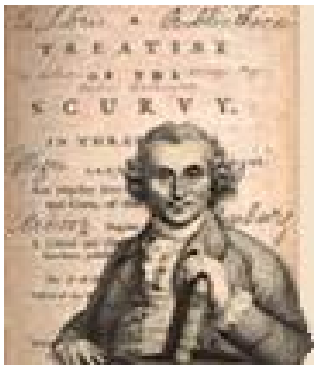

THE JAMES LIND ALLIANCE

Tackling treatment uncertainties together

Research priorities in Asthma

Description of a workshop to set priorities for treatment uncertainty research in Asthma, March 2007

April 2007

Introduction and context for this report

At a *Medicine and Me* meeting on asthma at the Royal Society of Medicine in August 2004, Professor Stephen Holgate (AIR Division, Southampton General Hospital and member of the British Thoracic Society) and Philippa Major (then Assistant Research Director Asthma UK) expressed enthusiasm to Dr John Scadding (Associate Dean RSM and co-convener of the James Lind Alliance) about establishing a James Lind Alliance (JLA) Working Partnership in Asthma.

Following a series of meetings, plans were drawn up to populate the Database of Effects of Uncertainties of Treatments (DUETs) with Asthma Treatment Uncertainties, and then develop methods for prioritising these uncertainties into a short list of 20 – 30. The final step would be a workshop at which members of Asthma UK and the British Thoracic Society (BTS) would agree their top ten shared priorities from the short list.

Prior to the workshop, all participants were asked to complete a declaration of competing interests for asthma research, and this was included in the workshop packs.

This report describes the workshop, both in terms of process and outcomes. Additional reports are also being prepared by two social scientists who observed the proceedings, and, in conjunction with Asthma UK and BTS, the JLA team will prepare a report of the whole experience, including the development of the DUETs Asthma Module. This will maximise our understanding of the process of developing and prioritising treatment uncertainties that can be shared with other JLA Working Partnerships and interested parties.

This report will be circulated widely with JLA strategic groups and affiliates and will be made available on the JLA website.

Objectives of the workshop

1. *To brief the group on the process for developing the DUETs Asthma Module, and the uncertainties to be prioritised*
2. *To reflect on and discuss participants' individual rankings of Asthma Treatment Uncertainties*
3. *In small groups, to rank the Asthma Treatment Uncertainties*
4. *To collate the small group rankings and look for themes of agreement and disagreement across small groups, and then to re-rank the Asthma Treatment Uncertainties*
5. *In the large group, to discuss and rank and if need be, vote to achieve a final 10 Asthma Treatment Uncertainties, for priority funding*

Participants of the workshop

Name	Title	Organisation
Ms Patricia Atkinson	Administrator, James Lind Alliance	James Lind Initiative
Ms Karen Bowler	Asthma Spokesperson	Asthma UK
Ms Debbie Campbell	Clinical Nurse Specialist - Asthma	Royal Brompton Hospital British Thoracic Society (BTS)
Ms Amanda Cook	Asthma Spokesperson	Asthma UK

Mr Ivor Cook	Asthma Spokesperson	Asthma UK
Ms Sally Crowe	Chair, James Lind Alliance, Strategy and Development Group	Crowe Associates
Ms Sheila Edwards	Chief Executive	BTS
Mr Mark Fenton	Editor, DUETs	James Lind Initiative
Mrs Jackie Fielding	Asthma Spokesperson	Asthma UK
Mr Lester Firkins	Chair, James Lind Alliance, Monitoring and Implementation Group	Medical Research Council
Ms Jude Frankau	PhD Student (Observer)	University of Aberdeen
Dr Colin Gelder	Consultant Physician, Editor, DUETs Asthma Module	Respiratory Medicine, Cardiff & Vale NHS Trust BTS
Mrs Loraine Hili	Asthma Spokesperson	Asthma UK
Prof Stephen Holgate	MRC Clinical Professor of Immunopharmacology	AIR Division, University of Southampton, BTS
Miss Leanne Male	Assistant Director, Research	Asthma UK
Mrs Judith Rogers	Training & Development Advisor (Facilitator)	Crowe Associates
Ms Dot Russell	Asthma Nurse Specialist	Asthma UK
Mrs Ruth Stewart	Research Officer (Observer)	Social Science Research Unit
Mrs Jenny Versnel	Executive Director Research & Policy	Asthma UK
Dr Samantha Walker	Research Liaison Officer	Asthma UK
Dr Marianne Miles	Patient and Public Involvement Lead	UK Clinical Research Network

The workshop methods

First Phase

As a positive start to the day, participants initially spent some time getting to know each other by describing their personal qualities and their involvement with asthma. This process complemented a biography document, which was compiled and circulated prior to the workshop.

The background to the James Lind Alliance Asthma Working Partnership was also described, again, with supporting material in the pre-workshop pack.

Ground rules for the priority setting meeting and a glossary of terms were introduced and discussed, as was the way in which the workshop would be facilitated, to promote interaction and discussion.

The next session was for information, and comprised short presentations from the team that had compiled the DUETs Asthma Module. The nature of uncertainties was discussed, followed by the processes that had been undertaken to assemble the database and reach the short-listed questions. From the Asthma UK survey this included the agreed taxonomy for the questions, the sub groupings and the frequency of times an uncertainty was found in the survey.

Discussion time following this section enabled several points to be made and these included:

- Some clarification questions about the development of the DUETs Asthma Module

- The need for questions that address uncertainties with specific groups such as children, older people and patients with health problems in addition to asthma (because many trials recruit the middle age band of people with asthma, and target participants who don't have co-morbidities)
- 'Effectiveness studies', research reflecting circumstances in the real world, are in short supply
- Awareness that many people with asthma don't take their medications as prescribed

Second Phase

Following this clarification phase, the participants were assigned to small groups, each of which had a mixture of people with asthma and/or carers, researchers, and clinicians.

Within each group, time was spent discussing, exploring and comparing each participant's individual rankings of 21 Asthma Treatment Uncertainties. One group included the rankings of an Asthma Spokesperson who was unable to attend the workshop.

Each group had a colour-coded set of cards referring to each of the 21 Asthma Treatment Uncertainties, so were able to move these around as opinions were expressed.

After some time considering these individual comparisons, the groups refocused on the Asthma Treatment Uncertainties as a whole, and started to identify shared priorities. Different groups approached this in different ways. For example, it was easier to construct a diamond/triangle shape with the most important uncertainties at the top, creating groups of priorities, than necessarily work in longitudinal line of all 21 uncertainties.

Moving from individual to group rankings also proved challenging for some participants, for example;

"I have a vested interest in Asthma Treatment Uncertainties that concern younger people as I am a parent of a young person with asthma – adolescents especially can slip between paediatric and adult services and there are lots of uncertainties about their treatments - but they aren't the only important group".

"There is a whole group of Asthma Treatment Uncertainties that are about long term side effects that are basically asking the same question but with different treatments, or ways of delivering the treatment".

"Given the large response rate to the Asthma UK's questionnaire, and the much smaller group meeting today, I would be concerned if today's prioritisation differed from the results of the Asthma UK survey"

"I don't understand after all this time using steroids in asthma that we don't have a clear understanding of what the long term effects are – I ranked this low down myself because I assumed that we already knew the answers to the question!"

"I see that we must have a prevention rather than cure approach to this so I have ranked these higher than current treatment questions".

"There is a tendency (as a person with asthma) to under self medicate because of concerns about long term steroid treatment but this then leads to less stable asthma and more acute episodes, so it is a vicious circle".

" Co-morbidity is the issue from my clinical perspective, so many people with asthma have other related or non-related conditions – maybe as much as 80%".

"I estimate that about 40% of patients use complementary therapies as part of their overall approach – what are the benefits and what are the harms?"

The facilitators for each group had the task of ensuring that no one person dominated the discussion or exerted undue influence on the group, and ensure that all group members participated in the discussion. They also had a master template to record the 1st round of decision making in the morning.

As the workshop approached the lunchtime break, groups were encouraged to focus on the final ranking of the Asthma Treatment Uncertainties. The pressure of time focussed the minds of group members, and two of the three groups were able to agree a ranking order for all 21 Asthma DUETs. The third group captured the individual rankings of each group member and where there were agreements in rank order.

Over the lunch period, the data from the three groups were entered into an Excel spreadsheet designed for the purpose.

This gave the team an aggregate score for each Asthma Treatment Uncertainties. Following lunch the whole group reconvened and discussed the aggregate scores after the first round of ranking. The purpose of this was not to reorder the list but to clarify between groups the issues for and against the group choices.

Observations at this stage of the priority setting were:

- There was already consensus about the top six Asthma Treatment Uncertainties
- However all groups had expressed the idea of grouping these questions as one, as they all addressed the core question of long-term effects of oral and inhaled steroids in children and adults; short-acting and long-acting bronchodilators; and combination and additive therapies.
- The uncertainty concerning magnesium sulphate for treatment of severe acute asthma should be deselected as a clinical trial is currently addressing this question.
- There was a middle group of Asthma Uncertainties about which there was moderate consensus.
- There was consensus about four Asthma Treatment Uncertainties at the lowest end of the priority ordering.
- There was a feeling that other vulnerable groups such as older people and those from ethnic minorities, should be considered alongside children in uncertainty questions

The three small groups were combined into two larger groups to create two new mixed combinations, again the balance between patients/carers and clinicians/researchers maintained**.**

This time the groups appraised and discussed the new aggregate ranking order from the first round of priority setting.

Similar processes were used as in the first round, but the focus here was on agreeing a list of top ten Asthma Treatment Uncertainties.

Similar discussions about Asthma Treatment Uncertainties that were closely related surfaced again, one group chose to combine these and treat them as a single, composite uncertainty, the other group chose to consider them individually (and they all remained in the top ten list). The time for this session was extended by 30 minutes to enable both groups to reach their decisions.

Final Phase

During the refreshment break the JLA team again collated the results from this second round of voting on a new Excel spreadsheet (this gave us records of each round of voting). The two sets of colour-coded cards were also displayed on poster boards, for ease of viewing.

The aggregate scoring was shared with the whole group, some observations made by the facilitators of the small groups, and the debate was then opened up for everyone at the prioritisation workshop.

There was remarkable similarity between the two groups' top five priorities. Both groups agreed that uncertainties about the long-term effects of treatment could be compressed into one indicative question, but that this was the overwhelming priority of the whole process, so it would be important not to lose this fact in compressing these uncertainties. This was done on the projected spreadsheet. A clinician remarked that by doing this, the final top ten was a more interesting and diverse group of Asthma Treatment Uncertainties.

Whilst there were some differences in the priorities in the lower rankings the whole group agreed the final top ten Asthma Uncertainties, and these are as follows:

The top ten asthma uncertainties

1 (a) What are the adverse effects associated with long-term use of *short and long-acting bronchodilators; inhaled and oral steroids; and combination and additive* therapies in adults?
(N.B this includes children aged 12 years old and over)

1 (b) What are the adverse effects associated with long-term use of *short and long-acting bronchodilators; inhaled and oral steroids; and combination and additive* therapies in children?

2. What is the most effective way of managing asthma with other health problems?

3. What are the key components of successful "Self- Management" for a person with asthma?

4. What is the most effective strategy to educate people with asthma and health professionals about managing the adverse effects of drug therapies?

5. What is the most effective way of managing asthma triggers?

6. What is the role of complementary therapies in asthma management?

7. What are the benefits of breathing exercises as a form of physical therapy for asthma?

8. What type of patient (children and adults) and health professional education is most effective in gaining asthma control?

9. What is the most effective way to manage consultations and asthma control in adolescence and young people?

10. Psychological interventions for adults with asthma?

What next for the Asthma priorities?

Having decided the final top ten Asthma Uncertainties participants discussed next steps.

The group agreed the following:

- Each uncertainty needs to be accompanied by a 'vignette' to give it some context. The JLA will co-ordinate this process for the Working Partnership. Stephen Holgate and Colin Gelder will split this task initially, and then send to Asthma UK for comment.
- The 'compressed' top questions concerning long term effects of steroids needs to be reworded – Mark Fenton to start this process off and then consult with Asthma UK and BTS.
- All of the Asthma Treatment Uncertainties need to be included in the Asthma DUETs Module, so that any interested clinician, researcher, research funder or patient/carer can see the original starting point for the exercise. Mark Fenton and Colin Gelder will do this.
- The Treatment Uncertainties will probably fare better with funders if they are expressed in the EPICOT format (**E**vidence, **P**atient, **I**ntervention, **C**omparison, **O**utcome), and/or PICOT format, Mark Fenton will check for this.
- The JLA is keen to use its links and networks to communicate the process as well as the outcomes of the workshop. Asthma UK and BTS have a vested interest in seeing research funded to address some of these Asthma Treatment Uncertainties. BTS to consider the top ten at its Research Committee, suggested recipients of this information to be: Medical Research Council (there is a highlight notice for respiratory research at present, UK Co-ordinating Centre for Health Technology Assessment, Wellcome Trust, and others. BTS and Asthma UK to take this forward with support from JLA.
- JLA to pursue a joint publication in BMJ; Peter Lapsley Patient Editor at BMJ is interested.
- Suggestion that the process and outcomes are shared at the BTS Winter Conference – need to submit an abstract for this, Sally Crowe offered to co-ordinate this
- The JLA and the Association of Medical Research Charities are co-hosting a conference on the 17th September at the Wellcome Trust entitled "Should

patients tell researchers what to do – if so how". It was suggested that Asthma UK and BTS should participate in this.

The JLA team presented a short summary of the day, and then, to re-energise participants, two teams undertook a treasure hunt! Thanks were expressed to all participants who undertook the task with great spirit and engagement.

Most participants completed evaluation forms. A summary of these will be included in the observation report of the workshop.

Comments from the Evaluation Forms

Fantastic effort with pulling it all together and keeping the energy going by the team. It really made it a worthwhile experience.

Shame there weren't more clinicians, but those who attended really gave good and balanced input.

Good mixture of views and all able to participate.

Managed to have a full day of discussions, agreements, disagreements and finally achieved a satisfactory result.

It was interesting to see how the dynamics of groups changed the priorities and how priorities were influenced by open discussions with lay and professionals.

Great day – focussed and knew what was happening – have a sense of achievement.

A most enjoyable and stimulating experience.