Recruitment to Cancer Clinical Trials

Marge Good, RN, BSN, MPH, OCN
SWOG CRA Plenary
May 1, 2008

Overview

• Why cancer clinical trials?
• Why people participate and why they don’t?
• What are the challenges?
• What are elements of success?
• What is the CRA role?
Why Cancer Clinical Trials?

• “Imperative to engage in clinical trials to improve outcomes such as survival, side effect profiles, combination therapies and quality of life.” (C-Change & Coalition for Cancer Cooperative Groups; 2007)
  – Vital component of FDA’s drug approval process
  – How we have therapies we have today.

Recent Statistics

• Harris Interactive (2000)
  – 85% of cancer patients (more than 8 out of 10) polled did not realize a clinical trial was an option
  – 40% did not understand the idea of a clinical trial
  – Public and patients willing to consider trials if informed (8 out of 10 would consider)
  – 75% felt clinical trials were associated with “high quality medical care”
  – Role of oncologist is essential
Recent Statistics

- 92% felt clinical trial would benefit themselves as well as help others in the future
- Patients participating in clinical trials cite it was a positive experience
- Even the perception that insurance coverage may be denied acts as a barrier
- 56% indicated “mostly true” that clinical trial participants were likely to receive a placebo
- 45% thought patients in clinical trials are “treated like a guinea pig”

Reasons for Participation

- Greater chance of being cured
- To further medical research
- Others will benefit
- Only way to receive new treatment
- Clinical trial includes the best treatment
- May receive more detailed information
- Being monitored by experts (locally & nationally)
Challenges

• Four Broad Groups
  – Physician-related
  – Protocol-related
  – Patient-related
  – Funding-related


Physician Challenges

• Small number of practicing oncologists who actively participate in clinical trials.
• Physicians excluded up to one-third from consideration even before reviewing protocol availability and eligibility
• Believe that more cancer patients should participate, but these same physicians do not uniformly encourage participation.
• Encouragement to participate drops off dramatically if patients express a reluctance to participate
• May possibly negatively impact relationship with patient
• No available protocol
• Eligibility criteria too restrictive; Poor patient performance status
• Increased time and effort (find a trial, establish eligibility, explain the trial, obtain informed consent, performed additional trial-related work)
• Associated paperwork (CRFs, 1572s, financial disclosures, IRB/regulatory, etc)
Protocol Challenges

- Strict protocol eligibility criteria
  - Cooperative groups have included “good clinical practice” guidelines
- Need for more sophisticated infrastructure in participating sites
  - accommodate newer targeted and vaccine therapies and other patient specific treatments
  - collection of, processing, storing and shipping of study samples (blood/tumor tissue)

Patient Challenges

- Treatment may be too severe or worse on a clinical trial
- Doctor may not know as much about the treatment
- “Standard treatment” thought to be better or desire to receive new therapy
- Clinical trial may involve extra inconveniences
- I may have less say in what happens to me
- Would feel like a guinea pig
- Fear of receiving placebo
- Geography-related – access away from home
- Desire to select treatment
- Fear of randomization
- Fear of 3rd party payer denial
Funding Challenges

- Publicly funded trials reimburse at approximately $2,000 per study subject
  - Median cost per subject for a phase II = $6,266; for a phase III = $3,427 (C-Change & Coalition for Cancer Cooperative Groups; 2007)
  - Federal budget for cancer research has decreased
- Insurance Coverage
  - Only 8% of patients failed to participate because of 3rd party denial of coverage Lara, et al. JCO 19(6) 2001: pp1728-1733
  - Harris Interactive - 3/4 of trial participants did obtain coverage and did not experience trouble in obtaining coverage

Elements of Success

- Committed Staff
- Financial Resources
- Accessible Ancillary Services
- Respect for Subjects
- Host Institution Support
- Emphasis on Safe Patient Care

(C-Change & Coalition for Cancer Cooperative Groups; 2007)
The CRA Role

• Wright and colleagues
  – Patients first approached by a physician vs a CRA, and then those patients whose decision was solicited by a CRA vs. a physician were more likely to enter a clinical trial.

Wright, et al. JCO 22(21) 2004: 4312-4318

The CRA Role

Completed model included 4 significant items
Patients entered trials when:
  1. They perceived personal benefits
  2. When they believed the CRA helped with their decision
  3. When they had less difficulty with their decision (the more difficult the decision the less likelihood of participation)
  4. When the CRA indicated that more time was spent with the patient.

Wright, et al. JCO 22(21) 2004: 4312-4318
The CRA Role

• Many patient-related challenges/barriers associated with education and communication
  – Misconceptions and drawbacks need to be dispelled
  – ↑ knowledge = ↑ participation
  – ↑ awareness = ↑ participation


Patient Challenges

• Treatment may be too severe or worse on a clinical trial
• Doctor may not know as much about the treatment
• “Standard treatment” thought to be better or desire to receive new therapy
• Clinical trial may involve extra inconveniences
• I may have less say in what happens to me
• Would feel like a guinea pig
• Fear of receiving placebo
• Geography-related – access away from home
• Desire to select treatment
• Fear of randomization
• Fear of 3rd party payer denial
Physician Challenges

- Small number of practicing oncologists who actively participate in clinical trials.
- Physicians excluded up to one-third from consideration even before reviewing protocol availability and eligibility.
- Believe that more cancer patients should participate, but these same physicians do not uniformly encourage participation.
- Encouragement to participate drops off dramatically if patients express a reluctance to participate.
- May possibly negatively impact relationship with patient.
- No available protocol.
- Eligibility criteria too restrictive; Poor patient performance status.
- Increased time and effort (find a trial, establish eligibility, explain the trial, obtain informed consent, performed additional trial-related work).
- Associated paperwork (CRFs, 1572s, financial disclosures, IRB/regulatory, etc).

What Works for Us

- Nursing CRA Focus
  - “Make it Easy” - Reduce burden of time, maintain protocol compliance and quality data collection.
    - Screen for potential patients.
    - Assist with consent process.
    - Write orders/cosigned by physician.
    - See patient before physician.
    - Physician time saved, can see more patients.
    - Patients pleased with attention.
    - Nurses pleased with autonomy and patient contact.
What Works for Us

• Maintain visibility and awareness
  – Nurses in office daily
  – Monthly updates to physicians and staff
  – Regular face-to-face meetings with physicians and staff

• Non-nurse CRA support staff
  – Nurse/CRA teams (1:1 ratio for treatment trials)

• Workload assessment

• Implement efficiency tools
  – Priority cards
  – Screening tools
  – Source documentation forms
  – Laptop computers/Palms
  – Web-based consent documents/protocols

What Works for Us

• Nurse Recruiter and CRA Team
  – Reviews all charts (new patients and returning)
  – Visibly present when physician ready to see patient or writes note regarding eligibility
  – Tracks and logs patients reviewed and/or seen
  – Sees patient after introduction by physician
  – Verifies eligibility (orders tests needed after consenting)
  – Follows patient through entry process and ready for first treatment…then assigns to another nurse for remainder of study…after initial forms and pathology submission completed (if applicable)
CRA Role

- Focus on decision support
  - CRA plays a role in patient’s perception
  - Spend time with patient/family
  - Supportive role
- Concern for bias and/or coercion

Customer Service
Making Service “Meaningful & Memorable”

- ABC’s of customer relationships
  - Attitudes - the way we feel about customer
  - Behaviors - the way we act with customer
  - Connections - the way we get involved with the customer

Five Service Principles

1. Know thy customer
2. Attitude is everything
3. Every contact counts
4. Keep it simple and sensible
5. Practice Makes Permanent

Know thy Customer

- Must understand and be ready to satisfy needs, wants and expectations
- Find out what matters
- Consistently demonstrate you know how they want to be treated
- Ask questions and listen carefully
- Use their name whenever possible
Attitude is Everything

• Attitude is expressed in our appearance, facial expression, body language, tone of voice and words we choose to use.
• Attitudes leave impressions that last
• Attitudes are contagious
• Healthy attitudes connect people
• Deadly attitudes disconnect people

Attitude is Everything

• Healthy Attitudes
  – I like you
  – I respect you
  – I care about you
  – I appreciate you

• In Words
  – Yes
  – Certainly
  – Of course
  – I’d be happy to

• Deadly Attitudes
  – I’m not interested in you
  – I’m more important than you
  – I’m too busy for you
  – I’m right; you’re wrong

• In Words
  – I’m too busy
  – You’ll have to come back
  – That’s not my job
  – You’ll have to wait
Every Contact Counts

• Opportunities to strengthen relationship
  – May appear in personal contacts, emails, phone conversations, etc
    • Opportunity to learn more about them
    • Reinforce trust
    • Build loyalty
    • Ensure compliance and retention

Keep it Simple and Sensible

• Communicate in terms easily understood
  – Confusion, uncertainty, lack of clear understanding ➔ changing mind about participation

• Remember to smile
  – Universal language that says you care and are interested in them
  – Can break down barriers of fear and resistance
Make a Good Impression

• First impression
  – the way we connect (tone of voice, smile, greeting)

• Second impression
  – How we contribute (how we answer question; what we actually do for them)

• Third impression
  – the way we conclude the interaction (ask if there is anything else we can do; thanking them)

Practice Makes Permanent

• No one is “perfect”
• Through practice we can improve skills to become permanent behaviors
• Find what works for you through trial and error process
• Takes commitment, time, dedication and patience
• Establishes a high standard of service