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15TH ISOP ANNUAL MEETING
27–30 OCTOBER 2015
CUBISM
IN PHARMACOVIGILANCE

Session type	**Abstract submission**
Topic	**Benefit / Burden of pharmacovigilance (Pharmacoeconomics and Pharmacovigilance)**
Presentation preference	**Oral - invited**
Abstract title	**Talking about harm and benefit information – the challenges in healthcare practice**

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Abstract text

Effective pharmacovigilance increasingly depends on patients playing their part, but the 'dialogue' is impeded because of patients' lack of knowledge of drug development and safety measures. However, the main barrier is the language we use, which is not the language of the man or woman in the street. Even many grass roots health professionals struggle to describe what 'pharmacovigilance' means – it is meaningless to patients. What words would they understand to describe the process?

Equally we talk about benefit/risk, whereas what we mean is the chance of benefit and the risk of harm. Pharmacovigilance should allow the patient and prescriber to understand the benefit/harm balance for a medicine and decide if it is right for them – but we currently only given them numerical information about the risk of harm ('affects less than 1 in 10 people') – and nothing about the chance of benefit. This means a truly informed decision is not possible. So, how can we best describe numerically the chance of benefit, and where can we source that information?

User testing of patient information leaflets is helping to make such leaflets fit-for-purpose, but wordings imposed by regulators are not tested. The wording associated with the Black Triangle initiative is a case in point: 'Warning – this medicine is subject to additional monitoring' means something quite different to some lay people – they think it means that **they** will have more tests or checks (monitoring) if they take the medicine. Equally the wordings recommended by PRAC appear less than ideal, and are un-tested.

Finally, Risk Management Plan summaries are designed to inform lay people about how the plans for safe use of medicines have been developed and put into practice. But what does user testing of RMP Summaries show? Are they fit for purpose?

This presentation will draw on academic research from the University of Leeds on describing benefit and harm information for patients, along with practical examples from user testing in practice by Luto Research, a spin out company of the University.