

Is the FDA's final guidance on the use of PROs to support label claims nearly here?

"There will be no major changes in principles or policy direction in the final guidance"



The long-awaited final guidance from the US Food and Drug Administration (FDA) may be only weeks away.

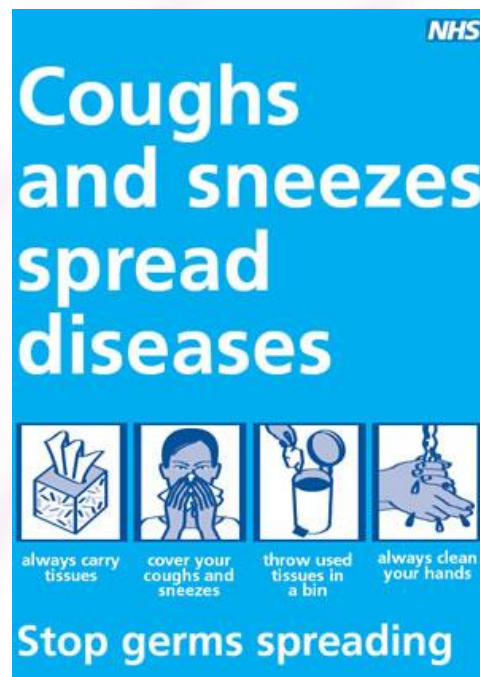
In a brief statement issued in September, Laurie Burke, Director of Study Endpoints and Label Development (SEALD) at the Centre for Drug Evaluation and Research (CDER) Office of New Drugs, indicated that the FDA plans to release final guidance this autumn on the use of patient-reported outcomes (PRO) data to provide evidence of treatment benefit.

Apparently, there will be no major changes in principles or policy direction in the final guidance compared with the February 2006 draft guidance but it will be much more detailed. Laurie Burke did not specify a date but she said the final document has been circulated among officials at the FDA and will be available soon. We will, of course, provide a summary of the guidance as soon as it is issued. So, watch this space!

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The H1N1 virus: a catalyst for behaviour change?



Each year, autumn brings with it a seasonal flurry of colds and flu viruses, to which many of us will expect to succumb without much concern. This year, however, the H1N1 virus (more commonly known as swine flu) pandemic raises the stakes and has changed many people's perceptions of and attitudes towards common cold and flu symptoms. You have only to witness the hostile stares that a hitherto innocent sneeze attracts to understand the widespread concern that the H1N1 virus has provoked. But are we actually changing our behaviour as a result? Encouraging the public to take up specific hygiene-related behaviours has proved useful in containing previous outbreaks of infectious disease but the adoption of such behaviours can be difficult.

The WHO's recommendations for protecting ourselves from the H1N1 virus are essentially behavioural, and include:

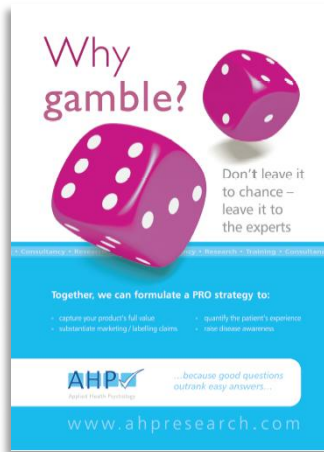
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ISPOR 12TH ANNUAL EUROPEAN CONGRESS

Health Care Decision Making in Europe: From Patients to Populations

24-27 October 2009

Le Palais des Congrès de Paris, Paris, France



The gamble often associated with outcomes research can be minimised by working with experienced health psychologists to formulate a patient-reported outcomes (PRO) strategy early in the development of a new treatment. In this way, potential PRO-related claims can be identified early and steps taken to maximise the likelihood of:

- 1) demonstrating treatment benefits that matter to patients
- 2) related claims being approved by regulatory bodies

At this year's ISPOR conference, we challenge those who are taking chances with their PRO strategies: **why gamble?**

AHP Research will be exhibiting once again at this month's ISPOR Europe Congress in Paris. We very much hope to meet you at our booth (#44). As well as the opportunity to meet our team and discuss your PRO research / strategic needs, we invite you to

collect complimentary copies of our latest scientific papers and try your luck at our roulette wheel (back by popular demand!). A fabulous prize awaits one lucky winner.

Outcomes research highlights at ISPOR Europe 2009

Sunday 25 Oct

15:15 - 16:15 W5: Symptom assessment in clinical trials – bridging the gap between EMEA and FDA

16:30 - 17:30 W11: Assessing treatment satisfaction during a product's lifecycle to facilitate market access: definitions, frameworks and measurement

Tuesday 27 Oct

08:30 - 09:30 W16: Assessing patient adherence for a positive change in health behavior

08:30 - 09:30 W17: Electronic capture of PROs - ePROs – status today and tomorrow?

In the News

▪ [The benefits of exercising for older adults](#)

Older adults who maintain or begin any type of physical activity appear to live longer and have a lower risk of disability. In the article, reported in the September issue of *Archives of Internal Medicine*, the authors emphasise that physical activity is a modifiable behaviour associated with health, good functional status and longevity and that encouraging a physically active lifestyle has become an "accepted public health goal". However, most published studies have focused on the benefits for younger or middle-aged adults. This longitudinal study included 1,861 adults born between 1920 and 1921 and monitored them at the ages of 70, 78 and 85. When compared with those who were sedentary (less than 4 hours of exercise per week), those who were physically active were more likely to remain

independent and experienced fewer declines in their ability to perform daily tasks and were less lonely.

▪ [Depression 'cuts cancer survival'](#)

Depression can damage a cancer patient's chances of survival. A review (published in *Cancer*) of 26 separate studies including 9,417 patients found death rates were up to 25% higher in patients showing depressive symptoms. In those diagnosed with minor or major depression, death rates were up to 39% higher. Increased risks remained even after other clinical characteristics that might affect survival were taken into consideration – though the researchers indicated that it was difficult to rule out the impact of other factors. They also indicated that the overall increased risk of dying from cancer due to depression was so small that patients should not feel that they have to maintain a positive attitude to beat the disease.



In the Journals

Developing a culturally tailored workbook for black patients with hypertension

1

The aim of the study was to apply qualitative methods in developing a culture-specific, educational workbook for black patients with high blood pressure.

2

The workbook was developed using qualitative data from interviews with 60 black primary care patients with hypertension.

3

From these analyses, themes describing patients' cultural beliefs about hypertension were derived and used to develop the workbook.

4

"Living with Hypertension: Taking Control", is a 37-page illustrated workbook with 11 chapters based on patients' perceptions. It focuses on strengthening participants' ability to take control and manage hypertension and on providing knowledge and health behavior techniques.

5

Results of the preliminary evaluation suggest that the workbook is acceptable and useful to its intended audience.

6

Qualitative methods were used to inform the design of a workbook, which may offer a practical and effective means of educating patients about blood pressure control in primary care settings.

Boutin-Foster C et al (2009). Applying qualitative methods in developing a culturally tailored workbook for black patients with hypertension. *Patient Education & Counselling*, 77(1); 144-147.

The H1N1 virus: a catalyst for behaviour change?

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- avoiding touching your mouth and nose
- cleaning hands thoroughly with soap and water (or cleansing with alcohol gels)
- avoiding close contact with people who might be ill

However, less than two weeks after the outbreak was given pandemic alert status by the WHO and in the face of an intense media and government campaign, public responses to swine flu were largely unaffected¹. Anxiety was low (approx 25%) and behaviour changes were limited, with most people reporting that they had not changed the frequency of their hand washing or of cleaning / disinfecting surfaces.

In the past week alone, there have been 14,000 cases in the UK (up 9,000 on last week)² – so, will an increase in the public's perceived susceptibility to swine flu prompt any changes in behaviour? Previous studies have shown that the public rarely panics in the face of a new health threat, so the more pressing concern for government and health agencies is to convince the public not only that the threat is real but also that there are effective and practical steps that they can take to reduce their risks.

References

- 1 Rubin GJ et al (2009) Public perceptions, anxiety, and behaviour change in relation to the swine flu outbreak: cross sectional telephone survey. *BMJ* 2009;339:b2651
- 2 <http://news.bbc.co.uk/1/hi/health/8285716.stm>

Making the headlines

- [GPs 'struggle with child obesity'](#)
- [We need to cut sodium consumption](#)
- [Genes blamed for 'early first sex'](#)
- [Bed sharing 'bad for your health'](#)
- [Children are 'exercising less'](#)
- [Overweight middle-aged women cut chances of enjoying healthy old age](#)

Systematic reviews: what are they and what do they entail?

In last month's *Good Questions*, we discussed the need for systematic reviews to support the choice of PRO instruments used in clinical trials. This month, we offer a brief overview of the methods involved in conducting a systematic review (see Fig 1).

A systematic review differs from other reviews (e.g. comprehensive, strategic or expert) insofar as they use explicit methods to locate primary studies and explicit criteria to assess their quality. Data are extracted from each included study and compared systematically in tabular format.

Following identification of a research question, the researchers need to develop a review protocol. The purpose of this document is to set out, in advance, the methods to be used in the review with the aim of minimising any biases that could be introduced by the researchers. The introduction needs to communicate the key contextual and conceptual factors relevant to the review question and provide justification for the review. It details the study inclusion and exclusion criteria using relevant elements of the PICOS strategy (e.g. population, intervention, comparators, outcomes, study design). The protocol also specifies the methods to be used for data extraction, quality assessment, synthesis of results and dissemination of review findings. The practical work begins with locating all appropriate studies for inclusion:

- Searching electronic databases
- Scanning reference lists of included papers
- Hand searching key journals / conference proceedings

- Identifying 'grey' literature and searching relevant internet resources

Abstracts / full papers are screened as required and a definitive list of studies for inclusion is generated. Following retrieval of included papers, data extraction and study synthesis begins. It is important that all aspects of a systematic review are conducted by at least two researchers (or by one with a quality assurance check by another) to minimise bias. The quality of studies is critically appraised and conclusions drawn based on this critique and pooling of data.

At AHP Research, we specialise in conducting systematic reviews relating to patient-reported outcomes (PROs) and offer in-house training courses for our clients. For further information, please [contact us](#).



Fig 1. Stages of a systematic review



Forthcoming events

24-27 Oct 2009

ISPOR 12th Annual European Congress
Paris, France

28-31 Oct 2009

ISOQoL 16th Annual Conference
New Orleans, USA

14-15 December 2009

UKSBM (UK Society for Behavioural Medicine) 5th Annual Meeting
Southampton, UK

7-10 April 2010

Society for Behavioural Medicine
Seattle, USA

Health Awareness - dates for your diary

- Lupus Awareness Month
- Breast Cancer Awareness Month
- PINS Awareness Week: 5-11 October
- Baby Loss Awareness Week: 9-15 October
- Global Handwashing Day: 15 October
- World Osteoporosis Day: 20 October

