



**Australian
Clinical
Trials
Alliance**

**Research Prioritisation
Survey Report:
Approaches and
attitudes to clinical
trial prioritisation in
Australian Clinical
Trial Networks and
Coordinating Centres**

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DISCLAIMER

The information in this document is for general guidance only. ACTA does not make any representations or warranties (expressed or implied) as to the accuracy, currency or authenticity of the information provided.

ABBREVIATIONS

ACTA	Australian Clinical Trials Alliance
CTN	Clinical Trial Network
JLA	James Lind Alliance
CHNRI	Child Health and Nutrition Research Initiative
COHRED	Council on Health Research for Development
ENHR	Essential National Health Research

EXECUTIVE SUMMARY

The ACTA Research Prioritisation Reference Group conducted a survey of ACTA's member organisations (Clinical Trial Networks and Coordinating Centres) in 2018 to understand the current approaches and practices around research prioritisation.

The aim of this survey was to identify methods, principles, criteria and tools that are currently used by Clinical Trial Networks (CTNs) in Australia to prioritise research questions/areas. Findings from the survey will be used to perform a comparison of CTNs' current practices with best practice guidelines, and to determine implications for practice. The questionnaire for this consultation was developed from a review of the literature, and feedback from members of the reference group. It was pilot-tested before use.

The results from this survey indicate that a substantive proportion of CTNs and Coordinating Centres do not conduct research prioritisation. The key barriers to increasing the number of CTNs and Coordinating Centres undertaking prioritisation included resource-related issues (i.e., funding, capacity), and knowledge-related issues. Some form of guidance, and practical tools will enable the network to engage more actively in priority setting and contribute to increased adoption of best practice approaches across the sector to deliver high quality trials contributing to optimal health outcomes for patients.

Most responses were from groups that had completed research prioritisation exercises previously, and who were thus more likely to complete all the questions in the survey. There were, however, sufficient responses received for barriers to prioritisation and identifying needs from groups that did not conduct formal prioritisation, hence we believe the findings of the survey remain useful in developing guidance and practical tools to support CTNs and Coordinating Centres in future prioritisation activity.

BACKGROUND

Like many others, the clinical trials sector is an environment of finite resources. In this context, resources include the availability of funding, the time and resources available to support trials, and the capacity of the health system to integrate research into care. Priority setting processes can assist in selecting trials to be conducted, ensuring that those selected are aligned with the decision-making needs of health professionals, consumers and policy decision makers, and that the trials supported are sufficiently strong and likely to be successful.

There are many ways to approach priority setting for research, from large, formal processes engaging multiple stakeholders, such as those used by the James Lind Alliance, to smaller-scale, consensus meetings or surveys; and from qualitative appraisal of proposals to quantitative, data-driven assessments based on burden of disease or economic data. The model selected should be appropriate for both the purpose of the prioritisation process (e.g., to identify new areas for research or to appraise specific proposals), and to the time and resources available to support the process (e.g., funded development work or unfunded, ongoing assessment needs).

The Australian Clinical Trials Alliance (ACTA) is a peak body representing Clinical Trial Networks (CTNs) and Coordinating Centres in Australia. ACTA's members primarily support the conduct of investigator-initiated, multi-site clinical trials, across a variety of clinical specialties. While most focus their activities in Australia, some operate routinely across Australia and New Zealand, and some also support the Australian sites of international, multi-site trials. As part of ACTA's role in the sector, it is working to develop practical guidance to support CTNs and Coordinating Centres on a range of topics, including research prioritisation. To underpin the development of this guidance, several information-gathering projects have been conducted to map current practice in research priority setting and identify good practice guidance.

ACTA's Research Prioritisation Reference Group is comprised of multiple experts from the field principally work on developing best practice guidelines for research prioritisation of clinical trials conducted by CTNs.

This report describes one element of this information-gathering activity – a survey of ACTA's member organisations on their current practices and views on prioritisation.

METHODS

The objectives of this survey were to identify among Australian CTNs and Coordinating Centres their current research prioritisation practices, their values around factors of importance in prioritisation processes, and the barriers to conducting prioritisation.

A survey (see Appendix 1) was developed based on preliminary work by ACTA staff and Reference Group F, which outlined major prioritisation methodologies, values important to prioritisation, and criteria commonly used to evaluate candidate topics for prioritisation purposes. Groups who did not conduct formal prioritisation were invited to express opinions on processes they may conduct in the future. The survey was piloted by two CTNs before being made available to the wider group.

An invitation to participate in the survey was sent to all CTNs and Coordinating Centres who were current members of ACTA in October 2018, and for whom current contact details were available ($n = 44$, including the two groups approached during the pilot phase, who were not contacted again). Contact was made via an email to the named contact person provided to ACTA for membership purposes. The email invitation included a survey link (through SurveyMonkey), and a request to either complete the survey directly, or redirect to the most appropriate person at the CTN or Coordinating Centre to complete. Participants were advised that responses would be kept confidential and providing a name and contact details was optional for those participants willing to be contacted for further information about their prioritisation work. Members were given three weeks to complete the survey and were sent one email reminder in the final week.

Responses to all questions asked (excluding contact information) are summarised in the Results section. Where appropriate, responses are summarised as percentages of the total number of survey respondents. Participants who did not respond to the survey were excluded from the analyses. Participants who answered some, though not all, questions, were included in the analyses, but treated as a separate response category. The only exception is responses to questions restricted to specific respondents (i.e., a 'no' response limiting further exploration in a follow-up question), in which case the number of respondents eligible for the question was taken as the total. For most questions participants could select multiple options. Results are presented as reported by the participants, and no analyses to identify associations or subgroup effects were undertaken.

RESULTS

Twenty-five responses were received (from the pool of 44 invited), including the initial pilot responses, and one response received after the submission deadline (57% response rate).

CONDUCT OF FORMAL PRIORITISATION

From the respondents 60% ($n = 15$) reported that their CTN or Coordinating Centre have a formal process for research for prioritisation, and 40% ($n = 10$) did not. All participants responded to this question.

Of those participants who did not conduct formal prioritisation, six responded to identify the reasons (see Figure 1). The reasons provided varied, but the most frequent responses included a lack of capacity/time, lack of knowledge of prioritisation tools and criteria, and lack of funding/resources to conduct prioritisation. Responses in the 'other' category included one group for whom prioritisation was not necessary, as each research proposal before the group was assessed on its merits, and this was manageable within current resources. Another group responded that the group conducted peer-led prioritisation of proposals received. Further details were not provided.

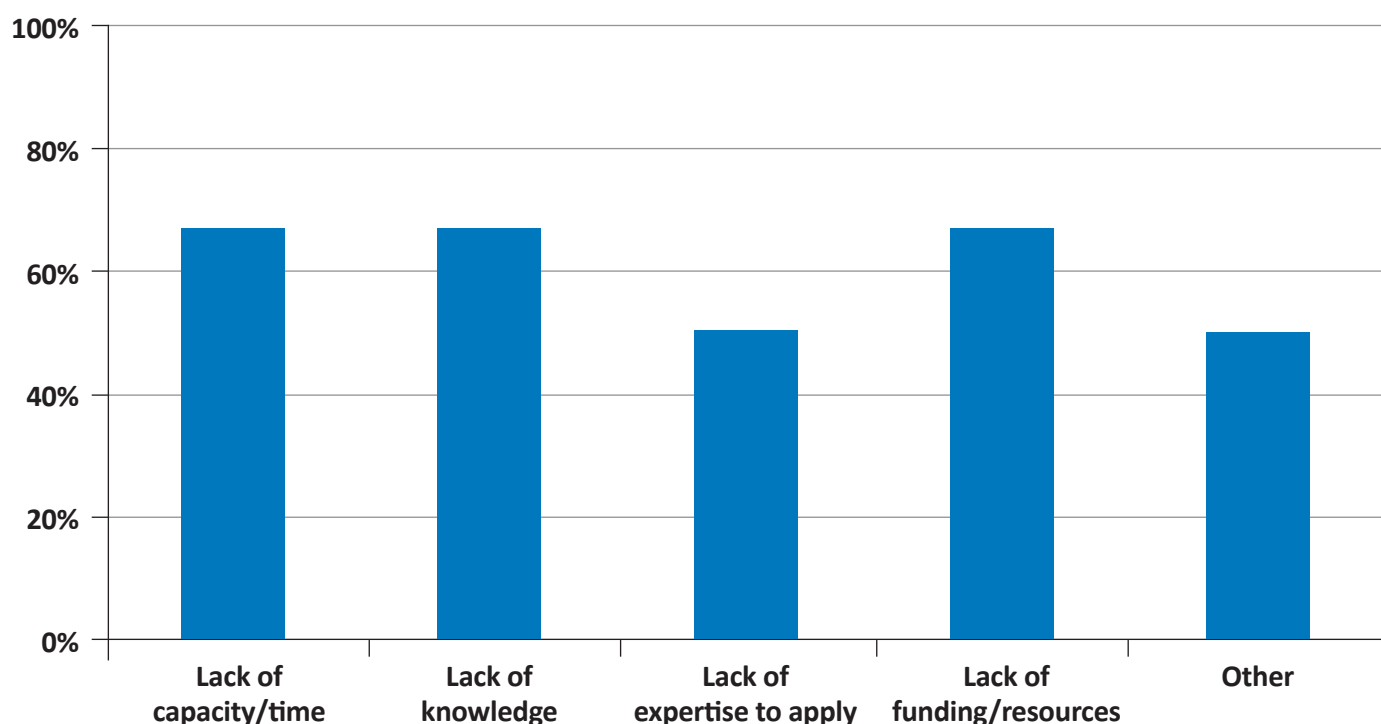


Figure 1: What are the reasons you do not formally prioritise research? ($n = 6$)

METHODS USED FOR PRIORITISATION

Respondents reported using a range of different methodologies (or considering using them in future), although the range of methodologies named was diverse. Most of the participants ($n = 18$, 72%) responded to this question. Of the options presented in the question, the largest group ($n = 5$, 28%) reporting using the James Lind Alliance (<http://www.jla.nihr.ac.uk/>) methodology, which may indicate that they used the methodology themselves, or had used the outcomes of a process conducted elsewhere (e.g., in the UK where this originated). Smaller numbers reported using the Essential National Health Research (ENHR) ($n = 3$, 17%), and Combined Approach Matrix (3D-CAM) ($n = 1$, 6%,) methods. None reported using the Child Health and Nutrition Research Initiative (CHNRI), or Council on Health Research for Development (COHRED) methodology.

Most respondents ($n = 14$, 78%,) reported using other types of methodologies. These responses included two (11%) national or international collaborations with stakeholders, one survey of clinicians, one Delphi survey (with unspecified participants), one had not used any methodology (but was considering options), and two were unsure. Six (33%) used internal advisory or scientific committees to assess proposals to the CTN for endorsement (one supported by a survey of CTN members, and one supported by a publication mapping exercise), making this the most frequently used methodology overall. One participant provided a link to an academic publication describing a formal prioritisation process.

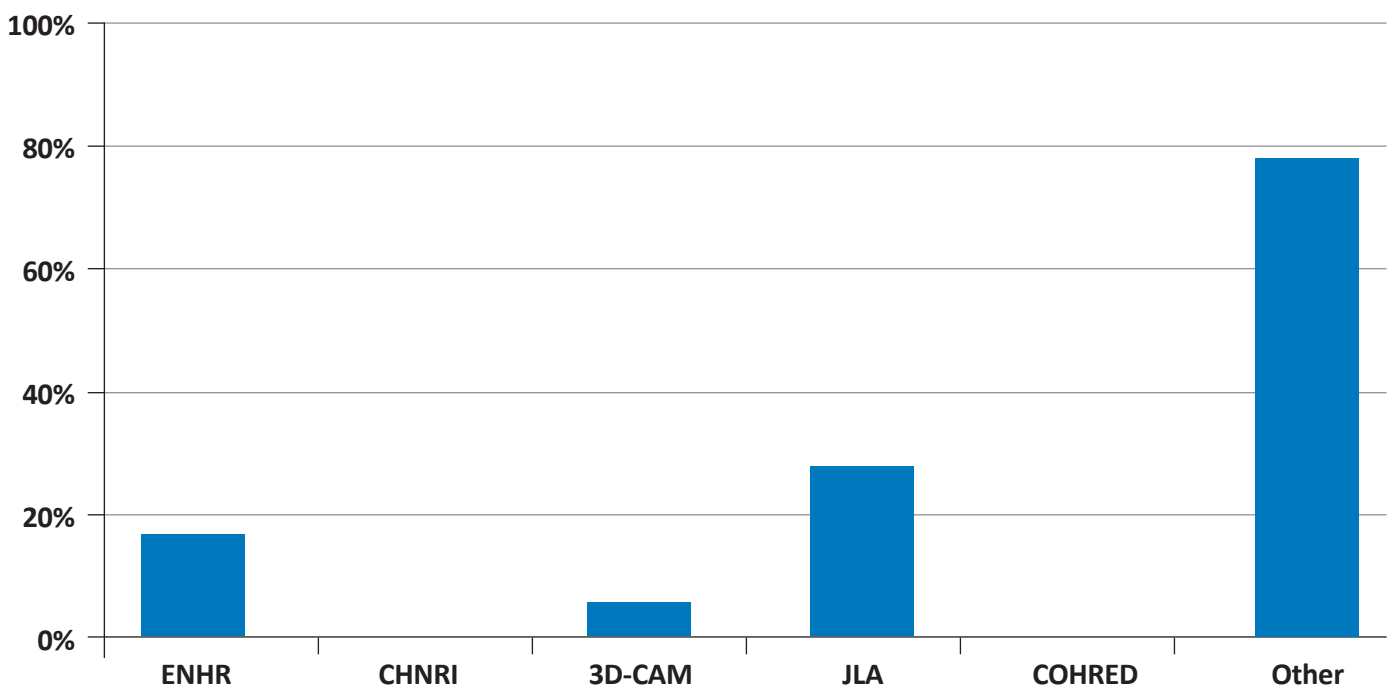


Figure 2: Which methods for prioritisation has your Network or Centre used (or would you consider using in future)? ($n = 18$)

PRINCIPLES OF PRIORITISATION

Prior to the development of the survey, the ACTA Reference Group had identified several principles commonly held to be important in prioritisation processes, and sought to validate these principles for use in guiding future recommendations from ACTA. Over two thirds (68%) of participants ($n = 17$) responded to the question on principles they consider important in any prioritisation exercise.

All respondents agreed that prioritisation processes should be clear, defensible and fit-for-purpose/realistic (i.e. appropriate to their aims). Almost all participants ($n = 16$, 94%) agreed that processes should be equitable, inclusive and pragmatic/manageable within the resources available. Most participants ($n = 15$, 88 %) agreed that processes should be transparent, robust, acceptable to stakeholders, accountable (including procedural fairness), and contributing to a self-improving cycle in response to feedback and outcomes achieved.

A third of respondents ($n = 6$, 35%) suggested other principles, although in fact these did not add new principles to the list. Three participants (18%) emphasised the feasibility of the process (which would be coded as 'pragmatic/manageable' in the principles framework), one (6%) emphasised that the process should be self-improving, and four (14%) emphasised that the process should give weight to the appropriate selection criteria, which is addressed as a separate question below.

No respondents provided a reason for their decision to not support one or more of the principles.

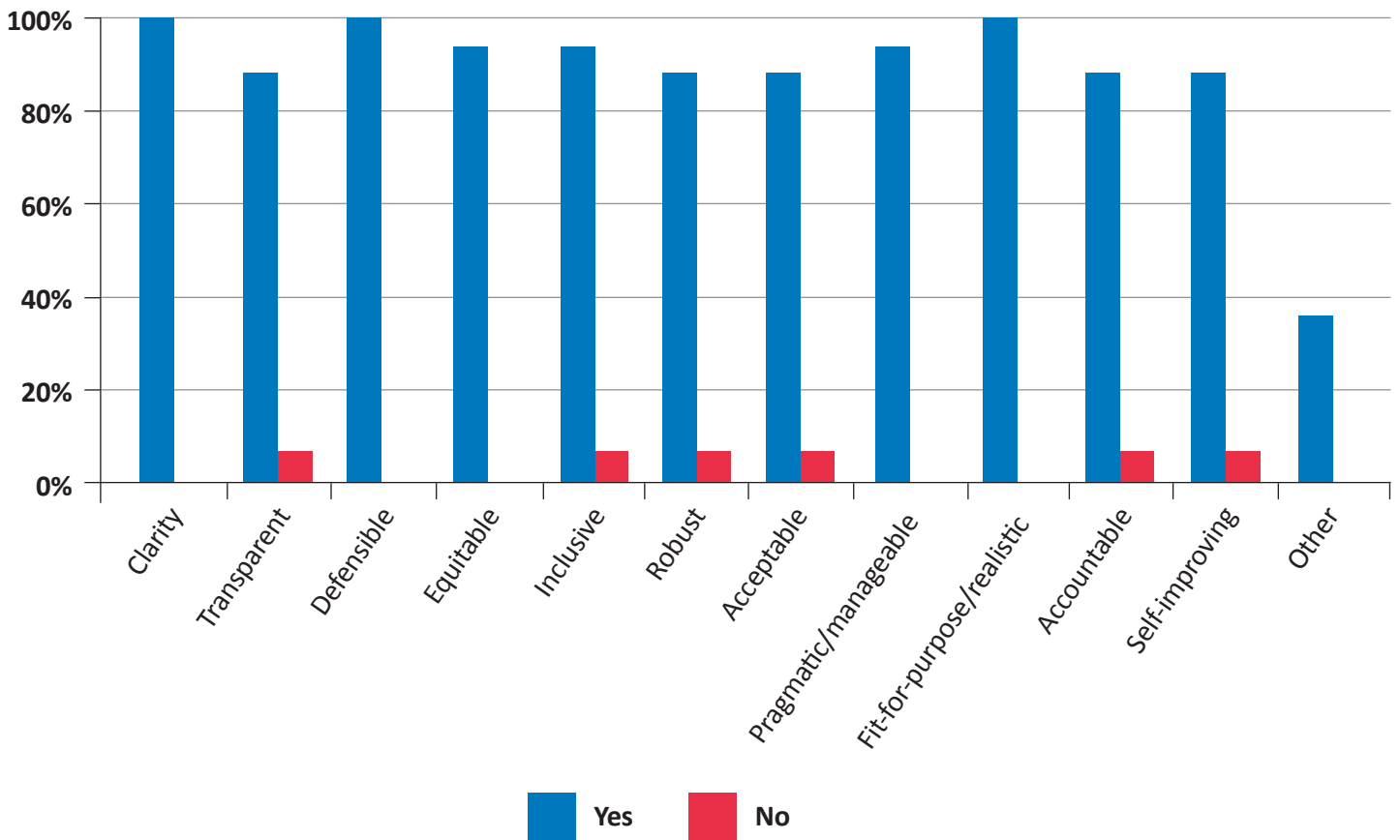


Figure 3: Which of these principles would you consider important in any prioritisation exercise? ($n = 17$)

CRITERIA FOR PRIORITISATION

Participants were presented with a range of criteria commonly used in prioritisation exercises to weight or rank topics or research proposals, and asked to identify whether they agreed these should be used in priority setting for clinical trials. Over two thirds of participants ($n = 17$, 68%) responded to this question.

All respondents agreed that the impact or significance of the research question, and the feasibility of the proposed study, should be used in priority setting. Almost all the participants ($n = 16$, 94%) agreed that burden of disease, knowledge gaps from reviews of the literature, the scientific rigour of the study design, innovation, the quality and capability of the research team, and alignment with issues of importance to end-users should inform prioritisation. Most ($n = 15$, 88%) agreed that alignment with national or organisational priorities, ethical/moral considerations, and whether the research represents value for money should also be considered. A large portion 76% ($n = 13$, 76%) agreed that whether the research would lead to capacity building in the health system, should be considered.

A small portion of participants ($n = 5$, 29%) identified other criteria that should be considered, including studies where there is a lack of existing reimbursable treatments for the condition (i.e., the study presents novel treatments for patients with few options), whether there are competing studies in the same space, and formal economic assessments including the value of information and return on investment. Other respondents used this question as an opportunity to note that value for money was difficult to assess, and that fundamental questions remained of importance even where the level of innovation was low.

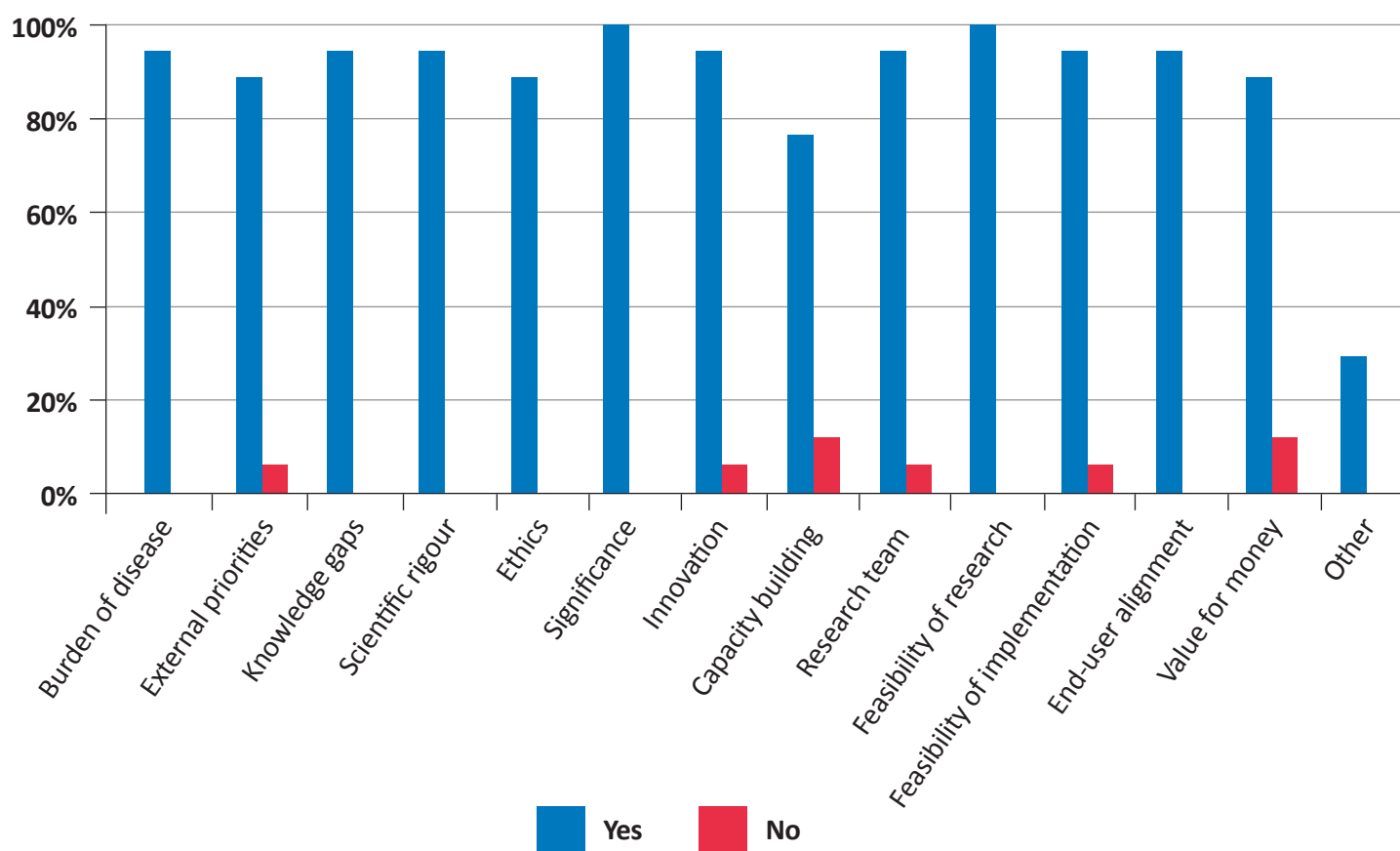


Figure 4: Which criteria would you consider important in prioritising research? ($n = 17$)

CTNs and Coordinating Centres were also invited to name additional external factors that influence their decision making about trials. Almost half of the participants ($n = 12$, 48%) responded to this question. Of these, 75% ($n = 9$) reported that the availability or likelihood of funding influenced their decisions, as a critical gatekeeping factor even before the highest priority trial could proceed. A third of these ($n = 3$, 25%) noted the impact on health service providers as important, both in the capacity to support the trial and the impact on their service delivery. One participant reported that projected research timelines, the level of interest in a proposal, conflict of interest and stakeholder consultation (including researcher and consumer networks), also influenced their decision making.

ASSISTANCE WITH PRIORITISATION

Participants were asked to identify any tools, or forms of guidance, that they would find useful to support their prioritisation activities. Just under two thirds of participants ($n = 15$, 60%) responded to this question. Of these, ($n = 12$, 80%) most agreed that a self-assessment checklist outlining issues to consider when planning prioritisation would be helpful. Almost three quarters ($n = 11$, 73%) agreed that they would find a detailed best practice guide and case studies of successful prioritisation helpful. Just over half ($n = 8$, 53%) would find a discussion paper on different priority setting methodologies helpful. Mentoring from other groups who had more experience in prioritisation was identified potentially helpful by 40% ($n = 6$).

Other forms of support identified as potentially helpful by 27% ($n = 4$), included guidance on how to involve consumers in priority setting processes ($n = 1$), or an online repository of practical tools (similar to the EQUATOR Network, $n = 1$). One respondent noted that tools would be useful to train research members of the CTN to enable them to drive future priority setting activities. One respondent reported that it would be unlikely that further guidance would change their approach, although the resources may be useful as a learning resources for staff.

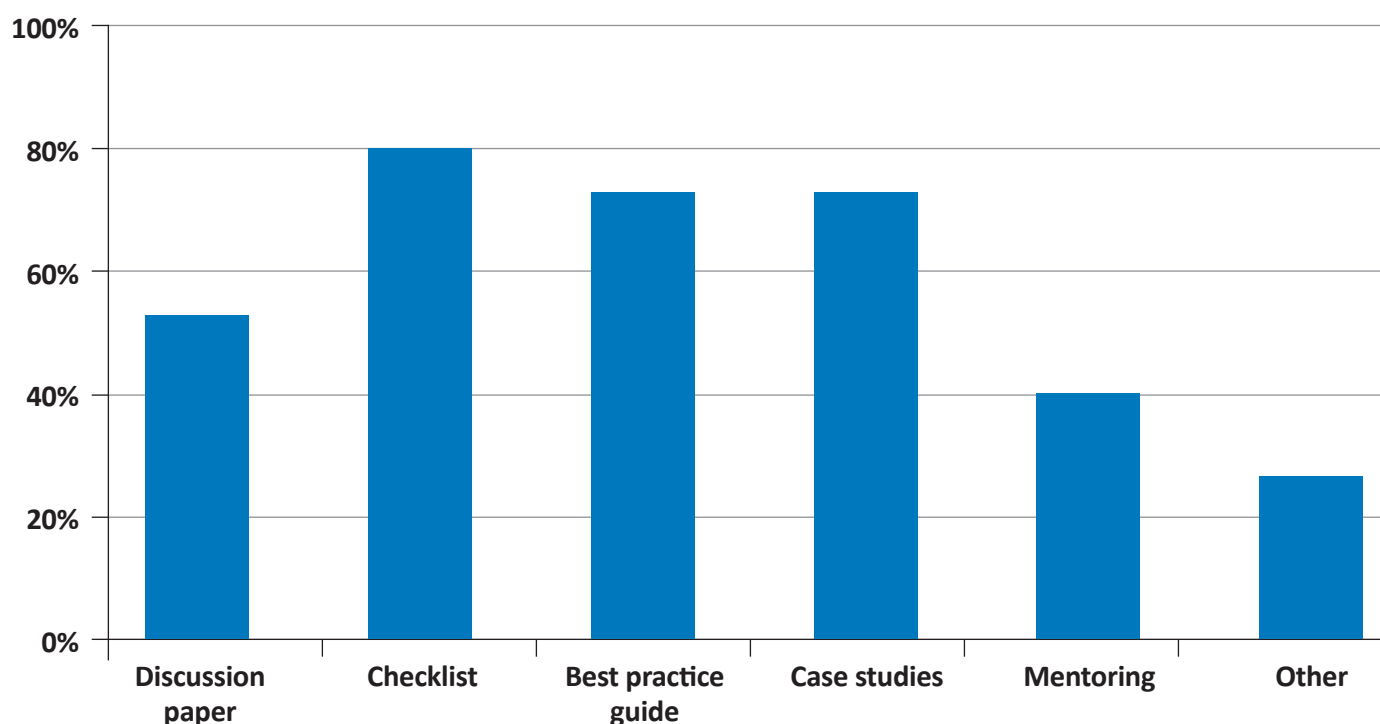


Figure 5: What practical tools would you find useful to assist prioritisation? ($n = 15$)

Finally, in response to an open-ended question seeking further comments by participants, one respondent noted that infrastructure mechanisms to enable priority setting projects would be of practical help, such as pathways to contact consumer organisations, mechanisms to collect and analyse data, a mechanism to disseminate surveys to appropriate groups, etc. One respondent noted that their group used a structured checklist to assess proposals, although this was not used for comparative priority setting or ranking.

DISCUSSION

SUMMARY OF KEY FINDINGS

The results of the survey indicate that while many CTNs and Coordinating Centres do conduct prioritisation of some kind, a substantive proportion do not. The key barriers to increasing the number of CTNs and Coordinating Centres undertaking prioritisation include resource-related issues (i.e., funding, capacity), and knowledge-related issues. As most CTNs and Coordinating Centres do not receive core infrastructure funding in Australia, this may limit the extent to which unfunded work such as prioritisation can occur, but guidance on practical and feasible approaches to prioritisation with limited resources may be of assistance. Knowledge-related issues around approaches to prioritisation and their practical implementation can also be addressed by future guidance tools or professional development opportunities (e.g., training or mentoring).

The methods used by each group in prioritisation are diverse, with no methodology dominant across the sector. Few respondents used large, comprehensive methodologies such as those designed by the James Lind Alliance, and there were a range of less formal consultations and survey methods used. The most frequent process used was a scientific or advisory committee, which was used to review submitted proposals, and may or may not be supported by broader literature reviews or surveys to identify gaps in the existing research.

There was broad (although not complete) agreement on the principles proposed as the basis for good prioritisation processes, and the criteria to be used for prioritisation, among those who responded to this question, which is unsurprising as many of the principles proposed are well-established and applicable to many research and decision-making processes. Some groups used a smaller number of criteria and a more limited overall process for prioritisation – assessing each proposed new trial on its scientific merits, rather than selecting among multiple competing options. This may reflect a low overall volume of trials in some areas, and the role the CTN or Coordinating Centre sees for itself. The comments gathered also indicated that practical support may assist groups to incorporate factors they are not currently considering.

STRENGTHS AND LIMITATIONS OF THE SURVEY

The sample size provides a small number of specific examples of CTN activity. These results of this survey will be supplemented by a literature review to identify current international practice in prioritisation relevant to clinical trials.

Participants might not have interpreted 'formal' research priority setting in the same manner across the board, and some may have considered their approaches as 'formal'. Future descriptors should include a definition of what a formal research priority setting approach incorporates. The framing of the questions around criteria may have prompted participants to name a broad range of criteria as relevant to prioritisation, but did not enable them to rank these criteria in order of importance or identify whether all criteria would in practice be incorporated into a single prioritisation exercise.

It is possible that the majority of responses were from groups that had completed prioritisation exercises, and those groups were also more likely to complete all the questions in the survey. However, enough responses were received from groups that did not conduct formal prioritisation, and sufficient responses were received on barriers to prioritisation and identifying needs, that we believe the findings of the survey remain useful in developing guidance and practical tools to support CTNs and Coordinating Centres in future prioritisation activity.

CONCLUSIONS

Although different CTNs and Coordinating Centres are not all engaged in formal priority setting processes, there is broad agreement on the principles and criteria that are relevant for use in priority setting for clinical trials. Those that are engaged in priority setting use a variety of methods, some more comprehensive than others.

The additional consideration of external factors, such as funding and the health service delivery context, represents an important additional dimension to be overlaid over the prioritisation criteria, reminding us that the practicalities of implementation within a broader context must be incorporated in any decision about which trials to conduct.

The results from the survey indicate that practical support for priority setting would be welcomed by CTNs and Coordinating Centres. This could include guidance, worked case studies and practical tools to enable them to engage more actively in priority setting. This may also contribute to increased adoption of best practice approaches across the sector to deliver high quality trials contributing to optimal health outcomes for patients.

APPENDIX 1

RESEARCH PRIORITISATION SURVEY QUESTIONS

This is a short survey on research prioritisation from the Australian Clinical Trials Alliance (ACTA). The survey has been put together to help us understand how CTNs and Coordinating Centres are thinking about research prioritisation, and which approaches you may be taking.

It doesn't matter if you are not currently prioritising research topics: we are also seeking feedback on principles for research prioritisation, what criteria you consider important, what a prioritisation framework should look like, and what tools might find useful.

Research prioritisation is one of ACTA's key activity areas this year. Our goal is to share good practice and develop practical guidance for CTNs and Coordinating Centres who wish to identify high priority research questions and use those priorities to inform the trials they support. A reference group has been established with broad representation from the sector to help inform this work.

As part of this work, we are now seeking your input. Any information you choose to provide will be used by members of the reference group and ACTA staff to inform the development of guidance. Your information will be treated confidentially. Any information included in documents for publication will be deidentified. If we wish to make any identifiable information publicly available, we will seek your explicit consent.

Thank you in advance for your participation. If you have any additional feedback about the design or conduct of the survey, please e-mail acta@cinicaltrialsalliance.org.au.

Question 1: Does your Network or Centre have a formal process for research prioritisation? Yes No
If 'Yes', please go to Q3.

Question 2: If 'No' to Q1, what are the reasons you do not formally prioritise research within your CTN?
Please tick all that apply.

- lack of capacity
- lack of knowledge about tools and criteria
- lack of technical expertise in applying these methods
- not considered a CTN priority at the moment, for reasons other than 1-3
- Other (please describe):

Question 3: If 'Yes' to Q1, can you describe the methodology used? If 'No', have you considered which methods you might use for future prioritisation activities? Please describe in as much detail as possible, or provide a link to a published paper or methodology:

- Essential National Health Research
- Child Health and Nutrition Research Initiative
- 3D-CAM: Combined Approach Matrix
- James Lind Alliance
- COHRED: Council on Health Research for Development
- Other (please describe):

Question 4: The ACTA reference group is developing a Principles Framework to guide research prioritisation. Below is a list of that could be included in this framework. Would you consider these principles important to your organisation if you were to prioritise research?

1. **Clarity:** clear definition of principles, purpose, and outcomes sought. Yes No
2. **Transparency:** process and governance arrangements are published in a public space. Yes No
3. **Defensible:** sound decision making; and transparent evaluation criteria. Yes No
4. **Equitable:** process and outcomes are fair; and decision making takes into account groups with greater unmet need. Yes No
5. **Inclusive:** identifies and includes all stakeholders and end users of research. Yes No
6. **Robust:** robust process and governance arrangements. Yes No
7. **Acceptable:** partners and stakeholders regard the process as satisfactory. Yes No
8. **Pragmatic/manageable:** process and governance are appropriate to the resources available. Yes No
9. **Fit-for-purpose/realistic:** methods have a reasonable chance of achieving their objectives. Yes No
10. **Accountable:** procedural fairness, decisions are published, and there is an appeals process. Yes No
11. **Self-improving:** a continuous, cyclical process, improved over time based on feedback and data. Yes No
12. **Other** (please specify):

Question 5: If 'No' to any or all of the principles in Q4, could you please provide a brief summary of why they are not relevant.

Question 6: This question is focussing on the criteria that could be used to prioritise research within your Network or Centre. In addition to criteria for prioritisation, you may wish to consider criteria for endorsement of trial.

- | | | | | |
|--|--------------------------|-----|--------------------------|----|
| 1. Burden of disease | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 2. Alignment with national/organisational priorities | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 3. Knowledge gaps from formal literature | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 4. The scientific rigor of the study design | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 5. Any ethical/moral considerations raised by researchers or research end-users | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 6. The impact or significance of the research outcomes | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 7. Whether the research will lead to innovation in the health system | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 8. Whether the research has the potential to build health system capacity | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 9. The quality and capability of the research team | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 10. The feasibility of implementing the output of research in the health system | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 11. Alignment with questions of importance to research end-users (including health policy makers, health system decision makers, health practitioners and the community) | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 12. Whether the research represents value for money (where the expected benefits outweigh the cost) | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| 13. Other (please specify): | | | | |

Question 7: Are there any external factors that influence your priorities, prioritisation processes or criteria (e.g., priorities or policies of local institutions, funders, collaborating institutions, etc.). Please provide a brief summary.

Question 8: What practical tools would you find useful to assist you prioritise? Please select all that are relevant.

- A discussion paper on relevant models of prioritisation
- A checklist for self-assessment: things to consider when planning a prioritisation process
- A detailed best practice guide to prioritisation
- Case studies of good practice prioritisation exercises
- Mentoring relationships with CTNs or other organisations who have conducted prioritisation exercises
- Other (please specify):

Question 9: Is there anything else you would like to tell us about the issues raised in this survey?

Question 10: Your Network or Centre has conducted a formal prioritisation process, would you be willing to provide the name of an individual in your group to participate in a short teleconference or videoconference (duration estimated at 30 mins) to allow us to ask further questions regarding your prioritisation processes?

Organisation:

Name:

Position:

Telephone:

Email:



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