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

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PAIR: Patient Advocates In Research

Why do we study biospecimens?

Hint: it's not about cool science, meeting regulations, or building careers!

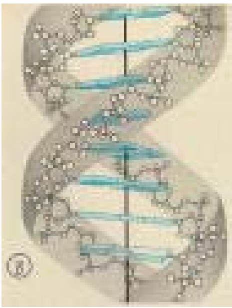
To find better treatment,
care, and prevention
for people

Where do biospecimens come from?

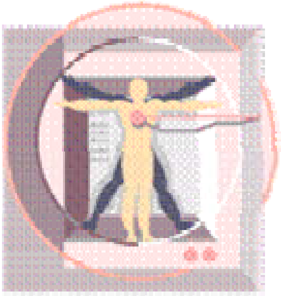
PEOPLE

Today, you've heard about…

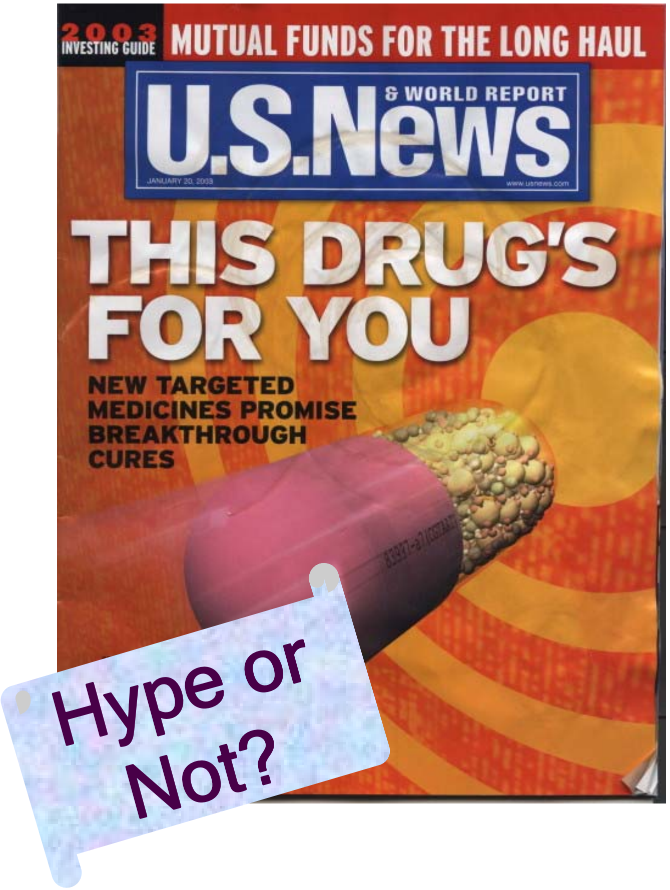
- How biospecimens help create new knowledge
  - Cool science
  - Quality and sharing information
  - May be a key to personalized medicine (if we ever get there)



- 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



2003 INVESTING GUIDE MUTUAL FUNDS FOR THE LONG HAUL

U.S.News & WORLD REPORT

JANUARY 20, 2003 www.usnews.com

THIS DRUG'S FOR YOU

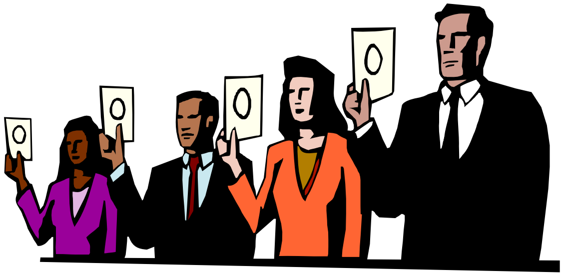
NEW TARGETED MEDICINES PROMISE BREAKTHROUGH CURES

Hype or Not?

- 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 17th 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

Data/information ≠ Knowledge

- The good news
  - More survivors
  - Rapid scientific discoveries
  - Increased expectations
- The challenges
  - Competing priorities
  - Shrinking budgets
  - Expanding costs
  - More regulation

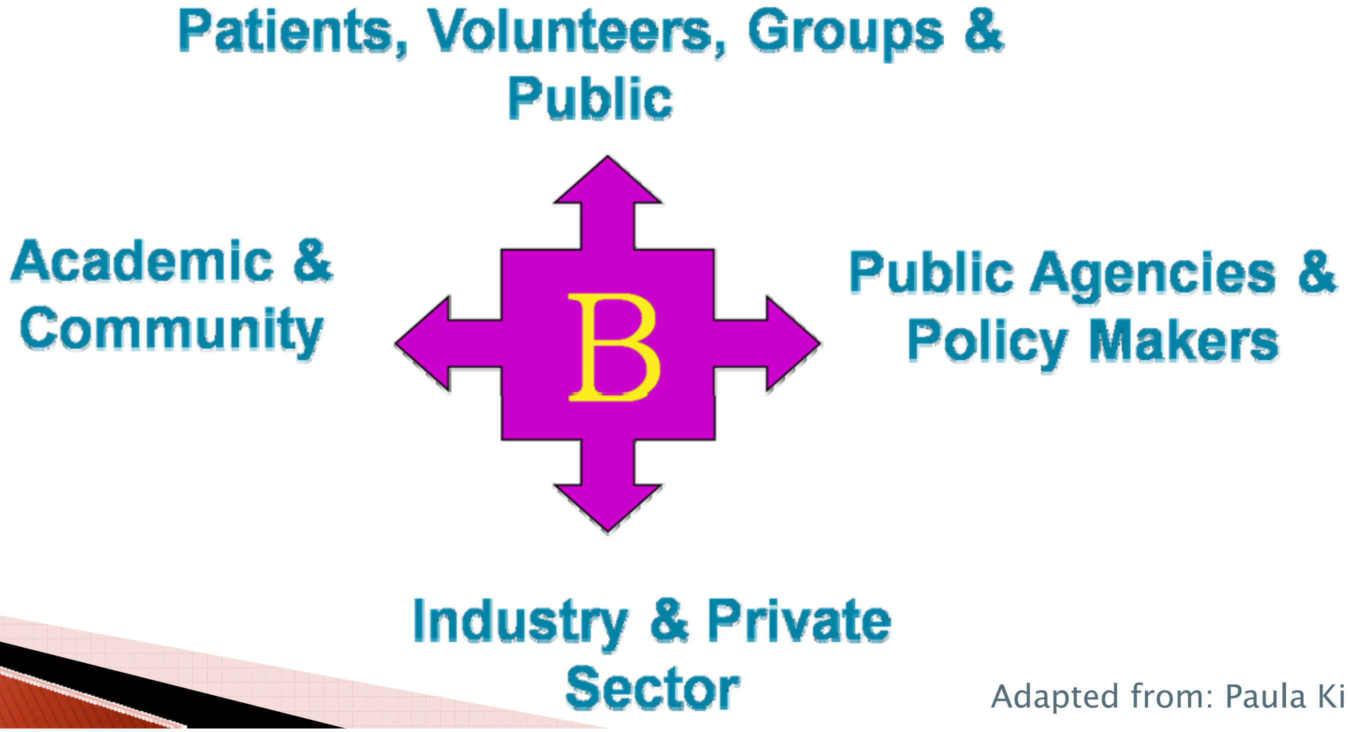
Dangers of not doing this well….

- 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!

Time to move the system

- Best practices are more than freezer stats
- Time to protect, partner, and share

Connect The Dots



Patients, Volunteers, Groups & Public

Academic & Community

B

Public Agencies & Policy Makers

Industry & Private Sector

Adapted from: Paula Kim

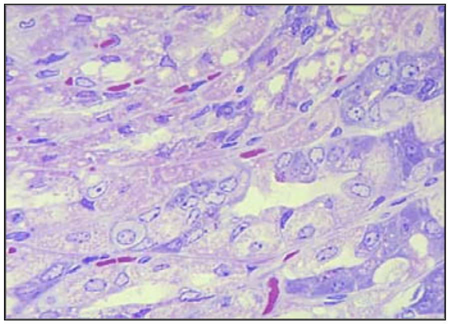
What do people have to do with biospecimens?

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

Example:
A reality check(point)

In the genetic/genomic age…

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

- Pros
  - Medical "miracles"
- Cons
  - Everyone knows all

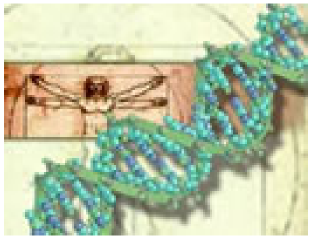
How Do We Protect People & Still Do Research?

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…



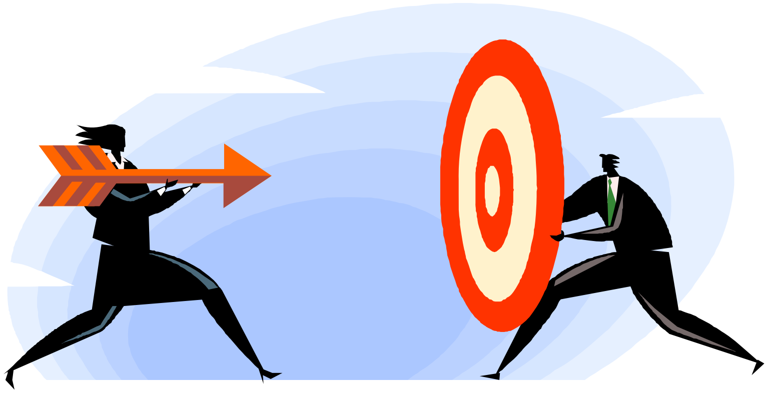
- Share the biospecimens and data with each other!
  - The more information researchers have, the faster they'll figure things out (expected)
- Communicate with us
  - Don't assume you know what's best for us
  - Acknowledge our contributions
  - Remind us about research regularly
    - Helps reinforce 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

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

Clinical words matter too: Cancer terms 102

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

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?

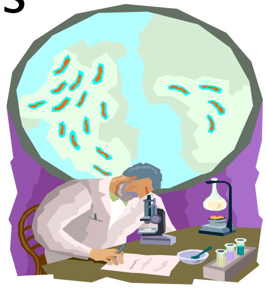
EGFR Inhibitor?

Proteomics?

Source: Paula Kim

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

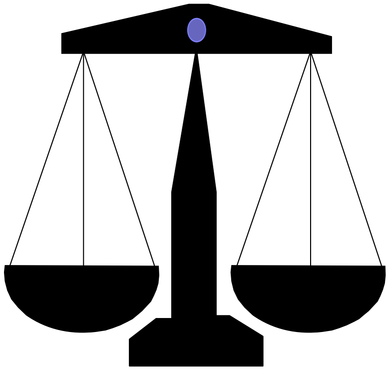


Examples of biospecimen partnerships

- 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, http://researchadvocacy.org/publications/pdf/tissue_ConsiderDonating.pdf
- Dana-Farber Cancer Institute brochure: http://dana-farber.org/res/tissue-banking.html
- The Wesley Research Institute brochure: http://www.wesleyresearch.com.au/docs/TISSUE_BANK.pdf

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:

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