Why an Effective Clinical Trial System Should Include Patient Advocates

Margo Michaels MPH
Executive Director/Founder
Education Network to Advance Cancer Clinical Trials (ENACCT), USA

Clinical Trials in a Globalized Society

-Building an Effective Cancer Clinical Trials System-

Tuesday, May 25, 2010

Today's talk

- What is research advocacy
- Aegis of research advocacy
- How are research advocates involved
- Strengths and Weaknesses of the US Model
- An example of Community Engagement in Clinical Research

A Research Advocate is...

- Lay person who focuses on specific activities that directly influence clinical, behavioral and basic science research.
- Seek to change how research is conducted
- Seek to influence decisions about what research should be funded.

Patient Advocates at Local and National Levels in the US

1. **At the community level**
   - serve on a hospital's Institutional Review Board
   - help educate other patients/public
2. **At the national level**
   - They influence research development and implementation

Aegis of Patient Advocacy-60s 70s

- Self help
- Consumer health
- Women's health

And in the 80s and 90s

- HIV/AIDS
- Breast Cancer

Influencing research development and implementation in the US

- Serve on scientific merit review panels that make research funding decisions
- Advise on the scope of research programs and suggest new research questions
- Help design studies that optimize patient participation
- Advise investigators through a Community Advisory Board

Typical "qualifications"

- Personal experience –as patient or family member
- Ability to represent a constituency
- Respect for (and belief in) the research process
- Specific skills and knowledge through training

What Skills and Knowledge are Needed for Research Advocates?

- Basic clinical concepts (screening, treatment, staging, prognosis)
- Basic science concepts (cellular behavior, genetics)
- Epidemiological concepts (incidence and prevalence, risk, study design, randomization)
- Basic statistics (p-value, confidence interval, odds ratio, risk ratio)
- Key aspects of community outreach and accessible communication and education strategies
- Ethical principles of research
- How new treatments are developed (from laboratory to phase 3 study to FDA approval)

What Skills and Knowledge are Needed for Research Advocates?

- reflect on the impact of research for individual patients and for the patient community, rather than for oneself
- reflect, question, and respond without becoming defensive
- Self-confidence to ask questions of physicians and scientists, and to disagree with them

Education Network to Advance CANCER CLINICAL TRIALS

Benefits of involvement

- contribute the “patient perspective” of benefits, risks and quality of life, often changing study design;
- remind scientists about the ultimate purpose of biomedical research
- improve plans for recruitment, retention, outreach and follow up of study participants
- provide insights on the accuracy, clarity and readability of consent forms

Education Network to Advance CANCER CLINICAL TRIALS

“Patient” perspective: not singular

- “Patient” hat: What’s the patient being asked to do? How does it compare to standard of care? Are the risks and benefits clear?
- “Community” hat: Is this an important trial? How would the answers to this trial help people with cancer?
- “Marketing” hat: Why would patients be interested in this trial? What are key points that should be emphasized?

ENACCT
Education Network to Advance
CANCER CLINICAL TRIALS

National entities using research advocates

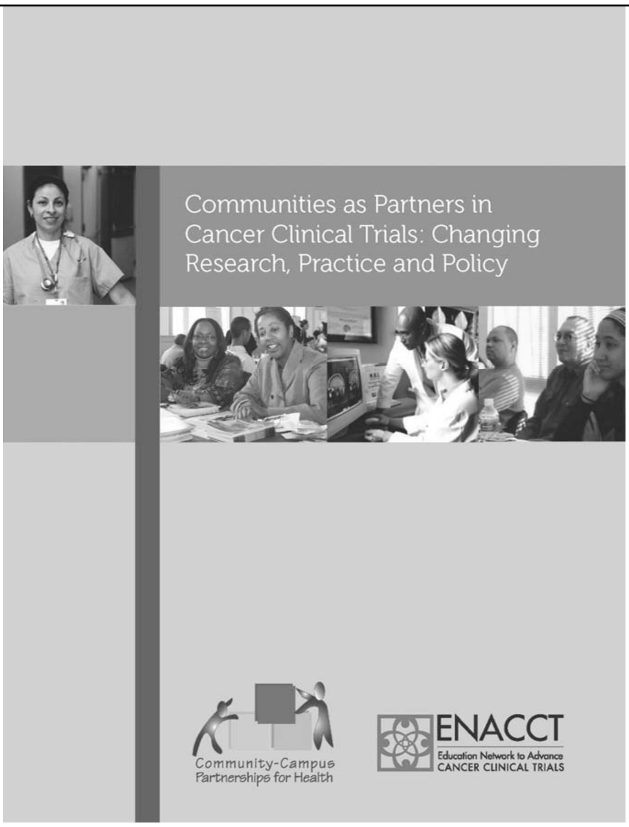
- National Cancer Institute
  - Scientific steering committees
  - Peer Review Committees
- Food and Drug Administration (FDA)
  - Cancer Drug Development Patient Consultant Program
  - Patient Representative Program
- Department of Defense Research
  - Required on peer review committees
- Academic cooperative groups
  - Serve on specific disease or treatment modality committees

ENACCT
Education Network to Advance
CANCER CLINICAL TRIALS

Example of Genentech Herceptin Trial

- Design and Implementation on Protocol
  - Widen eligibility criteria
  - Remove placebo arm
- Recruitment through network sites
- Before advocate involvement → 16 pts/month
- After → 40 patients/month

First National Report on Community involvement Cancer Clinical Research



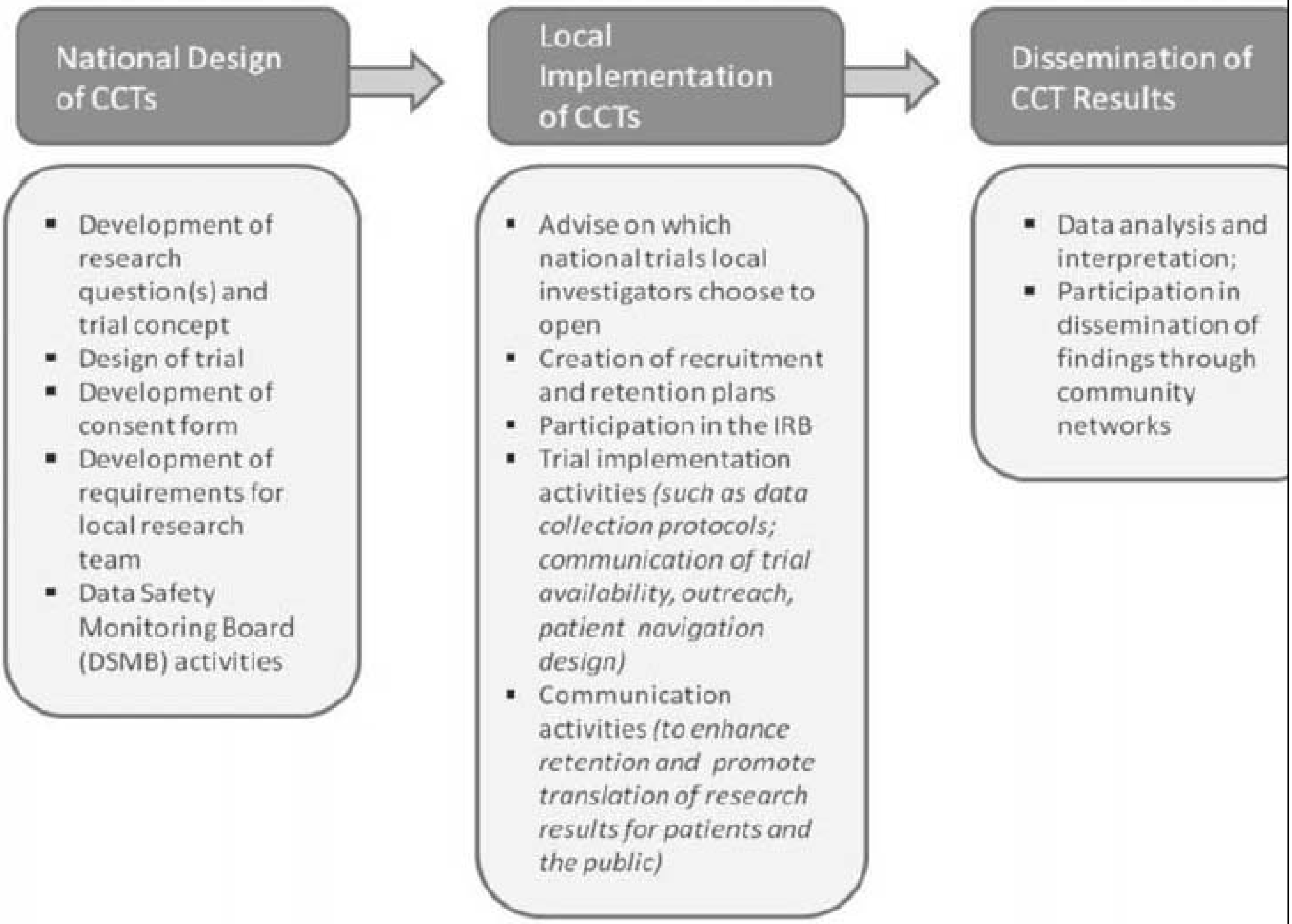
Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy

Community-Campus Partnerships for Health

ENACCT Education Network to Advance CANCER CLINICAL TRIALS

Outlines what can and should be done to improve accrual rates through use of community-based participatory research (CBPR) principles and approaches.

www.communitiesaspartners.org



National Design of CCTs

- Development of research question(s) and trial concept
- Design of trial
- Development of consent form
- Development of requirements for local research team
- Data Safety Monitoring Board (DSMB) activities

Local Implementation of CCTs

- Advise on which national trials local investigators choose to open
- Creation of recruitment and retention plans
- Participation in the IRB
- Trial implementation activities *(such as data collection protocols; communication of trial availability, outreach, patient navigation design)*
- Communication activities *(to enhance retention and promote translation of research results for patients and the public)*

Dissemination of CCT Results

- Data analysis and interpretation;
- Participation in dissemination of findings through community networks

---

Challenges of including lay persons in the research process

- **Handpicking ensures safety for the process**
  - Co-option?
  - Elitism ?
  - "professional advocate"
- Self selection
  - Uneven quality?
  - Legitimacy?

Challenges of including lay persons in the research process

- Is Advocate role required by law, or does it depend …?
- Are Advocate voices respected by scientists?
- Do Advocate voices have influence?
  - 1 vote
  - Undefined role
  - “stick to human subjects’ concerns”
- Tokenism
- Is their presence alone an important outcome?

Web Resources for Training advocates in US

- **NCI**

  -- www.cancer .gov
- **Coalition of Cancer Cooperative Groups**

  www.cancertrialshelp.org
- **Research advocacy network**

  www.researchadvocacy.org/
- **ENACCT**
  - www.ENACCT.org

ENACCT

Education Network to Advance
CANCER CLINICAL TRIALS

A few words about patient education

How can we increase 2-3% participation?

- **In the US…**
- **85% of all cancer patients never told about opportunity to receive treatment through a clinical trial**
- **75% would have been willing to participate**

- **Consider the “narrow window” of opportunity**

ENACCT
Education Network to Advance
CANCER CLINICAL TRIALS

Our Mission: To improve access to cancer clinical trials through education and collaboration with communities, health care providers, and researchers.

ENACCT's Unique Educational Approach

- Targets three different audiences
  - Community Members
  - Primary Care Providers
  - Clinical Research Teams
- Uses a train-the-trainer approach
- Addresses disparities, social justice, patient protection and systems change at the *local level*
- Action-oriented

Pilot Education Program (2006-08)

- **Goal:** to demonstrate the impact and feasibility of a community-driven outreach and education program to
  - Increase awareness about cancer clinical trials,
  - Enhance their acceptability, and
  - Improve access to them,
    - thereby increasing inquiry and ultimately patient accrual.

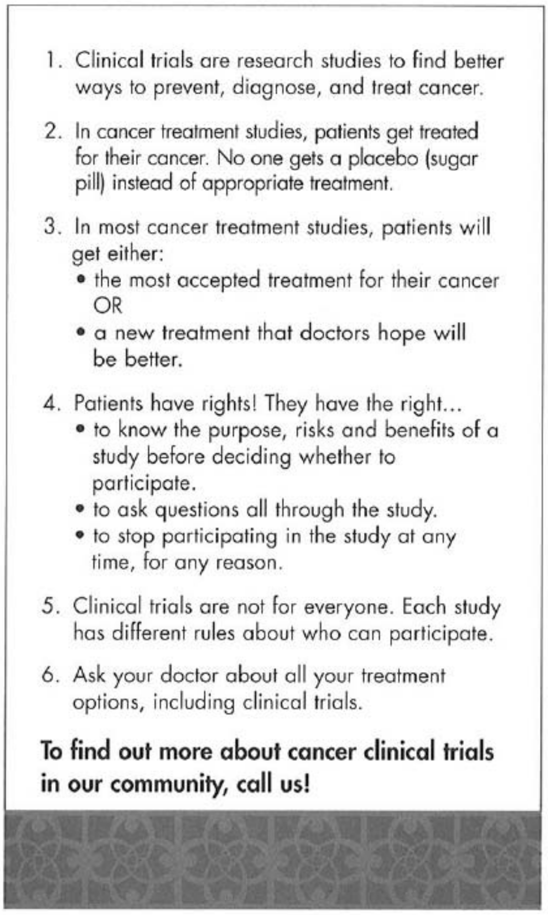
ENACCT's Pilot Education Program is made possible by the Lance Armstrong Foundation.

LIVESTRONG
LANCE ARMSTRONG FOUNDATION

Approach #1: Work to Create Community Literacy About Clinical Research

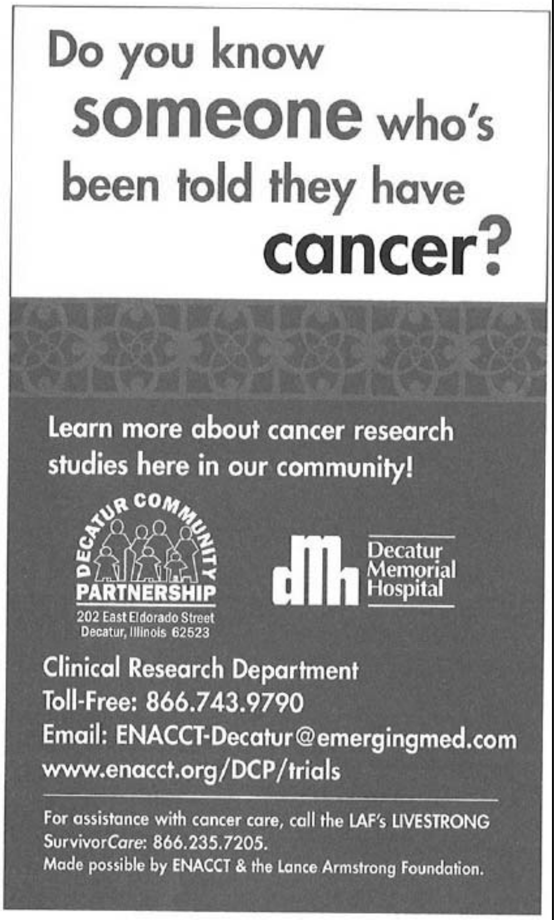
- **How can we change awareness and attitudes about CCTs?**
- Consider that the teachable moment <u>may not</u> be at the time of diagnosis

ENACCT
Education Network to Advance
CANCER CLINICAL TRIALS



1. Clinical trials are research studies to find better ways to prevent, diagnose, and treat cancer.
2. In cancer treatment studies, patients get treated for their cancer. No one gets a placebo (sugar pill) instead of appropriate treatment.
3. In most cancer treatment studies, patients will get either:
   - the most accepted treatment for their cancer OR
   - a new treatment that doctors hope will be better.
4. Patients have rights! They have the right…
   - to know the purpose, risks and benefits of a study before deciding whether to participate.
   - to ask questions all through the study.
   - to stop participating in the study at any time, for any reason.
5. Clinical trials are not for everyone. Each study has different rules about who can participate.
6. Ask your doctor about all your treatment options, including clinical trials.

To find out more about cancer clinical trials in our community, call us!



Do you know someone who's been told they have cancer?

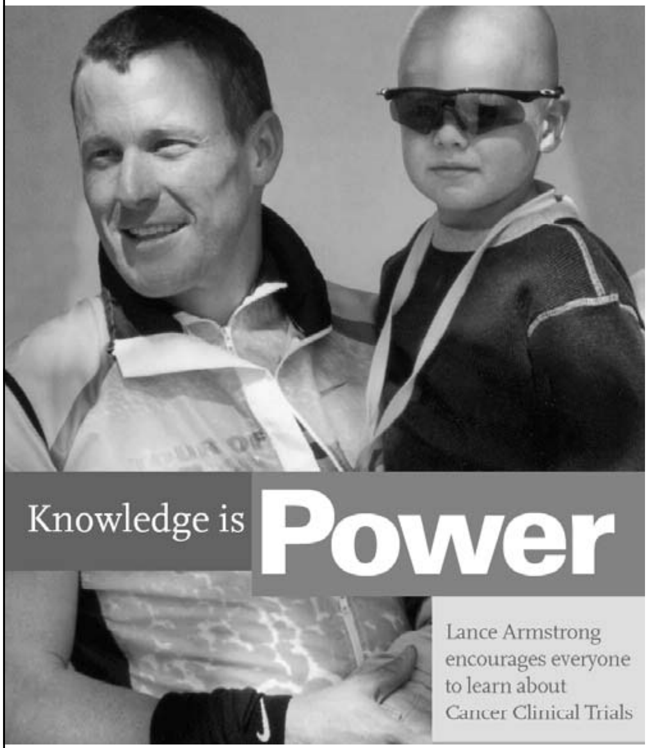
Learn more about cancer research studies here in our community!

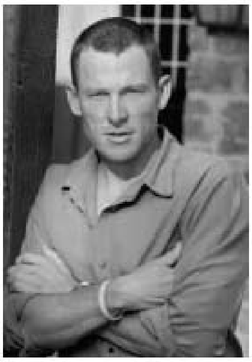
DECATUR COMMUNITY PARTNERSHIP
202 East Eldorado Street
Decatur, Illinois 62523

Decatur Memorial Hospital

Clinical Research Department
Toll-Free: 866.743.9790
Email: ENACCT-Decatur@emergingmed.com
www.enacct.org/DCP/trials

For assistance with cancer care, call the LAF's LIVESTRONG Survivor*Care*: 866.235.7205.
Made possible by ENACCT & the Lance Armstrong Foundation.



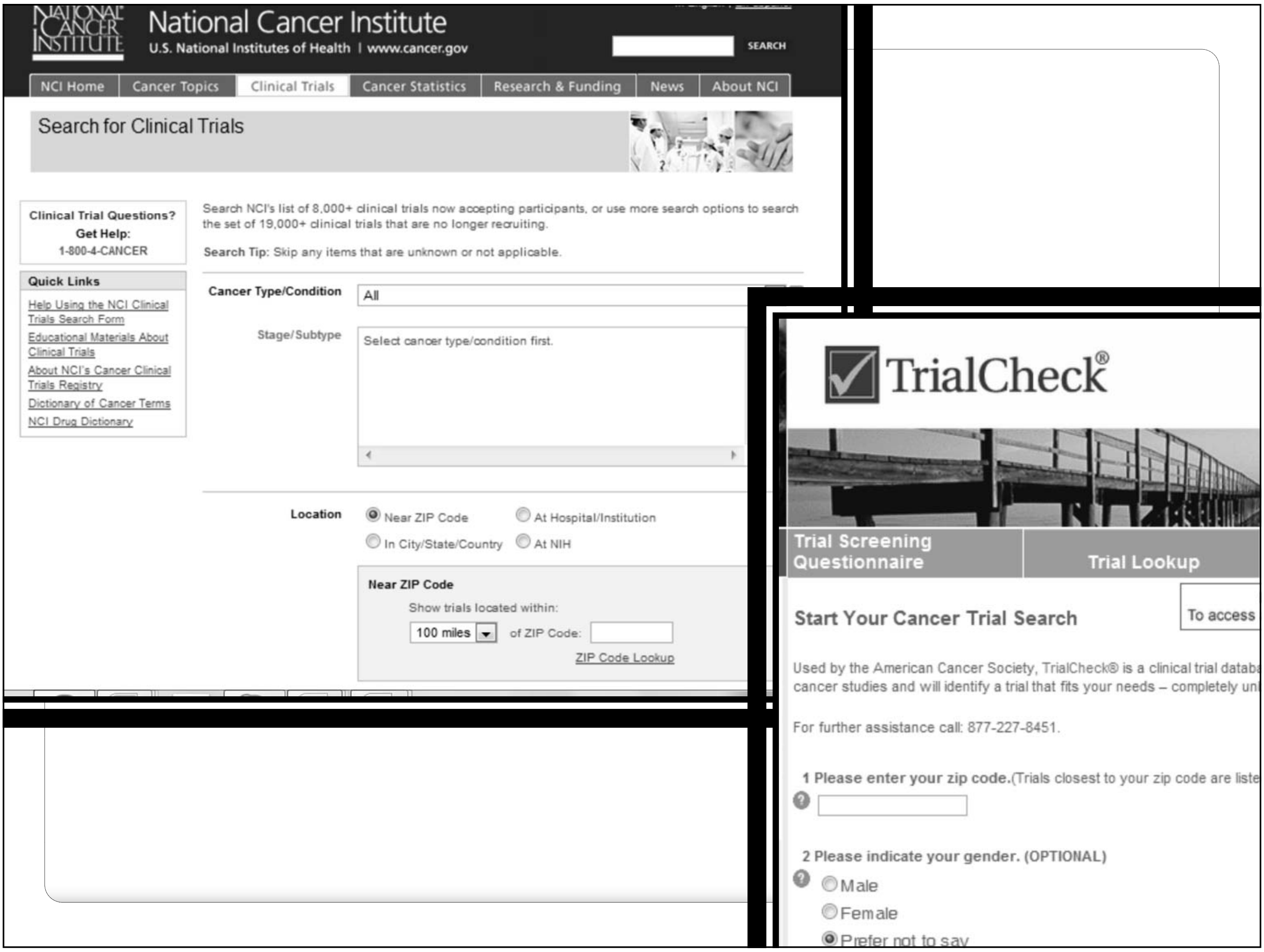


Knowledge is Power

Seven-time Tour de France champion and cancer survivor Lance Armstrong understands the importance of preparation, especially vital when facing an opponent like cancer. Through education, cancer patients can weigh their options, including clinical trials, more accurately. Says Lance, "There is a big misconception out there that you will get a placebo in a cancer clinical trial. The reality is that you will receive at least the standard therapy. People need to be aware that they are not going to get a sugar pill instead of treatment."

Who and when

- Importance of Role of Physician
- Websites
- Print materials
- Patient Service Organizations
- Other survivors



Search for Clinical Trials

Clinical Trial Questions?
Get Help:
1-800-4-CANCER

Quick Links

Help Using the NCI Clinical Trials Search Form
Educational Materials About Clinical Trials
About NCI's Cancer Clinical Trials Registry
Dictionary of Cancer Terms
NCI Drug Dictionary

Search NCI's list of 8,000+ clinical trials now accepting participants, or use more search options to search the set of 19,000+ clinical trials that are no longer recruiting.

Search Tip: Skip any items that are unknown or not applicable.

Cancer Type/Condition: All

Stage/Subtype: Select cancer type/condition first.

Location: ● Near ZIP Code ○ At Hospital/Institution ○ In City/State/Country ○ At NIH

Near ZIP Code
Show trials located within: 100 miles of ZIP Code:
ZIP Code Lookup

Start Your Cancer Trial Search

Used by the American Cancer Society, TrialCheck® is a clinical trial databa
cancer studies and will identify a trial that fits your needs – completely un

For further assistance call: 877-227-8451.

1 Please enter your zip code.(Trials closest to your zip code are liste

2 Please indicate your gender. (OPTIONAL)
○ Male
○ Female
● Prefer not to say

Community Leader Training Activities: Prompt to Action through Peer Trainers

- Clinical trial "basics" that focuses on the importance of clinical trials beyond the cancer patient
- Goal: Debunk myths, increase community awareness every patient asking about CCTs as treatment option

---

How many did we reach?

53 trainers

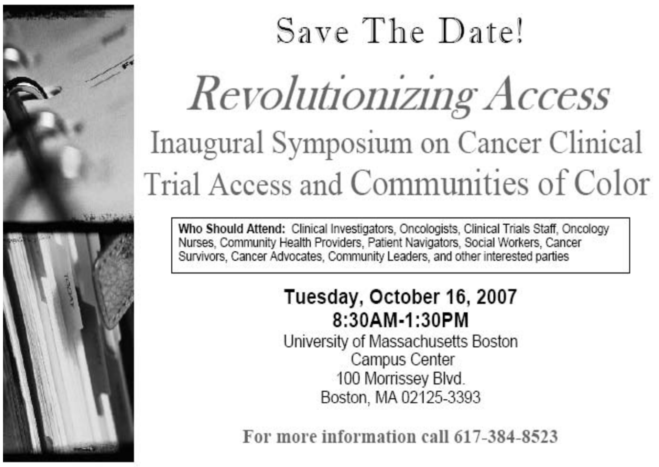
➔1000 leaders trained in workshops *(exceeding goal by 60%)*

- *66% minority*

➔4,000 community members were reached through presentations

What we learned: "Buzz" can work!

- **Change in knowledge, attitudes and beliefs**
- Increase in CCT inquiry
- 66% of those trained said they had spoken with at least one other person about CCTs
- 68% said knowledge ↑ in last year
- 40% said concern about raising awareness ↑ in last year



Save The Date!

Revolutionizing Access

Inaugural Symposium on Cancer Clinical Trial Access and Communities of Color

Who Should Attend: Clinical Investigators, Oncologists, Clinical Trials Staff, Oncology Nurses, Community Health Providers, Patient Navigators, Social Workers, Cancer Survivors, Cancer Advocates, Community Leaders, and other interested parties

Tuesday, October 16, 2007
8:30AM-1:30PM
University of Massachusetts Boston
Campus Center
100 Morrissey Blvd.
Boston, MA 02125-3393

For more information call 617-384-8523

Billboards
Radio shows
PSAs
Ethnic Newspapers
Screening Programs
Mugs, Bags, Fans

Today's talk

- What is research advocacy
- Aegis of research advocacy
- How are research advocates involved
- Strengths and Weaknesses of the US Model
- An example of Community Engagement in Clinical Research

NHS
National Institute for
Health Research

NCRN
National
Cancer
Research
Network

Co-ordinating the Patient Voice in UK Cancer Research.

David Ardron, Chair, NCRI Consumer Liaison Group.
British Embassy Tokyo, May 25th 2010.

The National Cancer Research Network is part of the National Institute for Health Research

---

“We need to work with our communities to understand their requirements”

Maria Ramalho-Notario

At NCIN/CaBIG Conference. 10th September 2009

Why patient involvement?

To ensure that research outcomes are of patient benefit, and will potentially and eventually lead to improvements in clinical outcomes.

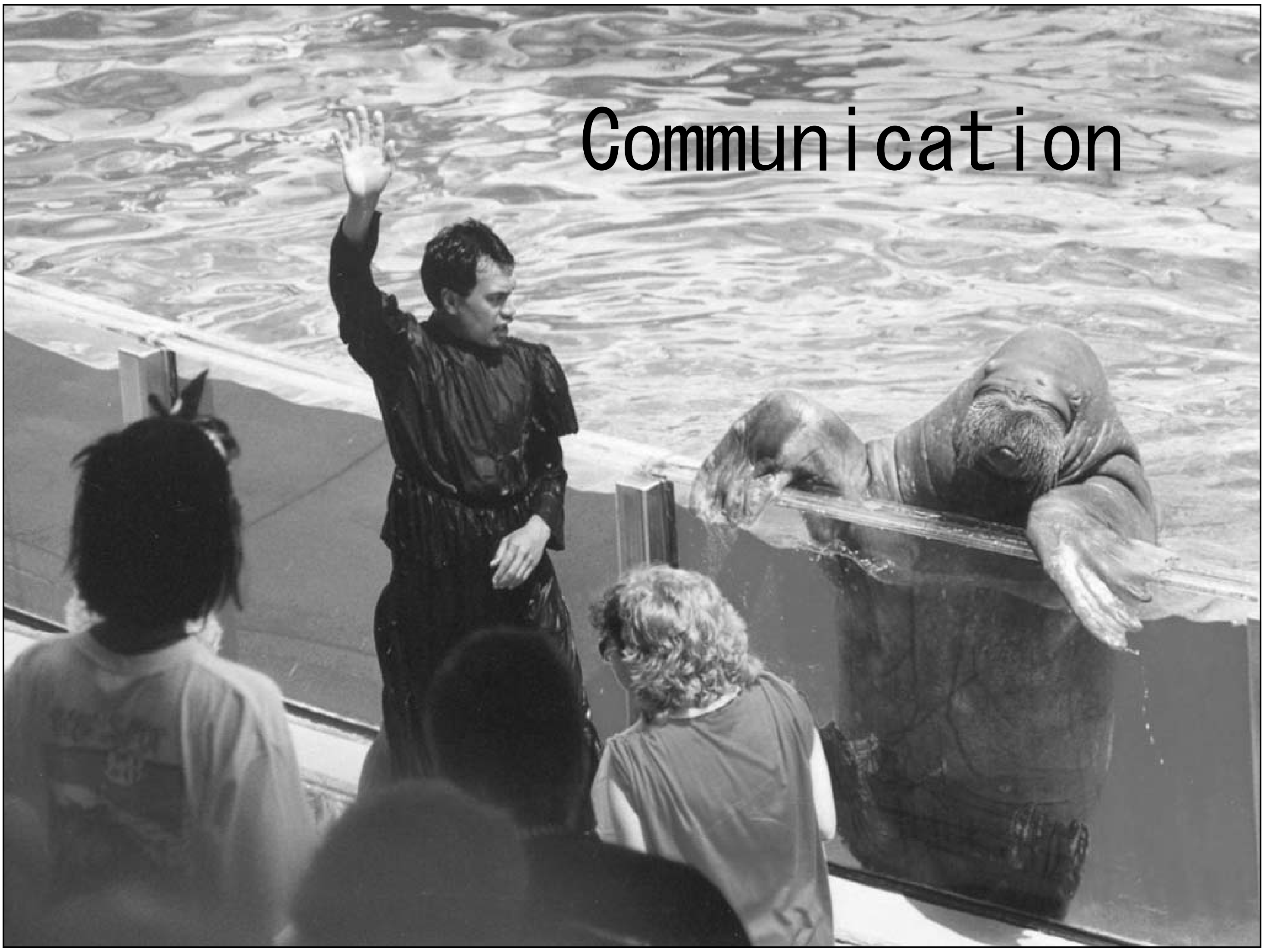
What are the Successes?

- Population of NCRI Structures (committees, conference, etc.)
- Reasonably effective contribution to research governance and management
- Widespread involvement in service development issues
- Many examples of involvement in local and national research studies
- Significant shift in the research agenda which is reflected in the CRS priorities

The United Kingdom Cancer Reform Strategy

- “Effective user involvement should have a central role to play in improving the quality of patient care and delivering a patient-centred NHS”.

Communication



Certainty and Uncertainty!
The Research Question.

- **If uncertainty exists then that should be addressed.**
- **If research is a realistic option then it should be offered! Issues of trusts opting out of trials.**
- **The elements of clinical research are poorly understood by the general public.**
- **‘Consumers’ have a role to play in helping to educate the patient population.**
- **Media, websites, DVDs, leaflets, patient information.**

“Even a fool can ask a question that the wisest man cannot answer”

“The person that asks a question is a fool for a minute but the person that doesn't ask is a fool forever”

IMPACT 1

- Langston et al. in CLINICAL TRIALS 2005 state that the impact of user involvement is “ subtle and is mainly the achievement of a well-informed and motivated cohort of participants”.
- Langston et al. suggest that user involvement leads to “richer data and enhanced credibility of the findings”.
- Oliver et al. 2007. suggest that “impact may be in terms of methodologically or ethically superior research, or more relevant research that is more likely to influence practice and hence improve health outcomes”.

IMPACT 2

- Oliver et al. 2004 “in commissioning users tend to focus on how research would look to patients while ‘experts’ focused on what was feasible”.
- Oliver et al. 2007. suggest that “impact may be in terms of methodologically or ethically superior research, or more relevant research that is more likely to influence practice and hence improve health outcomes”.

Progression

Co-operation

From Local.….

Local Involvement.

- Consumer Research Panels.
- Fully fledged panels in North Trent, Central South Coast, Humberside and Yorkshire Coast, SWSH, and, with other panels in set up in Avon, Greater Manchester, Lancs. & South Cumbria, North of England, Pan Birmingham, Peninsula, South West London, Sussex, Thames Valley, Three Counties, Yorkshire, etc.

Local Involvement.

- Evidence of University Groups using local support networks to help with research projects, e.g. Stirling University, and Lancaster University. Velindre Trust etc.
- Involvement in planning, managing, and disseminating elements of local and national research projects including clinical trials and supportive research studies, both qualitative and quantitative.
- Research for Patient Benefit.

…..To National

Clinical Trial Involvement

- **Clinical Trials**

The Royal Marsden, Medical Research Council, Southampton Clinical Trials Unit, Sheffield Experimental Cancer Medicine Centre.

Patients sit on Trial Management Groups for several of the National Cancer Research Portfolio Trials.

- **Governance**

Local Clinical Trials Executives in the Networks.

National Clinical Trials Awards Advisory Committee.

- **Research Ethics**

Patient members and some chairs of local and national research ethics committees.

Working Collaboratively for the Nation.

- **National Cancer Research Institute**
  - **Board and Sub Groups**
  - **Clinical Studies Groups**
  - **Strategic Planning Groups**
  - **Consumer Liaison Group**
  - **National Cancer Research Network**

- **Cancer Reform Strategy Initiatives**
  - **Advisory Board**
  - **Awareness and Early Detection NAEDI**
  - **Survivorship NCSI**
  - **Equalities NCEI**
  - **Intelligence Network NCIN**

Horizons

The Future?

Foundations

Inclusion

Education

Adaptation

Debate

Co-operation


Medicine

Any questions?

NCRN and NCRI websites
www.ncrn.org   www.ncri.org
NCRI CLG facilitator Karen Inns
North Trent Consumer Research Panel
Website address www.ntcrp.org.uk
Panel Facilitator
Dr. Karen Collins

THANK YOU.

Patient Advocacy and Clinical Trials in Japan

特定非営利活動法人
グループ・ネクサス
理事長　天野　慎介
Shinsuke Amano
Director General
Group Nexus

Contents 目次

1. Background（背景）
2. Patient Advocacy in Japan（日本の患者アドボカシー）
3. Clinical Trials for Patients（患者のための治験）

Background 1 my background

malignant lymphoma(2000)

- -chemotherapy,
- -radiotherapy
- -hematopoietic stem cell transplant

cancer patients were not provided with

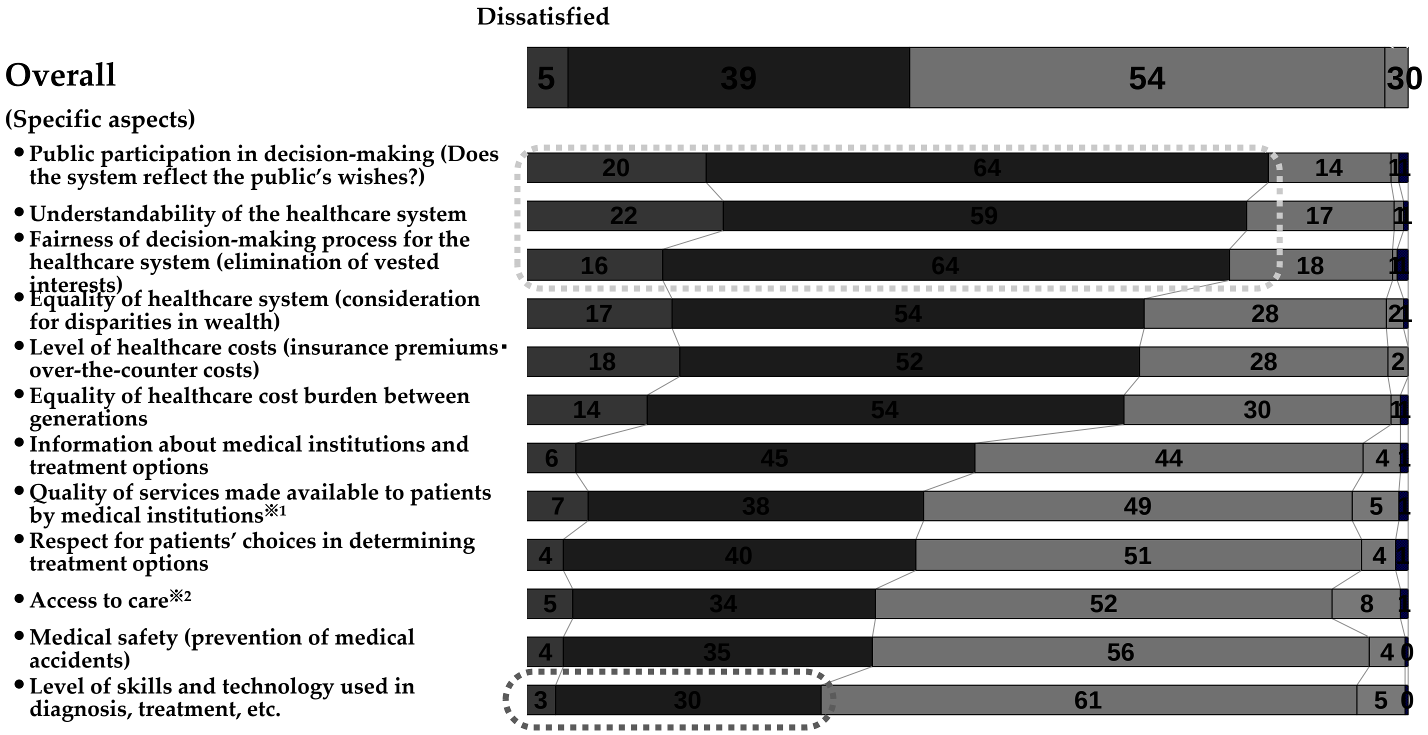
- -cancer-related information
- -networks or social support system

Background 2

Public Opinions

More than 80% of the public are dissatisfied with the decision-making process and understandability of the healthcare system, while the majority are satisfied with the medical services and treatments.

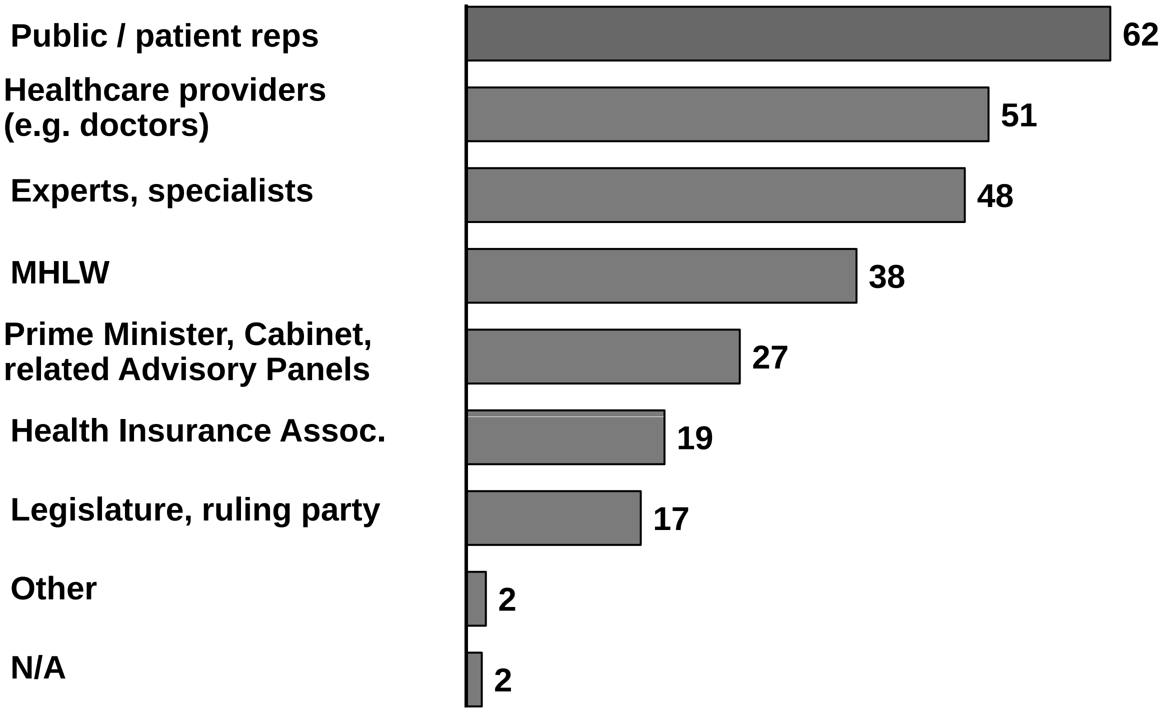
How satisfied are you with the current healthcare system?【Q4】



Public / patient representation chosen as the group to lead healthcare reform

(%; January 2008; n=1,082)

Who do you think should lead the decision-making in national healthcare system reform? (Up to 3)



Source: Healthcare Policy Institute, Japan, "2008 Public Opinion Survey on Healthcare Policy"

Background 3 Cancer Control in Japan

Cancer Control Act and Cancer Control Planning

-Approved June 2006 (Implemented April 2007)
➡ achieved by patient group coalition

-Establishing Cancer Control Promotion Council
➡ patient representative included

-Promoting Prefectural Cancer Control Programs
➡ prefectural council includes local patient leaders

Patient Advocacy in Japan

Patient representatives for regional cancer control committees gathered and shared their experiences and best practices.

Patient Advocacy in Japan

National Cancer Control Promotion Council proposed the comprehensive policy proposal.

Patient Advocacy in Japan

Comprehensive Proposal by CCPC (with active patient advocates) includes suggestions on Clinical Trials and Drug Approval System

ー抗がん剤の審査プロセスの迅速化
ー抗がん剤の適用拡大の審査プロセスの見直し
ーコンパッショネート・ユース（人道的使用）制度の創設
ー高度医療の改正（国内未承認薬、適用拡大等の早期承認）

Expediting procedure of drug approval
-Reviewing the system of PMDA (Pharmaceutical and Medical Devices Agency) which review and approve the cancer drug and increasing the subsidy.

Reviewing the approval process of expanding application of the approved drugs to cancer treatment
-Reviewing the systems of PMDA for the purpose of reviewing the approval process of expanding application of the approved drugs to cancer treatment.

Establishment of the systems on compassionate use
-Discussing the systems that allow patients to use the unapproved drugs safely under certain facilities and conditions

Revision of the systems of the highly-advanced medical treatment (Early ratification of the unapproved drugs and expanding the use of the approved drugs)
-Transforming the system of the highly-advanced medical treatment to be easier to conduct clinical trials.

Clinical Trials for Patients

ー治験の重要性について、患者アドボケートの認知は高まりつつある

⇒患者アドボケートができることをより明確化し行動していくべき

・患者や市民に向けた治験に関する普及啓発活動の実施
・必要な新薬の早期承認に向けた学会や企業との連携
・治験の安全性を高めるための活動
・治験臨床医の地位向上

-Awareness for Clinical Trials has been raised among patient advocates

⇒Concrete action plans and ACTION should be implemented

“What patient advocate can do?”
・Awareness campaign for patients and citizens
・Collaboration with academic society and industry
・Safety assurance campaign
・Praising CT doctors

Clinical Trials for Patients

and

INTERNATIONAL COLLABORATION!!!