

Minutes of the 15th Meeting of the Strategy and Development Group of the James Lind Alliance, Friends House, London, 5 May 2009

Participants:

Miss Lizzie Amis	Project Manager, Patient and Public Involvement Programme, NICE
Ms Patricia Atkinson	Administrator, James Lind Alliance Secretariat
Sir Iain Chalmers	Editor, James Lind Library
Ms Katherine Cowan	Independent Consultant
Mrs Sally Crowe	Director, Crowe Associates
Mr Lester Firkins	Business Consultant, Medical Research Council
Ms Jenny Hirst	Trustee, Insulin Dependent Diabetes Trust
Dr Susan Kerrison	Assistant Director Research and Development University College London Hospitals Trust
Prof Sandy Oliver	Editor, Cochrane Consumers & Communication Review Group
Sir Nick Partridge	Chair, INVOLVE
Ms Kay Pattison	NIHR National Programme Manager, Research and Development, Department of Health
Dr Sophie Petit-Zeman	Head of External Relations, Association of Medical Research Charities
Dr Morven Roberts	Acting Board Programme Manager HSPHRB, Clinical Trials Manager, Medical Research Council
Mrs Jenny Versnel	Executive Director of Research and Policy, Asthma UK
Ms Pamela Young	Specialist Programme Manager, NIHR HTA programme

Apologies:

Dr Brian Buckley	Primary Care Researcher, Cochrane Fellow and Chairman of Bladder and Bowel Foundation (formerly Incontact and the Continence Foundation)
Prof Glyn Elwyn	Chair, Primary Care, Cardiff University
Prof Stephen Holgate	Physician, Southampton General Hospital
Dr John Scadding	Emeritus Dean, Royal Society of Medicine
Mr Roger Steel	Patient & Public Involvement Manager, NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC)
Dr David Tovey	Editor in Chief, The Cochrane Library
Ms Philippa Yeeles	Programme Manager, UK Clinical Research Collaboration

1. Welcome from the chair

LF welcomed everyone to the 15th meeting of the James Lind Alliance (JLA) Strategy and Development Group (SDG). Roger Steel, will step down and be replaced by Derek Stewart, Associate Director for PPI at the Clinical Research Network Coordinating Centre.

2. Minutes of 23 January 2009 and matters arising

The minutes of the last meeting were accepted.

Item 3, Page 3 – LF asked SPZ if she had been able to write to the Wellcome Trust to find out how serious its commitment is to PPI. SPZ reported that at a recent AMRC Away Day David Lynn (Wellcome Trust Head of Policy, on AMRC board) had reiterated Wellcome Trust's decision not to involve patients in setting basic research agenda, but their commitment to such involvement, in principle, for clinical research. SPZ suggested writing to John Williams, Head of Clinical Activities at the Wellcome Trust, in part in light of the schizophrenia and epilepsy Priority Setting Partnerships (PSPs), to see whether he might join SDG. SPZ to make initial enquiry of John Williams.

Action: SPZ

LF thanked all the contributors to the April Affiliates Newsletter, predominantly KC as Editor, for an important document.

LF said that, as suggested by SH, he had written last October to Sir Alex Markham, Office for Strategic Coordination of Health Research (OSCHR), to draw his attention to findings

in the review of research on patient input to the clinical research agenda which had been commissioned by JLA and conducted by Ruth Stewart and SO. Following this letter, LF has been invited to meet two of the OSCHR boards PPI members, Dr Jon Sussex, Office of Health Economics and Dr Jim Elliot, Macmillan, to discuss these issues. LF and SO will meet with them on the 11 June.

3. Introduction

LF said that this meeting would examine the JLA Business plan in detail, in conjunction with the business tracker (notes and ideas from the last SDG have been included). Under the aegis of the James Lind Initiative, the JLA will be applying for further funding for 2010 - 2013. LF has proposed that his previously separate contract with the MRC be included in the JLA sub-budget from 1 April 2010. The budget requested would be predominantly for consultancy.

Business Tracker – Desired Outcome, Activity and Progress

1. Increased evidence of patients and clinicians working together to collect and prioritise treatment uncertainties. (a. Maintain portfolio of a minimum of 4 active priority setting partnerships)

Urinary Incontinence – LF said that a list of 10 prioritised uncertainties has been produced but the partnership is still awaiting publication of these before making the uncertainties more widely available. Several 'in-house' journals are interested in publishing the top 10. DUETs will be populated with all the uncertainties within the next 2 months. The top 10 list has been sent to PY, for consideration by the HTA Programme.

PY said that most of the top 10 would fall within the scope of the HTA Programme. IC thanked PY and her colleagues for the HTA Programme's long standing support of the JLA, most recently in a positive piece about the JLA in the NIHR HTA Programme 2008 Annual Report.

Type 1 Diabetes – SC said the plans for the exploratory workshop on 4 June are going well. There will be a good mix of patients, clinicians, and parents of children with type 1 diabetes in attendance. The objective of the day will be to generate some treatment uncertainties in type 1 diabetes and agree some shared objectives for priority setting. The outcome of the meeting is uncertain, the JLA team will aim to achieve agreement on the need to publish treatment uncertainties in DUETS. There will be a report of the day's proceedings.

Schizophrenia – KC said that DUETs is populated with uncertainties as identified by the researchers in Wales, funded by the Welsh Office for Research and Development (WORD). The next step is prioritisation. There is enthusiasm for this, but practical commitment has been harder to pin down. KC will be meeting with Rethink (a national mental health membership charity), and the original group from Wales in August, to discuss identifying additional uncertainties and how to move forward to shared prioritisation.

Epilepsy – KC said that the project is not JLA-managed as the epilepsy group has taken the project forward themselves, using JLA methods. The group has taken uncertainties from the Patient View epilepsy survey, which was commissioned by the JLA, and the uncertainties as identified by the research funded by WORD. IC said the latter had used focus groups to look at the uncertainties, but clinicians and patients had identified priorities separately. There are plans to input all of these uncertainties into DUETs. KC has requested that the JLA acts as an observer and receives a copy of the methods paper when written up. The Wales group is currently drafting a paper for submission to *Practical Neurology*.

Prostate Cancer – LF said the JLA PSP for prostate cancer is well underway. After initial contact from Vivienne Parry, Prostate Cancer Charter for Action, the following two people have taken the lead: Emma Halls, Chief Exec, Prostate Cancer Research Foundation (PCRF), and Sandy Tyndale-Biscoe, Chair, Prostate Cancer Support Foundation. An

awareness meeting has been scheduled for 10 June. Invitations have gone to 90 potential clinician and patient groups and there is a BMJ article in draft. The JLA will fund part of the first meeting and the PCRF will fund the rest, including input of data to DUETS. They have funders who are interested in the outcome. There will be minimal impact on the infrastructure of the JLA.

SC noted that there will potentially be a large number of participants in the prostate cancer PSP, Glyn Elwyn (GE) has suggested the JLA consider other methods for priorities voting such as adapted on-line Delphi, or using venues that have electronic voting equipment. SC will liaise with GE. LF said he would welcome any further thoughts and suggestions on this area of the Priority Setting Process.

KP said the NIHR had a lot of current activity that could feed into the prostate cancer PSP. PY will be invited to observe and act as advisor to the priority setting process. IC said the JLA must engage and involve the Cancer Specialist Collection, NHS Evidence team. LF will make contact with Dr Chris Alcock, the clinical lead for this team.

Action: LF

Vitiligo – SC is the chair of the steering group for SPRUSD (Setting Priorities and Reducing Uncertainties for people with Skin Disease) - a fully funded project co-ordinated by the Centre for Evidence Based Dermatology in Nottingham (includes eczema). They have approached this from a research perspective and SC said the challenge is to ensure the right balance of patient and clinician input. The systematic review is almost complete and the vitiligo PSP plans to harvest and assemble the uncertainties in DUETS by Sept/Oct 2009 – planned completion early 2010. The NIHR, Cochrane Skin Group and NHS Evidence Specialist Collection are also involved.

Eczema – SC said the eczema part of the SPRUSD project expects to start their PSP process early in 2010, following completion of their systematic review.

Stroke - Following a JLA presentation at a Cochrane conference in Edinburgh last March, Dr Alex Pollock, Research Fellow, Stroke Programme, Nursing, Midwifery and Allied Health Professionals Research, contacted LF to say that they would like to invite a member of the JLA to discuss the advisory steering group of DORIS (Database of research in stroke). LF will attend a meeting at the Stroke Unit in Glasgow on the 24 June to discuss possible future collaboration and how to work together to identify consumer priorities for stroke research.

Other possible PSPs

SC said the JLA has been invited by Ian Needleman, Professor of Restorative Dentistry and Evidence-Based Healthcare, UCL Eastman Dental Institute, to join their Steering Group on patient impacts of treatments for **gum disease**. Due to current commitments and limited resources, the JLA is unable to accept the invitation but has offered to look at, and comment on their research plan, and send a letter of support for their proposal, Ian Needleman was pleased to accept this offer.

SC said that the JLA had also been approached by Lelia Duley, Professor of Obstetric Epidemiology, University of Leeds, inviting the JLA and DUETs to collaborate in a bid to seek funding to create a DUETs module of uncertainties in **Hypertension in Pregnancy**. Lelia is currently collating uncertainties from systematic reviews. Her initial proposal for funding from the research for patient benefit programme was declined and she is actively seeking funding elsewhere.

2. Scoping and evidence collection of the impact that JLA PSPs make in the field of patient and clinician preference funded research

LF said there is more to be done to embed the JLA process, and part of that will be to support PSPs move on from the list-preparation stage to actual funding changes. He said he had expected the partnerships to have their own drive to ensure that this occurred, but as this is new ground, perhaps it is fair to use JLA skill and contacts to guide the stages.

There is a need to review and measure more precisely if and where funding changes are occurring.

a. Prepare a process flow for “What happens after the priority setting meeting”

LF said this would be a simple process with suggestions of how to progress.

b. Explore and develop a set of structures/guidance to support PSPs turn uncertainties into researchable questions, and then research proposals (Note it remains the responsibility of PSP’s to own and undertake this step)

LF said the aim would be to get the top 10 from DUETs into a format that makes it easier for potential funders to consider - Possibly allow “fast track” access based on needs of advertised needs funders/commissioners. IC said that this works with the HTA Programme.

KP said that the cost and method would be an important guide for future PSPs. It was agreed that explicit PSP recommendations would be of great value i.e. ‘current systematic review(s) need(s) updating/amending’, ‘systematic review(s) needed’; or new ‘primary research needed’.

JV said that the uncertainties that came forward in the Asthma PSP were very broad. There could be 6 or 7 things within a topic area and the difficulty was how to prioritise, and what to take forward. IC suggested going back to the original question to refine it.

NP asked what should happen if it was concluded that the list was not totally accurate? He suggested the guidebook should indicate that second rounds of priority setting could be considered.

SO said that it occurred to her that some research priorities might be 'cross cutting' rather than precise treatment uncertainties to be addressed with a single study. For instance, where people are concerned about side effects (generally or specifically named side effects), then these should be incorporated into any relevant trials, not just a single trial. However, side effects may not be the most familiar example in terms of implications for research, as addressing side effects within trials is challenging when their frequency is so low that the trials do not have the statistical power to detect them. Observational studies with cohort or case-control designs are more appropriate - so side effects identified as a priority should guide systematic reviews of these sorts of studies. This has implications for deciding whether a side effect uncertainty is a known uncertainty or not - are reviews of observational studies sought to check this?

Alternatively, there may be treatment outcomes that are a priority and may be applicable to many interventions and so could be incorporated into many trials, not just a single trial mounted for that particular purpose. Where this is the case, the cost of addressing an uncertainty might be the marginal cost of data collection for a particular outcome, not the cost of mounting a whole trial.

LF said if anyone else has any other practical thoughts to send them to him.

c. Develop a plan to support and track those uncertainties considered as priorities by a concluded PSP – towards research

LF said this is essentially for benefit of the JLA – to encourage PSPs to maintain communication with the JLA, so that monitoring of progress can be maintained. KP agreed that this was very important.

d. Gain agreement/understanding with key commissioners of what they seek as best practice from JLA/PSP members in the ultimate delivery of potential research questions/proposals

LF said this would be needed to support earlier guidance. It was suggested that a small working group could be set up to see how this could be done, ideally chaired by a research commissioner.

e. Survey and follow changes that should be occurring within clinical research

projects with regard to active and meaningful patient/clinician involvement in priority setting.

LF said this was an important and potentially large piece of work which would look at where we are, identify what's changed, keep in contact with key players, and reinforce the JLA message. This would be done as an annual survey of leading research funders. LF said this is very early thinking and how this would be managed would need more detailed consideration. It would be unlikely that planning on this could be started before January 2010

3. Produce an evidence-based Guidebook and Protocol in order that groups can work through a PSP – with or without JLA involvement.

KC said that she had made progress on the on-line resource. It would be a 'how to' guide and easy to update – users would be able to go into different sections/modules, depending on their needs and their stage of priority setting. The intention is that it would be widely applicable. A 'Critical Friends Group' (CFG) has been recruited to look at and provide input to the proposed structure and development of the content. This will be a live document that will be changed as needed. SO will be working on the evidence base of the guide book, using JLA and other existing evidence and case studies as examples.

IC said that more clinical involvement is needed and suggested Mark Welfare or Martin Burton to balance out the membership of the CFG group. KC will approach the suggested clinicians.

Action: KC

KC is also working on a protocol which would act as a contract, setting out what is expected of partners and of the JLA in terms of roles, resources and responsibilities.

4. Understand and publish the appropriateness of different PPI models for different purposes

SC made a presentation that included the following:

Nature of condition: Chronic and long term conditions; Acute and short term conditions; Rare and orphan diseases; Primary care – 'symptoms' approach; Public Health and Alternative and complementary.

Funding models: Fully funded – e.g. Research for Patient Benefit; Part funded - from partner organisations, JLA, other sources; Non funded - 'goodwill'.

Nature of partnerships: Small partnerships - 2 organisations; Stakeholder groups – Single disease perspective, Co-morbidity perspective; Adult/children; Research projects.

Methods: 1. Voting (by post/email/telecon/face to face); 2. Final step discussion and voting – face to face; Virtual? = taking voted shortlist to face-to-face discussion; What JLA needs is process(es) = reproducible, reliable, robust, and transparent.

SC said using a virtual voting method would take it out to a much wider stakeholder group, and that there are challenges in managing large groups. There are different ways of looking at this and she would liaise with groups highlighted in the work done by SO (Bibliography) and the TwoCan project SC welcomes any feedback on this.

SC said there is scope for a possible seminar next year to look at PPI within PSPs drawing on their own experiences. She said there is a proposal to set up a think tank to look at the nature of PPI in clinical research. This is a joint venture with UKCRC, AMRC, INVOLVE and JLA.

The PSP review paper written for the BMJ, co-authored by SPZ, SC and LF, will be submitted to the BMJ by end of May.

5. Ensure that JLA is understood by key related players within the UK research community – to maximise benefits to core funders

SC is creating a map of funders which will show how they differ – so that the JLA MIG can

work out how best to interact with each of these groups.

6. Enhance the ultimate commissioning/funding of prioritised research by understanding the perceived barriers to PPI Involvement by "industry"

SPZ said that a joint AMRC/JLA event will be held to look at the sensitivity of working with industry with the working title 'Does industry listen to patients, and if so why?' The provisional date for this event is 9 October. SPZ said that National Voices were keen to be involved in this project and it was agreed that they should be invited to be a joint partner. The 'think-tank' will explore the extent to which the research agenda of the pharmaceutical industry is or can be influenced by patients. This will be a half-day event chaired by Simon Denegri and will involve invited guests from across the relevant sectors.

It is hoped that the outcome will be examples of industry working with patients to set/guide research. Such information would hopefully be a step towards embedding patient views in the approaches adopted by industry. SPZ will take into account suggestions made when working up the final plan of the event.

7. JLA activities to develop influence and behaviour change within PPI

- Publication in the leading general journals – probably on process and wider impact
- Publication in appropriate disease-specific journals
- Place articles in charity newsletters
- Present at conferences
- Website management and activity
- Networking

4. Summary of day

LF said that this had been a very helpful discussion and he thanked everyone for coming.

5. Future meetings:

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