



**Global Forum on
Bioethics in Research**

Ethics of health research priority setting

Cross-cutting themes

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The Global Forum on Bioethics in Research (GFBR) convened in Montreux on 28 & 29 November 2023, to explore the topic of '**Ethics of health research priority setting**'. The Forum brought together 92 experts from 43 countries to discuss case studies relating to four broad themes. The Forum focused on the low- and middle-income country (LMIC) context where prioritisation could aid the allocation of scarce research resources, but where resources and capacity constraints impact on the ability to perform research priority setting and fund the prioritised research. Cases reflected on the role of government, stakeholder inclusion, accountability, transparency and the tension between national and international or funder research priorities. The full case studies can be found on [the GFBR website](#) and videos of the plenary sessions are available on the [GFBR YouTube channel](#).

This overview is structured around the cross-cutting issues that emerged throughout the full meeting, and draws on the [keynote presentation](#) by Joseph Millum (St Andrews University, Scotland, UK). A separate, longer [report](#) summarises the meeting discussions, session by session, and the range of views that were expressed in response to the presentations.

Introduction

- In its most general sense, **research priority setting is deciding or recommending to others about how to allocate scarce and valuable resources** (e.g. money and research time). **Ethics is an integral component of how health research priority setting is carried out** and also because priority setting itself necessarily involves **value judgements** which should be scrutinised.
- Global research resources are currently maldistributed, but it is not obvious exactly **how they should be distributed, who should decide and what criteria should be used**. Priority setting is needed to answer questions about how funds for health research should be allocated and it should be done in a **systematic and principled way**.
- Formal methods include those developed by the [Council on Health Research for Development](#), the [James Lind Alliance](#) (JLA), and the [Child Health and Nutrition Research Initiative](#), amongst others. Largely these methods aim to guide national research priority setting exercises and research agenda setting for specific patient populations. The GFBR reflected on the ethics of carrying out these exercises and also the ethics of less formal research priority setting.
- Health research priority setting is technically very hard, because there's uncertainty about which scientific studies are going to yield the most valuable results. However, **how resources are allocated predictably affects which populations benefit**, when not everyone can receive those benefits. The question of **who should benefit is an ethical question and is a question about justice**.
- The ethics of research priority setting is therefore **not just about the process of research priority setting but also about the fairness of the results**, meaning the ethical and technical aspects of research priority setting are necessarily intertwined.
- **Ethical guidance for health research priority setting is required** to complement existing technical guidance and methods.

Who sets health research priorities (and who should)

- What research gets done depends on the decisions by multiple actors e.g. government agencies, international organisations, funders (public, philanthropic, for profit), research institutions and individual researchers. **Everyone whose decisions affect what research is done have obligations to allocate resources that they control or influence in a way that is fair.**

- Every actor whose decisions affect what health research gets done is allocating a scarce resource but **they may not think about their decision as constituting or resulting from priority setting.**
- The value judgements about what research to do and therefore what populations to benefit are sometimes implicit. This **implicit priority setting should be made explicit and be guided by ethical principles.**
- There are also **many people who are not typically involved in decisions about the allocation of research resources** for whom there are ethical reasons to include (see below).

Power disparities

- The majority of research funding comes from high income country (HIC) institutions or multinational companies and the global governance regime (e.g. the incentivisation of medicines that can be patented) heavily favours interests of the wealthy.
- **Power imbalances can occur at all levels of decision-making** e.g. national government vs funder priorities, national government vs sub-national etc.
- Patients, families, carers, community members, clinicians and LMIC researchers often don't get to decide what research is conducted which leads to **research priorities that are skewed from what might be considered a globally just allocation of scientific resources.**

Role of government

- **Political leaders should be sensitised to the value of priority setting and its ethical nature for priority setting to be valued, performed, and acted on to identify and fund priority research.** However, a government's ability to undertake a robust health research priority setting process depends on a range of factors e.g. government stability, political will, funding and the competency of the individuals involved.
- Governments should **institutionalise health research priority setting and build capacity 'in-house' within a technical secretariat that is *not* impacted by political changes** in government. But what would this look like? Who should be involved? What is the role of funders? And how are the research priority setting team kept accountable and who holds them to account? Some countries have institutionalised priority setting, but often resources including money and people are lacking and capacity strengthening is needed to do the work well.
- **Governments should be transparent about their health research priority setting processes** e.g. the substantive criteria, methodology for stakeholder input (including who, how and why). This includes role clarity for those involved and what value they contribute to the process e.g. providing technical expertise to support the process vs responsibility for actual decision-making.
- **Decision-making should be evidence-based using robust data with the results of the process** being made explicit e.g. why certain areas are, or are not prioritised and the compromise or trade-offs that were made.
- **The steps between the research priority setting exercise and how to implement the priorities should be defined at the outset, along with plans for effective monitoring and evaluation.** Governments should be more intentional about ensuring that prioritised research is actually funded and carried out.
- **Governments should coordinate research priority setting processes** and manage **systems to identify emerging priorities**, working with the global research agenda, which fluctuates in response to global events (e.g. COVID-19). A balance needs to be **struck between reactive approaches, and commitment to a longer-term agenda and national priorities.**

- **Negotiation with funders is essential to align priorities and create a trust dynamic.** 'Alignment' could mean funders only fund research that is on the national agenda, or could be an issue of complementarity where funders recognise the value of certain research agendas which national governments are unable or unwilling to address.
- **However, government decisions-makers may stymie health research priority setting** and implementation of the identified priorities (e.g. by not allocating sufficient funds or time or due to the bureaucracy and the high turnover of personnel in politics). Research agendas might be hijacked by **political agendas** and priorities set without broad consultation or **health needs may clash with cultural values and political will** and therefore be excluded from consideration (e.g. stigmatised health conditions).

What are the goals of national health research priority setting in a democratic country?

- **Maximise equity weighted reduction in disease burden with priority to people who are worst off.** However, whether priority should be given to research that promises **health benefit in the short-term vs benefits in the longer-term** is a difficult question.
- **Proper and efficient use of national resources.**
- Ensuring that **people who have a stake are at the table** and that there are mechanisms in place to manage how they are included and the level of power and influence they have over the decision-making process.
- To consider **how health research (and its products) will be implemented and interconnect with health systems.**

How can governments democratise research priority setting exercises?

- **Varied stakeholder engagement** e.g. using surveys and open workshops.
- **Disseminate information within communities and provide training to people participating in the research priority setting process** to facilitate and maximise their involvement.
- Engage the **private sector** e.g. non-governmental organisations, research institutions, and advocacy groups.
- Ensure a **geographical representation** that is relevant to the scope of the research priority setting.
- Encourage a **multidisciplinary agenda** by including different disciplines in research priority setting (e.g. social scientists).
- However, **democratising the research priority setting process can be challenged by issues of power between stakeholders, conflicts of interest, added cost and complexity** (e.g. of increasing stakeholder representation) and **epistemic injustice resulting from insufficient data** (e.g. in some countries refugees are not counted as recipients of health care so the burden of their problems are not considered in research priority setting processes). **How to democratise research priority setting exercises sustainably is a significant ethical challenge, especially in countries characterised by extreme inequality.**

Contextual consideration that may impact the nature, process and success of national-level research priority setting

- Health research funding is a small part of health funding in many LMICs and this can **impact on what type of research is prioritised.** Even where funds are available there may be other constraint on **how the funds can be used.** For example, if **health needs clash with cultural values or political will** or if countries rely on external funders who influence what health issues can be on the table.

- **The timeframe and funding of health research priority setting may impact on which methodology is feasible.** Bottom-up processes can be costly and time-consuming, and challenging in terms of needing to work at the local level and engage a wide range of local stakeholders. Top-down processes may be less costly and labour intensive but will be less inclusive.
- **Short-term contracts and timelines for research priority setting make it a challenge to adhere to good research priority setting practices** and require innovative solutions, e.g. maximising the use of online tools for consensus-building. However, this can result in trade-offs, particularly in stakeholder engagement. Well-structured groups with a common objective sustain lower costs in organising themselves, which eases their participation in the process and results in effective lobbying. In contrast, civil society and equity-deserving sectors are more difficult to mobilise and this creates missed opportunities to enhance equity in the health research agenda.
- **There may be a lack of competency and capacity** of individuals and institutions to conduct health research priority setting. In some LMICs **external experts facilitate the health research priority setting process and, due to time constraints, there is limited opportunity for local capacity strengthening** to ensure that the approaches are well understood by the local research priority setters. As a result, they could be left with poorly understood, un-contextualised priority setting approaches, which they may not be in position to use in future.
- **Health research priority setting approaches and criteria should be adapted for local use** to take account of local values and realities. A failure to adapt them to the local contexts may result in their limited institutionalisation and the priorities that do not best match the country's need.
- **Stakeholders should be identified by a mapping process** to identify the end user. Macro level research gaps can be identified by researchers, government and funders. But publics and end user communities should give insights into the context and lived experience of the health issue.
- **Context goes beyond a single country:** Surrounding countries may guide or influence national priority setting e.g. due to the geographical distribution of disease across national borders.

Role of researcher funders

- **Funders significantly influence what research gets done** through their choice of strategic priorities. By setting priorities, funders define normative values regarding **what should be funded**. On the one hand this could be seen as problematic and as an imposition of power by funders. On the other hand, there may be potential benefits e.g. focusing a government's attention on research it has not prioritised, but which is important (e.g. mental health).
- Ideally, funders should have strategies to **help them understand national health research priorities so they can identify gaps and overlapping interests** and to ensure the relevance of the research they fund to priorities in local contexts. This could involve **discussions with local governments**. Even where there is no formal health research priority setting process and no national health research agenda, there will be high priority needs in a country.
- **Many funders coordinate between themselves to mitigate duplication of priorities and to identify and support complementary funding.** There are formal mechanisms (e.g. funders forums and strategic partnerships) and informal outreach to other funders working in the same areas. Sometimes funders launch joint funding calls, however, **co-ordination can be challenging due to bureaucracy and the differing pace of funding programmes.**
- **Recommendations for when funders set their research priorities:**
 - **Conduct stakeholder consultation** and tailor how to involve different groups in the process.
 - **Convene and support a forum of LMIC representatives** to feed into funders' priority setting process.

- Be aware and **understand how the process of priority setting is done in each country** and take account of what the priorities are.
- **Use and explain explicit criteria** for research prioritisation and **publish them for transparency**.
- **Recommendations for funders regarding grant schemes and processes:**
 - **Ask applicants to explain how their proposals meet national or local priorities.**
 - **Facilitate a shift in funding from HIC to LMIC researchers** to have global problems addressed via a Global South lens to support the decolonisation agenda.
 - **Support international consortium where each country receives money to fund their own research** and researchers.
 - **Promote fairness, equity, diversity and inclusion** e.g. through broader dissemination of funding opportunities, by supporting research and grant writing capacity building (especially for early career researchers) and by pairing up-and-coming institutions with well-known institutions to avoid the same people or/and institutions receiving funding time and time again.
 - **Look at health intersectorally.** Strategic priorities are often focused on treatment, whereas funding both discovery and social research would better improve human health.
 - **Ensure there is at least 1 peer reviewer from the country where the proposed research is taking place** to bring contextual understanding about the priorities in that setting.
 - **Provide funding for countries to perform health research priority setting processes** and build capacity in this field.

Relationship between funder and country priorities

- The scope of national priority setting is often guided by global priorities and the priorities of external funders. This raises fundamental questions about the **self-determination and autonomy of LMICs in setting their own research priorities in the context of insufficient local research funding**. Where governments have governing bodies to coordinate health research priority setting, but the bulk of the research is externally funded, those legitimate bodies may lose their power and influence. The concept of ownership is critical – but if governments don't have the resource to do health research priority setting and implement the outcomes, the ownership is not there. There is a need to decolonise research agendas and for **LMICs to define and implement their own national priorities**.
- Funders could channel funding through government agencies to allocate according to national priorities, but there may be risks in this approach (e.g. due to corruption or where governments may not value research and divert funding to other country needs). **Local researchers are often the ones who adapt external funding to local needs**. To this end, **it's important for national agendas to be broad to allow alignment between national and external funding interests so both can be met**.
- **Some country governments deny externally funded research that is not a national priority. However, this policy may be a concern in some contexts** e.g. if research is rejected for reasons other than research priorities, including where there is a conflict of interest within the government or a lack of neutrality.
- Even where government veto is based on research priorities, this could be **problematic if the country's research agenda is unfair**. For example, a **government may not prioritise research that is specific to the needs of some marginalised groups or on some topics (e.g. abortion)** due to the social and ideological context.
- Whether something is deemed a country priority or not does not mean that the research isn't potentially valuable. For example, mental health research is not prioritised in many countries, but is clearly a significant issue. In this context **a government veto on non-prioritised research could be detrimental to scientific progress and academic freedom**. There should be a **high threshold for refusing money from external funders if the research has potential value**.

Fair processes

- **Just outcomes require fair processes** (and designing fair processes requires a conception of a fair outcome) – so engagement is required on **both how to design a fair process and what substantive criteria should be used to allocate research resources**.
- The process should meet certain ethical criteria, including **the appropriate and meaningful inclusion of the various stakeholders in the research enterprise**.
- **Decisions on which groups to select and how to include them should be based on the reasons for including each group** e.g. the inclusion of scientists to acquire and synthesise scientific knowledge, or the inclusion of patient groups in relation to a specific disease to find out exactly what matters to them. **They should be included in ways so their voices are not drowned out** by others so the views of patients are a fair representation of the different patient experiences.
- Justice can be enhanced through **inclusivity and participation of members from diverse groups**, who should generally be included but not in a tokenistic or box-ticking way. Other principles to consider are **compensatory justice and restorative justice – not just to compensate but to restore and repair health disparities due to past injustices**.
- **Meaningful inclusion** can help establish context and the issues on the ground. This requires a well-defined and transparent process for selecting which stakeholders to include and **robust methodologies to engage different populations in the research priority setting process**. For example, identifying which groups are **marginalised in any given context** and how to ensure they are appropriately included.
- Resource constraints can impact on fair process and the inclusion of diverse groups, resulting in a **procedural injustice and distributive injustice if resources are not fairly distributed** towards the needs of these groups due to their limited involvement in the process.

Inclusion of marginalised groups

- 'Marginalised' by definition means excluded. People and groups may also be considered marginalised due to their:
 - **Location** e.g. tribal populations in India that live in the forests.
 - **Language**
 - **Lack of access to care**
 - **Lack of education**
 - **Low income**
 - **Sexuality** e.g. in some African countries, homosexual people are marginalised by the government and have no representation.
 - **Religion** e.g. in the Philippines, a deeply Catholic countries, HIV patients have only recently formed advocacy groups.
- Marginalised groups may need a more complex approach to include them in health research priority setting processes and because of the complexities, they can end up being missed out. **As research priority setting seeks to mitigate this marginalisation, the exercise itself is required not to compound existing axes of marginalisation**. Research priority setters need an awareness of the problem and to be proactive, working with organisations that can help facilitate contact and engagement with people or groups. **Local facilitation of the process would help build on pre-existing trust and rapport**.
- **Barriers and challenges to inclusion** include:
 - **Language, along with understanding** of the concept of research and health research priority setting processes, which can undermine attempts to give voice to communities in technical discussions. Community members may have health care expectations that are different from

- the aim of the research priority setting work, highlighting the need to **define, clarify, and be transparent about the difference between research and health services**. However, **understanding a community's health problems can give rise to research questions**. Where necessary, individuals could be invited to verbalise their suggestions, and these could be recorded, translated and summarised by the research team. This approach could address the need for inclusion, but **the process of synthesis by the study team raises an issue about the authenticity of the participants' voice**.
- **Marginalised groups (and the broader community) may need to be empowered through education or training to think about the links between research and health care so they can provide meaningful input to health research priority setting.** A small group of representatives can be trained on what research is and the importance of participating in research priority setting exercises to spread the information within their communities.
 - **Individuals and groups may be reticent to take part due to real or perceived power differentials and cultural differences.**
 - Understanding who is the right person to invite to a research priority setting exercise, mindful that there may be hierarchies within groups or 'expert' participants, leading to **questions around the authenticity of representation**. Individuals in a community will have different needs and some marginalised voices may be 'louder' than other marginalised voices. Advice could be sought from community leaders to help the research priority setting team understand the community's needs. However, such gatekeepers are **often hierarchical and don't necessarily reflect all thinking or diversity in a community nor represent the most marginalised**, thus there are risks of further excluding those already systematically excluded. It may be useful to **engage community members who have a health-related role in the community or community health workers to serve as a proxy for communities**.
 - Health research priority setting exercises should be **non-extractive and ideally give value back to individuals and communities**. But what, if anything, is owed? On the one hand, if the research prioritised by the community actually happens, then arguably that should be enough and nothing more may be owed. But if there is no follow-through to the priority setting exercise, then maybe participants *are* owed something. Parallels can be drawn with benefits-sharing in research e.g. **compensation for time, community-level benefits** such as community development, providing health and research education and, where feasible, **referral or ancillary care**.

Health research priority setting vs research: the role of research ethics committees (RECs)

- Even though health research priority setting processes are not generally categorised as research, or necessarily fall under research ethics governance, **research ethics guidance can help research priority setting teams to think about what is ethically required** (e.g. reciprocity). While it may not be necessary to obtain REC approval for individual priority setting exercises, or have the same level of scrutiny as research, health research priority setting involves engagement with people and data so **ethical values and a level of scrutiny ought to apply even if they aren't legally required**.
- **RECs could have a role in relation to health research prioritisation**, given their privileged access to research proposals. The following were proposed but would represent a significant addition to a REC's responsibility and may not be feasible given existing constraints on time, resources and expertise:
 - Check if research proposals **align with national priorities (including internationally funded research)**.

- **Review the social value of research proposals**, using their understanding of the local context e.g. whether the expected results can be implemented locally. But this raises the question of whether RECs should approve or reject proposals with low social value.
- **Conduct a portfolio analysis** of funded research to assess whether it gave rise to social value.
- **Write ethical guidelines for health research priority setting** and be involved in – and bring an ethics lens to – national exercises (this could be a role for a national REC, where one exists).
- **Bioethicists should also be involved in health research priority setting processes**, to advise on the principles that should guide decisions about what research to prioritise.

Transparency and accountability

- The **specific goals of research priority setting need to be defined for the process to have maximum impact**. Research priority setting across a very broad range of health issues will be a very different exercise to research priority setting with a narrower focus (e.g. maternal and child health). It's also important to understand the different research priority setting models and which is best for the given context and goals (e.g. the JLA model focuses on end users – participants and clinicians – but other models involve wider stakeholders).
- **In terms of accountability**, health research priority setting teams should **set reasonable expectations at the start of the process and be transparent regarding the scope of the exercise, what will happen to the views expressed during the process and who will make the final decision on the priorities**. Engagement in research priority setting comes with responsibility – those engaging must be accountable to those who take part. Once information has been collected, there's an obligation to do something about it – otherwise the trust will be lost. For example, if a list is developed and then doesn't get funded, this is an injustice if implementation was a ground rule at the outset. This can be a challenge where there are conflicting health needs and priorities e.g. within marginalised groups or between them and other groups involved in a research priority setting process.
- The **substantive values** that should guide health research priority setting processes include:
 - **Legitimacy and trustworthiness** of the party undertaking the research priority setting.
 - **Evidence based** - using data to map evidence, identify gaps and rank different needs and justify their inclusion in a priority list.
 - **Equity and maximising social value**.
 - **Trustworthy and transparent** processes.
 - **Accountability**.

Priority setting within research partnerships

- There are many **competing interests and complexities in research priority setting and partnerships add another layer**. A lot is presumed in the context of research priority setting within partnerships because it can be hard work to surface the interests, values, and disagreement, but this is required by the transparency principle and will benefit the partnership. It's important to **be transparent and recognise that power differentials exist in research partnerships, acknowledge the differences and discuss how to mitigate them**. This is especially true for Global North-Global South and Global North-Local South partnerships.
- The concept of 'power' could usefully be unpacked and to think instead about a **typology of 'powers'** and recognise the **balance of power** within partnerships. A party has to recognise the power they have, in order to negotiate. For example, research priority setting could be used as a negotiation tool if an LMIC researcher invites (potential) partners to pick from their priority list.
- Money often comes from Global North researchers so they bring their and their institution's demands. However, if Global North researchers want to use data from LMICs part of approval process could be

whether the **proposal matches the local researchers' and/or national priorities**. The onus should be on the Global North partner to yield power – as well as the Global South partner to assert power and negotiate, but this is difficult to implement in practice.

- **Guidance to help determine research priorities between research partners would be useful.**

Substantive criteria

- **Substantive criteria** should be used to compare or score different research options.
- The **allocation of resources to increase the social value of research is one agreed upon substantive criteria**. The social value depends on the:
 - **Probability of success** (providing benefit to patients).
 - **Magnitude of benefit** (how many patients benefit).
 - **Reduction of inequality** (the extent to which providing benefits to patients would reduce inequality and the benefits flow to those who are more disadvantaged).
- Although there is widespread agreement that the goal of research priority setting should be to generate social value, many significant ethical questions remain. **Substantive ethical judgement should not be replaced with more process, instead engagement with the hard, substantive questions is required** in order to design better processes that help achieve just outcomes. For example:
 - Should more common diseases get higher priority as they affect more people? But what then for neglected diseases?
 - How should equity be understood? How can we measure equity so it can be operationalised so that we can set priorities according to the effects of research on people who are more disadvantaged?
 - How should historical wrongs be taken into account? For example, should former Colonial powers be investing in more health research to benefit people in countries that were former colonies or other countries they have wronged?
- Other criteria that can be used in health research priority setting to select priorities include:
 - **Deliverability**, including consideration of **feasibility, affordability and scalability**.
 - **Immediacy**: The time element to deliverability gives rise to difficult questions about how to balance research that provides more immediate benefits in comparison to research that holds promise in the longer term.
 - **Equity**.
 - **Sustainability**. Can the outputs of the research be sustained and kept going in the long term in order to have an impact on current and future generations?

Monitoring and evaluation

- **Monitoring and evaluation plans should be included in research priority setting processes** to better understand what was achieved and what wasn't and to feed this learning into the next research priority setting process. Evaluation is also required to **assess return on investments, especially for resource-intensive bottom-up research priority setting, and to support efficiencies in the use of public research funds**.
- Evaluation should include a reflective exercise to **identify the extent to which the ethical aims of inclusion of diverse groups have been met**, and from that to assess the **effectiveness of the process and strength of the priority setting recommendations**.

Uptake of prioritised research

- Research priority setting is a multi-stage process which itself requires an investment of time and resources (which might otherwise have been used for valuable research). Therefore, there are ethical

obligations **to disseminate and put the priorities into practice**. A report that sits on a desk gathering dust will not lead to a just outcome.

- **Those who carry out priority setting exercises should disseminate and – if they have the power – implement the results**. And **those who make research decisions should look to the results of research priority setting exercises and use them to guide decisions** about what research to pursue or what funding calls to put out.