



**ONCOLOGY NURSING SOCIETY  
2009–2013 RESEARCH AGENDA**

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## I. EXECUTIVE SUMMARY

### A. Project background

The purpose of the Oncology Nursing Society (ONS) Research Agenda is to provide guidance for research initiatives to meet ONS's mission to promote excellence in oncology nursing and quality cancer care. The ONS Foundation's mission is to improve cancer care and the lives of people with cancer by funding oncology nursing research, scholarships, awards, and educational programs. The ONS Foundation Endowment provided support for the ONS 2009–2013 Research Agenda meeting. The ONS Research Agenda process has been a multi-method, stakeholder-driven, consensus-building effort since its initial development in 2001. The agenda has been revised every two years in response to rapid advances in oncology practice.

The 2011 meeting content leaders, content experts, and advanced practice nurses (APNs) carefully reviewed many documents in preparing the 2011 update. This document is not intended to set priorities for ONS for any other initiatives, such as education or policy. Our goal is that the research agenda can inform research initiatives of ONS and the ONS Foundation. High-priority topics are specified for each of the seven content areas, which are ordered in a logical fashion with no preference for any particular area.

### B. How to use this document

This document can be used to inform ONS' and the ONS Foundation's planning for their research initiatives as well as external individuals and groups regarding scientific priorities. This document can be used as a framework to achieve the missions of ONS and the ONS Foundation:

- (1) To increase the knowledge base for oncology nursing practice through identifying leading edge/critical priority areas of oncology nursing research
- (2) To develop future oncology nurse researchers who will be prepared to implement ongoing programs of research and to seek support from major sponsors
- (3) To prepare clinical nurses as critical consumers of research findings that can be applied to practice

### C. Cross-cutting themes

As you read this research agenda, you will note themes that apply to more than one content area. The themes identified by content leaders and experts fall into three broad categories and include:

#### (1) Individual/Population Issues

- **Cultural** sensitivity or cultural competence
- **Health disparities** (race or ethnicity, gender, income, education, sexual orientation, culture, geography, access, health literacy, medically underserved)
- **Lifespan orientation:** special needs at phases
- **Family as the care recipient**
- **Global health issues**

- **Ethics**
- **Personalized medicine**

## (2) Design/Methods Issues

- **Models** outside oncology nursing
- **Mechanisms** (biological, psychological, behavioral, socio-cultural) underlying responses to cancer and treatment
- **Longitudinal, multi-site or multi-level designs** (when appropriate to the question)
- **Intervention work** that builds on adequate descriptive work
- **Targeted interventions** for specific groups/populations (what works, for whom, and in what context, and for which outcomes)
- **Behavioral change** as an overarching theme underlying several intervention approaches
- **Informatics** or technologic innovations
- **Outcomes evaluation** using a multi-dimensional approach: *implementation outcomes* (feasibility, fidelity, penetration, sustainability, uptake and costs), *service outcomes* (efficiency, effectiveness, patient-centeredness), and *client outcomes* (satisfaction, function, symptoms)
- **Measurement science strengthening**

## (3) System Issues

- **Interdisciplinary teams**
- **Mentored** grants to optimize capacity building simultaneously with knowledge generation
- **Partnerships and team building** with other professional organizations (e.g., American Society of Clinical Oncology, Association of Pediatric Oncology Nurses)
- **Partnerships among researchers, clinicians, and regulators**
- **Workforce issues** of medical oncologists and oncology-certified APN or Nurse Practitioners
- **Cost** and cost-effectiveness measures embedded
- **Partnerships** joining researchers and service organizations to promote implementation
- **Health policy** implications of projects
- **Healthcare reform**

**D. Relationship to ONS Strategic Plan:** The 2009–2013 ONS Research Agenda, revised in 2011, represents the core work of ONS, “establishing priorities for oncology nursing research,” and contributes directly to the knowledge strategy, “generation and application of research.” The ONS Research Agenda provides important and timely direction for the research, evidence-based practice, and quality components of the ONS mission to promote excellence in oncology nursing and quality cancer care.

## II. CONTENT AREAS AND PRIORITY TOPICS FOR RESEARCH 2009–2013

### A. *Health Promotion*

**A.1.** Develop or test interventions to adopt or maintain health behaviors (e.g., tobacco control, physical activity, dietary change, weight management, stress management) that reduce risk factors for or prevent cancer.

A.1.1. Test the applicability of findings from other areas (e.g., diabetes), focusing more specifically on the underserved (e.g., ethnic minorities, urban poor, rural residents, older adults, sexual minorities).

A.1.2. Develop or test **early** interventions for risk reduction (e.g., with youth, on attitudes and beliefs, to enhance access and referral to human papilloma virus vaccine, with those at higher risk for hereditary cancers, to prevent tobacco use or overweight/obesity).

A.1.3. Develop or test innovative and cost-effective interventions targeting multiple health behaviors that can address key risk factors (e.g., overweight/obesity) and mechanisms of effects (e.g., biomarkers).

**A.2.** Develop or test interventions to increase first-time and interval cancer screening, with an emphasis on underserved and understudied populations (e.g., ethnic minorities, urban poor, rural residents, older adults, sexual minorities) and those at higher risk for hereditary cancers.

A.2.1. Develop or test culturally **responsive** interventions, including those that enhance healthcare providers' cultural competence.

A.2.1. Apply findings from other areas with more extensive research (e.g., breast cancer screening) to increase screening for other cancers.

A.2.2. Develop or test cost-effective and accessible multi-component and/or technology-based interventions.

A.2.3. Conduct comparative effectiveness trials to apply evidence-based intervention strategies in cancer screening to clinical and community practice settings.

### B. *Cancer Symptoms and Side Effects*

**B.1.** Develop in-depth knowledge of cancer-related symptoms and side effects in children and adults across cultures and ethnicities.

B.1.1. Determine causal pathways, including physiological and psychological mechanisms and genetic susceptibility.

B.1.2. Identify short- and long-term outcomes that are sensitive to symptom intervention.

B.1.3. Establish norms, cut-off scores, and minimally important clinical differences for symptom measures and harmonize different scales through co-calibration.

B.1.4. Develop and evaluate symptom interventions with a clear understanding of active components.

**B.2.** Develop and evaluate systems of care that integrate scientific knowledge of symptoms and side effects into oncology clinical practice.

B.2.1. Develop and evaluate symptom screening and assessment methods with the potential to improve care in the clinical setting.

B.2.2. Adapt symptom interventions with proven effectiveness and evaluate their feasibility in the clinical setting and effect on patient outcomes.

### **C. *Late Effects of Cancer Treatment and Long-Term Survivorship Issues***

**\*Definitions:** Long-term effects are any side effects or complications from therapy that continue beyond the end of treatment. Late effects occur months to years after treatment is completed. Aziz, N. (2007). Late effects of cancer treatment. In P.A. Ganz (Ed.), *Cancer survivorship*. New York, NY: Springer.

**C.1.** Develop or test and implement interventions to prevent or minimize adverse outcomes related to long term\* or late effects\* and risks associated with the development of comorbid illnesses.

C1.1. Conduct intervention trials to reduce long-term risks from cancer therapy with special attention to high-risk populations, specifically childhood cancer survivors and adults at risk for cardiovascular toxicity and bone loss.

C 1.2. Design healthy lifestyle behavior interventions to maintain a healthy weight; improve physical, functional, and psychological outcomes; minimize risk of recurrence; and prolong survival.

C 1.3. Conduct interventions that address social and work reintegration issues during and after cancer therapy.

C 1.4. Evaluate outcomes of survivorship intervention research on healthcare use.

**C.2.** Explore factors associated with the delivery of quality cancer care to survivors.

C.2.1. Develop and test the effects and efficiency of models of care to support the Institute of Medicine's (IOM's) recommendation for survivorship care (e.g., treatment summaries, surveillance and health promotion recommendations). Inherent in this effort is attention to unique needs of specific cancer populations.

C.2.2. Explore approaches that address system barriers to implementation of IOM recommendations.

C.2.3. Participate in health informatics initiatives to enhance cancer survivorship care delivery.

C.2.4. Explore effective ways to care for the growing number of survivors, with attention placed on older adult survivors and minority populations.

C.2.5. Explore challenges facing oncology and the oncology nursing workforce related to survivorship.

#### **D. End-of-Life (EOL) Issues**

Although no exact definition of EOL exists, it is a period of time marked by disability or disease that is progressively worse until death (National Institutes of Health (2004). *National Institutes of Health State-of-the-Science Conference Statement on Improving End-of-Life Care*. Retrieved from <http://consensus.nih.gov/2004/2004EndOfLifeCareSOS024html.htm>)

**D.1.** Develop knowledge of mechanisms and management of symptoms for patients with cancer near EOL and their families.

D.1.1. Develop or evaluate efficacious, feasible, cost-effective, culturally sensitive interventions for patients with cancer near EOL and their families.

D.1.2. Validate culturally sensitive symptom measures for assessing symptoms for patients with cancer near EOL and their families.

**D.2.** Develop knowledge that promotes quality of life (QOL) for patients with cancer near EOL and their families.

D.2.1. Conceptualize, develop, and validate specific measures of QOL for diverse groups.

D.2.2. Develop and/or evaluate efficacious, feasible, cost-effective, culturally sensitive interventions and systems of care for supporting QOL in patients with cancer near EOL and their families.

D.2.3. Develop and/or evaluate interventions for implementation early in the cancer trajectory to promote anticipation, discussion, and/or preparation for EOL issues with patients with cancer and their families to enhance QOL near EOL.

## **E. Psychosocial and Family Issues**

**E.1.** Well-designed intervention studies to reduce negative outcomes and improve positive outcomes in patients with cancer and their family caregivers

E.1.1. Research to test patient and family models that encompass both risk factors and protective factors and their relationship to outcomes

E.1.2. Intervention studies that identify patients and caregivers at higher risk of poorer outcomes and target interventions to meet their needs. These studies need to address cancer-related cost and resource use issues for patients and families.

**E.2.** Research focused on the impact of high risk for cancer, including a family history of cancer, on individuals and families

E.2.1. Exploratory research in areas pertaining to family communication and family functioning in disclosing test results, conflict and regret about pursuing genetic testing, role of significant others in decisions to pursue testing, and genetic testing in minority families

E.2.2. Testing of interventions using decision aids, risk communication strategies, and educational support for probands and their families

## **F. Nursing-Sensitive Patient Outcomes (NSPOs)**

**F.1.** Evaluate the effect of nursing care on promoting and maintaining treatment adherence.

F.1.1. Understand predictors (risk model), costs, settings, side effects, educational approaches, population, health literacy, and cognitive changes associated with adherence to oral chemotherapeutic agents.

F.1.2. Evaluate strategies for various innovative models of care (e.g., APN-led teams, patient-centered medical home, chronic care models) and the cost effectiveness related to adherence of care issues.

F.1.3. Explicate the issues of adherence in all aspects of a plan of care, including clinical trial participation, medications such as oral chemotherapeutic agents, diet, and self-care strategies.

F.1.4. Evaluate strategies for the identification and prevention of adverse events related to treatment, such as vascular devices.

F.1.5. Develop or test interventions that support adherence to care.

**F.2.** Expand knowledge regarding relationships between physical function and NSPO.

F.2.1. Explicate the relationship between nursing interventions and physical functioning for patients with cancer.

F.2.2. Evaluate the relationship between physical function and falls with injury for patients with cancer.

## **G. *Translation Science***

**G.1.** Identify and test implementation science methods and techniques designed to improve the capacity of clinicians to screen, assess, and deliver effective interventions and optimize oncology nursing care quality and outcomes.

G.1.1. Investigate methods to exploit technology and system redesign to link screening, assessment, interventions, and outcomes.

G.1.2. Promote research-practice partnerships to integrate efficacious, cost-effective interventions into clinical care.

**G.2.** Identify cognitive-behavioral, psychoeducational, rehabilitative, and self-management interventions (individual and multi-level) with demonstrated effectiveness in targeted populations, and refine, manualize, and evaluate those interventions for use by clinicians to address multiple outcomes. Based on feedback from a survey of ONS members, interventions that address pain, sleep, fatigue, and mood disturbances should be prioritized for funding.

G.2.1. Conduct exploratory analyses and test resultant hypotheses in experimental designs to develop new knowledge that allows interventions to be effectively targeted (that is, develop knowledge that contributes to identifying what interventions work best for whom and under which conditions/contexts, at what costs, and to achieve which outcomes).

G.2.2. Modify interventions for use by clinicians to target multiple outcomes simultaneously (e.g., symptom distress and functional status) and examine implementation, service, and client outcomes.

## COMPLETE 2009–2013 ONS RESEARCH AGENDA

### A. *Health Promotion*

**A.1.** Develop or test interventions to adopt or maintain health behaviors (e.g., tobacco control, physical activity, dietary change, weight management, stress management) that reduce risk factors for or prevent cancer.

A.1.1. Test the applicability of findings from other areas (e.g., diabetes), focusing more specifically on the underserved (e.g., ethnic minorities, urban poor, rural residents, older adults, sexual minorities).

A.1.2. Develop or test **early** interventions for risk reduction (e.g., with youth, on attitudes and beliefs, to enhance access and referral to human papilloma virus vaccine, with those at higher risk for hereditary cancers, to prevent tobacco use or overweight/obesity).

A.1.3. Develop or test innovative and cost-effective interventions targeting multiple health behaviors that can address key risk factors (e.g., overweight/obesity) and mechanisms of effects (e.g., biomarkers).

**A.2.** Develop or test interventions to increase first-time and interval cancer screening, with an emphasis on underserved or understudied populations (e.g., ethnic minorities, urban poor, rural residents, older adults, sexual minorities) and those at higher risk for hereditary cancers.

A.2.1. Develop or test culturally **responsive** interventions, including those that enhance healthcare providers' cultural competence.

A.2.2. Apply findings from other areas with more extensive research (e.g., breast cancer screening) to increase screening for other cancers.

A.2.3. Develop or test cost-effective and accessible multi-component and/or technology-based interventions.

A.2.4. Conduct comparative effectiveness trials to apply evidence-based intervention strategies in cancer screening to clinical and community practice settings.

### Progress 2004–2010

Since 2003, when Research in Health Promotion was first identified as an ONS priority topic, three health promotion studies have been funded by the ONS Foundation. Over the past seven years, research on health behaviors within the oncology nursing literature has addressed barriers to change (Niederdeppe & Levy, 2007), special populations (Andrews, Felton, Wewers, Waller, & Tingen, 2007; Jandorf, Gutierrez,

Lopez, Christie, & Itzkowitz, 2005; Satia, Barlow, Armstrong-Brown, & Watters, 2010; Spector et al., 2009; Underwood, 2006), innovative strategies for intervention delivery (Vandelanotte, Spathonis, Eakin, & Owen, 2007), and individually relevant outcomes (Nies & Sun, 2008). Health behavior theories have been evaluated for their relevance to breast cancer risk reduction and screening (Ham, 2006; Spector, 2007; Wood, 2008). Multidisciplinary, multicomponent, and community-based interventions have been identified as promising models for the adoption and maintenance of healthy choices (Bull, Eakin, Reeves, & Kimberly, 2006; Cokkinides, Bandi, Ward, Jemal, & Thun, 2006; Fowler, Rodney, Roberts, & Broadus, 2005; Greenwald, 2005; Kushi et al., 2006; Meyskens & Tully, 2005; Yancey & Tomiyama, 2007).

Several studies on nurses' smoking rates and smoking cessation interventions have been conducted over the past five years. Sarna et al. (2008) documented a decline in smoking rates among nurses in the Nurses' Health Study over the past 25 years, an encouraging trend, in part, because nurses who smoke may be less likely to offer tobacco control interventions to their patients. However, Chinese nurses, even with a very low rate of smoking, rarely offered smoking cessation interventions to patients, unless the nurses had specific training (Chan, Sarna, Wong, & Lam, 2007). A high prevalence of smoking (23.5%) was noted among Japanese nursing students (Suzuki, Ohida, Yokoyama, Kaneita, & Takemura, 2005). A framework for evaluating tobacco cessation education within nursing curricula to promote evidence-based practice was proposed by Heath and Andrews (2006). Nurses who were current or former smokers identified the need for smoking cessation interventions as well as additional support for concerns about confidentiality and guilt (Bialous, Sarna, Wewers, Froelicher, & Danao, 2004). Research on tobacco control continues to be needed in light of emerging statistics indicating that previous declining trends in tobacco use have not changed substantially in recent years (Cokkinides et al., 2006). Doolan and Froelicher (2006) found that smoking cessation research was needed particularly with older adults, sexual minorities, Native Americans, Alaskan Natives, Hispanics, and Asian Americans.

Similar to research on cancer prevention, cancer screening studies continue to target primarily breast cancer screening and particularly mammography, given that screening guidelines now identify breast self-examination as optional (Smith, Cokkinides, & Brawley, 2009). Research on breast cancer screening, including some work on breast and cervical cancer screening, has expanded in the past five years to address questions about the cost of screening promotion programs (Andersen, Urban, Ramsey, & Briss, 2004; Saywell, Champion, Skinner, Menon, & Daggy, 2004), screening in non-adherent women (Goelen, De Clercq, & Hanssens, 2010; Skinner et al., 2007), high-risk women (MacDonald, Sarna, Uman, Grant, & Weitzel, 2006; Martin & Degner, 2006), and diverse and underserved populations (Alkhasawneh, 2007; Anderson, Jun, & Choi, 2007; Ceber, Soyer, Ciceklioglu, & Cimat, 2006; Chen, 2009; Farmer, Reddick, D'Agostino, & Jackson, 2007; Fowler, 2006a, 2006b; Gözüm, Karayurt, Kav, & Platin, 2010; Grindel, Brown, Caplan, & Blumenthal, 2004; Grindel, McGehee, Patsdaughter, & Roberts, 2006; Güleser, Ünalán, & Akyıldız, 2009; Gürsoy et al., 2009; Hall et al., 2005; Hall, Hall, Pfriemer, Wimberley, & Jones, 2007; Ho, Yamal, Atkinson, Basen-Engquist, Tortolero-Luna, & Follen, 2005; Kim & Menon, 2009; Kim & Sarna, 2004; Lee-Lin et al.,

2008; Lee-Lin & Menon, 2005; Lee-Lin, Menon, et al., 2007; Lopez-McKee, McNeill, Bader, & Morales, 2008; Memis, Balkaya, & Demirkiran, 2009; Nahcivan & Secginli, 2007; Powe & Cooper, 2008; Russell, Champion, & Skinner, 2006; Russell, Perkins, Zollinger, & Champion, 2006; Steven et al., 2004; Taymoori & Berry, 2009; Thomas, 2004; Wu & Bancroft, 2006; Yarbrough, 2004). Descriptive studies and some early intervention work on cervical, colorectal, and prostate cancer screening also have been conducted (Conde et al., 2011; Gu, Chan, & Twinn, 2010; Gwede et al., 2010; Lee, Fogg, & Menon, 2008; Lee-Lin, Pett, et al., 2007; Menon, Belue, Skinner, Rothwell, & Champion, 2007; Menon et al., 2008; Olifee, 2006; Omran & Ismail, 2010; Rawl et al., 2005; Tung, Lu, & Cook, 2010). Although there is a decreasing trend in mortality from colorectal cancer, this is not evident for minority populations such as African Americans for whom risk of late diagnosis and increased mortality remains higher than for Caucasians (Meissner et al., 2004), underscoring the critical need for additional research on effective interventions to increase colorectal cancer screening. Hudson et al. (2007) indicated that interventions to enhance colorectal cancer screening may fare better if they provide more general health behavior change education, rather than focusing on colorectal cancer screening alone.

### **Rationale and Background**

Research on health promotion—health behaviors to prevent cancer and increase cancer screening—is urgently needed. Cancer incidence and mortality rates have decreased overall in recent years (Jemal, Siegel, Xu, & Ward, 2010), attributable in part to an increased understanding and awareness of risk factors, adoption of healthy lifestyle behaviors, and improvements in cancer screening and early detection. Oncology nursing research on health promotion has primarily addressed symptom management and lifestyle change in cancer survivors. In lieu of a cure, health promotion in the context of cancer risk reduction and cancer screening is a critical role for oncology nurses who are well positioned to contribute to primary and secondary prevention of cancer and cancer control in the United States, particularly with respect to cancer-related disparities. There are ongoing, long-term challenges to health promotion in the U.S. population that need to be addressed, particularly in terms of control of tobacco and overweight/obesity across the lifespan, as well as minimizing disparities in access to health promotion programs and cancer screening in the United States and internationally. Several important summaries have recently addressed the need for and challenges of health promotion for cancer prevention throughout the world, including tobacco control, overweight/obesity, physical activity, and diet (American Cancer Society, 2010; Samet & Yoon, 2010; U.S. Department of Health and Human Services, 2010; World Health Organization, 2009a, 2009b, 2010a, 2010b). These challenges and disparities remain, despite well-established models of health behavior change and extensive research on programs to promote healthy lifestyle and cancer screening behaviors. Intervention research is needed that goes beyond long-held theoretical models; targets diverse and underserved populations globally; addresses known and possible mechanisms of action, and applies and disseminates evidence-based interventions to both community and clinical settings.

Although chemoprevention and bilateral prophylactic mastectomy have been identified as cancer prevention options (McQuirter, Castiglia, Loiselle, & Wong, 2010), current strategies to decrease cancer incidence generally involve risk management through health behavior modification, such as tobacco control, dietary change to optimize energy balance and decrease obesity, and physical activity or exercise. In a review of epidemiologic studies on the association between physical activity and risk of breast cancer, the most active participants had, on average, a 30%–40% decreased risk for breast cancer compared to sedentary women (McTiernan, 2003). Similar results were found for the association between physical activity and colorectal cancer (Slattery, 2006). Although a strong evidence base has yet to be established, psychoneuroimmunological studies suggest that strategies that target tumor defense mechanisms (such as stress management) may be an effective health promotion intervention for cancer prevention (Antoni et al., 2008; Bryla, 1996; Park, Kang, & Weaver, 2010). Clinical trials of innovative interventions that support adoption as well as long-term maintenance of these health behaviors in diverse populations are important areas for nursing research (Wilhelmsson & Lindberg, 2007).

Predictions based on the most recent data available on cancer incidence, survival, and costs of care estimate cost of direct cancer care in 2020 to reach \$158 billion (Mariotto, Yabroff, Shao, Feuer, & Brown, 2011) clearly making the case for research into prevention and early diagnosis. As a health promotion strategy, cancer screening has been shown to decrease mortality from breast, cervical, and colorectal cancer by increasing early detection (Cokkinides, Bandi, Siegel, Ward, & Thun, 2007). Colorectal cancer screening by endoscopy also can prevent cancer, and the American Cancer Society and other professional organizations have recommended that cancer prevention should be the primary goal of colorectal cancer screening (Levin et al., 2008). Mammography screening rates and cervical cancer screening have increased steadily over the past decade to more than 50% of women, but these rates have leveled off in recent years. This leveling off undoubtedly reflects the success of the National Breast and Cervical Cancer Early Detection Program activities that were initiated in 1991 (Ryerson, Benard, & Major, 2002) as well as the tremendous number of intervention studies targeting barriers to breast cancer screening. Interventions have decreased the gap between racial or ethnic minority groups and Caucasian women's mammogram screening rates, but some disparity remains, particularly in terms of interval or ongoing screening (American Cancer Society, 2007; Cokkinides et al., 2007; Rakowski et al., 2004). In addition to beliefs, cultural attitudes, and knowledge, research has identified the pivotal role of healthcare professionals in facilitating breast cancer screening (Breen, Wagener, Brown, Davis, & Ballard-Barbash, 2001; Fox, Murata, & Stein, 1991; Fox & Stein, 1991; Meissner et al., 2004). Reminders from healthcare providers are generally the most effective strategies for promoting mammogram adherence in studies of women, regardless of their age or ethnicity (Levy-Storms, Bastani, & Reuben, 2004; Lukwago et al., 2003; Schwartz, Taylor, & Willard, 2003; Tu et al., 2003). Structural influences, such as policy and socioeconomic factors, health insurance coverage, and access to a regular source of health care, have been recognized as facilitating or impeding screening (Breen et al., 2001).

Research focused on screening for other cancers (most notably, cervical and colorectal) pales in comparison to breast cancer screening studies, and the knowledge gained from this research has been extended only minimally to other cancer screening studies. In contrast to trends in breast and cervical cancer screening, screening rates for colorectal cancer have continued to rise but are still less than 50% across racial or ethnic groups (Cokkinides et al., 2007). Disparities in cervical cancer screening by racial or ethnic minority groups and in colorectal cancer screening by gender and racial or ethnic minority groups also have been documented. Intervention research to enhance colorectal and cervical cancer screening, including human papilloma virus vaccine education and uptake, is needed (Anhang, Goodman, & Goldie, 2004; Saslow et al., 2007; Smith et al., 2009). This research may well be guided by successful intervention strategies and lessons learned from mammography screening trials (Meissner et al., 2004).

Multiple health behavior theories for guiding health promotion research are in the research literature, but very few have been tested adequately (Bowen et al., 2009). Research to understand and promote health behavior change has been carried out within the cardiovascular and diabetes specialty areas for many years, but scientists and clinicians still are challenged in their efforts to effectively accomplish long-lasting lifestyle change. Much work still must be done. A common agenda to share knowledge across specialties and disciplines, promote health behavior change, and thereby prevent chronic illnesses has been proposed by the American Cancer Society, American Diabetes Association, and American Heart Association (Eyre, Kahn, Robertson, & ACS/ADA/AHA Collaborative Writing Committee, 2004). In addition, recent research comparing the explanatory value of popular health behavior theories with regards to cancer screening show that there is over-reliance on placing narrowly defined determinants of behavior in a specific relationship to one another, entirely isolated from social context (Pasick & Burke, 2008). For example, constructs such as perceptions of illness, experiences with discrimination, and racism shape women's lives or negate or attenuate the effect of common Health Belief Model variables on breast cancer screening (Fisher, Burnet, Huang, Chin, & Cagney, 2007).

Intriguing new research suggests that a simultaneous approach to multiple behavior change may be superior to changing behaviors sequentially (Hyman, Pavlik, Taylor, Goodrich, & Moye, 2007). A recent World Cancer Research Fund/American Institute for Cancer Research (2009) report on diet, physical activity, and cancer underscored the need to address multiple aspects of health promotion to reduce cancer prevention and risk reduction. Health behavior theories and interventions emphasizing the multiple benefits of lifestyle change may prove more effective than focusing on cancer prevention in isolation. In fact, recent studies indicate that targeting healthy lifestyle behaviors during cancer screening encounters may be particularly effective (van der Aalst, van Klaveren, de Koning, 2010). Thus, we need to move away from single-level explanatory and descriptive models to more comprehensive and ecologic frameworks (Warnecke et al., 2008; Zapka & Lemon, 2004; Zapka, Taplin, Solberg, & Manos, 2003). Using such conceptual frameworks may help oncology nurses forge ahead with implementation of health promotion research for prevention of other cancers while

drawing from successes in breast cancer research. Meissner et al. (2004) discovered such parallels and summarized past research, current challenges, and recommendations for future research.

The continued unequal burden of cancer on poor, minority, and underserved populations underscores the need for much more research on screening for other cancers in these populations, which often experience challenges within the healthcare system. For example, about 90 million Americans have low health literacy (Nielsen-Bohman, Panzer, & Kindig, 2004) with limited access to, understanding of, and practice of lifestyle behaviors for health promotion, risk reduction, and cancer prevention. These barriers lead to confusion and nonadherence among patients and healthy individuals; therefore, health promotion efforts need to speak to a broader definition of culture that encompasses groups within underserved populations and even children and adolescents. We must consider culture and literacy in our interventions and develop and test innovative, new approaches to address these concerns. Oncology nurses can have a tremendous impact on addressing these disparities. Their role in health promotion is supported by the ONS Position on Prevention and Early Detection of Cancer in the United States. Overall, ONS believes these health promotion priorities will:

- Allow oncology nurses to keep pace with (even stay ahead) of leading edge research nationally
- Increase the focus on well populations with whom nurses may have an increased impact
- Increase the pool of fundable applications that also meet national research agendas (e.g., on health disparities, health literacy, and interdisciplinary research).

Pasick & Burke (2008) state that the "...apt subtitle for many of the studies to date could be "Culture: The Elephant in the Room" (p. 358). It is time to move away from the implicit assumption that relevant "...cultural differences **translate readily** ... into the psychological constructs..." (p. 358), and to better understand how cultural practices, products, philosophies, or environments may be used as vehicles that facilitate behavior change of patients and practitioners (Fisher et al., 2007; Pasick et al., 2009).

## Future Research Recommendations

### A.1.

- Descriptive and intervention research on promoting and maintaining health behaviors, such as healthy eating patterns, exercise or physical activity, and stress management
- Descriptive and intervention research on promoting and maintaining health behaviors in special populations that experience health disparities (e.g., ethnic minorities, urban poor, rural residents, older adults, sexual minorities)
- Pilot or feasibility research, particularly for the development of intervention studies that evaluate health behavior change targeted to messages about cancer prevention and/or groups at high risk for particular cancers

- Efficacy evaluation of making multiple health behavior changes versus changing one specific behavior; identify special populations for which multiple versus singular behavior change might be most efficacious.
- Testing an ecological model of theoretical underpinnings for health promotion behaviors that go beyond popular cognitive theoretical frameworks.

#### **A.2.**

- Descriptive and intervention research on promoting and maintaining screening for early detection of cancer, with an emphasis on cancers other than breast cancer
- Descriptive and intervention research on promoting and maintaining screening or early detection in special populations that experience health disparities (e.g., ethnic minorities, urban poor, rural residents, older adults, sexual minorities)
- Development of strategies (tools, resources, programs) that effectively communicate screening guidelines for multiple types of cancers
- Pilot or feasibility research, particularly for the development of intervention studies, that tests lessons learned from research on breast cancer screening to other types of cancer
- Testing an ecological model of theoretical underpinnings for cancer screening behaviors that go beyond popular cognitive theoretical frameworks.

### **B. Cancer Symptoms and Side Effects**

**B.1.** Develop in-depth knowledge of cancer-related symptoms and side effects in children and adults across cultures and ethnicities.

B.1.1. Determine causal pathways including physiological and psychological mechanisms and genetic susceptibility.

B.1.2. Identify short- and long-term outcomes that are sensitive to symptom intervention.

B.1.3. Establish norms, cut-off scores, and minimally important clinical differences for symptom measures and harmonize different scales through co-calibration.

B.1.4. Develop and evaluate symptom interventions with a clear understanding of active components.

**B.2.** Develop and evaluate systems of care that integrate scientific knowledge of symptoms and side effects into oncology clinical practice.

B.2.1. Develop and evaluate symptom screening and assessment methods with the potential to improve care in the clinical setting.

B.2.2. Adapt symptom interventions with proven effectiveness and evaluate their feasibility in the clinical setting and effect on patient outcomes.

### **Rationale and Background**

Understanding the nature and management of individual and multiple symptoms related to cancer and/or its treatment has long been a priority of oncology nursing. A symptom is a subjective experience that reflects the individual's interpretation of a change in bodily sensation, functioning, and/or cognition (Dodd et al., 2001). Each symptom is perceived in a unique way based on the sensation as well as the context of that experience (Rutledge & McGuire, 2004). Symptoms that occur during the cancer experience are complex phenomena; they can be present at diagnosis or result from treatment, other symptoms, or other chronic illnesses (Lacasse, 2010). In this section, a brief state of the science review as of 2011 and an agenda for future research are presented.

The ONS has a long-standing interest in cancer-related symptoms as well as side effects and long-term effects of therapy. In the 2008 ONS research priorities survey (Doorenbos et al., 2008), four symptoms were ranked in the top 20 priorities by the total ONS membership: pain (# 2), neuropathy (7), fatigue (14), and mucositis (20). In the same survey, the subgroup of nurse scientists ranked five symptoms in the top 20: neuropathy (4), sleep-wake disturbances (9), symptom clusters (15), fatigue (16), and pain (19). For each of the individual symptoms, the Oncology Nursing Society has developed evidence-based supportive care practice guidelines that have been compiled into a book and on the ONS Web site (Eaton & Tipton, 2009). The National Comprehensive Cancer Network (NCCN) also has developed supportive care guidelines for pain and fatigue (NCCN, 2010). The ONS Foundation has funded small and large grants related to symptoms and side effects. In 2010, 9 of 23 applications related to priority topic B.1 received funding from the ONS Foundation. No applications related to priority B.2 were submitted or funded.

Because of differences in the etiology and dimensions of different symptoms, most of the research to date has focused on individual symptoms or global symptom intensity or distress rather than groups of symptoms. There also has been interest in exploring the problem of multiple co-occurring symptoms (symptom clusters) in oncology populations (Barsevick, 2007a, 2007b; Miaskowski & Aouizerat, 2007). The definition of a symptom cluster, originally described by Dodd, Miaskowski, and Lee (2004), was refined by Kim, McGuire, Tulman, and Barsevick (2005) to include "two or more symptoms that are related and occur together (p. 278). The clustered symptoms may or may not share a common etiology. Despite the definition, clarity is lacking regarding how to operationally define a symptom cluster concerning the number of symptoms and the nature of the relationship between or among them.

## **Progress from 2004–2010**

### **Causal Pathways**

The development of knowledge about symptoms has included the understanding of causal pathways or mechanisms. These mechanisms could have physiological, psychological, behavioral, or socio-cultural components (Parker, Kimble, Dunbar, & Clark, 2005). There are several symptom models that reflect multiple influences on the symptom experience and suggest that a combination of mechanisms may be required to explain the symptom experience (Dodd et al., 2001; Finnegan, Shaver, Zenk, Wilkie, & Ferrans, 2010; Lenz, Pugh, Milligan, Gift, & Suppe, 1997; Myers, 2009; Parker et al., 2005).

Progress is being made in understanding the biologic etiology of cancer-related symptoms. Inflammatory processes have been proposed as the underlying mechanism for cancer-related fatigue, pain, and depression (Bower, 2007; Miller et al., 2008; Reyes-Gibby et al., 2008; Seruga, Zhang, Bernstein, & Tannock, 2008). The basis for inflammation and the development of symptoms is unclear. One possibility is alterations in the physiologic systems of the HPA axis. Adrenal cortex-derived steroids have potent effects on immune cell development, maturation, trafficking, and cytokine production (Bower, 2007; Irwin & Miller, 2007; Reyes-Gibby et al., 2007, 2008; Thornton, Andersen, & Blakely, 2010). Several investigations have addressed cytokine-symptom relationships and genetic polymorphisms associated with those relationships (Miaskowski et al., 2010; Myers & Myers, 2008; Rausch et al., 2010). The GENEQOL Consortium, an interdisciplinary and international group has been formed to investigate genetic disposition related to QOL outcomes (Sprangers et al., 2009, 2010). Papers have been published on genetic biomarkers related to CRF, depression, and cancer-related pain (Barsevick, Frost, Zwiderman, Hall, & Halyard, 2010; Shi, Cleeland, Klepstad, Miaskowski, & Pedersen, 2010; Sprangers et al., 2010).

### **Individual Symptoms and Symptom Clusters**

A host of symptoms are related to cancer and its treatment. Some, such as pain or fatigue, are well known to the oncology nursing community and have been systematically studied. Some treatment side effects have emerged with new therapies, such as cutaneous reactions due to epidermal growth factor receptor (EGFR) inhibitors; other commonly occurring cutaneous reactions, such as acute radio-dermatitis, have not been well studied because of measurement issues. Cancer or cancer therapy-related symptoms are important targets for study. The next section describes the research evidence and ideas for future research associated with several specific symptoms.

### **Cancer-Related Fatigue**

Cancer-related fatigue (CRF) continues to be a problem for individuals along the entire trajectory of cancer from diagnosis through treatment, survivorship, and EOL. Considerable research has been published on many aspects of this symptom, including clinical predictors and outcomes, biological and genetic associations, self-report measures, and intervention (both pharmacologic and nonpharmacologic). Several review papers have examined self-report measures of CRF (Barsevick, Cleeland, et al.,

2010; Hjollund, Andersen, & Bech, 2007; Jean-Pierre et al., 2007; Minton & Stone, 2009). However, little agreement exists regarding optimal and efficient measurement of CRF. CRF correlates in specific populations have been addressed (Andrykowski, Donovan, Laronga, & Jacobsen, 2010; Goedendorp et al., 2008; Minton & Stone, 2008; Wielgus et al., 2009). A major focus of research has been the biological correlates of CRF; three review papers have been published (Bower, 2007; Nicolson, Conklin, Nicolson, & Conklin, 2008; Schubert et al., 2007). Studies have examined inflammatory biomarkers of CRF (Bower et al., 2009; Inagaki et al., 2008; Orre et al., 2009; Panju et al., 2009); other biomarkers (Payne et al., 2008; Vardy, Rourke, & Tannock, 2007; Von Ah et al., 2008); and gene polymorphisms (Aouizerat et al., 2009; Collado-Hidalgo, Bower, Ganz, Irwin, & Cole, 2008). A systematic review and meta-analysis of pharmacologic interventions for CRF has been published (Minton, Richardson, Sharpe, Hotopf, & Stone, 2008). Several meta-analyses on nonpharmacologic interventions for CRF have been published as well (Goedendorp et al., 2009; Jacobsen, Donovan, Vadaparampil, & Small, 2007; Kangas et al., 2008).

To consolidate the wealth of evidence on CRF and develop a research agenda for future research, the National Cancer Institute (NCI) sponsored a clinical trials planning meeting (April 13–14, 2010) to advance the science of intervention research on CRF in the community setting. A link to the executive summary can be found at [http://transformingtrials.cancer.gov/files/Cancer\\_Related\\_Fatigue\\_CTPM\\_Executive\\_Summary\\_FINAL.pdf](http://transformingtrials.cancer.gov/files/Cancer_Related_Fatigue_CTPM_Executive_Summary_FINAL.pdf).

### **Sleep-Wake Disturbances**

Sleep-wake disturbances in patients with cancer continue to be the focus of research and publications by multidisciplinary teams often led by nurse scientists. Several review articles and book chapters were published (Berger, 2009; Berger & Mitchell, In press; Erickson & Berger, 2010; Kwekkeboom, Cherwin, Lee, & Wanta, 2010; Otte & Carpenter, 2009) but a meta-analysis of interventions for sleep-wake disturbances in patients with cancer has not been conducted to date. The sleep-wake disturbance section of the ONS Putting Evidence into Practice (PEP<sup>®</sup>) project was updated by Page, Berger, and Eaton (2009).

Two large randomized, controlled trials (RCTs) have been conducted using cognitive behavior therapy and behavior therapy. One study (Berger, Kuhn, Farr, Lynch, et al., 2009) showed group by time differences in the sleep intervention group of patients with breast cancer receiving adjuvant chemotherapy at the study midpoint, but not at the final endpoint (Berger, Kuhn, Farr, Von Essen, et al., 2009). The second study showed no differences between groups over time in a sample of various cancer diagnoses and stages with an intervention focused on fatigue and sleep (Barsevick, Stewart, et al., 2010).

Two pilot studies reported positive sleep outcomes. The use of therapeutic massage for 51 patients with breast cancer undergoing treatment (pre- and post-design) resulted in improved sleep after three weeks of 30-minute massages per week (Sturgeon, Wetta-Hall, Hart, Good, & Dakhil, 2009). Home-based *exercise* (n = 36) in a group with mixed

cancer diagnoses resulted in significant improvements in sleep quality compared with usual care (n = 36) (Tang, Liou, & Lin, 2010). No studies that tested education and information interventions were found.

Future research should include large RCTs to increase understanding of the active components of cognitive behavior therapy and behavior therapy interventions and to demonstrate effectiveness of complementary therapies, education and information, and exercise interventions for sleep-wake disturbances. Future research also needs to focus on translation of effective interventions into oncology clinical practice.

### **Changes in Cognitive Function**

Cognitive function is the information-processing component of behavior with multiple dimensions, including attention, learning and memory, executive functioning, mental flexibility, psychomotor speed, visuospatial ability, and language (Lezak, Loring, Hannay, & Fischer, 2004). Changes in cognitive function have been associated with cancer therapies (Bender et al., 2007; Corn et al., 2008; Jain, Krull, Brouwers, Chintagumpala, & Woo, 2008). Several meta-analyses have documented cognitive function related to cancer treatment (Anderson-Hanley, Sherman, Riggs, Agocha, & Compas, 2003; Falletti, Sanfilippo, Maruff, Weih, & Phillips, 2005; Jansen, Miaskowski, Dodd, Dowling, & Kramer, 2005). The domains of cognitive function that most commonly deteriorate during the cancer experience include attention, learning and memory, executive function, and psychomotor speed.

The science of cognitive function has been limited by the lack of pretreatment evaluation, comprehensive multidimensional neuropsychological assessments, methodologic deficiencies, and failure to account for competing explanations, including mood, treatment side effects, and other medications (Bender et al., 2007; Kayl, Wefel, & Meyers, 2008; Vodermaier, 2009). The long-term consequences of cancer and its treatment also remain unclear. Research to date suggests that adults with cancer have cognitive deficiencies prior to treatment when compared with healthy age-matched counterparts, which suggests that factors other than treatment could influence cognitive functioning (Ahles, 2007). Candidate mechanisms include difficulty coping with a cancer diagnosis, lingering effects of surgery or anesthesia, tumor-related factors, symptoms, and concomitant medications. Little is known about the pathophysiologic mechanisms underlying changes in cognitive function. Potential mechanisms include genetic susceptibility, DNA damage and telomere length, disruption of integrity of the blood-brain barrier, cytokine dysregulation, and reduction of estrogen and testosterone (Ahles, 2007; Dietrich, Monje, Wefel, & Meyers, 2008; Myers et al., 2008; Seruga et al., 2008; Taillibert, Voillery, & Bernard-Marty, 2007).

Assessment of cognitive function remains challenging because it requires the conduct of lengthy neuropsychological assessments. Clinical screening measures of cognitive function are not sensitive to the subtle changes that occur during the cancer experience (Vardy et al., 2007). A recent meta-analysis provided initial data on the sensitivity of neuropsychological tests used to evaluate chemotherapy-induced changes in cognition (Jansen, Miaskowski, Dodd, & Dowling, 2007). There are no proven pharmacologic or

nonpharmacologic interventions with demonstrated efficacy in managing changes in cognitive function. Behavioral interventions, including use of compensatory strategies and physical exercise, are being investigated (Ferguson et al., 2007; Kayl et al., 2008).

Future research related to changes in cognitive function should focus on (a) description of the long-term effects of cancer and cancer therapy on cognitive function, (b) identification of sensitive measures of cognitive function that can be applied in the clinical setting, (c) physiologic mechanisms and genetic susceptibility underlying changes in cognitive function, and (d) development and testing of interventions to ameliorate changes in cognitive function. Longitudinal studies should include pretreatment evaluations of cognitive function to distinguish baseline function from the effects of treatment.

### **Chemotherapy-Induced Peripheral Neuropathy**

Many traditional chemotherapy agents such as platinum, taxanes, vinca alkaloids and epothilones, as well as newer agents such as lenolidamide and bortezomib, can be neurotoxic (Quasthoff & Hartung, 2002; Windebank & Grisold, 2008). One element of that neurotoxicity is damage to the peripheral nerves, causing symptoms of numbness, tingling, hyperalgesia, hyperaesthesia, and pain. This symptom, chemotherapy-induced peripheral neuropathy (CIPN), can be progressive and irreversible. CIPN is one of the major causes for chemotherapy dose delays and reductions, jeopardizing a person's cancer outcomes. Besides being an unpleasant symptom that can disrupt sleep, CIPN can impair a person's functioning. Both fine and gross motor skills are impacted, such as the ability to button, fasten jewelry, carry things, and walk. The incidence of CIPN can range from 30%–70%, depending on the chemotherapy agent, cumulative dose, and personal risk factors (Kannarkat, Lasher, & Schiff, 2007; Windebank & Grisold, 2008; Wolf, Barton, Kottschade, Grothey, & Loprinzi, 2008).

To date, no proven pharmacologic or nonpharmacologic treatments exist for CIPN or for its prevention. There are also many unanswered questions related to its natural history and pathophysiology. In the past five to six years, nurse research scientists have focused on trying to better define the problem of CIPN and have begun intervention trials to try to ameliorate it. The ONS PEP statement on CIPN was first published in 2007 (Visovsky, Collins, Abbott, Aschenbrenner, & Hart, 2007). Most of the intervention research to date has been based on strategies with proven effectiveness for other types of peripheral neuropathy, in particular, diabetic neuropathy. This has not resulted in effective options in either prevention or treatment of CIPN. The most efficient way to move the science forward in this area is to better understand the natural history and pathophysiology of CIPN, as well as the risk factors that are important in predicting who is most likely to get CIPN and who is most likely to have progressive and irreversible symptoms. In addition, the lack of a universally accepted, well-validated measure of CIPN, including sensory and functional elements, is a barrier. The NCI-sponsored a clinical trials planning meeting addressed the critical need for effective interventions (March 23, 2009). An executive summary can be found at [http://transformingtrials.cancer.gov/files/CIPN\\_CTPM\\_Final\\_Executive\\_Summary\\_for\\_CCT\\_Aug\\_2010.pdf](http://transformingtrials.cancer.gov/files/CIPN_CTPM_Final_Executive_Summary_for_CCT_Aug_2010.pdf).

Important areas for future research include understanding self-reported symptoms and physiologic changes associated with the early development of CIPN, risk factors of patients who develop CIPN, and factors associated with more or less severe and/or irreversible symptoms. In addition, studies to elucidate in what ways the personal risk factors and physiologic changes are similar and different for each class of agents that are neurotoxic are needed. Current physiologic targets for prevention and treatment include serotonin and norepinephrine, vanilloid receptors, voltage-gated sodium and calcium channels, N-methyl-D-aspartate receptors, GABA receptors, and alpha receptors (Baron, 2006; Baron, Binder, & Wasner, 2010; Dworkin et al., 2010; Wolf et al., 2008). Clarification on how these targets fit within what is known about the pathophysiology of CIPN and the early onset of symptoms with various agents is needed. Nonpharmacologic strategies with promise include acupuncture, physical activity and exercise, and nerve stimulation procedures (Smith, Lai, & Cella, 2010; Visovsky et al., 2007). Large, rigorously designed trials are needed for interventions with promising pilot data and mechanistic objectives should accompany these studies. Finally, studies to further refine and validate the measurement of CIPN, both in terms of self report as well as physiologic markers, would be helpful.

### **Symptom Clusters**

Interest in exploring the science of symptom clusters has continued to be high (Barsevick, 2007a, 2007b). Several papers addressed conceptual and methodologic issues related to symptom cluster identification (Kim, Abraham, Kim, & Abraham, 2008; Miaskowski, Aouizerat, Dodd, & Cooper, 2007; Skerman et al., 2009). One systematic review was published (Xiao, 2010). Several studies have examined different statistical methods for identifying symptom clusters (Dirksen et al., 2009; Gwede, Small, Munster, Andrykowski, & Jacobsen, 2008; Kim et al., 2009b; Kim, Barsevick, et al., 2008; Maliski et al., 2008) and others have examined predictors and outcomes related to symptom clusters (Cheung, Le, Gagliese, & Zimmermann, 2010; Dodd et al., 2010; Ferreira et al., 2008; Kim et al., 2009a; Kozachik, Bandeen-Roche, Kozachik, & Bandeen-Roche, 2008). Little attention has been given to measurement of symptom clusters.

Several clinical trials have evaluated interventions to alleviate individual symptoms within a cluster with mixed results. A large RCT to evaluate centralized telephone-based care plus automated symptom monitoring was more effective than usual care in reducing two symptoms (pain and depression) in patients with cancer treated in urban and rural community-based oncology practices (Kroenke et al., 2010). An intervention for patients with lung cancer that included education plus progressive relaxation during radiotherapy demonstrated a beneficial effect on change in severity of a symptom cluster consisting of breathlessness, fatigue, and anxiety (Chan, Richardson, & Richardson, 2010). An intervention for persons undergoing stem cell transplantation consisting of education, exercise, and progressive relaxation resulted in an overall reduction in intensity of four of five symptom clusters for the intervention group (Jarden, Nelausen, Hovgaard, Boesen, & Adamsen, 2009). Two RCTs evaluating nursing interventions for gastrointestinal symptoms were not effective. Neither a structured nursing approach (advice, drug prophylaxis, nutrition counseling, and relaxation

training) nor a mobile phone-based remote monitoring and symptom management system was effective in reducing nausea and vomiting related to chemotherapy (Jahn et al., 2009; Kearney et al., 2009). A psycho-educational intervention for individuals with advanced disease was not effective in reducing symptom intensity, although it did improve QOL (Bakitas et al., 2009).

Future research on symptom clusters should determine criteria to be used in selecting symptoms for inclusion in a specific symptom cluster. The validity of rating scales of symptom clusters should be evaluated. Research is needed to determine whether assessment and management of a specific symptom cluster has positive effects on patient outcomes. Interventions that have been shown to influence more than one symptom need to be evaluated for their effect on a symptom cluster. Symptom clusters should be evaluated across cancer diagnoses, stages of disease, and cancer therapies. Work is needed to examine biologic pathways that influence multiple symptoms.

### **Systems of Care for Symptoms**

Symptom researchers have begun to address the implementation of symptom assessment in oncology clinical practice. One approach has been the use of technology to standardized clinical symptom assessment. Computerized symptom assessment systems are being developed for individual symptoms (Fann et al., 2009) and multiple symptoms (Koutnik-Fotopoulos, 2010; Tariman, Berry, Halpenny, Wolpin, & Schepp, 2009). One systematic review and pooled analysis of ultra-short distress assessments, including the distress thermometer (NCCN, 2010), showed that these are modestly effective in screening for mood disorders although the rule-out ability is stronger than the rule-in ability (Mitchell, 2007). Additional research is needed to evaluate symptom assessment and intervention systems for use in the clinical setting.

### ***C. Late Effects of Cancer Treatment and Long-Term Survivorship Issues***

**C.1.** Develop or test and implement interventions to prevent or minimize adverse outcomes related to long-term or late effects and risks associated with the development of comorbid illnesses.

C.1.1. Conduct intervention trials to reduce long-term risks from cancer therapy with special attention to high-risk populations, specifically childhood cancer survivors and adults at risk for cardiovascular toxicity and bone loss.

C.1.2. Design healthy lifestyle behavior interventions to maintain a healthy weight; improve physical, functional and psychological outcomes; minimize risk of recurrence; and prolong survival.

C.1.3. Conduct interventions that address social and work reintegration issues during and after cancer therapy.

C.1.4. Evaluate outcomes of survivorship intervention research on healthcare use.

## C.2. Explore factors associated with the delivery of quality cancer care to survivors.

C.2.1. Develop and test the effects and efficiency of models of care to support the Institute of Medicine's (IOM's) recommendation for survivorship care (e.g., treatment summaries, surveillance and health-promotion recommendations). Inherent in this effort is attention to unique needs of specific cancer populations.

C.2.2. Explore approaches that address system barriers to implementation of IOM recommendations.

C.2.3. Participate in health informatics initiatives to enhance cancer survivorship care delivery.

C.2.4. Explore effective ways to care for the growing number of survivors with attention to older adult survivors and minority populations.

C.2.5. Explore challenges facing oncology and the oncology nursing workforce related to survivorship.

### **Progress 2004–2010**

Over the past six years, a tremendous emphasis and increased awareness has been placed on cancer survivorship. Almost 12 million cancer survivors, or almost 4% of the population, live in the United States, and this number is expected to grow dramatically as more survivors live longer and the population ages. Cancer survivors report poorer health than the general population, lower QOL, more lost productivity, and more health limitations. Comorbid conditions such as diabetes, osteoporosis, and heart disease are common among survivors and have significant implications for collaborative care models in survivorship care (Cheung, Neville, Cameron, Cook, & Earle, 2009; Edgington & Morgan, 2011; Ganz, 2009). The recognition of long-term and late effects contributing to premature death in disease-free survivors has increased the need for surveillance guidelines, health promotion, identification of long-term and late effects and interventions to minimize adverse cancer treatment effects. The IOM's report (Hewitt, Greenfield and Stovall, 2006) *From Cancer Patient to Cancer Survivor: Lost in Transition* describes the state of the science. In that report, the IOM identifies eight domains of cancer survivorship research: descriptive and analytical (e.g., physiological and psychological effects), intervention research (e.g., to prevent or reduce adverse physiological or psychological effects), examination of survivorship sequelae in understudied cancer sites, follow-up care and surveillance, economic sequelae, health disparities, family and caregiver issues, and instrument development. In addition, the IOM's report (Adler and Page, 2008), *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*, identifies the gaps between the attention to biomedical aspects and psychosocial problems associated with cancer and its treatment. The IOM recommend that all patients with cancer and their families should expect and receive cancer care that ensures the provision of appropriate psychosocial health services.

The NCI's Office of Cancer Survivorship identifies five focal areas of research: chronic and late effects of cancer and its treatment, interventions, healthy lifestyle behaviors, benefit finding, and posttraumatic growth, and family. Over the past five years, the small grants program supported by ONS Foundation has awarded several small grants on long-term or late effects. The Lance Armstrong Foundation (LAF) has committed to survivorship care and research. Currently, eight NCI-designated comprehensive cancer centers are members of the LIVESTRONG® Survivorship Center of Excellence Network: University of Pennsylvania; Dana-Farber, Fred Hutchinson, Memorial Sloan-Kettering, Ohio State University, UCLA, University of Colorado, and University of North Carolina ([www.livestrong.org](http://www.livestrong.org)). While each center has created a unique survivorship program, they collectively serve as centers for model development and education (Ganz, 2009). However, significant challenges and system barriers still exist at the cancer center level as well as the community oncology practices to implement comprehensive survivorship care that is feasible, cost effective, and improves patient outcomes (Jacobs et al. 2009; Morgan, 2009).

## **Rationale and Background**

**C.1.** Many cancer survivors experience persistent effects of cancer treatment (e.g., peripheral neuropathy, fatigue, vasomotor symptoms associated with premature menopause of endocrine therapy, alterations in sexuality and fertility) (Feurstein, 2007; Ganz, 2007; Hewitt, Greenfield and Stovall, 2006). Long-term survivors have evidence of late effects, such as cardiovascular problems and psychological distress (Carver, Shapiro, Ng, et al. 2007; Ewer & Ewer, 2010; Hoffman, McCarthy, Recklitis, & Ng, 2009; Morris et al., 2009). Also, the majority of patients who undergo cancer treatment become physically deconditioned during the course of therapy, develop persistent fatigue, and may experience adverse psychological responses to the diagnosis and treatment. Sedentary behavior, being overweight or obese, and eating diets high in calories and fat are prevalent among the U.S. population and cancer survivors and are risk factors for diabetes, heart disease, and cancer (Eyre, Kahn, Robertson, et al., 2004; Mayer, Terrin, Menon, et al., 2007). Obesity is a risk factor for selected cancers, a strong risk factor for comorbid conditions, and is associated with a negative survival outcome (Wolin, Carson, & Colditz, 2010; Edgington & Morgan, 2011).

Compelling data points to health promotion in cancer survivors as a way to maintain a healthy weight and cardiovascular fitness, to enhance physical and psychological recovery from treatment, and to minimize risk for chronic illness (de Backer, Schep, Backx, Vreugdenhil, & Kulpers, 2009; Knobf, Musanti, & Dorward, 2007; Speck, Courneya, Masse, Duval, & Schmitz, 2009). A growing body of evidence from cohort studies with survivors of breast and colorectal cancer suggests that routine physical activity may decrease risk of recurrence and improve survival (Demark-Wahnefried, 2006; Meyerhardt, Giovannucci, Holmes, et al., 2006).

**C.2.** Survivorship programs are being created and implemented; however, to date, they provide care to only a select population of cancer survivors. There is a need to explore system issues, financial considerations, and provider issues that support or impair the

ability to provide quality care to the larger population of survivors. Electronic health records that can populate cancer survivorship treatment summaries and care plan templates are needed to facilitate widespread adoption of this IOM recommendation. Additional studies are needed on the impact these care plans have on patient outcomes. Consensus guidelines on surveillance and follow-up for different cancer sites are just emerging (Hollowell et al., 2010) and will need to be evaluated related to patient outcomes and cost effectiveness (Ganz, 2009; Jacobs et al., 2009).

The U.S. population is aging and becoming increasingly ethnically diverse. By 2030, the U.S. population will increase to approximately 365 million, including 72 million older adults (aged 65 years or older) and 157 million minority individuals. From 2010–2030, the total projected cancer incidence will increase by approximately 45%, from 1.6 million in 2010 to 2.3 million in 2030. This increase is driven by cancer diagnosed in older adults and minorities. Survivorship care must also address disparate outcomes for ethnic populations, many of whom are at higher risk for comorbid illness (Tammemagi, Nerenz, Nesluund-Duda, Feldkamp & Nathanson, 2005). These challenge the models of care between the oncologists and primary care providers. Finally, the growing number of cancer survivors and the predicted shortage of oncology specialists pose interesting workforce challenges and a need to explore shared care and nurse delivered models for the delivery of survivorship care (Oeffinger & McCabe, 2006).

### **Resources for Priorities**

As identified in the IOM report (Hewitt, Greenfield and Stovall, 2006), there is a need to conduct descriptive as well as intervention research. The IOM identifies multiple resources, specifically, the NIH, NCI's Office of Cancer Survivorship, Department of Defense, Agency for Health Care Research and Quality, Centers for Disease Control, the American Cancer Society, the LAF, and Susan G. Komen for the Cure<sup>®</sup>. The ONS Foundation, as noted above, also supports survivorship research. Many universities and some cancer centers may also provide small grants or intramural funds for pilot studies in the area of survivorship as do some cancer advocacy groups. These small grants should be funding pilot or preliminary data leading to intervention studies addressing survivorship issues.

### **D. End-of-Life Issues**

Although no exact definition of EOL exists, it is a period of time marked by disability or disease that is progressively worse until death (NIH, 2004).

**D.1.** Develop knowledge of mechanisms and management of symptoms for patients with cancer near EOL and their families.

D.1.1. Develop or evaluate efficacious, feasible, cost-effective, culturally sensitive interventions for patients with cancer near EOL and their families.

D.1.2. Validate culturally sensitive symptom measures for assessing symptoms for patients with cancer near EOL and their families.

**D.2.** Develop knowledge that promotes QOL for patients with cancer near EOL and their families.

D.2.1. Conceptualize, develop, and validate specific measures of QOL for diverse groups.

D.2.2. Develop and/or evaluate efficacious, feasible, cost-effective, culturally sensitive interventions and systems of care for supporting QOL in patients with cancer near EOL and their families.

D.2.3. Develop and/or evaluate interventions for implementation early in the cancer trajectory to promote anticipation, discussion, and/or preparation for EOL issues for patients with cancer and their families to enhance QOL near EOL.

### **Rationale and Background**

**D.1.** In an extensive review of the research on improving palliative care near the end of life by Lorenz et al. (2008), the authors suggested that the most common symptoms experienced near EOL are fatigue, pain, dyspnea, nausea, appetite loss, dry mouth, constipation, difficulty sleeping, confusion (delirium), anxiety, and depressed mood. Effective symptom management at EOL has been the focus of several research studies; however, the evidence is weak for symptoms such as constipation, fatigue, delirium, and dyspnea (Bookbinder & McHugh, 2010). Another systematic review suggested that there are inadequate assessment tools and intervention research to manage distress, sadness, and depression with persons near EOL (Wasteson et al., 2009). The development and evaluation of interventions in the areas of constipation, delirium, dry mouth, difficulty sleeping, distress, sadness, and depression for persons near the EOL are critical. In addition, information about differences in cultural and ethnic groups in the U.S. and worldwide is largely missing from these studies, as are symptom measures that have been validated on groups with varying ethnic backgrounds (Braga et al., 2007). Therefore, additional research that validates symptom measures and evaluates symptom management interventions for patients with cancer near the EOL and their families with age specific and culturally diverse groups is needed.

**D.2.** Research on QOL near EOL is fundamental to achieving the international goal of palliative or EOL care, which is to enhance QOL for patients and family members (Ferrell et al., 2007). QOL near EOL literature has focused primarily on patients; however, near EOL, the QOL of caregivers and families is equally important (Stajduhar et al., 2010). QOL measures are now being used to predict survival in palliative care patients (Grande, Farquhar, Barclay, & Todd, 2009) and, as such, have major implications for planning of provision of care. However, two systematic reviews of QOL instruments used with persons at EOL suggested that they do not reflect all the domains of QOL and often are burdensome (Albers et al., 2010; Grant & Sun, 2010). Important existential dimensions such as spirituality and hope in QOL often are missing. A review of studies on spirituality (Edwards, Pang, Shiu, & Chan, 2010) and hope (Kylma, Duggleby, Cooper, & Molander, 2009) at EOL confirm the importance of these

concepts. As well, QOL measures that are valid in culturally diverse and age-specific populations (pediatrics and older adults) need further development and evaluation. Few interventions have been developed that impact QOL for patients with cancer near EOL (Bakitas et al., 2009; Duggleby et al., 2007; McMillan & Small, 2007) and their families (Hudson, Remedios, & Thomas, 2010). There is a growing recognition that interventions early in the cancer trajectory are needed to improve QOL near EOL (Bakitas et al., 2009; Temel et al., 2011). Along with the development of tools to measure QOL, there remains the need to develop interventions that are culturally sensitive, feasible, and cost effective for patients near EOL and their families

## **E. Psychosocial and Family Issues**

**E.1.** Well-designed intervention studies to reduce negative outcomes and improve positive outcomes in patients with cancer and their family caregivers

E. 1.1. Research to test patient and family models that encompass both risk factors and protective factors and their relationship to outcomes

E.1.2. Intervention studies that identify patients and caregivers at higher risk of poorer outcomes and target interventions to meet their needs. These studies need to address cancer-related cost and resource use issues for patients and families.

### **Rationale**

**E.1.** In spite of many descriptive studies that document the stressful effects of cancer on family caregivers, only a few intervention studies have been conducted that include partners or other family caregivers (Cochrane & Lewis, 2005; Kim & Given, 2008). Intervention studies have lagged far behind descriptive research and the quality of some existing research is limited (Cochrane & Lewis, 2005). In view of the increasingly complex cancer care offered in community settings, a need exists for well-designed randomized clinical trials that help patients and their family caregivers increase their preparation, self-efficacy, and coping skills to manage illness; reduce their caregiver burden and emotional distress; and improve their QOL (Given, Sherwood, & Given, 2009; Keefe, Ahles, Porter, et al., 2003; Kershaw, Northouse, Kritpracha, Schafenacker, & Mood, 2004; Northouse, Mellon, Harden, & Schafenacker, 2009; Schumacher et al., 2008). A recent systematic review of studies on family caregivers by Stenberg, Ruland and Miaskowski (2010) and a meta-analysis of randomized clinical trials with family caregivers by Northouse, Katapodi, et al. (2010) both indicate the need for studies with samples of patients with cancer and family caregivers that have more racial, cultural, and socioeconomic diversity. The previous meta-analysis findings also indicated the need for more studies that examine caregivers' self-care behaviors and physical outcomes. The importance of research in this area is underscored in a study by Rohleder et al. (2009) who found that family caregivers of patients with cancer experience changes in their neurohormonal and inflammatory processes in the year following the patient's diagnosis, and that these changes may place caregivers at

greater risk for morbidity and mortality from diseases associated with excessive inflammation.

A direction in intervention research that continues to be important based on meta-analysis findings is identifying patients and family members at higher risk of more distress or poorer outcomes, and targeting interventions to those most in need. For example, in a recent study, McCorkle et al. (2009) screened patients for distress and offered those with more distress a psychiatric consultation, in addition to intervention sessions with an advanced practice nurse, which resulted in better outcomes. Interventions also are needed that target at-risk caregivers and distinguish between those who are burdened or depressed (Given et al., 2009). Caregivers of patients in the advanced phase of cancer may be an at-risk group because they report more depression than patients (Braun, Mikulincer, Rydall, Walsh, & Rodin, 2007) and seldom seek mental health services for their heightened anxiety and emotional distress (Vanderwerker, Laff, Kadan-Lottick, McColl, & Prigerson, 2005). Female patients and female caregivers also may be an at-risk group because a meta-analysis by Hagedoorn, Sanderman, Bolks, Tuinstra, and Coyne (2008) found that they are more distressed than male patients and male caregivers. Older adult caregivers (65-85 years of age) of patients and those who among the oldest (>85 years of age) are another at-risk group for which research is needed.

In order to identify high-risk patients and family members, a comprehensive screening tool is needed that can address a range of psychosocial stressors that interfere with patients' and caregivers' ability to manage the illness and maintain their QOL. A few studies since 2004 have reported on ways to identify high-risk patients and/or family members using the Family Relationship Inventory (Edwards & Clarke, 2004), the distress thermometer (Zwahlen, Hagenbuch, Carley, Recklitis, & Buchi, 2008), and predictors of depressed mood (Lewis, Fletcher, Cochrane, & Fann, 2008). Not all patients and caregivers need intensive programs of care. Determining what program is optimal for which patients and caregivers will produce better outcomes and use fewer healthcare resources.

In a time of limited resources, there is also a pressing need to examine cost and potential cost savings associated with interventions. According to Mandelblatt et al. (2008), a number of interventions have examined the economic benefit of interventions to increase cancer screening, but few have addressed cost and effects of behavior interventions in cancer survivorship. Recent studies by Bakitas et al. (2011) and by McCorkle et al. (2011) examined intervention effects and resource use in clinical trials. They found that cost-effectiveness as well as appropriate use of resources should be considered when assessing the economic benefits of interventions. There also is a need to document the value added by family members to patient outcomes in terms of duration of symptoms, QOL, untoward hospitalizations, emergency department visits, and caregiver outcomes (Given et al., 2009). In order to translate efficacious nursing interventions to practice settings, the cost of delivering interventions and their ability to reduce healthcare costs need to be assessed. Finally, in an era of cost constraint, a need exists to examine alternative modes of intervention delivery. Internet interventions

have the potential to meet the needs of patients and caregivers in a more cost-effective manner (Ritterband et al., 2003).

### **Progress Between 2004–2010**

A priority topic in the 2004–2007 ONS Research Agenda was to develop new models of individual and family adjustment to cancer and its treatment, incorporating concepts representing positive aspects of health and adaptation to illness. The use of qualitative approaches to describe meaningful and integrative positive health experiences was noted. Also noted was the lack of a common language, the relatively unfocused nature of research on positive concepts, specification of only a few mechanisms by which positive adjustment occurs, and the minimal number of interventions specifically targeting positive concepts.

Since 2004, the small but subtle shift toward research on positive health and adjustment noted by the previous agenda-setting team has continued. Considerable additional qualitative research has significantly increased researchers' understanding of the positive aspects of the cancer experience. This body of work is international (Lindqvist, Widmark, & Rasmussen, 2006; Mattsson-Lidsle, Snickars-von Wright, Lindholm, & Fagerstrom, 2007; Taleghani, Yekta, Nasrabadi, & Silvia, 2008), providing a basis for understanding global similarities and differences. However, only a few studies have explored positive health concepts in diverse cultural and ethnic groups in the U.S (Hamilton, Powe, Pollard, Lee, & Felton, 2007; Leak, Hu, & King, 2008; Morgan et al., 2005). Concepts most often explored include hope, spirituality, meaning, relationship with God or a higher power, commitment, healing, and transcendence (Chou, Liaw, Yu, & Tang, 2007; Prince-Paul, 2008; Reb, 2007). Research on these concepts is now sufficiently well developed that we could begin to tease out the differences between strengths individuals bring to the cancer experience and transformative changes that may occur as a result of the cancer experience or as the result of an intervention (Fife, Monahan, Abonour, Wood, & Stump, 2008). Model development and instrument testing remain limited, with only a few notable exceptions (Cole, Hopkins, Tisak, Steel, & Carr, 2008; Morrill et al., 2008; Reb, 2007). A few studies have tested interventions aimed at increasing positive adjustment. Examples include a study to test the effect of an animal-assisted activity on sense of coherence (Johnson, Meadows, Haubner, & Sevedge, 2008), an intervention to test the effect of a story-telling intervention on stress outcomes (Crogan, Evans, & Bendel, 2008), the effect of a life review intervention on spiritual well-being and happiness (Ando, Morita, Okamoto, & Ninosaka, 2008), and interventions using art as a way of self-transcendence (Lane, 2008; Walsh, Radcliffe, Castillo, Kumar, & Broschard, 2007).

The growth of studies addressing concepts of positive health, adaptation, and transformation has provided an important counterweight to the studies of distress that predominate in patient and family psychosocial and behavioral research. However, the 2009 agenda-setting team did not see research on positive adaptation versus distress as an "either/or" choice for the new ONS research priorities. Rather, as researchers have begun to study (Morrill et al., 2008; Thompson, 2007; Whitford, Olver, & Peterson, 2008), concepts pertaining to both resilience and adaptation *and* stress and distress

need to be incorporated into family-focused psychosocial and behavioral research. Doing so will lead to a better understanding of which individuals are most in need of intervention and which interventions are most efficacious.

A review of ONS funding in 2009 indicates that nine applications that were related to psychosocial outcomes were submitted but none were funded. In 2010, six proposals were submitted related to psychosocial outcomes and four were funded (67%).

A review of the ONS 2008 research priorities indicates that ONS members ranked caregiving and family adjustment to cancer in the top 20 of all ONS priorities. Both of these content areas increased dramatically in importance since 2004. Caregiving was ranked 48<sup>th</sup> in 2004 and moved to 15<sup>th</sup> in 2008. Family adjustment to cancer was ranked 39<sup>th</sup> in 2004 and increased to 18<sup>th</sup> in 2008. In summarizing the findings of the 2008 survey, Doorenbos et al. (2008) stated that the high rankings of caregiving and family adjustment to cancer indicate the increasing importance of family caregiving roles and the need to focus on family psychosocial issues. These investigators, and members of the team who developed the ONS PEP resources on caregiver burden, contend that oncology nursing research needs to test interventions to help families manage caregiving demands and facilitate family adjustment to cancer (Doorenbos et al., 2008; Honea, Brintnall, Given, et al., 2008).

## **E.2. Research focused on the impact of high risk for cancer, including a family history of cancer, on individuals and families**

E.2.1. Exploratory research in areas pertaining to family communication and family functioning in disclosing test results, conflict and regret about pursuing genetic testing, role of significant others in decisions to pursue testing, and genetic testing in minority families

E.2.2. Testing of interventions using decision aids, risk communication strategies, and educational support for probands and their families

### **Rationale**

**E.2.** Progress in genetic testing is occurring at a rapid rate and continues to raise a number of psychosocial questions because of its widespread availability (Meiser, 2005). Interest in this area is increasing, as evidenced by an entire issue of *Psychosocial Oncology* recently devoted to genetic testing and counseling (Patenaude, 2008). However, research remains limited. Families need more information to understand the basics of genetic illnesses and to address the risks and challenges they face knowing that they are at higher risk of developing cancer (Baumann, 2006). A large proportion of families undergoing genetic testing receive inconclusive results; therefore, the impact of uncertainty in the context of uninformative genetic test results is an area for further research (Meiser, 2005). Partners of some women at risk of breast and ovarian cancer report elevated distress in adjusting to their wives' health threat. Because partners play a critical role in facilitating decision making and providing support to these women, more research is needed on ways to involve partners and to provide them with information

and support (Mireskandari et al., 2006). Exploratory research about family communication and family functioning in respect to disclosing test results, perceived conflict, and regret about one's decision to pursue genetic testing is limited but growing (Aktan-Collan et al., 2011, Chivers et al., 2010). Intervention research is particularly limited in this area. Areas for future intervention research include ways to provide risk communication to the proband (person who chooses to be tested), use of decision aids for genetic testing, and ways to support the proband to disclose test results to family members. Testing of theoretical models that explain and predict the impact of genetic information on family dynamics might provide useful guidelines for the development of risk communication, genetic test disclosure, and decision aids interventions (Smith et al., 2011).

A review of the grants funded by the ONS Foundation that are pertinent to the impact of inherited risk of cancer on families indicated that three small grants were submitted from 2004–2008, but none of these small grants were funded. One major grant pertaining to genetic risk and families was funded during the four years. In 2009 and 2010, there were no applications for funding in this priority area. More research proposals need to be developed and funded in this area.

From the review of the 2008 survey of the ONS members, priorities pertaining to high-risk families and family genetics were not among the priorities identified (Doorenbos et al., 2008). It is possible that family genetic risk may have been included in the broader area of family adjustment to cancer, but that is not evident from the discussion of survey findings. There were, however, four individuals who wrote “genetics” as an important research priority. In view of the importance of genetics and the family, items pertaining to genetics and families need to be clearly delineated in future surveys.

### **Progress Between 2004–2010**

Since 2004, a growing number of studies have addressed this priority area. Researchers have found that knowledge of hereditary cancer risk factors is limited (Katapodi & Aouizerat, 2005, Weinrich et al., 2007). Studies have identified a lack of congruence between perceived risk, worry about cancer, use of expert consultation, objective risk factors, and genetic contributions to risk (Katapodi et al., 2009; Lancaster, 2005; Quillin et al., 2011). Interpretation of inconclusive test results may be rooted in individuals' perceived inherited risk (Maheu & Thorne, 2008) while emotional responses may be moderated by coping style (Shiloh et al., 2008). Women who perceive they have higher risk for developing breast cancer are more likely to seek genetic testing (Katapodi et al., 2004).

Research on the dynamics of communication of genetic testing results within families remains limited although it is increasing (Clarke et al., 2008; Koehly et al., 2008; MacDonald et al., 2007; van Oostrom et al., 2007). Few studies address communication between parents and offspring (Aktan-Collan et al., 2011; Peshkin et al., 2010). Research on diverse cultural perspectives also is slowly increasing (Kinney et al., 2010; MacDonald et al., 2008; Pal et al., 2011). Recently discussed ethical issues pertaining to genetic testing and families include the potential role for genetics services in

contacting at-risk relatives of deceased carriers of *BRCA2* mutations (Ormondroyd et al., 2008). A promising area for intervention research revolves around the enhancement of family communication process regarding hereditary cancer risk and the disclosure of test results. Specific needs identified are the development of educational materials, which mutation carriers can use to communicate genetic test results and cancer risks to family members, or interventions involving a staged approach, where family members are notified of their increased risk either face-to-face, via a letter, or through Web site resources (Ratnayake et al., 2010). Although increasing, research on family communication and functioning in relation to genetic testing is still in an early stage.

## **F. Nursing-Sensitive Patient Outcomes (NSPOs)**

**F.1.** Evaluate the effect of nursing care on promoting and maintaining treatment adherence.

F.1.1. Understand predictors (risk model), costs, settings, side effects, educational approaches, population, health literacy, and cognitive changes associated with adherence to oral chemotherapeutic agents.

F.1.2. Evaluate strategies for various innovative models of care (e.g., APN-led teams, patient-centered medical home, chronic care models) and the cost effectiveness related to adherence of care issues.

F.1.3. Explicate the issues of adherence in all aspects of a plan of care, including clinical trial participation, medications such as oral chemotherapeutic agents, diet, and self-care strategies.

F.1.4. Evaluate strategies for the identification and prevention of adverse events related to treatment, such as vascular devices.

F.1.5. Develop or test interventions that support adherence to care.

## **Rationale and Background**

**F.1.** Additional research is needed to fully develop the area of adherence. Adherence to oral chemotherapeutic agents and in all aspects of the care trajectory for patients with cancer, including the setting (inpatient and ambulatory care) and how care is organized and managed (cancer center, hospital, and community setting), is needed to identify patient and care provider obstacles. The barriers to adherence (i.e., side effects, cost, education, care provider approach, health literacy, the patient's cognitive status, and caregiver involvement) need to be considered. Adherence to care is a multifaceted problem. Predictive models of adherence to various aspects of care are not available. Research on the treatment effectiveness of education, both cognitive and behavioral, for various aspects of cancer treatment, remains limited in scope.

Knowledge about education, both cognitive and behavioral, and exercise interventions is more advanced in the area of breast cancer and needs additional development in other types of cancers. The research in the area of breast cancer also needs to be

extended, but the body of research to date could be used as a model for extending research into other types of cancer.

As models of all aspects of adherence predictors are developed, future studies could use the data to develop and test interventions for oral medication adherence and an adherence-to-care regimen. The impact of rendering a higher percentage of care in the outpatient setting and the cost-effectiveness of such practices need additional consideration. Beyond adherence to medication, many nursing sensitive interventions that correlate with the recommendations from the ONS PEP resources continue to need additional research.

### **Progress 2004–January 2011**

The NSPO focus on treatment adherence with oral agents was due to the growing number of oral agents available, shifting responsibility from inpatient care to the outpatient setting, and the need for the patient to closely follow-up and adhere to care. Prior to 2005–2009, no studies were funded by the ONS Foundation that targeted specific areas of infection, maintenance or promotion of physical function, functional status, and treatment. In 2004–2005, three studies were funded, with one focusing on prevention of adverse events, one on nursing interventions, and one on prevention of fatigue. Three studies were funded from 2006–2007: one on workforce issues (pain and nursing quality as related to certification) and two on adherence to treatment. In 2009 and 2010, one study each year focusing on adherence to treatment was funded by ONS Foundation and one study was funded by National Institute of Nursing Research that tests a biobehavioral intervention for patients with breast cancer. From 2009–2011, 19 studies were conducted and published by nurses and other healthcare professionals that addressed various aspects of cancer care and interventions. Several directly measure patient focused interventions (Dodd et al., 2010; Ingersoll et al., 2010; Rustoen, Mayer, & Miaskowski, 2010), whereas others measure interventions with pediatric patients (Ekti et al., 2008; Judge-Santacroce et al., 2010; Kato, Cole, Bradlyn, & Pollock, 2008).

For this updated review, treatment adherence focused on work that has been completed since the last agenda on adherence to oral agents but was expanded to additional nursing outcome efforts that study predictors and correlates of change in physical functioning during cancer treatment and adherence to all aspects of care. Several reviews of adherence research (Kelly & Agius, 2007; Palmieri & Barton, 2008) found the studies reviewed to be deficient in overall quality. Several intervention studies were located that tested different modalities to increase adherence to oral chemotherapeutic agents in adults (Espie et al., 2008) and adolescents (Malbasa et al., 2007) and to pain medication (Valeberg et al., 2008). Several clinical articles were found that would be useful in helping to identify future research studies (Greer, Pirl, Park, Lynch, & Temel, 2008; Lette & Lette, 2008; Miaskowski, Shockney, & Chlebowski, 2008). A variety of studies were located that dealt with adherence to various components of cancer treatment, reflecting a broader range of intervention research (Chung & Hwang, 2008; Daley et al., 2007; Fahey et al., 2008). Since the last review in early 2009, six studies have been conducted by nurses and other healthcare groups that have addressed

adherence and various oral medications (Denois et al., 2010, Eliasson et al., 2010, Hawwa et al., 2009, Hubery et al., 2009, Partridge et al., 2010, Partridge, et al., 2008). The majority of these studies, though well developed, were small with both cross-sectional and limited longitudinal data.

From 2005–2009, there was a call for innovative studies possibly using health message education for behavior change. Several studies were found that tested psycho-educational interventions, cognitive and behavioral interventions, nutritional interventions (Demark-Wahnefried & Moyad, 2007; Kangas, Bovjerg, & Montgomery, 2008; Knobf, Insogna, DiPietro, Fennie, & Thompson, 2008; Wyatt et al., 2007), and exercise (Pinto, Rabin, Abdow, & Papandonatos, 2008), but none used health message education. From 2008–2011, Decker et Al. (2009), in a pilot study, assessed the use of an automated voice response system and a nursing intervention to monitor adherence to oral medications. Kimman et al., (2010) explored patient satisfaction with nurse-led telephone follow-up after curative treatment for breast cancer and Curran and Meister (2008) studied a hospital based intervention to decrease distress in patients with cancer. Two studies focused on instrument development. One group developed an instrument to measure adherence to strength training (Huberty et al., 2009) and another a teaching tool for patients receiving oral agents (Kav et al., 2010).

A review of funding by ONS Foundation from 2009– 2010 indicated that of the six studies submitted in 2009 and the eight submitted in 2010, only one small grant was funded in each year. Also, during this period, the PEP resources for prevention and management of bleeding in patients with cancer was released for use.

A priority topic for the NSPO area was treatment adherence with oral agents due to the growing number of oral agents being used and the shifting responsibility from inpatient to outpatient care. This focus in the healthcare system continues to grow, requiring patients and families to increase their responsibility and understanding of self care. For this updated review treatment adherence focused on the work completed since the last agenda publication. Some progress has been made in the area of adherence. Interesting additions have been in the area of using messages and in instrument development. The review, as the last, included nursing outcome efforts that focused on study predictors and correlates of change in physical functioning during cancer treatment and adherence to all aspects of care.

### **Underserved or Minority Populations and Treatment Adherence**

The 2005–2009 report identified the need to research adherence in minority populations. No studies were found during that timeframe that focused solely on minorities. Three interventions studies were found that focused on screening adherence in urban and minority populations. For the 2009–2011 update, no studies were found that solely focused on minorities. Minority populations are included in all studies, but as a component of the sample. Another issue which needs to be addressed is cultural diversity in the development and use of interventions.

### **Future (2011–2013)**

Strides have been made in studying adherence to oral treatments as well as intervention studies for various aspects of cancer care. The studies typically are small and lack wide representation of various subject groups. As treatments options grow and change, it is important for research to test the nursing sensitive outcomes related to newer treatments in all populations and disease sites. Attention to treatment fidelity within and across demographics, disease, and culturally diverse groups is important. Changes in managed care and reimbursement also require researchers to capture cost-effectiveness of nursing outcomes and interventions.

## **F.2.** Expand knowledge regarding relationships between physical function and NSPO.

F.2.1. Explicate the relationship between nursing interventions and physical functioning for patients with cancer.

F.2.2. Evaluate the relationship between physical function and falls with injury for patients with cancer.

### **Rationale and Background**

**F.2.** Functional ability has been defined as the capacity to perform normally expected activities and tasks in pursuit of the fulfillment of life roles (ONS Research Agenda, 2004). The concept of physical function includes the biological, psychological, and social perspectives, and is a key determinant in patient perceptions of QOL. The concern regarding physical functioning and late effects of cancer treatment have only recently been documented; these deficits are anticipated to increase as anti-cancer therapies become more complex, and as the age threshold for active treatment continues to expand (Hewitt, Rowland, & Yancik, 2003; Snyder et al., 2008).

Perhaps because of the variety of inputs identified contribute to physical functioning, empirical research in this area remains underdeveloped. Clinicians may often accept physical function declines, in part because the primary goal may be eradication of cancer. This perspective neglects the persistent and deleterious effects of physical function declines in patients. In addition to alterations in social, family, and work roles, the risks of increased adverse events (such as falls and fractures) require clinicians to assess physical function before, during, and after cancer therapy, and to intervene appropriately.

### **Progress (2004– 2011)**

#### **Physical Function**

Research in studying the concept of physical function in patients with cancer has expanded, with an observed increase in publications. The studies often measure physical function in conjunction with related concepts, such as pain, fatigue or health-related QOL. Additional data are now available to link commonly used treatments for cancer and changes in physical function. Specifically, androgen-deprivation (Alibhai, Gogov, & Allibhai, 2006; Bylow, Mohile, Stadler, & Dale, 2007), surgery (Amemiya et al., 2007), radiation therapy (Silver, Dietrich, & Murphy, 2007), and systemic chemotherapy

(Given, Given, Sikorskii, & Hadar, 2007; Goodwin, 2007; Visovsky, 2006), have all been implicated in physical function declines for patients.

### **Measurement**

The Patient Reported Outcomes Measurement Information System (PROMIS) continues to develop, collate, test, and generate item banks of questions on a variety of relevant phenomenon, including physical function (NIH, n.d.). Readers are encouraged to browse the PROMIS Web site to search for related measures available for electronic or paper questionnaires.

In the specific setting of head and neck cancer, an international, interdisciplinary effort continues to develop and validate a comprehensive index of functioning for patients with head and neck cancer (Becker, Kirchberger, Cieza, Berghaus, Harreus, Reichel, & Tschiesner, 2010). This initiative serves as a useful model for other research groups to develop multi-dimensional measurements with strong internal and external validity.

### **Intervention Studies**

In prior research agenda plans, a specific recommendation was made to increase efforts to develop and test efficacious interventions for physical function. A series of literature reviews and empirical analyses suggest that exercise and physical activity are likely to improve physical function in patients with cancer (Conn, Hafdahl, Porock, McDaniel, & Nielsen; 2006; Luctkar-Flude, Groll, Tranmer, & Woodend, 2007; Knobf, Musanti, & Dorward, 2007). Since the previous report, several studies have now been published. An encouraging sign is the increased number of randomized trials that test effects of interventions on physical functioning. A three-arm randomized trial associated the receipt of relaxation instruction with an increase in the number of usual activities performed for patients (Christman & Cain, 2004). In one underpowered randomized trial, a marginal benefit of a diet and exercise regimen on physical functioning was observed (Demark-Wahnefried et al., 2006). In another randomized trial of a cognitive behavioral intervention, improvements in physical function were noted. However, personal and health characteristics of patients moderated the effect of this intervention (Doorenbos, Given, Given, & Verbitsky, 2006). These studies would suggest modest improvements in physical functioning are obtainable with nursing interventions. However, attention to sample size and study power, as well as confounding variables is important.

In 2009, Conn et al. (2009) published a meta-analysis summarizing data from 66 studies that used pre- and post-test comparisons to examine effects of physical activity interventions in patients with chronic illness. Of these, 22 comparison groups included cancer diagnoses. Across all studies, patient groups who received a physical activity intervention had significantly higher QOL scores following the intervention than controls with a modest overall effect size (0.27). In a secondary analysis, effect sizes were greatest for cardiac (0.21), cancer (0.15), and diabetes (0.04). Conn et al. pointed to the heterogeneity of outcome measures and the duration and dosing of interventions as possible contributors to modest effects.

### **Physical Function and Falls With Injury**

The recent policy decision by the Center for Medicare and Medicaid Services (CMS) to deny hospital reimbursements in cases where injurious falls have occurred, may provide a key advantage to link care providers and researchers to address a problematic area (Neergaard, 2008). A literature review identified one peer-reviewed, databased clinical study that examined the relationship between physical function and falls in a sample of patients receiving androgen-deprivation therapy for prostate cancer (Bylow et al., 2008). In 2011, the same literature search identified three new papers. A single-site study identified patterns and correlates of falls patients seeking care at a comprehensive cancer center (Overcash, Rivera, & Van Schaik, 2010). More recently, an NINR-funded doctoral dissertation explored patterns and correlates of falls in older adults with a cancer diagnosis using the Minimum Data Set (MDS) for a home and community-based service population (N = 967) (Spoelstra, Given, von Eye, & Given, 2010); 263 (27.2%) experienced a fall. The percent of patients who fell with injury was not reported. Increased assistive need with activities of daily living, female gender, presence of depression, and presence of pain were significant predictors of falls in multivariable analyses. The reliance on administrative data precluded examination of specific cancer diagnoses or stage.

Anecdotal reports from hospital leaders indicate a pervasive problem with injurious falls in patients with cancer. Although it may seem logical to link physical function with injurious falls, continued research in a multivariate context is required to disentangle this relationship. Following descriptive research in this population, novel interventions will be ripe for development and testing.

### **Research Funding Review**

The NIH database and the list of funded research projects from ONS were reviewed to identify active grants between 2009–2011 that study explicitly the physical function of patients with cancer (\* denotes PI is a nurse scientist).

- a. NIH (9)
  - i. Intermittent exercise and symptom management in breast cancer survivors. 5K07CA134936-02. Craft, Lynette L., Northwestern University
  - ii. Outcomes of oncology therapy in the elderly: Functional decline. 5M01RR000109-46. Dittus, Kim, University of Vermont and St. Agric College.
  - iii. Phase III trial of exercise training in postsurgical lung cancer. 5R01CA138624-02, Jones, Lee W., Duke University.
  - iv. Randomized trial of optimal type of aerobic training in breast cancer. 1R01CA142566-01A1, Jones, Lee W., Duke University.
  - v. Biobehavioral effects of Tai Chi Chih among elderly breast cancer survivors. 5R21CA135250-02, Kinney, Anita Y., University of Utah\*
  - vi. Improving exercise and diet in African American breast cancer survivors. 1R21CA149996-01, Sheppard, Vanessa B., Georgetown University.

- vii. Falls in the community dwelling elderly with a history of cancer. 1F31NR011522-01A1, Spoelstra, Sandra Lee, Michigan State University.\*
  - viii. Chemotherapy and disability in older hormone-refractory prostate cancer patients. 5R03CA138117-02, Wells, Kristen J., Moffitt Cancer Center and Research Institute.
  - ix. Feasibility and value of a website for assessing patient-reported outcomes. 5R21CA134805-02, Wu, Albert W., Johns Hopkins University.
- b. ONS Foundation Research Grants. No research grants were funded by the ONS Foundation in the area of physical functioning during the 2009–2010 period.

### **Future (2009–2011) Research Recommendations**

In addition to continued empirical research to investigate the efficacy of interventions to maintain or improve physical function, research that explicitly links physical function changes to injurious falls in this population is a ripe area of research, given recent national healthcare policy decisions. Physical function deficits also may impact other significant clinical outcomes, including pressure ulcers, hospital length of stay, and costs of care. The impact on costs to the insurers, providers, and patients, requires further analysis in this sample. A related issue is the necessity to evaluate the costs associated with the delivery of efficacious interventions in this setting. A gap is noted in the measurement and conceptualization in physical function; both subjective and objective measures are widely reported in the literature. Psychometric properties of such measures remain problematic, which may impact the ability to detect meaningfully significant findings. Disparities in physical function deficits have been reported by income, and race or ethnicity (Cheville, Troxel, Basford, & Kornblith, 2008). Therefore, it may be fruitful to link research programs focused on health disparities with those studying physical function to stimulate interest in this area. Finally, although it is not surprising to find a research focus on physical function in older adults (Schubert, Gross, & Hurria, 2008), it also may be appropriate to conduct a targeted study of patients with cancer younger than age 65; physical function limitations may exert negative effects on role function and effect long-term survivorship (Sherwood et al., 2008).

### **Resources for Priorities (Approaches, Funding Mechanism and Amount)**

Because of the interdisciplinary nature inherent to the proposed research priorities, collaborative funding mechanisms with interested parties are more likely to attract interest in this understudied area. Capitalizing on the national policy climate, studies to link physical function and injurious falls in patients with cancer is likely to attract additional research support. In addition to the ONS Foundation, interested funders might include the Department of Defense, the Agency for Healthcare Research and Quality, specifically the newly-established Patient Centered Outcomes Research Institute (PCORI), the NCI, the National Institute of Aging, the Centers for Disease Control and Prevention Chronic Care portfolio, and the Robert Wood Johnson Foundation, among others. A mechanism to develop and test interventions to reduce

physical function declines and related falls might be designed in a two-phase manner. A call for pilot proposals (\$10–\$20,000) would be followed by a larger study (\$150–\$200,000) to test promising interventions in a multi-site context. Research partnerships with institutional Clinical and Translational Science Awards (CTSAs) would also increase leverage in this understudied area.

## **G. Translation Science**

**G.1.** Identify and test implementation science methods and techniques designed to improve the capacity of clinicians to screen, assess, and deliver effective interventions and optimize oncology nursing care quality and outcomes.

G.1.1. Investigate methods to exploit technology and system redesign to link screening, assessment, interventions, and outcomes.

G.1.2. Promote research-practice partnerships to integrate efficacious, cost-effective interventions into clinical care.

### **Rationale**

The evidence base for cost-effective oncology nursing practice continues to expand; however, there remains a continuing gap between available evidence and current practice. If oncology nursing interventions with known efficacy and cost-effectiveness are not used by providers, consumers, and service systems, the impact of our science will be modest. There is a need to develop research-driven initiatives that directly enhance care quality and contribute to the field of translational research and implementation science in oncology nursing.

Implementation science refers to studies designed to (a) evaluate the *effectiveness* of an intervention in a population and (b) evaluate a process of *transferring to a target audience the knowledge, skill, and systems support* needed to deliver an intervention. A model of translational research that incorporates both of these aspects of implementation science has been proposed by Brekke, Ell, and Palinkas (2007).

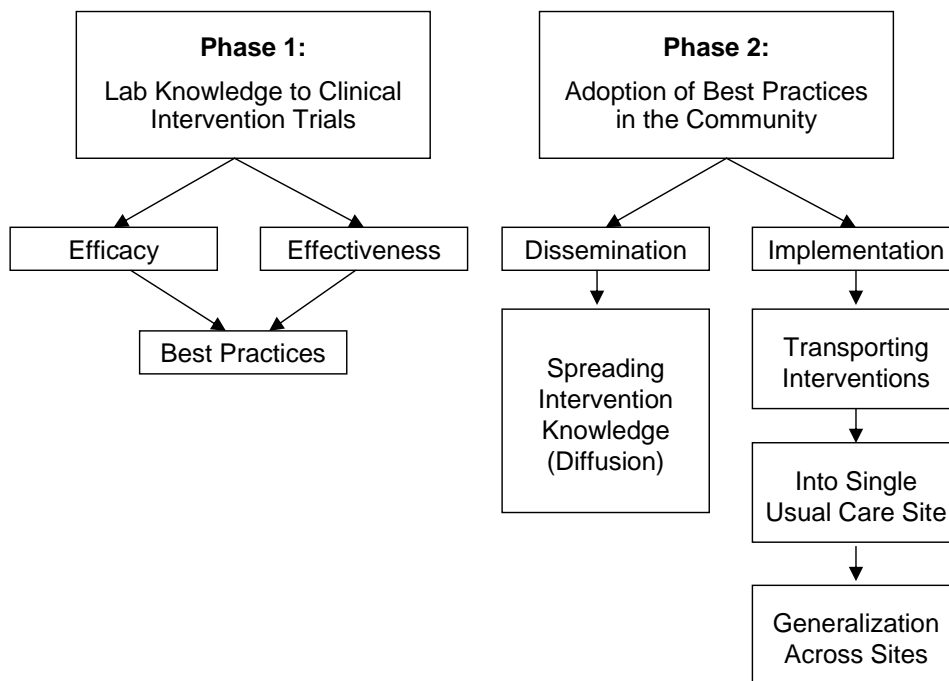


Figure 1. Conceptual Model for Translational Research

This priority encompasses strategies to (a) promote the adoption of cost-effective interventions by clinicians (e.g., audit and feedback, capacity building), (b) integrate cost-effective interventions into service systems (e.g., clinician reminder systems), (c) tailor tested interventions to ensure compatibility with a wide variety of service delivery models while preserving efficacy, (d) promote research-practice partnerships that increase the likelihood that cost-effective interventions can be embedded within care delivery processes, (e) enhance organizational capacity for sustained delivery of evidence-based interventions, (f) exploit informatics and technology for dissemination and sustained adoption, and (g) test system-wide efforts to routinely achieve evidence-based care, including the development, implementation, and evaluation of point-of-care information collection and clinical decision support.

### Progress (2004–2010)

Evidence syntheses for selecting an intervention to manage cancer symptoms are available for numerous symptoms via PEP resources and additional evidence-based guidelines are in development. The PEP resources have become the first targeted topics for translational research in oncology nursing. In addition, ONS has recommended that priority be given to translational work focused on symptoms of pain, fatigue, dyspnea, cognitive impairment, anorexia, and neutropenia. This priority builds nicely on the work done in the symptoms and NSPOs content areas. Two competitive practice grants were funded by the ONS Foundation in 2010; results are not yet available. No studies were funded in this topic area in 2009.

**G.2.** Identify cognitive-behavioral, psychoeducational, rehabilitative, and self-management interventions (individual and multi-level) with demonstrated effectiveness in targeted populations, and refine, manualize, and evaluate those interventions for use by clinicians to address multiple outcomes. Based on feedback from a survey of ONS members, interventions that address pain, sleep, fatigue, and mood disturbances should be prioritized for funding.

G.2.1. Conduct exploratory analyses and test resultant hypotheses in experimental designs to develop new knowledge that allows interventions to be effectively targeted (that is, develop knowledge that contributes to identifying what interventions work best for whom and under which conditions/contexts, at what costs, and to achieve which outcomes).

G.2.2. Modify interventions for use by clinicians to target multiple outcomes simultaneously (e.g., symptom distress and functional status) and examine implementation, service, and client outcomes.

### **Rationale**

There is an accumulating body of evidence concerning effective strategies to improve specific clinical outcomes such as pain, fatigue, mood, sleep disturbances, and caregiver strain. However, there have been few efforts to translate these research-tested interventions into programs that can be adopted and delivered by staff nurses. Examples include ECAM (Barsevick, 2006), SMaRT (Strong et al., 2008), CBT for sleep quality (Berger et al., 2008), CBT for symptom management (Doorenbos, Given, Given, & Verbitsky, 2006; Doorenbos et al., 2005; Given et al., 2008; Sherwood et al., 2005), uncertainty management intervention (Mishel et al., 2005), family-based interventions (Northouse et al., 2007), and APN case management (McCorkle et al., 2009). Symptom clusters have been an important focus of descriptive and correlation studies in oncology nursing, and there is evidence to suggest that symptoms including pain, sleep disturbance, fatigue, mood, and functional losses commonly co-occur. There also is overlap in the intervention categories (e.g., cognitive-behavioral therapy, exercise) that target multiple symptoms.

The development, dissemination, and testing in naturalistic settings of interventions that target multiple symptoms and that have been packaged for delivery by clinical oncology nurses would accelerate the adoption of effective interventions into clinical practice, promote greater system efficiency by simultaneously addressing multiple symptoms, and lead to improved patient and caregiver outcomes. Knowledge also is needed to promote the matching of subpopulations of individuals to specific interventions and intervention contexts (e.g., content, delivery source, dose, location, timing) based on demographic, behavioral, psychosocial, biologic and/or genetic factors.

In addition to testing the outcomes, such as implementation, service, and client outcomes identified in Proctor et al. (2008), resulting when these interventions are used in heterogeneous populations, empiric work is needed to identify the most appropriate measures for screening and for outcomes evaluation (including quality indicators).

There is a critical dearth of oncology clinical outcome measures established for use in pediatrics. In addition, attention to measurement issues will help to set the stage for comparative effectiveness research examining nursing interventions. In this regard, efforts are needed to promote harmonization of outcome instruments and endpoints across studies and to encourage attention to the application of methods based on modern measurement theory (e.g., item response theory, structural equation modeling) to optimize the psychometric properties of instruments. There also is a need to link these research-tested interventions with screening measures that identify those patients in need of intervention and with real-time outcomes evaluation that establish, in a diverse sample, the relationship between the intervention and improvements in multiple endpoints. In addressing this need for screening and evaluation measures, approaches are needed that capitalize on efforts such as the Patient Reported Outcomes Measurement Information System (PROMIS) ([www.nihpromis.org](http://www.nihpromis.org)), NIH Toolbox (<http://www.nihtoolbox.org/default.aspx>) and other recent initiatives designed to strengthen and streamline the evaluation and interpretation of symptoms, functional status, and other health outcomes.

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## **E. Psychosocial and Family Issues**

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## **F. Nursing-Sensitive Patient Outcomes (NSPOs)**

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## G. Translation Science

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