Global Observatory on Health R&D

Working paper series 1
(preliminary draft)

Assessing of R&D priority setting processes for neglected diseases

Work conducted by
London School of Hygiene and Tropical Medicine (LSHTM)
and the Global TB Centre
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About this paper

This background paper has been drafted to support the development of the Global Observatory on Health Research and Development (R&D) through a systematic examination of different approaches to define R&D priorities and funding needs (with a particular emphasis on tuberculosis (TB)).

The working paper provides analysis to help gain a better understanding of the different approaches and their strengths and weaknesses, in order to guide future processes for R&D prioritization for TB and other diseases.

Nine R&D prioritization approaches were identified and compared used a standardized template. This included approaches that were documented in published scientific papers and reports as well as undocumented processes run by industry/funders that were included based on structured interviews.
Contents

Executive summary ........................................................................................................... 2

PHASE 1: Identify research and development (R&D) prioritization processes and summarize key features ........................................................................................................ 4
  Approach ...................................................................................................................... 4
  Findings ........................................................................................................................ 7

PHASE 2: Analysis of stakeholders’ views on an optimal research and development (R&D) prioritization processes ........................................................................... 10
  Approach .................................................................................................................... 10
  Summary of key findings ............................................................................................ 12
  Emerging recommendations about R&D prioritization process ......................... 21
Executive summary

This work was conducted to support development of the Global Observatory on Health Research and Development (R&D) through a systematic examination of different approaches to define R&D priorities and funding needs used for tuberculosis (TB). The aim of the study was to gain a better understanding of the strengths and weaknesses of different approaches and guide future processes for R&D prioritization for TB and other diseases.

The work was conducted in two phases. In phase one, nine R&D prioritization approaches were identified and compared using a standardized template. This included approaches that were documented in published scientific papers and reports as well as undocumented processes run by industry/funders; the latter were included based on structured interviews.

In the range of R&D prioritization approaches we compared in phase one, the purpose and “owner” of the process largely determined which stakeholders were involved, how they determined priorities, how the final decision was reached and whether a transparent report was made available. Conversely, it appeared that transparency in reporting tended to drive better definition of the criteria used to assess research options and “fairer” processes for reaching consensus on the final list of priorities. In an attempt to avoid bias, the NIH/WHO TB Roadmap processes sought to identify critical gaps in knowledge rather than prioritize a particular area. While transparency of reporting and wider engagement of stakeholders can be recommended as critical components of any R&D prioritization process based on this analysis, other dimensions of the process we found to be more subjective: Which criteria should be used? Which information sources should be consulted? What process should be used for reaching the final list of priorities?

These were investigated in phase two through key informant discussions with stakeholders representing four distinct groups: academics (range of disciplines); funding body representatives; international policy makers/technical advisers and national disease control programme representatives (Asia and Africa).

There was consensus among stakeholders interviewed that the purpose of the prioritization exercise, and linked to this, the criteria for assessment of R&D options needs to be clearly defined at the outset. The data and information required by experts involved in the prioritization exercise will follow directly from the assessment criteria selected. It was recognized by several stakeholders that all experts would have some degree of bias and that an unbiased ranking of R&D options may not be possible or even useful. Trade-offs between different criteria for ranking options, and decisions on the values of most importance to WHO (or the priority setting agency) should be made and communicated transparently; this will result in a more specific and meaningful list of R&D priorities being generated.
Effectiveness/efficacy and deliverability at scale within high disease burden settings were the two criteria that stakeholders from all groups commonly cited as being key for scoring R&D priorities. In terms of information required to score R&D options, one assessment that is rarely provided but important according to members from all stakeholder groups is evaluations of past investments to assess real impact achieved (as opposed to projected impact based on assumptions that are often inaccurate). A key recommendation was to include a broad range of stakeholders, with front-line country experts being essential. In terms of process, the following was suggested by the majority: a combination of initial discussions about the criteria that should be used to rank R&D options, followed by independent ranking, followed by a further discussion and consensus generation around the final list of priorities.
PHASE 1: Identify research and development (R&D) prioritization processes and summarize key features

Approach

- Review of reports and publications on existing R&D prioritization processes
- Development of a framework and structured template to conduct a standardized comparison R&D prioritization processes, based on seminal papers 1, 2
- Using the template, hold key informant discussions with academics, international policy makers, funding body and industry representatives who had been involved in R&D priority setting for tuberculosis (TB) and selected comparator health areas
- Identify and select eight to ten R&D prioritization processes for comparison; include information from processes documented in published literature, as well as approaches used by informants that have not been published
- Produce a comparison table of the R&D prioritization processes based on the standardized structured template (Table 1).

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## Table 1: Standardized template for assessing and comparing R&D prioritization exercises

<table>
<thead>
<tr>
<th>R&amp;D prioritization approach structure</th>
<th>Definition used for assessment/comparison</th>
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<tbody>
<tr>
<td>Was there a clearly stated purpose for the exercise and what was it?</td>
<td>Y/N + reason, or goal, for conducting the R&amp;D prioritization explicitly defined in report or during interview</td>
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</tbody>
</table>
| Which stakeholders were involved in process? | □ Academics  
  o From a single discipline such as one of: basic science, epidemiology, operational/translational research, health economics, health policy and systems research etc.  
  o From multiple disciplines: two or more disciplines  
  □ International policy-makers / technical experts: representatives of WHO and other policy or technical assistance bodies working across multiple countries  
  □ National disease control programme representatives  
  □ Civil society: advocacy groups, community groups etc.  
  □ Funding body representatives: NIH, Gates, Wellcome Trust etc.  
  □ Patients  
  □ Physicians: whose primary occupation is treating (TB) patients in high-burden settings  
  □ Industry representatives or product development partnerships |
| What information was reviewed? | □ Funding disbursed  
 □ Ongoing studies / pipeline  
 □ Disease burden / epidemiology  
 □ Cost and related outcomes of investments (cost-effectiveness, cost-benefit etc.)  
 □ Projections of future impact on epidemiology  
 □ Published literature  
 □ Other |
<table>
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<tr>
<th>R&amp;D prioritization approach structure</th>
<th>Definition used for assessment/comparison</th>
</tr>
</thead>
</table>
| What criteria/values were used to prioritize areas? | □ Effectiveness/efficacy: impact on reducing disease burden or adverse consequences of disease  
□ Necessity: addressing critical knowledge gaps that limit progress on disease control  
□ Cost-effectiveness: cost of delivery relative to impact is appropriate for high disease burden settings  
□ Deliverability: investment will produce an output that can be implemented and deliver impact in settings with high disease burden (feasibility)  
□ Equity: knowledge or tool produced will benefit all populations including vulnerable groups and populations in low resource settings  
□ Sustainability: output implementation can be supported by finances and infrastructure available in high disease burden settings for the long term  
□ Other |
| What methods were used to decide on priority list? | □ Independent ranking / scoring/ weighting  
□ Consensus through discussion  
□ Public voting / show of hands  
□ One team leader decides  
□ Other |
| How were the results communicated and to whom? | □ Written policy briefs (short)  
□ Online detailed report (long)  
□ Infographics or other visual aids  
□ Materials in local languages  
□ Seminars to communicate results |
| How were the priorities and priority-setting exercise evaluated? | Process for obtaining feedback from stakeholders (directly involved in process and others) about the approach used for priority setting and/or the emerging priorities. As described in report or during interview. |
| Transparent report of priorities and process | Y/N based on reports or documents made publicly available. Level of information about who was involved, what information was provided, how decisions were reached and specific priorities that emerged was reviewed. |
| How easy is it to repeat the exercise every 3-5 years? | Easy/moderate/hard based on how frequently exercise is conducted at present and/or interviewee’s description of resources involved |

[NIH, National Institutes of Health; R&D, research and development; TB, tuberculosis; WHO, World Health Organization]
Findings

**Definition of purpose**

- The purpose of the R&D prioritization exercise tended to be explicitly defined, with variation in purpose related to the “owners” of the process.

- Approaches used by the World Health Organization (WHO) (TDR or TB roadmap) and Child Health and Nutrition Research Initiative (CHNRI) – unlike funding bodies or industry – were usually aiming to define priorities for investment by funders. However, when the “owner” was a body that had its own funds for investment the purpose was for internal decisions and this influenced how the processes were run.

- While the purpose was clearly defined, the values used to assess alternative research options, which should be linked to the purpose, were less explicitly stated.

**Stakeholders involved in the prioritization process**

- There was substantial variation in which stakeholder groups were involved in the processes we compared.

- Academics, technical experts from the WHO (and similar agencies) and funders were among the most commonly included stakeholder groups.

- Representatives of National Disease Control Programmes, civil society, TB patients and physicians were rarely involved; these groups tend to be closer to the realities of accessing TB services in high-burden settings and their exclusion may result in deliverability and acceptability of research options being weighted less appropriately.

- Since the majority of processes relied heavily on selected “experts” to determine the priorities, variations in who is selected to be involved will likely have a major influence on outcomes of the process.

**Information reviewed during prioritization process**

- There were again large differences in the information that was taken into account by those involved in the prioritization process, and the sources used were often poorly defined.

- Some processes – such as CHNRI – relied mainly on the opinion of technical experts and did not appear to dictate what information these experts should consider.

- Published scientific literature was not considered explicitly in most processes except systematic reviews or the WHO TB Roadmap that commissioned systematic reviews as part of the process.
The range of information sources reviewed was generally limited to specific groups of experts or a scan of current literature across the processes we assessed.

One experienced funder commented that it was not possible to obtain an unbiased set of priorities through consultation with experts (academic or non-academic). Review of literature, scientific meetings etc., if performed in sufficient detail, could help to identify critical gaps and recommendations could be made to support funding for those gaps.

Criteria used to assess alternative research options

- The majority of processes involved assessing research options against multiple (generally three to six) criteria. It was recognized that too many criteria make the processes logistically challenging.
- While processes that produced a report tended to be more explicit in the criteria applied and their definitions, internal processes for funding and industry bodies were not as clear.
- Effectiveness/efficacy was one of the most commonly used criteria across tools.
- Sustainability, and related to it, cost-effectiveness, were assessed less frequently, and when they were considered by industry bodies the view tended to be based on whether investment in a product would result in long-term profit.
- Additional criteria used by industry and funding bodies included manufacturability / business case (i.e. return on investment).
- Further additional criteria that emerged included: public opinion, alignment with Sustainable Development Goals and avoiding harm.

Method used to arrive at a final list of research priorities

- The method used to determine the priority list depended on the “owner” and purpose of the exercise.
- Some bodies conducting priority setting for internal purposes reached decisions in a less formal manner without a clearly defined method; the approach tended to involve discussion and decisions taken by leadership.
- One funding body stated that a team cannot be accountable for priorities and only an individual can be; therefore, final decisions are made by a single team leader.
- Processes conducted using WHO (TDR or TB Roadmap) or the CHNRI approach used more formal and transparent methods to arrive at the priority research areas; a
consensus based approach (usually Delphi technique) or independent ranking, or a combination was used.

- Of note is that with systematic reviews, researchers involved are responsible for determining recurring evidence gaps cited in the literature, which may or may not be subject to personal biases in interpretation.

**Evaluation and feedback of process and priorities**

- When the “owner” of the process was a funding or industry body, the review process was ultimately limited to internal feedback, even if wider consultation had been performed at early stages in the process.

- The WHO TB Roadmap and TDR processes engaged more widely with regional stakeholders for feedback.

- Feedback tended to be solicited more on the priorities emerging than the processes used to reach them.

**Transparency of reporting**

- As expected, transparent reports were not produced when the process was conducted for internal priority setting.

- Improvements in transparency of reporting and effectiveness of communication could be assisted by the development of a checklist of minimum elements to report regarding the methods and process; this could build upon the standardized template developed for this project.

**Ease of repeating exercise**

- While several processes were easy to repeat, even on an annual basis, the ones that were more robust tended to require more time and resources, making them harder to repeat. All processes, with resources, could be repeated every five years.

- The duration and resource requirements of the processes were related to the number of stakeholders involved, the methods used for reaching consensus on the priority list and the information reviewed.

- Funding and industry bodies that used less robust processes for internal priority setting tended to be easier to repeat.
PHASE 2: Analysis of stakeholders’ views on an optimal research and development (R&D) prioritization processes

Approach

- A semi-structured interview guide was designed to explore perceptions and views about how an ideal R&D prioritization process would be structured.

- Specific questions on key stages in the process, along with slides to probe on views, were prepared to present during interviews (please see figures 1 - 3).

- Stakeholders representing four distinct groups were purposively identified:
  - Academics from three UK institutions (range of disciplines)
  - Funding body representatives
  - International policy makers/technical advisers
  - National disease control programme representatives (Asia and Africa)

- Interviews lasting between 20 and 45 minutes were conducted in person or via Skype with: six international policy makers, five funders, nine academics and four national tuberculosis (TB) programme representatives.

- Interviews were voice recorded with consent followed by transcription or captured through detailed notes.

- Framework analysis was conducted in which relevant statements and quotes from each interviewee was input into a standardized template organized according to the following questions:
  - What information should be gathered & presented to inform the experts?
  - Which criteria/values should be used to assess research priorities?
  - What method should be used to decide on a final priority list?
  - Which stakeholders should be involved?

- Research quality control procedures: relevant quotes were extracted using the standard template by one researcher (not involved in conducting interviews), and compiled qualitative data was analysed independently by another researcher. All analysis was conducted without identifying respondent.
Figures 1 - 3: Slides used to initiate discussions during semi-structured interviews

**Question 3A**
INFORMATION NEEDED – Please tick all that you think should be reviewed

- Current R&D funding by topic area
- Number of current studies/pipeline
- Epidemiology/Disease burden in different sub-groups
- Cost effectiveness of investments
- Projections based on modelling of future impact
- Other – please specify

**Question 3B**
CRITERIA TO ASSESS R&D AREAS – Top 3

- Effectiveness/efficacy
- Necessity/ knowledge gaps
- Cost-effectiveness
- Deliverability
- Equity
- Sustainability
- Other – please specify
Summary of key findings

- There was consensus among stakeholders interviewed that the purpose of the prioritization exercise, and linked to this, the criteria for assessment of R&D options needs to be clearly defined at the outset. The data and information required by experts involved in the prioritization exercise will follow directly from the assessment criteria selected. We therefore present findings from the two questions – what information should be presented and what criteria should be used to prioritize – in a combined section reflecting the answers received.

- It was recognized by several stakeholders that all experts would have some degree of bias and that an unbiased ranking of R&D options may not be possible or even useful. Trade-offs between different criteria for ranking options, and decisions on the values of most importance to the WHO (or priority setting agency) should be made and communicated transparently; this will result in a more specific and meaningful list of R&D priorities being generated.

- However for TB and other health areas (vaccines and malaria) similar challenges were experienced in removing some research areas from the list owing to “political correctness”, particularly when a major funder or agency such as the WHO is seen to endorse the priority list.
Effectiveness/efficacy and deliverability at scale within high disease burden settings were the two criteria that stakeholders from all groups commonly cited as being key for scoring R&D priorities.

- While cost-effectiveness was considered important, some stakeholders felt that if an intervention is effective and can be delivered at scale (taking into account current health system capacities), then costs may be secondary; scale-up can reduce costs and if the intervention is really successful it will save costs in the long run, resulting in funds being mobilized.

In terms of information required to score R&D options, one assessment that is rarely provided but important according to members from all stakeholder groups is evaluations of past investments to assess real impact achieved (as opposed to projected impact based on assumptions that are often inaccurate).

- There was also mention of the need to include comparisons of investments into biomedical versus non-biomedical interventions, including health systems investments. Such information would be important as a precursor to ranking R&D options.

“Have we looked back at what we've already got and what is going on? Is it doing what we thought it was going to do?“

“...showing the impact of the existing portfolio for TB versus other things...other approaches and to make a very honest comparison because we need to. I need to be convinced that this investment in biomedical interventions is really justified in terms of impact and I feel like it’s just a lack of imagination rather than being convinced about what we’re doing.”

“We are interested in whatever we have done, how much is (achieving) good impact.”

When asked about which experts to involve and the process that should be used for deciding on the final priority list (consensus versus public voting versus independent ranking), there was agreement that the arrangements made can have a large influence on the priorities that emerge. Stakeholders warned about the potential for bias to creep in and that the process can be gamed to influence which priorities emerge.

- A key recommendation here was to have a broad range of stakeholders with front-line country experts being essential. It was emphasized that the prioritization process should avoid involving a small group of experts and being “incestuous”; people from outside TB should be included as well.

- In terms of process, a combination of initial discussions about the criteria that should be used to rank R&D options, followed by independent ranking, followed
by a further discussion and consensus generation around the final list of priorities was the optimal approach suggested by the majority.

"I think it does have to be a combination of the two. I actually think that the numerical ranking should lead into the consensus process because if you just dive straight into the consensus process there is the risk of individual biases”

Detailed findings about criteria and information for ranking of R&D priorities

- Across the four stakeholder groups there was broad agreement that the key value/purpose of investments needs to be made explicit at the start of the process.

  “This is an interesting area and answers really depend on ethical principles and values. It is very political...need to first decide on what you want to achieve in terms of values and set the strategic purpose, before doing prioritization exercise”

- It was acknowledged that important conversations about criteria and values might be uncomfortable as trade-offs need to be made, including deprioritizing some research areas owing to lack of resources. Failure to do this, however, and arriving at a huge list of research areas requiring a massive budget – something which previous exercises were criticized for – means that the outputs are less meaningful.

  “To be honest, I’ve seen recently enough WHO people make intents to do something like what is a global TB research agenda and then they come up and say it is going to cost $4bn dollars and to me that’s absolutely not helpful, that’s not helpful at all.”

- There was a strong sentiment, particularly among funding body representatives, that prioritization exercises and previous calls for action by the WHO are less useful than they could be because the purpose is not clear and specific enough; some funders explained that this is why they do not use the WHO research priority agendas.

  [talking about WHO] “…is a lack of clarity of their drivers, what are their priorities, what is the thing that they’re trying to achieve, what’s your identity effectively...so that would be my sort of framework from which I’d start and then you prioritize the information you’d like from that.”

  “Go back to your basic mission to improve TB in a global context; that will guide you, I think, in what the most important questions are. I don’t really believe in a sort of call to action...ministers who are pontificating, it just gets us nowhere.”

- All interviewees were comfortable selecting three or four criteria that R&D options should be ranked on the basis of, and one international policy maker who had extensive experience of prioritization exercises stressed that multiple criteria (3-5) should be adopted to rank each option against as one criterion is not enough.
Effectiveness/efficacy along with deliverability were the two criteria that were considered most important by the majority. These together appeared to contribute to the key aim of investments, which is impact.

- Achieving an impact on disease control, rather than filling knowledge gaps per se, was identified as being important, including to academic stakeholders:

  “Knowledge gaps, less so, less so, I think it’s primarily about identifying things that are likely to have a big impact and working out whether or not you can deliver them at scale, and the cost will eventually take care of itself if it’s a good enough intervention”

- In stark contrast, some funders stated that it is only knowledge gaps that can be objectively identified as other criteria can be influenced by individual bias, which they believed everyone holds.

A number of interviewees in different stakeholder groups emphasized that while effectiveness is critical, deliverability needs to be assessed early or in parallel with effectiveness. There was recognition that, in the past, considerations about deliverability in resource constraint health systems has been left until too late.

“You’ve got to do your efficacy work, but don’t wait 4 years… let’s also run parallel effectiveness studies, deliverability scale up, let’s try and get that evidence working together and I’m not sure people think like that.”

International policy makers taking a global view also mentioned affordability as an important criterion, which they believed linked to equity, so that people who need the new tool/drug can access it. Some highlighted that WHO, owing to its unique mandate, should consider equity even if other prioritization bodies do not.

Our analysis revealed that concepts around what is meant by equity varied however, with some linking equity to cost-effectiveness (lower cost tools are more equitable as they can be accessed by resource constrained populations), and others noting that interventions for reaching vulnerable populations can often be less cost-effective but good for equity. There was general agreement though that WHO should take a public health perspective/egalitarian view, and the aim should be to maximize benefit to the most people through cost-effective use of resources.

Some national programme managers and academics additionally mentioned the importance of considering sustainability of tools or products being developed (which encompassed cost of implementation and ability to implement at scale in high burden countries):
“I think for programmes, sustainability is very important you know, because what will happen when donors will go away…”

However other stakeholders, including academics and international policy makers, felt that cost is less important than effectiveness; they felt that resources could be made available if the impact is large (illustrated through an earlier quote).

- A point was raised about the perspective from which costs are considered, as an intervention may be cost-effective from a patient perspective when it saves patient costs but not from a health system perspective.

Similarly, one academic stakeholder suggested that sustainability may be less important if there is an intervention that can eradicate the disease and it therefore does not have to be delivered for the long term.

Another academic stakeholder also stressed that effectiveness should be thought of in terms of impact on quality of life of affected people and not just in terms of deaths or new cases averted.

Apart from effectiveness/efficacy, deliverability, sustainability and equity, three additional criteria were mentioned:

- Likelihood of success from the investment, for which information about risks of failure from pipeline products is needed;

- The principle of “do no harm” from introducing the new product or tool; it was highlighted that we have managed to create drug resistant TB by scaling up TB treatment without strengthening health systems, and we may be expanding resistance by scaling up MDR-TB treatment without ensuring adequate infrastructure is in place;

- Political acceptability, for which information about political commitment from national policy makers was also identified as important.

Linked to the agreed overall assessment criterion (impact), stemming from effectiveness and deliverability, a number of stakeholder mentioned that the following information is useful to consider:

- Disease burden, epidemiology, mortality statistics, with indicators linked to global goals such as the Sustainable Development Goals and the End TB strategy.

- Costs and affordability to countries along with feasibility of implementation.

“…often there is an over-emphasis on the technical and the scientific, and less concentration on how are you going to deliver these things. And how are you going to fund them and how are you going to get them into the existing health system.”
Information about likely impact on epidemiology from alternative investments and their relative cost-effectiveness. However, several stakeholders were more interested about information about the impact of actual investments taking into account health systems constraints, rather than forecasts based on assumptions that they felt are often inaccurate.

“So its maybe not even cost-effectiveness...it is like a value for money kind of step. But I would want that exercise to be grounded in reality, so to take the data we have now for TB or HIV resource tracking and start from looking historically at the investments and what they yielded and try to come up with some kind of relationship there, rather than think about it prospectively, which is I think too subject to kind of vague expert opinion.”

There were mixed views about the importance of information about funding for different R&D areas and the existing pipeline; some funders and academics felt this was less useful while others thought that it is important to consider this in order to avoid duplication and funding gaps that result in some research getting neglected.

One academic emphasized that a more nuanced approach to pipeline and funding analysis is needed, looking not just at the number of studies or amount of funding but also to question whether these are the right kinds of studies: “...the current funding I think is less indicative of the type of studies that are already happening...that’s too blunt an instrument”

Apart from numerical data, some academic and international policy stakeholders suggested that a detailed “situational analysis” to understand what is happening in high disease burden countries (at health facility level) is important so that new developments can address critical bottlenecks.

For TB in particular, it was stressed that considering health systems in high burden countries is important. This involves looking at the potential impact of health systems investments and health systems constraints that would prevent new products from having the intended impact.

“Often involves going out and seeing how things work, so it’s not just epidemiology, I would call it if you like the practice of disease control at the basic management unit because that’s replicated throughout the country...”

Some additional information that is not usually considered in prioritization processes but identified as useful by stakeholders interviewed was:

- Time to achieve public health impact from the investment
- Impact beyond TB/interconnectedness: “Some basic science research is beneficial to more than one disease area and this is an advantage”
Finally, it was recognized that the information available to assist with any priority setting exercise will be constrained by time and resources available and that it is not possible to have full systematic reviews for every topic.

**Detailed findings about process to reach a final list of priorities**

- There was consensus that, following agreement on the criteria for assessment and reviewing information, the process used for arriving at a final list of priorities is critical. It was emphasized that decisions on who to involve and how R&D options are scored are important, and a well-designed process can avoid one stakeholder group being overly represented.

  - The need for strong governance of the process and clarity on how the decisions were reached was highlighted.

  - It was recognized that there is no ideal process and, in general, stakeholders acknowledged strengths and weaknesses across different methods for generating a list of priorities and that bias is inevitable as individuals have disciplinary perspectives or institutional positions.

  > “There is still is no gold standard approach. There is no method that is categorically better than another one. Although I suppose the other, kind of, key finding is that you get the priorities - the priorities you get are usually based on who you ask essentially.”

- In relation to which stakeholders to involve, there was more clarity, and stronger views were expressed by stakeholders. In general, all stakeholders recommended that a combination of national and international experts should be involved in the prioritization exercise.

  - In country experts include national programme representatives and academics, with frontline implementers being essential participants. Research officers in national programme as well as national programme managers should be involved as they often have better information about research priorities.

  - International experts include international academic institutions, funders, industry representatives, and technical experts such as the WHO.

- Having a broad set of experts involved in the priority setting exercise was deemed essential by a number of stakeholder, and there was some (self) criticism of relying on the same experts again and again.

  > “…it relates to the deliverability side of it and that is to what degree do we really engage the ultimate demand stakeholders, which are at the end of the day, the patient, the healthcare workers and the country decision makers in this kind of...”
development of future interventions. My gut feeling is that the lion share of the conversation is what can we do, from our analysis that we think would be helpful, and I don’t think we do enough of a job balancing that with a deep conversation with the country’s national TB control coordinators themselves…”

- One national programme representative suggested specifically involving potential resistors in the decision-making process.

- Some stakeholders mentioned the importance of involving experts beyond TB, such as those knowledgeable about the Sustainable Development Goals.

- On funders, one stakeholder suggested considering not only global funders such as Gates and NIH but also emerging economies such as China

Some international policy makers recommended that the priorities should be driven by countries themselves and not by funders.

- A specific suggestion on this point made by a number of stakeholders was that priority setting for ‘upstream’ R&D (basic science) could be done at the global level and priority setting for diagnostics and tools that are closer to being implemented should be led at regional or country level to ensure input from front-line implementers.

There were mixed views about whether funding body representatives, particularly ones from industry, should be involved in any ranking or voting process. Their involvement for buy-in was considered important but some suggested they should be involved as observers owing to possible conflicts of interest.

“…products are made by industry, they’re not made by academics so if it is about profits, you’re going to have to include industry in the process in a way that is appropriate”

Some funder and industry representatives, however, emphasized that excluding them from processes owing to conflicts of interest is undue since academics and other stakeholders also have personal biases.

There was also discussion about the involvement of civil society representatives and TB patients. Distinction between the TB community and civil society were made.

- While the importance of involving affected people was generally agreed upon, there were questions about who really represents TB patients; some interviewees felt that there is no representative group of “typical” TB patients.

In terms of the process to reach a final list of priorities, the general view was that a combination of discussion and independent ranking is important. Here our analysis did not indicate vastly different views across stakeholder groups.
Open voting through a show of hands was criticized as “people are influenced by others in the room”. Objective numerical ranking independently was preferred, after getting consensus on which factors experts are ranking on the basis of.

“I think process is important and so having a kind of general open discussion among people who are reacting to maybe a landscape type of document that lays out the options and then voting, like by putting your name card up or whatever, is not going to work, I mean it is too susceptible to a loud voice in the room”

Bringing experts together was considered useful for an initial discussion but after that it was recommended that experts should be allowed to reflect on the information independently and rank without being in a group. Following this they should come together to again discuss rankings.

Strong individual expert opinions, which can bias the whole group, may also be informative according to some stakeholders, including a national programme representative and some academics, who thought that an analysis of ranking differences between expert groups could be useful.

“And if there’s a really big contrast there that gives you...that can then be used for a discussion”
### Emerging recommendations about R&D prioritization process

| **Purpose** | Clearly and explicitly define the ultimate goal of investments and, linked to this, 3-5 criteria on which R&D options should be evaluated.  

The purpose may be ‘biased’ towards a specific remit, but this will always be the case and is acceptable as long as the values applied are transparent.  

Difficult decisions and trade-offs between criteria and investment options should not be avoided as an overly long list of R&D priorities requiring an unrealistic funding budget is not useful. |
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<tr>
<td><strong>Values</strong></td>
<td>Commonly mentioned criteria for assessing R&amp;D options were effectiveness/efficacy and deliverability, which together lead to impact and progress towards global disease control goals.</td>
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<tr>
<td><strong>Information</strong></td>
<td>In terms of information that should be considered by experts when scoring options against agreed criteria, it was suggested that, in addition to epidemiological information, evaluations of previous investments to see which ones yielded the most impact per unit of investment is useful.</td>
</tr>
<tr>
<td><strong>Experts</strong></td>
<td>A broader group of experts – international and in country – including national programme representatives, academics, funders and technical agencies (WHO etc.), with an emphasis on front-line implementers, was suggested. Experts from outside of TB should also be included.</td>
</tr>
</tbody>
</table>
| **Ranking process** | A combination of discussion to reach consensus and independent ranking of R&D options was recommended.  

Broadly, the process favoured was to start with a discussion on the assessment criteria and hear different experts’ views on R&D options; then allow time for experts to review information presented to them and independently score alternative R&D options; finally collate scores and have another discussion to agree upon emerging priorities. |