

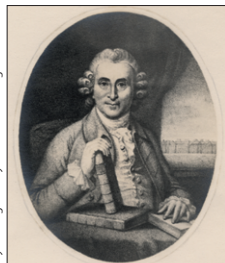
The James Lind Alliance: patients and clinicians should jointly identify their priorities for clinical trials

Dec 1 sees the launch of the James Lind Alliance at the Clinical Excellence conference in Birmingham, UK. Convened jointly by INVOLVE, the Royal Society of Medicine, and the James Lind Library, the James Lind Alliance aims to bring patients and practising clinicians together in a new way to identify and address the most important uncertainties they face about the effects of care and treatments.¹

In many areas over the past 10 years, involving patients, and to a lesser extent the public, in research has moved from a radical concept to an accepted and valued part of the research cycle. However, the past 10 years have also seen a decline in the number of non-commercial clinical trials,² and the needs of patients and practising clinicians are still rarely discussed when deciding research priorities. Rather, the needs of industry and academia take precedence.

Clinicians might not always face important uncertainties about treatments and discuss them openly with patients, for understandable reasons.³ Yet discussion of well-informed uncertainties about treatments is essential to fully understand the real priorities of patients and to set the agenda for future trials of treatment.^{3,4}

The James Lind Alliance is named after an 18th-century Scottish naval surgeon who, faced with uncertainty about how best to treat scurvy, did a controlled trial to find the best treatment for the, then, often fatal disease. Lind's trial showed that citrus fruits were much more effective than the other five treatments in the comparison, including those recommended by the Royal College of Physicians and the Admiralty. "The most sudden and visible good effects were perceived from the use of oranges and lemons; one of those who had taken them being, at the end of six days, fit for



James Lind (1716–94)

Royal College of Physicians of Edinburgh

duty.” Lind reported his clinical trial in the context of an exhaustive review of all that had been written on scurvy and treatments for it.⁵

The James Lind Alliance is an initiative to open up discussion between patients and clinicians to agree on priorities for future research on the effects of treatments. As in Lind’s day, some of the uncertainties prioritised jointly by patients and clinicians will need to be addressed in systematic reviews of existing information. Where systematic reviews have already laid bare the need for further research, the Alliance’s goal will be to ensure the research actually happens. Some questions that are important to patients and practising clinicians might not be of great interest to industrial or academic researchers. The challenge will then be clear: whose priorities should determine which systematic reviews or new studies should be designed and funded?

So how will the Alliance tackle its goals? The Alliance will facilitate and host meetings of organisations representing (and including) patients, and organisations representing clinicians who share a common interest in a specific health issue. To ensure fair play and independence, each meeting will be chaired by a person who has no vested interest in the decisions that participants reach. And, the Alliance will require that all contributors declare any competing financial or other relevant interests.

Each patient-clinician partnership will consider available data on variations in current practice which suggest areas of uncertainty, and unanswered questions about the effects of treatments. After prioritising these questions, participants will draw up a joint action plan for the partnership.

To prepare for meetings, unanswered questions about the effects of treatments will be assembled and categorised. Sources for these questions will include question-answering services for patients (such as national voluntary organisations and patient groups, NHS Direct, and NHS Direct Online), clinicians (eg, ATTRACT), clinical guidelines, and systematic reviews. To facilitate the gathering of unanswered questions, the Database of Uncertainties about the Effects of Treatments (DUETs) is being assembled as a service for members of the James Lind Alliance.

The involvement of patients will help to ensure that important questions are not overlooked because of emphasis on: chronic but not acute health problems; severe but not common health problems; and disease-specific but not cross-cutting issues, such as social care, improved surgery, and anaesthesia.

In addition to clearly articulating a new research agenda on the basis of the needs of patients and practising clinicians, the James Lind Alliance is also determined to encourage greater

openness of information about clinical trials and research. Patients and clinicians should be able to find complete and reliable information about trials that are in progress, but currently this is very hard to do. It is extraordinary that there is no systematic way to see which trials are currently open for participation. Nor can patients or clinicians assess the importance of the questions being addressed, whether these questions have been answered in previous research, if patients have been involved in the design of the trial, or whether a trial is scientifically and ethically robust.

Even more surprising is that the results of clinical trials are not necessarily made public. The James Lind Alliance believes that all clinical trials should be registered at inception and that their results should be made freely available and easily accessible. Although the pharmaceutical and medical technology industries play an essential role in developing new treatments, they clearly have competing interests and their priorities are not necessarily the same as those of patients and clinicians. The James Lind Alliance, through review and discussion, will challenge these distortions in the therapeutic research agenda and promote a principle that states that patients and clinicians should work together to agree which uncertainties matter most and deserve priority attention.

In its 2004 budget, the UK Government committed to spending an additional £100 million each year on medical research and development by 2008. Clearly, the aims of the James Lind Alliance are ambitious. But with increased funding and the creation of the UK Clinical Research Collaboration,⁶ the goal of which is to establish the UK as a world leader in clinical research, formation of the Alliance could not be more timely.

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We declare we have no conflict of interest.

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- 4 Tallon D, Chard J, Dieppe P. Relation between agendas of the research community and the research consumer. *Lancet* 2000; **355**: 2037–40.
- 5 Lind J. A treatise of the scurvy. In three parts. Containing an inquiry into the nature, causes and cure, of that disease. Together with a critical and chronological view of what has been published on the subject. Edinburgh: Printed by Sands, Murray and Cochran for A Kincaid and A Donaldson, 1753: www.jameslindlibrary.org (accessed Nov 15, 2004).
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