Expert peer review on anaesthetics in neonates review

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      Halothane is no longer indicated for anaesthesia in neonates as safer alternatives exist.

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes
   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      Halothane has the potential to cause arrhythmias and malignant hyperthermia. It is contraindicated in case of jaundice and it is a potent cardiac depressant and respiratory depressant – this excludes its use in neonates as safer products have become available.

      More evidence of safety of sevoflurane and desflurane need to be obtained.

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost been provided
      Yes
   b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      All the anaesthetics recommended for inclusion are cost effective. Sevoflurane and desflurane are costly and have not been recommended for inclusion.

   c. Please provide any additional relevant information with reference

   d. Is the product available in several low and middle income countries?
      Yes

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences)
Not applicable

b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable

All the recommended medicines are listed in guidelines (WHO, NICE).

5. Are there special requirements for use or training needed for safe/effective use? 
If yes, please provide details in 1-2 sentences

Yes – all these medicines should be administered only by trained medical doctor with the necessary skills for administration, monitoring and resuscitation if necessary.

6. Is the proposed product registered by a stringent regulatory authority? 
Yes

7. Any other comments

The data on efficacy and safety of anaesthetics in neonates is scarce. All attempts to improve this state of affairs should be done in order to make informed choices on selection of agents in this age group.

8. What is your recommendation to the committee (please provide the rationale)?

1. Halothane should be deleted from the list due to safety reasons and availability of agents with better efficacy and safety.

2. Isoflurane should be retained on the list with an indication that it is an example of its class with a square box symbol. It is mentioned in all the guidelines and there is evidence of it being efficacious and relatively safe.

3. Sevoflurane need not be included in the list. More information of efficacy and safety in neonates is required. It is also very costly at present.

4. Desflurane should not be included in the list as there is insufficient data to include it at the present time. It is also not found in any of the guidelines.

5. Nitrous oxide – should remain in the EML for maintenance of anaesthesia and analgesia. It is also mentioned in guidelines.

6. Oxygen – should remain in the EML.

7. Ketamine – should remain in the EML. It is licensed for use in children including neonates.

8. Propofol – is not recommended for use in neonates as safety has not been well documented. This age restriction should be mentioned in the EMLc. It may be retained.

9. Thiopental – should be listed in EMLc. It is licensed for use in neonates and can be used for induction. It is widely available and not costly.

10. Local anaesthetics – no change to be made in the local anaesthetics presently listed in EMLc.