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Geriatric Assessment with Management Intervention in Older Adults with Cancer: A Randomized Pilot Study

Allison Magnuson¹, Tatyana Lemelman², Chintan Pandya¹, Molly Goodman¹, Marcus Noel¹, Mohammed Tejani¹, David Doughtery¹, William Dale³, Arti Hurria⁴, Michelle Janelsins¹, Feng Vankee Lin¹, Charles Heckler¹, and Supriya Mohile¹

¹University of Rochester, Rochester, NY

²New York Medical College, Valhalla, NY

³University of Chicago, Chicago, IL

⁴City of Hope, Duarte, CA

Abstract

Background—Older adults receiving cancer therapy have heightened risk for treatment-related toxicity. Geriatric Assessment (GA) can identify impairments, which may contribute to vulnerability and adverse outcomes. GA management interventions can address these impairments and have the potential to improve outcomes when implemented.

Methods—We conducted a randomized pilot study comparing GA with management interventions versus usual care in patients with stage III/IV solid tumor malignancies (N=71). In all patients, a trained coordinator conducted and scored a baseline GA with pre-determined cutoffs for impairment. For patients randomized to the intervention arm, an algorithm was used to identify GA management recommendations based upon identified impairments. Recommendations were relayed to the primary oncologist for implementation. GA was repeated at 3 months. The primary outcome was grade 3-5 chemotherapy toxicity. Secondary outcomes included feasibility, hospitalizations, dose reductions, dose delays and early treatment discontinuation.

Results—Mean participant age was 76 (70-89). The total number of GA management recommendations relayed was 409, of which 35.4% were implemented by the primary oncologist. Incidence of grade 3-5 chemotherapy toxicity did not differ between the two groups. Prevalence of hospitalization, dose reductions, dose delays, and early treatment discontinuation also did not differ between the two groups.

Conclusions—An algorithm can be used to guide GA management recommendations in older adults with cancer. However, reliance upon the primary oncologist for execution resulted in a low prevalence of implementation. Future work should aim to understand barriers to implementation and explore alternate models of implementing geriatric-focused care for older adults with cancer.

Corresponding Author: Supriya Mohile, MD, MS, University of Rochester, Wilmot Cancer Institute, 601 Elmwood Avenue, Box 704, Rochester, NY 14642, Phone: 585-275-0394, Fax: 585-273-1042, Supriya_mohile@urmc.rochester.edu.

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Keywords

Geriatric Assessment with Management; Cancer; Geriatric Oncology; Geriatric Assessment with Management

Background

Cancer is primarily a disease of older adults, with the majority of cancer diagnoses and cancer-related deaths occurring in patients over the age of 65.^{1,2} Older adults with cancer commonly have additional age-associated conditions, such as geriatric syndromes or comorbidities,^{3–5} which may complicate cancer therapy. A GA is recommended to help objectively evaluate the overall health status of an older adult considering cancer therapy.⁶ GA is a validated assessment tool that evaluates a variety of domains that commonly affect older adults, including evaluation of physical function, comorbidity, polypharmacy, cognition, psychological status, social support and nutritional status. GA has been shown to detect impairments not captured by oncology performance status assessment⁷ and has demonstrated feasibility for incorporation it is in the oncology setting.⁸ Domains in GA are predictive of chemotherapy toxicity.^{9–11} The Cancer and Aging Research Group (CARG) chemotherapy toxicity score is a validated tool that predicts the likelihood of chemotherapy toxicity and incorporates not only cancer- and treatment-specific variables, but also domains from the GA, such as a history of falls and difficulties with medication management.^{9,11}

Rates of treatment-related toxicity for older adults receiving chemotherapy are higher than the younger population, and geriatric factors have been shown to influence the likelihood of toxicity in this population.⁹⁻¹¹ Implementing geriatric assessment (GA) with targeted management interventions to address specific impairments may help to improve older adults' tolerance of therapy and cancer-related outcomes.¹² A few select studies in geriatric oncology have evaluated the impact of GA on change in treatment plan and GA management interventions in a non-randomized fashion.^{13–19} Although GA with management interventions has not yet been formally evaluated in the older cancer population in randomized studies, multiple studies in the non-cancer setting demonstrate benefit from GA management, suggesting potential benefit in the oncology setting as well.²⁰⁻³⁴ GA can identify specific impairments, such as cognitive impairment or limited social support, and targeted management interventions can be used to support these vulnerabilities in patients receiving cancer therapy.¹² GA management interventions are utilized frequently by geriatricians in the non-cancer population with the goal to reverse or provide support to areas of impairment identified on GA. An example of a targeted management intervention based upon GA impairment is implementing physical therapy and home safety evaluations for individuals with impaired physical function or falls. GA with targeted management interventions has been studied extensively in the general geriatrics population and have been shown to reduce mortality,^{28,31} hospitalizations³² and functional decline.³¹ A Delphi study was conducted of geriatric oncology experts to develop consensus on high-priority GAbased targeted management interventions for older adults with cancer;^{35,36} however, to date, no randomized, prospective studies have reported on the feasibility and utility of GA with management interventions in older adults receiving cancer treatment.

With the aging of the population and the limited number of geriatrics-trained health care providers, it is not realistic for all older adults with cancer to be cared for by oncology professionals with have additional geriatric expertise. Therefore, models of care need to be developed to support oncologists in incorporating geriatrics into routine oncology care. An algorithm could be used to guide oncology practitioners in the use of GA management interventions. We conducted a randomized pilot study to assess the feasibility and preliminary efficacy of GA with an algorithm to guide GA management interventions on chemotherapy toxicity and other outcomes (hospitalizations, dose reduction, dose delays, and early termination of treatment) of older adults with advanced cancer starting a new cancer treatment regimen.

Methods

Study Participants

Eligible subjects were age 70 and over with a diagnosis of an advanced (stage III or IV) solid tumor malignancy. Patients were seen and evaluated by their primary oncologist and received a plan for initiation of first- or second-line treatment. Eligible treatment regimens included chemotherapy, chemoradiotherapy, or targeted therapy with or without chemotherapy. Eligible patients were able to read and understand English, able to provide informed consent (as assessed by their primary oncologist), had a life expectancy of 6 months or greater, and had a planned treatment regimen lasting at least 3 months. Patients were excluded if they had a planned surgery within three months of consent or if they had a referral to a geriatric oncologist.

Study Design (Figure 1)

Eligible patients were approached by the study coordinator with permission from the primary oncologist. Following consent, baseline clinical, demographic and GA data was collected. Eighty-three patients consented to participate in the study, however 12 patients did not complete the baseline assessment and thus were not randomized. Following collection of baseline information, patients were randomized using block randomization. Patients were followed for three months after treatment initiation and GA was repeated 3 months after treatment initiation. Following the patients' completion of all study procedures, their medical records were reviewed by a blinded study investigator in order to capture the administered treatment regimen for each cycle including any supportive care medications, and outcomes including grade 3-5 chemotherapy toxicity, hospitalizations, dose reductions, dose delays, and treatment discontinuation. Toxicities were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE version 4.0).

Measures

Clinical and demographic information was collected by study coordinators. At baseline, GA was performed, including measures in the following domains: physical function, cognition, nutrition, social support, psychological status, comorbidity, and polypharmacy (Table 1).⁸ The majority of GA measures were collected using patient self-report questionnaires. A study coordinator conducted objective cognitive and objective physical performance

assessment measures. Tumor and treatment characteristics were collected from the medical record. GA measures were evaluated again at 3 months after treatment initiation. A CARG chemotherapy toxicity score was calculated at baseline using clinical and GA measures.⁹

Intervention: GA with targeted management recommendations

A previously developed algorithm, based upon expert consensus,³⁵ was used to formulate management recommendations for specific GA impairments with minor adaptations based upon availability of local resources (Table 1). For patients randomized to the intervention arm, the coordinator scored the GA and identified impairments (defined by pre-determined scoring cutoffs for each GA domain). The coordinator then summarized GA impairments with management recommendations and delivered recommendations to the patient's primary oncologist within one week of assessment. At the 3-month follow-up time point, the primary oncologist reported whether these recommendations had been implemented.

Statistical Analysis

Descriptive analyses were performed to summarize patient characteristics, GA results and feasibility measures. T-test (continuous data) and Chi square tests (categorical data) were used to compare baseline characteristics and GA results between usual care and intervention groups including age (continuous), gender (male vs female), race (white versus other), marital status (single vs married vs divorced vs separated), income status (<20K vs 20-50K vs 50-100K vs >100K), education (<high school vs high school vs >high school), impaired activities of daily living (none vs 1), impaired instrumental activities of daily living (none vs 1), history of falls (none vs 1), self-reported limitations in physical activity (yes vs no), comorbidities (3 vs > 3), impaired vision (yes vs no), impaired hearing (yes vs no), Geriatric Depression Screen (5 versus >5), impaired social activities (a little/none vs all/ most/some of the time), distress score (<5 vs 5), self-reported Karnofsky performance status (>80 vs 70), Blessed-Orientation-Memory-Concentration test (10 vs >10), Short Physical Performance Battery Score (9 vs >9), and Mini-cog score (normal vs abnormal). Outcome variables, including incidence of NCI CTCAE grades 3 chemotherapy toxicity (yes vs no), hospitalizations (yes vs no), dose reductions (yes vs no), dose delays (yes vs no), early treatment terminations (yes vs no), and hospice enrollments (yes vs no), were calculated for both arms. Logistic regression was used to examine each variable in a univariate analysis and stepwise selection using entry and retention of P values of >0.1 and clinical significant variables. Separate regression models were used for each outcome variable. Investigators assessing outcomes and statisticians were blinded to allocation. All analysis were performed using SAS statistical software (SAS 9.3, NC). All statistical tests were 2-sided and p values <0.05 were considered statistically significant. The Institutional Review Board at the University of Rochester approved the study.

Results

Patient Characteristics

Seventy-one patients were randomized between November 2013 and January 2015. The mean age of study participants was 76 (range 70-89, SD 4.98). At baseline, patient demographics and GA variables were not significantly different between the two arms,

except for a greater percentage of patients in the intervention group with Instrumental Activities of Daily Living (IADL) impairment (Table 2). Additionally, there was a significant difference in the CARG toxicity score, with the intervention arm having more patients in the high-risk CARG group (p=0.04).

Study Feasibility and Intervention Uptake (Table 3)

Among all eligible patients who were approached and asked to participate in this study, 75% consented. Twelve patients withdrew following consent but prior to completion of baseline assessment and were not randomized; three ultimately declined chemotherapy prior to starting treatment, one transitioned to hospice prior to initiating treatment and eight felt overwhelmed with the study procedures and declined to participate further.

GA at 3-month follow-up was completed on 89% of patients who had completed baseline assessment (N=63/71). Reasons for lack of 3-month follow-up data include withdrawal from study (3 patients), death due to disease (2 patients), or loss to follow-up (2 patients). Of the 37 patients randomized to the intervention group, recommendations for GA management interventions were relayed to the primary oncologist within the target time-frame in 34 patients (92%). Overall uptake of recommended interventions by the primary oncologist was 35.4% (145/409). The most frequently implemented interventions were avoidance of neurotoxic agents in patients with a history of neuropathy risk (73%), social work referral (71%) and nutrition counseling information (63%). The lest frequently implemented interventions (0%), co-signature for chemotherapy consents in patients with cognitive impairment (8%) and vitamin D screen and repletion in patients with a fall history (12%). (Table 3)

Follow-Up Assessment, Chemotherapy Toxicities, and Treatment Outcomes (Figure 2)

Repeat GA at 3-month follow-up showed no significant differences between patients in the two arms in any of the self-reported measures. The difference in IADL status between the two arms was no longer present at 3 months (usual care = 38% impaired, intervention = 49% impaired; p=0.38). The occurrence of grade 3-5 toxicities did not differ significantly between the two arms (61% in usual care versus 57% in the intervention arm, p=0.74). No differences were observed between the two arms in the number of hospitalizations, dose reductions, dose delays, early treatment terminations, or enrollments in hospice.

Toxicity based upon CARG chemotherapy score

The baseline CARG chemotherapy toxicity score was used to evaluate the likelihood of chemotherapy toxicity for each patient and averaged for each arm.^{9,11} The average CARG chemotherapy toxicity score for the usual care arm was 8.06, with a mean likelihood of toxicity of 58%. Compared to the anticipated toxicity of 58%, observed toxicity in the usual care arm was 61% (p = 0.56). The average CARG chemotherapy toxicity score for the intervention group was 8.78, with a mean likelihood of toxicity of 60%. Compared to the anticipated toxicity in the intervention group was 57% (p=0.55).

Discussion

In this prospective, randomized pilot study of a GA management intervention, it was feasible to use a pre-specified algorithm to develop GA management recommendations independent of geriatrician input, with recommendations relayed to the primary oncologist in >90% of intervention subjects. However, only a third of these recommendations were ultimately implemented by the primary oncologist into care plans for the patients. Recommendations that were more oncology-based, such as "consider initial dose reduction" in patients with multiple impairments and "consider avoiding neurotoxic agents" in patients with diabetes mellitus or neuropathy were more frequently implemented by the oncologists. Recommendations for referrals that were logistically more feasible (i.e., cancer center-based, such as social work referral or nutrition consult), were also implemented at higher frequency. Recommendations for interventions that were more "geriatric-specific" and may have been less familiar to oncologists were less likely to be implemented, such as "recommend a personal emergency response system (PERS)" for patients with impaired physical function.

The patients in this study represent a vulnerable population, with 74% scoring impaired on the objective physical performance measures, nearly 30% screening positive for cognitive impairment, and 36% having >3 comorbidities. Despite the vulnerability of this population, we were able to accrue patients; 75% of approached patients consented to participation. Considering the vulnerability of this population, retention of patients over the 3-month course of the study was also reasonably high with only 11% drop out mainly due to progressive illness. There were a significant number of patients who consented to participate in the study and then withdrew prior to completing the baseline assessment due to feeling overwhelmed with study procedures (8 patients). Given the pilot nature of the study, a large battery of assessment tools was used and this could potentially be limited for future studies to minimize this dropout. Older adults are frequently underrepresented in clinical trials, and enrolling vulnerable older adults in oncology clinical trials is an important step toward increasing the knowledge base for this population.³⁷

The intervention did not demonstrate a significant impact on cancer-related outcomes, including chemotherapy toxicity, hospitalizations, dose reductions, dose delays, early treatment terminations, or hospice enrollments. Older adults with cancer are at increased risk for treatment-related toxicity. Prior studies evaluating chemotherapy toxicity in older adults demonstrated rates of grade 3-5 toxicity between 53% and 64%.^{9–11} Our study is consistent with these results; 59% of patients experienced toxicity within the first three months of treatment. The current study was designed as a pilot study with a modest sample size, and did not have adequate power to detect significant difference in outcomes between the two arms. This limits the conclusions to be drawn from a negative result. A larger sample size with greater power would have the ability to detect a smaller difference between the control and intervention groups, and a larger, multi-site study evaluating the impact of GA with management recommendations in this population is underway (NCT02054741; Geriatric Assessment Intervention for Reducing Toxicity in Older Patients With Advanced Cancer). Kalsi and colleagues observed benefit from comprehensive geriatric assessment interventions on tolerance to chemotherapy in a non-randomized fashion.¹⁴ In this study,

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they compared subjects who received a GA with recommended interventions as compared to a historical cohort. Investigators determined that the intervention group was more likely to complete cancer treatment as planned, had fewer required treatment modifications, and had a trend towards lower toxicity rates.

This study design explored a model of care for implementing geriatric interventions in the management of older adults with cancer, independent of a geriatrics provider. To our knowledge, this is the first study in geriatric oncology to evaluate the feasibility of implementing GA management recommendations independent of a geriatrics provider using an algorithm. We determined that it is feasible to utilize an algorithm to guide GA management recommendations, although ultimate implementation of the more geriatricsbased recommendations by oncologists was low and low uptake of the recommendations may have diminished the strength of the intervention for improving outcomes. Limited uptake of GA management recommendations by non-geriatrics providers has been demonstrated in other studies as well.^{38,39} Wildiers, et al evaluated the implementation of GA management recommendations in older adults with cancer in Belgium. In this study, patients aged 70 and over were enrolled at diagnosis or disease progression and underwent GA. Concrete geriatric recommendations were developed and relayed to the treating physicians. In this study, 35.3% of all the geriatric recommendations were performed, which is similar to our study. In a meta-analysis of controlled trials of comprehensive GA in the non-cancer population, studies in which geriatricians retained control over implementation of medical recommendations were more likely to be effective than those that relied upon the primary care provider for implementation.³³ Therefore, limited implementation of GA management recommendations is the most likely reason for the lack of improvement of the intervention on outcomes in this pilot study.

Alternate models for implementing these recommendations need to be explored. The ELCAPA study evaluated the influence of a geriatrician-led GA on cancer treatment decision-making by oncologists and found that GA results prompted modification of the cancer treatment plan in 20% of patients enrolled onto the study.¹³ Clearly, a useful model would be direct involvement of a geriatrics provider; however, given the limited number of geriatric practitioners and the increasing numbers of older adults with cancer, this model of care would not be feasible for the majority of patients. An alternative model would be to engage other care team members, such as nursing and social work, into the implementation of GA management recommendations. A trial is in progress evaluating the feasibility of a nurse practitioner in developing and implementing GA management interventions (NCT02517034). Studies in non-cancer settings have evaluated the feasibility and impact of non-physician driven interventions and have demonstrated benefit. For example, the DEED II study evaluated the effects of a GA with multidisciplinary management intervention on elderly patients discharged from the emergency department (ED).³² In this study, a research team member, typically a nurse, evaluated subjects randomized to the intervention and initiated immediate interventions or referrals based upon the GA. Investigators determined that patients randomized to the intervention had lower rates of admissions to the hospital in the 30 days after the initial ED visit and lower rates of repeat ED visits in the 18-month follow-up period. Additionally, enhanced geriatrics education for oncologists may be another mechanism to increase the implementation of geriatric-specific interventions into

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oncology practice. Prior studies of educational programs for non-geriatrics providers have demonstrated improvements in clinician knowledge about geriatric issues and may alter treatment practices.^{40,41}

There are limitations to this study. The study was performed at a single institution, and was not performed as a cluster randomization; oncologists who enrolled multiple patients onto the study may have observed patterns of GA management recommendations from patients enrolled on the intervention arm and may have later applied similar recommendations to subsequent patients enrolled on the usual care arm, thus minimizing the observed effect of the intervention. However, given the limited uptake of recommendations in this study, this explanation is less likely. Nonetheless, future studies could be designed as cluster randomized studies to minimize this potential bias. The two arms in our study were not perfectly balanced, with patients in the intervention arm having higher rates of IADL impairment and greater frequency of high-risk CARG chemotherapy toxicity scores, potentially minimizing the benefits of the intervention. Future studies should enroll a larger sample size to achieve more balanced arms. Additionally, as described, the low implementation of GA management recommendations limits interpretation of the ability of the intervention to improve cancer-related outcomes; future studies should explore alternate methods for implementation.

In conclusion, this pilot study demonstrated that utilizing an algorithm to guide GA management recommendations to oncologists in older adults with cancer is feasible. In this study, we were able to recruit older, vulnerable adults with cancer readily to a clinical trial and observed a high prevalence of geriatric issues and chemotherapy toxicity in this population. This demonstrates a need for further supportive care interventions for this population. Rates of implementation of GA-based recommendations by the primary oncologists were low and this study adds to the literature that reliance on oncologists to implement GA-based interventions limits feasibility. Further research is needed to understand barriers to implement GA management recommendations in older adults with cancer.

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Figure 2. Summary of primary and secondary outcomes

Table 1

Geriatric Assessment domains, scoring tools and management interventions

Assessment Tool	Scoring Cutoff	Targeted GA Management Recommendations						
Physical Function								
ADL/IADL Fall History SPPB	 ADL/IADL impairment + history of falls SPPB <9 	 Consider PT and/or OT referral Provide Handouts (Fall precautions, Energy conservation, exercise) Home Safety Evaluation Vitamin D Screen with repletion Consider initial dose reduction Medication review – minimize high risk medications Personal Emergency Response System if Alone Visiting Nurse Services and Home Health Aid Referral 						
Nutrition								
Weight loss <5% in past 6 months Social Support	Current weight and weight 6 months ago	 Handout (nutritional counseling) Nutrition referral Consider Meals-On-Wheels 						
Older Adults and Resources and Services Questionnaire (OARS) Medical Social Support Survey	• Any answer "none of the time" or "a little of the time	 Visiting Nurse Services and Home Health Aid Referral Ride Assistance Programs Social Work Involvement Consider Meals-On-Wheels 						
Cognition								
Blessed Orientation Memory Concentration Test (BOMC) Mini-Cog	 BOMC >10 Mini-Cog abnormal 	 Identification of health care proxy Co-sign for consents Delirium risk handout Pillbox Medication review – minimize high risk medications Social work involvement Consider initial dose reduction 						
Polypharmacy		r						
Medication review	S medications Any high risk medications	Pillbox Minimize high risk medications						

	Assessment Tool		Scoring Cutoff		Targeted GA Management Recommendations			
[Comorbidity							
		OARS Comorbidity survey	•	Self-report of Diabetes Mellitus, Kidney disease	•	Consider initial dose reduction Diabetes history – potentially avoid neurotoxic agents Kidney disease history – avoid nephrotoxic agents		
	Psychological				1			
Γ	•	Geriatric Depression Screen (GDS)	•	GDS score >5	•	Consider pharmacologic therapy		
					•	Consider referral for psychotherapy/psychiatry		
					•	Social work involvement		
					•	Support group information		
					•	Consider referral to chaplain/ spiritual counseling		

Table 2

Patient demographics and baseline geriatric assessment results

Patient Demographics						
	Control	Intervention	P Value			
Gender	Male – 54% Female – 46%	Male – 59% Female – 41%	0.66			
Income Level	$50K - 74\% \\ > 50K - 26\%$	$50K - 83\% \\ > 50K - 17\%$	0.37			
Insurance Coverage	Medicare – 37% Medicare + Medicaid – 3% Medicare + Private – 43% Medicare + Private – 17%	Medicare - 38% Medicare + Medicaid - 5% Medicare + Private - 41% Medicare + Private - 16%	0.96			
Race	Caucasian – 97% Other – 3%	Caucasian – 91% Other – 9%	0.36			
Education Level	High School – 60% > High School – 40%	High School – 57% > High School – 43%	0.96			
Marital Status	Married – 65% Other – 35%	Married – 57% Other – 43%	0.63			
Tumor type	GI – 38% Lung – 47% GU – 15% Other – 0%	GI – 48% Lung – 37% GU – 8% Other – 5%	0.16			
Tumor Stage	III - 32% IV - 68%	III - 27% IV - 72%	0.80			
Line of therapy	First – 94% Second – 6%	First – 95% Second -5%	1.00			
Baseline Geriatric Assessment Results						
	Control	Intervention	P value			
Activities of Daily Living (ADL) impairment	20%	27%	0.48			
Instrumental Activities of Daily Living (IADL) impairment	31%	59%	0.02			
3 Comorbidities	29%	41%	0.29			
Physical Activity Impairment	60%	65%	0.67			
Geriatric Depression Screen >5	12%	19%	0.52			
Vision Impairment (self-report fair or worse)	14%	8%	0.47			
Hearing Impairment (self-report fair or worse)	29%	19%	0.34			
History of Falls	23%	27%	0.77			
Self-rated Karnofsky Performance Status <70	14%	22%	0.32			
Short Physical Performance Battery <9	69%	73%	0.68			
Abnormal Mini-Cog score	19%	33%	0.12			
Blessed Orientation-Memory-Concentration Test score >10	6%	3%	0.61			
Baseline Cancer and Aging Research Group (CARG) Toxicity Score	Low-9% Medium-76% High-15%	Low-19% Medium-46% High-35%	0.04			

Table 3

GA management recommendations and implementation rates

GA management recommendations	
Intervention	% Uptake
PT/OT Referral	24% (6/25)
Fall Precautions Counseling Handout	44% (11/25)
Home Safety Evaluation	28% (7/25)
Vitamin D Screen With Repletion	12% (3/25)
Consider Initial Dose Reduction	55% (17/31)
Minimize Psychoactive Medications in cognitive impairment	40% (4/10)
Personal Emergency Response Device	0% (0/10)
Energy Conservation Handout	44% (8/18)
Exercise Regimen Handout	44% (8/18)
Home Nursing/Home Health Aid Referral	41% (7/17)
Nutrition Counseling Handout	63% (5/8)
Nutrition Referral	50% (4/8)
Meals-On-Wheels Referral	21% (3/11)
Ride Assistance Programs	33% (3/9)
Social Work Referral	71% (15/21)
Identification of Health Care Proxy	31% (4/13)
Co-signature For Treatment Consents in cognitive impairment	8% (1/13)
Delirium Education Handout	31% (4/13)
Pillbox Recommendation	18% (5/28)
Minimization of High Risk Medications	36% (5/14)
Polypharmacy Medication Reduction	50% (1/2)
Avoidance of Neurotoxic Agents (Diabetes Comorbidity)	73% (8/11)
Avoidance of Nephrotoxic Agents	40% (2/5)
Consider Pharmacologic Therapy for depression	14% (1/7)
Referral for Psychotherapy	14% (1/7)
Support Group Information	58% (7/12)
Chaplaincy/Spiritual Counseling	33% (4/12)