*i*CAHE JC Critical Appraisal Summary

Journal Club Details

Journal Club location	Women's & Children's Hospital
JC Facilitator	Resmey Sok
JC Discipline	Pharmacy

Background

Article provided by Journal Club.

Article/Paper

Kang, HJ, Loftus, S, Taylor, A, DiCristina, C, Green, S & Zwaan, CM 2015, 'Aprepitant for the prevention of chemotherapy-induced nausea and vomiting in children: a randomised, double-blind, phase 3 trial', *Lancet Oncol*, vol. 16, pp. 385–94.

Please note: due to copyright regulations CAHE is unable to supply a copy of the critically appraised paper/article. If you are an employee of the South Australian government you can obtain a copy of articles from the DOHSA librarian.

Article Methodology: Randomised Controlled Trial

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International Centre for Allied Health Evidence (iCAHE)

CONTACTS
www.unisa.edu.au/cahe
iCAHE@unisa.edu.au
Telephone: +61 8 830 22099
Fax: +61 8 830 22853

University of South Australia
GPO Box 2471
Adelaide SA 5001
Australia

CRICOS Provider Number 00121B

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Ques No.	Yes	Can't Tell	No	Comments
1	✓			**Did the trial address a clearly focused issue?** **P** - Patients aged 6 months to 17 years with a documented malignancy (original diagnosis or relapsed) who were scheduled to receive chemotherapeutic agent(s) associated with at least a moderate (>30%) risk of emesis in the absence of prevention measures, and who were expected to receive ondansetron as part of a chemotherapy-induced nausea and vomiting preventive regimen **I** - age-based and weight-based blinded regimen of aprepitant (125 mg for ages 12–17 years; 3·0 mg/kg up to 125 mg for ages 6 months to <12 years) plus ondansetron on day 1, followed by aprepitant (80 mg for ages 12–17 years; 2·0 mg/kg up to 80 mg for ages 6 months to <12 years) on days 2 and 3 **C** - placebo plus ondansetron on day 1 followed by placebo on days 2 and 3; addition of dexamethasone was allowed **O** - The primary efficacy endpoint was the proportion of patients who achieved complete response (defined as no vomiting, no retching, and no use of rescue medication) during the 25–120 h (delayed phase) after initiation of emetogenic chemotherapy
2	✓			**Was the assignment of patients to treatments randomised?** Patients who satisfied all study entry criteria were randomly assigned (1:1) to the aprepitant group or the control group by an interactive voice response system with a stratified randomised block design. More information has been provided on this in the article under the *Randomisation and Masking* section P387.
3	✓			**Were all of the patients who entered the trial properly accounted for at its conclusion?** The flow of participants is shown in Figure 1: Trial profile and details of participants who could not complete the study are outlined in detail in the results section. **Is it worth continuing?** YES
4	✓			**Were patients, health workers and study personnel 'blind' to treatment?** Detailed in the *Randomisation and Masking* section P387.

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5	✓			**Were the groups similar at the start of the trial?** Baseline demographics were similar between treatment groups. In general, treatment groups were balanced with regard to primary malignancies and the type and emetogenicity of administered chemotherapy agents.
6	✓			**Aside from the experimental intervention, were the groups treated equally?**
7				**What are the results?** Text, tables, graphs and figures were used to present the results. Percentages, P-values and 95% confidence intervals (CIs) were calculated and reported. *Bottom line result:* Addition of aprepitant to ondansetron with or without dexamethasone is effective for the prevention of chemotherapy-induced nausea and vomiting in paediatric patients being treated with moderately or highly emetogenic chemotherapy.
8				**How precise was the estimate of the treatment effect?** Precision of this study can be determined based the confidence intervals presented in Table 4 (overall adverse events). *Notes on confidence intervals [used to determine precision of results] Confidence intervals (CI) describe the uncertainty inherent in the observed effect and describe a range of values within which one can be reasonably confident that the true effect actually lies. If the CI is relatively narrow, the effect size is known precisely. If the interval is wider the uncertainty is greater, although there may still be enough precision to make decisions about the utility of the intervention. Intervals that are very wide indicate that we have little knowledge about the effect, and that further information is needed. The width of the CI for an individual study depends to a large extent on the sample size. Larger studies tend to give more precise estimates of effects (and hence have narrower CI) than smaller studies.
9	Journal club to discuss			**Can the results be applied in your context? (or to the local population?)** *Consider whether* ☐ *Do you think that the patients covered by the trial are similar enough to the patients to whom you will apply this?, if not how to they differ?*

10		**Were all clinically important outcomes considered?** *Consider* □ *Is there other information you would like to have seen?* □ *If not, does this affect the decision?*
11		**Are the benefits worth the harms and costs?** *Consider* □ *Even if this is not addressed by the review, what do you think?*
12		**What do the study findings mean to practice (i.e. clinical practice, systems or processes)?**
13		**What are your next steps? (e.g. evaluate clinical practice against evidence-based recommendations; organise the next four journal club meetings around this topic to build the evidence base; organize training for staff, etc.)**
14		**What is required to implement these next steps?**

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