

Guidelines and Guidance

Communicating the Results of Clinical Research to Participants: Attitudes, Practices, and Future Directions

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Recent commentaries advocate routinely offering study results to research participants [1,2]. However, debate continues over the scope and limits of investigators' responsibilities in this regard. A 2006 review identified 30 national and international policies and guidelines concerning the duty to return research results [3], of which 21 were published in the last decade. Worldwide interest in this complex issue will likely continue to rise in light of the increasing relevance of the results of biomedical research to participants' health and well-being.

Unfortunately, many policies and commentaries on communication of results either do not adequately take into account relevant available data, or fail to recognize the lack thereof. For example, existing data on participant desire and investigator support for communication of research results have not been synthesized, nor have the data on potential positive and negative consequences that communication of results may have for both participants and researchers.

The results of clinical research may be classified as either aggregate study results, representing synthesized data and conclusions drawn from groups of research participants, or individual results, representing distinct items of data collected from or about individual participants. In this article, we present a narrative review of available data on the effects of communicating aggregate and individual research results on participants, investigators, and the research enterprise. We also present available data on disclosure practices and the attitudes of investigators and participants towards communication of research results. Our aim is not to provide definitive analyses of any of these domains; rather, it is to highlight trends in the literature as well as areas that require further investigation.

Data on Communicating Research Results

A literature search revealed 28 empirical studies concerning communication of research results (Text S1). Because these studies encompass many different participant populations and research settings, we did not pool quantitative data or conduct a formal quality assessment of studies. Of the 28 studies summarized below, 22 are primarily quantitative and six are primarily qualitative [4–9]. Sample size ranged from 13 [7] to 8,941 [8]. Twelve studies involved either cancer research or the attitudes of patients with cancer [7,10–20]; seven studies involved genetics research [7,9,11,20–23]. Ten studies were conducted in the United States [9,10,16–21,24,25], nine in the United Kingdom [4–8,11,26–28], four in Canada [14,15,29,30], one in France [23], and one

in Sweden [22]. Three studies enrolled a multinational participant population [12,13,31].

Participant attitudes towards disclosure. Eighteen studies provided empirical data on participants' desire to receive study results [5–11,14–16,18–23,27,32]. Nine studies involved aggregate study results, eight involved individual results, and one involved both (Table 1). Of studies that reported desire to receive results as a percentage of respondents, a median of 90% (range 20%–100%) wished to receive study results. In studies not reporting percentages, mothers of pediatric patients with cancer rated the importance of aggregate study results at a mean of 4.5 of a maximum importance of 5 [10], parents of infants in a randomized controlled trial of extracorporeal membrane oxygenation (ECMO) "felt strongly they should be sent the trial results" [5], and relatives of deceased patients with prostate cancer stated that they "had a right to know information that they could use to make personal risk management decisions" [7]. When asked an open-ended question about their experience in a study allowing them to access their individual obstetric records, 99 of 247 pregnant women volunteered a desire to receive aggregate study results without being prompted [6].

Nine studies assessed participants' reasons for wanting aggregate or individual study results. Participants in these studies cited clinical significance (e.g., treatment, prevention, or understanding of a disease) for self or relatives [7–11,23], respect for participants in research or a "right" to receive results [5,11,14], and raising public awareness of research [14]. Interestingly, Wendler et al. reported that the mere

Funding: DIS was supported by a grant from the Ethics in Public Life Initiative of the University of Michigan through the Office of the Vice President for Research. The funding source did not review or approve the manuscript prior to publication. The opinions expressed are the authors' own. They do not represent any position or policy of the United States National Institutes of Health, Public Health Service, or Department of Health and Human Services.

Competing Interests: The authors have declared that no competing interests exist.

Citation: Shalowitz DI, Miller FG (2008) Communicating the results of clinical research to participants: Attitudes, practices, and future directions. PLoS Med 5(5): e91. doi:10.1371/journal.pmed.0050091

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Abbreviations: ECMO, extracorporeal membrane oxygenation; REB, research ethics board

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The Guidelines and Guidance section contains advice on conducting and reporting medical research.

Table 1. Participant Desire for Study Results

Study	Year	Type ^a	N	Population	Comment
Elbourne [6]	1987	A	247	Pregnant women allowed access to their obstetric records	99 of 247 women mentioned looking forward to receiving study results in response to an open-ended question about their feelings regarding enrollment.
Bunin et al. [10]	1996	A	109	Mothers of pediatric patients with brain tumors	Mothers of patients rated the importance of study results as 4.5/5 on Likert scale.
Snowdon et al. [5]	1998	A	24	Parents of infants in a clinical trial of ECMO	Qualitative description that parents of infants in trial "felt strongly they should be sent the trial results."
Partridge et al. [16]	2003	A	51	Women in a breast cancer treatment trial	96% of respondents wanted to be informed of trial results.
Schulz et al. [19]	2003	A	382	Retinoblastoma survivors and parents of affected children	1.4% of respondents would have preferred not to receive results regarding their risk of developing future cancers.
Fernandez et al. [15]	2005	A	20	Adolescents with cancer and parents of children with cancer	90% of participants wished to receive the results of research in which they participated.
Partridge et al. [18]	2005	A	94	Women in a treatment trial for ductal carcinoma in situ	90% of participants elected to receive results related to the early closure of the trial.
Dixon-Woods et al. [8]	2006	A	8,941	Women in a randomized controlled trial of antibiotics during pregnancy	20% of participants requested trial results. Many of those requesting aggregate results also wanted information regarding their treatment allocation.
Fernandez et al. [14]	2007	A	40	Adolescents with cancer and parents of children with cancer	100% of 30 parents and 10 adolescents would want to receive study results regardless of implication. >95% felt they had "strong" or "very strong" rights to receive study results.
Wendler et al. [32]	2002	I	504	Research participants and Medicare recipients questioned about research with stored samples	88.8% of respondents would want to receive study results of uncertain clinical significance.
Richards et al. [11]	2003	I	1,484	Women participants in an epidemiological study of breast cancer genetics	93% of participants indicated a desire to be informed if a <i>BRCA1</i> or <i>BRCA2</i> mutation was found.
Fong et al. [21]	2004	I	429	Adult Hawaiians questioned about research with stored samples	90.7% of respondents would want individual research results disclosed to them. 82.1% would want their physicians to be notified of results.
Hoeyer et al. [22]	2004	I	589	Randomly selected residents of a Swedish county	83.4% of respondents would want to receive research results containing information about genetic predisposition to disease. However, 66% of these would only want results if there was treatment or prevention available.
Ormond et al. [9]	2004	I	808	Participants in a genetics database	96% of participants wanted to be recontacted if "medically significant" findings came out of their participation.
Dinnett et al. [27]	2006	I	2,067	Participants in a cardiovascular disease prevention trial	67% of participants wanted to be unblinded to their treatment allocation and receive their on-trial lipid profiles.
Ormondroyd et al. [7]	2007	I	13	Relatives of deceased male participants with <i>BRCA2</i> mutations	Qualitative description that 13 members of 3 families (100% of participants surveyed) believed that clinically significant results should be communicated to relatives of a deceased participant.
Wendler et al. [20]	2007	I	561	Patients with cancer and participants in Alzheimer disease research	78% of participants and 90% of patients would want to know individual results of predictive Alzheimer disease testing if the investigator knew results.
Moutel et al. [23]	2005	B	125	Patients with HIV in a pharmacogenomics study	71% of respondents wanted aggregate study results; 76% wanted individual results.

^aType of research results targeted by the named study: A = aggregate study results, I = individual results, B = both.

doi:10.1371/journal.pmed.0050091.t001

fact that investigators have information about participants that participants lack contributes to the desire to receive individual research results [20]. In a study by Fernandez et al., participants suggested that the possibility of causing distress to families of deceased participants or situations in which participants were harmed or not helped by the research could be reasons for not disclosing research results [14]. However, Partridge et al. reported that participants wanted to be contacted with aggregate results even if they were not helped by the research [16].

Ten studies [5,8–11,14–16,18,19] assessed participants' preferences for the method of receiving research results. Two prospective studies of adolescent patients with cancer and parents of children with cancer by Fernandez et al. report that (1) 60% of participants felt communication of results by mail would be satisfactory, though 50% stated that they would prefer face-to-face contact [15]; and (2) approximately 75% of participants would prefer to receive results with positive or neutral implications by letter or e-mail, while approximately 53% of participants would prefer to have results with negative

Table 2. Investigators' Support for Communicating Research Results

Study	Year	Type ^a	N	Population	Comment
Garcia [4]	1987	A	16	Doctors and midwives involved in a randomized controlled trial of fetal heart monitoring	One-third of those interviewed felt that results of the study should be shared with mothers who had participated.
Fernandez et al. [12]	2003	A	150	Primary investigators in the Children's Oncology Group	69.3% of investigators supported or strongly supported the development of a guideline mandating provision of research results to participants. Investigators felt major barriers to implementation were preparation of lay summary of results (70%) and time involved in communication of results (62%).
Partridge et al. [17]	2004	A	796	Oncology physicians and nurses	78.9% believed trial results should be offered in most cases. 79.6% would be willing to offer trial results. 83% believed that trial results should be communicated by participants' physicians. 16.2% of respondents "believed an obligation to offer results...would make them less likely to enroll patients on studies."
Rigby et al. [31]	2005	A	158	Investigators presenting oral abstracts at American Society of Hematology Annual Meeting	69% of investigators supported or strongly supported the concept of return of research results.
MacNeil et al. [30]	2007	A	77	Canadian REB chairs	94.8% of REB chairs supported offering research results to participants after a study's completion.
Di Blasi et al. [26]	2002	I	139	Investigators who conducted placebo-controlled trials	75% of investigators who did not inform participants of their treatment allocation (40/53) would consider informing them in the future.

^aType of research results targeted by the named study: A = aggregate study results, I = individual results.
doi:10.1371/journal.pmed.0050091.t002

implications communicated in person [14]. Participants in a longitudinal genetic database were "relatively open with regards to how they would prefer to be recontacted" with individual results [9], and participants in a clinical treatment trial for breast cancer preferred that their physicians communicate the aggregate results of clinical trials in which they participated [16].

Participants were asked to retrospectively evaluate written communication of research results in five studies [5,8,10,18,19]. Mothers of child participants in an epidemiological study of brain tumors found written aggregate study results understandable and important; however, 40% wanted a phone number to call with questions [10]. Written notification of aggregate study results with contact numbers was also the preferred method of communication for retinoblastoma survivors and participants in a trial of antibiotics during pregnancy [8,19]. In addition, 74% of women informed by mail of the early stoppage of a phase II trial of breast excision for ductal carcinoma *in situ* felt comfortable with this method of notification [18]. However, parents of infants who had taken part in a clinical trial of ECMO reported mixed experiences with receiving written communication about aggregate study results, as many felt the information was either too complex or too simplistic [5].

Investigator attitudes and practices regarding disclosure.

Five studies assessed investigators' support for communicating research results to participants [4,12,17,26,31]. Four studies involved aggregate study results and one involved individual results (Table 2). A substantial majority of investigators surveyed in four studies supported communicating study results to participants [12,17,26,31]. In the remaining study, only one-third of six midwives and ten physicians surveyed favored the communication of clinical trial results regarding fetal heart monitoring techniques [4].

Cancer investigators identified the cost and time involved in preparing a lay summary as well as difficulty in contacting participants as major barriers to communicating aggregate study results [12]. Clinical investigators also identified possible biasing of study follow-ups and cost as major barriers to communicating individual results [26]. In both cases, a minority of investigators identified negative psychological consequences as a perceived barrier to communication of research results [12,26]. Cancer clinicians in another study expressed a reluctance to inform participants of negative study conclusions owing to a desire to protect participants from harmful psychological consequences [17].

The chairs of Canadian research ethics boards (REBs) overwhelmingly supported offering research results after the conclusion of the study [30], and the monitoring committee of a pharmacogenetics study involving HIV-infected patients strongly favored communicating results of "direct benefit" to the participant, but expressed doubts regarding the communication of other results [23].

Six studies assessed the practices and policies of investigators and institutions concerning the communication of research results to participants [12,13,17,26,29,31]. Four studies involved aggregate study results, one study involved individual results, and one involved both (Table 3). Communicating research results seems to represent the exception to practice. For example, only five of 150 institutions surveyed by Fernandez et al. had a formal mechanism for returning research results to participants [12], and only 3% of 180 consent forms for leukemia clinical trials indicated that participants could receive study results [13]. Furthermore, only nine of 22 Canadian REBs surveyed had policies addressing communication of results or required investigators to address the issue themselves [29].

Impact of disclosure on participants. Eight studies empirically assessed the impact of receiving study results, all

Table 3. Research Results Communication Practices

Study	Year	Type^a	N	Population	Comment
Fernandez et al. [13]	2003	A	181	Consent forms for leukemia studies from different institutions	2.8% of informed consent documents indicated that participants had a right to receive study results.
Fernandez et al. [12]	2003	A	150	Principal investigators in the Children's Oncology Group	5 institutions (3.3%) had a formal mechanism to return aggregate results to research participants. Only one of these provided a written lay summary to participants.
Partridge et al. [17]	2004	A	796	Oncology physicians and nurses	62.4% of respondents reported offering results to patients less than one-fifth of the time.
MacNeil et al. [29]	2006	A	22	Canadian university-based REBs	9 REBs addressed the disclosure of research results themselves (2) or required investigators to do so in their research applications (7).
Di Blasi et al. [26]	2002	I	139	Investigators conducting placebo-controlled trials	45% of investigators informed all or most participants of their treatment arm allocation. 5% informed those who requested to know, and 50% did not inform. Most participants were informed in person (48%) or by mail (25%).
Rigby et al. [31]	2005	B	158	Investigators presenting oral abstracts at American Society of Hematology Annual Meeting	30% of investigators indicated that they had a formal plan for the offer of research results to participants; 40% of these returned aggregate and individual results. 7% reported that their institutional review board or REB required the offer of research results. 23% did not know whether such a policy existed.

^aType of research results targeted by the named study: A = aggregate study results, I = individual results, B = both.

doi:10.1371/journal.pmed.0050091.t003

of which involved aggregate results [5,7,8,10,11,18,19,24] (Table 4). These studies used various methods of assessing participants' reactions to receiving study information, including interviews [5,7,8,11], Likert scales of possible psychological reactions [10,19], the revised Impact of Event Scale [18], and the McMaster Health Index Questionnaire [24]. All but one study [24] reported some incidence of negative psychological consequences for participants, including increased anxiety, anger, guilt, or upset. However, six studies [5,7,8,10,19,24] reported psychological benefits for participants from receiving research results, including pleasure, satisfaction, and relief.

Importantly, the vast majority of participants reported feeling that it was important to receive study results, despite potentially negative emotional impact (Table 1). For example, Schulz et al. [19] reported that approximately a quarter of retinoblastoma survivors or parents of children with retinoblastoma indicated that receiving aggregate study results regarding their risk of developing second malignancies made them "very" to "extremely" frightened, anxious, or sad. However, 20% of participants were "very" to "extremely" relieved by the results, and only 1.4% of participants in this study would have preferred not to receive results.

Three studies examined correlations between education and psychological impact of disclosure: one found that participants with less than a college education were significantly more sad, angry, overwhelmed, or frightened than those with a college education [19], one found the opposite [18], and one found no correlation between educational level and psychological impact of disclosure [10].

Only the study by Schulz et al. addressed clinical follow-up after receiving research data [19]. The study authors found that despite their recommendations, only 18% of participants spoke with their physicians about the disclosed results, 16% of survivors attended cancer screening check-ups, and 12% of parents of child retinoblastoma survivors took their children to be screened. The authors hypothesized that the impersonal

nature of written communication may have led to poor utilization of clinically significant information.

Impact of disclosure on investigators. One study addressed the costs of communicating research results. Dinnett et al. reported that expenses associated with communicating treatment allocation and lipid profiles to participants included preparation, printing, and distribution of letters as well as additional salary support for existing staff. The authors also report receiving only 21 phone calls after unblinding 1,391 participants [28].

Impact of disclosure on the research enterprise. Buchwald et al. show trends (p -values between 0.09 and 0.13) indicating that after communication of aggregate study results, 726 participants were more likely to be (1) satisfied with their decision to enroll, (2) satisfied with randomization allocation, and (3) disposed to advise others to join a research study after communication of aggregate study results [24]. Snowdon et al. report that of 31 parents notified of their infant's allocation to the ECMO or standard care groups in a completed clinical trial, few said that this information affected their view of the trial, randomization, or their doctor [5].

Discussion

As we have conducted a narrative review of studies concerning communicating research results to participants, rather than a systematic review, definitive conclusions about findings and their ethical import cannot be drawn. Nevertheless, the data reviewed here suggest several important implications. Available data consistently indicate that research participants want aggregate and clinically significant individual study results made available to them. Participants' desires do not necessarily determine policy, but respect for participants requires taking their preferences seriously. Though investigators appear to support the communication of aggregate study results, less is known about investigators' attitudes towards communicating individual

Table 4. Impact on Participants of Receiving Research Results

Study	Year	Type ^a	N	Population	Comment
Buchwald et al. [24]	1993	A	368	Patients assigned to partial ileal bypass surgery for hyperlipidemia	Patients' perceptions of their emotional quality of life improved after disclosure of study results relative to a control group.
Bunin et al. [10]	1996	A	109	Mothers of pediatric patients with brain tumors	Patient mothers reported feeling moderate levels of guilt and anger. Patient mothers who felt the results applied to them felt also felt moderate levels of satisfaction and relief.
Snowdon et al. [5]	1998	A	24	Parents of infants in a clinical trial of ECMO	Even when results were emotionally exacting, the information removed uncertainty, provided an endpoint to difficult events, promoted discussion within couples, and acknowledged their contribution to answering an important clinical question.
Richards et al. [11]	2003	A	21	Patients with breast cancer tested for <i>BRCA-1</i> or <i>BRCA-2</i> mutations	Several women were "shocked" to learn of their risk of a second breast cancer or ovarian cancer.
Schulz et al. [19]	2003	A	382	Survivors of, and parents of survivors of retinoblastoma participating in epidemiological research	Approximately 25% of respondents indicated that receiving aggregate study results regarding their risk of developing second malignancies made them "very" to "extremely" frightened, anxious, or sad. However, 20% were "very" to "extremely" relieved after receiving results.
Partridge et al. [18]	2005	A	94	Participants receiving notice of the early closure of a treatment study for ductal carcinoma <i>in situ</i>	Receiving results was associated with greater anxiety than not receiving results; however, anxiety levels were mild overall.
Dixon-Woods et al. [8]	2006	A	20	Women in a randomized controlled trial of antibiotics during pregnancy	Half of participants expressed feelings of pleasure on receiving study results. For some women, the results revived memories of a difficult time.
Ormondroyd et al. [7]	2007	A	13	Relatives of deceased male participants with <i>BRCA2</i> mutations	Some participants expressed anxiety upon learning of their relative's mutation. Genetic counseling helped alleviate this anxiety. Some participants were pleased to be recontacted.

^aType of research results targeted by the named study: A = aggregate study results.

doi:10.1371/journal.pmed.0050091.t004

research results or about the costs and time required to do so. Future research should focus on these issues, including ways to facilitate communication of results by addressing investigators' concerns.

It may be helpful to consider the significant body of literature from the 1990s concerning worker notification of research showing increased occupational health risk [10]. Employers initially resisted notifying workers of risk, citing concerns of causing unduly negative psychological reactions as well as affecting workers' insurability, employability, and credit rating [33–36]. Subsequent research showed little evidence that notification of occupational health risks leads to significant long- or short-term psychological consequences [37–39]. One study also reported that after 3,189 notification letters were mailed containing a toll-free number for additional information, only 40 calls were received, suggesting that cost of follow-up after communication of results may not be especially burdensome [40]. Authors in the occupational health literature have carefully assessed the method, timing, and content of risk-notification procedures; clinical investigators considering how to approach communication of research results may find these analyses and the lessons learned useful [34,40–46].

Both the clinical research and occupational health literature demonstrate that some participants will show positive and/or negative psychological changes after receiving research results. However, studies of the psychological impact of genetic testing demonstrate that individuals tend to exhibit less emotional distress than anticipated by clinicians, and show strong coping skills in dealing with undesired

results [47–50]. Likewise, the balance of evidence suggests that false reassurance is not a significant problem for the communication of research results [51–55]. Three studies that identify false reassurance suggest that inadequacies in explaining results may be to blame, and recommend that, in the case of genetic testing, the implications of positive and negative results be emphasized equally [56–58]. The impact of communicated study results may also vary by study type and characteristics of the participant population, including diagnoses, health status, education, and health literacy. Investigators should therefore tailor their communication practices with respect to the situation and needs of their intended audience. Future research should assess the effect of various modes of communicating research results on psychological sequelae, health behaviors, and understanding of results by participants. Importantly, despite the potential for negative psychological consequences, participants want the opportunity to receive research results. These data suggest that fear of psychological harm should not be used as a reason not to offer research results, without clear evidence of a threat to participants' safety.

The costs of communicating research results to a study population remain unknown. However, in the absence of data, two points should be considered. First, concerns over cost of disclosure often stem from the assumption that research results must be communicated in person, and in the case of genetics research, by trained genetic counselors. Though in some cases, in-person disclosure may encourage follow-through on clinical recommendations and discourage false reassurance, participants often prefer to receive results

in writing with contact information. Second, although there will undoubtedly be some expenditure associated with communicating research results, cost should not be used as an argument against routine offering of study results to participants unless communicating results would substantially compromise the feasibility of the research. Future research should therefore assess the actual cost of various communication strategies.

It remains unclear whether communicating research results to participants will significantly affect participants' perception of investigators and biomedical research, or influence their likelihood of enrolling in future studies. More empirical data will be needed to resolve this issue; however, participants tend to be grateful when they receive study results, suggesting that such communication may bolster public opinion of investigators and the research they conduct.

Our analysis of the empirical literature on disclosure of research results to participants also revealed that the impact of presenting aggregate results to participants may equal that of presenting individual results. For example, while post-trial disclosure of treatment randomization or communication of individual genotypes may be clear examples of information relevant to individual participants, aggregate results of epidemiological studies may be just as individually relevant if participants know their own risk factors. Furthermore, many studies we found did not explicitly identify a focus on aggregate study results, individual results, or both. As communicating these two types of results may pose different practical and ethical challenges, researchers should specify the type(s) of results under consideration.

The literature on communication of research results is limited by a lack of commonly used and well-validated measures for most outcomes of interest. This limitation may be especially problematic given that framing effects can result in widely differing estimates of preferences, attitudes, and impact. Additionally, detailed data extraction is often impossible when the impact of disclosure on participants is reported either qualitatively or using a Likert scale. It will therefore be necessary to employ rigorous study designs (e.g., controlled trials and longitudinal studies) to assess the effects of communicating research results. Finally, 16 of the 28 studies we identified involved either cancer or genetics research. Future research should consider issues specific to other clinical research settings as well as to sociobehavioral research.

As discussion and research move forward, we recommend that investigators include their planned approach to communicating aggregate and individual results in study protocols and address disclosure in informed consent documents. Research ethics committees should review the appropriateness of investigators' plans for communicating results. Much still rests, however, on careful examination of the ethical issues involved in determining investigators' responsibilities for communicating research results to participants. Policies should incorporate available empirical data into an ethical framework that (1) respects and supports the collaborative relationship between investigators and research participants and (2) enhances trust in, and trustworthiness of, research and researchers. ■

Supporting Information

Text S1. Search Methodology

Found at doi:10.1371/journal.pmed.0050091.sd001 (80 KB DOC).

Acknowledgments

The authors thank Susan Dorr Goold, Scott Kim, Scott Roberts, and Peter Ubel for helpful comments during the preparation of this manuscript. Mr. Shalowitz had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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