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Frequency and format of clinical trial results dissemination to patients: a survey of authors of trials indexed in PubMed

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ABSTRACT

Objective Dissemination of research findings is central to research integrity and promoting discussion of new knowledge and its potential for translation into practice and policy. We investigated the frequency and format of dissemination to trial participants and patient groups.

Design Survey of authors of clinical trials indexed in PubMed in 2014–2015.

Results Questionnaire emailed to 19 321 authors; 3127 responses received (16%). Of these 3127 trials, 2690 had human participants and 1818 enrolled individual patients. Among the 1818, 498 authors (27%) reported having disseminated results to participants, 238 (13%) planned to do so, 600 (33%) did not plan to, 176 (10%) were unsure and 306 (17%) indicated 'other' or did not answer. Of the 498 authors who had disseminated, 198 (40%) shared academic reports, 252 (51%) shared lay reports, 111 (22%) shared both and 164 (33%) provided individualised study results. Of the 1818 trials, 577 authors (32%) shared/planned to share results with patients outside their trial by direct contact with charities/patient groups, 401 (22%) via patient communities, 845 (46%) via presentations at conferences with patient representation, 494 (27%) via mainstream media and 708 (39%) by online lay summaries. Relatively few of the 1818 authors reported dissemination was suggested by institutional bodies: 314 (17%) of funders reportedly suggested dissemination to trial participants, 252 (14%) to patient groups; 333 (18%) of ethical review boards reportedly suggested dissemination to trial participants, 148 (8%) to patient groups. Authors described many barriers to dissemination.

Conclusion Fewer than half the respondents had disseminated to participants (or planned to) and only half of those who had disseminated shared lay reports. Motivation to disseminate results to participants appears to arise within research teams rather than being incentivised by institutional bodies. Multiple factors need to be considered and various steps taken to facilitate wide dissemination of research to participants.

Strengths and limitations of this study

- ► Largest survey of current dissemination practices of authors of biomedical research.
- ► Describes frequency and format of what was disseminated.
- ► A survey can only report what authors said they did, not what they actually did in practice.

INTRODUCTION

Dissemination of research findings is central to research integrity and supports the translation of new knowledge into policy and practice. Dissemination is the process by which findings are communicated to target audiences, including policy makers, academics, health professionals, patients, the public, and research funders. Dissemination is considered to be a shared responsibility between funders and researchers but there is variation in expectations and practice.[1 2] Traditionally, dissemination has targeted health professionals, policy makers and academics through journal publications and presentations at conferences.[3] Researchers are encouraged and motivated to publish and disseminate to their peers to advance their careers[4] and to satisfy processes such as the Research Excellence Framework in the UK (www.ref.ac.uk). There are no such strong motives to drive dissemination to patient participants or communities of patients to whom the findings might be relevant.

Dissemination to participants has attracted debate and many agree it is an ethical imperative and essential marker of respect to people who participate in research studies, which often place a high burden on their time and energy.[5–8] Furthermore, the Declaration of Helsinki, the set of ethical principles regarding human experimentation developed by the World Medical Association states that "a*ll medical research subjects should be given the option of being informed about the general outcome and results of the study*".[9] Regulatory authorities have recently stipulated that results of clinical trials must be published in

open-access databases[10] and recommendations for sharing individual research data have also been made[11] although these have different ethical and practical implications to the dissemination of a study's aggregated results.[12 13] Some funders, including the Patient-Centered Outcomes Research Institute in the USA and the National Institute for Health Research (NIHR) in the UK, ask researchers to share results with study participants, but there is debate on what dissemination to patients means and how best to do it.[14–16]

The frequency with which results are shared with participants has been investigated[6 17–20] but routine practice in this respect is not known. Nor is whether results are shared in an easy to read format, despite participants' interest to read them and researchers' willingness to share them.[12 21 22] This paper reports a large survey of researchers from a wide range of clinical specialties about a specific clinical trial they had recently published, to determine the frequency and format of dissemination to trial participants and wider patient communities, and to explore barriers to doing so.

METHODS

Questionnaire development and administration

Development and pretesting

The survey (online supplementary appendix 1) was developed by the authors, piloted with 10 researchers to check for ambiguous questions and that the skip format was appropriate, and revised as necessary.

Patient and public involvement

Two members of the research team are patients living with long-term medical conditions. All members of the research team and one of *The BMJ's* former patient editors helped develop the questionnaire, which was reviewed by two members of *The BMJ's* international patient advisory panel; who also commented on the draft manuscript.

Survey administration

Identified authors (see below) were sent an invitation to complete the survey by email on 24 January 2016 using SurveyMonkey. The email offered entry into a prize draw for an Amazon voucher. Reminder emails were sent to non-respondents two and 4 weeks following the initial invitation. Completion of the survey was taken to indicate consent to participate. Authors could choose not to take part and were notified that they were free to stop and withdraw at any time.

Sampling and search strategy

The targeted sample was authors of clinical trials published in 2014 or 2015 in journals indexed in PubMed. While issues of dissemination to participants are potentially of importance to all research involving patients, we focused on clinical trials because of the way they are indexed and coded (and therefore accessible) and because they are a major element in the evidence base for healthcare. We identified them using two searches and removed duplicate titles (as initially we planned to focus on just 1 year): (clinical trial[Publication Type] AND ('2014'[PDAT]: '2014'[PDAT])) NOT 'clinical trials as topic'[MeSH Terms] and (clinical trial[Publication Type] AND ('2015'[PDAT]: '2015'[PDAT])) NOT 'clinical trials as topic'[MeSH Terms]. We used a Perl script to extract the email address of the first named author from the affiliation section of the record, along with the following variables from the PubMed XML: first author's first name, first author's surname, journal name, publication date and article title. We excluded email addresses if there was no named author.

One person was invited to participate per trial report. To avoid sending more than one invitation to authors with two or more eligible trials, we removed trials with duplicate email addresses. We also excluded authors who had previously asked not to be contacted by *BMJ* for marketing and other reasons.

Eligibility criteria and screening question

We included authors of published protocols because protocols are not categorised/indexed in PubMed in a way that would allow them to be easily identified. Additionally, trials for which the protocol was published in 2014 or 2015 might have been completed by the time of the survey and authors were free to respond in relation to the completed study. If they had not yet disseminated, authors were asked if they had plans to disseminate so they could also respond about a protocol in this way.

Only reports of clinical trials in humans were included in the analysis. We included a screening question at the start of the survey to exclude reports of laboratory or animal studies, preclinical trials without patients, studies where there were no study participants, and studies that were not clinical trials.

Data analysis

Data are presented as number and percent of the total number of authors of eligible trials with individual patients recruited. Open ended answers were grouped into themes by SS and verified by AP.

RESULTS

Sample

The PubMed search identified 26 185 clinical trial reports, but we subsequently excluded 5798 reports (see figure 1). We used SurveyMonkey to send emails to authors of 20 387 reports, but 1066 resulted in delivery failures. 3127/19 321 (16%) responded to the survey and a further 88 emailed to disqualify themselves (stating their publication was: not a clinical trial n=48, a protocol with no results available n=20, secondary analyses n=15, a methodological paper n=2, an animal study n=2, a laboratory study n=1). Of the 3127 who responded to the first screening question, 437 were disqualified from taking part as they stated their publication was not a clinical trial

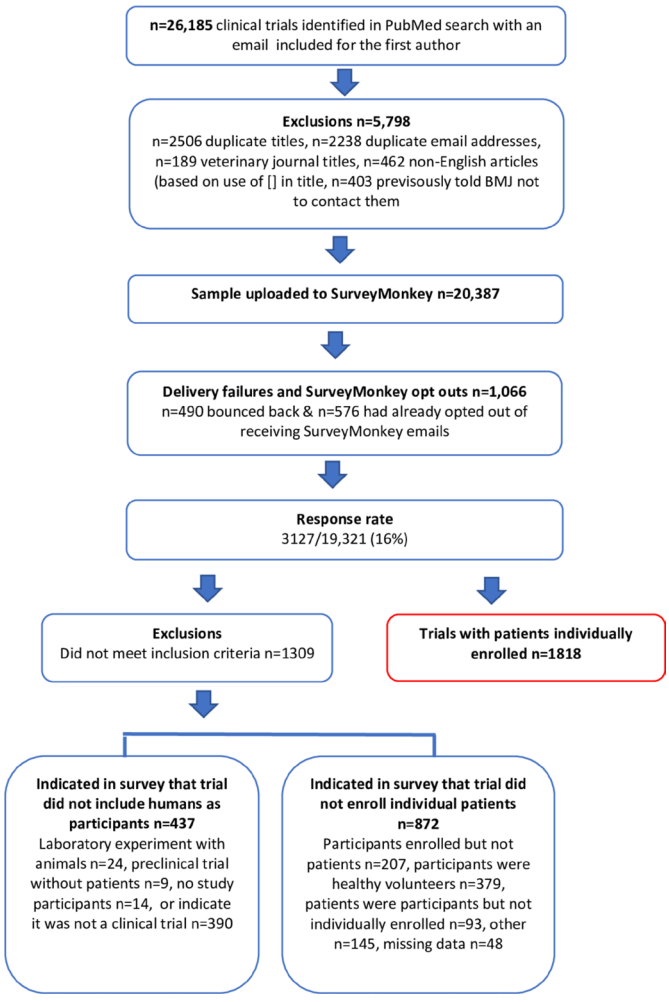

Figure 1 Flowchart indicating response rate and eligible trials.

Table 1 Respondent characteristics for 1818 trials where patients were individually enrolled

Respondents' work and clinical trial experience	n (%)
Type of work institution	
University	903 (50)
Private research centre	53 (3)
Public research centre	57 (3)
Hospital or health institution	492 (27)
Industry	22 (1)
Other	36 (2)
Number of years as an active researcher	
1–5	268 (15)
6–10	432 (24)
11–20	489 (27)
21–30	251 (14)
More than 30	121 (7)
Proportion of clinical trials with patients that respondents had been involved in where results were disseminated to participants	
Zero	299 (16)
Up to 20%	687 (38)
21–40%	208 (11)
41–60%	172 (9)
61–80%	121 (7)
81–100%	190 (10)

Percentages do not sum to 100% due to missing data.

(n=390) or that it was a trial without human participants (n=47). Of the remaining 2690 trials, 1818 with patients individually enrolled are the focus of this paper.

Respondent and trial characteristics

The 1818 respondents were working in 71 different countries, mostly in universities (50%) or hospital or health institutions (27%) and had been active researchers for a broad range of years (table 1). The trials were published in over 600 different journals and 345 (19%) were reported as having some funding from industry, 905 (50%) had some non-industry funding, and 538 (30%) had no external funding.

Dissemination to trial participants

498 (27%) of the 1818 authors reported that they had already disseminated results to participants and another 238 (13%) planned to do so, 600 (33%) did not plan to, 176 (10%) were unsure, and 306 (17%) responded with '*other*' or did not answer.

As we received a low response rate for the survey and those who did not respond may have been less likely to have disseminated we report some sensitivity analysis: if non-responders were 20% less likely to have disseminated (or have plans to disseminate) than responders, then the overall proportion who have disseminated (or have plans to) would be 21% (4137/19 321) and if non-responders were 40% less likely it would be 5% (898/19 321).

For 1225 (67%) of the 1818 trials, at least one of the author team had access to participant identifiable data. Of the 600 respondents who indicated that there were no plans to disseminate, 418 (70%) confirmed that authors had access to the identifiable data.

Of the 498 authors who had disseminated results to participants, 198 (40%) shared documents or presentations they had prepared for an academic/clinical audience, 252 (51%) shared documents or presentations prepared specifically for lay readers, 111 (22%) shared both academic documents and materials prepared specifically for lay readers, and 164 (33%) provided individual study results (table 2). When trial participants were offered lay documents or presentations, these were most frequently (34%, n=170) sent directly to them; 10% (n=48) of authors made the results available on a website and 16% (n=82) invited participants to a meeting. Where documents or presentations written for an academic audience were shared, the journal publication was most frequently shared (28%, n=139), followed by an academic

Table 2 Type of information offered to the participants in trials for which authors had already disseminated or planned to disseminate results

Type of information	N (%) of trials		
	Already disseminated to participants, n=498	Plan to disseminate to participants, n=238	Already disseminated or plan to combined, n=736
Documents or presentations written for an academic/clinical audience	198 (40)	105 (44)	303 (41)
Full study report	56 (11)	24 (10)	80 (11)
Journal publication(s)	139 (28)	67 (28)	206 (28)
Academic summary	74 (15)	47 (20)	121 (16)
Documents or presentations prepared specifically for lay readers	252 (51)	114 (48)	366 (50)
Participants sent a lay summary	170 (34)	82 (35)	252 (34)
Lay summary posted on a website	48 (10)	39 (16)	87 (12)
Trial participants invited to attend workshop or meeting	82 (16)	23 (10)	105 (14)
Both documents or presentations written for an academic/clinical audience and documents for lay readers	111 (22)	61 (26)	172 (23)
Individualised study results, such as outcomes, scores or analysed data	164 (33)	49 (21)	213 (29)

Authors could indicate multiple options.

summary (15%, n=74) or the full study report (11%, n=56).

906 (50%) of the 1818 authors reported that trial participants had been asked if they wanted to receive the study results. 571 of these 906 (63%) authors had already disseminated trial results to participants or planned to do so, but 142 (16%) had no plans to disseminate to the participants.

Perceived benefits of dissemination of results to patients

Respondents' comments on the benefits of disseminating results to patients included supporting the spread of knowledge in the patient community, increased accountability for researchers, and an opportunity to empower patients. The potential to motivate people to participate in future research studies was noted by many and some suggested dissemination might encourage patients to consider interventions which could lead to better outcomes for them. It was also suggested that it might improve the doctor–patient relationship through building confidence and trust. Respondents further suggested that the impact of dissemination could be extended by giving patients the opportunity to share results within their own communities; there were mixed views on whether dissemination should be mandatory.

Barriers or challenges to dissemination to patient participants

All participants were asked to describe barriers or challenges to dissemination and we grouped these into seven key themes (box 1 contains illustrative quotes). It is important to note, however, that some authors reported that there were no barriers to dissemination and described successful approaches.

Researchers' perceptions of what interests patients and what they can understand

Some researchers said they did not think patients would be interested in receiving study results; others assumed a failure to ask for them represented a lack of interest in getting them. Many were concerned that patients would lack the ability to understand the results and their implications.

Difficulties in reaching patients

Respondents described potential problems such as what to do about dissemination if participants may have died, and how to reach patients who don't have access to the internet, are illiterate, critically ill, cognitively impaired, minors, or in other vulnerable groups. Dissemination was also seen as challenging if a long time had elapsed between conducting the study and its publication. Additional difficulties cited included not being able to give personal feedback; having to disseminate in different languages; difficulty in writing lay summaries; and only having access to anonymised datasets. Some felt restricted by data protection rules and some were not confident about how and when they could contact trial participants in the absence of relevant guidelines.

Lack of early planning and support

Some researchers reported that they did not have ethical approval or patient consent for dissemination, plans to

Box 1 Illustrative quotes describing barriers and challenges to disseminating to trial participants

Researchers' perceptions of what interests patients and what they can understand

"The results has scientific and medical interest, but they are not interesting nor directly useful for patients". (17347)

"Basically the patients are operated and doing well and therefore they are not very interested any longer—they care about themselves and not others". (19292)

"Study participants are interested only in their health recovery and usually don't ask about study results". (9096)

"Patients should be given info if they request results otherwise this should not become mandatory—it would become another unnecessary task mandated to researchers". (2772)

"Small part of abdominosurgical procedure, difficult to understand for patient, no further consequence". (14807)

Difficulties in reaching patients

"You cannot give information to participants that is not interpreted. As many will fall well below norms or are clearly not doing well, dissemination without the opportunity to intervene is unethical …. so I will not do it". (6117)

"One difficulty is the gap in time between when the study is completed and the results are available. The study is closed for IRB purposes. Adding another communication to patients will require additional work at all levels, from the sponsor to the investigator to the IRB". (5247)

Lack of early planning and support

"We did not get IRB approval at the time of the study to contact participants following their participation in the study. Also, since the study is now closed with the IRB, we are not to have contact with the participants". (7460)

"IRBs and regulatory bodies in my country do not put emphasis or a sense of obligation to ensure that study results reach the participants. It is not mandatory at the time of approval of a study and little or no follow-up is done". (8580)

"It needs to be required by EMA and FDA and all ethics committees and built into the protocols. It also needs to be funded as part of the study. Currently, in study budgets, there is not a line item to address the process". (2126)

Lack of incentives and cultural expectations

"To be blunt, I am an academic researcher and there is no incentive for me to do it, other than that it is the right thing to do. There is no pressure from funders or my department, and it doesn't factor in to my promotion so it feels like something extra I need to make time for". (10880)

"Gets lost in the shuffle of so many other priorities and it is not mandated. But I would imagine participants would be interested in knowing the results". (9025)

"There is also the issue of what academic credit one gets. Eg people will spend time writing papers after finishing on a project but they will get no acknowledgement for spending time preparing lay summaries and actively disseminating to patients. There needs to be trial manager/research associate time built into grant funding for the post-trial dissemination. There also needs to be a shift so that dissemination to patients and public carries more weight than it currently does. For example whilst I am passionate about this and feel it is more important in many ways than writing a journal article I have never been set an objective to go to a patient group to discuss the trials but have been set objectives about writing articles". (5750)

Continued

Box 1 Continued

"… for annual review and promotion, disseminating results to patients does not count whereas publishing in a journal or presenting at a professional meeting does count". (7555)

"Just not a part of the research culture I work in. Would be easy enough to do ….". (8490)

"Because it is not expected to disseminate results to patients involved in the study". (2094)

"We weren't trained as researchers to think in this way … It is not part of the grant getting, research publishing environment we work in". (11511)

Type of results

"The results have no bearing on the care/management of the patients who participated". (9612)

"The trial results would concern the participants about their future. However, they could not change their own risk in the future". (7996)

"If the trial has a negative outcome maybe the patients feel that they waisted their time participating in the trial". (5794)

"The main barrier is to determine whether the results are meaningful, reproducible and helpful to the patients involved. If they are not, they should not be disseminated to patients". (10704)

Uncertainty on which patient groups to share study results with

"… there are patients with chronic diseases and with acute diseases like trauma, sepsis, ARDS, cardiac arrest; and these do not have patients groups". (8212)

"There are no patient organisation representing critically ill patients … and thus no obvious group of patients outside of the study to approach". (3916)

Researcher-specific reasons for non-dissemination

"It's not standard practice here or anything I've seen done by coauthors or mentors. Until I saw this survey it honestly never occurred to me to offer this". (19036)

"Didn't think of it at the time. I absolutely will in the future. Time and cost is secondary". (10267)

"Participants can access the result with published article". (3743)

"The results are published and so accessible for anyone that is interested". (10846)

do so were not included in the study protocol and results were not offered to participants at the outset. Earmarked financial support for dissemination was unusual, and where it was available, it was often not accessible by the time the study was published. Researchers also stated that funders did not require or mandate dissemination and that it would provide an additional burden to the research team.

Lack of incentives and cultural expectations

Respondents described the lack of expectation, academic recognition or reward for disseminating to participants and patient groups compared with disseminating to researchers and clinical audiences.

Type of results

Study-specific reasons included concern over misinterpretation of unclear, inconclusive or discouraging study results; negative results; preliminary results; and complex

Table 3 Dissemination of results to patients outside of those who took part in the trial (n=1818)

Dissemination method	N (%) of trials			
	Already shared	Plan to share	Nether shared nor plan to	Don't know
By direct contact with relevant patient charities or patient groups	379 (21)	198 (11)	692 (38)	199 (11)
Via informal patient communities (eg, shared on social media)	248 (14)	153 (8)	780 (43)	209 (12)
Via presentations at conferences where patients are represented	650 (36)	195 (11)	492 (27)	153 (8)
Via the mainstream media	351 (19)	143 (8)	692 (38)	247 (14)
By publishing lay summaries on the trial website or somewhere publicly accessible	432 (24)	276 (15)	540 (30)	206 (11)

Percentages do not sum to 100% due to missing data.

or technical results (eg, a comparison of surgical techniques). Some felt that it was not necessary to disseminate results of all studies, particularly when findings would not change management, or would be of no benefit to individual participants; or where knowing the results might cause distress.

Uncertainty on which patient groups to share study results with

Authors reported that in some instances it was difficult to identify which patient groups to disseminate to (eg, studies conducted in emergency or acute settings).

Researcher-specific reasons for non-dissemination

Respondents spoke of unfamiliarity with the concept of disseminating results to patients and linked communities, it not being usual practice, not having received training in how to do it and perceiving that it was not their responsibility. Some were unsure of what and when they should disseminate, others felt it was unnecessary if participants had already been given their own clinical results or the trial reports were available in a journal publication or trial registry. Some indicated they were concerned about breaching copyright by sending journal articles to patients.

Wider dissemination to patient groups

Table 3 shows how respondents shared or planned to share results with patients beyond those who took part in the trial. Among the 1818 authors, 845 (46%) shared or planned to share results with patients outside the trial via presentations at conferences with patient representation, 708 (39%) by publishing lay summaries online, 577 (32%) by direct contact with charities/patient groups, 494 (27%) via mainstream media and 401 (22%) via informal patient communities.

Barriers and challenges to dissemination to patient groups

Some felt disseminating to wider patient groups was easier than reaching trial participants, but others disagreed, citing lack of guidance on how to do this and not knowing how to find or approach relevant patient groups and organisations. Concern was also expressed about misinterpretation of results if the full context of the study was not understood—a particular risk, respondents suggested, if social media were used for dissemination. Mention was also made of raising expectations which can't be met if people were unable to access the intervention/treatment studied. Others noted that it was not possible to make clear recommendations on the basis of results from a single study. In addition, the dissemination of results from trials involving drugs sponsored by pharmaceutical companies was viewed as illegal off label promotion or advertising.

External suggestions to disseminate

Table 4 shows the sources of suggestions to disseminate to trial participants and wider patient groups. Relatively few respondents reported that dissemination was encouraged by institutional bodies such as research funders (314, (17%) suggested dissemination to trial participants and 252 (14%) suggested dissemination to other patient groups) or ethical review boards (333 (18%) suggested dissemination to trial participants and 148 (8%) suggested dissemination to other patient groups). Motivation to disseminate appears to have arisen more from within research teams rather than from institutional bodies.

Patient involvement in dissemination

A minority of the 1818 respondents reported they had, or planned to involve patients in dissemination activities (table 5): interpreting the study findings and potential impact of their study (271, 15%), developing the content of the materials for dissemination (305, 17%), contributing to writing or commenting on the manuscript (169, 9%), selecting the most appropriate dissemination method (295, 16%), and presenting and sharing results with other patients or the public (366, 20%).

DISCUSSION

Our study shows that two-fifths of clinical trialists had disseminated results to trial participants (or planned to) up to 2 years after publishing their study. Half of those who had (or planned to) disseminate shared documents

Table 4 Suggestions from relevant parties to disseminate results to trial participants and patient groups (n=1818)

Suggested dissemination	N (%) of trials		
	Yes	No	Don't know
To trial participants			
Principal investigator	907 (50)	488 (27)	184 (10)
Other members of the research team	708 (39)	598 (33)	217 (12)
Patient and public involvement representative(s) involved with the trial	260 (14)	901 (50)	287 (16)
Research funder(s)	314 (17)	882 (49)	251 (14)
Ethical or institutional review board	333 (18)	872 (48)	258 (14)
Academic institution	302 (17)	880 (48)	259 (14)
Regulatory bodies	144 (8)	931 (51)	320 (18)
To patient groups			
Principal investigator	706 (39)	626 (34)	210 (12)
Other members of the research team	579 (32)	683 (38)	240 (13)
Patient and public involvement representative(s) involved with the trial	212 (12)	922 (51)	300 (17)
Research funder(s)	252 (14)	903 (50)	281 (16)
Ethical or institutional review board	148 (8)	979 (54)	296 (16)
Academic institution	238 (13)	917 (50)	284 (16)
Regulatory bodies	83 (5)	971 (53)	339 (19)

Percentages do not sum to 100% due to missing data.

prepared specifically for lay readers and a quarter shared both these and those written for an academic/clinical audience. Sharing with patients and patient groups more widely was mostly done via presentations at conferences where patients were represented or by publishing lay summaries on the trial website or a publicly accessible website. Sharing results directly with charitable organisations, and patient groups and communities, for example, via social media was less frequent. Furthermore, only a minority of authors involved patients in planning their dissemination strategies to study participants. Respondents reported that funders, academic institutions, ethical review boards and regulatory bodies rarely suggested dissemination to trial participants and linked patient groups. In addition, respondents described many perceived barriers and practical challenges to dissemination.

Previous studies describing the frequency of sharing study results with participants have taken different approaches, and heterogeneity makes direct comparisons

Table 5 Patient involvement in dissemination of the research

Type of patient involvement	N (%) of trials			
	Already asked for this involvement	Plan to ask for this involvement	No plan to ask for this involvement	Don't know
Interpreting study findings and potential impact of the study	183 (10)	88 (5)	1172 (65)	126 (7)
Developing the content of the materials for dissemination	178 (10)	127 (7)	1105 (61)	151 (8)
Contributing to writing or commenting on manuscript drafts	117 (6)	52 (3)	1259 (69)	122 (7)
Selecting most appropriate dissemination method	155 (9)	140 (8)	1072 (59)	178 (10)
Presenting/sharing results with other patients or the public	211 (12)	155 (9)	998 (55)	187 (10)

Percentages do not sum to 100% due to missing data.

difficult.[6 17–20] Recent research includes a survey of over 3000 health research participants in the USA with 33% reporting they had received results from a study they had participated in[19] and a survey of 414 researchers in the USA with 56% able to recall studies for which they were investigators where results were not disseminated to participants.[20] A survey of authors of community participation studies showed dissemination to participants and the public occurred in 98% of studies but few included details about it in publications.[18]

Respondents to our survey indicated that few research funders, regulators, ethical review boards, and academic institutions requested dissemination to participants. And while we found a higher proportion of requests from ethical review boards (18%) than an earlier study in the USA (7%),[17] this is still low. Recent reviews of informed consent documentation at Canadian research institutions[23] and policies and recommendations for dissemination by major US research funders[24] have also revealed a lack of support for disseminating results to patients. Our finding that only a minority of authors involved patients in their dissemination plans is very much in line with a previous survey.[25] Similarly, our respondents' reports of barriers to dissemination have been reported in previous smaller surveys and include: concern about emotional effects on participants; participants' difficulty understanding results; logistical issues; and researcher, financial and regulatory barriers.[6 20 21 26] The potential for dissemination to participants and patient communities being harmful should not be overlooked. Findings from scientific studies are not always reported objectively and their clinical importance can be amplified and distorted via press offices, mainstream media outlets and social media. Misunderstanding of the clinical importance of study results may lead to unintended consequences including provoking unjustified concern or false hope among patients, which may result in increased clinical visits and requests for inappropriate treatment. Poor reporting of study results poses a problem for both health professionals and the patient community. Rigorous accurate, accessible, and objective reporting is in everyone's interest.

Study strengths and limitations

This is the largest cross-disciplinary survey to date about the dissemination of results of clinical trials to patients. Asking respondents about practice in relation to specific studies rather than for general opinions and practice provides a better sense of the frequency of dissemination. However, our study has several limitations. While the response rate is similar to other surveys conducted with researchers[27 28] and we generated a large and varied sample, the generalisability of the results may be compromised by the low response rate. We do not know if responders differed from non-responders in terms of the characteristics of the trials, the authors, or the funding received; it is possible that those who responded were more likely to have disseminated than those who did not. One reason for the low response rate may be our general search of PubMed to identify clinical trials, because the number of authors who informed us their study was not a clinical trial (eg, it was a protocol or methodological paper) suggests that many may have ignored the invitation. Furthermore, some will not have received it, with approximately 18% of email addresses of authors in PubMed estimated to be invalid.[29] We also restricted the sample to journals in English. Additionally, by using Perl script to extract author details we were not able to include reports of trials where there was no email address in the relevant field, where the email address was not in the format abcd@xyz or where moderators prevented automatic extraction by substituting the @ symbol. Finally, we did not exclude published protocols from the sample so the proportion of authors who had already disseminated would probably have been higher if we had.

Study implications

The call for dissemination of trial results to participants is not new but our work shows that it is still not regarded as an essential component of the research process. Many respondents had not considered it and only half asked participants if they wanted to be informed of the study results. This is surprising given that The Declaration of Helsinki requires this[9] and respondents indicated that dissemination to participants and patient communities has the potential to improve public trust in medical research, encourage people to participate, raise health literacy and increase uptake of research findings.

Dissemination of results to patients is a shared responsibility of funders, regulators, ethical review boards, universities and researchers. Yet our study makes it clear that that the latter get little guidance and support for it from the former. We clearly need a better understanding of why this is and what can be done to support and motivate researchers to share results and make dissemination an integral part of the research process. Our findings suggest the following:

1. Clear policy and practical guidance.
   Explicit policy and clear guidance are needed on when, what, and how to share results with patients and their linked communities. This should be developed and informed by the best available evidence, which needs to come from research testing different formats and modes of delivery.
2. Incentivise dissemination by making it mandatory.
   Funding organisations should incentivise dissemination beyond publication in peer reviewed journals.[14] They could (as a few funders currently do) make research funding conditional on the inclusion of appropriate plans for dissemination to participants and linked communities in accessible formats.[11 24] In addition they could allocate money and support for these activities, offer training to improve grantees' competency in this respect,[24] make the expectations of researchers clearer,[30] and support research to identify effective dissemination strategies. While some organisations are

already striving to facilitate dissemination to patients, even where this practice is encouraged, more could and should be done to equip researchers with the necessary skills and resources.

3. Increased scrutiny from ethical review boards.
   Ethical review boards should routinely review the inclusion and appropriateness of investigators' dissemination plans to participants[11 12] and linked communities. With the sometimes-lengthy delay between study recruitment and study publication, researchers need a clear steer from the outset about when and how to contact participants and linked organisations.[8] They also need guidance on how to disseminate results that have the potential to cause harm to patients and unnecessary burden on health professionals if misunderstood.
4. Encourage early planning of dissemination.
   Researchers should plan for dissemination in the early phases of their work and include these plans in their study protocols, informed consent procedures and applications for ethical approval.[11 12 23] Good practice could be to ask study participants (and/or next of kin) when seeking consent if they want to receive results (as interest in receiving results varies[15 31 32]) and to inform them that they will be asked again at the end of the study. Re-offering results in this way moves the onus away from patients having to request them while respecting their choice and right to decline.[5 7]
5. Improve training.
   Researchers receive little training in communicating findings to stakeholders, and most spend less than 10% of their time on all dissemination activities.[25] They need better guidance on how to plan, resource and implement dissemination,[2] particularly to patients and their linked communities. Universities should teach that dissemination to patients and the public is a core element of good practice and equip researchers with the skills and support to communicate effectively with patients, the public and media outlets.[14] Investigators should be taught not to make assumptions about whether and what results patients may understand and value.[11] Increasingly networked patient communities are adept and skilled at accessing and communicating the results of research to members. And the patient community as a whole is interested in both positive and negative findings.[12] Researchers need to better understand that objective unsensational reporting is crucial for health professionals, policy makers, patients and the public. They need to consider the potential for results to cause unjustified concern and potential harm if they are over interpreted and spun in a way which exaggerates their importance. All end users of research, whether they are clinicians, policy makers or patients, need to understand the limitations of a single study in the context of existing knowledge.
6. Development of standards.
   Academic institutions should develop standardised content for patient information leaflets about participating in clinical trials and in the patient consent forms. This should include details of when, how and what results will be shared to ensure there is transparency about this and help promote the importance of dissemination to participants.[23] Standards for the content of dissemination materials for participants and linked communities should be developed and adopted for all types of health research. To avoid misinformation and the potential for harm, these should include sections on how to interpret the results, study limitations and implications for management and treatment (as applicable).
7. Support from journals.
   Journals have a key role in dissemination and translation of knowledge into practice. Currently, patients and the public have limited access to the results of research, as much of the scientific literature still requires a subscription.[33] Even if access is possible, articles may not be understandable to generalists and lay audiences for most are written for narrow specialist clinical and academic audiences. Journal editors should promote open access research and support its dissemination in a form which can readily be understood and encourage this by asking researchers to report how they have done this or plan to do so.[34] Journals should also encourage authors to write clear abstracts which are accessible to a non-specialist general medical audience, and informed patient communities and in addition consider publishing lay summaries, and upload these as open access supplementary files. Journals publishing protocols can ask authors to describe how their research will be shared with participants, to encourage early planning.

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Competing interests SS and TR are employed by *The BMJ* which has a patient partnership initiative. AP works on a freelance basis for *The BMJ* and is a senior research advisor at Stanford University, where she is responsible for advising and seeking funding on dissemination of research studies. AP and TR are patients with long-term medical conditions and are committed to increasing the dissemination of results to patients. MC has been involved in many clinical trials and systematic reviews, such that he has had to organise the dissemination of his own research and use material disseminated by others. He seeks funding for these trials and reviews, as well as for research into methodology, including dissemination.

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