

Biospecimens: Impressions from the human side of the skin

**BRN Symposium
March 16, 2009**

Deborah E. Collyar

- **PAIR: Patient Advocates In Research**
- **PART: Patient Advocate Research Teams**
- **CALGB CARE: Committee on Advocacy,
Research Communication, Ethics, and Disparities**

How does the Public think cancer research works?

Focus = making people's lives better

The Public assumes...

1. System moves quickly:

Discoveries



Development

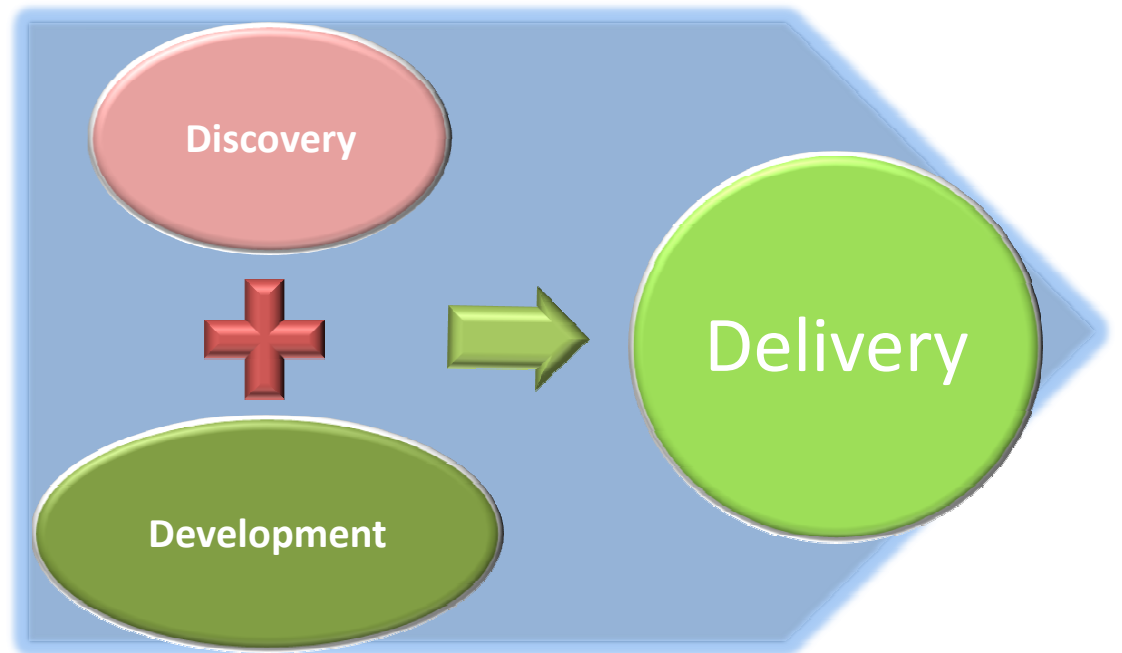


Delivery to clinic

2. Scientists share

3. Remain connected

Reality? Not quite...

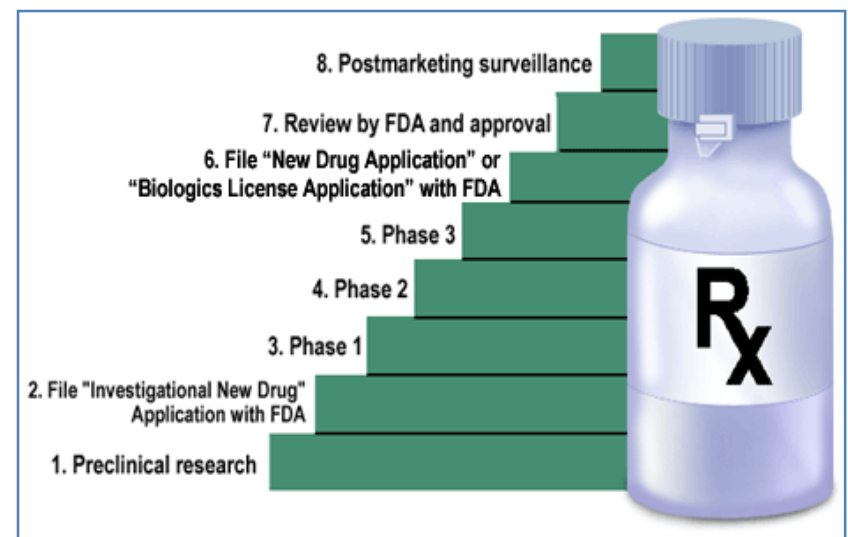


Translational research is hard

Development in non-development world

1. Academic focus = knowledge, not **results**
 2. Institutional policies/interests (i.e. **IP**)
 3. Regulations: Human protection
 4. Scientist motivations: PI **credit**
 5. Advancing technology
 - Data sharing / **protectionism**
 - Dogma **status quo**
 - Validation **markers**
- Preclinical + clinical trial
- Markers + agents

Lots of excuses



Translational research is hard



The real reasons?

1. Development is overlooked, therefore a bottleneck
 - Not “exciting/fun” enough; lots of failures, repetitious
 - No immediate career perks
 - Doesn’t fit complacency of tenure
2. No organized, coherent system to produce results
 - Lots of ‘silos,’ and myopic thinking
 - Rely on individuals & serendipity

Reaction when people find out?

- How can that be?
- What happened to the war on cancer?
- Why pay for it if we don't get results?



Result = **mistrust**

Today's buzzwords



Promises

- “Personalized” medicine
- Genetic testing/molecular risk
- Better control
- Manageable

For all?

- Biospecimen collections
- Multiple risks per person
- What has to **change?**
 - Scientifically/data
 - Clinical trial/biospecimens
 - Socially/culturally
 - Access/costs/rationing

*NOTE: ‘cure’ and ‘chronic’ are **not realistic** yet*

Promises: are we there yet?



- **Few** successes

- HER2:
 - Trastuzumab/Herceptin®
- Bcr-abl, KIT:
 - Imatinib esylate/Gleevec®
- EGFR:
 - Cetuximab/Erbitux®, Erlotinib/Tarceva®

- **Collaborations** slow

- No one person, company or institution can solve
- Barriers: feudal model
 - Institutional
 - Research culture
 - Regulatory
 - \$\$\$\$

- **Real life** issues

- Most drugs stop working
- Costs force rationing

USA TODAY Home News Travel Money Sports Life Tech W

News » Health & Behavior Medical Resources Health Information Your Health: Kim Painte

Study: Many cancer patients forgoing care because of cost

Updated 10/13/2008 12:57 PM | Comments 388 | Recommend E-mail | Save | Print | Reprints & Permissions | RSS

By **Liz Szabo, USA TODAY**

At a time when they're already fighting for their lives, more cancer patients are now struggling to pay for their medicines.

One in eight people with advanced cancer turned down recommended care because of the cost, according to a new analysis from Thomson Reuters, which provides news and business information. Among patients with incomes under \$40,000, one in four in advanced stages of the disease refused treatment.

Of late-stage colon cancer patients, 12% spent more than \$25,000 out of pocket, according to the survey, in which 1,767 people answered an online questionnaire. This type of survey

COSTS FOR FIRST YEAR OF CANCER TREATMENT

The cost of cancer care has increased dramatically in recent years both for patients and for their insurance plans. Depending on a person's insurance plan, patients could be on the hook for tens of thousands of dollars, experts say.

	2003	2006	Percent increase
Paid by health plan	\$37,504	\$57,657	54%

We need to get research right

Data/information ≠ Knowledge ≠ Results

- The **good** news
 - More survivors
 - More discoveries
 - More expectations
- The **challenges**
 - Shrinking budgets/
higher costs
 - More regulation

Dangers of not doing this well....

- False +/-, other inaccuracies affect millions
- Un-validated biomarkers ≠ commercial products
- Leaves some groups behind
- **Wastes time, \$\$\$, erodes trust, and costs lives**
- Business as usual won't work anymore

How do biospecimens fit in?

- Mice & cell lines get cured.
- People don't.
 - Biospecimens → 'personalized medicine'
 - Bench → bedside → beyond



Where do biospecimens
come from?

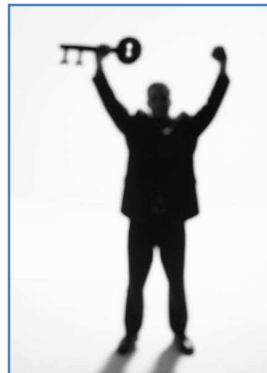
PEOPLE



What do biospecimens mean to you?



- End to a means?
- Tool/resource?
- Cool science?
- Publications?
- More grants?
- Regulations?
- Hassles?
- Career?
- Specimens aren't the end goal
- Means to reach **real goal**
 - **Results** that improve prevention, treatment, diagnosis, or care



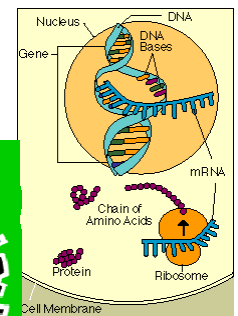
What do biospecimens mean to people?

Many things....

- Nothing
- Hope
- Pain
- Diagnosis
- Vulnerability
- Fear
- Science
- Loss of privacy
- Spiritual connection
- Loss of self, family, community

What can **you** do?

- ⊙ Understand past research atrocities = mistrust
- ⊙ Explain issues so they have informed **choice**
- ⊙ Acknowledge psychological & physical aspects
- ⊙ Respect their beliefs



What IS a patient's reality?

➤ Patient **A**: breast ca

- 27y Asian woman
- Career
- Married, no kids
- Lives in metro area

➤ Patient **C**: lung ca

- 45y Latina/Hispanic woman
- Never smoked
- Married, 3 kids, no insurance
- Lives in city, no car

➤ Patient **B**: breast ca

- 74y Black woman
- Retired, widowed
- Lives in rural area
- Family lives far away

➤ Patient **D**: lung ca

- 68y White man
- Heavy smoker, alcoholic
- Retired businessman
- Lives in suburbs

It depends...

- Lifestyle, age, support system, insurance status, responsibilities, culture, spirituality, transportation, attitude... **they all matter!**

For people, it's not about “cool” science



- It's a **life** decision, not a medical one
 - Includes biospecimens
 1. Are there extra procedures/costs/visits?
 - What level of extra pain/suffering?
 2. What are risks to me? My family?
 - Valid concerns: cultural beliefs important too
 3. Will options remain open, or close?
 - Performance status, future options & choices
 4. How does it effect work, family, social life?

Note: **pediatric** oncology does a much better job!

Time for more honesty between patients and doctors they never see

Patients: **altruism**

- Don't enroll in trials for 'future patients'
 - Secondary endpoint, at best
- Primary endpoint is **hope**
 - The 'lottery' concept
- Donate for the future
 - Adds meaning to a life
 - '**Insurance**' for progeny
 - Don't understand risks
- Want advances for all, including **diverse** groups

Pathology: **custodianship**

- **Honor** signed consents
- Don't hoard samples, data, or stack deck on usage committees
 - Forge **win/wins** between surgery, pathology, imaging, and researchers
- **Send** all requested biospecimens to researchers/banks
- Eliminate myopic **vision**

People don't give parts of themselves to be stockpiled forever.
Stop it! They want you to **share**.

Who are cancer patient advocates?

- Personal experience w/cancer
- Varied backgrounds
- Different approaches
- Speak and represent a group, not selves
 - Crucial to learn about cancer, research & issues

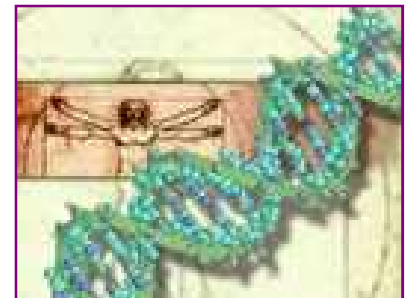
Common Cause

- Make things better for cancer patients



How research patient advocates fit

- Focus is on cancer **research**:
from epidemiology, to lab science, to
clinical trials, to public knowledge
- Apply special *patient expertise* to help
research **operations**:
 - Creates more relevant results for patients
 - **Challenge** current thinking
- Helps identify **barriers** that block advances
to cancer prevention, detection,
diagnosis, and treatment
- Take **action** to **resolve** issues



PARTnership examples...



- Biospecimens
 - ▶ Help **fix** 'tissue issues'
 - Help find new resources, collaborators
 - Help fix problems in collection/banking
 - Non-therapeutic **biopsies**
 - ▶ **Consent** and protections
 - Help create understandable forms
 - Develop patient consent processes
 - Work with IRBs and national regulators
 - ▶ **Usage**
 - Who, what, when, where, why, and how
 - Especially with commercial partners/benefactors
 - ▶ **Educate**
 - Scientific and public communities

Ex: CALGB CARE

CARE

Committee on Advocacy, Research Communication, Ethics & Disparities

4 Sub-Committees

Patient Advocacy

Co-Chairs:
Laura Cleveland
Deborah Collyar

Research Communication

Co-Chairs:
Mira Katz, Ph.D.
Ann Partridge, MD

Ethics

Co-Chairs:
Jeffrey Peppercorn, MD
Deborah Collyar

Disparities

Co-Chairs:
Cecilia DeGraffinreid
Deborah Collyar

Themes: Service, educational, and research activities

Development

Approval

Activation

Accrual

Compliance

Results

Reviews:

- Operational
- Concept
- Protocol

Informed consent:

- Templates
- Lexicons

Accrual plan:

- Tools
- Special populations
- Biospecimens

Tracking and advice:

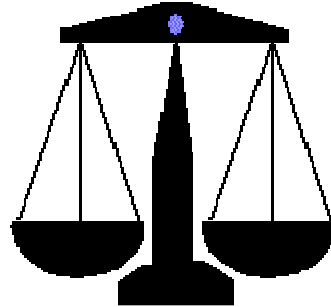
- Resource networks
- Protocol evaluation
- Accrual Plan adjustments

Participant communication:

- Letter templates
- Summaries
- Research results

Examples: a word for **IRBs**

Balance, not total protection



Research 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 **decent**, not total, protection
- Many willing to take some **risks**
- Want good **information**

Patient advocates are ready to help.

Are you? e.g.

1. Collect blocks marked for **disposal**...
 - Will that help? How?
2. Rapid **autopsy** program
 - Lessons from pilots? Families?
 - Why, who, what, where, when, how?
3. Incorporate biomarkers + **imaging** + drugs
 - Build effective plans (different than efficient)
4. caBIG tools, eHealth records, social networks
 - www.armyofwomen.org, www.twitter.com
5. Future tools, new regulations, etc.



Closing patient perspectives

I am a person, not a disease



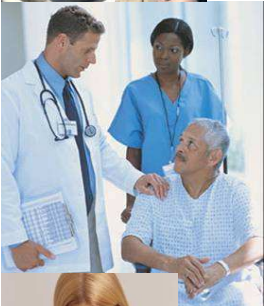
Explain it to me in MY language



Don't try to save me from myself



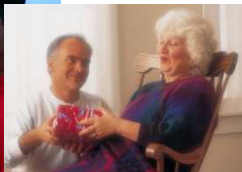
I will contribute if it helps me too



I want control over something



I have a life outside doc's office



It's my decision because it's MY life

So, why are we here?

- **Symposium**

- “Convivial meeting for drinking, music, and intellectual discussion among the ancient Greeks.”
- “Conference to discuss a topic, especially one in which the **participants** form an audience.”

- **Dialogue**

- “Exchange of ideas or opinions on a particular issue to reach an amicable agreement/settlement.”

- **Requirements:**

- Expect to **change** your opinion (we’re all learning)
 - Active listening is a skill (formulate response AFTER they speak)
- Practice the **Golden Rule**
 - Do unto others as you want them to do unto you
- **Communicate**; starting **today!**

Dialogue, don't duel-og

In another 15-30 years...

▶ What will we tell our kids?

“Don’t worry about cancer”

- **OR** -

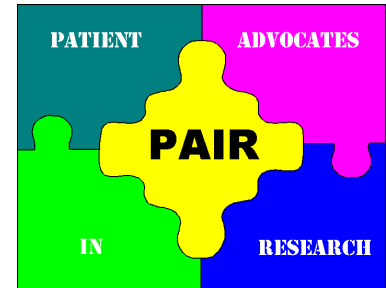
“Prepare for the fight of your life”

▶ If we don’t **transform** the system **NOW**, they will face the same problems



A screenshot of the MSNBC website. The top navigation bar includes the MSNBC logo, a search bar, and links for MSN Home, Mail, Sign In, and msn. Below the navigation bar, the page is categorized under 'Health / Second Opinion'. The main article is titled 'More profit than progress in cancer research' in red text, with a sub-headline 'With so many expensive drugs available, why aren't we doing better?'. The article is a commentary by Robert Bazell, Chief science and health correspondent for NBC News, updated on June 10, 2008. To the right of the article is a 'Sponsored links' section featuring 'Psychology Degree Online' and 'AARP Auto Insurance From The Hartford'. A large blue arrow points from the text 'they will face the same problems' to the article title. At the bottom of the article, there is a banner for 'CONFRONTING CANCER', an NBC Nightly News special series.

Thank you...



- Patient Advocates

- PAIR advocates (~200)
 - SPORE advocates (~220)
 - NCI CARRA advocates (~170) and DCLG (15)
 - Cooperative Group advocates (~80)
 - FDA advocates (~20)
 - Many others
- Experienced:
for creating new opportunities
 - New:
for fresh ideas & energy
 - And to those who made a
difference before their death

- Research teams for
 - Dedication
 - Efforts
 - Collaborations

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

- For more information,
contact
collyar@att.net