How we can make clinical trials better for & with people & patients

Health Literacy in Clinical Trials: Practice and Impact

NASEM

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PAIR: Patient Advocates In Research

The U.S. health ~~care~~ ***crisis*** system

Patients are PEOPLE

Congratulations! You have…

It’s like a new planet with:

- No roadmap
- No dictionary
- No survival training

What is it like to be a “patient”?

People need better treatments… but not at all costs

Issues start with:

- (mis) Diagnosis
- Confusion at each step
- Technology for ‘big data,’ not patient results
- Costs (many kinds)
- Clinical trials?

Patient dilemmas & decisions

Invasive? Non-invasive? Biopsy?

2nd pass? Am I Going to Die?

Risk? Genomics?

Personalized? Precision?

Academic Center? Local?

Tissue donation? Biospecimen?

Family genetics? Which treatment?

Targeted Therapies?

Informed consent? Eligible?

Ineligible?

Biomarker?

EGFR Inhibitor? Proteomics? Kras?

Insurance? Radiation?

Immunotherapy?

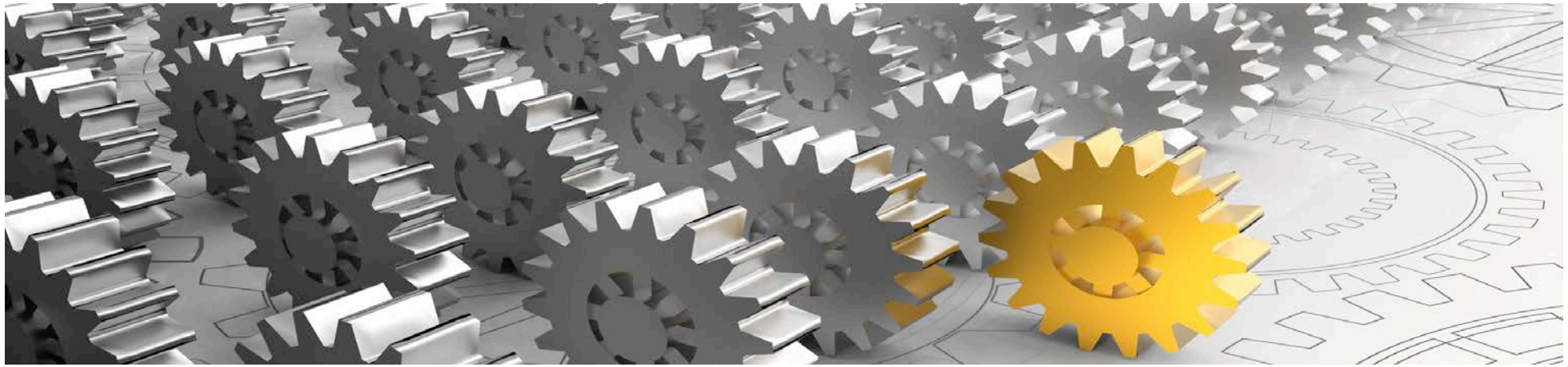
Words matter: Terms 101

Term	Scientific/Medical	Public Definition
Negative test	That's too bad	This is good, right?
Positive test	That's too bad	This is good, right?
Cure	5 year survival rate	Never again
Tumor Mutation Burden	Good!	Sounds bad, WTH?
Support services	Help science	Fit medical condition into life
Lay	All non-scientists	Down?
Environment	Patient controlled	External forces
Community	Non-academic center	Where I live
Medical advance	Incremental adjustment	A cure

What do patients want?

Patients want ***BETTER***,
not just more treatments.

And answers that work for them,
not just other people.



e.g. Immunotherapy (IO)… as of 2019

The “latest greatest” (again)

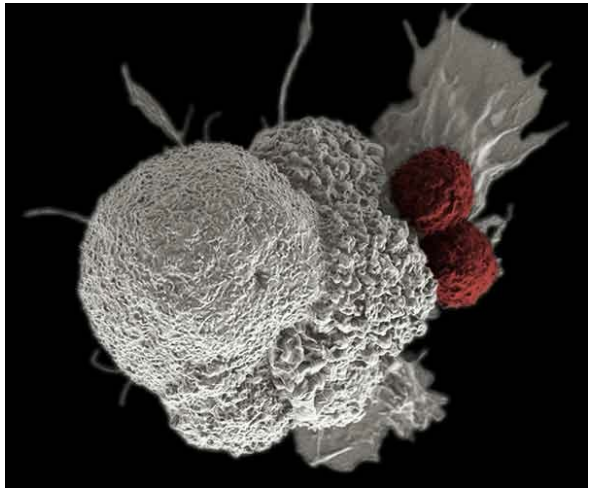
For a **minority** of cancer patients

- Most still get surgery, radiation, and/or chemotherapy

Promising, but…

- Many tumors don’t respond
- Not a total replacement therapy
- Side effects
- Trial results don’t transfer to commercial use
- Costs galore

Please set reasonable expectations!



What do patients want from immunotherapy?

Less hype, more realism

- Compared regimens > guidelines
- Integration w/other treatments
- Better care
- “C” word issue (cure)

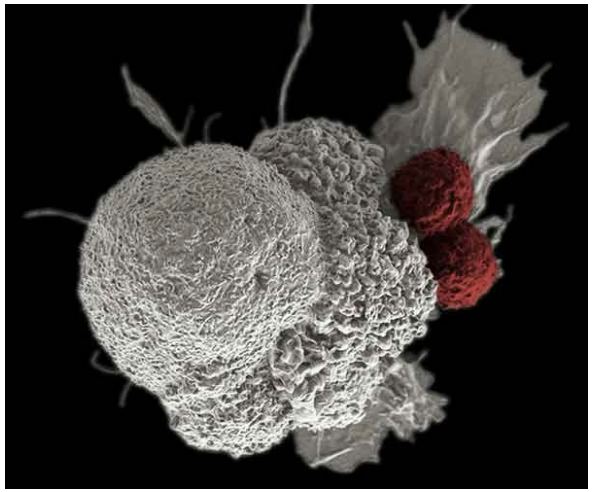
Fewer irAEs

- ≥ grade 2 can be serious
- Autoimmune is serious
- Possible age factors?

CONTEXT

Report additional info

- Response rates
  - Comparable to chemotherapy
- Duration of response
- Financial toxicities
- QOL & PROs



https://www.inspire.com/groups/american-lung-association-lung-cancer-survivors/discussion/opdivo-beware-the-hype-and-commercials/

https://jitc.biomedcentral.com/articles/10.1186/s40425-017-0300-z

http://yourcenter.uvacancercenter.com/autoimmune-disorders-and-cancer-whats-the-connection/

https://www.medscape.com/viewarticle/897946

http://bit.ly/2LD4YPX

PAIR represents **people** first, then research

Clinical Research:

Concept and protocol design/review ⟷ feasibility

Recruitment plans & materials ⟷ understanding

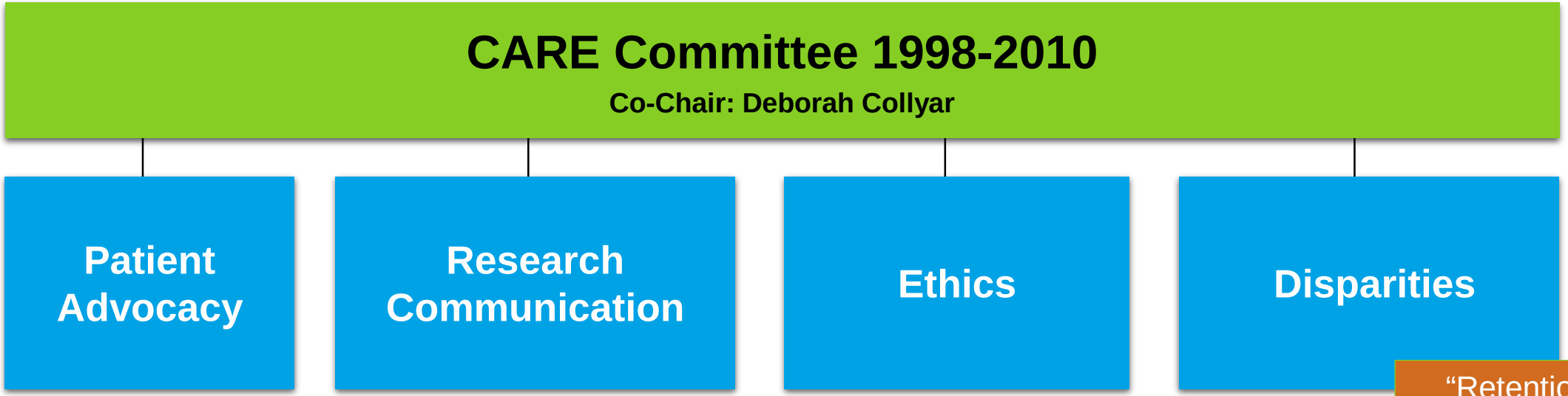
Regulatory, collaborators, etc. → speed

Ethics/Institutions Review Boards → risk & info

Communities and populations ⟷ influence

Plain language summaries → results & context

e.g. Cancer & Leukemia Group B



Themes: Service, educational, and research activities

Development → **Approval** → **Activation** → **Recruitment** → **Endurance** → **Results**

Reviews:
Operational
Concept
Protocol

Informed consent:
Templates
Lexicons

Recruitment plan:
Tools
Special populations

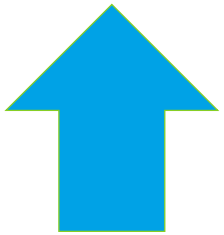
Tracking and advice:
Resource networks
Protocol evaluation
Accrual Plan adjustments

Participant communication:
Thank you letters
Research summaries

Which statement is correct?

A. “the patient failed the treatment”

B. “the treatment failed the patient”

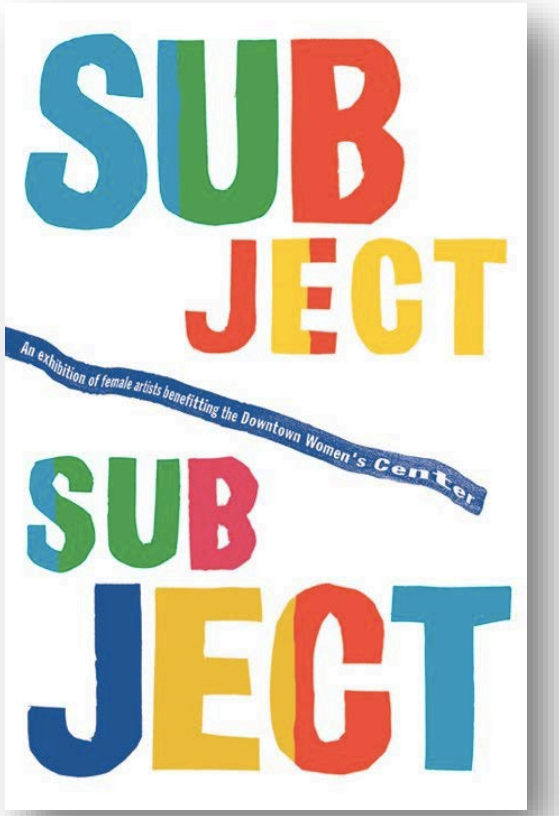


Please **stop** using this one!

i.e. Informed Consent

What do patients want to know?

- ✓ I am not alone (others before me)
- ✓ Why are you doing this?
  - What is known/unknown?
- ✓ What to expect
- ✓ How bad can it get: what's my 'safe' word?
- ✓ What happens after?



ONGOING COMMUNICATION IS KEY!

Why are we doing trial summaries in the first place?

For trial participants & public

- ✓ To share what was learned
- ✓ "You made a difference"

For sponsors

- ✓ Shows respect + goodwill
- ✓ Good for HCPs too

Plus…

- ✓ We TOLD them we would!
- ✓ Oh, & Regulation (EU) 536/2014
- ✓ Canada & US coming along too

Words Matter series from PAIR

http://www.merriam-webster.com/dictionary/lay says

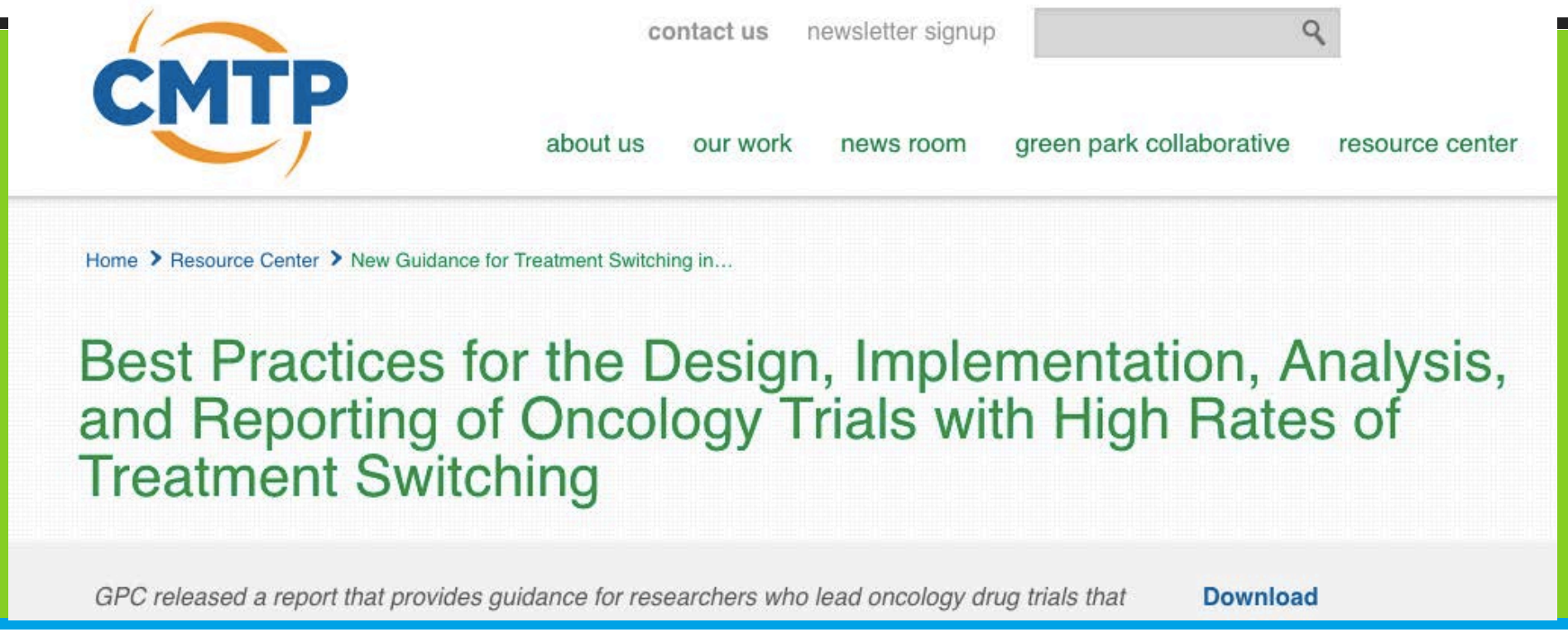
LAY means:

1. To beat or strike down with force
2. To put or set down, *especially* bury
3. To bring forth and deposit an egg
4. Calm, allay
5. Bet, wager
6. To press down giving a smooth &even surface
7. To set in order or position
8. To impose as a duty, burden, or punishment
9. To place on something
10. Prepare, contrive
11. To bring against or in contact with something
12. To bring to a specified condition
13. Assert, allege
14. To copulate with

Need an explanation for *people*

e.g. public, plain language

e.g. Crossover (treatment switching) 2016



International consortium

Australia (IRB), UK (NICE), US (FDA)

Multi-stakeholders

Clinicians, regulators, companies, patient advocates, payers

What *should* clinical trials really be about?

Design & conduct with ***clinical use*** in mind

Re-think traditional phases & designs

Connect trials together

Technology for patient results, not ‘big data’

PROs = more than AEs

Let’s make patient-centered **change** happen!

Critical learning after clinical trials

Shorter FDA approvals

- Long-term impact & issues? Treatment regimens?
- Best results? Which populations?

Conditional approvals/REMS

- Everyone needs more information; make these count
- Access is crucial (after clinical trials, label, etc.)

Plan on real world studies

- Patient needs/preferences: before, during & after trials
- Partner with us to provide real value on pricing

In summary,

People (& providers) need the 4 Cs…

Clear Communication of Content in CONTEXT

For THEM, no matter their role in health

Patient Advocates In Research (PAIR)

Where research meets reality

Thank you! Get in touch

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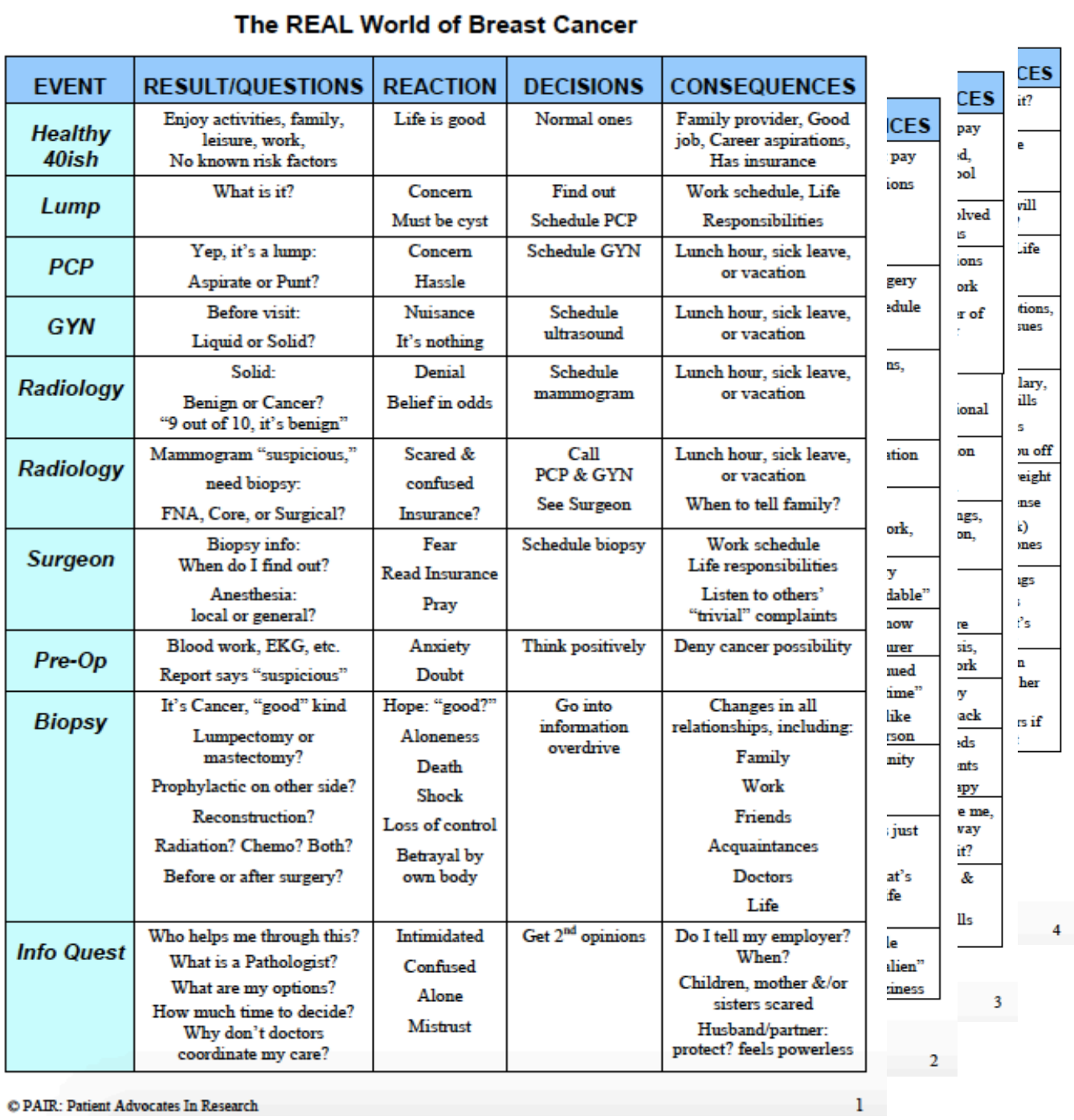
The Real World of BC

- Composite of hundreds
  - Family, job, insurance
- 15 steps < diagnosis
- 19 steps < clinical trial
  - Doesn't join a trial
- Ends w/50th birthday
  - New metastasis



The REAL World of Breast Cancer

EVENT	RESULT/QUESTIONS	REACTION	DECISIONS	CONSEQUENCES
Healthy 40ish	Enjoy activities, family, leisure, work, No known risk factors	Life is good	Normal ones	Family provider, Good job, Career aspirations, Has insurance
Lump	What is it?	Concern Must be cyst	Find out Schedule PCP	Work schedule, Life Responsibilities
PCP	Yep, it's a lump: Aspirate or Punt?	Concern Hassle	Schedule GYN	Lunch hour, sick leave, or vacation
GYN	Before visit: Liquid or Solid?	Nuisance It's nothing	Schedule ultrasound	Lunch hour, sick leave, or vacation
Radiology	Solid: Benign or Cancer? "9 out of 10, it's benign"	Denial Belief in odds	Schedule mammogram	Lunch hour, sick leave, or vacation
Radiology	Mammogram "suspicious," need biopsy: FNA, Core, or Surgical?	Scared & confused Insurance?	Call PCP & GYN See Surgeon	Lunch hour, sick leave, or vacation When to tell family?
Surgeon	Biopsy info: When do I find out? Anesthesia: local or general?	Fear Read Insurance Pray	Schedule biopsy	Work schedule Life responsibilities Listen to others' "trivial" complaints
Pre-Op	Blood work, EKG, etc. Report says "suspicious"	Anxiety Doubt	Think positively	Deny cancer possibility
Biopsy	It's Cancer, "good" kind Lumpectomy or mastectomy? Prophylactic on other side? Reconstruction? Radiation? Chemo? Both? Before or after surgery?	Hope: "good?" Aloneness Death Shock Loss of control Betrayal by own body	Go into information overdrive	Changes in all relationships, including: Family Work Friends Acquaintances Doctors Life
Info Quest	Who helps me through this? What is a Pathologist? What are my options? How much time to decide? Why don't doctors coordinate my care?	Intimidated Confused Alone Mistrust	Get 2nd opinions	Do I tell my employer? When? Children, mother &/or sisters scared Husband/partner: protect? feels powerless

Data sharing resolution

- Signed by all NCTN adult patient advocate committees
  - 127 total patient advocates
- Articles in media (2017)
- Requested by U.S. VP
- Presented to CEO Roundtable
- Project Data Sphere

Bertinoloi M et al NIJM 2017

A Resolution to Share Legacy Cancer Clinical Trial Data; a Right of Consented Patients

Submitted by the Patient Advocate Committee of the Alliance for Clinical Trials in Oncology on the behalf of all patients who have participated in cancer clinical trials to improve treatments and outcomes for all cancer patients in the future.

Sharing data is essential to bring together vast amounts of legacy cancer clinical trial data to advance medical discoveries. Discoveries made through collaborations and sharing data are discoveries that cannot be made using small isolated data sets. Barriers to sharing data must be resolved so that all legacy NCTN clinical trial data can be shared in a way that benefits all patients.

WHEREAS, patients volunteer to participate in clinical trials for many reasons, including to help themselves, others, and to help improve treatments for future patients;

WHEREAS, patients who volunteer to participate in clinical trials;

- are informed about potential benefits and risks, including the risk of the loss of confidentiality;
- have signed an informed consent document indicating knowledge and acceptance of potential risks (including potential loss of confidentiality) and receive printed copies for future reference;
- voluntarily donate their personal information, tissue, blood, and other biological samples for future research while participating in clinical trials;
- expect that the samples and information they submit will be used to further understand and improve the treatment of future patients in a way that is concordant with current research practices;

WHEREAS, current technology permits data sharing to collect data from various clinical trials to gain better knowledge, understanding, and improve the treatment of future patients;

WHEREAS, patients acknowledge that loss of confidentiality, identification of individuals and misuse are potential risks of data sharing;

WHEREAS, data sharing projects (e.g., Project Data Sphere) take high security measures to ensure that there is minimal possibility of loss of confidentiality or misuse of data collected.

Therefore, be it

RESOLVED, that patients who participate in clinical trials are aware of the potential loss of confidentiality and signed an informed consent document acknowledging this as a possibility and,

RESOLVED, that patients who participate in clinical trials expect their samples and information to be used to benefit future patients. Not allowing data sharing in an open and transparent process could negatively affect the potential to discover new medical and scientific advancements translating to future patients' treatment and,

RESOLVED, that sharing patient data collected in clinical trials is essential, and would be a disservice to patients not to use their data in the most productive and efficient way possible to advance treatments and preventive measures for future patients,

And be it finally

RESOLVED, that barriers of federal agencies and research institutions to restrict the sharing of clinical trial data should be immediately resolved, and full support granted to National Cancer Institute's National Clinical Trials Network (NCTN) groups and other accredited cancer research organizations to allow and encourage sharing of legacy cancer clinical trial data.