

Tissue Issue II Think Tank Meeting Summary

Action Plan

After 1.5 days of productive discussion, the participants in the Tissue Issue II Think Tank focused their plans on the two topics and associated actions below. The ultimate goal for these and subsequent actions is to create an environment in which stakeholders such as patients, clinicians, and researchers have access to the tissue they need, when they need it, to pursue the health of the patient.

Topic – Give a Bit of Yourself for Cancer Research

Tissue donation for research is as important as blood donation. A campaign to make the public aware of this is needed to encourage tissue donation and to put public pressure on the need to improve biobanking. Public pressure could help to improve problems that occur between biospecimen donation and use in research—the “middle problem.”

Actions – Give a Bit of Yourself for Cancer Research

- The group will determine how to generate a list of 10 key activating questions that patients can ask their doctors about tissue donation and biorepositories.
- Mary Lou Smith and Elda Railey will test these 10 questions with patients and then make them available on the internet.
- Mary Lou Smith will ask Cynthia Chauhan to write a patient’s letter to their doctor, to be added to the patient file and passed along to an institution’s compliance officer, expressing their wish to donate tissue for research.
- Kemp Battle offered to share information about innovative work being done in the area of consents.
- Michael Katz will create a template for five success stories, including statistics such as the number of lives saved resulting from tissue donation. He will also create a template of the "what-ifs": in other words, what benefits may come when patients decide to participate in research by donating tissue. The potential topics for the success stories were:
 1. Chronic myeloid leukemia: CML is almost always positive for the Philadelphia Chromosome. About a decade ago imatinib (Gleevec) revolutionized the treatment of CML. Since then, additional drugs have further improved treatment: dasatinib, nilotinib, bosutinib, and ponatinib.
 2. HER2/neu is overexpressed in some breast cancers. Herceptin is a drug that is effective in HER2-positive patients.
 3. ALK fusions occur in some lung cancers. Crizotinib is a drug that has been found to be effective in ALK fusion-positive patients.
 4. Colon cancer
 5. BRAF mutations in melanoma. BRAF inhibitors like vemurafenib are effective in patients with BRAF V600E mutations, as well as several other related mutations (such as L597 mutations).
 6. GIST (curative)
 7. Cervical cancer vaccine, sepsis, and Alzheimer disease were also suggested.

- Linda House will put together a plan for a media campaign; this plan may contain Facebook, radio, and other components.
- Linda House will schedule an episode of the Cancer Support Community radio show in January or February.
- Liz Horn offered to contact Helen Moore at OBBR (now named BBRB), Genentech, Celgene, and/or other pharmaceutical companies to see what information is available on market testing of the public's baseline understanding of tissue donation and banking for research.

Topic – Spotlight on Biorepositories

A detailed understanding of the current state of biorepositories in the United States is needed before significant progress can take place with respect to the issues outlined during the first Tissue Issue meeting. Josh LaBaer noted that the NCI already dedicates funds to biobanks and suggested that without an explanation of what those funds are being used for, NCI will be unlikely to dedicate additional funding to biobanking. In addition, peer pressure and clear identification of role model biorepositories will help all biorepositories improve performance.

Actions – Spotlight on Biorepositories

- LaBaer J. 2012. Improving International Research with Clinical Specimens: 5 Achievable Objectives. *J Proteome Res*. Epub Sep 21 2012 was included in the meeting materials. Josh LeBaer to send out copies of a related paper: Gundisch S, Hauck S, Sarioglu H, Schott C, Viertler C, Kap M, Schuster T, Reischauer B, Rosenberg R, Verhoef C, Mischinger H-J, Riegman P, Zatloukal K, Becker K-F. 2012. Variability of Protein and Phosphoprotein Levels in Clinical Tissue Specimens during the Preanalytical Phase. *J Proteome Res*. Epub Nov 8 2012.
- Liz Horn, Connie Rufenbarger, Liz Frank and/or others in the group to start working on writing a white paper about the need for an inventory of biobanks, including beginning to outline the questions a survey of biobanks might ask.

Background

In February 2012, the participants in the Tissue Issue I Think Tank identified a broad range of hurdles facing access to tissue for cancer research. The group focused on a set of problems known as “the middle problem”—issues that occur between biospecimen donation and use in research—such as compliance, institutional ethics review, informed consent, communication of research results to tissue donors, the need for data sharing, and best practices for biospecimen collection, handling, and sharing. In addition, the group discussed the need for longitudinally collected biospecimens, community involvement in biorepositories, and public and other stakeholder awareness of issues surrounding biospecimens, biorepositories, and research using biospecimens.

The purpose of the Tissue Issue II Think Tank was to build upon the first meeting by generating a list of needed actions and then formulate an action plan. To start this process, meeting participants each submitted two priority actions for consideration by the group. These actions fell into three broad categories: 1) a movement or campaign to galvanize the nation to “wake up” to tissue issues; 2) an outcome-based action, such as a pilot or demonstration project; and

3) communication of standards to provide nurturance to the field by codifying and communicating best practices to stakeholders.

On November 15 and 16, 2012, the group convened at the DFW airport Grand Hyatt Hotel to formulate the action plan. The meeting was hosted by Research Advocacy Network and was structured as a “Think Tank,” as was the previous meeting. Unrestricted grant funds from Genentech and Celgene funded the travel and meeting expenses.

Participants

As in Tissue Issue I, a diverse group of scientists and advocates attended the think tank. Several others participated by phone.

In-person attendees

- **Cynthia Chauhan**, Patient Advocate, Mayo Clinic Breast SPORE
- **David Eberhard**, Associate Professor, University of North Carolina – Chapel Hill
- **Liz Frank**, Lead Advocate, Dana Farber/Harvard Cancer Center Breast Cancer Program
- **Charles Geyer**, President and Chief Medical Officer, CTNet – Statewide Clinical Trials Network of Texas
- **Andrew Godwin**, University of Kansas Medical Center
- **Liz Horn**, Director, Genetic Alliance Registry and BioBank
- **Linda House**, Executive Vice President, External Affairs, Cancer Support Community
- **Michael Katz**, Vice President, International Myeloma Foundation; Co-Chair, Patient Rep Committee, ECOG
- **Kemp Kernstine**, Professor and Chair, Division of Thoracic Surgery, UT Southwestern Medical Center
- **Joshua LaBaer**, Director and Professor, Arizona State University; Biodesign Institute, V.G. Piper Center for Personalized Diagnostics
- **Connie Rufenbarger**, Director of Project Development, The Catherine Peachey Fund, Inc.

Phone Participants

- **Dan Hayes**, Professor and Clinical Director, Breast Oncology Program, University of Michigan Comprehensive Cancer Center
- **Ginny Mason**, Executive Director, Inflammatory Breast Cancer Research Foundation

Contributors

- **Kay Kays**, Research Advocate ALLIANCE; University of Arizona GI SPORE External Advisory Board, AzMN Tissue Donor Awareness Project (TDAP); Pancreatic Liaison/TGen, PanCAN
- **John Minna**, Professor, Hamon Center for Therapeutic Oncology, Internal Medicine, Pharmacology, UT Southwestern Medical Center
- **Christie Pratt**, Patient Advocacy Coordinator, Department of Thoracic Oncology

Hosts

- **Elda Railey**, Co-Founder, Research Advocacy Network
- **Mary Lou Smith**, Co-Founder, Research Advocacy Network

Meeting Facilitator

- **Kemp Battle**, Meeting Facilitator and Board Member, Genetic Alliance

Meeting Reporter

- **Christine Micheel**, Program Manager, My Cancer Genome, Vanderbilt University

Discussion of Potential Areas of Action

Three broad categories of action were discussed by the group: 1) an awareness campaign; 2) a pilot or demonstration project; and 3) ways to provide nurturance to the field through communication of best practices. The actions proposed in advance of the meeting were summarized and categorized, and the resulting list was provided to meeting participants.

Early on day 2, Kemp Kernstine energized the group by proposing that patient contribution of biospecimens should be compulsory, and that this is justified because some patients are dying because others are not donating tissue. The discussion that followed covered potential areas of action including institutional red tape, approaches to informed consent (including shorter and universal forms), public readiness to donate tissue, public awareness of the need for tissue donation, sharing of biospecimens for research, patient and community involvement in biorepository governance, communication with tissue donors about use of biospecimens, and more. From this discussion, consensus on the value of a public awareness campaign developed.

On day 1 and the morning of day 2, Josh LaBaer suggested that a survey of existing biorepositories could help solve several problems: first, funding agencies like the NCI are unlikely to dedicate additional funds to biobanking without a better understanding of the return on investment of funds currently dedicated to biobanking; and second, focusing peer and public attention on high- and low-performing biorepositories will provide best case examples for other biorepositories to model and motivation for low-performing biorepositories to improve. The group discussed the 1999 survey sponsored by the National Bioethics Advisory Commission and carried out by the Science and Technology Policy Institute (then operated by RAND, now operated by the Institute for Defense Analyses).

Other ideas discussed and captured in the meeting reporter's notes included:

- Creation of an informed consent app to help patients and doctors navigate the informed consent process.
- Creation of a repository like ClinicalTrials.gov that biobank standard operating procedures can be deposited into before tissue research results are published.
- Creation of tools to enable patients to participate actively in the informed consent process, including patient-driven informed consent documents.
- Re-engaging Stand Up to Cancer with respect to the public awareness campaign.

- A U.S. News and World Reports' ranking of biobanks.
- Sanjay Gupta support of a public awareness campaign.
- Support for responsible research and, therefore, responsible use of biospecimens.

List of Resources Discussed

Below is a list of projects, reports, and institutions discussed during the meeting and captured in the meeting reporter's notes.

- The National Bioethics Advisory Commission (NBAC; <http://bioethics.georgetown.edu/nbac/>; charter expired 2001) sponsored the 1999 RAND survey. The Science and Technology Policy Institute (STPI; <https://www.ida.org/stpi.php>) did the work (STPI was then a center within RAND; STPI operated by IDA since 2003). The title of the report—authored by Elisa Eiseman and Susanne B. Haga—was “Handbook of Human Tissue Sources: A National Resource of Human Tissue Samples,” and it is available at http://www.rand.org/pubs/monograph_reports/MR954.html.
- ISBER – International Society for Biological and Environmental Repositories; <http://www.isber.org/index.cfm>.
- CAP – College of American Pathologists; [Biorepository Accreditation Program](#)
- CLIA – Clinical Laboratory Improvement Amendments; <http://wwwn.cdc.gov/clia/default.aspx>.
- Komen Tissue Bank - <http://komentissuebank.iu.edu/>.
- NCI Board of Scientific Advisors - <http://deainfo.nci.nih.gov/advisory/bsa/bsa.htm>.
- Red Cross – <http://www.redcrossblood.org/>; look for promotions such as zoo tickets for blood donation by searching Google.
- Stand Up 2 Cancer - <http://www.standup2cancer.org/>
- OBBR/BBRB – From <http://biospecimens.cancer.gov/default.asp>: “The Office of Biorepositories and Biospecimen Research (OBBR) has been moved to the [Cancer Diagnosis Program](#) of the [Division of Cancer Treatment and Diagnosis](#) of the National Cancer Institute, and will now be known as the Biorepositories and Biospecimen Research Branch (BBRB).”
- CAHub - <http://cahub.cancer.gov/>
- NCATS – National Center for Advancing Translational Sciences (<http://www.ncats.nih.gov/>) database of approved and investigational drugs, <http://tripod.nih.gov/npc/>
- National Mesothelioma Virtual Bank - <http://www.mesotissue.org/>, Michael Becich
- Sanjay Gupta - http://www.cnn.com/CNN/anchors_reporters/gupta.sanjay.html.
- U.S. News and World Reports - <http://health.usnews.com/>.
- Gina Kolata - http://topics.nytimes.com/topics/reference/timestopics/people/k/gina_kolata/index.html.
- NIST - <http://www.nist.gov/index.html>.
- ClinicalTrials.gov - <http://clinicaltrials.gov/>.
- YouTube - [http://www.youtube.com/t/about_youtube](http://www.youtube.com/t/about_youtube;); <http://en.wikipedia.org/wiki/YouTube>.
- Twitter - <https://twitter.com/about>; <http://en.wikipedia.org/wiki/Twitter>.

- Facebook - <https://www.facebook.com/facebook>; <http://en.wikipedia.org/wiki/Facebook>.
- Flickr - <http://www.flickr.com/>; <http://en.wikipedia.org/wiki/Flickr>.
- Pinterest - <http://business.pinterest.com/>; <http://en.wikipedia.org/wiki/Pinterest>.
- Survey monkey - <http://www.surveymonkey.com/>;
http://en.wikipedia.org/wiki/Survey_monkey.
- iPhone Apps - http://en.wikipedia.org/wiki/Mobile_app.