

Report of the James Lind Alliance (JLA) Steering Group on the development of the JLA during 2004/2005

Background

The development of the James Lind Alliance (JLA) reflects a decision taken by the Medical Research Council (MRC) in 2003, set out in the MRC report entitled 'Clinical Trials for Tomorrow'. Having made clear its commitment to "involving patients/consumers in all aspects of the clinical trials it funds", the Council specified four policies intended to promote public engagement in publicly funded clinical trials. The fourth of these was:

"to set up a communications and discussion forum on randomised controlled trials, involving patients, practitioners, researchers and others. The forum will engage with the public and media to explore perceptions of RCTs, provide information about them, and raise their profile."

To support the promotion of this objective, the MRC and the Department of Health appointed Iain Chalmers and Patricia Atkinson to establish a programme of relevant work, which it was agreed should be called the James Lind Initiative (Chalmers 2003). Reports on progress in this programme of work are submitted to and discussed at intervals at a joint MRC/DH Project Group, chaired by Diana Dunstan.

Conceptualisation

After wide consultation during the autumn of 2003, it was decided that the challenge of engaging with the public and media to explore perceptions of randomised clinical trials, provide information about them, and raise their profile, should be approached indirectly. **The strategy adopted was to encourage wider recognition of uncertainties about the effects of treatments**, and consideration of the responsibilities of health professionals when faced with such uncertainties.

There was an encouraging response, from lay and professional people, to a BMJ editorial written to promote discussion about therapeutic uncertainties (Chalmers 2004). It was against this background that representatives of the Royal Society of Medicine (John Scadding), INVOLVE, formerly Consumers in NHS Research (Nick Partridge) and the *James Lind Library* (Iain Chalmers) jointly proposed that an alliance be established to promote partnerships of patients and clinicians to identify and prioritize important uncertainties about the effects of treatments. The proposed Alliance was named after a 18th century Scottish naval surgeon – James Lind - who had confronted uncertainty about how to treat scurvy by conducting a clinical trial comparing six of the alternative treatments, showing that oranges and lemons were effective.

A James Lind Alliance (JLA) Secretariat was established in Oxford under the aegis of the James Lind Initiative, and the Royal Society of Medicine hosted London-based meetings of the JLA co-convenors (and others). During the early summer of 2004, the three co-convenors drafted and consulted others on the texts of an introductory brochure and more detailed documents setting out the proposed objectives and working methods of the JLA. In June 2004, the JLA Secretariat distributed copies of these to over 400 individuals, together with copies the BMJ editorial on therapeutic

uncertainty and a detailed description of the early evolution of the James Lind Alliance published in the March 2004 issue of *Health and Social Campaigners' News* (**Annexe 1**). The following month, James Lind Alliance brochures were distributed with the INVOLVE newsletter to over 3000 individuals and organisations.

Launch

The James Lind Alliance was officially launched at the end of 2004 with a commentary co-authored by the Chair of INVOLVE and the Associate Dean at the Royal Society of Medicine published in *The Lancet* (Partridge and Scadding 2004 **Annexe 2**), and with several presentations made by patients and clinicians at the James Lind Alliance session at the annual Clinical Excellence (NICE) meeting in Birmingham (Arnold 2005; Jobling 2005; Oliver 2005; Thornton 2005 **Annexe 3**).

The principal aims of the Alliance are:

- **To draw attention to the importance of a research agenda that addresses unanswered questions about treatment uncertainties prioritised jointly by patients and clinicians.**
- **To promote working partnerships and collaborations between patients and clinicians to identify and promote their shared priorities for therapeutic research.**
- **To increase general awareness and understanding of the need to refocus the therapeutic research agenda.**

Progress in meeting operational objectives for 2005

Seven operational objectives for the Alliance were set for 2005. Progress in addressing each of these is reported below.

Objective 1: Set up a steering group of interested and experienced individuals to guide and appraise the work of the JLA. Members of this group will make a declaration of competing interests.

Support for the JLA's objectives is reflected in the variety and status of the 19 people who have agreed to help guide the evolution of the Alliance as members of its Steering Group (**Annexe 4**). The Steering Group is chaired by Sally Crowe, and met for the first time in January 2005, and again in May and September 2005 (minutes available at www.lindalliance.org). All of the current members have made declarations of competing interests, and all have agreed to continue to serve until the summer of 2006.

Six members of the Steering Group constitute a Development Group, chaired by Lester Firkins, which meets every month to help maintain momentum on agreed action points, and to deal with other matters arising between meetings of the Steering Group (minutes available at www.lindalliance.org).

Objective 2: Support and develop a Database of Uncertainties about the Effects of Treatments (DUETs) to underpin and inform the deliberations of JLA Working Partnerships.

With support from the National Knowledge Service for a part-time editor (Mark Fenton) and software design by Update Software (Hazim Timimi), a Database of Uncertainties about the Effects of Treatments (DUETs) has been established as a resource to help identify priorities for new research. It is publicly accessible through www.duets.nhs.uk, and a detailed report of its development is available (Fenton et al. 2006).

Objective 3: Foster awareness of the JLA through a programme of communication activities, to encourage organisations and individuals to affiliate to the JLA, and to help to develop Working Partnerships of patients and clinicians.

Awareness of the Alliance has been promoted through **mass mailings**. During 2005, with help from the National Coordinating Centre for Health Technology Assessment, the RSM and INVOLVE, the JLA Secretariat assembled contact details for relevant patient organisations and clinician organisations. In September 2005, 750 packs of JLA introductory material were mailed out, including substantially redrafted introductory documents agreed by the Steering Group (**Annexe 5**). In October, details of an important end-of-year JLA meeting were notified (by email alert and post) to all those on the JLA mailing list. In November 2005, 2,700 JLA leaflets and flyers for the meeting were distributed with the INVOLVE newsletter, and (electronically) to patient organisations and groups associated with NICE. Smaller mailings were undertaken through the North West Users Research Advisory Group, the Commission for Patient and Public Involvement in Health, and the 114 member charities of the Association of Medical Research Charities.

A James Lind Alliance **website** (www.lindalliance.org) was piloted for 4 months from November 2004, and after taking account of feedback, launched in April 2005. There has been an encouraging growth in the numbers of visitors to the site during the course of 2005, from 675 in the quarter following its launch in April, to 2561 in the final quarter of the year. The website contains all the material distributed in the mass mailings, as well as more detailed guidelines for those considering establishing and supporting Working Partnerships of patients and clinicians, and details of the first of these, in asthma. The website lists all affiliated organisations and affiliated individuals who have indicated that they wish their names to be added. Visitors to the website can affiliate to the JLA on-line, and sign up to receive email alerts. The site also includes a section of articles and references to articles relevant to the JLA's objectives.

Awareness of the JLA has also been fostered through **presentations at meetings** (**Annexe 6**). Among these, those at the Clinical Excellence meetings organised by NICE in December 2004 and December 2005 have been very important in drawing the JLA to the attention of a wide variety of people involved with the NHS. The turnout of nearly 100 people for the JLA meeting on Saturday 3 December 2005 at the RSM (which donated the cost of the venue) was very encouraging. A programme of very challenging presentations (**Annexe 7**) stimulated lively discussion.

Presentations in the morning session drew attention to evidence showing mismatches both between what researchers are researching and unanswered questions asked by patients and clinicians, and other mismatches between treatment outcomes studied by researchers and those regarded as important by patients. A report of this part of meeting was published promptly in *Health and Social Campaigners News International* (**Annexe 8**). The Secretariat has begun to compile a bibliography of papers and empirical research relevant to these issues (**Annexe 9**). The afternoon provided an opportunity for the JLA to learn from the experience of other organisations endeavouring to engage patients in assessing research (NICE) or in planning research (National Clinical Research Network) – and to present the development the first JLA Working Partnership (in asthma) and the Database of Uncertainties about the Effects of Treatments (DUETS).

Finally, awareness of the JLA has been promoted through **articles** in publications reaching patients and clinicians (**Annexe 10**).

The number of organisations and individuals registering as **JLA Affiliates** has been growing steadily (**Annexe 11**) in response to these efforts to foster awareness about the James Lind Alliance, as has the number of individuals who have asked to be added to the JLA **email alert list**.

Objective 4: To support and enable the creation of at least two pilot JLA Working Partnerships to identify shared priorities for therapeutic research.

The challenge

Promoting the evolution of JLA Working Partnerships has been (and will probably continue to be) the most challenging aspect of the JLA's work. A decision was taken early in the life of the JLA that Working Partnerships would be encouraged and supported only when organisations had approached the JLA expressing a wish to work together in this way.

The JLA has been handicapped by the lack of relevant previous experience to draw on. Although there are many examples of efforts made to identify the research priorities of patients and the research priorities of clinicians separately, examples of attempts to identify research priorities shared by both patients AND clinicians – the JLA's objective – are very rare. The most fully developed example is probably the QRD programme developed by the Alzheimer's Society; but even this exemplary initiative was not confronted with the challenge of persuading two separate organisations to work collaboratively, only to persuade patients, carers and clinicians already associated with the Alzheimer's Society to work together.

For better or worse, the JLA has decided to try to foster collaboration among existing organisations. Fostering partnership working in these circumstances has not been straightforward. It requires patience, sensitivity and an appreciation that it cannot be assumed that the involved stakeholders necessarily share exactly the same objectives, or that they agree on the means for pursuing them.

Asthma

In discussions about the JLA between John Scadding, Stephen Holgate (academic respiratory physician, Southampton) and Philippa Major (Assistant Director of Research, Asthma UK) following a RSM “Medicine and Me” event on asthma in April 2004, Stephen Holgate and Philippa Major expressed enthusiasm for establishing a JLA Working Partnership involving the British Thoracic Society and Asthma UK. In February 2005, these organisations applied jointly for registration as a JLA Working Partnership in Asthma.

There have been three meetings of the JLA Asthma Working Partnership in 2005. At the most recent of these, those representing the Working Partnership considered unanswered questions about the treatment of asthma which had been assembled in the asthma module of the Database of Uncertainties about the Effects of Treatments (DUETs). Now that they have this ‘grist for their mill’, a meeting of the Working Partnership in April will filter these questions, and agree participants and procedures for a formal priority setting meeting in the summer of 2006.

The development of the JLA Asthma Working Partnership has been relatively slow and cautious. The two partner organisations have not previously worked together in such a strategic and close partnership, and they have needed time to build mutual trust and a common understanding of each other’s perspectives. The quality of the dialogue has improved with each meeting, however, and commitment to real progress seems genuine. Several key individuals are particularly enthusiastic about the objectives of the Working Partnership, albeit also sometimes overwhelmed with the complexity and scale of the challenge.

The Asthma Working Partnership is the ‘first child’ of the JLA, and it is inevitable that mistakes will be made whilst the JLA endeavours to learn ‘on the job’. This experience is being recorded, however (**Annexe 12**), and will help those involved in fostering other Working Partnerships to tackle the challenge.

Possible future developments

Interest in establishing a JLA Working Partnership in epilepsy has been expressed by several leading UK epilepsy clinicians and researchers. At the time of writing, the epilepsy charities, through the Joint Epilepsy Council, are being approached to assess enthusiasm for forming a Working Partnership. In relation to neurological disease in general, it is important to report that the Association of British Neurologists (ABN) has affiliated to the JLA, and to recognise that close links already exist between the ABN and the Neurological Alliance, the umbrella organisation representing the numerous neurological patient charities. This augurs well for the development of Working Partnerships in neurological disease. (**Annexe 13**)

As stressed above, the JLA is unable to draw on much relevant previous experience of fostering collaboration among patients AND clinicians, working together, in identifying research priorities, and there is apparently no experience to guide the Alliance about how to pursue this objective. As reported in the previous section, progress does now appear to be being made by the JLA Asthma Working Partnership towards a priority setting meeting, but nearly two years have passed since it was first proposed by Stephen Holgate and Philippa Major.

It was suggested by one of the people at the JLA Annual meeting that it was too much to expect existing organisations to pursue the JLA's relatively radical objectives efficiently, and that progress would be faster and more successful if it was based on existing collaborations among groups of individual patients and clinicians among whom mutual respect and successful collaboration had already been established.

In addition to considering alternative ways of establishing JLA Working Partnerships, however, it is important to consider whether the approach to research priority setting being promoted by the Alliance is already being adopted by others – for example, the clinical studies groups in the National Clinical Research Networks – and if not, what mechanisms for priority setting are being used. It has so far proved difficult to obtain a clear picture of the way that topics are being chosen.

Charities funding medical research are diverse, and use diverse methods for identifying their priorities. Common to many, however, is the involvement of a wide range of stakeholders in their activities: most disease areas are of interest to several professional groups as well as to patients and carers, and many charities are finding ways for these latter to be involved in shaping research strategies. Through the representation of the AMRC on the JLA steering group, there is enthusiasm for the possibility that the JLA method of fostering joint working could be extended from its current focus (enabling clinicians and patients to together identify research priorities in treatment uncertainty) to assist charities wanting to find effective ways of uniting professionals and patients/carers in ensuring that research strategies are rooted in shared interests.

Objective 5: To develop, evaluate and describe a workable process that supports and enables JLA Working Partnerships to function effectively; to plan and prepare for JLA meetings, and to agree a shared therapeutic research agenda.

The JLA Steering Group decided that it would not be helpful to be too prescriptive in describing the processes to be used in efforts to establish Working Partnerships. Instead it had been hoped to learn and develop from experience of different types of Working Partnerships. With the benefit of experience only from asthma to call on, a process flowchart has been produced which reflects current thinking (**Annexe 14**). This will need modification, depending on the nature and relationship between members of future Working Partnerships. In particular, there will be differences due to different sizes of the memberships of partner organisations, and a need to reflect any existing experience in garnering and prioritising patient and clinician views on research needs.

Objective 6: To create a platform for widespread publicity to encourage new JLA Working Partnerships.

See text under objective 3, above.

Objective 7: To begin the process of making provision for the continuing development of the JLA, including a three-year strategy, starting in 2007.

Grant support for the James Lind Initiative – and thus the JLA Secretariat – currently runs until the end of 2006. Iain Chalmers' discussions with senior staff at the MRC and the DH have indicated that an application should be made for extension of the current funding, covering the period to 31 March 2010.

Other activities intended to promote the objectives of the JLA

In addition to the seven operational objectives agreed for the JLA during 2005, six so-called 'influencing objectives' were listed in the launch documents indicating less direct ways in which the objectives of the JLA might be promoted (**Annexe 15**). Assessment of progress in these spheres is more difficult to capture, and impossible to capture completely.

Proposed objectives for 2006 and 2007

By the end of 2006, the JLA will have:

1. Concluded the priority setting cycle of the JLA Asthma Working Partnership, and prepared and published a detailed summary.
2. Established two further JLA Working Partnerships to refine the suggested processes for future partnership models to develop priorities of treatment uncertainty
3. Reviewed the resources needed to achieve successful partnerships.
4. Explored whether some medical research charities or other funders wish to, and can, extend JLA methods of fostering joint working to help unite professionals and patients/carers in ensuring that research strategies are rooted in shared interests.
5. Adopted the lessons learned from the piloted working partnerships and other models, such as Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT), and reviewed the JLA publicity material in the light of this.
6. Explored with the Clinical Research Networks how research priorities are identified, and the extent to which they have been selected because they are known to reflect the shared priorities of patients and clinicians.
7. Collaborated with other organisations in organising two symposia to discuss issues relevant to the JLA's objectives.
8. Established a mechanism for rotating off the Steering Group a third of its members every year, from the summer of 2006, and drawing new members from among the JLA Affiliates.

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

By the end of 2007, the JLA will have:

1. Demonstrated that the award of research funding has been influenced by the prioritised uncertainties from JLA Working Partnerships.
2. Established processes through which those who have been involved in establishing successful Working Partnerships provide support to those involved in developing additional Working Partnerships, thus fulfilling the current role of the JLA Development Group.
3. Concluded two further JLA Working Partnerships.

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Sally Crowe
Chair, JLA Steering Group
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