NICE National Institute for Health and Care Excellence

2018 surveillance of sedation in under 19s: using sedation for diagnostic and therapeutic procedures (NICE guideline CG112)

Surveillance report

Published: 12 December 2018

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Surveillance decision

We will not update the guideline on sedation in under 19s: using sedation for diagnostic and therapeutic procedures.

During surveillance editorial or factual corrections were identified.

Reasons for the decision

No new evidence was identified that suggested NICE guideline CG112 should be updated. No ongoing studies were identified, so it is unlikely that new evidence will be available in the near future.

Overview of 2018 surveillance methods

NICE's surveillance team checked whether recommendations in sedation in under 19s: using sedation for diagnostic and therapeutic procedures (NICE guideline CG112) remain up to date. The 2018 surveillance followed the static list review process, consisting of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews and national policy.
- A search for ongoing research.
- Examining related NICE guidance and quality standards.
- Examining the NICE event tracker for relevant ongoing and published events.
- Consulting on the decision with stakeholders (first consultation dates 17 to 28 September 2018).
- As part of the surveillance review we held a second consultation to obtain stakeholder feedback on refreshing recommendation 1.2.3 (second consultation dates 15 to 26 October 2018).

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence considered in surveillance

Cochrane reviews

We searched for new Cochrane reviews related to the whole guideline. We found 3 relevant Cochrane reviews published between January 2012 and June 2018.

One review (Conway et al. 2016) includes analysis suggesting that oral midazolam produces less effective sedation than chloral hydrate for children undergoing non-invasive diagnostic procedures. However, the findings were influenced by 1 study which was in lumbar puncture (an invasive procedure) and as such the review does not provide clear

evidence of an impact on the guideline. A second review (Fong et al. 2017) which compared chloral hydrate against several other methods of sedation for neurodiagnostic procedures in children is not directly relevant to the general population that is covered by the guideline. The third review (Lourenço-Matharu et al. 2012) which covers sedation of children undergoing dental treatment provides evidence in support of recommendation 1.9 in the guideline.

Previous surveillance

We also considered studies identified in an evidence update in 2012. The 2012 evidence update included 13 studies in the following areas:

1.6 Painless imaging

The evidence from the following studies supports the recommendations:

- Evidence suggests that a single dose of propofol may be suitable for magnetic resonance imaging (MRI) procedures lasting up to 30 minutes (Cho et al. 2010).
- Continuous propofol infusion may be better than intermittent dosing for longer procedures (Hassan et al. 2011).
- Oral chloral hydrate may be effective for sedation during auditory brainstem response testing (Avlonitou et al. 2011).

1.8 Painful procedures

- Evidence suggests that propofol is suitable for procedural sedation in children and young people (Lamond 2010; Mallory et al. 2011). Evidence from these studies supports the guideline.
- Propofol and ketamine may be suitable as a specialist sedation regimen in children and young people (Andolfatto and Willman 2010; David and Shipp 2011; Shah et al. 2011). NICE guideline CG112 does not make specific recommendations about specialist techniques for procedural sedation, a specialist could choose to use ketamine with propofol, so this evidence does not contradict current guidance; however this combination remains a technique for specialist use only.

- Limited evidence suggests that midazolam may be more effective given by buccal aerosol than given orally or by intranasal aerosol (Klein et al. 2011). Further evidence would be needed to determine the optimum method of administration of midazolam before changing the guideline.
- Limited evidence suggests that nitrous oxide may be preferable to midazolam in sedation in children and young people in whom establishing an intravenous line is expected to be difficult (Ekbom et al. 2011). Further studies comparing midazolam with nitrous oxide may be useful to determine the preferred first-line drug for procedural sedation in children and young people.

1.9 Dental procedures

- Limited evidence suggests that ketamine may be associated with a higher rate of successful dental procedures than midazolam (Bahetwar et al. 2010). Using ketamine for dental sedation is an advanced technique, which is likely to be used only by specialist teams, so this study is unlikely to affect NICE guideline CG112.
- Limited evidence suggests that midazolam plus fentanyl may result in a higher rate of successful dental procedures than midazolam alone (Pandey et al. 2010). This evidence is unlikely to affect NICE guideline CG112, because the combination of midazolam and fentanyl would be considered a specialist sedation technique, which is not covered in the guideline.
- Limited evidence suggests that adding sevoflurane to nitrous oxide does not improve the rate of successful dental procedures (Soldani et al. 2010), so this study is unlikely to affect NICE guideline CG112.

1.10 Endoscopy

- Limited evidence suggests that propofol plus remifentanil may be associated with shorter time to waking and using lower doses of propofol, but may be associated with more respiratory events compared with propofol plus fentanyl (Hirsh et al. 2010). Further studies are needed to establish the safety of remifentanil with propofol for procedural sedation in children, thus this limited evidence is unlikely to affect an update to the guidance.

  Overall, the evidence from the evidence update in 2012 did not have an impact on the recommendations and we found no new evidence in these areas to suggest an update.

Ongoing research

We checked for relevant ongoing research. No relevant studies were identified.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and services related to NICE guideline CG112.

We sent questionnaires to 12 topic experts and received 3 responses. The topic experts either:

- participated in the guideline committee who developed the guideline or
- were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty.

The 3 experts indicated that recommendations in this guideline do not need to be updated.

One expert highlighted that sedation is a continuum, and it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be competent and able to rescue patients whose level of sedation becomes deeper than initially intended. The expert felt that the American Society of Anesthesiologists (ASA) classification of levels of sedation should be acknowledged in

the guideline. We have checked the full guideline and the glossary clarifies that depression of consciousness is a continuum. It also acknowledges the level of sedation varies over time because of 2 main factors: the change in the concentration of the sedation drug within the patient and the variation in the stimulation that opposes sedation. In line with the ASA definitions, 3 levels of sedation are also mentioned in the recommendations: minimal, moderate and deep. Furthermore, the guideline includes recommendations on personnel training which outlines requirements of competency for sedation practice. We do not plan to make changes based on the feedback received.

Views of stakeholders

Stakeholders are consulted on all surveillance reviews except if the whole guideline will be updated and replaced. Because this surveillance proposal was to not update the guideline, we consulted on this.

First consultation (17 to 28 September 2018)

Overall, 6 stakeholders commented; of these, 2 were government organisations and 4 were professional bodies. One stakeholder agreed with the decision to not update the guideline, 1 disagreed and 4 did not state a response.

One stakeholder suggested that that the guideline should include new drugs relevant to paediatric sedation, noting dexmedetomidine. Additionally, a stakeholder advised that pre-sedation assessment, covered by recommendation 1.1, should include growth assessment by BMI (body mass index) rather than weight alone. However, a strong signal was not identified through this surveillance review to indicate that the recommendations relating to issues highlighted by stakeholders need updating. We will monitor these areas and consider again at the next surveillance review of the guideline.

We received feedback from 2 stakeholders about recommendation 1.2.3, which mentions applying the 2-4-6 fasting rule for elective procedures; for further information see the details below provided in the second consultation.

See appendix A for full details of the first consultation stakeholders' comments and our responses.

Second consultation (15 to 26 October 2018)

During the first consultation on the proposal not to update NICE guideline CG112, we received feedback from 2 stakeholders about recommendation 1.2.3, which mentions applying the 2-4-6 fasting rule for elective procedures:

- Apply the 2-4-6 fasting rule[1] for elective procedures using any sedation technique other than those in recommendation 1.2.2 (that is, apply the 2-4-6 fasting rule for deep sedation and moderate sedation during which the child or young person might not maintain verbal contact with the healthcare professional).

The stakeholders highlighted that preoperative fasting of clear fluids for children, currently 2 hours in NICE guideline CG112, should be revised to be in line with current practice and recent guidance which supports a reduction to 1 hour. We also noted the Association of Paediatric Anaesthetists of Great Britain and Ireland consensus statement on clear fluids fasting for elective pediatric general anesthesia was published in April 2018.

To address this issue, we consulted stakeholders on refreshing recommendation 1.2.3 to highlight changes in professional guidance supporting a reduction to 1 hour of the fasting period for clear fluids.

Six stakeholders provided a response and 4 agreed that the text should be revised, 2 did not state a response. See editorial amendments for details of the change that will be made.

See appendix B for full details of the second consultation stakeholders' comments and our responses.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

No equalities issues were identified during the surveillance process.

Editorial amendments

During surveillance of the guideline we identified the following points in the guideline that

should be amended:

- Footnote 6 will be updated to refer to the present time point and to update the link to the British National Formulary for children. The text will state: At the time of the 2018 surveillance review no drugs have a UK marketing authorisation specifically for sedation in all ages of infants, children and young people under 19. The prescriber should follow relevant professional guidance, taking full responsibility for the decision, and using a drug's summary of product characteristics and the British national formulary for children. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing and managing medicines and devices for further information.
- The patient-centred care section of the guideline will be replaced with the following 'informed decisions' information:
  - People have the right to be involved in discussions and make informed decisions about their care, as described in your care.
  - Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

We will revise recommendation 1.2.3 to state:

- Refer to professional guidance for fasting for elective procedures using any sedation technique other than those in recommendation 1.2.2 (that is, for deep sedation and moderate sedation during which the child or young person might not maintain verbal contact with the healthcare professional).

We will revise the footnote connected with recommendation 1.2.3 to state:

- Note that in 2018 a change to the 2-4-6 fasting rule (fasting times should be as for general anaesthesia: 2 hours for clear fluids; 4 hours for breast milk; 6 hours for solids) was endorsed by the relevant professional bodies (see for example the Association of Paediatric Anaesthetists of Great Britain and Ireland consensus statement on clear fluids fasting for elective pediatric general anesthesia), supporting a reduction to 1 hour of the fasting period for clear fluids.

Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we decided that no update is necessary.

ISBN: 978-1-4731-3188-0

[1] Fasting times should be as for general anaesthesia: 2 hours for clear fluids; 4 hours for breast milk; 6 hours for solids.