Clinical trials play a significant role in improving cancer treatment, symptom management, and healthcare delivery. Patients seeking clinical trial options often rely on oncology nurses to help them navigate the process. ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies that can be used to assist patients and family members interested in clinical trials. Learn more about it and how you can use its search tools, study statuses, and trial results data in your patient education.

Target Audience: Registered Nurses, Advanced Practice Nurses

Level of Content: Advanced

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Full Disclosure:
Nothing to Disclose

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Full Disclosure:
Nothing to Disclose

Objectives:
At the end of this session, participants will be able to:
1. Understand the context for educating individuals about oncology clinical trial participation.
2. Gain knowledge on the scope of ClinicalTrials.gov, the tools available for finding studies, and tips for navigating the contents of a study record.
3. Identify key elements to discuss with individuals who are considering participating in research.

Bibliography:
What are Cancer Clinical Trials?
- “research studies conducted with people to find better ways to prevent, diagnose and treat cancer”
- May include new drugs, approaches to surgery or radiation therapy, combinations of treatments or methods such as gene therapy.
- Final step moving basic scientific research from the laboratory into treatments for people with cancer.

Yesterday’s Clinical Trials are Today’s Treatments
- How do we know how to treat patients?
- How do we know which types of treatments are effective in treating specific cancers?
- What modality should be used?
- What toxicities should we expect?
- What outcomes can be anticipated?
- How are results communicated?

Why Do We Need Clinical Trials?
- Prevent
- Treat
- Control
- Decrease incidence and mortality
- Improve Quality of Life
- Decrease the cost of cancer care

Problem Significance
- No standard effective treatments exist for many types of cancer.
- Further improvement of effective therapies is needed for all cancers.
- Communication of clinical trial results.

Barriers to Participation
- Participant
  - Lack of information/awareness.
  - Lack of access.
  - Fear, distrust or suspicion.
  - Financial and personal concerns.
- Physician
  - Lack of awareness
  - Loss of control of patients care
  - Belief that standard therapy is best
  - Concern of additional administrative burdens

Lack of Awareness
Publication facilitates the open exchange of information among researchers, and increasingly with patients.

Not all research can be published in peer reviewed journals!

Notion of “bad research” if positive findings are not indicated.
Lack of Awareness

- 40% of adults report that they do not understand the idea of a clinical trial.
- 1998 NCI Survey – 85% of cancer patients were not aware of clinical trials – however, 75% would have participated if they have known it was possible.

Care Coordination/Navigation

- Education is required for both the patient and the health care team with regards to clinical trial availability.
- Health care providers may provide clinical trial:
  - Education
  - Care Coordination
  - Navigation
  - Search Tools

About ClinicalTrials.gov

- Clinical studies registry and results database
  - Over 183,000 studies (trials & observational studies)
  - Studies with locations in all 50 states & >180 countries
  - Privately and publicly funded studies involving humans
  - Study information submitted by sponsors or principal investigators
- Web Site & registry launched in February 2000
  - Results database, in September 2008
  - >16,000 studies with results
- Database updated nightly
- Usage
  - 98 million page views per month
  - 64,000 visitors per day

Content of a Study Record

(One Record per Unique Study Protocol – Single NCT Number)

- Protocol section
  - Submitted at trial initiation; updated throughout trial lifecycle
  - Summarizes information from trial protocol: e.g., Condition, Interventions, Study Design
  - Includes recruitment information (e.g., eligibility, locations)
- Results section
  - Submitted after trial completion/termination
  - Summarizes trial results
  - Participant flow
  - Baseline characteristics
  - Outcome measures (including statistical analyses)
  - Adverse events

Why Register and Submit Results?

- Ethical and Scientific Rationale
  - Responsibility to research participants, patients, and the public
  - Research integrity
  - Evidence-based medicine
- Required by various policies and laws

Selected Policies and Laws

- Journal editor requirement for publication (ICMJE)
  - Registration (prospective) for all interventional studies
- U.S. Federal Law (FDAAA 801)
  - Registration & results for “applicable clinical trials” of drugs, biologics, and devices
  - Results currently limited to “approved” products (but proposed to expand to include unapproved)
- NIH encourages for all NIH-supported trials
  - Registration & results for all clinical trials (including those not subject to FDAAA 801)
  - Proposal issued by NIH in Nov 2014 to make this a requirement
Sample Uses of ClinicalTrials.gov

- Identify trials of potential interest for an individual or user community
- Track progress of a specific trial and availability of summary results
- Identify completed or ongoing trials for specific conditions/interventions
  - Supplements a literature review
- Identify researchers and/or centers of relevance to specific conditions/interventions

Methods for Finding Trials

- Basic Search
- Advanced Search - allows for a focused search
  - https://clinicaltrials.gov/ct2/search/advanced
- See Studies by Topic
  - Conditions/Rare Diseases, Drugs, Dietary Supplements, Sponsor/Collaborators, Locations
  - https://clinicaltrials.gov/ct2/search/browse
- See Studies on Map
  - https://clinicaltrials.gov/ct2/search/map

Search Results Tools

- RSS Feed
  - Receive automatic updates on a specific search
  - https://clinicaltrials.gov/ct2/resources/rss
- Download Search Results
  - Choose study fields to include
  - Select file format (tab- and comma-separated values format is appropriate for a spreadsheet)
  - https://clinicaltrials.gov/ct2/resources/download

Additional Resources

- ClinicalTrials.gov Online Training – brief animated tutorials
- Topics currently available: Basic Search, Advanced Search, Customize Your Display, Downloading Search Results, Modify a Search, RSS Feed Setup for a Search, Study Record Details
- Find Studies: https://www.clinicaltrials.gov/ct2/search/index
- Why Should I Register and Submit Results?: https://www.clinicaltrials.gov/ct2/manage-recs/background

Clinical Trial Participation Impact

- Expands beyond patient care and education.
  - Institute of Medicine – A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group System
  - ASCO - Exemplary Clinical Trial Site Characteristics
  - Commission on Cancer Accreditation – Cancer Program Standards

Transparency

- ClinicalTrials.gov provides easy access to publicly and privately supported clinical trials on a wide range of diseases and conditions.
- Reporting of positive and negative findings helps researchers prevent unnecessary duplication of trials.
- Establishes trust with clinical trial participants that information is put to maximum use to further knowledge about their condition.
Enhancing Clinical Trial Awareness

- Promote trial involvement through education.
- Many people do not have access to Internet.
- Nurse navigators, clinical research nurses and oncology nurses in general may identify potential participants.
- Education through Community partnerships, patient advocates, support groups, churches, senior centers – before diagnoses are made.

Enhancing Awareness

- If patients aren’t being offered clinical trial participation, they aren’t being provided with all of their treatment options!
- Clinical Trial results have not been consistently reported to trial participants – ClinicalTrials.gov provides another avenue for the information to be provided.

Oncology Nursing Society Resources

- ONS – Oncology Clinical Trials Competencies
  – Communicate
  – Educate
  – Advocate
- ONS Special Interest Group – Clinical Trials Nursing
  – Share Best Practices

ClinicalTrials.gov

The advancement of medicine requires broad access to clinical trials and their findings.

It is our responsibility to fulfill ethical obligations to human research volunteers by:
- Registering trials and submitting summary results
- Contributing towards the dissemination of information regarding the tools and resources available to health care professionals and the individuals we serve.

ClinicalTrials.gov

- Compliance with reporting provides public assurance that the rights, safety and well being of trial subjects are protected and that clinical trial data are credible.
- Principles are translated into legal requirements.
- Exemplary clinical trials sites, incorporate timely and accurate clinical trial awareness and requires the engagement of health care professionals in the clinical trial education and awareness process.

Tools to Reach Your Audience

- Investigators
  – Tumor conferences, MDCs, newsletters, brochures, posters, educational venues
- Community
  – Investigators, referring MDs, website, radio/TV, newspaper, posters, newsletter
Target Your Message

- Clinical trial participation is essential in reducing cancer burden.
- Clinical trial availability raises the bar of oncology practice in your community.
- Clinical Research is a team effort.
- Research cures cancer.

Conclusion

- Clinical trial success depends on accrual.
- Increase trial awareness in both the lay and physician community.
- Area resources influence marketing efforts.
- Research is not complete until it has been reported!
- Need to build upon what has been learned.

ClinicalTrials.gov

Information Resources

- https://clinicaltrials.gov/
- http://www.cancer.gov/clinicaltrials
- http://www.asco.org/practice-research/clinical-trial-resources