Reviewer’s report

Title: Unsedated Peroral Wireless pH Capsule Placement vs. Standard pH Testing: A Randomized Study and Cost Analysis

Version: 2 Date: 28 February 2012

Reviewer: Jody Church

Reviewer’s report:

Major Compulsory Revisions

1. All of the inputs that into the costing model need to be included in Table 4 for better transparency. This includes resource use, unit costs and probabilities used in the calculations. It is a simple model and therefore should be easy to replicate.

2. The authors state that the cost analysis is from a public payer perspective and thus exclude costs resulting from lost productivity (assumptions, paragraph 2) but then calculate the indirect costs (which are productivity costs). It should state “societal” perspective as they have included costs borne to the patient.

3. In the assumptions section (paragraph 2) is says that “93% of the WC group would have worked during the testing period (see results)”, however this statistic is not in any of the results tables. Furthermore, it is not clear in the cost analysis what percentage was used in the EGD+WC group. As per comment 1, this should all be in a table of model input parameters.

4. The primary aim was to determine whether the placement of WC is as effective and better tolerated than SC. The paper therefore assumes that in measuring pH levels, WC and SC are equal in effectiveness. The report discusses patient discomfort in the conclusion and abstract but does not discuss failure rates which a key form of effectiveness for this product. Furthermore, the study was only powered for VAS discomfort scores and not powered to detect difference is technical success. Also the VAS for chest discomfort in the WC was statistically significantly higher than the SC group but is also not discussed.

Minor Essential Revisions

1. More information on the wage rate used would be helpful to understand the indirect costs applied in the model.

2. The model assumes that 100% would not work in the SC group, however the mean VAS score of ‘ability to do usual activities’ was 75. Please explain the discrepancy.

3. Only 43 patients were asked about whether they would work, but does 43 patients have sufficient power to detect a difference between the groups? Furthermore, the question on whether they would work is hypothetical and is questionable whether this would reflect actual experience.

4. It is not appropriate to only drop the failure rate of ESM+WC in the sensitivity analysis, given that the failure rates between the WC and SC groups were not
statistically significant.

Discretionary Revisions

1. In the introduction (paragraph 2), it may be more appropriate to discuss the duration of the testing period before reporting on how it affects daily living, as well as how long these effects last.

2. In the introduction (paragraph 4), the authors mention “Endoscopy also increases patients risk…”. It is unclear what this risk is. This same point is in the discussion but the reader has no indication what risks are associated with endoscopy.

3. In the introduction (paragraph 5) it states that “data from clinical study informed the cost-analysis”, however data was also used from the literature for the EGD+WC group.

4. As a discussion point, the reasons for not using a validated quality of life instrument, such as the SF-36.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests