



CHAPTER CAPSULE

Celebrating 39 Years

VOLUME XXX
ISSUE 3
SUMMER 2015



Providing optimal care through promotion of professional standard, networking and development

ONCOLOGY PHASE 1 CLINICAL TRIALS: WHY DO PATIENTS PARTICIPATE? ARE THEY ETHICAL?

LISA MALBURG ANP-BC, AOCN

It is estimated that 1,658,370 new cases of cancer will be diagnosed in 2015. Of the patients living with cancer, an estimated 589,430 will die during 2015 (American Cancer Society, 2015). Fortunately, cancer death rates have been declining at a rate of 1.4-1.8 percent a year since 2002 (Kohler, 2015). This decline is largely due to advances in early detection as well as new approved therapies. These new therapies are developed through a well defined process of clinical research. Clinical trial participation by adult cancer patients has been traditionally low. Only 3% of adult patients agree to participate in clinical trials (Insititute of Medicine (US) Forum on Drug Discovery, Development, and Translation, 2010). Clinical trials can be classified by type and phase. Most clinical trials in cancer are treatment trials. These trials involve a series of steps, also called phases. The drug being evaluated goes through preliminary testing on animals and then proceeds through phases 1 through 3 trials in humans. The goal is to obtain FDA approval if efficacy and safety are demonstrated (National Cancer Institute).

The purpose of phase 1 clinical trials is not to demonstrate efficacy but to find a safe dose, to verify the method of administration, and to assess side effects (toxicities).

Although no placebos are utilized in phase 1 trials, the dosage the patient receives varies depending on the time of study entry. Dose escalation is done three patients at a time in order to identify any serious toxicities. When serious side effects (dose limiting toxicities or DLTs) are encountered, the dosage is reduced to the next lowest level. A minimum of three additional patients are treated at that dose. If this dose appears tolerable, then the maximum tolerated dose (MTD) has been determined. This is also sometimes referred to as the recommended phase 2 dose (R2PD) (Ivy, 2010). Phase 1 trials are appropriate for patients who have exhausted standard treatment options or for whom limited treatment options exist. The largest recent examination of the treatment benefit received from phase 1 trials revealed an overall response rate of 10.6 % in 10,402 patients. This response rate had increased with the advent of molecular targeted therapies from 6% seen previously (Horstmann, 2005). Italiano, et al. (2008) recently reviewed the efficacy of phase 1 trials at their own institution from 2003 through 2006 and found a 7.2 % objective response and a 41% stable disease rate. 56.6 % of patients were able to go on and receive additional treatment after their participation in a clinical trial. For some tumor types, progression free survival rates were similar to those of FDA approved 3rd line therapies (Italiano, 2008).

Most clinical trials in cancer are treatment trials. These trials involve a series of steps, also called phases.

Despite these advances in the efficacy of phase 1 clinical trials for advanced cancer patients, the relatively low response rate has brought several ethical issues to the forefront for discussion. These include therapeutic misconception, participants' motivation, and patients' ability to give informed consent (Seidenfeld, 2008). Therapeutic misconception means unrealistic expectation of benefit of the trial design. Therapeutic misestimation is incorrectly estimating the chance of research benefit (Godskesen, 2013). These two concepts were studied by Pentz, et. al (2012). They reported that sixty-five of 95 respondents (68.4%) had therapeutic misconception, which was associated in a multivariate analysis with lower education and family income (P = .008 and P = .001, respectively), but it was not associated with the vulnerability of having hardly any treatment options. Eighty-nine of 95 respondents (94%) had therapeutic misestimation, although only 18% reported this estimate was based on fact. Sulmasy, et. al (2010) found similar results in qualitative

research looking at expectations of therapeutic benefit. Median expectations of therapeutic benefit varied from 50% to 80%. Justification for this expectation invoked hope and optimism. This was related to the effect of positive thinking on outcome, fighting cancer as a battle

and a faith in God or science. However, contrary to the belief of some bioethics experts, many patients reported being told that few patients would benefit and that there were uncertainties in the clinical research. Despite this they still expected personal therapeutic benefit. (Sulmasy, 2010).

The second issue of concern involving phase 1 clinical trial patients

Continued on following page

WHAT'S INSIDE...

FROM THE EDITOR	2
HIGHLIGHTING A MEMBER	3
MEETING SUMMARIES.....	3
FROM THE PRESIDENT.....	11
OFFICERS AND STAFF	12

FROM THE EDITOR

CAROLE BAUER

RN, MSN, ANP-BC, OCN, CWOCN

40 YEARS OF ONCOLOGY NURSING

It is amazing to me that the Oncology Nursing Society is 40 years old this year. I have been a nurse since 1982- that is 33 years...only 7 years short of the length of time of the Oncology Nursing Society. While I have not always been a member all those 33 years, I have always been and will always be an oncology nurse.

Throughout my career, I have often thought of the milestones I have lived through as an oncology nurse. I can remember when we first began to use ports for infusions. I remember it so clearly as it was the year my first child, now 30, was born. I was just working weekends so it was a big learning curve to learn about ports.

Medications to care for cancer patients have changed. Pain

management has also changed significantly with the advent of long acting pain medications and topical delivery systems. I remember when the only option for pain management was methadone and a green morphine elixir. The list of chemotherapies now includes biotherapies. Something that no one had thought of when I first became an oncology nurse.

But the thing that has remained the same over all of these 33 years is the quality care that nurses committed to oncology provide. Yes, the tasks have changed, but the compassion, commitment, curiosity, and courage of those providing has not. Oncology nurses are a bred of their own and I am proud to be one; one who puts caring for cancer patients above all else.

...the thing that has remained the same over all of these 33 years is the quality care that nurses committed to oncology provide.

So what can we look forward to in the coming years? Will we see improved prevention strategies? Will there be better ways to detect cancer at earlier

stages? Will treatments be customized to each person's genetic makeup? Will cancer be eradicated? Will cancer become a chronic illness? Will cancer be preventable? The sky is the limit. All I know is that no matter the direction oncology nurses will be there supporting, caring, providing compassion to not only the patient, but to the family and the entire health care team.

ONCOLOGY NURSING SOCIETY CONGRESS

BY PAM LASZEWSKI, RN, OCN

AND CLARA BEAVER, MSN, RN, AOCNS, ACNS-BC

The sunshine filled city of Orlando opened its arms and welcomed 3,000+ oncology nurses to Congress 2015. Congress is always an exciting place to be. It has so much to offer everyone. There are many lectures and learning opportunities to be had. There is no time to sleep as the learning starts at 6 AM and goes late into the evening. One of favorite morning lectures is always the ONCC breakfast. At this breakfast they take time recognize all the certified nurses' and their achievements, mixed in with a fun/educational lecture. You are able to connect with friends from all over the world who are going through many of the same things as you. Don't forget the vendors who are there sharing all of their education about new and old products.

Congress opened up with a celebration of the 40 year anniversary. The keynote speaker was Kevin Sowers RN, MSN. He is the President of Duke University Hospital. Mr. Sowers took us on a journey over the last 4 decades of cancer care. He talked about how the oncology nursing society was formed by a small group of oncology nurses who felt they could make a difference. It is amazing how much has changed over the past 40 years. Not only has treatment changed, but also the way nurses use their voice to protect themselves and our patients. It was a nice historical presentation which made the audience proud to be oncology nurses and proud to be part of such a wonderful organization.

The lectures are always well presented and very interesting. Some of this year's topics included pain management, complimentary therapy, social media, mucositis and HPV. The lecture on mucositis discussed using Low Level Laser therapy. Annette Quinn, from UPMC Presbyterian Shadyside discussed how they were having very good results from using this therapy.

The MDONS nurses were represented at Congress in many poster presentations. Pam Laszewski and her team presented their research on Promoting Adherence to Skin Care Practices among Radiation Oncology Patients. Brenda Kramer and Ann Payne presented their poster on Improving Patient Care in the Ambulatory Setting. Clara Beaver and Sandy Randolph had a poster titled Using an Auditory Cue to Increase Adherence to Timely Pain Reassessment.

ONS started a new program this year with some nurses doing e-posters. These posters were electronically displayed and the nurses gave a short presentation on their findings. MDONS member Lindsey Cleveland was able to present her poster and findings on Bedside Shift to Shift Report. Susanne Suchy also presented her research on Increasing Gynecological Oncology Patient Satisfaction with Pain Management through Nurse Education during the e-poster presentations.

Paula DesJardins provided a podium presentation on Using Technology to Improve Nurse and Patient Outcomes. She discussed how a new electronic medical record system was implemented in a multicenter hospital system. The overall theme of her presentation looked the use of nurses to help develop EMR nursing assessments with a focus on patient care.

There was a lot of nursing research presented at congress. There were posters on chemotherapy administration, patient education, radiation therapy, infection control and many more. It is always interesting to read about the continuing evidence based research that is happening. The authors of the posters are there to discuss any questions or ideas that may be had.

I always walk away from congress feeling regenerated and ready to increase my practice with the knowledge that I have learned. I look forward to informing my co-workers about the new things that I learned. I also look forward to being able to network with the new friends that I met. It a privilege to be able to stand with your peers and listen to all of the nursing accomplishments that are happening around the world. Knowing that we are making a difference for our patients each and every day.

ONCOLOGY PHASE 1 CLINICAL TRIALS: WHY DO PATIENTS PARTICIPATE? ARE THEY ETHICAL?

Continued from front cover

is their motivation for participation. Two recent studies found that expectation of benefit was their primary reason for participating and altruism their least common motivator (Nappo, S.A., Iafrate, G.B., & Sanchez, Z.M, 2013). Catt, et al. (2011) had 40 patients complete a questionnaire. Most patient 36/40 (90%) consented to trial entry. The four main reasons for trial entry were: expectation of some medical benefit (21%); trial the best available option (21%); to maintain hope (15%) and to help with research (13%). Only one patient gave altruism as their main reason for trial participation. These researchers believe that phase 1 patients are generally optimistic and that informed consent needs to be carefully obtained.

The third issue that needs to be carefully considered in phase 1 clinical trial patients is adequate communication by the health care team regarding the aims of the trial, low chance of benefit, and risk of unknown side effects. Given the optimism present in these patients, this is a daunting task. Two reviews of the literature have been done in recent years addressing this issue. Cox, Fallowfield, and Jenkins (2006) reviewed 12 studies on patient comprehension of the informed consent. They found that less than 45% of patients understood the true aim of the trial. In addition, 85% of patients expected to achieve benefit from the treatment and 30% expected significant side effects. The patients overestimated both the benefit and the risk of the treatment. It is believed that although the patients were told that 5 of 100 patients would benefit (frequency type expression), they believed that their chance of being one of the 5 that will benefit is 90% (belief type expression). The researchers found that extended time to discuss the study with staff and additional educational materials such as CD ROM improved understanding of the aims and potential benefits and risks of the trial. A second literature review was done in 2010 (Jenkins, Anderson, & Fallowfield, 2010). This review found some improvement in understanding of the purpose of the trial. This understanding ranged from 40% to 97% in the 12 studies reviewed. Patients continued to overestimate their chance of benefit and many of the studies demonstrated lack of concern about side effects. They also shared that their chance of benefit was higher than that of other patients participating in the trial. When further questioned, patients shared that they were voicing their hope for benefit rather than their expectation of benefit. Educational interventions such as a DVDs improved patients' understanding of the aims, possible risks and benefits of the trial. Both of these reviews discuss that patients need a clear, unbiased discussion of their prognosis, aims of the trial, impact of trial on their quality of

life, low chance of potential benefit, and possibility of unknown side effects. Hope and optimism appear to be common characteristics of these patients.

Informed consent, patients' motivations for participation, and therapeutic misperception remain major issues for patients participating in phase 1 clinical trials. Proper education is paramount to ensure that patients have the proper information to make an informed decision regarding their participation. Personal expectation of benefit is the primary reason given for participation. Properly trained oncology nurses have been identified as key to helping to improve understanding of patients consenting to phase 1 trials (Cox, Fallowfield, & Jenkins, 2006). By doing this successfully, nurses can help to maintain hope and quality of life for these end stage patients.

References

- American Cancer Society. (2015). *Cancer Facts and Figures: 2015*. Atlanta: American Cancer Society.
- Catt, S. L. (2011). Reasons given by patients for participating, or not, in phase 1 clinical trials. *European Journal of Cancer*, 47, 1490-1497.
- Cox, A. F. (2006). Communication and informed consent in phase 1 trials: a review of the literature. *Support Care Cancer*, 14, 303-309.
- Godskesen, T. N. (2013). Phase 1 clinical trials in end-stage cancer: patient understanding of trial premises and motives for participation. *Support Care Cancer*, 21, 3137-3142.
- Horstmann, E. M. (2005). Risks and benefits of phase 1 oncology trials, 1991 through 2002. *New England Journal of Medicine*, 352(9), 895-904.
- Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. (2010). *Clinical Trials in Cancer. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary*. 6. Washington D.C.: National Academies Press.
- Italiano, A. M. (2008). Treatment outcomes and survival in participants of phase 1 oncology trials carried out for 2003 to 2006 at Institute Gustave Roussy. *Annals of Oncology*, 19(4), 787-792.
- Ivy, P. L.-M. (2010, March 15). Approaches to Phase 1 Clinical Trial Design Focused on Safety, Efficiency, and Selected Patient Populations: A Report from the Clinical Trial Design Task Force of the National Cancer Institute Investigational Drug Steering Committee. p. 1726.
- Jenkins, V. A. (2010). Communication and informed consent in phase 1 trials: a review of the literature from January 2005 to July 2009. *Support Care Cancer*, 18, 1115-1121.
- Kohler, B. S. (2015). Annual Report to the Nation on the Status of Cancer 1975-2011. *Journal of the National Cancer Institute*, 107(6).
- Nappo, S. I. (2013). Motives for participating in a clinical research trial: a pilot study in Brazil. *BMC Public Health*, 13, 19.
- National Cancer Institute. (n.d.). *cancer.gov*. Retrieved May 8, 2015, from What Are Clinical Trials?
- Pentz, R. W. (2012). Therapeutic misconception, misestimation, and optimism in participants enrolled in phase 1 trials. *Cancer*, 118(18), 4671-4578.
- Seidenfeld, J. H. (2008). Participants in phase 1 oncology research trials, are they vulnerable? *Archives of Internal Medicine*, 168(1), 16-20.
- Sulmasy, D. A. (2010). The culture of faith and hope, Patients' justifications for their high estimations of expected therapeutic benefit when enrolling in early phase oncology trials. *Cancer*, 116(15), 3702-3711.



Pharmacology Updates in Oncology Practice

Earn 6.5 Contact Hours While Getting the Latest Info for Oncology Nurses • September 26, 2015 • Memphis, TN

Join ONS in Memphis, TN for a full day of the latest updates in pharmacology. You'll learn about topics like safe handling, medical surveillance, immunology, and updates in recently approved and recently expanded indications of pharmacologic agents. Plus, network with other attendees to learn from one another and form career connections. [Enroll Now>>](#)

FROM THE PRESIDENT

HEATHER LOWRY, MSN, RN, WHNP-BC

A patient's spouse recently said to me "you can only control the things you can control, don't worry about the things you can't". There are many things that affect us as nurses, and our patients, that we wish we had some or more control over. In many instances we do not have any control, but perhaps in other instances we do.

In April I had the opportunity to attend ONS Congress. The 40th Anniversary of ONS was well celebrated with fabulous events and state-of-the-art presentations with nurses from around the world. Nurse researchers presented their findings on topics ranging from new guidelines for disease management, innovative medications, alternative therapies and survivorship. When I think back to this conference I think about how these men and women are making great advances in the world of oncology. Some of the more interesting presentations that really caused me to stop and reflect were on issues related to self-care of the oncology nurse, leadership and advocacy.

One of the events I attended was a luncheon on pancreatic cancer. This is a cancer I really did not know much about. I was heartbroken watching the slides showing the grim prognosis of this disease. However, it was inspiring to learn about the Pancreatic Action Network and the efforts being done to make changes in a disease that is not easy to control. New, innovative clinical trials are underway that may lead to better advancements and life expectancy of patients affected by pancreatic cancer. Although these men and women most likely cannot change the course of their prognosis, the advancement in these trials offer hope to make changes in the treatment of this disease and in the prognosis of future pancreatic cancer patients.

Another presentation I attended was on self-care of the oncology nurse. Many of us have very busy lives, we work hard, and often it seems we don't always have much time to do the things we should do

for ourselves. Working in healthcare can sometimes feel like we are in a world of increasing demands and limited resources. Often we have similar demands at home. Taking time for one's self often goes on the back burner. Ignoring what our body, soul and mind yearn for can take its toll but, there are many things we can do to refresh our nursing passion and to feel rejuvenated. Even something as simple as a quick break, aromatherapy, taking a walk, getting adequate sleep, eating healthy and doing something we enjoy can lead to a refreshed perspective.

Alec Stone, ONS Health Policy Director presented new information at Congress related to public health policy. We learned of some very scary issues happening around the country related to "control". Control of access to care, medications and insurance issues were some of the issues mentioned. The USPTF recently proposed new guidelines for changes in screening mammography. These new guidelines limit how often a mammogram can be performed and restrict the age recommendations for screening mammograms. Many organizations related to the treatment and prevention of breast cancer, including the ACS, do not agree with these guidelines. The USTF however is attempting to mandate their new guidelines with Affordable Care Act. Doctors, nurses and other health care providers involved in the field of breast cancer are up in arms and committed to taking action to convey the importance of annual screening mammogram. These are men and women who do not accept the premise of don't worry about what you can't control.

I am so glad I was able to get a chance to attend ONS congress this year and to see the great difference people are making in oncology nursing. So, maybe we cannot control everything, but we can control some things, and maybe it's those little things that we can control that make a difference in the lives of a cancer patient. Perhaps something small we can do for ourselves to make our jobs more satisfying may be the most important. Maybe we all take a step back and look at the bigger "picture" and be aware of what is happening around us, weather at our institutions, locally or nationally and control what we can and not worry about what we can't but know that all of us have the potential to make a difference. ●

I am so glad I was able to get a chance to attend ONS congress this year and to see the great difference people are making in oncology nursing.

ONS 40th Anniversary Celebration



The Oncology Nursing Society (ONS) was officially incorporated on July 17, 1975. Throughout 2015, ONS is celebrating the Society's 40th anniversary with a look back on its history and a glimpse into what ONS and the oncology nursing profession may look like in the future.

ONS began with a charter membership of fewer than 500 members and has since become a powerful force in cancer care. Join us in [honoring our past accomplishments](#) as we continue to prepare oncology nurses with the knowledge and tools they need to provide quality, safe cancer care to patients and their caregivers. [Learn More>>](#)



Win a Free ONS Membership

We're celebrating our 40th anniversary this year—and we want you to celebrate, too. Enter to win a free one-year membership when you correctly take on [our anniversary trivia challenge](#). [Learn more>>](#)

THE CHAPTER CAPSULE

...is a publication of the Metropolitan Detroit Chapter of the Oncology Nursing Society. MDONS is devoted to improving the quality of care given to patients experiencing cancer. This newsletter is published four times a year, in spring, summer, fall and winter. Letters and articles from members are welcomed. All material is subject to editing for space and clarification. Neither the Metro Detroit Chapter nor the ONS National Office assumes responsibility for opinions expressed herein. Acceptance of manuscripts does not indicate or imply endorsement. Materials may be submitted to:

Carole Bauer, RN, MSN, ANP-BC, OCN, CWOCN • 6116 Smithfield Drive, Troy, MI 48085



2015 MDONS OFFICERS

PRESIDENT

Heather Lowry

Heather.Lowry@beaumont.edu

PRESIDENT ELECT

Pam Laszewski

laszewski@karmanos.org

PAST PRESIDENT

Gayle Groshko

Gayle.Groshko@beaumont.edu

SECRETARY

Ann Calcaterra

ACalcaterra@beaumont.edu

TREASURER

Joanne Gondert

joanne.gondert@@beaumont.edu

NEWSLETTER CO-EDITORS

Carole Bauer

bauer.carole@gmail.com

Denise Weiss

weissd@karmanos.org

STAFF

Susan Wozniak

Susan.Wozniak55@gmail.com

Theresa Benacquisto

theresab65@comcast.net

Nancy Morrow

Nanmor04@yahoo.com

Melissa James

objee@gmail.com

Rita Dundon

313-881-8584

Mary Wilson

MFW1311@aol.com

Loretta Biskup

edbiskup@yahoo.com

Sabrina Richer

sabrina.richer@bms.com

Gayle Snider

gayle.snider@infusystems.com

Michelle Wallace

mwallace@beaumont-hospitals.com

Angela Maynard

amaynard@beaumont-hospitals.com

Susan Hansell

susan.hansell@comcast.net

Sandy Remer

sdremmer@earthlink.net

Heather Lowry

Heather.lowry@beaumont.edu

Angela Swantek

A_swantek@yahoo.com

Patti DuLong

DulongP@habitant.org

Laura Jaronski

Laurajaro@sbcglobal.net

Michelle Manders

michelle.manders@beaumont.edu

Kirsten D'Angelo

Kirsten.DAngelo@beaumont.edu