

JLA Lab activity 3: Alternative funding sources for priority setting activity

Inflammatory Bowel Disease (Australia) (priority setting in association with the JLA)

Report – February 2023

Introduction

The James Lind Alliance (JLA) initiative was established in 2004 to bring patients, carers and clinicians together in [Priority Setting Partnerships \(PSPs\)](#) to identify and prioritise the [Top 10 unanswered questions](#) that they would like to see answered by research. JLA PSPs provide an important opportunity for the users of research to help shape the research agenda. There are now over 135 completed PSPs in the UK and internationally.

The defining characteristics of JLA PSPs are that they adhere to a set of principles, namely:

- transparency of process
- balanced inclusion of patient, carer and clinician interests and perspectives
- exclusion of non-clinician researchers from voting (they may be involved in all other aspects of the process)
- exclusion of groups or organisations that have significant competing interests, for example pharmaceutical companies
- a maintained audit trail from original submitted uncertainties, to final prioritised list
- a recognition that making priority decisions does not create new knowledge but reviews existing evidence of uncertainty.

The costs involved in undertaking a PSP vary, but funding is sourced by PSPs themselves. There are undoubtedly groups and health areas which would benefit from working with the JLA to set research priorities, but which are unable to because of a lack of available funding. Sources of funding for PSPs vary, but the [JLA Guidebook](#) (version 10, dated March 2021) states:

“JLA PSPs must avoid being influenced by parties with a commercial interest in their topic. This includes avoiding PSPs being directly funded by a commercial organisation that could benefit commercially from the results.”

Exclusion of industry funding has been a feature of the JLA since its conception in 2004.

Since 2013 when the JLA Coordinating Team at the National Institute for Health and Care Research (NIHR) was established, there have been several instances where the JLA has been approached to consider whether a JLA PSP can be funded directly by money sourced from a commercial organisation. Hitherto, the JLA has been unable to accommodate these requests as they would impinge on the principle of exclusion of groups or organisations that have significant competing interests, leading to a (perceived or actual) risk of influence on the results, and the undermining of the JLA's reputation for independence.

However, the global pandemic put many potential PSPs under severe financial pressure, a pressure that was likely to prevent some groups from using the robust JLA method to set research priorities with their communities. The JLA now wishes to consider whether it is appropriate and proportionate to continue to rule out commercial organisations as a possible source of PSP funding.

The JLA Lab approach to test the influence of a commercial funding source

The JLA recognises the funding challenges faced by potential PSPs, so initiated the process of testing the assumption about the risks and possible influence of commercial funding on priority setting activity.

In considering this fundamental policy change, it is important to understand what the impact of commercially funded PSPs might be, both on a practical level (whether it influences the scope and the priorities) and in terms of reputation (whether public perception of the priorities is undermined by association with a commercial funder). This project was undertaken in the JLA Lab which is a safe exploratory space where new ideas and methods can be developed and tested, away from JLA PSP activity. The aim is to support innovation and address some of the challenges of our stakeholders, whilst protecting the integrity and reputation of JLA PSPs. Some activities tested in the JLA Lab, if deemed appropriate, may be considered for incorporation into the standard JLA methodology in the JLA Guidebook and will contribute to the evolution of the JLA. Not all ideas tested in the Lab may be suitable for adoption as JLA methodology.

In May 2020, the JLA established a priority setting exercise with [Crohn's & Colitis Australia](#). This differed from a standard JLA PSP in that the work was funded by mixed unrestricted grants from a pharmaceutical organisation and philanthropy.

As this activity was undertaken within the JLA Lab, it was not described, branded, or reported as a JLA PSP. The JLA is committed to reporting and evaluating all activity in the JLA Lab.

The scope of this report is to inform debate about the following question: **What effect, if any, does commercial funding of a JLA PSP have on process and outcome?**

It is unlikely that the outcomes of this single report will provide the answer as to whether commercial funding of a priority setting exercise is likely to influence the process or outcome, and an assessment of the wider impact on the reputation and perceived integrity of the priorities is beyond its scope. Nevertheless, the intention here is to report on the work undertaken and provide results of the feedback generated from participants in the exercise which overall may contribute to the evidence for future considerations into possible

commercial funding for priority setting activity. It is likely that further activities may take place in future to help continue our assessment.

The priority setting work with Crohn's & Colitis Australia

Crohn's & Colitis Australia approached the JLA to set priorities for research in inflammatory bowel disease (IBD). An estimated 100,000 Australians live with IBD. The aim of the priority setting work was to identify unanswered questions relating to prevention, treatment, symptoms, diagnosis and living with IBD. The funding for the activity was made clear on the project website, which stated that 'This project is supported by Janssen Australia, Takeda Pharmaceuticals Australia and a generous anonymous philanthropist'. Crohn's & Colitis Australia considered alternative funding sources which may have been available to them at a future date, but during the Covid-19 pandemic, philanthropic donations were less available, and it was felt that this would introduce an unacceptable delay to this important project.

The Australian Setting

The Crohn's & Colitis Australia team discussed the JLA principle of PSPs not being funded by pharmaceutical organisations with their Scientific, Medical and Quality of Care Committee and highlighted to the JLA the strict requirements of the [Medicines Australia Code of Conduct](#), which prohibits "inappropriate influence on the approval, recommendation, prescribing, and/or use of a product". In their view this longstanding code is an effective tool to avoid commercial gain. As an example, the code states:

"Medicines Australia recognises and supports positive and beneficial relationships between industry and health consumer organisations. Companies may enter into relationships with health consumer organisations with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community."

"When entering into relationships with health consumer organisations, Companies should refer to Working Together—A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies, developed through collaboration between Medicines Australia, the Consumers Health Forum of Australia and other health consumer organisations. The manual is available on the Medicines Australia website www.medicinesaustralia.com.au"

Priority setting process and documentation

Apart from the funding source, this priority setting exercise replicated the standard rigorous and inclusive priority setting method used in JLA PSPs. The priority setting exercise was supported by Katherine Cowan, Senior Adviser to the JLA. The exercise involved a Steering Group made up of people living with IBD, carers and clinicians. The report [Consumer-Driven Research for Crohn's Disease and Ulcerative Colitis](#) describes the process and the agreed Top 10 priorities.

In line with the JLA principles of transparency, the [project protocol](#) is published on the JLA website and was agreed by the people living with IBD, carers and clinicians on the Steering Group. It states:

"The Crohn's & Colitis Australia (CCA) RPP is a project that will use the same approach as a PSP using a different funding model. Whereas JLA PSPs do not have direct links to commercial funding sources, the JLA has agreed to work with Crohn's and & Colitis Australia under the aegis of its JLA Lab (a conceptual experimental space) to develop a priority setting exercise that replicates the JLA method but is funded by mixed

unrestricted grants from two pharmaceutical organisations and philanthropy. **The pharmaceutical organisations will not take part in the process or have access to data or materials of the priority setting work until it is publicly available information. There is no requirement to report to the funders during the process, other than to mention the source of funding in any publications.**“

Feedback from the project lead

In line with usual JLA processes, the JLA sought feedback at the end of the priority setting process from the individual leading the project. In an online survey, the JLA encourages honest feedback about the performance of the JLA coordinating team, the JLA Adviser, and the methods and process used. Overall, the response was positive about the process and in addition the respondent indicated the perception that the commercial funding source made little difference to the outcome:

“This JLA Lab process had partial pharma funding. While I think it is possible that this affects perceptions of the outcome to outsiders, I personally think it had absolutely no material impact on the project.”

Feedback from Steering Group members

All JLA PSP Steering Group members are sent an online questionnaire at the end of the PSP process seeking feedback on the JLA Adviser’s performance as well as JLA processes throughout the exercise, to gather feedback on whether in their view JLA principles were upheld and to help the JLA to improve its processes.

Nine of 12 Steering Group members from the IBD priority setting work responded to the survey.

- 4 patients, service users or representatives of those people
- 5 health professionals or members of professional bodies

In addition to the usual feedback survey questions, Steering Group members were asked:

“The project received pharmaceutical company funding, without any conditions or restrictions on how it was used. To what extent do you think this may have influenced:

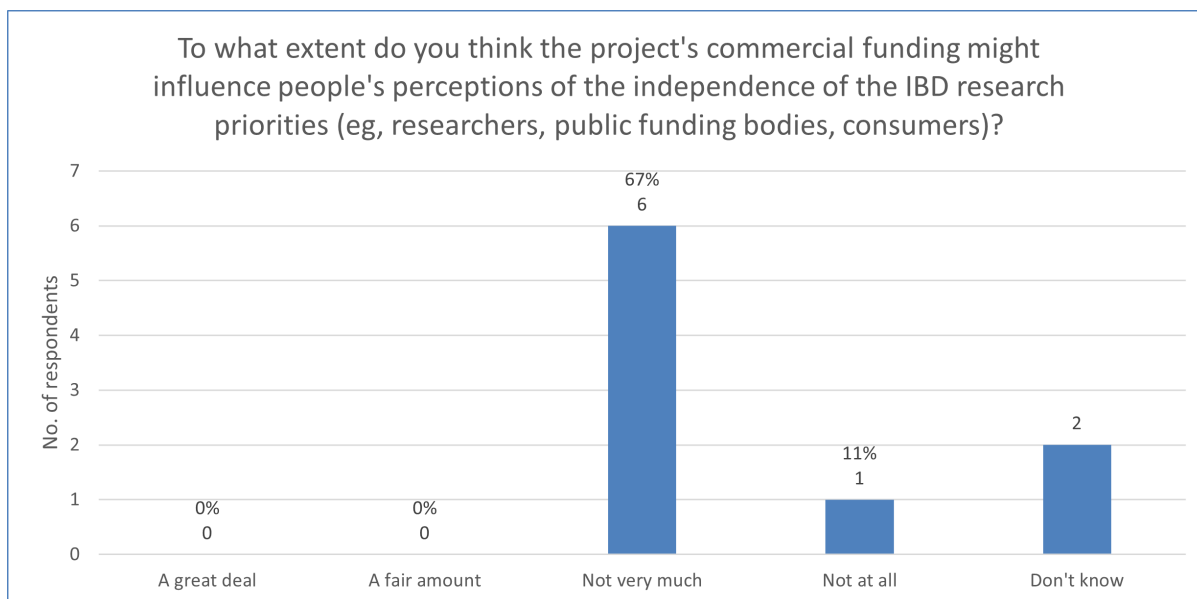
- *The scope and focus of the project*
- *The decisions made by the Steering Group*
- *The way the project engaged with consumers and healthcare professionals (including through surveys and the workshop)*
- *The final selection of the Top 10 research priorities.”*

Overwhelmingly, respondents felt that the source of funding had made no difference to any of the stages involved in the project.

Steering Group members were also asked:

“To what extent do you think the project’s commercial funding might influence people’s perceptions of the IBD research priorities (e.g., researchers, public funding bodies, consumers)?”

Of the nine respondents, six answered 'not very much', one answered 'not at all' while two answered 'don't know'.



Two respondents provided additional comments:

“It needs to be made clear in the publicity and roll out of findings that the Pharma were completely removed from any influence on the project.”

“I feel sometimes consumers may not understand the rules around commercial funding and the rules around their input (or lack of).”

Generally, feedback from the Steering Group about the priority setting process was positive. Of the nine who responded, all either strongly agreed or agreed that:

- This process was effective in helping to identify and agree the Top 10 priorities
- The process was fair and independent
- There was equal participation between patients, carers and clinicians.

In addition, all the respondents said that they would recommend the JLA priority setting process to others, providing comments such as:

- *“Highly professional. Organisers great facilitators. Sound process.”*
- *“Consumer-led research is a priority of our funding bodies.”*
- *“It was a very involved, but clear and logical path to find research priorities for all involved and I think very valuable for IBD. I am interested on how the data will be used to attract IBD funding and improve research in the area.”*
- *“It was very interesting and informative.”*
- *“JLA priority setting was a very clear & focused process.”*
- *“consumer involvement in the health sector is critical to improve outcomes for people living with chronic conditions. The JLA process underpins the trusted relationship between clinician and patient, ensuring balanced interactions and that the voice of both is heard, listened to and contributes to collective decision making. In summary, the collective wisdom of the IBD community within the health sector was captured via a rigorous process and produced consensus agreement of the top 10 research*

priorities leaving everyone feeling satisfied with the outcome and proud of their contribution to the project.

Feedback from workshop participants

As with any typical JLA PSP, the final stage of the priority setting exercise was a priority setting workshop to agree the final Top 10 list of priorities. The IBD priority setting exercise final workshop took place in February 2022. The workshop was attended by 12 patients/carers and 11 healthcare professionals.

Seventeen questions were taken to the workshop for discussion and prioritisation. At the start of the workshop, participants were made aware of the source of funding for the priority setting work during two presentations – one from Katherine Cowan about the JLA process, and one from Leanne Raven, CEO of Crohn's & Colitis Australia, about the background to the project. The workshop followed the usual methodology for a JLA PSP priority setting workshop, which involved a mix of plenary and small group discussions. It was held online, chaired by Senior JLA Adviser Katherine Cowan, supported by three other JLA Advisers, so that four breakout groups could be facilitated. The workshop culminated in a priority list of questions for research for IBD.

As with typical JLA PSP workshops, attendees were sent a questionnaire afterwards seeking feedback on their reflections of the order of priority of the questions (which would not change the order agreed at the workshop but may provide the organising team with extra insight into the discussions which happened and the decisions which were made), as well as the workshop preparation and process.

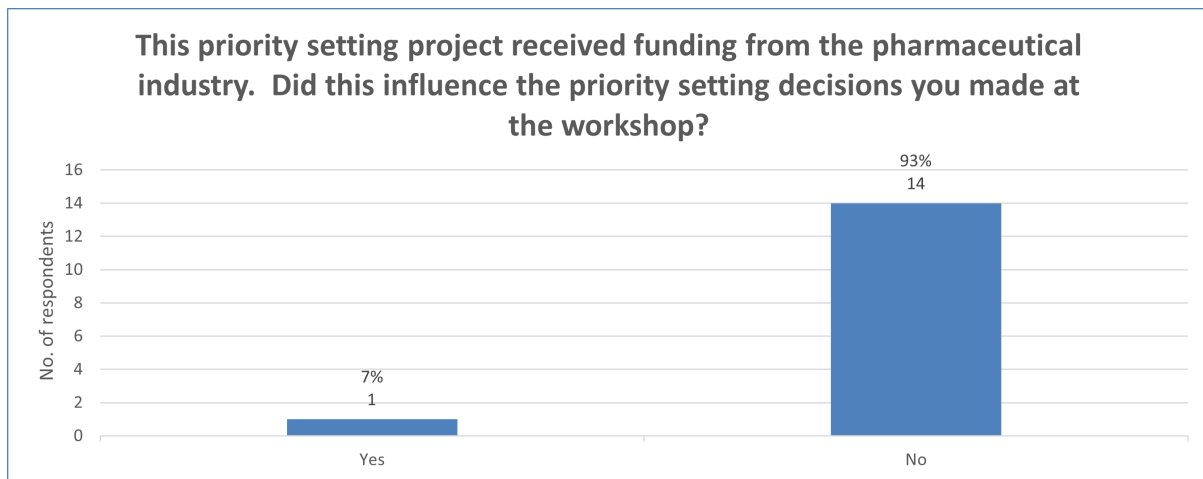
18 of the 23 attendees responded.

- 10 individuals living with IBD
- 2 carers/relatives
- 6 healthcare professionals.

In addition to the standard JLA questions described above, participants were also asked for their views on the funding of the exercise and whether they felt it had influenced the decisions made:

“This priority setting project received funding from the pharmaceutical industry. Did this influence the priority setting decisions you made at the workshop?”

Of the 15 responses, 14 suggested that the funding did not have an influence.



Eight respondents provided further comments:

“I wasn’t aware of this funding - now I recall it being said but it in no way did it influence anything I said.”

“Doesn’t matter where the funding comes from it’s about what’s going to help the most moving forward whether it is pharmaceutical stuff or not.”

“There appeared to be very little obvious influence from this funding body.”

“I have strong opinions about some of the medication I have tried, this does not however give me strong opinions about the pharmaceutical industry. The facilitation was really well done, the process impartial and then funding is funding - get as much as you can from wherever you can.”

“It matters little where the money comes from to fund such an event; rather more important that the participants are aware of the reason they themselves are there. Be it government money; big pharma or private non-named sources; what really matters is that the information is handled in a manner to answer by quality research- in this case re IBD - the problems deemed paramount. Once the results, hence information is publicly released; if one is being realistic, we should be thankful on behalf of all sufferers of IBD that someone had the fortitude to put their hands in pockets.”

“As a HCP I am fully aware of the absolute necessity of industry support to fill the void of government/grant/philanthropic support to achieve progress for the IBD community. In this case there was no industry promotion, product naming or product advocacy. Nor was there payment direct or in kind so I am completely satisfied that the process was free of industry influence”.

“I felt that it was actually good to have pharmaceutical industry support, and that the questions would be taken quite seriously and potentially get more attention/funding. I liked that other than supporting it they were not included in the process - great to know they too want to hear directly from patients and healthcare professionals. I do worry that they may focus on later funding only research on the questions that relate to the pharmaceutical industry though, but ultimately the questions that were prioritised reflect a wide range. I think funding the priority setting workshop and actually finding the most important questions from stakeholders to influence research is more important than any concerns that only pharmaceutical type questions will be answered.”

“I did not know and if I did, it would not have changed my input.”

Discussion

The Inflammatory Bowel Disease (Australia) priority setting exercise in association with the JLA was the first exercise to work with the JLA to use an unrestricted fund from the pharmaceutical industry. This report describes what took place and there are many questions for consideration by JLA stakeholders.

Feedback from those leading the project and those participating in the workshop suggests that the source of funding made little difference to the outcomes of the exercise, that the interests of commercial organisations were very unlikely to have influenced the results and that the priority setting exercise delivered a transparent, fair and robust output that is likely to be credible for the community of interest. However, it is likely that more time is needed to evaluate any effect of commercial funding on the process and outcomes of the exercise. The context in which the priorities were set is likely to be important and if the JLA was to support another JLA Lab priority setting exercise to test funding from commercial sources, for example in the UK, the outcomes and discussion may be very different.

Monitoring of any effect of commercial funding is likely to be a long-term exercise and the JLA may need to review the impacts of this exercise after a period of time, when the funded research and other impacts of the priority setting work can be seen more clearly.

Overall, the JLA reiterates its commitment to JLA PSPs and the principles. This priority setting activity was not described as a JLA PSP but an alternative activity which supports our community and tests a different approach. The JLA has endeavoured to ensure that this test has not affected or undermined any standard JLA PSP, and it recognises that one potential outcome from this exercise is that it could confirm that the JLA should not engage in priority setting activity that draws on commercial funding. The JLA would only consider making changes to core principles following consultation with the wider JLA stakeholder community, including the JLA Advisory Group and wider public consultation.

We welcome feedback from the JLA community on these discussion points and any other factors that the JLA might consider in terms of the involvement of commercial funding to support priority setting exercises. As it stands, the JLA principle of prohibiting commercial funding of PSPs still stands but the JLA will be happy to consider opportunities to explore this principle further.