Return of aggregate results to study participants: Facilitators, barriers, and recommendations

Gina M. Sgro [a,*], Maureen Maurer [b], Beth Nguyen [c], Joanna E. Siegel [c]

[a] *American Institutes for Research, Atlanta, GA, USA*
[b] *American Institutes for Research, Chapel Hill, NC, USA*
[c] *Patient-Centered Outcomes Research Institute, Washington D.C., USA*

ARTICLE INFO

ABSTRACT

Background: Most researchers and study participants believe that the summary, or aggregate, results of health research should be returned to study participants. However, researchers often do not return aggregate results. A better understanding of the impediments to results return could support improvements in this practice.

Methods: This qualitative study convened eight virtual focus groups, four with investigators and four with patient partners from research studies funded by the Patient-Centered Outcomes Research Institute (PCORI). In total, 23 investigators and 20 partners participated. We explored perspectives, experiences, influences, and recommendations related to aggregate results return.

Results: Focus group participants described the ethical importance of returning aggregate results, as well as the benefits to study participants. They also noted important impediments to results return, emphasizing IRB and logistical challenges and describing a lack of support for the practice both on the part of institutions and the field at large. Participants highlighted the value of patients and caregivers' perspectives and contributions to results return, which focused on returning the most relevant findings through effective channels and formats. They further emphasized the importance of planning and identified resources that could support results return.

Conclusion: Researchers, funders, and the field can better facilitate results return by promoting standardized processes in research, such as the earmarking of funds for results return and inclusion of results returns milestones in research plans. More intentional policies, infrastructures, and resources that support results return may lead to more widespread return of study results to those who make these studies possible.

1. Introduction

As patient-centeredness has become more of a priority in health care, so has making the results of health research understandable, useable, and available to lay audiences [1]. These efforts include those to actively disseminate relevant evidence to clinicians, patients, and others who can use them to inform health care decisions. But they also include the immediate imperative of returning plain language results directly to research participants, a practice that the field at large has yet to fully embrace.

Most researchers and health research participants believe that the summary, or aggregate, results of health research should be returned to study participants. Researchers largely support the practice, viewing it as an ethical responsibility and an important part of conducting research [2,3]. Similarly, the majority of health research participants want to receive aggregate results, regardless of whether the intervention or treatment studied was beneficial, to understand any clinical implications and inform future health decisions and behavior [4–9]. Despite this support, researchers often do not return aggregate results to research participants, even when they initially intend to do so [2,3,10,11]. Getz and Farides-Mitchell [12] estimated that only 2% of global clinical trials completed or terminated between 2015 and 2017 had returned plain language results to study participants by 2018. Furthermore, researchers often lack formal or specific plans for results return, regardless of their intentions or support for the practice [3,13].

A number of factors appear responsible for the shortfall in results return activity. Some researchers cite barriers, such as financial or logistical obstacles and Institutional Review Board (IRB)-related policies [11,14]. In addition, researchers in some studies expressed concerns about participants' health literacy and the potential for results to cause

emotional harm [9,11,14–16].

The practice of returning aggregate results to study participants has gained the support of some funding agencies, including the National Institutes of Health and the Patient-Centered Outcomes Research Institute (PCORI). Authorized by Congress in 2010, PCORI funds comparative effectiveness research, including randomized controlled trials (RCTs), observational studies, and other research [17], and views patients—people with an illness or injury or the caregiver or family member of such person—and other healthcare stakeholders as equitable partners whose lived experience and expertise influences the design and conduct of research to be more patient centered, relevant, and useful [18]. Consistent with this perspective, PCORI has, since its inception, been committed to supporting awardees in returning the aggregate results of their studies to study participants and has continued to build on initial efforts to support this practice.

While some PCORI awardees have returned results for their PCORI-funded research or previous studies, others have not or are just beginning the process. To support continued progress among awardees and inform the field, PCORI undertook a qualitative study to better understand awardees' perspectives and experiences with aggregate results return, factors that influence the return of results to study participants, and the supports that may further facilitate results return.

This article summarizes findings from focus groups with PCORI investigators (principal investigators [PIs] or researchers designated by PIs), who intended to or had already returned aggregate results, and patient and caregiver partners who contributed to the design and conduct of PCORI-funded studies (hereafter patient partners).

Our research questions were: (1) What processes and strategies do study teams use or plan to use when returning aggregate research results to study participants? (2) What are the facilitators and challenges to returning aggregate research results to study participants?

2. Methods

We designed a qualitative study consisting of eight virtual focus groups to explore PCORI investigators and patient partners' experiences, perspectives, and considerations related to results return. To facilitate virtual engagement and participants' comfort speaking freely, we limited focus group size to six participants and segmented by audience. We conducted four investigator focus groups in June 2021, followed by four focus groups with patient partners in October and November 2021 to capture a range of perspectives and common themes within and across audiences. The American Institutes for Research's IRB (IRB00000436) reviewed all study materials.

2.1. Sampling and recruitment

2.1.1. Investigators

The investigator sampling frame consisted of PCORI-funded study PIs who submitted a draft final research report (DFRR) to PCORI in the 30 months prior to recruitment. We excluded studies that did not support results return (e.g., methods studies, secondary analyses). To ensure representation from recently completed projects, we recruited PIs who submitted their DFRRs within the past 21 months first, followed a week later by those who submitted their DFRRs 22–30 months prior. Recruitment emails contained a link to an online form where investigators indicated their results return intentions, stage, and plans, as well as their focus group availability. Investigators later completed an online demographic form.

Eligible investigators included a PI or researcher on the study who intended to return results to study participants, regardless of whether they succeeded. We limited participation to one investigator per study. Each focus group included at least one investigator in each stage of the results return process—interested, plan developed, currently working on, or finished returning results.

2.1.2. Patient partners

For the patient partner focus groups, we updated the sampling frame to reflect studies with a DFRR submitted in the 30 months prior to partner recruitment. All other project characteristics remained consistent. We did not exclude studies for which an investigator participated in the focus groups.

We asked PIs to recruit the patient partners who worked with their research teams. We contacted PIs who submitted a DFRR within the past 21 months first, followed a week later by those with a DFRR submitted within the past 22–30 months. The emails to PIs described the purpose of the partner focus groups, requested recruitment assistance, and contained draft email language and a flyer with study infromation to share with partners. The flyer also contained a link to an online form where interested partners reported their contact information, demographic characteristics, involvement in the results return process, and availability for the focus groups. All partners who signed up could participate in the focus groups, including partners from the same study.

2.2. Data collection and analysis

2.2.1. Online form

We programmed the online forms and investigator demographic survey in Airtable, a cloud-based platform. An analyst conducted descriptive analyses in Excel.

2.2.2. Focus groups

The study lead (GS) moderated all eight focus groups virtually via Zoom. The 60-min focus groups were recorded and transcribed, and participants received an honorarium for their time. Prior to each session, the moderator explained the concept of aggregate results return to facilitate the discussion.

The study lead developed deductive codebooks based on the focus group topics (see supplemental materials) and trained an analyst to code the transcripts in NVivo 12.0 software (QSR International). The study lead reviewed the coded transcripts and met regularly with the analyst to discuss the coding and emerging themes. The study lead completed a thematic analysis of the output, summarized findings by audience, and worked with the full team (MM, JS, BN) to identify and finalize emergent themes across audiences.

3. Results

In total, 23 investigators and 20 patient partners participated in the focus groups. We contacted 95 PIs for the investigator focus groups and received online forms from 24 investigators. We later invited 108 PIs to recruit patient partners for focus groups and received online forms from 24 partners. The focus groups ranged in size, with 5–6 investigators per group and 3–5 partners per group.

Each investigator represented a different study; partners represented 12 different studies. Across both audiences, 31 studies were unique. For four studies, both an investigator and a patient partner participated in the focus groups. For five studies, 2–4 partners from the study participated. Study characteristics included 25 RCTs and 6 observational studies funded under four PCORI priority content areas (Exhibit 1).

Exhibit 2 shows the demographic characteristics of the participant study sample. Of investigators, 17 were PIs and 6 were researchers designated by their study PIs. Across both audiences, a majority of participants were non-Hispanic White (76% of investigators and 70% of patient partners) and had high levels of education, with most attaining a bachelor's degree or higher.

3.1. Reasons for results return

3.1.1. Ethical and moral responsibility

Investigators expressed an ethical and moral responsibility for returning results, noting that study participants deserved to receive the

Exhibit 1

PCORI-funded study characteristics.

Characteristic	Number of studies (N = 31)
Participation	
Investigator only	19
Patient partner(s) only	8
An investigator and a patient partner	4
Study design	
RCT	25
Observational	6
PCORI priority content areas	
Assessment of prevention, diagnosis, and treatment options	12
Addressing disparities	8
Improving healthcare systems	7
Communication and dissemination research	4

Exhibit 2

Participant demographic characteristics.

Demographic	Investigators (n = 21)[a]	Patient partners (N = 20)
Gender		
Female	15 (71%)	11 (55%)
Male	4 (19%)	9 (45%)
Race		
Asian or Asian American	0	0
Black or African American	1 (5%)	4 (20%)
American Indian/Alaska Native	0	1 (5%)
Native Hawaiian/Other Pacific Islander	0	1 (5%)
White	16 (76%)	14 (70%)
Self-reported as multiracial	1 (5%)	0
Self-reported as another race	1 (5%)	0
Ethnicity		
Hispanic	0	1 (5%)
Education Level		
High School/GED or Associate degree	0	0
Some college	0	3 (15%)
Bachelor's degree	1 (5%)	8 (40%)
Master's degree	4 (19%)	5 (25%)
Professional degree	14 (67%)	4 (20%)

[a] Two investigators did not provide demographic information.

results since their contributions made the research possible. An investigator explained, "You have an ethical obligation to share with your participants and the rest of the world … what you found through their participation." Patient partners concurred. One partner commented, "People have a right to know the outcome of whatever it is they participated in, especially if they donated their time and their energy for very little or no compensation."

3.1.2. Valuing contributions of study participants

Investigators and patient partners acknowledged the importance of valuing the contributions of study participants. Investigators described the need to honor participants' contributions throughout the research, noting that returning results showed participants their importance. One investigator explained that participants wanted "to know that they had made a difference that was going to … help somebody else."

Patient partners emphasized that returning results made participants feel valued and accomplished and confirmed that their contributions mattered. One partner expressed, "Just seeing the results lets me know that I've accomplished something." Partners further conveyed that not receiving results as participants in previous studies had the opposite effect. A partner elaborated, "You might have participated for a whole year … and then you don't hear anything. You begin to wonder, 'Was it worth it? Why did I even do this?'"

3.1.3. Transparency and trust in research process

Patient partners reported that returning results provided accountability, transparency, and validation of the research process. One partner noted that receiving results confirmed that researchers "did what they said they were going to do." Further, partners conveyed that returning results, regardless of intervention or treatment effectiveness, was equitable, helped to build trust, and encouraged future participation in research. This was particularly important when the study involved populations that were hesitant about research or the medical system. A partner explained, "That's an equitable thing, that you need to understand where things went, especially if the research outcome wasn't what maybe you had expected it to be … transparency is incredibly important to build trust in that process."

Similarly, investigators reported that participants appreciated receiving results regardless of the research outcome. An investigator relayed, "We always felt [concerned] showing them this data that did not look promising … but they felt very different."

3.1.4. Information for decision making

Partners noted that results return provided study participants with information that could inform their health-related decisions and behaviors. Two partners explained, "Suppose there were these three treatments … had I known the results, maybe they would've impacted my choice," and "people could use that information to create lifestyle change." An investigator reinforced this point, noting "What we do is try to help people. If they don't know about it, then it's not helping them very much."

3.2. Experiences with results return

3.2.1. Status of results return

In the online form, all investigators reported intending to or having already returned results for their PCORI-funded studies (Exhibit 3). Those who had not yet returned results reported being interested in (17%), having a plan (17%), or working on results return (22%), while 52% had already returned results. Two investigators selected more than one response, indicating that they were returning results after different phases of the project.

Most partners reported involvement in the results return process (65%) in the online form. However, at the beginning of the focus groups, some partners had difficulty differentiating between aggregate results return and dissemination of findings, so it is unclear whether this result is accurate.

3.2.2. Products and channels

Through the online form, investigators reported on their planned or actual formats and channels for returning aggregate results (Exhibit 4). Most often, investigators planned or had already returned PCORI-prepared lay language summaries (44%), infographics/pictographs (39%), and newsletters (39%) to study participants. They also most often planned or had already returned results via email or other electronic delivery (44%) and through study websites/portals (35%).

Exhibit 3

Investigators' intentions and stage of results return for PCORI studies.

Intention/Stage of Aggregate Results Return	Investigators (N = 23)[a]
Interested but plan not developed	4 (17%)
Plan developed but process not started	4 (17%)
Currently working on returning results	5 (22%)
Finished returning results to study participants	12 (52%)

[a] Two investigators selected more than one response.

Exhibit 4
Investigator-reported formats and channels for results return.

Format/Channel	Investigators (N = 23)
Format Planned or Used for Returning Results	
Lay language summary (prepared by PCORI[a])	10 (44%)
Infographic or pictograph	9 (39%)
Newsletter	9 (39%)
Factsheet or brief	6 (26%)
Scientific publication	6 (26%)
Video	2 (9%)
Mobile app	1 (4%)
Letter	1 (4%)
Presentation	1 (4%)
Not yet decided	1 (4%)
Channel Planned or Used to Return Results	
Email or other electronic delivery	10 (44%)
Study website or portal	8 (35%)
In-person meeting or town hall	6 (26%)
Study social media site	4 (17%)
Webinar	3 (13%)
Community flyer	1 (4%)
Translation projects	1 (4%)
Organization's communication channels	1 (4%)

[a] PCORI prepares a lay language summary describing findings from each funded research study and posts this summary to the PCORI website shortly after study completion. In many cases, research teams planned to or had distributed this summary to their study participants for purposes of results return.

3.3. Patient partners' and other stakeholders' contributions to the results return process

Investigators reported engaging patient partners, community members, and other stakeholders—established advisory panels, trusted community organizations, providers, and health system stakeholders—in aspects of the results return process. One investigator offered, "We have patients and caregivers who are continually involved in all aspects of the study … then we have a larger group that we go out to for greater diversity of opinions."

Investigators credited patient partners with proposing ideas for results return that resonated with study participants, offering guidance on which results to return, influencing the format and channels for returning results, and providing insight into language acceptable to study participants. An investigator commented, "While we basically understood what results people needed to hear … caregiver partners made it very clear … how to present results so that they would be most accessible and useful to the people who were going to receive them."

Patient partners noted that people with lived experience brought a different perspective to the research, understood what information was important to return, and knew how best to translate and communicate the information. For example, one partner reported asking a group of researchers, "Has anybody here had part of *your* brain removed?" Another partner explained, "Our study was based on interpersonal violence … the patient leadership team were all survivors of interpersonal violence, and the researchers were not. Our perspective was valuable."

Investigators acknowledged that they sometimes had difficulty paring down results for participants and that, at times, the feedback they received from patient partners was humbling. One investigator relayed, "It was really important for us to not be in our ivory tower as researchers and say, 'Well, this is what we think it should look like.'" Another investigator offered, "As researchers, we're very programmed to 'What is your primary outcome? What is your effect size?' Having community … and parent advisors as part of the process helps us strip down some of that."

3.4. Considerations for reporting results to lay audiences

3.4.1. Focus on meaningful results

Partners emphasized that the results returned should be meaningful to study participants. One partner conceded, "Some of the information that came out of the study excited our researchers and our doctors, but it wasn't really important to us." Partners also recommended including a reminder of the study purpose, highlighting key findings, and explaining next steps in the results returned to participants. A partner elaborated, "What are the key successes, key failures? What's working? What's not working? How they're going to move forward or not."

3.4.2. Use plain language and simple formats

Investigators reported returning plain language results, often seeking feedback from patient partners or consulting the literature to identify acceptable language. Partners similarly conveyed the need for investigators to translate scientific language into plain language, limit the use of abbreviations, define abbreviations and technical terms when used, and avoid "talking down" to study participants. A partner elaborated, "If the results were originally written for submission to a journal or another academic outlet, those are not the same people that are in your study. So, translate that for the people who are participating."

Investigators and partners also emphasized sharing results in simple and concise formats, with partners recommending newsletters, videos, presentations, social media, emails, and educational materials as potential options. An investigator offered, "We try very hard to make the graphics simplified, intuitive, and visually appealing for the study participants."

3.4.3. Tailor communication channels

Investigators and partners alike discussed tailoring communication channels to the study population's preferences and characteristics. Investigators reported tailoring communication channels based on participants' ages, race, cultures, and languages; this included mailing results to older participants and using email and social media platforms (e.g., YouTube, Facebook) to return results to younger participants. One investigator explained, "Facebook Live, which I would never imagine would have been successful, has been wildly successful in being able to give some of our results back."

Partners concurred that preferences may vary by participants' ages, as well as socioeconomic status and living situations. A partner commented, "Suppose it's a study that dealt with 18- to 24-year-olds. That might need a different response than if you're doing a study that was from [ages] 50 to 65." Another partner offered, "Some people may not have access to electronics or may be homeless." Given this, partners suggested asking participants early on for their communication preferences to help ensure results are received.

3.5. Facilitators

3.5.1. Plan ahead for results return

Investigators emphasized that planning for results return from the beginning of a study was critical to success. They mentioned the need to budget accordingly and obtain IRB approval up front to contact participants for results return, cautioning that not planning ahead could be expensive, time consuming, and make results return infeasible.

To achieve results return, some investigators reported embedding the process into their study milestones and dissemination plans. An investigator explained, "Since returning results was built into the milestones, it made it much easier to just do it as opposed to not do it." Investigators also noted that planning for results return from the beginning enabled them to incorporate the valuable perspectives of patient partners and community members into the process. An investigator acknowledged, "You learn so much more by involving patient advocates in those sorts of activities from the very beginning."

3.5.2. Maintain communication with study participants

Investigators found that maintaining updated contact information for study participants both facilitated results return and increased the likelihood that the results would reach participants. In addition, sending periodic communications helped to provide context for results returned years after participation and informed investigators when contact information was no longer valid. An investigator elaborated, "We stayed in contact with our participants on a regular basis, sent birthday cards, sent quarterly newsletters, and had contests in a newsletter … We only had eight returns of our final newsletter with the [study] results …"

3.5.3. Engage patient partners and other stakeholders

Investigators described the contributions of patient partners, community members, and local trusted organizations as both valuable and a facilitator to results return. An investigator explained, "Patient representatives … had a point of view that was unique, and they would sometimes see things the rest of [us] would never have thought of."

Seeking the input of these groups also was important when working with populations from other cultures and those hesitant about research or the medical field. One investigator explained, "Families needed to hear from other parents. Having the parents involved really gave credibility."

3.6. Challenges to results return

3.6.1. Timing of results return and lack of study resources

When asked about challenges, investigators noted the timing of results return, which occurs after a study has ended. At that point, if funds have not been specifically earmarked for results return, additional funds may not be available. Further, after a study has ended, investigators often move on to other projects. An investigator summarized, "waiting until the end of the project, sometimes teams … break up and you don't have the resources that you had while the project was ongoing."

3.6.2. System and publication barriers

Another challenge was the lack of institutional support to return results to lay audiences, particularly in contrast to the emphasis on publishing results in scientific journals. Investigators reported that academic institutions had infrastructures in place to incentivize and support scientific publications but lacked similar infrastructure and supports for results return to study participants. One investigator commented, "We're rewarded and incentivized for peer reviewed journal articles." Further, investigators reportedly often lack the knowledge, skills, and resources to translate and graphically depict results for lay audiences. Given these barriers, investigators noted that results return often required a personal commitment. One investigator stated, "It's really out of your heart that you're going all the way to the end and not so much that the system encourages you to do it."

Investigators believed that it was important to wait to return results until after their studies had undergone peer review to ensure the results are "correct and final." However, they also described delays in peer review by journals, embargos on information sharing, and reticence among researchers to distribute unpublished results as barriers to results return. An investigator explained, "If you return [results] to patients and somehow the media picks it up, journals may not be as interested."

3.6.3. Not obtaining IRB approval early on

Investigators reported that another barrier was not obtaining IRB approval early on to contact participants to return results, including through multiple communication channels. Further, some investigators expressed hesitancy about modifying their IRB applications if they did not obtain approval to contact participants initially. An investigator noted, "Anytime we talked about touching the IRB approval, we … almost saw it as a third rail."

3.7. Support needed

Investigators identified supports that would help facilitate results return, particularly when researchers lacked knowledge, skills, and resources to translate and visually display results for lay audiences. These supports included receiving training in or assistance with plain language translation and data visualization, best practice guidelines for effective results return strategies and channels, and examples of successful results return products.

4. Discussion

Findings from this study provide new insights into facilitators and challenges to results return, supports needed to facilitate the process, and recommendations for successful results return from the perspectives of investigators and patient partners engaged in patient-centered research. They also extend the research on preferences and important considerations for aggregate results return [4,5].

In this study as in others [3,6,7,9,10], investigators cited ethical and moral motives for wanting to return aggregate results to study participants and reported using similar products and channels to return results. Patient partners' perspectives in this study underscored investigators' views, emphasizing that participants have a right to receive aggregate study results and adding that returning results regardless of the study outcome encourages trust in researchers and future research participation and potentially informs health decisions. Unlike other studies [9, 14–16], investigators did not express concerns about patients' health literacy or the potential for results to do harm. Rather, they emphasized, and patient partners reiterated, important strategies for results return, including using plain language, simple and concise formats, and channels tailored to the audience.

Investigators in this study perceived a number of impediments to results return, including not obtaining IRB approval to recontact participants, logistical (e.g., cost, timing) challenges, and the lack of incentives for aggregate results return [3,11]. They also noted that results return typically occurs at a time when funding may be depleted and research teams are no longer working together and further acknowledged lacking the skills to translate results into plain language and simple formats. As a result, researchers operating outside of a dedicated infrastructure for returning aggregate results may find themselves without the knowledge, skillsets, and supports necessary to translate results for the lay public or to return results effectively and consistently.

The field at large would benefit from further consideration of how to establish results return as a standard practice. To help address the disconnect between results return intentions and practice, funders and academic institutions may consider putting policies, structures (e.g., incentives), and resources into place that prioritize, promote, and support researchers in returning results and help to standardize the practice. Establishing results return as a project expectation may encourage researchers to plan ahead by building the process into project milestones and obtaining appropriate IRB approvals up front, thereby avoiding common barriers to the practice. Maintaining updated contact information and periodically communicating with study participants also may facilitate results return.

Incentivizing and supporting results return beyond the study period may help researchers return results after the study has ended, including in cases where there are delays in peer review and publication or journal embargo periods. For example, funders could support activities related to results return (e.g., drafting results, seeking input from partners, deciding format and channel) within the study period even if results return will not occur until later. Or funders could develop mechanisms to support results return activities after the closeout of a research grant or contract.

Funders may also consider earmarking funds for results return and providing researchers with capacity-building supports to facilitate results return. These might include training, consultation, or assistance

with plain language translation and data visualization; best practice guidance documents; or examples of result return products that demonstrate how to present data for different audiences.

Finally, this study highlights the contributions and value of collaborating with patients, caregivers, community members, and other stakeholders to develop strategies for returning results in ways that are meaningful to study participants. Researchers can benefit from recognizing the unique perspectives, expertise, and insights patients and caregivers can offer to the results return process that researchers might not otherwise recognize or consider. These may include perspectives on results of interest, as well as insights into language, formats, and communication channels that will resonate with participants.

4.1. Limitations

We conducted eight focus groups with 43 investigators and patient partners from 31 PCORI-funded studies; findings may not be fully generalizable. In particular, investigators' views do not reflect those who do not explicitly intend to undertake results return. In addition, investigators and patients and caregivers not associated with PCORI may have different perspectives on facilitators and supports needed to accomplish results return. Even with these limitations, the diversity of investigators' experiences and backgrounds in this study suggest that findings are transferable outside of PCORI.

4.2. Future research

Future research could assess the adoption and success of policies and practices by academic institutions and funders to support and promote results return, as well as explore strategies for returning results for different study types. In addition, future studies could assess study participants' comprehension, perceptions, and preferences related to aggregate results returned from health research to better understand how well the language, formats, and channels resonate. Findings could then inform the development of guidelines, trainings, and tools for broad dissemination that will help to standardize and continuously improve the practice.

Funding

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The authors do not have permission to share data.

Acknowledgements

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2023.101136.

References

[1] PCORI, Reporting of research results to study participants. https://www.pcori.org/impact/putting-evidence-work/reporting-research-results-study-participants, 2020. (Accessed 6 January 2023).

[2] C. Heaney, G. Tindall, J. Lucas, S.B. Haga, Researcher practices on returning genetic research results, Genet. Test. Mol. Biomarkers 14 (6) (2010) 821–827, https://doi.org/10.1089/gtmb.2010.0066.

[3] C. Long, R. Purvis, E. Flood-Grady, et al., Health researchers' experiences, perceptions, and barriers related to sharing study results with participants, Health Res. Pol. Syst. 17 (25) (2019), https://doi.org/10.1186/s12961-019-0422-5.

[4] H. Bruhn, M. Campbell, V. Entwistle, et al., What, how, when and who of trial results summaries for trial participants: stakeholder-informed guidance from the RECAP project, BMJ Open 12 (2022), e067019, https://doi.org/10.1136/bmjopen-057019.

[5] C.R. Long, M.K. Stewart, T.V. Cunningham, T.S. Warmack, P.A. McElfish, Health research participants' preferences for receiving research results, Clin. Trials 13 (6) (2016) 582–591, https://doi.org/10.1177/1740774516665598.

[6] P.A. McElfish, R.S. Purvis, A.J. Scott, L.K. Haggard-Duff, S. Riklon, C.R. Long, "The results are encouragements to make positive changes to be healthier:" qualitative evaluation of Marshallese participants' perceptions when receiving study results in a randomized control trial, Contemp, Clin. Trials Commun. 17 (2020), 100543, https://doi.org/10.1016/j.conctc.2020.100543.

[7] A.H. Partridge, N. Hackett, E. Blood, et al., Oncology physician and nurse practices and attitudes regarding offering clinical trial results to study participants, J. Natl. Cancer Inst. 96 (8) (2004) 629–632, https://doi.org/10.1093/jnci/djh096.

[8] R. Purvis, T. Abraham, C. Long, M. Stewart, T. Warmack, P. McElfish, Qualitative study of participants' perceptions and preferences regarding research dissemination, Am. J. Bioeth. 8 (2) (2017) 69–74, https://doi.org/10.1080/23294515.2017.1310146.

[9] D.I. Shalowitz, F.G. Miller, Communicating the results of clinical research to participants: attitudes, practices, and future directions, PLoS Med. 5 (5) (2008) e91, https://doi.org/10.1182/blood-2005-02-0556.

[10] M.Z. Raza, H. Bruhn, K. Gillies, Dissemination of trial results to participants in phase II pragmatic clinical trials: an audit of trial investigators intentions, BMJ Open (2020), 10e035730, https://doi.org/10.1136/bmjopen-2019-035730.

[11] S. Schroter, A. Price, M. Malički, T. Richards, M. Clarke, Frequency and format of clinical trial results dissemination to patients: a survey of authors of trials indexed in PubMed, BMJ Open 9 (2019), e032701, https://doi.org/10.1136/bmjopen-2019-032701.

[12] K. Getz, J. Farides-Mitchell, Assessing the adoption of clinical trial results summary disclosure to patients and the public, Expet Rev. Clin. Pharmacol. 12 (7) (2019) 573–578, https://doi.org/10.1080/17512433.2019.1615441.

[13] H. Rigby, C.V. Fernandez, Providing research results to study participants: support versus practice of researchers presenting at the American Society of Hematology annual meeting, Blood 106 (4) (2005) 1199–1202, https://doi.org/10.1182/blood-2005-02-0556.

[14] F.A. Miller, R.Z. Hayeems, L. Li, J.P. Bytautas, What does 'respect for persons' require? Attitudes and reported practices of genetics researchers in informing research participants about research, J. Med. Ethics 38 (1) (2012) 48–52, https://doi.org/10.1136/jme.2010.041350.

[15] C.R. Long, M.K. Stewart, P.A. McElfish, Health research participants are not receiving research results: a collaborative solution is needed, Trials 18 (1) (2017) 449, https://doi.org/10.1186/s13063-017-2200-4.

[16] R.S. Purvis, C.R. Long, L.R. Eisenberg, et al., First do no harm: ethnical concerns of health researchers that discourage the sharing of results with research participants, AJOB Empir. Bioth. 11 (2) (2020) 104–113, https://doi.org/10.1080/23294515.2020.1737980.

[17] PCORI, Research we support. https://www.pcori.org/research/about-our-research/research-we-support, 2021. (Accessed 17 February 2022).

[18] PCORI, The value of engagement. https://www.pcori.org/engagement/value-engagement, 2018. (Accessed 10 January 2022).