

SITC Cancer Immunotherapy Winter School
A COMPREHENSIVE CANCER IMMUNOTHERAPY EDUCATION PROGRAM

sitc
Society for Immunotherapy of Cancer

Patient Considerations that Impact Treatment & Clinical Trials

Deborah Collyar
PAIR: Patient Advocates In Research

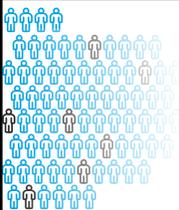


#SITCWinterSchool 2022

© Patient Advocates In Research (PAIR)

1

First: please don't blame patients!



PATIENTS don't 'fail' treatment.

TREATMENTS fail patients.

PATIENTS also **respond** ...their disease may not



Let's work together on accurate language

© Patient Advocates In Research (PAIR)

2

"It is more important to know what kind of a patient the disease has, than to know what kind of a disease the patient has."

? Claudius Galen (130-210 CE)
In DDN, February 2021

3

The U.S. ~~healthcare~~ disease crisis system

Patients are PEOPLE

Who just landed on a new planet with:

- No roadmap
- No dictionary
- No survival training



© Patient Advocates In Research (PAIR)

4

Clinic & trial issues start early

People need better results... Benefits MUST outweigh costs

Issues start with:

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



© Patient Advocates In Research (PAIR)

5

'Patient' can include...

People/patients

- Those who have a medical condition/disease/illness
- Can include comorbidities

Carers/caregivers/helpers

- Those who feel powerless, but want to help
 - Family, friends
- Those who are paid by someone to help patients function better

Sometimes even medical providers/sites

- Those in health systems who provide medical care
- Can include general care and clinical trials



© Patient Advocates In Research (PAIR)

6



Congratulations!
You've just been diagnosed with unamit, a serious medical condition

Treatment options:

- xyzimab + ydonwunit - OR - wutzmortexinib

New clinical trial:

- WOWzer therapy ± either treatment

Which would you like?

© Patient Advocates In Research (PAIR)

7

WT...Heck?

Hey, where is my primer on being a patient?



© Patient Advocates In Research (PAIR)

8

What is missing for patients? CONTEXT

9

Lots of Terms

Used by industry, regulatory, & research

Don't actually make sense to sites or the provider community, let alone patients & their carers!

10

Words matter:
PAIR 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 |
| Genomic profiling | Precision medicine | Targeting suspects? |
| Support services | Peripheral topics | Fit medical into life |
| Lay | Non-scientists | Down? |
| Environment | Patient controlled | External forces |
| Community | Non-academic center | Where I live |
| Medical advance | Incremental success | A cure |
| Clinical trial | Human research | Sterile, judgment |
| Biospecimens | Tissue for analysis | Mutant creature? |

11

What do patients want to know?

- ✓ I am not alone (others before me)
- ✓ Why are you doing it?
 - What is known/unknown
- ✓ What to expect
 - Exploratory v. validated
- ✓ How bad can it get... 'safe' word?
- ✓ What happens after?

MORE THAN INFORMED CONSENT

12

Notes on immunotherapy...

The "latest greatest"?

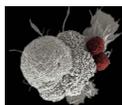
Few cancer patients are treated with IO

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

Immunotherapy promising, but...

- Many tumors don't respond
- Not a replacement therapy
- Side effects
- Trial results don't often transfer to commercial use

Please set **reasonable expectations!**



13

What do patients want from immunotherapy?

Less hype, more realism

- C word is "cure," not cancer
- Integrate w/other treatments
 - Surgery, radiation, chemo, etc.
- Better complete care

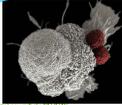
Report additional info

- Response rates
 - Compare to chemotherapy, etc.
- Duration of response
- Financial toxicities
- Side effects & PROs

Fewer irAEs

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

CONTEXT + Reasonable Expectations



14

Words matter: more PAIR 101

| Term | Scientific/Medical | Public Definition |
|-------------------------------|--------------------------------|-------------------------------------|
| Immunotherapy | Focused on immune system | Therapy to fix cancer |
| Informed consent | Legal paperwork | Understandable info |
| Efficacy | Drug evaluation | Effectiveness for me |
| Tumor Mutation Burden | Good! | Bad? |
| Vaccine | Vehicle for immunotherapy | Prevention |
| Cytokine Release Syndrome | Systemic inflammatory response | Death Star? |
| Direct/digital clinical trial | COVID-related study | Study that thinks about me |
| Artificial Intelligence (AI) | Machine learning, algorithms | A sci-fi movie, robots on steroids? |
| RWD | Real World Data | Is that mine? How to fix? |

15

1st words to eliminate

- Informed consent
- Schema
- Randomized
- & many more!



16

CONTEXT: Patients are not all the same, including risks

In treatment

Immune-compromised
Specific subtype issues

Metastatic

Comorbidities?
Immune system?
Inflammation?

**In remission/
living with**

Long-term side effects?
Comorbidities?
Social Determinants of Health?

© Patient Advocates In Research (PAIR)

17

Helping all patients...

Race ≠ ethnicity ≠ minority

- Race**
Differences/similarities in biological traits
- Ethnicity**
A shared cultural heritage that is learned
- Minority**
Smaller population than the controlling majority

Ageism: pervasive

Socioeconomic status (SES) matters

© Patient Advocates In Research (PAIR)

18

Cover patient diversity in your clinics & trials

FDA eligibility expands: age, brain mets, HIV, washout periods, concomitant medications, prior therapies, laboratory reference ranges and test intervals, and performance status. PMID: 33563632

"Retention"
"Adherence"
"Compliance"

Development → Approval → Activation → Recruitment → Endurance → Results

Better pre-planning pays off...

- > Include questions that answer patient needs
- > Use improved FDA eligibility criteria¹
- > Include Comprehensive Geriatric Assessments (CGA)²
- > Recruitment plans + community workers³ + health literacy
- > Address systemic racism

© Patient Advocates In Research (PAIR)

19

Ex: the "everyone" of 65+ year old patients...

Marathon runners → Regular exercise → Mobility issues → Cognitive issues → Assisted living → Nursing home

Why exclude so many from...

- > Clinical trials + treatment options?
- > Who is 'responsible' to show benefit? To include patients?

Time to create a "healthy aging" program + geriatric assessment
Connect research + pilots + initiatives + community + PEOPLE

© Patient Advocates In Research (PAIR)

20

Remember that roadmap idea?

- Details**
 - What is my condition/disease?
 - General information exists
 - Details usually don't
- Experts**
 - Who do I talk to?
 - How many specialists?
 - Where do I find them? Who coordinates my care?
- Options**
 - What can I do?
 - For my condition/disease? Clinical trials?
 - How will this impact my lifestyle?
- Trials**
 - Are there clinical trials for ME?
 - No matter the sponsor
 - What should I expect?
- Cost**
 - How much will this take?
 - For treatment, tests, checkups, other care?
 - Initially? Ongoing?

© Patient Advocates In Research (PAIR)

21

We also want permanent COVID-19 changes +

- DCTs, local options, telemedicine, etc.
- Adaptive design** in protocols (since 1969)
 - Learn as we go, pre-determined
 - Rules to analyze, stop, etc.
- Master protocols**
 - Platforms, umbrellas, baskets, whatever
 - More chances for newer approaches
- Patient-relevant endpoints**
 - Include PROs and patient experience
- Crossover/treatment switching**
 - https://www.clinicaltrials.gov/ct2/resources/Treatment_Switching_Guidance_Document_OCT_2016.pdf

© Patient Advocates In Research (PAIR)

22

Patient Reported Outcomes (PROs), etc.

Patient-Reported Outcomes for Cancer Patients Receiving Checkpoint Inhibitors: Opportunities for Palliative Care-A Systematic Review

✓ <https://pubmed.ncbi.nlm.nih.gov/30905677/>

Patient-Reported Outcomes During Immunotherapy for Metastatic Melanoma: Mixed Methods Study of Patients' and Clinicians' Experiences

✓ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7180512/>

© Patient Advocates In Research (PAIR)

23

Recruitment plans help

Journal of Clinical Oncology
An American Society of Clinical Oncology Journal

Enter words / phrases / DOI / ISBN / authors / keywords / etc.

Latest Articles | Issues | Browse By Topic | Special Content | Authors | Subscribers

COMMENTS AND CONTROVERSIES

Managing Accrual in Cooperative Group Clinical Trials

Tsai L, Demery J, Jara M, Yako J, Dobosik E, Calyer J, Mira L, Kati J, Garo L, Skarow M, Jiang L, Shoval E

Show More

First Page | Full Text | PDF | Figures and Tables

Designing a multicenter clinical trial is a process affected by time, economic, and political constraints. Unfortunately, this can result in overlooking needs or concerns of the potential participants of the study. Given the magnitude of resources spent on developing and implementing clinical trials, we have examined the value of systematic accrual management at various stages of proposal development, activation, delivery, and enrollment.

MAGNITUDE OF THE PROBLEM

© Patient Advocates In Research (PAIR)

24

Treat them for financial toxicity. Every. Time.

Serious Adverse Events (SAE)

- Adds to physical, mental, emotional & financial stress
- Impacts Overall Survival (OS)
- It's never over for them

Don't assume. In US...

- At least 67 million people uninsured (post-COVID)
- Another 28% are underinsured (> 92m)
- Many choose between rent, food, kids, or treatment

Extend life + wellbeing

- Social determinants of health matter
- What about comorbidity treatments?



Not just drug prices either!

Ramsey SD, et al. Financial insolvency as a risk factor for early mortality among patients with cancer. JCO 2016; 34:980-986. © Patient Advocates in Research (PAIR)

25

Takeaway messages

- ✓ Pre-plan with patients in mind + in design
- ✓ Build trust + relationships
- ✓ Include diversity in language, age, ethnicity, etc.
- ✓ Help create equity in health systems & clinical trials

- ✓ Help train sites + patient representatives
- ✓ Include patient experience/PRO data
- ✓ Health literacy builds understanding + action



© Patient Advocates in Research (PAIR)

26

SITC Cancer Immunotherapy Winter School
A COMPREHENSIVE CANCER IMMUNOTHERAPY EDUCATION PROGRAM

Resources (a few examples)

Health Literacy (HL) & Plain Language (PL)
<https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html>

Health Literacy Media (HLM) <https://www.healthliteracy.media/> and <https://www.c3i.media/>

PROs & Patient Engagement
<https://www.fda.gov/media/104989/download>
<https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical>
[https://www.valicmbielljournal.com/article/S1098-0115\(12\)01451-9/fulltext](https://www.valicmbielljournal.com/article/S1098-0115(12)01451-9/fulltext)

SHARE services & materials (e.g. Novela in English & Spanish)
<https://www.sharecancersupport.com/>
<https://www.sharecancersupport.org/wp-content/uploads/sites/1731/2016/04/Be-Brave-They-re-Your-Breasts-en-us.pdf>

Training
<https://www.ctti-clinicaltrials.com/projects/patient-groups-clinical-trials>
<https://www.pccori.org/engagement/>
<https://researchadvocacy.org/>

#SITCWinterSchool



Society for Immunotherapy of Cancer

© Patient Advocates in Research (PAIR)

27

Patient Advocates In Research (PAIR)



Where research meets reality

Thank you! Get in touch
Deborah Collyar

-  deborah@tumortime.com
-  <https://collyar.wordpress.com/>
-  www.linkedin.com/in/deborahcollyar/
-  @deborahcollyar
-  www.facebook.com/DeborahCollyarAuthor/

© Patient Advocates in Research (PAIR)

28