How to Return Research Results to Patients and Families?
The Children’s Oncology Group Experience

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COG Educational Track at APHON, 2020
Disclosure

- Dr. Kim Pyke-Grimm has no industry relationships.
- Off label use will not be discussed.
- Currently, I am a Postdoctoral Fellow in Palliative Care at Stanford University supported by the Stanford University School of Nursing Alumnae.
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Objectives

- To describe benefits of returning research results to study participants.

- To identify how participants and families can access return of research results from the Children’s Oncology Group.

- To identify how return of research results can be used in a clinical setting.
Ethics & Return of Results

- Beneficence
- Veracity
- Respect for People

Autonomy
Justice
The Research Experience

**Patient/Parent**
- Diagnosis is made
- Study offered
- Decision making - consent
- Participates in study
- Completes participation
- Enters survivorship care

**Children’s Oncology Group**
- Study monitored by protocol committee
- All patients complete study
- DSMC releases data
- Abstracts presented, manuscripts published

The world's childhood cancer experts
Patient/parent wonders, “Whatever happened with that study?”
Question

- Have any of your patients or families asked you about the results of the clinical trial they were enrolled in?
What is a Research Result?

Definition: An item of information obtained by experiment or other scientific method¹

¹Source: http://www.oxforddictionaries.com/us/definition/american_english/result
Considerations in Returning Research Results

Potential Benefits

- Participants’ contribution to research recognized
- Participants feel valued and appreciated
- Results disseminated in a more accurate and nuanced way
- Information may be useful in decision-making
- Broader public understanding of social benefits of research

Potential risks

- Distress in revisiting diagnosis or death
- Misunderstanding of adverse information
- Anger or sadness about results describing unfavorable outcomes

Bubela et al. 2004; Moynihan et al. 2000; Fernandez et al. 2003; Partridge & Winer 2002; Miller et al. 2008; Schulz et al. 2003; Markman 2006; Fernandez et al. 2004
Clinical Trials

70% of all children with cancer in North America enroll in a COG clinical trial

Many RCTs compare current best-known treatment/intervention (standard arm) vs. experimental treatment/intervention

These studies include clinical trials (phases I-III)
An Epidemiology Precedent

“It is valuable to many parents to receive information about results of research in which they have participated. We found little evidence of strong negative effects…”

Informed Subjects of Epidemiologic Study Results
Greta R. Bunn, Anne E. Kazak and Olga Machtman
Pediatrics 1996;97:486
COG Return of Results Task Force

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

Conrad V. Fernandez, Kathleen Racicome, Robert J. Wells, Jay R. Long, Wendy Pelletier, Mary C. Hooke, Rebecca D. Potts, Robert B. Noffs, Justin N. Baker, Maureen O’Leary, Gregory Bumann, Peter C. Adamson, and Steven Jeffe

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

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.
## Application of Recommendations

<table>
<thead>
<tr>
<th>Topic</th>
<th>Recommendation</th>
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</thead>
<tbody>
<tr>
<td>Which research results?</td>
<td>• Results of primary aims of COG Phase I, II, III studies</td>
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<tr>
<td></td>
<td>• Primary aims of phase I, II and III studies initial priority</td>
</tr>
<tr>
<td></td>
<td>(beginning with Data Safety Monitoring Committee (DSMC) release)</td>
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### Application of Recommendations

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<tr>
<td>When (in scientific process) to offer results?</td>
<td>• <strong>Primary analyses:</strong> One year from DSMC release</td>
</tr>
<tr>
<td></td>
<td>• <strong>Release with publication of primary findings manuscript</strong></td>
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## Application of Recommendations

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<th>Topic</th>
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<tr>
<td>Who should be offered return of results (ROR)?</td>
<td>• Lay summary is offered to <strong>all participants</strong></td>
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<tr>
<td></td>
<td>• Summary <strong>openly accessible</strong> on COG website</td>
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<tr>
<td>When and how should participants <strong>first</strong> be offered ROR?</td>
<td>• Informed consent document</td>
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<tr>
<td></td>
<td>• COG letter given at participant’s study completion and/or in the LTFU clinic</td>
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<td></td>
<td>• At <strong>re-consent</strong> for minors reaching age of majority</td>
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<tr>
<td>How to disseminate lay summary?</td>
<td>• Register on COG public website for email notification (participant responsible for keeping contact info current)</td>
</tr>
<tr>
<td></td>
<td>• In “accessible level” of English (local translation as needed) using a <strong>consistent template</strong></td>
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<tr>
<td>How to handle results anticipated to cause distress?</td>
<td>• Participants should have access to a clinician at their home institution</td>
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<tr>
<td>How to address questions that arise from receiving results?</td>
<td>• Participants should be directed to clinicians at their home institution to ask questions about results</td>
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<tr>
<td>What about legal and regulatory issues?</td>
<td>• Education of COG members and others about their roles and responsibilities r/t ROR</td>
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<tr>
<td>What follow-up research should be done?</td>
<td>• Evaluation of use and impact of the COG website in returning results to participants</td>
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What are my Rights as a Participant?

Included under "what are my rights as a participant?" in studies

- ROR paragraph explains how to receive results
- Advises that peds oncology team can give more information about how to do this
- Reminds that the summary of results may not be available until several years because treatment for all enrolled patients must be completed first

Remember – the consent is signed when they enroll. This might not be remembered when the treatment is completed.
Language Embedded in Consents

What are my rights as a participant?

During your follow-up visits after treatment, you may ask to be given a summary of the study results, which will only be available after the study is fully completed. A summary of the study results will also be posted on the Children’s Oncology Group website (http://www.childrensoncologygroup.org). To receive the results, you may either (1) go to the COG website to check if results are available or (2) register your information with the COG on its web site and have an email sent to you when the results are available. Your pediatric oncology team from your hospital can give you additional instructions on how to do this. Please note, that the summary of results may not be available until several years after treatment for all people on the study is completed, and not only when you complete treatment.
**Consents**

- Do you think that patients or families remember what they read in a consent?
- Do they keep a copy?
- Do they ask questions triggered by the consent form such as return of results?
- OR… is this just forgotten?
Case Study

Lawrence is an 8 year-old male who was diagnosed with Wilms tumor at 20 months of age. He was treated on AREN0532. He is being seen in long term follow-up clinic today and his parents ask, “what did the study show?”

You are his clinic nurse. What would you do?
Return of Results Website

- Do you know where the public COG website is?
- Do you know how to navigate to the Return of Results Webpage?
Letter to Participant/Family

Available on Children’s Oncology Group public website:

At end of therapy in follow-up clinic
Website Registration for RORs

Step 1
- The patient/family or interested member of the public registers their email associated with a particular study.

Step 2
- Registrant is notified that they are responsible for keeping email contact up to date.

Step 3
- Once a new lay summary is posted to the website, an automatic notification email is sent to all those who register.
“COG is committed to returning a summary of results to participants. You are receiving this email as you registered to receive a notification once a summary of study results is posted. Recall that this may be several years from when you registered to allow the study data to mature.

You can access these results by clicking on the embedded link which will take you to the COG website.

https://childrensoncologygroup.org/return-of-result

This page has links to the results as well as to Frequently Asked Questions. Please note that we recommend discussing these results with your clinical team, if you have questions. This email is not monitored for return questions.

We thank you for your interest.”
C232_Return of Research Results
ROR Website Search Options

- Search by study number
- Search by cancer type
- Search in cancer type (identified by name, number, or years open)
Searching for AREN0532

Results of Completed COG Studies

You may find the study that you are interested in one of several ways:
- Enter a key word related to the study of interest into the Key word box below.
- Click on a disease type to open a list of all the studies related to this disease.
- If you know the 8 character study code number enter this in the study box (eg AREN0533)
- You may modify your search to look at only studies that are Open or Closed
- You may narrow your search by looking in the Status Column at the Year the study was Open or Closed.

Cancer Type

- Bone Cancer: Ewing Sarcoma
- Bone Cancer: Osteosarcoma
- Bone Cancer: Sarcoma
- Bone Marrow Transplant: Allogeneic Bone Marrow Transplantation
- Bone Marrow Transplant: Allogeneic Stem Cell Transplantation
- Bone Marrow Transplant: Autologous Bone Marrow Transplantation
- Bone Marrow Transplant: Autologous Stem Cell Transplantation
- Bone Marrow Transplant: Bone Marrow Transplant
- Bone Marrow Transplant: Cord Blood Transplant
- Bone Marrow Transplant: Hematopoietic Stem Cell Transplant
- Bone Marrow Transplant: Stem Cell Transplant
- CNS/Brain Tumor: Anaplastic
- CNS/Brain Tumor: Anaplastic Glioma
- CNS/Brain Tumor: Astrocytoma
- CNS/Brain Tumor: Ataxia
- CNS/Brain Tumor: Brain Stem Glioma
- CNS/Brain Tumor: Central Nervous System Tumor (CNS Tumor)
- CNS/Brain Tumor: CNS/Brain Tumor
- CNS/Brain Tumor: Craniopharyngioma

Type of Study

- Phase I (e.g., PK/PD)
- Phase II (therapeutic)
- Phase III (therapeutic)
- Bone Marrow Transplant
- Developmental

Open Year (Select One)

Closed Year (Select One)

Study Status

- Active
- Closed

Search Terms

AREN0532

Search
Display All
Clear Form
Searching for AREN0532

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>Protocol Title</th>
<th>Study Description</th>
<th>Study Summary</th>
<th>Summary of Results</th>
<th>Status</th>
<th>Phase</th>
<th>Opened Year</th>
<th>Closed Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>AREN0532</td>
<td>Treatment for Very Low and Standard Risk Favorable Histology Wilms Tumor</td>
<td>AREN0532 Description</td>
<td>AREN0532 Summary</td>
<td>View Results</td>
<td>Closed</td>
<td>3</td>
<td>2006</td>
<td>2013</td>
</tr>
</tbody>
</table>

Showing 1 to 1 of 1 entries
SUMMARY OF RESEARCH RESULTS FOR
AREN0532
Treatment for Very Low, Low and Standard Risk Favorable Histology Wilms Tumor

1. Introduction

The Children’s Oncology Group (COG) is committed to offering a summary of research results to participants in its research studies. When participants or their parents/guardians consented to the study, it was stated in the consent form that we would share the study results. This summary tells about the main results of the study. There can be benefits and risks to learning study results. A benefit for some people is knowing that they contributed to the research, and that their participation is appreciated. Another benefit is that what was learned from the study may help them make decisions about health and medical care now or in the future.

For some people, a risk of getting study results is that it may make them feel distressed remembering a difficult time in life, or upset about the study results. This is especially true if being in the study did not help the child’s condition.

Please talk with your child’s cancer doctor about any questions or concerns you may have about this summary. Your doctor is in the best position to explain these results in relation to your child’s medical issues.

COG thanks all the patients and families who have taken part in our research studies. Patients and families who have taken part in COG research have helped us learn and advance the care of children with cancer.

2. Brief background - reason for the study

This study examined favorable histology Wilms tumor and had the following goals and aims:

1. To find out if it was safe to treat children less than 2 years of age with small, stage I Wilms tumors with surgery alone (no chemotherapy). This group of tumors was called Very Low Risk (VLR) Wilms tumor. We also wanted to find out in this group of children if...
COG ROR Lay Summary Process

DSMC release of study data

*Communication & Publications process

Notification of Nurse Liaison for RORs who assigns study to Summary Subcommittee Member

Study Chair, DCN, Study Nurse, Study statistician & PAC member develop and approve ROR lay summary

Final version to ROR Committee Co-chairs, COG Statistician & COG Chair

ROR lay summary posted on COG website after DSMC release and primary findings are published
Nursing Implications

Offering return of research results is an ethical imperative

- COG has a mechanism for doing this
- Parent/patient advocates in COG “carried the flag” for this program
- Nurses and other disciplines have shaped it

- Nurses should be aware of how to access ROR to provide anticipatory guidance
- Know that one “size does not fit all” — not everyone will want to receive research results
Thank you!