

Minutes of the 9th Meeting of the Strategy and Development Group of the James Lind Alliance, Royal Society of Medicine, 19 June 2007

Participants:

Ms Patricia Atkinson	Administrator, James Lind Alliance Secretariat
Sir Iain Chalmers	Editor, James Lind Library
Mrs Sally Crowe	Director, Crowe Associates
Mr Lester Firkins	Business consultant, Medical Research Council
Ms Jenny Hirst	Trustee, Insulin Dependent Diabetes Trust
Mr Nick Partridge	Chair, INVOLVE
Dr John Scadding	Dean, Royal Society of Medicine
Dr Chris Watkins	Board Programme Manager, Medical Research Council
Ms Philippa Yeeles	Programme Manager, UK Clinical Research Collaboration
Ms Pamela Young	Senior Programme Manager, National Coordinating Centre for Health Technology Assessment

Apologies:

Prof Glyn Elwyn	Chair, Primary Care, Cardiff University
Prof Stephen Holgate	Physician, Southampton General Hospital
Dr Marcia Kelson	Director, Patient involvement Unit for NICE
Dr Marianne Miles	Patient/Public Liaison Lead, UK Clinical Research Network
Dr Sandy Oliver	Editor, Cochrane Consumers & Communication Review Group
Dr Sophie Petit-Zeman	Head of External Relations, Association of Medical Research Charities
Dr Peter Sneddon	Head of Research Programmes, Department of Health
Dr David Tovey	Editor, Clinical Evidence, BMJ
Prof Charles Warlow	Neurologist, Western General Hospital, Edinburgh
Dr Mark Welfare	Gastroenterologist/Senior Lecturer, Northumbria Healthcare NHS Trust

(Some of the above members were unable to attend due to problems with trains)

1. Welcome from the chair

SC welcomed members to the ninth meeting of the James Lind Alliance (JLA) Strategy and Development Group (SDG). SC said that Tony Harrison has stepped down due to other commitments. She will write to him and thank him for his valuable input.

2. Minutes of 5 February 2007

The minutes of the last meeting were accepted.

Matters arising:

Item 5, JLA Objective 1. SC has replaced IC as a member of the UKCRC Patient and Public Involvement Project Group.

3. Working Partnerships update

Asthma – SC gave an overview of the priority setting workshop report, and said that there were now 10 uncertainties with the appropriate vignettes which are undergoing a final review before presentation to funders. It will be up to the Working Partnerships (WP) to decide how to seek funding for the research needed, it was felt that the JLA needed to provide some ongoing support for these important next steps. IC congratulated the JLA team involved in the process for achieving this outcome.

Action: SC

CW raised the following comments:

- It is important that the questions should be disseminated correctly
- The WP need to be sensitive to the way the uncertainties are presented to particular funders
- A report of the process should be published in a medical journal to inform other researchers
- The process and outcome need to be presented worldwide, not just to the MRC and other NIHR.

SC said that she is currently working on an article for the BMJ with GE, with support from Peter Lapsley, Patient Editor at the BMJ. The article will include the process of the Asthma workshop and DUETs. Members of the WP and others involved in the process will be invited to contribute as co-authors. IC suggested that the authorship of the article should be "The James Lind Alliance Working Partnership in Asthma". When the first draft is complete it will be circulated for comment. The deadline for submission is September.

Action: SC & GE

PYe questioned how this piece of work might relate to the work of the Office for Strategic Coordination of Health Research (OSCHR). OSCHR has been set up in response to a recommendation in the Cooksey Review to create a single, coherent strategy for publicly funded health research in the UK. OSCHR's main function is to act as an oversight body which will develop a single health research strategy working with the Medical Research Council, the National Institute for Health Research and other government funded health research organisations. NP suggested that it would be helpful to seek advice on this from Dr Liam O'Toole, Chief Executive, UK Clinical Research Collaboration and Interim Director of OSCHR.

SC said that the way the data are presented is crucial, and that AUK and BTS should do it together. NP said they would get a bigger 'buy in' if there was agreement between clinicians and patients. SC & LF will be meeting with AUK & BTS to reflect on the WP and prioritisation process and discuss the way forward. PYo said she was pleased to see the report and that DUETs is potentially an important source of topics for the HTA Programme. She will look at the questions most suitable for the HTA Programme when the vignettes are available.

JH said that this process should be commended to patient organisations as one successful method of inclusive priority setting. It was suggested that the member organisations of WPs should publish suitable articles about the process in their newsletters/journals.

Incontinence – LF gave an update on the development of the Incontinence WP and said that it was very encouraging and interesting to compare the process with the first WP. LF said that the awareness day went well, a report is being written up by Jude Frankau and will be circulated when it is ready. There are several individuals/organisations interested in carrying the initiative forward. A letter has been sent requesting them to register their interest in being part of a Steering Group.

Epilepsy – LF informed the group that he will be participating in a teleconference with IC and other interested participants, which has been organised to discuss populating DUETs. This is a DUETs-led initiative and is another way of how a WP could be started. JS will send LF details of an earlier Epilepsy teleconference to add to the epilepsy diary.

Action: JS & LF

Diabetes - JH recently spoke at the UKCRN Diabetes Clinical Studies Advisory Group, which she reported were not yet ready to be involved in considering a JLA WP. Diabetes is a huge topic and a variety of organisations could assist contributing uncertainties for inclusion in DUETs. For the time being, this would be an appropriate vehicle for engagement. The idea of a JLA WP seems too complex at present, but might emerge from the DUETs work. SC said that Martin Lodemore identified several groups that could contribute to DUETS, and that the JLA resource would be better used promoting a diabetes DUETs at this time.

Vitiligo - Hywel Williams, Clinical Lead for the NLH Skin Conditions Library based at the Centre of Evidence Based Dermatology, University of Nottingham, wrote to SC and LF about the Vitiligo Prioritisation Proposal that he is planning to submit to the National Institute for Health Research. He is proposing a programme of research in skin diseases, which would include systematic reviews to identify uncertainties, to prioritise those uncertainties into important and feasible trials, and then to reduce those uncertainties in

further research. The JLA (SC) is a co-applicant in connection with the element of the proposal proposing a WP to prioritise research on the treatment of vitiligo.

4. DUETs – Progress towards DUETs modules

IC gave a report on progress in developing DUETs modules, beginning with a presentation of the National Library for Health (NLH) Specialist Libraries website (www.library.nhs.uk), showing the link to DUETs. The NLH Specialist Libraries would be providing the infrastructure through which DUETs modules would be assembled and maintained. Some NLH Specialist Libraries had already begun soliciting contributions to the collection of questions of uncertainties using the feedback form. IC said that SO and Jenny Gray had derived sub bibliographies from the main JLA bibliography, which had now been published on the DUETs website.

IC said that he would be convening a meeting of research funders, to find out what kinds of standard reports they would like to be able to generate from DUETs. Participants in the Asthma WP process would be invited to contribute to this discussion.

After discussion the following actions were raised:

1. Flag JLA prioritisation process on DUETs website
2. Explore how groupings of similar uncertainties could be displayed
3. Show traffic to DUETs from NLH site

Action: IC

5. JLA Objectives

1. *Explore with the Clinical Research Networks how research priorities are identified*

There was discussion on the draft project specification 'A description of research priority setting (and the presence of patient and public involvement in priority setting), amongst the main clinical research funders in England'. SC said that the JLA has set aside 20k, and that TwoCan Associates have been approached with a view to taking this forward in the autumn.

PYe said the project specification sounded close to work done by Máire O'Donnell and Vikki Entwistle entitled, 'Consumer involvement in decisions about what health-related research is funded' (Health Policy 70 (2004) 281-290), which considers why and how research funders involve consumers in decisions about what health-related research is funded. PYe said that the JLA needs to use what O'Donnell and Entwistle have done to reflect and feed back to the organisations they studied, to find out if things have changed over the 4-5 years since their research was done. IC agreed. SC will contact Máire O'Donnell and Vikki Entwistle to find out what they think of the proposed JLA project specification versus what they did in 2002/3. LF pointed out that replicating the original study is a large piece of work that will take time and resources. What the JLA needs in the short term is a pragmatic approach to help the Alliance understand how priority setting is done by research funders. The specification under discussion is not a research project but an information gathering exercise that could be developed further along the lines of the O'Donnell and Entwistle study in due course.

Action: SC

The following questions/comments were raised from this discussions:

- a) The proposed information gathering exercise would give added value to the JLA prioritising and reporting process
- b) How do we make sure the JLA work gets plugged into the process (that is a question that could be asked)
- c) Have the methods used by the JLA had any impact on their way of thinking?
- d) Inform the organisations that the JLA would like to work with them and needs to understand how they work

The important input/feedback from this discussion will be reflected in the final draft of the project specification ('A description of research priority setting (and the presence of patient and public involvement in priority setting), amongst the main

clinical research funders in England'). The SDG agreed progress of this piece of work as it stands.

Action: SC

2. Collaborate with other organisations in organising two symposia to discuss issues relevant to the JLA's objectives

Joint JLA/Lancet conference: How can clinical trialists serve the needs of clinicians and patients more effectively?, 25 June 2007, RSM. The response to this seminar has been very encouraging (there have been approximately 200 registrations). The event will be reported in the Lancet, BMJ, HSCNews, INVOLVE and RSM News.

Joint JLA/AMRC symposium: Should patients tell researchers what to do? If so how?, 17 September 2007, Wellcome Collection Conference Centre. The preparations for this event are progressing well. All the speakers and the case studies by AUK and OMERACT have been confirmed.

Proposed Seminars for 2008

Joint JLA/AMRC/ Health Coalition Initiative Transparency Seminar (The Health Coalition Initiative is a network of voluntary health organisations and pharmaceutical companies (<http://www.healthcoalitioninitiative.org.uk/>)). NP will contact Richard Tiner, ABPI and Simon Denegri, AMRC (which has produced a transparency guidance report), and will find out more and discuss the proposed seminar. The JLA may need guidance on the scope of the seminar. It was suggested that the UKCRC be involved to assist with this.

Action: NP

'Patient-Reported Outcome Measures versus Patient-Important Outcome Measures' Seminar. SO and Kirstie Haywood at the RCN Institute are currently in discussion about the review of PROMS (Patient Reported Outcome Measures) Tools. OMERACT (outcome measures for rheumatology clinical trials) want PROMS to be more patient-friendly and are involving patients in their development. There is a synergy with the objectives of the JLA and PROMS. SC has asked IC to produce a half page brief to explain the rationale for this seminar. IC will contact Kirstie and SO to inform them of this discussion and invite them to take the lead in exploring the possibility of a meeting on this topic.

Action: SC

3. Explore whether some medical research charities/other funders can extend JLA methods. (via Affiliates or other networks)

Ways of improving/managing the JLA database to promote better communication and engagement is dealt with in objective 7.

4. Conclude the priority setting cycle of the JLA Asthma Working Partnership
Objective met

5. Establish two further JLA Working Partnerships

Objective partly met – There is one more partnership to be decided before the next SDG meeting. This item is dealt with in more depth in item 3 of these minutes.

6. Adopt the lessons learned from the piloted working partnerships and other models

Observation of the Asthma Workshop

The observation report of the Asthma WP workshop prepared by Ruth Stewart, Social Science Research Unit, Institute of Education, University of London, has been completed. A one-page summary of the key feedback points from the report was presented for discussion. The JLA will endeavour in future to implement the changes suggested. SC said she anticipated collaborating with the SSRU in preparing a paper for publication. The full report is currently available on http://www.lindalliance.org/Whats_new.asp.

Overall the JLA has embraced a variety of methods, and now has a more varied, less prescriptive, approach to its objectives. JS said that the initiatives taken by the JLA is promoting its ethos in several ways. He suggested that the JLA should focus on four key principles:

1. Assembling evidence of uncertainties - DUETS
2. The need for parity in numbers of clinician and patient participants, and broad stakeholder involvement
3. Comprehensive documentation of the work involved, so that lessons are learned and shared
4. Evidence of shared research priorities promoted

NP said that there is another manifestation of the impact of the JLA, namely, a sense that 'uncertainties', as a term, is used far more than it was 3 years ago. IC noted that paragraph 14 f in the GMC's booklet 'Good Medical Practice' now stated that doctors must help to address uncertainties about the effects of treatments.

LF said that all of this would be a useful product to present to the JLA's funders. Exposing different ways of promoting patient - and clinician-focussed research is as important as the articles produced, the WP's developed, and the resulting sets of important questions. LF suggests that the JLA work on presenting this as a deliverable for next year.

7. *Review the resources needed to achieve successful partnerships*

JLA systematic review of material in the JLA bibliography

SC said that SO and Jenny Gray are keen to follow up the work of the JLA Bibliography by doing a systematic review of all the papers. The estimated cost is £53,000. SC will ask SO to produce a paper describing the proposed work for discussion with potential sources of funding.

Action: SC

Review of JLA Web-based Affiliates database

Relationship management of Affiliates and contributors to JLA using CHROME CRM a web-based database. PA said that the CHROME package had been purchased, and that it was now in the early implementation stage. It was scheduled to be live within the next 6 weeks. The system will initially be used by the MIG but access would be available to all the SDG if required.

8. *Secured funding to support the continued development of the JLA from 2007 to 2010*

Metrics for Business Plan for 2007-2008

LF gave an overview of the metrics document, which records the deliverables/outcomes of the JLA work. It was suggested that the document could have electronic links to all related reports. CW said the document brings clarity to what the JLA wants to achieve, and that he liked it.

6. JLA Objectives for 2008-2009

The JLA MIG will work on a draft of objectives for the next year and circulate to the SDG for comment via email.

Action: MIG

7. Summing up

SC thanked everyone for coming, and said that the feedback was extremely helpful. She suggested that the key actions are:

1. Establishing methods for presenting DUETs data in ways helpful to research funders
2. Incorporate the learning from the Asthma Observation work into the JLA guidance and modus operandi
3. Reviewing the models of WPs. It is probably sensible to work up disease-specific DUETs before embarking on Working Partnerships (unless they are funded)
4. Progress a 3rd seminar planned for Spring 2008, either Patient-Reported Outcome Measures v Patient-Important Outcome Measures, or Transparency in Funding

Research

5. Review the marketing and promotional JLA materials as so much has changed!

Future meetings

- **27 September 2007, 1pm – 4pm**
- **Jan and May 2008 – PA to investigate dates**