Research Advocacy Network

Advancing Patient-Focused Research

Results of Advocate Survey -Next Steps for Precision Medicine

April 1, 2019

In November 2017 Research Advocacy Network brought together NCI Steering Committee and NCTN advocates at a symposium to learn more about precision medicine trials like NCI-MATCH. The proceedings and recorded lectures play-back is available at: https://researchadvocacy.org/precision-medicine-symposium. On the last day of the symposium, a think tank session was held with advocate attendees to prioritize issues and propose solutions to address in our advocacy roles. During the think tank, the issues and suggested solutions listed here received the highest priority for further action at that time.

- **Awareness that not all results will have actionable mutations.**
  Solution discussed: Develop a checklist for informed consent documents to improve understandability of requirements for precision medicine trials. Consider delivering materials with multiple types of media (paper, video, etc.).

- **Inconsistent language and terms used by the healthcare team.**
  Solution discussed: Work toward more use of more consistent language and terms related to precision medicine among the healthcare team. Provide a glossary.

- **Access to tumor profiling including patient awareness of tumor profiling and physician knowledge of how to use such tests.**
  Solution discussed: Educate patients about tumor profiling. Provide materials to physicians that is patient friendly.

- **Site resources**
  Solution discussed: Examine cost barriers and look at ways to address-foundation or alternate funding to cover the costs. Patient consent should include an optional consent to use the tissue for research.

- **Precision medicine trials often have narrow eligibility requirements and even those with actionable mutations may be denied entry.**
  Solution discussed: Advocates in NCTN groups question each concept/ protocol for eligibility requirements

- **Small size of precision medicine trials does not result in strong evidence to change clinical practice**
  Solution discussed: Explore and evaluate endpoints for statistical significance and meaningfulness to patients and ways to increase sample size to provide stronger evidence.

Research Advocacy Network has now received funding from ECOG-ACRIN Foundation to continue working on the issues identified. Since quite some time has elapsed since the symposium and think tank, we gathered feedback by conducting an online survey to help determine next steps. We are pleased to share the results of that survey in this report.

There were 27 responses received in a one-week period. There were 4 questions posed.

Results from **Question 1-*Do you agree these are still important issues?*** revealed a strong motivation to continue discussing these topics with 100% of the respondents answering they felt these issues were still important.

Responses from **Question 2-** ***Are there issues you would add?*** included:

- Return of results of testing to the patient (6 responses)
  - Also, important issue for clinical test results sent back to community-based sites (RNs, staff) as well as to patient participants.
  - Access to biomarker testing results. Deeper dive on biomarker testing results besides just sharing major biomarker status (e.g. ALK+) Integration of biomarker testing consult (similar to genetic counselor consult).
- Financial toxicity / costs
  - Regarding costs for the patient's clinical trials...the informed consent asks the participant to ask their insurance company to pay for tests and procedures. A list of those items are not spelled out to the participant. I think advocates need to be involved in getting this issue addressed. I think this leaves clinical trial participants open to paying for things that they aren't completely aware of.
  - Out of pocket costs for patients, especially after a new drug becomes FDA-approved.
  - Rural and frontier areas present logistical issues
- Education
  - About precision trials in general.
  - Patient-friendly explanatory materials in advance of the physician appointment. This may prepare the patient to discuss the testing with the doctor and how to utilize the information in decision-making. Without such information, any 'consent' may be inherently coercive.
  - Tumor profiling education is mentioned in #3, but a wider scope of education is needed. The information available to patients/families has become even more confusing in terms of whether current tumor profiling, genetic testing, precision medicine, etc. is aspirational or actionable in-patient care/prevention/screening.
  - Patients need to better understand targeted therapy.
  - There needs to be a much broader community understanding of immunotherapy for the patient- what's happening, possible application, etc. The patient should already have some base understanding before they are sitting in front of the doctor. Otherwise, they are in essence blindsided and the doctor has a much bigger job to do, which is a big 'ask' on their time and expertise.
  - Health literacy of participants needs to be addressed with culturally and linguistically appropriate learning/teaching styles.

- Trial participation/ design
    - More about trial design, e.g. should a drug for a specific mutation be added to a baseline treatment or given alone
    - Is the trial disease-specific (my preference, such as MMRF's MyDRUG or LLS's AML Master) vs not disease-specific, such as NCI MATCH
    - Better rules for handling multiple mutations
    - Re-designing and re-thinking the precision trial structure. It would appear to me there may continue to be some biases among researchers who are not culturally cognizant when considering precision medicine. Will there be biases in recruiting? In terms of meaningfulness of precision medicine, what is the strategy for providing education and recruitment to under-represented populations?
    - Increase participation in clinical trials among patients seen in community cancer centers (85% of total cancer patients).
    - Inclusion of PROs specifically designed for precision medicine trials. So many current tools do not capture long-term adverse effects.
    - Proximity to institutions that offer precision medicine trials and treatments, resulting in logistical, financial, and other burdens (change of physician, transfer of records, etc.).
- Testing at progression and need for re-biopsy.
- Awareness to Pathologists in regard to decisions about need to hold back and/or release of tissue at patients' requests to enter clinical trials.
- How to get more evidence from real world/off label use. Clinical trial data is too limited but how to match biomarkers with results?
- Understanding when to pursue a targeted approach vs immunotherapy

Responses to **Question 3.** ***Please share if you know of projects addressing the issues?***

Actionable mutations

- ICAN/Exon 20 Group Molecular Tumor Board (applies to all rare lung cancer mutations).
- There is a great deal of research in kidney cancer to determine which gene mutations are responsible for metastatic growth in tumors which are generally slow-growing.
- MMRF MyDRUG has baseline regimen which everyone receives, including those that have no mutation

Inconsistent language

- Have been involved in some pharma discussions where this issue is raised frequently but not sure how much it has helped.
- LUNGevity Take Aim Initiative, LungCan Biomarker Testing Advocacy Project
- SWOG Plain Language project is working this issue, though focused on announcement of trials

Access to tumor profiling

- ICAN Global Sequencing Campaign, under development.
- Several patient advocate groups provide information to encourage tumor profiling where the disease is rare, or found at an especially young age, including KCCure and NORD
- Pancreatic Cancer Action Network will be launching "Precision Promise" in 2019. (https://www.pancan.org/research/precision-promise/) Although this is specific to pancreatic cancer, this initiative touches on many of the topics we discussed. Some of these program points may be transferrable to other clinical trials?

- LUNGevity Take Aim Initiative

Site resources

- SWOG Financial Reimbursement of Logistical Expense project (specific to SWOG Clinical Trials)
- http://www.ascopost.com/News/59192 and https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2696871?resultClick=3

Narrow eligibility requirements

- ICAN's Personalized Medicine Programs work with clinicians and industry to influence protocol amendments in order to expand patient access to the experimental agent.
- NCI education to their advocates of need to address these issues in evaluating study submissions at Task Force and Steering Committee levels.
- SWOG and ALLIANCE patient advocates use this kind of information to help shape more inclusive trials, reflecting the patient population
- SWOG is attempting to scrutinize eligibility requirements to note if they are too stringent.
- LUNGevity Scientific and Clinical Roundtable
- ASCO published a statement on Reducing Health Disparities among Sexual & Gender Minority Populations
- ASCO/FOCR eligibility criteria and related/supporting NCI/NCTN activities (note: the solution recommended is standard practice at SWOG and I would hope across the NCTN
- ACRIN Advocates published a training to address recruitment of minority/underserved populations for researchers

Evidence to affect clinical practice

- FDA is considering MRD testing as PFS surrogate marker for Myeloma. It would be great to have the I2team present status of the FDA engagement.
- ICAN's Patient-Reported Outcomes Study for Rare Lung Cancer Mutations
- I think trials like NCI Match and TAPUR are working toward this goal but will still have limited data
- NCI education to advocates of need to address these issues in evaluating study submissions at Task Force and Steering Committee levels.
- The solution recommended is standard practice at SWOG, formalized during SWOG Executive Review of each trial. I hope standard across the NCTN

Question 4 asked *What do you need to know and/or what tools would be helpful in addressing these issues?*

- A helpful tool would be an informative brochure placed in community oncologist's offices explaining targeted therapy and tumor profiling
- Develop a toolkit for Navigators, Advocates & Promotores/Community Health Workers.
- Consider adding Spanish translation to reach a broader audience. All patient materials should be written at a 7th grade reading level OR lower.
- Disease specific profiling used today, what percentage of clinical trials use them as inclusion/exclusion criteria
- Have access to publications / presentation abstracts from conferences whose questions and concerns have formed new groups and studies
- Development of decision-making tools for patients offered precision medicine
- Collection and validation of patient needs and priorities, including environmental scan in and out of the cancer space. Best, good and emerging practices to address same.

- Institutional awareness of the importance to involve research patient advocates in addressing these issues
- Training and tools to more effectively present the advocate and patient perspective to study team and other members of review panel.
- This is a very important project bringing NCTN advocates together; updates on progress will be very helpful.

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