



# EXPLOITATION AND COMMUNITY ENGAGEMENT: CAN COMMUNITY ADVISORY BOARDS SUCCESSFULLY ASSUME A ROLE MINIMISING EXPLOITATION IN INTERNATIONAL RESEARCH?

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## Keywords

community engagement,  
exploitation,  
community advisory boards,  
international research

## ABSTRACT

*It has been suggested that community advisory boards (CABs) can play a role in minimising exploitation in international research. To get a better idea of what this requires and whether it might be achievable, the paper first describes core elements that we suggest must be in place for a CAB to reduce the potential for exploitation. The paper then examines a CAB established by the Shoklo Malaria Research Unit under conditions common in resource-poor settings – namely, where individuals join with a very limited understanding of disease and medical research and where an existing organisational structure is not relied upon to serve as the CAB. Using the Tak Province Border Community Ethics Advisory Board (T-CAB) as a case study, we assess the extent to which it might be able to take on a role minimising exploitation were it to decide to do so. We investigate whether, after two years in operation, T-CAB is capable of assessing clinical trials for exploitative features and addressing those found to have them. The findings show that, although T-CAB members have gained knowledge and developed capacities that are foundational for one-day taking on a role to reduce exploitation, their ability to critically evaluate studies for the presence of exploitative elements has not yet been strongly demonstrated. In light of this example, we argue that CABs may not be able to perform such a role for a number of years after initial formation, making it an unsuitable responsibility for many short-term CABs.*

## INTRODUCTION

Community engagement is becoming an increasingly common feature of externally-funded health research in low- and middle-income countries (LMICs). The community advisory board (CAB) constitutes the most popular mechanism for engagement in such research, though it is by no means the only approach undertaken.<sup>1</sup> CABs are

generally composed of community members who share a common identity, history, language, and culture, but their function can vary considerably. Depending on how power over the research is shared with them by researchers, the role of CABs can range from information exchange and consultation on specific matters to a more substantial partnership, where the community is empowered to engage in shared decision-making about research projects. Yet the latter is a much rarer occurrence in comparison to having a CAB serve an information provision function.<sup>2</sup>

<sup>1</sup> S.C. Quinn. Ethics in Public Health Research: Protecting Human Subjects: The Role of Community Advisory Boards. *Am J Public Health* 2004; 94(6): 918–922; P.O. Tindana, J.A. Singh, C.S. Tracy et al. Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. *PLoS Med* 2007; 4: e273.

<sup>2</sup> R.R. Sharp & M.W. Foster. Involving Study Populations in the Review of Genetic Research. *Journal of Law, Medicine, and Ethics* 2000; 28(1): 41–51; R.P. Strauss, S. Sengupta, S.C. Quinn et al. The Role of

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Conflict of interest statement: No conflicts declared

The CAB model has been criticised for being prone to a number of limitations such as a lack of power to influence the research agenda, overrepresentation by certain groups with particular agendas, and reliance on volunteers with competing priorities for their time.<sup>3</sup> In the context of international clinical research, Solomon Benatar and Peter Singer have noted that '[a]lthough community advisory boards have been formed and used constructively, participation of communities in the design of trials largely remains an unfulfilled aspiration, except for isolated examples.'<sup>4</sup>

Nonetheless, the incorporation of a community's views and its collaborative involvement are considered to be a meaningful way to, amongst other things, reduce the potential for exploitation in international clinical research. While the precise definition of what constitutes exploitation remains heavily debated, there is some agreement that it is characterised by one party taking advantage of another party's vulnerability or the power differential between them in order to extract an unfair proportion of research benefits.<sup>5</sup> When international clinical research is characterised by certain features, the possibility of trial participants and host communities being exploited can be significantly lowered. Research that is responsive to the health needs and priorities of its host community, provides an appropriate standard of care to trial participants, and delivers post-trial benefits such as the medical treatment or practice it develops is less likely to result in an unfair distribution of benefits.<sup>6</sup> As such, avoiding or minimising exploitation has been identified as the underlying objective of requirements for responsiveness, standard of care, and post-trial benefits in international research ethics guidelines.<sup>7</sup> It has been suggested that achieving each of these

requirements can be facilitated by effective engagement. Community engagement may be helpfully employed during the research process to ensure that international research is relevant to the health needs of its host community,<sup>8</sup> to guarantee the services offered at study clinics reflect a locally appropriate standard of care, and to better achieve an equitable distribution of benefits within host communities.<sup>9</sup> CABs can also supplement the role of ethics committees by providing an account of whether studies meet the requirements from community members' perspectives, which can assist ethics committees in their own review process.

Yet there has been little reflection on what core competencies a CAB must have to reduce exploitation in research or exploration of whether CABs have been able to develop such capacities in practice. No clear benchmarks have been identified regarding what is needed for a CAB to critically evaluate studies for features of exploitation or to ensure its findings are addressed. Few, if any, studies have demonstrated the ability of CABs to promote responsiveness, an adequate standard of care, and post-trial benefits in international research. There is also little empirical evidence describing how these capacities can be developed or the length of time required to do so. Thus far, studies have mainly detailed how standalone CABs and community liaison systems have been set up with appropriate representation as part of individual trials (i.e. the Microbicides Development Programme's PRO-2000 microbicide trial) and longstanding research programmes in LMICs (i.e. Wellcome Trust's Major Overseas Programmes in Kenya and Thailand).<sup>10</sup> Some

Community Advisory Boards: Involving Communities in the Informed Consent Process. *Am J Public Health* 2001; 91(12): 1938–1943; K.W. Slevin, M. Ukpogon & L. Heise. 2008. *Community Engagement in HIV Prevention Trials: Evolution of the Field and Opportunities for Growth*. aids2031 Science and Technology Working Group.

<sup>3</sup> Slevin et al., *op. cit.* note 2.

<sup>4</sup> S.R. Benatar & P.A. Singer. Responsibilities in International Research: A New Look Revisited. *J Med Ethics* 2010; 36: 194–197, p. 195.

<sup>5</sup> D.B. Resnik. Exploitation in Biomedical Research. *Theoretical Medicine* 2003; 24: 233–259; R. Macklin. 2004. *Double Standards in Medical Research in Developing Countries*. Cambridge: Cambridge University Press; A. Ballantyne. HIV International Clinical Research: Exploitation and Risk. *Bioethics* 2005; 19: 476–491; S.R. Benatar & T.E. Fleischer. Ethical and Policy Implications of Clinical Drug Trials Conducted in Developing Countries. *Harvard Health Policy Review* 2005; 6: 97–105.

<sup>6</sup> We recognise that a lack of responsiveness, appropriate standard of care, and post-trial benefits are not the only features associated with exploitative research and that consensus on the association of these features with exploitation may not be universal.

<sup>7</sup> A.J. London. 2008. Responsiveness to Host Community Health Needs. In *The Oxford Textbook of Clinical Research Ethics*. E. Emanuel et al., eds. New York: Oxford University Press: 737–744; E.J. Emanuel. 2008. Benefits to Host Countries. In *The Oxford Textbook of Clinical*

*Research Ethics*. E. Emanuel et al., eds. New York: Oxford University Press: 719–728; E.J. Emanuel & J. Hawkins, eds. 2008. *Exploitation and Developing Countries: The Ethics of Clinical Research*. Princeton: Princeton University Press; J. Millum. Sharing the Benefits of Research Fairly: Two Approaches. *J Med Ethics* 2011; doi:10.1136/medethics-2011-100118.

<sup>8</sup> National Bioethics Advisory Commission (NBAC). 2001. *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*. Washington DC: NBAC; UNAIDS & WHO. 2007. *Ethical Considerations in Biomedical HIV Prevention Trials*. Geneva: UNAIDS; M. Parker & S. Bull. Ethics in Collaborative Global Health Research Networks. *Clinical Ethics* 2009; 4: 165–168.

<sup>9</sup> Tindana et al., *op. cit.* note 1; J.V. Lavery. Putting International Research Ethics Guidelines To Work for the Benefit of Developing Countries. *Yale J. Health Pol'y L. & Ethics* 2004; 4: 319–336; M. Valley, C. Shagi, S. Lees et al. Microbicides Development Programme: Engaging the Community in the Standard of Care Debate in a Vaginal Microbicide Trial in Mwanza, Tanzania. *BMC Med Ethics* 2009; 10: 17.

<sup>10</sup> V. Marsh, D. Kamuya, Y. Rowa et al. Beginning Community Engagement at a Busy Biomedical Research Programme: Experiences from the KEMRI CGMRC-Wellcome Trust Research Programme, Kilifi, Kenya. *Soc Sci Med* 2008; 67: 721–733; C. Shagi, A. Valley, S. Kasindi et al. A Model for Community Representation and Participation in HIV Prevention Trials Among Women who Engage in Transactional Sex in Africa. *AIDS Care* 2008; 20: 1039–1049; R. Hasunira. 2010. *Community Involvement in HIV Prevention Research: Experiences and Perceptions of Communities Participating in the MDP* 301

recent work, however, has described CABs' role in determining the standard of care offered to trial participants at the PRO-2000 trial site in Mwanza, Tanzania and developing a compassionate-use post-trial access program for a drug tested by the HIV Prevention Trials Network in Thailand.<sup>11</sup>

To get a better idea of what is necessary and achievable, this paper first makes some preliminary suggestions regarding the core elements and capacities a CAB must have *before* it can be considered capable of reducing exploitation. The paper then examines a CAB established under conditions common in resource-poor settings – namely, where individuals join with a very limited understanding of disease and medical research and where an existing organisational structure is not relied upon to serve as the CAB. Using the Tak Province Border Community Ethics Advisory Board (T-CAB) as our case study, we assess the extent to which it might be able to take on a role minimising exploitation were it to decide to do so. Although T-CAB has not yet assumed such a role, our data suggests it may be moving in that direction. The paper investigates whether, after two years in operation,<sup>12</sup> T-CAB is capable of assessing clinical trials for exploitative features and addressing those found to have them. T-CAB was set up by a longstanding research programme – the Shoklo Malaria Research Unit (SMRU) – that has been conscientious in its effort to perform clinical studies that benefit both its research participants and their communities on the Thai-Myanmar border. SMRU is part of Wellcome Trust's Major Overseas Programme in Thailand. After years of informal engagement with the population of Karen and Myanmar refugees, migrants, and displaced persons to whom it provides healthcare and with whom it conducts its research, SMRU facilitated the creation of the T-CAB in January 2009.<sup>13</sup> We collected data on T-CAB in early 2011 through in-depth interviews, direct observation at T-CAB meetings, and examination of T-CAB documents

and analysed them thematically to assess whether T-CAB has the core competencies necessary to minimise exploitation in research.

## CORE CAB COMPETENCIES FOR REDUCING EXPLOITATION

We argue that three core aspects of CABs concerning process, knowledge, and power are essential if they are to contribute to reducing exploitation in international clinical research.

First, procedural aspects of CABs must be organised to facilitate the consideration of and response to potential and actual exploitation in research. These include the charters that outline their function, recruitment strategies, and agenda-setting processes. For CABs to take responsibility for reducing exploitation, they must view it as part of their formal function. Assuming that a CAB's charter specifies its role, we suggest that it state that the CAB is responsible for (among other things) advising researchers on issues related to exploitation. The charter should explicitly state that researchers *and* CAB members can contribute to the agenda of meetings. This will allow CAB members to bring up issues related to exploitation in cases where researchers do not appear to be aware of the issues or interested in addressing them. CAB members should be able to revise the charter as necessary. While it may be preferable to have a democratically elected set of members who are representative of their community, this may not always be feasible in contexts where formal community structures and mechanisms for elections do not exist.<sup>14</sup> In such cases, the method of CAB member selection must be, at a minimum, not biased towards choosing individuals with certain allegiances (e.g. to a particular village chairman or political party). A range of views, ethnicities, and backgrounds in the host community should be reflected on the CAB and every effort should be made to achieve equal participation of men and women. Efforts should be made to avoid selecting members with conflicts of interest as, among other concerns, this may have implications for CAB members' views on what constitutes exploitation.

Second, CAB members must have a good understanding of the features associated with exploitation. This means comprehending debates on exploitation, as well as debates on responsiveness, standard of care, and post-trial benefits, and reaching consensus on what the CAB considers constitutes exploitation. CABs may decide that exploitation has a procedural component (i.e. taking advantage of power imbalances) and/or an outcome-oriented component (i.e. unfair distribution of benefits). They may choose to rely on definitions provided in ethics

*Microbicide Trial in Masaka, Uganda*. Kampala: HEPS-Uganda; P.Y. Cheah, K.M. Lwin, L. Phaiphun et al. Community Engagement on the Thai-Burmese Border: Rationale, Experience and Lessons Learnt. *International Health* 2010; 2: 123–129.

<sup>11</sup> Valley et al., *op. cit.* note 9; S.F. Morin, S. Morfit, A. Maiorana et al. Building Community Partnerships: Case Studies of Community Advisory Boards at Research Sites in Peru, Zimbabwe, and Thailand. *Clin Trials* 2008; 5: 147.

<sup>12</sup> We chose to look at a CAB that had been operating for two years in order to get an initial indication of how far CABs might get towards developing the core competencies necessary to minimise exploitation in such a period. We felt a two-year period was an appropriate timeframe to look at, as it constitutes a reasonable amount of time for capacity building to have occurred. However, we would emphasise that our research constitutes a first step towards determining how long it might be realistic to expect a CAB to take to become able to reduce exploitation. It would be useful to evaluate CABs that have been in existence for longer periods as well in future studies.

<sup>13</sup> Cheah et al., *op. cit.* note 10.

<sup>14</sup> Cheah et al., *op. cit.* note 10.

guidelines such as the CIOMS guidelines or they may not. Beyond understanding key concepts, CAB members must be capable of critically assessing studies for features of exploitative research. At first, this may consist of knowing what questions to ask researchers, but eventually CAB members may rely on their own knowledge to judge trials. For example, being able to determine whether or not a study falls short of responsiveness requires having multiple pieces of information. Assuming that responsiveness is defined as focusing on the health needs and priorities of a community where a need for research exists, CAB members must have an understanding of various diseases and their causes, knowledge of whether people in their community have the disease that researchers are proposing to study, knowledge of whether that health condition is a priority, and knowledge as to whether clinical research is needed to address that health condition in the community. Determining whether a disease is a health priority of the community will further require having a definition of what constitutes a priority. While this definition may vary by CAB, it could mean diseases that are common in the community, often cause death, and/or can result in other severe health outcomes.

Third, with respect to power, CAB members must have the authority to act if proposed research is identified as having exploitative features. They must be able to do more than simply advise researchers of their concerns, recommend that a study be revised or rejected, and hope that researchers respond. Mechanisms of accountability to CABs might include statements in the CAB charter that require its recommendations to be directly provided to all relevant ethics committees. The charter should affirm that, where CABs identify studies as having exploitative features, researchers must demonstrate to the CAB how they have addressed the issues. In the event that the CAB is not satisfied with researchers' response, it should be able to communicate its concerns directly to the ethics committee(s) reviewing the study, who must then investigate the concerns. To be able to make use of mechanisms of accountability as needed, CAB members must feel comfortable rejecting and proposing significant changes to studies, which may be difficult to achieve. CABs may feel beholden to the research group that first established them and/or may lack confidence that nothing bad will happen to them if they demand modifications or reject its studies.

Although we have described a number of components that we feel are necessary for a CAB to be capable of having an impact on exploitation in research, it is less clear how long it will take and how difficult it will be for CABs to develop such competencies. At present, there is little, if any, empirical evidence to answer this question.<sup>15</sup>

<sup>15</sup> In saying this, we are not implying CABs cannot develop the competencies that we describe. Rather, we indicate a lack of evidence exists one way or the other.

As such, we decided to look at a CAB set up as a newly-formed body with members that lacked a strong understanding of disease and research in order to see what it had achieved after two years in operation. Our case study research will show that T-CAB is not currently mandated to reduce exploitation. Nonetheless, we felt it was useful to evaluate whether T-CAB otherwise has the capacity to minimise exploitation, as it may decide to take on such a function in the future and revise its charter accordingly.

## THE CASE STUDY: T-CAB

Although SMRU's T-CAB was set up under conditions common to resource-poor settings, it is not a conventional CAB in certain respects. Many CABs are established for a specific study for a fixed, short-term period. T-CAB, in contrast, was set up as a long-term CAB for SMRU. It reviews many different studies and continues to operate beyond their conclusion.<sup>16</sup> Additionally, T-CAB was not formed in an area where the community is relatively homogenous and stable. Instead, the population living on the Thai-Myanmar border is fluid, as its members (economic migrants, displaced persons, and refugees) are quite mobile, and comprises many overlapping sub-communities.<sup>17</sup> This has created challenges for the organisation that may not be experienced by other CABs.<sup>18</sup>

At the time of our research in March 2011, T-CAB had 15 members (five women and ten men) aged 23 to 57 years from the Karen ethnic group. These individuals were drawn from Mae Sot, Thailand (where SMRU's main office is located) and the villages surrounding SMRU clinics,<sup>19</sup> which serve as its trial-sites. T-CAB also has two SMRU staff members (from Myanmar and Malaysia) serving as its coordinators. These individuals are present at each T-CAB meeting and act as facilitators, but they do not participate in T-CAB members' deliberations about the acceptability of the SMRU studies presented at meetings. T-CAB meetings are generally held at the SMRU office in Mae Sot from 9am to 12:30pm, with

<sup>16</sup> This means that, unlike short-term, single-study CABs, T-CAB did not come into existence after the sole study on which it was meant to provide advice had already been reviewed by relevant ethics committees. Instead, it is able to assess SMRU studies (developed from 2009 onwards) before/during the ethics review process performed by the Mahidol University Faculty of Tropical Medicine Ethics Committee.

<sup>17</sup> K.M. Lwin, P.Y. Cheah, C.P. Kin et al. Motivations and Perceptions of Community Advisory Boards in the Ethics of Medical Research: The Case of the Thai-Myanmar Border. (under review)

<sup>18</sup> Cheah et al., *op. cit.* note 10; Lwin et al., *op. cit.* note 17.

<sup>19</sup> The five SMRU clinics that served as sites for its vivax malaria treatment trial are located within an hour's drive of Mae Sot. Two are located to the North of Mae Sot and three are located to the South.



morning tea and lunch provided by SMRU. In its first two years, T-CAB met every four to six weeks.<sup>20</sup>

## METHODS

Data on T-CAB were collected as part of a broader assessment of SMRU and its ongoing vivax malaria treatment trial, which seeks to describe the epidemiology and compare the efficacy of three treatments for vivax malaria (<http://clinicaltrials.gov/ct2/show/NCT01074905>). We relied on a mix of qualitative research methods – in-depth interview, direct observation, and document analysis – to gather information on T-CAB's process, knowledge, and power. Participant recruitment and data collection methods are comprehensively described in Pratt et al. (2012).<sup>21</sup> In-depth interviews were conducted with four current T-CAB members, a T-CAB coordinator from SMRU, and two SMRU investigators who presented the vivax malaria treatment trial to T-CAB. T-CAB members were asked to describe the function of T-CAB, how being part of T-CAB has impacted them, the training that they have received as part of T-CAB, the skills they have gained, and the ethical issues they have learned about. They were asked to describe what happens at T-CAB meetings, what SMRU does with T-CAB recommendations, and what T-CAB does when its comments and recommendations are not acted upon. T-CAB coordinators were asked a similar set of questions. Investigators were asked what recommendations T-CAB members had made regarding the vivax malaria treatment trial and whether they related to responsiveness, standard of care, or post-trial benefits. Interview data were supplemented by direct observation at two T-CAB meetings in March 2011 and by an examination of the minutes from T-CAB meetings held in 2009, 2010, and 2011. Ethical approval for the study was obtained from the Ethics Committee of the Faculty of Tropical Medicine at Mahidol University, the Tropical Research Ethics Committee at Oxford University, and the Monash University Human Research Ethics Committee.

All interviews were transcribed verbatim and translated from Burmese to English (where required). To ensure the accuracy of translation, two interviews were re-translated by a co-investigator who is fluent in Burmese and English. There were no significant discrepancies between his translation and that of our transcriber. Data was analysed according to the principles of thematic analysis described in Braun and Clarke (2006), with

co-coding performed independently by two researchers.<sup>22</sup> Themes were identified that related to the objectives of T-CAB, the selection of T-CAB members, the capacities built through T-CAB membership, and the role of T-CAB in practice.

## RESULTS

### T-CAB objectives

Notably, our data showed that the initial objectives set for T-CAB in 2009 did not explicitly relate to minimising exploitation. At the time of its establishment, T-CAB had three main goals. The first of these was for T-CAB, after a period of training to develop its members' knowledge and understanding of diseases such as malaria and medical research, to advise SMRU as to whether its proposed studies were acceptable and perceived as beneficial by communities in the region. The second objective was for T-CAB to advise SMRU researchers on the ethical and operational issues of their studies. The third aim was for T-CAB to act as a 'bridge' between the border communities and SMRU researchers.

The first of these objectives reflects the fact that preliminary dialogue with T-CAB members revealed that they lacked knowledge in medicine and research mainly due to a paucity of opportunities in their home country. As such, within two years, SMRU's goal was to undertake intensive training with T-CAB members so that they gained an understanding of diseases like malaria and others experienced by their communities and an appreciation of the need for research on these diseases and the processes involved in conducting clinical trials.<sup>23</sup>

Engagement on research studies was to consist of formal meetings being organised, at which SMRU investigators would present research studies to T-CAB members. Here, it was anticipated that T-CAB members would advise SMRU on the ethical and procedural aspects of the studies, including informed consent, compensation, and confidentiality.<sup>24</sup> The second version of the T-CAB charter, approved by T-CAB members and SMRU in March 2010, affirms that the board will 'play a key role advising SMRU on the ethical considerations in a research project especially the informed consent process. Examples of other areas of importance are wording the information sheet in the Karen and Burmese language, recruitment procedure including recruitment aids, compensation, risk/benefit.' No mention is made of T-CAB advising SMRU on the responsiveness, standard of care, or post-trial benefits of proposed research

<sup>20</sup> In 2012, T-CAB meets every six to eight weeks (Lwin et al., *op. cit.* note 17).

<sup>21</sup> B. Pratt, D. Zion, K.M. Lwin et al. Closing the Translation Gap for Justice Requirements in International Research. *J Med Ethics* 2012; doi:10.1136/medethics-2011-100301.

<sup>22</sup> V. Braun & V. Clarke. Using Thematic Analysis in Psychology. *Qualitative Research in Psychology* 2006; 3: 77–101.

<sup>23</sup> Cheah et al., *op. cit.* note 10.

<sup>24</sup> Cheah et al., *op. cit.* note 10.

projects. This is perhaps because such issues are complex and a basic understanding of research and medical care is required to comprehend them.

Even so, T-CAB coordinators affirm that part of T-CAB's role as a 'bridge' between its members' communities and SMRU researchers is to influence and direct SMRU's research aims. Though this is not explicitly stated in the T-CAB charter, current T-CAB members have also stated that they perceive T-CAB's role to entail ensuring that the research SMRU carries out responds to genuine community needs and not just SMRU's needs.<sup>25</sup> This suggests that T-CAB members view themselves as being responsible for promoting the responsiveness of studies, which, in turn, may indicate that T-CAB is moving towards assuming a role minimising exploitation. Since the initial goals of T-CAB were seen as a starting point that would evolve over time to reflect the growing experience of members, the T-CAB charter can and should be amended to reflect this perspective. An expanded mandate that includes ensuring studies' responsiveness can be described in the third version of the T-CAB charter.

## T-CAB recruitment and composition

Initial recruitment for T-CAB occurred in late 2008. Potential members were first approached by SMRU staff through personal contacts. A pool of key community workers was targeted.<sup>26</sup> For example, T-CAB member 02 (a social worker) reports that a female nurse first contacted his village chairman, who then nominated him for a role in T-CAB because he had a Thai identity card and could, therefore, easily travel to and from Mae Sot. Since it was established, the composition of T-CAB has changed slightly. 11 of its 15 members in 2011 are founding T-CAB members.<sup>27</sup>

Most current T-CAB members have completed primary school or high school and two have completed tertiary studies (one member has a bachelor's degree and another has a master's degree in public health). T-CAB members are literate and have jobs in various disciplines. They include teachers, pastors, social workers, farmers, a village chairman, an administrative assistant at a local clinic, and an interpreter. The vast majority of T-CAB members are Karen, though other ethnic groups are represented such as the Kachin, Mon, and Burmese. They are from at least six different villages in Thailand and Myanmar and have various political and religious (Buddhist, Christian, animist) affiliations. Their participation

in T-CAB is voluntary, with members receiving compensation for their time and transportation costs.

## Capacities built through T-CAB membership

T-CAB meeting minutes confirm that the training conducted from 2009 to 2011 included the following topics: what is malaria (*falciparum* and *vivax*), what is research, what do the different phases of clinical trials entail, what is the difference between research and clinical care, what are the ethical issues in research such as the right to refuse, what is informed consent, what is a placebo, and what are randomisation and blinding. While the complexity of the topics being taught is increasing, they have, thus far, not included the concept of exploitation or the ethical issues associated with it, though the training session on placebos in 2009 did include the information that it is unethical to use a placebo in a study if a well-established drug exists for the disease-under-study. The concept of standard of care (i.e. that a particular level of care is owed to trial participants in SMRU studies; this might consist of the highest global standard, proven effective treatment, or the local standard) was apparently not discussed.

When asked to describe how being part of T-CAB has impacted them, all members affirmed that they have gained knowledge about malaria and health. T-CAB member 04 gave examples of the knowledge that she has acquired, which includes understanding that there are two types of malaria (*vivax* and *falciparum*), that the *vivax* parasite can go into the liver, that the drug mefloquine can treat malaria, and that medicines exist that can block the transmission of HIV from mother-to-child. T-CAB members further demonstrated an understanding that it is important to do medical research to identify better treatments where drug resistance has emerged and lowered the effectiveness of existing treatments.

Two of the four T-CAB members interviewed spoke of being able to educate their communities as a result of acquiring knowledge about malaria.<sup>28</sup> T-CAB member 03 explained that:

*for my family, I am able to protect them from malaria disease. Another thing, I am able to advise the people who are not able to come to clinic by saying not to take medicines blindly and if they have fever, there is SMRU clinic where they can go. I have advised them like that.*

One T-CAB member also mentioned gaining skills related to building and sustaining an organisation, specifically abilities related to undertaking discussions and negotiations amongst people with different viewpoints. Other

<sup>25</sup> Lwin et al., *op. cit.* note 17.

<sup>26</sup> Cheah et al., *op. cit.* note 10.

<sup>27</sup> In 2012, T-CAB has 12 members (nine men and three women), seven of which are founding T-CAB members. All 12 have served on T-CAB for at least two years (Lwin et al., *op. cit.* note 17).

<sup>28</sup> The fact that T-CAB members view T-CAB as a place to learn and as a catalyst for their taking on a role as health educators is re-affirmed by the research described in Lwin et al., *op. cit.* note 17.

T-CAB members affirmed that they often disagree, as their backgrounds and experiences are quite varied (e.g. different religions, jobs), and that they must work with one another to reach compromises and make collective decisions. Being able to arrive at collective decisions is essential if T-CAB is to continue to function. Finally, a T-CAB coordinator noted that T-CAB members' capacity to voice their opinions has grown. Initially, T-CAB members were very quiet during meetings. After two years, they engage in much more discussion and ask lots of questions at meetings, though this may vary by gender. (The female T-CAB members did not ask many questions at one of the meetings observed in March 2011.) The change is significant because most T-CAB members are from the Karen ethnic group, which has a long history of persecution and oppression by the Myanmar military government. Many T-CAB members would have grown up in an environment where individuals lack the freedom to say what they think without risking their safety. As a result, their willingness to 'dare' to express how they feel at T-CAB meetings is a tremendous accomplishment.

When asked to describe their knowledge of research ethics, T-CAB members primarily identified the right to refuse to participate and the right to withdraw from research. According to T-CAB member 03,

*for our public, they can participate in the study if they want to and also they don't have to participate if they don't want to. But even though they don't participate in the study, they can get treatment [at SMRU clinics] and also if they do participate, they still can get treatment . . . I have told them that after joining the study, they can withdraw during the study even before the scheduled months are completed.*

While understanding concepts such as the right to refuse to participate and withdraw from research may seem basic, a T-CAB coordinator commented that the achievement is actually significant. It reflects awareness not only that research is different from clinical care but also that individuals have a *choice* to be involved or not. An SMRU investigator suggested that members of the Karen ethnic group are not used to being able to make choices and are more used to being told what to do. Understanding that ethical research involves choosing to participate is, therefore, another particularly important accomplishment for this group.

### T-CAB role in practice

T-CAB members' primary role consists of attending meetings where they are presented with summaries of upcoming SMRU studies. Meeting agendas are set by T-CAB coordinators. Once a study has been presented, T-CAB members are able to ask T-CAB coordinators and SMRU investigators questions and to give their

views and opinions on the ethical and procedural elements of the study. Multiple studies may be presented during a single meeting. For example, three studies, two involving medical research, were put before T-CAB members at a meeting observed in March 2011. Based on the information provided by SMRU, T-CAB members then discuss each study amongst themselves and make a collective decision as to whether a study is acceptable or not. This approval (or rejection) is documented and made available, upon request, to ethics committees. So far, no SMRU studies have been deemed unacceptable by T-CAB. Some T-CAB members also take it upon themselves to report back to their communities regarding what they learn and discuss at T-CAB meetings, but this is not a formally mandated part of their role.

After one year, review of the comments and questions made by T-CAB members during their first 12 meetings indicated that, of the 61 issues raised, the majority were related to risk and safety (26.2%) and the recruitment and consent process (26.2%). Other comments and questions were classified as relating to study procedures (23%), benefits to participants<sup>29</sup> (8.2%), research concepts (4.9%), background and study rationales (4.9%), and confidentiality (4.9%).<sup>30</sup> As an example, over two meetings in September 2009 and January 2010, T-CAB members considered SMRU's vivax malaria treatment trial. Here, they mainly asked investigators to better explain aspects of the trial's design. One member did voice a question pertaining to study design. She challenged the feasibility of a feature of the trial, suggesting that the trial's two-year follow-up might not be practical given the mobility of migrant workers from the border population. Other questions put to trial investigators included what compensation was to be provided to the control group and what risks existed for control group members. Investigator 03 notes that, at the time of the meeting,

*I think the T-CAB was pretty new when I was there, so we had to really explain what and why and what is Pv [vivax], what is primaquine, what is chloroquine. I think now, after it being a year, they might have a deeper understanding of studies and could probably make more comments about the consent process . . . I think I spent a lot of time getting them to understand why we're doing the study, and its importance, and the study drugs and why we use them. So I actually think I spent more time explaining that to them so that they understood the study and then they could see if they felt it was ethical or not.*

<sup>29</sup> These comments referred to the health benefits of participating in studies (e.g. getting study treatments and study-related examinations during trials). They did not specifically refer to the standard of health care provided by SMRU, ancillary care, or post-trial benefits.

<sup>30</sup> Cheah et al., *op. cit.* note 10.



At the January 2010 meeting, SMRU investigators asked T-CAB for input on two specific issues related to implementing the vivax malaria treatment trial – optimising follow-up and identifying any problems with enrolling infants in the trial. As such, discussion about the trial at that T-CAB meeting focused on those two issues. The vivax malaria treatment trial was subsequently agreed to be acceptable and beneficial by T-CAB.

The majority of comments voiced at meetings in 2010 and 2011 relate to similar issues as those expressed in 2009. However, T-CAB coordinators noted that some of the topics discussed by T-CAB have shifted to more complicated ethical issues like data sharing and the use of results in university-led research compared to drug company-led research. A small number of questions raised by T-CAB members at meetings in 2011 may relate to features of exploitation, despite members not having a concept of exploitation in research. For example, at a T-CAB meeting observed in March 2011, an upcoming SMRU medical research project was presented, that will evaluate the accuracy of a rapid diagnostic test (RDT) for placental malaria. T-CAB members' questions on the study related to the rationale for conducting it (i.e. why is there a need for an RDT when microscopy can be used to diagnose placental malaria), the features of the RDT, risks to participants, and the current availability of the test on the market. Asking whether a need for an RDT exists may be an example of a T-CAB member attempting to assess the study's responsiveness.

At another T-CAB meeting in 2011, a question was raised about a proposed fever diagnostics study that related to the issue of ancillary care.<sup>31</sup> A T-CAB member asked 'After recruitment, will you treat all the disease of the patient?' Investigators responded that participants would receive routine care at SMRU clinics. T-CAB meeting minutes did not provide evidence of T-CAB members having input into what non-study-related diseases were treated during the fever diagnostics study, though this may be because they were happy with the investigators' answer, as routine care at SMRU clinics covers a wide range of illnesses.

Ultimately, T-CAB's role does not extend beyond providing SMRU with comments and recommendations on its proposed studies. T-CAB member 03 affirms that '[t]hey [SMRU investigators] want our opinion and we present our answers but taking action or no is not our concern.' There is no mechanism of accountability if SMRU chooses not to implement T-CAB's recommendations or undertakes a study that T-CAB has deemed unacceptable. When asked what T-CAB would do if SMRU ignored its suggestions, T-CAB member 02

states: '[o]ur needs, we presented. If SMRU doesn't do the work, what can we do? We are not capable.'

## DISCUSSION

The paper has looked at the achievements of a CAB set up by a research unit dedicated to performing studies on the main health problems of its research population. Substantial time and effort has gone into establishing T-CAB and progress has been made on many fronts since it was formed in 2009. Our case study research demonstrates that T-CAB's adoption of a role minimising exploitation in the future may not be successful without further capacity building and mechanisms of accountability being put in place.<sup>32</sup> After two years in operation, some of the procedural elements that we identified as necessary for a CAB to reduce exploitation are in place (i.e. unbiased recruitment) or starting to be put in place. Although the current charter does not explicitly give T-CAB a mandate to reduce exploitation, T-CAB members may be starting to view it as part of their role. As the charter is continually revised, it should be modified to reflect T-CAB members' self-identified role in assessing SMRU studies for one feature of exploitation – lack of responsiveness. While T-CAB members are not elected or considered representative of a typical member of the border population (due to their being literate, having better jobs, and not being displaced), they represent a range of religions, jobs, political affiliations, and communities on the border. Only one third of T-CAB members are female though, which may be the result of most women in the border population having to look after their households or not being able to travel easily. T-CAB members are also not involved in setting the agenda of meetings.

The first two years of T-CAB's operation have aimed at developing members' understanding of basic concepts of disease, medical research, and ethical considerations in research such as informed consent, balancing risks and benefits, and compensation. Significant progress has been made in T-CAB members' knowledge of malaria and research, their capacity to voice opinions, and their ability to undertake discussions and negotiate with people who hold different views. Training has not yet

<sup>31</sup> By asking this question, the T-CAB member did not demonstrate awareness of the concept of ancillary care as it is understood in the bioethics literature.

<sup>32</sup> It may be argued that T-CABs' lack of understanding of the features of exploitation are unsurprising given that reducing exploitation is not a mandated function for the CAB. As such, T-CAB members have not been educated on such concepts. In response, we would note that the data shows that, when T-CAB was created, its members still needed to learn basic concepts of research and research ethics and would not have been likely to comprehend more complex concepts like exploitation until those foundations were established. Even if T-CAB had been given a role in minimising exploitation in 2009, it is unlikely that its members would have been able to critically assess SMRU studies for responsiveness, standard of care, and post-trial benefits in the first year or two of operation.



covered the concepts of exploitation, responsiveness, standard of care, or post-trial benefits. Data collected from interviews and T-CAB meeting minutes did not indicate an understanding of such concepts. As a result, T-CAB members' ability to critically evaluate studies for the presence of exploitative elements was not strongly demonstrated.<sup>33</sup> Nevertheless, the capacities that T-CAB members have developed are foundational for one-day being able to understand the concept of exploitation and to reach a consensus on how T-CAB will define it and its features. Members are starting to discuss more complicated ethical issues and, in the future, may receive training on exploitation that will enable them to develop their ideas on such issues.

In terms of accountability, since it was established, T-CAB has evolved to implement a more formal process by which its acceptance or rejection of SMRU studies is documented and can be requested by ethics committees. Nevertheless, T-CAB members do not feel that they have the authority to take action if SMRU does not adhere to their recommendations and they have no direct line of communication with the Ethics Committee of the Faculty of Tropical Medicine at Mahidol University in Bangkok. All communication from T-CAB to Mahidol's ethics committee occurs through SMRU. In addition, only a few T-CAB members speak Thai or English.

Thus, the paper has shown that we cannot assume that CABs (even those set up by longstanding research partnerships dedicated to equity) have aims that include combatting exploitation. Where CABs are newly formed organisational structures whose members have a limited understanding of research and research ethics, the core competencies necessary to reduce exploitation will take a considerable amount of time to develop and may grow gradually as the CABs evolve. Such CABs will take a number of years to be able to assess studies for exploitative characteristics and to address those found to have them. Thus, our findings draw attention to the limits of short-term community engagement's impact on exploitation in research. Where CABs are established for specific studies for a fixed period, they are much less likely to be in operation long enough to contribute to reducing exploitation in a meaningful way, particularly as a supplement to the ethics review process. Ethics committee review of the study will generally be completed before the CAB is set up or has developed the necessary competencies. In certain cases, the duration of international clinical

trials is nearly a decade (e.g. the PRO-2000 microbicide trial). Here, it may be possible for short-term CABs to have time to develop the capacity to minimise exploitation before the trial ends. In these instances, it may be useful for CABs to take on such a role, as modifications to ongoing trials can be made in order to make them less exploitative, though we note that a trial's lack of responsiveness would be almost impossible to alter once the trial has started. However, where studies are shorter (i.e. 2–4 years), it will not be useful for study-specific CABs to be given the task of minimising exploitation because our data suggests they may not become capable of performing it in time to have an impact.

Furthermore, even where CABs possess the elements of process, knowledge, and power that we have described, it is uncertain what sort of effect they will have on exploitation. It seems possible that CABs' capacity to minimise exploitation may reflect the research groups that set them up. Research groups that are committed to setting up high-calibre CABs may be less likely to conduct exploitative research, which means that these CABs' will not frequently be in a position to reject highly exploitative studies.

#### Acknowledgements

The authors would like to thank Cindy Chu and Minthura Wynn for their support in this work. We thank all study participants and the staff at SMRU. We would also like to express gratitude to the Australian Federal Government and Monash University for the Australian Postgraduate Award scholarship (2009–2012) that made this research possible.

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<sup>33</sup> Here, we are not suggesting that SMRU studies demonstrate a high potential for exploitation. In fact, the evidence suggests the opposite is true (Pratt et al., *op. cit.* note 23). Nonetheless, even where studies are not highly likely to possess exploitative features, it is still possible to evaluate them for the presence of such features.