relevant based on nurses' scope and domains of practice and for which there is evidence linking nursing interventions to outcome achievement.
Purpose: This paper provides an historical view of nursing sensitive outcomes measurement and presents the findings of two empirical studies exploring outcome indicators sensitive to nursing care.
Methodology: A scoping review of the theoretical and empirical literature was conducted. Evidence for the following nurse-sensitive outcomes was reviewed: functional status, symptoms, mortality, health care utilization, safety, and satisfaction. Two studies, one involving acute care, and the second involving acute care, home care, and long-term care settings, were conducted testing the outcomes for sensitivity to nursing care and evaluating approaches to measurement. The first study involved secondary analysis of hospital discharge abstract databases, focusing on the relationship between nurse staffing, nurse education, and 30-day hospital mortality. The first study employed a longitudinal descriptive design; data were collected at the time patients were admitted to health services, daily for symptom outcomes, and at health care discharge. Data on nursing interventions were collected through chart audit.
Results: High quality care is conceptualized as having three dimensions: ensuring that care is safe, effective, and provides patients with the most positive experience possible. The outcome domains and approaches to measurement were found sensitive to nursing interventions and nurse staffing variables in acute care, home care, and long-term care settings.
Conclusion: Nursing sensitive outcomes measurement is feasible and there are valid and reliable measures for assessing nursing sensitive outcomes. Patient-centred care underscores the importance of a multi-disciplinary approach to outcomes measurement and should include the patient's perspective in outcomes measurement. This paper concludes with a discussion of where nursing sensitive outcomes measurement fits within a patient-centred approach to care.

92 INVITED

Selecting appropriate outcome measures for exercise interventions in cancer survivors

K.S. Courneya[1]. [1]*Univeristy of Alberta, Physical Education, Edmonton, Canada*

Background: Selecting appropriate outcome measures for clinical exercise trials is a balance between the desire to show positive results (what is likely to change) and the desire to demonstrate clinically meaningful results (what is important to change). Moreover, selecting an appropriate primary outcome measure will depend on the patient population, the type of exercise intervention, and the timing of the exercise intervention (e.g., during treatment, survivorship, end of life). The purpose of this presentation is to provide an overview of: (a) the various outcome measures that have been examined in previous exercise trials in cancer survivors, (b) theoretical models that may be useful in organizing, selecting, and analyzing outcome measures for exercise trials, and (c) exercise trials that have tested some of the proposed theoretical relationships among the various outcome measures.
Materials and Methods: An overview of the literature of previous exercise interventions trials in cancer survivors and theoretical models of exercise outcomes in cancer survivors.
Results: Exercise interventions in cancer survivors have typically measured multiple outcomes from multiple health categories including health-related fitness (e.g., aerobic capacity, muscular strength and endurance, flexibility, body composition), objective physical functioning (e.g., chair rise, stair climb, lifting/reaching), patient-reported physical functioning (e.g., physical functioning subscales from various quality of life scales, late-life function scale), activities of daily living (e.g., housework, gardening, shopping), biomarkers (e.g., insulin, immune function), psychosocial functioning (e.g., depression, anxiety, stress, self-esteem, happiness), and quality of life (e.g., various quality of life scales). Few studies have included treatment or disease outcomes. Moreover, few studies have included outcome measures from all the key health categories or followed a theoretical model in the selection of the outcome measures. Finally, few studies have examined whether changes in health-related fitness or objective physical functioning mediate changes in patient-reported outcomes or treatment/disease outcomes.
Conclusions: Exercise researchers have included a wide variety of outcome measures in their trials with the most common being health-related fitness, psychosocial functioning, and quality of life. Moreover, many exercise researchers have selected a health-related fitness outcome as their primary outcome. Although such an outcome has a high likelihood of changing, it may not be considered clinically meaningful by itself. Consequently, researchers should consider including additional clinically relevant outcomes for cancer survivors and examine the link between fitness and functioning, and the clinical outcomes. Moreover, selecting a health-related fitness outcome as the primary outcome typically requires a much smaller sample size to demonstrate efficacy which usually leaves the trial underpowered for other clinically important outcomes. Ideally, the selection of outcomes measures should be influenced by the needs of the particular patient population and follow a theoretical model, most likely including measures of health-related fitness, objective physical functioning, patient-reported physical functioning, activities of daily living, psychosocial functioning, quality of life, and treatment/disease outcomes.

93 INVITED

Design and methodological challenges in cancer-related quality of life research

T. Kroll[1]. [1]*University of Dundee – School of Nursing and Midwifery, Alliance for Self Care Research, Dundee, United Kingdom*

The presentation will examine challenges related to the design and methodology of research that focuses on capturing 'quality of life' in people with cancer. The relationship between health-related and general quality of life (QoL) concepts and the underlying assumptions (e.g. stability, dimensionality, scope) will be reviewed and critiqued. Specifically, issues such as multi-morbidity, complex marginalisation, transition periods (childhood, adolescence, adulthood, old age; stages of cancer) will be explored with regard to quality of life concerns. Questions about who contributes to the conceptualisation of (health-related) QoL and whether QoL can ever be considered an outcome measure (as opposed to temporary process measure) will be discussed. The conceptual debate will then be followed by a brief examination of how quality of life is currently 'assessed' in various clinical and non-clinical settings and contexts.
Several quality of life measures are used in the literature (e.g. Life Satisfaction Index, Visual Analog QoL scale, Quality of Life Index, Quality of Life Index, Philadelphia Geriatric Morale, Quality of Life Scale, Faces Scale and Hospice Quality of Life Index. They vary in the number of items, content domains, degree of internal and external validity and cancer specificity. Findings from a review of systematic reviews in the area of cancer-related QoL studies show that primary studies frequently combine multiple QoL measures with psychometric properties that have been ascertained to a varying degree. Rarely, measures are adapted and examined for their sensitivity and specificity in distinct environments and with subgroups of cancer patients.
Frequently, narrow inclusion/exclusion criteria create an artificially constrained sample whose QoL is assessed (usually but not always the same narrow set of individuals that matched the validation criteria for the instrument) and then extrapolated to a larger group. Study instrumentation itself may rule out study participation of people with communication, mobility or sensory impairments. If sampling, consenting and study administration procedures are not adjusted. Non availability of alternative formats to obtain consent, exclusive reliance on proxy respondents, insufficient researcher training, reliance on a single QoL measure may compound inaccuracy of findings. Few research publications indicate whether specific accommodations were made for people with cancer-related impairments to participate in a research project. Non-inclusion in QoL studies may have serious consequences There is no guarantee that health interventions are effective in the same way or may even carry risks for individuals whose 'QoL' has not been considered in primary studies. Examples from effectiveness and observational QoL studies will be used to examine specific problems.
The presentation will conclude with a number of key recommendations for future cancer-related QoL research.

94 INVITED

Patient-reported outcomes in cancer research

G. Velikova[1]. [1]*Cancer Research UK Centre, University of Leeds, Leeds, United Kingdom*

As a result of new and improved therapeutic interventions, cancer survival rates are improving and the nature of cancer care is changing. Many cancers are now being managed as chronic diseases, treated over a prolonged period of time to achieve disease control, prolongation of life and palliation. High quality cancer care aims to improve a range of patient outcomes including not only survival but also important subjective outcomes such as symptom control, functioning and health related quality of life. Meeting those challenges requires routine use of robust and valid measures of patient self-reported outcomes in cancer research and care.
This presentation will describe the current state of the art in this research area in 3 sections:

1. Development and evolution of patient-reported outcome measures (PROMs), including health status questionnaires, quality of life instruments, screening measures for psychological morbidity and measures focusing on single concepts such as pain, fatigue, satisfaction with care.
2. Using PROMs in clinical trials as primary or secondary outcomes of treatment. Examples will be given from trials successfully implementing PROMs. The impact on those findings on clinical decision-making will

be discussed, based on findings from individual trials and systematic reviews.
3. Overview of the applications of PROMs in daily oncology practice to support and improve individual patient care.

The presentation will briefly describe technical aspects of real-time data collection (such as the use of touch-screen computers, mobile devices and web-based data collection). The main focus will be on the impact of PROMs on process of care (doctor-patient communication, decision-making) and on patient well-being and satisfaction with care. The experience of using PROMs during cancer chemotherapy in Leeds Cancer Centre, Leeds, UK will be presented.

Scientific Symposium (Tue, 22 Sep, 09:00−11:00) **Role of PET imaging**

95 INVITED

New PET-Tracers for imaging pathophysiology and response

S. Reske[1]. [1]*University of Ulm, Clinic for Nuclear Medicine, Ulm, Germany*

Metabolic imaging with PET and PET/CT using F-18 fluordesoxyglucose is now a routine tool in clinical practice for therapy response evaluation, viability assessment of posttherapeutic residual masses, restaging and potentially staging in Hodgkin's disease and Non-Hodgkin's lymphoma. Beyond imaging glucose metabolism, important molecular and cellular targets and pathophysiological important pathways can be addressed: these include amino acid transport/protein synthesis for imaging multiple myeloma with radiolabelled amino acids such as C-11 methionine, proliferation with F-18 fluorothymidine angiogenesis with radiolabelled RGD-peptides, apoptosis with F-18 labelled anexin-V, membrane turnover with F-11/F-18 choline, tumour receptors and antigens with CD20, CD33, CD45 or CD66 radiolabelled monoclonal antibodies. Advanced pharmacokinetic modelling improved cellular targeting significantly and is available for more efficient therapeutic targeting when antibodies are labelled with therapeutic radionuclides. Intense preclinical research is focussed on development of measuring tumour cell tracking, imaging of tumour stem cells, cell signalling and gene expression with appropriate probes and reporter gene approaches. Multimodality imaging with PET/CT, SPECT/CT, PET/MR both in small animal and clinical/preclinical settings will close the gap between traditional anatomical based morphological and molecular imaging based functional imaging approaches.

96 INVITED

PET imaging of non-Hodgkin lymphoma: defining methodologies for early prediction of response

C. Haioun[1], J. Dupuis[1], E. Itti[2], K. Belhadj[1], I. Gaillard[1], T. El Gnaoui[1], F. Kuhnowski[1], M. Meignan[1]. [1]*Hopital Henri Mondor, Lymphoid Malignancies Unit, Creteil, France;* [2]*Hopital Henri Mondor, Nuclear Medicine, Creteil, France*

Achieving a complete response to first-line therapy is an important goal in managing patients with aggressive lymphomas such as diffuse large B-cell lymphoma (DLBCL), as long-term outcome is greatly improved compared with those patients with residual disease. ^{18}F- Fluorodeoxyglucose positron emission tomography (FDG-PET) is emerging as a powerful technique for the assessment of response in patients with DLBCL and also appears to be a valuable predictor of long-term outcome. A number of studies have shown that patients who have a negative PET scan (during the induction phase or after several cycles of induction chemotherapy) have a significantly better event-free survival (EFS) than those who have an abnormal PET scan. This suggests that it may be possible to use FDG-PET to identify poor responders during the course of induction therapy and modify their treatment accordingly. This approach is being investigated in an ongoing GELA (Groupe d'Etude des Lymphomes de l'Adulte) study (07−3B Study). Patients under the age of 60 years of age and with an age adjusted-IPI score of 2–3 were randomized to receive four cycles of either R-ACVBP14 + intrathecal methotrexate (MTX it) + G-CSF (group A) or R-CHOP14 + MTX it + G-CSF (group B). PET assessments are performed at baseline and after the second and fourth cycle of therapy. Further treatment is then given according to response, as assessed by PET. Patients from either treatment group who are PET positive after the fourth cycle of treatment leave the study to receive salvage therapy. Those who are PET negative after both the second and fourth cycle of treatment continue to receive induction therapy (group A: MTX iv, R-ifosfamide-vepeside, cytarabine; group B: 4 cycles of R-CHOP14 + G-CSF), while those who are PET positive after the second cycle but PET negative after the fourth cycle receive more intense, consolidation therapy − MTX iv followed by Z-BEAM (^{90}Y-ibritumomab tiuxetan plus BEAM) with autologous stem cell support. Indeed, for patients who are PET positive at the end of induction therapy, consolidation therapy involving ^{90}Y-ibritumomab tiuxetan may be an appropriate option. The results of this study should help determine the value of using PET assessment during the course of induction therapy to modify the course of treatment and also the role of ^{90}Y-ibritumomab tiuxetan as consolidation therapy in poor risk patients with DLBCL.

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97 INVITED

Role of FDG-PET and PET/CT in treatment planning of other haematological tumours

L. Specht[1]. [1]*Rigshospitalet University of Copenhagen, Oncology and Haematology, Copenhagen, Denmark*

FDG-PET has been extensively investigated in Hodgkin lymphoma, whereas less data are available in myeloma and leukemias.
Hodgkin lymphoma (HL): Initial staging determines the treatment plan. PET detects more disease sites than conventional imaging methods. However, there are methodological problems, in particular the lack of a valid reference test. Nevertheless, PET is today considered part of the routine staging of HL. In published series PET changed disease stage in 10−40% of cases, more often upstaging than downstaging patients, leading to changes in treatment strategy in about half. Whether these changes will lead to improvement in outcome is still unknown.
Early response evaluation with PET after 1−2 cycles of ABVD is highly predictive of outcome, but whether treatment should be modified on this basis is not known. Moreover, the predictive value of an early PET may be lower with more intensive regimens like BEACOPP. Randomized trials are testing if treatment reduction in PET negative and treatment intensification in PET positive patients can improve outcome. Despite the lack of randomized evidence, treatment intensification in patients with a positive PET-scan after 4 cycles of therapy has become a widespread practice.
Radiotherapy in HL has changed dramatically. The old treatment strategy maximized the use of radical radiotherapy, and extensive treatment fields were used. In the modern era, radiotherapy is part of a combined modality treatment, and smaller volumes and doses are employed. In most situations the volume for radiotherapy is only the initial (pre-chemotherapy), macroscopically involved tissue volume in early stage disease, and residual masses after chemotherapy in advanced disease. This has led to dramatic reductions in the normal tissues being irradiated, and equally dramatic reductions in the risk of serious long-term complications. One major problem with more and more conformal radiotherapy is the need to define the target volume very precisely to avoid geographical misses. Image guidance is essential. PET is increasingly being incorporated in the planning process, and changes treatment fields in about 1/3 of early stage patients. To be able to use combined PET and CT for the planning of