Engaging Research Participants with Results: A Rights Informed Approach

Mathew Sunil George (✉ sunil.george@canberra.edu.au)

University of Canberra Faculty of Health <https://orcid.org/0000-0003-4844-4324>

Rakhal Gaitonde

Achutha Menon Centre for Health Science Studies

Rachel Davey

University of Canberra Faculty of Health

Itismita Mohanty

University of Canberra Faculty of Health

Penney Upton

University of Canberra Faculty of Health

Research article

Keywords: dissemination, agency, participants, engagement, knowledge sharing, research results, ethics, rights.

Posted Date: July 20th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-43527/v1>

License: This work is licensed under a Creative Commons Attribution 4.0 International License. [Read Full License](#)

Abstract

Introduction

Sharing findings with research participants is gaining attention as an ethical imperative for the research community. However, current discussions on this topic typically take a paternalistic approach to the issue, with the research team having the power to decide whether or not the sharing of results should be carried out and how this is done. In this paper we propose an alternative approach to engaging participants with the findings from the research to which they have contributed.

Methods

The ethnographic fieldwork for our study was carried out in multiple phases from August 2018 to January 2019 and again from August 2019 to December 2019 among two vulnerable communities in the south Indian state of Kerala. Engagement of research participants with findings was integrated into the research protocol and various strategies including forming partnerships with participants and identifying appropriate forms of dissemination among the different categories of participants were carried out during fieldwork. The format and mode of dissemination varied depending on the participant category and was tailored to ensure that each participant was able to engage actively with the findings as opposed to merely passively receiving the results from our study.

Results

Previous research studies that had been undertaken among our participants had not shared research results with them and were interpreted by the communities that researchers were not interested in making any difference to their situation. Building reciprocal relationships in a way that minimised power disparities and tailoring outputs to forms that promoted active engagement were key factors that helped participants to engage with our results. Such engagement added value to our research by enabling us to jointly evolve the recommendations from our study.

Conclusion

Participants contribute to the success of research by providing information that is sought by researchers. Compared to the dominant bio-medical research ethics framework, a rights informed approach to sharing research results with participants acknowledges this and recognises their agency to engage with research findings. Such an approach is not only socially responsible and ethical, but also improves the impact and legitimacy of research among the participants and the larger population that they represent.

Background

Health research has the capacity to affect the lives of both research participants and the larger communities within which the research is embedded. The knowledge generated by such research can improve how societies organise themselves to improve their health (1). Given this significance, historically a lot of attention has been paid to ensuring scientific rigour and integrity of the research processes especially when it comes to the design, conduct and reporting of research findings(2). The last fifteen years has also seen a growing interest in the sharing of knowledge that is generated by research and making it accessible to both individuals and institutions not involved in the research process(3). This has also been reflected in policies adopted by several funding agencies and institutions which make research available through open access mechanisms(4–7). Most of these discussions, while acknowledging that the outputs of research should be freely available for all stakeholders in society, limit accessibility primarily for those belonging to academic, policy makers and programme implementers. However, in recent times the sharing of research results with another important research stakeholder - study participants - has started to gain attention (8, 9). The Declaration of Helsinki for example states that “*all medical research subjects should be given the option of being informed about the general outcome and results of the study*”.(10) Health research participants often wish to know the results of the research in which they participated. However, most of them do not have access to such results despite increasing numbers of researchers promising to share findings (11, 12). One reason for this may be the fact that while researchers are required to publish their findings in peer reviewed journals for both professional and organisational reasons, there is no strong motivation driving dissemination to participants or engaging participants further in the research process(12). Also, it is increasingly recognized that sharing findings with study participants in a meaningful way goes far beyond merely providing them with simplified versions of the findings (13).

Traditionally, research participants are conceptualised as taking a passive role in the research process, having a time-limited function that ends once they provide the information that was sought from them (14). However, there is growing consensus that the active involvement of participants in health research (for example as members of a study advisory committee) improves both the credibility of results and their direct applicability to others(15). This move from participants being a mere data source to active collaborators in research, has also been presented as a consequence of the overall ethical demand for democratisation of research processes(15, 16). With this increased recognition of the active role of participants in the design and conduct of research, another area that has begun to merit greater attention is the sharing of research findings with participants. This has especially been the case for community based participatory research (17, 18) and is the focus of this paper.

Most discussions on sharing research findings with participants have stemmed from a bio-ethical framework(2, 8, 19). The principles of autonomy, non-maleficence, beneficence and justice have been used to unpack the issues around sharing research findings with participants in the last few years. Thus, those who advocate the sharing of research findings with participants have argued that flowing from the principle of autonomy, participants have both a right to know about the results of research conducted among them and the ability to take a decision whether they would like to know about the results or not (8, 20). Under this approach researchers routinely offer the option to provide results to the participants who then decide whether they would like to accept it or not. The obligation of researchers to share results with participants has also been recognised as a principle arising out of respect for communities where the research was carried out(8, 21, 22). Yet another perspective from which sharing results has been encouraged is that of accountability of the researchers(13, 23). Those who take this approach point out that participants make significant contributions to research and are no less important than other stakeholders such as

funders, researchers etc. Participants provide information that is sought out by the researcher and in return researchers owe them information in the form of results(23). Others however have argued that sharing results is not as straightforward as it seems and any such decisions should involve a careful consideration of the harms and risks versus any benefits that this might offer to participants(24, 25). How best to accomplish this is also not clear and this issue is far more complex than it might at first appear (19, 26).

Conceptual Frameworks To Understand Sharing Of Results

The idea of sharing research findings with study participants has been around for some time especially in clinical research. In the field of environmental health research, Morello-Frosch and colleagues discuss three possible frameworks to understand the process of sharing results with participants (27):

1. A clinical ethics framework where the focus is on the reporting back of individual results especially in situations where clinical action is required to protect the participant. Here decisions about sharing results rests with scientists and medical experts(28).
2. A community based participatory framework where there is a strong focus on communicating both aggregate and individual results to participants using protocols that are jointly developed by both the research team and the participants. The decisions rest with both the researchers and the community that was participating in the study(17).
3. Citizen-science 'data-judo' where there is a strong emphasis to report back both aggregate and individual results to participants to promote action at both the individual and community level including advocacy for change. The lead is taken by communities and advocacy groups who have marshalled their own scientific resources to conduct a study with a view to influence policy change(29).

While discussing data sharing practices in social sciences, Jeng and colleagues draw out two broad dimensions that affect decisions about whether research findings and data are shared or not (30). The first dimension concerns the motivations and characteristics of the individual researchers, whilst the second refers to contextual features of the research such as data characteristics, the research culture of the institutions involved in the research, and the infrastructure required to support data sharing.

These frameworks highlight the importance of sharing results with participants and suggest strategies to achieve this. However, the approach to data sharing highlights the power imbalance that researchers hold about the decision making in this process. By allowing researchers control over the decision whether or not results can be shared, it highlights the ongoing paternalistic approach to decision making and treats the community as a group that does not have its own agency to engage with research results in a way that promotes their overall well-being.

Decisions to share research results are influenced by a number of considerations including pragmatic and ethical factors. In this paper, we discuss our experience of engaging participants with the results of our study, the different stages in this process and our learnings from this exercise. We then draw out implications for researchers and suggest a rights informed framework that can promote an active model of sharing research results that acknowledges not only the value that participants bring to the research process but in addition is respectful of their own agency.

Methods

Study setting and methodology

Our study sought to understand the experience of accessing healthcare services for two diverse marginalised groups in the south Indian state of Kerala. Detailed descriptions of the study setting, and their main findings have been published previously(31). The ethnographic fieldwork for our study was carried out from August 2018 to January 2019 and again from August 2019 to December 2019. Phases included: 1. Building rapport and trust with the participants; 2. data collection in the form of interviews, focus group discussions and participant observations and concurrent analysis; 3. member checking and sharing results with participants (the focus of this paper). Thus, sharing of research findings with participants was decided a priori during the study design.

The research participants in this study were either:

1. Community participants- Indigenous communities and widows above the age of sixty and living by themselves (hereafter referred to as widows),
2. Health system participants such as community health workers, nurses and doctors. Having multiple stakeholders required us to discuss and evolve appropriate mechanisms that would promote active engagement and sharing of results with each stakeholder.

Integrating Engagement With Participants Into The Research Protocol

It is important that planning for sharing research results takes place early in the research process, and a clear communication plan should be developed(12, 32). In this study, the decision to share results with participants was made during the research design stage. An initial dissemination plan was integrated into the study protocol. Right from the beginning, our approach was that study participants have the right to know about the findings. This decision was also influenced by our own positionalities of respect for the agency of participants that had evolved from previous experiences of working with vulnerable communities and engaging research participants with results. This enabled us to identify approaches to discussing this issue with participants during the data collection process, and ensured we planned for adequate time and resources to enable engagement with participants at the end of our study.

Forming Partnerships With Participants

Ethnographic research places a great emphasis on extended contact with participants and building relationships which are reciprocal, as this helps to avoid power disparities and gives greater access to the lived reality of the participants(33). In this study we were particularly conscious of the fact that we were working with vulnerable communities and that building partnerships of mutual respect was key to the success of the research. We did this by spending time with these communities to understand the specific contexts in which they lived, adopting their customs during interactions both at the times of the initial visits and for data collection, acknowledging their concerns about the research topic and research processes in general. Such extended contact enabled us to understand the existing power differentials and to take steps to build relationships that were reciprocal and respectful.

The Human Research Ethics Committees of the University of Canberra (20180074) and the Indian Institute of Public Health Delhi (IIPHD_IEC_03_2018) provided ethical approval. Regulatory permissions were obtained from the Kerala Department of Health (GO(Rt)No2677/2018/H&FWD). Permissions were also obtained from the local health officials before fieldwork began.

Results

Impact on community of previous research results not being shared

During the initial phase of fieldwork among the Indigenous communities, one of the key barriers to building rapport was the negative experience of the community with previous research studies. Several research groups had carried out data collection with the community, but hardly anyone returned to share their findings with them. The lack of engagement by researchers, post data collection, made community members feel that researchers were far more interested in getting their work done rather than helping the community address their situation. Some even wondered if the researcher accurately reported the information that they had provided.

Health system participants (especially doctors) were also keen to point out the benefits of disseminating the results and the limitations of not doing so. Many felt that if research aims to impact the local health system where it was carried out, then it is important for researchers to share their findings with key stakeholders both at the implementation level and at the policy level. This they felt would help to improve their practice by understanding what promotes access to better health and healthcare for the community. According to the health system participants, results published in scientific journals and other professional avenues were hardly accessible to practitioners in the field as most of them especially in developing country settings did not have the resources or the time to make regular use of many journals.

The failure of researchers to come back and share findings gave participants the impression that researchers were only concerned about their professional careers, rather than empowering the community through their research. The community felt that this was unfair as they had spent time and shared information about their lives with researchers. Such experiences also meant that communities were not eager to participate in future research as they considered such exercises futile.

People like you come here for research, but once they finish their work, there is no sign of them. They don't tell us what they have found out and neither do we know what has happened to the report that they wrote. Once they have collected whatever they want no one ever comes back.

Indigenous Community FGD, TI10

I don't think so far anyone has come and spoken about their findings here. Usually what happens is that people will do some surveys or carry out interviews. But once that is over, they do not come back. We won't even know where they are or what happened to them after that.

Healthcare provider IDI, MO_4

As part of the initial process of building rapport with both groups of participants, we discussed this issue and entered into mutual agreements with participants that the results of our study would be shared once we had completed analysis of our data. These discussions enabled us to build more equal relationships with participants and to some extent address any power disparities that might have existed between participants and researchers.

Inaccessible research outputs

Peer-reviewed publications, technical reports and policy briefs are some of the traditional avenues through which research results are disseminated. However, for most research participants, especially in the developing world, access to such outputs is highly limited even for medical professionals. Furthermore, most of the traditional avenues established to disseminate research results cater primarily to the research community and other stakeholders such as funders, policy makers and other professionals associated with the subject being researched. etc. Research outputs are therefore tailored to suit such audiences. They are not easily accessible (either physically or intellectually) for other audiences and a different approach is therefore required. For example, marginalised groups have been reported to be eager to hear results, preferring material that is read out to them or uses pictures and other forms of visual or verbal dissemination (34). The community participants in our research were unable to read reports or summary documents which were produced by researchers. What evolved in our consultations was that a verbal presentation followed by a discussion of the results either in an individual or a group setting would be far more effective for our participants. Merely receiving a copy of a research report was not going to help them engage with the findings and understand what was being reported.

I don't know what they are writing about us. I hope they are writing what we say (laughs). But what can we do about it? We can't read what they write, and they also don't tell us what they finally write in those reports.

Engaging communities with results

Once data analysis was completed, the key findings from our study were presented to all the research participants. As there were multiple categories of participants, we engaged in discussions with each group to identify what would be the best format to share the results of our study. This process enabled us to identify different formats for different categories of participants. For example, the Indigenous communities who participated in this study lived in a close-knit circle and had a community mechanism to discuss issues of common concern. Given our research focus, village chiefs felt the most appropriate forum for sharing the results would be their village meeting. In keeping with this tradition, in each village where data was collected the village chief called for a meeting where everyone from the village was present. Aggregate results were presented one by one and a discussion on each of these results was carried out in the village meeting that was presided over by the village chief.

With the widows, individual meetings were held to talk about the results on a one-to-one basis in their homes. This format suited them the most as each of our participants from this category lived by themselves. Gathering them together would have been counterproductive as it would have disrupted their daily routine and put them in the company of others they did not know well. This would have diminished their ability to engage with the results, ask questions and comment on them freely. With the healthcare providers such as doctors and community health workers, individual meetings were preferred over group settings.

While the aggregate results that we presented were the same for all stakeholders, it was important to ensure that the language and idioms used to describe the results, were accessible for the different participants. For example, given that we were looking at the issue of access to healthcare, it was natural for us to prepare our reports using terms that are readily understood by those with a background in health. However, this would have meant that participants from the community would have found it difficult to engage with our results actively. In order to ensure that this did not happen, discussions were held with some of the Indigenous participants to explore what would be the best form in which to present our results. These discussions helped us to understand that while presenting results it would be useful to use imagery and context that was relevant to the community instead of presenting generic results. For example, having village chiefs convene the village meeting (*oor kootam*) and preside when results were disseminated drove home the importance of the discussion and improved participant engagement. Secondly while discussing results, imagery and analogies that resonated with their situation and that were drawn from their lives increased the salience of the conversation for participants. For example, while discussing the gradual decline of Indigenous healing traditions and the increasing acceptance of western medicine, parallels were drawn to how the official language of the state (Malayalam) had taken over tribal dialects, resulting in tribal terms being replaced with Malayalam words. Thus, the Indigenous word for mother '*avva*' was replaced by the Malayalam word '*amma*'. Using this imagery resonated with the community and led to discussions about how the neglect of healing traditions should be seen within the overall context of Indigenous ways (including language) not being valued by society. With the community of widows, before presenting results to all participants, feedback was sought from two participants to ensure that the language being used to describe findings could be understood.

With all participants, the results were used to stimulate discussion around the larger issue of access to healthcare and what it meant for them. This was done to ensure that the process of sharing of results was not monopolised by the researcher, but participants were able to discuss the significance of our results to their lives and how they could use it to address some of the gaps in their access to healthcare, the barriers that they face and how they might be addressed. This form of active engagement enriched the research in two specific ways. Firstly, it confirmed that our results captured the lived reality of the participants. Secondly, it also enabled us to jointly evolve recommendations to address the issues that had been identified.

For example, one of our findings was about the importance of decentralising the delivery of healthcare services. During our discussions, some of the widows pointed out that there was a specific aspect of decentralisation that would help them the most. Participants explained that while the neighbourhood clinics had made a difference to their ability to access healthcare services, they still had to travel great distances for diagnostics. This engagement enabled us to evolve a specific recommendation about decentralisation that was relevant to the community.

Another example was the discussions with medical officers working among the Indigenous communities. Some of them pointed out how decentralisation had several components and could be operationalised in multiple forms. As they were more aware of the prevailing policy context, they suggested that tailoring the suggestions related to policy and practice to the local policy context would give a greater chance for policy makers to act on them. Thus, among the list of suggestions we had prepared, two of the medical officers pointed out that appointing young tribal women as community health workers in the villages was not only effective to decentralise healthcare, but also more likely to be acted upon as it was in line with the thinking among policy. Such feedback helped us to tailor some of our recommendations to align with the local policy context when knowledge transfer engagements were undertaken with key policy makers.

Handling multiple viewpoints and unfavourable results

Research results often have findings that are not favourable to all stakeholders who participated. Furthermore, as research findings report multiple participant viewpoints, some stakeholders may find the dominant themes to emerge from a study are not representative of their own views. It is critical that researchers acknowledge this during knowledge transfer and also prepare to engage with participants who might feel that their views have not been adequately represented, or that views contrary to their own have been highlighted. Our study had observations about how healthcare services were planned and delivered which made it difficult for communities to access healthcare. For example, in the case of the Indigenous communities, the centralisation of healthcare was a decision that was taken by officials in the local health system in order to ensure that most of the services were provided in a secondary care hospital under the supervision of specialist doctors. However, this had the impact of excluding many of the villages who lived far away from this particular hospital. With the widows, the issue of physical infrastructure that was not elderly-friendly was pointed out by some of our participants as being a deterrent to visit the public

healthcare facilities even when they required care. We had anticipated that some of the health system participants, particularly those in charge of the local health system might be unhappy with findings that appeared critical of their service provision. We addressed this by ensuring that the language we used while describing our results did not suggest that any specific individual or institution was primarily responsible for any negative findings. For example, while discussing the issue of centralisation we allowed those who disagreed with the finding, particularly from the health service, to present their side of the story. Secondly, we were careful to communicate to all participants that our aggregated findings were meant to identify systemic issues and did not apply to one particular individual or institution.

The group discussion format that was employed to engage Indigenous participants enabled greater engagement and discussion among all those present. However, it also posed some unique challenges. For example, in one of the early village meetings, a community member objected to some of the findings that he felt portrayed the local health system in a poor light. We prepared for this by clearly communicating at the beginning of each meeting that it was fine to disagree with the results that were being shared and that everyone present had a right to discuss the results and comment on them.

Discussion And Conclusion

A rights-informed framework to sharing results

The last decade has seen a move towards ensuring that the results of scientific research are freely available for those who are interested to know more about them. However, most discussions focus on enabling the availability of research results for others in the scientific community to promote further research and knowledge sharing with academic and clinical audiences. Research that reported the sharing of results with participants primarily came from work that used community based participatory designs. But this is changing with calls to share individual results becoming pronounced in health research as well.

Our experience of sharing results with different categories of participants shows that the decision to engage participants with research results has implications across all phases of research. (See Fig. 1). Engaging participants requires researchers to undertake a host of activities from building partnerships with participants, evolving the appropriate form and template for sharing results and finally preparing and engaging participants who hold different views regarding the results as well as varying agency with the outputs of research. This means that research teams need to plan in advance and allocate adequate time and resources for these processes to be carried out. Engaging with participants during the process of sharing results using methods that promote discussion provides opportunities for discussing solutions⁽²⁷⁾. We found that this helped us to formulate recommendations that were jointly evolved with the different participants, thereby ensuring that our recommendations are grounded in the lived reality of our participants.

Most approaches to sharing research results with participants use the principles of bioethics as the beacon to guide the process. However, these approaches allow researchers the primacy in deciding whether the participants can receive results or not. While the lens of accountability does bring in the aspect of the important contribution of participants, it still focusses on the research processes and the sharing of results as an outcome of accountability to ethical and rigours research processes. Taking a rights-informed approach not only includes in its ambit the ethical and accountability arguments but acknowledges that participants have a right, by virtue of their participation which is key to the conduct of any research, to know the outcomes.

A rights-informed approach considers participants on a level plane with other stakeholders such as the researchers, institutions, funders etc. who are generally understood to have a right to research findings by virtue of their contributions to the successful conduct of research. Power imbalances in researcher-participant relations are especially strong in health research where researchers are not only considered to be the 'experts' but also tend to have special relationships with the local health system which further deepens this imbalance. A rights-informed approach addresses some of the inherent power relationships that exist between the researcher and the participants by acknowledging that participants make a significant contribution to the success of research and by virtue of this they have the right to receive results. When research participants do not have access to the results, it further adds to the distance between the research community and the participants. Consequently, research remains as something that is distant and disconnected from people's daily lives and its improvement⁽³⁵⁾. Engaging participants with results is an effective way to address this. It also helps to ensure that research participants appreciate the role and value of research in solving issues pertinent to their lives.

Traditional approaches to sharing results presumes that stakeholders such as policy makers and programme managers are the ones who have the power to act upon research findings. Dissemination of results therefore prioritises them over participants. As our experience shows, approaches that engender respect for participants and acknowledges their agency shows that even vulnerable communities are able to engage actively with research findings, add value to it, embed it into their context and add value to the overall research processes.

From our experience we believe that engaging participants with research results cannot be undertaken as an activity that is added at the end of the research cycle. It is important that researchers plan for actively engaging participants with results right from the beginning and identify and evolve the most effective mechanisms of results dissemination during the data collection phase (Refer Fig. 2). This will aid the development of clear communication plans and strategies. It is also important to plan for support options such as counselling services or follow ups with specialists in case adverse results are being communicated, particularly in health-related research.

Institutional ethics committees should engage with this issue and support researchers by drawing up guidelines that promote the active engagement of participants with research results.

Engaging participants with research results takes time and requires resources. In some cases, this includes developing outputs that will aid the process of engaging participants with results such as handouts in local languages, and locally relevant audio-visual material. Funding bodies should actively support this process by highlighting the sharing of results as a participant right; recognising the value of such engagement for the interpretation and application of findings; and finally, by ensuring that sufficient resources are available for researchers to carry out dissemination activities which are appropriate to the

participant population. It is imperative for research translation that research results do not only find their way into peer-reviewed publications, reports and policy briefs. Recognising, respecting, and valuing the rights, agency and ability of study participants to engage in the dissemination process is not optional. It is essential for bringing together the key research processes of investigation, identification, and implementation of ideas. It bridges the gap between discovery and delivery of new knowledge. In short, a rights informed approach to engaging participants with study findings is not only socially responsible and an ethical imperative, it also has implications for the influence and impact of research where it most counts - the study participants and the larger population they represent.

Abbreviations

FGD

Focus group discussion

IDI

In-depth interview

Declarations

Ethics approval and consent to participate

The Human Research Ethics Committees of the University of Canberra (20180074) and the Indian Institute of Public Health Delhi (IIPHD_IEC_03_2018) provided ethical approval for this study. Regulatory permissions were obtained from the Kerala Department of Health (GO(Rt)No2677/2018/H&FWD) the local administration in Attapadi and the District Medical Office at Kottayam. All participants gave informed consent prior to data collection.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to the danger of compromising the confidentiality and anonymity of the participants but are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests

Funding

This work was carried as part of the Ph.D. research of the first author. Field work was supported through a grant available for all Ph.D. candidates towards project expenses at the University of Canberra

Authors contributions

MSG carried out the data collection and drafted the manuscript with contributions from RG, RD, IM, and PU. MSG and PU were involved in the analysis of the data. All authors were involved in the design of the larger study from which the data for this manuscript emerged. All authors read and approved the final manuscript.

Acknowledgements

We sincerely thank all the participants of our study– the Indigenous communities in Attapadi, widows in Kottayam, the doctors, other healthcare workers and the key informants who shared their experiences with us. Many thanks go to the Department of Health, Government of Kerala and all the officials at both Attapadi and Kottayam for granting the requisite permissions to carry out this research and the support provided during the course of the study.

Author information

Affiliations

¹ Health Research Institute, Faculty of Health, University of Canberra, Bruce, ACT-2617, Australia

Mathew Sunil George, Rachel Davey, Itismita Mohanty and Penney Upton

References

1. Alliance for Health Policy and Systems Research. Strengthening health systems in developing countries: The promise of research on policy and systems. Geneva: WHO; 2004 [cited 2020 19th May]. Available from: https://www.who.int/alliance-hpsr/resources/Strengthening_complet.pdf.
2. Ferris LE, Sass-Kortsak A. Sharing research findings with research participants and communities. *Int J Occup Environ Med*. 2011;2(3):172–81.
3. Fecher B, Friesike S, Hebing M. What Drives Academic Data Sharing? *PLOS ONE*. 2015;10(2):e0118053.
4. Wellcome Trust. Open access policy 2020 [cited 2020 21st May]. Available from: <https://wellcome.ac.uk/grant-funding/guidance/open-access-guidance/open-access-policy>.
5. NHMRC. National Health and Medical Research Council Open Access Policy Canberra: National Health and Medical Research Council; 2018 [cited 2020 19th May]. Available from: https://web.archive.org/web/20180507073906/https://www.nhmrc.gov.au/_files_nhmrc/file/research/nhmrc_open_access_policy_15_january_2018_v2.pdf.
6. Australian Research Council. ARC Open Access Policy-Version 2017.1 Canberra: Australian Research Council; 2017 [cited 2020 20th May]. Available from: <https://www.arc.gov.au/policies-strategies/policy/arc-open-access-policy-version-20171>.
7. European Commission. Access to and Preservation of Scientific Information in Europe: Report on the implementation of Commission Recommendation C(2012) 4890 final. Brussels: European Commission; 201.
8. Fernandez CV, Kodish E, Weijer C. Informing study participants of research results: an ethical imperative. *IRB*. 2003;25(3):12–9.
9. Miller FA, Christensen R, Giacomini M, Robert JS. Duty to disclose what? Querying the putative obligation to return research results to participants. *J Med Ethics*. 2008;34(3):210–3.
10. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2013;310(20):2191–4.
11. Long CR, Stewart MK, McElfish PA. Health research participants are not receiving research results: a collaborative solution is needed. *Trials*. 2017;18.
12. Schroter S, Price A, Malicki M, Richards T, Clarke M. Frequency and format of clinical trial results dissemination to patients: a survey of authors of trials indexed in PubMed. *BMJ Open*. 2019;9(10):e032701.
13. Taylor J. Reporting research findings to participants is an ethical imperative. *BMJ*. 2019;367:l6324.
14. Bromley E, Mikesell L, Jones F, Khodyakov D. From subject to participant: ethics and the evolving role of community in health research. *Am J Public Health*. 2015;105(5):900–8.
15. Domecq JP, Prutsky G, Elraiyah T, Wang Z, Nabhan M, Shippee N, et al. Patient engagement in research: a systematic review. *BMC Health Services Research*. 2014;14(1):89.
16. Thompson J, Barber R, Ward PR, Boote JD, Cooper CL, Armitage CJ, et al. Health researchers' attitudes towards public involvement in health research. *Health Expect*. 2009;12(2):209–20.
17. Bishop R. Initiating empowering research. *N Z J Edu Stud*. 1994;29:175–88.
18. Wallerstein N, Duran B. The conceptual, historical, and practice roots of community based participatory research and related participatory traditions. In: Minkler M, Wallerstein N, editors. *Community Based Participatory Research for Health*. San Francisco: Jossey-Bass; 2003. pp. 27–52.
19. Rigby H, Fernandez CV. Providing research results to study participants: support versus practice of researchers presenting at the American Society of Hematology annual meeting. *Blood*. 2005;106(4):1199–202.
20. Fernandez CV, Kodish E, Taweel S, Shurin S, Weijer C, Children's Oncology G. Disclosure of the right of research participants to receive research results: an analysis of consent forms in the Children's Oncology Group. *Cancer*. 2003;97(11):2904–9.
21. Partridge AH, Hackett N, Blood E, Gelman R, Joffe S, Bauer-Wu S, et al. Oncology physician and nurse practices and attitudes regarding offering clinical trial results to study participants. *J Natl Cancer Inst*. 2004;96(8):629–32.
22. Shalowitz DI, Miller FG. The search for clarity in communicating research results to study participants. *J Med Ethics*. 2008;34(9):e17.
23. Shaul RZ, Reid L, Essue B, Gibson J, Marzinotto V, Daneman D. DISSEMINATION TO RESEARCH SUBJECTS: OPERATIONALIZING INVESTIGATOR ACCOUNTABILITY. *Accountability in Research*. 2005;12(1):1–16.
24. Markman M. Providing research participants with findings from completed cancer-related clinical trials: not quite as simple as it sounds. *Cancer*. 2006;106(7):1421–4.
25. Dixon-Woods M, Jackson C, Windridge KC, Kenyon S. Receiving a summary of the results of a trial: qualitative study of participants' views. *BMJ*. 2006;332(7535):206–10.
26. Adam T, Hsu J, de Savigny D, Lavis JN, Rottingen JA, Bennett S. Evaluating health systems strengthening interventions in low-income and middle-income countries: are we asking the right questions? *Health Policy Plan*. 2012;27(Suppl 4):iv9–19.

27. Morello-Frosch R, Brody JG, Brown P, Altman RG, Rudel RA, Perez C. Toxic ignorance and right-to-know in biomonitoring results communication: a survey of scientists and study participants. *Environ Health*. 2009;8:6.
28. Shalowitz DI, Miller FG. Disclosing individual results of clinical research: implications of respect for participants. *JAMA*. 2005;294(6):737–40.
29. Morello-Frosch R, Pastor M, Sadd J, Prichard M, Matsuoka M. Citizens, science and data judo: leveraging secondary data analysis to build a community-academic collaborative for environmental justice in Southern California. *Methods for Community-Based Participatory Research for Health*. 2012:547–80.
30. Jeng W, He D, Oh JS. Toward a conceptual framework for data sharing practices in social sciences: A profile approach. *Proceedings of the Association for Information Science and Technology*. 2016;53(1):1–10.
31. George MS, Davey R, Mohanty I, Upton P. "Everything is provided free, but they are still hesitant to access healthcare services": why does the indigenous community in Attapadi, Kerala continue to experience poor access to healthcare? *International Journal for Equity in Health*. 2020;19(1):105.
32. Hernick AD, Brown MK, Pinney SM, Biro FM, Ball KM, Bornschein RL. Sharing unexpected biomarker results with study participants. *Environ Health Perspect*. 2011;119(1):1–5.
33. Hoare KJ, Buetow S, Francis K, Mills J. Using an emic and ethnographic technique in a grounded theory study of information use by practice nurses in New Zealand. *Journal of Research in Nursing*. 2012a;18(8):720–31.
34. Quandt SA, Doran AM, Rao P, Hoppin JA, Snively BM, Arcury TA. Reporting pesticide assessment results to farmworker families: development, implementation, and evaluation of a risk communication strategy. *Environ Health Perspect*. 2004;112(5):636–42.
35. Wells K, Jones L. "Research" in community-partnered, participatory research. *JAMA*. 2009;302(3):320–1.

Table

Section and topic	Item	Reported on page no
Aim	Report the aim of PPI in the study	9
Methods	Provide a clear description of the methods used for PPI in the study	9–11
Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	11–18
Discussion & conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	19–22
Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well	22

Figures

Research Design

- 1. Incorporate sharing results into the research timeline
- 2. Craft an initial plan for how results will be shared
- 3. Budget for adequate resources

Data collection

- 1. Build relationships with participants that are devoid of power imbalances
- 2. Identify most appropriate format for engaging participants with results

Dissemination

- 1. Produce outputs (results) most suited to engaging participants
- 2. Identify most appropriate format for engaging participants with results
- 3. Plan for negative results and how they will be handled
- 4. Engage with queries and clarify doubts

Figure 1

Phases of research and activities to engage participants with results

Researchers	<ul style="list-style-type: none">1. Integrate engaging participants with results into the research protocol2. Engage with communities to identify most appropriate forms of communicating results3. Develop and test a clear communication plan to implement when engaging with participants4. Plan for follow up and support options especially in the case of adverse results that are shared
Ethics Committees	<ul style="list-style-type: none">1. Encourage research proposals to include explicit details on engaging participants with results in ethics applications2. Develop guidelines on engaging with participants and on handling adverse results and providing support options especially in the case of medical and health research
Funders	<ul style="list-style-type: none">1. Provide resources earmarked to support the engagement of researchers with participants including the development of outputs that would support greater engagement of participants with results.

Figure 2

Implications of engaging research participants with results.