Recommendations for the Return of Research Results to Study Participants and Guardians: A Report From the Children's Oncology Group

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ABSTRACT

Purpose

The Children's Oncology Group (COG) strongly supports the widely recognized principle that research participants should be offered a summary of study results. The mechanism by which to do so in a cooperative research group setting has not been previously described.

Methods

On the basis of a review of the available empirical and theoretic literature and on iterative, multidisciplinary discussion, a COG Return of Results Task Force (RRTF) offered detailed recommendations for the return of results to research study participants.

Results

The RRTF established guidelines for the notification of research participants and/or their parents/guardians about the availability of research results, a mechanism for and timing of sharing results via registration on the COG public Web site, the scope of the research to be shared, the target audience, and a process for creating and vetting lay summaries of study results. The RRTF recognized the challenges in adequately conveying complex scientific results to audiences with varying levels of health literacy and recommended that particularly sensitive or complex results be returned using direct personal contact. The RRTF also recommended evaluation of the cost, effectiveness, and impact of sharing results.

Conclusion

These recommendations provide a framework for the offering and returning of results to participants. They can be used by individual investigators, multi-investigator research collaboratives, and large cooperative groups.

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INTRODUCTION

The potential benefits of offering to return aggregate results from completed research studies to participants and their guardians are widely recognized.¹⁻³ These benefits include recognition of the participants' contribution to research, enhancement of the notion that participants feel valued and appreciated, dissemination of more accurate and nuanced results than may be portrayed in the lay media,^{4,5} providing of information that may be useful for short- and long-term medical decision making,^{1,2} and promotion of a broader public understanding of the societal benefits of research. Some authors have voiced caution about establishing a uniform requirement to offer research results,⁶ citing the potential for distress in revisiting a diagnosis or death, misunderstanding of

adverse information, or anger at results describing unfavorable outcomes.^{7,8} In addition, an equitable process for offering research results to participants raises resource concerns.⁹

Despite the potential for adverse effects, most research participants indicate that they place a high value on the offer of results.^{10,11} This finding is striking both for a summary of results and for individual results.¹²⁻¹⁷ An obligation to offer a summary of results is increasingly reflected in regulatory requirements at both the national and global levels¹⁸⁻²⁰; it is required by institutional review boards (IRBs)^{21,22} and recognized as a responsibility by researchers.^{23,24} Several investigators have recently tested mechanisms other than a Web site by which to return results, and reports of participants' experiences and satisfaction with these efforts are beginning to appear.^{12,25-29}

As research participants, researchers, regulatory agencies, and IRBs have endorsed the principle of returning results to participants, it has become clear that there is no published process for implementation in large research groups. Children's Oncology Group (COG) leadership therefore charged a Return of Results Task Force (RRTF) with developing guidelines. The deliberative process and specific recommendations are presented here for other researchers to consider and adapt to their own contextual requirements.

METHODS

Setting

The COG is a National Cancer Institute–funded pediatric oncology cooperative group with more than 200 institutions in North America, Australia, New Zealand, and parts of Europe. It registers more than 10,000 new patients each year for clinical and biologic research studies.

Task Force

The RRTF was first convened in October 2008, led by the COG Bioethics Committee, and met regularly in conjunction with semiannual COG research meetings. Members were drawn from a wide range of COG committees and organizational units, as listed in the Appendix (online only).

The RRTF focused its efforts on developing recommendations for returning a summary of aggregate research results, recognizing that individual-level research results and incidental findings unrelated to research aims are distinct challenges that must be addressed separately. The RRTF recommen-

dations are meant to be complementary to existing COG mechanisms to release data relevant to individual patient care, such as information about early closure of a trial for reasons related to efficacy or toxicity.

The RRTF reviewed the available literature, generated drafts of recommendations, held several face-to-face meetings, circulated multiple drafts electronically for revision, invited input from the full membership of the COG, and finally provided recommendations to the COG Executive Committee. The Executive Committee approved the RRTF recommendations in July 2010 and is responsible for their implementation. In preparation for this report, the literature review was updated. The authors representing the RRTF have reviewed these guidelines as currently written and continue to endorse them.

RESULTS

The RRTF identified key questions to be addressed in the policy. The deliberations, available literature, and recommendations are discussed in association with each of these questions and summarized in Table 1. As with any large task force, complete agreement on all issues was not always reached; however, these results reflect majority agreement, with minority opinions noted as appropriate.

Which Research Results Should Be Offered?

Recommendation 1. Results reporting the aims of all COG-sponsored phase I, II, or III studies and epidemiologic, biologic, and

Table 1. COG Recommendations for Offering and Returning a Summary of Research Results to Study Participants

Question	Recommendation
Which research results should be offered?	1. Results reporting the aims of all COG-sponsored phase I, II, or III studies and epidemiologic, biologic, and cancer-control studies should be offered proactively 2. As a condition of sharing data or specimens for secondary analysis, requesting investigators should be required to provide a lay summary of results
When in the scientific process should research results be offered?	3. Consistent with the requirements of ClinicalTrials.gov, results should be posted within 1 year of completing data collection for the prespecified primary outcomes of the study 4. If an abstract is to be presented at a meeting before this 1-year deadline, then a lay summary should be released as soon as is acceptable by the meeting's organizers and no later than the scientific presentation or publication of results 5. Participants should be notified that the results as presented in meeting abstracts may evolve over time 6. For secondary analysis, provision of the lay summary should occur with acceptance of the manuscript for publication
Who should be offered research results?	7. A summary of results of COG research studies should be offered to all participants 8. A summary of results posted on the COG public Web site should be openly accessible to any interested party
When and how should participants first be offered research results?	9. Participants should be informed of the intent to offer results within the informed consent document and reminded of this intent either upon completion of their study participation, in the long-term follow-up clinic, or both; participants should also be offered results when confirming ongoing consent for research from children who have now reached adulthood 10. Notification should include the mechanism by which the participant will be offered results, the anticipated timing of the results' release, and the potential risks and benefits of receiving results.
How and in what form should the lay summary of research results be disseminated to participants?	11. Return of results should be provided via a publicly accessible Web site; participants (and interested members of the general public) should be able to register for e-mail notification of a lay summary posting related to the study; the participant is responsible for maintaining currency of the e-mail contact information 12. The lay summary should be in an accessible level of English and, when locally relevant, translated into additional languages 13. The creation and content of the lay summary should follow a consistent template 14. Once available, either a PDF of the scientific report or an electronic link that describes these findings should be posted in the lay summary portal of the Web site
How should results anticipated to cause distress be handled?	15. The institutional principal investigator should be routinely notified of the posting of a lay summary; because distress may occur unpredictably, all participants should have access to a clinician at their home institution
How should questions that arise from lay summaries be addressed?	16. Participants should be directed to clinicians at their home institution to ask questions about the results
Which regulatory and legal issues are relevant?	17. COG members should be educated about their roles and responsibilities in implementing this policy; members are individually responsible for knowing their local, legal, and regulatory requirements
What follow-up research should be performed?	18. The use and impact of the COG Web site in returning research results to participants should be evaluated

Abbreviation: COG, Children's Oncology Group.

cancer-control studies should be offered proactively. The RRTF recognized that the COG conducts a large portfolio of studies encompassing primary clinical efficacy aims and developmental therapeutics, as well as biologic, banking, epidemiologic, and cancer control/supportive care studies.³⁰ In addition, expanded use of data and specimens for aims that were not anticipated at the time of original consent (ie, secondary analysis) is frequent. Respect for participants and for the value they personally place on the results were felt by the task force to drive the offer of the return of results.^{17,31} Thus, the scope of research results that should be offered proactively to individual participants is broad and should include at least primary and secondary aims of all COG studies. Results of these aims should be posted even if they become available many years after study closure.

Recommendation 2. As a condition of sharing data or specimens for secondary analysis, requesting investigators should be required to provide a lay summary of results. The timing of secondary analysis of existing data sets is not predictable, nor is the generation of findings from banked tissues.^{32,33} The RRTF recommended that a mechanism be in place to share secondary results. Participants should be educated about the possibility of the late timing of secondary analyses and the lack of predictability of scientific use of banked tissues. As a condition of access to the tissue bank, a commitment should be required of the requesting scientist to provide a lay summary to be posted on the COG Web site concurrently with publication of the scientific report, consistent with embargo restrictions.

When in the Scientific Process Should Research Results Be Offered?

Recommendation 3. Consistent with the requirements of ClinicalTrials.gov, results should be posted within 1 year of completing data collection for the prespecified primary outcomes of the study. A number of options were considered with respect to defining a time point in the scientific process when results should be shared. These included at study closure, at data release by a data safety monitoring board, at a fixed time point after data release, at the time of peer-reviewed publication in the scientific literature, or after publication. The majority of the RRTF members believed that the summary results should be rigorously vetted before being shared but that participants should also not be the last to know. This is congruent with opinions expressed by parents of children and adolescents with cancer.¹¹ Although a conventional test for the veracity of the results is a peer-reviewed publication,¹ significant concern was expressed by some that this interval is too long and does not acknowledge the posting of data through abstracts or the lack of conversion of some abstracts to full publications.^{34,35}

In establishing a timeline that would be measurable, the final recommendation specified that a lay summary be posted at the time of abstract publication and no later than 1 year after data release by the Data Safety Monitoring Committee, a timeframe congruent with the Federal Food Drug and Cosmetic Act requirements for public posting of results at ClinicalTrials.gov.³⁶

Recommendation 4. If an abstract is to be presented at a meeting before this 1-year deadline, a lay summary should be released as soon as is acceptable by the meeting organizers and no later than the scientific presentation or publication of the results. The RRTF recognized that the presentation of data through abstracts at meetings may generate considerable interest in both the scientific and patient communities, even though these may not be ultimately published as full manuscripts.³⁷ Publication of abstract results may lead to participants

learning of results through public media.³⁸ Negative consequences of this include learning about personally relevant information as the last to know, receiving potentially distressing information without appropriate support, and inconsistent information access by participants.

Recommendation 5. Participants should be notified that the results in abstracts may not be final. The RRTF emphasized the need to educate participants that the data in abstract form may not be fully mature. In addition, early interpretation of the data for an abstract may not have been subject to demanding, independent peer review.^{39,40} A recent study demonstrated that up to 10% of abstracts differ significantly in their final conclusions when published in full manuscript form.⁴⁰ The RRTF recommended that results presented in abstract form be accompanied by clear warnings about their limitations with respect to guiding subsequent clinical choices.

Recommendation 6. For secondary analysis, provision of the lay summary should occur with acceptance of the manuscript for publication. For lay summaries generated for secondary aims, secondary analyses, or biobank research, provision of the lay summary to the COG should occur with acceptance of the manuscript for publication. This different time point from primary aims recognizes that results may be generated at unpredictable time points after closure of the study.

Who Should Be Offered the Results of Research?

Recommendation 7. A summary of results of COG research studies should be offered to all participants. Any process that is developed to return results should recognize that the ability to request and access data will vary. Given the potential benefits, an offer of results should be made proactively to all participants and/or guardians, and not offered only to those who possess the means to make a request.¹ Thus, in general, a mechanism to offer results should be transparent and relatively simple to access without significant burden to the participant.

Recommendation 8. A summary of results posted on the COG public Web site should be openly accessible to any interested party. The RRTF proposed a Web-based, technology-driven automatic notification to registered participants of the posting of a summary of results. Because the research is publicly funded, open access is endorsed by the National Institutes of Health.⁴¹ The Web site is a public resource, and lay summaries are not confidential. The RRTF endorsed access by any interested member of the public. It is likely that health care providers will also take advantage of these open-access summaries to support discussions with participants and the clinical management of pediatric cancer patients.⁴²

When and How Should Participants First Be Offered Research Results?

Recommendation 9. Participants should be informed of the intent to offer results within the informed consent document and reminded of this intent either on completion of their participation in the study, in the long-term follow-up clinic, or both. Participants should also be offered results when confirming ongoing consent for research from children who have now reached adulthood. The RRTF recommended that participants be informed prospectively that the COG intends to offer them a summary of results. Three time points were considered, and all were adopted. First, a statement of the intent to offer research results should be made during the initial consent discussion. A statement to this effect has been included in the template for

COG clinical trial consent forms since 2006 despite the absence of a consistent mechanism to accomplish this. However, some evidence suggests that participants' retention of informed consent discussions may be suboptimal.^{43,44} A second time point was situated in the iterative contact that frequently occurs as part of a research study. A natural opportunity arises to reinforce this offer at the time when a participant completes study participation and, by extension, during long-term follow-up. A third time point is at the point of confirming ongoing consent for research in participants who have reached the age of majority. Parents have indicated that adolescents may be mature enough to consent for research at an even earlier age,⁴⁵ and thus, access to results is likely appropriate even before the age of majority.

Recommendation 10. Notification should include the mechanism by which the participant will be offered results, the anticipated timing of the release of results, and the potential risks and benefits of receiving results. Consent discussions should also include a general disclosure of potential risks and benefits of receiving research results. The potential for emotional and other harms should be discussed, and plans should be established to support the participants.^{7,25} The statistical design of the study should make the expected time to availability reasonably predictable. The participants should also be informed of the long timeframe that may encompass the analysis of secondary aims, data or bio-banked tissues as well as the possibility that study conclusions may evolve with time.

How and in What Form Should the Lay Summary of Research Results Be Disseminated to Participants?

Recommendation 11. Results should be provided via a publicly accessible Web site. Participants (and the general public) should be able to register for e-mail notification of a lay summary posting related to the study. Participants are responsible for maintaining currency of their e-mail contact information. The RRTF recommended an enhancement to the existing COG public Web site to provide a single access point for patients and families for clinical trials information. We believed that this is most effectively done through a Web site portal that can provide a lay summary of a new or ongoing protocol (currently called family summaries), information about amendments and study-related announcements, and the return of research results at the conclusion of the study. This has the advantage of engaging participants with the COG Web site from the onset of the study, thus improving their familiarity with the site and their ease of access to results in the long term.

Most study participants will be comfortable with accessing health-related information on the Internet,⁴⁶ and thus, provision of results through a designated Web site portal is reasonable.²⁶ All posted lay summaries related to a study would be retained in their original format and posted in chronologic order. The task force recognized that not all participants would have access to or feel comfortable with a Web site,^{11,47,48} and thus, alternate means should be provided. Because individual results are not being considered, and the results are in the public domain, security and confidentiality of these data are not required.

A repeated concern expressed by researchers is the burden and infeasibility of tracking participants for the purpose of sharing results.⁴⁹ The RRTF agreed that this is an unrealistic expectation of the researchers. Thus, the duty of updating this contact information would be that of the participants, a responsibility endorsed by parents of pediatric research participants as properly situated with them-

selves.⁵⁰ It is the responsibility of the interested participant to register for automatic e-mail notification of study results or to check periodically to determine if secondary analyses or biobank results have been posted.

Recommendation 12. The lay summary should be written in an accessible level of English and, when locally relevant, translated into additional languages. It was recognized that there will be a broad range of health literacy among individuals who access the COG Web site. The summary should be generated at a reading comprehension level accessible to the lay public.^{51,52} We recognized that this is only one aspect of health literacy. The translation of all lay summaries into languages used by COG research participants was felt to be resource prohibitive. Thus, the RRTF recommended that the lay summaries be published in English and that information be provided on how to obtain translation services. Where other languages (such as Spanish) are regionally prevalent, translation strategies should be provided by local institutions using current best practices.

Recommendation 13. The creation and content of the lay summary should follow a consistent template (Table 2). The RRTF recommended a process for the creation and vetting of the lay summary. The

Table 2. Recommended Components of a Template for Return of a Summary of Results to Research Participants

Main Section	Elements to Consider
Introduction	Thank you for taking part in the research General description of risks and benefits of receiving results Direction of questions to personal health care providers
Name of study	Include formal and lay name
Brief background reason for the study	List major questions asked in the study
Brief summary of what occurred in the study	List major interventions, including elements such as randomization
What are the major findings of study?	Include an interpretation as to whether these are positive or negative findings
What did researchers learn that will be helpful to children with this condition in the future?	Highlight if the experimental or standard arm will likely become the standard of the future
What are the next research steps?	Include a general statement of how the results from this study will be built upon
Are there any steps that you or your child should consider now because of findings of this study?	Provide a recommendation if there is clear evidence; provide a suggestion if less clear; qualify that any recommendations listed must be discussed with health care team
Are there any steps that you or your child should consider for the future because of study findings?	Provide a recommendation if there is clear evidence; provide a suggestion if less clear; qualify that any recommendations listed must be discussed with health care team Provide reference to long-term follow-up guidelines such as http://www.survivorshipguidelines.org/
Whom do I contact to receive additional information?	Direct participant to treating institution
Provide date of summary	Indicate whether and when update may be expected
Provide a list of publications with references that were generated from this study	This may be provided separately on the Web site

lay summary will be generated by the Nursing Discipline Committee, reviewed by the Patient Advocacy Committee and by an expert in communications, and vetted for accuracy by the study chair and statistician. Once posted, the lay results summaries should not be altered. If an amendment is required, the lay summary page should have an annotation indicating that an amendment has been posted. The template outlined in Table 2 for the elements that should be included in a lay summary is based primarily on feedback from parents and adolescents¹¹ and on an existing Web site from the United Kingdom (<http://cancerhelp.cancerresearchuk.org/trials/>).

Recommendation 14. Once available, either a PDF of the scientific report or an electronic link that describes these findings should be posted in the lay summary portal of the Web site. A majority (91%) of parents of children with cancer indicated in a study that they would want the opportunity to review the scientific publication of study results.¹¹ The RRTF recommended that access to original scientific publications be supported, when feasible. For example, a hyperlink to the journal PDF could be provided as part of the lay results summary page, if the publication is in open access.

How Should Results Anticipated to Cause Distress Be Handled?

Recommendation 15. The institutional principal investigator should be routinely notified of the posting of a lay summary. Because distress may occur unpredictably, all participants should have access to a clinician at their home institution. Studies have shown that participants want the results of research in which they have participated, even when those findings have negative implications.^{11,12,17,29} However, the RRTF recognized that there will be times⁷ when the receipt of a summary of results may warrant more direct personal contact (eg, when a high rate of serious long-term adverse events were noted or when the experimental intervention performed especially poorly).³¹ The potential for the need for personal contact should be flagged by the study chair and/or by the development team during creation of the lay summary.

The RRTF recommended that when a more personal process is required because of the sensitivity or implications of the results, COG institutional principal investigators be informed proactively of this fact. The institution is then responsible for dissemination of the results. Appropriate professional support should be available, especially if immediate clinical interventions are required, or the results have distressing implications for individuals.²⁵ Although conversations between the clinician and participant may be facilitated by a lay summary, the summary should be posted on the Web site only after a reasonable length of time to allow personal contact to occur.

How Should Questions That Arise From Lay Summaries Be Addressed?

Recommendation 16. Participants should be directed to clinicians at their home institution to ask questions about the results. Regardless of the anticipated level of distress, a process to access a clinician at the home institution should be made available to all participants. The institutional principal investigator and lead clinical research associate should be notified of the posting of a new lay summary so that the institution may prepare itself for questions. The principal investigator or clinical research associate should then be responsible for notification of the health care team.

Participants' questions should be addressed by their treating institution and health care providers. Because the study chair and COG protocol committee are unlikely to have either the jurisdictional authority or the full clinical context of the patient (and his or her family), study committee members should not typically discuss results with participants from institutions other than their own.

Which Regulatory and Legal Issues Are Relevant?

Recommendation 17. COG members should be educated about their roles and responsibilities in implementing this policy. Members are individually responsible for knowing their local, legal, and regulatory requirements. The offer of results to all participants may raise issues related to the local conduct of the research study. A participant may have suboptimal recall of what was covered under consent,⁴³ either as a result of being a child at the time of the study or forgetting or not fully understanding his or her participation.⁴⁵ These questions about participation should be addressed at the local institutional level.

From a regulatory point of view, the RRTF does not believe that central or local IRB review of each lay summary to be posted on the COG public Web site is required. The task force was not constituted to make a formal regulatory determination on this question. However, given the public nature of data on ClinicalTrials.gov, we believe there is no necessity to clear these postings with central or local IRBs, nor should there be any breaches of journal-imposed embargos or financial advantage, because all the data will be in the public domain. However, the RRTF did note that it would be important to obtain clarification by journal editors of embargo policies in light of ClinicalTrials.gov requirements to publicly post results within 1 year, because this timeframe is also being used for the posting of lay summaries of results.

Because the COG operates in multiple countries, the two regulatory affairs departments of the COG (located in Canada and the United States) would find it difficult for reasons of expertise, staffing, and language skills to maintain familiarity with the local legal, regulatory, and ethical requirements related to the return of research results. Thus, local researchers should be encouraged to alert the COG Regulatory Affairs Department about any affirmative obligation of researchers to disclose results or, conversely, any conflict between local and national laws, regulations, and policies and the COG policy to return research results.

The US Common Rule does not speak directly to this issue.⁵³ The TriCouncil Policy Version 2, which describes Canadian human research obligations, currently requires the offer of a return of results with potential relevance to the participant.⁵⁴ The US Food and Drug Administration Amendments Act of 2007³⁶ states that results must be reported to ClinicalTrials.gov within 1 year of completing data collection for the prespecified primary outcome, and the National Institutes of Health NNOT-OD-08-033 indicates that publicly supported peer-reviewed articles must be submitted to PubMed Central within 1 year of publication.⁵⁵ The public provision of results in a lay format should not be compromised by these requirements.

What Follow-Up Research Should Be Conducted?

Recommendation 18. The use and impact of the COG Web site in returning research results to participants should be evaluated. The offer of a summary of results has only recently been recognized as a principled obligation of researchers. Methods used to provide research results have ranged from summary letters to leaflets to personal

contact.^{12,25-29} These studies continue to demonstrate high interest by participants in research results. They also show that participants' experiences of receiving results are generally, although not uniformly, positive. Nevertheless, formal research to evaluate the effectiveness and costs of this COG initiative is needed. Evaluation should encompass frequency of access, understanding of summaries, psychological impact, perceived utility by participants, and impact on health care providers at COG institutions. The Web-based mechanism proposed here offers opportunities to embed surveys of individuals who access results, facilitating ongoing evaluation of the results return process.

DISCUSSION

The RRTF has provided detailed recommendations for the return of research results in a consistent and accessible manner to participants. Although the primary mechanism for the offer of results is an open-access portal on the COG Web site with notifications of new postings e-mailed to registered individuals, the RRTF recognized that other means may be preferred by participants,^{25,27,31} especially if the information is expected to be distressing. The Web site archive of lay summaries may thus be used either as the sole means of communication or as a tool to facilitate discussion in clinical settings. We believe that proactive registration for notification of posting of results is an essential component of this plan that addresses the uncertainty of timing of availability of results and treats participants in a uniform manner, such that the results are offered to all, not just those with the means to request them.

The strength of these recommendations lies in the wide multidisciplinary input, including representatives of the patient and family community, through the COG Patient Advocacy Committee. These recommendations are rooted in published evidence and should be widely adoptable within the cooperative group setting and by research teams that have existing Web sites. Although initial implementation

within the COG was delayed for organizational reasons, research groups considering adopting such a Web-based mechanism should be aware that the resources required to do so, based on the limited evidence to date, are likely modest. One limitation is the translation of these recommendations to researchers with insufficient resources to support a Web site. Even for these individuals, however, the task force recommendations provide the necessary elements to offer results in paper format.

We believe these recommendations could serve as a template that a wide variety of research organizations could adapt to their specific needs and contexts. Although the exact components of a process to return results may vary from institution to institution, we believe that universal participant access to a lay summary of results is appropriate and congruent with current ethical standards.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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

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