It’s All About the Patient: Putting Biospecimen Research in Perspective

NCI OBBR Best Practices Forum
Seattle
January 29, 2008

Deborah Collyar
PAIR: Patient Advocates In Research
Why do we study biospecimens?
Hint: it’s not about cool science, meeting regulations, or building careers!

To find better treatment, care, and prevention for people

Where do biospecimens come from?

PEOPLE
Today, you’ve heard about...

- How biospecimens help create new knowledge
  - Cool science
  - Quality and sharing information
  - May be a key to personalized medicine (if we ever get there)

- How will you **apply** it so that:
  - Patients in Peoria get the same care as honky-tonkers in Houston?
  - How to discuss with people who don’t understand the medical system or cancer in 15 minutes or less?
The promise

- Targeted therapies
- ‘Seek and Control,’ not ‘Search and Destroy’
- Genetic testing
- Fewer side effects
- Ability to predict and prevent
- Longer remission
- Longer survival
- Ultimately, die of something else

Adapted from: Paula Kim
Are we there yet?

- Very few successes
  - HER2: Trastuzumab (Herceptin)
  - EGFR: Cetuximab (Erbitux), Erlotinib (Tarceva)
  - Bcr-abl, KIT: Imatinib mesylate (Gleevec)

- Collaborations critical, but increasing slowly
  - No one person, company or institution can solve
  - System still follows 17\textsuperscript{th} century model
    - Barriers: institutional, research culture, regulatory, etc.

- Pathology used to be separate from patients
  - Keepers of the blocks, few standards, nobody cared
  - Now, specimens considered buried treasure!
    - How to get enough, right kind?
    - How to compare data?
We need to get this right

The good news
- More survivors
- Rapid scientific discoveries
- Increased expectations

The challenges
- Competing priorities
- Shrinking budgets
- Expanding costs
- More regulation

Data/information ≠ Knowledge

Dangers of not doing this well....
- False +, −, or other inaccuracies affect many people
- Can’t reproduce findings, un-validated biomarkers
- Wastes time, $\$, and erodes trust
- We don’t have time for this!
Best practices are more than freezer stats
Time to protect, partner, and share

Connect The Dots

Patients, Volunteers, Groups & Public
Academic & Community
Public Agencies & Policy Makers
Industry & Private Sector

Adapted from: Paula Kim
What do people have to do with biospecimens?

Everything!

- Biospecimens wouldn’t exist without people who get diseases or illnesses
- Clinical data enhances their value

Do people **know** this?

- No!
- Opportunity to connect them to research that **helps** them!
How do people think about biospecimens? They don’t!

- Most willing to give without thinking of ramifications
  - They need to understand issues for informed *choice*
- Privacy and confidentiality are valid concerns
  - Understand past research atrocities = mistrust
- Culture and beliefs = *attitudes*
  - Some believe the spirit lives throughout the body
  - Be cognizant of different cultures (multiple ones)
    - Everyone needs to understand potential of medicine
      - Dialogue about good AND bad uses to protect against misuse
- Depends on your approach
  - We are *research participants*, NOT human subjects
  - Acknowledge the psychological and physical aspects
In the genetic/genomic age…

- **DNA** = Human Bar Code
  - Everybody wants it
  - Affects YOUR Family Members

- **Pros**
  - Medical “miracles”

- **Cons**
  - Everyone knows all

**Example:** A reality check(point)

**How Do We Protect People & Still Do Research?**

© PAIR: Patient Advocates In Research
Expectations of a research participant...

- Ensure the **public trust**
  - Resolve IP issues so progress can be made
  - Operate in a culture of transparency, fairness, and accountability to all stakeholders
    - Especially regarding **commercial** partners

- Patient care comes first, even in a trial
  - Save a little for **future** clinical benefit too
    - Why wouldn’t he/she want new tumor marker tests once commercially available?
      - Won’t your Aunt Annie or your son Sam want them?

- **Adhere** to informed consent requirements
  - Including check box choices

Adapted from: Mary Lou Smith, Deborah Collyar
More expectations of research participants...

- **Share** the biospecimens and data with each other!
  - The more information researchers have, the faster they’ll figure things out (expected)

- **Communicate** with us
  - Don’t assume you know what’s best for us
  - Acknowledge our contributions
  - Remind us about research regularly
    - Helps reinforce participation and adherence for extra procedures > reinforces trust, increases visibility

- **Give research results** (general summaries)
  - Publish so others can benefit
  - Enhances understanding of research benefits
  - Alert to findings that could affect us/family members
  - Oh, and plan now for ‘personalized medicine’

Adapted from: Mary Lou Smith, Deborah Collyar
Patient advocates can help
We share **common goals** with research

- **Progress** Against Cancer
  - Treatment, ‘cure’, and ultimately prevention

- Increase Creativity & **Innovation**

- Eliminate Barriers & **Speed** Things Up

- **Protect** People from Harm
How Patient Advocates In Research (PAIR) Operate

Purpose: more relevant, effective research for people

- **Prod, & assist** multidisciplinary research
  - Discoveries > to practical results for patients
  - Infuse patient experiences/issues into research dialogue
  - Resolve/eliminate systemic barriers
  - Assist w/biospecimens and data
  - Bring higher degree of ethics, understanding, purpose
  - Help create better clinical trials

- Work with government agencies
  - Improve regulations and policies

- Work with others
  - Institutions, organizations, companies, public

- Help harness technologies for practical results
### Words matter: Cancer terms 101

<table>
<thead>
<tr>
<th>Term</th>
<th>Scientific Community</th>
<th>Public Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Test</td>
<td>That’s too bad; now what?</td>
<td>This is good, right?</td>
</tr>
<tr>
<td>Positive Test</td>
<td>That’s too bad; now what?</td>
<td>This is good, right?</td>
</tr>
<tr>
<td>Carcinoma In Situ</td>
<td>Pre–cancer, not to worry</td>
<td>Cancer, very worried</td>
</tr>
<tr>
<td>Support Services</td>
<td>Help science (e.g. pathology, epi)</td>
<td>Fit cancer into regular life</td>
</tr>
<tr>
<td>Chemoprevention</td>
<td>Drugs that reduce risk</td>
<td>Danger, stay away</td>
</tr>
<tr>
<td>Lay</td>
<td>All non–scientists</td>
<td>Down?</td>
</tr>
<tr>
<td>Environment</td>
<td>Patient controlled (e.g. diet, risk)</td>
<td>External forces (e.g. chemicals)</td>
</tr>
<tr>
<td>Community</td>
<td>Non–cancer center</td>
<td>Where I live and get treatment</td>
</tr>
<tr>
<td>Medical Advance</td>
<td>Incremental adjustment</td>
<td>New treatment</td>
</tr>
</tbody>
</table>

© PAIR: Patient Advocates In Research
<table>
<thead>
<tr>
<th>Term</th>
<th>Scientific Community</th>
<th>Public Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure</td>
<td>5 year survival rate</td>
<td>Never get it again</td>
</tr>
<tr>
<td>Clinical Trial</td>
<td>Research study</td>
<td>Sterile, experiment</td>
</tr>
<tr>
<td>Nodal dissection</td>
<td>Remove lymph nodes</td>
<td>A chemistry experiment?</td>
</tr>
<tr>
<td>Neoadjuvant</td>
<td>Pre-operative</td>
<td>Some kind of art?</td>
</tr>
<tr>
<td>Tumor Progression</td>
<td>Tumor is growing, bad news</td>
<td>Progress against tumor, good!</td>
</tr>
<tr>
<td>Treatment Failure</td>
<td>Patient failed the treatment</td>
<td>Treatment failed the patient</td>
</tr>
<tr>
<td>Complete Response</td>
<td>Specified time period</td>
<td>It doesn’t come back</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>‘Instrument’ measurement</td>
<td>How to live with cancer</td>
</tr>
<tr>
<td>Palliative Care</td>
<td>Handle symptoms, hospice</td>
<td>Complete care</td>
</tr>
</tbody>
</table>

© PAIR: Patient Advocates In Research
Patient Dilemmas with Words and Decisions...

- Invasive? Non-invasive?
- Academic Center? Local?
- Informed Consent?
- How to pick treatment?
- Do my kids need genetic testing?
- Where is my tissue?
- Eligible? Insurance?
- Am I Going to Live?

Personalized medicine?
Biospecimen?
Biopsy? 2nd pass?
Targeted Therapies?
EGFR Inhibitor?
Proteomics?
Where do patient advocates fit into biospecimens?

- **Help resolve ‘tissue issues’**
  - Researchers need tissue, never seem to have right kind
  - We can help find new resources, collaborators
  - Find process glitches (e.g. collection/banking)
  - Non-therapeutic biopsies

- **Consent and protections**
  - Help create understandable forms
  - Develop sensible consent processes for patients
  - Work with IRBs and national regulators
    - Help change policies and procedures to create coherent approaches
  - Follow-up procedures for clinical data

- **Usage**
  - Who, what, when, where, why, and how
  - Especially with commercial partners/benefactors

- **Educate**
  - Scientific and public communities
Examples of biospecimen partnerships

- Cooperative group patient advocates
  - E.g. CALGB, ECOG, etc.
- SPORE patient advocates
  - All funded disease sites
- VHL Family Alliance
- Multiple Myeloma Research Consortium
- Disease-oriented advocacy group biobanks
  - Genetic Alliance members (e.g. rare diseases, others)
- Friends for Life study
- Arizona AzTransNet, Myeloma Network
- Many more!
And now, a word for our IRBs

**Balance**, not total protection

- Research needed to make things BETTER!
  - Protect from unethical situations
  - Some diseases have better checks/balances
    - Science review, etc.

- Life isn’t 100% risk-free!
  - 99.2% chance of living daily (www.census.gov)
  - Patients want good, not total, protection
  - Most willing to take some risks
  - Want good information
And everyone in institutions...

1. Understand: you provide **SERVICE** = people biz
   - e.g. tissue banks, clinical trials
   - Competition = ANYTHING that’s easier to do

2. Deal with a PATIENT’s **reality**, not HCPs
   - Show “WIIFM:” their needs & motivations
   - Help them PARTICIPATE, not subject

3. Caution: **Don’t** oversell!
   - Provide quality, unbiased information

4. Go where the people go – go to **communities**!
   - People and patients are what make your work possible
   - Community workshops in common language (patient advocates can help)
   - Ties research results to value
     - Shows how they can personally help
How can YOU Help?

1. **Share** with your colleagues
   - Specimens, data, knowledge
   - Work to make this easier

2. **Train** yourself & office on:
   - Cultural competency & geriatrics
   - Listening & problem-solving
   - Use tools & tip sheets
   - Other?

3. Treat everyone with **respect**
   - Make consent real
   - Tape record discussions
   - Involve family if possible
   - Learn about their situation

4. **Explain** everything that is collected
   - Specimens AND data
   - Who has access, how, protections

5. Explain how options fit
   - Use **analogies**
     - Context of everyday life
     - Explain their commitments (i.e. visits & procedures)

6. **Don’t** answer ‘what if it were you?’
   - Help them with #1–5 instead!
Resources about biospecimens and people...

- The PRISM Readability Toolkit (Group Health, Seattle)  
  PRISM@ghc.org (all consents)
- NCI tissue brochure:  
  http://www.cancer.gov/clinicaltrials/resources/providingtissue
- Research Advocacy Network (RAN) materials:  
  http://researchadvocacy.org/publications/pdf/tissue_WhatIsTissue.pdf,  
- Dana–Farber Cancer Institute brochure:  
- The Wesley Research Institute brochure:  
15 Years ago...

- No one talked about cancer
  - Very large black-hole
  - Cancer much the same for 30 years

- We need people to
  - Help fix system problems **BEFORE** they impact patients
  - Find medical **solutions** before cancer hits
  - Help people find and consider **clinical trials**
  - **Educate** scientific & medical communities
  - Educate patients & public
  - **Take action**!
In another 15–30 years...

- What will we tell our children and grandchildren?
  
  “You don’t have to worry about cancer”
  
  – OR –
  
  “Prepare yourself for a major fight for your life”

- If we don’t change and move the system **NOW**, they will face the same problems
Now is the time to partner...

1. To address important *issues* to potential participants
2. To *fix* the biospecimen and research systems
3. *Involve* the greater advocacy community to educate and empower their constituents
4. To *increase* public awareness of the promise of tissue research
5. To realize that promise with tangible *results* for people

And in this order!
Thank you to...

- **Patient Advocates**
  - In PAIR (~200)
  - In SPOREs (~220)
  - In NCI CARRA (~170) and DCLG (15)
  - In Cooperative Groups (~80)
  - In FDA (~20)
  - Many others
  - Experienced: for creating new opportunities
  - New: for fresh ideas & energy
  - And to those who made a difference before their deaths

- **Researchers and staff for**
  - Dedication
  - Efforts
  - Collaborations

  - Paula Kim, Translating Research Across Communities (TRAC)
  - Mary Lou Smith, Research Advocacy Network (RAN)

Thanks for all you do for cancer patients and their families!

For more information, please contact:

Deborah Collyar, collyar@att.net