Alliance Patient Advocate Committee (PAC)

Patty Spears	Pat Gavin	Coleen Crespo
Raleigh, NC	*Grand Rapids, MI*	*Durham, NC*
Co-Chair	*Co-Chair*	*Vice-Chair*

Alliance Group Meeting, Chicago IL on November 3, 2017

Patient Advocate Committee (PAC)

ROLE: Patient Advocates in the Alliance for Clinical Trials in Oncology (Alliance) represent the perspective of patients and their families in the development and delivery of innovative clinical trials.

GOAL: Patient Advocates work together with multidisciplinary cancer professionals to develop and advance outstanding research in the treatment and care of cancer patients and the prevention of cancer.

2 Question…

1. Who are Research Patient Advocates (RPAs) and why is their involvement important?

2. Who are the Alliance patient advocates and what do they do?

Who are Research Patient Advocates?

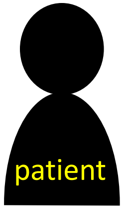
Types of Patient Advocacy

What we advocate for

- Political
- Support
- Fundraising
- Watchdog
- **Research**

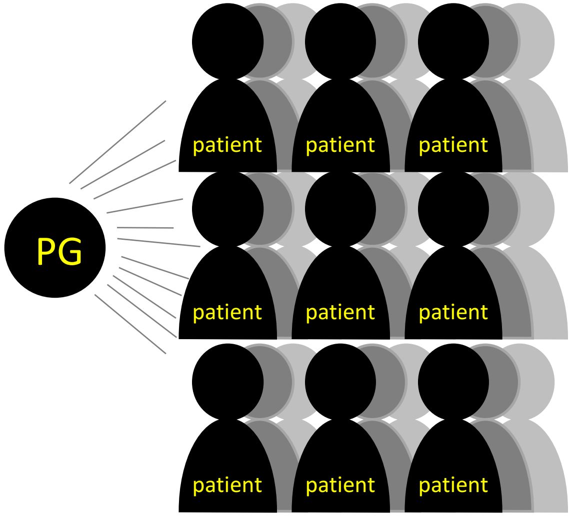
Who we are

- Patients
- Patient Groups or Organizations (PG)
- **Research Patient Advocates (RPA)**



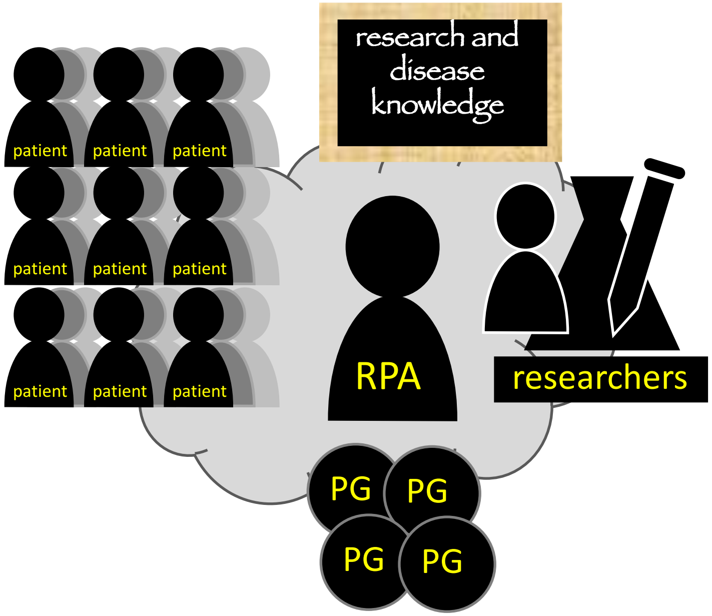
Individual patients

- have been diagnosed with a disease
- **personal experiences to share**
- limited to single experiences
- **lack deep knowledge of clinical research**
- **don't often know what they need from researchers**
- don't know the questions to ask
- Don't how the research system works



Patient organizations and groups (PGs)

- May lack knowledge about clinical research
- **grant access to multiple patients with the disease - regards to recruitment**.
- rarely delve into the details of research development or design.
- Most push for access to new treatments, even when the best approach is still unknown for patient communities.
- **PGs are the easiest group to identify**



Research Patient Advocates (RPAs)

- have personal experience with the disease
- **developed significant knowledge of the disease**.
- **RPAs can spend years learning about the research process.**
- can help improve clinical trial success by
    - connecting patient needs to trial processes
    - bridging gaps
    - resolving research barriers
- **understand research policy and programs**
    - improved operations for research projects that can cut timelines
- The challenge is finding them.

Spears, Collyar. DIA Global Forum, September 2017 9(6) 14-15

	Development Plan	Trial Development	Ongoing Study	End of Study
Patient Contributions	◆ Identify the question ◆ Assist with trial design ◆ Be co-Investigators	◆ Detect recruitment Issues ◆ Broaden eligibility criteria ◆ Review informed consent	◆ Refine recruitment steps ◆ Spot retention issues ◆ Reduce amendments	◆ Update patients on study ◆ Present study results ◆ Ensure understandability

Patient

- Relay their personal experience with disease
- Add a sense of urgency and need to accelerate research
- Give advise on potential recruitment and retention barriers, based on their personal experience
- Fill out Patient-Reported Outcome (PRO) instruments

Patient Group/ Organization (PG)

- Provide broad information about the patient community/communities they serve
- Provide access to patients to share their personal experience
- Give advise on potential recruitment and retention barriers for their patient community
- Distribute clinical trial information to aid recruitment
- Distribute written public summaries of completed clinical trials to their patient communities

Research Patient Advocate (RPA)

- Relay detailed understanding of patient populations, as well as their own personal experiences
- Provide solutions to accelerate research through collaborations and breaking down road blocks
- Work closely with research team as a co-investigator and give feedback about appropriate design
    - e.g., study endpoints, Bayesian methods, crossover, PRO and other trial considerations
- Address recruitment/retention for each patient population and environment
- Help write and review informed consent documents for readability and understanding by patients
- Advise and adjust potential recruitment and retention strategies for each patient community
- Participate as members of data safety monitoring boards, IRBs, advisory boards, etc.
- Assist with written public summaries of completed clinical trials and research programs
- Write articles for wide public distribution about research and study questions
- Help present study information in public and scientific forums

Spears, Collyar.
DIA Global Forum, Sept 2017

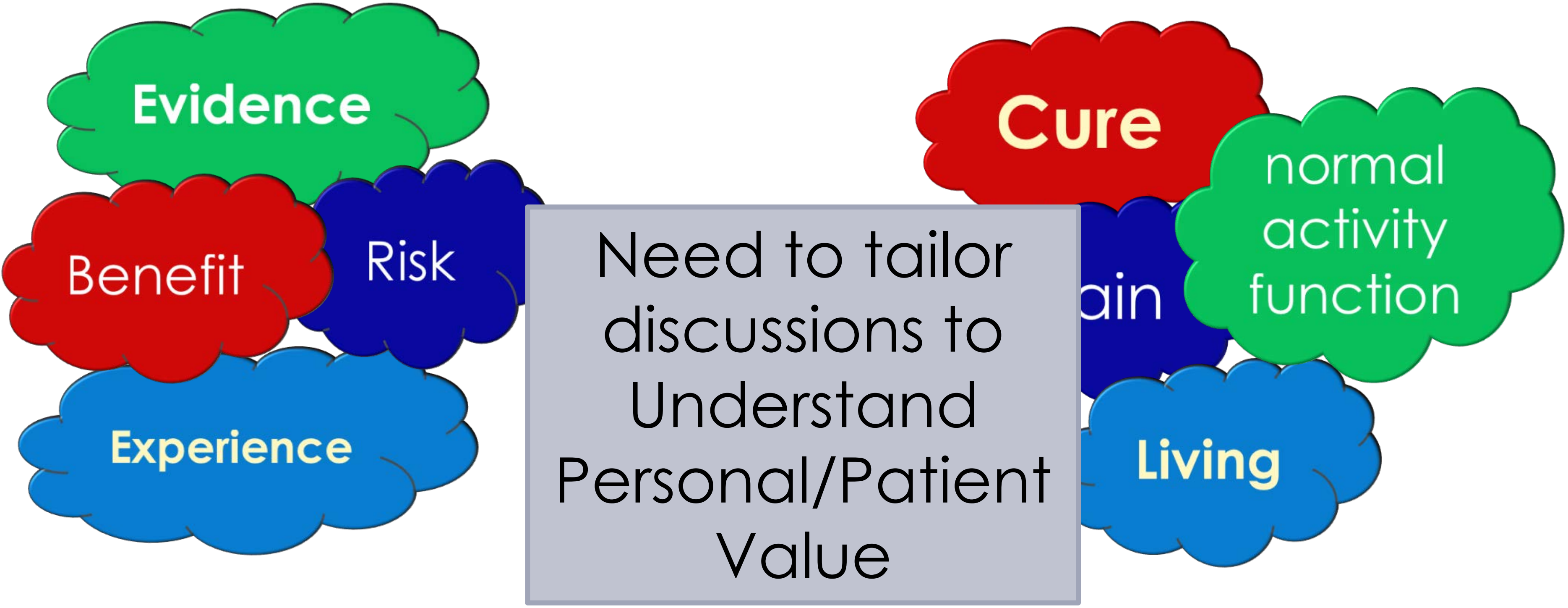
Why is Advocate Involvement Important?

The Perception of Value

Different stakeholders may have different perspectives about value

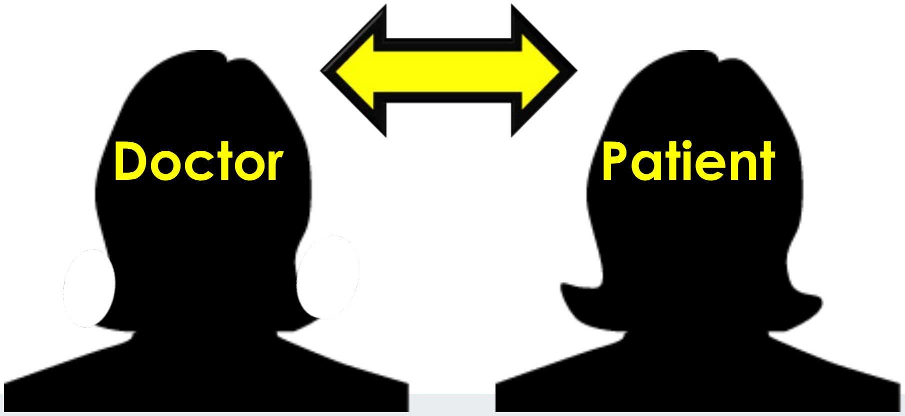
- Society vs Pharmaceutical Industry
- Individual vs Population
- Patient vs Physician
- Researcher vs Society

Patient vs. Physician Perspective



Need to tailor discussions to Understand Personal/Patient Value

PHYSICIAN
Communicating harm/benefit in a way the patient can understand to make an informed decision



PATIENT
Understanding harm/benefit and make an informed decision that is right for them

Value IS about perspective

Study by Dilla et al (2016) regarding perspectives of oncologists, health care policy makers, patients and the general public found:

- “Oncologists most valued gains **in survival**, whereas patients assigned a higher monetary value to treatments that enhanced **QoL**.” (Dilla 2016)
- Not only do you need to continue for effective drugs that **save lives**, but you need to be mindful of the **quality of life** of the patient through the collection of PROs and aware of financial burdens in the overall treatment of the patient.

Patient-Centered Care

- The IOM (Institute of Medicine) defines **patient-centered care** as: "Providing **care** that is respectful of, and responsive to, **individual patient preferences**, needs and **values**, and ensuring that **patient** values guide all clinical decisions." May 15, 2015

- Patient-centered care is the practice of caring for patients (and their families) in ways that are **meaningful** and **valuable** to the **individual patient**. It includes listening to, informing and involving patients in their care.

How do you …

- Ensure the intervention in meaningful to patients?
- Speed up the process of drug discovery?
- Maintain the patient as the center of drug development?

Become Patient Centric

Add Urgency
Engage Patients!

- **Early and often** – throughout the entire drug development cycle
- Patients understand the **burden of treatments**
- Patients **know what is important** to them – they know what is patient centric and what is not
- Patients can help design clinical trials that **will accrue and retain participants**
- Patients can help **identify barriers and potential accrual problems** before trials open, saving time and money and ensuring the completion of trials

Who are Alliance Patient Advocates?

Cancer patients and caregivers from all walks of life with the common goal of helping researchers develop and implement clinical trials that address patient issues through advancing the science.

Members of Alliance disease and modality committees. Patient Advocates attend and participate in scientific meetings, review study concepts and protocols, and assist in designing study accrual strategies.

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Patient Advocate Committee

May 2016

21 Patient Advocates

Members of the Alliance Patient Advocate Committee (PAC) participate in most committees of the Alliance and continue to bring the voice of the patient to all work conducted by the Alliance.

- Pat Gavin
  - *Co-Chair*
- Patty Spears
  - *Co-Chair*
- Coleen Crespo,
  - *Vice-Chair*
- Laura Cleveland
- Deborah Collyar
- Jo-Ellen DeLuca
- Karen Durham
- Bob Harrison
- Kay Kays
- Shelly Kuhlmann
- Pam Moffitt
- Phyllis Nassi
- James Omel
- Jane Perlmutter
- Hank Porterfield
- Ivis Sampayo
- Yasmeem Watson
- Jack Whelan
- Sara Whitlock
- Peggy Devine (NT)
- Karl Schwartz (NT)

Representation on Disease Committees

- **Breast**
  - Patty Spears*
  - Jane Perlmutter
  - Ivis Sampayo
- **GI**
  - Kay Kays*
  - JoEllen Deluca*
  - Yasmeem Watson*
- **GU**
  - Hank Porterfield*
  - Bob Harrison*
  - Jack Whelan
- **Leukemia**
  - Laura Cleveland*
- **Lymphoma**
  - Jack Whelan*
  - Karl Schwartz
- **Myeloma**
  - Jim Omel*
- **Neuro-oncology**
  - Shelly Kuhlmann*
- **Respiratory**
  - Pam Moffitt
  - Sara Whitlock

Representation on Modality Committees

- **Experimental Therapeutics**
  - Deborah Collyar
- **Radiation Oncology**
  - Sara Whitlock
- **Transplant**
  - Jim Omel
- **Ethics**
  - Deborah Collyar
  - Jane Perlmutter
- **Publications**
  - Deborah Collyar*
- **Data Safety Monitoring Board**
  - Patty Spears
- **Leukemia Correlative Science**
  - Laura Cleveland
- **Pharmacogenomics**
  - Phyllis Nassi

ACS Committees

- **Cancer Care Delivery Research**
  - Deborah Collyar
  - Pat Gavin
  - Jane Perlmutter
  - Patty Spears

Representation on Cancer Control Committees

- **Cancer in the Elderly**
  - JoEllen DeLuca
  - Pam Moffitt
- **Community Oncology**
  - Karen Durham
  - Pat Gavin
- **Health Disparities**
  - Coleen Crespo*
  - Ivis Sampayo*
  - Phyllis Nassi*
- **Health Outcomes**
  - Karen Durham*
  - Jane Perlmutter*
- **Prevention**
  - Coleen Crespo
  - Hank Porterfield
  - Patty Spears
- **Symptom Intervention**
  - Jim Omel
  - Jane Perlmutter

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What do Alliance Patient Advocates do?

Actively engage in the Alliance clinical trial process. Patient Advocates' participation ensures inclusion of patient perspective and concerns as trials are developed.

Volunteer at the local, regional and national levels. Involvement may be in research advocacy or other advocacy areas such as support or fundraising. Through these activities, Alliance Patient Advocates keep close affiliation with patients and are uniquely qualified to bring the patient voice and perspective to the research table.

We are here to help…

EXAMPLES

- **Concept**: We are willing to review concepts before they are officially submitted to the SCRC for review, and provide feedback.
- **Protocol**: Once a trial is approved, we can be a resource when you write the consent form, to ensure the reading level is appropriate and the protocol is understandable.
- **Accrual:**
  - If you have a study idea that you are not sure will accrue well, the PAC can be a resource for feedback during pre-concept development.
  - The PAC can be a resource in patient material development for complex trials, which can enhance participants understanding of the trial and therefore accrual.
  - If a trial is not accruing as planned, the PAC can be a resource to identify potential patient barriers.

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We are here to help… (cont.)

EXAMPLES

- **Results**: We support returning research results to participants. We have been involved in publishing study result summaries on the Alliance website and are continuing this endeavor (Deb Collyar).

- **Patient Materials:** We are a resource to all committees and the NCI for patient facing materials development.
  - **Brochures:** We have helped to develop and SOP on the inclusion of patient brochures in all Alliance clinical trials.
  - **Participant Thank You Letters:** We have helped to develop and SOP on the inclusion of participant thank you letters in all Alliance clinical trials.
  - **Accrual Checklist:** We helped develop the current Alliance Accrual Checklist and have been involved in developing a more comprehensive accrual checklist for all NCTN trails

We are here to help… (cont.)

EXAMPLES

- **Data Sharing**: We support sharing data from current and completed Alliance and all NCTN trials. We initiated a resolution that was signed by all NCTN advocates and over 200 supporters.
- **PCORI projects:** We are a resource to all Alliance run PCORI projects and provide a patient perspective to their development, conduct, analysis and dissemination.
- **Publications:** Several of our members have been contributing or senior authors on a variety of cancer and clinical trial publications.
  - There were a total of **13** publications from November 2015 to 2016.
  - Ten PAC members have published **over 80 articles** that range from personal stories to ASCO Guidelines.

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Recognition

Jack Whelan was recently awarded the AACR Distinguished Public Service Award in April 2017.

- The Distinguished Public Service Award honors the extraordinary contributions of an individual or group whose groundbreaking, innovative work exemplifies the AACR's mission to accelerate the prevention and cure of all cancers through research, education, communication, and collaboration. Distinguished public service takes many forms, and past winners have included generous philanthropists, government officials, advocates, and members of the media. **Whelan embodies the substance and spirit of this award.**

Put a face on your research

Questions?

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