SOAP
Society for Obstetric Anesthesia and Perinatology

Society for Obstetric Anesthesia and Perinatology (SOAP) Advisory in Response to Shortages of Local Anesthetics in North America

The following are not intended as standards or absolute requirements and cannot guarantee any specific outcome.

In North-America (United States and Canada) bupivacaine is in critical shortage due to an apparent increase in drug demand, as well as back orders from the suppliers.

This clinical practice advisory and safety alert is intended to inform and provide some suggestions to all anesthesia providers who work in labor and delivery. These suggestions are meant to provide guidance in the face of critical shortages and are not meant to dictate clinical practice.

Drug shortages are a patient safety concern due to the following reasons: [3,4]

1. Medication errors due to substitution
2. Inappropriate substitution
3. Improper use or handling of single dose medications
4. No alternative medication available and therefore different and potentially inadequate therapy Current estimates for the medication shortages:

- For most bupivacaine solutions with epinephrine (0.25%, 0.5% and 0.75%), the next shipments are expected to occur in March 2018. [1,2]
- For most isobaric bupivacaine solutions (0.25%, 0.5%), the next shipments are expected to occur mid-March 2018. [1,2] ○ For hyperbaric spinal bupivacaine solutions (0.75% 2 ml), the next shipment will b announced in April 2018. Current estimated recovery is expected by September 2018. [1,2] ○ For ropivacaine, most solutions should be released again by end of March or in May according to origin.[2,5,6]

<u>Recommendations:</u>

- Determine current inventory (e.g. isobaric bupivacaine 0.25%, isobaric bupivacaine 0.5%, hyperbaric bupivacaine 0.75%) in your institution's pharmacy: what is in stock, what has been ordered and what will be shipped and available to you in the next weeks.
- Based on your monthly volume of deliveries (neuraxial labor analgesia and cesarean delivery rate) and your clinical practice protocols, determine if the supply will be sufficient to cover your needs.
- Consider asking your institution's pharmacy if they are able to prepare, single dose, preservative free, sterile syringes of bupivacaine (according to the latest regulatory requirements)- to minimize wasted bupivacaine.
- Each hospital may develop its own policies on dealing with medications suffering from national drug shortages.

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Possible alternative strategies:

- **For planned cesarean delivery**: a spinal anesthetic with hyperbaric bupivacaine 0.75% (1.6-2 ml) may be substituted with:
  - Isobaric preservative-free bupivacaine 0.5%* at a dose between 12-13 mg, or approximately 2.52.6 ml, if being administered with supplemental opioids (e.g. fentanyl).[9] Higher doses of bupivacaine (up to 15 mg, 3 ml) may be required if supplemental opioids are not available.
  - An epidural anesthetic or dural puncture epidural (DPE) with subsequent dosing with epidural lidocaine or chloroprocaine is also an option if no bupivacaine is available.
- **For epidural labor analgesia:**
  - If using bupivacaine for analgesia initiation and/or epidural top-ups, instead of a large vial of isobaric bupivacaine 0.25% (e.g. 10ml or 30 ml) being used for each case, consider using smaller vials or smaller volumes of isobaric bupivacaine if they can be prepared by your pharmacy into single dose syringes.
  - For labor epidurals using combined spinal-epidural (CSE) analgesia, for spinal initiation instead of using a large vial of isobaric bupivacaine 0.25% (e.g. 10 ml or 30 ml) for each case, consider using single dose aliquots (e.g. 1 ml or 2.5 mg) with or without added opioid if they can be prepared by your pharmacy.
  - Ropivacaine may be used as an alternative to bupivacaine. Ropivacaine is 40% less potent than bupivacaine (e.g. 0.1% ropivacaine is equivalent to 0.0625% bupivacaine).[10]
- If possible, consider requesting that all bupivacaine solutions be primarily made available to Obstetric Anesthesia and that other Anesthesia divisions be mindful of shortage and use other local anesthetics whenever feasible.

* The vials containing preservative-free isobaric bupivacaine 0.5% (10ml, 20ml or 30ml) have a label indicating '*not for spinal use*' however there is no medical reason preventing single use of these vials for spinal anesthesia. It can be drawn under standard sterile conditions by the anesthesia provider at the recommended dose, or aliquoted by the institutional Pharmacy for conservation purposes (in 3ml syringes).

For further updates, please check the SOAP website: https://www.soap.org/

References:

1. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
2. http://www.ahfsdruginformation.com/category/drug-shortages/
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5. https://store.ashp.org/Default.aspx?TabID=251&productId=154702179
6. https://www.drugshortagescanada.ca/shortage/8417
7. https://www.emlab.com/services/usp-797-testing/
8. U.S. Pharmacopeia Convention, Inc.: General Chapter, 797. Pharmaceutical Compounding-Sterile Preparations. The United States Pharmacopeia, 37th Revision and The National Formulary. 32nd Edition, Rockville, Md.: United States Pharmacopeia Convention; 2014. p. 410-53.
9. Sng BL, et al. Hyperbaric versus isobaric bupivacaine for spinal anaesthesia for caesarean section. Cochrane Database Syst. Rev. 2016 Sep 15; 9:CD005143
10. Polley LS, et al. Relative analgesic potencies of ropivacaine and bupivacaine for epidural analgesia in labor: implications for therapeutic indexes. Anesthesiology. 1999 Apr;90(4):944-50.

USP 797 Note: USP 797 states that single-dose/single-use vials opened in less than ISO Class 5 air quality be used within one hour, with any remaining contents discarded. Single-dose/single-use vials opened in ISO Class 5 air quality can be used up to six hours.

not intended to ensure a successful patient outcome in every situation and is not a guarantee of any specific outcome. The SOAP advisory is subject to periodic revision as additional data becomes available.