Name: Jacqueline Sneddon
Job title: Principal Pharmacist
Organisation / Institution: Evidence Directorate, Healthcare Improvement Scotland
Is this input submitted as an organisational or individual response? Organisational
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1. The overarching aim of the workstream is to better understand how society uses evidence to judge the risks and benefits of medicinal products. In your view, what are the key factors underpinning this process that the Academy should consider?

Use of evidence from research papers, Health Technology Appraisals and safety reports such as MHRA which are often translated into commonly accessed public media sometimes not recognising the significance of reported data and the conclusions which can be drawn from it. Translation of scientific content for the public by the authors can be helpful in ensuring that the true risks and benefits are reflected. The use of social media such as blogs can often over publicise the risks of medicines as contributors often have a point
to prove due to their own negative experience.

2. When evaluating the risks and benefits of medicinal products, what are the strengths of evidence that originates from different sources?

Our methodologies are based on the hierarchy of evidence/levels of evidence, see: http://www.cebm.net/wpcontent/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf Well conducted RCTs and systematic reviews/meta-analyses of RCTs should have taken steps to minimise bias and confounding and as such correlate with a higher strength of evidence and be applied to decision making with a higher degree of confidence. However assessment of the quality and applicability of the evidence in relation to effectiveness and efficacy is key to establishing the strength of a body of evidence. Consideration to observational studies, case series/reports (considered to be lower level evidence), adverse event reporting systems and expert opinion are also relevant to this decision making particularly in relation to harms. However it is a challenge to combine information from such disparate sources (eg clinical experts and clinical trials) in a meaningful way. We also have experience of using more holistic views about medicines through work with patient groups which has proved beneficial in capturing information not included within the scientific literature.

3. When evaluating the risks and benefits of medicinal products, what are the limitations of evidence that originates from different sources?

Limitations of higher level evidence centre on the rigidity of design and strict inclusion/exclusion criteria potentially leading to results that are not generalisable. Bias in these designs can be increased due to issues with sample size leading to inability to adequately assess safety outcomes and failure to build in specific aspects of trial design such as failure to conceal allocation, loss to follow up , lack of the intention to treat principle and selective reporting of outcomes.

Observational studies which provide different perspectives on outcomes associated with an intervention in a more representative population would be more appropriate when attempting to evaluate risk and benefit but these also have limitations including length of follow up and confounding in cohort studies and recall and survivor bias in case control studies. Evidence from the scientific literature is generally published data and will miss unpublished data from trials which may obscure some of the negative aspects of medicines particularly in the development phase. Evidence from softer sources such as patient groups may be overly emotive due to their closeness to the situation of medicine use.

5. Please highlight any broadly applicable principles that should govern the presentation, interpretation and weighting of evidence about medicinal products.

It is essential that those presenting, interpreting and weighting the evidence are skilled in critical appraisal to ensure a true picture of the evidence is conveyed. Interpretation of clinical trials is often complex so knowledge of the clinical context is also important to understand the background information. We have been leading on working package 3 of the European Union DECIDE project which is looking at this question. We have focused on patients and the public and also to a small extent the media and have made a number of changes to the way in which evidence is presented to patients and the public in clinical guidelines. Further information is available on the project website http://www.decide-collaboration.eu/ other partners have looked at clinicians and policy makers. A number of further findings from this research should be published later in 2015.

6. Concerns have been raised about how industry funding impacts on the validity, or the perception of validity, of evidence. For example, the ability of academic researchers funded by industry to remain impartial when evaluating evidence has come into question. How should conflicts of interest be addressed? How important is industry funding in generating and analysing evidence? Other than industry sponsorship, what are other potential sources of conflicts of interest?

Transparency is key to ensuring that readers of research reports etc are aware of any conflicts. It is also important that industry makes all results available as unpublished data may be important in evaluating the strength of published data. It is inevitable that some researchers working within clinical areas will have conflicts but there are also clinicians who are against industry collaboration and can give a more balanced view.

7. Please outline any past, current or planned initiatives to examine how patients, citizens and healthcare professionals (and those who seek to inform them) evaluate scientific evidence about medicinal products.

Within our organisation we have several years experience of working with patients and the public in evaluating both medicines and non-medical technologies. We have established processes for Patient Groups to participate in health technology appraisals and our meetings where decisions about use of medicines are held in public. We have been involved in the DECIDE project as listed in the answer to question 5. In addition we have been heavily involved in the revision of the Guidelines International Network (G-I-N) Public Toolkit which aims to involve patients and the public in the development of clinical practice guidelines. More details at http://www.g-in.net/working-groups/gin-public/toolkit a major revision is planned to be launched in October

2015. In addition we carried out a systematic literature review as part of DECIDE which looks at this area in the wider research literature. Kirstine Loudon, Nancy Santesso, Margaret Callaghan, Judith Thornton, J Harbour, Karen Graham, Robin Harbour, Ilkka Kunnamo, Helena Liira, Emma McFarlane, Karen Ritchie, Shaun Treweek. "Patient and public attitudes to and awareness of clinical practice guidelines: a systematic review with thematic and narrative syntheses" BMC Health Services Research, published 27 July 2014 (doi:10.1186/1472-6963-14-321).

8. What are the most effective ways of communicating evidence to various stakeholders and engaging with them about such evidence?

Different communication methods are required for different audiences. Websites and email subscription e.g. UKMI daily update from NICE are effective for healthcare professionals. Newsletters either electronic or hard copy may be useful for providing less detailed information. Patient information leaflets are useful for specific medicines or groups of medicines. Social media may be useful for some professional and public groups. Kirstine Loudon, Nancy Santesso, Margaret Callaghan, Judith Thornton, J Harbour, Karen Graham, Robin Harbour, Ilkka Kunnamo, Helena Liira, Emma McFarlane, Karen Ritchie, Shaun Treweek. "Patient and public attitudes to and awareness of clinical practice guidelines: a systematic review with thematic and narrative syntheses" BMC Health Services Research, published 27 July 2014 (doi: 10.1186/1472-6963-14-321).