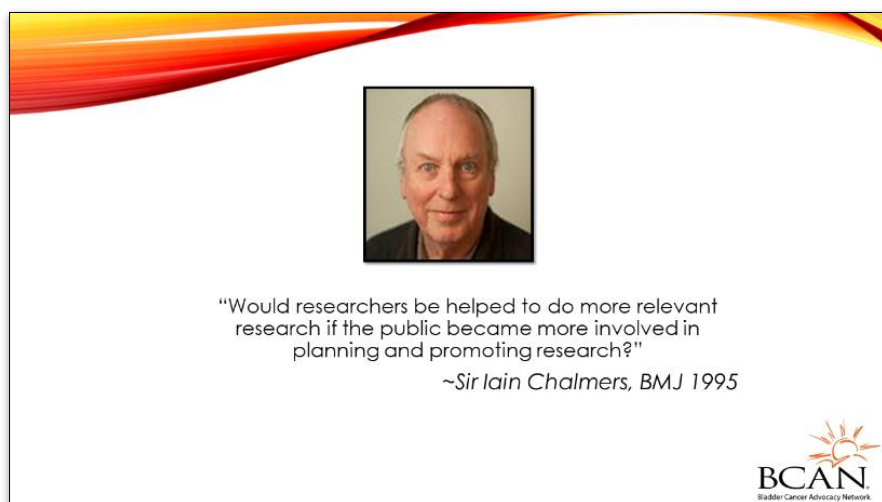


ENGAGING PATIENTS ON TEAMS: RESEARCHER PERSPECTIVE

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Dr. Angela Smith: That was an incredible overview of what it means to be a Patient Research Advocate. I am a researcher and I'm going to share very briefly my own experience with engaging patients on teams. Not all researchers engage patients on their teams, but I think that it's very valuable. I'm going to share my experience with it and then I'm going to turn it over to Bob to talk about the patient perspective, since we have worked very closely together.

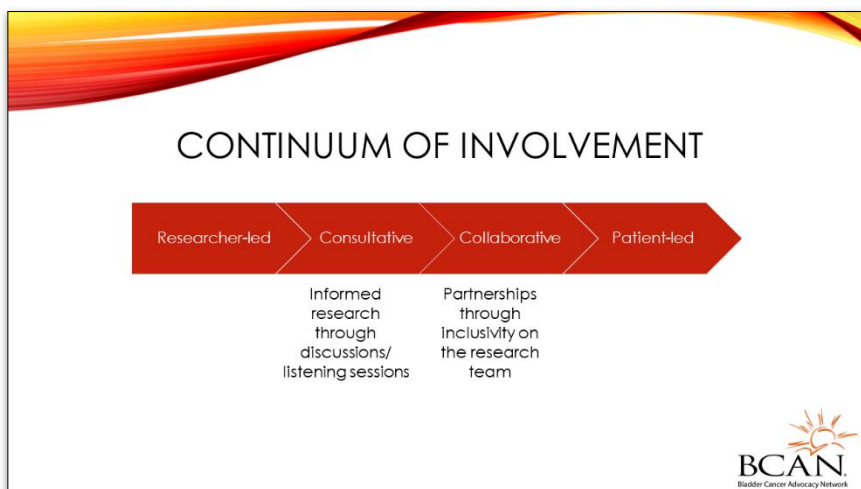
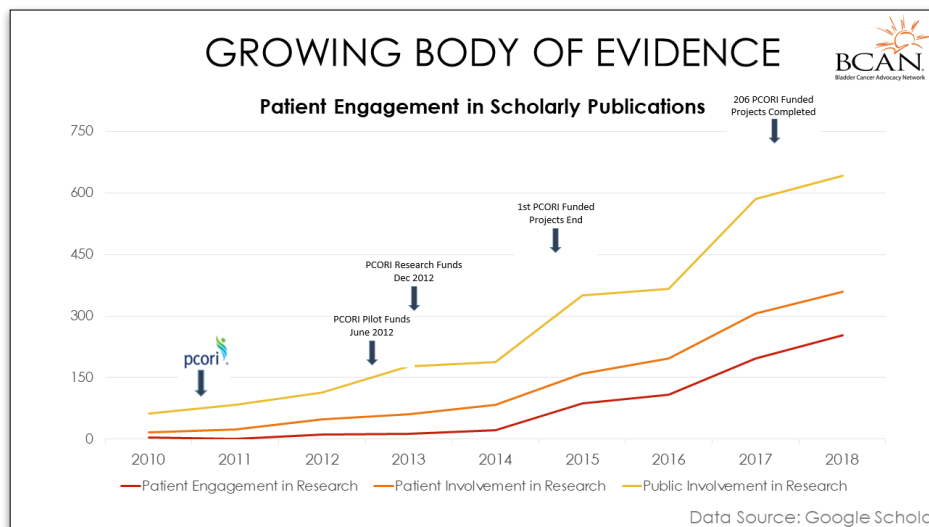


I'd like to start with this quote, because this is, I think this question, which was posed in back in the mid 90s, is really what took off in terms of the Patient-Centered Outcomes Research Movement. The question is, would researchers be helped to do more relevant research, if the public became more involved in planning and promoting research? I think it was like the well, duh, yeah, moment for me to think, "Why don't we have a patient at the table helping us?" First, to make sure we're asking the right question. Two, if we are asking the

right question, are we studying it the right way? Are we making sure we are looking at the outcomes that matter the most to patients who are impacted by the disease?

Dr. Angela Smith:

There's been this growing body of evidence that patient engagement has been taking off, particularly in the research world, and that came about with the Patient-Centered Outcomes Research Institute (PCORI) and many other things as well. I do think that this funding organization funded specifically research that was patient-oriented, patient-centered. They were very big and they still are, with regard to engaging and involving the patient in the entire process. We can see that just taking off over the last decade. You can see back in between 2017 and 18, over 240 funded projects have been completed and that number is actually moving up very rapidly. There's been a continuum of involvement in terms of patient engagement and research just in general. Initially research was researcher-led.



There's consultative, where patients would inform research through some discussions and maybe some listening sessions. There's collaborative, where the partnership is actually a part of the research team. It's inclusivity on the research team, meaning that when I as a researcher I'm sitting at the table with my statistician and maybe with another researcher, maybe with a yet another urologist. I also have a patient there at the table with us, all of whom have an equal say, in what we're designing and what we're doing. Then it can go all the way to

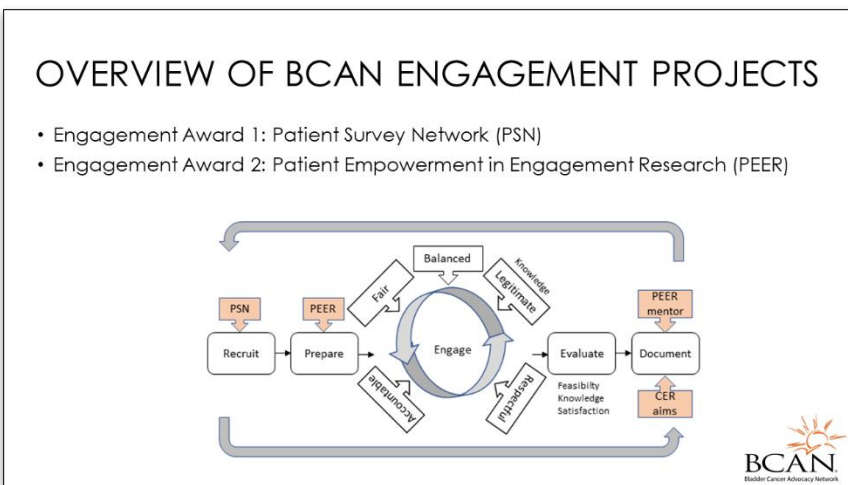
the other side of the spectrum where it patient-led. There's a lot of great studies that have examples of that as well.

The way that studies are, or at least with large studies, in particular, clinical trials are designed, just that there is an overarching organization system. You have an executive committee. Then, usually, you have three coordinating centers. You have the data coordinating center. That's like the statistics section, the number crunching, the clinical coordinating center, which is getting the data from clinical sites and things of that nature. Then there's the stakeholder coordinating center. That's where I, as a researcher, engage with patients. In my particular study, which I'll just talk about very briefly in a moment, we have a National Advisory Board so that we can disseminate the results of the study effectively.

We have a Patient Advisory Board, which you're going to hear a little bit more about from Bob. Then we have a Clinician Advisory Board. All three of those are incredibly important, because we need to have everyone at the table, so we better understand how we can have success with that particular clinical trial. There's a lot of engagement techniques. I won't belabor the point because I want to have time for questions at the end. There are a lot of engagement techniques to get patient input. They can range from interviews, to focus groups, to meetings and surveys, et cetera. There's lots of evidence for the fact that, adding patient engagement team can improve the study. I am a big believer. Like Stephanie always says I'm definitely drinking the Orange Kool-Aid, of course, but on patient engagement in research.



We have study development and at least in my studies, we have patients assist with selecting the topic and prioritizing how important it is, informing how we design the study, how we select the outcomes, and then moving into how we recruit patients and how we retain them. Who's better to ask than a patient? How do we analyze the data? Then how do we disseminate it to the community? How do we interpret it? Because, we want to make sure that not just researchers read it, but patients, of course. Again, this seems like an obvious thing, but I don't believe this is how research was done in the past and we're trying to change that. I do believe and I've seen this, absolutely, that having a patient on my team has improved the quality of the patient-facing material they get, when they are looking at joining clinical trial. It informs how the patients access their information. It has changed how researchers, including myself, communicate about the findings and all this are so important.



Dr. Angela Smith: As a very brief overview of what we've done, and there's been a lot over the last five years, we have had several engagement awards. This is funded by PCORI and this webinar series is funded by a PCORI Engagement Award, the third one. The first one, was a patient survey network where we recruited patients around the country to get a sense of what questions, what research questions are really unanswered. What should we be studying as researchers? And who's better to ask than a patient who

has been impacted by bladder cancer?

This is probably relevant to many people who are listening to this webinar is, how do we empower patients to become engaged? Because it's hard if you have never really dipped your toe into research? What does that mean? We created a way in which, if you have no experience at all, but you have an interest, you can actually self-train through a series of modules. When we partner together, we partnered, of course, with BCAN because of their wonderful advocacy in the area of bladder cancer. It just kind of created and developed organically. From a research standpoint, I felt that it was the perfect place to put this together because BCAN has always incorporated patients and brought together patients, and caregivers and researchers. I think that it was just a natural place to almost test or organically grow this patient engagement mindset. We did that, I guess, about five years ago, and we were fortunate to get that PCORI Engagement Award and things took off from there.

I will say that there were very uncertain expectations at the beginning because, again, this is not how research has been typically done. With time, we really developed a really good process. Over time, we've really grown the PEER program, that program of research advocates, quite a bit over time. This webinar is one of the ways in which we will hope to grow it further. If you're someone listening, who you've never done it before, this is for you to know that you're welcome. We want to have new people who don't have experience. We know that you can do this, especially if you have the drive and motivation to get back in that way. Certainly, yes, there's some gaps between the research and patient, but we've been able to, I think, successfully bridge those gaps.

PARTNERSHIP ACTIVITIES

- BCAN Annual Think Tank
- PEER Online Curriculum
- BCAN Leadership Summit
- PEER Monthly Working Group Calls
 - Grant and Manuscript Writing
 - Survey Creation and Development
 - Research Design

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COMPARISON OF INTRAVESICAL THERAPY WITH SURGERY AS TREATMENT OPTIONS FOR RECURRENT BLADDER CANCER (CISTO)

PCORI @PCORI Following

Congratulations to @gorejohn @uw for study funding approval. Find study info here.

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CISTO: Comparison of Intravesical Therapy and Surgery as ...
Bladder cancer is the fourth-most-common cancer in men and 10th-most-common cancer in women. In 2017, over 77,000 Americans were diagnosed with bladder cancer, and about thre...

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In terms of the activities that we've done, we had the annual Think Tank, which is where the annual scientific meeting of BCAN. Then we created an online curriculum that I just mentioned. We also have these leadership summits that are annual as well and I would encourage you to look into that because that's another place where we delve into research advocacy. From there, we actually had held some monthly working group calls and we talked about grant writing where we can get funds to basically fund our research. We created some surveys and we talked about some research design. One of those developed into a clinical trial that has now been funded. It's a \$3 million PCORI-funded trial, answering the number one question voted by patient to non-muscle invasive bladder cancer, which is, what do we do when BCG no longer work? That compared surgery with medical management or intravesical therapy. I'm not

going to talk a lot about this because Bob is one of our patient advocates on this study, on our advocate advisory board. I'm going to leave it to him to talk a little bit about that.

Dr. Angela Smith: There we go. Really, what I wanted to say very briefly is, this was a patient-informed research question and from patients. We actually published an article that goes through all of the most important questions and PCORI saw that. For the first time ever, bladder cancer was listed as one of their 18 key priority areas, to really give us an avenue to get funding, or at least have a chance for getting funded. We use that to inform the study. We then went back to patients who were in that first cohort of asking, what would you prioritize? And we asked them about the design, would they be willing to sign up for a study in which you would get one of these two treatments?

The majority of people said yes, but really what it came down to is, they wanted to have the choice of which one it would be. That was a really important piece of information, so we can design a study. The other thing that came up was the most important type of outcomes to study. Of course, survival and spread of disease came up, but also caregiver burdens, financial burdens, and many other outcomes that we ended up incorporating into the study. This is what the study design of clinical trial looks like.

Patients for whom BCG stops working, they choose whether they undergo surgery to have their bladder removed or some kind of bladder sparing treatment and then we look at 12 months, quality of life, we look at survival, we look at decisional regret, financial toxicity, which is the cost of the treatment, and healthcare, so all of these derived from patients and Bob will discuss, again the patient perspective on this.

Again, this partnership has grown tremendously over the last several years. I anticipate this will continue to grow as we get more patients interested and involved in this type of involvement, in this type of advocacy, which is different, but some really feel very passionately about it. Certainly, expectations have changed over time, but really the proof of our success has been that, we've been successful in getting grant funding, which means that we have money to answer these

CISTO: Patient-Informed Study Design

Study design

Criteria for Patient Selection: NMIBC BCG failure, Unresponsive, Relapsing, Intolerant

Treatment Arms:

- Radical Cystectomy
- Bladdersparing: Intra-vesical therapy, Immune oncology

Outcomes (12-month):

- Primary: Generic HRQOL
- Secondary: BC-specific survival, Cystectomy, Urinary QOL, Decision regret, Financial toxicity, Health care use

*Bob will discuss patient perspective of being on the patient research team

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GROWTH OF PARTNERSHIP

- Researchers and patients were unsure in the beginning
 - Patients had a big influence on the researchers and drove the direction
- Expectations changed over time
 - Not exactly what we envisioned - allowed needs, gaps, and opportunities to guide us
- Relationship strengthened over time
 - Getting to know each other
 - "Proof" of success → successful grant funding
- Relationship grew stronger with in-person and video activities
 - BCAN Summit, Think Tank, video conference calls
 - Researchers truly valued the patient opinions
- Creating connection between Patient Survey Network and researchers
 - Standard operating procedures document to explain how the PSN can be used, who can use it, and for what purpose(s) – along with a process for applying for use

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important questions. We have grown stronger through the Think Tank through video conference calls, through these types of webinars and creating that connection. With regard to our partnership and funding, one of the working groups with other patient advocates has designed a potential grant for looking at improving discomfort related to cystoscopy. Fingers crossed, because we'll have our results at that point, and we'll share that back with everyone.

Really, we have had proof and evidence based on that funding. I do believe that the potential value for patients have been immense. I know as a researcher, from my perspective, it has really clarified and streamlined my research. I really feel very strongly that what I do is important and really answering the question is more important to patients.

With this CISTO study that I mentioned, I talked about large trial for non-muscle invasive bladder cancer in patients for whom BCG stops working. We had this advocates advisory board, and basically it's made up of, I can't remember exactly the number, maybe 10, 12 patient advocates. With that, let's move on to a Patient's Perspective on Engagement in Research

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