

Mesh International Engagement Workshop Trusting, Collaborating and Listening: Engaging Public and Communities with Vaccine Studies

Report on Session 4/ Day 4 (8 October 2020): Supporting Strong Practice in Engagement in Clinical Trials

Authors: Siân Aggett, Cathy Slack, Robin Vincent

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Introduction

This report outlines key themes and discussion points coming from session 4 (day 4) of a workshop from Oxford University’s Global Health Network with members of the online platform [Mesh](https://mesh.tghn.org) which focuses on public and community engagement around global health. There were 30-40 delegates. Recordings of the presentations and other resources from across all four sessions are available here:

<https://mesh.tghn.org/2020-events/workshop-trusting-collaborating-listening/>

Three previous workshop sessions had explored the themes of ‘building trust’, ‘listening’ and ‘collaborating’ for engagement in vaccine research and development. Sharing learning and drawing comparisons across people, places, positions and partnerships was a focus of the workshop. In session 1 - ‘*Trusting*’ - delegates shared the critical importance of a sense of trust, and strategies for building trusting relationships with participating communities and other stakeholders. These included recommendations such as transparency, responsiveness and sensitivity towards social memory and the historical context from which ‘distrust’ might be borne. The session concluded that engagement itself cannot be held accountable for addressing all of the structural issues and forces from which trust or, mistrust might emerge. Session 2 - ‘*Collaborating*’ - surfaced the importance of appreciating the full range of actors who might want to participate when it came to engagement and vaccine research. Such actors include those within one trial (communications, social research, engagement teams), staff across multi-sited studies or even staff associated with neighbouring (perhaps ‘competing’) trials whose engagement loci might overlap. The session highlighted the importance of identifying common or divergent values and approaches as well as emphasised the effort necessary for working towards synergy rather than competition and confusion. Session 3 - ‘*Listening*’ – focused on the importance of, and strategies for, informing research with voices of community and public stakeholders. Examples included participatory research

design and methods, gauging public perspectives through social media listening and creating spaces to discuss difficult but important topics such as 'risk'. Responsiveness to inputs was underscored as critical, as well as preserving listening strategies and channels for public and community feedback even during emergency conditions.

Delegates were drawn from a professional network of academics and practitioners who are already proponents of supporting engagement in global health research including clinical trials. Many delegates are already deeply involved in critical thinking around implementing engagement at the highest standard and are immersed in practical challenges of achieving this first hand.

Session 4 was supported through the Good Clinical Trials Collaborative (GCTC), a joint collaboration from Gates, Wellcome and the African Academy of Science. The session aimed to reflect on the resources that already exist and to explore how we can continue to encourage good engagement practice in clinical trials. What works and why? What might be needed and what lessons and opportunities might be capitalised on in developing future guidance? It also aimed to inform the thinking of the GCTC who are motivated to see engagement appropriately incorporated into guidelines.

Session Structure

The session was framed by, Nick Medhurst from the GCTC who highlighted some core questions: Whose perspectives are incorporated into decisions around randomised clinical trials (RCTs) and who decides what matters? How can the regulatory and bureaucratic burden around clinical trials be appropriately reduced? (A goal of the GCTC). He noted values underpinning these questions, such as overcoming traditional power lines, hearing from those most impacted by disease and research, and inviting such voices to shape the fabric of research or to assess the likely social value of research.

The session started with a provocation piece from paediatrician Beatriz da Costa Thome who presented certain challenges of ensuring strong practice in community engagement with clinical trials from her first-hand experience in Brazil. This was followed by a series of short presentations and discussions. The first set of presentations was around the Good Participatory Practice (GPP) Guidelines, their origins in HIV trials and how these have been adapted to different disease and contexts. The second set of presentations highlighted different leverage points that various stakeholders are using to ensure that engagement both takes a central position in vaccine trials, and is implemented to a good standard. Delegates were invited to feed into the conversation directly during discussion time and also through an online visual exercise using 'Padlet' software (available on [Mesh](#)). Presentations were made by the following speakers:

- Nick Medhurst- The Good Clinical Trials Collaborative (A joint initiative from Gates, Wellcome and the African Academy of Science)
- Beatriz da Costa Thome-Department of the Federal University of São Paulo (Member of Nuffield Council of Bioethics Panel on the Ethics of Research during Humanitarian Emergencies)
- Stacey Hannah-AIDS Vaccine Advocacy Coalition(AVAC)
- Stephanie Seidel- TB Alliance
- Lisa Schwarz- McMaster University (Member of WHO COVID 19 task force)
- Jim Lavery- Emory University
- Sharon Abramowitz- Consultant with UNICEF Communications for Development
- Cathy Slack- HIV AIDS Vaccines Ethics Group, University of Kwazulu-Natal
- Ntando Yola-HIV Prevention Trials Network and Desmond Tutu HIV Foundation

Discussion

Several key themes were addressed in discussions flowing from the presentations:

1. The Value of Engagement in Clinical Trials
2. The (Complex) State of Engagement in Clinical Trials
3. What Good Engagement Looks Like in Clinical Trials
4. How to Support Good Engagement in Clinical Trials

1- The Value of Engagement in Clinical Trials

The value and motivations for engagement for randomised controlled trials, in general, was not explored in depth given delegates' familiarity with this debate. There was implicit consensus that there are practical and ethical benefits to engagement in that engagement informs and improves research and public health (e.g., ensuring ethical protocols and appropriate scientific designs, ensuring acceptance by community stakeholders, amongst others) as well as fostering respectful and trusting relationships between stakeholders.

Two speakers alluded to these benefits in their presentations; Beatrix da Costa Thome illustrated how engagement can bring 'hard to reach' populations into the research at an early stage ensuring appropriate design and buy-in, and Ntando Yola illustrated how without engagement in clinical trials it is hard to generate the understanding, interest and demand for any resulting public health benefits such as HIV prophylaxis.

Cathy Slack and colleagues analysed guidance documents for engagement and ethics review and noted key features of engaged trials, which seem to be particularly valued in ethics guidance: that the engagement is broad and inclusive, that it starts early and is sustained throughout the research cycle and that it is dynamic and responsive to context.

The value of engagement is borne out by previous crises triggered by relationship breakdowns between research and other stakeholders. For example, The Good Participatory Practice Guidelines (GPP) were borne from public backlash around perceived engagement failures in HIV prevention trials:

'We said, 'My goodness! We have done our due diligence in terms of making sure these trials are approved by ethics boards and IRB s and follow GCP (Good Clinical Practice Guidance), but something else broke down here.' And, that was a broad civil society engagement piece. That was, that was when GPP (Good Participatory Practice) was developed.'

(Stacey Hannah)

Despite the considerable benefits and value of engagement, speakers from the HIV sector noted that engagement is still, not a requirement in much research is readily overlooked in budgeting, or brought into planning processes too late in the day to inform decisions in the way that it could.

2- The (Complex) State of Engagement in Clinical Trials

The session's conversations frequently touched on why engagement within clinical trials might fail to be designed or implemented to a satisfactory standard. Most panel members

raised concerns of sufficient time and resources especially during a health emergency, and touched on deeper, more complex issues about accountability, agency and power.

In Beatriz da Costa Thome's provocation, she explained how she and colleagues involved in the development of the Nuffield Council of Bioethics Guidelines for Research during Humanitarian Emergencies spoke with community stakeholders as well as researchers involved in trials during health emergencies and in most instances encountered engagement that was "poorly done" if attempted at all. She noted that in large international collaborations even local academics in lower resource settings can be marginalised from decision-making within the research, let alone local communities. She illustrated this with an example during the Zika epidemic where her team found a consent form written in German rather than translated for the Northern Brazilian research population.

"So we can imagine - how honest and explanatory and engaging was the constant process, not to speak of the whole research endeavour?"
(Beatriz da Costa Thome).

Uneven progress

There was some recognition that engagement progress has been uneven across various kinds of health research. Positive attitudes towards engagement activities for some trials are not necessarily mirrored elsewhere within health research and this uneven regard for engagement is a principal barrier which engagement proponents face.

Inadequate Resource

It was noted that when funding gets tight it is often engagement budgets that are pulled first. Contributors unanimously agreed that community engagement is generally under-resourced in comparison with overall research budgets.

'There continues to be a lack of global stage for community engagement. Capacity and community engagement is always over-committed and under-resourced.'(Participant)

'Funders' were pinpointed as better able to change this situation than other stakeholder bodies, because of their ability to make resourcing decisions and because of funders' role as 'culture change agents' - detailing what budgets must include and holding research institutions accountable. There was a need for appropriate funding channels for engagement uncoupled from specific studies, to build general 'authentic community engagement capacity' – an investment which pays off:

'The United States hasn't made substantial investments in engagement infrastructure and are unable to compensate for the lack of community engagement capacity now... in contrast when you take examples like Rwanda or Uganda, or Sierra Leone, who have been making very, very strong strategic commitments to long term integrated community engagement capacity, over the course of the last five to seven years, especially in the public health sector, what you're seeing is the capacity to leverage community engagement capacity for all aspects of public health response, which likely includes clinical trials capacity.'
(Participant).

Complacency and neglect

It was suggested that it is important to incentivise research programmes to stay alert to the context and not to slip into uncritical and habitual engagement practice.

'Its really really important ... to do this ... broader assessment of who might be out there? Who might be asking questions? And, Where might there be controversy?'
(Participant).

There was some concern that the COVID pandemic had in some instances been used to undermine sound engagement because of time-pressure and constrained resources.

Little Accountability

Accountability structures can overlook engagement as a requirement. The examples Beatriz gave of engagement done well were entirely due to the team's own initiative and she suggested that research could have been conducted without any engagement or any overt penalty.

"I can tell [you] that the Research Ethics Committee that looked at this protocol never asked us; are you going to engage communities? How is it going to be?"(Beatriz da Costa Thome).

Little consensus and commitment to engagement goals and outcomes

It was noted that the field is moving away from engagement as a 'nice-to-have' towards engagement as 'essential', however, some attendees remarked that the goal or purpose of engagement is not always viewed in the same way across stakeholders, which affects assessments of whether engagement has met its' goals and has been 'effective'.

3- What Good Engagement Looks Like in Clinical Trials

Attendees volunteered several features of what they regard as good engagement practice.

Engage Early

The importance of early engagement, especially of groups that are at risk of being marginalised or at risk of their voices not being incorporated came through from all speakers. This consensus was, in part, a reaction to the fact that it is rare in some fields for engagement processes to be introduced at such an early stage.

Include Engagement at the Design Stage

It was commended that some funders supported engagement in advance of trial design, especially since once research is designed and approved it can be very difficult to reshape processes to accommodate engagement of the kind that might inform research conduct and perhaps increase the likely social value of the research in the eyes of public and communities.

'I think it can be really helpful to actually get properly funded pieces of work to actually learn from communities about priorities and concerns.'
(Participant)

Sustained/ On-going Engagement

The importance of building and sustaining capacity for the public and communities to understand research and therefore make informed decisions or hold research accountable was highlighted. This was connected to observations about an alternative funding route to engagement that is not "coupled" to specific trials. How might

engagement and capacity for engagement be sustained within a context irrespective of specific research programmes and their activities?

'These themes of trust and collaboration are really something that is continuous, and not just dictated by one particularly clinical trial.'

(Participant)

Beatriz da Costa Thome talked about the importance of working with social researchers whose approach is naturally 'engaged' anyway and who already had knowledge of the research community and experience in involving members of the research community directly in the design of the research including the research tools, and their dissemination.

'I can say we were pretty successful, and then the community, you know, really opened up because they felt they were represented. And we went back to share the results. So again, I guess this was one good example in which we really tried to, to include everyone from the beginning.'

(Beatriz da Costa Thome)

Involve a Diverse Range of Stakeholders

A consensus was that a well-designed engagement strategy includes plans to engage with a diverse range of stakeholder groups. Diversity was mentioned several times and highly valued. Ntando Yola also underscored the need for multi-level engagement, at local, provincial/ state, national and international levels.

Remember The importance of Civil Society

The significance of an informed and actively engaged civil society in facilitating meaningful engagement is something that may be overlooked from the standpoint of a research programme or study. Who is responsible for fostering this? Might it be something that merits funding from those funding research itself? To do this to a genuine degree costs time, which is not always easy to carve out within current incentive structures. Ntando Yola is working to operationalise the Good Participatory Practice Guidelines in HIV and TB trials with civil society groups across South Africa. To inform his strategy he led a national stakeholder consultation with civil society organisations, community engagement practitioners, and community advisory boards amongst others. The outcome of this consultation was an agreement to create a national forum separate from specific studies, which would continuously engage with stakeholders including provincial and national structures.

'...it really created accessibility of researchers, the ethics committees...and regulatory bodies as well as funders and policymakers...'

(Ntando Yola)

Support Engagement at a Global Level

Delegates mentioned the need for international pressure and oversight to hold research to a good standard of engagement. Organisations such as AVAC offer support through training and guidance. Other international bodies or collaborations might further support through other means.

'Should there be more of a standardised approach to clinical trials which may require some kind of, you know, international regulatory body?'

(Lisa Schwartz)

'International agreements or standards for practice really are so important because there needs to be an agreement at every level that this is an important part of how we do research, and especially now that so much of this research especially for emerging pathogens is publicly funded.'
(Participant)

Adapt to Context

The GPP guidelines are designed to encourage those implementing them to root their engagement strategy and approaches in an understanding of the context (e.g., health condition, trial type, social and political context etc.). It must not be disconnected from larger structural processes and decisions. The workshop discussions took place both within the context of COVID 19 and the US elections, which underscored how medical research can be politicised and used as part of a divisive political campaign and the potential that this has to shift public/ community discourse and attitudes. This too can raise specific considerations for engagement practices and strategies. Is the 'community' polarised in opinion? Is opinion following political discourse?

Be Reflective and Flexible

It was noted that engagement approaches need to be flexible and adaptable as relationships develop during the course of a study. Speakers highlighted the value of introducing flexibility into research itself so that it is able to reflect and respond to the context as time unfolds. One way of ensuring the required degree of sensitivity might be to employ people who already know and understand the research context. In this way, engagement might play a monitoring role analogous to and complementary to social research. This degree of flexibility is not something that is always supported by the structures governing research but is something that may ensure that engagement efforts can deliver something of meaning and value.

Cathy Slack also identified the need for flexibility when researchers submit engagement plans, to prevent "locking" researchers into pre-ordained engagement processes:

'...What we might be identifying in the empirical research is concerns about rigidity. So applicants are concerned that if they give a stakeholder engagement plan to an IRB which is approved, that they are locked into some sort of engagement process that they can't change without an amendment.'
(Cathy Slack).

Embrace Change

Attendee Mark Marchant suggested that the principal goal of engagement on the part of research ought to be 'change' – that committing to engagement means committing to change and it is this fundamental objective that is often missing from the structures governing research:

'The object of listening and deliberation, learning from communities and doing that engagement work in the first place ought to be change. If we are not open about the fact that the object of community engagement is change then we might fail to meet the institutional requirements of actually responding to that two-way communication/two-way dialogue in the form of real changes in the programme of research that really fit the community's concerns. (...)' 'Don't ask me what I want for dinner if you are going to cook whatever you want anyway.'
(Mark Marchant)

4- How To Best Support Engagement in Clinical Trials

Attendees recommended strategies for improving the quality of engagement in research, which may suggest particular methods or entry points in the research cycle that might be pertinent to supporting engagement in clinical trials.

Use Good Participatory Practice Guidelines (GPPs)

As set out by Stacey Hannah, AVAC is an advocacy organisation for HIV prevention based in the US but which works globally primarily in areas of the world that have the highest burden of HIV. Part of their work is to support engagement policies around research and development processes for new prevention interventions (e.g., vaccines, prep and microbicides). The Good Participatory Practice (GPP) guidelines were originally developed in 2007 by AVAC along with UNAIDS to encourage sponsors and study teams to implement participatory practices. This was in response to controversies and public backlash that arose connected to HIV prevention trials in Africa in the mid-2000s. The guidelines are structured in a very practical way. The meat of the document is in section three where the guidelines walk through the clinical trial lifecycle and articulate what some of the considerations are at each stage and what practices could be put in place to ensure that stakeholders are engaged well at each stage or in informing the broader research agenda. The guidelines understand “stakeholders” broadly as anyone who could be impacted by a clinical trial or anyone who could have an impact on a clinical trial. Stacey noted that it is helpful when international GPP guidelines are incorporated into national ethics guidance at a country level.

Figure: Layers of Biomedical HIV Prevention Trial Stakeholders (GPP Guidelines p15)



The TB Alliance (a non-for-profit organisation focused on the development of TB drugs) first adapted the GPP guidelines for use in the context of TB rather than HIV. This necessitated the question: How does GPP apply to clinical trials more broadly than HIV

prevention? Since then, the guidelines have been further adapted. The WHO developed guidance for Good Participatory Practice in Health Emergencies and have also convened a 'Task Force' to adapt the guidelines for COVID 19 related trials. Stephanie Seidel from TB Alliance stated that TB drug research had not come up against controversy and public backlash as had happened in the HIV field. In a sense, she felt that this lack of a crisis point made it more challenging to generate buy-in for engagement within the field of TB research. Lisa Schwarz has been working with the WHO to develop the Good Participatory Practice Guidelines further for using in epidemics and now specifically COVID 19.

Ensure the Tools Needed to Implement Guidelines

All presenters who have worked to adapt Good Participatory Practice (GPP) guidelines for their specific fields and contexts have found that further resources and support is required to ensure their implementation in practice. AVAC has a wealth of practical resources to support this on their web pages: <https://engage.avac.org/>. The guidance also needs to be made relevant and accessible for a variety of audiences, given that the guidance is used to cater for a wide range of audiences from frontline community liaison teams to principal investigators. For this reason AVAC and the WHO COVID 19 task force have worked to generate a range of documents including toolboxes, summary checklists, and overview documents to help with specific tasks such as developing or working with existing community advisory boards.

Engage Affected Stakeholders When Creating or Refining Guidelines

Some recommendations were given for the development of guidelines themselves. Firstly, to recognise that any newly developed guidelines for the field must take into account other national and international guidance, so that guideline recommendations for engagement do not introduce conflicting norms, where possible. Also, guidelines ought to incorporate a diversity of voices and perspectives from across the global north and south in their development if they are to hold weight.

'One real threat [to any guidelines developed] is early neglect of affected stakeholders, and it's a sure-fire way to make sure that they stay on the shelf.'
(Cathy Slack)

Set Standards

Sharon Abramowitz described working with UNICEF on the implementation of Minimum Standards and Quality Indicators for engagement within their communications for development programmes. The standards are hoped to improve the *quality, accountability, harmonisation, and optimization* of community engagement actions by generating systematic accountability for sustained community engagement capacity within humanitarian and development programmes, which might include research. She noted that the standards were developed through a global consultation process that included donors, practitioners and researchers and pertain to different parts of the organisational structure and stakeholder partnerships. The standards can be leveraged to design and monitor a wide range of activities, including capacity building, research and communications.

PART A: Core Community Engagement Standards	PART B: Standards Supporting Implementation
1. Participation 2. Empowerment and Ownership 3. Inclusion 4. Two-way Communication 5. Adaptability and Localization 6. Building on Local Capacity	7. Informed Design 8. Planning and Preparation 9. Managing Activities 10. Monitoring, Evaluation, and Learning
	PART C: Standards Supporting Coordination and Integration
	11. Government Leadership 12. Partner Coordination 13. Integration
	PART D: Standards Supporting Resource Mobilization
	14. Human Resources and Organizational Structures 15. Data Management 16. Resource Mobilization and Budgeting

There are risks of any list of standards being taken as prescriptive (and where they are treated as a tick box exercise) however, there may be merit in thinking about how UNICEF’s is holding different parts of an organisation and wider stakeholders accountable for ensuring that engagement efforts are supported and meaningful.

Strike a Balance Between Standards and Bureaucratic Over-Regulation

There was some tension between the need for consistent standards for engagement while ensuring that standards are flexibly applied in diverse contexts. It was noted that engagement is not a requirement in Good Clinical Practice (GCP) and not scrutinised through existing GCP processes, because it is generally viewed as an ethics requirement and better accommodated in ethics guidance. Many panellists and delegates were calling for increased attention to engagement, while at the same time underscoring the need for flexibility and agility.

Use the Ethics Review Process

Cathy Slack noted that Research Ethics Committee (REC) review is an opportunity for both the applicants and the REC to try and shape better engagement in the field during the review process. Cathy and colleagues have reviewed a number of ethics guidelines and has found overlap in how they understand the key features and practices of “engaged trials”. All the guidelines encourage RECs to review engagement, irrespective of some delegate’s reported experiences of RECs failing to review engagement. With this gap between the guidance and practice in mind Cathy and her team have developed online training for RECs (Institutional Review Boards or IRBs) in what to look out for in engagement plans and how to permit these to be sufficiently flexible/ open to change, yet transparent enough for the REC to assess if engagement plans are consistent with international norms and guidance. Cathy cautions that enlisting RECs in this way might not offset all perceived deficits in engagement; however, it is a unique opportunity early on in the research process to impact good engagement in the field. (For the online course: go to <https://engage.avac.org/> and register, then click on LEARN and choose course entitled “Strengthening Engagement Through Ethics Review”). Some attendees noted that their IRBs had not made inquiries about engagement when protocols were submitted, while others noted that RECs did make broad inquiries.

Build Engagement into Organisational Practice

A reoccurring point in workshop discussions was the availability of certain strong institutional players (e.g., KEMRI-Wellcome in Kenya) who have community engagement embedded in their programme whereas many other institutions do not and do not feel the imperative to do so. At KEMRI all protocols have a dedicated section for the study team to declare their engagement activities.

Make use of Organisational Learning and Knowledge Co-Production

Jim Lavery's described work in neglected tropical diseases (specifically lymphatic filariasis) in Haiti. While this work is not clinical trials per se, there are parallels (e.g., drug administration involves episodic mass events, which are not continuous over years). He described work to explore a decline in uptake, and found that while much good engagement was happening this was "outward-facing" "on the front line" and "at an operational level". What was lacking, however, was a process of organisational learning where there is feedback into institutional processes and practices.

'The insights that were being gathered through these engagements with various stakeholders were not being incorporated into the day-to-day operations and planning and revisions and management of the programme itself.'
(Jim Lavery)

His team is now focussing on a knowledge co-production strategy involving the 'persistent non-compliers' with the program. They are emphasizing how the program should be designed to increase the likelihood that the target community will actually use it.

Think Carefully About Social Value

Nick Medhurst suggested that clinical trials might not be sufficiently informative of public health; in which case, research participants could be getting a 'raw deal' insofar as they take on risks and make contributions to trials with low social value. Guidance could respond to this problem by encouraging proper scrutiny of design and encouraging collaboration. Some attendees noted that thought around engagement and clinical trials has overemphasised research participant experience over the social value of trials. It was also noted that trial findings/ data are often not packaged in a way that address the uncertainties of decision-makers (e.g. policy-makers, program implementers) nor the constraints on their decision-making.

We don't think strategically enough about what key decision-makers might have on their desks, what contextual factors might constrain their decisions, and whether trials are designed effectively to reduce uncertainty around those key contextual issues rather than not simply reducing uncertainty around your primary and secondary endpoints.
(Jim Lavery)

Redefine 'Good Research' or 'Good Clinical Practice'

One way to embed engagement in practice might be to define good research incorporating engagement principles, such as in Jim Lavery's work where he has taken steps to incorporate 'fair partnerships' into a global health programme's concept of 'effectiveness'.

'The logic is that the notion of effectiveness was very narrow. Effectiveness is about how much coverage you get, how much technical, how many of the technical details that you cover. The idea of fairness sits outside this realm. We are trying to argue that fairness should be seen as an integral component of the very concept of effectiveness itself and I think there are some analogies in how we think about clinical trials.'

(Jim Lavery)

In this Jim drew on COHRED's research fairness initiative (<https://rfi.cohred.org/>). While not limited to clinical trials, this might be a helpful framework to build understanding between researchers and a host community, as well as between researchers and host country partners, to avoid duplication and to understand "disconnects".

Harness the Expertise of Community Stakeholders

Beatriz da Costa Thome presented a case study from her work in Brazil where she stated that engaging with local community stakeholders worked well in strengthening the research design. She noted that the research team in this instance was diverse, including local social scientists who already knew the context as well as people from the local community who were employed as advisers from the start. The community in this instance comprised residents of informal settlements in the city of Sao Paulo - considered both vulnerable and 'hard to reach'.

'They actually did help us finalise the research tools, the questionnaires, they went back to us and said, 'This is way too long, no one's going to ever answer all these questions. They, also got back to us saying, 'So this is not the right question to ask.' Or, 'If you want this answer, you should ask this way.'

(Beatriz da Costa Thome)

Strike a Balance Between 'Educating' and 'Consulting' public and communities

A tension implicit throughout the workshop discussion was the line between responding in an accountable way to community stakeholder inputs while recognizing that such inputs may reflect variable capacity/ expertise in research:

'I will just say just in response to some comments really about treatment trials sometimes not being what patients or communities want. I think that that's a really important perspective, but I think it's also important to realise that clinical trials do bring necessary treatments to different disease areas, and it's our responsibility to educate.'

(Participant)

Prepare Engagement Strategies for Specific Scenarios in Advance

A practical suggestion that came up during the session was the idea of generating potential scenarios and suggested strategies for intelligent management of such scenarios, such as when a trial arm is stopped (an accepted part of the research process that can be misconstrued by those outside of research). This suggestion is endorsed by the GPP guidelines.

Clarify Where Engagement Responsibility Begins and Ends

Setting defensible limits around engagement might be important. Cathy Slack pointed out that there is a lot of guidance available for clinical trials around "why" to engage, "when" to engage, "who" to engage and "how" to engage, but little about 'how much to engage'. The question of responsibility is perhaps an important one for guidance to tackle. Some attendees had raised the difficult issue of how much engagement efforts should for example offset structural inequalities. Whilst engagement often attempts to promote

dialogue by creating a more even playing field, what is engagements' or research's responsibility to really address structural inequalities such as poverty and injustice.

'These are questions about "how much to engage?" In ethics guidelines, we don't enjoy enough direction about that and I wonder it's not just an academic issue. It's something that really faces people on the ground.'

(Cathy Slack)

Conclusions and Way Forward

In this workshop session, we heard how different stakeholders might strategically support engagement, including guideline developers, funders, RECs, and civil society/activists. All these stakeholders have different "levers" that they might pull to support engagement in clinical trials.

'...we need to look inward a little bit more - to inside sponsor organisations, institutions, donor organisations, regulatory organisations, ethical review committees, to make sure that we're all taking the role and responsibility that we have to incorporate good participatory practices into each aspect.'

(Stephanie Seidel)

We also heard how trial experiences from different diseases (e.g. TB, HIV, Ebola, COVID and others) can be shared to strengthen how engagement is conceptualised and practised. We heard attendees from across the global north and south describe complexities and remedies that were not necessarily unique to their context, and might yield helpful insights for others working in other contexts.

The presentations and discussion underscore the following future opportunities:

1. To share critical and practical resources for engagement across 'silos' created between stakeholder groups, settings and diseases
2. To get discussion threads going on Mesh to take on selected concerns identified in the session
3. To share relevant publications and grey literature including project reports with the wider community of practice through Mesh (and other relevant channels)
4. To lookout for draft GCTC guidelines and offer input to the drafting team.

References/Resources

MacQueen KM and Auerbach JD (2018) Journal of the International AIDS Society 21(S7):e25179 <http://onlinelibrary.wiley.com/doi/10.1002/jia2.25179/full> | <https://doi.org/10.1002/jia2.25179> Including:

It is Not Just about "the trial": the critical role of effective engagement and participatory practices for moving the HIV field forward. MacQueen KM and Auerbach JD.

Strengthening stakeholder engagement through ethics review in biomedical HIV prevention trials: opportunities and complexities

Slack et al.

WHO guidelines on Good Participatory Practice for Trials of Emerging Pathogens (GPP-EP)

https://www.who.int/docs/default-source/blue-print/gpp-epp-december2016.pdf?sfvrsn=79d1cf43_2

GPP-EP were prepared in 2016 by the WHO to support prevention and treatment trials of emerging (and re-emerging) pathogens that were likely to cause severe outbreaks. The guidelines address how to engage community stakeholders and promote ethical standards throughout the research process.

A sub-group of the WHO's Coronavirus Social Science Task Force is currently working with Mesh to develop tools for helping researchers to incorporate GPP-EP in their COVID-19 research work. Similar tools have already been developed by AVAC in the context of HIV trials (see below).

AVAC - Good Participatory Practice (GPP) Guidelines

<https://www.avac.org/good-participatory-practice>

These Good Participatory Practice (GPP) Guidelines were developed by AVAC and UNAIDS for HIV prevention trials, they are valuable to clinical trials across fields, research areas, geographies and populations. They provide trial funders, sponsors and implementers with systematic guidance on how to effectively engage with all stakeholders in the design and conduct of biomedical HIV prevention trials. The guidelines are available in multiple languages. AVAC has also developed an array of supplementary GPP tools.

AVAC Good Participatory Practice Tools

<https://www.avac.org/gpp-tools>

AVAC has developed a large set of supplementary tools to help research teams and other stakeholders understand, implement, and monitor the GPP guidelines. Including:

The GPP Summary Sheets

<https://www.avac.org/resource/gpp-summary-sheets/>

At-a-glance look at the GPP guidelines for individuals who may not be primarily responsible for implementing GPP, but who need to understand them. They are organised according to the stages of the trial life cycle: planning, trial conduct and post-trial. Each stage outlines GPP topic areas highlights key practices and lists considerations for various stakeholders.

The Good Participatory Practice Guidelines for TB Drug Trials

<http://www.cptrinitiative.org/resources/gpp-tb-resource-document/>

In TB trials, resources to support researchers interested in engaging local communities have been limited. These guidelines thus address a critical need that was revealed by interviews conducted with prominent members of the TB research community. They are an adaptation of the UNAIDS-endorsed *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* to the specific context of TB drug trials.

NIHR Resource Guide for CEI in Global Health Research

<https://mesh.tghn.org/articles/guide-nihr-resource-guide-cei-global-health-research/>

Researchers funded by the NIHR Global Health Research Programme are expected to involve patients and the public in planning, implementation and evaluation of their research. This resource guide provides community engagement links, resources, references and learning to offer research teams and funding applicants a starting point.

UNICEF - Minimum quality standards and indicators in community engagement

<https://www.unicef.org/mena/reports/community-engagement-standards/>

With the support of the Bill and Melinda Gates Foundation, UNICEF C4D has developed 'Minimum quality standards and indicators in community engagement' to provide globally established guidance on the contribution of community engagement in

development practice as well as humanitarian action. The objective of the standards is to support the implementation of high quality, evidence-based community engagement at scale in development and humanitarian contexts.

Community Stakeholder Engagement (CSE) Monitoring Toolkit

<https://mesh.tghn.org/articles/guide-community-stakeholder-engagement-cse-monitoring-toolkit/>

This user-friendly set of quantitative and qualitative monitoring and evaluation tools allows users to capture, collate and analyse Community and Stakeholder Engagement (CSE) data at the clinical trial site-level. The database is designed to support engagement teams working on clinical trials on a daily, monthly, quarterly and biannual basis.