The practicality and sustainability of a community advisory board at a large medical research unit on the Thai-Myanmar border

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ABSTRACT

Community engagement is increasingly promoted to strengthen the ethics of medical research in low-income countries. One strategy is to use community advisory boards (CABs): semi-independent groups that can potentially safeguard the rights of study participants and help improve research. However, there is little published on the experience of operating and sustaining CABs. The Shoklo Malaria Research Unit (SMRU) has been conducting research and providing healthcare in a population of refugees, migrant workers, and displaced people on the Thai-Myanmar border for over 25 years. In 2009 SMRU facilitated the establishment of the Tak Province Community Ethics Advisory Board (T-CAB) in an effort to formally engage with the communities it serves [8]. The aim was both to obtain advice and also to establish a participatory framework within which studies and the provision of health care can take place. In this paper, we draw on our experience of community engagement in this unique setting, and on our interactions with the past and present CAB members to critically reflect upon the CAB’s goals, structure and operations with a focus on the practicalities, what worked, what did not, and on its future directions.

Keywords: Ethics, Community Engagement; Community Advisory Boards; Developing Countries; Thailand; Myanmar; Global Health; International Research

1. INTRODUCTION

There is now a widespread recognition of the importance of community engagement, for example through community advisory boards, in guiding the conduct of clinical research [1]. This is particularly so for research conducted in developing countries, away from major hospitals, and for studies that will recruit vulnerable groups of people [2,3]. Potentially, CABs can play a number of important roles. These include ensuring that: the information given to study participants is understandable; that the study is culturally acceptable; that issues of consent, confidentiality, and compensation (where appropriate) have been addressed according to locally acceptable standards; and, more broadly, that the rights of participants are safeguarded [4-6]. These considerations are particularly important in communities where norms, standards and expectations are likely to be different from those of the ethical and scientific review committees that govern clinical research. Most CABs are ad hoc, short term and are established to inform particular studies. There is little published experience of “general purpose” CABs which have existed for several years and have reviewed many different studies [7].

The Tak Province Community Ethics Advisory Board (T-CAB) was set up in January 2009 as an effort initiated by the Shoklo Malaria Research Unit (SMRU), part of the Mahidol Oxford Tropical Medicine Research Unit (MORU), to formally engage with the communities it serves [8]. The aim was both to obtain advice and also to establish a participatory framework within which studies and the provision of health care can take place. The hope was that what is in reality a range of vulnerable and complex communities could eventually be not just passive recipients of services, but could identify their own problems and organise solutions. It was hoped that in a small way, this process might be supported through the participation of individuals from the communities in understanding and planning local medical services and re-
search activities.

The Thai-Myanmar border community and the rationale and structure of the T-CAB have been described in detail previously, and a brief summary with some additional background is provided below. In this paper we describe the evolving experience of the advisory board as it has matured over several years and discuss possible future directions.

1.1. The Thai-Myanmar Borderline Population in the Tak Province: Demographics and History

The Thai-Myanmar border region has been unstable for several decades. Since the 1980s political conflicts within Myanmar have forced hundreds of thousands of refugees to take shelter in Thailand. In addition the economic stagnation in Myanmar has driven millions of migrant workers to the border region and into Thailand in search of work and healthcare. As a consequence of these two sets of factors, the political situation in Myanmar has shaped the population of the border region, and recent changes in Myanmar continue to affect it. An estimated 2 - 3 million Burman and Karen migrants and refugees now live in Thailand, and a large proportion of these have no legal status. The border population is highly mobile, moving between the two countries and in some cases resettling to third countries. Major political changes inside Myanmar have occurred since the establishment of the T-CAB and the effects of these on the population in this area over the coming years are uncertain. Health care provision is very limited in the border areas such as Kayin state (directly across the border from Tak province). Often people will travel for long distances to access health care on the Thai side of the border, including at clinics run by SMRU.

1.2. Shoklo Malaria Research Unit: Its Origins and the Ethical Issues Relating to Research & the Community

Since 1986, the Shoklo Malaria Research Unit (SMRU-MORU), attached to the Faculty of Tropical Medicine, Mahidol University in Bangkok, and the University of Oxford, UK, has worked among the border population to reduce the impact of multi-drug resistant malaria and other infectious diseases. SMRU’s focus has always been on the groups at most risk from malaria: children and pregnant women. Beyond the serious impact that malaria has in the Myanmar “displaced” population, there is also a global dimension to malaria on the Thai-Myanmar border because the malaria parasites found in this part of Asia are some of the most drug-resistant on earth and their expansion and spread is a very real threat (research has already demonstrated that the most drug-resistant malaria parasites found in Africa originated in Southeast Asia) and must be stopped. This is particularly urgent and important in the “displaced” population living along the border since there is now evidence that the malaria parasites in this region have become resistant to the artemisinin combination therapies (ACTs) now at the forefront of global malaria treatment [9-11]. The conducting of research in this setting presents a range of important ethical issues not encountered elsewhere. Some of these issues have been discussed previously in relation to this population [12,13].

The main SMRU offices and laboratories are in the border town of Mae Sot. The centre of clinical activities for refugees is a health care network consisting of a hospital in Mae La refugee camp and five clinics spread along the Thai-Myanmar border. These facilities are run by locally trained Karen and Myanmar staff, many of whom grew up and live locally. Further information on the structure of SMRU is available at http://www.shoklo-unit.com/.

1.3. Tak Province Border Community Ethics Advisory Board (T-CAB): Structure & History

Since its creation in the 1980s, SMRU has been informally engaging with village and community leaders, key workers, patients, and their relatives, a process which over the years has improved the provision of healthcare and the conduct of research. However, it was recognised within SMRU that there was a need to establish a more robust and formal participatory framework within which discussion of the implications for communities of research studies could take place. Although all research conducted by SMRU is reviewed by at least two ethics committees: the University of Oxford Tropical Medicine Ethics Committee (OxTREC, based in Oxford) and the Mahidol University Faculty of Tropical Medicine Ethics Committee (based in Bangkok), it was felt a supplementary formal advisory body would add value.

It was in this context that the T-CAB was established in 2009. Its founding document, the T-CAB charter (which is available in English, Thai, Karen and Burmese) describes the operational guidelines and constitution of the CAB.

2. EVOLUTION OF THE T-CAB

2.1. Goals

Although community engagement is promoted as a marker of good ethical practice in the context of international collaborative research in low income countries, there is no widely agreed definition of community engagement, and the approaches adopted and the justifications given for its use vary. In addition to its agreed in-
trinsic value as a way of treating communities with appropriate respect, community engagement is also usually taken to be of instrumental value in many different ways. Community engagement is, for example, seen to be of value in: the development of more effective and appropriate consent processes; improved understanding of the aims and forms of research; higher recruitment rates; the identification of important ethical issues; the building of better relationships between the community and researchers; the obtaining of community permission to approach potential research participants; and even in the provision of better health care.

At the time of its establishment, the CAB had three main goals. The first of these was that after a period of training—about diseases such as malaria and the nature and goals of research—members would be able to advise on whether a study is acceptable to, and perceived as beneficial by, the communities in the region. The second was that the CAB would play a key role in advising researchers on the ethical and operational aspects of proposed studies, including informed consent procedures, fair compensation, risks and benefits, and protecting the confidentiality of research subjects. The third goal was that the CAB would act as a “bridge” between the communities and researchers. It would on the one hand provide communities with an opportunity to express views on proposed research and to influence and direct research aims, and on the other provide a means by which the researchers might feed back the results of the research to the community. The T-CAB was not set up to replace existing methods of community engagement but to supplement it in a more formal way.

A series of interviews conducted with the T-CAB members revealed that the goals of the CAB had evolved from those set out at the Board’s inception. CAB members felt that in addition to the above goals, they see the CAB as a place to learn and to better themselves. They also feel that through Board membership their responsibilities towards their communities have increased. For example they now see themselves as health educators and health care workers, and find they are obliged to help out in non-health matters including getting travel documents for their fellow villagers. These roles and responsibilities were not part of the original remit of the CAB, but have evolved out of the experience of CAB membership and in doing so pose new challenges for the CAB as an institution. Because the CAB is in theory independent, it can evolve in a way that is responsive to the community needs. Supporting the CAB, especially in non-health matters, is not SMRU’s role.

2.2. CAB Membership

At establishment, potential T-CAB members were approached by SMRU staff through personal contact (October 2008) [8]. They were drawn from an existing pool of key community workers residing in SMRU catchment areas. It was felt that approaching the potential members individually was the most respectful and acceptable way in this community. There is no formal community structure for the border population, such as a border “committee” that we could have approached, and there was no mechanism for formal elections either. In its first year the T-CAB consisted of 14 volunteer members who were identified by SMRU as being independent (non-employees), “representative” of the community, and capable of fulfilling the role required. There were six women and eight men, aged between 21 and 57 years, with various levels of education, most of whom were community leaders and key workers (e.g. village chairman, pastor, teacher, social worker). All T-CAB members were either Burmese, Thai or Karen. Membership was collectively agreed and a secretary was elected to be the rapporteur. All but one member spoke Karen; most could also speak Burmese, and a few spoke some basic English or Thai.

As described in our paper in 2010, there are many challenges in setting up a CAB. Some of these relate to the question of how the relevant “community” is to be identified. Given the wide range and diversity of religious, political, language, and ethnic groups in the region the question of what constitutes the community and who may be a community “representative” is both complex and politically sensitive.

The 2012 CAB has 12 members aged between 26 and 60 years who live in a range of different settings in the border area. They are generally seen as more “representative” than the first committee. Seven of them live in villages opposite the SMRU clinics on the Myanmar side of the border and five on the Thai side. There are nine men and three women on the CAB, and half of them have served since the CAB was established. There are currently three NGO workers, two teachers, two farmers, two village officers, a pastor, a taxi driver, and a housewife.

When the CAB was established, a decision was made that whilst there would need to be a CAB secretary, no other formal “offices” would be established in an attempt to create an environment, at least in the meeting room, where—insofar as this was possible—everyone was equal. The concern was that were a “chair” to be created, the most influential members would be elected and other members would be unable to express their own views. The findings from our interviews suggest that whilst the
CAB worked reasonably well without a chair, the members feel more comfortable with a chair and co-chair as they are more used to a structured committee. Hence from 2011 onwards, the CAB elected a chair and a co-chair.

2.3. Organisation of Meetings

The CAB has met formally 33 times (up to December 2012) since its establishment. It has considered and commented on 31 studies during this time. The T-CAB has reviewed a wide range of study types: twelve clinical trials, seven social science projects, five observational studies (with no medical intervention), five evaluations of diagnostic tests, one prevalence survey of a malaria-related genetic condition, and one malaria prevalence study. Meetings are usually moderated by an SMRU staff who sets the agenda before the meeting and sends out the meeting invitation. The moderator ensures that there is lively discussion and members get to voice their opinions. Meetings typically involve an update of the important issues that occur in the members’ areas, the presentation of up-coming studies followed by discussion and a review of the information that will be provided to participants. The CAB met formally twice in 2008, four times in 2009 (in 2009, there was fighting and instability along the border), nine times in 2010, ten times in 2011, and eight times in 2012. Within T-CAB meetings the discussion is normally in Burmese and then translated into Karen, with the moderator asking questions of members to check understanding. Thai and English are also used when appropriate.

As described in our 2010 paper there have been many challenges in organising these meetings [8]. Meetings require simultaneous high-quality translation into the main languages spoken in the area: Burmese & Karen. The members are a group, with a wide range of experience, from health professionals to those with little formal education. Ensuring that all participants can follow discussion takes time, and some areas (primarily informed consent, and the methods and rationale for research) have been revisited several times in order to make sure that all members understand. In the first year, minutes were taken in English by an SMRU staff member and then translated into Karen and Burmese. This was costly, time consuming and practically challenging, as minutes could not be emailed to members (most of whom do not own computers or have e-mail accounts), and could only be handed out during the next meeting.

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Since 2011, two sets of meeting minutes are taken; in English by an SMRU staff member and either in Karen or Burmese by a T-CAB member identified at the start of the meeting as the minute taker (not necessarily the chair or co-chair). Minutes in Karen/Burmese are handwritten and at the end of the meeting, photocopied and circulated to all members. This avoids the requirement for costly translations and also ensures that meeting minutes are available to everyone in a timely fashion.

2.4. Review of Studies

Since the CAB has been in existence every SMRU clinical study has been presented by the researcher to the CAB for discussion. The members give suggestions and advise on the ethical and operational aspects of studies: what informed consent procedures are appropriate, how much information should be provided to potential subjects, how much compensation is deemed fair and not coercive, and how the confidentiality of research subjects can be protected, as well as assessing other culturally sensitive issues as they see fit.

Advising on the use of locally appropriate language to communicate with patients and potential study participants is a key function of the T-CAB. Information sheets for study participants are written in Burmese or in Karen. These information sheets are reviewed by the T-CAB as an independent check that the meanings of terms are clear in both languages. Information sheets are typically built around a field-tested template, as for the majority of studies the basic ideas of consent do not vary importantly, and only study specific terms need to be added.

The majority of studies conducted by SMRU recruit participants who attend clinics either with fever, or for antenatal services. Most of the studies discussed by the T-CAB do not represent new demands from participants that cause major ethical concerns, but there are some studies that have justified special attention, the following are three examples of this.

2.4.1. Example 1: Age of Consent

An example of T-CAB deliberations was over the question of the age at which a woman could be considered an adult and capable of deciding her own treatment choices and whether to participate in research. This provoked a lot of debate and differences of opinion within the T-CAB. A common view was that even if a woman is under the age of 18 if she is married and pregnant then she is an adult and should be able to decide for herself whether to join in studies. Other members felt that the Thai legal age of consent, 18, should be respected and binding even if this was not the social norm for the community. Researchers decided that even though local standards may be determined more by status than actual age, that it is necessary to follow national legal guidelines, even if in the context of the Karen border community this means treating someone considered an adult woman as a minor.

2.4.2. Example 2: Compensation

A study was proposed, which would involve the recruitment of people with glucose-6-phosphate dehydro-
genase deficiency (G6PD deficiency, a common hereditary condition that protects against malaria but also predisposes towards haemolysis) to receive primaquine (a licensed and widely used antimalarial). This required standby blood donors in the unlikely event that a blood transfusion was suddenly required. Primaquine is usually not recommended for people with G6PD deficiency, but an effective radical cure of Plasmodium vivax malaria (most other drugs cannot prevent relapse) was wanted for this population and so dosages and safety needed to be assessed in a highly controlled environment.

The T-CAB discussed the risks and benefits of the study, and eventually decided that there was a small risk of emergency transfusion among participants to be weighed against a potentially large benefit to local people if treatment guidelines could be revised to allow an effective drug for vivax malaria to be widely used. However, the requirement for standby blood donors generated intense debate over what could and could not be expected of community members, and whether this crossed a threshold at which payment should be made to compensate for the time and inconvenience demanded. This was the first time compensation for non-study patients had been discussed—in this case these were standby blood donors.

It is hoped that the T-CAB can now be a key part of drawing up a blanket policy on payments to study participants, to achieve consistent standards between studies. There is a real dilemma as there are various international sponsors of studies and they have differing policies on remuneration. The credibility of a community agreed position would help insist on consistent guidelines when dealing with sponsors.

2.4.3. Example 3: Concerns around Drug Company Led Research vs. University Led Research

Rapid diagnostic tests (RDTs) for the diagnosis of malaria can help facilitate rapid, effective treatment. This is particularly important in resource-limited settings. Many RDTs have been developed, and testing their sensitivity and specificity against microscopy in various epidemiological settings is important. RDTs are generic and some proprietary, and this subject was discussed as a study of a new RDT was presented. Some members of the T-CAB were concerned that knowledge to be gained through a collaboration and unpaid volunteers might later be withheld by a company that wished to profit from it. Other SMRU studies of RDTs (using similar methods) and initiated by university groups did not provoke any suspicion among T-CAB members and so it is unlikely that there were other unspoken issues. Considerable detail about the company and the use of data from the study was required before the T-CAB felt comfortable that the research was bona fide.

Since 2011 the T-CAB has provided a formal opinion on all studies. In order to ensure that they are not biased, a form is completed after adequate time for deliberations, put in a sealed envelope and given to the researchers after the meeting. The CAB’s opinion about a study is now documented and made available upon request to the relevant ethics committees. In addition to study-specific ethical issues and operational concerns, the authors noted that over the life of the CAB the content of the topics discussed by the CAB has noticeably shifted to more complicated ethical issues like data sharing and bio-banking.

We have also been encouraging researchers to present their results to the CAB, both at a convenient interim and at the end of the study, as a way of providing feedback to the community. This is over and above the feedback given to an ethics committee, who usually just get simple reports annually and at study close out.

2.5. Capacity Building

In addition to reviewing proposals for research, CAB meetings also provide training opportunities for T-CAB members in areas relevant to the discussion. To be able to offer advice the T-CAB members need a minimum level of knowledge of the specific issues relating to research methodology and of the diseases and drugs being studied at SMRU. The Karen, who make up most of the border population, are one of the most persecuted minorities in the region, and apart from NGO-run schools there is limited access to education. Although the CAB members have a higher than average level of education in the community, most of them have little or no knowledge of medical research or formal ethical concepts.

In the beginning we focused on the following themes: types of malaria, its epidemiology, treatment and the current knowledge gaps; tuberculosis; HIV/AIDS; and the challenges of obtaining valid informed consent. In 2011-2012 topics included more complex subjects like the history of artemisinin combination therapy for malaria, artemisinin resistance, challenges in antimicrobial resistance, concepts in medical research including research methods, randomised controlled trials, blinding, and the role of ethics committees and community engagement. Discussions and activities included topics that are not directly related to specific research projects, but related primarily to developing the T-CAB itself. These workshops allow for an opportunity to look in more general detail at issues surrounding the involvement of the community in medical research, and at more general ethical questions surrounding SMRU and the local population. Classroom teaching and group work forms the backbone of training, but where possible this is supported by other teaching methods. The presentation and
handling of the equipment to be used is a useful teaching tool. Visits to study facilities to observe activities, for example guided tours of our microbiology and malaria laboratories and insectariums, help members to understand where blood samples go and what they are needed for.

3. DISCUSSION

3.1. Evaluating the CAB

Very little has been published on the evaluation of community engagement, which is surprising given its importance in the context of international research ethics. Whilst there have recently been some examples of published attempts to share experiences in and models of good practice in community engagement, there remains a dearth of evidence and advice about the development, introduction and evaluation of sustainable community engagement activities, and there have been a number of calls for the evaluation of the many different models of engagement. The T-CAB has functioned long enough to allow some assessment of its performance in relation to research, and how it has met the aspirations of the researchers when it was established. What have been the strengths and weaknesses of this particular approach? What have been the real functions as opposed to what was envisaged? What alternatives might be considered, and where do we go from here? Although the authors are clearly not able to offer an unbiased assessment of the impact of the T-CAB within the wider community, several lessons have been learnt.

The T-CAB emerged from a particular environment and time. The board has developed from a group of strangers drawn from different sub-communities that make up the border community. Amongst the members there are many differences in ethnic and political backgrounds, locations, religion, and legal status; and yet when brought to SMRU every four to eight weeks they have formed an effective and functioning group. Although the CAB model was chosen as a way of formalising community engagement, it is not the conventional CAB model, where a CAB is established for a particular study or programme, e.g. an HIV vaccine study, for a fixed length of time in a defined geographical area where the community members are homogenous, at least for the purpose of the particular study or programme, and CAB members are somewhat representative of the community. Instead, the T-CAB reviews a wide range of studies, and its members are a heterogeneous group of individuals who live either side of the porous Thai-Myanmar border, where the population is fluid and comprises many overlapping sub-communities.

The average CAB member is literate, has basic education, has a better than average job, and is not “displaced”, whereas the average community member is illiterate, poor, vulnerable and most of them earn daily wages. What are the “border community” and the sub-communities that it consists of, and how representative is the T-CAB of this fluid and hard to define population? What are the unique ethical challenges when researchers engage with host communities for longer periods? What are the key success indicators, and how can they be measured? How successful has the T-CAB been, and according to whom?

3.2. Future Directions

The T-CAB is not intended to replicate an ethics committee or a scientific committee. Its role is complementary but different from both. The long-established relationship between SMRU and the populations it serves, of which the T-CAB forms an important component, combined with the leadership role in the T-CAB of articulate local Karen staff, has meant that many potential problems that an outside research team might face in establishing new clinical studies are identified and addressed at an early stage. The T-CAB is semi-independent, i.e. it is not part of the unit hierarchy, and therefore is able to provide a useful and important space for the discussion of ideas and fresh opinions. It offers an opportunity for community members to speak to researchers and to SMRU with enhanced authority. The existence of the T-CAB also promotes critical thinking among researchers wishing to introduce new studies. These researchers are aware that that they must consider carefully how best to explain and justify these in ways that will be acceptable to T-CAB members, who they must address as local representatives charged primarily with safeguarding the most vulnerable, ensuring that research addresses local needs, and respecting the interests and rights of potential research subjects.

Extensive and continuing training was an important factor which made it possible for the T-CAB to engage effectively with SMRU, and the fact that this was possible and is on-going is one important advantage of continuity in a long-term CAB. T-CAB members needed to gain experience and develop the skills required to make judgements about which research studies will be relatively unproblematic and which will raise substantive ethical issues calling for in-depth discussion and analysis. It is the opinion of SMRU too, that the T-CAB has been and continues to be valuable, and that the CAB can very usefully complement external scientific or ethical review as a way of ensuring that research is informed by genuine community engagement and is conducted to the highest possible ethical standards.

It is striking that there has been little research on the effectiveness of and challenges associated with different forms of engagement and little or no evidence base on
which to base engagement strategies. Against this background, plans are currently underway to evaluate systematically the CAB over the next year using a combination of qualitative and quantitative approaches. One area so far unaddressed is the view of the local community(ies). To what extent does the T-CAB serve their needs? Do they know of the existence of the T-CAB? If so do they get feedback from the T-CAB, and are they able to approach the T-CAB about any concerns they may have?

3.3. Lessons Learnt

The T-CAB has been in existence for almost four years and valuable lessons have been learnt which will hopefully help its sustainability.

- **Flexibility**: the structure and operations of a long term CAB must be flexible and evolve over time in order to continue to be fit for purpose.
- Researchers, ethics committees and other stake-holders must be realistic about what the CAB can do. The CAB is not meant to replace an ethics or a scientific committee, rather it plays a complementary role filling the gaps in the current approval system (SMRU studies are reviewed by two ethics committees, one in Bangkok and one in Oxford).
- Long term CABS have an advantage over study specific ad-hoc CABS, as their members can build expertise through training and experience, and are exposed to a variety of different studies and study designs.
- CABs should be adequately funded and should have a dedicated facilitator(s).
- There should be adequate time in meetings for members to have in-depth discussions and time to deliberate on topics that concern the members (not necessarily the researchers). Meeting duration and frequency should be adequate to build group momentum and group dynamics.
- On-going evaluation in one form or another is important to ensure that the CAB is still fit for purpose and members are motivated.
- Repetition is necessary to improve understanding of research concepts, specific research studies and ethical issues.
- Social activities in between meetings or after meetings are necessary to build relationships among members and between members and researchers.

4. CONCLUSION

In this paper we describe the background and rationale of the T-CAB and discuss how the goals, membership and other operational aspects have matured from its beginnings to its current incarnation. The experience of running T-CAB meetings over several years has created a membership that are now exposed to the ethical and practical issues surrounding medical research. The members, the community, and the researchers have all benefited in one way or another and we continue to refine strategies to make it a practical, fit-for-purpose, effective and sustainable CAB.

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