PHARMACY VISION 20/20

CSHP SEMINAR 20 • OCTOBER 21-25

Disneyland RESORT

Geriatric Oncology: Identifying Challenges of Cancer Treatment in an Aging Population

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DISCLOSURE

- I have no potential conflicts of interest to disclose

LEARNING OBJECTIVES

1. Describe the role of comprehensive geriatric assessments for older oncology patients.

2. Discuss the impact of polypharmacy in the geriatric oncology population.

3. Identify methods to improve treatment strategies for geriatric oncology patients.

INTRODUCTION

- Number of patients ≥ 65 years rising dramatically
- Incidence of cancer is increasing in elderly population
  - More than 50% of all malignancies in the United States occur in pts ≥ 65 years
- Cancer is the leading cause of death in men and women age 60-79 years
    - More than 70% cancer related deaths in the United States occur in pts ≥ 65 years

Smith, BD et al. JCO 2009, NCCN Older Adult Oncology V1.2020, Noone AM et al. SEER Cancer Statistics Review 2018

Relationship Between Cancer and Aging

- Increased susceptibility of environmental carcinogens
- Accumulation of mutation along extended lifespan
- Pro-tumorigenic tissue environment
- Decreased immune function

Repetto L et al. European J Ca 2003

TREATMENT CONCERNS IN GERIATRIC ONCOLOGY

- Underrepresentation of elderly patients in cancer research
- Treatment decisions more complex due to comorbid conditions and functional disabilities
- Biological characteristics of cancers and responsiveness to treatment may differ in elderly patients

NCCN Older Adult Oncology V1.2020, Hurria A et al. JCO 2015, Mohile SG et al. JCO 2018

Age Related Physiologic Changes

- Age-related changes impact all the body's cells, tissues, organs, and systems
  - Failure to maintain homeostasis under physiologic stress
- Pharmacokinetic and pharmacodynamics of cancer treatment may change with age
  - Elderly patients may display alterations in drug metabolism, distribution, and excretion

Soto-Perez-de-Celis E et al. Lancet Oncol 2018, Walko CM et al. JCO 2014

PHYSIOLOGIC CHANGES BY ORGAN SYSTEM

↓Cortical volume

↓Synaptic density

↓Attention and memory

↓Cardiac output

↑Arterial stiffness

↓Heart rate modulation

Conduction abnormalities

↓Muscle mass

↓Strength and power

↓Elastic recoil

↓Lung volume

↑Ventilation-perfusion inequality

Adapted from Soto-Perez-de-Celis E et al. Lancet Oncol 2018.

PHYSIOLOGIC CHANGES BY ORGAN SYSTEM

↓Volume

↓Blood flow

↓First pass metabolism

↓Drug clearance

↓Renal mass

↓Glomerular filtration rate

↓Drug clearance

Change in renal vasculature

↓Acid secretion

↓Drug absorption

↓Bone mineral density

↑Fracture risk

↓Bone marrow reserve

Adapted from Soto-Perez-de-Celis E et al. Lancet Oncol 2018

Pharmacokinetic Considerations in the Elderly

Physiologic Changes	Pharmacokinetic Outcome
↑ Body fat	Increased volume of distribution and half life of lipophilic drugs
↓ Total body water	Increased plasma concentration of hydrophilic drugs
↓ Serum albumin	Increased free fraction of highly protein bound acidic drugs
↓ Hepatic mass	Phase I metabolism of some drugs may be slightly impaired, decreased CYP450 enzymes (CYP1A2, CYP2C9, CYP2C19, CYP2D6)
↓ Hepatic blood flow	First pass metabolism can be less effective

Adapted from Klotz U. Drug Metabolism Rev 2009

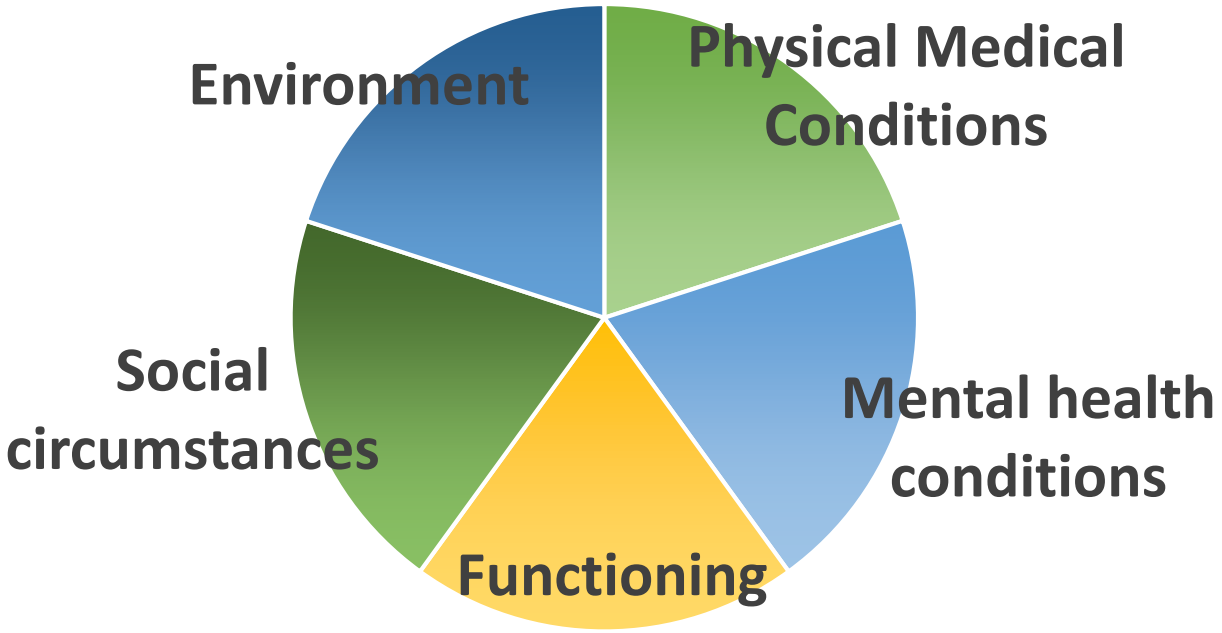
COMPREHENSIVE GERIATRIC ASSESSMENT (CGA)

- Comprehensive researched model for healthcare delivery to frail elderly patients
- Multi-disciplinary in depth evaluation
  - Assessment of functional abilities, physical performance, nutritional status, comorbidities, cognition, psychological state, and social support

NCCN Older Adult Oncology V1.2020, Soto-Perez-de-Celis E et al. Lancet Oncol 2018

Mohile SG et al. JCO 2018

DOMAINS OF CGA



- CGA divided into domains that correspond to different aspects of aging related issues
- Domains are evaluated through validated tools

Soto-Perez-de-Celis E et al. Lancet Oncol 2018, Mohile SG et al. JCO 2018

APPLICATION OF CGA IN GERIATRIC ONCOLOGY

- CGA can detect reversible geriatric issues not found on routine oncology care
  - Help predict toxicity from cancer treatment
  - Provide prognostic information to help estimate life expectancy
  - Allows for targeted intervention

American Society of Clinical Oncology (ASCO), International Society of Geriatric Oncology (SIOG), and the National Comprehensive Cancer Network (NCCN) recommend performing CGA in all older patients with cancer

NCCN Older Adult Oncology V1.2020, Soto-Perez-de-Celis E et al. Lancet Oncol 2018

CGA: Functional Status

- Eastern Cooperative Oncology Group (ECOG) or Karnofsky performance scale (KPS) not reliable in elderly patients
- Older patients should have activities of daily living (ADL) and instrumental activities of daily living (IADL) evaluated
  - ADL: self care, mobility, balance, and continence
  - IADL: ability to perform daily activities like shopping, cooking
- Gait speed may be predictive of survival and mortality
- Assessment of fall risk

NCCN Older Adult Oncology V1.2020, Soto-Perez-de-Celis E et al. Lancet Oncol 2018

CGA: COMORBIDITY

- Comorbidities may impact cancer prognosis and treatment tolerance
  - Chronic diseases speed up loss of organ function
  - Interaction of cancer treatment with comorbidity may impact functional status or worsen comorbidity
- Randomized adjuvant chemotherapy trial (n=3759) in high risk advance stage colon cancer found pts with diabetes had higher rates of overall mortality and cancer recurrence
- Charlson Comorbidity Index (CCI) and Cumulative Illness Rating Scale (CIRS) commonly used to determine risk of mortality with comorbidity

Soto-Perez-de-Celis E et al. Lancet Oncol 2018, Meyerhardt JA et al. JCO 2003

CGA: NUTRITIONAL STATUS

- Malnutrition and weight loss associated with treatment complications and increased mortality in elderly cancer patients
  - Severe hematologic toxicity, poor chemotherapy tolerance, increased length of hospital stay
- Inadequate calorie intake often cause of malnutrition
- Monitor body mass index (BMI) or unintentional weight loss in past 6 months

NCCN Older Adult Oncology V1.2020, Soto-Perez-de-Celis E et al. Lancet Oncol 2018

CGA: COGNITION

- Evaluation of cognition should include patient cognitive assessments as well as caregiver observations

- Medications considerations for cognitive impairment
  - Anticholinergics, antipsychotics, benzodiazepines, corticosteroids, and opioids

- Cognition impairment leads to increased risk of functional dependence and higher risk of death

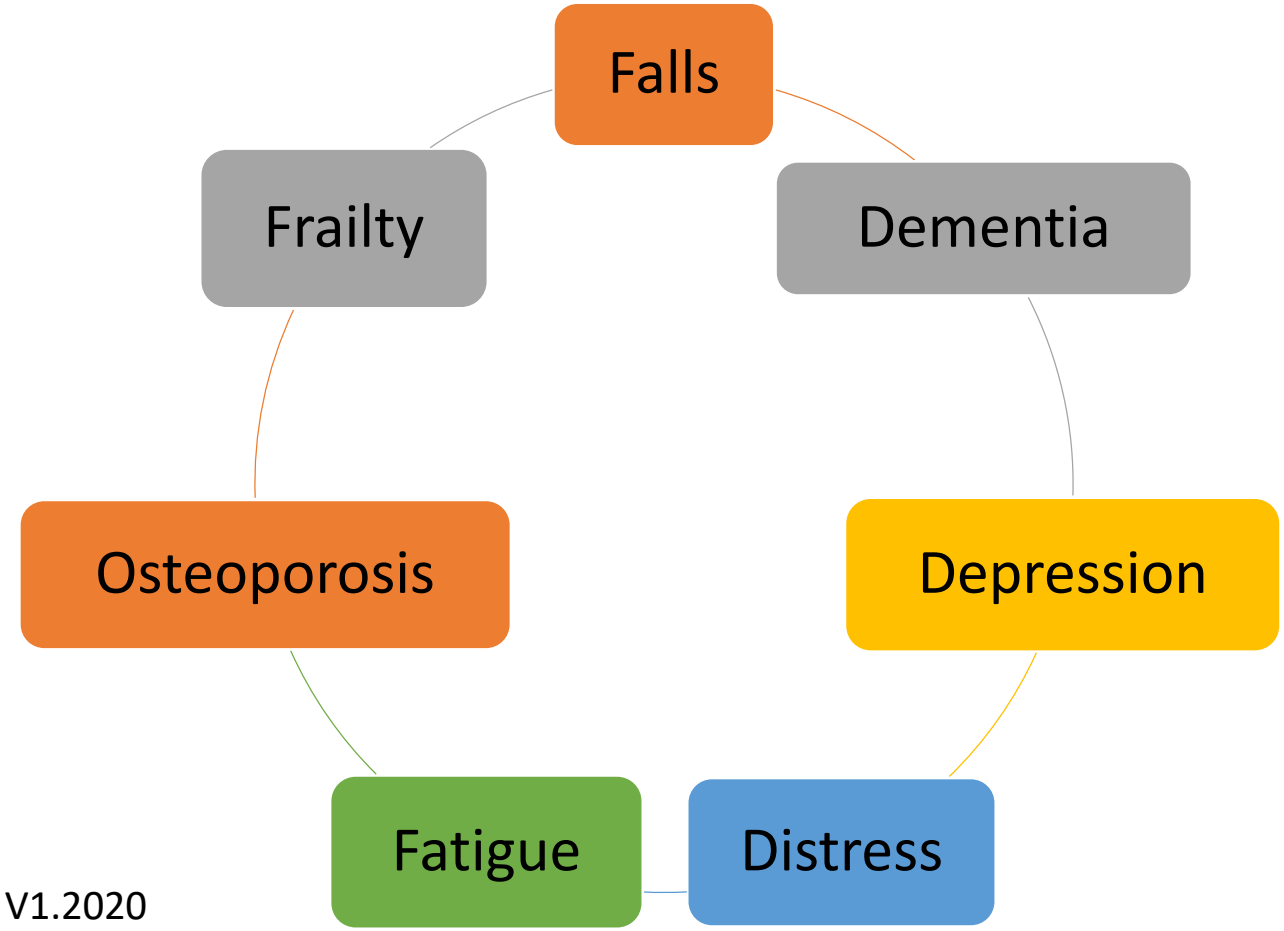
NCCN Older Adult Oncology V1.2020, Soto-Perez-de-Celis E et al. Lancet Oncol 2018

CGA: SOCIOECONOMIC SUPPORT

- Social support critical due to complexity of cancer treatment
  - Elderly patients may have less social support due to death of spouse or friends
- Social isolation and minimal support associated with increased cancer mortality
- Evaluate patient living situation, availability of caregiver, and financial status

NCCN Older Adult Oncology V1.2020, Soto-Perez-de-Celis E et al. Lancet Oncol 2018, Kroenke CH et al. JCO 2006

CGA: GERIATRIC SYNDROMES



NCCN Older Adult Oncology V1.2020

CGA: POLYPHARMACY (PP)

- Use of increased number of medications, inappropriate medication use, or medication duplication
  - Includes prescribed medications, over the counter (OTC) medications, and complementary and alternative medications (CAMs)
  - No consensus definition, but many studies utilize ≥ 5 medications as cutoff

NCCN Older Adult Oncology V1.2020, Hersh LR et al. Curr Oncol Rep 2017, Bushardt RL et al. Clin Inter Aging 2008

POLYPHARMACY AND GERIATRIC ONCOLOGY

- Geriatric oncology patients have a high prevalence of PP
  - Multi-center prospective longitudinal study (n=500) in patients ≥ 65 yrs undergoing outpatient chemotherapy found that polypharmacy observed in >60% patients

- Many geriatric patients meet the criteria for polypharmacy before starting therapy

Hersh LR et al. Curr Oncol Rep 2017, Maggiore RJ et al. J Am Geri Soc 2014

RISK FACTORS FOR POLYPHARMACY

- Comorbid conditions
  - Cancer patients older than 70yrs have an average of 3 comorbid conditions at the time of cancer diagnosis
- Hospitalizations
  - More frequent non elective admission for treatment complications
- Prescribing Cascades
  - Medications prescribed to counteract toxicity from another medication

Hersh LR et al. Curr Oncol Rep 2017, Zeber JE et al. Crit Rev Onc Hematol 2008, Sharma M et al. JCO 2016

CONSEQUENCES OF POLYPHARMACY

- Adverse drug events (ADE)
- Drug-drug interactions
- Poor medication adherence
- Increased morbidity

NCCN Older Adult Oncology V1.2020, Hersh LR et al. Curr Onc Rep 2017, Popa MA et al. JGO 2014

Study	Population	Polypharmacy Definition	Outcomes
de Glas et al	≥65 yrs who underwent breast cancer surgery	≥ 4 daily meds	Associated with increased risk of post-operative complications [OR 1.84, (95% confidence interval (CI) 1.46-2.32)]
Freyer et al	≥70 yrs with stage III/IV ovarian cancer	≥ 6 daily meds	Lower overall survival (p = 0.04) in patients with polypharmacy
Hamaker et al	≥65 yrs with metastatic breast cancer receiving single agent palliative chemo	≥ 5 daily meds	Associated with grade 3-4 chemotherapy related toxicity [Unadjusted OR 6.38, 95% CI 1.99-23.47)

De Glas NA et al. Breast Cancer Res Treat 2013, Freyer G et al. Ann Oncol 2005, Hamaker ME et al. Breast 2014

POTENTIALLY INAPPROPRIATE MEDICATIONS (PIMS)

- Medications lacking evidence based indications
- Treatment risks may outweigh benefits
- Significantly associated with ADEs
- May potentially interact with other medications or diseases

American Geriatrics Society 2019 Beers Criteria Update Expert Panel. J Am Geriatr Soc 2019

EVALUATION OF POLYPHARMACY/PIMS

- American Geriatrics Society (AGS) Beers Criteria
  - Identifies PIMs with potential risks that outweigh benefit
- Categories
  - PIMS to avoid in older adults
  - PIMS to avoid in older adults with certain diseases
  - Meds to use with caution
  - Clinically important drug interactions
  - Medication consideration in renal dysfunction

American Geriatrics Society 2019 Beers Criteria Update Expert Panel. J Am Geriatr Soc 2019

BEERS CRITERIA CONSIDERATIONS

Advantages

- Widely used screening tool for PIM use, endorsed by AGS
- Comprehensive and well organized list of PIM
- Studied in cancer population

Disadvantages

- Does not address drug-nutrient interactions, medication underuse, CAM, over the counter medications, or medication adherence
- Requires continuous updating

American Geriatrics Society 2019 Beers Criteria Update Expert Panel. J Am Geriatr Soc 2019

Evaluation of Polypharmacy

Medication Appropriateness Index (MAI)

- Measures appropriate prescribing based on a 3 point rating scale of a 10 item list
- Medication assessment: indication, effectiveness, dosage, directions, DDIs, drug disease interactions, drug duplication, and cost
- Time intensive
- May be used in conjunction with BEERS

START/STOPP Criteria

- START determines appropriateness of initial medication prescribing (22 criteria)
- STOPP evaluates existing medication regimens (65 criteria)
- Assesses DDI and drug disease interactions, duplicate therapies, and drugs that increase fall risk
- May be used in conjunction with Beers

Hanlon JT. J Clin Epidemiol 1992, Gallagher PF. Age Ageing 2008

ONCOLOGY PHARMACIST AND POLYPHARMACY

- Multidisciplinary collaboration
- Take appropriate medication history and reconciliation
- Patient education of polypharmacy
- Medication assessment

NCCN Older Adult Oncology V1.2020

ONCOLOGY PHARMACIST MEDICATION ASSESSMENT

- Does every medication match a known medical problem?
  - Deficiencies or duplications?
  - Review prescription, IV/PO chemo, OTC and CAMs
- Are the dosages appropriate (age, renal/liver function)?
- Drug-drug interactions or drug-disease interactions
  - https://drug-interactions.medicine.iu.edu/Home.aspx
  - https://www.mskcc.org/cancer-care/diagnosis-treatment/symptom-management/integrative-medicine/herbs

NCCN Older Adult Oncology V1.2020

ONCOLOGY PHARMACIST MEDICATION ASSESSMENT

- Evaluate PIMS
  - Beers criteria, START/STOPP, MAI
- Are medications causing current complaints?
- Can the regimen be simplified?
- Are there less expensive alternatives of equal utility?

NCCN Older Adult Oncology V1.2020

Pharmacist Role In Polypharmacy Assessment

- Retrospective evaluation of pharmacist led medication assessment to determine prevalence of PP, excessive polypharmacy (EPP) and PIM use at a ambulatory senior adult cancer center between January 2011 and June 2013 (n=248)
  - PIM categorized by 2012 Beers criteria, STOPP criteria, and the Healthcare Effectiveness Data and Information Set (HEDIS) criteria
- Prevalence indentified: PP (41%), EPP (43%), and PIM (51%)
  - PIM use associated with PP and increased comorbidities
- Pharmacist driven medication assessment revealed high incidence of PP, EPP and PIM in elderly cancer population

Nightingale G et al. JCO 2015

Steps to Deprescribe

- Establish clear and reasonable therapeutic endpoints
- Reconcile all medications and determine indications
- Assess each drug for current/future benefit vs harm
- Prioritize drugs with most unfavorable risk/benefit ratio and least likelihood of withdrawal symptoms for deprescribing
- Monitor for improvement or ADEs after discontinuation plan implementation

NCCN Older Adult Oncology V1.2020, Sharma M et al. JCO 2016

Pharmacist Led Medication Deprescribing

- Prospective evaluation of pharmacist led medication deprescribing intervention in a geriatric oncology clinic (n=26)
  - PIM categorized by 2012 Beers criteria, STOPP criteria, then MAI (3 tool model)
  - Real time deprescribing occurred after discussion with geriatric oncologist, pharmacist, patient and caregiver
- Endpoints
  - Incidence of PIMS
  - Mean number of medications deprescribed, potential cost avoidance, pharmacist intervention times

Whitman A et al. Support Care Cancer 2018

Pharmacist Led Medication Deprescribing

- Results
  - 312 medications, mean number per patient was 12
  - 119 PIMS identified with three tool assessment
  - 73% (87/119) PIMs deprescribed, mean of 3 meds deprescribed per patient
  - Healthcare expenditures of $4282 were potentially avoided per patient
- Pharmacist led deprescribing interventions feasible and may lead to improved patient outcomes and cost savings

Whitman A et al. Support Care Cancer 2018

APPLICATION OF CGA IN ELDERLY CANCER PATIENT

Study	Patient Population	Outcomes
Clough-Gorr et al	≥65 yr women with Stage I-IIIA breast cancer (n=660)	Pts with ≥ 3 cancer specific CGA deficits had higher all cause and cancer related death rate at 5 and 10 yrs
Klepin et al	≥60 yr patients with newly diagnosed acute myeloid leukemia (n=74)	Impaired cognition and objective physical function associated with shorter overall survival
Soubeyran et al	≥70 yr patients with cancer starting chemotherapy (n=348)	Lower nutritional assessment score and poor mobility predicted early death (within 6 months of starting chemotherapy)

Clough-Gorr KM et al. European Journal of Cancer 2012, Klepin HD et al. Blood 2013, Soubeyran P et al. JCO 2012

Select Geriatric Assessments By Domain

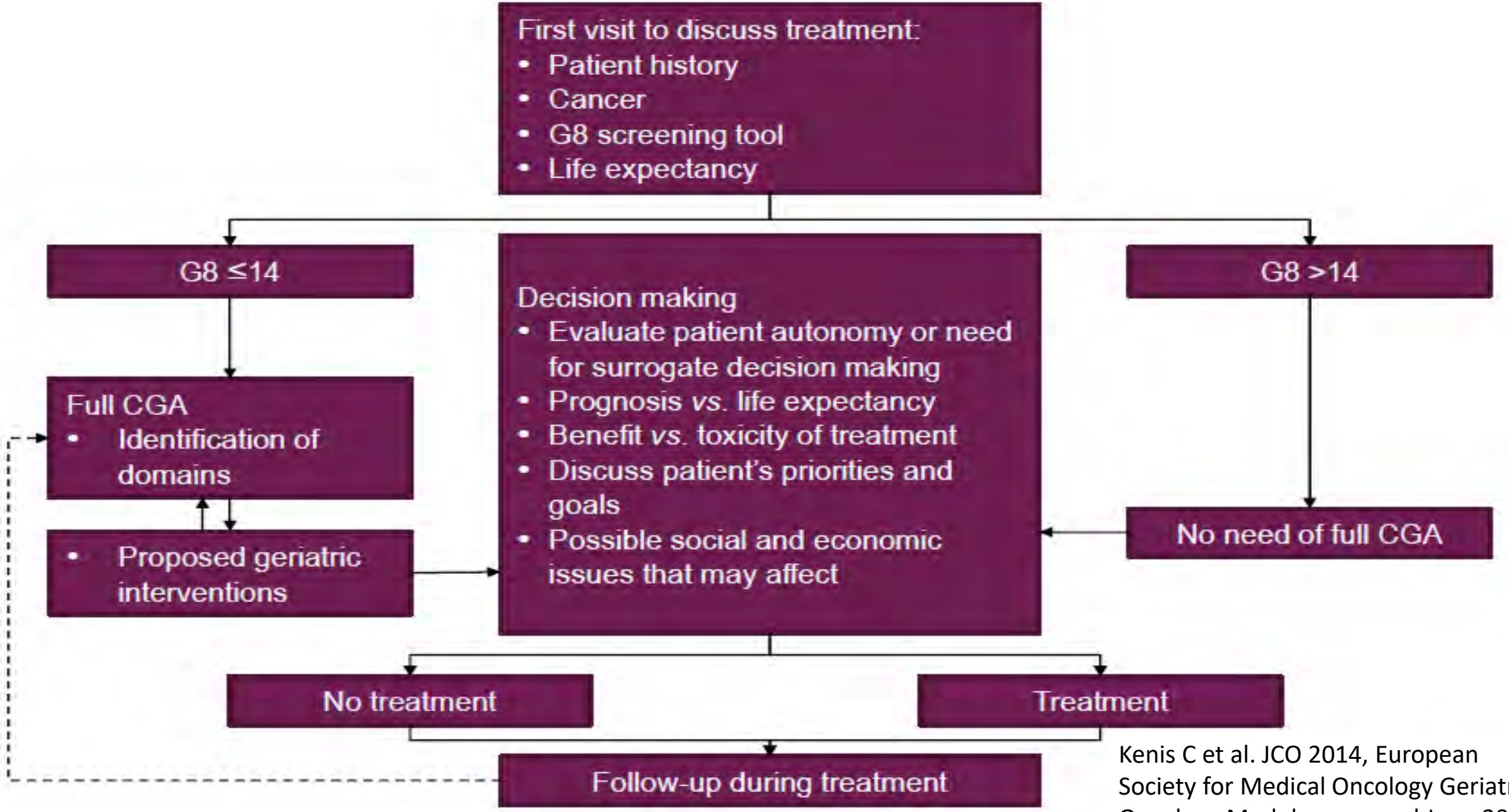
Domain	Geriatric Assessment Tools
Functional status	ADL/IADL, Timed Up and Go (TUG), Short Physical Performance Battery
Comorbidity	Charlson comorbidity index, Cumulative Illness Rate Scale - Geriatric
Nutritional status	Body mass index, Mini Nutritional Assessment, unintentional weight loss
Cognition	Mini Mental State Examination, Mini-Cog
Social support	Medical Outcomes Study
Polypharmacy	Number of medications, Beers Criteria, START/STOPP, Mai

NCCN Older Adult Oncology V1.2020, Soto-Perez-de-Celis E et al. Lancet Oncol 2018, Mohile S et al. JCO 2018

APPLICATION OF CGA

- Multiple geriatric screening tools have been tested and validated
  - May be administered via self reporting, electronically, or by clinical interview
- CGA is time consuming and may not be practical for all elderly oncology patients
- Geriatrics 8 (G8) developed specifically for elderly oncology patients
  - Eight item survey with numerical score 0-3
  - Score of < 14 abnormal and correlates with decreased overall survival

NCCN Older Adult Oncology V1.2020, Kenis C et al. JCO 2014



Kenis C et al. JCO 2014, European Society for Medical Oncology Geriatric Oncology Module, accessed June 2020

Potential Interventions for impaired CGA Domains

Domain Impaired	Potential intervention
Functional Status	Physical therapy, occupational therapy, evaluate fall risk
Cognitive	Involve family/caregiver, minimize PIMs, delirium prevention, cognitive testing
Comorbidity	Involve primary care provider, review medication list, assess medication adherence
Social support	Transportation assistance, financial assistance, home health care, spiritual care
Nutrition	Nutrition consult, supplemental nutrition, oral care, swallow evaluation
Polypharmacy	Pharmacist medication review, evaluate PIMS

NCCN Older Adult Oncology V1.2020, Mohile S et al. JCO 2018

Treatment Decision Making in Elderly Cancer Patients

- Assessment with CGA to identify risk
- Chronological age vs functional age
- Life expectancy
  - https://eprognosis.ucsf.edu/leeschonberg.php
  - Useful tool to estimate general mortality risk in older adults
- Treatment modalities: surgery, radiation therapy, chemotherapy, targeted therapy, and immunotherapy

NCCN Older Adult Oncology V1.2020, Mohile S et al. JCO 2018

Chemotherapy in Elderly Patients

- Anti-metabolites
  - Cytarabine arabinoside (ara-C): increased risk of neurotoxicity in older patients due to toxic metabolite ara-U
  - 5-fluorouracil (5FU): no difference in clearance by age, but some studies have demonstrated increased risk of leucopenia and mucositis in older patients
- Platinum agents
  - Cisplatin and carboplatin clearance impacted by renal function.
  - Elderly patients more likely to have increased toxicity due to impaired creatinine clearance.

Walko CM et al. JCO 2014, Hurria A et al. BJC 2008

Chemotherapy in Elderly Patients

- Taxanes
  - Pharmacokinetics (PK) of paclitaxel q3week in 153 patients ages 55-86 showed ↑ area under the curve (AUC) and ↓ drug clearance in older patients
  - PK study of docetaxel q 3weeks showed no difference in AUC in age, but patients ≥ 65 years had more febrile neutropenia and grade 4 neutropenia
- Anthracyclines
  - Association seen between older age and risk of congestive heart failure after cumulative doxorubicin dose of 400mg/m^2
  - Evaluate patients for risk factors

Walko CM et al. JCO 2014, Hurria A et al. BJC 2008

TARGETED THERAPY AND ELDERLY PATIENTS

Drug	Mechanism	Main ADE	ADE seen in Elderly
Sunitinib	VEGF inhibitor	Hypertension, pancytopenia, diarrhea, vomiting, hand/foot syndrome, hypothyroidism	Fatigue, cough, peripheral edema, anemia, decreased appetite, thrombocytopenia
Bevacizumab	Anti-VEGF monoclonal antibody	Fatigue, asthenia, hypertension, proteinuria, bleeding, anorexia, diarrhea	Venous thromboembolic events, thrombocytopenia, bleeding, GI perforation
Vemurafenib	BRAF inhibitor	Fatigue, rash, arthralgia, nausea, cutaneous squamous cell carcinoma, keratoacanthoma	Cutaneous squamous cell carcinoma, kerathocanthoma, QTc prolongation

VEGF = Vascular endothelial growth factor, BRAF = B-Raf proto-oncogene

Daste A et al. European J Cancer 2016

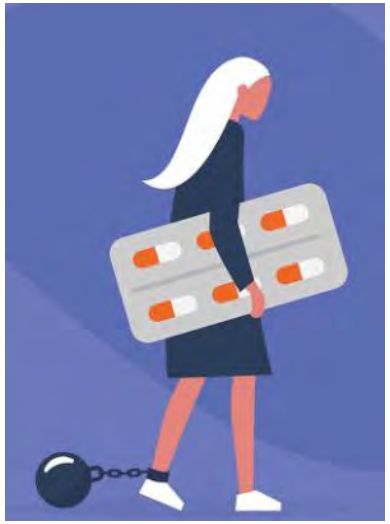
IMMUNOTHERAPY AND ELDERLY PATIENTS

- Older adults with good performance status benefit from checkpoint inhibitors (PD-1 or PD-L1)
- Toxicities of checkpoint inhibitor monotherapy appear similar across age groups
  - More hospitalizations seen in elderly patients
- Geriatric assessment may be useful to gauge fitness for more intense combination therapies

Kanesvaran R et al. ASCO Education book 2018.

Additional Treatment Related Toxicities

- Myelosuppression
  - Risk of neutropenia may be decreased by filgrastim
  - Epoetin not recommended for cancer patients whose treatment goal is curative
- Mucositis
- Chemotherapy induced nausea vomiting
- Diarrhea
- Insomnia
  - Cognitive behavior therapy and lifestyle modification



NCCN Older Adult Oncology V1.2020

Predictors of Chemotherapy Side Effects

Chemotherapy Risk Assessment Scale for High Age Patient Score (CRASH)	Cancer and Age Research Group Score (CARG)
• Evaluation tool predicting ADEs to chemotherapy • Hematologic toxicity: IADL, lactate dehydrogenase, diastolic blood pressure, and chemotherapy toxicity • Non-hematologic toxicity: malnutrition, cognition, and chemotherapy toxicity • Takes 20-30 min to complete	• Predicts probability of experiencing ≥ grade 3 toxicities • Evaluates fall risk, hearing ability, ability to take medications • Age, gender, height/weight, cancer type, dosage, number of chemotherapy agents, hemoglobin, and Crcl • Takes 5 min to complete

Extermann M et al. Cancer 2012, Hurria A et al. JCO 2011

CRASH Score

CRASH Score Calculator

This score stratifies patients in 4 risk categories of severe toxicity. Reference for derivation and validation results: Extermann et al. Cancer, Epub Nov 9,2011 http://www.ncbi.nlm.nih.gov/pubmed/22072065. Formal clinical applications of the score still need to be studied.

*** Please click on each link to view/close help on assigning scores**

Chemotherapy risk

Chemotherapy risk 0

Hematologic Risk Factors

Diastolic blood pressure 0

IADL 0

LDH 0

Non-Hematologic Risk Factors

ECOG PS 0

MMS 0

MNA 0

Submit

Description	Score	Risk
Heme Score	5	Med High
Non Heme Score	5	Med High
Combined Score	8	Med High

https://www.moffitt.org/eforms/crashscoreform/

CARG Score

Gender
Select

Patient's Age

Patient's Height
Select

Patient's Weight
Select

Cancer Type
Select

Dosage
Select

Number of Chemotherapy Agents
Select

Hemoglobin
Select a value

How is your hearing (with a hearing aid, if needed)?
Choose

Number of falls in the past 6 months
Choose

Can you take your own medicines?
Choose

Does your health limit you in walking one block?
Choose

Total Risk Score		%Risk
Low	0 to 3	25%
	4 to 5	32%
Mid	6 to 7	50%
	8 to 9	54%
High	10 to 11	77%
	12 to 19	89%

https://www.mycarg.org/?page_id=934

ONCOLOGY PHARMACIST ROLE

- Identify polypharmacy and PIMS through medication assessment continuously
- Evaluate DDIs and drug disease interactions
- Understand role of CGA in geriatric oncology patient
- Ensure appropriate dosing of chemotherapy
- Monitor and manage chemotherapy toxicities
- Assess for non-adherence

CONCLUSION

- Incidence of cancer in geriatric population continues to increase
- Treatment should be individualized based on comprehensive geriatric assessment
- Oncology pharmacists play a valuable role in the geriatric oncology care with management of polypharmacy, medication safety, and chemotherapy toxicity management

QUESTION 1

Which of the following is a domain of a comprehensive geriatric assessment?

a. Function
b. Nutritional assessment
c. Cognition
d. All of the above

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a. Function
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QUESTION 2

Which of the following is not a risk factor for polypharmacy in elderly patients?

a. Poor nutritional status
b. Frequent hospitalizations
c. Comorbid conditions
d. Cancer treatment with multiple ADEs

QUESTION 2

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b. Frequent hospitalizations
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d. Cancer treatment with multiple ADEs

QUESTION 3

What would be an appropriate supportive care option for elderly cancer patients?

a. Lorazepam for treatment of chemotherapy induced nausea/vomiting
b. Lifestyle modifications for management of insomnia
c. Oxycodone for treatment of neuropathic pain
d. Diphenhydramine for prevention of infusion related reactions

QUESTION 3

What would be an appropriate supportive care option for elderly cancer patients?

a. Lorazepam for treatment of chemotherapy induced nausea/vomiting
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