Clinical trials are research studies that test how well medical approaches work in people. They can include studies in the prevention, screening, diagnosis and treatment of cancer. The first documented clinical trial in the US was in 1931 by Amberson et al. Location was in Northville, MI and entitled “Randomized treatment of TB.” Also, in 1937 the National Cancer Act established the NCI as the first disease-orientated division of NIH. Then in the 1950’s the NCI began to fund the cooperative oncology group.

Currently, in 2014 there are 4 groups referred to as the National Clinical Trials Network (NCTN). They include ECOG-ACRIN; NRG Oncology (NSABP, RTOG, GOG); SWOG; and Alliance (ACOSOG, CALGB, NCCTG). Also, in 2014 the insurance coverage requirements for clinical trial participation go into effect as mandated by the Patient Protection and Affordable Care Act.

Types of clinical research include observation studies through case report, descriptive, analytical and Cohort studies. Other studies are interventional to include diagnostic, treatment, and behavioral research.

The new drug development process involves twelve steps to completion. It begins with preclinical animal testing. Next an investigational new drug application is submitted that outlines what sponsor of a new drug proposes for human testing in clinical trials. The Phase 1 studies usually involve 20-80 people. Phase 2 studies usually involve a few dozen to 300 people. Phase 3 studies typically involve several hundred to about 3000 people. The FDA and the drug sponsors usually meet just before the new drug application (NDA) is submitted. This submission is the formal step for a drug to be considered for marketing approval. After the NDA is received, the FDA has 60 days to decide to file it for review. If the FDA files the NDA, a review team evaluates the research for the drug safety and effectiveness. The FDA also reviews information that goes on a drug’s professional labeling and inspects the facilities where the drug is manufactured. Finally, the FDA reviewers approve the application or issue a complete response letter.

As mentioned above, there are three phases of clinical trials. Phase I is the first step in drug testing in patients with the purpose to evaluate dose, route, frequency, and toxicity. Phase II trials determine the safety and effectiveness of a medication. This usually focuses on a particular
FEATURE ARTICLE

In 2007, the NIH Clinical Center Nursing Department began a four year initiative to define and delineate the practice within the specialty of clinical research nursing. Two distinct roles were decided at this time. First the clinical research nurse who is involved with the patient. Next the research nurse coordinator who is engaged in study coordination.

One of the main roles for nurses in ethics of clinical trials is in the element of informed consent. They serve as a patient advocate to assist the PI in obtaining informed consent and reconsent and serve as a key role as educator. Continuous assessment of patient comprehension of the consent form and treatment plan is needed. Also, mitigating therapeutic misconception by unrealistic expectation of benefit of trial design is done through further education of the clinical trial process. At Karmanos Cancer Institute, the clinical trial nurse may participate with a Feasibility Review Committee and/or a Protocol Review and Monitoring Committee.

Nursing for clinical trials in the future include participation in biosafety review of protocols involving biological agents and develop SOP's. Also, participating in biosafety IRB meetings to initiate evaluation of new types of administration for patient/staff safety. This is to include electroporation device delivery which requires two nurses to deliver the medication.

Find clinical trials through web sites: Karmanos.org/FindTrials and clinicaltrials.gov.

Ethics in clinical research is the discipline of dealing with what is good and bad and with moral duty and obligation. These principles of conduct may govern an individual or a group. The history of clinical research ethics begins with the Nuremberg Code of 1947. Other ethic articles include the Declaration of Helsinki; Belmont report in 1979; and Code of Federal Regulations, 1981.

Members of the clinical trial research team include the principle investigator (PI) who is responsible for all activity of the trial; signs a FDA 1572 assuming overall responsibility; and delegates tasks to appropriately trained staff. Sub-investigators include physicians, NP’s, and PA’s. The final member of the team is the clinical trials nurse.4

Regulatory authority beyond the FDA include the Office for Human Research Protection (OHRP) and the International Conference on Harmonization (ICH).

type of cancer and have less than 100 patients. Phase III clinical trials compare a new medication with the current standard therapy. Finally, Phase IV trials occur after FDA approval and look at long term safety and effectiveness of a treatment. The maximum timeline for drug development is 20 years after filing the application due to patent expiration.

Key concepts of clinical trials design include:

- Randomization: process of assigning research patients to a treatment group or a control group.
- Blinding/Masking: minimize biases from differences in patient assessment or interpretation.
- Control Groups: group of participants that do not receive the treatment being studied, they receive standard of care. It is necessary to distinguish patient treatment outcomes from outcomes caused by other factors.
- Clinical Trial Designs:
  1. Parallel Design
  2. Crossover Design
  3. Factorial Design
  4. Basket Trials

1. Single: subject does not know treatment assigned.
2. Double: patient and provider do not know treatment assigned
3. Triple: patient, provider, and statistician do not know treatment assigned.

- Ethics in clinical research is the discipline of dealing with what is good and bad and with moral duty and obligation. These principles of conduct may govern an individual or a group. The history of clinical research ethics begins with the Nuremberg Code of 1947. Other ethic articles include the Declaration of Helsinki; Belmont report in 1979; and Code of Federal Regulations, 1981.

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Regulatory authority beyond the FDA include the Office for Human Research Protection (OHRP) and the International Conference on Harmonization (ICH).
I hope all you wonderful oncology nurses were able to enjoy Oncology Nursing Month. I would like to take this opportunity to celebrate you, and thank you for your dedication, compassion and hard efforts. How did you celebrate you? In order to continue providing care and support to those in need, nurses need to take care of themselves. Caring for the caregiver i.e., you, your colleagues, is preventative medicine for compassion fatigue. Compassion fatigue is the physical, emotional, social and spiritual sequela from working closely with cancer patients and families (Aycock & Boyle, 2009). Below are signs and symptoms of compassion fatigue.

<table>
<thead>
<tr>
<th>PHYSICAL</th>
<th>BEHAVIORAL</th>
<th>PSYCHOLOGICAL</th>
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<tbody>
<tr>
<td>Tachycardia</td>
<td>Chemical abuse</td>
<td>Critical of others</td>
</tr>
<tr>
<td>Insomnia</td>
<td>Tardiness/absenteeism</td>
<td>Feelings of low</td>
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<tr>
<td>Myalgia</td>
<td>Medication errors</td>
<td>personal accomplishment</td>
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<tr>
<td>GI complaints</td>
<td></td>
<td>Boredom</td>
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<tr>
<td></td>
<td></td>
<td>Depression</td>
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Perry (2008) published a phenomenological study on explaining the characteristics of nurses that seem to avoid compassion fatigue. In this study, oncology nurses were asked to identify colleagues whom they would want as their nurse. Seven oncology nurses were recognized by their contemporaries as exemplary caregivers. Through a semi-structured interview, three themes emerged.

Moments of Connection
This theme is one of connecting with patients and their families. Having the ability to put themselves in the role of others. Thinking that the person lying in the bed could be you, enriches caring.

Making Moments Matter
The second theme is on the ability to truly appreciate the significant moments in the nurse-patient relationship. For example, ponder the level of trust patients have in you in order to confide their personal feelings.

Energizing Moments
The final theme is on maintaining a sense of humor, positive attitude along with a sense of self confidence and awareness.

итель supports further means of repelling compassion fatigue. Oncology nurses in a community hospital located in Pennsylvania (Fetter, 2012) implemented interventions to protect against compassion fatigue. Tactics included a remembrance tree. In a staff only area a tree made of construction paper is posted on a bulletin board. When patients pass, a leaf is made with their name and obituary. The trees are changed with the seasons. Having a counselor or psychologist available is helpful, although less effective when time is delayed for support. Many oncology units utilize bereavement cards (Fetter; Aycock & Boyle, 2009). Taking time to reflect and write the well wishes can be therapeutic to the oncology staff.

An interesting study from Anderson and Gustavson (2016) explored the impact of knitting on compassion fatigue. Nurses from a comprehensive cancer center in Washington, D.C. worked with volunteer knitting instructors. The knitting intervention took place during breaks, lunch or a debrief session after a stressful situation. Data was collected on compassion fatigue before and after six weeks of study participation. A reduction in burnout scores was noted. Unfortunately the sample size was small as many felt too busy to participate.

Hopefully this issue of Letter from the Editor has provided insight on identifying compassion fatigue along with interventions to consider. Your unit or colleagues may have suggestions that have worked. Employing strategies is a form of self-care; a necessity for a long and healthy career in oncology nursing.


When I attended my first MDONS “Updates in Oncology” Conference on February 8, 2017, it was encouraging to see this metro Detroit Chapter of Oncology Nursing Society’s growth and development. At its origin, a small group of 16 oncology nurses met over 23 years ago, and today a large event center housed oncology nurses from across Southeast Michigan. The conference was a reflection of MDONS mission to promote oncology nursing standards, study and exchange information, encourage the specialty of oncology nursing, and foster oncology nursing’s professional development and diversity.

The conference’s keynote presentations strove to reflect MDONS core values:

Promoting professional oncology nursing standards. The conference’s subject matter encompassed a wide range of subjects, three of these being Ethical and Legal Issues for Oncology Nurses, Patient Safety in Radiation Oncology, and the Role of Oncology Nurses in Clinical Research. Each of these talks provided interesting food for thought to take back to the workplace, promoting a safe, effective, and innovative oncology environment.

Study, research, and exchange of information. MDONS highlighted many important educational topics as well. Teresa Knoop, a guest speaker from Nashville, Tennessee’s Vanderbilt-Ingram Cancer Center, gave a talk on the four new FDA approved cancer drugs in 2016/2017. Three approved cancer therapies treat solid tumors, and one new therapy treats hematologic cancer. As cancer research makes strides every day to uncover new cures, Teresa also helped us conference attendees recognize new cancer therapy drugs and some of the pharmacokinetics behind them, starting with breakdown of the drug’s generic name.

Another hot topic in healthcare today involves the diagnosis of Economic Toxicity. It is important for any healthcare provider to be aware of this growing concern, and the conference made sure to bring this discussion to light. From learning how to navigate the various insurance companies, foundations, and fundraisers, to knowing the go-to people and departments that can help patients with financial strain, it is important for nurses to have open eyes and ears on this subject.

Fostering professional development and diversity. We are lucky to work in metro Detroit’s diverse cultural climate, and with that comes certain challenges and responsibilities when providing care to a diverse patient population. Dr. Lisa Newman shed light on this interesting subject matter, and more specifically on African American Ancestry related to Triple Negative Breast Cancer. Data shows that African Americans with high-risk breast cancer have a higher mortality rate, socioeconomic disparities, advanced stage distribution, and an increase in adverse tumor features. She also talked about caring for not only the African American patient population in our hometown, home state, and home country, but also encouraging healthcare providers to take a more global view and collaborating with providers and patients across the world.

Encouraging the specialty and practice of oncology nursing. The most influential point I gained from this MDONS conference, was the encouragement found in simply having a roomful of nurses come together for a common purpose and shared goal. Not only was it wonderful to see nurses, physicians, pharmaceutical companies, and vendors come together to celebrate oncology care, but it was enlightening to have nurses at just my little table, that came from Beaumont, Michigan Medicine, St. John Providence, and Henry Ford, who all got to share stories and “talk shop.” The camaraderie was felt throughout the room, and it was a camaraderie of specialized oncology nurses from different health systems, striving to grow and learn from each other in order to provide the best care to their cancer patients.
MEET A MEMBER

INTRODUCING MELISSA JAMES

DENISE WEISS PhD, FNP, BC

You may know her already as she is the current president of MDONS, Melissa James. Melissa graduated from Madonna University with her bachelors’ degree in nursing ten years ago in 2007. In her senior year, an emersion class brought Melissa to Karmanos Cancer Center’s Bone Marrow Transplant floor, 10 Webber-North. She enjoyed working with the patients, families and staff and it showed. She was asked to stay on with the team after graduation and has not looked back. While working with the bone marrow transplant team, Melissa grew in her role as staff nurse and soon became the unit’s preceptor. All of her hard work was validated with the Blood and Marrow Transplant Certification (BMTCN) in 2014. Teaching nurses new to bone marrow transplant allowed Melissa to realize her passion for imparting skill and knowledge. In 2015 Melissa had an opportunity to work fully in the role as an educator and joined the reigns of nursing education for oncology nurses. “I knew I wanted to be a nurse when I was in high school,” Melissa explained. She took a class that would transition to credit hours in a nursing assistant program. The instructor left a strong, positive impression that carried Melissa through college. But it was the emersion class in oncology that left no doubt in her mind that oncology nursing was where she belonged. Melissa anticipates returning to school for graduate studies in the future, but for now is very happy working closely with staff.

When not working at Karmanos Cancer Institute or residing over the Metro-Detroit Oncology Nurses Society, you are likely to find Melissa reading a thriller novel by Stephen King, walking her dog Angus, or playing one of her preferred string instruments—piano or violin. You may want to check in with Melissa prior to making a purchase as she is known as an “Extreme Couponer”. Black Friday is her holiday and she will let you know where to find the best bargain in town.

So next time you see our President say hello, you may learn of a local giveaway. For inspiration, Melissa would like to share a quote.

“You cannot get through a single day without having an impact on the world around you. What you do makes a difference, and you have to decide what kind of difference you want to make.” —Jane Goodall

CONGRATULATIONS!!

CYNTHIA ULREICH RECIPIENT OF THE ADVANCED PRACTICE SCHOLARSHIP AWARD

NOCNP AT HFHS WORKING ON HER DNP AT OAKLAND UNIVERSITY
The Gamma Knife technique was developed in Sweden in the 1950s. At this time, there are 269 facilities using it worldwide, 123 are in the USA, and 3 of them are in Michigan (Beaumont, Karmanos and Midland). Gamma Knife is a procedure that uses 201 beams of radiation intersecting together to come up with a high dose and a precise focus targeting abnormal tissue in the brain to within a 0.1mm accuracy. It is a single fraction, one day treatment. Radiation works by damaging the DNA of the tumor cell, inhibiting its ability to grow, causing it to shrink and eventually dissolve.

A topical followed by local anesthetic injection is used on the patient's forehead before the fixation device made of titatinum is applied to immobilize the patient's head. Systemic pre-medications typically include dexamethasone IV (to minimize brain irritation) and valium IV (to relax the patient). The procedure is overseen by both a neurosurgeon and radiation oncologist. It uses the imaging guidance of MRI, CT or CT angiogram, as indicated. Patients are typically able to resume previous activities after the procedure. Common side effects are headache, discomfort at pin sites, and bruising. Cerebral edema can occur so patients are typically placed on tapering doses of steroid. A follow-up MRI is typically done anywhere from 10 to 24 weeks, depending on the reason for the procedure.

Gamma Knife is used for patients with tumors that are 3cm or less, have a Karnofsky Performance Scale of 70 or more, and a well-controlled underlying disease or co-morbidities. It is typically used when there is 10 or less tumors present, although some centers in Japan are reportedly using it for up to 25 tumors. It can also be used in arteriovenous malformations by scarring the lumen of the malformed vessel leading to the occlusion of the said vessel, and allowing for new circulatory pathways to form over 2-3 years.

Other conditions for which Gamma Knife is currently being studied include Parkinsons disease, epilepsy, chronic intractable pain, depression, OCD, cluster headaches and migraines.
Hello Everyone. Hope you and your family have been enjoying the wonderful Michigan summer. This year MDONS members have been busy participating in the numerous events taking place across the country. I thought I would take the time to share with you what we have been doing!

The year started with our 27th Annual Updates in Oncology Conference. This year’s conference included topics on Triple Negative Breast Cancer, Clinical Trials, the reimbursement process, legal issues pertaining to health care, patient safety in radiation oncology (which could be applied to every aspect of nursing care delivery), and new cancer drugs where our guest speaker educated the audience on how to break down the drug name (monoclonal antibody) to understand where the drug is working and where the drug was derived.

In March, MDONS held our Spring Mini Conference, the topic was CNS Oncology. Two of our own members, Gayle Groshko (MDONS programs chair) and Michelle Manders (MDONS secretary) gave exciting and insightful lectures on Stereotactic Body Radiation and the diagnosis and treatment of surgery, external beam radiation therapy, chemotherapy, and gamma knife patients. They both were such great presenters.

Also in March, MDONS member Susan Wozniak (MDONS virtual community chair) coordinated the 2017 Annual Tar Wars Program. The Tar Wars program takes smoking cessation education to the elementary schools in the area. The students then have a poster contest to which MDONS members select winners. The winners receive prizes for their work. This year we had a tie, so two winners were selected. I would like to mention a special thank you to Denise Henderson, Jessica Daniel, and Jennifer Burgoyne from Karmanos Cancer Institute who volunteered their time to represent MDONS and their institution for Tar Wars 2017. It was a great success. Members were excited in May to attend the 42nd Annual ONS Congress in Denver, Colorado. Our President Elect, Pam Laszewski was awarded ONS Radiation Oncology Nurse of the Year. We also had members speaking at podium lectures and at poster presentations. The hot topic at congress this year was the growth and excitement surrounding immunotherapy in practice. There were also great sessions on Hazardous Drug Safety, evidence based research, and managing pain in high risk patients. We couldn’t be in Denver and not discuss the use of medical marijuana, which was interesting.

Also in May, MDONS members gathered for the Annual President’s Dinner. Our speaker soothed us with a presentation on Aromatherapy and how it is used in the hospital setting as a complimentary and integrative therapy. During the President’s Dinner we awarded our Annual MDONS Outstanding Advanced Practice Oncology Nurse of the year to Clara Beaver, MSN, RN, AOCNS, ACNS, BC.

Our MDONS members have also been busy advocating for health care at the local and national level. Gayle Groshko spent time up in Lansing for Legislative Day speaking with Representatives on the health care system and health care reform. In September, Susan Wozniak will embark on a trip to Washington, DC to represent MDONS in the inaugural ONS Capitol Hill Day. This is an event where oncology nurses can advocate for their profession, their colleagues, and their patients on a national scale. We look forward to hearing about her experience.
FROM THE PRESIDENT

As you can see, our members have been busy hard at work educating, advocating, and presenting at the local and national level. We are so blessed and proud to have such a wonderful membership. As I watch all of the amazing work we are performing, it is a reminder to me of why I became a nurse. I believe that nursing is a calling, a feeling you have that you need to care for people. I think of it like a codependent relationship. I NEED to make people feel better, in order for me to feel better. I cannot think of many professions that are like that. I am so proud of what we do every day and what our profession represents. In closing, I would like to share a poem written by Suzanne Gordon, journalist/author/editor, whose career was focused on patient safety, communication, and teamwork.

“Just a Nurse”
I’m “just a Nurse”. I just make the difference between life and death
I just have the educated eyes that prevent medical errors, injuries, and other catastrophes.
I’m just a researcher who helps nurses and doctors give better, safer, more effective care.
I just work in a major teaching hospital managing and monitoring patients who are receiving experimental, cutting edge treatment.
I just educate patients and families about how to maintain their health.
I just make the difference between a person staying in their own home and going to a nursing home.
I’m just a professor of nursing who educates future generations of nurses.
I just make the difference between dying in agony and dying in comfort and with dignity.
I’m just central to providing the real bottom line in health care.
Don’t YOU want to be “Just a Nurse” too?

Suzanne Gordon, 2004

I would like to say thank you to all of our members, all 594 of you for attending and supporting MDONS. I would also like to recognize all of our board members and committee members who make all the programing and activities possible. Please check out the MDONS website for upcoming events and activities, or if you are interested in becoming a board or committee member at metrodetroit.vc.ons.org

SAVE THE DATE

What:
MDONS FALL MINI CONFERENCE:
IMPLEMENTATION OF A SURVIVORSHIP PROCESS
By Lisa D’Andrea and Jeanne Parzuchowski

When:
SATURDAY, OCTOBER 21, 2017

Where:
BEAUMONT GROSSE POINTE
Connelly Auditorium;

REGISTRATION/BREAKFAST 8:00–8:30
PROGRAM 8:30–11:45

3 CE applied for. For an active discussion, please bring a copy of a survivorship care plan if you are using one
I have been an Oncology Nurse since the start of my nursing career in 2004. I have never experienced an ONS Congress until this year. I applied for the scholarship through this chapter by writing an essay and won. I thank everyone for the opportunity that allowed me to go to this fabulous learning journey. During the opening ceremony I cried the entire time, the energy was overwhelming and reminded me once again why I wanted to be a nurse since I was in third grade. It was a busy time filled with learning, meeting new friends and walking (got my steps in). I would encourage everyone to go to ONS Congress for this wonderful learning opportunity and be re-energized on why you became and oncology nurse.
OUR ANNUAL PRESIDENT’S DINNER WAS MAY 5, 2017 AT MAGGIANO’S LITTLE ITALY. WE LEARNED THE LATEST ON AROMATHERAPY BY MAUREEN MCDONALD CTRS-ADS.

CONGRATULATIONS TO CLARA BEAVER, ADVANCED ONCOLOGY NURSE OF THE YEAR.

HAVING FUN AT THE SPRING MINI CONFERENCE.