

ENACCT
Education Network to Advance
CANCER CLINICAL TRIALS

Pilot Education Program (PEP)

A Community-Centered Model for
Enhancing Cancer Clinical Trials
Participation Among Medically
Underserved Populations

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Presenter Disclosures

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(1) The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

Other: Lance Armstrong Foundation

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ENACCT PEP Team

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

Only national organization solely focused on implementing evidence-based, community-centered approaches to cancer clinical trials education.

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Why Cancer Clinical Trials (CCTs)?

- Quality treatment option
- Only 3% of all cancer patients receive their treatment through a clinical trial
 - even lower among minorities and medically underserved



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State of Cancer Clinical Research: Some Points to Consider

- Researchers have **difficulty in recruitment** and retention, especially among minority groups
- **Poor understanding** among patients and members of the public
 - Distrust, fear and suspicion
- **Referrals (or encouragement)** from PCPs, surgeons and non participating oncologists need to be enhanced

McCaskill-Stevens W, et al. (1999). Journal of Clinical Oncology, 17(13):1022-1039; Pinto HA, et al (2000). Annals of Epidemiology, 10(6):Suppl:578-84; Lonato L, et al (1997). Contemporary Clinical Trials, 18(4): 328-352; Hudson SV, et al. Cancer Control, 2005 Nov;12 Suppl 2:93-6; CODA. (2000, July). NCI study of Primary Care Physicians' Attitudes, Knowledge, and Practices Related to Cancer Clinical Trials. Final Study Results; Weinberg, A.D., et al., Texas Medicine, 2004, 100(4): p. 66-72; Crosson, K. et al., Journal of Cancer Education, 2001, 16(4): p. 188-192; Roberts, F. (2002). Soc Sci Med, 55(11), 1947-1955; Aldige, C. et al. Conversations in care web-book: Chapter 9 Communicating about clinical trial enrollment: Patients and advocates speak out.

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Who is *interested* in participation?

- 85% eighty-five percent of cancer patients surveyed were unaware that clinical trials were a treatment option.
- 75% would have been willing

Comis, JCO, 2000

Minorities may be as willing to participate in research, but are **less likely to be asked.**

Wendler PLOS, 2007




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Who is offered participation?

- **Subjective assessment** which patients seem to be 'good study patients' are more likely targeted for recruitment.
- Patients in clinical trials are significantly *more* likely to be insured; and
- Geographic areas with *higher* socioeconomic levels have *higher* levels of clinical trial accrual.

Joseph G. Cancer. 2009 Feb 1;115(3):608-15; Simon, M. S., & Du, W. (2004). Journal of Clinical Oncology, 22, 2052-2059; Saterre, W. B., et al. (2002). Journal of Clinical Oncology, 20, 2109-2117.



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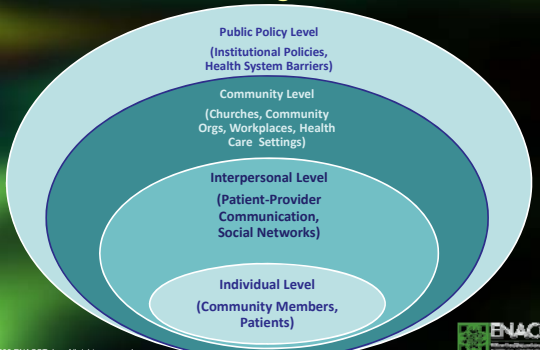

“without a concerted effort to [enhance access and increase participation in these trials], **ethnic minority and medically underserved communities will continue to lag behind the American majority** in benefiting from ... medical breakthroughs in cancer prevention, treatment, and control.”

an important strategy “to obtaining quality cancer treatment [and reducing cancer health disparities] may be through increased access to cancer clinical trials.”




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Community-Based CCTs Education: Socio-Ecological Model


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Innovative Theory-Based Educational Approach: 3 Target Groups



Trained "peer trainers" and "provider trainers" lead interactive workshops in their community

National expert leads "Enhancing Recruitment and Retention Efforts" for CCT teams.



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ENACCT's Pilot Education Program

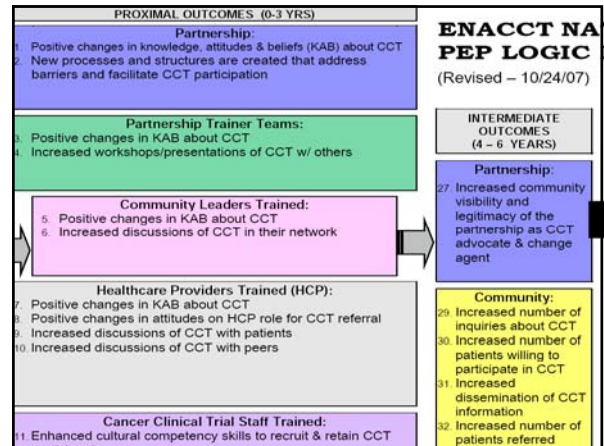


- **Goal:** to demonstrate the impact and feasibility of a community-driven outreach and education program to
 - Increase awareness about cancer clinical trials,
 - Enhance their acceptability, and
 - Improve access to them,
 - thereby increasing inquiry and ultimately patient accrual.

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




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Welcome to the ENACCT Trainer Tool Kit.

- Based on NCI CTES
- Messages of social justice and access to care
- Tests at 8th grade level
- Available in Spanish and Korean

•Videos

•Slides

•Trainer and Trainee Guides

•Curricula changed 3 times from ongoing trainer feedback

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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).

3. In a cancer clinical trial, you get the best of both worlds. You get the best of both worlds. You get the best of both worlds.

4. Patients in cancer clinical trials get the best of both worlds. They get the best of both worlds. They get the best of both worlds.

5. Clinical trials are research studies to find better ways to prevent, diagnose, and treat cancer.

6. All patients in cancer clinical trials get the best of both worlds. They get the best of both worlds. They get the best of both worlds.

Do you know someone who's they have cancer?

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

Key Proximal Outcomes: Trainers Running Workshops

75 trainers (53 CLs and 22 HCPs)

- ➔ 1000 CLs trained in workshops (exceeding goal by 60%)
 - 66% minority
- ➔ 4,000 community members were reached through presentations
- ➔ 461 HCPs trained (exceeding goal by 3%)
 - 62% nurses
- ➔ 61 CCT staff trained (missing goal by 50%)

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Key Proximal Outcomes: CCT Attitudes and Beliefs

1ST ASSESSMENT

- Partnership Leaders highest AB (p<0.03)
- CCT Staff
- HCP Trainers
- HCP Trainees
- CL Trainers
- CL Trainees

OVER TIME AS MORE FAVORABLE

- HCP Trainers (1 site, p=0.01)
- CL Trainers (2 sites, p=0.04)
- CCT Staff
- CL Trainees

LESS FAVORABLE OVER TIME (NS)

- HCP Trainees
- Partnership Leaders

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Key Proximal Outcomes: HCP Trainee KAB and Their Role (Pre-Post)

Outcome	N	Mean First	Mean Last	Mean Difference	Std Dev	T	Significance Level**p<.001
KAB about CCT	362	3.90	3.98	.08	.55	2.89	0.00
Attitudes on HCP role for CCT referral	361	2.64	4.00	1.36	1.00	25.88	0.00


Key Proximal Outcomes: CL Trainee KAB-Boston Only

N	Pre-Test Mean	Post-Test Mean	Diff	Std. Dev.	T	p
164	14.1	14.6	.5	2.69	2.35	0.02*

Quotes from the Field: Community Leaders

"Some people come with all kind of reservations [about CCTs] and then they hear, number one, we're not selling it. They're hearing both sides of it-then they're open."

"The knowledge base that I had before coming to this program was such that I wouldn't have recommended anyone [to CCTs] because of what had happened regarding African Americans and treatment of African Americans as a result of clinical trials."




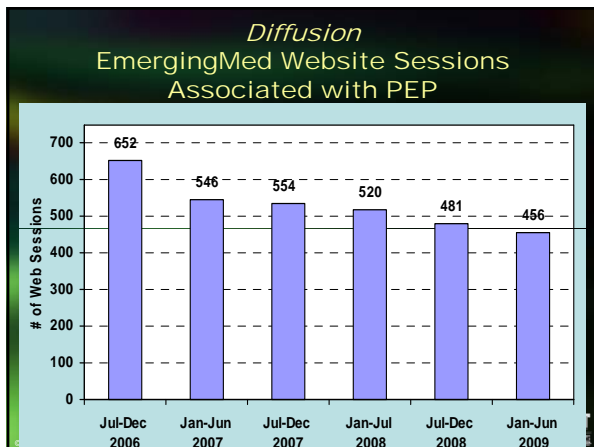
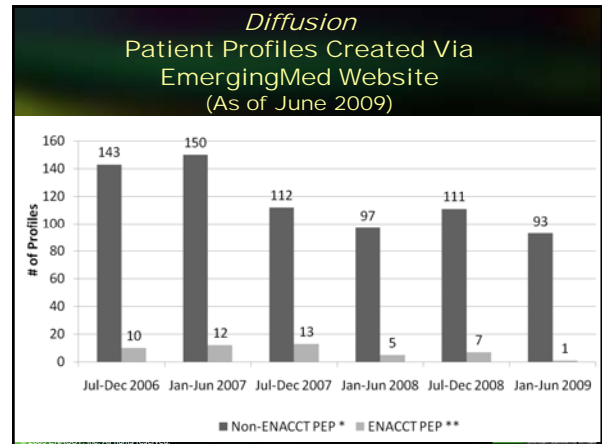
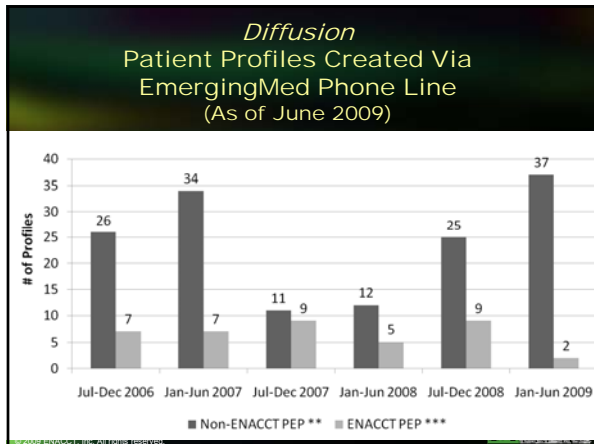
- ### Key Proximal Outcomes: CL Diffusion to Peers
- Data from representative sample: 71% of CLs engaged in dissemination of CCT messages.
 - At first assessment, trainees
 - perceived themselves with ability to talk with others and
 - reported intentions to talk about CCTs in their networks
 - Over time they had lower perceptions about their ability to talk with others but showed increased intentions to do so (p>.05).
 - 49,000 "palm cards" distributed

- ### Key Proximal Outcomes: HCP Diffusion to Peers, Patients and Their Role
- (at 1st assessment post training)**
- Increase in discussions with peers and patients about CCTs in the last 12 months
 - More likely to encourage participation in cancer clinical trials among patients

Quotes from the Field: Primary Care Providers

*"The thought of a clinical trial option needs to be planted very early...The primary care physician **can** say "Hey, ask your oncologist about a clinical trial." Then, they [patients] think about it before they hit the oncologist."*





Key Proximal Outcomes: CCT Staff

Outcome	N	Mean First	Mean Last	Mean Diff	Std Dev	T	Signif Level
Enhanced CC Skills to recruit and retain CCT participants	28	3.71	4.35	.63	.64	5.19	0.00 $\alpha=0.58$ $p<0.01$
Increased advocacy efforts of CLAS standards within institution	27	2.41	3.52	1.11	.88	6.54	0.00** $\alpha=0.91$ $p<0.05$

Quotes from the Field: Cancer Clinical Trials Staff

"We will use these training tools ... and begin [a] dialogue for cultural competency."

"Opened my mind to looking at people with a more open mind and understanding."

"I can now talk to people about cancer clinical trials in a way that I've never been able to before."

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- ### Key Intermediate Outcome: Creation of New Processes and Structures to Reduce Access Barriers
- Achieved change in consent process:
 - use of OHRP-approved "short form" and process for Limited English Proficiency patients in local CCOP (Tacoma)
 - Advocated for Insurance Coverage (Tacoma)
 - Implemented Six Sigma quality improvement methods to improve patient recruitment process (Decatur)
 - Launched two city-wide Clinical Trials Symposia targeting community partners and health care institutions (Boston)
-
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Data Limitations

- **Survey**
 - Response rate varies from as low as 9.6% to as high as 72%
 - **poor response rate** of CL, HCP trainees & CCT staff, especially over time
 - Computer precluded the participation of some
 - Unfamiliar email from evaluation team
 - Time Lag
- **Trainee/Trainer Selection**
 - Eligibility criteria – CL Trainees, HCP and CCT staff trainees—were not followed closely, subsequently affecting survey group findings.
- **Pilot Project**

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Conclusions

- Training that is informed by, and run through local communities **can**
- Generate action through diffusion-community "buzz" (*discussions, calls, website hits, etc*)
- Generate behavior change in Primary Care Providers to be more likely to discuss CCTs
- Build awareness among CCT staff
- Medically underserved groups, through local and trusted organizations, **DO** want to learn about this issue

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Conclusions

- We **CAN**, in some important ways, increase collaboration across sectors through coalitions
 - Consent process
 - Insurance reform
 - Community forums
- Community coalitions may not have the appropriate infrastructure or influence to take on this issue, especially those who hadn't worked in subject beforehand
 - Clear need for additional synergy across target groups

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Future Directions

- Our experience is allowing us to be better able to
 - Refine community, provider and CCT education efforts
 - Find ways to bring the three targeted audiences together to work, collaborate, and support each other in their work regarding CCT access
 - Still need to identify and emphasize a common vision that will unite them.
- Still need to refine "so what?"

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For More Information...

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