Special Foods Subcommittee of PTAC
Teleconference held 5 September 2013

(minutes for web publishing)

Special Foods Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Special Foods Subcommittee meeting; only the relevant portions of the minutes relating to Special Foods Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Special Foods Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 7 November 2013, the record of which will be available in February 2014.

Minutes of the Special Foods Subcommittee of PTAC teleconference Thursday 5 September 2013

1 0.5kcal/ml oral feed (preOp) for patients undergoing elective surgery

Application

1.1 The Subcommittee reviewed an application from Nutricia LTD for the listing of 0.5kcal/ml oral feed (preOp) on the Hospital Medicines List (HML) for the metabolic conditioning of patients undergoing elective surgery.

Recommendation

1.2 The Subcommittee **recommended** that preOp for patients undergoing elective major abdominal surgery as part of the Enhanced Recovery After Surgery (ERAS) protocol be listed on the HML with a high priority, subject to the following restriction:

> 400 ml as part of an Enhanced Recovery After Surgery (ERAS) protocol 2 hours before major abdominal surgery.

1.3 The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule*.

Discussion

1.4 The Subcommittee noted that the application was for a 0.5 kcal/ml liquid oral feed (preOp) which provided 100 kcal and 25.2 g of carbohydrate in a 200 ml bottle.

1.5 The Subcommittee noted that this application has arisen as a result of the implementation of the HML. The Subcommittee noted that when the Hospital Subcommittee reviewed the use of hospital pharmaceuticals in 2011, one DHB hospital had been using preOp as part of a Enhanced Recovery After Surgery (ERAS) protocol.

1.6 The Subcommittee noted that it had reviewed an application for preOp at its August 2012 meeting. The Subcommittee noted that in considering preOp in 2012 it had recommended that this product should not be included on the HML. The Subcommittee also noted that preOp had been reviewed by the Hospital Pharmaceuticals Subcommittee of PTAC at its December 2011 meeting and that the Hospital Pharmaceuticals Subcommittee of PTAC had recommended that preOp should not be included on the HML.

1.7 The Subcommittee noted the following publications in relation to the metabolic conditioning of patients undergoing surgery:

- Soop et al. Preoperative oral carbohydrate treatment attenuates immediate postoperative insulin resistance. Am J Physiol Endocrinol Metab 2001 Apr; 280 (4): E576-83

- Hausel et al. Preoperative oral carbohydrates improve well being after elective colorectal surgery. Clin Nutr 1999; 18 (suppl 1):80

- Hausel et al. Randomised clinical trial of the effects of oral preoperative carbohydrates on postoperative nausea and vomiting after laparoscopic cholecystectomy. British Journal of Surgery 2005 Apr; 92 (4): 415-21

- Ljungquist et al. Preoperative nutrition – elective surgery in the fed or the overnight fasted state. Clin Nutr 2001; 20 (supplement 1): 167-171

- Noblett et al. Pre-operative oral carbohydrate loading in colorectal surgery: a randomised controlled trial. Colorectal Disease 2006; Sep; 8(7): 563-9

- Nygren et al. Safety and patient well-being after preoperative oral intake of carbohydrate rich beverage. Clin Nutr 1996; 15 (supplement 1): poster 28

- Nygren et al. Preoperative oral carbohydrate administration reduces postoperative insulin resistance. Clin Nutr 1998: 17: 65-71

- Nygren et al. Preoperative oral carbohydrates and postoperative insulin resistance. Clin Nutr 1999 Apr; 18 (2): 117-20

- Soop et al. Preoperative oral carbohydrate treatment attenuates endogenous glucose release 3 days after surgery. Clin Nutr 2004 Aug; 23 (4): 733-41

- Svanfeldt et al. Effect of “preoperative” oral carbohydrate treatment in insulin action – a randomised cross-over unblended study in healthy subjects. Clin Nutr 2005 Oct; 24 (5): 815-21

- Vermeulen et al. Gastric emptying, glucose metabolism and gut hormones: evaluation of a common preoperative carbohydrate beverage. Nutrition 2001 Sep; 27 (9): 897-903

- Awad et al. A meta-analysis of randomised controlled trials on preoperative oral carbohydrate treatment in elective surgery. Clin Nutr 2013 Feb; 32 (1): 34-44

1.8 The Subcommittee noted the following publications in relation to the Enhanced Recovery After Surgery (ERAS) protocols:

- Sammour et al. A programme of Enhanced Recovery After Surgery (ERAS) is a cost-effective intervention in elective colonic surgery. N Z Med J 2010 Jul; 123 (1319): 61-70

- Spanjerberg et al. Fast track surgery versus conventional recovery strategies for colorectal surgery. Cochrane Database Syst Rev. 2011 Feb 16; (2): CD007635

- Gustafsson et al. Guidelines for Perioperative Care in Elective Colonic Surgery: Enhanced Recovery After Surgery (ERAS) Society Recommendations. World J Surg 2013 Feb; 37 (2): 259-84

1.9 The Subcommittee noted the following guidelines relating to pre-operative fasting:

- Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: a report by the American Society of Anesthesiologist Task Force on Preoperative Fasting. Anesthesiology. 1999 Mar;90(3):896-905.

- European Society of Anaesthesiology. (Smith et al). Perioperative fasting in adults and children: guidelines from the European Society of Anaesthesiology. Eur J Anaesthesiol. 2011 Aug;28(8):556-69

- Weimann et al. ESPEN Guidelines on Enteral Nutrition: Surgery including organ transplantation. Clin Nutr. 2006 Apr;25(2):224-44

- Gustaffson et al. Guidelines for perioperative care in elective colonic surgery: Enhanced Recovery After Surgery (ERAS®) Society recommendations. Clin Nutr. 2012 Dec;31(6):783-800.

1.10 The Subcommittee noted that the available guidelines relating to pre-operative fasting generally support the use of clear fluids containing carbohydrates up to 2 hours before surgery. The Subcommittee noted that the guidelines consider clear fluids containing carbohydrates are suitable for consumption up to 2 hours before surgery and do not mention osmolality of the solution being an issue. The Subcommittee noted that a cross-over randomised study indicated that there was no difference in residual gastric volumes in 8 healthy volunteers 120 minutes after ingesting an 805 mOsm/kg carbohydrate solution when compared to ingesting a 260 mOsm/kg carbohydrate solution (preOp).

1.11 The Subcommittee noted that some local anaesthetic guidelines allow commercially available “sport electrolyte drinks” as part of their clear oral fluids 2 hours prior to surgery and that these fluids generally have a substantially higher osmolality that 260mOsm/kg.

1.12 The Subcommittee considered that the evidence indicated that pre-operative fasting contributes to patient discomfort and that clear fluid containing carbohydrates can contribute to the patient’s wellbeing during the preoperative period.

1.13 The Subcommittee considered that the evidence reviewed indicates that preoperative oral carbohydrate conditioning results in reduced post-operative insulin resistance. The Subcommittee considered that this evidence was of moderate strength.

1.14 The Subcommittee noted a Cochrane review (Spanjerberg et al 2011) which indicated that ERAS protocols are associated with reduced complications and length of hospital stay. The Subcommittee noted that the trials that were reviewed were predominantly in patients undergoing colorectal surgery. The Subcommittee considered that the data were relatively low in quality.

1.15 The Subcommittee considered that the evidence presented suggests that the effect of a preoperative oral carbohydrate feed on reducing insulin sensitivity was confined to a 50 g dose of oral carbohydrate received 2 hours prior to surgery and there appeared to be no additional benefit from doses given earlier than that (e.g. 6 hours prior to surgery). Furthermore, the 6 hour prior to surgery dose (“night before dose”) had not been tested experimentally against normal diet and was excluded from some of the local ERAS protocols. The Subcommittee noted current guidelines relating to general anaesthesia for elective surgery in healthy patients and considered that generally, pre-operative patients would be able to consume carbohydrate in the form of normal diet up to 6 hours prior to surgery.

1.16 The Subcommittee noted the paucity of evidence to support the use of 0.5 kcal/ml oral feed in children.

1.17 The Subcommittee considered that an equivalent product to preOp could be made by mixing 50 g maltodextrin powder with water. However, the Subcommittee noted that this approach may be draining on resources and logistically problematic, noting that the maltodextran powder is hard to measure and dispense as it absorbs water and becomes sticky, and must be re-packaged. The Subcommittee was not aware of any suitable pre-packaged powders available.

1.18 The Subcommittee considered that alternative clear carbohydrate solutions, e.g. apple juice, could be utilised for pre-operative conditioning. However, members noted that the volume of these solutions that may be required to reach the intake of carbohydrate recommended by the ERAS protocols may be prohibitive.

1.19 The Subcommittee considered that the supportive care required for colorectal surgeries could be distinguished from other surgeries due to issues relating to ensuring the gut was adequately healed after surgery.

1.20 The Subcommittee considered there was no evidence of benefit for the use of preoperative oral carbohydrate feed for surgeries requiring a hospital stay of less than 2 days post-surgery.

1.21 Overall the Subcommittee considered that there was moderate quality evidence for the use of 400mls of 0.5 kcal/ml carbohydrate feed as preoperative metabolic conditioning 2 hours prior to surgery for patients undergoing elective major abdominal surgery as part of the ERAS protocol.