1.3 need defined too? | This has been defined by reference to NICE |

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| | | guidelines, see section 4.3.13. |
| Assessment Group | In para 1.3, first bullet, "HbA1c less than 8.5%". Why was that figure chosen? It could mean that some PCTs would not fund CSII for people with HbA1c of e.g. 8.4%. The NICE guideline target is 7.5%, but most guidelines recommend a lower target (e.g. 6.5%) in people who have early signs of complications, such as microalbuminuria. Should it say 7.5% in para 1.3? | The Appraisal Committee does not recommend a target HbA1c level of 8.5% as a threshold. This is the level at which the use of CSII was judged cost-effective. |
| Assessment Group | same para, second bullet, 3rd line: should it say "occurrence of moderate or severe hypoglycaemia" | The Appraisal Committee's decision to use the phrase disabling hypoglycaemia reflects the fact that CSII is only cost effective when hypoglycaemic episodes affect the quality of life. |
| Assessment Group | Para 1.5, line 3. How big a fall in HbA1c should be required? I suggest "at least 0.5%". Otherwise people who had trivial improvements such as 0.1% or 0.2% could continue CSII. And next line should perhaps have "rate of moderate or severe hypoglycaemic episodes". The extra cost of CSII is about £1700, which would be taken away from other diabetes services. | This decision is left to the patient / carer and treating physician. See FAD section 4.3.14. |
| Assessment Group | Para 1.6. As I said at the meeting, I think CSII should be considered in some people with type 2 - those who have BMI under 26 and who are failing on MDI. Type 2 is often a progressive disease in terms of pancreatic beta cell function and some people will have little insulin production left, and in effect be more like type 1. | The Appraisal Committee noted there are some type 2 diabetics who may benefit from CSII but the Appraisal Committee could make no |

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| | | recommendation in the absence of evidence, see FAD section 4.3.10. |
| Assessment Group | Para 2.2, second sentence is correct but could be misunderstood. Perhaps revise to "with the greatest relative increase in children younger than five years, though absolute rates are highest in older children". | Comment noted. |
| Assessment Group | Para 2.3, very end. I would add amputation, because it's one of the most expensive complications of diabetes. | The FAD has been amended accordingly. |
| Assessment Group | Para 2.4. The second sentence is true for conventional insulin regimens but not for those who are DAFNE trained. I suggest amending to "On conventional insulin regimens such as twice daily mixtures, daily life activities...." | The FAD has been amended accordingly. |
| Assessment Group | Para 4.1.3 Number of studies. Please delete "identified" and insert "reported", because we identified more than the number cited, but did not include them all. | The FAD has been amended accordingly. |
| Assessment Group | Para 4.2.1. "all other publications used the CORE model". I am sure that is correct, but one paper didn't give details, though two of the authors were from CORE. You could say "Nearly all studies used the CORE model". | The FAD has been amended accordingly. |
| Assessment Group | Para 4.2.6 - it would be better to say that the average cost of a severe hypo episode was £65. | The FAD has been amended accordingly. |
| Assessment Group | Related guidance - the last two bullets are not really related. | Comment noted |
| Assessment Group | Research needs. We still need trials of CSII versus MDI in pregnancy, starting pre-conception, and in type 2s with BMI under 26 and poorly controlled on MDI. We also need long-term follow-up (several years) to see if benefits are sustained, and with recording of DKA and QALYs. There is also the issue raised by Reaney and Speight of the optimum measure of quality of life in diabetes. | Comment noted. |
| DOH | Section 1.1<br>We are concerned that without more specific implementation guidance, this technology | The Appraisal Committee recommendations for |

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| | appraisal could result in inequity between different children's services. This is in part due to the wording of the guidance, for example: 'multiple-dose insulin (MDI) therapy is considered to be inappropriate'. We feel that the use of terms such as 'inappropriate' could be widely interpreted by clinicians. | young children are further explained in FAD section 4.3.8 and allows for the clinical opinion to decide on a case by case basis. |
| DOH | Section 1.2<br>We consider that it is important that the appraisal Committee explain why they define multiple-dose insulin (MDI) therapy as having failed providing long acting insulin analogues have been used if appropriate (referring to TA53), but do not make a similar statement about the importance of providing high quality structured patient education in diabetes, referring to an equally appropriate document, TA60.<br>Since the publication of the first appraisal of pump therapy (TA57), structured education has become a recognised part of good management of Type 1 diabetes. However, due to an initial withdrawal of the mandate for TA60 to the NHS until January 2006, appropriate structured education (e.g. DAFNE) is not as widely available as NICE would wish if its recommendation on TA60 were to be rigorously implemented. We feel that the Committee can thus help to promote the implementation of NICE guidance by either giving education the same weight as long-acting analogues, or by explaining why it has not done so. | The importance of structured education has been stressed. See FAD section 4.3.12 and 4.3.15. |
| DOH | Section 1.2<br>The Insulin Pump Working Group expressed concern at the use of the term 'failure'. We feel that it could be perceived as a perverse incentive; some people with diabetes who have poor glycaemic control may be recommended for pump therapy, therefore removing the incentive for them to manage their diabetes. | The FAD has been amended accordingly. |
| DOH | Section 1.3<br>In our view, the previous appraisal of pump therapy was not acted upon equally throughout England. One reason for this was, we feel, lack of clarity over the definition of | The eligibility criteria have been clarified in the guidance section (see 1.1- |

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| | failure of MDI therapy, and the role of clinicians who interpreted this very individually. In our opinion, this has not been adequately rectified in this appraisal, and it would be helpful if this could be made clearer in these recommendations. The words 'high level of care' are subject to local interpretation. This is one reason why the DH / Diabetes UK working party, set up after the previous appraisal to try to help its implementation, recommended that pump therapy should be commissioned as a routine part of a comprehensive community-wide service for Type 1 diabetes. This will ensure that options for delivering insulin treatment and the protocols for governing its introduction are agreed across every diabetes community to ensure that access becomes more equable | 1.5). High level of care is referenced to NICE clinical guidelines, see FAD section 4.3.13. |
| DOH | Section 1.4<br>In our view, it would be helpful if the report emphasised the importance of providing education in the use of pump therapy, using the same criteria as applied to other forms of patient education to ensure high quality for patients. These criteria are laid down by the Structured Education Working Party and have been recommended by the Type 2 guideline group in their draft guidelines. | The FAD does stress the importance of structured education, see section 4.3.12 and 4.3.15. |
| DOH | Section 4.1.3<br>It is understandable that the Committee decided that the evidence from observational studies as well as randomised control trials (RCTs) should be considered: partly because of limited RCT evidence, but also because it was felt that these observational studies better reflected the real world. The Committee commented that overall, these studies show a benefit on both glycaemic control, especially when very poor, and hypoglycaemia. However, we feel that the Committee does not note that pump therapy consists of two components: the pump itself, and the education and training in how to match insulin to food and exercise that is essential to its safe use. In our view, the Committee does not discuss how they distinguished between the benefits accruing from the pump and the benefits accruing from the education. | The Appraisal Committee was aware that structured education, of itself, could have a beneficial effect on the management of diabetes, see FAD section 4.3.12.<br><br>Structured education has been emphasised as part of |

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| | We feel that this matter is of great significance, because TA60 reports that there is evidence that structured patient education (specifically DAFNE) can result in identical outcomes to that now reported for pumps. Both DAFNE and pumps can reduce HbA1c (in both the effect is greater the higher the HbA1c level), both can reduce severe hypoglycaemia and both give high and often enthusiastic patient satisfaction. The logical conclusion would be that MDI 'failure' should only be considered when both long-acting analogues and high quality structured education have been tried. It is the experience of several DAFNE centres (as mentioned in the DAFNE submission) that patients referred for pump therapy who first attend DAFNE programmes may decide not to proceed to the pump because the issues that were troubling them had been resolved. We feel that, as this issue has considerable resource implications for the NHS, this report needs to discuss it with a view to providing written argument as to why such course was or was not recommended. The costs to PCTs which will presumably be produced as part of the implementation guidance that follows this appraisal will vary according to whether this is included or not. | MDI. |
| DOH | Section 4.3.6<br>We feel that, when looking at the transition of children to adult services, there needs to be clarification about whether children will need to meet the adult criteria when they reach the age of 12 years. There are much stricter criteria for adults, so there is the potential that children who do not meet the adult criteria may have their pump removed. The Insulin Pump Working Group advises that it is poor practice for a pump to be removed, especially if clinical and personal goals are being met.<br>The guidance suggests that people who are unable to maintain an HbA1c level of less than 8.5% can be recommended for pump therapy as a treatment option. This figure is higher than in the previous document and could result in fewer people being eligible for pump therapy. | This has been clarified in the FAD, see FAD section 4.3.9. Children are expected to undergo a trial of MDI between the ages of 12 and 18. |

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| DOH | Section 4.3.12<br>This is the ideal place to discuss the need for local protocol and guideline to cover all aspects of insulin management including referral pathways, and ensure that the 'pathway' for pump therapy is a standard part of every commissioned Type 1 diabetes service. In our opinion, this has the best chance of ensuring that the discretionary elements involved in this appraisal do not result in unequal access due to different and potentially idiosyncratic interpretation by individual clinics. | This was not within the remit of this appraisal. . |
| NHS QIS Reviewer 1 | Whether you consider that all the relevant evidence has been taken into account.<br>Yes | Comment noted |
| NHS QIS Reviewer 1 | Whether you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence.<br>Yes | Comment noted |
| NHS QIS Reviewer 1 | Whether you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.<br>Yes | Comment noted |
| NHS QIS Reviewer 1 | Whether you consider that there are any potential policy implications for SEHD?<br>Possibly. There has not to date been a SEHD policy on pump therapy. In particular whether pump therapy should be available in every diabetes clinic, one per health board, or possibly in a small number of centres? The Scottish Diabetes Group has done information gathering on the numbers of pump patients, and may now be producing a policy, but to date it has been left to MCNs to formulate a local strategy. This will have some bearing on the costs of pump services in Scotland. | Comment noted |
| NHS QIS Reviewer 2 | Whether you consider that all the relevant evidence has been taken into account.<br>A large body of evidence has been reviewed both clinically and from a cost effectiveness perspective. Other relevant evidence if it exists which would be useful relates to guiding | Comment noted |

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| | the critical mass of patients necessary to maintain relevant skills for teams managing CSII and for benefits or disadvantages of group education for CSII | |
| NHS QIS Reviewer 2 | Whether you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence.<br>Generally yes. It must be presumed that the figure of 8.5% for HbA1c levels at which CSII can be offered has been chosen arbitrarily from the evidence relating to the improvements accrued in patients with higher starting levels of HbA1c (9%) this is probably reasonable. There are two figures where the derivation is not clear: the start up costs for CSII is this average figure? There is a possibility of reducing these costs through the introduction of structured education. Also the figure of £65 related to costs of managing severe hypoglycaemia, what treatment ensues to contribute to this cost eg medical therapy, paramedic support, assessment and management in an A&E, subsequent overnight stay and follow up. These costs will be relatively higher for patients from more remote areas, however there could be greater clinical and financial benefits in introducing CSII in these areas for patients with disabling hypoglycaemia | The estimation of start up costs is detailed in the Assessment Report.<br><br>The cost for an episode of hypoglycaemia is an average of costs taken from a previous NICE appraisal. |
| NHS QIS Reviewer 2 | Whether you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.<br>The recommendations are basically sound but there are significant changes in the recommendation for both children and adults with type 1 diabetes. 1.1: It is likely that a substantial number of parents or carers will look to the profession to provide CSII for their children early given the opportunity to move to this option without a trial of MDI, this will necessitate development of expertise within paediatric specialist teams, increased resource both in paediatrics and eventually in adult diabetes. In Scotland there is a relatively high incidence of type I diabetes in children and there is an incremental increase with rurality and more northern regions. 1.3: adult patients can be considered for CSII when HBA1c > 8.5 % or disabling hypoglycaemia. This is a substantial change in the guidance and will increase numbers of people being eligible and it introduce | Comment noted. |

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| | difficulty for diabetes specialist teams and health boards to gauge costs for business case development. 1.5: no guidance is provided as to the degree of fall in HbA1c that constitutes a failure. | |
| NHS QIS Reviewer 2 | Whether you consider that there are any potential policy implications for SEHD?<br>It is likely that there will be a commensurate increase in resource required to manage this new activity due to greater number of children and adult Type 1 patients. Many of these individuals may be self presenting and would not be excluded by reason of competency. Consideration should be given to whither further filters should be applied eg use of quality of life questionnaires to assess anxiety levels and compulsory participation in a structured education programme.<br>Consideration should be given to a 'pump contact' being initiated to ensure due care of the device and achievement and maintenance of targets particularly improvements in HbA1c.<br>Structured education should be a prerequisite for any patient embarking on CSII. While structured education can be delivered locally, CSII should be carried out centrally in centres with a critical mass of patients and experience. This will be particularly relevant in small remote or island communities. Specialist teams in a tertiary centre could be responsible for these areas to provide the most cost effective service and prevent dilution of expertise.<br>It is important to stress the need for specialist paediatric pump teams.<br>A unified approach to CSII would be possible and advantageous in Scotland | Comment noted |
| NHS QIS Reviewer 3 | Whether you consider that all the relevant evidence has been taken into account.<br>Evidence relating to the quality of life benefits of pump therapy and glycaemic excursions has not been given adequate consideration.<br>Quality of Life<br>The quality of life benefits (as reported in Diabetes UK's response to the final scope of the NICE Health Technology Appraisal review of CSII) go beyond reducing | Quality of life benefits of CSII were included in the appraisal of cost effectiveness of CSII, see FAD section 4.3.3. |

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| | hypoglycaemia and fear of recurrent hypoglycaemia and have not been given due consideration within this appraisal process. The use of this technology elicits strong responses from users with many not wishing to revert back to MDI. Whereas we acknowledge that the Committee considered observational studies and evidence submitted, the evidence given by patient organisations and available in less “rigorous” studies must be given more weight (see reference below). The weakness of research in this area should not be used as a means to undervalue the important impact on quality of life of this technology, that has been identified by people with diabetes. Diabetes UK Scotland is calling for further research to be undertaken in assessing the quality of life benefits of CSII.<br>Quality of life improvements have been noted in various studies which include increased flexibility in food timing and diet, convenience, an increased sense of autonomy, particularly in children, improved social relations and improved sleep. Some of these improvements have also been identified by the carers of those using CSII.<br>Diabetes UK Scotland recommends that CSII should be made available to people with diabetes requiring insulin based on individual clinical need, patient choice and suitability. Suitability should consider the motivation and ability of an individual to use the insulin pump, and clinical need should take into consideration all quality of life benefits. | |
| NHS QIS Reviewer 3 | Hba1c level<br>The use of Hba1c as the measure of control excludes consideration of glycaemic excursions. A person with diabetes can have good control as defined by their Hba1c level, but can be experiencing glycaemic excursions that impact negatively on their health. CSII has been shown to improve fluctuations in glycaemic excursions but this has not been taken into account in the recommendations.<br>Diabetes UK Scotland disagrees with the whole premise that a person over the age of 11 years must have failed on MDI therapy before CSII is considered as a treatment option. Diabetes UK Scotland questions the selection of 8.5 per cent as the decisional | The available evidence based improvements on outcomes in terms of changes in HbA1c. The Appraisal Committee was only able to make recommendations on this basis. |

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| | level. Good glycaemic control is recognised as being in the range between less than or equal to 6.5 and 7.5 per cent. The JBS2 guidelines identify that optimal control is less than or equal to 6.5 per cent, with an audit target of less than 7.5 It is important to consider that the optimal target may not be suitable for all people, impacting on quality of life in relation to hypoglycaemia , therefore a range is given. | |
| NHS QIS Reviewer 3 | General comment<br>Section 2.5: When discussing good control it is important to acknowledge the benefits of the Hba1c range between 6.5 and 7.5; however targets should be individualised to take into account the importance of quality of life. | Comment noted |
| NHS QIS Reviewer 3 | Whether you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence. There is concern that not enough weight has been given to quality of life benefits such as flexibility in food timing and diet, convenience, an increased sense of autonomy, particularly in children, improved social relations and improved sleep. In addition, whilst the Committee discuss the benefits CSII can bring in relation to glycaemic excursions this is then ignored in the recommendations. Diabetes UK Scotland questions the use of QALYs in adequately assessing all quality of life benefits. | Quality of life benefits are included in the assessment of CSII, see FAD section 4.3.3 |
| NHS QIS Reviewer 3 | Cost effectiveness and Quality of life<br>Section 3.4: Some of the costs attributed to CSII would also be costs associated with MDI. All people with diabetes on insulin will require lancets, test strips, glucometers, education at initiation of insulin and ongoing education. This should be acknowledged.<br>Section 4.2: Much of the cost effectiveness analysis is based on Hba1c levels and reductions in hypoglycaemia and fear of hypoglycaemia. Whereas these parameters are important they are not the only parameters to be considered. The QALY method of quantifying quality of life into a cost effectiveness calculation is not a sophisticated enough tool to be used to measure the quality of life benefits that can be achieved through CSII use. People with diabetes should not be penalised by restricted access to | The FAD has been amended accordingly.<br><br>A number of quality of life benefits have been included in the assessment, see FAD sections 4.3.3. |

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| | CSII because of the lack of available tools to adequately translate quality of life appropriately in terms of cost effectiveness.<br>Section 4.3.6: It appears inappropriate that all quality of life measures have been grouped together and considered within the three percent increment that is attributed to the avoidance of severe hypoglycaemia. The other quality of life benefits will not have the same "cost" as avoidance of hypoglycaemia. The quality of life measures that appear not to have been considered are:<br>Flexibility in food timing and diet<br>Convenience<br>An increased sense of autonomy, particularly in children<br>Improved social relations<br>Improved sleep | The Appraisal Committee judged the addition of a plausible small increment for quality of life benefit to be sufficient (see FAD 4.3.6). For people with lower levels of HbA1c, who experience disabling hypoglycaemia, the Appraisal Committee 'considered that there would be a greater quality of life benefit due to the avoidance of the fear of hypoglycaemia'. See FAD 4.3.7 |
| NHS QIS Reviewer 3 | General comments regarding accuracy<br>Section 2.2: The statement about Type 2 diabetes fails to acknowledge the increasing numbers of children developing Type 2 diabetes.<br>Section 2.3: The sentence relating to the symptoms of severe hypoglycaemia needs to be amended to state "very occasionally *death*"<br>Section 2.5: Not all people with Type 2 diabetes will need to lose weight therefore it is better to refer to weight management than weight loss.<br>Section 3.2: For clarity please alter these statements as follows:<br>The pump can be programmed to deliver a *different* basal rate of insulin *each hour* throughout the day, with higher infusion rates at meal times *which maybe a bolus or extended over a chosen period of time…* | The FAD has been amended accordingly. |

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| | Section 4.3.6: What is appropriate in relation to long acting insulin analogues? | |
| NHS QIS Reviewer 3 | Whether you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.<br>CSII must be available as a choice of insulin administration for all people with diabetes who have the commitment and competence to use the technology. It should not be perceived as being reserved as a specialised treatment for those who are not achieving a particular level of control, and it should not be restricted on the basis of cost. This could be seen as creating a perverse incentive for poor control and limits the treatment choices available. This directly contravenes the government's agenda to increase choice for people with long term conditions to support self management. Choice of treatment is one of the key "choices" that people with diabetes wish to make on the basis of individual clinical need.<br>Diabetes UK Scotland is concerned with the following with regards to the recommendations:<br>The use of an Hba1c level to determine whether or not an individual should be considered for pump therapy will unfairly restrict access to CSII. The Hba1c level will exclude access to CSII for people with diabetes achieving an Hba1c of less than 8.5 per cent. The Hba1c level chosen does not reflect current evidence regarding good blood glucose control. It does not take account of individuals who will have an Hba1c within the range of 6.5 to 7.5 per cent, but who are experiencing significant fluctuation in their glycaemic excursions.<br>• The recommendations as they stand do not consider the quality of life benefits of CSII beyond reducing hypoglycaemia as stated in Diabetes UK's submission on the final scope of the NICE review.<br>• The recommendations exclude people with Type 2 diabetes from accessing CSII<br>• The age cut off that requires those over the age 11 to have been failed by MDI | The Appraisal Committee is responsible for recommending cost-effective uses of NHS resources.<br><br>The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective. |

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| | therapy does not consider the clinical and quality of life benefits that pump therapy can bring. In addition the recommendation to make the age cut off 11 years of age is in appropriate and will particularly disadvantage adolescents (See Question iv).<br>• The recommendation regarding removing CSII where it is not deemed successful is problematic. It does not identify the need to review progress and provide support to address any issues before the removal of CSII is even considered. | |
| NHS QIS Reviewer 3 | Implementation<br>Education as part of implementation<br><u>Section 1.4:</u><br>It is important that the specialist team initiating people onto pump therapy are delivering education, and are competent to deliver this education. The pump therapy specialist team need to be working together with the individual's diabetes care team where they are not the same, and this should be explicitly referenced.<br><u>Section 1.4:</u> The recommendation regarding the importance of the team members needed within the trained specialist team, should state "must comprise" rather than "should normally comprise". | Defining the exact composition of teams delivering pump services is outside the remit of this appraisal and a decision for the treating centre. |
| NHS QIS Reviewer 3 | Reviewing the effectiveness of CSII<br><u>Section 1.5/ 4.3.11:</u> This recommendation does not identify the need to review progress and provide support to address any issues before removal of CSII is even considered. It is vital that a review that involves the individual with diabetes takes place. Diabetes UK also queries why adults and children over 11 years old have been singled out with regards to this recommendation as the safety implications would apply to all on CSII. As a result, Diabetes UK Scotland recommends the recommendation is changed as follows: Following initiation, CSII use should be reviewed with an individual (and where appropriate, their carers) where improvements in glycaemic control or quality of life are not apparent. Appropriate target improvements should be set by the responsible | The FAD states the requirement for increased support before withdrawal of CSII, see FAD section 4.3.14. |

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| | healthcare team in partnership with the individual (and where appropriate, their carers). The decision about whether to continue CSII therapy or not should be made in partnership based on individual clinical need and choice.<br>The decision about whether or not a person continues on CSII is a case by case consideration and should not be decided on the basis of national recommendations. Similarly the definition of a reasonable time period is for case by case consideration as a decision made by an individual in partnership with their healthcare professional team. | |
| NHS QIS Reviewer 3 | Whether you consider that there are any potential policy implications for SEHD?<br>Diabetes UK Scotland believes that some members of the diabetes community will be unfairly excluded from accessing CSII as a result of the recommendations as they stand. These concerns are outlined below.<br>People with Type 2 Diabetes<br>Section 1.6 and 4.3.9: The decision not to recommend CSII for people with Type 2 diabetes appears to have been made on cost effectiveness grounds owing to a lack of available evidence. However, by restricting access to CSII, this will potentially continue to limit the number of people with Type 2 diabetes using CSII therefore continuing to limit the evidence available. One small study has demonstrated that CSII improves the bioavailability of insulin which suggests that CSII would be a suitable option for people with severe insulin resistance.<br>The distinction between types of diabetes is also unhelpful when considering forms of insulin administration. What needs to be considered is where a person is physiologically and psychologically with their use of insulin. Some people with Type 2 diabetes have the same insulin requirements as people with Type 1 diabetes and therefore should be considered as eligible for CSII on the grounds of individual need, suitability and personal choice considering both quality of life and biological factors.<br>The demographics of people with Type 2 diabetes are also changing, with an increasing number of children being diagnosed with Type 2 diabetes. The impact of a younger | The Appraisal Committee acknowledges that some type 2 diabetics may benefit from CSII but cannot recommend the use of CSII in type 2 diabetics in the absence of evidence, see FAD section 4.3.10. |

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| | population with Type 2 diabetes includes people having Type 2 diabetes for a longer duration, the possibility of more people progressing to insulin use at a younger age and more pregnant women with Type 2 diabetes. As a result to exclude people with Type 2 diabetes from the recommendations for CSII is to exclude many people who have a right to access a choice of treatment that may provide the best benefits for them. | |
| NHS QIS Reviewer 3 | Hba1c level<br>The inclusion of a particular Hba1c level (8.5 per cent) as an indicator that MDI has failed is both unfair and restrictive. Having to *fail* to achieve an Hba1c level of 8.5 percent instantly restricts access to CSII for those individuals who are achieving good control and ignores the quality of life benefits that can be gained from CSII. Diabetes UK also questions the selection of 8.5 per cent as the decisional level. Good glycaemic control is recognised as being in the range between less than or equal to 6.5 and 7.5 per cent. The JBS2 guidelines identify that optimal control is less than or equal to 6.5 per cent, with an audit target of less than 7.5. [9] It is important to consider that the optimal target may not be suitable for all people, impacting on quality of life in relation to hypoglycaemia, therefore a range is given. | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective. |
| NHS QIS Reviewer 3 | Age cut off<br><u>Section 4.3.6:</u><br>The decision to include an age cut off that requires those over the age of 11 to have been failed by MDI therapy will unfairly restrict access to CSII. It does not consider the clinical and quality of life benefits that can be achieved on CSII. Furthermore the choice of age 11 as a cut off is peculiar and based on a broad generalisation regarding the ability of child to use MDI at school. Not all children older than 11 will be able/ allowed to self inject an afternoon dose of insulin in school. The upheaval to the child and other family members caused by parents having to go into to school during the day to give an injection will not be adequately addressed by this generalisation. Many local paediatric services organise their clinics in age bands. The usual age bracket for juniors ends at | Comment noted. The Appraisal Committee considered clinical expert evidence that children 12 years and older could undertake a trial of MDI which may be effective at achieving good glycaemic control. |

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| | age 12 not age 11.<br>This age cut off will particularly disadvantage adolescents who will be going through their transitional phase of life. The transitional phase is well recognised as a stage when many young people experience difficulties with their diabetes control and engagement with services. The quality of life benefits that CSII can bring, particularly in enabling more flexibility in the young person's routine make CSII a very valid treatment option for this age group.<br>Diabetes UK Scotland urges NHS QIS to consider the comments made above and ensure that they do not inappropriately restrict access to this treatment option for people with diabetes with the competence and commitment to use this technology. We look forward to feedback in due course. | |
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| Web Responses<br>Carer | Appears to be an adequate summary of suitable patients based on medical parameters<br>It may be prudent to have refresher courses for pump users. Is the reduced amount of insulin factored in to the cost calculations? No long acting & far less fast acting insulin is consumed. Are all pumps similar? Did some pumps perform better than others? | Decreased insulin requirements and costs are factored into the appraisal. Individual types of pumps were not appraised separately. |
| NHS Professional | I do not believe the education the education is a one-off. There is the intense initial education & then there will always be on-going education. Some people initially will only want to use the basic functions of the pump but in time may want to use the more advanced features. Others, like all education, will forget certain things & need a recap session. | Comment noted |
| Carer | I think you need to make it clearer whether trouble with hypoglycaemia means seizures/fits/unconsciousness. My son's diabetes team at Derriford Hospital interpret the current guidelines this way and in the absence of seizures use 7.5% as the magic figure to submit an application to the PCT for pump funding. As this document stands they will | The definition of disabling hypoglycaemia needs to be made on an individual basis by health professionals in |

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| | probably now only apply for patients with HbA1cs over 8.5% so even fewer patients will qualify. What do you actually mean by hypoglycaemia? Is it any level under 4mmol needing hypo treatment, symptomatic hypoglycaemia or fits/seizures/unconsciousness? What about those with hypoglycaemia unawareness? | consultation with patient and carers. The guidance cannot make recommendations that will cover every individual situation. |
| Carer | Item 1.3 - what about other effects on quality of life being reasons for CSII, such as needle phobia, lumps and uncomfortable areas from injecting? Children over 11 being embarrassed to inject in front of friends. Not being able to vary the amount of insulin administered at particular times of day like you can on CSII by programming the pump. Depression caused by the above issues (and other issues) and a child's quality of life. Should these not be reasons to use CSII as well? As a parent we carb count all meals and correct any high blood sugars on MDI, but a child over 11 will not always have the confidence to do this themselves. My sons HBA1c is around 7.0 because of our vigilance and hard work, but our son would like more control himself using CSII would give him this - should those with reasonable control of their diabetes be excluded from gaining better control and more independence. Just because they are over 11 and can inject themselves at school should not exclude them from the other benefits of CSII. | Quality of life benefits are considered, see FAD section 4.3.3. Adolescent embarrassment about insulin injections also extends to the use of pumps. It is not cost-effective to use CSII in people who are well controlled on MDI. |
| Carer | Item 1.3: Why is the level set at less than 8.5%. I believe it used to be set at 7.5%. 8.5% seems way too high. You say further down in this report that less than 7.5 is good control, but it is no way near normal. I know a young boy on CSII who is able to achieve an HBA1c of 5%. This is what I would like to be able to achieve for my son who has an HBA1c of 7% (and is probably still in honeymoon). Why should he not be given the tools to achieve a normal HBA1c too? | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective. |
| Carer | 1.3 A level of 8.5% is too high 1.4 What about people falling under community hospitals where there is no DSN and no interest in pump therapy? This is unfair on the diabetic | See above.<br>All eligible people have the |

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| | persons in that catchment area.<br>Does this education include the carers e.g. parents of a diabetic child and later in life the child's education? At present carers of children cannot do a DAPHNE course which is an important part of matching insulin to carbs<br>The healthcare professional needs to ensure that the schools also have the competence to use CSII therapy effectively. | option of pump therapy and the NHS will have to implement NICE guidance<br>It was outside the remit of this appraisal to consider eligibility to undergo education. |
| NHS professional | 1.2 Given that in the first recommendations there was a limit set to the number of people thought to be appropriate for this therapy (2-3%) should one reading these recommendations assume this ceiling has now been lifted and that anyone reaching the criteria can be trialled on a pump (i.e. up to 50% of type 1 patients). If this is not the case it would be useful if an indication of a putative ceiling is included (5%, 10% or 20%?!) 1.5 QOL goals seem to be completely absent from this section - does that reflect the view of the Committee that QOL improvement is not a valid goal? 1.6 given that with prolonged disease duration the insulin secretory reserve of people with type two diabetes may become identically deficient to type 1, I wonder if a statement regarding c-peptide negativity could clarify the statement<br>Does this statement mean that other devices that are likely to become available will not be eligible until a future re-appraisal? In particular there are a number of single use pump devices that are already available in the US and I'm informed will shortly become available in the UK. Pricing appears to be cost neutral overall (with a reduced start-up cost, therefore good for trials of therapy) and I feel sure many patients would prefer such devices - could a statement to the effect that devices which are EU / MDA approved, supported in the UK and broadly cost neutral with those already available could be considered to be covered within this guidance? | Yes – all people who fit into the criteria in the recommendations can be considered for treatment with CSII. It is outside the remit of the appraisal to recommend what the expected proportion of people with diabetes who would go on to pumps should be.<br>Type 2 – see above<br>The appraisal does not recommend any particular pump models. |
| NHS Profession | 1.1 We select for CSII very carefully. Despite this people frequently become very used to CSII and take it for granted and the commitment to good management disappears. I | Agreeing on what constitutes an improvement |

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| al | think all people should sign a contract of some kind which is reviewed by both the diabetes team and the financing authority at regular (? 6/12) intervals. Until this is done, taxpayer's money is going to continue to be wasted. This has happened to 2 of the families that I look after and I would like to be able to either enforce good management or remove the pumps from these families. 1.3 An HbA1c cut off of 8.5% is much too high. This implies that 8.5% is the level at which it is no longer safe to be. In our clinic we strive for 7% or less according to current recommendations. 50% of the children are 7.5% or less but may still have very erratic control. Of significance is post-prandial hyperglycaemia - often unrecognised, but which may be causing significant damage - there is evidence which demonstrates that post-prandial hyperglycaemia may cause significant endothelial damage. Even using MDI and low glycaemic index food it is sometimes impossible to eradicate this problem without causing iatrogenic hypoglycaemia.<br>2.3 The first sentence should read complications not problems. A complication is completely different to a problem. Somewhere in 2.3 there should be a reminder that both Type 1 and Type 2 diabetes in early pregnancy are potentially catastrophic for the foetus unless well controlled PRIOR to pregnancy. Abnormalities can arise soon after cell differentiation commences which would be long before a woman would even know that she was pregnant. 2.5 I do not regard good control as an HbA1c of 7.5%. The DCCT (NEJM -1993) indicates that 7% or less is associated with a significant reduction in long term complications. I am never happy with 7.5% and someone on CSII should be easily able to achieve an HbA1c of between 6 and 7%.<br>3.2 Cannula may need resiting every 2 days - this should be mentioned because of cost implications to PCTs<br>A meta-analysis of the available relevant evidence might give further clarification. A wider search, including trials in progress might reveal more work in this area. | is an individual decision for patient and health professionals.<br><br>The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective.<br><br>The FAD has been amended accordingly. |
| NHS | Point 1.5 offers a very narrow view of measures of success of CSII. There should be | Quality of life improvements |

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| professional | QOL indicators for children and young people, where the insulin pump has made a significant impact on their emotional or social wellbeing, without necessarily demonstrating a fall in HbA1c. A very important measurable improvement would be a reduction in the number of episodes of Diabetic Ketoacidosis/reduced number of hospital admissions. This point also fails to suggest a timescale - is this a deliberate strategy? | are included, see FAD section 4.3.3.<br><br>The recommendations are general, allowing decisions to be made on an individual basis. |
| NHS Professional | Hba1c of 8.5% represents a poor standard of care to aim for. GP QoF targets 7.5% and most specialist bodies recommend 7% or lower. 8.5% risks much greater microvascular disease and younger age type 1s are at great risk of this. The target should be 7%. Interesting that this section quotes HbA1c of 7.5% as indicating good control- see comments above<br><br>Accu Chek spirit has 6 year warranty as standard<br><br>A serious issue to consider is if patients with severe hypoglycaemia and HbA1c<8.5% are denied CSII, they may to be considered for islet or whole pancreas transplant as the only option. As well as the great cost, there is a great shortage of donors. The 8.5% target is unwise.<br>Most pump services are up and running so this will not be a problem | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective.<br><br>Noted in assessment report<br><br>Such patients are eligible for CSII, see FAD section 1.1 and 4.3.7. |
| Carer | The cost of these pumps seems reasonable when the technology involved is considered. For the NHS, the cost will be offset in short term by far less wastage of insulin, less practitioner time spent treating diabetic episodes etc. and in the long term by greatly reduced complications for those sticking to CSII. Some models have a facility for automatic blood sugar testing (with a separate cannula) which is transmitted to the | The economic analysis did take in to account that the costs of CSII are partially offset by prevention of complications. |

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| | unit wirelessly. This is the first step towards a commercially available artificial pancreas, or at least Islets of Langerhans. This is the future of diabetes treatment (until a more permanent cure is refined and understood. The sooner type 1 DM sufferers are weaned onto pump therapy, the better.<br>Thank you for taking all of this into account. Some small observations:<br>Please make this technology available to as many type 1 DM sufferers as possible, as soon as possible.<br>Thank you for all your work on these vital issues. It may be better, in my humble opinion, not to waste any more resources on<br>Please endeavour to move this forward to coincide with the release of new models of pump and a more closed loop | |
| Carer | Not enough consideration is given to quality of life. For children in particular and pump can really improve their quality of life by giving them independence and therefore giving them greater self esteem. Many children find it difficult to give themselves injections pumps make it much easier for the child to control the dosage themselves (or in can be programmed). This means that going to friends houses for tea is much easier and less embarrassing for the child as the carer does not need to go round to give the injection. This may sound minor, but for a child in their early years this is a big deal. | Quality of life improvements with CSII are factored into the analysis, see FAD section 4.3.3. |
| Patient | I welcome the appraisal Committee's recommendations especially for children under the age of 11 where MDI may not be an option.<br>I commend the recognition of the very vulnerable & difficult group to manage...the under 5s<br>3.2 could we not say 2-3 days as 3 days may be the norm but in some cases it can be every 2 which may cause queries on costs<br>I agree with the recommendations especially in the delivery of small doses in children<br>Implementation for Paediatric teams may be difficult when they deal with more than 1 PCT for funding of pumps. I would like to see advised that Paediatric teams providing a | Comment noted |

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| | pump service would have a funding stream from the PCTs to enable them to have a pool of pumps within secondary care then consumables set up on a case by case basis. This would enable | |
| NHS professional | These are sensible and pragmatic suggestions that will be easily understood by patients and healthcare professionals. A pre-pump contract drawn up between the healthcare team and the patient may help withdrawal of pump treatment if it proves unsuccessful. | Comment noted |
| NHS Professional | Children younger than 11???more clarity and its use in younger age groups is very effective due to improved absorption CSII could have a role in insulin resistant type 2 patients what about patients with poor sites, with wide areas of lipohypertrophy<br>3.4 is very generalistic. Education is not one off but on going and with specific pump follow up clinics to ensure this therapy is maximised as patients do have to have a commitment to it, it is not an easy option for the person with diabetes<br>Guide lines need to be very clear but not prescriptive key assessment for suitability for pump therapy is vital for its appropriate use and success | CSII is recommended for children younger than 12 year of age. The Appraisal Committee recognised the importance of education but did not hear the evidence or make recommendations for exactly what this should involve. |
| NHS professional | The HbA1c standard of 8.5% is too high. The effect of such a target would be to exclude the patients most able to benefit from pump therapy - i.e. the ones with control that is suboptimal, but who are striving to achieve it.<br>I agree with the statement that optimal control in uncomplicated T1 diabetes requires a HbA1c of <7.5% - and this should be the target for defining eligibility for treatment with a pump - not 8.5%.<br>Specific consideration needs to be given to concomitant use of glucose monitoring systems - eg Medtronics CGMS system.<br>I think a period of MDI therapy, even for children under 11y is appropriate. Schools are under an obligation to promote the welfare of children with health needs to facilitate their inclusion. Our service routinely uses lunchtime injections, and works with schools to achieve this. | CSII is not cost-effective when HbA1c is lower than 8.5% (in the absence of disabling hypoglycaemia)<br><br>Appraising glucose monitoring systems was not within the remit of the appraisal. |

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| NHS Professional | 4.38 Not to consider CSII in people with Type 2 diabetes is short termism approach. These individuals can be severely insulin resistant (especially those from ethnic minority backgrounds), they have significant difficulties self-managing their diabetes and maintaining an HbA1c<8.5%. Subsequently when the cost to the NHS, economic, personal and societal costs of the impact of developing complications is factored in the cost of CSII is less onerous. | There was no evidence of benefit in type 2 diabetics – a view supported by clinical experts. The costs of complications are factored into the economic analysis |
| NHS Professional | Education pre-pump start and initiation, for each patient is hugely time consuming. In order for the patient to receive adequate education and on-going support with their pump requires one-to-one time with a pump specialist (usually a diabetes specialist Nurse). For example, the appointment to start a pump usually takes between 2-3hours, daily telephone contact is required for the first week and weekly appointments there-after to make the necessary adjustments to the various insulin rates, assessing blood glucose levels in addition to training on the technical aspects of the pump functions. It can vary from patient to patient but generally can be up to 6 months before the patient is competent using their pump. The better the educational support, the better chances of maximising pump therapy. In my area most adjustments are made by the DSN not the Medical Team. An emphasis on Patient Education must be made.<br>Regarding training costs incurred for patient education, I would contest that costs would higher. I don't know what their figure £240 relates to? My comments are based on my own clinical practice and experience. Pre-pump preparation approx 1hour. Pump start 2-3 hours. Appt for the first set change 60-90 minutes. Daily telephone contact for the first week and weekly 60 minute appts for the first 4-6 weeks and monthly thereafter until 6 months approx. This gives a rough idea, Some patients need more, some a bit less. This is relating to DSN appointment only, not doctor or dietician, which would be extra. | The assessment report estimated the costs of start-up as equal to the costs of a DAFNE course in Aberdeen. This is an approximation and the Appraisal Committee was aware of the approach used. The Appraisal Committee was also aware that the initial period– if it costs more than CSII would be less cost effective than estimated. |
| NHS Professional | 1.3 feel HbA1c level should be lower i.e. 7.5% as in original document or taken out all together. 1.4 I think trained team needed (not specialist team) otherwise will limit ability to provide. 1.5 include perceived improvement in quality of life, i.e. less anxiety re | Comment noted.<br>The avoidance of hypoglycaemia is sufficient |

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| | hypoglycaemia. Child having frequent hypos may find have higher HbA1c after use but better overall control. | reason for continuing on CSII, see FAD section 1.4 |
| NHS professional | These recommendations are more appropriate for the patients that I see and would like to consider for pump therapy than the earlier appraisal. I support them. | Comment noted |
| Carer | 1.1 How is commitment and competence to be measured? And by who? 1.3 Why is an HbA1c of 8.5% being quoted as a target level when the previous level was 7.5%? This is a huge backward step. The American Diabetes Association now recommends an HbA1c of 6.5%, as the sort of level people should be aiming to achieve where possible. “Good control is indicated by a value of less than 7.5% (normal range for people who do not have diabetes is 4.5-6.1%)” Nice Guidance 2004 1.5. An HbA1c might be higher post pump if someone had been experiencing swings from high to low. Less fluctuation might mean a rise rather than a fall, but there may be less cell damage due to blood glucose excursions. Someone could have an HbA1c of 5.9% on five injections a day, but be experiencing terrible control and their life may be blighted by serious uncontrollable hypos. On other insulin regimens like MDI, treatment is not withdrawn if a patient fails to achieve the recommended HbA1c. You do not return to 2 injections a day. There should be patient care plans in place.<br>Some of these costs are applicable to MDI (Basal bolus) regimens as well. The initial training, insulin, testing strips, blood glucose monitors. Patients moving on to basal bolus regimens also require additional medical support when a new regimen is initiated<br>If you want evidence for improved quality of life using CSII, there are many thousands of pump users in the UK, from children to adults, who would be keen to testify what difference insulin pump therapy has made to their everyday experience.<br>My child had an HbA1c of around 7.4% before starting pump therapy and suffered from extreme hyper and hypoglycaemia which resulted in seizures. Especially at night, as my daughter has no hypo awareness at all when asleep. Since going on a pump her blood | The FAD has been amended. The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost-effective.<br><br>The FAD has been amended accordingly.<br><br>The Appraisal Committee read and heard this |

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| | glucose levels do not fluctuate so wildly and we are able to give a reduced basal rate during sleeping hours to try to prevent the serious night time hypos which occurred in the past | testimony, see FAD section 4.3.3. |
| NHS professional | 1.3 The NICE guidance on type 1 diabetes in children states that a HbA1c of less than 7.5% is the target. Why has a higher HbA1c level been chosen for insulin pump therapy? Many of the children I feel would benefit most from pump therapy have a HbA1c below 8.5%, but cannot achieve less than 7.5% without disabling hypoglycaemia. | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective. |
| Carer | I am shocked that the acceptable HbA1c in this document is quoted as 8.5%.In previous NICE guidelines an HbA1c of 7.5% was what was considered acceptable and necessary to reduce complications. In the US this level is below 6.5%. What evidence has been used to justify this? My children have HbA1c of 7.4%. They need pumps for the variable basal rate. My 8 yr old would only need to have better quality of life to keep his pump. My 11 year old would have to prove a better HbA1c - though his reflects lots of lows during the night and day to keep it so low. His HbA1c may go up as he achieves balance and avoids hypos and swings. He would be safer but criticised for it and may lose his pump. Is this fair? How would you test us for commitment and competence? In a clinic not embracing pump therapy this could be used as a stick to beat the patients and carers and refuse pumps to many.<br>The definitions here are great. They stress the desperate need for good glycaemic control especially in those diagnosed young. They seem to disagree with the recommendations in the first section. You talk about the severe complications and address the psychological effects of this disease on the whole family and the patient. Are not these reasons enough to be given a choice of treatment which suits you, though it may not show startling reductions in HbA1cs? Children's needs are so difficult to | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective.<br><br>The Appraisal Committee is responsible for making recommendations on the |

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| | manage, especially the young going into and through puberty. The previous statements do not allow for this most crucial time to be shown good guidance and be given every opportunity to learn for yourself how to keep your body healthy. How can a young person learn with the threat of loss of pump were they to make any mistakes which raise HbA1c? You even say in para 2.5 that acceptable HbA1c is 7.5%. Is the previous 8.5% a typo which might cost us dear? | cost-effective use of NHS resources |
| | I would argue that many of these costs are also appropriate to those starting basal/bolus therapy. Also, they do not give the comparative savings acknowledged by the Working Party on Pump therapy (2007), which prove savings year on year on the care required for complications and in-patient treatments over the years of using pumps. If medical insurance companies are willing to fund pumps in the States, there can be no better indication that pumps save money if viewed in a bigger picture. Should this not be reflected in your guidance or this information will merely hinder those professionals wishing to implement pump therapy from within PCTs as yet proving to be reticent to initiate it. | Savings on costs of complications are included in the economic analysis |
| | The one thing missing from the studies is a report into how well adult users of pumps maintain their HbA1cs and avoid complications if they have been started on CSII therapy from being a child. Does the use of the pump and ability to maintain good healthy levels improve if the user has been exposed and educated in pumps from an earlier start? I would also ask you to define reasonable in terms of length of time to see differences when moving to CSII in clinics or PCTs ant-pump this time period could be used to dissuade or even bar many from the therapy. These guidelines are vital tools for those seeking a better quality of life. You have to ensure they give us tools to help rather than giving other the tools to prohibit the use of such modern technologies. Many clinics spend very little time or money on the mental health issues around Type 1. Would hate to have to prove my children's anxiety about hypos if it was the only criteria upon which to base a claim for pumps therapy. It could tie you up for many many months whilst your child suffers long-term problems. I still question the HbA1c of 8.5%. This is being set | Comment noted |

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| | prohibitively high for financial reasons not clinical!<br>I think these guidelines will set back the push forward for new technologies particularly for young people wanting to access CSII. I hope inadvertently you will have made the task of proving need and qualifying criteria for CSII far more difficult when faced with many PCTs who are reluctant to embrace these new technologies. You will find more and more patients will be exercising their patient choice to move to areas where pump therapy is progressive and not restricted. I have moved to a clinic over an hour and a half away to be able to have pumps for my children. When this country is so far behind the standards of Sweden, France, USA, Italy and many of the worlds developed nations in terms of diabetes care, is it right to advocate a raising of the HbA1c seen as needed to prolong health and life? I feel ashamed when I speak to friends in other countries and have to describe the appeal for a referral I had to lodge to have my children considered for insulin pumps. I was successful, despite their lack of hypo awareness over-night and frequent hypos during the day, because I was able to quote from NICE guidelines. This document means I would not be successful again. Is that right?<br>You have not referenced Making Every Young Person with Diabetes Matter (April 2007)<br>Why change HbA1c values to 8.5% when these other publications have it lower?<br>I would say this needs reviewing sooner in the light of the comparative price reduction for new technologies. Would the report not give scope to the demands for the Pump companies to reduce their UK process to bring them in-line with the costs in the USA. We pay more for the same technology here - why? This Committee might have a louder voice to ask these questions. Also newer technologies - such a sensor pumps - will be here soon. The Committee may have new guidance to add if the newer technologies provide life-changing advances in therapy i.e. artificial pancreas trial etc etc | |
| Health professional | 1.3 The figure of 8.5% is too high given that the DCCT study showed that 7.5% was the point at which significant reduction of diabetic complications occurred. Children in particular should be better protected from the long-term complications of diabetes by | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. |

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| | having a lower target HbA1c. Women planning pregnancy are advised to aim for a much lower HbA1c and this should be reflected in the guidance. 1.5 Children experience great difficulty in maintaining good control through growth spurts and puberty, and this should be reflected in the guidelines. They should not be threatened with a return to injection therapy when they may be working very hard at their control but be struggling with effects of hormones and rapid body changes.<br>2.4 Children often get little support in school in managing their diabetes, which increases stress on the child and family. All children should receive support in measuring blood glucose and taking appropriate action, administering insulin and ensuring food intake and exercise are balanced. | This is the level at which the use of CSII was judged cost- effective. |
| Carer | 1.3. Diabetes UK state the following: The target for HbA1c is 6.5 per cent or below since evidence shows that this can reduce the risk of developing diabetic complications e.g. nerve damage, eye disease, kidney disease and heart disease. Individuals at risk of severe hypoglycaemia should aim for an HbA1c of less than 7.5 per cent. Any parent of a child with diabetes desperately wants to reduce their child's chances of developing these terrible complications. Could the people making these decisions about who should have the best care and tools to manage diabetes (CSII therapy) imagine leaving their own children on 8.5% without making strenuous efforts to correct this? Strenuous efforts to do so involve regularly checking blood sugars through the day and night to try to keep levels low and giving extra injections of insulin to bring down high blood sugar levels. By having the HBA1c set at such a high level seems to penalise children whose parents are making these efforts and preclude them from receiving the tool that could help them have a better quality of life now and a better chance of a long life. Surely having a pump should not just be about these figures.<br>4.1.2 There are many adults and children (not just in the UK but around the world) who have had their lives improved by CSII. I know this because I have spoken to them myself via email and their experiences should be taken into account. Why is an HbA1c of 8.5% | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective. |

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| | being quoted as a target level when the previous level was 7.5%? This is a huge backward step. The American Diabetes Association now recommends an HbA1c of 6.5%, as the sort of level people should be aiming to achieve where possible. Why is the UK so far behind in their care of diabetes than the rest of Europe and the United States?<br>The quality of life for the children 11 and over should be considered too. My son gets embarrassed when with his friends - if they have snacks or food he has to get out an insulin pen, put a needle on it, calculate the amount of insulin needed to cover the food and inject (not much fun for a lad trying to fit in with his peer group, making him feel self conscious and different). He would much prefer to have a pump that he could use to bolus for the food he has eaten rather than having to inject himself. Surely these psychological issues are just as important as percentages.<br>You don't seem to have mentioned the Making Every Young Person with Diabetes Matter document, which certainly doesn't have the tone that youngsters as young as 11 should fit the same criteria as adults in terms of reviews of their care etc.<br>2011 seems a long way away considering how technology moves on and the fact that pumps should get cheaper over time. Pumps are much cheaper in USA - why not here? Can pressure /incentives be brought to bear to bring down prices and therefore increase the amount of people that can be given the chance of a more normal life, and a healthier one at that. | |
| Carer | 1.1 How will competence be measured? By who? 1.3 why is 8.5% now being quoted? The American diabetes association recommends 6.5% Is this figure a mistake? 1.4 for those in areas where this does not exist will there be a centre of excellence to go to or is it a postcode lottery? 1.5 a rise in hba1c following pump therapy does not automatically mean glycaemic control is not improved i.e. where the previous hba1c was only lower at the expense of hypoglycaemia<br>3.4 Some of these costs are applicable to MDI Basal bolus regimens as well. The initial training, insulin, testing strips, blood glucose monitors. Patients moving on to basal bolus | The FAD has been amended. The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost-effective. |

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| | regimens also require additional medical support when a new regimen is instigated. Long term cost of chronic illness due to poor control?? Impact on quality of life is significant if not measurable. | The FAD has been amended accordingly. |
| Carer | In 1.3, how can an HbA1c of 8.5% be described as adequate control when the previous level was 7.5%? The Association now recommends an HbA1c of 6.5%, as the sort of level people should be aiming to achieve where possible.<br>3.4 Some of these costs are not in addition to MDI therapy. Any type 1 diabetic will require insulin, lancets, test strips and glucometers and medical support whether they are using a pump or not. | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective.<br>The FAD has been amended accordingly. |
| NHS professional | I have real concerns about the omission of adolescents and young adults as a group. They are a very difficult group to manage and have the worst metabolic control. There is NO evidence that MDI improves their long term control, the few RCTs are too short lived and there is much observational evidence to suggest that they do better on CSII. Also most individuals with repeated admissions for DKA have been shown to have greatly reduced admission rates on CSII. The increased baseline HbA1c to 8.5% conflicts with evidence suggesting that metabolic control improves as a whole for those with HbA1c >7.5% There is also a real ethical issue here. If an individual is on CSII, it has greatly improved the quality of their life, yet not satisfied some arbitrary unvalidated targets, are you really suggesting stopping what for the patient is an effective treatment. You'll be legally challenged I think. It's not our diabetes! Would you stop somebody from using insulin if they didn't control themselves properly? Finally there are well documented cases of type 2 diabetes especially with very high insulin needs responding very well to CSII. Exclusion is not justified on any evidential basis<br>It has been clearly demonstrated by the findings of the DCCT that there is no threshold effect of HbA1c and complication rates, and that the lowest HbA1c achievable without | The Appraisal Committee was aware of the issues for control of diabetes in adolescents and young adults. The Appraisal Committee heard expert evidence that children aged 12 and older would be able to undertake a trial of MDI which could provide effective glycaemic control. The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged |

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| | unacceptable hypoglycaemia should be the target. Lowering HbA1c does increase the risk of severe hypoglycaemia, it is well recognised that CSII reduces the risk of severe hypoglycaemia. Therefore CSII should be available to individuals who have so-called acceptable control (HbA1c<7.5%) who want to further intensify their diabetes control but are unable to do so without hypoglycaemia. Are we seriously telling patients that they don't have to have better results than 7.5% or indeed 8.5% as is to be recommended by this advice? | cost- effective. |
| | It is probably a myth that individuals on CSII get catheter infections. Careful observation shows that most of these episodes are reactions (a better term than infection) to the catheter and are influenced by the type of insulin infused. The greatest incidence of reactions is to insulin Lispro, but also occurs with both insulin aspart and glulisine. It is a very individual response. True infections are uncommon. | The FAD has been amended accordingly. |
| | I do not feel that the Committee have adequately addressed the needs of adolescents and young adults. The evidence for benefit of MDI as the only intervention over the long term in this group has not been demonstrated. It is clear from the observational studies that adolescents do particularly well on CSII. As a clinician I have known of many children over the age of 11 who will NOT self inject at school. Furthermore our own observations suggest that the MAJORITY of school aged adolescents on MDI regularly miss their lunchtime injection, and this is in a clinic in the lowest decile for HbA1c results in the UK. Given that this is the group of individuals who are at greatest risk of inadequate control, but also at greatest risk of hypoglycaemia with intensification (DCCT evidence) then to set the criteria for CSII as the same for mature adults is discriminatory and frankly wrong. They should be treated almost as a separate category of high risk and CSII available as an option for all. Remember only 50% of patients offered CSII will take it. | Evidence for this age group was not available separately – they were not identified as a group more likely to benefit from CSII |
| | Well we know how effective these methods have been in raising awareness, availability and uptake of CSII in the UK. Still the lowest in the developed world! | |
| | Should be reviewed sooner than this as both the technology and expertise in CSII are | |

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| | changing rapidly. No later than 2010 | |
| NHS professional | I do not think that an HbA1c of <8.5% is necessarily acceptable when people are having major problems with hypoglycaemia, particularly in pregnancy or if they have established complications? Given the importance of tight glycaemic control, why should such suboptimal control be acceptable when CSII can facilitate improved glycaemic control with a reduced risk of hypoglycaemia? | Patients with good control but with disabling hypoglycaemia are eligible for insulin pumps, see FAD section 1.1 |
| Carer | I am disappointed that MDI therapy is considered to have failed at a HbA1c of 8.5% or less even though good control is usually considered to be 7.5% or below and some authorities recommend even lower levels. This seems a backwards step from the previous guidance which used the clinically more appropriate 7.5%. Disabling hypoglycaemia is mentioned but not patients whose blood glucose (BG) levels fluctuate widely throughout the day resulting in an adequate HbA1c at the cost of a poor quality of life and probably future complications as a result of the hyperglycaemic episodes? Research has found that the mean difference between an individual's (adults) lowest and the highest hourly basal rate on a pump was 127% and ranged from 25 to 300% when optimised to reduce these BG fluctuations (King & Armstrong, A Prospective Evaluation of Insulin Dosing Recommendations in Patients with Type 1 Diabetes at Near Normal Glucose Control: Basal Dosing). A flat basal insulin injection cannot hope to match the basal insulin requirements of many of these patients. Research has also shown that juveniles (aged <20) have an even more pronounced and sustained night time peak in basal insulin needs.<br>I'm not sure why insulin, lancets, test strips and glucometers are included in this list as these items will be needed even without a pump. Some costs will also go down, e.g. insulin pen needles. We carried out more tests during multiple daily injections because blood glucose levels fluctuated more and were less predictable than during pump use. If control is poor enough to consider prescribing an insulin pump then further education will obviously still be required even if a pump is ultimately considered unsuitable for the | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective.<br><br>The FAD has been amended accordingly. |

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| | patient. Education should therefore not be seen as an additional cost caused by pumps. We have needed less help from clinic staff since the one day of pump training we received compared to the help we needed using multiple daily injections. We needed much more help from staff with day to day management because of the more unstable blood glucose control my daughter had. Before the pump my daughter suffered seizures twice but this has not been a problem since using the pump so we have also had less need of help from the ambulance service. | |
| Carer | I am worried that HBA1cs will be used to remove some off pump therapy even if the quality of life has improved on the pump.<br>Good that the danger of hypoglycaemia recognised.<br>I am worried that if my son wants a pump his good HBA1c will be used to prevent this, even though he is having worrying hypos. | Comment noted |
| Carer | How do you intend to finance these recommendations when most trusts only have funding for just a few pumps a years (some trusts have not facilities which requires an out of area referral). Its all very well having these guidelines but funding at a local level is extremely difficult not just for the pump but for DSN time to support the introduction and support of a pump. As a parent I can only say that I wish we had been encouraged to look at a pump earlier rather than struggle on for so many years not improving HbA1c - god only know that damage we may have done. The local issue has always been funding and no amount of guidelines will change this practice. As a parent I feel a pump should be available to every child who wants one as the payback in years to come with better control at a younger age I am convinced will cover the extra expenses. | All trusts will have to comply with NICE technology appraisal guidance |
| Patient | The HBA1C level of 8.5% is not the optimum level for the avoidance of complications. The Diabetes Control and Complications Trial found that intensively treated patients had lower average blood glucose levels than conventionally treated patients even when they had the same HbA1c. It was concluded that the lower average BG levels may explain the link between intensive treatment and both increased hypoglycaemia and decreased | Comment noted |

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| | microvascular complications compared with conventional treatment. A second study looked at data from the DCCT and compared how well average BG predicted cardiovascular disease compared to HbA1c. | |
| Patient | HbA1C of 8.5% is too high as the risk of complications at even 7.0% is significantly greater. This limit should be reduced. As stated further down the document good control is judged to be when the HbA1C is 7.5% or lower in section 2.5. The OR should be made clearer in 1.3 so that it is clear a patient only needs to meet one, not both of the requirements. | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective. |
| Patient | Currently the UK has lower usage of CSII than most other European Countries. CSII was first initiated in the UK and is a proven method for improving control, lifestyle and productivity of diabetic patients - hence the high usage of pumps in virtually all other Westernised Countries. The upfront costs of CSII are comparatively low compared with the costs of complications of diabetes. Why is it that diabetic patients are being discriminated against? Does a cancer patient have to prove that they have tried all other possible methods of pain control before being allowed to use a pump to deliver their pain medication? This appraisal is yet another short term cost cutting exercise which will be very costly for Diabetics throughout the UK and is a wasted opportunity to improve the treatment options available for this chronically sick group of people who have to live with discrimination throughout every path of their lives without the NHS employing similar tactics. Point 1.3 needs to have the criteria relaxed. Diabetes is all about failure - failure to achieve correct blood sugar results so often and with so little encouragement. Now the NHS is failing us too. | Comment noted |
| Patient | Para 1.3 - the limit of less than 8.5 is most unwise. Where is the evidence to substantiate a move to such a high limit? To run at an HBa1c as high as 8.4 (or even lower than this) is inviting long term health complications as well as a low quality of life. | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. |

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| | Certainly I would consider my health to be in danger if my blood sugars were running this high! 1.5 - HbA1c levels may well stay the same after starting on a pump despite the fact that overall control has significantly improved. Lots of high sugars and lots of low sugars can lead to quite a respectable HbA1c. I think people with diabetes are well able to judge whether their control has improved with the addition of a pump. I personally would not put up with the inconvenience of a pump if it did not significantly help my control! Targets are in my view quite inappropriate here - it is impossible to set targets which are meaningful. A decrease in hypos could be accompanied by too many hyperglycaemic episodes, yet the target would still be met. I think the targets set out here are quite simply nonsense.<br>2.5 So if good control is indicated by an HbA1c of less than 7.5, where does the 8.5% level mentioned above come from??<br>3.4 Insulin is not an additional cost as it is also needed for injection regimes. Same applies to lancets, test strips and glucometers.<br>4.1.2 - my quality of life is without doubt significantly better whilst using an insulin pump. I have been on a pump for just over 7 years. My HbA1c levels are largely unchanged pre/post pumping, but my overall control is much better, with far fewer excursion outside the range (about 5-10) within which I try to keep my blood sugars. 4.3.11 I return to the same point - my HbA1c has not improved on a pump despite my having significantly better control and fewer excursions outside an acceptable range. Frequency of hypos is not something which can be measured scientifically by a clinician in any event. So the use of these targets, linked to pump withdrawal, is a nonsense which I would most strongly oppose.<br>None, except that I believe many individuals who would benefit from an insulin pump are still having problems getting one. In other words, what is set out above is not happening in practice.<br>If the target/withdrawal principles are to be included, and also the 8.5% ceiling, both of which I strongly oppose, then review would be required much sooner than 2011. | This is the level at which the use of CSII was judged cost- effective.<br><br>The FAD has been amended accordingly.<br><br>Improvement in quality of life is included in the assessment, see FAD sections 4.3.3. |

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| Patient | You state in 2.5 below that a good HbA1c level is 7.5. Why is the limit for failing MDI set at 8.5? This is even more curious when the 7.5 limit is considered too high by many people. Patients should not need to have tried all variations of MDI if it is obvious that just changing the type of insulin will not resolve the problem causing the high HbA1c level. There is no mention of quality of life issues as a possible condition for starting CSII. Diabetics have to live with their diabetes, not just survive it, and allowance should be made for considering these issues.<br>This last statement that good control is indicated by an HbA1c level of less than 7.5% conflicts with the statement at 1.3 above. There is evidence that even the 7.5% figure is too high, and that the value should be less than 7%. | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective. |
| Patient | 1.3 Due to A1cs being based on a total average of glucose in the blood over 3 months reoccurring hypos can lower this average giving a false impression so highering the target range could be derogatory. Quality of life should also include patient's employment and effects of MDI within a work pattern and also reflect the interaction of both work and social life effect on an individual quality... 1.5 Measuring improvements of A1cs and hypo alone to obtain whether an improvement has been achieved, is problematic in many ways... This leaves a very open ended interpretations of this guideline, due to lack of time scale and that of good results achieved could end with the patient being left with the stress and worry of having there therapy removed giving a negative effect or unfair time scale... | See above |
| Public | It would be wonderful if this therapy could be made available to more people. I struggled to gain any sort of control for 44 years until I tried a pump, which completely revolutionised it for me. The guidelines suggest it should only be for people who have problems, and yet it could make a significant difference to the development of problems for many people. Why is it not appropriate for Type 2, when some type 2s have as many difficulties as type 1s? I agree it needs to be properly introduced and explained, and the person using it needs to be competent to use it (or the parent/carer in the case of a | There was not sufficient evidence to recommend CSII as cost effective in type 2 diabetes though the FAD does acknowledge some people may benefit |

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| | child). An HbA1c of less than 8.5 does not necessarily mean someone does not have a problem - it is after all an average, and could be achieved despite significant highs and lows.<br>What about MODY? This puts young people's health at risk, and they will have diabetes for a long time in all probability.<br>However large the cost appears to be, it must be measured against the cost of treating diabetic complications, hospital admissions etc. It is likely that the long term results of CSII make these events less likely, or at least delay them. Quality of life is also considerably improved. | |
| Carer | As a parent of a child with diabetes my aim is to make her blood sugar levels mimic those of a person without diabetes. This means the HbA1c needs to be near to 5.5%. Insulin pumps have been shown to reduce HbA1c and used to be issued to people who could not get their HbA1c below 7.5%. I cannot understand the reasoning behind increasing this threshold to 8.5%, which is LOWERING STANDARDS, unless it is to save money in the short term. Poor control will lead to more long term complications and cost more in the long term. This country should be embracing new technologies which improve quality of life and save money in the long term.<br>If good control is acknowledged as being below 7.5%, then why has the threshold for pump therapy been raised to 8.5%. Studies have shown that blood glucose control in children with diabetes in this country is very poor, with 85% not achieving an HbA1c below 7.5%. In America, the recommendation is to have an HbA1c below 6.5%. Surely we should be decreasing the threshold, not increasing it.<br>As said previously, costs could be recouped by a lessening in future complications, provided that adequate training and support is given | 8.5% is not a new standard. This is the HbA1c level at which the use of CSII was judged cost- effective. |
| NHS professional | 1.1 Why aged 11 cut-off point? Research has shown adolescents & toddlers in particular benefit most from CSII, both ages being difficult to control diabetes for different reasons.Additionally, 1.1 who decides MDI is inappropriate, I worry this can be used as | See above |

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| | a get-out clause to effectively bar CSII for some children if funders have financial/budgetary concerns, if staff are not trained or available, or if consultant does not believe in CSII. The 8.5% recommendation is atrocious, it may well be money/biggest effective result driven, but consideration should be given to DCCT research proving 6.05% is the target to aim for to reduce long term complication prospects. My son has had HbA1c 6-7.3% over past 5 years, at age 17 he has retinopathy, bleed in left eye. Denying children of all ages CSII as their HbA1cs may be 8.5% & over is going to condemn many more children to earlier complications, especially those who have been diagnosed young. This will not be cost effective for future nation's health, short term savings against long term complications. 1.5 HbA1cs can't continually drop, & aren't actually proof of good control, it should be removed completely, its a nonsense, escape clause.<br>Please remember some children with diabetes die every year, dead-in-bed syndrome is still with us, how many of those who died had been using a pump at the time of their death? Or even a sensor? One we know of was on injections, and had had a severe hypo only 2 months before she was found dead-in-bed. My own son has no glucagon response, which should be another consideration for having a pump, and sensor, especially of the child also has hypo unawareness, or is too young to be able to recognise and tell. Unfortunately we still hear of have clinicians who think hypos are not dangerous, or tell parents that if your child hypos in her sleep, it will wake them up. Pumps and education are needed more than ever to try and prevent any more dead-in-bed deaths they devastate the whole extended family for ever, and leave them feeling guilty. Pumps should be looked at for this reason as well. As for good control being under 7.5%, this may reflect constant glucose swings, from 1mmol to 30+ mmols, especially with children on injections, experience of this, when son was in this position, yet the HbA1c, showing the average, did not tell the full story,HbA1c OK, control crap! The difficulty is that intensive education should actually be offered to all people with diabetes, not just those going onto CSII. The reality is education isn't available to all. We | Continuation of CSII does not require continuously decreasing HbA1c levels, but sustained decreases in HbA1c levels, see FAD section 1.4 and 4.3.14. |

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| | have had no education since August 2000 from the hospital, pump or otherwise.<br>Lancets, test strips etc are also required for injection users! It's been shown those on pumps actually need less ongoing support from the diabetes team following successful initiation of CSII, they get to self-manage!<br>4.2.4 The cost of hospitalisation appears too low, my sons costs when we were on holiday for paramedics and ambulance for severe hypo which affected his heart rhythm, was over Â£1000, and that did not involve an overnight stay. This was the first and only time since using CSII he had such a severe life-threatening episode (which started at 4am and the hypo did not awaken him, I tried, in vain, to). I give myself nightmares wondering what the situation would have been on injections.<br>In addition to NICE technology appraisals being implemented, NICE should also be able to implement their guidelines, specifically those on management of diabetes (2004) and the National diabetes audit should have to include questions and information in its audit on CSII details from all hospitals, numbers on pumps, clinical targets etc, and numbers fulfilling criteria for pumps who have not been offered CSII and reasons why not. How are we ever going to improve care for children with diabetes in the UK if we don't ask the relevant questions and act on the results?<br>As before, these NICE guidelines contain good stuff, unfortunately they are not enforceable and in may places are certainly not used. They may be referred to as good practice, but as I have been told by a senior nurse on one occasion,<br>By the time this review comes into effect I assume it will be 2008, so 2011 is 3 years. It is a long time if the HbA1c requirement increases to 8.5%, perhaps it should be shortened to see how disastrous an effect this will be, supported by ongoing national monitoring of effect via National Audit. What I fail to understand is why diabetic pump users are subject to this close scrutiny, discrimination and intervention in the UK, when other pump users for other purposes, i.e. thalassaemia, asthma, chronic pain control, are not they don't have their own NICE technology assessments, so why do diabetics? | This is an estimate. Costs to the NHS may vary from charges in a private hospital<br><br>NICE technology appraisal guidance is mandatory in the NHS. |

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| | | NICE only appraises topics that are referred to it by the DH. |
| Carer | Like the USA, I think the only criteria needed for pump use should be personal choice and capability of carb counting. Multiple injections should be regarded as second rate treatment not a primary treatment. Also people with type 2 diabetes are successfully treated with the pump in the USA and elsewhere in the world.<br>Pump therapy may be more costly to manage, but ultimately it could save the NHS millions of pounds to reduce diabetes complications later.<br>Adolescents have body image problems and have different priorities during teenage years than diabetes control. My son lost over one stone in weight after pump therapy and while I am trying to leave him to deal with his diabetes control to become an independent adult, his management isn't as strict as mine. Do you want to penalize him if his HbA1c happens to be elevated during this training time? Also as teenagers and students generally sleep late in the mornings, injections would be missed. The insulin is delivered continuously whether they are awake or not. | The Appraisal Committee is responsible for making recommendations on the cost-effective use of NHS resources<br><br>Cost savings due to complications avoided are taken into account in the economic evaluation |
| Carer | I can not understand why the Hba1c guideline has been set at 8.5%, when it has been well documented by the DCCT trial that a HBa1C of above 7.5% can cause long term complications. In fact, in that study, anything above 6.5% leads to an increased risk of complications. To take away an insulin pump just because the HbA1c has not come down is cruel. My son wears his pump 24 hours a day, he has grown up with it and it is part of him, to take it away would be devastating for him. Instead those who struggle with an HbA1C should be given extra support not punished. What kind of message does that send children? Injections are a punishment for not complying with a pump?!<br>The insulin is not a cost specific to the pump. The cartridges used to provide insulin injections actually cost more than the vials of insulin used to fill the reservoirs for a pump. | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective. |

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| Carer | 1.3 The level of 8.5 is concerning especially as ideal level when child is charted looks at 6 - 7.5. Why has level been raised? 1.4 trained teams are ideal but supportive and knowledgeable teams are fine, for nearly 3 years we have had little contact with the DSN or dietician and now only meet every 6 months for a review and daughter is 13 years old. 1.5 Having a child who has had diabetes for 10+ years I find this comment very disappointing, my daughter had a good Hb level but this was achieved by erratic levels which greatly affected her day to day life as well as ours, this was supported by having use of a CGMS. For us the Hb did reduce but for some the difference may be marginal but may mean better quality of day to day life, less trauma due to the concerns of hypers and hypos. How can such a simple statement be used fairly??<br>Agree in the main to 2.3 & 2.4; however it confuses me why many health departments nationally do not start carb counting at diagnosis, and do not mention the inflexibility of some regimes, options should be discussed, e.g. twice daily injections versus MDI. These things seem to be age related, I believe full and accurate information should be given at diagnosis and reviewed quite quickly to help support the families in the best regime for them to suit their lifestyle. Why should diabetes be allowed to restrict when more flexibility is available at the outset even in terms of MDI. Make the complications clear and fully support the family, don't hide information, people take this on at different levels over different time frames. 2.5 Why is 7.5 being quoted when 8.5 is the level to be considered for CSII, are we looking at just cost here? Levels have to be a lot higher to achieve an Hb of 8.5<br>3.4, our daughter has a pump and we happily supply all batteries, the insulin, lancets, test strips and meters are the same whatever regime you use though there may be more test strips used. We had two hospital appointments, one to view pumps available and agree on best pump and one to commence pumping, the health team during our visits have learnt a great deal from us. We did have DSN support for the first week of pumping. We have now reduced our annual visits from 4 to 2 so this reduces costs. Cost savings for reduced hospital visits must be considered. My daughter has only | See above<br><br>Comment noted |

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| | visited her GP for minor things like tonsillitis in the last 10 years, we have medication at home in case there is a site infection, we have had one in nearly 3 years. With CSII for us and a supportive view to her health care by us and my daughter she is a happy and healthy individual who just happens to have diabetes. This has been helped greatly in recent year by her pump as hormonal teenagers are very volatile in many ways. I would suggest that your studies are conducted on less stable individuals as adults of 30 - 40 should be much easier to control than growing children.<br>As noted before a fairer more even study may produce more accurate results which would put children in a fairer light. A review in 2009 may be appropriate. | |
| Carer | I have just been informed that my 8 year old son may not be able to get a pump because we are working like Trojans to maintain a good level of sugars and because of this he has to suffer 7 or 8 injections. If we just didn't care and his HbA1c was high he would be eligible for funding. This is ridiculous and very upsetting for a little boy who hates injecting but copes because of our support. Your guidelines need to change. It has just ruined his Christmas learning he might not get funding. | Comment noted |
| Patient | How do you define competence and commitment? These are subjective terms. Please give measurable criteria to ensure consistency. A1C benchmark of 8.5% is TOO HIGH. All current standards of care published by say 6.5%-7.0%. The Diabetes Control and Complications Trial (DCCT) showed in 1994 that an A1C above 7.0% is correlated with higher rates of diabetes complications. If a prospective pump user's established diabetes care team is not trained to initiate and supervise insulin pump therapy, the patient must be referred to a specialist team for evaluation before pump therapy may be denied. Non-specialist teams may not deny patients who wish to be evaluated for pump therapy access to specialist teams. In the case of patients who's A1Cs were below the benchmark before starting pump therapy, an increase in A1C – so long as the A1C remains within range of the benchmark, is acceptable as it signals a reduction of hypoglycaemia episodes. CSII therapy is not recommended for people with type 2 | 8.5% is not recommended as a benchmark. It is the HbA1c level at which the use of CSII was judged cost- effective. |

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| | diabetes unless MDI has failed. Patients diagnosed with type 2 diabetes whose diabetes whose diabetes is not under control despite compliance with insulin therapy may be evaluated for CSII<br>Sec 2.4: Diabetes mellitus is a chronic condition in which both morbidity and treatment affect quality of life. For patients on conventional insulin therapy (2-3 injections/day) or MDI (3+ injections/day) daily life activities may need to be arranged around a relatively inflexible structure of meal times and insulin injections. Sec 2.5 Causes of beta-cell dysfunction in patients with type 2 diabetes are under investigation as the United Kingdom Prospective Diabetes Study (UKPDS) showed that seven years after diabetes diagnosis many patients produce only half as much insulin as non-diabetic individuals. Insulin requirements change depending on food intake, hormonal changes, stress levels, exercise or illness. Many type 2 diabetes patients can achieve control of their diabetes using a basal insulin and oral medications but all type 1 diabetes patients and many type 2 diabetes patients require both bolus and basal insulin. The Diabetes Control and Complications Trial (DCCT) showed conclusively that in type 1 diabetes, achieving good control of blood glucose through an intensive regimen, including frequent SMBG, reduces the risk of complications. UKPDS showed similar findings in type 2<br>Starlet is not currently (9 Dec. 2007) approved by any regulatory agency and Animas just launched the IR 2020 in the UK - please confirm available insulin pump models with ALL manufacturers before the final guidance is published. The pump is programmed to deliver basal rates of insulin throughout a 24-hour period, with boluses (doses) programmed separately at meal times and to correct glycaemic excursions. The main advantage of modern insulin pumps is that they can deliver different basal rates of insulin at different times of the day and night. It is recommended that the disposable cannula is removed and replaced every 72 hours (3 days). All insulin users, whether on MDI or a pump, require insulin, lancets, test strips and glucometers for monitoring. In the cases of young children going on to pump therapy, their parents or guardians receive education and support. | Comment noted |

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| | Include word isophane as synonym for NPH. Sec. 4.1.4: what number & types of centres specifically? Sec. 4.1.7: The time of puberty was also identified as a difficult time to control diabetes because of fluctuations in sex and growth hormones, which dramatically affect insulin sensitivity throughout adolescence. Children also have a greater lifetime risk of complications because complications are more likely the longer the duration of diabetes, and an early onset makes for a potentially longer time lived with diabetes. Sec. 4.2.4: is it really only Â£413 when someone needs to take a day or two off work? Reduced productivity is a cost. Sec. 4.2.6: severe hypos cost only Â£65?? 4.3.1: effective use of NHS resources includes prevention of expensive diabetes complications!!<br>Sec. 4.3.6: ...for whom, despite a high level of care, it has been impossible to maintain a HbA1c level of less than 7.5%, or who experience disabling hypoglycaemia at an A1C below 7.5%. Sec. 4.3.10: Additionally, the use of effective insulin pump therapy would require replacing the cannula every at least every 72 hours and programming the pump (similar degree of difficulty to operating a mobile phone). Sec. 4.3.11: reasonable time period? What is it? What about people who lose control for a short time after getting control? 4.3.12: Furthermore, the whole package of care provided to all people with diabetes, including pump users, should include....<br>6.1 given that the Exubera product has been discontinued by Pfizer I am not sure that it is relevant anymore!<br>What will happen when new models of insulin pumps are released to the market before 2011? Will they be available to patients or will pump companies be allowed to distribute only the models of pumps that were on-market as of the date this guidance becomes effective? Please clarify. It would be a severe injustice to UK patients with diabetes if they are not allowed access to incremental improvements in insulin pump technology because this was not specified. | |
| Carer | 1.1 The age of 11 is completely arbitrary and neither scientifically nor evidence-based. | The Appraisal Committee |

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| | 2- dose and MDI regimes are more likely to result in severe hypoglycaemic events yet 2.3 All children therefore have severe hypoglycaemic episodes. 2.3/2.5 One of the main drawbacks of 2-dose and MDI regimes is the unpredictability of action of insulin, both in duration and quantity. The sensitivity of children to insulin and the small doses they are on increase the margin of error to unacceptable levels when insulin is injected. One drop remaining on the insulin needle after injection may be 50% of a dose. Injection pens allow adjustments in 1/2 unit increments only. The statement<br>3.2 The only insulin delivered is rapid-acting delivery is much more precise doses can be measured to 1000ths of a unit ability of setting variable basals is extremely useful and not applicable to MDI. Maximum bolus can be set, much safer than an insulin pen. Technology is improving all the time for instance Medtronic now do a pump which can receive readings from CGSM. 3.4 Most of these costs (should) apply to any other insulin regime.<br>4.1.8 The Committee might wish to recommend that further RCTs of CSII therapy are undertaken for its future reference. When an intensive insulin regime is recommended by the care team, its mode of delivery (MDI or CSII) must also be a clinical decision in consultation with the patient. Unfortunately, the proposed guidelines will be seen as a backwards step by the diabetes community, with reference to arbitrary ages and HbA1C levels. The supporting documentary evidence submitted by the small numbers of insulin pump users in the UK and the specialist diabetes teams that use them have been given insufficient weight in this appraisal. | judged that older children can undergo a trial of MDI<br><br>Comment noted |
| Patient | These seem like good recommendations.<br>Parents of all children with type 1 should be offered the insulin pump.<br>The consumable costs can vary a lot depending on many factors.<br>The quality of life issue i.e. the flexibility of life when using a pump is so important as it does give a feel of what it would be like to be normal.<br>Within 3 months should be a maximum time. | Comment noted |

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| | Overall a good consultation document.<br>The date should be brought forward to the September of 2010 | |
| Patient | My HBA1C was 7.9 when I commenced on pump therapy. With the suggested 8.5 level then I would not have been considered. I am eternally grateful that I was selected for pump therapy. It has changed my life. I have control over my life and I am not constantly worried by high blood sugar readings. My HBA1C is now 7.1 so therapy has had an impact on my long term health and my risk of complications is now minimal which I think is very important to me and to the financial burden that I will now not cost NHS.<br>It states that rate for pump is 0.6 per kg I am using far less insulin than this. I have halved the amount of insulin that I require since starting pump. The least amount of insulin necessary to treat must be advantageous. Insulin is weight gaining and I am now able to loose weight as a result of using less insulin.<br>Long term savings that are made by reduction in complications should also be considered. | Comment noted<br><br>Savings that are made by reduction in complications are included in the economic evaluation |
| Patient | I consider it to be totally inappropriate to set targets for people. Targets will only create STRESS, stress will have the wrong effect and only produce worse results and the whole situation will become a vicious circle. Providing other people like me with an Insulin Pump will I am sure save the NHS money and give back to many diabetic patients a reasonable quality of life once again. I am very serious about this matter and my wife who suffered hell for many years will back me up. | Comment noted |
| Patient | The use of an A1c value is somewhat meaningless. Since an A1c is an average, it is possible to obtain a value much lower than 8.5% via huge swings, which make patients feel awful and decrease QoL/productivity, even without recurrent hypos. 8.5% is also a startlingly high number, Given complication risk associated with that level, the recommendations following DCCT and the fact that previous guidance used 7.5%. It is acknowledged later in this guidance that good control is represented by a value under 7.5%. Using 8.5% does a disservice to those regularly achieving 8% Para 1.5 implies | The Appraisal Committee were aware that HbA1c is an average.<br><br>See above for responses to specific issues |

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| | that if there is no improvement in glycaemic control, the pump will be withdrawn. It is not clear over what time period this applies. As a CSII user for 6yrs, I've seen great improvement in my control and my life. My A1cs have improved greatly over time, but my last A1c was higher than the previous one and Id had more hypos. It is not possible to see improvement indefinitely. This guidance seems inappropriate to long term users of CSII. QoL is also an important outcome measure which is not addressed in Para 1.5, nor is a reduction in the anxiety about hypoglycaemia mentioned as an indication in 1.3 Para 2.4 is an accurate appraisal of QoL issues, and illustrates their importance. The inflexibility of an MDI regime would make it impossible for me to do my job as an NHS dentist, and is also unworkable for many people who fulfil important job roles that demand flexibility and good control. Work can be difficult aside from the issues caused directly by complications. I feel these issues are important enough that they should be considered an indication for CSII on their own. | |
| Patient | 8.5% is far too high and it should be recommended for teenagers because it is not possible for us to get control on injections because of growth spurts and go to bed late / get up late, which can be dealt with on a pump, but not on injections. The part about training is a complete joke I have never had it.<br>If normal people have a maximum HbA1c of 6%, why is the target for diabetics 8.5% and a good control 7.5%, this is rubbish and a complete contradiction. I'm now 17 years old and have never had an HbA1c over 7.5% since I used a pump but I now have long term complications in my eye which will affect my sight so even 7.5% is not good enough. Also the HbA1c doesn't mean your levels are actually always low, it usually means an average and you have highs and lows. So it doesn't really mean anything to have this HbA1c unless you know what it is made up from.<br>I've used a pump for 7 years and have never ever had a site infection. I buy my own batteries, that's no problem, I also buy batteries for other things I use. Education? I don't get any, I was trained with my mum and dad by a nurse in August 2000 and then she left | The Appraisal Committee does not recommend a target HbA1c level of 8.5%. This is the level at which the use of CSII was judged cost- effective.<br><br>Comment noted |

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| | and we have never had any help since, we have to try ourselves and when things go wrong there is no one who really can help as out nurse doesn't do pumps and the hospital don't do downloading them.<br>Actually, as someone who has used injections and pumps, there is a big difference between quality of life, on injections my life was actually total crap and I never went out except to school and I was always having hypos or being forced to eat stuff when I wasn't hungry and didn't want to. All that stuff above, it's not for real man!! Know what I mean? Any kid can use a pump, it's easier than a mobile phone, we all learn computers at school and get to make them. You people doing this must be much older than me if you think its hard to use a pump. You should try injections, now that's hard init? pumps do really little amounts of insulin, injections don't, and sometimes they leak out your skin, or hit lumps and stuff and you go unconscious. I can't understand what all the fuss is about pumps, all children should have one so should teenagers, cos they protect us from dying from really bad hypos. I hypo slower with my pump so I can do something about it, if I'm awake of course.<br>Don't know what to say about this one. It would be nice not to have to travel a long way for my clinic but like they don't do pumps right here right now.<br>Don't know about this one either. Does it mean pumps have to be looked at again in 3 years time? Why? They're just pumps, although having ones that play games and mobile phone for help would be good too. When do you look at injections again? Do you check these out every 3 years too? | |
| Carer | Pumps are essential for children and teenagers who have bad hypos. All children seem to have hypos at some time and it's really frightening as a dad to watch this and think your child is dying. Sometimes the glucagon doesn't work and an ambulance has to take your child to hospital. Having a pump reduces how serious hypos are. Having a teenager, and its really hard during this age for the parents and their youngster, everything changes. When my son is growing, when he is ill, when he is moody, and | Comment noted |

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| | sometimes for no known reason at all, his blood sugar levels are all over the place. His HbA1c has gone up and down a lot during the last few years as he has grown and started to go out with his mates. Being able to eat pizza and be like them has been better by having a pump and may have helped stop his HbAS1c going as bad as it might have, but 8.5% is much too high. If he had not had a pump, I think he might have died from a hypo (he had one that affected his heart), like someone my partner knows whose daughter died from a hypo one morning this year and she was only 12 years old and was on injections. Having a pump is not about HbA1c in real life, it's about living the best you can.<br>My son has had short term problems and now has eye problems although he has had so called good Hba1cs, and someone he was at school with is also 17 and they found out this year he has kidney problems from his diabetes and its serious. He didn't have a pump, always had injections. Surely if normal people without diabetes are 4-6% Hba1c, then we should be aiming at 4-6% for our children and teenagers with diabetes to get to? Why is it acceptable for them to be 8.5% when we know that means they will get long-term complications? Using the glucose sensor is also a good idea and can save lives, it alarms for hypos so is useful for children who have no awareness of hypos<br>Never known any site infections happen but there have been problems when my son bleeds at cannula sites. But then, on injections, he could eat his meal, have his insulin injected afterwards, and within minutes have a seizure, and collapse unconscious, bruised from where he fitted. This doesn't happen with a pump as the insulin goes in slowly. The matter of education, the back up is very poor, almost non-existent, and certainly the only emergency help or advice is to call an ambulance. You might think we get education and all that stuff, well, in my experience, nothing has been available for the past 6 plus years, we just have to muddle through or phone the pump company. I used to work in plastics and would have thought some of the consumables should be a lot cheaper than they are. I think they are cheaper abroad.<br>I'm just a dad, and all that research stuff, well, I only know about my son and about | |

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| | others from other parents, its easier for family life having your child on a pump, easier to go out, be spontaneous, less emergency supplies to carry, better quality of life, more able to take part in school activities more able to be normal and less areas for schools to discriminate against your child for having diabetes. Injections aren't cool for kids, especially if they have to go to matrons office to get them, and as teens find diabetes embarrassing and may try to hide it and not take their insulin if its by injection. Using a pump isn't just about getting good HbA1c although that's an added benefit, it's about your child getting their personality back and being able to live the best life and get the best use of education they can. Highs and lows stop them being able to learn the same, their brains need to be normal blood levels so they can get exams the same as their mates, and be able to get jobs.<br>That's good, Our local health people didn't seem to have that stuff in place when our son originally wanted a pump. Does that mean that if you're auditing implementation, you will now enforce it? It is certainly needed.<br>That's a lot of guidance, but I understand that you don't actually enforce them, if you did my son would have had education, would have a pump nurse, diet and exercise advice and podiatrist, none of which he gets, in fact they don't even look at his diary. You need to look at making sure we get the basics as well as pumps, there is so much missing from care for our children with diabetes you wouldn't believe it. To date, care received over the majority of the past 9 years has been severely lacking, despite all those guidelines you show. They are just that, guidelines, no one we have seen in clinics has actually taken any notice whatsoever of them.<br>Thoughts are, why review in 3 years, is this review faulted? It is looking at financial aspects especially, so is it a cut back and are you looking to check if you can get away with reducing access to pumps through the 8.5% and making people get targets? Would a sooner review be better? if something major change? Or a later review? What was wrong with the previous report of 2003? Pump technology has improved so the HbA1c level should be reduced, but it's gone up instead. So I'm not sure about this one. If it | |

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| | says 8.5%, I would review it sooner rather than later, but where will you get any real evidence from, as its those who aren't on pumps and who don't make a fuss or understand seriousness of diabetes this is going to affect most, and in years to come when long-term complications may be irreversible. | |
| INPUT letter | I am writing as a mother of a teen with diabetes, a member of INPUT and UK Children with diabetes Advocacy Group, and note a mere 19% of children nationally achieved an acceptable HbAlc of 7.5% or under, which incidentally includes children still in the honeymoon period, and 8% failed. Whilst I realise this is an improvement on the previous figure of 86% failing, I am still disappointed at;<br>1. yet another year of the majority of children failing to achieve reasonable glycaemic control, or even HbAlc targets<br>2. Lack of audit information supplied from many hospitals/centres in this IT age<br>3. Lack of collection of some current very relevant related information that could be used to audit, interrogate and improve staffing and services for children with diabetes and their long-term prospects of future complication-free or reduced, healthier life and determination of compliance with NICE guidelines. Namely lack of questioning as to whether children use pumps or injection<br>regimens, spilt into figures for age and glycaemic control by delivery device and regimen.<br>4. Additionally, I would like to see, of those children failing to achieve HbAlc targets, or experiencing hypo problems, how many are offered insulin pump therapy during the year, and how many are not, and reasons for not offering pumps for children with HbAlc's over 7.5% (at present, if NICE guidelines change, over 8.5% in future).<br>I think it is very important that public health organisations, including NICE, The Information Office and government health departments, should listen to us parents who are involved in the care of these children 24/7/365, as we unfortunately have so much lived experience of the condition and of the questions that need asked and answered, | Comment noted |

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| | and we need you to do this on our behalf as part of the UK's NHS and governmental partnership. | |
| | My son was diagnosed at 8 years of age, had 2 years of pretty poor control until he went on a pump at aged 10 years, and has had reasonable control since, i.e. HbA1cs ranging from 5.1io -7.3io, yet on 5th November this year we received the bad news that he has the start of retinopathy, having a haemorrhage in his left eye. I obviously have no comeback on the less than adequate care and education we received during those first 2 years, and in fact since as well, yet there are massive implications for his future, 9 years after diagnosis. I do not want others to share this experience, and am pleased NI E guidelines and national Audits are there to help provide basic good standards for practise.<br>However, unless these standards are enforced, and there are many places that do not comply with the 2004 NICE guidelines for diagnosis and management of type 1 diabetes and the Technology Assessment for CSII, (I am also a nurse, I know this from both sides), and without collecting data that can help improve outcomes, how are we ever going to get to having a majority of our children achieving reasonable control? And all the research has shown that reasonable control can indeed be achieved for children and young people. | Comment noted. |
| | Suggestions?<br>That lay parents of children with diabetes be included in the National Audit preparation, and their views listened to.<br>That NICE guidelines be enforceable, and adequate numbers of lay parents/inspectors/members of patient support groups such as INPUT and UKCDWAG be used either voluntarily or employed, to give national feedback on every single diabetes centre where children are treated in the UK. We are happy to do this, we want improvement.<br>That data about pump and sensor use be included in the national date collected. | Comment noted. |

| Comment from | Nature of comment | Response |
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| | That's every diabetes centre/hospital that treats children return information, for all we know the real situation may actually be very much worse! | |
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