NATIONAL COLLABORATING CENTRE FOR NURSING & SUPPORTIVE CARE (NCC-NSC)

NICE national clinical guideline – Sedation for diagnostic and therapeutic procedures in children and young people

Minutes from the third guideline development group meeting; Thursday 19th March 2009 held at Royal College of Nursing, 20 Cavendish Square, London W1G 0RN, Room 107

Present

Paul Averley (PA)	General Dental Practitioner, Queensway Dental Practice, Billingham
Peter Crean (PC)	Consultant Paediatric Anaesthetist, Royal Belfast Hospital for Sick Children
Nick Croft (NC)	Reader and Consultant Paediatric Gastroenterologist & Co-Director London SENCE Medicines for Children Local Research Network, Queen Mary's School of Medicine and Dentistry
Nick Girdler (NG)	Professor of Sedation Dentistry, Newcastle Dental Hospital & School
Susan King (SK)	Consultant Radiologist, Weston General Hospital
Christina Liossi (CL)	Senior Lecturer in Health Psychology, University of Southampton
Liz McArthur (LM)	Lead Clinical Nurse Specialist - Paediatric Pain & Sedation, Royal Liverpool Children's Hospital
Farrah Pradhan (FP)	Patient/Carer Representative
Mike Sury (Chair; MS)	Consultant Anaesthetist, Great Ormond St Hospital for Children NHS Trust
Daniel Wallis (DW)	Consultant - A&E Medicine, St George's Hospital
Madeleine Wang (MWg)	Patient/Carer Representative

Apologies

Neil Morton (NMo)	Consultant in Paediatric Anaesthesia & Pain Management, Royal Hospital for Sick Children, Glasgow
Heather McLelland	(HM) Nurse Consultant, Emergency Care, Calderdale Royal Hospital

In attendance

Ian Bullock (IB)	Chief Operating Officer, NCGC-ACC
Sarah Davis (SD)	Senior Health Economist, NCC NSC
Anayo Akunne (AA)	Health Economist, NCC NSC
Nahara Martinez (NMa)	Systematic Reviewer, NCC NSC
Sue Latchem (SL)	Guidelines Commissioning Manager, NICE
Maggie Westby (MWy)	Senior Research & Development Fellow, NCC NSC

Welcome, introduction, apologies and declarations of interest (DoIs)

GDG Chair, Mike Sury (MS) welcomed everyone to the meeting. AA was welcomed to the group as this was his first meeting. Apologies were shared with the group. MS asked if there were any updates to individual DoI's. IB confirmed the principles by which GDG members should apply in relation to managing any potential conflicts. There were no updates to DoIs.

Minutes, and matters arising

MS asked GDG members if there were any points to share relating to accuracy, and also asked for any matters arising from the previous meeting. There were no matters arising. MS asked the group if there were any problems accessing materials or if any GDG members found any user challenges relating to Claromentis. Some members reported problems, but these had been resolved successfully. MWg requested hard copies of documents to be available at the meeting. MS thanked the GDG for their commitment to forum discussions in preparation for the agenda items, and in particular discussions on the clinical and review questions. He emphasised that opinions stated in emails must not be treated as final statements of opinion. All statements of personal opinion must be made at open GDG meetings to allow full discussion.

MS Briefly reviewed progress so far and praised the GDG for making good progress in developing the clinical questions. He reminded the GDG it needed to focus on questions that will make the greatest difference to reducing variation in the practice of sedation.

Action: NCC technical team to continue to post all materials onto Claromentis.

Clinical questions and Review Questions
IB introduced this session by providing the policy context, and how Lord Darzi's choice of language in his presentation of the White Paper 'High Quality Care for All' has seen a shift in emphasis to how clinical guidelines are viewed by both commissioners and providers of healthcare. Recommendations are likely to form the basis of clinical advisory statements that will form the basis of NHS care, and how quality will be measured against these.

IB also referred to the principle of answering clinical questions, that the question determines the chosen research method that is best placed to answer the original question. Within the guideline, there will be a variety of research methods, including clinical and cost effectiveness reviews, narrative reviews and consensus methods.

Clinical questions
IB facilitated a focussed GDG discussion in reviewing the valuable forum discussions following GDG meetings 1 and 2, in refining the number of clinical/systematic review questions and preferred methodology to answer the clinical questions agreed at the previous GDG meetings. The following discussions and agreements were reached.

- Assessment – PA asked about the preferred method for looking at tools to facilitate assessment. IB confirmed that this would be best addressed through a combination of sub group narrative review and consensus methods. MWg highlighted issues to do with variance between tools, CL asked how the group would establish limitations of the tools. IB expected these to be addressed through consensus work.

Action point:

GDG agreement to deal with questions 1, 2 and 3 through consensus methods. Question 3 - if needed, technical team will support a narrative review in supporting sub group activity/consensus work.

- Preparation – PC questioned whether the GDG would be able to reach agreement on fasting across this large and diverse population, and referred to current variance, referring to how emergency departments would have a different approach. DW responded by affirming that in his opinion we could actually reach consensus. IB reported that it is possible that we could refer to published guidance in this area (for example, the RCN's perioperative fasting guideline), particularly in reference to the advent of NHS Evidence that is likely to support this published guidance with an approved kite mark of quality. The GDG talked about how fasting recommendations for sedation are likely to be specific to setting, and discussed the need to consider intended depth of sedation, drugs used and the urgency of the procedure. DW also pointed out the importance of safety, and MWy agreed that the technical team would collect adverse event data, stratified by whether or not the patients had been fasted. As a result, the GDG agreed that the consensus work on fasting should be postponed until the adverse events reviews have been completed. MWg emphasised the importance of timing in how patients are prepared psychologically, with CL agreeing that the three main areas of what, when and how should be able to covered through consensus discussion and agreement.
- Children's views and experience: IB reported that NICE, through PPIP, was keen to work with children of 5 years and older to find out their perspective on sedation,

across a range of settings. This would be over and above normal NICE processes and IB would facilitate this work with NICE (Victoria Thomas and Marcia Kelson) and the patient carer representatives.

Action point:
GDG agreement to deal with questions 4, 5 and 6 through consensus methods. Question on fasting to be postponed until after adverse events reviews have been completed.
IB to continue to work with NICE and patient carer representatives on children's views and experience.

- Communication – PA asked whether types/depth of sedation would be covered. IB confirmed that this is an area that would inform final publications that would help the implementation of the guideline. MWg shared with the group that these publications would be targeted at children and young people, and language used would be appropriate.

Action point:
GDG agreement to deal with questions 7, 8 and 9 through consensus methods.

- Clinical environment and monitoring – There was acceptance by GDG members that this was an area that should be emphasised within the guideline and that consensus methods were acceptable.

Action point:
GDG agreement to deal with questions 10, 11, 12 and 13 through consensus methods.

- Training and competence – 14 and 15. GDG agreement to deal with these through **narrative review** supported by consensus work.

Action point:
GDG agreement to deal with questions 10, 11, 12 and 13 through narrative review and consensus methods.

- Effectiveness, safety and limitations – 16 and 17. GDG agreement to deal with these through systematic review of clinical effectiveness and safety evidence. DW commented that clinical question 16 should not be specific for individual procedures, and the GDG agreed to replace 'for different procedures' with '(multifactorial)'. CL suggested and the GDG agreed to replace 'non-pharmacological' with 'psychological' in question 17. This term would also include play therapy and distraction techniques.

Action point:
GDG agreement to deal with questions 16 and 17 through systematic review.

IB facilitated GDG discussions and refinement of the review questions.
Review questions

- GDG agreement to answer questions 1, 2, 3, 4, 5, and 6 through consensus or narrative review methods
- GDG agreement to answer questions 7, 8, 9, 10, 11, 12, 15 and 16 by systematic review
- GDG agreement to withdraw questions 13 and 14 from systematic review focus as they are pharma interventions not in wide use/unlicensed/unavailable in standard UK practice.

NG raised the issue about oral temazepam, as it is in use in older children. GDG discussion reached agreement that it should be added into the midazolam review.

Economic review
SD presented findings from the economic review. The presentation can be found on Claromentis/sedation work programme/GDG meeting 3. The conclusions were that there is a lack of high quality, relevant cost-effectiveness studies within the existing literature, but there were some relevant UK costing studies comparing sedation with general anaesthesia in dentistry. The GDG were concerned that trial based evaluations using non-RCT designs had been excluded from the review. MWy confirmed that this would be consistent with the approach being taken within the clinical effectiveness reviews and that the methodological rationale for this approach is determined by the need to have confidence in the effectiveness of interventions that may have significant adverse events.

Economic plan
SD presented the economic plan for the guideline, asking the GDG to confirm where the likely focus for economic analysis is to be. The presentation can be found on Claromentis/sedation work programme/GDG meeting 3. SD identified clinical questions 16 and 17 as the areas of high priority for further economic analysis, with the remaining clinical questions providing information on the complete care pathway, which would be captured within the cost-effectiveness analyses informing the decision to recommend a particular sedation technique. The GDG agreed with the priorities as they were presented. SD also presented a broad outline of how the cost-effectiveness analysis could be conducted and sought guidance from the GDG on the important outcomes that need to be captured and potential subgroups that may be considered within the analysis. SD informed the GDG that the plan will be circulated for comment before being signed-off by the Health Economist, the GDG Chair and representatives from NICE and the NCC.

Actions: SD to circulate the Economic Plan to the GDG for comment.

Midazolam: Preliminary review
MWy presented the methodical approach used by the technical team in relation to systematic review. The presentation can be found on Claromentis/sedation work programme/GDG meeting 3. MWy also asked the GDG about the outcome measures to be reported for the intervention reviews: the GDG added length of stay, following discussion of the health economics outcomes. This would be divided into: pre-procedure duration of sedation, duration of procedure and duration of recovery (end of procedure to discharge).

NMa presented preliminary findings from the Midazolam review as a sample review, in order to clarify with the GDG the methods used and approaches to analysis. The presentation can be found on Claromentis/sedation work programme/GDG meeting 3.
The review reported a range of different interventions and comparisons, and there was a need to interpret some of the outcome measures (e.g. different definitions and scores/scales used), which vary across studies. These factors may make comparability across studies difficult. The GDG agreed that outcome assessment data will be collected regardless of how this information is reported. It was also agreed that motion and resistance can be associated with cooperation and crying and struggling with distress.

The GDG gave the following advice on data extraction: fasting data will be collected, where reported. Three outcomes will be added on length of stay (as above). Data on oxygen desaturation with a cut-off of 95% or less will also be collected, as part of the outcome on respiratory support.

The GDG discussed the importance of the level of sedation; data for this, where reported, will continue to be collected. Stratification by sedation level may be necessary, but this was not finalised. The GDG confirmed the need for adverse events reviews to analyse results by setting.

Developing recommendations in areas of consensus

IB presented to the group possible consensus methods, and affirmed the technical team's intention to support this important work by using nominal group technique (NGT) methodology. IB shared the plan for addressing consensus work, which is to allocate GDG members to one of four
sub groups, and to ask them to work together in preparation for GDG meetings 4 and 5. IB recognised that sub group 4 dealing with training and competence would be also supported by a narrative review. The methodology underpinning NGT can be found on Claromentis/sedation work programme/GDG meeting 3.

Allocation of GDG members to the following groups are as indicated below:

1. Assessment and Preparation Subgroup – clinical questions 1, 2, 3, 4, 5 and 6
LM, CL and NMo (sub group lead to be determined) joined by NMa

2. Communication Subgroup – clinical questions 7, 8 and 9
MWg, FP, SK and MS (subgroup lead to be determined)

3. Clinical environment and monitoring Subgroup – clinical questions 10, 11, 12 and 13
PC, PA, HM (subgroup lead to be determined) joined by AA

4. Training and competence Subgroup – clinical questions 14 and 15
DW, NG, and NC (subgroup lead to be determined) joined by IB

Ways of working for subgroups in preparation for GDG meeting 4 and 5

1. Establish a nominated person who will make the communication work (subgroup lead)
2. Start with broad sharing of ideas, experience, expertise, evidence (broadest definition which includes any publication, case study, patient story, audit data, pilot study etc) and get this on paper.
3. Establish more formal communication, by:
    - E mail
    - Teleconference (request **emma.nawrocki@rcn.org.uk** /01865 787104)
    - Forums via Claromentis
4. Set up at least two formal sessions or maintain an e mail threaded discussion between now and GDG 4 and 5 (April 27-28)
5. Work towards having the basis of information shared and recorded to work more formally together in distilling this to reach subgroup consensus during the morning of GDG meeting 4 (April 27th)
6. Prepare a presentation during this more formal subgroup activity to share with the whole GDG on the afternoon of GDG meeting 4 (April 27th)
7. Following wider GDG discussion/challenge to preliminary subgroup consensus work, reflect the decisions reached in focussed preparation of preliminary consensus statements in your subgroup area on the morning of GDG meeting 5 (April 28th). This may be one or several statements, depending on the need for topic coverage. Remember, 'less is more' when implementation of our guideline is targeted at healthcare professionals.
8. Subgroups will present preliminary recommendations for formal consensus voting on the afternoon of GDG meeting 5 (April 28th).

Date and time of next meeting: 27th and 28th April 2009 at the NCC's new offices, (Regent's Place, 338 Euston Road, London NW1 3BT) commencing at 10am.