

Provider Decision Making Criteria for the Use of Chemotherapy

in Older Patients with Colon Cancer

Lisa Radcliff

Oregon Health & Science University



DNP Clinical Inquiry Project Report & DNP Portfolio Approval

Student Name: Lisa Radcliff

Degree: Doctor of Nursing Practice

Title of Study:

Provider Decision Making Criteria for the use of Chemotherapy in Older Adult Patients with Colon Cancer

APPROVED:

Committee Chair: Deborah Messecar, RN, PhD
(name and credentials)

Signature:

Committee Member: Mark Seligman, MD
(name and credentials)

Signature:

Committee Member:
(name and credentials)

Signature:

Dean, School of Nursing: Chris Tanner, RN, PhD

Signature:

Date: 5/24/12

Submit completed original form to the Graduate Program office.

Clinical Inquiry Project Executive Summary**Lisa Radcliff, NP****Doctor of Nursing Practice Candidate****OHSU School of Nursing**

With the growing older patient population and the prevalence of colon malignancies in this age group, thorough assessment prior to consideration for chemotherapy is necessary.

Review of current literature shows that this group of patients is under treated when compared to younger patients (Davidoff et al., 2009). The lack of older patients included in clinical trials makes evidence-based decisions for older adults with colon cancer difficult for the provider (Levitz & Lichtman, 2005). Before specific recommendations on the appropriate candidates for therapy can be proposed, provider decision making criteria used in evaluating the older adult with colon cancer for consideration of chemotherapy needed to be determined and examined.

In this clinical inquiry, several variables were assessed for being predictive of offering therapy including age of patient at onset of disease, stage of disease, performance status, number of co morbidities, and patient living situation. After the first evaluation of chart reviewed data, it was determined that not being offered any therapy was a very rare event. Therefore, the question was further refined to assess if the therapy offered was the standard of care or an alternate therapy. Of 403 patient offered therapy for colon cancer, 68 patients were offered an alternative regimen than the defined standard of care. Further evaluation showed that older age and poor performance status were very predictive in being offered an alternative therapy. Stage of disease, co morbidities, and living situation were not found to be statistically significant predictors of not be offered the defined standard of care, but were still deemed important for inclusion in future practice evaluation. Further research needs to be done in this area.

The Clinical Problem

Description and Significance

In the United States today, we have a growing population of older adults requiring healthcare assistance for a cancer diagnosis. In clinical oncology practice, the criteria for evaluating the patient appropriateness for therapy and offering chemotherapy can vary by institution and provider. Often this age group is excluded from clinical trials making evidence-based decision making criteria unavailable to the provider. There are limited age-specific guidelines for chemotherapy use in the elderly, especially for patients over the age of 75 (Levitz & Lichtman; 2005). This deficit in current research contributes to provider under treatment of this patient population. However, advanced age alone should not preclude the use of effective cancer treatment that could improve quality of life or extend meaningful survival (National Comprehensive Cancer Network, 2011).

Epidemiology of Population Affected.

According to the United States Census Bureau (2010), the American population is 301,461,533 people. 6.1% of citizens are over the age of 75 years (approximately 18.4 million people). In contrast, only 10 years prior, this percentage was 5.8% or 16.6 million people. This population group is continuing to grow as healthcare improves and longevity increases.

According to the Center for Disease Control and Prevention SEER data from 2008, cancer of any type has an incidence of 2274 per 100,000 persons age 75+ years. This is compared to 463 per 100,000 persons of all ages and 227 per 100,000 persons under the age of 65 years. The incidence of cancer in patients over 75 years is substantially higher than the general population.

From 2004-2008, the age at diagnosis for cancer of the colon and rectum was approximately 26.2% for ages 75-84 years and 12.2% 85+ years (SEER, 2008). From 2004-2008, the median age at death for cancer of the colon and rectum was 75 years of age. Approximately 29.8% died between the ages of 75 and 84 years, and 20.7% 85+ years of age (SEER, 2008).

Background of the Problem.

When an older adult presents with a malignant disease process, several aspects go into the decision making by the provider as to whether or not this individual is a candidate for anti-neoplastic therapy. Factors providers may weigh include, but are not limited to, age, performance status, co-morbidities, extent or stage of malignancy on presentation, and/or independence/social support system availability. Describing the provider decision making criteria used in clinical practice will help determine if older age is an unnecessary barrier to receiving therapy. This information could then be used to more readily identify those older adults would most likely benefit from therapy. Thus clinicians would have a better way of evaluating the risk that being older adds to the equation.

Organizational/Knowledge.

Currently, there are no overarching institutional guidelines at Oregon Health & Science University (OHSU) for chemotherapy treatment in the older adults. Treatment decisions are at the provider discretion, with the assumption that the decision is based upon ethical practice and current evidence-based research. Given the lack of inclusion of the older adult population in clinical trials, finding evidence-based research can be challenging.

Since the evidence base to inform treatment decisions in older adults is limited for this population, what is needed is knowledge translation. Knowledge translation is a process that includes evaluating the existing practice-based evidence from the literature, local practice data, and national standards or opinions of recognized experts, then applying that knowledge to the clinical problem at hand.

Importance to Advanced Practice.

This clinical inquiry arose to examine the current practice in decision making for chemotherapy for older adults, with the future plan to improve the likelihood that the appropriate older adult patients are recognized and offered therapy. Careful evaluation of the older adult is a factor that will be increasingly important as this patient population continues to grow in the future.

Advanced practice nurses are expected to be leaders in knowledge translation. They should be able to integrate their clinical experience with judicious use of research evidence to enhance treatment decisions that maximize the well-being of the patient. The findings of this clinical inquiry are intended to increase the knowledge base upon which chemotherapy treatment decisions for older adults are made, to possibly improve patient outcomes, and provide leadership in the dissemination of knowledge useful to all oncology clinicians.

Desired Outcome/Impact.

The desired short term outcome of this clinical inquiry was to ascertain if older adults in the OHSU Community Oncology clinic setting, who might benefit from chemotherapy for colon cancer, were being excluded from treatment due to age, aside from comorbidities or other

contraindications and considerations. The desired long term outcome was to increase the number of patients considered for treatment, as deemed appropriate through improved provider screening, by first evaluating the pertinent pieces of provider decision-making.

Purpose Statement.

The goal of this inquiry was to identify the relative weight assigned to several different provider clinical decision making criteria when offering or withholding anti-neoplastic therapy to patients with a colon malignancy. An additional goal was to evaluate the relative significance of age in comparison to other identified criteria such as comorbidities, performance status, stage of disease, and living situation. If, after controlling for these other factors, age was still a predictor of not being offered chemotherapy, the clinical practice group was to be informed and measures taken to address this issue. This may have included creation of a screening guideline for use at the initial patient consultation.

Clinical Inquiry Question.

What was the relative importance of age on the likelihood of being offered chemotherapy, after controlling for comorbidities, performance status, stage of disease, and living situation, in a patient with a biopsy-proven colon malignancy?

Conceptual Framework

The basis of this inquiry was framed by the assumption that there are a number of factors that predict how well or poorly a patient tolerates chemotherapy, both physically and mentally. In the initial assessment of the patient, the provider considers multiple factors, including age,

extent of disease, comorbidities, performance status, and living situation. Age, extent of disease, and comorbidities speak to physical tolerance to therapy and possible potential problems that could arise during the course of therapy. Performance status and living situation are a vaguer and more abstract indicator of the patients' ability to navigate the difficulties of therapy, including caring for themselves at home, transportation, nutrition, and coping with illness. All of these factors are routinely screened for as they are thought to play a role in patients' likelihood of tolerance and success or failure through therapy.

The National Comprehensive Cancer Network (NCCN) has published a generalized Senior Adult Oncology Guideline. This guideline recommends screening for possible risk factors of adverse outcomes, defined as: comorbidities (congestive heart failure, renal insufficiency, neuropathy, anemia, osteoporosis, GI problems, diabetes, lung disease, hearing or vision loss), geriatric syndromes (functional dependency, mobility problems, dementia, falls, nutritional deficiency, delirium, depression, polypharmacy), and socioeconomic issues (poor living conditions, no caregiver, low income, no transportation, lack of prescription drug insurance coverage). If risk factors are not modifiable, the guideline recommends "alternate treatment options to reduce toxicity". The guideline also states that older adult patients receive similar clinical benefits to treatment as younger patients in both adjuvant and metastatic colon cancer (NCCN Senior Guideline, 2011).

Review of Literature

Despite several studies highlighting no difference in efficacy, outcomes or patient experience for older adults with colon cancer receiving chemotherapy, several reports of studies

and expert opinion articles identify a disparity in the frequency of treatment of the elderly patient for colon cancer.

Critical synthesis of relevant literature.

State of science.

According to Levitz & Lichtman (2005), 70% of colorectal patients are over the age of 75 years, and yet less than 1% are accrued to clinical trials. After a thorough literature review, they found that age at diagnosis is the strongest determinant of receiving adjuvant chemotherapy for stage III colon cancer. Bouchardy et al (2001) also noted a disparity in the number treated when evaluating for age. Using a two group non-randomized analysis of stage III colon cancer patients, they found 50% of patients under the age of 70 years received therapy, compared with less than 10% of patients over 70 years of age. They also observed no significant difference in chemotherapy efficacy between the two age groups. Another large retrospective chart analysis study to examine this issue observed that patients over the age of 80 years are less likely to receive surgery and/or chemotherapy for colorectal cancer (Hardiman et al, 2009).

Jessup et al (2005) found that elderly patients have the same benefit as younger patients but are less frequently treated (n=85934). Sargent et al (2001) took this idea of efficacy one step further. Not only do select elderly patients with colon cancer receive the same benefit from fluorouracil-based adjuvant chemotherapy, there was no significant increase in toxicities either. Feliu et al (2009) also found that chemotherapy toxicity does not seem to increase with age and therapeutic results are comparable in the adjuvant setting as well as in advanced disease.

Winget et al (2010) examined more variables in relation to this issue. They found age, co-morbidities, and lower income to be significant factors when considering therapy for patients with colorectal cancer over the age of 75 years. They also noted that this age group was 8.7 times more likely to not have a consultation with an oncologist. Jorgenson et al (2011) reaffirmed this idea through physician survey. They found that surgeons were significantly less likely to refer an older patient (80 years or more) with node-positive cancer for adjuvant therapy.

Gaps.

One question yet to be answered is the importance of co-morbidities. Etzioni et al (2008) found co-morbidities to be a significant patient factor, recommending more research in the area of evidence-based standards of care for the elderly, including an assessment of functional status. Gross et al (2007) found that while chronic conditions appear to be a significant barrier to the receipt of adjuvant chemotherapy, it provided a significant survival benefit to colon cancer patients with the particular conditions studied. Kahn et al (2010) also found that older adults (75 years or more) were less likely to receive the standard of care and more likely to be excluded for comorbidities. Quiport et al (2011) found that patients age less than 75 compared with age greater than 70 years were more likely to receive adjuvant therapy (95.5% versus 50.7%) or palliative chemotherapy (82.4% versus 42.2%). When examined with co-morbidities, these numbers remained significant. The question of importance of co-morbidities still remains to be answered and represents a gap in the current evidence.

Critique.

Other criteria of possible significance to medical oncology providers when offering therapy to older patients include performance status and living situation. Kohne et al (2001) found that “fit” elderly patients should be offered therapy, recommending that this group of patients be more thoroughly examined for functional, social, and mental status. While this seems an obvious conclusion, very little research of this patient population is available to examine the roles of these variables in provider decision making.

Other sources of evidence.

The National Comprehensive Cancer Network (NCCN) has issued a guideline for the standard of care for colorectal patients, recommending chemotherapy for those patients that meet criteria for stage III or IV colon cancer. However, this well recognized standard does not speak to patient demographics such as age in any fashion. The NCCN Senior Oncology Guideline (2011) has a limited geriatric assessment guideline available.

Arnoldi et al. (2007) developed a tool for geriatric assessment of cancer patients as candidates for therapy. They evaluated “frailty” using these variables: activities of daily living, comorbidities (using the Charlson Index), and performance status (using the Karnofsky and ECOG scales). Although a small sample was used, their model showed a correlation between frailty and poor outcomes.

Repetto et al. (2002) utilized a comprehensive geriatric assessment (CGA) to evaluate elderly cancer patients. They found a strong association between ECOG performance status score and the CGA results. However, they did not evaluate treatment outcomes associated with their findings. Furthermore, a disproportionate amount of the sample was in very good health.

Nevertheless, use of the CGA provides substantial information during functional assessment.

Tucci et al. (2009) used CGA to assess elderly patients with diffuse large B-cell lymphoma and included treatment outcomes as a study variable. They found that the CGA was an efficient method to identify patients that would benefit from a curative approach. However, the study did not identify any obvious causes of poor outcomes.

Girre et al. (2008) considered the weight of a geriatric consultation and evaluation on the final oncology treatment plan. They found that one-third of the sample patients had their treatment plan modified after the consultation. However, the study did not evaluate whether these modifications improved the outcomes of these older patients.

In the Journal of Clinical Oncology, Rodin and Mohile (2007) discussed the use of the CGA, pointing out, while appropriate, it can be very time consuming and inefficient. They recommend a shorting screening tool, the Vulnerable Elders-13 Survey, to identify areas of concern for further investigation, suggesting this method is more effective and productive. They present this tool as a convenient and practical option for assessment, however, not speaking to its validity or evaluating outcomes.

Summary.

In summary, the bulk of the existing literature recognizes an age disparity in treatment of elderly colorectal patients, some of these studies highlighted co-morbidities as a potential issue, and very few studies considered functional status or social support, instead recommending further review in this area. Several studies suggested the use of a comprehensive geriatric assessment; however the assessment itself lacked consistency and represented a time burden. A

few tools for assessment exist but have not been well evaluated or adopted. According to Maas et al (2007), “so far in oncology there are no prognostic validation studies reported using geriatric syndromes or information based on CGA in its decision making strategies.” The question remains which of these variables are significant in provider-decision making so that further investigation can proceed where required.

Methods

Clinical Inquiry Design

A retrospective chart analysis was employed using data from the Oregon Health & Science University Community Hematology Oncology clinics to answer the clinical inquiry questions. This clinical inquiry project used chart information collected at the time of the initial patient consultation and documented at the time of treatment decision making (which may have been at subsequent visits after the initial consultation). The data collected focused on variables of provider decision making criteria when offering or withholding chemotherapy to stage III or IV colon cancer patients who, according to the National Comprehensive Cancer Network (NCCN) guidelines, should have been candidates for this type of therapy.

In a retrospective chart analysis, clinical researchers use data collected at the point of care to answer inquiry questions that were not part of the original purpose of the charting documentation. Strengths of this approach include using concrete data from a substantial sample to form a conclusion as opposed to expert opinion or individual case study. Limitations of this approach preclude the researcher from manipulating or intervening to evaluate a possible change or improvement in outcomes.

Other considered approaches to answer this clinical question included individual clinician interview regarding their decision making or mock vignettes for expert review. This method was used by Keating et al (2008) and Krzyzanowska et al (2009) using clinical cases and soliciting provider responses to case scenarios. Both studies found an age bias but lacked any further insight into provider decision making. Interestingly, Keating et al (2008) found that younger

physicians were more likely to offer treatment than their older colleagues. The main disadvantage with a case scenario option is the difference between the providers' perception of their practice versus the actual practice pattern.

The following criteria were used for evaluating the potential of the chart record for answering the clinical inquiry question. The chart data was available for export to EXCEL file format. The chart record included documentation of important clinical parameters such as age, diagnosis and stage of disease, medical and social history, which have been identified to weigh upon the clinician's decision making. The electronic medical record at this practice had treatment decisions available for a broad variety of candidates for this type of diagnosis and chemotherapy, including at least 300 colon cancer patients.

Setting

The inquiry took place at the Community Hematology Oncology Clinics, a division of the Knight Cancer Institute at Oregon Health & Science University (OHSU). This is a group of ambulatory infusion clinics in the greater Portland, Oregon and surrounding suburban area. The patient population is adults, mainly cancer patients, receiving treatment in the outpatient setting (as opposed to the hospital). The concept of the group is to deliver care near the patient's home in their community. Examinations and infusion therapy take place on site.

The Community Hematology Oncology clinics at OHSU represent a diverse patient population, having both urban and suburban clinic settings, in both higher and lower income areas. This group of clinics is very similar to any community-based oncology service one would encounter near a large metropolis. However, when looking with a geographical focus, the

northwestern United States may present some regional differences when compared with other areas around the United States, such as the south eastern area, for example, in variables such as income, access, and cultural beliefs. However, given the focus on provider decision-making criteria and exclusion of the patient preferences/issues, these differences were acknowledged and set aside.

The provider group consists of medical doctors and nurse practitioners who function to evaluate and care for patients receiving chemotherapy. The provider mix is varied in age, race and gender. All of the providers are certified in oncology; medical doctors are certified via examination by the American Board of Internal Medicine; nurse practitioners are certified via examination by the Oncology Nursing Certification Cooperation.

The organization readiness to change at OHSU is driven by the provider group within the division of Community Oncology. Several providers within the group have acknowledged the importance of this clinical decision-making and voiced their interest in the outcome of this study as a focus for practice improvement.

The main driving force for change is the provider group and their interest in providing optimal evidence-based care to their patients. The most significant restraining force to change is the additional time burden on the provider of a more thorough analysis of the patient if not already in practice.

Sample

Inclusion criteria.

The sample included all patients with a biopsy-proven diagnosis of a colon malignancy and an evaluation by a provider at an OHSU community oncology clinic between 2000-2011.

Exclusion criteria.

The sample excluded all patients with a different type of malignancy (i.e. rectal, anal, gallbladder, etc.), a colon malignancy that would require surgical management only (defined as stage I or II), patients without a previous biopsy available for a verifiable tissue diagnosis, patients where the chemotherapy decision was not available, and patients under the age of 40 (required by the OHSU Knight Cancer Institute Review Board).

Size.

A preliminary examination of the electronic records at the OHSU Community Oncology clinics indicated that over 1000 patients had an ICD-9 code associated with their chart indicating a diagnosis of colon malignancy, with approximately a third of that sample over the age of 75 years.

Rationale.

The sample was one of convenience due to easy accessibility of the patient population via the electronic medical record over an extended period of time.

Sampling method.

The sampling method was a random electronic chart call with two parameters: date of birth and range of ICD-9 codes. The electronic medical record had mineable data available from

2000 through 2011. The chart call consisted of all patient charts with ICD-9 codes: 153.00 - 153.99. These ICD-9 codes include all colon malignancies (excluding rectal and anal malignancies due to differences in treatment algorithms). This list was then further defined by date of birth using month and year format to determine age at onset of disease.

Intervention

This project was retrospective and therefore did not include a true intervention. However, the possibility of a future intervention based on these findings is possible. Currently the screening process for evaluation of the older adult for chemotherapy is done by direct interview by the clinician during the initial consult. This interview generally includes the history of present illness, general medical and surgical history, current medications, and social history. This may be an extensive or limited history based on individual provider preference and/or time constraints. Hence this practice improvement project focused on existing practices to determine whether new parameters or screening methods needed to be developed in this area.

Measures

The evaluation focused on the pertinent factors that potentially shape provider decision making when offering chemotherapy to older adults. Patients that met the inclusion criteria had their chart reviewed for the described variables listed below.

The patient chart was first screened for whether or not a patient was offered therapy. The dependent variable was whether the patient was offered chemotherapy by the provider, yes or no. For a number of the patients who were offered chemotherapy, instead of the standard chemotherapy regimen, an alternative modified therapy was offered rather than no treatment at

all. These patients were counted as not having been offered the standard of care. Then, these 2 groups were examined further for the variables listed below. If variable data was not available or obvious after chart examination, the absence of information was noted. A second logistic regression was done using the same predictor and outcome variables but only including those patients who were age 75 years and older, dividing into 2 groups those that were offered therapy and those that were not, and re-examined for the variable data.

Variable assessment.

The dependent variable was whether chemotherapy was offered, regardless of whether it was received, as evidenced in the provider notes.

Age was recorded and defined as the patient's date of birth in month/year format at the time of decision making (also referred to as the consult date). Later, the entire sample group was further divided by patients born before 1936 and those born after 1936 for comparison.

Performance Status was defined using the Eastern Cooperative Oncology Group (ECOG) performance scale:

0=fully active,

1=restricted in physically strenuous activities but still ambulatory and able to do light work,

2=ambulatory and able to do all self-care but no work activities,

3=capable of only limited self care, confined to a bed or chair 50% of waking hours,

4=completely disabled, no self care, totally confined to bed or chair (ECOG, 2006).

This performance evaluation variable was chosen as it was readily available in the electronic medical record. It is a widely used and well recognized performance scale.

The Eastern Cooperative Oncology Group was established in 1955 to facilitate multi-center oncology clinical trials. ECOG is one of the largest clinical cancer research organizations in the United States and is funded primarily by the National Cancer Institute. The ECOG performance scale was developed in 1982 and published in the American Journal of Clinical Oncology (Oken et al, 1982). According to ECOG, the “scale and criteria are used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis” (ECOG, 2006).

Co-morbidities were identified as available in the chart record and weighted according to the Charlson Co-morbidity Index. This is a widely used comorbidity index designed by Mary Charlson in 1987. The index identifies and weighs a list of 19 co-morbidities. The total score is calculated and then placed into four categories as deemed prognostic for mortality. There is also an optional extension to integrate scoring for advancing age. Due to the specific examination of age in this inquiry, the age score was withheld. (Extermann, 2000)

The Charlson Co-morbidity Index includes major organ systems pertinent to decision making in chemotherapy treatment, specifically cardiovascular, pulmonary, renal, and hepatic systems. However, it should be noted that this scale does not reflect on neuropathy of any degree, or more specifically peripheral neuropathy, an important factor due to one of the agents

used to treat colon cancer, oxaliplatin. This may be an area of concern to be considered further in the discussion section of the completed project.

The stage of the colon malignancy upon initial consultation was recorded using the standard set by the American Joint Committee on Cancer (AJCC, 2010). The two options available to define this variable were stage III or stage IV, recognizing that these two stages of colon cancer are appropriate for chemotherapy (NCCN, 2010), and excluding stage I or stage II due to controversy of appropriateness of chemotherapy not to be addressed in this project.

The patient's living situation was recorded to be used as evidence of (or lack of) social support using the following scale:

1=alone,

2=with spouse,

3=with family,

4=assisted living facility or skilled nursing facility.

The bulk of the literature regarding comprehensive geriatric assessment of the elderly cancer patient identifies this variable as pertinent to overall outcome. However, evidence-based research of a direct correlation between living situation and the cancer patient outcome appears to be scarce.

Data collection procedures

Data collection was facilitated using the electronic medical record available at the OHSU Community Hematology Oncology clinics. The software system in place from 2005 -2011 was Aria by Varian. This software does retrieve information from the electronic medical record that was in place prior to 2005 if current patients did have visits in the prior period of time. This software system allowed for electronic mining of birth date, diagnosis by ICD-9 code, stage of disease, co-morbidities, living situation, and ECOG status. Further provider decision making, including offering chemotherapy, or evaluation of missing variables not input correctly by providers (i.e. free text rather than a mineable field) was accomplished by direct individual chart review. Pam Hilger was the manager of this software system during the abovementioned time period. She assisted in the software access and chart call of the requested data.

The data was then organized in an EXCEL file using an individual research number to identify each subject to exclude their name and using only month and year of birth to establish age, further removing unique identifiers by deliberately eliminating the day of birth as requested by the OHSU institutional review board.

Analytic Methods

Correlation and logistical regression for significance of different variables.

The aim of this clinical inquiry project was to examine the relative importance of the following clinical parameters: comorbidities, performance status, stage of disease, living situation, age in general and age over 75 on the likelihood of being offered guideline-directed chemotherapy treatment. A logistic regression model was constructed to address this aim. The logistic regression procedure estimates the probability that an event will occur for a dichotomous

dependent variable. The minimum specifications for this type of analysis are a dichotomous dependent variable, and one or more predictor variables. The odds ratios computed for each predictor was interpreted.

Logistic regression models have several assumptions about the data. These include that: 1) the true conditional probabilities are a logistic function of the independent variable; 2) no important variables are omitted nor extraneous variables included; 3) independent variables are measured without error; 4) observations are independent; and 5) independent variables are not linear combinations of each other. We tested for link error to address issues 1 and 2, using the Stata command link test after the logit or logistic command (UCLA Academic Technology Services, 2012). For the purpose of this research, we assumed that 3 was true. Variance inflation factor was used to address 4 and 5. Output of logistic regression from the Stata software contains the log likelihood chi-square and pseudo R-square for the model and these were used to give us a general gauge on how the model fits the data.

Cost analysis.

Cost was not addressed in this project as we were examining current practice and not implementing change in usual care or procedure. The cost of a possible future proposed practice change based on this research would require a more in-depth cost analysis, especially if the proposed change requires increased provider time during patient evaluation.

Proposed presentation of data.

Data was provided in a table format for demographics to acknowledge significant variables or trends. All results will be presented at a public forum and to the provider group specifically.

Data Management Plan and Protection of Human Subjects

Patient cases were identified by medical record number unique to this electronic medical record system only and cross matched to a random number identifier. This list was kept separate from patient data. At no time were patient names or other personal information attached to the data collection file.

Health Insurance Portability and Accountability Act (HIPAA) protected patient data did not leave the clinic and was not cross-referenced at any point with data for evaluation. Once a tracking system was in place, the master list remained with the clinic. All data abstracted from the chart, including hard copies, reports, and external drives, was kept secure by the individual conducting the inquiry project. All persons with access to data rigorously followed procedures to ensure confidentiality of data.

Dissemination of Information to Key Stakeholders

The clinical inquiry data and evaluation will be made available to the hosting agency and its provider group for a further action plan as appropriate. Information from this Clinical Inquiry Project report, after approved in its final version, will be made available to the provider group in June 2012.

Anticipated timeline.

Evidence evaluation: August 2011

Proposal approval by advisor, mentor, and agency: December 2011

Data collection: January and February 2011

Data evaluation: March 2012

Written summary: April 2012

Submission: May 2012

Committee members/participants.

Deborah Messecar, PhD, OHSU nursing faculty

Mark Seligman, MD, OHSU oncologist

Results

Sample

The chart call from Aria electronic medical record system resulted in 622 patient charts associated with an ICD-9 code for colon cancer. Of these, n=212 charts were excluded from further review due to wrong diagnosis code, different malignancy than colon, history of colon cancer that was not a current problem, stage I or II, no biopsy-proven diagnosis, no chemotherapy discussion notes available, or lack of data to appropriately assess inclusion and exclusion criteria.

A total of 410 patient records were included in the analysis. Of these, only n=7 were not offered treatment for their colon malignancy. Various reasons for not offering therapy among these seven patients included diagnoses of dementia, Alzheimer's disease, and severe autism. Early in the project, it was clear that not being offered any therapy was too rare of an event to proceed with the original planned analysis. However, of those 403 patients offered treatment, n=68 were offered a modified therapy different than the current standard of care, due to concerns that they could not tolerate a full standard regimen. Because the original clinical inquiry project question sought to determine the predictors of not being offered standard therapy, and these 68 patients were offered an alternative to the standard therapy, proceeding with the original planned analysis, but comparing being offered the standard therapy with being offered an alternative therapy, seemed reasonable and consistent with the original aims of the project. Hence, this data analysis focused instead on the predictors of receiving a modified chemotherapy regimen.

Originally unknown, the EMR system, though only implemented in 2005, allowed for data availability back to 2000, so the chart call included patients from 2000-2011 seen by the provider group Oregon Hematology Oncology Associates, then Pacific Oncology, now OHSU. The standard of care for colon cancer was defined as 5-FU (oral or IV form) plus oxaliplatin for patients diagnosed after 2004. For patients diagnosed prior to 2004, the standard of care was defined as 5-FU IV plus irinotecan. A modified chemotherapy regimen was defined as 5-FU alone (oral or IV) or irinotecan alone.

Findings

Table 1.

Characteristics of the Sample Patients by Variable.

Characteristics of Total Sample N=410	Mean	Range
Age (n=410)	67 years	40 – 95 years
Characteristics of Logistic Regression Sample n=403	Number	Percent %
Therapy		
Standard of Care	333	81.02
Modified regimen	68	16.55
Stage		
III	209	50.85
IV	201	48.91
ECOG		

Completely Independent	172	41.85
Ambulatory and able to do light work	162	39.42
Ambulatory but unable to work	49	11.92
>50% of time in chair/bed	10	2.43
Requires assistance with ADLs, completely bedridden	2	3.89
No data	16	
Number of Comorbidities		
0	229	55.72
1	74	18
2	60	14.6
3	22	5.35
4	15	3.65
5	1	0.24
6	3	0.73
7	1	0.24
8	0	0
9	1	0.24
No data	5	
Living Situation		
Alone	97	23.6
Spouse or significant other	255	62.04
With family	41	9.98

ALF/SNF	15	3.65
No data	3	

The stage of disease on presentation was roughly equal. The above table indicates that 55% of the sample had no co morbidities, surprising given the average age of 67 years.

Data Analysis

All statistical analyses were completed using Stata version 11. Binary logistic regression was the primary statistical model employed in the analysis, with a focus on the predictors of being offered the standard of care or an alternative chemotherapy regimen. Initially, the plan had been to examine predictors of not being offered any treatment, but as stated in the sample section, this was a very rare event so the outcome variable was changed from treatment/no treatment to treatment standard of care/treatment other.

The following possible treatment influencing decision factors were examined as predictors of the treatment regimen offered: stage of disease, number of comorbidities, performance status (ECOG score), living situation, and age. Table 2 presents the results of the binary logistical regression. The overall regression model was significant in predicting the outcome ($\text{prob} > \text{chi}^2 = 0.0000$). However, three of the variables that were assumed to influence treatment decisions were not significant (stage of disease, comorbidities, and living situation). Possible reasons for this finding will be explored in the discussion section. The odds ratio of being offered an alternative treatment regimen other than the standard of care doubled for those with a compromised performance status ($\text{OR}=2.04, p<0.000$). The odds of being offered an alternative treatment regimen other than the standard of care also increased by 22% for each additional year of age ($\text{OR}=1.22, p<0.000$).

Table 2.

Provider Decision Making Variables and Predictive Value of Offering an Alternative Therapy Regimen

Variable	Odds Ratio	<i>P</i> value	95% CI
Stage	0.78	0.498	0.38 – 1.59
Number of Comorbidities	1.11	0.403	0.86 – 1.42
ECOG	2.04	0.003	1.27 – 3.27
Age at onset	1.21	0.000	1.15 – 1.28
Living Situation		0.218	

In addition to the above findings, age at onset was converted into a categorical variable by dividing the sample at age greater than or equal to 75 years. When age at onset was treated this way, the regression model showed that, for the older group, ECOG status was even more predictive of receiving an alternative regimen instead of the standard of care. When age at onset was treated as a continuous variable (rather than a dichotomous variable), the older the patient is on a continuous scale, the less likely they are to be offered the standard of care.

Discussion

Interpretation/Context

In contrast to national benchmarks and treatment rates, this particular provider group at OHSU does offer the majority of older colon cancer patients the expected standard of care

chemotherapy regimen. Evaluation of those patients that were offered an alternative regimen revealed that providers associated poor performance status (defined as ECOG score) and older age with inability to tolerate the standard of care. Thus, these 2 variables were significant in logistic regression models of provider decision making. Stage of disease, co morbidities, and living situation, while routinely collected information during the patient consultation visit, were not associated with the type of therapy offered. This may be due to other influencing factors as discussed in the limitations section. However, given the literature supporting efficacy and outcomes in the older adult patient, these findings may indicate that we weigh age too heavily in decision making.

As previously mentioned, the stage of disease on presentation was roughly equal. Half of the sample presented at stage III for adjuvant therapy with curative intent. The other half of the sample presented with metastatic disease (stage IV) for palliative therapy with the hope of prolonging survival, but without curative intent. This variable may indicate that we are not detecting and diagnosing colon cancer early enough to be curable. Given the preventative nature of routine screening colonoscopy, this is an unfortunate finding.

Situation Analysis

The clinical inquiry project process allowed the DNP student to act as principal investigator, under faculty supervision, in an area of their choosing. This level of autonomy is rewarding but also presents challenges that create an excellent learning opportunity. For example, this particular project seemed fairly straightforward in its design. However, after evaluating results from 10% of the sample early in the data collection process, it was obvious that one alternative of the initially proposed dichotomous outcome was an extraordinarily rare

event, making it impossible to do the originally proposed analysis. However, facing this challenge prompted a rethinking of what the dichotomous outcome should be for this analysis. Taking a closer look at the data, we identified a more useful approach to this issue. Still using the initial proposed variables of provider decision making, a modification of the treatment question was identified and applied. Basically, we retained the original question which sought to identify predictors of not being offered standard NCCN guideline therapy but our dichotomous outcome became being offered NCCN treatment versus receiving an alternative modified dose. The ability to step back midstream, evaluate the situation, and find the most useful application of evidence exemplifies the hallmark of translational research and the role of the clinical doctorate in nursing.

Outcomes

The outcome of this project was intended to drive practice change if necessary. Originally, the perceived end point would be a useful tool and/or a more in-depth evaluation of the older adult prior to chemotherapy. The results have identified a different but important issue: the ECOG variable is no longer routinely collected or available as a result of a change in medical record software used in the clinics. Due to the significance of this variable in this clinical inquiry project, the DNP nurse will recommend to the provider group reinstating this practice as a piece of screening these particular patients. Furthermore, this issue may be brought to the attention of the electronic medical record department at OHSU for consideration of inclusion in all documentation. On a larger scale, this begs the question of how charting systems drive practice patterns, an excellent area for future research.

Limitations

In general, the medical community recognizes the importance and impact of the patient's co morbidities on their overall health and ability to endure treatment. This variable was not found to be statistically significant in this project. However, the tool used (the Charlson Comorbidity Index) may account for this limitation. This tool was not developed for oncology patients specifically, but rather any patient in general. Therefore the particular co morbidities included and weighted were not always applicable to a pre-chemotherapy screening. More importantly though, the tool did not include certain areas of concern for screening oncology patients. For example, neuropathy of any etiology is important as many chemotherapeutic agents can potentiate and worsen this issue, significantly impacting health and quality of life of the patient. As previously mentioned, the NCCN has a guideline for assessing the older adult patient. It is not a tool so much as an outline. However, a useful tool could be created from this guideline and implemented for better assessing patient's co morbidities prior to therapy.

The stage of disease as defined by the AJCC was also not a statistically significant variable in decision making. In retrospect, this may have been more useful if the patient had been evaluated by the extent of their disease instead. For example, a stage IV patient may have a single liver metastases or grossly metastatic disease involving liver and lungs, but both findings are the same stage of disease. These two different scenarios can greatly impact goals of therapy and thus treatment algorithms. Unfortunately, there is not a scale or tool for "extent of disease". This is a subjective evaluation by the consulting provider. In some other types of malignancies, the AJCC has started to recognize different levels of stage IV disease, and identified a naming process. This could be an area of further research and implementation for colon cancer in the future.

With regards to the importance of the social history of the patient, living situation is one piece of the picture. This variable was also not statistically predictive of the type of treatment offered. However, as with the other variables, is still deemed of importance. This variable could be grouped with other items in the patient's social history and named external influencing factors, to include such issues as transportation, insurance coverage, medication management, polypharmacy, caretaker availability, travel distance, etc. All of these issues are known to impact the patient's ability to receive appropriate care. However, measuring and weighting these factors in decision making is difficult. This is often an area of expertise for social work and appropriately they should be included in the decision making algorithm. This could be an area of further multidisciplinary collaboration.

The variable of gender (patient and/or provider) was not collected. However, in hindsight, this may have been a useful piece of information. There may be a subtle bias when treating older adults between male and female patients. Even more interesting, one could evaluate outcomes between the gender of the provider crossed with the gender of the patient. This is an area for potential further research.

Conclusions

In conclusion, the population of older adults is growing. These patients will continue to require medical care. Thorough patient evaluation is necessary to offer safe and effective treatment to older patients with colon care. This clinical inquiry showed that performance status and age were very predictive of being offered the standard of care or an alternative therapy. These variables should always be assessed during the patient consultation. Furthermore, while the other variables of stage of disease, co morbidities, and living situation were not significant in

predicting treatment type, there are still considered pertinent details and should be investigated further.

References

- American Joint Committee on Cancer (AJCC). (2010). *Cancer staging manual*. 7th Ed.
- Ananda, S., Field, K., Kosmider, S., Compston, D., Desai, J., Lim, L.C., ...Gibbs, P. (2008). Letter to the Editor Correspondence: Patient age and comorbidity are major determinants of adjuvant chemotherapy use for stage III colon cancer in routine clinical practice. *Journal of Clinical Oncology*. doi: 10.1200/JCO.2008.18.7443
- Arnoldi, E., Dieli, M., Mangia, M., Minetti, B. & Labianca, R. (2007). Comprehensive geriatric assessment in elderly cancer patients: an experience in an outpatient population. *Tumori*, 93(1), 23-25.
- Bailey, C., Corner, J., Addington-Hall, J., Kumar, D., Nelson, M. & Haviland, J. (2003). Treatment decisions in older patients with colorectal cancer: the role of age and multidimensional function. *European Journal of Cancer Care*, 12, 257-262
- Bouchardy, C., Queneau, P.E., Fioretta, G., Usel, M., Zellweger, M., Neyroud, I., ...Sappino, A.P. (2001). Adjuvant chemotherapy for colon carcinoma with positive lymph nodes: use and benefit in routine health care practice. *British Journal of Cancer*, 85(9), 1251-1257. doi: 10.1054/bjoc.2001.2035

- Davidoff, A.J, Rapp, T., Onukwugha, E., Zuckerman, I.H., Hanna, N., Pandya, N. & Mullins, C.D. (2009). Trends in disparities in receipt of adjuvant therapy for elderly stage III colon cancer patients. *Medical Care*, 47(12), 1229-1236.
- Eastern Cooperative Oncology Group (ECOG). (2006). Introduction to ECOG. Retrieved from <http://www.ecog.org/general/intro.html>
- Eastern Cooperative Oncology Group (ECOG). (2006). ECOG Performance Status. Retrieved from http://www.ecog.org/general/perf_stat.html
- Etzioni, D.A., El-Khoueiry, A.B. & Beart, R.W. (2008). Rates and predictors of chemotherapy use for stage III colon cancer. *Cancer*, 113(12), 3279-3289. doi: 10.1002/cncr.23958
- Extermann, M. (2000). Measuring comorbidity in older cancer patients. *European Journal of Cancer*, 36(4), 453-471. [doi:10.1016/S0959-8049\(99\)00319-6](https://doi.org/10.1016/S0959-8049(99)00319-6)
- Feliu, J., Sereno, M., De Castro, J., Belda, C., Casado, E. & Gonzalez-Baron, M. (2009). Chemotherapy for colorectal cancer in the elderly: Who to treat and what to use. *Cancer Treatment Reviews*, 35, 246-254. doi: 10.1016/j.ctrv.2008.11.004
- Foley, K.L., Tooze, J.A., Klepin, H.D., Song, E.Y. & Geiger, A.M. (2011). Adjuvant chemotherapy among Medicaid-enrolled patients diagnosed with nonmetastatic colon cancer. *American Journal of Clinical Oncology*, 34(2), 120-124. doi: 10.1097/COC.0b013e3181d2ed93

- Girre, V., Falcou, M., Gisselbrecht, M., Gridel, G., Mosseri, V., Bouleuc, C., ...Mignot, L. (2008). Does a geriatric oncology consultation modify the cancer treatment plan for elderly patients? *Journal of Gerontology*, *63A*(7), 724-730.
- Gross, C.P., McAvay, G.J., Guo, Z. & Tinetti, M.E. (2007). The impact of chronic illnesses on the use and effectiveness of adjuvant chemotherapy for colon cancer. *Cancer*, *109*, 2410-2419. doi: 10.1002/cncr.22726
- Hardiman, K.M., Cone, M., Sheppard, B.C. & Herzig, D.O. (2009). Disparities in the treatment of colon cancer in octogenarians. *American Journal of Surgery*, *197*, 624-628. doi: 10.1016/j.amjsurg.2008.12.018
- Maas, H.A., Janssen-Heijnen, M.L., Rikkers, M.G. & Wymenga, M. (2007). Comprehensive geriatric assessment and its clinical impact in oncology. *European Journal of Cancer*, *43*, 2161-2169. doi:10.1016/j.ejca.2007.08.002
- Jessup, J.M., Stewart, A., Greene, F.L. & Minsky, B.D. (2005). Adjuvant chemotherapy for stage III colon cancer. *Journal of the American Medical Association*, *294*(21), 2703-2711. doi: 10.1001/jama.294.21.2703.
- Jorgensen, M.L., Young, J.M. & Solomon, M.J. (2011). Older patients and adjuvant therapy for colorectal cancer: Surgeon knowledge, opinions, and practice. *Diseases of the Colon & Rectum*, *54*(3), 335-341. doi: 10.1007/DCR.0b013e3181ff43d6
- Kahn, K.L., Adams, J.L., Weeks, J.C., Chrischilles, E.A., Schrag, D., Ayanian, J.Z., ...Fletcher, R.H. (2010). Adjuvant chemotherapy use and adverse events among older patients with

- stage III colon cancer. *Journal of the American Medical Association*, 303(11), 1037-1045. doi: 10.1001/jama.2010.272
- Keating, N.L., Landrum, M.B., Klabunde, C.N., Fletcher, R.H., Rogers, S.O., Doucette, W.R., ...Kahn, K.L. (2008). Adjuvant chemotherapy for stage III colon cancer: do physicians agree about the importance of patient age and comorbidity? *Journal of Clinical Oncology*, 26(15), 2532-2537. doi: 10.1200/JCO.2007.15.9434
- Kohne, C.H., Grothey, A., Bokemeyer, C., Bontke, N. & Aapro, M. (2001). Chemotherapy in elderly patients with colorectal cancer. *Annals of Oncology*, 12(4), 435-442.
- Krzyzanowska, M.K., Regan, M.M., Powell, M., Earle, C.C. & Weeks, J.C. (2009). Impact of patient age and comorbidity on surgeon versus oncologist preferences for adjuvant chemotherapy for stage III colon cancer. *Journal of the American College of Surgeons*, 208(2), 202-209. doi: 10.1016/j.jamcollsurg.2008.10.016
- Levitz, J.S. & Lichtman, S.M. (2005). Adjuvant therapy for colon cancer in the elderly: treat or don't treat? *Community Oncology*, 2, 331-336.
- McCleary, N.J. (2010). Treatment considerations in elderly colorectal cancer patients. *Clinical Advances in Hematology & Oncology*, 8(5), 337-339.
- National Cancer Institute: Surveillance Epidemiology and End Results (SEER). (2008). Cancer statistics: fast stats (search terms: SEER incidence, age-adjusted rates, 1975-2008, all races, both sexes, all cancer sites). Retrieved from <http://seer.cancer.gov/faststats/selections.php?series=cancer>

National Cancer Institute: Surveillance Epidemiology and End Results (SEER). (2008). SEER stat fact sheets: Colon and rectum incidence and mortality. Retrieved from

<http://seer.cancer.gov/statfacts/html/colorect.html#incidence-mortality>

National Comprehensive Cancer Network (NCCN). (2010). NCCN guidelines for treatment of cancer by site. Retrieved from

http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

National Comprehensive Cancer Network (NCCN). (2011). NCCN guidelines version 2.2012: Senior adult oncology. Retrieved from

http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T. & Carbone, P.P. (1982). Toxicity and response criteria of the Eastern Cooperative Oncology Group. *American Journal of Clinical Oncology*, 5(6), 649-655.

Quipourt, V., Jooste, V., Cottet, V., Faivre, J. & Bouvier, A. (2011). Comorbidities alone do not explain the undertreatment of colorectal cancer in older adults: A French population-based study. *Journal of the American Geriatrics Society*, 59(4), 694-698. doi: 10.1111/j.1532-5415.2011.03334.x

Repetto, L., Fratino, L., Audisio, R.A., Venturino, A., Gianni, W., Vercelli, M., ...Zagonel, V. (2002). Comprehensive geriatric assessment adds information to Eastern Cooperative Oncology Group performance status in elderly cancer patients: an Italian group for geriatric oncology study. *Journal of Clinical Oncology*, 20(2), 494-502.

Rodin, M.B. & Mohile, S.G. (2007). A practical approach to geriatric assessment in oncology.

Journal of Clinical Oncology, 25(14), 1936-1944. doi: 10.1200/JCO.2006.10.2954

Sargent, D.J, Goldberg, R.M., Jacobsen, S.D., Macdonald, J.S., Labianca, R., Haller, D.G.,

...Francini, G. (2001). A pooled analysis of adjuvant chemotherapy for resected colon cancer in elderly patients. *New England Journal of Medicine*, 345(15), 1091-1097.

Tucci, A., Ferrari, S., Bottelli, C., Borlenghi, E., Drera, M., & Rossi, G. (2009). A

comprehensive geriatric assessment is more effective than clinical judgment to identify elderly diffuse large cell lymphoma patients who benefit from aggressive therapy.

Cancer, 115, 4547-4553. doi: 10.1002/cncr.24490

University of California Los Angeles (UCLA) Academic Technology Services. (2012). Logistic

Regression Diagnostics. In *UCLA Academic Technology Services Web Books* (lesson 3).

Retrieved from

<http://www.ats.ucla.edu/stat/stata/webbooks/logistic/chapter3/statalog3.htm>

U.S. Census Bureau. (2010). Age and sex data set: 2005-2009 American Community Survey 5-

year estimates. Retrieved from http://factfinder.census.gov/servlet/STTable?_bm=y&-geo_id=01000US&-qr_name=ACS_2009_5YR_G00_S0101&-ds_name=ACS_2009_5YR_G00

http://factfinder.census.gov/servlet/STTable?_bm=y&-geo_id=01000US&-qr_name=ACS_2009_5YR_G00_S0101&-ds_name=ACS_2009_5YR_G00

[ds_name=ACS_2009_5YR_G00](http://factfinder.census.gov/servlet/STTable?_bm=y&-geo_id=01000US&-qr_name=ACS_2009_5YR_G00_S0101&-ds_name=ACS_2009_5YR_G00)

U.S. Census Bureau. (2000). Age groups and sex: Census 2000 Summary File. Retrieved from

http://factfinder.census.gov/servlet/QTTTable?_bm=y&-geo_id=01000US&-qr_name=DEC_2000_SF1_U_QTP1&-ds_name=DEC_2000_SF1_U

[qr_name=DEC_2000_SF1_U_QTP1&-ds_name=DEC_2000_SF1_U](http://factfinder.census.gov/servlet/QTTTable?_bm=y&-geo_id=01000US&-qr_name=DEC_2000_SF1_U_QTP1&-ds_name=DEC_2000_SF1_U)

Winget, M., Hossain, S., Yasui, Y. & Scarfe, A. (2010). Characteristics of patients with stage III colon adenocarcinoma who fail to receive guideline-recommended treatment. *Cancer*, *116*(20), 4849-4856. doi: 10.1002/cncr.25250

Appendices

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
Levitz, J.S., & Lichtman, S.M. (2005).	Provide guidance regarding the use of adjuvant chemotherapy in elderly patients with colon cancer	Systematic literature review	I	n/a	n/a	n/a	70% of colorectal patients are 75 yrs+ <1% of adults 75yrs+ are accrued to clinical trials Age at diagnosis is the strongest determinant of receiving adjuvant chemotherapy for stage III colon cancer	
Bouchardy, C., et al. (2001).	Evaluate use and benefit of adjuvant chemotherapy for lymph node positive colon cancer (stage III)	Two Groups, non-randomized	II	182	Stage III colon cancer -excluded rectal, not operated, palliation Geneva 1990-1996	Surgery +adjuvant therapy (55) vs. surgery only (127) Other variables: Tumor size, T class, N class, hist grade/diff, anatomical sites, social class, health care sector, method of discovery, age,	50% of patients under 70 yrs received therapy, compared with <10% of patients 70yrs+ <i>P</i> <0.001 Comorbidity was absent in about 2/3 of the patients aged 70yrs+ who did not receive	

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
						gender, nationality, marital status,	therapy No sig difference in chemotherapy efficacy between age groups	
Bailey, C. et al. (2003).	Investigate the role of age and multidimensional functional status in treatment decisions in older patients with colorectal cancer	One Group/before and after	III	337	Adenocarcinoma of the colon or rectum Duke's C (stage III)	OARS Multidimensional Functional Assessment Questionnaire and the Rotterdam Symptom Checklist	The likelihood of patients receiving adjuvant chemotherapy decreased significantly with age 75yrs+ $P<0.001$	
Keating, N.L. et al. (2008).	Understand how patients age and comorbidity influence cancer physicians adjuvant chemotherapy recommendations	Descriptive study	IV	1096	Physicians that had seen at least 10 colon cancer cases in the last month recommended by patients identified through CanCORS	Physician survey using six clinical vignettes	Younger physicians were more likely to recommend adjuvant therapy than older physicians	No correlation with actual patient care
Ananda, S. et al. (2008).	To compare the results of a previous survey on physician practices to actual clinical practice in the use of adjuvant chemotherapy for stage II colon	Cohort	II	252	Stage III colon cancer, s/p surgery and candidate for adjuvant therapy per standard protocol 4 hospitals in Melbourne, Australia 1/2003-2/2008	Provider and patient decision making was analyzed	Age and comorbidity were the strongest predictors of a medical oncologist not recommending adjuvant therapy	The number of patients declining treatment against medical advice increased with age $P<0.001$

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
	cancer, examining age and comorbidity							
Etzioni, D.A, El-Khoueiry, A.B. & Beart, R.W. (2008).	To identify the rates at which chemotherapy is administered for stage III colon cancer in the US and plan strategies for improving use rates	Systematic review of literature	I	22 studies	1990 to present Stage III colon cancer	n/a	Age and comorbidity were the most significant patient factors, but also racial and socioeconomic disparities	Recommend evidence-based standards of care in elderly patients; sig body of research suggests that chemotherapy is well-tolerated and efficacious in an elderly patient population; of all articles, none included assessment of functional status
Hardiman, K.M., Cone, M., Sheppard, B.C> & Herzig, D.O. (2009).	To examine disparities in treatment of colon cancer related to age	Retrospective chart analysis	IV	10433	Age over 80 years Colorectal adenocarcinoma 1998-2004 Oregon	Surgery and/or chemotherapy for colon cancer	Patients 80+ yrs are less likely to receive surgery and/or chemotherapy for colorectal cancer; this age group is growing and 1/3 rd of colon malignancies are diagnosed 80+yrs	Comorbidities were not evaluated. Recommend inclusion in clinical trials and well-defined guidelines for the elderly.
Krzyzanowska, M.K, Regan, M.M., Powell, M., Earle, C.C. & Weeks, J.C.	To study surgeons' versus oncologists' preferences for adjuvant	Descriptive study	IV	681	318 surgeons 363 oncologists Identified through the AMA's Physicians	Physician survey using eight clinical vignettes	Physicians tended to withhold treatment in older patients (p<0.0001) and	Very few of surgeon respondents were oncology surgeons

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
(2009).	chemotherapy for elderly patients with stage III colon cancer				Masterfile Must be practicing in a SEER area, practice >5 hrs per week, be out of training, and have seen colon cancer cases in the last year		those with more severe comorbidities (p<0.0001)	Vignettes were not validated formally
Winget, M., Hossain, S., Yasui, Y. & Scarfe, A. (2010).	To identify patient characteristics associated with not receiving guideline-recommended treatment for stage III colon cancer	Chart review	IV	772	Age, sex, yr of diagnosis (2002-2005), region, comorbidity score, histological grade, # of +lymph nodes, distance to facility	n/a	317 75yrs+ (128 did not receive surgery, 126 did not receive chemo) Age=p<0.0001 Comorbidities=p=0.0002 Lower income=p=0.001 Patients 75yrs+ 8.7x more likely not to have a consultation with an oncologist Patients 75yrs+ 3x more likely to not receive adjuvant chemotherapy	
McCleary, N.J. (2010).	Treatment considerations in elderly colorectal patients	Expert Opinion	V	n/a	Elderly patients with colorectal cancer	n/a	Besides stage, histology, and disease presentation, need to consider	Challenges: competing medical conditions that impact

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
							medical conditions, medications, physical functioning, social support, life expectancy, physiologic reserve	physiologic reserve and tolerance of therapy; also lack of clinical trial data in the older adult
Davidoff et al. (2009).	To examine differential rates of oncologist evaluation and treatment	Retrospective analysis of SEER data	IV	7176	Age >65 yrs White or AA race Stage III colon cancer 1997-2002	n/a	Age 70+ were less likely to receive an oncology evaluation p<0.001 Age 75+ were less likely to receive adjuvant treatment p<0.001	This study was focused on race disparity
Quipourt, V., Jooste, V., Cottet, V., Faivre, J. & Bouvier, A. (2011).	To investigate the influence of comorbidities on treatment modalities of colorectal cancer according to age	Retrospective data analysis	IV	2921	Colorectal cancer 2004-2007 French Digestive Cancer Registry Burgundy	n/a	Age <75 yrs 95.5% received adj chemo, as opposed to 50.7% of pts age 75 yrs+, p<0.001 Age <75 yrs 82.4% received palliative chemo, as opposed to 42.2% of pts age 75yrs+, p<0.001 When crossed with comorbidities, these numbers	

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
							remained significant for 0, 1, 2 and were not sig for 3 or more	
Foley, K.L., Tooze, J.A., Klepin, H.D., Song, E.Y. & Geiger, A.M. (2011).	To describe the characteristics associates with chemotherapy use in a Medicaid-insured population with colon cancer	Retrospective cohort design	III	692	Medicaid-insured Regional colon cancer North Carolina Age, sex, race, and comorbidity score using Charlson Comorbidity Index	n/a	Very low utilization of chemotherapy among the Medicaid population (42%); strong independent relationship of age to receipt of chemo regardless of comorbidity status in pts >65yrs	
Jorgensen, M.L., Young, J.M. & Solomon, M.J. (2011).	To identify factors affecting surgeons' decisions to refer older patients for adjuvant therapy	Descriptive analysis	IV	102	Physician survey of knowledge, opinion, and self-reported practice using different patient referral scenarios	n/a	Surgeons were significantly less likely to refer an older patient (80 yrs) with node-positive cancer for adjuvant therapy than a younger patient (60 yrs), p<0.001	There is a lack of consensus among surgeons regarding how older patients will react to treatment
Feliu et al. (2009).	To identify appropriate patients for treatment of colorectal cancer	Systematic Literature Review	I	n/a	n/a	n/a	Chemotherapy toxicity does not seem to increase with age and therapeutic results are	Recommend close collaboration between geriatricians and oncologists

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
							comparable in the adjuvant setting as well as in advanced disease. Life expectancy and comorbidities still require consideration. Age itself should not be a contraindication.	
Gross, C.P., McAvay, G.J., Guo, Z. & Tinetti, M.E. (2007).	To examine the effect of comorbidities on the use and effectiveness of adjuvant chemotherapy for colon cancer	Cohort	II	5330	Age 67 yrs+ Stage III colon cancer 1993-1999 SEER data	Evaluation for number of comorbidities and types of comorbidities	Although chronic conditions appeared to be a strong barrier to the receipt of adjuvant chemotherapy, adjuvant therapy appeared to provide a significant survival benefit to patients who had colon cancer with the conditions studied	
Kahn et al. (2010).	To evaluate adjuvant chemotherapy use and outcomes for older patients	Observation	V	675	Stage III colon cancer s/p surgical resection 2003-2005 Followed for 15 months	Given adj therapy, adverse events	Older adults (age 75yrs +) were less likely to receive therapy, less likely to receive	

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
	with stage III colon cancer						the full standard of care, more likely to be excluded for comorbidities, and do not experience more adverse event than younger patients	
Jessup, J.M., Stewart, A., Greene, F.L. & Minsky, B.D. (2005).	To determine whether adjuvant chemotherapy is used as a standard of practice and whether it failed to benefit any specific sets of patients.	Prospective data analysis	IV	85934	Stage III colon cancer	Given adj therapy	Elderly patients have the same benefit as younger patients but are less frequently treated.	
Sargent et al. (2001).	To evaluate efficacy and toxicity of chemotherapy for colon cancer in patients more than 70 years old	Pooled analysis of 3 randomized trials	I	3351	Stage II or III colon cancer s/p surgery	Given or not given adjuvant chemotherapy	Selected elderly patients (>70yrs) with colon cancer can receive the same benefit from fluorouracil-based adjuvant therapy as their younger counterparts (p<0.001), without a significant increase in toxic effects.	
Kohne, C.H.,	To evaluate to	Systemic	I	n/a	Adjuvant and	n/a	Fit elderly	

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
Grothey, A., Bokemeyer, C., Bontke, N. & Aapro, M. (2001).	what extent chemotherapy should be offered to the elderly patient with colorectal cancer	literature review			metastatic use of chemotherapy in patients >70 yrs		patients should be offered therapy. Elderly patients need more attention regarding their functional, social, and mental status..	
Arnoldi, E., Dieli, M., Mangia, M., Minetti, B. & Labianca, R. (2007).	To apply cancer geriatric assessment in elderly cancer patients, in order to select which are eligible for oncological treatment or supportive care only.	Random selection	I	153	Elderly (>70yrs) cancer patients	Comprehensive geriatric assessment	Identifying patients as frail or fit for therapy can be prognostic for a higher risk of mortality.	
Girre et al. (2008).	To describe the treatment plan modifications after a geriatric oncology clinic assessment of health and functional status	Random selection	I	105	Older (>70yrs) cancer patients	Geriatric consultation for assessment	Modification of 38.7% of treatment plan sample cases after assessment	
Rodin, M.B. & Mohile, S.G. (2007).	To present a tool for assessment of potential toxicity or adverse outcome in treatment of the elderly	Systemic literature review	I	n/a	Older (>70yrs) cancer patients	n/a	Recommend a shortened version of a comprehensive assessment using the Vulnerable	

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
Tucci et al. (2009.)	To analyze if a simple comprehensive geriatric assessment (CGA) could objectively identify elderly patients with diffuse large cell lymphoma (DLCL) who can be effectively treated with anthracycline-containing immune-chemotherapy	Random Selection	I	84	Older (>65yrs) patients with diffuse large cell lymphoma	CGA	Elders-13 Survey CGA is an efficient method to identify elderly DLCL patients who can benefit from a curative approach with anthracycline-containing immunochemotherapy. Further study is needed to discern why unfit patients seem to have poor outcomes.	
Repetto et al. (2002).	To appraise the performance of Comprehensive Geriatric Assessment (CGA) and to evaluate whether it could add further information with respect to the Eastern Cooperative Oncology Group performance status (PS).	Random Selection	I	363	elderly cancer patients (> 65 years)	CGA	The CGA adds substantial information on the functional assessment of elderly cancer patients, including patients with a good PS.	

Author, Year.	Objective	Study Type	Level of Evidence	N	Pt Characteristics	Intervention	Results	Other
Maas et al. (2007).	To review the value of CGA on the following endpoints: recognition of health problems, tolerance to chemotherapy and survival.	Systemic literature review	I	n/a	Elderly cancer patients	n/a	There are no prognostic validation studies reported using geriatric syndromes or information based on CGA in its decision making strategies.	

