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Working with Community Advisory Boards/Groups to support community engagement in clinical research

General and COVID-19 specific considerations

There is wide agreement that community engagement (CE) is important to strengthen collaborative partnerships and ethical practice across many research types and settings, often including interaction with 'representatives' of communities.

Arguments for strengthening CE in international research include to :

• Strengthen the design, acceptability and quality of research.

• Strengthen informed consent processes in research through dissemination of information on research goals, risks and benefits, and incorporating local views into consent processes .

• Identify and minimise 'internal risks' (those only visible to those within a community), and risks that can be imposed externally such as stigmatization of the community .

• Support alignment of research approach and outcomes (measurable as well as intangible outcomes, such as increased trust in public health messaging) with engaged population's priorities.

• Empower communities and demonstrate respect, both as a goal in itself and to, in turn, strengthen mutual understanding, trust and credibility of researchers .

Community Advisory Boards/Groups (CAB/Gs), or variants of these, are the most widely documented structures supporting CE. Here we share some information on establishing and working with different types of advisory groups and consider adaptations in the context of COVID-19 studies. Many of the issues that need consideration are not specific to COVID-19, so we begin with those non-specific issues.

KEMRI Community Representative attend one of 3 annual meetings with Community Engagement staff

General issues and considerations of establishing and working with CAB/Gs

Two key challenges for establishing and working with CAB/Gs include defining the communities of interest in research, and identifying who 'authentically' represents those communities:

• Defining communities of interest: In much non-participatory health research (including clinical research), relevant communities are at least initially often defined by researchers who are external to communities . Definitions of communities are therefore often related to the nature of the research activity, such as for example whether the research involves a particular geographical area or illness group. Some CAB/Gs therefore seek to include members from a broad cross section of the community ('broad community', e.g. Shubis et al.), and others from a particular population ('populations specific' e.g. Morin et al.).

• Selection of representatives of selected communities: Individuals might speak on behalf of a particular community (more commonly practiced), or be typical members of that community. Representatives who speak on behalf of communities are often relatively charismatic, well known, and outspoken, such as leaders of large women's groups or religious elders . Such characteristics may make these representatives more able to voice their views and options, and ensure they are heard, but it may also mean they are rather unusual and offer atypical ideas or approaches. Typical community members' views reflect those of their communities through being mainstream and representative, including for example, based on where they live, their socio-economic status or their religion. Typical community members may be less well known and vocal, but have greater contact with and awareness of everyday issues and concerns in their communities. In order to ensure that the voices of the most vulnerable and marginalized are heard, it might be necessary to have a specific groups set up to include their perspectives (for example the lowest income groups, or people living with disabilities).

While working through CAB/Gs can strengthen research relationships and ethical practice , challenges include:

• **Defining communities and their representatives,** as described above, including an over-dependence on CAB/Gs as 'the' community voice(s); multiple channels or approaches are often needed including interactions with community leaders and including the voices of the most vulnerable/least vocal.

• **Facilitating appropriate selection of members.** Deciding on what form of representation is aimed for and how to select members can be challenging, including ensuring transparent and democratic (where relevant) processes, and maximising the potential for members to feel able to raise their views with each other and with research staff.

• **Facilitating appropriate motivation (intrinsic and extrinsic) of members.** Payments can introduce relationship challenges between representatives and their community members, but where there is no motivation, or where there are unmet costs to volunteers, the goals of CE will be undermined . Levels of payment must cover direct and indirect costs (compensation), and there should be an additional motivation, but the latter may be achieved through non-monetary means including making sure the experience is positive and that members feel valued (e.g. through refreshments, ensuring that CAB/Gs questions are answered, and that they are given feedback on what influence their contributions have had on the research).

• **Ensuring clarity in roles and adequate training to fulfil those roles;** inadequate discussion on both researcher and CAB/G member expectations, and on limitations on what can be achieved, can undermine relationships and CAB/G functioning. Inadequate training in what research is, and on basic ethics principles and processes in research, can undermine CAB/Gs members' ability to make meaningful contributions.

• **Avoiding 'politicisation',** whereby members take on gate-keeping roles and block out voices of vulnerable groups; again multiple channels may be needed.

• **Tensions** around the dual potentially conflicting functions that some CAB/Gs have of both advancing the research and protecting the community , and power inequities, whereby CAB/G members may feel bound by the researchers' decisions or unable to take action if their recommendations are not followed.

COVID-19 specific issues and considerations of establishing and working with CAB/Gs

An important issue in engaging with communities for COVID-19 related clinical studies is that **time may be limited to get studies up and running. Further important considerations include ensuring that:**

- Any interactions with CAB/Gs do not undermine, and ideally support, essential activities of key local stakeholders working to respond to COVID-19, particularly Ministries of Health and leading health NGOs. CAB/G engagement will therefore likely need to follow or be preceded by discussions with those key stakeholders.

- Bringing together CAB/Gs does not cause any physical or social harms through placing individuals at risk of infection, or stigma for being seen to contribute to the spread of the virus. This may require non face-to-face interactions, with possibilities including Zoom, Skype or – more commonly for community groups in low-income settings – WhatsApp groups or telephone discussions. Training and information sharing may need to be through videos and animations.

- Interactions with CAB/Gs do not inadvertently add to unhelpful rumours or concerns, or feed into raised expectations that cannot be met (for example for treatment and health care support for CAB/G members and their families). Where interactions cannot be in person, these types of problems may be particularly heightened.

Bearing in mind the above considerations, when selecting or identifying CAB/Gs in collaboration with local stakeholders you will need to:

- **Define your communities of interest** (for example based on roles, locations, or type of illness) and the form of representation you are aiming for (speaking on behalf of, or typical of). Where there is a large mix of different types of members, consider the ability for all members to be open and honest in the discussions/interactions, and whether several groups or engagement approaches would be best.

- Ideally begin by **working in settings with CAB/Gs already in place, only setting up new CAB/Gs where needed and possible.** Working with groups that already have an understanding of health research, of basic ethics principles in research, and of how advisory roles in health research work will often be more straightforward than starting

something completely new. It's important to work with the rules and agreements that local institutions have already developed, so that these locally developed processes are not unintentionally undermined.

- **Where there are no existing CAB/G** structures in place, or they need to be supplemented, think carefully about alternative groups or networks that can take on some of the CAB/G roles e.g. patient/caregiver support groups, community health workers or frontline staff from local health organisations. Particular care is needed where involving frontline staff to ensure that proposed CAB/G activities do not undermining their responses to the pandemic, or overburdening them at a critical time. Also to note is that while a potential advantage of working with these groups may be relatively easy identification of members and explanation of the work, a potential challenge is their independence from the institution and ability to adequately 'represent' wider community members. Engaging with the local Research Ethics committee in identifying alternative networks maybe a helpful strategy.

- **Where you are setting up a new CAB/G, establish how you will select** (identify and approach) potential CAB/G members, carefully considering the best mix to represent the communities of interest.

- **Be clear and specific about your aims/goals for engaging with your communities of interest from the outset,** and check what the goals and expectations of CAB/G members are; goals are often not properly discussed, and can be multiple and conflicting. Emphasise where relevant where responsibilities end (for example it may not be a responsibility of CAB/Gs to share government or research institution messages to communities). It is good practice to revisit aims/goals explicitly at the start of each meeting, including the value of diverse perspectives and respectful inclusive processes.

- **Consider feasibility and representational limitations where face-to-face meetings cannot take place –** you may only be able to include members able to use smart phones or computers to join virtual meetings. Some groups may thereby be systematically excluded from participation (e.g. the lowest income groups or the elderly). Consider how these groups' perspectives might be brought forward, especially if the excluded group is a key part of the research population.

When working with CAB/Gs it will be important to

• **Clarify what all parties expect to get out of the interactions, and discuss what is and is not feasible.**

o Be explicit from the outset about the anticipated end point for the CAB/G if it is established for the purpose of supporting response or research during the Covid-19 pandemic.

o Be explicit about ground-rules regarding confidentiality, and external messaging from the meetings.

o Ensure any necessary support, e.g. data bundles and transport, as well as time compensation where relevant, are provided.

o Agree on how CAB/G advice will be documented, and – where appropriate – shared with ERCs or government actors.

• **Develop a clear and effective training plan** including information on research/the research institution, research ethics, COVID-19, the specific study/studies being planned, and the role and functioning of the CAB/Gs. Note that there is a strong potential that where community members are unhappy with their governments/Ministries of Health, that CAB/G interactions will becoming an avenue for raising this. Careful handling of these issues will need to be discussed from the outset, including referral of issues raised.

• Consider **developing a brief Terms of Reference (TOR)** to outline all of the above agreements.

• **Ensure that relationships are built and protected over time,** including through giving feedback on discussions, and that there is a clear exit plan.

Depending on the study and context, combinations of the following types of group may be needed, together with wider stakeholder engagement				
	Community wide CAB/G (e.g. CAB on Thai/ Burmese border. Cheah et al. 2010)	**Study/disease specific CAB/G** (e.g. IAVI CAB/Gs for HIV related studies)	**Advisory network across a community** (e.g. Kemri Community Representatives in Kenya – see Kamuya et al., 2013)	**Carefully selected group of individuals** (e.g. careful selection of those with disabilities, young people, or lowest income women)
Form of representation	**Advise researchers on behalf of the communities they represent**		**Advise researchers through being typical of those communities**	
Potential opportunities	• Often relatively well known, confident, prominent and outspoken, e.g. religious elders, local chiefs or elders, and leaders of women's groups, youth groups, and other CSOs, CBOs, or local NGOs). • Better able to voice their views and options, and ensure they are heard. • Having gate-keepers in the CAB/G may reassure community members		• May have greater contact with and awareness of everyday issues and concerns in their communities than the more outspoken leaders	• Better able to represent the most vulnerable and marginalized where specifically selected to be made up from those groups
Potential challenges	• May be rather unusual or have atypical ideas or approaches • May not adequately represent vulnerable groups unless specifically made up of that group • Gate-keepers may persuade people to join studies, which might not be an agreed goal of CAB/G members.		• Potentially best works where there is a long term established research institution	• Challenging to identify potential members and set up adequately open discussions with research groups

A case study – Africa Health Research Institute

In March 2020, as the first cases of COVID-19 were identified in South Africa, a COVID-19 related module was designed by members of the research team at the Africa Health Research Institute for inclusion in the questionnaire used for on-going data collection in a Demographic and Surveillance area 200 km north of Durban in KwaZulu-Natal covering 90,000 people. The Community Advisory Board members, all local people, who advise AHRI at this research site were invited to comment on the questions to be asked and the modifications that had been made to the protocol, prior to submission for ethical approval. The research team was aware that there were a number of rumours circulating about the origins of COVID-19 and stories about how it was spread and could be prevented. Just as the CAB meeting was being arranged gatherings were banned by the Government and restrictions put on people's movements to prevent the spread of the virus. The CAB members were still very keen to help and over the space of 24 hours in late March a group of them, with access to smart phones which could access video-conferencing software, were convened by the chair to represent the wider group. The research team leader made a presentation to the CAB members over their phones, answering questions and clarifying what was planned. This interaction also provided an opportunity to share information on COVID-19 with the CAB members present. The CAB members then met privately to discuss the application and gave their approval for the work to go ahead at the end of their meeting. AHRI reimbursed the air time/data used by the CAB members. All those who took part expressed their thanks for the effort made to involve them in a timely manner.

Members of the African Health Research Institute Community Advisory Board

A case study - KEMRI Wellcome Trust Research Programme (KWTRP)

KWTRP works closely with approximately 225 community representatives (referred to as KEMRI Community Representatives – KCRs), drawn from a research population of over a quarter million people living across a geographical area in Kilifi County, Coastal Kenya. This KCR network is in effect a set of CABs, organized into mixed gender groups based on where they live. KCRs include typical community members of varying literacy and socio-economic status; they are elected by their local communities to offer views and advice to KWTRP for a three year period. The KCR network advises KWTRP on institutional policy and practice across studies, and are consulted for input into specific study plans.

Partial lock-downs introduced rapidly in early March following the identification of COVID-19 cases in Kenya brought a halt to face-to-face engagement activities. To maintain a means of engaging with KCRs, a WhatsApp group has been formed with all KCR members with a smart phone (total 97/225). KCRs are using the WhatsApp group to ask questions including on: (i) what the research institution is doing to help with the COVID-19 fight; (ii) whether the research institution is conducting research on COVID-19; iii) and broader COVID-19 concerns. The WhatsApp group provides an avenue for consultation with members for upcoming COVID-19 studies, as well as collecting and responding to other concerns raised concerning the Pandemic. Importantly, the CAB members also share rumors they have heard in the community, which gives us an opportunity to share the government's public health messages. An important challenge we face is that most of our CAB members do not have smart phones, and some have low literacy levels. We could engage through direct phone calls, but we are also keen to develop other innovative ways of reaching these members during this period.


KEMRI Community Representative sharing their views on a potential Shigella controlled Human Infection study

A case study – Mahidol Oxford Tropical Medicine Research Unit (MORU)

MORU with partners from Thailand, Malaysia, UK and Italy are planning an online survey and qualitative study on the social, ethical and behavioural aspects of COVID-19. The study focuses on the impact of quarantine, self-isolation, travel restrictions and social distancing measures to curb the spread of COVID-19. On 30th March 2020, we conducted a 3-hour virtual meeting (on Microsoft Teams) of the Bangkok Health Research Interest Group where we obtained input using an adapted version of cognitive testing on selected questions from our online survey. We also had an open discussion on COVID-19 public health measures which helped shaped our interview guide.

The MORU Health Research and Ethics Interest Group (HREIG) is a form of CAB that was established in August 2019 with the view to building a mutually beneficial partnership with members of the public. Group members meet regularly to provide advice to researchers on ethical, practical and community engagement aspects of MORU programmes. HREIG members are members of the public who are based in Bangkok and have an interest in health research. They were not drawn from a specific patient community, rather were recruited through advertisements. Before COVID-19 was reported in Thailand, the HREIG would meet in person, but this was no longer feasible under lock down, leading us to experiment with this virtual meeting approach instead. We were surprised and pleased with how well this worked and look forward to further consultations using this approach in future studies.
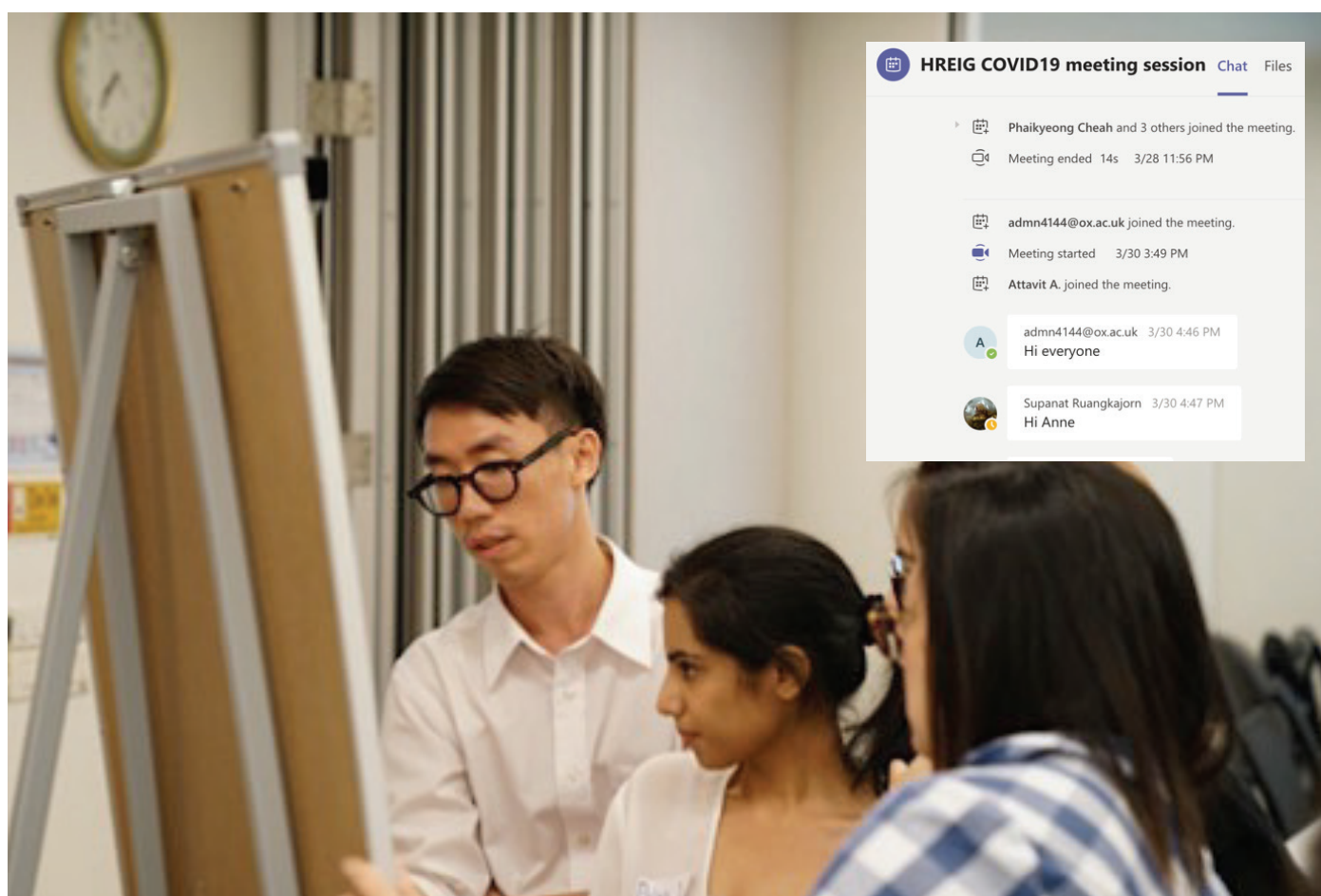
Bangkok Health Research Ethics Interest Group
SEBCOV: Social, ethical and behavioural aspects of COVID-19 in the UK, Thailand, Malaysia and Italy

Links to related potentially useful tools and papers:)

• IAVI produced training tool for CAB/Gs http://www.iavi.org/images/ Clinical_Research_Centers/ IAVI_Community_Advisory_Board_ Guidance_Tool.pdf

• NIHR toolkit https://opendocs.ids.ac.uk/opendocs/bitstream/ handle/20.500.12413/14708/ NIHR_Community_Engagement_ Involvement_Resource_Guide_2019.pdf?sequence=2&isAllowed=y

• SC-CTSI toolkit - https://sc-ctsi.org/uploads/resources/ CommunityAdvisoryBoard_Toolkit.pdf#asset:789

• Mlambo, C.K., Vernooij, E., Geut, R. et al. Experiences from a community advisory Board in the Implementation of early access to ART for all in Eswatini: a qualitative study. BMC Med Ethics 20, 50 (2019). https://doi.org/10.1186/s12910-019-0384-8

• Zhao, Y., Fitzpatrick, T., Wan, B. et al. Forming and implementing community advisory boards in low- and middle-income countries: a scoping review. BMC Med Ethics 20, 73 (2019). https://doi. org/10.1186/s12910-019-0409-3

This document draws primarily on the following publications:

1. Kamuya DM, Marsh V, Kombe F, Geissler PW and CS Molyneux (2013). Engaging communities to strengthen research ethics in low-income settings: selection and perceptions of members of a network of Representatives in coastal Kenya Developing World Bioethics, 13, 10-20.

2. Adhikari B, Pell C, Cheah PY. Community engagement and ethical global health research. Global Bioethics. 31:1, 1-12, DOI: 10.1080/11287462.2019.1703504

3. Angwenyi V, Kamuya D, Mwachiro D, Kalama B, Marsh V, Njuguna P and Molyneux CS, 2014. Complex realities: Community engagement for a paediatric randomized controlled malaria vaccine trial in Kilifi, Kenya. Trials, 15:65.

4. Cheah PY, Khin ML, Phaiphun L, Maelankiri L, Parker M, Day NP, White NJ, Nosten F. Community engagement on the Thai-Burmese border: Rationale, experience and lessons learnt. Int Health. 2010;2:123-129. (CA)

5. Marsh, V., Mwangome, N., Jao, I. et al. Who should decide about children's and adolescents' participation in health research? The views of children and adults in rural Kenya. BMC Med Ethics 20, 41 (2019). https://doi.org/10.1186/s12910-019-0375-9

6. Nyirenda, D et al. 2017. We are the eyes and ears of researchers and community': understanding the role of community advisory groups in representing researchers and communities in Malawi. Dev World Bioeth. 1–9.

Authors and contact information:

For more information please contact:

Noni Mumba, Alun Davies or Sassy Molyneux at the KEMRI-Wellcome Trust Research Programme in Kenya: Nmumba@kemri-wellcome.org, adavies@kemri-wellcome.org; or smolyneux@kemri-wellcome.org or Supanat Ruangkajorn, Anne Osterrieder or Phaikyeong Cheah at MORU in Thailand: Supanat@tropmedres.ac, anne.osterrieder@ndm. ox.ac.uk, Phaikyeong@tropmedres.ac

References:

i. Adhikari B, Pell C, Cheah PY. Community engagement and ethical global health research. Global Bioethics. 31:1, 1-12, DOI: 10.1080/11287462.2019.1703504; Council for International Organizations of Medical Sciences and World Health Organization. (2002). International ethical guidelines for biomedical research involving human subjects (3rd ed.). Geneva: CIOMS; Hankins C for the World Health Organization, 2016. Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens (GPP-EP); Kamuya DM, Marsh V, Kombe F, Geissler PW and CS Molyneux (2013). Engaging communities to strengthen research ethics in low-income settings: selection and perceptions of members of a network of Representatives in coastal Kenya Developing World Bioethics, 13, 10-20.

ii. R.P. Strauss, et al. The role of community advisory boards: involving communities in the informed consent process. Am J Public Health 2001; 91: 1938-43.

iii. R.R. Sharp & M.W. Foster. Grappling with groups: protecting collective interests in biomedical research. J Med Philos 2007; 32: 321-37., L.F. Ross. 360 Degrees of human subjects protections in community-engaged research. Sci Transl Med 2010; 2: 45cm23, L.F. Ross, et al. Nine key functions for a human subjects protection program for community-engaged research: points to consider. J Empir Res Hum Res Ethics 2010; 5: 33-47., L.F. Ross, et al. Nine key functions for a human subjects protection program for community-engaged research: points to consider. J Empir Res Hum Res Ethics 2010; 5: 33-47.

iv. Diallo, et al, op.cit note 1, Doumbo et al op.cit note 1

v. D. Brieland. Community advisory boards and maximum feasible participation. Am J Public Health 1971; 61: 292-6., Morin et al, op.cit note 9; Sharp & Foster op.cit note 4; Shubis et al op.cit note 9

vi. V.M. Marsh, et al. Working with Concepts: The Role of Community in International Collaborative Biomedical Research. Public Health Ethics 2011; 4: 26-39.

vii. Shubis et al, op.cit note 9.

viii. Morin et al, op.cit note 10.

viix. C. Molyneux, et al. The role of community-based organizations in household ability to pay for health care in Kilifi District, Kenya. Health Policy Plan 2007; 22: 381-92.

x. Reddy et al, op. cit note 8;, Shubis et al, op.cit note 9;,. Morin et al, op.cit note 10.

xi. Gikonyo et al, op.cit note 31

xii. Kamuya DM, Marsh V, Kombe F, Geissler PW and CS Molyneux (2013). Engaging communities to strengthen research ethics in low-income settings: selection and perceptions of members of a network of Representatives in coastal Kenya Developing World Bioethics, 13, 10-20.

xiii. Reddy et al, op.cit note 8