<u>HEALOZONE – HEALTH TECHNOLOGY APPRAISAL</u>

Personal Statement. Professor Elizabeth Kay

Introduction

Appropriate clinical decision making and treatment of dental decay requires that the clinician understands both the natural history of the disease and the predictors and risk factors for it. There is no completely sensitive and specific diagnostic system for dental caries and therefore the diagnostic criteria for intervention rely on estimation of the probability and utility of disease sequelae, i.e. appropriate care is based on patient preferences for the outcomes of treatment.

It would therefore seem that before the efficacy of Healozone as a treatment modality can be adequately assessed, three sets of questions must be addressed.

- (1) What is the natural history of the carious lesions which might be treated by Healozone? i.e is it possible to distinguish the level of 'activity' of a given lesion, what would be the 'normal' rate of progression of a lesion from one stage to another, what is the outcome if such carious lesions were left untreated, or were treated by conventional means.
- (2) How accurate, reliable and valid are the methods we use for diagnosing carious lesions which might be treated using Healozone?
- (3) If persons with carious lesions were randomly assigned to receive conventional care, no care, and Healozone therapy, would they experience qualitatively

different outcomes, i.e. would health related outcomes, such as tooth longevity or functional ability be affected differently.

Whilst the evidence cited in the assessment document suggests that ozone can "disinfect" lesions, no evidence, particularly with regard to (3) is presented.

Current Evidence

Clearly, the efficacy of Healozone as a treatment modality needs to be tested in randomised controlled trials.

A recent Cochrane Review¹ has assessed the evidence pertaining to whether ozone is effective in arresting or reversing the progression of dental caries. Trials of ozone were included in the review if they were randomised and controlled, if the randomisation was concealed, and if they made appropriate comparisons to ozone application. Outcomes had to be measured after 6 months.

The Review revealed only three eligible trials of ozone and the conclusion was that ozone showed inconsistent effects on caries, and on caries progression and regression. The reviewers stated that because of lack of consistency between outcome measures, there was no reliable evidence that application of ozone had an effect on the caries process. The reviewers' conclusion is worthy of note. "There is a fundamental need for more evidence of appropriate rigour and quality before the use of ozone can be accepted into mainstream primary dental care or can be considered a viable alternative to current methods for the management and treatment of dental caries."

As systematic review of randomised controlled trials is widely considered to be the most robust form of scientific evidence, and this review was amended and updated in May 2004, there is little further that this personal statement can add.

 Rickard GD, Richardson R, Johnson T, McColl, Hooper L. Ozone therapy for the treatment of dental caries (Cochrane Review) in: The *Cochrane Library*, Issue 4, 2004. Chichester UK: John Wiley and Sons, Ltd.