OPEN LETTER

Community engagement in Genomics research; Challenges and lessons learnt in the AWI-Gen study at Dikgale Health and Demographic Surveillance System (HDSS) Site, South Africa [version 1; peer review: 1 approved with reservations, 1 not approved]

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Abstract

As health research often requires consent from participants and permission from community gate keepers, community engagement is considered an integral process of health research. Community engagement is also important in building trust between the research team and participants, gathering information on the needs and expectations of the community with respect to the project and present the community with an opportunity to gain more information on the goals of the research. Although there are published guidelines on how to conduct community engagement activities, the concept itself and the way in which it is put into practice is highly contextual. In this paper we reflect on the community engagement strategy used in the AWI-Gen Phase 1 study at the Dikgale Health and Demographic Surveillance System (Dikgale HDSS) site, the challenges encountered throughout the research process and the lessons learnt. Lastly, we highlight possible improvements to the CE strategic framework for AWI-Gen Phase 2 in Dikgale HDSS that may enhance the participation of the community.

Keywords

community engagement, genomics, demographic surveillance, South Africa

Open Peer Review

Reviewer Status

Invited Reviewers

version 1
12 Aug 2020

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Any reports and responses or comments on the article can be found at the end of the article.
Introduction
Community engagement (CE) is gaining momentum and recognition in health research (Musesengwa & Chimbari, 2017) globally. While no universal definition for CE exists, the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommends that CE be defined as ‘interactions with those from a particular subgroup or geographical community from which trial participants will be drawn as opposed to other stakeholders (UNAIDS, 2011). Although the specific goals for engaging the community may differ from one project to another, the process of CE is generally believed to enable effective access to the target community, manage health risk and community expectations and facilitate consent process (H3Africa-consortium, 2014). However, success of these processes depends on the nature of the research, the goals of engagement and how considerable is the CE process to the values, culture and traditions of the community involved in the research (H3Africa-consortium, 2014; Tindana et al., 2015). Guidelines on designing a CE strategy in the context of research exist in the field of genetic research (H3Africa-consortium, 2014), and HIV/AIDS research (UNAIDS, 2011). These guidelines are documented in general terms and could be adopted for other health-related research. The detail on implementation strategy is left to respective projects due to the diverse nature of the communities in which research is conducted. Even with these guidelines, literature suggests that CE processes face a wide range of challenges before, during and after the completion of the research project (Chimbari, 2017). Some documented challenges include postgraduate students leaving before the project is completed, the expected community support not always received and community research assistants not fully understanding the research process (Chimbari, 2017). A lack of community support was also reported in a review of studies conducted in developed countries (Walsh & Sheridan, 2016). The documentation and publication of experiences of CE provide insights to other researchers in similar settings and an opportunity for improvement in future research projects. In this paper, we reflect on the community engagement strategy used in the AWI-Gen Phase 1 study (Ali et al., 2018; Ramsay et al., 2016) at the Dikgale HDSS site, the challenges encountered throughout the research process and the lessons learnt. We also highlight possible improvements on the CE process in AWI-Gen Phase 2 at Dikgale HDSS site that may enhance among other aspects, the participation of the community.

Dikgale Health and Demographic Surveillance System (Dikgale HDSS) site profile
The Dikgale HDSS site is one of the six collaborative research sites (from four African countries) in the AWI-Gen Phase 1 project that focused on ‘the interplay between genomic and environmental risk factors for cardiometabolic diseases in four sub-Saharan African countries’ (Ali et al., 2018; Ramsay et al., 2016). The Dikgale HDSS site is located approximately 40 km north-east of Polokwane, the capital of Limpopo Province and nearer to the University of Limpopo. In the South African context, Dikgale HDSS is considered a rural area in which communities typically comprise of households clustered in villages and residents engage in small-scale food production on local land. Utilities such as electricity and networks are available, but water shortage occasionally occurred. The site is served by three Primary Health Care clinics, with one district hospital that is approximately 10–30 km from the Dikgale HDSS site (Alberts et al., 2015).

When it was founded in 1996, the Dikgale HDSS site comprised of eight villages of approximately 8071 people (pale dots in Figure 1). By 2009, a decision to expand the Dikgale HDSS was undertaken resulting in 15 villages with an estimated 36,000 people, predominantly of northern Sotho speaking ethnicity (Alberts et al., 2015). Unemployment in the population is high (Maimela et al., 2016). A substantial proportion of the adult population live away from homes in the Dikgale HDSS site as temporary migrants in search of employment (Alberts et al., 2015). Administratively, the Dikgale HDSS site has traditional structures in which each village is headed by an Induna (gatekeeper). The Indunas are accountable to one chief, their communities and the tribal council. The communities in the Dikgale HDSS site are heterogeneous in respect of religion.

AWI-Gen Phase 1 study community engagement strategy in the Dikgale HDSS site
The research team consisted of academic and non-academic members. The non-academic members of the team were the field workers, professional nurse and data capturers. The study had postgraduate students nested in it. The AWI-Gen project had a target sample size of 2000 participants (between 40 and 60 years) and that became one of our goals for engaging with the community. In addition, we needed the community to understand the AWI-Gen study, particularly the genetics aspects to support the informed consent process. Although we had previously conducted studies in the same community, this was the first time we were undertaking a genetic study in this community.

The engagement strategy involved three different levels: Engagement of stakeholders started at the institutional level with the application of the ethics approval from Wits Ethics Committee followed by the Medunsa Research Ethics Committee. The second level of stakeholder engagement involved the Department of Health in Limpopo Province of South Africa. The third level of engagement involved the target community as depicted in Figure 2.

Community entry
Entry into the community was via the tribal council. The tribal council consists of the local chief, the Indunas (village gatekeepers), traditional leaders and other village elders. This council is inclusive of both men and women. An initial meeting at the tribal council office was arranged and made to coincide with the tribal council’s usual scheduled meeting. The use of such traditional CE mechanisms that are familiar to
Figure 1. Map showing the Dikgale Health and Demographic Surveillance System site and its location within South Africa. Paler dots represent households in the original surveillance area, and darker dots households in the extended surveillance area.

Figure 2. AWI-Gen Phase 1 community engagement strategy at Dikgale HDSS site.
the community were found to have minimal social disruptions that may be associated with projects conducted by people from outside of the community (Tindana et al., 2011). The research team was first given the opportunity to present their project in the local language (northern Sotho), ahead of the tribal business for the day. Thereafter, the research team had to address questions and concerns regarding the benefits of study to community, potential dangers and how the findings of project will be communicated. After the meeting, the team was granted permission to enter the villages and engage with the people. The indunas also committed to inform and sensitize their respective communities about the project and the need to co-operate and participate. Indunas in this community are well respected and trusted by their community and hence their word is convincing (Figure 2). The positive influence of village leaders was also noted in other studies (Campbell et al., 2013; Ramjee et al., 2010), while other studies encountered challenges with the involvement of community leaders (Ndekha et al., 2003; Tedrow et al., 2012). However, the success of this strategy relies on ensuring that the community leaders understand the potential benefits of the project and securing their buy-in before its commencement (Minkler, 2005).

Following the granting of permission to conduct the study by the tribal council, the field workers with prior experience of recruiting from the Dikgale HDSS site (for other studies) received training on the AWI-Gen project aims, objectives, procedures and information sheet. These training sessions were attended by all team members including postgraduate students. The field workers piloted the questionnaire on some staff members at the University.

Once the field workers were considered knowledgeable on the project, they initiated the door to door sensitization and recruitment of the targeted age group of 40 to 60 years whose names were extracted from the Dikgale HDSS census database. Interested participants were transported to the study centre at the University of Limpopo on a scheduled date. At the centre, the researchers explained to the group of participants information relating to the project aims, objectives and all procedures that each participant had to undertake. Any questions from the participants were answered in a friendly and transparent manner. Participants were then requested to consent by filling and signing the consent form in the local language. Participants then went through all procedures at this stage. These processes included anthropometric measurements, urine and blood sampling, scanning for body fat. Participants whose results were not within normal values were referred to the primary health care clinics for further investigations and management.

**Ethics and consent**

The AWI-Gen study, which included the community engagement strategy, obtained ethics approval from the Human Research Ethics Committee of the University of Witwatersrand and the Medunsa Research and Ethics Committee of the University of Limpopo (MREC/HS/195/2014:CR). Permission to conduct study in Dikgale HDSS was sought from tribal chiefs. Participants were only included after providing written informed consent. Participants found to have medical abnormalities unknown to then were referred to primary health care clinics for further management.

**Post-study feedback of research findings**

In the post-study period, the feedback of other test results was provided at an individual and community levels (Figure 2). To achieve individual feedback, fieldworkers went door to door and invited participants to a central place in each village. On average, 25 participants gathered on a pre-determined date. It was during the feedback sessions that participants were made aware of the AW-Gen Phase 2, for which they were invited to take part. The researchers privately provided a one on one feedback of individually prepared results referring participants with results which were not within normal values to primary health care clinics for further testing and management. Of the 1399 who participated, 1106 participants (79.1%) received their results (according to signed registers), while some participants were lost to follow-up due to reasons that included death, imprisonment and emigration from Dikgale HDSS site.

At the community level, a summary of findings for all health assessments performed in the community was presented to the Community Advisory Group (CAG), comprising of representatives from the university, indunas and chiefs. This is a committee that was formed following the Dikgale HDSS expansion to cover 100,000 individuals and renaming to DIMAMO Population Health Research Center (PHRC) under the SAMRC (South Africa Medical Research Council), SAPRIN (South African Population Research Infrastructure Network) project (detail in last section: New developments at the Dikgale HDSS site). During this feedback session, the CAG was sensitized on the upcoming AWI-Gen Phase 2. The AWI-Gen Phase 2 aims to retain majority of the participants from Phase 1 and recruit new participants from villages in the expanded area, in order to achieve the target number of participants.

**Community Engagement Challenges encountered by the Researchers in AWI-Gen Phase 1.**

The Dikgale HDSS site has an established relationship with its founders, the University of Limpopo-based researchers. This relationship over the years has led to the development of trust necessary to gain community support. However, despite this positive environment and engagement with the community at levels of leadership (chief, indunas), fieldworkers (peers) and the individuals in the villages, the project experienced some challenges particularly prior to and during the project.

**Local understanding of genetics and genomics**

Training of the fieldworkers on the concept of ‘genetics’ and ensuring a good understanding was fundamental considering their role as mediators and negotiators between the project team and the community (Marsh et al., 2010; Staunton et al., 2018). These training sessions included piloting the information sheet and questionnaire on other university non-academic staff and responding to questions that arose from these interviews. Based on the information given to the community they agreed to participate. We did not test whether the participants clearly understood the concept of ‘genetic test’, but low levels of literacy.
coupled with a lack of vocabulary for genetic terms in indigenous African languages (Tindana et al., 2012) may have contributed to a lack of understanding during the consent process.

The project attracted a high number of participants per day in the initial stages of the research process itself, but this support declined as the project progressed. Daily participation dropped and became a major concern. Investigations revealed diminished interest in the project by the community owing to delays in receiving their promised compensation for the long hours spent at the centre undergoing all the procedures. The length of time the participants spent at our research site due to some procedures taking long time may have also contributed to the decline. The news of these delays spread widely and the project team together with the fieldworkers had to attend to these and restore community confidence. The spread of negative news was experienced in other studies (Ramjee et al., 2010). While the drop in daily participants could have contributed to the project being unable to reach its target sample size, other factors could not be ignored. The high number of temporary migrant workers who leave their homes for towns in search of employment and those who leave very early in the morning and return home very late may also be accountable for the low turnover. Attempts to engage with them during weekends were fruitless as some cultural events such as burials and church services take place during weekends. Fortunately, with the expansion of Dikgale HDSS site to approximately 100,000 people in 2019, under the SAMRC (South Africa Medical Research Council), SAPRIN (South African Population Research Infrastructure Network) project, it is envisaged that the sample size could be achieved in the AWI-Gen Phase 2 (https://www.samrc.ac.za/media-release/new-population-research-centre-be-launched-university-limpopo). The challenge of participants migrating rural to urban areas in search of employment was also experienced in an HIV study in KwaZulu Natal Province of South Africa (Ramjee et al., 2010).

Involvement of students in engagement process
The involvement of postgraduate students is well acknowledged as it promotes capacity development (Chimbari, 2017). However, our project experienced challenges as some students who had roles in the project left before the end of the project. The lesson learnt is that postgraduate students should not assume sole responsibility for certain aspects of the project but rather provide assistance to full-time appointed project members. This will minimize or avoid any disruptions when students leave anytime during the project.

Funding for CE activities
Since our project was institution-based, all finances relating to the project were managed by the institution’s finance department. This arrangement had its own challenges. The financial claims made by the contracted transport company that was responsible for transportation of participants to the centre were at times not paid on time due lengthy procedures. Unpaid claims resulted in the transport services being halted and cancellation of scheduled collection of participants and frustration to the participants. At times, some participants that could attend before the change of date were unable to create another opportunity.

A vehicle will be available for transporting our participants and this development may address the challenge experienced with contracted transport. These challenges are not unique to AWI-Gen but have been reported in other projects with similar arrangements to ours (Chimbari, 2017). Such challenges provide lessons and create room for improvement.

Addressing community concerns and expectations
Our community engagement results feedback sessions revealed the participants’ major concern regarded the long turn-around time of results in the Phase 1 study. The delay of results was due to the centralized processing of samples that is aimed at providing uniformity to the tests and procedures in all the AWI-Gen six sites, as well as the project’s plan of giving results at once after processing approximately 11,000 participants of the study. While centralized processing of samples will continue in AWI-Gen Phase 2 to allow for comparison with Phase 1 results, some Point of Care machines will be used at each centre to provide participants with immediate results. The preference on timing of feedback is known to differ between research professionals and participants (Cox et al., 2011). Our participants were required to come in a fasting state and after withdrawal of blood, they were provided with food to allow them to take their various medications. However, some participants felt that the food should be increased. The AWI-Gen Phase 2 has budgeted for any inflation related costs and this concern will be addressed accordingly.

The perception that blood collected for research is sold, persists in this community as well as other communities within the African continent (Ramjee et al., 2010). There is therefore the need for researchers to continuously educate and reassure the rural communities that blood will never be sold as it is unethical. This process could involve engaging the CAG in Dikgale HDSS to educate their communities, as they are respected leaders. The strength of community engagement is that it reveals what the community perceive as their problems and some participants from AWI-Gen Phase 1 expect cancer screening in future studies. While cancer testing is not included in AWI-Gen Phase 2, it does not rule out its inclusion in future phases. Meanwhile, tests that have been added to AWI-Gen Phase 2 include lung function, cognition and gut microbiome.

Another key lesson learned was that the use of one central meeting place per village for feedback sessions was not welcomed by majority of participants as they had to walk long distances to the venue of these community meetings. Some participants could not come to the meeting and the researcher had to visit their homesteads to give feedback. In future, feedback will be provided at multiple sites in a village to reduce the walking distances. Overall, the participants’ response was good, and they were already looking forward to Phase 2 of the project.

New developments at the Dikgale HDSS site
In 2019, the Dikgale HDSS site increased its survey population to 100,000 people. The inclusion of new villages resulted in a change of name and Dikgale HDSS site is now known as DIMAMO Population Health Research Centre (PHRC). The
centre now has a community engagement (CE) team and formal structures for CE are established. These developments are also beneficial to the AWI-Gen project that runs on the DIMAMO PHRC platform.

Conclusion
The challenges highlighted in this post-study analysis provides an opportunity to improve our CE implementation strategy by using visual aids to disseminate information and help participants’ understanding. We hope to establish a uniform culturally sensitive approach to participants through the CE officer. We also plan to implement an ongoing feedback system (community to researcher) that would help detect problems early enough and generate bi-partisan (researchers and participants) solutions. Our community engagement implementation strategy will continue to be responsive to challenges and adaptive to change. We recommend a more systematic approach to community engagement to facilitate an evaluation process.

Data availability
No data are associated with this article.

Acknowledgements
We would like to thank all the participants from DHDSS site. We are also thankful to the professional nurse and fieldworkers for their assistance during the recruitment process and data capturers and scientists. Investigators responsible for the conception and design of the AWI-Gen study including: Michele Ramsay, (PI,Wits), Osman Sankoh (co-PI, INDEPHTH), Stephen Tollman and Kathleen Kahn (Argincourt PI), Marianne Alberts (Dikgale PI), Cathrine Kyoobutungi (Nairobi PI), Halidou Tinto (Nanoro PI), Abraham Oduro (Navrongo PI), Shane Noris (Soweto PI), Scott Hazehurst, Nigel Crowther, Himla Soodyall and Zane Lombard (Wits).

We would like to acknowledge each of the following investigators for the significant contributions to this research, mentioned according to affiliations are: Wits AWI-Gen Collaborative centre-Stuart Ali, Ananyo Choudhury, Scott Hazehurst, Freedom Mukomana, Cassandra Soo; Soweto (DPHRU): Nomsees Baloyi, Yusuf Guman and Lisa Micklefield.

The people acknowledged under this section have given the author the permission to mention their names in this manuscript.

References


SAMRC (South Africa Medical Research Council), SAPRIN (South African Population Research Infrastructure Network). New population research centre to be launched at the University of Limpopo. Reference Source


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Noni Mumba

Health Systems and Research Ethics, Center for Geographical Medicine, KEMRI-Wellcome Trust Research Programme, Kilifi, Kenya

An interesting paper to read, and exciting that researchers are documenting their CE experiences.

1. I did not fully understand what the study itself was about, since there is very minimal information about the research that was conducted.

2. There is a thin line between CE and communicating study information at household level (Fig 2). The actual CE activities (that are not directly targeting participants), should be outlined better.

3. For instance, the authors documents 3 stages of engagement, including ethics committees (not usually part of CE), and stakeholder engagement. Could they elaborate how these were done? There is mention of referral to health facilities - were these stakeholders engaged? What were some challenges faced with engaging the government health stakeholders (if engaged)?

4. Recommendations relating to CE such as working with CAGs and spreading out venues for meetings are clear. Other recommendations relate more to study implementation and ethical issues (such as study reimbursements to participants) rather than to CE.

5. The CAG features quite a lot in the paper; the author should consider elaborating a bit more on this group; including what their role is.

6. I find that there is a major concern coming out in the paper, that of community not understanding the aspects of genetics (which was one of the 2 goals of CE for this project). I would have wanted to see more written up about this in terms of why this was the case (language is mentioned... was there anything else?), and a little bit more about how this will be resolved in the next phase (beyond CAGs and Fieldworkers).

7. Finally, it is good that a CE team is now in place. I suggest the author shares this article with...
the team, to be assisted to refine it better.

Is the rationale for the Open Letter provided in sufficient detail?
Partly

Does the article adequately reference differing views and opinions?
Yes

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Community and Public Engagement practitioner; planning and implementing of monitoring and evaluation for Engagement; Review of health research proposals and advising on CE/PE components; capacity building on Engagement; Review of research and engagement grant proposals; Advising on ethical issues raised during study implementation that have an impact on community relationships; Advising/Training on Safeguarding of vulnerable communities in the course of research participation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 17 August 2020

https://doi.org/10.21956/aasopenres.14172.r27755

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**Paul Ndebele**
Center on Commercial Determinants of Health, Milken Institute School of Public Health, The George Washington University, Washington, DC, USA

1. First sentence in abstract - CE is necessary for some studies - not all.
2. The paper should include a brief description of the AWI-GEN study including study procedures. This provides context.

3. The ethics and consent section is a repetition.

4. The section on Funding for CE is discussing funding for transport - not CE.

5. The paper is describing challenges that the study faced - and is not specific to CE. For CE it only describes two strategies (meeting at beginning with chief and council and feedback meeting).

6. Community was not even consulted in the design of the study?

Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Yes

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Partly

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Bioethics, Social Science

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.