



The James Lind Alliance

"Tackling treatment uncertainties together"

www.lindalliance.org

Annual Report

April 2010 – March 2011

Summary of key achievements

- During 2010-2011, the James Lind Alliance (JLA) completed three Priority Setting Partnerships (PSPs), establishing a top 10 list of patients', carers' and clinicians' shared priorities for research in vitiligo, prostate cancer and schizophrenia. A further 11 PSPs are being facilitated, with an additional five in the early stages of discussion.
- The JLA launched its Guidebook (www.JLAguidebook.org), a practical evidence-based guide to setting up PSPs. Not only is this an essential resource for all PSPs, it has also drawn international attention to the work of the JLA.
- The JLA's profile has continued to grow. There were over 84,000 visits to the JLA website and the JLA Guidebook during the year. A re-launch of the Affiliate programme and application process saw Affiliate members increase by 74 per cent, bringing the total to 329.
- The JLA published two research reports: one exploring what happened after the completion of the Asthma PSP; and another to study patients' and clinicians' research priorities. Two event reports were also published, describing the outcomes of an event looking at industry's attitude to patient involvement, and an event exploring the opportunities to progress patient involvement in research prioritisation and commissioning.

Annual report

This review sets out the activities and progress of the James Lind Alliance (JLA) from April 2010 to March 2011. It should be read in conjunction with the JLA Performance Tracker 2010-2011 (Annexe 1).

1. Background and context

- 1.1. A non-profit UK-based initiative, the JLA is part of the James Lind Initiative, and is funded by the National Institute for Health Research (NIHR).
- 1.2. The aim of the JLA is to bring patients and clinicians together to identify and prioritise treatment uncertainties for research. The JLA does this in three main ways, which are covered by this annual report:
 - Facilitating Priority Setting Partnerships (section 3)
 - Commissioning research (section 4)
 - Awareness raising (section 5)
- 1.3. The JLA is funded by the NIHR until 31st March 2013.

2. Resource and capacity

- 2.1. The JLA is led at a strategic level by the Strategy and Development Group (SDG), which is chaired by Lester Firkins. This meets three times per year. Minutes of those meetings are made publicly available on the JLA website at www.lindalliance.org/Internal_Meetings.asp. A list of current members is at Annexe 2.
- 2.2. The JLA is managed through the Monitoring and Implementation Group (MIG), chaired by Sally Crowe. This meets monthly, by teleconference and in person, alternately. A list of current members is at Annexe 3.
- 2.3. The JLA Secretariat is administered by Patricia Atkinson (as part of her JLI-funded role). Sally Crowe, Lester Firkins and Katherine Cowan undertake practical day-to-day activities on a consultancy basis, with further consultancy support from Sophie Petit-Zeman and Sandy Oliver. They are supported by members of the SDG and MIG as required.

3. Facilitating Priority Setting Partnerships (PSPs)

- 3.1. **Skin disease:** with support from NIHR, a project called **Setting Priorities and Uncertainties for People with Skin Disease (SPRUSD)** was established in 2008 at the Centre for Evidence Based Dermatology in Nottingham. SPRUSD has several streams of work, including full funding over five years for two JLA PSPs:
 - 3.1.1. **Vitiligo:** the PSP was completed in March 2010. Since then, the vitiligo team has made various efforts to try to influence the research agenda based on the identified topics. Five research vignettes were submitted to the HTA

prioritisation panel and are now under consideration for funding. News on the results of the HTA prioritisation panel will be available around September 2011. In addition, the pharmaceutical company Clinuvel is currently preparing to run a pilot multi-centre trial on afamelanotide for the treatment of vitiligo, which was the sixth uncertainty in the top 10.

3.1.1.1. An article published in the British Journal of Dermatology which describes the process is at Annexe 4.

3.1.1.2. The Vitiligo PSP top 10 treatment uncertainties are at Annexe 5.

3.1.2. **Eczema:** this PSP commenced in March 2011, and it is anticipated that final priority setting will take place at the end of 2011.

3.2. **Prostate Cancer:** this PSP was established in 2009 in partnership with the Prostate Cancer Research Foundation (now Prostate Action) and the Prostate Cancer Support Federation, supported by the Prostate Cancer Charter for Action. It carried out its interim prioritisation exercise during 2010, and completed its workshop and agreed its priorities for research in October 2010. Work is now underway to promote the top 10 to research funders and influence the prostate cancer research agenda.

3.2.1. The Prostate Cancer PSP top 10 list of treatment uncertainties is at Annexe 5.

3.2.2. An evaluation of the participants' experiences of the priority setting process is at Annexe 6.

3.3. **Schizophrenia:** the Schizophrenia PSP completed its priority setting exercise in January 2011. Steering Group members included the Universities of Swansea and Nottingham, Rethink, Hafal, the Institute of Psychiatry and the Mental Health Research Network's Service Users in Research project. A full-time worker was recruited to coordinate the PSP by the University of Swansea in September 2010. Interim prioritisation took place in November 2010, and the final priority setting workshop took place in January 2011, resulting in a top 10 set of research priorities. The Steering Group agreed a dissemination strategy in February 2011 and work is now underway to promote the findings to a wide audience, including an invited editorial in *Nature*.

3.3.1. The Schizophrenia PSP top 10 treatment uncertainties are at Annexe 5.

3.4. **Type 1 Diabetes:** a Type 1 Diabetes PSP was established following a workshop in June 2009, with funding from the Insulin Dependent Diabetes Trust. The steering group includes representation from the Diabetes Research Network, Diabetes UK, the Insulin Dependent Diabetes Trust, Juvenile Diabetes Research Foundation, NHS Evidence – diabetes, and the Scottish Diabetes Research Network. An online survey to gather treatment uncertainties was launched in March 2010 and a final priority setting meeting will take place in May 2011.

3.5. **Ear, Nose and Throat - Aspects of Balance:** this PSP is led by the British Association of Otorhinolaryngologists (part of ENT-UK). The Steering Group first convened in January 2010 and an initial awareness meeting was held in May 2010. This was followed by a period of harvesting treatment uncertainties, principally online, throughout winter 2010. The final priority setting meeting took place in May 2011.

3.6. **Life after Stroke in Scotland:** this PSP emerged from a project funded by the Scottish Government's National Advisory Committee for Stroke. In June 2009 DORIS (Database of Research in Stroke) asked the JLA to help it identify treatment

uncertainties, evidence gaps and research priorities. Between October 2010 and January 2011 a roadshow was taken to each of the Scottish NHS regions to raise awareness of the project and to collect uncertainties. The process of checking these and developing a long list of true uncertainties is taking place during Spring 2011.

- 3.7. **Pressure Ulcers:** this PSP is led by a collaborative research group based at York University with the Cochrane Wounds Group, as part of a wider wounds-related NIHR Programme Grant. Its initial awareness meeting took place in March 2011, and it is anticipated that a Research Fellow will be appointed to coordinate the PSP in May 2011. A Steering Group is currently being formed.
- 3.8. **Intensive Care:** funded by the Scottish Intensive Care Society, a special event to identify and rank intensive care treatment uncertainties was run jointly in October 2010 by the Edinburgh Critical Care Research Group, the University of Edinburgh and the JLA. The exercise essentially constituted an extremely condensed version of the JLA process. This has resulted in initial discussions within SDG about the feasibility and acceptability of an abbreviated JLA process that enables partners to produce a verified patient and clinician agreed priority list but over a shortened timescale without compromising the JLA process integrity.
- 3.9. **Lyme Disease:** first discussed in October 2010, the Steering Group is still being formed, to ensure adequate clinical representation. This PSP will be fully funded by the charity Lyme Disease Action, with no costs incurred by JLA budgets. An information specialist and survey designer have been recruited. The PSP's initial awareness meeting took place in May 2011, after which treatment uncertainty harvesting and prioritisation will begin.
- 3.10. **Cleft Lip and Palate:** a Steering Group was established in June 2010. Members include representatives of paediatric dentistry and plastic surgery, and patient group, the Cleft Lip & Palate Association. It is anticipated that the Craniofacial Society will part-fund the PSP, and an initial awareness meeting has been scheduled for June 2011.
- 3.11. **Head and Neck Cancer:** a Steering Group was formed in June 2010, supported by ENT UK and the Head & Neck 5000 project. An initial awareness meeting was held in March 2011, and the group is undertaking harvesting of treatment uncertainties during Spring / Summer 2011.
- 3.12. **Pre-term birth:** this PSP is being carried out with funding from the NIHR, as part of a wider research programme. Clinicians and service users will help to identify a 'core set' of outcomes for evaluating care during very pre-term birth and investigate methods for clinicians and service users to work together on prioritising these and other uncertainties in pre-term birth, both face-to-face and at a distance. Peri-natal and neonatal interventions will be included, although prevention will be excluded. The funding has enabled the appointment of a PhD student, based at the Social Science Research Unit at the Institute of Education, University of London, to coordinate the PSP and carry out a comprehensive evaluation of its activities and impacts.
- 3.13. **NICE Guidelines Production:** The JLA and UK Database of Uncertainties about the Effects of Treatments (UK DUETs) team were invited to meet with the National Institute for Health and Clinical Excellence (NICE) Research and Development team to identify opportunities to assist in making the prioritisation of research recommendations more transparent and robust, both during and at the end of a guideline process. Both teams have attended guideline development meetings at

various stages and JLA is awaiting further invitations to take the dialogue forward if deemed appropriate.

- 3.14. **Emergent PSPs:** a number of potential PSPs have been identified and are in the early stages of discussion, or are in the process of applying for grants to fund the required activities. These include the following: Type 2 Diabetes, Infertility in Obese Women, Dementia, Anaesthesia and Perioperative Care, and Depression.

4. Commissioning research

- 4.1. During 2010/11, the JLA's budget was targeted towards supporting PSPs, resulting in fewer research projects being commissioned. However the following reports were produced under the aegis of the JLA.

4.1.1. **Asthma: what happened next?** This paper was published on the JLA website in September 2010, documenting research activity following completion of the asthma treatment uncertainty PSP in 2007. The activity recorded ranges from uncertainties being submitted to commissioning research programmes, to partner organisations' own research and strategy development. The report is at Annexe 7.

4.1.2. **Patients' and clinicians' research priorities:** if research addresses the questions of greatest relevance to patients and clinicians, decision-makers will be better equipped to design and deliver health services which meet their needs. To this end, a number of initiatives have engaged patients and clinicians in setting research agendas. This paper aimed to scope the research literature addressing such efforts. A systematic search strategy combined electronic searches of bibliographic databases with hand-searching and contacting key authors. Two researchers, initially working independently, described the relevant reports. Published in *Health Expectations* in December 2010, the study was funded by the JLA. The abstract is at Annexe 8.

5. Awareness raising

- 5.1. The JLA has worked to increase awareness of the importance of acknowledging treatment uncertainties and identifying those regarded as important by patients and clinicians. Activities during 2010/11 are listed below.

5.1.1. Seminar programme:

5.1.1.1. **Does industry listen to patients and if so, why?** The guiding principle for this invitation-only meeting, which took place in October 2009 was: "notwithstanding the tensions that can exist between the two sectors, there is massive potential for mutual benefit if charities and/or patient groups and industry work together." The event thus asked how listening to and working with patients can become a vital part of the business model for the pharmaceutical industry in developing new treatments. The report of the event was published in July 2010 and is at Annexe 9.

- 5.1.1.2. **Building on success – opportunities to progress patient and public involvement in research prioritisation and commissioning:** a conference which took place in February 2010, co-hosted by the JLA, INVOLVE and the Association of Medical Research Charities, with funding from the UK Clinical Research Collaboration. The purpose of this event was to see whether, based on the evidence resulting from this work, agreement could be reached on a number of actions to improve both the processes and impact of patient and public involvement in research prioritisation and commissioning. A report of the event was published in September 2010 and is at Annexe 10.
- 5.1.2. Publications: thirteen publications either on or referencing the JLA have been produced in a range of journals or health research websites (Annexe 11).
- 5.1.3. Presentations: fifteen presentations on the JLA were given during 2010/11 (Annexe 12).
- 5.1.4. Website: during 2010/11, www.lindalliance.org was visited over 50,000 times, a six per cent increase on 2009/10 (which had seen an increase of 21 per cent on the previous year). The final month's total, for March 2011, was 5102 visits – an increase of 27 per cent from the total visits received in April 2010.
- 5.1.5. Affiliate programme: organisations and individuals who identify with the objectives of the JLA and wish to be kept apprised of progress and opportunities can become JLA Affiliates. In September 2010, the JLA re-launched its Affiliate programme with a new simplified application process, both online and on paper (see Annexe 13 for the Word version of the application form). Following the re-launch, membership grew by almost 70 per cent. The Affiliates newsletter continued to grow and attract positive feedback. Production was increased from quarterly to bi-monthly. Editions from April, July, September and November 2010, and from January and March 2011 are at Annexes 14 to 19. As at March 2011, 158 organisations and 171 individuals are Affiliates, an increase of 74 per cent from March 2010 (when the total was 190). (Annexe 20)
- 5.1.6. JLA Guidebook: the JLA Guidebook was launched in May 2010. See Annexe 21 for the press release. Seven articles were produced which made direct reference to the Guidebook (included in previous Annexe 11 - publications). Since its launch, it has received over 30,000 visits, with monthly visits in March 2011 almost double the number in May 2010. The Guidebook was updated, to reflect advances in the JLA methodology and to include new examples of good practice, and re-launched in the Newsletter in March 2011. The downloadable version of the Guidebook is at Annexe 22.

6. Partnership working

6.1. The concept of *partnership* is central to the JLA way of working. This can include collaborative conferences, research, articles and publications, or committee representation.

6.2. Key partners during 2010/11 have been:

- 6.2.1. AMRC, the Association of Medical Research Charities, a membership organisation of the leading medical and health research charities in the UK.

- 6.2.2. The NIHR Health Technology Assessment programme, which produces independent research information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS.
- 6.2.3. The Cochrane Collaboration, the UK Cochrane Centre, which prepare, maintain and disseminate systematic reviews of healthcare interventions
- 6.2.4. INVOLVE, which promotes and supports active public involvement in NHS, public health and social care research.
- 6.2.5. invoNET, a specialist network of researchers, clinicians, patients and carers interested in PPI in research.
- 6.2.6. NIHR CRN CC, the National Institute for Health Research Clinical Research Network Coordinating Centre (formerly UKCRN), which supports clinical research and facilitates the conduct of trials and Topic Specific Research Networks. The JLA works with the Patient and Public Involvement (PPI) network, the *Way Forward* PPI project and individual Clinical Studies Advisory Groups, such as diabetes.
- 6.2.7. NHS Evidence, Specialist collections - Evidence in Health and Social Care, with links being established despite the service being in flux.
- 6.2.8. PatientView, a research and publishing organisation that works with patients and health and social campaigning groups.
- 6.2.9. PenCLAHRC, the Peninsular Collaboration for Leadership in Applied Health Research and Care is an NIHR-funded collaboration of higher education institutions and NHS organisations in the South West of England, focused on delivering high-quality applied health research. It works with patients and clinicians to generate and prioritise of research questions of local importance. The JLA is working with PenCLAHRC to compare methods, share learning and to collaborate in raising awareness of the value of patient and clinician involvement in research priority setting.
- 6.2.10. UK DUETs, the UK Database of Uncertainties about the Effects of Treatments. It is part of NHS Evidence and a crucial part of the priority setting process. Mark Fenton, Editor, UK DUETs, works closely with Information Specialists within each individual PSP to oversee the processing of patients', carers' and clinicians' treatment uncertainties, and the searching of relevant research databases. His role and the partnership between UK DUETs and the JLA are critical components in ensuring that data entering the priority setting process is robustly checked. This is a key element of quality control for any PSP.
- 6.2.11. National Voices, a coalition of more than 200 national health and social care organisations promoting a stronger voice for all those who come into contact with NHS and care services, and the voluntary organisations that help them.
- 6.2.12. The JLA is also represented on a number of committees including the Cochrane Priority Setting Methods Group, the UK Reviews Infrastructure Advisory Board, NIHR CRN CC PPI Way Forward Implementation Steering Group, the Learning and Development Subgroup Meeting for NIHR PPI Way Forward Programme, the UK DUETs Steering Group, the Database of Research in Scotland Advisory Board, the NIHR Dermatology Programme Grant Award Steering Committee, and the NIHR CRN Wider Forum Group.

7. Next steps

- 7.1. The JLA will continue to follow its objectives as agreed with its funders, until March 2013.
- 7.2. A set of Performance Metrics and Tracker for 2011-2012 has been established (Annex 23).
- 7.3. As requested by its funders, the JLA is taking steps to 'mainstream' its methods by the time the current funding period expires. Negotiations are taking place with the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), under the chairmanship and guidance of Dr Kay Pattison, NIHR management. Although models have yet to be agreed, NETSCC would seem to be a logical environment to take forward and develop the methods that JLA has pioneered. Partnership working can be maintained and developed while continuing to support condition-specific PSPs. A proposal for funding has been made by NETSCC and a decision is expected by Autumn 2011. If successful, it is likely that the JLA and NETSCC would work in partnership to March 2013 to ensure a smooth transition to a more mainstreamed model.
- 7.4. During 2011 it is planned that JLA will be working on a defined project for MRC to examine the "potential for broadening input into setting the MRC's research agenda." Headline terms of reference have been agreed and a meeting is scheduled for May 2011 to confirm detail. It is anticipated that Sandy Oliver, Professor of Public Policy at the Institute of Education, will provide much of the academic and research effort under contract to JLA.
- 7.5. The JLA intends to produce its next annual report following the financial year 2011-2012, followed by a final report on the current funding period in early 2013.

Lester Firkins

Chair, Strategy and Development Group

List of annexes

Annexe	Title
1	JLA Performance Tracker 2010-2011
2	Strategy & Development Group Members List
3	Monitoring & Implementation Group Members List
4	Vitiligo PSP article, British Journal of Dermatology
5	JLA PSP top 10s
6	Prostate Cancer PSP evaluation
7	Report: Asthma PSP - what happened next?
8	Report: Patients' and clinicians' research priorities
9	Event report: Does industry listen to patients and if so, why?
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11	JLA Publications List
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