Global Forum on
Bioethics in Research

Ethics of health research priority setting

Meeting report

Montreux, Switzerland
28 and 29 November 2023

W: www.gfbr.global **E:** gfbr@who.int

CONTENTS

Executive Summary

The Global Forum on Bioethics in Research (GFBR) convened in Montreux, Switzerland on 28 & 29 November 2023, to explore the topic '**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 scare research resources, but where resources and capacity constraints impact on the ability to perform research prioritisation and to fund the prioritised research. The cases studies reflected on the role of government, stakeholder inclusion, accountability, transparency and the tensions between national, international and funder research priorities.

This report summarises the meeting presentations and the range of views that were expressed, while a separate policy overview draws together the cross-cutting themes. The full case studies can be found on the GFBR website and are linked in this report. Videos of the plenary sessions are available on the GFBR YouTube channel.

- **Theme 1: Reflections from three national research priority setting exercises: stakeholder inclusion, transparency and evidence.** Research priority setting at the national level has marked influence in not only the research interest domain in which priorities are being set, but also in the wider ecosystem. Consequently, it is operationalised in a contested space. In this session three speakers presented case studies about **national research priority setting in different country contexts: Uganda, Peru and Malawi. They highlighted the need for stakeholder engagement, and that it is crucial for the research priority setting process to be seen as fair, legitimate, and just**. Understanding the failure or success of national level priority setting is also complex.

- **Theme 2: Amplifying marginalised voices in research prioritisation: the James Lind Alliance approach.** It is widely recognised that **marginalised voices often don't have the presence or influence in research prioritisation processes that they should be afforded**. When voices are engaged, they may need amplification to truly influence in the context of the status quo, power dynamics and real or perceived hierarchies. And even where amplification occurs, it often entails the voices of those who experience marginalisation being reinterpreted by researchers and funders. **Speakers in this session described the significant effort that has been made to engage marginalised voices in research priority setting in Ethiopia and India**. They described the required time and commitment and iterative engagement at multiple levels, to achieve tractable engagement. They spoke about the difficulty of achieving consensus across a wide range of stakeholders, where the views of marginalised voices were very different from other stakeholders. Both presentations had an underlying theme around who should lead research priority setting exercises involving marginalised voices, providing a deep ethical challenge for research prioritisation.

- **Theme 3: Governance of research priority setting: the role and responsibility of government.** It has been argued that states should be primarily responsible for ensuring their population's health and, in effect, setting their national health research priorities. It is thus important to consider the role and responsibility of governments in setting these priorities. This raises a key ethical question: **What are the ethical principles that should guide governments as they engage in health research priority setting?** This session considered this question by interrogating two aspects of this role: i) processes through which the priorities are set and ii) the substantive values that should be reflected. The case studies consider the different approaches taken by national governments, as well as how the processes contributed to or detracted from substantive values of health priority setting. **Drawing on experiences from South Africa, Philippines, Uganda, Tanzania and Zambia, the session discussed the importance of ensuring that national agencies are provided with the necessary authority, tools and resources to lead the process** and **examined the processes by which a government ensures fair and equitable representation and the translation of priorities into actual research**. The session raised the issue of government stewardship in ensuring clear strategic direction that is communicated effectively and building capacity within government departments to undertake research priority setting processes.

- **Theme 4: Ethical and practical challenges to research priority-setting.** The overall goal of research priority setting is to promote health and health equity by focusing limited resources for health-related research (e.g. funding) on the most important research questions. However, **there are ethical and practical challenges to achieving this goal, even when researchers and research funders are well-intentioned**. Case studies from **Uganda, Kenya and India** described these challenges and identify possible ways of addressing them. The session considered why **collaborations between researchers in high- and low-resource settings sometimes fail to address research priorities in low-resource settings**, even when their stated goal is to promote health and health equity there. It also examined the **difficulties of adhering to institutional research priorities when health institutions in low-resource settings enter collaborations with researchers from high-resource settings**. Finally, the session addressed how researchers and funders may aim to address important health problems but **fail to develop interventions that are feasible to implement in low-resource settings due to contextual constraints**.

- **Research funder panel.** Funders significantly influence what research gets done through their choice of strategic priorities. This session involved representatives from four funders: **Wellcome**, the **South African Medical Research Council**, the **Fogarty International Centre-US National Institutes of Health** and the **Global Health EDCTP3 Joint Undertaking.** The funders described the factors that influence their organisation's research priority setting and the challenges they face. Discussion focused on the **importance of funders working together, and with governments in LMICs, to better understand each others' priorities, to assess overlap and to promote complementarity**.

Introduction

The Global Forum on Bioethics in Research (GFBR) convened on 28 & 29 November 2023, to explore the topic of '**Ethics of health research priority setting**'.

The meeting brought together the global bioethics and research community and others to explore ethical challenges including: **who** does (and who should) set priorities? **how** should priorities be set? what **substantive criteria** should be used? and **how can power disparities be mitigated** in research priority setting processes?

This report contains extracts from the case studies presented at the meeting, and the discussion. The cases were predominantly from LMIC contexts. We thank the presenters for their work. The full case study write-ups and slides are available on the GFBR website.

Case studies were invited through an open application process. An international, expert Planning Committee[1] selected the speakers and structured the meeting around the following themes:

- Theme 1 Reflections from three national research priority setting exercises: stakeholder inclusion, transparency and evidence
- Theme 2 Amplifying marginalised voices in research prioritisation: the James Lind Alliance approach
- Theme 3 Governance of research priority setting: the role and responsibility of government
- Theme 4 Ethical and practical challenges to research priority setting
- Research funder panel

With experts from 43 countries (see map of GFBR participants' countries), the meeting delved into the key ethics and governance issues regarding the prioritisation of global health research.

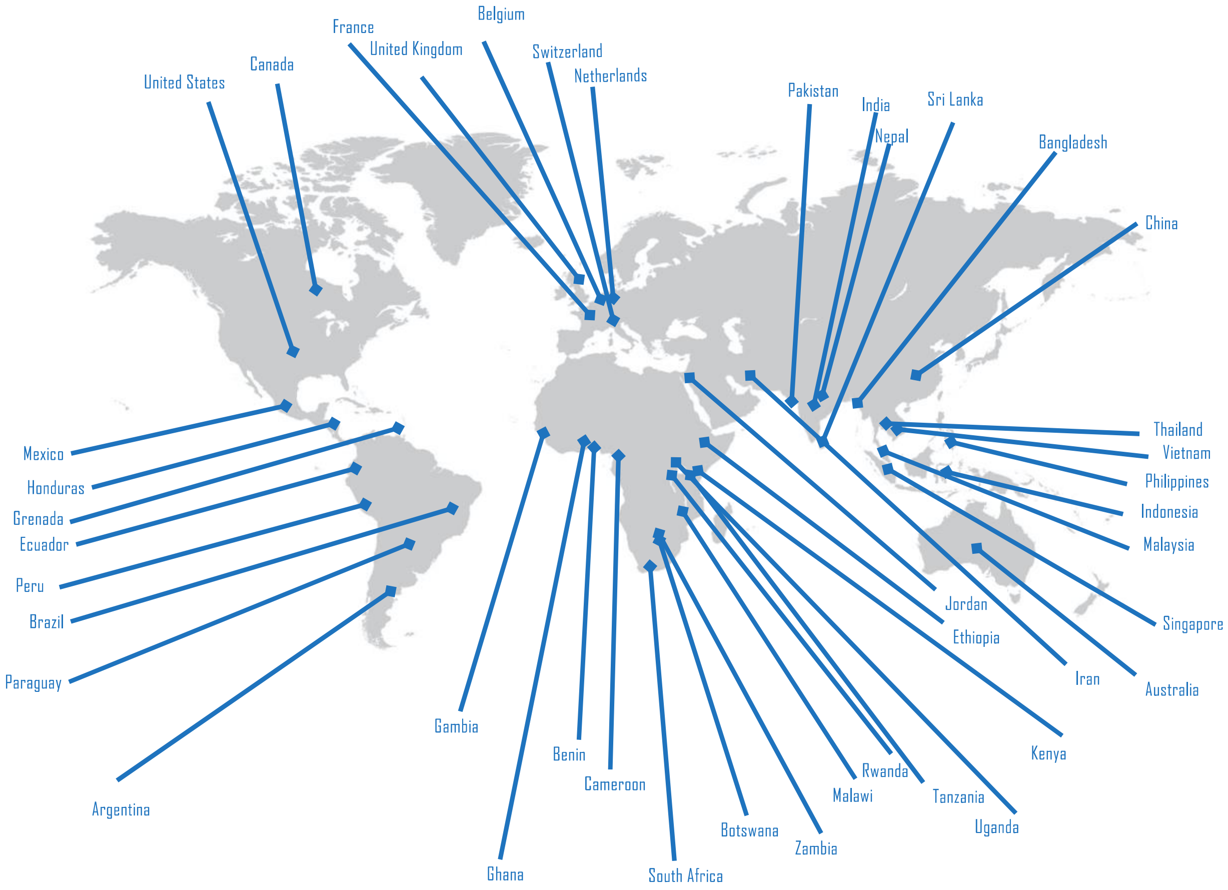

Figure 1 GFBR participants: The 92 participants from 43 countries brought a wide range of expertise to this important topic, including: bioethics, research ethics, policy, regulation, health researchers, and funders, at all career stages. 67% of participants were from LMICs.

---

[1] Katherine Littler, Switzerland; Joseph Millum, UK; Soumyadeep Bhaumik, India; Toto Gronlund, UK; Sharon Kaur, Malaysia; Francis Kombe, South Africa; Mona Nasser, UK; Bridget Pratt, Australia; Ludovic Reveiz, USA; Annette Rid, USA; Nicola Barsdorf, South Africa; Claudia Chamas, Brazil

Keynote

Joseph Millum (St. Andrews University, Scotland, UK) keynote slides and video.

In 1990 the Commission for Health Research and Development published a seminal report that identified what came to be known as the 10/90 gap: the gross mismatch between the burden of illness which is overwhelmingly in LMICs and investment in health research which is overwhelmingly focused on the health issues of industrialised countries. Much has changed since the report was published but problems remain, as evidenced by the case of neglected diseases, which represent 13% of the global burden of disease but attract only 2% of the estimated global spending on health research.

Global research resources are 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.**

> **Ethics is an integral component of health research priority setting. It's not just that research priority setting should be carried out in an ethical manner, but priority setting itself necessarily involves value judgements which should be scrutinised.**

In its most general sense, **research priority setting is deciding or recommending to others about how to allocate scare and valuable resources**. Scarce in the sense of money and research time and valuable given the potential benefits of that research to human health. 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 setting priorities but also about the fairness of the results. Values are being expressed through the exercise and being expressed in the results of the exercise. The ethical and technical aspects of research priority setting are necessarily intertwined.

> **There are many individuals and entities who make decisions about what research gets done. Everyone whose decisions affect what research is done has obligations to allocate resources that they control or influence in a way that is fair.**

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. Every actor whose decisions affect what health research gets done is allocating a scare 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.** Also, there are many people who are not typically involved in decisions about the allocation of research resources for whom there are ethical reasons to include.

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. Meanwhile 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.

How should research priorities be set? Formal methods include those developed by the Council on Health Research for Development, the James Lind Alliance, 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. GFBR reflected on the ethics of carrying out these exercises and also the ethics of less formal research priority setting.

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.

Fair processes: The process should meet certain ethical criteria, including the **appropriate and meaningful inclusion of the various stakeholders** in the research enterprise. **Members of diverse groups should generally be included but not in a tokenistic or box-ticking way**. 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.

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? 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?

There is an ethical obligation to disseminate and use the results of research priority setting. It's valuable only if it affects what research gets done.

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 further ethical obligations **to disseminate and put the priorities into practice.** Those who carry out priority setting 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.

1. Reflections from three national research priority setting exercises: stakeholder inclusion, transparency and evidence

***Session summary**: Research priority setting at the national level has marked influence in not only the research interest domain in which priorities are being set, but also in the wider ecosystem. It is often a marker of macro level policies or values. Consequently, it is operationalised in a contested space. Stakeholder engagement, and the process being seen as fair, legitimate, and just are crucial. Understanding the failure or success of national level priority setting is also complex. In this session three different speakers presented three case studies from three country contexts – Suzanne Kiwanuka from Uganda, Ramón Ponce Testino from Peru and Sibongile Kaphaizi from Malawi.*

Chair: Soumyadeep Bhaumik, The George Institute, India

Re-imagining the ethics and the utility of existing frameworks for research priority setting: a case study of the family planning research and learning agenda in Uganda
Suzanne Kiwanuka – Makerere University, Uganda
Family planning research and learning agendas (FPRLAs) enable countries to systematically identify priority evidence gaps and create a knowledge base for more equitable family planning programming. They also aid in reducing duplication of evidence generation and enhancing the utility of existing evidence by aligning stakeholder resources around an expected outcome. The Research for Scalable Solutions (R4S) project has supported researcher teams and family planning stakeholders across 6 countries (Côte d'Ivoire, Malawi, Mozambique, Nepal, Niger, and Uganda) to develop FPRLAs.

Suzanne Kiwanuka presented on the experience of developing a FPRLA for Uganda. It was a two-year multistage process involving a review of family planning evidence from 115 documents, analysis of secondary data and engaging stakeholders (n>150) in multiple engagements (e.g. Delphi panel survey). The process was country-led and dominated by program implementors, academics, and policy-makers, but also included multi-stakeholder representation. In Uganda, the resulting FPRLA was disseminated by the Ministry of Health on its webpage and it has been used as a source document to inform program design and research questions.

Aspects of the process that worked well included:

- Evidence mapping and inclusion of programmatic evidence.
- Multi-stakeholder participation to generate research priorities, as a way of enhancing ownership and the potential utility of the research agenda.
- Dissemination of research priorities (through workshops and online via the Ministry of Health knowledge platform) and monitoring and evaluation of the resulting FPRLA.

Ethical issues

- **Stakeholder engagement**: There was minimal involvement from cultural leaders, advocacy groups and funders in the process.
- **Missed-opportunity for family planning user inclusion**: The process overlooked people with lived experience, in particular the youth. Having recognised this gap, social research is currently being carried out to better understand their perspectives on family planning.
- **Tension between funder and local priorities**: The process of generating the Ugandan FPRLA was country-led and didn't rely on Global North partners. The Ministry of Health owns the FPRLA and is lobbying government and international partners to focus their research on the FPRLA. Although a positive step towards fostering equity by **decolonising research priority setting**, the utility of the FPRLA will depend on the availability of research funds and the willingness of funders to align themselves to the FPRLA.

An assessment of the priority setting exercise for health research in Peru

Ramón Ponce Testino – Pontifical Catholic University of Perú, Peru

In Peru, since 2009, the Ministry of Health (MINSA) through the General Office for Research and Technology Transfer of the National Institute of Health (INS-OGITT) has carried out health research priority setting. The first process took place between 2009 and 2010, and established priorities for the period 2010-2014. The second and the last process took longer, from 2014 to 2018, and established priorities for 2019-2023. Between both processes (i.e. from 2015 until 2018) there were no official health research priorities in the country.

Ramón Ponce Testino was not directly involved in the research priority setting process and presented as an external commentator on the exercises. He described the 2014-2018 process as including three stages:

1. Stage 1 (2014-2015): Participatory workshops and round tables in all 24 regions to deliberate on the priorities of each region using methodology adapted from the Combined Approach Matrix. INS-OGITT devised the prioritisation criteria for the identified needs.
2. Stage 2 (2015): Prioritisation and consolidation of the regional priorities into a national list of 21 health problem, achieved through virtual consultation with experts (174) and resulting in a ranked list.
3. Stage 3 (2018): Consolidation of the final list of prioritised problems for the whole country at one main national workshop using a deliberative approach involving 118 participants in 10 working groups. Criteria were used (knowledge gap, feasibility, and consequences) to identify 58 national research priorities, corresponding to 10 health problems.

Ethical issues

- **Governance**: The 2014-2018 exercise took 4 years to complete but the first exercise took only 1 year, raising questions about what is the appropriate timeframe required to do a 'good job'? This, and the lack of priorities between the two processes, call into question the independence of the exercise with respect to context (political issues or institutional limitations). It was also unclear if there are clear criteria to evaluate the success of the process.
- **Fairness and inclusion**
    - Although driven by a participatory approach aimed at reaching consensus, most of the people involved in the different stages of the process were MINSA's officials and subject experts. In order to demonstrate the legitimate and fair aggregation of interests during the procedure more inclusive mechanisms for the identification and engagement of other relevant stakeholders should be encouraged.

    - It was unclear how the process preserved the integrity of the regional participatory and plural consultation from Stage 1 as the process moved through to Stage 3.

- **Transparency**
    - OGITT has process guidelines but transparency about how the priorities are set or how certain criteria were defined was limited (e.g. the criteria 'consequences').
    - The process should be publicly accountable and transparent.
    - Participation of actual researchers in the priority setting process was sparse.

Balancing ethics and stakeholder interests: insights from Malawi

Sibongile Kaphaizi – Ministry of Health Research Department, Malawi

Malawi's first National Health Research Agenda (NHRA) outlined the country's priorities for the period 2012-2016. It served as a reference for researchers, policymakers, program implementers, academic institutions, health development partners, and other stakeholders. The initial NHRA development process was funded by donors, but it lacked an implementation strategy. The midterm assessment of the agenda revealed that the established objectives were not achieved, primarily due to resource constraints and because ownership of the agenda was not well-defined. The Ministry of Health's Research Division has taken the lead in facilitating the development of the second NHRA as part of its mandate to promote and coordinate health research efforts.

Having worked directly on the research priority setting exercises, **Sibongile Kaphaizi** reflected on the time lapse between NHRA I and NHRA II and the overall need to improve on first agenda, specifically implementation. The development of NHRA II commenced in 2017 but was stalled due to financial constraints. Work involved a number of phases:

- **Preparatory phase** (2021), including a departmental level planning committee choosing 10 disease themes to be incorporated into the NHRAII.
- **Induction workshop** (2021) where the themes underwent review, and thematic working groups, comprising additional experts in specific fields, were established.
- **Data collection and themed workshops** (2022) encompassing all three regions of Malawi, bringing together experts from various sectors, including the Ministry, public and private entities, research institutions, and representatives from diverse fields.
- **Prioritisation** where each working group decided which method to use depending on what data was available (e.g. Essential National Health Research (ENHR) and the Child Health and Nutrition Research Initiative (CHNRI), alongside the Nominal Group Technique).
- **Consolidation,** culminating in a national consultative workshop and stakeholder analysis and mapping to inform implementation.

Challenges included coordination of activities and that there was no dedicated funding support to the NHRA development, which sometimes resulted in the process being rushed.

Ethical issues

- **Stakeholder involvement**: Policy-makers and experts were well-represented but users were limited.
- **Barriers to participation**: The open invitation to meetings and thematic workshops encouraged interested parties to participate and express their viewpoints. But this resulted in individuals with sufficient resources and a strong commitment to advancing their personal agendas or specific research interests having a greater advantage over those who lacked the resources to attend. Also, more extensive communication about the workshops would have helped reach a wider audience.

- **Procedural justice**: The rushed nature of the process impacted on inclusion and fair process, including the limited involvement of equity-deserving groups.
- **Distributive justice**: Resources were not fairly distributed towards the needs of equity-deserving groups due to their limited involvement in the process.
- There was **poor implementation** of NHRA I but there is good political will towards the development and implementation of NHRA II. **Sibongile** identified the need for dedicated funding to support both priority setting **and** implementation.

Plenary panel discussion

The speakers were asked about the integration of politicians – as representatives of the public – in their research priority setting exercises. The exercise in Malawi tried to incorporate politicians in the data-collection phase and policy-makers reviewed the draft NHRA and provided feedback. In Uganda they were involved during the validation meeting and they were given the opportunity to provide feedback on drafts. But they were not involved as actively as the research priority setting team would have liked. The politicians were given access to the final FPRLA to be used for lobbying. Ramón commented that involving politicians can sometimes be an obstacle to the health research priority setting. **Bureaucracy and the high turnover of personnel in politics can create challenges for the priority setting process and implementation of the identified priorities**.

The speakers discussed the feasibility of implementing the identified priorities. In Malawi, **feasibility can be impacted by financial constraints for certain kinds of research e.g. clinical trials and research involving technology**. Generally, external funding is required to implement this kind of research. It’s only recently that Uganda has been actively funding research, but researcher have gained credibility with funders and government.

GFBR participants asked if the research priority setting exercises were supported by ethical guidance. The processes in Uganda and Malawi were pursued as technical exercises and the teams only started to reflect later on the ethics and what could have been done better, especially regarding inclusion and which stakeholders were missed from the process.

The case studies highlight that most health research priority setting guidance focuses on process and technical issues and not on ethics and values. **Ethical guidance for health research priority setting is required** to complement existing technical guidance and methods. Also, **there’s a need for policy guidelines to inform implementation of the national research agenda, including timebound monitoring, evaluations and reviews built into the process**.

Breakout group discussion

Nature and goals of priority setting

Some GFBR participants found it helpful to **characterise health research priority setting as a *system*, rather than a process or a goal in and of itself**. Thinking about health research priority setting as a system means thinking in the longer-term, and making improvement over time, rather than thinking about starting and finishing a process. It also invites a transdisciplinary approach involving different stakeholders and consideration of governance issues, human resources, budget, implementation and monitoring.

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 rank different needs and justify their inclusion in a priority list.
- **Equity and maximising social value**.
- **Trustworthy and transparent** processes.
- **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 a wider range of stakeholders).

Contextual consideration for national-level research priority setting

Every country is different, making it **hard to learn from other country processes and experiences and difficult to map these onto another context**. e.g. who/which organisation(s) is responsible for the process, who to involve, the role of funders, scope of the exercise etc. **Understanding the specific context is important and necessary to promote justice and inclusion in the research priority setting process**. GFBR participants identified the following contextual considerations that may impact the nature, process and/or success of national-level research priority setting:

- **Funding and timings**: **Research priority setting could be constrained by the timeframe dedicated to the process and/or by funding.** Many LMICs have limited resources to conduct health research priority setting.
- **Methodology**: What approach is feasible with the given resources and time? 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.
- **Lack of competency and capacity** of individuals and institutions to do research priority setting and whether it is seen as important and useful process to invest in (e.g. by government).
- **Who should be involve in a research priority setting exercise**: Stakeholders should be identified by a mapping process aimed at identifying the end users, (this will provide necessary context for feasibility). 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.
- **Constraints:** 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.
- **Corruption and conflicts of interest** e.g. political or religious views may influence the process, or outcomes. **Authoritarian governments may have priorities set by powerful people based on their interests**.

- **Power dynamics and imbalance**. In some countries the national research agencies and pharmaceutical companies set the research agenda. Other relevant stakeholders should also have a voice.

Decolonizing health research agendas

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**. There is a need to decolonise research agendas and for **LMICs to define and implement their own national priorities so that these are not defined by external drivers and organisations. External funders** need to be respectful of local decision-makers but **do not always ask governments what their priorities are.**

However, it was noted that **some countries have no national research agenda or defined priorities**. Also, it is not just a problem of trying to align external funding with national priorities: the community-level needs may differ from national and global-level priorities.

LMICs can't always fund their priorities themselves. One suggestion was for funders to channel funding through government agencies to allocate according to national priorities, but some GFBR participants considered there were risks of corruption in this approach. Several GFBR participants shared their experience that **local researchers are the ones who end up adapting 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**.

Justice as an ethical issue in health research priority setting – how can it be improved?

GFBR participants agreed that health research priority setting processes **in resource-limited LMICs should be guided by principles of distributive justice and procedural justice to ensure benefits reach those who need them most**. The following points were stressed to achieve this goal:

- Justice can be enhanced through **inclusivity and participation** of communities and patients and not leaving minority groups out of the research priority setting process.
- **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 included. However, GFBR participants agreed **there is currently a lack of clarity regarding when inclusion is required and how it should be done** to ensure it is both meaningful and feasible in context.
- The **steps between the research priority setting exercise and how to implement the priorities should be defined**: a report that sits on a desk gathering dust will not lead to a just outcome.
- **The process should be evaluated** to better understand what was achieved and what wasn't and to feed this learning into the next research priority setting process.

There are key arguments grounded in principles of equity and justice for identifying who are the most vulnerable in a society. This should be the priority group that research moves to address the needs of, particularly in the context of an evidence-based medicine paradigm. **Inequity of health access should also be a core component of contextual information.** For example, addressing questions of what has been tested in a population that is relevant to that population e.g. where pregnant women or young people have been excluded from the development of certain approaches and treatments, is this a priority gap to address? 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**.

GFBR participants discussed whether **transparency and representation** are enough for a health research priority setting process to be called fair and just? Both are important but the representation needs to be meaningful. Can people be brought into the process in a way that those people with less power don't feel intimidated? GFBR participants agreed that health research priority setting needs both procedural values and substantive values – **for procedural values, transparency is one, but accountability is also needed**. **The shape and landscape of the rules of engagement need to be clearly articulated from the outset**, otherwise people will become frustrated. 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.

There's also a need to explicitly identify power within the health research priority setting process and what would happen if there is a significant stakeholder group who is not happy with the outcomes. Given that not all groups and interests can be represented in a process and there will always be people who are excluded, an appeals process is important.

2. Amplifying marginalised voices in research prioritisation: the James Lind Alliance approach

***Session summary**: It is widely recognised that marginalised voices often do not have the presence and influence in research prioritisation that we would hope and expect they would be afforded by researchers and funders. Even when voices are engaged, they may need amplification to truly influence in the context of the status quo, power dynamics and real or perceived hierarchies. And even where amplification occurs, it often entails the voices of those who experience marginalisation being reinterpreted by researchers and funders.*

Zelalam Mengistu (Ethiopia) described the significant effort that has been made to engage such marginalised voices, using the James Lind Alliance (JLA) approach. This has required time and commitment and iterative engagement at multiple levels, to achieve tractable engagement with those whose voices are to be heard. While also using an adapted form of the JLA approach, Jaya Singh Kshatri (India), presented on the difficulty of achieving consensus across this wide range of stakeholders, where the views of marginalised voices are very different from other stakeholders, such as healthcare professionals. Both presentations had an underlying theme around leadership – namely, who should lead research priority setting exercises involving marginalised voices, providing a deep ethical challenge for research prioritisation.

Co-chairs: **Toto Gronlund**, JLA Adviser (National Institutes for Health Research, UK) and **Bridget Pratt**, Australian Catholic University, Australia

Co-chair, **Toto Gronlund** introduced the JLA initiative and its approach to research priority setting which involves 7 steps and a steering committee that includes end users (and often doesn't include researchers). The process engages a large number of people with a wide range of views, while the final priority setting stage is a consensus workshop with a small group of people. There are no pre-determined criteria and participants make their own priorities. The outcome of the process is a set of priorities and the aim is to include something in the research agenda that matters to people (understanding it will not be a complete list of priorities).

Co-chair, **Bridget Pratt** outlined the components and considerations for meaningful engagement in health research priority setting:

- Who initiates the engagement (leadership).
- For what purpose (scope).
- Who participates (diversity).
- How they participate (being heard).

'Decentralised priorities for central schemes': experience of Department of Health Research's prioritisation exercise for the Model Rural Health Research Units across India

Jaya Singh Kshatri – Indian Council of Medical Research, India

The Department of Health Research, Ministry of Health and Family Welfare has established Model Rural Health Research Units (MRHRU) across India, with the aim of creating infrastructure for transfer of technology to the rural level for improving quality of health services to rural population and to provide an interface between researchers, health systems and the community. There are currently 28 MRHRUs with plans to establish another 11 over the next 4 years. Each MRHRU is an independent unit established within the campus of a rural health center, with dedicated infrastructure, equipment and staff and an annual recurring corpus of funds to carry out locally relevant research. Each MRHRU is managed by a nodal officer, who is a researcher from the Indian Council of Medical Research.

Jaya Singh Kshatri explained that a priority setting exercise was conducted to identify key research questions, nationally, for all MRHRUs focusing on the domains of public health, clinical research, health systems and implementation research. They used a modified JLA approach which included researchers. A steering committee was convened to provided overall technical guidance. A nationwide survey was conducted to elicit priorities from a broad range of participants.

Ethical issue

- **Representation on the steering committee**: The committee exclude people from urban areas and attempted to recruit mostly from rural settings and no-one from outside India. This created challenges and limitations with respect to priority setting expertise on the committee. The proportion of representation given to each stakeholder group on the committee (e.g. academia, funders, community) and the justification for their role on the committee, was also a challenge, acknowledging that each member brought their own values to the table.
- **Barriers to inclusion**: Diversity of expertise, understanding and languages was an issue in technical discussions and undermined attempts to give voice to communities.
- **Fixed resources and setting boundaries**: The national scheme had a fixed purse, and the research priorities were very diverse. It was challenging to balance the scope of the national scheme of MRHRU with local priorities and it became clear that more localised approaches were needed to rank the research questions. Involving managers at national and local levels proved very important.
- **Diversity of views and disagreements**: The level of divergence in priorities between researchers, clinicians and patients was significant and required intensive moderation.

Jaya concluded that the process was complex, resource intensive and especially challenging considering the diversity of the country. While it was important to have a national set of priorities, defining local priorities was also important in addition to defining what was *not* a local priority.

Women's pelvic floor disorders, Gondar, Ethiopia JLA Priority Setting Partnership

Zelalem Gashaw – University of Global Health Equity, Rwanda

Pelvic floor disorder is a major public health problem in Ethiopia. The disorders result in emotional, physical, social, and economic suffering of women and their families. Research prioritisation in this field has mainly been led by researchers, pharmaceutical and technology industries but evidence has shown there is a mismatch between the research that has been conducted and the questions that patients and health care providers want to have answered. This research priority setting process aimed to identify unanswered questions related with pelvic floor disorders cause, diagnosis, treatment, and impact by bringing together patient, carer and clinician perspectives and then prioritise what they agree are the most important in Gondar, Northwest Ethiopia.

Zelalem Gashaw described an ongoing research priority setting exercise taking place at the subnational level in Ethiopia on pelvic floor disorders. The JLA approach is being used with context specific modifications. The first phase prioritisation survey involved 392 participants (251 patients, 69 carer and 72 health professional). In the second phase, the research priority setting team went to the end users with a list of questions for them to prioritise and involved 124 participants (72 patients, 15 carers and 37 health professionals). The top 20 research questions were identified and will be narrowed to 10 final priorities at a future workshop.

Ethical issues

- **Equal involvement** is a key principle of the JLA approach. Piloting of the prioritisation survey revealed that many patients and carers had difficulty understanding the survey, possibly due to illiteracy, impacting on their involvement in the process. The steering committee of patients, carers, and clinicians decided participants should be asked to verbalise their suggestions, and these should be recorded, translated and summarised by the study team. Although this approach addressed the need for inclusion, **the process of synthesis by the study team raised an issue about the authenticity of the participants' voice**.
- **Transparency** is another key principle of the JLA approach but was hard to achieve given the participants' limited understanding of the process and aims.
- **Ancillary care**: Is it ethical to go back to women to rank research priorities when they have not received treatment for their condition? The team addressed this by approaching some new women, so they did not over-burden the same women to help the project several times. The team also facilitated treatment for a few women who they'd identified as requiring urgent care.

Plenary panel discussion

The speakers were asked how they made their language accessible to community members, including how they communicated the concept of 'research'. **Zelalem** explained that local health providers were trained and an approach was piloted that didn't work well initially in practice. Subsequently, the team used simple questions to elicit the women's thoughts e.g. what ideas or questions do you have about your health issue? What difficulty did you have during diagnosis?

Jaya explained that, in his context, community members had health care expectations that were 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**. GFBR participants discussed whether research priority setting teams should provide minimal care or referral to care as part of the research priority setting process? **Zelalem** explained that the women involved in their research priority setting process were already on waiting lists to receive care.

The speakers were asked what changes they would make with respect to transparency and participant understanding if they were to repeat their research priority setting processes. **Zelalem** pointed to better training of data collectors – their team saw improvements between the piloting and implementation in how to explain the research component to the women in more accessible and understandable ways. In terms of engagement, **Jaya** warned it should never be a tick-box exercise and research priority setting teams should make the utmost effort, understanding that marginalised groups exist within many communities. **Zelalem** reflected that anything that participants say could be framed as a question if it is within scope of the prioritisation efforts. **Just having conversations has an impact and can sensitise populations and can inform research prioritisation**.

Breakout group discussion

What do we mean by 'marginalised voices'

Marginalised by definition means excluded, e.g. due to lack of access to care, low education, low income etc. Marginalised groups may need a 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 should not 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. The smaller the voice, the more likely that they will not be included, or their priorities will get dropped off during a research priority setting process. This means 'the usual' engagement is not enough for marginalised voices and for equity.

GFBR participants identified a range of reasons why people or groups could be considered marginalised, for example, due to:

- **Location** e.g. tribal populations in India that live in the forests.
- **Language**
- **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 country, HIV patients have only recently formed advocacy groups.
- **Health issues** e.g. groups of **rare disease patients.**
- **Social issues** e.g. drug users.

GFBR participants warned against the unintended consequences of labelling groups as marginalised, including that their engagement could turn into a box-ticking exercise that lacks meaning. **A blanket strategy for engagement will not work: research priority setting processes need to employ contextual strategies** e.g. identification of their location, their type, and why they are considered a marginalised population. This can be followed by social mobilisation activities (identifying leaders who have influence in the community) and engagement to build trust. In research, community engagement is needed before and during the study to build trust and ensure the social value of the study. The same should apply to research priority setting exercises and they should learn from community engagement practices in research: there is no need to reinvent the wheel.

Barriers and challenges to participation of marginalised groups

GFBR participants identified a number of barriers and challenges regarding the participation of marginalised groups in research priority setting:

- Purposefully targeting marginalised people already makes a **value judgement** at the start of the engagement process.
- **More time and resources are required**, along with routes in to the community e.g. community leaders.
- What **method of engagement should be use, and what level of engagement is required**? Methods will depend on who is being engaged and listened to.
- **Reticence from the groups about taking part** and finding ways to mitigate this.
- **A lack of understanding within the group about research and research priority setting, which may undermine the process.**
- **Power differentials and cultural differences**. Effective engagement needs time and a 'safe space'. Engagement may be affected by the presence of Westerners in a process – people may be more or less likely to speak openly about their priorities in the presence of someone foreign.
- Sometimes, marginalised groups are organised, and they have a speaker to represent them in priority setting exercises. The **challenge is when they are not organised and so may be left out of decisions**, resulting in a less equitable research agenda.
- How should **divergent views *within* the marginalised group** be addressed?
- Marginalised people may have knowledge and their own perspective, which conflicts with what is already assumed. How should **divergent views *between* marginalised groups and others be** addressed?
- Participating in health research priority setting exercises **should not be detrimental or create difficulty for those taking part** e.g. in terms of having to take time off work or having to travel to be involved.

Hierarchies, representation and who to engage

GFBR participants discussed how to ensure that the right person is invited 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. While it may not be feasible to include all individual needs and priorities, the advice of leaders could be sought to help the research priority setting team understand what research topics have more traction for the whole community. However, some GFBR participants noted that 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. Given the potential diversity of marginalisation and vulnerabilities, how can health research priority setting teams cater for all intersectionalities in their processes? This reinforces the above point about representativeness and the question of what this might require in a specific setting.

One useful approach may be to **engage community members who have a health-related role in the community**. Zelalem explained that individual women were uneasy speaking about their health needs, so the research priority setting team worked with the leader of the women's development army who lives in the village. As head of an association that focuses on the women's health, the leader has the women's trust and knows who has what health issues. Other GFBR participants **saw a role for community health workers to serve as a proxy for communities to inform priority setting, given their in-depth knowledge of lived-through reality of health problems**. Local facilitation of the process was also considered important, to build on pre-existing trust and rapport.

Reciprocity, benefits and giving value back to individuals and 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? Some GFBR participants identified the need for reciprocity in research priority setting exercises **(e.g. access to ancillary care or referral)**. Other GFBR participants argued that 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. Several parallels were drawn with benefits-sharing in research:

- **Incentives and compensation:** Some GFBR participants **thought a payment should be provided to incentivise participation.** Others preferred the idea of **compensation involving other types of incentives (e.g. food)**, because marginalised groups in vulnerable situations could otherwise be inadvertently coerced into taking part.
- There may be **community-level benefits** such as community development, providing health and research education.
- **Ancillary care**: GFBR participants questioned whether there's an ethical imperative to provide a level of care, or referral, for those who need it. While it may be possible in some narrowly-focused research priority setting exercises (e.g. **Zelalem**'s case study), health research prioritisation can often be very broad and include a number of health issues, making the provision of specific ancillary care less feasible.
- **Sharing the results of priority setting exercises with communities**.
- Ultimately, **a key 'benefit' would be that the needs and priorities of marginalised groups have been included in the final list and been implemented**.

Health research priority setting vs research: the role of research ethics committees

Even though health research priority setting processes are not generally categorised as research and do not 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 research ethics committees (REC) approval for individual health research priority setting exercises, or have the same level of scrutiny as 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**.

Zelalem's research priority setting work received REC approval and was treated as research. Some GFBR participants considered this appropriate given that research priority setting involves ethical issues that should be considered before the exercise takes place. Others saw health research priority setting as distinct from research and so not requiring REC approval.

Separate to the issue of whether RECs should review individual health research priority setting processes, GFBR participants identified **a broader role for RECs 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 understand 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 protocols 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).

Many GFBR participants considered it **too much to ask RECs to have veto power over which research proposals are funded based on their alignment with national and local priorities**, but there may be scope for them to give useful feedback to their governments and funders in an advisory role on the potential social value of research.

GFBR participants identified an **essential role for bioethicists in health research priority setting processes, to consider the principles that should guide decisions about what research to prioritise**.

Transparency and accountability in the research priority setting process

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. 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 the health research priority setting.

Setting the boundaries of health research priority setting is an important but sometimes difficult task. For disease-specific priority-setting, the boundaries may be clear, but when the process is broader, it can be challenging especially if there was no evidence-mapping beforehand. Some GFBR participants reported on research priority setting processes that started with a fair idea of boundaries, but the boundaries ended up being shaped in a different way during the process. This reflects the nature of a deliberative dialogue during a priority setting process and that people may enter a decision-making process with one perspective and leave with new understandings and a shift in perspective. **It's important to document discussions so that it is explicit why certain priorities are established through the process.**

3. Governance of research priority setting: the role and responsibility of government

Session summary*: It has been argued that states should be primarily responsible for ensuring their population's health and, in effect, setting their national health research priorities. It is thus important to consider the role and responsibility of governments in setting these priorities. This raises a key ethical question: What are the ethical principles that should guide governments as they engage in health research priority setting? This session considers this question by interrogating two aspects of this role: i) processes through which the priorities are set and ii) the substantive values that should be reflected. The case studies consider the different approaches taken by national governments, as well as how the processes contributed to or detracted from substantive values of health research priority setting. Lydia Kapiriri (Canada) discussed the importance of ensuring that national agencies are provided with a) the authority to lead the process and manage different stakeholders, b) appropriate tools and c) resources. Joseph Oraño (Philippines) raised the issue of government stewardship in ensuring 1) clear strategic direction that is communicated effectively and 2) outsourcing research priority setting exercises. Gugulethu Eve Khumalo (South Africa) examined the processes by which a government ensures fair and equitable representation and the translation of priorities into actual research.*

Chair: **Sharon Kaur**, Universiti Malaya, Malaysia

Prioritising health research in KwaZulu-Natal, South Africa: who sets the priorities, and how are they translated into research conducted?

Gugulethu Khumalo – KwaZulu-Natal Department of Health, South Africa

The Department of Health in KwaZulu-Natal (KZN) sets health research priorities every five years. The first priority setting exercise was conducted in 2013 through a series of workshops. Due to budget and other constraints, the second was conducted in 2018 through an online survey. In each of the priority setting exercises, participants were requested to submit the research questions that would most impact health and health care in their spheres of work, or in their communities using their discretion. In 2013, the research questions were analysed qualitatively, by coding and grouping into themes, and the number of research questions in each theme was recorded. Priority questions were communicated to research organisations in KZN, for incorporation into their own research agendas.

Gugulethu Khumalo explained that in KZN, research prioritisation is mandated and guided by the National Health Act, but there is little guidance on who should be included in the process and how it should be done. Her presentation focused on the question of **who sets the priorities, who are the stakeholders** and whether **their voices and concerns are translated into prioritised research**.

During the first prioritisation in 2013 the research priority setting team went into each district to engage with participants and involved a diverse group of stakeholders. One hundred and eighty-eight (188) people attended the workshops, including health care workers, traditional healers, community leaders, academics, and representatives from non-governmental and faith-based organisations. 1018 priority research questions were identified but only 28% of the prioritised research was subsequently conducted. In 2018, the second prioritisation exercise involved an online survey of 73 participants who were mainly health care workers from within the Department of Health. The survey generated 213 priority research questions.

Ethical issues

- **Representation**: The online survey by definition excluded all those who did not have access to computers and internet connectivity, thus effectively excluding traditionally poor and voiceless groups. Because the participants in 2018 were more homogenous than in 2013, the research questions generated were less rich, and failed to reflect the concerns of people from the variety of cultural, economic, and social settings within the province. This raises the question of **how to democratise health research priority setting exercises sustainably, especially in countries characterised by extreme inequality**.
- **Translation of priorities**: There was a mismatch between the identified research priorities and the research that subsequently took place. Governments and funders should be more intentional about ensuring that prioritised research is actually funded and carried out. To this end, **should governments refuse to grant permission to conduct research that is not aligned with priorities, or is this an infringement of academic freedom?** There's a need to strike a balance between prioritised research and researcher interests.

Health research priority setting experiences from Uganda, Tanzania and Zambia

Lydia Kapiriri – McMaster University, Canada

Many low-income countries, including Uganda, Tanzania and Zambia have instituted National Health Research Authorities (NHRAs) to manage their health research systems. Among their duties, NHRAs should set research priorities. While the three countries have conducted several health research priority setting exercises, there are no standardised approaches for facilitating the sharing of their experiences. This project used case studies in

Zambia, Uganda and Tanzania to describe and evaluate their health research prioritisation based on a framework which was validated in Zambia and internationally.

Lydia Kapiriri described the systematic evaluation of the NHRA's role in priority setting which involved key informant interviews with people involved in the prioritisation processes. Relevant policy documents were also reviewed. The evaluation was assessed against the Kapiriri & Martin 2017 Framework for evaluating health research priority setting which highlights best practice, including procedural and substantive ethical criteria.

The project identified that all 3 countries had legitimate NHRAs. All three countries had some elements of fair process but no incentives for compliance. Explicit criteria (including equity) were used but depended on the guiding health research priority setting framework used for prioritisation.

Ethical issues

- **Fragmentation of research priority setting**: Although the NHRAs are the legitimate institutions to set national health research priorities, other organisations within the countries also set health research priorities and often with no clear linkages with the national processes. This fragmentation undermines the NHRA's legitimacy and work.
- **Whose priorities should count**? Power imbalances were identified at all levels of decision-making e.g. national vs funder, national vs sub-national.
- **Capacity building in health research priority setting processes**: Often, external experts facilitated the research priority setting process and due to time constraints there was little opportunity for local capacity strengthening to ensure that the approaches are well understood by the NHRAs. As a result, the NHRAs are left with poorly understood, un-contextualised priority setting approaches, which they may not be in position to use in future.
- **Adaptation**: The approaches and recommended criteria were not adapted for local use and so didn't take account of local criteria, values and realities. While the NHRA recognise the need to use the current health research priority setting approaches, failure to adapt them to the local contexts may have contributed to their limited institutionalisation.
- **Evaluation**: Due in part to resource and capacity constraints, there was no real examination of the success of the prioritisation process itself, beyond identifying which priorities were implemented.

Lydia recommended that **governments and funding agencies should provide legal, financial and technical resources to enable NHRA's to deliver on their research priority setting mandate**. This could include a participatory process whereby NHRAs are introduced to the strengths and limitations of current health research priority setting approaches to inform their decision-making on the choice and contextualisation of the adopted approach. This would strengthen the NHRA's capacity and further strengthen their legitimacy. The NHRAs should **implement systematic evaluations of their process so they can learn and share experiences and identify areas for improvement**.

Ethical challenges and improvement pathways: a case study on health research priority setting in the Philippines

Joseph Oraño – Alliance for Improving Health Outcomes, Philippines

The Philippine Department of Health and Department of Science and Technology (DOST) led the creation of the Philippine National Health Research System (PNHRS) in 2013. The PNHRS is the integrated framework for health research in the Philippines to ensure that research contributes to health policymaking. Under the PNHRS, the Research Agenda Management Committee (RAMC) offers guidance on shaping the country's health research agenda, aligning with societal goals across various sectors. The Philippine Council for Health Research and

Development (PCHRD) is the secretariat of the PNHRS and RAMC. The PNHRS first published a National Unified Health Research Agenda (NUHRA) in 2006. The NUHRA is an advocacy document to guide health research activity, generate research support and funding, and promote research translation. It is developed every 6 years and implemented over a period concurrent with the Presidential term of office. Since 2017, the Alliance for Improving Health Outcomes (AIHO) has been providing technical assistance to the PNHRS and RAMC in the conduct of research priority setting workshops, and development and evaluation of research agendas.

Joseph spoke from his perspective of working for AIHO, the contract organisation that has supported a number of research priority setting processes, including NUHRA 2017-2022 and NUHRA 2023-2028. These processes applied a combination of principles and research priority setting frameworks such as the JLA framework, PNHRS Guidelines for Health Research Prioritisation, bottom-up with top-down inputs approach, multi-criteria decision analysis, nominal group technique, and consensus-building in participatory stakeholder consultations.

Ethical challenges

- **Weak research agenda stewardship** in the country is an unintended effect of public policy: any new long-term DOST-funded research initiative or institution is required to produce a research agenda prior to receiving funds meaning that when the research priority setting is conducted, participants are unaware of the scope of work, capacity, and resources that will be available to the research initiative. At its core, ranking research priorities is about making choices and those choices should be based on defined context, scope, and values enshrined within a transparent process. Inadequate research agenda stewardship is also manifest in outsourcing the research priority setting process to contractors. The technical capacity of contractors increases but the information asymmetry widens between contractors and RAMC on a methodological and inclusive research priority setting process. Finally, weak stewardship is demonstrated by the non-inclusion of implementation, monitoring and evaluation plans during the research priority setting process.
- **Monitoring and evaluation (M&E) mechanisms are required to address inefficient policy tools and** support efficiency and effectiveness. Assessing returns on investments for resource-intensive, bottom-up research priority setting remains uncertain due to a lack of a relevant and effective M&E system. These inefficiencies in the national health research system introduce inefficiencies in the use of public research funds.
- **Resource constraints affect equitable health research priority setting**. Short-term contracts and timelines for research priority setting make it a challenge to adhere to good practices and require innovative solutions, e.g. maximising the use of online tools and platforms 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.

Joseph recommended strengthening stewardship of the research agenda and the need to shift mindset on the purpose of a research agenda. Capacity development should be prioritised and the timelines for health research priority setting extended to support best practice. Finally, methods for M&E should be developed and built into health research priority setting processes.

Plenary panel discussion

Lydia was asked if NHRAs engage with international funders. She explained that NHRAs have made efforts to include funding agencies in their prioritisation processes. She identified a role for funders to support NHRAs to build capacity in health research priority setting processes that are credible and trustworthy. In turn, the NHRAs should then include the funders as stakeholders in their processes. This would make for an improved process with greater funder buy-in to national priorities.

The speakers were asked if their priority setting was actually useful and impactful. The processes were useful in the sense that they helped identify gaps and had the potential to draw attention to neglected research areas by including a broad range of stakeholders in the process. However, whether a process makes a difference depends on whether the priorities are funded, and many were not. It's also hard to evaluate how useful a process has been because there is a lack of M&E.

The presentations pointed to **the need to institutionalise health research priority setting**, but questions arise: 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 the resources including money and people are lacking and they need capacity strengthening to be able to do their work well.

Breakout group discussion

Role of government in research priority setting

Political leaders should be sensitised to the value of priority setting and its ethical nature for the exercise 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 the stability of the government and the competency of the individuals involved. **Capacity building within government is essential,** along with **political will**. If the government is not willing to put money into health research, then it's unlikely it will invest in research priority setting processes or, if it does, it's likely the priorities and goals will not be fulfilled.

GFBR participants identified national governments as having the legitimacy through democratic accountability to act as gatekeepers who **promote and protect the interests of their populations** by determining what health research is conducted. This role could include:

- **Institutionalising health research priority setting and building capacity 'in-house'** within a technical secretariat that is *not* impacted by political changes in government.
- **Being transparent** e.g. about 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.
- Making **evidence-based decisions using robust data** and being explicit about why certain areas are, or are not prioritised and the compromise or trade-offs that have been made.
- **Coordinating research priority setting processes** and managing **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**.

- **Mapping funder priorities** and coordinating with funders to avoid duplication and to be complementary and synergistic.
- Using the prioritised research agenda effectively i.e. **implement the research and conduct M&E.**

However, the following challenges were identified:

- **Government decisions-makers may stymie** health research priority setting (e.g. by not allocating sufficient funds or time).
- Research agendas might be hijacked by **political agendas** and priorities set without broad consultation.
- Ideally a government would mandate funding for health research priority setting and commit at least 5 years of funding priorities, but **LMIC political instability can affects research priority setting processes and policy sustainability**.
- **Health needs may clash with cultural values and political will** and therefore be excluded from consideration (e.g. stigmatised health conditions).
- People at **higher levels of government may not hear the evidence**, and may take money from research and put it into treatment if they think research is not helpful. Politicians should be involved to help navigate the hierarchies and communicate the evidence and research needs.

How should governments address the issue of external funders with differing priorities to their own?

Some countries don't devote much of their GDP to health research and hence may rely on external international 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. **If there's no investment to go along with the ownership, then the system and the process becomes fundamentally flawed – investment in the process and its outcomes is crucial.**

Should countries deny research that is not a national priority? GFBR participants advised that in India the research agendas are set by the government and there's a legal requirement for all foreign funds to go into a single account so the government can see what research is being funded. A committee of experts screens and approves externally funded research. **Projects can be denied if they do not align with the country's research priorities, even if the project has already been funded** by external funders. Some GFBR participants responded with concern that in some LMIC contexts, if foreign funds go to government account, the researcher may never receive them or their work could be controlled by the government. For this reason, they preferred their institution to handle grant funds. Also, on the question of **whether government should reject proposals**, some GFBR participants considered that in their context this may lead to research being rejected for reasons other than research priorities, particularly where there is a conflict of interest within the government and a lack of neutrality.

Even if government denial is based on research priorities, **it can't be guaranteed that the country's research agendas are fair** (e.g. in terms of **representation** in the research priority setting that developed the priorities or given the social and ideological context which may prioritise some research topics over others). For example, a **government may decide that no research can be done for some marginalised groups or on some topics (e.g. abortion) which can lead to unfair agendas**. If there is a cultural or political reason something is not on a priority list, this could be a strong reason why a funder could think this is a neglected area it wants to prioritise.

GFBR participants noted the difference between research that has no value and research that may be valuable but is not a priority. From an individual researcher perspective, **whether something is deemed a priority or not does not mean it isn't (or shouldn't be) a priority. For this reason,** GFBR participants **considered a government veto on non-prioritised research to be problematic** and that researchers should be able to apply for international funding to pursue their academic freedom. **For example, mental health research is not prioritised in many countries, but is clearly a significant issue.** It was suggested that **there should be a high threshold for refusing money from external funders if the research has *some* social value**.

GFBR participants agreed that LMIC governments should commit to providing resources for at least some national priorities, rather than relying on external funders. **Governments should also negotiate with funders to align priorities.** However, what does it mean to 'align'? This 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.

Some GFBR participants characterised this relationship as a partnership, which can sometimes be hard, for example if the ideological politics in a country is an obstacle to certain research. When governments are working with funders in this global partnership they need to think globally and act local – but sometimes people in government just think locally and act locally. Funders can bring big issues and priorities, like climate change which some governments may not prioritise over other national concerns (e.g. economics problems). But governments need to think globally and act locally to make the most of these opportunities and how to target them to local needs.

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

Suggested goals include:

- **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 verses 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**. However, many LMICs focus on disease specific research with little attention to health systems research and policy.

How can governments democratise research priority setting exercises?

GFBR participants recognised the potential for democratic deficit in government priority setting processes e.g. prioritisation based on greatest disease burden versus the duty of governments to address health inequalities. During the presentations, different examples were given of how to **democratise the process through more varied stakeholder engagement e.g. using surveys and open workshops.** Additional ideas on **how to reach different populations in order to democratise health research priority setting exercises** included:

- Information should be disseminated within communities, and training provided to people participating in the research priority setting process to facilitate and maximise their involvement.
- Engage the private sector e.g. NGOs, 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).

Challenges for democratising the research priority setting process include:

- **Power** – some institutions have greater power than others and can distort the exercise.
- Governments are often satisfied with the status quo and don't want to involve wider stakeholders for fear of having **a more complex and challenging process**.
- The **cost of including equity considerations** and increasing stakeholder representation.
- **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 is not taken into account in research priority setting processes.
- Special interests or **conflict of interest of stakeholders** that are invited to participate (e.g. funders).

Priorities of individual researchers

GFBR participants agreed that even in functioning, democratic societies, it wouldn't be appropriate to leave priority setting to the national level only. Individual researchers should also play a role. This brings challenges from a governance perspective to understand how to build a system that gets people to take responsibility for different aspects of research priority setting. It was noted that national priorities may have a perverse incentive or distorting effect on research in terms of incentivising researchers to propose or reframe their own research to fit the prioritised areas to get the funding for career reasons.

4. Ethical and practical challenges to research priority setting

***Session summary**: The overall goal of research priority setting is to promote health and health equity by focusing limited resources for health-related research (e.g. funding) on the most important research questions. However, there are ethical and practical challenges to achieving this goal, even when researchers and research sponsors are well-intentioned. This panel discussed three cases to describe these challenges and identify possible ways of addressing them. According to John Barugahare (Uganda), researchers and sponsors may address important health problems in low-resource settings but fail to develop interventions that are feasible to implement in these settings. David Nderitu Wanjeri (Kenya) discussed why collaborations between researchers in high- and low-resource settings sometimes fail to address research priorities in low-resource settings, even when their stated goal is to promote health and health equity there. Finally, Starlin Vijay Mythri (India) examined the difficulties of adhering to institutional research priorities when health institutions in low-resource settings enter collaborations with researchers from high-resource settings.*

Chair: **Annette Rid**, Department of Bioethics, NIH Clinical Center & NIH Fogarty International Center, USA

The US-Kenya Partnership: A model North-South 'unequal friendship' in health research where a balanced priority setting remains but a mirage

David Nderitu Wanjeri – Egerton University, Kenya

The IU-Kenya Partnership was built to improve the health of the Kenyan public through the interrelated tripartite missions of education, research, and clinical service between Moi University and Moi Teaching and Referral Hospital (both in Kenya) and a consortium of health research institutions in North America led by Indiana University (IU). An earlier research study about the partnership revealed that a Global North – Global South collaborative partnership is a form of Aristotelian 'friendship among unequal parties'. Such a friendship consists of a superior partner and an inferior partner, with superiority and inferiority based on the expected contributions and benefits of each partner: the superior party is expected to provide tangible benefits and in turn expects 'immaterial' benefits, while the inferior party is the recipient of the material gains and gives 'honour' in return.

David Nderitu Wanjeri explained that the IU-Kenya Partnership has always strived for equity, if not equality, since its initiation more than three decades ago, but this remains a work in progress.

Partners from Kenya benefit from:
- Healthcare infrastructure and institutions leading to improved healthcare for the community.
- Capacity strengthening through training, mentorship, and research funding.
- Increased research activities leading to higher university rankings.
- Research ethics capacity strengthening.

Partners from North America benefit from:
- Pride and satisfaction for altruism by working with communities and institutions in Kenya.
- Gaining knowledge of tropical diseases.
- Increased competence in clinical care due to hands-on experience in Kenya.
- Academic career progression and higher university profiles due to the relative ease of getting research grants for collaborating with Kenyan partners and for creating publication opportunities.

Ethical issues
- **Inequities** are implicitly evident through the imbalance in agenda setting, decision making, roles of partners and also assumption of positions in various programs and projects of the Partnership and remuneration.
- There was a perception from some Kenyan partners implying that **since the Global North partners provide funds they should have a bigger stake in deciding how the funds are utilised** in terms of the areas of research, the type of projects and the management of funds.
- The Global North was also **perceived as more competent and thus should lead** (the perception being they are better trained and are more competitive in grants (with an English language advantage)).
- The Global South partners can be **perceived as having a laidback attitude, likely due to the fact Kenyans have to wear many hats** (physicians, lecturers, researchers, etc.) meaning research is not their main priority. Also, some Kenyan partners consider it a privilege to work with North American partners and are less concerned about being 'dominated' within the Partnership.

David concluded that during the Partnership there have been significant steps forward in how the partners work together. In one of the most successful programmes of the Partnership – the Academic Model Providing Access to Healthcare (AMPATH) Research Network – the overall directorship, research working groups, research cores, and specific research projects are each co-led by a partner from both Kenya and North America. But there's still a need to adjust Global North – Global South partnerships in consideration of power imbalances and contextual issues. Partnerships should be based on fair contributions and realistic expectations.

Health research priorities in low resource settings – perspectives from rural North-east India

Starlin Mythri – Makunda Christian Leprosy and General Hospital, India

The case focused on a not-for-profit hospital situated in a remote rural part of North-East India which delivers secondary level healthcare. The hospital provides medical, surgical, pediatric and obstetric services to mostly poor and marginalised communities like Dalit and tribal or religious minorities. About 124,000 people accessed care at the hospital in 2022. The hospital was approached by a global health research organisation to participate in a multi-centric maternal and child health (MCH) research project with two goals: 1) to develop data-driven pregnancy risk stratification algorithms and commercial tools to address biological vulnerabilities which adversely affect MCH outcomes, and 2) to generate useful public health information regarding the readiness of local health facilities to provide MCH care.

Starlin's institute was interested in participating in the proposed research due to the opportunities it provided to better understand and engage with their surrounding communities. They were selected due to the availability of an appropriate sample in the hospital and in the surrounding communities and also due to their prior hospital-based research experience. The project consisted of demographic surveillance of about 150,000 individuals living in about 35,000 households and follow-up of a pregnancy cohort of about 2,000 women. The project team was not equipped to conduct such a big task and to meet the global funder's data standards as they lacked institutional research and data management capacity.

Ethical issues

- **Priorities and the ends of research**: In **Starlin**'s view, efficient solutions are those that strengthen public health systems and community development to address health inequities. However, the efficient solutions according to the global funder were more technological. The funder's aim to develop technological innovations threatened to perpetuate inequalities for those who don't have access to those technologies.
- **Priorities and purpose of the resource**: A genomic study 'add on' was proposed by a researcher in the national coordinating institute. The study aimed to validate the findings of an earlier national study to predict the risk of preterm birth. The hospital participated due to their existing relationship with the researcher and in the hope that the study might bring benefits through knowledge generation. However, the research team soon realised that the generation of such knowledge was far from the lived reality and priorities of their vulnerable populations. Blood collection at every antenatal care visit could not be ethically justified given that the women were not going to benefit directly from the genomic study, and given the risks of soft-coercion, therapeutic misconceptions, and exploitation of their trust.
- **Global North – Local South interactions were problematic** resulting in unequal relationships. Local partners generally lack skilled human resources, governance, M&E systems resulting in unsustainable research programs. Potentially fruitful work will be lost if capacity building of the local partners isn't built-in to the Partnership and work-plan.

Starlin pointed to the need for improved dialogue between Global North – Local South partners to strengthen the local voices and to identify sustainability in research programs alongside the priority setting activities. He asserted that the needs of vulnerable communities should be the priority (and not research that holds no benefit for them). **Global North funders should be held accountable to ensure they uphold the research priorities** and do not misuse their power by softly making the local partners participate in additional research which is not a local research or healthcare priority.

'Deliverability of interventions' as a criterion in priority setting for health research: the case of H3Africa and gene-based interventions

John Barugahare – Makerere University, Uganda

This case addressed the following issue: 'How should comparative judgements be made about the social value of research (e.g. likelihood, magnitude, distribution of potential benefits)?'. The case argued that in order to increase the likelihood of improving and optimising health benefits from research and improving the fairness of their distribution within and between countries, *deliverability* of the proposed interventions in target countries/societies should be considered in global health research priority setting, along with other criteria.

John Barugahare argued that **the social value of research is realised if and when the researched interventions are implemented to deliver care to those who would benefit most**. The concept of 'Conversion Factors' means the mediating factors between a good and the achievement of the potential utility it offers. 'Conversion Factors' are the necessary conditions for the interventions to be delivered and in the context of health research can include, physical infrastructure, skills set and technology. If the 'Conversion Factors' are not present, and the interventions are not deliverable in a particular context, social value cannot be derived from those interventions.

John described that it is possible to develop interventions which are scientifically efficacious and safe, for conditions that account for a high proportion of mortality and morbidity among the most deserving populations, but at the same time fail to significantly improve their health, and hence fail to positively impact global health equity. He gave the example of gene-based interventions which have the potential to deepen health inequalities if the medical innovations cannot be fairly and equitable delivered to those who need them most. The GeneXpert machine is described as being cost-effective at diagnosing TB including at early stage and is in principle ideal for LICs like Uganda. However, the challenges to deliverability reduce its utility in Uganda (e.g. access to electricity especially in rural areas and the need for refrigeration).

John concluded that **deliverability should be a complementary criterion to other priority setting criteria to ensure research creates social value**. However, ethical issues arise when thinking about its implementation:

- What is a reasonable timeframe for the results of research to lead to interventions that can be delivered to those who need them?
- On whom do obligations to ensure deliverability fall?
- Should research sponsors or researchers in low-resource settings always prioritise interventions that are deliverable?
- From the point of view of equity, does the relative time of waiting to access an approved intervention between two societies matter?
- What potential challenges may be encountered in applying the criterion of deliverability of interventions at the time of reviewing research grants, and how can these be mitigated?

Plenary panel discussion

Some participants expressed concern that the deliverability criterion could limit forward-looking, ambitious research. **John** argued that deliverability matters from the point of view of equity – if researchers develop an intervention today that can be implemented in one society immediately and another society in 10 years – one society will be 10 years ahead of the other. He asserted that people who conduct research priority setting need to consider developing interventions that can be accessed quickly to derive social value 'now'. However, there are many outstanding questions about how to implement the deliverability criterion (above).

Participants acknowledged that in Global North – Global South partnerships funds often flow in one direction and the inequalities within these partnerships need to be considered. **Starlin** suggested that the first step in decolonising research prioritisation is being mindful of the local research practices and existing conditions and working within them. **David** argued that decolonisation starts from the Global South, including the ability to fund 'our' own research and not accepting the role of being the 'inferior' partner. **John** expressed reservations about the rhetoric of decolonisation and pointed out that all relationships are affected by power dynamics. Strategies are needed to deal with the power imbalances, including increasing capacity to negotiate.

Breakout group discussion

What steps should be taken to ensure that the fruits of research can be delivered in low-resource settings?

GFBR participants proposed the following criteria to ensure that the fruits of prioritised research can be delivered in LMICs:

- **Deliverability** (referencing the 'Conversion Factors' in John's talk)
- **Feasibility, affordability** and **scalability** as components of deliverability.
- **Immediacy**: The time element to deliverability gave rise to different opinion. Some GFBR participants favoured the idea of prioritising research that gives a more immediate benefit. Others noted that basic research can take time to come to fruition but can be very valuable. There is also an equity component, for example around intellectual property issues where an intervention may not be available immediately but generics may be available in future – so the benefit may take time to be realised.
- **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?

Who is responsible for ensuring deliverability happens?

Prioritisation occurs at different levels (researchers, local, national). Different value systems come into play but all should be thinking about deliverability. In the same way that the research priority setting process should be a partnership, so to should the responsibility for ensuring deliverability. **Government and the respective leadership in the health and research sectors** should take a key role. For example, Ministries of Health would be the best actor to generate local evidence to inform policymakers. Partnerships are essential and not limited to the health sector – other sectors are also important (economic, business), along with funders and researchers.

GFBR participants identified the challenge that researchers may get more respect and recognition for research that is innovative and more publishable, rather than research that is deliverable.

How can power differentials in research priority setting be addressed?

In the context of this session, power differentials were discussed in relation to priority setting within research partnerships.

There are many competing priorities 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 the power differentials exist, 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.

Other issues raised in relation to power differentials included:

- **Who controls the money**? 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 consider '**does the proposal match 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. GFBR participants commented that while it is easy to talk along these lines, it is difficult to implement in practice.
- **Transparency about the intention, aims and objectives of the partnership** is a key foundation for trust. It's hard to have trust where there is uncertainty or opaque relationships or a lack of clarity about roles. There's also a need to recognise that trust exists alongside distrust, which has to be managed and mitigated via mechanisms such as contracts, memorandums of understanding, etc.
- **Transparency in the research priority setting process** within a partnership so that decision-makers can be held accountable, along with active dissemination of the priorities to the other people in the partnership.
- Involve **sociologists and ethicists in the partnership to promote reflexivity.**

Mutual trust can be created by focusing on strategies to balance power between partners and on incentives that meet each partners' needs. But problems can arise if researchers are not able to negotiate for what they need and there can be vulnerability of LMIC researchers, attributed to weak institutional policies and administration. Funders can help by encouraging recipient institutions to create (better) policies and set high standards. It was noted that some funders have mechanisms to check and evaluate the research partnerships they fund and to encourage equitable collaboration between Global North and Global South researchers. This can also be assessed through funder criteria for program evaluation e.g. assessing the number of papers, key author roles etc.

GFBR participants agreed that guidance to help determine research priorities between research partners would be useful.

5. Research funder panel session

Chair: **Ludovic Reveiz**, Pan American Health Organization, USA

In this session, four funder representatives introduced their organisations and responded to the questions:

- When does research priority setting take place in your institution?
- Are there limitations regarding funder's obligations in terms of priority setting and how do you build these into your decision-making processes?

Carleigh Krubiner explained that **Wellcome** (UK) recently launched a new 10-year strategy with 3 key health priority areas:

- **Mental health** - Wellcome has a dedicated lived experience team that provides advice.
- **Climate and health**, including understanding the impacts of climate change; research on adaptation and mitigation strategies and influencing policy and implementation.

- **Infectious disease**, including a focus on the drivers of infectious diseases; Anti-Microbial Resistance (AMR) investment and vaccines.

These priorities were set based on consideration of: urgency; magnitude and the scale of people affected with some priority to the most affected and opportunity for real world impact.

Wellcome conducts mid-term strategic reviews every few years and has an annual delivery planning process. Challenges include having time for authentic engagement whilst operating on an annual fiscal strategy and how to make the large funding commitments while also authentically including lived experience in the institution's priority setting processes.

Mongezi Mdhluli explained that priority setting at the **South African Medical Research Council** (SAMRC) usually takes place after national elections and focuses on government priorities that mostly address the four colliding epidemics facing South Africa: infectious diseases, maternal health, child health, climate and health. The strategic plan is reviewed annually for the annual plan, which gives SAMRC the opportunity to adjust or change the priorities. SAMRC also funds emerging innovations along with issuing requests for applications. Challenges include getting funding on a cycle basis which requires the funding to be spent within a specific timeframe.

Barbara Sina, from the **Fogarty International Center-US National Institutes of Health (FIC-NIH)**, explained that 27 institutes make up the NIH. Usually there's a 5-year strategic plan, primarily focused on discovery science. The NIH is funded by the USA taxpayers and so Congress decides on research priorities, but they are lobbied by a variety of US stakeholders. The research priority setting process is very US-centered and 'patchwork' across the institutions. A research council provides public oversight of research priorities.

85-90% of the grant applications received by FIC-NIH are unsolicited and not in responses to a specific call. Applicants must provide a rationale for the proposed project and explain how it meets the priority setting requirements of their country. Extra points are given to projects that are tailored to country priorities. FIC-NIH's mission is to build research capacity in LMICs and it supports research training programs to this end. The institute sets up pilots or small funding for areas that are not well-addressed by other areas of the NIH and there is a think tank within Fogarty that inputs into what research to prioritise.

Michael Makanga described how the **Global Health EDCTP3 Joint Undertaking** (**Belgium)** is funded in cycles of 10 years (by the European Union, Member states (European and African) and other global partners). Global Health EDCTP3 funds research that accelerates medical interventions in the fight against infectious diseases in sub-Saharan Africa, including late-stage product development and product implementation research. The initiative uses both bottom-up and top-down approaches to address local priorities and global security (e.g. regarding preparedness for future pandemic and epidemics). Competitive calls are issued on the priority topics and the partnership also focuses on research capacity strengthening.

Implementation of the 10-year strategy involves an annual work program that has to be approved by the governing board as the overall decision-making body. There is a multi-stakeholder consultation process, along with input from advisory councils and stakeholder groups, including patient groups, who help to identify research gaps.

Challenges include balancing research excellence and equity, diversity and inclusion in funding decisions. This has been addressed by pairing up-and-coming institutions with well-known institutions. Risk management can also be a challenge when the neediest countries and institutions often have weaker financial structures to manage grant funding. Funders need to ensure that there are risk management structures in place but this is still a work in progress for many countries.

Plenary panel discussion

GFBR participants asked if and how the different funders talk to each other about their priorities. **Funders aim to coordinate to avoid duplication but also 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**. Many funders tried to collaborate during the Covid-19 pandemic, including gathering data on what has been funded in order to avoid duplication. However, this is challenging to do.

The funders commented on the strategies they have put in place to advance equity and innovation:

- Establish fair competition between stronger institutions vs developing institutions.
- Purposefully seek out diversity amongst applicants.
- Making funding opportunities open to researchers from both HICs and LMICs.
- Capacity development fellowships to support research capacity building.
- Adaptability of priorities through an emergency fund.

Breakout group discussion

How should funders take account of national priorities when designing international grants programs?

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 **discussion with local government** and/or putting the onus on researchers (e.g. the NIH asks grant applicants how their proposal aligns with national priorities). It was noted that some funders work directly with Ministries of Health, so they are aware of national priorities. Taking this a step further, funders could have a focal point within countries to identify and fund specific needs e.g. prioritise research with marginalised groups which may otherwise be missed.

Funders should recognise the diversity of how different countries may conceptualise national priorities (especially in contexts where explicit and official national priorities are not set). Even where there is no formal health research priority setting process and no health research agenda, there will be high priority needs.

What one insight from this meeting would you want health researcher funders to take on board?

Recommendations for when funders set their research prioritise:

- **Map evidence to assess complementarities** with governments and other funders and to identify gaps.
- **Conduct stakeholder consultation** and tailor how to involve different groups (e.g. researchers, communities). This reflects the requirement of some funders for their funded researchers to undertake public engagement. The funder should likewise listen and find out what matters to people and what would work in their context.

- **Convene and support a forum of LMIC representatives** to feed into funders' health research priority setting.
- 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 if their proposal addresses their country's 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 and not only by specific diseases**. Funding poverty interventions would have a spill-over effect on multiple diseases. Strategic priorities are often focused on treatment, whereas funding both discovery and social research would better improve human health.
- **Help researchers to make connections and form collaborations** rather than duplicating or overlapping research efforts. This requires more transparency about what is being funded and coordination to determine what is being over-researched and where there are overlaps.
- **Ensure there is at least 1 peer reviewer from the country where the proposed research is taking place** to bring contextual understanding.
- **Provide funding for countries to perform health research priority setting** and build capacity in this field.

6. Pecha Kucha sessions

"Pecha Kucha" translates from Japanese roughly as "chit-chat". Pecha Kucha presentations are designed to be delivered quickly and concisely, with slides **automatically** advancing every 20 seconds. They are an informal opportunity for GFBR participants to find out about each other's research, viewpoints and experience.

Two Pecha Kucha sessions took place at GFBR. Speakers are listed below and the session chairs were:

- Phaik Yeong Cheah, Mahidol Oxford Tropical Medicine Research Unit, Thailand
- Mona Nasser, University of Plymouth, UK

1	Empowering communities in research - a model for shared decision-making and research priority setting in a rural population during a public health emergency *Margaret Kaseje – Tropical Institute of Community Health and Development, Kenya*
2	Ethical issues in relation to engagement and involvement of marginalised and vulnerable groups in setting health research priorities 2013-2018, Tanzania *Emmanuel Makundi – National Institute for Medical Research, Tanzania*
3	The ethics of the Philippine National Health Research System's (PNHRS) 2017-2022 National Unified Health Research Agenda (NUHRA)

	Daphne Maza – Philippine Council for Health Research and Development, Philippines
4	Consideration of values when setting research priorities: a value-oriented guidance tool for priority-setting exercises *Wim Pinxten – Hasselt University, Belgium*
5	Conducting high priority research in over-researched communities in Pakistan: the ethical burden *Sualeha Siddiq – Sindh Institute of Urology and Transplantation, Pakistan*
6	Contribution of public universities to tackle leading causes of mortality in Ecuador: evidence based on 100 years of scientific production *Ivan Sisa – Universidad San Francisco de Quito USFQ, Ecuador*
7	Upholding autonomy and beneficence in research priority setting exercises in Ghana *Benedict Weobong – University of Ghana, Ghana*
8	Mitigating disparity by harnessing fair process in heath research priority settings: what India might learn from It? *Abhishek Ghosh – Postgraduate Institute of Medical Education and Research, India*
9	Ebola Virus Disease outbreak response in West Africa *Edward Kusewa – St Paul's University, Kenya*
10	Need for awareness among funders, grant proposal reviewers, researchers and research ethics committees about ethical priority setting for research *Valerie Luyckx – University of Zurich, Switzerland*
11	Lack of research of an endemic noncommunicable disease in Honduras: the case of Mesoamerican Nephropathy (MeN), a bioethical perspective *Guimel Peralta – Central American Technological University, Honduras*
12	Ecology of engagement. A model for prioritising research in mental health *Iliana Romero – Colectivo de Salud Mental TLP, Mexico*
13	Prioritising rare inherited diseases research in LMICs: the ethical dilemmas of cochrane evidence synthesis *Teguh Sasongko – International Medical University, Malaysia*

Annex 1: Background information on GFBR and meeting content

The Global Forum on Bioethics in Research (GFBR) is the principal global platform for debate on ethical issues pertaining to international health research. Its core aims are to give voice to low- and middle- income country (LMIC) perspectives in debates about global health research ethics and to promote collaboration.

The Forum meets annually to address a specific topic in research ethics. The meeting is case study based to enable participants to understand the practical issues 'on the ground' in addition to broader ethical and governance questions. 89 case studies were submitted for this meeting. 11 cases studies were selected for full oral presentation (see links throughout the report) and 13 case studies were selected for short Pecha Kucha presentations.

Participants are selected through a competitive process and come from a diverse range of disciplines, countries and career stages. Awards are available to LMIC colleagues to cover travel and accommodation.

All participants were encouraged to report the meeting recommendations in their home countries and to continue the discussion in their local context. Fellowships were available for LMIC participants to explore issues that arose during the GFBR meeting in greater detail, establish new collaborations, and develop new ideas for resolving issues that could not be resolved at the meeting itself. 16 fellowship applications were received after the meeting and 5 were selected for funding. For details see: gfbr.global/fellowships.

Annex 2: List of abbreviations

GFBR: Global Forum on Bioethics in Research
LMIC: Low- and middle-income country
HIC: High income country
REC: Research ethics committee
WHO: World Health Organization

Acknowledgements: We are grateful to the presenters whose work forms the basis of this report and want to thank all the GFBR participants for their engagement with the topic and each other. Thanks also to the session and breakout group chairs, and to the notetakers.

GFBR funders*:* We would like to extend our thanks to GFBR's funders: Wellcome; the National Institutes of Health; the South African Medical Research Council and the UK Medical Research Council.

Members of the GFBR Steering Committee: Katherine Littler, Switzerland; Michael Parker, UK; Ross Upshur, Canada; Teck Chuan Voo, Singapore; Carla Saenz, USA; Phaik Yeong Cheah, Thailand; Jantina De Vries, South Africa; Ana Palmero, Argentina; Paul Ndebele, USA; Anant Bhan, India; Anna Chiumento, UK; Sharon Kaur, Malaysia; Caesar Atuire, Ghana. Funder members: Carleigh Krubiner, UK; Mongezi Mdhluli, South Africa; Rachel Knowles, UK; Barbara Sina, USA.

Members of the GFBR Planning Committee for this meeting: Katherine Littler, Switzerland; Joseph Millum, UK; Soumyadeep Bhaumik, India; Toto Gronlund, UK; Sharon Kaur, Malaysia; Francis Kombe, South Africa; Mona Nasser, UK; Bridget Pratt, Australia; Ludovic Reveiz, USA; Annette Rid, USA; Nicola Barsdorf, South Africa; Claudia Chamas, Brazil

Breakout group notetakers: Many thanks to the following participants for taking notes of the discussion: Ana Palmero, Barbara Sina, Anna Chiumento, Rachel Knowles, Donya Razavi, Teck Chuan Voo, Marisha Nanayakkara-Bruce.

Author: Adrienne Hunt

Case study write-ups and presentations from this meeting are available on the GFBR website.