Cancer Clinical Trials: Enhancing Infrastructure and Accrual

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Off-Label Use Disclosure(s)

I do not intend to discuss an off-label use of a product during this activity

Financial Disclosure(s)

I have not had any relevant financial relations during the past 12 months to disclose
Objectives

• Describe the essential role of clinical trials in advancing cancer care

• Discuss specific strategies to support developing/enhancing a cancer clinical trials infrastructure within your organization

• Identify approaches to improving patient accrual to cancer clinical trials

The Problem

What we don’t know about cancer kills people…and greatly diminishes quality of life
The Answer

Cancer clinical trials have been the key to remarkable improvements in both survival and quality of life

18 Million Cancer Survivors Projected

Major Oncology Practice Change: Breast Conservation - 1985

- Studies demonstrate that lumpectomy + radiation therapy is as effective as mastectomy for early stage breast cancer.

- This approach dramatically reduces physical and cosmetic side effects
  - Quicker recovery after surgery
  - Improved quality of life


Major Oncology Practice Change: Organ Preservation in H & N Cancer

1991

- A Phase III randomized trial shows that induction therapy, involving initial treatment with CTX followed by RT, is as effective as standard treatment but allows many patients with advanced laryngeal cancer to avoid surgical removal of their larynx and vocal cords.

- Until this time, such surgery, followed by radiation, was the only proven treatment for these patients.

- This regimen remained the standard for more than a decade, until researchers discover that giving radiation and chemotherapy at the same time is more effective.

www.cancerprogress.net
Major Oncology Practice Changes: First Oral Chemotherapy

2001-2004

- The FDA approves capecitabine (Xeloda) for patients with advanced (metastatic) colon cancer, and later for patients with stage III colon cancer (cancer with limited spread in the surrounding tissue) who have had surgery to remove the tumor.

- Capecitabine is a pill version of the widely used intravenous chemotherapy drug 5-fluorouracil that offers comparable effectiveness that is more convenient for patients.

- Recently, capecitabine has been combined with the drug oxaliplatin (Eloxatin) as an initial therapy for metastatic colon cancer and for early-stage colon cancer.

www.cancerprogress.net

Major Oncology Practice Changes: Antiemetics

1991

- New class of antiemetic drugs, 5-HT3 RAs alleviate major side effect of cancer treatment
- Ondansetron (Zofran) is approved by the FDA to prevent vomiting caused by chemotherapy and/or radiation.
- The drug works by deactivating the nervous system’s natural trigger for vomiting.
- Other similar drugs are soon approved, including granisetron (Kytril), dolasetron (Anzemet)

2003

- Longer acting 5-HT3 agent approved
- Additional class of antiemetic approved, aprepitant, fosaprepitant (Emend)

These agents make it possible for the majority of cancer patients to receive chemotherapy in the ambulatory setting, with minimal disruption to their routines.

www.cancerprogress.net
Major Oncology Practice Changes: Palliative Care in Lung Cancer

2009

• A head-to-head trial shows that patients who received standard chemotherapy along with palliative care (specialized treatment to address the symptoms of cancer, but not treat the disease) immediately after their diagnosis with advanced lung cancer lived three months longer and had a higher quality of life than patients who had chemotherapy alone.

• Patients who received the combination approach were also less likely to undergo aggressive therapy at the end of life, such as resuscitation.

www.cancerprogress.net

Clinical Cancer Advances: Genetics

• Genetic basis of anthracycline-related heart disease risk in childhood cancer survivors is revealed

• Genetic marker helps to inform choice between RT and chemotherapy in elderly patients

• Genetic markers linked to better treatment response and longer survival in patients with oligodendroglioma

**The Most Critical Reason**

- Patient Perspectives
  - [http://www.cancerprogress.net/stories.html](http://www.cancerprogress.net/stories.html)

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**Cancer Clinical Trials**

- Clinical trials: the engine that drives lifesaving cancer treatment
- Key to translating cutting edge laboratory discoveries that extend and improve life
- It takes years of research effort to achieve advances and tremendous resources: patients, investigators, & public & private investment
- On the threshold of major advances in cancer prevention, detection, and treatment…but only through commitment to research
Setting the Stage: Cancer Clinical Trials in Context

- Clinical research trials form the backbone of advances in cancer care

- Less than 5% of adults diagnosed with cancer are treated on a clinical trial

- Distance to a cancer center offering clinical trials known barrier to participation in clinical trials

- As of 2012, the CoC requires community hospital cancer programs (CHCPs) to provide cancer patients with access to clinical research trials and to enroll 2% of their population onto clinical trials in order to maintain their accreditation.

- Many CHCPs currently lack the infrastructure, qualified personnel, and experience to effectively accrue to and safely manage patients on clinical trials.

Setting the Stage: Cancer Clinical Trials in Context

- The NCI has created an infrastructure of clinical cancer research that is unmatched anywhere in the world.

- The foundation of this system is the NCI-designated Cancer Centers, which have been the bedrock of the continual improvements made in prevention, screening, treatment, and palliative care.

- 85% of cancer patients receive care at the local level.

- If we want to bring the latest scientific advances to the patient, we need to develop programs to reach patients in the communities where they are treated.
The Idea

Clinical Trials Training

TRAINING COMMUNITY NURSES AND ADMINISTRATORS TO IMPLEMENT CANCER CLINICAL TRIALS

This investigation is funded by the National Cancer Institute (1R25CA 168551-01)
Project Objectives

- Provide basic research education to support the ability to implement, treat, and assess subjects on clinical trials in an ethical and safe manner.

- Assess the effectiveness of the research education on knowledge, skills, and satisfaction

- Provide networking and post-course follow-up.

- Assess organizational structure and clinical trials activities 6, 12, and 24 months after completion.

Curriculum Framework

**Key Elements of Workshop Curriculum**

- Overview of the History of Clinical Research
- Overview of Clinical Trials Designs
- Essential Elements of a Protocol
- Protocol Development
- Regulatory & Legal Issues
- Roles and Responsibilities of the Research Team
- Clinical Trials-Related Communication
- Barriers to Recruitment/Retention of Subjects in a Diverse World
- Clinical Trials Patient Management
- Clinical Trials: Administrative Workshop
- Data Management
- Working with Sponsors
- Ensuring Quality in Clinical Trials

**Program Evaluation**

- Program outcomes measured at 4 levels
  - Effectiveness of the curriculum
  - Perceived benefit of CCN trainees
  - Perceived benefit of CPA trainees
  - Organizational outcomes:
    - number of clinical trials open
    - number of patients screened
    - number of patients accrued onto clinical trials
Baseline Data

- **During Application Process**
  - Organizational variables
  - Cancer registry data
  - Team goals (SMART)

- **Posters**
  - Institutional barriers and facilitators

- **Pre-tests**
  - Assessment of knowledge

Major Focus of Organizational Goals

- Education and training
- Developing infr
Major Goal Categories

<table>
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<th>Goal</th>
<th>Frequency (%)</th>
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<tr>
<td>Communication</td>
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<tr>
<td>Infrastructure</td>
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<tr>
<td>Budgeting/Billing</td>
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<tr>
<td>Program Development</td>
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Goal Examples: Communication

- To provide the press release letter for participating in CT program to our hospital marketing/PR department director (Joanna Rudisill) within 2 weeks (by 10/21/13).

- Develop a clinical trial advertisement to be placed strategically in physician practices regarding clinical trials within the next 12 months (October 2014).
**Goal Examples: Infrastructure**

**Development of Tools for Managing Programs**

- Within 6 months develop a potential clinical trials screening form for Breast Cancer, Prostate Cancer and Hepatobiliary Cancer.
- Refine/create tracking forms for patient screening, tracking, and reporting (by 10/1/14)

**Goal Examples: Infrastructure**

**Development of Tools for Managing Programs**

- Develop tool to evaluate current protocols w/o participants enrolled and establish parameters for study closure and/or justification for leaving them open. Basic outline by 10/1/13. Full implementation by 1/1/14.

- Develop clinical trials dashboard to demonstrate accruals, open studies, new studies presented, protocols closed, protocols by disease site, subjects who come off of study early.
Goal Examples: Patient Education

- Develop a clinical research brochure that can be included in new patient info packet. Basic Outline by 7/1/13. In use by 10/1/13.

- Within 9 months conduct a clinical research public education program.

Post-Course Follow-Up

- Monthly phone calls led by workshop faculty
- Ongoing email access to workshop faculty
- Discussion board
  - Materials for call discussions
  - New information
  - “Tool kit”
  - Sample SOPs
Follow-Up Conference Calls

- Monthly X 4 months
- Goal review and progress to date
- Monthly topic that builds on course content
  - Billing progress
  - SOPs
  - Infrastructure
  - Learning from each other
  - Continued networking

Poster Sessions

- Ice Breaker
- Networking
Clinical Trials Participants
N = 71

- CT: 8
- NJ: 2
- MD: 2
- NH: 3
- VT: 1
- MA: 2
- NY: 2
- PA: 4
- DC: 1
- GA: 2
- IL: 3
- IN: 1
- IA: 2
- KS: 2
- LA: 1
- ME: 2
- MI: 1
- MN: 1
- MO: 1
- MS: 1
- NV: 6
- OH: 1
- OR: 2
- PR: 3
- RI: 1
- SC: 2
- TX: 1
- WA: 1
- WI: 1
- WY: 2

Upcoming Courses

- June 5th & 6th, 2014
  City of Hope National Medical Center
  Duarte, California

- October 9th & 10th, 2014
  University of Pennsylvania
  Philadelphia, PA
Upcoming Courses

- Online application process
- Competitive selection process