

Good Questions

Issue Seven

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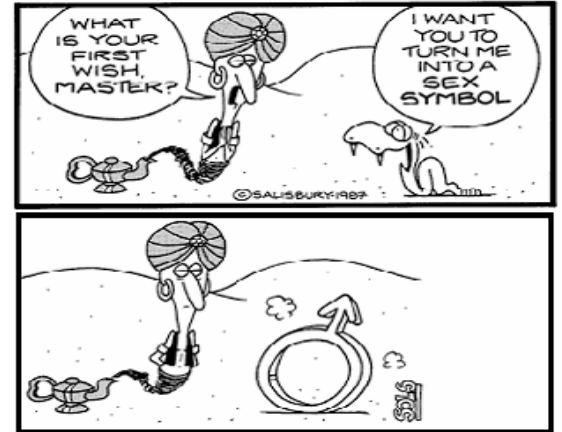
Cognitive debriefing: what is it & how important is it?

“Cognitive debriefing” (CD) is a term used frequently in the pharmaceutical industry to refer to the extended method of pilot testing questionnaires to ensure understandability and comprehensibility. With the recent dissemination of regulatory guidance^{1,2}, those of us working in the field of outcomes research (within the pharmaceutical industry) include CD as one of our core skills and as part of our everyday work.

But does it have a wider remit?

While CD is recognised increasingly as a vital step in linguistic validation (i.e. a process that ensures the validity of a new translation of a measure, confirming that it is understood as originally intended), its use in the development of new measures or use of existing measures in new populations is rare. This remains the case despite widespread acknowledgement that such work requires patient input.

In fact, the terminology itself may well deter people from using what is essentially a very simple (although rigorous and effective)



process. The US Food and Drug Administration (FDA) defines CD as “a qualitative research tool used to determine whether concepts and items are understood by patients in the same way that instrument developers intend. Cognitive debriefing interviews involve incorporating follow-up questions in a field test interview to gain a better understanding of how patients interpret questions asked of them”¹.

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AHP goes mobile!

Recognising that our work increasingly takes us away from the office (and out of direct contact with our clients), several members of our

team now have internet-capable mobile phones, enabling us to pick up emails and phone calls when we are away from the office. We hope that this will make us more accessible to our clients and associates. We look forward to hearing from you soon!

AHP collaborates with UKITC on islet transplant research programme

We are pleased to announce our collaboration in a 4.5 year multi-centre research project funded by Diabetes UK. Islets are the group of cells that contain the insulin-producing beta cells needed to maintain blood glucose control. In people with Type 1 diabetes, those cells have been destroyed and so they must inject insulin to remain healthy. In the UK, a small number of people have already received a transplant but this new research means that we will be able to investigate both biomedical and psychological outcomes for approx. 100 islet transplant recipients. Please [contact us](#) for further information.

Does one size fit all? Assessing the true impact of insulin pump therapy

In the latest issue of *Diabetic Medicine*, Jane Speight and Dr James Shaw (Newcastle University) comment on a recent review of the impact of insulin pump therapy on quality of life (QoL) (Barnard et al, 2007). Speight and Shaw argue that the review cannot draw firm conclusions due to the limitations of earlier pump therapy studies. They conclude that not only is a consensus needed about the how to measure the impact of diabetes on QoL but also that more innovative trial designs are needed to take account of patient priorities and preferences. Please [contact us](#) for a copy of the editorial.

Research focus

This month, we introduce a new feature to "Good Questions", highlighting recent scientific publications that demonstrate the value of taking a health psychology perspective. We hope you will find them as interesting as we have. If you would like to suggest an article for us to feature in a future issue, please [contact us](#). In this issue, we report on a recent paper by Lytsy and Westerling¹

What influences patient expectations on lipid-lowering drugs?

One of the largest causes of mortality and morbidity across the Western world is also one of the most avoidable². Cardiovascular disease (CVD) is not only preventable in terms of lifestyle and behaviour modification, but it can also be treated with a range of well-established drugs (statins), which have been shown to be most effective in those with a history of CVD (i.e. as secondary rather than primary prevention)³.

As with most long-term conditions, particularly those that are asymptomatic, adherence to CVD medication generally deteriorates over time. Treatment decisions are usually initiated by the clinician, who weighs up the chances of avoiding or delaying a CVD event against any potential adverse events. However, the patient, who may have other priorities, does not necessarily share this rationale. So, the crucial question is how can we encourage patients to sustain their tablet-taking in the long-term?

Lytsy and Westerling outline a number of factors believed to influence adherence, including the patient's:

- knowledge of/ attitude to the disease
- presence of existing risk factors
- use of concurrent medications
- expectations of the treatment

Their research focuses on the last of these, i.e. what factors are associated with higher and lower treatment expectations? In contrast to the clinician's rationale for prescribing a statin, their findings suggest that previous CVD does not seem to affect patient expectations of treatment.



More important it seems are the clinician patient relationship, the patient's social support and their perceived control of own health. The authors conclude: *"rational reasoning does not seem to be relevant to patient's expectations of their own statin treatment"*¹.

What are the implications of this? The relationship between the clinician and his/her patient is paramount. If patient dissatisfaction with the explanation of treatment is related to the patient's low belief in treatment benefit and subsequent discontinuation of treatment, this suggests that improving the patient-clinician dialogue will have benefits for long-term medication adherence.

References

- 1 Lytsy P & Westerling R (2007) Patient expectations on lipid-lowering drugs. *Pat Educ Couns* 67: 143-150.
- 2 Willet WC (2002) Balancing life-style and genomics research for disease prevention. *Science* 296: 695-8.
- 3 Pignone M et al (2000) Use of lipid lowering drugs for primary prevention of CHD: meta-analysis of randomised trials. *BMJ* 321: 983-6.

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 us your answers.

What kind of study is also referred to as a "think aloud" study?

Answers to: info@ahpresearch.com. The lucky winner will receive a voucher for Amazon.co.uk. The closing date is 12 noon on **Friday 10th August**. 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.

Last month's "Good Answer" was 'Ireland'.

"rational reasoning does not seem to be relevant to patient's expectations of their own statin treatment"

In Brief

■ ['Insulin pill' hope for diabetes](#)

The search for reliable oral insulin has been a long one. Typically, ingested insulin is degraded in the stomach without being absorbed into the bloodstream. However, researchers at UK company Diabetology and Cardiff University have developed a capsule with a special coating that protects the drug from acids in the stomach, allowing it to pass into the small intestine where it is absorbed. Early trial findings, presented at the American Diabetes Association (ADA) by Dr Steve Luzio, show that oral doses achieve the necessary changes in the body's blood sugar handling to treat Type 2 diabetes. These preliminary findings (N=16) should be treated with caution, but this is an exciting development for the millions of people with diabetes worldwide and may have particular benefits for those with psychological insulin resistance.

■ [Vaccine developed for high blood pressure](#)

Problems associated with long-term adherence to blood pressure (BP) medication have led a Swiss company to develop a long-lasting vaccine. Cytos Biotechnology (based in Zurich) has produced a vaccine (now in Phase II trials) that may reduce BP for several months at a time. The greatest reduction in BP has been observed in the morning, when most strokes and heart attacks are known to occur.

■ [NICE advice drives up treatment costs](#)

Health economists have outlined their concern that primary care trusts (PCTs) are being pushed into spending too much money on life-saving drugs by the National Institute for health and Clinical Excellence (NICE), and that more cost-effective treatments are not being considered. Typically, the cost-effectiveness of medicines is calculated according to the number of quality adjusted life years (QALYs) afforded by the treatment. NICE does not have a formal limit for the cost of drugs, but uses a de facto cut-off point of about £30,000 per QALY. However, Prof Brian Stirling (Birmingham University) has expressed concerns that this 'high' limit may drive out more cost-effective conventional treatments, and that 'Local NHS organisations will find it even more difficult to remain within budget' unless the limit is reduced.

What's happening at AHP?

- Lee-Yee Chong is currently enjoying a well-deserved holiday in Singapore to attend the graduation ceremony for her PhD, which was awarded in May. Congratulations Dr Chong - we are delighted for you!
- Welcome to Leena Khagram MSc, who joined the team as a Research Assistant in June. We hope Leena will be very happy in her new position.
- Congratulations to Aysha Malik on winning a place on the MSc Health Psychology at UCL. Aysha will continue as a Research Assistant on a part-time basis while she completes her Stage 1 qualification.
- Our best wishes also go to Aysha for her forthcoming wedding. We wish her and her husband-to-be, Tanzeel, every happiness as they set out on their new life together.

In the News...

FDA approves first drug for treating Fibromyalgia

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01656.html>

Alzheimer's disease to quadruple worldwide by 2050

http://www.jhsph.edu/publichealthnews/press_releases/2007/brookmeyer_alzheimers_2050.html

Vaccines for drug addiction

<http://psychcentral.com/news/2007/06/22/vaccines-for-drug-addiction/>

David Woodhead on gathering evidence

<http://www.hsj.co.uk/healthservicejournal/pages/Ool070628woodhead>

Eating disorders in teens with Type 1 diabetes

<http://diabetes.about.com/od/childrenanddiabetes/a/type1disorder.htm>

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So, what is involved in CD? As implied by the name, the process has its origins in cognitive psychology, where participants are often asked to solve complex reasoning tasks and 'think aloud' through the steps that they take to solve the task. Similarly, CD can be conducted to inform our understanding of the path the respondent takes when completing a questionnaire. CD takes the form of a semi-structured interview:

- to determine what a question means to the respondent, i.e. what do they think of when they read that question?
- to improve the clarity of instructions, a question or its response options
- to identify repetition (redundancy) in a measure
- to determine whether the newly designed measure is appropriate and understandable to the lowest educated person in a particular population
- to identify any important concepts or items that are currently missing but need to be included.

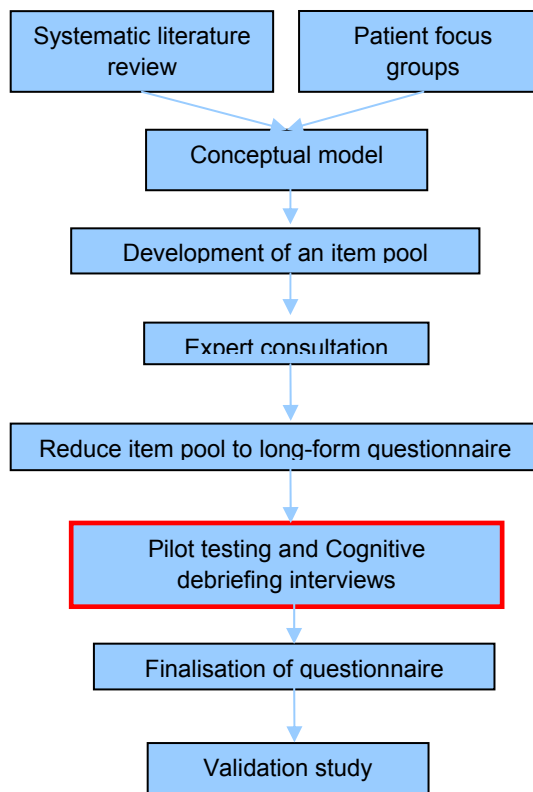
Data from the interviews are then used to refine the questionnaire ready for inclusion in the main study (see figure).

Importantly, the purpose of the CD is to assess the questionnaire, not to assess the respondents. Participants need to be encouraged to express their opinions, so that they feel uninhibited in voicing any problems that they may have with the questionnaire. It is only when the participant feels entirely at ease that you will be able to identify any difficulties with the questionnaire.

David French and colleagues have recently published a paper in the *Journal of Health Psychology*³ suggesting that CD offers very real benefits for anyone undertaking a questionnaire study. In their paper, they report two studies focusing on the problems encountered by people when they complete questionnaires designed to test the theory of planned behaviour (TPB). Such questionnaires are often quite complex and French et al reported that most people had "identifiable problems with the majority of questions":

- respondents re-read questions, i.e. they were aware of their own difficulty understanding the wording of questions
- respondents queried the sense of questions

Questionnaire development diagram



- respondents answered a different question from the one asked, i.e. they were unaware of their misunderstanding

Given that researchers developing a new measure for a one-off study rarely undertake CD, French et al's findings have potentially serious consequences for the validity of many such studies.

So, CD represents a rigorous yet simple process to ensure that the participant completes the questionnaire as intended by the researcher. Given the ease and relative inexpense associated with CD, the question is not how important is it but can afford to conduct your next questionnaire study without it?

References

- 1 Food and Drug Administration (FDA) (2006). Guidance for industry: patient-reported outcome measures: use in medical product development to support labelling claims: draft guidance. Health and Quality of Life Outcomes, 4:79.
- 2 Committee for Medicinal Products for Human Use (CHMP): Reflection Paper on the Regulatory Guidance for the Use of Health-Related Quality of life (HRQL) Measures in the Evaluation of Medicinal Products. <http://www.emea.europa.eu/pdfs/human/ewp/13939104en.pdf>
- 3 French et al (2007) What do people think about when they answer Theory of Planned Behaviour questionnaires? A 'think aloud' study. *J Health Psy* 12(4): 672-687.

Forthcoming events:

15 - 18 Aug 2007
EHPS 21st Annual Conference:
Maastricht

12 - 14 Sept 2007
Division of Health Psychology Annual Conference: Nottingham

10 - 13 Oct 2007
ISOQOL 14th Annual Congress:
Toronto

20 - 23 Oct 2007
ISPOR 10th Annual European Congress:
Dublin

13 Dec 2007
UKSBM 3rd Annual Scientific Meeting:
Warwick

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