Australian Clinical Trials Alliance

Research Prioritisation Framework

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THE PURPOSE OF THIS DOCUMENT

This document will assist Clinical Trial Networks (CTNs) and other organisations who are interested in setting priorities for the conduct of clinical trials (e.g., Australian Government, funding organisations).

ACKNOWLEDGEMENTS

This document was developed by A/Prof Haitham Tuffaha, with input from Prof Rachael Morton, Anitha Balagurunathan, Miranda Cumpston, and ACTA's Reference Group on Tools for Research Prioritisation (see Appendix A). The guidance included draws on a range of resources, including the framework developed by Nasser and colleagues (Nasser 2013), as well as a review of prioritisation methodologies by Tuffaha and colleagues (Tuffaha etal 2018), a survey of Australian Clinical Trials Networks and Coordinating Centres, and a pragmatic review of current practice in prioritisation for clinical trials.

We acknowledge the contributions of ACTA CTN members and members of ACTA's Tools for Research Prioritisation Reference Group in the preparation, development and review of this document.

USE OF THIS DOCUMENT

ACTA requests that the following acknowledgement is included in any CTN operational processes that are developed and documented using knowledge gained from this document. This will assist ACTA in identifying the usefulness and impact of this document in creating efficient and effective processes for CTNs.

> *"[Name of CTN] acknowledges the contribution of ACTA to the development of operational processes within our network (reference: Research Prioritisation Framework)."*

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 Trials Network
WHO	World Health Organisation
AKTN	Australasian Kidney Trials Network
ANZMUSC	Australia & New Zealand Musculoskeletal Clinical Trials Network
COHRED	Council on Health Research for Development
MCDA	Multiple criteria decision analysis

INTRODUCTION

Clinical trials are conducted in an environment of limited resources – whether that be the allocation of funding, the dedication of staff time and infrastructure, or the capacity of the health system to recruit participants. With that in mind, it is important to ensure that resources and capacity are directed to trials that answer questions of importance to stakeholders, and that represent the best possible investment.

Prioritisation can be reflected in a number of different activities: consultation processes generate topics of interest or specific proposals for further research; funders rank and weight specific research proposals to allocate limited funding; and Clinical Trials Networks (CTNs) assess trial proposals to meet minimum standards for endorsement and support by the CTN community of trialists.

While some CTNs already undertake large-scale consultation and prioritisation activities (such as AKTN, ANZMUSC and others), many do not. There are different reasons for this, and different approaches taken. Some CTNs review and endorse proposals as they come in, rather than setting priorities and directions, although criteria are used even in this context to identify trials of a minimum standard to proceed. Other CTNs would like to undertake priority setting, but may have limited resources to do so, or barriers in identifying and conducting an appropriate methodology.

This document by ACTA Reference Group F, (Tools for Research Prioritisation), provides a practical guide and good practice framework for CTNs and other organisations interested in setting priorities for the conduct of clinical trials (e.g., Australian Government, funding organisations). The guide provides a general framework that can be adapted and applied flexibly to a variety of activities, depending on the situation and objectives of the particular organisation.

The aim of this Framework is to enable CTNs to think through their objectives and options, and to consider adding appropriate good practice strategies to their priority setting and selection processes.

A GOOD PRACTICE FRAMEWORK

The framework outlined in this document (see Figure 1) is intended as a continuous cycle to guide the planning, conduct and evaluation of clinical trials. The start and end points of the process may depend on the scope and priorities of the specific exercise. Some steps may be skipped (e.g., in selection process that aim to prioritise among existing worked-up proposals and do not require the topic generation stage, or where priorities of funders guide the selection of topics), and some steps may be revisited iteratively as the process proceeds (e.g., stakeholders such as consumers may be engaged in the definition of criteria, the generation of topics and the selection of proposals, and separate weighting and scoring systems may be appropriate for topics compared to fully worked-up proposals).

Over time, organisations will find themselves at different stages of the process, and the priorities identified should be reviewed and refreshed periodically.

The framework outlines ten steps or stages in a priority setting exercise:

1. Form a leadership team
2. Develop scope and objectives
3. Identify and engage stakeholders
4. Develop selection criteria
5. Develop methods to weight and score criteria
6. Identify research topics
7. Select topics
8. Generate research proposals
9. Select proposals
10. Conclude and evaluate.

Further discussion relating to each stage of the framework is included in this guide. The framework primarily draws on that outlined by Nasser and colleagues (Nasser, 2013), but additional sources are cited where appropriate.

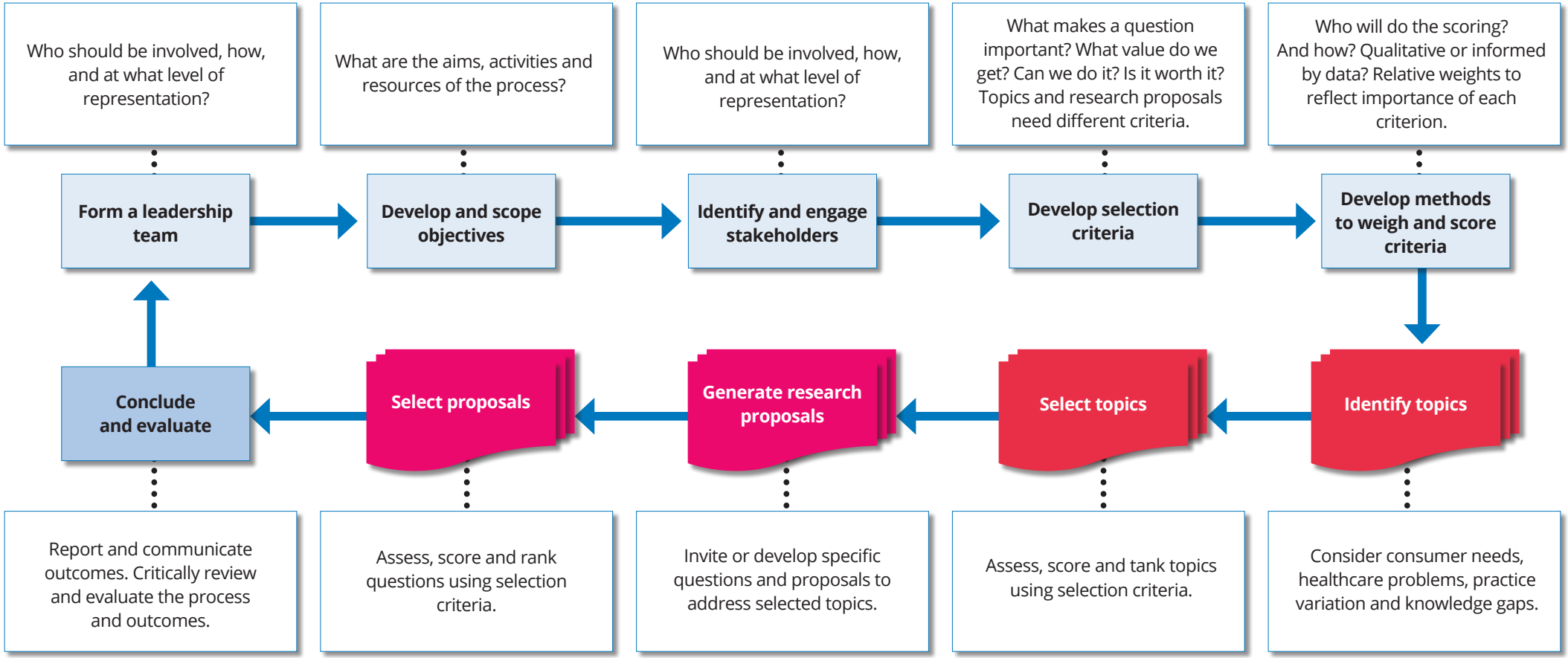

Figure 1: Framework for clinical trial prioritisation. Adapted from Nasser, 2013, *J Clin Epi, 66*, 511–21.

1. FORM A LEADERSHIP TEAM

The process should begin with identifying an appropriate team to take leadership of, and responsibility for, the priority setting process. Leadership is needed to plan, engage with stakeholders, coordinate efforts, implement and disseminate recommendations and evaluate the process. This team should appropriately represent stakeholders, their interests and values, and should be acceptable to stakeholders, committed and capable.

For CTNs, the leadership team or working group will often be appointed by the Executive Committee, and may be established on a project basis, or as a standing subcommittee where priority setting, and assessment are intended to become ongoing activities of the organisation.

There are many ways to constitute the leadership team, and the structure, members and terms of reference should reflect the needs of the organisation. Consider the following:

- Include representation from researchers, trial managers, clinicians, consumers and other stakeholders (e.g., policy makers, funders).
- One group may be sufficient, or a small managing/working group may be supported by a larger advisory group. The balance of representation on each group could be the same, or the smaller group could include more 'technical' experts while the larger group includes a wider consultative group of stakeholders.
- Conflict of interest should be considered where members of the group may also be involved in the development of specific proposals to be considered during the process.
- Although the leadership team may make recommendations about final prioritised topics or selected proposals, final decision-making will usually rest with the formal leadership of the organisation, such as a CTN's Executive Committee. The decision-making process (including each of the steps in this framework) should be transparent and defensible, particularly where the allocation of resources is involved.

2. DEVELOP SCOPE AND OBJECTIVES

There are many different types of prioritisation exercise. Council on Health Research for Development (COHRED) advised in 2010 that, "there is no single best method for priority-setting, and therefore, the method for, and process of, priority-setting should largely be driven by weighing the complexity of methods against what is to be achieved, and what resources are available."

The leadership team should be clear about their scope and objectives before proceeding. It is important to have a clear idea of what will happen to the outcomes of the prioritisation exercise. Some examples of very different objectives include:

- Identifying a set of priority topic areas in which the development of trial proposals will be generally promoted to researchers.
- Identifying trials that meet a minimum threshold for endorsement.
- Ranking and selecting research questions to be further worked up and proposed to funders for consideration.
- Ranking and selecting from a group of existing trial proposals to allocate funding or other support (e.g., with CTN resources).

The leadership team should assess the current situation of the organisation, available resources, and stakeholders' needs and funders' expectations to define the focus and scope of research prioritisation (i.e., what is it about and who is it for), the target audience (e.g., researchers, funding organisations), who will be included in the process, the intended timeframe (i.e., long-term or short-term priorities), and possible sources of data to inform the process (e.g., burden of disease, current practice patterns, value of information, return on investment).

Pragmatic considerations and context may determine the scale of the priority-setting process. For example, where the available resources and staff time are limited, or where there is an immovable deadline, a less complex, informal approach may be appropriate. Where there is funding and staff time available to support the process, there are methods available for more in-depth, structured approaches to consultation and data gathering, although these may require longer timelines and different types of expertise. Some of the major methodologies are outlined in Appendix B.

Underpinning these considerations, priority setting process should consider the key principles that will inform the process. Methods developers (Bryant, Viergever, Whear, 2014; WHO, 2013) and Australian CTNs generally agree that a good practice priority setting process should be:

- **Clear:** has clear definition of principles, purpose, and outcomes sought.
- **Transparent:** both the process and governance arrangements are published in a public space.
- **Defensible:** has sound decision making; and transparent evaluation criteria.
- **Equitable:** process and outcomes are fair and take into account groups with greater unmet need.
- **Inclusive:** identifies and includes all stakeholders and end users of research.
- **Robust:** has robust and defensible process and governance arrangements.
- **Acceptable:** partners and stakeholders regard the process as satisfactory.
- **Pragmatic/manageable:** process and governance are appropriate to the resources available.
- **Fit-for-purpose/realistic:** methods selected have a reasonable chance of achieving their objectives.
- **Accountable:** has procedural fairness, decisions are published, and there is an appeals process.
- **Self-improving:** a continuous process of cyclical activity, improved over time and involving more individuals and data.

Once these decisions have been made, the leadership team should develop a detailed workplan, including the methodology to be used, financial resources, a budget and communications, evaluation and monitoring plans.

3. IDENTIFY AND ENGAGE STAKEHOLDERS

The leadership team should map out in advance which stakeholders should be included in the exercise to ensure equity, feasibility and implementation/uptake of recommendations. Different stakeholders (such as consumers, clinicians and health system managers, policy makers, potential users of the priorities for decision-making, and the people affected by prioritisation decisions) should be involved in the process to ensure broad and inclusive representation. Leadership teams should consider ensuring diverse representation from different sectors, balancing of factors such as gender, geographical location and socioeconomic status.

Stakeholders can be identified through a number of different processes, for example:

- Participants are considered through an open nomination process.
- Participants are identified through representing institutions and organisations (e.g., hospitals, universities, consumer groups).
- Participants are identified by the leadership team based on their expertise.

Stakeholders may be engaged through number of different processes, for example:

- Through their representation in a working group.
- Through consultation, such as focus-group discussions, workshops, interviews, online surveys or open calls for input.

The extent and nature of participation of different stakeholders may vary in depth and breadth, and different approaches may be appropriate in different contexts. Stakeholders may be involved at different stages of the process and with different roles, such as contributing opinion, evidence or suggestions to generate topics, being formally involved in ranking or scoring, being involved in the design of proposals addressing priority topics or contributing as part of the leadership team. Stakeholders may also be involved as members of the organisational leadership (such as a CTN Executive Committee) making final decisions about priorities.

ACTA has developed an in-depth toolkit around engaging consumers in research:
https://involvementtoolkit.clinicaltrialsalliance.org.au/

4. DEVELOP SELECTION CRITERIA

Criteria are used to focus discussion around research priorities and to ensure that important considerations are not overlooked. A prioritisation process will require criteria appropriate for the objective of the process and may require different sets of criteria for different stages (such as generating topics of interest, developing researchable questions, and selecting specific clinical trial proposals).

Selection criteria should be closely related to the purpose of the exercise and the actions you wish to take afterwards, for example, to encourage trialists to generate trials, to encourage funders to fund selected proposals, or to initiate trials in practice. The criteria should be meaningful and persuasive for those people making decisions, whether the leadership group, an Executive Committee or a funding panel. As such, there may not be one set of criteria that are appropriate for all purposes.

Possible selection criteria may be identified through literature reviews, Delphi and consensus approaches, surveys of stakeholders, or through the adoption of an existing methodology. The final set should be a manageable number of independent criteria. It may be helpful to sort criteria into representative categories. For example, selection criteria may fall under:

- Relevance (i.e., why should we do it? including the burden of disease, equity and knowledge gaps).
- Appropriateness (i.e., should we do it? including scientific rigour and suitability to answer the research question).
- Significance of research outcomes (i.e., what will we get out of it? including impact, innovation, capacity building).
- Feasibility (i.e., can we do it? including team quality and research environment).
- Value for money (i.e., is the proposed research potentially cost effective?).

The assessment criteria must be clearly defined, meaningful in distinguishing relative priority, and feasible for participants to assess. Where criteria require objective assessment, technical data can be provided such as burden of disease, systematic review of existing evidence, and value of information (return on investment).

The following sets of criteria are intended to be generically applicable to most process types, although CTNs should modify their criteria according to their scope and the purpose of the exercise. The specific methods and extent of effort used to generate information in different categories may be tailored depending on the process (for example, it may not be feasible within a brief process to conduct new economic assessments if these do not already exist).

What criteria should be included to select research topics?

- Relevance (i.e., why should we do it?), including:
  - Alignment with stakeholder needs including international, national or local health policy makers, health system decision makers, health practitioners and the community
  - Burden of disease: including on individual patients and/or the broader community or health system
  - Equity: whether the topic addresses a question of importance to communities experiencing disadvantage in the community or health system, or has the potential to address inequities of treatment or outcome
  - Knowledge gaps: based on an understanding of existing research findings, for example through systematic reviews and other trials currently in progress, in the context of questions relevant to current practice and policy.
- Appropriateness (i.e., should we do it?), including:
  - Ethics: ethical and moral considerations from the perspective of researchers or research end-users
  - Scientific basis: whether there is supporting evidence of how the proposed intervention might work and its underpinning mechanisms
  - Answerability: whether the topic can be translated into a specific research proposal.
- Significance of research outcomes (i.e., what will we get out of it?):
  - Innovation: whether the research has the potential to lead to innovation in the health system
  - Capacity-building: whether the research has the potential to build capacity and/or collaboration in either the health system or the research sector
  - Implementability: the extent to which it would be feasible and appropriate to implement research findings into policy and practice, should this be appropriate once the findings are available.
- Feasibility (i.e., can we do it?) including:
  - Feasibility: whether it would be feasible to conduct research on this topic in practice. (e.g. number of available patients for trials, level of funding required, available expertise to conduct research, available facilities/equipment/ skills required to conduct research in topic area).

These criteria were all considered important, although it is noted that a topic area may be considered important while not meeting every criteria (e.g., comparative effectiveness questions may not score highly on innovation but could have the potential for high impact).

What criteria should be included to select specific research proposals?

Over and above the importance of the topic that it addresses, there are additional criteria that are important to consider at the level of specific research proposals.

- Relevance (i.e., why should we do it?), including:
  - Proposal's alignment with organisational/national needs and priorities
  - Proposal presents a clear knowledge gap and considers existing evidence.
- Appropriateness (i.e., should we do it?), including:
  - Research question is clear in terms of the population, intervention, comparator, and outcomes.
  - Scientific rigor: including the validity of the study design, its appropriateness to the research question, and clarity of the research plan.
- Significance of research outcomes (i.e., what will we get out of it?), including:
  - Ability to change practice and influence policy (implementability)
  - Ability to support innovation
  - Ability to build research capacity and collaboration.
- Feasibility i.e., can we do it? Including:
  - Fundability: potential for the proposal to successfully attract funding
  - Whether it would be feasible to conduct this research proposal
  - Team quality and capability: experience and capacity of the research team, their track record for successful conduct and completion of trials
  - Research environment in which the study is proposed.
- Value for money (i.e., is the proposed research potentially cost effective?)
  - The budget is justifiable for the proposed activities and duration
  - Expected research benefits exceed research cost: the proposal is value for money based on its return on investment.

Of note, 'value for money' may be more important for funders and CTNs that fund research studies; therefore, most CTNs may generally focus on the merit criteria of Relevance, Appropriateness, Significance, and Feasibility. An implicit assumption may be made that research proposals that score highly in these criteria are potentially value for money.

5. METHODS TO WEIGHT AND SCORE CRITERIA

Once the selection criteria have been defined, consideration should be given to how to apply the criteria in practice. This usually means identifying a system to weight each criterion and score or rank it, in order to enable a list of relative priorities to be established among the proposed topics or proposals.

The complexity of the system used should be appropriate to the scale and context of the selection process. For example, processes that aim to identify topics of interest may have no limit on the number to be selected and may not require formal ranking or complex scoring. Similarly, processes that aim to identify proposals that meet a straightforward quality threshold may be simpler than processes aimed at competitive selection and the allocation of scarce resources.

Weighting indicates that some criteria are considered more important than others and will have more influence over the final ranking of a topic or proposal. Weighting is commonly observed in scoring systems for funding allocation (e.g., 40% for scientific quality, 30% for significance, and 20% for feasibility).

There are various methods available to elicit these weights, some of which require technical expertise to ensure they are appropriately applied. It could include:

- Deliberations/discussions among participants.
- Formal processes such as multiple criteria decision analysis (MCDA), which involves selecting the criteria (i.e., attributes), scoring the criteria, weighting criteria and calculating aggregate scores for each research proposal. Each criterion is assigned a weight based on stakeholders' preferences and trade-offs between criteria.
- Techniques to reflect participants' preferences and trade-offs between criteria (e.g., discrete choice experiments).

Once the weights have been decided, a system of scoring should be determined. This score may be based on objective data (e.g., burden of disease or return on investment), or it may be more qualitative (e.g., a Likert scale or score out of 10, based on the judgement of each participant). Some criteria may not be amenable to scoring and may be dichotomous (yes/no) in nature (e.g., does the proposal address one of the funder's prespecified topics of interest).

Scoring generated from multiple criteria can be combined in a range of ways, such as:

- Consider all criteria simultaneously: scores on the criteria are multiplied by the weights, and these weighted scores are then summed across the criteria to get a total score for each research topic/question
- Criteria are applied as successive sieves with a predefined order (i.e., eliminating topics/questions which fail to meet a criterion). With each additional criterion applied, research topics/questions can be short-listed.

Scores from multiple participants are commonly combined using a simple average. In Delphi processes, average scores are fed back to participants in cycles, providing data on the average scores of the group and allowing participants to modify their scores in response, thus (hopefully) generating a consensus.

Importantly, double counting of scores may happen when value for money is explicitly considered alongside certain merit criteria where there is a potential for overlap (e.g., overlap between research significance and research value for money). One option to overcome this issue is to evaluate value for money in a separate step to the merit assessment whereby the estimation of research benefits and costs is performed only for research proposals that meet the required levels of Relevance, Appropriateness, Significance and Feasibility. An advantage of this approach is that quantitative methods to assess value for money (e.g., return on investment) are only applied to a shortlist of high-quality research proposals. Value for money (return on investment) can be prospectively assessed using analytical approaches such as Value of Information (VOI) analysis and the Payback approach. These methods will be discussed in a separate document.

Once the weighting and scoring are complete, this should then allow a decision-making process. In some cases, this will be a decision as to whether or not topics or proposals meet a threshold (top 20 most interesting topics, or trials that meet minimum criteria for endorsement). In other cases, decisions will require ordered ranking (for example, in the allocation of finite resources, in which the amount of resources remaining may depend on the resources required for each trial deemed successful in ranked order). Using an absolute scoring system rather than relative ranking can assist groups to return to priority setting processes as new topics and proposals arise over time, enabling new ideas to be scored and added to existing ranked lists retrospectively.

6. IDENTIFY TOPICS

The aim at this stage is to identify a set of within-scope research topics as a starting point. At this stage the aim is idea generation – the topics will be prioritised and selected at the next stage – but the topics should not be so broad that they encompass too many areas of possible research, making them difficult to assess, or fail to identify the important knowledge and evidence gaps.

How to identify these topics?

- Public consultation by public forum, roundtables, focus groups and surveys
- Targeted consultations of experts
- Evidence-based situation analysis (disease burden, health care system, health research system)
- Literature review
- Scenario building, projections and horizon scanning.

Some processes will express topics as answerable research questions (e.g., using the PICO format), while some will aim to identify broader topic headings and leave the articulation of questions to the research proposal stage. In some cases, these steps may be separated, for example consulting with consumer groups to identify broad topics and articulating these as researchable questions within the leadership team. How easy it is to articulate specific answerable questions at this stage may depend on the research area. Some areas with large bodies of existing trials and active research communities may identify relatively narrow gaps in the available evidence, that can be readily expressed as specific questions, while other fields may identify broader areas with limited existing research.

In some methodologies, this stage may be combined with the following selection stage, for example in a single workshop bringing together key stakeholders to identify and select topics. Other processes may pause at this stage, for example to collect or generate data to inform the various selection criteria.

7. SELECT TOPICS

Identified topic should be collated and refined to form a short list of clear research topics. The length of the list will depend on the objectives of the exercise, but should be short enough to indicate meaningful priority, and to be useful for the next stages of the process. The agreed criteria for topic selection can then be assessed using the agreed scoring mechanism and used to inform final discussions. Further thought should be given to:

Who will score topics?

- A group of experts
- Working group of different stakeholders.

How will the necessary information (burden of disease, knowledge gap) to guide criteria assessment be collected and provided?

- The group of experts will use their knowledge and experience to systematically score research options against the criteria
- Individual experts (within or outside the leadership team) may be delegated to obtain and collate technical information to be shared with the group.

If consumers and researchers or clinicians are both scoring the topics, what weight will we give to their scores?

- Equal weights
- Different weights given (e.g., to consumer contributors compared to researchers with technical expertise)
- Adjust expert scores by the score obtained from consumers.

How will the final list of topics be decided?

- Rank topics according to their scores and consider topics above a certain agreed threshold
- Ranking and discussion to achieve consensus (i.e., give decision-makers the opportunity to change scores and consider additional aspects, either informally during a discussion meeting or through a formal process such as Delphi).

8. GENERATE RESEARCH PROPOSALS

In response to the selected topics, groups for whom this is within scope may then proceed to identify specific research proposals to address the topics. This may be an active task undertaken as part of a prioritisation process, either conducted or commissioned by the leadership group, or may rely on individual researchers or research teams to develop and make proposals to the decision-making organisation (e.g., as part of a Clinical Trials Network's periodic reviews of proposed new work). Dissemination of the topics may be required to elicit proposals, for example through advertising on websites, newsletters, or targeted calls for proposals.

Research projects should be specified in terms of a specific, answerable research question, methods designed to answer that question, and the resources needed. Proposals should be in sufficient detail to enable assessment of the agreed criteria, and comparison to alternative proposals (if relative ranking is required as part of the process).

A standard template that specifies the structure of the proposal and the supporting information required can be helpful. The level of detail required will depend on the nature of the process and the criteria used. A straightforward approach to outlining a research question could use a familiar format such as EPICOT (see Table 1), while other processes may require extensive supporting documentation to enable the criteria to be assessed and scored.

Table 1: EPICOT format to outline a research recommendation (Brown, et al., 2006)

E *Evidence* (What is the current state of the evidence?)
P *Population* (What is the population of interest?)
I *Intervention* (What are the interventions of interest?)
C *Comparison* (What are the comparisons of interest?)
O *Outcome* (What are the outcomes of interest?)
T *Time stamp* (Date of recommendation)
Optional elements:
d Disease burden or relevance
t Time aspect of core elements of EPICOT
s Appropriate study type according to local need

9. SELECT RESEARCH PROPOSALS

The process for selecting questions should be determined using similar parameters to the process of selecting broader topics, although different decisions about process can be made for this stage. Once determined, the criteria and scoring system should be applied, and final decisions made about the selected topics.

Again, the process may vary depending on the objectives of the process. A process aiming to endorse all trials meeting a given set of criteria may be a relatively straightforward process, while a highly competitive process may require extensive documentation, scoring and discussion to determine final agreement. It is often appropriate for discussion to take place in addition to the quantitative scoring process before final decisions are made, to ensure that any issues leading to a lack of consensus are considered. Where this occurs, the process of decision making should be transparent.

The group may be making decisions for immediate implementation or may be determining a research agenda for implementation over a longer period, such as two to five years. It should also be noted that the priorities selected by the group may have influence beyond the boundaries of the current process and may inform priority setting or selection of trials to support by other organisations, including research organisations, health services and funders.

10. CONCLUDE AND EVALUATE

Once the priority setting process is completed, the leadership team should prepare a report describing the actions and decisions that have taken place including agreed final list of priorities. To inform future priority setting, groups should also consider how to evaluate the success of the priority setting process.

The evaluation should consider the following:

- Identification of outcomes that should be monitored and evaluated as a measure of performance.
- Performance evaluations during and after the completion of the process.
- Specification of appeal mechanisms that can be used for challenge and dispute resolution regarding decisions related to the priority setting exercise.

What outcomes should be measured?

Process indicators:

- Rating of transparency, inclusiveness
- Stakeholder satisfaction
- Adherence to budget and timeline
- Successful submission of research proposals addressing the identified priority topics.

Outcome indicators:

- Interest or action generated among stakeholders in response to the priorities.
- Successful grant proposals for external funding
- Successful commencement and completion of trials addressing the stated priorities
- Publications
- Capacity building, such as through engagement of trial sites, research and clinical staff
- Measures of implementation and impact of trial outcomes, where appropriate
- Return on investment.

Finally, either the leadership group of the priority setting exercise, or the sponsoring organisation, should plan how long the priorities set will be considered as 'current', and when a review or updated priority setting process will be required to identify new priorities in light of the evolving research landscape.

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APPENDIX A: ACTA REFERENCE GROUP ON TOOLS FOR RESEARCH PRIORITISATION

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APPENDIX B: METHODS, APPROACHES AND CRITERIA FOR HEALTH RESEARCH PRIORITISATION

There are three broad approaches to setting priorities for health research:

- The use of interpretive assessments, which rely on consensus views of informed participants.
- The use of technical analyses, which relies on quantifiable epidemiological, clinical, financial or other data, and
- Compound (comprehensive) approaches, which provide structured, detailed, step-by-step guidance for the entire priority setting process.

INTERPRETIVE ASSESSMENT METHODS

Covers a number of tools, all focused-on forecasting, scenario creation & 'visioning' by experts. These include visioning (creates a picture of possible futures), scenario creation (builds scenarios from an assessment of trends and drivers), and Delphi (panel of experts who answer questionnaires in two or more rounds to achieve consensus). These approaches are good to reflect emerging patterns in the future; however, they do not provide methodology for identifying participants, lack criteria transparency, and have the potential for investigators and facilitators to bias opinions.

TECHNICAL ANALYSES

Include burden of disease (relating research to burden of disease), value of information analysis (considers value of research in reducing decision uncertainty), prospective pay-back approach (value of research to influence practice), Programme Budgeting and Marginal Analysis (involves mapping of existing activity and expenditure then resources are allocated across activities to maximise benefits). These approaches provide an objective assessment of value for money; however, they do not consider important criteria such as equity and broad stakeholder's involvement; furthermore, they require resources and technical capacity to be performed effectively.

COMPREHENSIVE APPROACHES

Provide structured, detailed, step-by-step guidance for the entire priority setting process. They assist in most of the steps in the prioritisation including preparatory work and scoping, including participants, identifying priorities and ranking/deciding on these priorities. Table B.1 (overleaf) summarises these comprehensive approaches.

Table B.1

	ENHR	CHNRI	3D-CAM	JLA	Evidence GAP	COHRED
Overall process	Stewardship by small working group. Both quantitative and qualitative information used. Consider areas that are amenable to research, research already underway and links to existing strategies.	Includes soliciting ideas from different participants on the given health topic and using independent ranking system against pre-defined criteria to prioritise research ideas.	A comprehensive method including measuring disease burden, analysing determinants, identifying present level of knowledge, evaluating cost and effectiveness, and present resource flows.	Brings patients, carers and health professionals to identify questions and uncertainties. Qualitative and quantitative data gathering and analysis to develop very specific questions.	Considers what is and is not known by mapping completed and ongoing systematic reviews and impact evaluation.	High-level approach delineates important steps of a priority setting process
Inclusiveness	Participants are involved through a small representative working group of researchers, decision makers, health service providers and communities.	Participants are identified by management team based on their expertise. May include stakeholders who might not have technical expertise but have views on the health topic of concern.	Involves individual, household and community; health ministry and other health institutions; other sectors apart from health; and macroeconomic level actors.	Participants are identified through Priority Setting Partnerships which brings patients, carers and clinicians equally together.	Includes consultation with relevant decision makers and other key stakeholders, often in the form of an informal advisory group.	Formation of a taskforce with wide representation.
Identifying priorities	Research ideas are gathered from different stakeholders. Consensus building using methods such as brainstorming, nominal group technique, roundtable is then used.	Research ideas are generated by participants or by management team based on the current evidence. Uses online surveys/ questionnaires.	Five-step process including measuring the disease burden, analysing determinants, getting present level of knowledge, evaluating cost and effectiveness, and present resource flows.	Treatment uncertainties defined as no up-to-date, reliable systematic review addressing uncertainty, or systematic review that shows such uncertainty exists. Virtual interim priority ranking, and a final priority setting workshop to agree 10 prioritised uncertainties through consensus building	Questions are developed through expert consultation, preliminary literature search, mapping workshops and online surveys.	Choose method best suited to local context and needs either through comprehensive approaches (ENHR, CAM, Burden of Disease) or foresighting techniques (Visioning, Delphi). Allows using more than one method to optimise usefulness of results.
Criteria	Criteria are agreed on by brainstorming a large collection of possible criteria, eliminating duplicates and defining each one. Criteria then put into representative categories: relevance (why should we do it?), appropriateness (should we do it?), impact (what will we get out of it?), and feasibility (can we do it?)	Answerability, equity, impact on burden, deliverability, effectiveness. Other criteria can be used depending on the needs and context.	NA	NA	Clinical importance ('How clinically important is this question?'), novelty ('Does this question represent an emerging area of clinical practice?') and controversy ('What is the level of variability regarding opinion and/or practice for this question?').	Criteria depend on the comprehensive approach selected.

Acronyms: ENHR: Essential National Health Research; **CHNRI:** Child Health and Nutrition Research Initiative; **3D-CAM:** Combined Approach Matrix; **JLA:** James Lind Alliance; **COHRED:** Council on Health Research for Development.

	ENHR	CHNRI	3D-CAM	JLA	Evidence GAP	COHRED
Ranking of priorities	Point score to each criteria OR number of score choices to each criteria.	Point score to each criteria in the scale of 0, 0.5 and 1 or in the scale of 0 to 100.	NA	Consensus building	Using a scale of 1 to 4. Full evidence search is performed for questions with the highest scores.	Ranking techniques that can include direct and indirect valuation techniques.
Advantages	Working group enhances and facilitates activities. Representative groups of criteria to guide criteria selection and use.	Simple, inclusive, replicable. Considers existing evidence.	Considers existing evidence. Involves a broad range of stakeholders. Includes equity as a lens across all areas. Includes cost-effectiveness.	Inclusive. Considers existing evidence and knowledge gaps. Suitable for detailed analyses within specific diseases.	Considers availability and quality of existing evidence. Suitable for detailed analyses (e.g. specific diseases).	Discusses wide range of options. Flexible to contexts and needs.
Disadvantages	Small group may limit inclusivity. Too resource intensive. Vague criteria. Does not consider value for money.	No interaction (e.g., face-to-face) between participants. Does not consider value for money.	Logistically difficult and time-consuming. No clear criteria to identify and score priorities.	Resource intensive to identify and verify uncertainties. No clear criteria to identify and score priorities. Does not consider value for money.	New. Focused on knowledge gaps. Time consuming. Does not consider equity or value for money.	Too general and unspecific. Lack of criteria transparency.

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