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Community engagement on the Thai–Burmese border: rationale, experience and lessons learnt

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Abstract

Community engagement is increasingly promoted in developing countries, especially in international health research, but there is little published experience. The Shoklo Malaria Research Unit (SMRU) conducts research with refugees, migrant workers, displaced people, and day migrants on the Thai–Burmese border, and has recently facilitated the set up of the Tak Province Border Community Ethics Advisory Board (T-CAB). Valuable lessons have been learnt from consultation with the T-CAB especially in the area of participant recruitment and the informed consent process. A lot of new research questions have emerged from consultation with the T-CAB. This paper describes our experience, lessons learnt and the unique challenges faced working with the T-CAB from its initial conception to date. We conclude that consultation with the T-CAB has made improvements in our research in particular operational and ethical aspects of our studies.

Keywords

Community engagement; Community advisory board; Ethics; Community; Migrants; Border population

1. Introduction

Community engagement is increasingly promoted in international health research in developing countries but there is a paucity of published experience. Most of the documented experience has been in the field of HIV/AIDS research,^{1,2} genetics,³ and in recent years tropical medicine research in resource-poor settings.^{4–6} Given the complexity of the concept, it is not surprising that there is no universally accepted definition of community

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Authors' contributions: FN, KML, PYC, NPD, NJW and MP conceived and designed strategy and research agenda for community engagement. KML, PYC, FN, LP and LM were responsible for community mobilisation, and organisation of meetings and training. KML, PYC, FN, LP and LM facilitated the T-CAB (Note: KML, LP and LM speak English and Burmese fluently; LP and LM speak English, Burmese and Karen fluently). KML and PYC analysed the data. PYC, KML, MP, FN, NPD drafted the manuscript. FN, NJW and NPD supervised the research program. PYC is guarantor of the paper.

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engagement, but it could be loosely defined as ‘the process of working collaboratively with and through groups of people affiliated by geographical proximity, special interest, or similar situations to address issues that affect them’.⁷ It involves a continuous dialogue and a two-way flow of information and views, together with opportunities to get involved. There is a need for further research, including identification of authentic community representatives, methods of engagement, situations where engagement is needed and strategies to overcome challenges faced in engagement with vulnerable populations.

The Shoklo Malaria Research Unit (SMRU) is a field research site of the Bangkok based Wellcome Trust funded Mahidol–Oxford Tropical Medicine Research Unit (MORU). It has been involved in providing healthcare and conducting operational research in the border population for more than twenty years. SMRU clinics are located on the Thailand side of the border directly across the river from the Burmese villages, and within the refugee camps in the Tak Province (see Figure 1). The Tak Province, which lies in the northwestern region of Thailand and borders Burma (Myanmar), is a place of convergence of refugees, migrant workers, displaced people and day migrants who cross into Thailand for employment and other activities. These Burmese nationals, who are largely from the ethnic Karen community, form the ‘border population’. There is limited access to medical personnel and facilities on either side of the border, hence a large number of them access SMRU’s clinics. The population is highly mobile in that it moves between the two countries and some have been resettled to third countries. This region of South East Asia has been unstable for decades.

Political conflicts within Burma have forced almost 200 000 refugees to take shelter in Thailand since the 1980s. In addition, the economic stagnation in Burma has driven millions of migrant workers to the border and to Thailand in search of work. Most of them work without legal status and are subject to exploitation and abuse. This is an area of multidrug resistant malaria (some of the most resistant parasites in the world are found here) and in recent years there seems to be an increased availability of counterfeit medicines. SMRU has been set up to tackle malaria in this border population, studying the epidemiology, treatment and prevention. In 20 years, it has treated more than 150 000 patients of all ages and gender including more than 20 000 pregnant women. It has become the largest single center study site in the world by the number of patients recruited in randomized controlled studies. This research effort has had a dramatic impact on the morbidity and mortality caused by malaria, first in the refugee population then in the region. The evidence produced by this program has significantly influenced the recent changes in malaria therapy introduced worldwide i.e. the use of the artemisinin combination treatments (ACT).

This paper focuses on the rationale for community engagement in the Tak Province border population, how we began to formalise the process, the unique challenges faced, lessons learnt, and the experience of working with the Tak Province Community Ethics Advisory Board (T-CAB) from its initial inception.

2. Rationale for community engagement and the establishment of the Community Advisory Board

2.1. Compliance with international regulations

Over the last ten years there has been massive proliferation of regulations affecting the conduct of human research. All clinical trials worldwide are expected to comply with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP) guidelines,⁸ although in most developing countries there is no legal requirement to do so. The ICH-GCP was developed in order to harmonise regulations in the US, Europe and Japan to enable mutual

acceptance of clinical trial data by the regulatory authorities in those countries. It is not surprising that compliance with ICH-GCP is challenging in most non-commercial trials with limited funding that do not have commercial outcomes, particularly in resource-poor settings. Engaging the community's help is one way of achieving compliance with these regulations creatively and practically, and of taking into consideration local cultural sensitivities without compromising international research standards.

2.2. Ethical issues arising from globalisation of research

Researchers have raised concerns arising from the globalization of clinical research especially in developing countries.⁹⁻¹² Potential ethical issues include those relating to the informed consent process, selection of patients, transparency of clinical trial results, compensation and confidentiality. We recognise these concerns and know that they are further amplified in the border population due to their legal and social status, and hence believe that having the benefit of practical advice from the community will help address these concerns.

2.3. Lack of representation in the ethics committees

All research projects conducted by SMRU are reviewed by at least two ethical committees (ECs): the Faculty of Tropical Medicine EC (FTMEC) of Mahidol University based in Bangkok, Thailand; and the University of Oxford Tropical Research EC (OxTREC) in Oxford, UK. These two committees ensure that clinical research studies conducted in the border population meet international ethical and scientific standards, and all related guidelines, and are not in any sense inferior to any trial conducted in wealthier nations. However, as neither committee has members who have worked with the border community, it is difficult for them to make ethical recommendations about issues specific to this population.

2.4. The need to formalise community engagement

Various forms of community engagement have been described, with a range of expressed goals.⁷ It has been acknowledged by social behavioural researchers that probably the most prominent mechanism for community engagement in international research has been the use of Community Advisory Boards (CAB),¹³ defined as 'being composed of committee members who share a common identity, history, symbols and language, and culture'.¹⁴ There is worldwide acknowledgment of the need for community engagement in biomedical research, especially in international research involving minority groups and other vulnerable populations in developing countries.¹⁰

The border population has, over the last two decades, developed a strong relationship with SMRU, and they have played an important role in global malaria research efforts.¹⁵ We have been informally engaging with the community for many years. There has been ongoing dialogue and interpersonal communication with village and community leaders, key workers, patients and their relatives which over the years has improved the way we provide healthcare and conduct research. However, there has been an increasing need in recent years to formalize this process and incorporate it as part of project planning, development and implementation.

Based on this rationale and to formalise existing engagement with the border community, SMRU with support from the Ethox Centre, a multidisciplinary bioethics research centre in the University of Oxford's Department of Public Health, facilitated the establishment of the Tak Province Border Community Ethics Advisory Board (T-CAB) in January 2009. The T-CAB charter, which describes the operational guidelines and constitution of the group was developed in English and then translated into Karen, Burmese and Thai in March 2009.

2.5. Desired goals

We hope to achieve the following three broad goals within two years of the establishment of the T-CAB: after intensive training the T-CAB members will have an understanding of the concept of diseases like malaria and others affecting their community, will have an appreciation of the needs for, and procedures by which medical research projects are undertaken in their community. They will advise if a study is acceptable to the community; whether a study will be perceived by the community as beneficial.

They will advise on the ethical and operational aspects of studies: what informed consent procedures are appropriate, how much compensation is deemed fair and not coercive and how to protect confidentiality of research subjects as well as assessing other culturally sensitive issues as they see fit.

The T-CAB will act as a bridge between researchers and the community. They will provide the community with a voice to express views on proposed research, with opportunities to influence and direct research, based on their needs. The T-CAB will provide a mechanism to inform the community of the results of the studies, which will help them understand how the research can be translated into practical action.

The above goals were thought to be realistic but are expected to evolve over time as the board members are exposed to more research proposals.

3. Methods

Potential T-CAB members were approached by SMRU staff through personal contact. They were from an existing pool of key community workers residing in SMRU catchment areas. Letters of invitation were sent out to these individuals asking them to attend the first meeting to discuss the concept. Eight men and a woman accepted the invitation. During the first meeting, there was a brief introduction to SMRU and its roles, a brief summary of the diseases that affect the border community, particularly malaria, and a presentation of the desired roles of a CAB. The attendees were asked to share their views and consider participation if they were interested. They were also asked to invite other potential members, especially women, who might be interested in becoming members to attend the next meeting. After several more meetings which consisted of training sessions and discussions of the structure and operations of the committee, the T-CAB was officially formed on 8 January 2009 (see Figure 2). The T-CAB consists of fourteen members, six women and eight men aged between 21 and 57 years with various levels of education, most of whom are community leaders and key workers (e.g. village chairman, pastor, teacher, social worker). All T-CAB members are either Burmese or Thai nationals from the Karen ethnic group. Membership was collectively agreed among the members, and a secretary was elected to be the rapporteur. All but one member speak Karen; most can also speak Burmese, and a handful can speak English and Thai. Most of them live on the Burmese side of the border. The board charter was developed in English and then translated into all three relevant languages: Karen, Burmese and Thai. The charter included details on the meeting format and quorum, scope of the board, decision making procedures and membership criteria.

4. Results and Discussion

From October 2008 to October 2009, twelve half-day meetings were held and minutes of the discussions and questions asked during the review of each project, as well as the researchers' responses, diligently recorded. In some important sessions e.g. where a randomised controlled trial was presented, minutes were simultaneously taken in English and Karen, and video recording was used. These comments and questions were analysed

according to category giving us valuable insight into what the board members were concerned about and what training may be required or should be repeated in the future.

To date, seven research studies have been presented to the T-CAB. There were four randomised controlled trials (RCTs), two prospective observational studies and a questionnaire based study. Two of the RCTs involved children, and one involved pregnant women. The T-CAB members were supportive of all the studies, and thought that they were beneficial to the community. Of the 61 issues discussed, the majority were related to risk and safety (26.2%) and the recruitment and consent process (26.2%). The others were procedural (23%), benefits to subjects (8.2%), research concepts (4.9%), background and rationale (4.9%), confidentiality (4.9%) and other locally specific issues (4.9%).

The members were also asked to review the participant information sheet in detail with the long term aim of improving the overall consent process in the future. In general, they thought that information sheets should be no more than one to two pages long, and focus on the rationale of the study, potential risks and the duration of participation or commitment (directly translated from Karen/Burmese) to the study. Researchers should draw the participants' attention to alternative available treatments relatively early in the consent process. Children ten years old and above should be asked to provide assent if they are able to, and parental consent should not be compulsory if one is married regardless of their age.

Besides presenting new studies to the T-CAB, we also presented the results of two recently completed malaria RCTs. The members were asked to disseminate the information to the community via existing channels.

5. Challenges and lessons learnt

5.1. Community and Representativeness

Much has been discussed about how best to constitute a CAB.⁷ The average member of the border population has only basic education, is illiterate and does not speak English or Thai. It was thought that to be effective, the T-CAB should be made up of individuals who have a higher than average level of education, can read and write in their own language (usually Karen), have an interest in serving the community, and not be 'displaced'. Representativeness appears to be a common concern in the establishment of CABs.¹⁰ The term 'community representative' was heavily discussed among the SMRU working group and the T-CAB members, and it was concluded that it would not have been feasible to have members who were authentically and truly representative of their community. Authenticity implies fair, balanced and accurate representation of the many and varied constituents within a community. In addition the T-CAB members were not elected representatives, but self appointed. The T-CAB members are fully aware of this and they themselves agree that they are not true community representatives. This was thought to be a reasonable trade off for representativeness. Other groups have also struggled with membership criteria for CABs, for example Shubis et al.⁴ found that when the communities were asked to elect individuals to represent their village, the community leaders selected themselves, and that led to inconsistent attendance, gender imbalance and political infighting.

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; there is no border 'committee' as such that we could have approached, and there was no mechanism for formal elections either.

5.2. Voluntary nature of T-CAB membership

Membership and criteria for replacement of members was discussed at length. Participation was voluntary and SMRU has been providing an allowance for their inconvenience (per diem) at a locally acceptable rate. All the T-CAB members have regular jobs; some have senior positions appointed by the government. Taking time out of work regularly to serve as a T-CAB member may be misunderstood and not seen positively. On the other hand, for some members, attending the T-CAB meeting may be lucrative compared to their daily wages. This situation is apparently not unique to our group.⁴ The members also voiced their inability to attend meetings too frequently due to other commitments. Initially meetings were held every two to four weeks, but we have resolved to not hold meetings more often than every four weeks.

5.3. Understanding of disease concepts and medical research

Before any effective engagement was possible, basic training sessions were conducted. As the members did not have any background knowledge, the first couple of sessions were didactic, but the training style was changed to be more participatory. We started from the very basic, for example, what is research? what is the difference between research and medical care? what is malaria? what is informed consent? what are the elements of valid consent? what are the common ethical issues in research? All training sessions were conducted by SMRU facilitators (PYC, FN, KML, LM, LP).

It was clear from the queries raised that even the basic training sessions needed to be repeated and the training style varied to maximise uptake and effectiveness. Training was very time consuming and often took half of the meeting duration. It was clear that some of the members were more reserved than others, especially the female and younger members. Different training approaches, e.g. participatory techniques, and separate training sessions for men and women were thought to be necessary in the future.

5.4. Lost in translation

The working language for SMRU is English, but of the fourteen founding members of the T-CAB, only two can read and write English fluently; the other members speak little or no English. Communication among SMRU facilitators and the T-CAB members has been slow and challenging. Every meeting was conducted in at least two languages, mostly three. All meeting materials were translated from English to both Karen and Burmese, every question raised by the members translated to English, and the answers in English translated back to Karen and Burmese. This slowed the discussion process quite significantly, making each meeting less productive than desired.

5.5. Validity of the T-CAB

Since there is no formal community structure or formal governance in the border community, there was a question of whom or which organization should appoint the T-CAB members. As the T-CAB is not attached to any organization, as they should be independent to be unbiased, the members were self-appointed. The T-CAB remains a group of individuals without official status or formal standing. One can question the validity or status of the T-CAB and therefore any decision made by them. Currently the T-CAB only has an advisory role but we hope that with time it may be possible to convince the ECs that the T-CAB role is important and they could collectively represent the official lay arm of the local EC or even a subcommittee of the EC.

5.6. Relationship between SMRU and the border population

The border population has over the last twenty years developed trust and respect for SMRU as it has played a significant role in provision of healthcare to them. More than 95% of SMRU staff were recruited from the local population and this has ensured that the work conducted here was acceptable to the community. We believe that the trust and respect of the community, although much appreciated by SMRU, plays a part in preventing any spontaneous criticisms of our health and research activities. In addition, this is a hierarchical society where one does not usually question those in authority or individuals with higher social standing in the society like doctors and healthcare workers. Many of the potential ethical issues were raised by SMRU initially; they were sought, solicited and prompted by us.

5.7. Travel restrictions and lack of independence

Thousands of Burmese nationals cross the Thai-Burmese border without any legal documentation on a daily basis. The authorities on both sides of the border are fully aware of this but have not taken any serious action for various political reasons and because of pressure from humanitarian groups and non-governmental organizations. The complexities are beyond the scope of this paper, but suffice to say that the same goes for some of the T-CAB members. This situation poses a logistical barrier for attending meetings and taking part in any activities outside the 'safe' hours, and 'safe' zones. Every T-CAB meeting to date has been organized and funded by SMRU including provision of the meeting venue and transportation. This dependence on SMRU may be a factor that influences the 'independence' of the T-CAB. The T-CAB in theory is independent of SMRU and should be able to advise other research groups in the area in the near future, but the lack of independence could be a major stumbling block.

6. Conclusions

We have obtained valuable advice from interactions with the T-CAB especially in the area of participant recruitment and the informed consent process. New research questions have emerged from consultation with the T-CAB, for example, to what extent does the T-CAB contribute to the review and development of information sheets and the informed consent process? to what extent does the T-CAB provide resources to study participants when questions about ethical conduct of research arise? to what extent does the T-CAB influence the community's perception on research? and what is the best way of disseminating information to the community about the T-CAB and our research activities? It is evident from the experience and lessons learnt that the first aim should be to enhance the knowledge and understanding of medical research concepts amongst T-CAB members. We will continue to conduct training and educational sessions. In order to evaluate whether the desired goals are met, we will track the impact of the T-CAB in terms of the number and nature of the comments and changes in the studies. In addition, by the use of semi-structured interviews and questionnaires we will assess the members' level of knowledge and understanding of medical research periodically.

The T-CAB's role and goals are expected to evolve over time. It may also be appropriate to have geographical clusters, a network of representatives or representatives at different levels rather than a single committee; this has been proven to be successful in some communities.^{5,6} A substantial research agenda is necessary to understand the potential roles and effectiveness of the T-CAB's input in the development and implementation of research studies in the Tak Province.

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Figure 1.
Map of the location of the Shoklo Malaria Research Unit office in Mae Sot, Tak Province, Thailand, and the Mae La refugee camp and the clinics along the Thai-Burmese border.

Figure 2.
A typical Tak Province Border Community Ethics Advisory Board (T-CAB) meeting:
Members are discussing a participant information sheet of a randomised controlled trial.
Photo by Viriya Hantrakun.