Patient and Public Involvement in Cancer Research

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What is public involvement in research?

Public involvement in research is research being carried out *with* or *by* members of the public, rather than *to*, *about* or *for* them.
Involvement

Where members of the public are actively involved in research projects and in research organisations.

Participation

Where people take part in a research study.

Engagement

Where information about research is provided and disseminated
Why involve patients and public in research? (Cancer World 6/2015)

- 2011 Alesandro Liberati, clinical statistician and founder of the Italian Cochrane group. Looking for evidence-
multiple myeloma

- Of 1384 trials listed, only 107 were phase II/III

- The Lancet (vol 378 p1777-78) drew attention to the mismatch between what clinical researchers do and what patients need.
Contribution can be many and varied.

**Last 10 years**

- Improve quality of research
- Contribute to how it is designed, conducted and delivered.

**Now**

- Identify future research priorities and questions
- Inform design and development of innovations
- Participate in research studies
- Advocate for adoption and implementation of research
How can we involve people in health care

[Cartoon image of a waiting room with a person saying "It's helped us cut unnecessary visits by over 23%."]
Participation is on a continuum

Public involvement in science

Public engagement in research

Patient/Public participation in research

Patient/Public involvement in research

Experience based co-design

Advising and reviewing

Contributing to design and research question

Acting as co-researchers

As co-applicants

Staff/patients/carers co-designing service
Attitudes to Patient/Public involvement in research (Boaz et al 2014)

- Interviewed 19 researchers from 3 Biomedical Research Centres (Qualitative research)

Findings

Though there was consensus in definitions but there was variation in attitudes.

- Positive attitude to PPI
- Pragmatic accommodation of PPI
- Concern re knowledge and skill
- Resistance to sharing power and control
Positive Attitude to Patient/Public involvement

“I think its really important. You get better research, better questions, better challenged. You design your studies differently, you choose different outcome measures”

Pragmatic accommodation of Patient/Public involvement

“You just need the box ticked! Nowadays you have to demonstrate some engagement ”
Concern regarding knowledge and skill

“But how could somebody who’s not a scientist have influence in the design of any sort of experiment. I cannot imagine that the general public would have any sort of positive impact on that ”

Concern regarding sharing power and control

“I’m also a bit scared of this idea of handing over some of the power and control to the public so they can influence how research is conducted ”
Members of the public as subjects or silent partners is no longer a tenable position to maintain (Boyle, Slay & Stephens 2010)

Need

Partnership
Reciprocity
Openness

Co-production
6 Characteristics of Co-production
(Boyle, Slay & Stephens 2010)

1. Building on people’s existing capabilities
2. Promoting mutuality and reciprocity
3. Developing peer support networks
4. Breaking down boundaries
5. Facilitating as well as delivering
6. Recognising people and their experiences as assets
Improving breast and lung cancer services using experienced based co-design Tsianakas et al (2012)
How to incorporate patient and public involvement in the research process

- Identifying & prioritising
- Design
- Development of the grant proposal
- Undertaking / managing
- Analysing & interpreting
- Dissemination
- Implementation
- Monitoring & evaluation
Identifying & prioritising

Patients & the public can:

• Though local user groups and organisations help inform research priorities

• Be consulted about research topics and priorities, important to them as service users

• Collaborate with researchers to identify topics for research

• Identify topics for research themselves
Design

Patients & the public can:
• Inform the design of the research study
• Clarify the research question and affirm its importance
• Ensure the methods selected are appropriate for patients
• Assist in creating a recruitment strategy
• Review and comment on proposed questionnaire and data collection methods
Development of the grant proposal

Patients & the public can:

• Help to ensure that the research proposed and chosen methods are ethical
• Inform areas where patients and public could be involved
• Provide on going advice, be co-applicants
• Define outcome measures
• Advise on lay summary
• Raise awareness re cost of involvement, expenses etc
Undertaking/managing

Patients & the public can:

• Be part of the steering group
• Steer the group through the process
• Assist in writing the patient information and consent forms
• Produce updates that are patient friendly
• Assist in conducting interviews and surveys
Analysing and interpreting

Patients & the public can

• Assist the research team in developing themes from data

• Be consulted to see if they understand and interpret data in the same way as the research team
Analysing and interpreting

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e.g. Hubbard et al (2015) Supportive care needs of women with breast cancer in rural Scotland
Dissemination

Patients & the public can:

• Advise on different avenues for dissemination
• Jointly present findings with researchers
• Write information for local groups
• Assist with publication
• Help distribute results within their networks
• Produce summary of findings
Implementation

Patients & the public can:

• Increase the likelihood the results are implemented by adding validity to the research

• Develop patient information for new services/interventions within the hospitals and GP services
Monitoring and evaluating

Patients & the public can:

• Have continuous involvement with the study to maintain focus and address issues as they arise

• Collaborate with researchers to evaluate the research process

• Reflect on their role and what they have learned
Experience of Arja Leppanen (Sweden)
Needs and Expectations

- Consider why you are involving people in your research - what do you think their perspective will bring?
- What are your expectations of users?
- What are their expectations of their role?
- What skills/experience would those you involve need to take part in this project?
- Should you have a role description?
Considerations

• Training

• Costs

• Organisation
A Framework for Evaluation (Rowe & Frewer 2000)

Acceptance criteria
- Representativeness
- Independence
- Early involvement
- Influence
- Transparency

Process criteria
- Resource accessibility
- Task definition
- Structured decision making
- Cost effectiveness
References


Improving Patient Participation in Cancer Clinical Trials

EUROPA DONNA – The European Breast Cancer Coalition
ED Vice President 2011 - 2013
ED Turkey, Executive Board Member
ECCO PAC Member
SEMA ERDEM
Today’s standard treatment options are the results of former researches...

Clinical Trials serve as vehicles of innovation and progress resulting in:

- Improved clinical outcomes
- Personalized treatment plans which are more effective and less toxic
Life Cycle of Clinical Trial

- Development
- Ethical approval
- Patient accrual
- Treatment completion
- Follow-up
235 cancer patients at two NCI cancer centers in SE and Midwest US

Clinical trials offered in 20% of the consultations

75% of patients consented

Patients who did, based their decisions on personal reasons and their physician’s communication behaviour during the discussion
• 400 internal medicine patients at Mayo Clinic
• 76% desired to be informed by their physician about current trials
• 28% had participated in a clinical trial
• 68% showed interest in participating in clinical trials
• But only 24% in case of potential adverse effects
Why ED got involved

EU supported Network of Excellence
39 Partners in 21 Countries

Aim: To integrate, strengthen and facilitate translational and clinical breast cancer research

1st project: MINDACT clinical trial - EORTC co-ordinator

A KEY STUDY QUESTION IMPORTANT TO PATIENTS
CLINICAL APPLICATION OF GENOMICS FOR IMPROVED TREATMENT TAILORING

BENEFITS:

Only women who NEED chemotherapy RECEIVE it!

Reduce toxicity & side effects
Reduce cancer care costs
Reduce burden on health care systems
WHAT IS MINDACT?

Study based on a « 70-gene signature » identified by the Netherlands Cancer Institute as a new tool to assess risk of cancer coming back

The analysis of thousands of genes of the tumour with this new tool may better identify who needs adjuvant chemotherapy

**Aim:**

Validate the hypothesis in 6000 women over 3 years

**Outcome:**

- Save women from unnecessary treatment
- Develop new tools to better individualize breast cancer treatment
Europa Donna & MINDACT

ED on:

• Steering Committee
• Legal/Ethics Committee
• Spreading of Excellence Committee
Steering Committee

43 members, all institutions including clinicians, researchers. Meets twice a year plus 4 teleconferences

• One member from advocacy org- ED

• All aspects of trial design, development and management and budget
Legal/Ethics Committee

Meets once a year plus 2 teleconferences. EORTC, Transbig Scientific Board, Lawyer, Ethicist, Medical Journalist, ED Advocate. Includes Intellectual Property Rights Committee (IPR)

• Consent agreements, patient information sheets, transfer of biological materials, cross-border issues
• To see that the trial is conducted in accordance with all laws / intl treaties and accepted ethical standards.
• Resolve ethical issues raised.
• Review and approve:
  - Material transfer agreement (Transfer and banking of tissue country to country)
  - Patient informed consent forms
Spreading of Excellence Committee

6 members: PR Firm, Researcher, FECS, Transbig (2), ED Advocate. Met twice a year plus 4 teleconferences

Review, develop, and disseminate information, documents and educational materials on project:

For public:
• Web information, presentations, pamphlets
• Conferences, training courses, media material
• Press conferences, press releases

For patients:
• DVD, pamphlets, consent forms, information sheets
Why Communication is Important

Patients and public often:
• Unaware of trial opportunities
• Not informed/information insufficient
• Have a negative mindset
• Media coverage often not balanced/sensational
• Fear of negative effect on relationship with physician
What Advocates Contribute

- Informed link between professionals and prospective participants
- Involvement in CT design can ensure clarity and readability
- Advocate involvement can result in better and more user friendly design
- Better understanding by potential trial participants
- Explain patient concerns and suggest ways of dealing with them
- Clarify language; Ensure readability of printed information, including consent forms
- Represent patients needs & consumer perspective; adds balance
1. Proceed carefully and thoughtfully from the outset; consider who is conducting the trial; what is the important question the trial will answer for patients.

2. Start with one trial only that complements your goals.

3. Ensure adequate resources; identify trained advocates available with time to dedicate to project.

4. Understand time commitment: meetings, teleconferences, review materials, lengthy, complex documents.
5. Obtain funding for advocacy work ie admin, time, resources etc. from trial group in advance

6. Study application; understand what role you are prepared to play and which you are not and state this clearly

7. Be attentive - advocates are not there to rubber stamp the materials

8. Be assertive when necessary; need time to study materials in advance, ask questions and participate actively in order to ensure credibility, independence, a real consumer perspective
ED and Research

• ED clinical trial brochure (2001, 2012)
• EU Parliament resolutions
• BIG (HABITS AND HERA)
• Partner in TRANSBIG/MINDACT (2004)
• EPF and Clinical Trial Directive
• BIG Scientific Committee; EMA
• EDALC/ Advocate’s Guide to Understanding breast cancer research
• Various meetings to promote patient advocates in research
BIG and ED Collaboration
2012-2014

- MINDACT Steering Committee
- MINDACT Legal/ethics Committee
- NABCG/BIG-Survivorship WG and informed consent form for Genomics WG
- BIG Biobanking Working Group
- Liaison to public on new directions
Patient Advocate’s Role

• Unique perspective of patients is essential for all aspects of clinical trial development, design and launch

• Convince and explain to public-lay people incl politicians, health ministries, others

• Ensure meeting needs of users-patients
Patient Advocate’s Voice is essential and important to all aspects of clinical trial development – EC research now requires patient advocate.

Advocates need to keep up with changing economic environment, personalised medicine, new research directions.
Why We Are Here Today

- ED is the advocacy voice for European breast cancer research and clinical trials
- Current resources are not adequate
- Need new ED advocates trained and ready to participate actively & effectively in research projects
Patient groups have important role-credibility

New EU regulations for patient groups EC, EMA
New EFPIA rules on working with NGO’s
EPF developing capacity planning programs

More impact,
but more transparency, professionalism required
greater accountability
Alice in Wonderland

- **Alice:** Would you tell me, please, which way I ought to go from here?
  
  **The Cat:** That depends a good deal on where you want to get to.

  **Alice:** I don't much care where.

  **The Cat:** Then it doesn't much matter which way you go.

  **Alice:** ...so long as I get somewhere.

  **The Cat:** Oh, you're sure to do that, if only you walk long enough.

*(Excerpt from Alice in Wonderland)*

What does this all mean???
It is not the things we do in life that we regret on our dead-bed, It is the things we do not!

Find your passion and follow it, that passion will be grounded in the relationships you have with people and what they think of you when you go away...

Continue the fight Against Cancer...
Thank you!