

# Good Questions

Issue Eleven

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## “Why gamble?” wins at ISPOR!

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On 20-23 October, more than 1,500 delegates from around the world descended on Dublin’s fair city for the 10th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Those attending included pharma company executives, academics, researchers, students and regulatory authority representatives alike.

AHP was proud to be a sponsor and our stand took pride of place at the centre of the exhibition hall. Our roulette wheel provided welcome light relief for many delegates, who tried their luck to win our Nintendo Wii. Congratulations to Ba Luong of Solvay Pharmaceuticals who was the lucky winner. We hope that Ba and other less lucky delegates won’t be gambling with their PRO strategies when they get back to the office!



## Alcoholism – what is the impact on quality of life?

Alcohol has been enjoyed for thousands of years and the problems that can accompany excess alcohol intake have undoubtedly been around as long. Alcohol has always had an ambivalent position in society due to the physical and psychosocial impact of excess consumption but only this month have doctors called for compulsory labelling of alcohol content and the number of units on packaging in a bid to help tackle excess drinking and alcoholism.

Alcoholism (the popular term for two disorders: alcohol abuse and alcohol dependence) may affect up to 2.8 million people in the UK<sup>1</sup>. Paradoxically, such statistics rely on individuals to self-report something about which they may be in denial. In the early stages of alcoholism, individuals may experience only subtle biomedical or health-related changes<sup>2</sup>

making subjective perceptions of the psychological, social and physical impact of alcoholism fundamental to diagnosis and treatment.

Alcoholism is widely acknowledged to have a huge impact on the individual and his/her family, eg in terms of self-esteem, autonomy, stress, work, social isolation, sleep and affective state<sup>3</sup>, domestic and marital functioning, harmony at home, peace of mind, reputation, self-respect, and religion<sup>4</sup>. Despite this, QoL has rarely been assessed formally in either clinical practice or research<sup>5</sup>. We recently undertook a systematic review to identify and assess the suitability of existing instruments used to measure the impact of alcoholism on QoL.

We identified 16 generic instruments that have been used to assess issues of relevance to QoL in alcoholism research,

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## Alcoholism ...

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with the EQ-5D, Nottingham Health Profile, SF-36, and WHOQoL-BREF amongst the most widely used. The WHOQoL-BREF is the only one that can be considered a generic measure of QoL, while the others measure health status, in other words, quality of health rather than quality of life. In addition, the generic instruments include many irrelevant items (eg pain and mobility) and exclude more pertinent and potentially important issues (eg sleep, working life, cognitive functioning, social isolation), which are likely to be of greater relevance and contribute to a more valid and sensitive measure. Furthermore, as health status is likely to be impaired only when alcoholism begins to cause health problems (and far beyond the point at which it may have impacted on the QoL of the individual and that of their family), many of the studies that have used generic measures of health status may have under-reported the full impact of alcoholism on QoL.

An alcohol-specific measure, which claims to epitomise health-related QoL for people with alcohol-dependence has been derived by reducing the SF-36 (French version) to the 9 items most relevant to alcoholism. Despite the use of rigorous statistical methods and demonstration of adequate psychometric properties, the AIQoL 9<sup>6</sup> is limited by its origins. Thus, it shares the disadvantages inherent in other generic measures (as discussed above).

In conclusion, an alcohol-specific measure is needed, derived from systematic evaluation of the impact of alcoholism on QoL, through literature review and patient interviews. In addition, existing research considers only the alcohol abusers' perspective, but we would encourage the evaluation of the impact of alcoholism on the QoL of family, friends, and colleagues.

*"An alcohol-specific questionnaire is needed, derived from systematic evaluation of the impact of alcoholism on QoL"*



Above: Matt Reaney presenting this research at the 10<sup>th</sup> Annual European ISPOR Congress in Dublin (October 2007).

This work will also appear as a chapter in Martin CM (ed.) 'Identification and treatment of alcohol dependency', to be published early 2008. Please [contact us](#) for a copy of the poster or for notification of publication.

### References

1. Cabinet Office Strategy Unit (2003) [Alcohol misuse: How much does it cost?](#) Downloaded from <http://www.cabinetoffice.gov.uk/strategy/>
2. Burge S K & Schneider F D (1999). Alcohol-Related Problems: Recognition and Intervention. American Family Physician. Downloaded from <http://www.aafp.org>
3. Foster J H, Peters T J, Kind P (2002). Quality of life, sleep, mood and alcohol consumption: a complex interaction. *Addict Biol*, 7:55-65.
4. Foster J H., Powell J E, Marshall E J, Peters T J (1999). Quality of life in alcohol-dependent subjects--a review. *Qual Life Res*, 8, 255-261.
5. Spitzer R L, Kroenke K, Linzer M, Hahn S R, Williams J B, DeGruy 3<sup>rd</sup> F V, Brody D, Davies M (1995). Health-related quality of life in primary care patients with mental disorders. *JAMA*, 274:1511-1517.
6. Malet L, Llorca P M, Beringuier B, Lehert P, Falissard B (2006). AIQoL 9 for measuring quality of life in alcohol dependence. *Alcohol Alcohol*, 41:181-187.

## Patients encouraged to ask good questions!

A new leaflet produced by the UK Department of Health is designed to encourage patients to ask questions of their healthcare providers. The leaflet called "Questions to ask" offers a range of simple questions that a patient might want to ask about what treatment, if any, is best for the individual, what happens next and who to contact. In addition, it offers top tips for issues to consider:

- before the appointment
- during the appointment
- before leaving the appointment
- after the appointment

The leaflet is written in plain English in a user-friendly format and is available from the [Department of Health website](#) and. It is also available in a large print and a range of languages from Arabic to Urdu.



## In the Journals

### *Equivalence of electronic and paper-and-pencil administration of PRO measures: A meta-analytic review*

- 1** Electronic administration of patient reported outcome (ePRO) measures is becoming increasingly popular in medical and drug development studies. Evidence is needed to demonstrate that scores derived from ePROs do not differ from scores derived from paper-based PROs.
- 2** The aim of this study was to assess the equivalence of ePRO assessments with their paper counterparts.
- 3** A literature review identified 65 studies assessing equivalence between electronic and paper versions of the same measure (46 met strict inclusion criteria).
- 4** A meta analysis showed that the mean scores derived from electronic measures were 0.2 points higher than the mean scores from paper measures.
- 5** 94% of correlational studies (N=32) showed average correlations greater than 0.75; almost identical to within-mode test-retest correlation.
- 6** The authors concluded that electronic and paper measures produce equivalent scores. Administering PRO measures electronically has the additional potential to increase patient's willingness to take part and reduce data management burden.

NOTE: Despite these results it is important to note that the FDA Draft guidance on PRC endpoints requires researchers to undertake a full validation study when transferring a measure from paper to electronic mode of administration.

<sup>1</sup> Chad J et al. (in press). Equivalence of electronic and paper-and-pencil administration of patient-reported outcome measures: A meta-analytic review. *Value In Health*

## In the news...

### **FDA is failing to oversee human clinical trials**

<http://www.bmj.com/cgi/content/extract/335/7622/691-b>

### **Boots could host 150 walk-in centres in its stores**

[http://www.hsj.co.uk/news/boots\\_could\\_host\\_150\\_walkin\\_centres\\_in\\_its\\_stores.html?](http://www.hsj.co.uk/news/boots_could_host_150_walkin_centres_in_its_stores.html?)

### **Many lacking good diabetes care**

<http://news.bbc.co.uk/1/hi/health/7062473.stm>

### **Hypnotherapy outperforms other treatment approaches for smoking cessation**

<http://www.medscape.com/viewarticle/564668?src=mp>

### **New definition of myocardial infarction (MI)**

<http://www.medscape.com/viewarticle/564652?src=mp>

### **Patients win right to have their advance decisions honoured**

<http://www.bmj.com/cgi/content/extract/335/7622/688-b>

### **FDA panel: No cold medicine for young children**

<http://www.medscape.com/viewarticle/564562?src=mp>

## Good Answers?

Every month in "Good Questions", we give you the opportunity to benefit from your own "Good Answers". Just give some thought to the problems we pose and send your response to us.

### **Approximately how many people does alcoholism affect in the UK?**

Answers to: [info@ahpresearch.com](mailto:info@ahpresearch.com). The closing date for entries is 12 noon on **Friday 30th November**.

The closest estimate will win an Amazon voucher. We will publish the answer to this month's problem in next month's issue, along with the name of the winner. If you would prefer to remain anonymous, just let us know.

## Are medical devices more challenging to evaluate than drugs?

This was the good question asked at the recent ISPOR conference (Dublin, 21-23 Oct 2007), as the first in a new annual series of symposia to focus specifically on the evaluation of medical devices.

Michael Drummond (Professor of Health Economics, University of York) chaired contributions from Rosanna Tarricone (Economic Affairs Director, EUCOMED) and Adrian Griffin (Director of Health Outcomes, Johnson and Johnson), providing regulatory and industry perspectives.

Medical technology (MT) differs somewhat from pharmaceuticals in the following ways. Innovation in MT:

- derives from close integration with end users, especially clinicians, meaning that development of new technologies is dependent on feedback from those end users.
- is highly dependent on users' ability and training
- often impacts dramatically onto clinical practice, interprofessional relationships service organisation, and delivery.

Thus, key issues when assessing MT include:

- **Appropriate evidence:** RCTs are generally unsuitable and, when no alternative is available, unethical. Blinding is impossible. Timescales may also be important. For example, in orthopaedics, where outcomes may not be known for up to 20 years, NICE accepts registry data and modeling.
- **Learning curve:** the time taken to develop skills and perfect techniques is often not seen in HTA reports.
- **Relevance of organisational factors:** training of staff is a key issue, which may add considerable costs to a relatively inexpensive technology.

In conclusion, the speakers indicated that medical devices are not more challenging than drugs, but do offer their own unique challenges and dilemmas. Importantly, managing the diffusion of technological innovations into the real world requires a comprehensive approach that takes account of the context in which the new technology will be used.

## In Brief

### ■ [Schoolgirls to get 'cancer jab'](#)

The human papilloma virus (HPV) virus has long been established as the main cause of cervical cancer and may be responsible for up to 400 deaths a year. It has been announced this month that British schoolgirls will be vaccinated against HPV from September 2008. The Joint Committee on Vaccination and Immunisation recommended that vaccinations start at the age of 11, but schoolgirls in England will not be targeted for immunisation until 12-13 years with a catch-up option up to age 18. There are concerns that earlier immunisation may encourage promiscuity.

Two primary care trusts have recently piloted the vaccination programme, encountering no major obstacles with parental acceptance and reporting that the parent's main concern is "long term safety" even though they do not believe their daughters are as yet at risk of HPV.

### ■ [The new rules for defeating cancer](#)

"Being skinny and not eating red meat" are the new rules for avoiding cancer according to the World Cancer Research Fund (WCRF) who recently assembled an expert panel to complete the most comprehensive review of research to date linking diet and cancer. Researchers found

that even a slight increase in weight can significantly increase risk of more than six types of common cancers. Rising rates of obesity in the UK make this new information particularly alarming. With an emphasis on providing "practical lifestyle recommendations" to prevent cancer, the WCRF made a total of ten recommendations. These include dietary suggestions (limiting sugary drinks and alcohol intake; eating foods of plant origin) as well as lifestyle behaviours (such as remaining as physically active as possible and breastfeeding in the case of new mothers).

### ■ [Obesity crisis as serious as climate change](#)

The threat posed by obesity in the UK is a 'potential crisis on the scale of climate change', health secretary Alan Johnson has warned. He said the magnitude of the problem was becoming clear for the first time. A government-commissioned (published on 17 Oct 07) shows that half the population could be obese within 25 years.

In order to tackle this epidemic successfully, we need to understand the factors that motivate people. Please see [last month's](#) Good Questions for a full discussion.

## Forthcoming events:

20 Nov 2007

Diabetes UK workshop  
'Dealing with hypoglycaemia':  
London and Manchester

14 Nov 2007

World Diabetes Day

13 Dec 2007

UKSBM 3rd Annual  
Scientific Meeting:  
Warwick

20 February 2008

Critical Appraisal Skills  
Training (UKCRN):  
Manchester

21 February 2008

Social Context in Clinical  
Research Training  
(UKCRN):  
Manchester

For further details on any  
of these events, please  
visit our [events](#) webpage.