Providing Research Results to Participants: Attitudes and Needs of Adolescents and Parents of Children With Cancer

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ABSTRACT

Purpose

There is an increasing demand for researchers to provide research results to participants. Our aim was to define an appropriate process for this, based on needs and attitudes of participants.

Methods

A multicenter survey in five sites in the United States and Canada was offered to parents of children with cancer and adolescents with cancer. Respondents indicated their preferred mode of communication of research results with respect to implications; timing, provider, and content of the results; reasons for and against providing results; and barriers to providing results.

Results

Four hundred nine parents (including 19 of deceased children) and 86 adolescents responded. Most parents ($n = 385$; 94.2%) felt that they had a strong right to research results. For positive results, most wanted a letter or e-mail summary ($n = 238$; 58.2%) or a phone call followed by a letter ($n = 100$; 24.4%). If the results were negative, phone call ($n = 136$; 33.3%) or personal visits ($n = 150$; 36.7%) were preferred. Parents wanted the summary to include long-term sequelae and suggestions for participants ($n = 341$; 83.4%), effect on future treatments ($n = 341$; 83.4%), and subsequent research steps ($n = 284$; 69.5%). Understanding the researcher was a main concern about receiving results ($n = 145$; 35.5%). Parents felt that results provide information to support quality of life ($n = 315$; 77%) and raise public awareness of research ($n = 282$; 68.9%). Adolescents identified similar preferences.

Conclusion

Parents of children with cancer and adolescents with cancer feel strongly that they have a right to be offered research results and have specific preferences of how and what information should be communicated.

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INTRODUCTION

There is increasing acknowledgment that researchers have a moral obligation to offer a summary of the results of a clinical trial (and in some cases individual results) to research participants and their families.¹⁻⁵ Results can directly benefit participants and families by helping them to make future health care-related decisions or may indirectly benefit research as a whole.² However, there may also be negative implications of returning results to participants, such as emotional distress, the dissemination of premature conclusions, and additional resources and costs associated with conveying results.⁶⁻¹⁰ The relative importance of these benefits and risks from the participants' perspective is not known.

There have been conflicting reports regarding whether research participants wish to receive

results.¹¹⁻¹⁵ This is in contrast to an increasingly vocal patient advocate lobby that supports the offer of results. Institutional review boards are becoming increasingly aware of this issue, and more than a third of United States and Canadian institutional review boards require researchers to address this matter.^{16,17} As researchers support^{10,18-20} and begin to routinely respond to this obligation, specific guidance is needed to provide results in a manner that respects the participant.^{13,21}

This is the first study in a multinational, multicenter setting to determine the specific needs and attitudes of adolescents with cancer and parents of children with cancer with respect to an offer of research results. The opinions of adolescents and of parents of deceased children have seldom been explored. These findings may be used as a template to design a suitable process for the offer of results to participants of clinical trials.

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Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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The Appendix is included in the full-text version of this article, available online at www.jco.org. It is not included in the PDF version (via Adobe® Reader®).

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METHODS

Study Setting

This study was conducted at five hospitals caring for pediatric oncology patients—three in Canada (Halifax, Montreal, and Vancouver) and two in the United States (Atlanta and Memphis)—chosen to give a broad ethnic and linguistic diversity. The study was approved by each institutional research ethics board and in accordance with an assurance filed with and approved by the Department of Health and Human Services, where appropriate. Informed consent was presumed on the return of the anonymous questionnaires.

Study Participants

Previous research participation was not necessary. The study was designed to offer the questionnaire at each site to 20 consecutive adolescents and 100 consecutive parents of children of any age newly diagnosed with cancer, including those subsequently deceased. Adolescents were defined as patients diagnosed with cancer in a pediatric institution and at least 12 years of age or older at the time of the study. Adolescent and parents of children with cancer were identified as potential participants based on the date of their cancer diagnosis and were subsequently surveyed in follow-up. The start of the diagnosis interval was from January 1, 2001, and continued until the 100 consecutive parents or 20 consecutive adolescents diagnosed from that date forward had been contacted. It is likely that the majority had completed cancer-directed treatment by the start of the study in September 2005. One site (Montreal) continued until a target of 100 responses had been received and did not contact parents of deceased patients. At the Memphis site, recruitment was through a random sample of a long-term follow-up clinic. Thus three of the five sites offered the questionnaire to parents of children who had died. All demographic variables, including race and ethnicity, are self-reported.

Study Instruments

Adolescent and parent questionnaires were developed by the method of Dillman²² and validated through focus groups, expert review, and a pilot study.^{21,23} The adolescent questionnaire (28 items) and the parent questionnaire (38 items) took 15 to 20 minutes to complete. The questionnaires were translated into French and back-translated into English. Oral translation in Spanish or reading of the questionnaires for literacy issues was allowed.

We sought to determine whether a measure of affect would be useful in predicting the desired modality for return of results. The age-appropriate Positive and Negative Affect Schedule for Children (PANAS-C) or Positive and Negative Affect Schedule - Expanded Form (PANAS-X)²⁴ measure of affect was included in the parent and adolescent questionnaires. The Child and Expanded versions of the PANAS consist of an equal number of positive and negative mood adjectives and have excellent psychometric properties.²⁵

Study Design

A preannouncement was sent 1 week before the questionnaire. Self-administered questionnaires were distributed between September 2005 and September 2007 by mail with a cover letter and a stamped return envelope. Two reminders were sent to nonrespondents at each site at 2- and 5-week time points. The exception to this process was the Memphis site, where questionnaires were provided in the long-term follow-up setting. In Vancouver, some of the questionnaires were provided to those consecutive patients identified to be eligible coincident with a follow-up clinic visit. Questionnaires were completed on site or returned by stamped mailer. A token of appreciation was provided to participants. All data were centrally entered in duplicate and checked.

Statistical Analysis

Data were analyzed in SAS 9.1.3 (2005; SAS Institute, Cary, NC). Descriptive statistics were used to present the survey. Missing data and nonresponse rates are reported as percentages. Pearson's χ^2 test, *t* test, and the Mann-Whitney tests as appropriate were conducted to assess the associations between demographic characteristics and attitudes. The variables were identified a priori and included the following for parents: age, sex, education, race/ethnicity, country of study, family income, access to and comfort with the Internet, comfort with medical language, and whether they or their child has

been enrolled on a clinical study. Variables analyzed for adolescents included age, sex, education, race/ethnicity, access to and comfort with the Internet, and comfort with medical language. The results of the psychometric PANAS measures were used to examine whether positive or negative affect predicts (1) a participant desire for return of results and (2) the mode by which they would like the results. The skewed distributions of the values of attitudes found precluded examination of these associations by multivariate analysis, as a result of a strong indicated desire to receive research results.

RESULTS

Participant Population

Three additional parents had the questionnaires read to them. No participant required a Spanish translator. All respondents in the Montreal site used the French translation of the questionnaire. Study sites varied in the number of average newly diagnosed cases per year: Halifax, 60/yr; Montreal, 125/yr; Vancouver, 150/yr; Atlanta, 330/yr; and St Jude's, 416/yr.

Response rate was 442 (70.5%) of 627 parents and 112 (60.5%) of 185 adolescents. Some parents and adolescents declined to participate, leaving 409 parent questionnaires and 86 adolescent questionnaires for analysis. Nineteen of the parent respondents had a child who had died. Missing items were uncommon (median, 0.49%; range, 0 to 14.7%), except for the PANAS psychological measures (median, 17.1%; range, 15.9% to 20.1%). Two hundred ninety-one (71%) of 409 parents and 51 (59%) of 86 adolescents wanted a summary of the results of this study. Tables 1 and 2 provide the demographic details of the parent and adolescent respondents, respectively. The median age was 18 years for the adolescent category. When we compared the adolescent category respondents 18 years of age or younger versus older than 18 years of age, there were no significant differences with respect to sex, comfort in medical language, expression of rights to research results, or best reasons provided for returning results. Experience with research and access to and comfort with the Internet or medical language are reported in Appendix Table A1 (online only).

Participant Preferences for Receiving Research Results

Most parents felt they had a right to be offered results, although less strongly if the child had reached an age of majority (Appendix Table A2, online only). Adolescents also indicated that they had a very strong (*n* = 49; 57%) or strong (*n* = 24; 28%) right to results.

Respondents were asked to consider a theoretical situation wherein they had taken part in a study. The research results were categorized as good (participant potentially benefited), bad (participant potentially harmed), or neutral (results for all participants the same regardless of treatment). Respondents indicated the modality by which they would want to receive each category of results (Table 3). Both adults and adolescents had an increasing preference to receive results with negative implications by a more personal means of communication, although a substantial proportion of adolescents still indicated e-mail or letter as the preferred modality (43%).

Respondents indicated whether they would accept an offer of results categorized by positive, negative, or neutral implications (see responses in Appendix Table A3, online only). The descending order of parental preference for who should provide results was the researcher (*n* = 91; 22.2%), cancer physician (*n* = 87; 21.3%), family physician (*n* = 33; 8.1%), and research nurse (*n* = 66; 16.1%). A minority (*n* = 121; 29.6%) did not feel the need for personal contact.

Table 1. Demographic Characteristics of Participating Parents of Children With Cancer (n = 409)

Factor	No.	%
Age, years		
Median	40	
Range	15-74	
Relationship to child		
Mother	337	82.4
Father	59	14.4
Other legal guardian	4	0.9
Mother and father completed survey together	6	1.5
Highest level of education		
Grade 8	9	2.2
High school	88	21.5
College	136	33.3
University	152	37.2
Other	22	5.4
Financial income of family*, \$		
Less than 20,000	34	8.5
20,000-40,000	77	19.4
40,000-60,000	93	23.4
60,000-100,000	107	26.9
More than 100,000	87	21.9
Race/ethnicity		
White	351	85.8
Asian	20	4.9
African American	18	4.4
Aboriginal	4	0.9
Latin	5	1.1
Middle Eastern	5	1.1
Other	11	2.7
Diagnosis of child		
Acute myeloid leukemia	9	2.2
Acute lymphoblastic leukemia	161	39.3
Brain tumor	43	10.5
Hodgkin's lymphoma	21	5.1
Non-Hodgkin's lymphoma	29	7.1
Neuroblastoma	32	7.8
Wilms' tumor	24	5.9
Osteosarcoma	14	3.4
Ewing sarcoma	11	2.7
Rhabdomyosarcoma	13	3.2
Retinoblastoma	18	4.4
Other	31	7.6
Age of child at diagnosis, years		
Median	5	
Range	0-19	
Current age of child, years		
Median	9	
Range	1-24	
Child deceased		
Yes	19	6.3
No†	281	93.4

*Income choice was Canadian or US dollars, depending on site of survey. Results are combined given relative parity of currencies.
†Denominator includes only data from sites that contacted parents of deceased patients.

Table 2. Demographic Characteristics of Participating Adolescents (> 12 years old) With Cancer (n = 86)

Factor	No.	%
Age, years		
Median	18	
Range	12-22	
Sex		
Male	38	44.2
Female	39	45.3
Highest level of education		
Grade 8 or less	21	24.4
High school	19	22.1
Beyond grade 12	17	19.8
Race/ethnicity		
White	68	79.1
Asian	3	4.4
African American	5	5.8
Aboriginal	0	0
Latin	1	1.1
Middle Eastern	2	2.3
Other/not listed	3	3.5
Diagnosis		
Acute myeloid leukemia	1	1.1
Acute lymphoblastic leukemia	20	23.2
Brain tumor	9	10.5
Hodgkin's lymphoma	8	9.3
Non-Hodgkin's lymphoma	7	8.1
Neuroblastoma	2	2.3
Wilms' tumor	2	2.3
Osteosarcoma	5	5.8
Ewing sarcoma	1	1.1
Rhabdomyosarcoma	2	2.3
Retinoblastoma	0	0
Other	3	3.5

Information Requested in the Summary of Results

Parent and adolescent respondents information needs fit three themes: factual information, health implications for the child, and general research information (Table 4). Almost all parent respondents wished to be provided with a list of the scientific publications that were generated from the study (n = 372; 91%). Fewer adolescents were interested in receiving such a list (n = 51; 59%).

Timing of Return of Results

The typical steps of data analysis and the peer-review process for medical publication were briefly described.

Parents. Most parents indicated they wanted to be informed of results before publication. Most parents wanted results as soon as the study was accepted for publication (n = 136; 33.3%), followed by after peer review but before publication (n = 110; 26.9%), as soon as the study is finished and analyzed (n = 98; 24.0%), and a few only after publication (n = 49; 12.0%).

Adolescents. As with parents, most adolescents indicated they would not want to be the last to know. Their order of preference was as follows: as soon as the study is finished and analyzed (n = 28; 32.6%), as soon as study is accepted for publication (n = 22; 25.6%), after peer review but before publication (n = 13; 15.1%), and only after publication (n = 11; 12.8%).

Adolescents had similar preferences: order of preference was the researcher (n = 28; 32.6%), cancer physician (n = 22; 25.6%), family physician (n = 4; 4.7%), and research nurse (n = 8; 9.3%). Again, a minority (n = 14; 16.3%) did not feel the need for personal contact.

Table 3. Preferences for Modality of Return of Research Results Categorized by the Nature of the Implications of Results Reported by Parents of Children With Cancer (n = 409) and Adolescents (> 12 years old) With Cancer (n = 86)

Preference	Good Results		Neutral Results		Bad Results	
	No.	%	No.	%	No.	%
Parent						
Internet Web site	24	5.9	20	4.9	7	1.7
Letter or e-mail	238	58.2	241	58.9	100	24.4
Phone call or phone call followed by letter	100	24.4	53	13.0	136	33.3
Personal visit to clinic or research lab	38	9.3	34	8.3	150	36.7
Do not want results	1	0.2	2	0.5	4	1.0
Other	6	1.5	6	1.5	11	2.7
Adolescent						
Internet Web site	19	22.1	14	16.3	10	11.6
Letter or e-mail	58	67.4	52	60.5	37	43.0
Phone call or phone call followed by letter	13	15.1	17	19.8	18	20.9
Personal visit to clinic or research lab	12	14.0	12	14.0	35	40.7
Do not want results	2	2.3	5	5.8	2	2.3
Other	2	2.3	2	2.3	4	4.7

Reasons For and Against Providing Research Results

Parents and adolescents were asked about the reasons for (Table 5) or against (Table 6), providing research results to participants. The reason of citing distress to families caused by death of the participant was not statistically different for parents of a deceased child versus those of a living child. Many parents and adolescents indicated there was no good reason to avoid giving results.

Barriers to the Return of Results

Parents. We asked whether a serious complication or death would make it more difficult for the respondent to personally receive research results. Almost half of parents indicated that this would indeed make it harder (n = 191; 46.7%). However, there was no significant difference in this opinion between parents of deceased children and those of living children. Other barriers included concern about the ability of the researcher to communicate results in an un-

derstandable manner (n = 145; 35.5%). Lesser concerns included thinking about the original illness (n = 70; 17.1%) and costs associated with getting the results (n = 68; 16.6%).

Adolescents. Adolescents were primarily concerned about understanding the results (n = 43; 50.0%). Lesser concerns included thinking about the original illness (n = 8; 9.3%), costs associated with getting the results (n = 23; 26.7%), and lack of time (n = 20; 23.3%).

Factors Tested to Predict the Mode of Return of Research Results

Parental education, economic status, ethnicity (white v others), status of the child (deceased v alive), comfort with medical language, personal participation or authorization for their child's participation in research, and Internet access were not independent predictors of whether parents wished a return of results or the mode by which results should be returned. Current parental and adolescent affect (negative v positive) as described by the PANAS measures could not be

Table 4. Preferences for Elements That Should Be Provided in a Summary of Research Results as Reported by Parents of Children With Cancer (n = 409) and Adolescents (> 12 years old) With Cancer (n = 86)

Element	Parents		Adolescents	
	No.	%	No.	%
Reason for study	322	78.7	54	62.8
What was done on the study as a participant	220	53.8	23	26.7
What the good results were	370	90.5	63	73.2
What the bad results were	341	83.4	60	69.7
Are there any long-term problems for participants?	341	83.4	45	52.3
What is the next step for researchers studying this area?	284	69.5	38	44.2
Do I need to do anything for my future health because of the study?	290	70.9	48	55.8
Contact number for researcher or research nurse	212	51.8	20	23.3
Did the researchers learn anything helpful?	340	83.1	52	60.5
Other	11	2.7	3	3.5

NOTE. Respondents could choose more than one option.

Table 5. Reasons for the Offer of Return of Research Results as Reported by Parents of Children With Cancer (n = 409) and Adolescents (> 12 years old) With Cancer (n = 86)

Reason	Parents		Adolescents	
	No.	%	No.	%
Emphasize the importance of participant to the research project	220	53.8	40	46.5
Emphasize the importance of participant to research in general	181	44.3	40	46.5
Decrease the chance that the participant will feel used by the researcher	66	16.1	17	19.8
Provide information that may improve quality of life	315	77.0	54	62.8
Provide information that may prevent future harms	259	63.3	51	59.3
Raise public awareness of importance of research	282	68.9	50	58.1
Reduce secrecy surrounding research	115	28.1	20	23.3
No good reasons to return results	4	1.0	2	2.3
Other	20	4.9	0	0

NOTE. Participants could choose multiple reasons.

Table 6. Reasons Not to Offer Return of Research Results as Reported by Parents of Children With Cancer (n = 409) and Adolescents (> 12 years old) With Cancer (n = 86)

Reason	Parents		Adolescents	
	No.	%	No.	%
Distress caused by old memories for those who participated in studies to treat serious illness	73	17.8	27	31.4
Distress caused by learning the participant was not helped by research	54	13.2	18	20.9
Distress caused by learning the participant was harmed by research	107	26.2	18	20.9
Distress for families if the participant has since died	119	29.1	27	31.4
Distress caused by complications resulting in employment or insurance issues	59	14.4	7	8.1
Distress if the participant had received a superior treatment arm (guilt)	24	5.9	6	7.0
No good reasons to avoid giving results	222	54.3	32	37.2
Other	15	3.7	1	1.1

NOTE. Participants could choose multiple reasons.

assessed with respect to influencing attitudes to return of results as a result of a lack of statistical power.

DISCUSSION

Our study indicates that most parents of children with cancer and adolescents with cancer value an offer of return of research results regardless of positive or negative outcomes and feel that they have a strong right to receive them. The degree to which an individual participant considers results positive or negative may vary with their personal context and the nature of the research, although for the most part, one can make an assumption about the potential impact.

One must also acknowledge that results that imply a participant may have benefited or been harmed by research are not the same as research results that may be interpreted as “bad” or “good” news in other ways. We found that both parents and adolescents will generally accept impersonal means to communicate results with positive implications; however, 70% of parents and 60% of adolescents indicate their preference for results with negative implications to be communicated by either phone or personal visits. This latter oral communication process has significant resource implications.⁶ One will need to determine whether the attitudes expressed are best case preferences or whether less resource-intensive modalities to return results (especially ones with negative implications) are acceptable.

We found that parents and adolescents have a dual rationale for supporting the return of research results. According to them, receiving results may have direct health care implications impacting immediate quality of life, allowing for preventative measures or surveillance, and helping in future health care decisions, observations made by other studies as well.^{12,26,27} A second rationale is more intangible and includes increased understanding by the general public about the importance of research participation, and a reduction in secrecy.^{2,28} Our respondents did express a strikingly strong interest in the research outcomes and the next clinical and research steps contemplated, suggesting that they considered themselves partners in the enterprise.

Some studies have reported the potential operational pitfalls of returning research results.^{8,15,27,29,30} A uniform undertaking to consis-

tently offer the return of results will require increased grant budgets and timelines to allow for peer review, retain contact with participants, prepare lay summaries, and distribute results. In part, this burden to researchers is mitigated by our previous finding that parents feel personal responsibility for retaining contact for the purpose of receiving results.²³

There has been concern that return of results can cause distress to participants.^{7,31} In our study, some parents and adolescents reported distress as the strongest reason for not wanting a summary of results. These were related to learning of the participant being harmed and rekindling old memories, as well as potential impacts on insurability and employment. Of note, results from parents of deceased children were not significantly different from those parents with children who had survived with respect to concerns about personal distress in receiving results. It will be important to confirm these findings in a larger cohort of parents who have children who have died. It will also be important to prospectively evaluate the financial and personal impact of programs to return results. It will be essential to carefully inform participants of the risks and benefits of receiving results and of the distinction between a summary versus individual results, the latter requiring a higher degree of clinical reliability and validity before being offered.^{9,27,32}

A Web site–based return of results might have circumvented some of the logistic and cost issues, but unfortunately, neither the parents nor the adolescents indicated this would generally be a preferred way of communicating results. This parallels the findings of Baker et al³³ and others, who found that less than half of their respondents used the Internet for obtaining clinical health care information, and even fewer reported any substantial impact on health care use.

Our study has identified the specific elements that participants would want researchers to address. These issues fall into two categories: (1) study-related issues directly relevant to the participant, and (2) broader issues of how the results will impact future research. Both parents and adolescents wanted a reminder of the context of the study and the positive and negative aspects of the results, in addition to recommendations that they should consider for immediate and future personal health interventions. The interest in broader issues extended to how these results impact on current therapy for others and how the study results will be used in future research. These detailed elements should assist in building templates for a broad range of clinical trial settings.

To our knowledge, this is the first international, multicenter study describing participant needs and attitudes for the offer of return of results. Our study included institutional settings of various size, adolescents and parents of deceased children, those experienced and inexperienced with research participation, and a range of patients from those recently completing treatment to those with long-term follow-up. These wide experiences allow greater generalization of the findings. Limitations include inclusion of relatively few parents whose children had died and the fact that all respondents understood English or French. Alternate, culturally sensitive modalities to return results may be needed for other populations. We did not examine individual diagnoses, stage, or treatment factors. Finally, as respondents were asked to comment on theoretical scenarios, future studies will require careful assessment in actual research settings.

In conclusion, parents of children with cancer and adolescents with cancer place high value on the return of research results. We identified specific needs of participants with respect to timing, mode, provider, and content of lay summaries of research results, as well as the reasons for and against providing results and the barriers to providing them. Regardless of negative implications, participants wanted

to receive results, but conveyed in an appropriately supportive and personal manner. The future offers opportunities to systematically explore the impact on participants, researchers, and the research enterprise of different modalities for the offer and return of results to participants.³⁴ The detailed preferences provided here allow for researchers to plan for a responsive process in offering to provide research results.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

Conception and design: Conrad Vincent Fernandez, Rebecca Davis Pentz, Charles Weijer, Eric Kodish

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