IMPLEMENTING STANDARDIZED GERIATRIC SCREENING TOOLS IN ELDERLY BREAST AND GYNECOLOGIC CANCER PATIENTS

UNIVERSITY OF HAWAIʻI AT MĀNOA NANCY ATMOSPERA-WALCH SCHOOL OF NURSING

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Abstract

Problem Statement: Despite an aging patient population, geriatric assessment was not routinely used at the Kapiʻolani Women's Cancer Center. A standardized workflow considering resource and time limitations was needed to evaluate geriatric vulnerabilities before starting antineoplastic therapy.

Purpose: To implement a standardized process for identifying patients needing a comprehensive geriatric assessment (CGA) and at increased risk for chemotherapy toxicity.

Methods: The Geriatric 8 (G8) and the Cancer and Aging Research Group Chemotherapy Toxicity Tool (CARG) were administered alongside a standard clinical assessment for breast and gynecologic patients with cancer, ages 70 and older who were starting a new regimen of antineoplastic therapy. A post-implementation chart review was conducted to identify the number of patients screened over a three month period.

Results: Three out of six eligible patients were assessed with the G8 and CARG. One patient had an abnormal G8 score, and another patient had a moderate CARG score.

Discussion: The goal of initiating a standardized workflow for geriatric screening and chemotherapy toxicity risk was met. Due to the small sample size, further investigation is needed to assess the impact of the tools on provider practice.

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Implementing Standardized Geriatric Screening Tools in Elderly Breast and Gynecologic Cancer Patients

Age is one of the most significant risk factors for cancer (National Cancer Institute, 2021). Statistics from the Surveillance, Epidemiology, and End Results (SEER) Program show that over half of new cancer cases from 2015 to 2019 were above the age of 65. About 29.2% are between 65 and 74, 18.5% between 75 and 84, and 7.8% above 84 (National Cancer Institute, n.d.).

As the life expectancy of the U.S. population increases, oncology treatment for older patients is shifting from symptomatic to curative (Korc-Grodzicki, Holmes, and Shahrokni, 2015). Despite this shift, older patients remain heavily underrepresented in treatment clinical trials (Sedrak et al., 2020). Standard treatments may not be suitable for this demographic without additional consideration for age-related vulnerabilities and impairments (Decoster et al., 2015). This can include functional status, comorbidities, and socioeconomic aspects (Decoster et al., 2015).

There is growing evidence to support the use of geriatric assessment (GA) tools to help bridge these treatment gaps. GA tools can provide insight into function, comorbidity, falls, depression, cognition, nutrition, and chemotherapy toxicity (Mohile, Dale, Somerfield, and Hurria, 2018). While highly beneficial, it is essential to recognize that these additional evaluations take time. A comprehensive GA (evaluation that encompasses all previously listed domains) for one patient may take up to several hours to perform (Williams et al., 2014). For busy oncology clinics, this time commitment may not be practical. Several oncology groups, such as the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN), recommend using pre-screening tools to increase feasibility. One such tool is the Geriatric 8 (G8), which identifies patients needing GA. Another tool is the Cancer and

Aging Research Group (CARG) Chemotherapy Toxicity Tool for predicting (Grade 3 to 5 toxicities). Both tools have been validated for use in older adults and can be administered in about five minutes (Bellera et al., 2012; Mohile et al., 2018)

Needs Assessment

The Kapi'olani Women's Cancer Center (KWCC) endorsed an aging patient population. KWCC clinicians recognized the need to evaluate geriatric risk before initiating antineoplastic therapy; however, resource and time limitations hindered a standardized workflow. A retrospective chart review of ten randomly selected breast and gynecologic cancer patients over 70 confirmed this. The review revealed that zero patients received the G8, two received the CARG, and only one received a comprehensive geriatric assessment (this was not initiated as part of the patient's cancer care, and it was performed after antineoplastic therapy had started).

At the time of the initial needs assessment, the clinic had four oncology providers and no designated geriatricians. Each clinic provider cares for approximately 15 to 20 patients per day. Initial consults and treatment consults (chemotherapy counseling) are allotted 60 minutes. Follow-up appointments are allotted 15 to 30 minutes. Standard clinical assessments include history, physical exam, lab work-up, and Eastern Cooperative Oncology Group (ECOG) performance status.

PICOT

Will adding the G8 and CARG to standard clinical assessment before starting antineoplastic therapy, increase the number of breast and gynecologic oncology patients 70 and older screened for geriatric assessment and chemotherapy toxicity over three months?

- Population: Breast and gynecologic oncology patients 70 years and older

- Intervention: Implementation of the G8 and CARG in addition to standard clinical assessments prior to starting antineoplastic therapy
- Comparison: Current clinic practice
- Outcome/Timing: By the end of DNP project implementation, the KWCC will have implemented the G8 and CARG for breast and gynecologic oncology patients 70 years and older prior to starting antineoplastic therapy

Purpose and Objectives

This evidence-based project aimed to implement a standardized process for identifying patients needing a comprehensive geriatric assessment and at increased risk for chemotherapy toxicity. The following objectives were completed within three months of the project start date:

1. 90% of participating KWCC providers and staff will have completed an educational session about geriatric assessment, the G8, and the CARG.
2. 75% of newly diagnosed breast and gynecologic oncology patients 70 and older will have had a G8 and CARG screening before starting antineoplastic therapy.
3. Kapi'olani Women's Cancer Center will have established a workflow for patients needing further geriatric evaluation.

Theoretical Framework

With permission (Appendix A), the Johns Hopkins Evidence-Based Practice Model (JHNEBP) was used to guide this project. This model follows a three-step process called PET which stands for Practice Question, Evidence, and Translation (Dang et al., 2022). Following this framework, the author identified a clinical issue, recommended an evidence-based intervention, and implemented appropriate screening tools based on clinic fit and feasibility.

Synthesis of the Evidence

Evidence Search

PubMed and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) were the primary databases used in this literature search. Predominant search terms included "Comprehensive Geriatric Assessment," "Medical Oncology," "Breast Oncology," "Gynecologic Oncology," "Antineoplastic Toxicity," "Geriatric 8," and "CARG." Initial searches were filtered by "English language" and "published within the last 10 years." Selected articles discussing the G8 were specific to its use as a geriatric assessment screening tool. About 80 abstracts were reviewed. After removing non-relevant and duplicate articles, a total of 18 articles were critiqued. Mosby's levels of evidence model was used for ranking evidence quality (Appendix B).

Vulnerabilities in Geriatric Oncology Patients

Clinical trials determine the benefits, risks, and safety of cancer therapeutics. Unfortunately, older patients remain highly underrepresented in oncology trials (Sedrak et al., 2020). Patients aged 65 to 74 comprise less than 25% of enrolled participants in the National Cancer Institute (NCI) cooperative group clinical trials (Sedrak et al., 2020). Patients 75 and older comprise less than 10% (Sedrak et al., 2020). Low representation means treatments are not being well-tested in this population. This risks under and over treatments with standard therapies (Marosi & Köller, 2016).

Age brings many physiologic and social changes that can impact disease vulnerability and treatment tolerance (Korc-Grodzicki et al., 2015). Age-related metabolic changes can alter pharmacokinetics and impact drug uptake and clearance (Marosi & Köller, 2016) Korc-Grodzicki et al., 2015 introduced the concept of frailty and the need to distinguish between

physiologic and chronologic age for older adult patients. Patients of the same age may not share the same comorbidities, functionality, and resilience (Korc-Grodzicki et al., 2015). Some may be able to tolerate standard therapies, while others need additional risk assessments and supportive care (Korc-Grodzicki et al., 2015). GA and GA-related tools may be able to identify these additional needs.

Geriatric Assessment

GA is a multi-dimensional evaluation that can provide clinicians with enhanced insight into the health of older patients. For cancer care, this can provide opportunities for informed decisions and optimization of patient outcomes (Korc-Grodzicki et al., 2015). Domains vary, but GA typically looks at social status, comorbidities, functional status, physical function, cognition, nutrition, medications, and psychological status (Korc-Grodzicki et al., 2015). GA has shown usefulness in identifying unrecognized health problems, predicting adverse outcomes, and initiating early intervention for correctable deficits (Korc-Grodzicki et al., 2015). For example, a study by Hernandez Torres and Hsu (2017) found that the GA recognized at least one unidentified problem (missed by traditional oncology assessment) in 70% of its participants.

Despite growing evidence to support the use of GA in clinical practice, barriers in timing and resources have limited widespread implementation. Performing a GA can be time-consuming, taking up to several hours to complete (Williams et al., 2014). To increase practicality, several oncology organizations support using geriatric screening tools as a starting point. Two highly studied tools include the G8 for GA screening and the CARG for accessing chemotherapy toxicity risk.

Guidelines

GA and GA screening tools are supported by several oncology groups, including the American Society of Clinical Oncology (ASCO), the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG), National Comprehensive Cancer Network (NCCN), and the Italian Society of Geriatrics and Gerontology (SIGG). Guidelines are summarized below:

The 2018 ASCO guidelines recommend GA for patients 65 and older receiving chemotherapy (Mohile et al., 2018). ASCO endorses the G8 primarily as a mortality predictor but notes that it can be used to screen for patients needing a CGA. ASCO also recommends the CARG for estimating chemotherapy toxicity risk (Mohile et al., 2018).

The 2020 SIGG guidelines recommend a CGA for all patients 65 and older (Fusco et al., 2020). When CGA is not feasible, they recommend a two-step approach using a screening tool such as the G8 to identify patients needing a full CGA (Fusco et al., 2020). SIGG also recommends using prediction tools like the CARG for estimating chemotherapy toxicity risk (Fusco et al., 2020).

The 2021 EUSOMA and SIOG guidelines recommend geriatric screening as a minimum starting point for treatment decision-making in patients 70 and older (Biganzoli et al., 2021). In addition, they also support the use of chemotherapy toxicity calculators for estimating the risk of Grade 3 to 5 toxicities (Biganzoli et al., 2021).

The 2021 NCCN guidelines for older adult oncology recommend CGA for all older adults whose ability to tolerate treatment is questionable or has identified abnormalities from a geriatric screening tool (Dotan et al., 2021). NCCN also recommends using a geriatric screening tool for those without concerning deficits (Dotan et al., 2021).

Geriatric 8

The G8 screening tool identifies patients in need of geriatric assessment. This eight-item tool looks at disability, nutrition, cognition, depression, and comorbidities, similar to domains covered in CGA (Bellera et al., 2012). The tool takes about five minutes to complete and does not require specialized knowledge of geriatrics to perform (Decoster et al., 2015; Bellera et al., 2012). Scores range from zero to 17 points. Fourteen or below calls for geriatric assessment (Bellera et al., 2012).

The G8 has consistently performed with one of the highest sensitivities among GA pre-screening tools. The original validation study determined that a cut-off value of 14 provided the best balance between sensitivity and specificity, maintaining at least 80% and 60%, respectively (Bellera et al., 2012). Subsequent reviews have shown similar findings. Van Walree et al. (2019) found a median sensitivity of 85% and median specificity of 64%. Garcia, Agar, Soo, To, & Phillips (2021) found sensitivities ranging from 44.7% to 97% and specificities ranging from 44% to 100%. Most studies were willing to trade specificity for sensitivity because they aim to capture as many vulnerable patients as possible (Bellera et al., 2012; Garcia et al., 2021).

In line with this, a multicenter study found that the G8 performed with a false positive rate of 35.6% and a false negative rate of 23.5% (Bellera et al., 2012). A more recent prospective cohort study found a similar result, misidentifying 38% more patients needing a GA than the comparison tool (VES-13). Despite the higher rates of false positives, the authors concluded that over-detection is preferred over under-detection (Bellera, Artaud, Rainfray, Soubeyran, & Mathoulin-Pélissier, 2017)

CARG

The CARG calculator identifies chemotherapy toxicity risk in older adult patients. This 11-item tool looks at age, cancer type, chemotherapy regimen, hemoglobin, creatinine clearance, hearing, medications, and physical and social activity (Battisti & Arora, 2022). These variables were identified in the original prospective multicenter study as factors that increased the risk for chemotherapy toxicity (Hurria et al., 2011). The tool is validated for patients 65 and older and takes about five minutes to complete (Mohile et al., 2018). Scores range from zero to 23 points. Zero to five is low risk, six to nine is intermediate risk, and ten and above is high risk (Hurria et al., 2016).

In both the developmental and validation studies, the CARG was a better predictor of toxicity than the standard performance status (Karnofsky performance score) (Hurria et al., 2016). In addition, The CARG may help prompt preventative measures and provide additional information when weighing the benefits and risks of chemotherapy treatment (Hurria et al., 2011; Hurria et al., 2016). A multicenter community study by Mariano et al. (2019) found that the CARG influenced treatment and supportive care plans. Based on the CARG, 2.6% (five patients) received dose reductions (Mariano et al., 2019). Four out of the five patients were deemed high risk by the CARG (Mariano et al., 2019.) Supportive care changes were the most significant, with 38.5% (74 patients) receiving additional support. These changes included frequent follow-ups and laboratory monitoring, family support and end-of-life discussions, and palliative and social work referrals (Mariano et al., 2019).

The CARG was designed and validated primarily for Grade 3 to 5 toxicities, but Hurria et al. (2011) notes that Grade 2 toxicities may also be significant for older populations. A general consensus among many studies is that chemotherapy toxicity tools like the CARG should inform

decisions, not be the deciding factor of whether a patient receives chemotherapy or not (Battisti & Arora, 2022; Biganzoli et al., 2021).

Gaps and Limitations

GA and GA screening tools have shown promising benefits for cancer care in older adults; however, a consistent limitation across the literature has been the heterogeneity of populations. The G8 has shown high sensitivity and moderate specificity across most studies, however a few outliers demonstrated notably lower values in specific populations. One example was a prospective cohort study of men with prostate cancer that reported a sensitivity of 44% (Garcia et al., 2021). This variation in subset populations indicates a need for further validation of the G8 in specific types and stages of cancer. Regarding chemotherapy toxicity tools, most studies focused on Grade 3 to 5 toxicities. As mentioned earlier, Grade 2 toxicities may also be significant for older adults (Hurria et al., 2011). Future evaluations and adaptations of the CARG should be in predicting lower-level toxicities and potential use in newer therapies. Future research considerations for both tools should include repeat screenings and prospective studies to evaluate long-term outcomes for geriatric patients.

Methods

Project Design

All DNP project tasks relate to quality improvement and do not produce generalizable knowledge. Therefore, as outlined in the University of Hawaii Human Studies Program memorandum, 2021 (Appendix C), this project did not require Institutional Review Board (IRB) application and review.

The author has completed the Collaborative Institutional Training Initiative (CITI) training and Health Insurance Portability and Accountability Act (HIPAA) training for research

ethics and patient privacy protections. Adhering to HIPAA guidelines, collected data was de-identified except for participants' age and cancer type.

Setting

This quality improvement project was implemented at the Kapi'olani Women's Cancer Center in Honolulu, Hawaii. This clinic is located within the Kapi'olani Medical Center for Women & Children, a Hawaii Pacific Health (HPH) network entity. The Kapi'olani Women's Cancer Center caters to preventing and treating breast, ovarian, endometrial, cervical, vulvar, and vaginal cancers (Hawaii Pacific Health, (n.d.)).

Participants

Project participants were breast and gynecologic cancer patients aged 70 years or older, starting a new regimen of antineoplastic therapy. Participants were selected at their scheduled in-office "chemo teach" or chemotherapy counseling appointments.

Intervention

This DNP project was designed to implement a standardized process for identifying patients with geriatric vulnerabilities. The project intervention entailed implementing two geriatric screening tools, the G8 and the CARG. Two nurse practitioners administered the tools in addition to standard clinical assessment. One specialized in breast oncology, and the other in gynecologic oncology.

The intervention was implemented in the following steps:

1. Before tool implementation, the author held an educational session at KWCC for participating clinicians and staff. The presentation provided an overview of geriatric assessment and instructions for administering the screening tools and documenting the scores.

2. The author provided printed copies of the G8 and CARG to the clinicians. The author also emailed an electronic version of the screening tools and a cover letter reiterating participant eligibility criteria (Appendix D).
3. The clinicians administered the G8 and CARG on eligible patients during their “chemo teach” or chemotherapy counseling appointments.
4. The clinicians’ documented the G8 and CARG scores in the patient’s progress note.
5. Participants with an abnormal G8 score were followed up with in office or referred for additional geriatric evaluation. Interventions for participants with an elevated CARG score were initiated at the clinicians' discretion.

Data Collection

At the end of the implementation period, a chart review was conducted to identify the number of patients assessed with the G8 and CARG. Patient records were reviewed for the following key terms: "Geriatric 8," "G8," "CARG," "Screening," and "Older Adult." For comparison, a list of new chemotherapy starts between October and December 2022 was obtained from the KWCC pharmacy to identify the number of patients eligible for the intervention. Discrepancies between the lists were noted, and patients eligible for screening but not screened were marked as missed. G8 scores, CARG scores, geriatric assessment referrals, and related provider notes were recorded on a secured spreadsheet without patient identifiers. In addition, a debrief with the participating nurse practitioners was conducted to evaluate the limitations and sustainability of the project intervention.

All data files were collected and stored in a secured Google Drive located within the University of Hawaii at Manoa's Google@UH Drive system. Data uploaded and downloaded from Google Drive are automatically encrypted in transit between Google Drive and the web

browser using the TLS protocol. All files uploaded to Google@UH Drive are encrypted while stored on Google's servers. Data was stored in the author's secured file folder that uses file encryption and is only accessible with dual-authentication identification password protection.

Analysis

Project objectives one, two, and three were evaluated using quantitative and qualitative data. Objective one was measured by dividing the number of providers and staff who attended the educational meeting by the number of KWCC providers and staff who agreed to participate in the project. Project objectives two and three used data derived from the post-implementation chart review. Objective two was measured by dividing the number of patients who received the intervention by the number of eligible patients. Objective three was measured by the initiation of referrals or in-office follow-ups for abnormal G8 and CARG scores.

Results

Objective 1: Two nurse practitioners agreed to participate in the project. Two nurse practitioners and six staff members attended the educational session at KWCC. The objective goal of 90% was exceeded with 100% attendance by participating providers.

Objective 2: The KMCWC pharmacy report of new chemotherapy starts identified six eligible patients. The post-implementation chart review revealed that three out of the six patients received the G8 and CARG. The goal of 75% was not met, with only 50% of eligible patients completing the intervention.

Table 1

Results of Post Implementation Chart Review - G8 and CARG Scores

Age	Cancer Type	G8 Score	CARG Score	Referrals/Interventions
70	Breast	---	---	N/A
73	Breast	---	---	N/A
80	Breast	11	8	Deferred GA
85	Breast	14	5	No interventions
82	Endometrial	---	---	N/A
74	Ovarian	12	6	N/A

Objective 3: The post-implementation chart review revealed that one patient had an abnormal G8 score of 11. Scores 14 and below indicate a need for geriatric assessment. Per the clinician's note, this patient deferred further geriatric assessment. In addition, one patient had a moderate CARG score with no treatment modifications or additional follow-ups noted in the progress note. The goal of an established workflow for patients needing further geriatric evaluations was met.

Discussion

This DNP project intended to implement a standardized process for evaluating geriatric risk before starting antineoplastic therapy. Despite only meeting two of the three project objectives, a new process was successfully initiated at the clinic. In line with the literature, the results of this project showed that geriatric screening tools could be practically implemented in an outpatient setting.

Limitations

The results of this project were limited to a small sample of six patients, only three of whom received the intervention. A short implementation period and limited provider time (participating nurse practitioners were part-time) may have contributed to the small sample. In

addition, the 50% screening rate signifies that the project workflow needs refining before long-term implementation.

Two of the missed patients were due to confusion about the definition of "new" therapy. The two patients started their initial treatment at KWCC but moved off-island and started a different regimen before returning to the clinic. Because KWCC providers did not initiate the new treatment, the patient should have undergone the project intervention before continuing. Future screenings should be initiated before starting any "new" antineoplastic regimen, including initial, subsequent, and those not first initiated by a KWCC provider. The third missed patient did not have a "chemo teach" appointment and therefore was not identified for the intervention. Screening parameters should be changed to include all appointment types. Providers can determine when it is possible and appropriate to administer the screening.

In a post-implementation debrief, the participating nurse practitioners expressed positive feelings toward the intervention. They had no difficulty administering or interpreting the tools and stated that they could be completed in a reasonable amount of time. As mentioned earlier, a small sample of patients received the intervention, and most scores were within normal range. The NPs felt they needed more opportunities to evaluate if and how the screening results influenced their practice. In addition, the providers noted that they work jointly with medical oncologists, which may further limit their ability to modify treatments regardless of screening findings. They recognized a more significant opportunity for enhancing supportive care.

Future Considerations

Future considerations for this project include integrating the G8 and CARG into the electronic health record (EHR) system and expanding use to other KWCC providers. EHR integration would streamline the screening process and increase the number of patients captured.

An example of EHR integration could be when a provider orders antineoplastic therapy; the clinical reminder system will generate a pop-up window for patients that meet the age requirement. This pop-up would direct the provider to complete the G8 and CARG. Upon completion, the scores would automatically transpose into progress notes, and the system would recommend for or against further geriatric evaluation.

Expanding use to other KWCC providers will require educational sessions and active advocation by the project's participating NPs. The education sessions should be similar to the session for this project, including an overview of geriatric assessment and screening tools. Active advocation by the project's NPs is ongoing, and the response has been positive. For example, one of the NPs recently introduced the G8 and CARG to a KWCC medical oncologist, who expressed great interest in sharing the tools with her team. Continued advocation will aid in further sustainability at the project site.

It is important to note that treatment modifications are not the only way to address screening findings. As recognized by the participating project providers, there is a significant opportunity to enhance supportive care. Providers should consider increasing check-ins (phone and in-office visits) to evaluate disease symptoms, the efficacy of symptom management, and early identification of adverse events. It also provides a chance to reinforce disease and treatment information and counsel patients and their families. Additional considerations include administering fluids, monitoring Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs), managing comorbidities, performing medication reconciliation, performing mental health evaluations, and, perhaps most significant, discussing goals of care. These assessments can support early referrals to receive additional services. These may include

physical therapy (PT), occupational therapy (OT), nutritionist, home health aid, counseling (patient and caregiver), and palliative care.

DNP Essentials

All nine essentials of doctoral education for advanced nursing practice were fulfilled throughout the project's implementation. Most predominantly Essential I (Scientific Underpinning for Practice), Essential III (Clinical Scholarship and Analytical Methods for Evidence-Based Practice), and Essential VIII (Advanced Nursing Practice). Essential I was demonstrated by recognizing the significance of age-related health disparities for older oncology patients and acknowledging the impact of geriatric screening in improving patient outcomes. Essential III was demonstrated by appraising existing literature for validated geriatric assessment tools and advocating for standardized use in an outpatient oncology setting. Finally, Essential VIII was demonstrated using a conceptual framework to implement evidenced-based tools. This implementation involved educating participating providers on geriatric screening tools, evaluating tool usage through quantitative and qualitative analysis, and identifying limitations and improvements for long-term sustainability at the project site.

Conclusion

The use of GA in cancer care for older adults has shown great potential, however, incorporating it into regular practice can be challenging, especially for busy oncology clinics with limited time for additional patient assessment. Geriatric screening tools have made it more feasible, however it is important to increase the willingness of providers to use them. This DNP project aimed to introduce a standardized workflow for GA screening in an outpatient oncology clinic. Despite some limitations, this quality improvement project has demonstrated that GA tools can be practically applied in a busy oncology setting. In the future, integrating GA

assessments into an EHR and continuing education and advocacy by clinic providers will hopefully lead to increased use of GA tools in routine practice. By promoting the use of GA and its associated tools, health care providers can help improve the safety and quality of geriatric cancer care.

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Appendix A

Johns Hopkins Nursing
Center for Evidence-Based Practice

Thank you for your submission.
We are happy to give you permission to use the Johns Hopkins Evidence-Based Practice model and tools to adhere to our legal terms noted below.
No further permission for use is necessary.

You may not modify the model or the tools without written approval from Johns Hopkins.
All references to source forms should include "© 2022 Johns Hopkins Health System/Johns Hopkins School of Nursing."
The tools may not be used for commercial purposes without special permission.
If interested in commercial use or discussing changes to the tool, please email ijhn@jhmi.edu.

Downloads:

2022 JHEBP Tools- Printable Version

2022 JHEBP Tools- Electronic Version

Would you like to join us? *Group rates are available, email ijhn@jhmi.edu to inquire.*

EBP Boot Camp: We are offering a 5-day intensive Boot Camp where you will learn and master the entire EBP process from beginning to end. Take advantage of our retreat-type setting to focus on your project, collaborate with peers, and get expertise and assistance from our faculty.

EBP Skill Build: This 3-day virtual workshop gives you a front-row seat to our EBP training and provides every participant with the guidance and support they need to get their EBP projects started.

Appendix B

Mosby's Level of Evidence		
Level	**Description**	**Evidenced Reviewed**
I	Evidence from a systematic review or meta-analysis of all relevant RCTs (randomized controlled trial) or evidence-based clinical practice guidelines based on systematic reviews of RCTs or three or more RCTs of good quality that have similar results.	12
II	Evidence obtained from at least one well-designed RCT (e.g. large multi-site RCT).	3
III	Evidence obtained from well-designed controlled trials without randomization (i.e. quasi-experimental).	0
IV	Evidence from well-designed case-control or cohort studies.	1
V	Evidence from systematic reviews of descriptive and qualitative studies (meta-synthesis).	2
VI	Evidence from a single descriptive or qualitative study.	0
VII	Evidence from the opinion of authorities and/or reports of expert committees.	0

Appendix C

UNIVERSITY of HAWAI'I SYSTEM

Office of Research Compliance
Human Studies Program

August 6, 2021

MEMORANDUM

TO: Rick Ramirez, DNP, APRN-Rx, AG-ACNP-BC, FNP-BC, ENP-C, CEN, CPEN
Doctor of Nursing Practice Program Director and Assistant Professor
AG-PCNP Specialty Coordinator
APRN Clinical Course Series Faculty Coordinator
University of Hawai'i at Mānoa
School of Nursing and Dental Hygiene

FROM: Victoria Rivera
Director, Office of Research Compliance, Human Studies Program
University of Hawaii

SUBJECT: Doctor of Nursing Practice Program

This memorandum intends to clarify the University of Hawaii (UH), Human Studies Program (HSP) position regarding the quality improvement (QI) project required by the UH School of Nursing and Dental Hygiene's Doctor of Nursing (DNP) Program.

Based on our discussions, students enrolled in the DNP Program are required to complete a QI project in order to meet the *AACN Essentials of Doctoral Education for Advanced Nursing Practice* for this professional degree. According to the AACN guidelines, since this is a practice doctorate, "requiring a dissertation or other original research is contrary to the intent of the DNP. The DNP primarily involves mastery of an advanced speciality within nursing practice."

Therefore, by definition, the DNP quality improvement project required by the UH School of Nursing is not considered human subjects research as defined under federal regulations at 45 CFR 46. To very briefly summarize, *research* is a systematic investigation designed to contribute to generalizable knowledge, and *human subject* means a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information. Quality improvement/program evaluation focuses on making judgements about the program, to improve or futher develop program effectiveness, and inform decisions about future programming. As part of the DNP program, students are familiarized with the difference between conducting a QI project and a research project.

Given the purpose of the DNP quality improvement project, it is the position of the UH Human Studies Program that these projects are considered "NOT human subjects research" (NHSR) and as such, does not require IRB review. To be clear, this is not a determination of "Exempt" status under 46.101, as these are categories of *research* considered to be exempt from IRB review. Please ensure that DNP students understand that the results of these types of QI projects may be presented or published, but must not be labled as human subjects research.

Please feel free to contact our office for any questions.

cc: Alice Tse, SODNH Department Chair and Graduate Chair

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Appendix D

DNP Project - Implementing Standardized Geriatric Screening Tools in Elderly Breast and Gynecologic Cancer Patients

Tools

- **Geriatric 8 (G8) -** Identify patients who may benefit from comprehensive geriatric assessment
- **CARG Chemo-Toxicity Calculator -** Provides risk estimates for grade 3-5 chemotherapy toxicity

Implementation Plan

Timeline

- 3-month period (October-December)

Eligibility Criteria/Selection Process

- 70 years or older, diagnosed w/ breast and/or gynecologic cancer
- Have not started antineoplastic therapy
- Eligible patients will be selected in order of their scheduled in-office appointment

Tool Administration

- Administered during chemo counseling
- Printed copies of the G8 and CARG to be packaged with chemo consent

Documentation

- G8 and CARG scores to be written in patient progress notes
  Example: "CARG Score: _____" / "G8 Score: _____"

Follow-up

- Patients in need of further evaluation can be followed up with in clinic or referred out based on provider preference

Geriatric 8 (G-8)

Scoring: *Total score ranges from 0-17. Scores of 14 or lower may indicate need for further evaluation.*
Normal *(>14 points)*
Abnormal *(*0-14 points*)*

RISK PREDICTOR	RESPONSE	SCORE
1. Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing, or swallowing difficulties?	0 = severe reduction in food intake 1 = moderate reduction in food intake 2 = normal food intake	
2. Weight loss during the last 3 months?	0 = weight loss >3 kg 1 = does not know 2 = weight loss between 1 and 3 kg 3 = no weight loss	
3. Mobility	0 = bed or chair bound 1 = able to get out of bed/chair but does not go out 2 = goes out	
4. Neuropsychological Problems	0 = severe dementia or depression 1 = mild dementia or depression 2 = no psychological problems	
5. Body Mass Index (weight in kg/height in m^2)	0 = BMI <19 1 = 19 ≤BMI < 21 2 = 21 ≤BMI < 23 3 = BMI ≥ 23	
6. Takes more than 3 medications per day	0 = yes 1 = no	
7. In comparison with other people of the same age, how does the patient consider his/her health status?	0 = not as good 0.5 = does not know 1 = as good 2 = better	
8. Age	0 = > 85 1 = 80-85 2 = < 80	
	TOTAL SCORE:	

CARG

Cancer and Aging Research Group (CARG) Chemo-Toxicity Calculator

Scoring: *Total score ranges from 0-23. Score estimates percent risk of grade 3 or greater toxicity.*
Low risk *(0-5 points)*
Intermediate risk *(6-9 points)*
High risk *(10-23 points)*

VARIABLE	RESPONSE	SCORE
1. Age, years	0 = < 72 years 2 = ≥ 72 years	
2. Cancer type	0 = Other 2 = Gastrointestinal or genitourinary	
3. Dosage (for first dose of chemotherapy)	0 = Reduced dose 2 = Standard dose	
4. Number of chemotherapy drugs	0 = 1 2 = > 1	
5. Hemoglobin, g/dL	0 = ≥ 11 g/dL (male) ≥ 10 g/dL (female) 3 = < 11 g/dL (male) < 10 g/dL (female)	
6. Creatinine clearance, mL/min	0 = ≥ 34 mL/min 3 = < 34 mL/min	
7. Hearing	0 = Excellent/good 2 = Fair/poor/totally deaf	
8. Number of falls (in the past six months)	0 = None 3 = ≥ 1	
9. Needs help taking meds	0 = No 1 = Yes	
10. Walking ability (within one block)	0 = Not limited 2 = Limited	
11. Social activity	0 = Not decreased due to health 1 = Decreased due to health	
	TOTAL SCORE:	