Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Community engagement as a relational process: constructing trust in clinical vaccine trials in Thailand, a qualitative study

Kriengkrai Prasert
Nakhon Phanom Hospital
Panisara Chaijum
Kasetsart University Chalermphrakiat Sakon Nakhon Province Campus
Passakorn Ongarj
passakorn.on@ku.th

Kasetsart University Chalermphrakiat Sakon Nakhon Province Campus
Suriya Naosri
Nakhon Phanom Hospital
Jiraphut Kittiwatanachod
Nakhon Phanom Hospital
Sarunpattori Khunarsa
Nakhon Phanom Hospital
Sutthichai Nakphook
Nakhon Phanom Hospital
Prabda Praphasiri
Nakhon Phanom Hospital

Research Article

Keywords: Community engagement, Trust, Vaccine trials, Qualitative research, Vaccine hesitancy, Health systems, Healthcare workers

Posted Date: May 25th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9399107/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.

Abstract

Background

Community engagement is critical to the conduct of clinical vaccine trials in real-world settings, yet participation and trust are often explained mainly at the individual level, with limited understanding of how they are constructed within community systems. This study aimed to explore the process of community engagement in clinical vaccine trials and to examine how trust is developed within community settings.

Methods

A qualitative study was conducted in Nakhon Phanom Province, Thailand, between November 2025 and March 2026. In-depth interviews were conducted with 27 purposively selected participants representing diverse and sometimes overlapping roles within the local vaccine trial ecosystem, including healthcare workers, community leaders, village health volunteers, research-related actors, parents, and community members. The study covered three vaccine trial contexts: influenza, COVID-19, and dengue vaccines. Interviews were conducted in Thai, audio-recorded, and supplemented with field notes. Data were transcribed verbatim and analyzed using qualitative content analysis.

Results

Community engagement emerged not as a single decision but as a multi-level relational process shaped by interactions among system structures, social networks, information environments, and lived experience. Trust was not a pre-existing condition; it developed through interactions with healthcare workers, observation of others, and direct experience of participation. Care processes functioned as experiential evidence through which participants assessed the safety and credibility of the trial. Decision-making involved negotiation across formal and informal information sources and varied across vaccine contexts, with familiar vaccines supporting more routine acceptance, while newer vaccines and those involving children prompted more cautious deliberation.

Conclusions

Community engagement in clinical vaccine trials should be understood as a dynamic and relational process in which trust is continuously constructed and negotiated. Designing ethical and effective engagement therefore requires attention not only to information provision but also to social relationships, system coordination, and responsive care practices within community contexts.

Introduction

Community engagement has become an essential component of public health interventions, particularly in the context of clinical research conducted in real-world settings. In vaccine trials, especially those conducted at the community level, participation is not solely a technical process but is deeply embedded in social, cultural, and relational contexts. Effective community engagement has been shown to strengthen the ethical conduct of research and improve the responsiveness of research to community concerns and is also associated with improved recruitment and participation in health research, particularly in settings where community dynamics play a critical role [1–5].

In the context of vaccine research, trust is widely recognized as a key determinant of public participation. Previous studies have highlighted the importance of trust in healthcare providers, institutions, and vaccine safety in shaping vaccine acceptance and hesitancy, and more broadly influencing engagement with health systems and research institutions [6–9]. Similarly, communication strategies and context-sensitive community engagement approaches have been identified as important in addressing vaccine hesitancy and fostering participation [1, 10]. In the context of biomedical research, Good Participatory Practice (GPP) guidelines emphasize the importance of sustained, bidirectional engagement between researchers and communities to ensure ethical conduct, mutual trust, and social legitimacy [11–13].

However, existing literature has largely conceptualized participation and trust at the individual level, focusing on attitudes, beliefs, risk perception, and decision-making processes of participants, with limited attention to the relational and processual mechanisms through which trust is constructed and negotiated in real-world community settings [9, 14, 15]. Qualitative studies in low- and middle-income settings have shown that participation in research is shaped not only by individual decision-making, but also by community narratives, prior experiences with health systems, and locally embedded interpretations of research activities [16, 17]. While these perspectives provide important insights, they may not fully capture the complexity of participation in real-world settings, where decisions are shaped by interactions across multiple levels, including community networks, institutional structures, and lived experiences. In particular, limited attention has been given to how trust is formed, negotiated, and transformed during the process of participation, rather than being treated as a pre-existing condition.

In Thailand, Nakhon Phanom Province has been a key site for multiple clinical vaccine trials, including influenza, COVID-19, and dengue vaccine trials. The province is characterized by strong community health networks, including village health volunteers and local leaders, who play a central role in health communication and public engagement. These contextual features provide a unique opportunity to examine how community engagement operates as a relational process embedded within existing community health systems, particularly in relation to participation in clinical vaccine trials.

Given these gaps, this study aims to explore how community engagement in clinical vaccine trials was experienced and negotiated in a real-world provincial setting in Thailand and to examine how trust developed during participation (Fig. 1). Specifically, the study addressed four interrelated questions: how community engagement operated in practice; how trust was formed, reinforced, challenged, and transformed during participation; how social networks and information environments shaped decision-

making; and how these processes varied across vaccine contexts. By focusing on Nakhon Phanom Province, where community health networks and clinical vaccine trial activity have been longstanding, this study sought to generate contextually grounded insights with broader relevance for the design of ethical and effective community-engaged vaccine research.

This study contributes an analytic interpretation of community engagement as a multi-level and relational process, in which trust is understood not as a fixed precondition of participation but as an emergent outcome shaped through ongoing interactions, care experiences, and negotiation of information within community settings. This interpretation aims to advance conceptual understanding of community-engaged vaccine research and to inform the design of more context-responsive and ethically grounded engagement approaches.

Methods

Study design and setting

This study employed a qualitative research design conducted between November 2025 and March 2026 in Nakhon Phanom Province, Thailand, to explore community engagement in clinical vaccine trials within real-world community settings. A qualitative approach was considered appropriate because the study focused on experiences, perceptions, decision-making processes, and social interactions that could not be adequately understood through quantitative measurement alone.

Nakhon Phanom Province was selected as the study setting because of its established village health volunteer and community leadership structures and its longstanding experience with multiple vaccine trials. The analysis covered three clinical vaccine trial contexts, influenza, COVID-19, and dengue, reflecting different levels of familiarity, perceived risk, and social decision-making (Table 1).

Table 1. Comparative characteristics of community engagement across three vaccine trial contexts

Dimension	Influenza	COVID-19	Dengue
Participants with context experience (Group 2, n=17)	4	10	4
Perceived familiarity with vaccine	High	Low	Low–moderate
Perceived disease severity	Moderate	High	Moderate–high
Initial risk perception	Low	High	High
Complexity of decision-making	Low	High	High
Primary decision-maker	Individual participant	Individual (with peer influence)	Parent / guardian (proxy)
Use of wait-and-see strategy	Low	High	High
Degree of family/community deliberation	Low	High	High
Trust formation pathway	Institutional (routine familiarity)	Experiential (fear → reassurance via care & peer observation)	Relational (family negotiation; VHV role modeling)
Key engagement challenge	Maintaining routine participation rates	Addressing uncertainty and fear of novel vaccine	Navigating parental responsibility and pediatric risk perception

Abbreviations: VHV = village health volunteer; COVID-19 = coronavirus disease 2019.

Note: Ratings are analytic summaries derived from dominant patterns across participant accounts and are not quantitative scores. Participant counts refer to Group 2 (community members and parents, n = 17); key informants (Group 1, n = 10) held system-level roles spanning all three contexts. "Complexity of decision-making" reflects degree of deliberation, consultation, and negotiation reported by participants.

Participants and sampling

Participants were selected using purposive sampling to capture a wide range of perspectives relevant to community engagement in clinical vaccine trials. Eligible participants included individuals who had direct experience with or a role in vaccine trial-related activities in the study area, including community leaders, village health volunteers, health personnel, research-related actors, volunteers or participants, parents and community members.

Because roles within the local context often overlapped, participants were not treated as belonging to rigidly separate categories. Recruitment continued until sufficient depth and variation had been achieved

to address the research questions and no substantively new themes were identified in ongoing analysis. A total of 27 participants were included. Participants were contacted directly by the interviewer in most cases. When a participant could not be readily located, local community or project-linked contacts helped identify the participant's home and guided the interviewer there.

Data collection

Data were collected through in-depth interviews between November 2025 and March 2026. Interviews were guided by a semi-structured interview guide developed for this study (Supplementary File S1). Interviews used open-ended questions to explore participants' experiences, perceptions, decision-making, information environments, trust formation, and views on community engagement in clinical vaccine trials. Interviews were conducted 1–3 times per participant, depending on the depth of information provided and the need for follow-up clarification. Each interview lasted approximately 30–45 minutes and was conducted in a location that was convenient for the participant and allowed privacy.

Interviews were conducted in Thai, were audio-recorded with participants' permission, and were supplemented with field notes to capture contextual observations and relevant issues not fully represented in the recordings. All participants provided informed consent before participation. No participants declined to take part in the study. All in-depth interviews were conducted by Panisara Chaijum, who has formal training in nursing and community health and longstanding professional experience in community public health and primary care in Nakhon Phanom Province. Because of this background and familiarity with the local health system, reflexive attention was maintained throughout data collection and analysis to reduce the influence of prior assumptions on interpretation. Quotations were translated into English by a research assistant and checked by Dr. Prabda Praphasiri.

Data analysis

Data were analyzed using qualitative content analysis. Interview recordings were transcribed verbatim and reviewed for accuracy. The analytic process began with repeated reading of the transcripts to achieve familiarity with the data, followed by open coding to identify meaningful units relevant to community engagement, trust, decision-making, information processes, system coordination, and care experiences. Codes with conceptual similarity were grouped into categories, and categories were then compared across participant groups and vaccine contexts to develop higher-order themes.

Analysis was iterative and interpretive. Emerging patterns were examined across participants and contexts to identify commonalities, differences, and relationships among themes. Themes were subsequently interpreted in relation to relevant literature and conceptual perspectives to develop a deeper understanding of community engagement as a multi-level process.

To enhance trustworthiness, triangulation was undertaken by comparing accounts across different participant groups, including health personnel, community leaders, and community members. Coding

and interpretation were conducted by Prabda Praphasiri. Data were managed manually through repeated transcript review, coding notes, and thematic grouping across participants and vaccine contexts.

Reflexivity

The researchers recognized that data generation and interpretation were shaped by the positions and prior experiences of the research team. Reflexive attention was therefore maintained throughout the research process, particularly in relation to assumptions about vaccine trials, community participation, trust, and the local health system context. Continuous reflection and systematic review of the data were used to reduce premature closure in interpretation.

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki. The study was approved by the Ethics Committee of the Nakhon Phanom Provincial Health Office, Thailand (Approval No. REC 124/2568), on 10 November 2025 prior to data collection. All participants provided written informed consent before participation. Confidentiality and anonymity were maintained throughout the study.

Results

Overview of participants

A total of 27 participants were included in the study between November 2025 and March 2026 (Table 2). Participants represented multiple roles within the local clinical vaccine trial ecosystem, including health personnel, research-related staff, community leaders, village health volunteers, parents, and community members with experience related to influenza, COVID-19, and dengue trial contexts. Roles were often overlapping, reflecting the relational nature of community engagement in the study setting. Participants ranged in age from 24 to 68 years. Across vaccine contexts, community engagement did not occur at a single point in time. Participants described engagement as unfolding across preparation, participation, and follow-up, with experiences in each phase shaped by the interaction of system structures, social networks, information processes, and direct experience. The findings are organized into six main themes reflecting participants' experiences and perspectives on community engagement in vaccine trials (Figure 2).

Table 2. Characteristics of study participants

Characteristic	n	%
Total participants	27	100
Group		
Key informants (health/system/community roles)	10	37
Community members and parents	17	63
Sex		
Female	20	74.1
Male	7	25.9
Age (years)		
Mean	42.9	
Range (min, max)	(24, 68)	
Primary role		
Health personnel (physician, hospital/clinic staff, district health officers)	4	14.8
Research nurse / administrative staff	1	3.7
Community leaders (local government)	1	3.7
Village health volunteers (VHV)	4	14.8
Trial participants (direct volunteers)	14	51.9
Parents / guardians (proxy decision-makers)	3	11.1
Vaccine trial context (All participants, n=27)		
COVID-19 only	7	25.9
COVID-19 and influenza	6	22.2
Influenza only	5	18.5
Dengue (parents of child participants)	6	22.2
Three vaccines	3	11.1
Number of interviews per participant		
1 interview	19	70.4
2 interviews	5	18.5
3 interviews	3	11.1
Interview duration (minutes)		

Range (min, max)	(30, 45)

Abbreviations: VHV = village health volunteer.

Note: Roles were not mutually exclusive and often overlapped within the local community health context. Vaccine context experience was self-reported by all participants at interview.

Theme 1: Perceptions of “experimental vaccines” and risk evaluation

Participants commonly associated the term “experimental vaccine” with uncertainty and potential risk, particularly at the early stage of decision-making. This perception was more pronounced in the context of newer vaccines, such as COVID-19 vaccines, where fear of unknown side effects was frequently expressed:

“When I heard the word ‘experimental,’ I thought they were trying it on us first. I didn’t know what would happen.” (Volunteer, COVID-19 vaccine)

However, risk perception was not fixed. Participants often reassessed risks by comparing potential vaccine risks with the perceived severity of the disease. In high-risk contexts, such as the COVID-19 pandemic, some participants were willing to accept uncertainty:

“Even though I was afraid, I wanted protection because I had to meet many people.” (Volunteer, COVID-19 vaccine)

Differences were also observed across vaccine types. Familiar vaccines, such as influenza vaccines, were generally perceived as safe and routine, while newer vaccines or those involving children, such as dengue vaccines, required more cautious and complex decision-making, particularly among parents.

Theme 2: Trust as an evolving and experience-based process

Trust did not emerge as a pre-existing condition but developed progressively throughout the participation process (Figure 3). At the initial stage, participants often relied on trust in healthcare providers and local health workers:

“If the doctor says it’s good, I believe it. They wouldn’t give us something unsafe.” (Volunteer)

As the process continued, trust was reinforced through observation of others’ experiences and direct personal experience. Seeing others participate without adverse effects reduced uncertainty:

“When I saw others getting vaccinated and nothing happened, I felt more confident.” (Volunteer)

Trust further evolved after participation, particularly when participants experienced continuous care and follow-up:

“At first I was worried, but after the injection and follow-up calls, I felt reassured.” (Volunteer)

Theme 3: Social influence and community-based information processes

Decision-making was embedded within social relationships rather than being an individual process. Participants frequently consulted family members and relied on community experiences when making decisions:

“I had to discuss it with my family first because it involved my child.” (Parent)

In many cases, participants adopted a “wait-and-see” approach, using others’ experiences as reference points:

“I waited to see how others reacted before deciding.” (Volunteer)

Information within the community was not homogeneous. Participants encountered both formal information from health authorities and informal information, including rumors, which sometimes created uncertainty:

“Some people said there could be serious side effects, so I hesitated at first.” (Volunteer)

However, informal information did not only discourage participation. It also functioned as part of a process where participants evaluated and negotiated different sources of information before making decisions.

Theme 4: Care experience as a basis for evaluating safety

Participants’ experiences of care played a central role in shaping their perceptions of safety and trust. Initial concerns often focused on whether support would be available in case of adverse effects:

“I was worried that if something happened after the injection, no one would take care of me.” (Volunteer)

During and after participation, structured procedures and continuous follow-up helped alleviate these concerns. Participants highlighted the importance of monitoring and accessibility to healthcare staff:

“They explained everything, checked on us, and followed up regularly. It made me feel safe.” (Volunteer)

In some cases, care extended beyond clinical procedures and was perceived as personal attention:

“It felt like they really cared for us, not just as participants.” (Volunteer)

These experiences influenced how participants evaluated the safety and credibility of the project. This suggests that participants assessed safety not only through information provided at enrolment, but also through the responsiveness, continuity, and accessibility of care they experienced during and after trial participation.

Theme 5: System-level coordination and community engagement

The implementation of vaccine trials relied on coordination across multiple levels, including provincial authorities, local health systems, and community networks. Communication through established administrative structures ensured consistent messaging:

“When all agencies communicated the same message, people understood and trusted it.” (Health officer)

Village health volunteers and community leaders played key roles as intermediaries, facilitating communication and engagement:

“They helped explain, follow up, and connect the project with the community.” (Health staff)

In addition, adapting activities to local contexts, such as organizing vaccination sites within communities, improved accessibility and participation:

“They came to the village, so it was easy for people to join.” (Volunteer)

Theme 6: Dynamic roles of participants in the community

Participants’ roles were not static but evolved over time. Initially, most participants acted as recipients of information. However, after gaining experience, some became informal communicators within the community:

“After I joined and nothing happened, I told others it was safe.” (Volunteer)

Village health volunteers, in particular, played multiple roles, including information providers, coordinators, and role models:

“I had to get vaccinated first so people would believe me.” (Village health volunteer)

Parents, especially in the context of dengue vaccination, took on decision-making roles on behalf of their children, reflecting a different layer of responsibility:

“I had to decide for my child because they couldn’t decide for themselves.” (Parent)

Discussion

This study advances current understandings of community engagement in clinical vaccine trials by demonstrating that participation is not a discrete individual decision, but a multi-level relational process shaped through interactions among system structures, social networks, information environments, and lived experience. Across influenza, COVID-19, and dengue trial contexts, trust, risk interpretation, and willingness to participate were continuously formed and re-formed during preparation, participation, and follow-up rather than simply existing in advance of participation.

Community participation as a multi-level process

Consistent with previous studies, community engagement was found to play a critical role in facilitating participation in vaccine-related activities, particularly through the involvement of trusted community figures and locally embedded networks [1,2]. However, this study extends existing literature by demonstrating that participation cannot be fully explained through individual-level factors alone. Instead, participation emerged through the interaction of system structures, social networks, and experiential processes. This interpretation is consistent with qualitative evidence from vaccine trial settings demonstrating that community engagement operates through layered relational processes between research teams and locally embedded actors [18,19].

These findings challenge approaches that focus primarily on individual-level determinants such as risk perception, attitudes, and beliefs [7,14,15], suggesting that such frameworks may be insufficient for understanding participation in real-world contexts where decisions are socially situated and relationally constructed. This suggests that participation is not simply influenced by context, but actively produced through ongoing interactions across these levels.

Trust as an emergent and dynamic process

Trust has been widely recognized as a key determinant of vaccine acceptance [6,7]. While previous studies often conceptualize trust as a pre-existing condition influencing behavior, the findings of this study suggest that trust is better understood as an emergent process that develops over time, shaped by relational and institutional dynamics rather than fixed prior to participation [13,20].

Trust evolved through multiple pathways, including interactions with healthcare providers, observation of others’ experiences, and direct participation. Importantly, trust was not stable; it could be reinforced or challenged depending on new information, experiences, or social interactions. This aligns with the concept of social amplification of risk [21], where perceptions are shaped through social processes rather than objective information alone.

The findings also highlight the role of institutional legitimacy in shaping trust at the system level, consistent with broader work on trust in health systems and health care institutions [9,20]. The alignment between external stakeholders and local governance structures influenced the acceptability of engagement approaches, underscoring the importance of context-sensitive implementation in vaccine research. These findings suggest that trust should not be treated as a prerequisite for participation, but as an outcome of engagement processes that unfold over time.

Social influence and information negotiation

This study demonstrates that decision-making within communities is not a simple response to information but a process of negotiation across multiple sources of knowledge. Participants relied on family discussions, peer experiences, and informal communication in addition to formal health information.

While previous research has often framed informal information and rumors as barriers to vaccine uptake [7], the findings here suggest a more nuanced interpretation. Informal information functioned as part of an “uncertainty management” process, where individuals delayed decisions to observe outcomes among peers. This highlights the importance of understanding information flow as a complex ecosystem rather than a unidirectional communication process.

Care experience as a mechanism of trust formation

Another key finding is the role of care experiences in shaping perceptions of safety and trust. Consistent with research on patient experience and with qualitative evidence from community vaccine research in low- and middle-income settings [22,23], participants' perceptions of care quality influenced their engagement. However, this study extends this understanding by showing that care functions as a form of experiential evidence through which participants actively evaluate the safety, credibility, and trustworthiness of the trial.

Rather than relying solely on scientific information, participants assessed safety through their interactions with the healthcare system, including follow-up, responsiveness, and accessibility. At the same time, this relational dimension of care may also introduce power dynamics, where close relationships with providers influence decision-making, raising important ethical considerations for community-based research.

Variation across vaccine contexts

The study also highlights differences in participation across vaccine contexts. Familiar vaccines, such as influenza vaccines, were associated with routine acceptance, whereas newer vaccines, particularly those introduced during uncertain conditions such as COVID-19, were associated with higher levels of concern

and deliberation. Vaccines involving children, such as dengue vaccines, introduced additional layers of responsibility, leading to more complex decision-making among parents, consistent with evidence that disease characteristics and perceived risk profiles are key determinants of trial participation decisions [24].

These findings reinforce the importance of context in shaping risk perception and participation, suggesting that engagement strategies should be tailored to specific vaccine characteristics and target populations.

Conceptual contribution

Building on these findings, we interpret community engagement in clinical vaccine trials as a multi-level and relational process arising from interactions among system structures, social networks, information processes, and participant experiences.

Within this interpretation, trust is not a static determinant that exists prior to participation; rather, it is continuously constructed, negotiated, reinforced, and sometimes challenged over time. This analytic interpretation helps explain why participation cannot be fully understood through individual knowledge or attitudes alone. It also helps clarify the role of care as experiential evidence: participants did not assess credibility solely through formal information, but also through what they directly observed and experienced in the conduct of the trial. At the same time, the findings suggest that trust may overlap with other social processes, including power relations, normative expectations, and community pressure, and should therefore be interpreted cautiously rather than treated as an isolated construct.

Implications for public health practice

The findings suggest that effective community engagement in clinical vaccine trials requires more than information dissemination. First, engagement strategies should be designed as continuing processes that begin before enrolment and continue through follow-up, rather than as isolated recruitment activities. Second, the role of trusted intermediaries, including village health volunteers, community leaders, and local health personnel, should be supported as part of the engagement infrastructure rather than treated as informal add-ons [25]. Third, responsive care systems matter not only for participant safety but also for how communities interpret the credibility of the trial process. Finally, engagement strategies should be tailored to vaccine context: familiar vaccines may be processed through more routine trust, whereas newer vaccines and vaccines involving children may require more extended deliberation, reassurance, and family-level decision support.

More broadly, high participation should not automatically be interpreted as evidence of trust, because participation may also reflect social influence, expectations, institutional legitimacy, and local structural conditions. Ethical clinical vaccine trials should therefore prioritize informed, voluntary, and context-

sensitive participation within community settings. These findings have implications for the design of community-engaged vaccine trials, particularly in strengthening relational engagement strategies and integrating care practices as core components of ethical trial implementation.

Strengths and limitations

This study has several limitations. First, it was conducted in a single province with a distinctive history of clinical vaccine trial activity and strong community health networks; the findings should therefore be interpreted as analytically transferable rather than statistically generalizable. Second, participants held diverse and sometimes overlapping roles, which enriched understanding of the local system but may also have blurred boundaries between perspectives as community members, intermediaries, and research-linked actors. Third, concepts such as trust, social influence, normative pressure, and power relations may overlap in practice and cannot always be separated cleanly in qualitative interpretation. Finally, because the study was designed to understand processes and relationships in depth, the findings should be used to explain mechanisms and interactions rather than to make quantitative comparisons or broad predictive claims.

Conclusion

Community engagement in clinical vaccine trials should not be understood as an individual decision driven only by knowledge or attitudes. In this study, engagement emerged as a multi-level and relational process shaped by the interaction of system structures, community networks, information environments, and participant experience across preparation, participation, and follow-up. Trust was not fixed in advance; it was continuously constructed, negotiated, and reshaped through formal communication, observation of others, and lived experience of care. Recognizing this complexity is essential for moving beyond individual-level models and for designing ethical, context-sensitive, and effective clinical vaccine trials in community settings.

Declarations

Acknowledgements

The authors wish to thank all 27 participants, including health personnel, community leaders, village health volunteers (VHV), and vaccine trial volunteers in Nakhon Phanom Province, for their time and willingness to share their experiences.

Authors' contributions

K.P. and P.C. contributed equally to this work. Conceptualization: K.P., P.C., Sutthichai Nakphook, P.P. Methodology: K.P., P.C., Sutthichai Nakphook, P.P. Validation: P.O., Suriya Naosri, J.K., P.P. Formal analysis:

Suriya Naosri, S.K., P.P. Investigation: K.P., P.C., P.O. Resources: K.P., P.C., P.O., P.P. Data curation: Suriya Naosri, S.K. Writing – original draft: J.K., P.P. Writing – review and editing: all authors. Visualization: J.K., P.P. Supervision: P.O., P.P. Project administration: P.P. All authors read and approved the final manuscript.

Funding

No funding was received for this study.

Availability of data and materials

The datasets generated and analysed during the current study are not publicly available due to confidentiality and anonymity commitments made to participants but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. The study was approved by the Ethics Committee of the Nakhon Phanom Provincial Health Office, Thailand (Approval No. REC 124/2568) on 10 November 2025. All participants provided written informed consent prior to participation.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

References

1. Tindana PO, Singh JA, Tracy CS, Upshur REG, Daar AS, Singer PA, et al. Grand challenges in global health: community engagement in research in developing countries. PLoS Med. 2007;4(9):e273. https://doi.org/10.1371/journal.pmed.0040273
2. MacQueen KM, Bhan A, Frohlich J, Holzer J, Sugarman J. Evaluating community engagement in global health research: the need for metrics. BMC Med Ethics. 2015;16:44. https://doi.org/10.1186/s12910-015-0033-9

3. Treweek S, Lockhart P, Pitkethly M, Cook JA, Kjeldstrøm M, Johansen M, et al. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. BMJ Open. 2013;3(2):e002360. https://doi.org/10.1136/bmjopen-2012-002360
4. Bower P, Brueton V, Gamble C, Treweek S, Smith CT, Young B, et al. Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. Trials. 2014;15:399. https://doi.org/10.1186/1745-6215-15-399
5. Lavery JV, Tinadana PO, Scott TW, Harrington LC, Ramsey JM, Ytuarte-Nunez C, et al. Towards a framework for community engagement in global health research. Trends Parasitol. 2010;26(6):279–83. https://doi.org/10.1016/j.pt.2010.02.009
6. Larson HJ, Clarke RM, Jarrett C, Eckersberger E, Levine Z, Schulz WS, et al. Measuring trust in vaccination: a systematic review. Hum Vaccin Immunother. 2018;14(7):1599–609. https://doi.org/10.1080/21645515.2018.1459252
7. Dubé E, Laberge C, Guay M, Bramadat P, Roy R, Bettinger JA. Vaccine hesitancy: an overview. Hum Vaccin Immunother. 2013;9(8):1763–73. https://doi.org/10.4161/hv.24657
8. Hall MA, Dugan E, Zheng B, Mishra AK. Trust in physicians and medical institutions: what is it, can it be measured, and does it matter? Milbank Q. 2001;79(4):613–39. https://doi.org/10.1111/1468-0009.00223
9. Ozawa S, Sripad P. How do you measure trust in the health system? A systematic review of the literature. Soc Sci Med. 2013;91:10–4. https://doi.org/10.1016/j.socscimed.2013.05.005
10. World Health Organization. Community engagement: a health promotion guide for universal health coverage in the hands of the people. Geneva: WHO; 2020. Available from: https://www.who.int/publications/i/item/9789240010529
11. AVAC and UNAIDS. Good participatory practice guidelines for biomedical HIV prevention trials. 2nd ed. New York: AVAC; 2011. Available from: https://www.avac.org/gpp
12. Dickert N, Sugarman J. Ethical goals of community consultation in research. Am J Public Health. 2005;95(7):1123–7. https://doi.org/10.2105/AJPH.2004.058933
13. Pratt B, Cheah PY, Marsh V. Solidarity and community engagement in global health research. Am J Bioeth. 2020;20(5):43–56. https://doi.org/10.1080/15265161.2020.1745930
14. Brewer NT, Chapman GB, Gibbons FX, Gerrard M, McCaul KD, Weinstein ND. Meta-analysis of the relationship between risk perception and health behavior: the example of vaccination. Health Psychol. 2007;26(2):136–45. https://doi.org/10.1037/0278-6133.26.2.136
15. Larson HJ, Jarrett C, Eckersberger E, Smith DMD, Paterson P. Understanding vaccine hesitancy around vaccines and vaccination from a global perspective: a systematic review of published literature. Vaccine. 2014;32(19):2150–9. https://doi.org/10.1016/j.vaccine.2014.01.081
16. Molyneux CS, Peshu N, Marsh K. Understanding of informed consent in a low-income setting: three case studies from the Kenyan Coast. Soc Sci Med. 2004;59(12):2547–59. https://doi.org/10.1016/j.socscimed.2004.03.037

17. Geissler PW, Pool R. Popular concerns about medical research projects in sub-Saharan Africa: a critical voice in debates about medical research ethics. Trop Med Int Health. 2006;11(7):975–82. https://doi.org/10.1111/j.1365-3156.2006.01655.x
18. Marsh VM, Kamuya DK, Parker MJ, Molyneux CS. Working with concepts: the role of community in international collaborative biomedical research. Public Health Ethics. 2011;4(1):26–39. https://doi.org/10.1093/phe/phr007
19. Dietrich JJ, Munoz J, Tshabalala G, Makhale LM, Hornschuh S, Rentas F, et al. A qualitative study of stakeholder and researcher perspectives of community engagement practices for HIV vaccine clinical trials in South Africa. J Community Psychol. 2023;51(3):998–1015. https://doi.org/10.1002/jcop.22951
20. Gilson L. Trust and the development of health care as a social institution. Soc Sci Med. 2003;56(7):1453–68. https://doi.org/10.1016/S0277-9536(02)00142-9
21. Kasperson RE, Renn O, Slovic P, Brown HS, Emel J, Goble R, et al. The social amplification of risk: a conceptual framework. Risk Anal. 1988;8(2):177–87. https://doi.org/10.1111/j.1539-6924.1988.tb01168.x
22. Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. BMJ Open. 2013;3(1):e001570. https://doi.org/10.1136/bmjopen-2012-001570
23. Shuro L, Lawrence E, De Man J, Knight L, Schneider H, Tabana H. A qualitative process evaluation of community-based participatory research and human-centered design in the 'Let's talk about vaccines' approach in Mozambique and Malawi. Res Involv Engagem. 2025;11(1):11. https://doi.org/10.1186/s40900-025-00677-4
24. De-Los-Rios-Pinto A, Fernandez-Guzman D, Soriano-Moreno DR, Sangster-Carrasco L, Morocho-Alburqueque N, Pinedo-Soria A, et al. Factors associated with the intention to participate in COVID-19 vaccine clinical trials: a cross-sectional study in Peru. Vaccine. 2022;40(26):3566–72. https://doi.org/10.1016/j.vaccine.2022.04.003
25. Shumba CS, Kiraithe P, Kambo I, Shaibu S. Community health volunteers' experiences of implementing COVID-19 vaccine education and promotion in Kenya: a qualitative descriptive study. Front Public Health. 2024;12:1406959. https://doi.org/10.3389/fpubh.2024.1406959

Figures

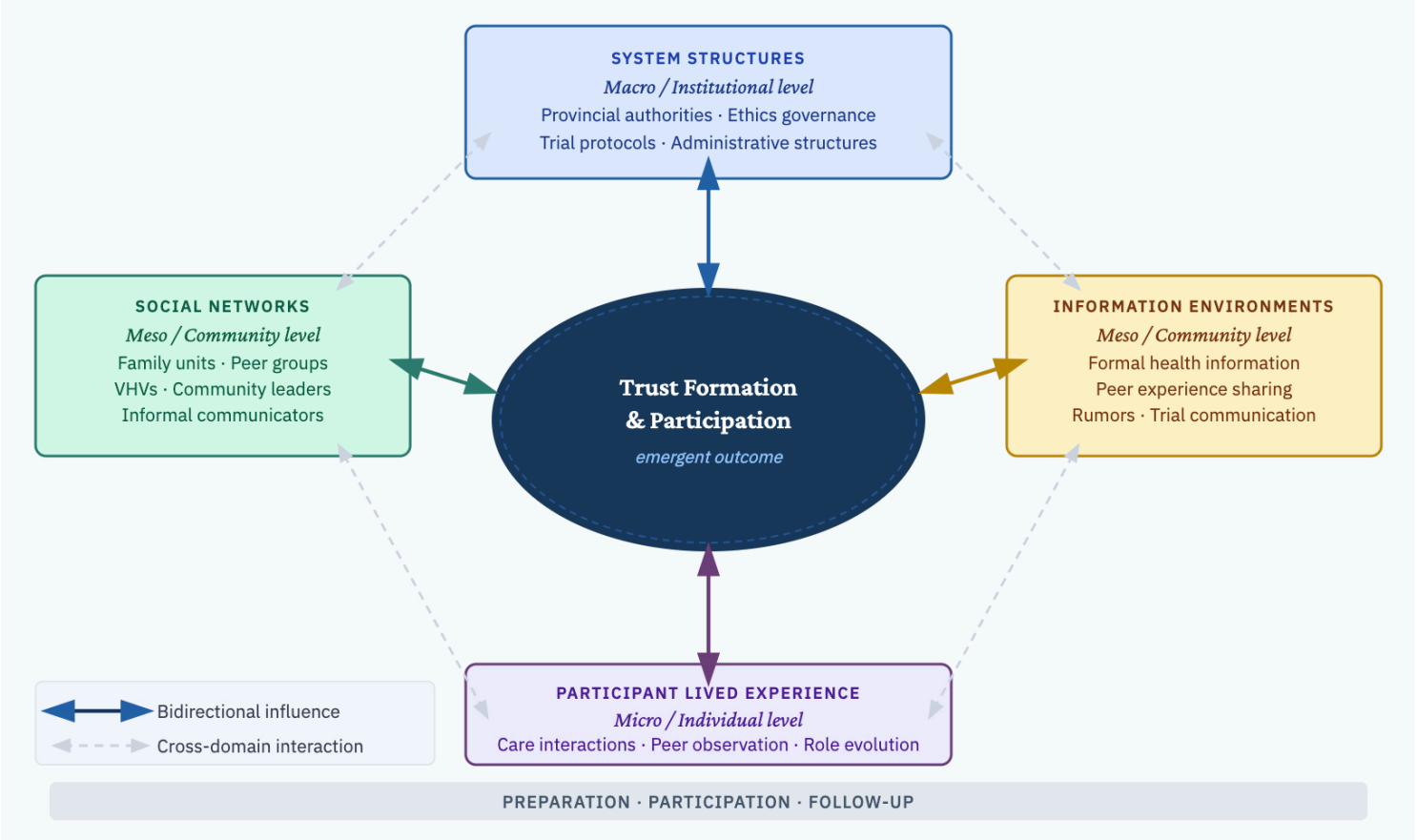


Figure 1

Analytic framework: community engagement in clinical vaccine trials as a multi-level relational process.

Abbreviations: VHV = village health volunteer.

Note: Solid bidirectional arrows indicate direct, mutually shaping relationships between each domain and the emergent central outcome. Dashed arrows represent cross-domain interactions. Trust formation and participation are emergent outcomes arising from interactions across all four domains and are continuously renegotiated across three temporal phases of engagement: preparation, active participation, and follow-up.

Theme 1 **Perceptions of "experimental vaccines" and risk evaluation** Risk perception was dynamic and context-dependent, reassessed against perceived disease severity and prior vaccine familiarity. Newer vaccines elicited higher concern; familiar vaccines were treated as routine. *"When I heard the word 'experimental,' I thought they were trying it on us first. I didn't know what would happen."* — Volunteer, COVID-19 trial	**Theme 2** **Trust as an evolving and experience-based process** Trust was not a precondition for participation but emerged progressively through interactions with health workers, peer observation, and direct experience of structured care and follow-up. *"At first I was worried, but after the injection and follow-up calls, I felt reassured."* — Volunteer
Theme 3 **Social influence and community-based information processes** Decision-making was socially embedded. Participants consulted family, relied on peer experiences, adopted wait-and-see strategies, and actively negotiated formal and informal information including rumors. *"I waited to see how others reacted before deciding."* — Volunteer	**Theme 4** **Care experience as a basis for evaluating safety** Structured care procedures, continuity of follow-up, and perceived personal attention functioned as experiential evidence through which participants evaluated the safety and credibility of the trial. *"They explained everything, checked on us, and followed up regularly. It made me feel safe."* — Volunteer
Theme 5 **System-level coordination and community engagement** Multi-level coordination across provincial authorities, local health systems, and community networks ensured consistent messaging and improved trial accessibility through community-embedded delivery. *"When all agencies communicated the same message, people understood and trusted it."* — Health officer	**Theme 6** **Dynamic roles of participants in the community** Participant roles evolved over time from information recipients to informal communicators and role models. VHVs held multiple layered roles; parents carried distinct proxy decision-making responsibilities. *"I had to get vaccinated first so people would believe me."* — Village health volunteer

Figure 2

Overview of six themes describing community engagement in clinical vaccine trials: descriptions and illustrative quotations.

Abbreviations: VHV = village health volunteer.

Note: Quotations were originally collected in Thai and translated into English. Participant role labels reflect primary role at time of interview; roles were often overlapping in practice. Themes were derived through qualitative content analysis of 27 in-depth interviews conducted across influenza, COVID-19, and dengue vaccine trial contexts.

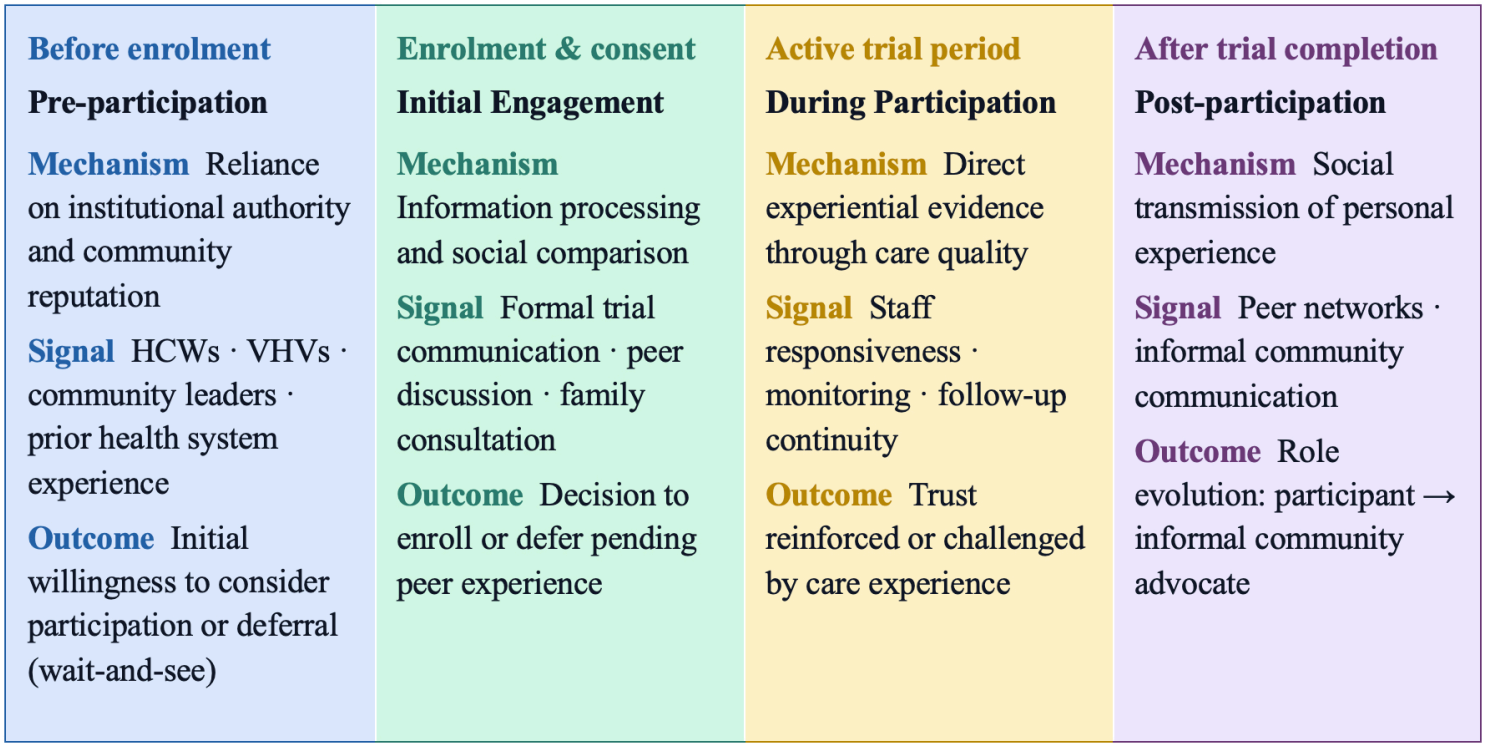


Figure 3

Stages and mechanisms of trust formation during clinical vaccine trial participation.

Abbreviations: HCW = healthcare worker; VHV = village health volunteer.

Note: Stages are not strictly linear. The dashed arc represents potential regression to earlier stages, reflecting the iterative nature of trust formation. Findings are derived from in-depth interviews with 27 participants across influenza, COVID-19, and dengue vaccine trial contexts in Nakhon Phanom Province, Thailand.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CommunityInterviewGuideEN.docx