



Evidence-Based Series #16-4

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Effective Use of Advanced Practice Nurses in the Delivery of Adult Cancer Services in Ontario

*D. Bryant-Lukosius, R. Cosby, D. Bakker, C. Earle, B. Fitzgerald, V. Burkoski,
and the Advanced Practice Nursing Guideline Development Group*

Report Date: May 11, 2015

An assessment conducted in November 2022 deferred the review of Evidence-Based Series (EBS) 16-4. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document ([PEBC Assessment & Review Protocol](#))

EBS 16-4 is comprised of 3 sections. You can access the summary and full report here:

<https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2166>

Section 1:	Guideline Recommendations
Section 2:	Evidentiary Base
Section 3:	Development Methods, Recommendations Development and External Review Process

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PEBC Report Citation (Vancouver Style): Bryant-Lukosius D, Cosby R, Bakker D, Earle C, Fitzgerald B, Burkoski V. Effective use of advanced practice nurses in the delivery of adult cancer services in Ontario. Toronto (ON): Cancer Care Ontario; 2015 May 11. Program in Evidence-based Care Guideline No.: 16-4.

Conference Citations (Vancouver Style): Bryant-Lukosius D, Cosby R, Earle C, Bakker D, Fitzgerald B, Burkoski V, et al. Effective use of advanced practice nursing roles in cancer control: results of a systematic review [abstract]. *Cancer Nurs.* 2015;38(4S);0-134.

Bryant-Lukosius D, Cosby R, Bakker D, Burkoski V, Earle C, Fitzgerald B, et al. Effective use of advanced practice nurses (APNs) in cancer control [abstract]. Presented at: CANO/ACIO; 2013 Oct 20; Vancouver, BC.

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Evidence-Based Series 16-4: Section 1

**A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)**

**Effective Use of Advanced Practice Nurses in the Delivery of
Adult Cancer Services in Ontario:
Guideline Recommendations**

*D. Bryant-Lukosius, R. Cosby, D. Bakker, C. Earle, B. Fitzgerald, V. Burkoski,
and the Advanced Practice Nursing Guideline Development Group*

Report Date: May 11, 2015

SUMMARY OF RECOMMENDATIONS

PREVENTION

- No recommendations can be made about the utilization of advanced practice nursing (APN) roles for cancer prevention.

SCREENING

- In primary care and community-based settings, nurse practitioners (NPs) working in alternate provider roles can be utilized to improve access to breast and cervical cancer screening.
- As alternate providers to physicians, NPs can provide safe and effective care in performing esophagoscopy, flexible sigmoidoscopy, and colonoscopy for cancer screening.

DIAGNOSIS

- For women with cervical dysplasia, NPs are an appropriate alternate provider to physicians in performing colposcopy-guided biopsies to diagnose cervical cancer.

TREATMENT

- Clinical nurse specialist (CNS)-led care is an appropriate alternate model to care provided by physicians, particularly for newly diagnosed patients undergoing surgery or radiation therapy.
- The addition of complementary CNS care may improve psychological and mental well-being and survival for patients with a new diagnosis of cancer who are post cancer surgery, or receiving chemotherapy or radiation treatment.

SURVIVORSHIP/POST-TREATMENT FOLLOW-UP CARE

- For patients with breast and colorectal cancer, CNS- or NP-delivered telephone follow-up may provide a safe and acceptable alternate model to outpatient clinic follow-up care provided mostly by physicians.

- The addition of a complementary and comprehensive assessment and intervention program provided by a NP may be effective for reducing menopausal symptoms in women following treatment for breast cancer.

PALLIATIVE CARE

- The complementary addition of CNS care to cancer services may improve health-related quality of life (HRQL) and mental and social well-being for patients with advanced cancer or cancer-related pain, while providing similar or improved outcomes related to healthcare utilization.

END-OF-LIFE CARE

- No evidence-based recommendations can be made about the utilization of APN roles for end-of-life care.

OTHER RECOMMENDATIONS

- For those involved in planning, implementing, and evaluating CNS and NP roles (e.g., healthcare administrators, researchers, and advanced practice nurses), careful selection of outcomes that are the target of specific CNS and NP interventions is required.
- No recommendations can be made about the effectiveness of CNS or NP roles for improving healthcare provider outcomes.
- No recommendations can be made about the cost effectiveness of CNS or NP roles in cancer control.

GUIDELINE OBJECTIVES

The guideline objective was to make evidence-based recommendations about APN roles (i.e., CNS, NP) for optimizing patient, provider, and health system outcomes across the cancer journey. Based on this objective, this guidance document address two specific questions:

- (1) For which patient populations and in which situations (types of needs, practice settings, phase of the cancer journey) have APN roles demonstrated equivalence or improved outcomes or reduced harms in appropriate controlled comparative studies of cancer care?
- (2) What specific patient, provider, or health system outcome indicators are associated with CNS or NP roles?

TARGET POPULATION

The target population includes patients across the cancer journey (i.e., prevention, screening/diagnosis, treatment, survivorship/recovery, palliative care, end-of-life care).

OUTCOMES OF INTEREST

Potential outcomes of interest include: quality of life; physical, functional, psychosocial and mental health; morbidity; mortality; symptom management; patient and provider satisfaction; health care utilization; costs; and quality of care.

INTENDED USERS

The intended users of this guideline include:

- Healthcare administrators who plan the delivery of services in cancer and other health care settings
- Chief Nurse Executives
- Models of care steering committees
- Healthcare policy makers
- Registered nurses (RNs), advanced practice nurses, physicians and other allied health professionals involved in the delivery of cancer care
- APN educators and researchers
- Directors of Interprofessional Practice
- Professional associations (e.g., Canadian Association of Nurses in Oncology, Registered Nurses Association of Ontario)

As with any planning strategy, the complete range of clinicians with the knowledge, skills, and competence to provide various care options should be considered in the context of patient need, quality goals, access, demand, and availability of resources. This guideline provides evidence-based recommendations related to appropriate clinical roles for advanced practice nurses.

Canada recognizes two types of APN roles, the CNS and the NP. According to the Canadian Nurses Association, CNSs and NPs provide *“an advanced level of clinical nursing practice that maximizes the use of graduate educational preparation, in-depth nursing knowledge and expertise in meeting the health needs of individuals, families, groups, communities and populations. It involves analyzing and synthesizing knowledge; understanding, interpreting and applying nursing theory and research; and developing and advancing nursing knowledge and the profession as a whole”* (1). CNSs and NPs have overlapping and complementary skill sets. Both roles are involved in the delivery of direct and indirect clinical care, providing organizational leadership, leading or participating in research and evidence-based practice activities, and educating patients, nurses, and other health providers. The two roles differ with respect to their scope and focus of practice. CNSs have the same regulated scope of practice as an RN. While CNSs provide clinical care they tend to have greater expertise and responsibilities for leading organizational change, education, evidence-based practice, and research (2,3). NPs have an expanded regulated scope of practice (i.e., RN-EC) that gives them the authority to diagnose, prescribe, treat and refer patients to other providers, and to admit and discharge patients from hospital (4,5). With this expertise, NPs tend to have greater role responsibilities related to clinical care but also engaged in leadership, education, evidence-based practice, and research.

ALTERNATE APN ROLES

Alternate APN roles are introduced as a replacement or substitute for another provider, most often a physician. The aim is to provide services that reduce cost or address workload or workforce shortages while maintaining or improving the quality of care (6). Studies of alternate roles are usually designed to assess for equivalent outcomes.

COMPLEMENTARY APN ROLES

Complementary APN roles are introduced to augment the services of existing healthcare provider roles with the goal of improving quality of care (7). Studies of complementary roles compare APN plus standard care with standard care alone and are designed to assess for improved outcomes.

Note, this guideline focuses solely on direct evidence specific to CNS and NP roles and does not include evidence or recommendations related to additional roles that could be provided by RNs or other types of clinicians (e.g., radiation therapists). Clinical activities listed below may also be appropriate to be offered by alternative, appropriately trained care providers.

In the section that follows, recommendations related to Questions 1 and 2 are provided beginning with recommendations for Question 1. These recommendations are presented by phase of the cancer journey.

RECOMMENDATIONS, KEY EVIDENCE, AND JUSTIFICATION

RESEARCH QUESTION #1

For which patient populations and in which situations (types of needs, practice settings, phase of the cancer journey) have APN roles demonstrated equivalence or improved outcomes or reduced harms in appropriate controlled comparative studies of cancer care?

The following factors were taken into consideration in formulating guideline recommendations about the effective use of CNS and NP roles in cancer control:

Current Status of APN

- APN roles in Canada are not new. CNSs and NPs have existed in Canada for almost 60 years. In 2013, there were 424 Adult NPs, 1635 Primary Healthcare NPs, and 848 CNSs and RNs in APN roles in Ontario (8).
- Compared with other countries with similar APN experience, Canada has yet to fully exploit CNS and NP expertise in healthcare, including cancer control. For example, NPs and CNSs are far more integrated into the healthcare system in the United States, making up 6.5% and 2.5% of the RN workforce, respectively (9). In Canada, NPs and CNSs each make up 1% or less of the RN workforce. In a survey of patients with chronic conditions in primary care settings, those in the United Kingdom were more likely to receive care from a NP compared with similar patients in Canada (48% versus 22%) (10).
- Nurses working in cancer care make up a very small proportion of the Canadian nursing workforce. In 2010, there were 3953 RNs (including CNSs and NPs) (1.5% of all nurses) working in oncology in all provinces and territories (11). In 2013 in Ontario, there were 497 RNs (includes CNSs), 55 NPs, and 138 registered practical nurses working in oncology (8). Given the rising incidence/prevalence of cancer and gaps in access and quality of care, there are opportunities to optimize generalist, specialized, and advanced nursing roles in cancer control.

Quality of Evidence

- Multiple systematic reviews demonstrate the safety and effectiveness of CNS and NP roles in a variety of contexts (12-14). The findings of this systematic review are consistent with other reviews.
- The overall quality of the evidence reported in this systematic review is poor (moderate to high risk of bias in all but one study) and the results of individual studies must be interpreted with caution. However, the consistent pattern of results demonstrating equivalent or improved quality of care and patient health outcomes for different types of APN roles across varied patient populations, geographic jurisdictions, and phases of cancer is compelling.

Future Directions

- Further research about the effective development and use of CNS and NP roles in Canada is required.
- Innovative approaches that optimize the scope of practice and expertise of all members of the healthcare team are required to deliver timely, coordinated, accessible, and efficient models of patient-centred cancer care (15).

PREVENTION

RECOMMENDATION 1

No recommendations can be made about the utilization of APN roles for cancer prevention owing to a lack of data at this time.

Future research should: i) examine the broader international literature about the effectiveness of primary prevention strategies delivered by advanced practice nurses in the non-cancer literature that may be relevant to cancer; and ii) assess the need to optimize APN role involvement in primary and secondary cancer prevention services.

Summary of Key Evidence for Recommendation 1

- No comparative studies about the effective use of advanced practice nurses related to the primary or secondary prevention of cancer were identified.

Justification for Recommendation 1

There is no evidence currently available on which to make a recommendation regarding the use of advanced practice nurses in cancer prevention.

Qualifying Statements for Recommendation 1

- The lack of research studies related to cancer prevention was a surprising finding given that health promotion and illness prevention are important aspects of APN and, in particular, NP roles in primary care (16-18).
- Relevant studies on the primary prevention of chronic diseases including cancer (e.g., health promotion/healthy lifestyle interventions related to diet, exercise, smoking cessation, alcohol use) may have been missed in this review because of the cancer-specific focus of the literature search strategies. The absence of research about APN roles in primary prevention has been noted in a non-cancer-specific systematic review of CNSs and NPs (14). Research on these roles has focused on the management of episodic conditions, secondary prevention, and chronic disease management (14).
- People with a history of cancer may be at risk for developing a second cancer and other chronic conditions including cardiovascular disease, pulmonary disease, diabetes, and hypertension (19-21). Efforts to improve the long-term health of cancer survivors through secondary prevention strategies are required.

SCREENING

RECOMMENDATION 2

In primary care and community-based settings, NPs working in alternate provider roles can be utilized to improve access to breast and cervical cancer screening.

Summary of Key Evidence for Recommendation 2

- NPs providing same-day services in primary care clinics for underscreened patients had improved breast and cervical screening rates compared with physician chart reminders (22).
- Two studies demonstrated that the quality of Papanicolaou (Pap) smears conducted by NPs was not detectably different and, in some cases, was superior to physicians (23,24).

Justification for Recommendation 2

The evidence demonstrated consistent results with similar or improved patient outcomes, and no reported harms, with respect to breast and cervical cancer screening for NPs working in alternate provider roles.

Qualifying Statements for Recommendation 2

- No studies compared RNs and NPs in performing Pap smears.
- Quality of Pap smear is defined as the proportion of satisfactory smears and the proportion of smears with endocervical cells.

Additional Implementation Considerations

- In Canada, RNs (who have acquired competency through additional training) and NPs are authorized to perform Pap smears.

RECOMMENDATION 3

As alternate providers to physicians, NPs can provide safe and effective care in performing esophagoscopy, flexible sigmoidoscopy, and colonoscopy for cancer screening.

Summary of Key Evidence for Recommendation 3

- The sensitivity and specificity of NP-conducted sigmoidoscopy and esophagoscopy was found to be no different to that of physicians (25,26).
- Compared with physicians, NP-led colonoscopy was found to provide equivalent quality of care with respect to procedural pain, duration of the procedure and depth of insertion, and improved care related to patient satisfaction and detection of adenomas (27).

Justification for Recommendation 3

The evidence demonstrated consistent similar (i.e., no difference) or improved patient outcomes, with no reported harms, with respect to esophagoscopy, flexible sigmoidoscopy, and colonoscopy for cancer screening for NPs working in alternate provider roles.

Qualifying Statements for Recommendation 3

- The studies included patients at average risk for colorectal cancer and at above-average risk for colorectal cancer and esophageal cancer.

Additional Implementation Considerations

- In Ontario, RN-performed flexible sigmoidoscopy is standard care in 14 sites and has been found to be a safe and effective model of care (28). No studies were identified that compared RNs with NPs in performing flexible sigmoidoscopies.

DIAGNOSIS**RECOMMENDATION 4**

For women with cervical dysplasia, NPs are an appropriate alternate provider to physicians in performing colposcopy-guided biopsies to diagnose cervical cancer.

Summary of Key Evidence for Recommendation 4

- Two studies found the sensitivity and specificity of colposcopy-guided cervical biopsies conducted by NPs to be no different than those conducted by physicians (29,30). NPs were more likely to take two or more biopsies and this was associated with improved sensitivity (29). These results are based on randomized controlled trial and chart review data.
- One study found that compared with physicians, there was greater consistency between Pap smear and biopsy, less variability and greater consistency with standards of care, higher rates of patient follow-up, and better documentation by NPs.

Justification for Recommendation 4

The evidence demonstrated consistent similar (i.e., no difference) or improved patient outcomes, with no reported harms, with respect to colposcopy-guided biopsies to diagnose cervical cancer performed by NPs working in alternate provider roles.

Additional Implementation Considerations:

- NPs may be particularly effective at improving access to care for women with cervical dysplasia in underserved communities.

TREATMENT

RECOMMENDATION 5

CNS-led outpatient supportive care is an appropriate alternative model to the provision of such care by physicians, particularly for newly diagnosed patients undergoing surgery or radiation therapy.

Summary of Key Evidence for Recommendation 5

- CNS-led care was evaluated in five studies involving patients considering reconstructive surgery due to breast cancer (31), receiving homecare for lung cancer (32), undergoing radical prostatectomy for prostate cancer (33), and receiving radical radiation therapy for head and neck, bladder, or prostate cancer (34,35).
- CNS-led care is associated with similar or improved patient health outcomes and satisfaction with care including:
 - delay in symptoms and physical impairment for lung cancer patients
 - reduction in early urinary and gastrointestinal symptoms, less fatigue, and better physical functioning for patients receiving pelvic radiation
 - reduction in urinary symptoms, improved continence for prostate cancer patients
- Substitution of physician care with CNS management did not lead to unnecessary duplication of services for patients receiving radiation therapy.
- CNS-led care is not associated with reduced healthcare utilization (e.g., hospital length of stay, readmissions, and emergency department visits) but may lead to a reduction in diagnostic tests, prescriptions, and clinic visits.
- No studies of NPs related to the treatment phase of the cancer journey were identified.

Justification for Recommendation 5

Several studies demonstrated consistent reduced harms, or similar (i.e., no difference) or improved patient outcomes, with very few reporting negative outcomes with respect to patients undergoing surgery or radiation therapy for CNSs working in alternate provider roles. The benefits of CNS care exceeded the harms.

Qualifying Statements for Recommendation 5

- It is not possible to make recommendations about the specificity of interventions to be included in the package of services offered in alternate models of CNS-led care for patients receiving cancer treatment. Overall, the studies are small and heterogenous.

Additional Implementation Considerations

- In general, CNS care most commonly involved a package of interventions or services that included comprehensive and holistic patient assessments, provision of information, development of patient self-care management skills, symptom management, psychosocial support, and care coordination with patient referral to other healthcare providers and services, including physicians as required (31-35). Patients also had on-demand access to the CNS as needed via telephone and ad hoc clinic appointments (31,33-35).
- Developing CNS care interventions requires careful assessment of unmet patient population health needs and integration of clinical practice guidelines for the assessment and management of specific disease- and treatment-related symptoms and side effects.

- In some instances, CNSs provided medical care outside of their regulated scope of practice such as communicating a diagnosis (33), discussing treatment options (31,33), and ordering diagnostics tests (33,34) or symptom management medications (34,35). In these cases, CNSs used predetermined and physician agreed-upon protocols or medical directives (33-35), and had completed additional training (31,35).

RECOMMENDATION 6

The addition of complementary CNS care to usual care may improve psychological and mental well-being and survival for patients with a new diagnosis of cancer who are post cancer surgery or receiving chemotherapy or radiation treatment.

Summary of Key Evidence for Recommendation 6

- Complementary CNS care was evaluated in six studies for patients receiving chemotherapy and/or radiation therapy (36,37), undergoing radiation therapy alone (38,39), or who were post cancer surgery (40-42).
- The studies included patients with breast, gynecological, head and neck, gastrointestinal, lung, or urological cancers.
- The addition of CNS care to usual care did not improve HRQL for patients receiving radiation or chemotherapy (36-38), except for unmarried women with breast cancer who had improved HRQL and mood (37).
- There were no differences in symptom distress (42) or radiation treatment side effects for patients who did or did not receive CNS care (38,39).
- There were variable results related to psychosocial and mental health outcomes.
- One study evaluated the impact of CNS care on survival (42). There were no survival benefits for elderly patients post cancer surgery who had early stage solid tumour cancers. Patients with advanced stage cancer in the CNS group had improved survival at two years (67% versus 40%, 95% confidence interval [CI], 1.33 to 3.12; p=0.001) due to fewer deaths from postoperative complications.
- The addition of CNS care to usual care did not lead to reduced health service use, but importantly, was also not associated with increased healthcare costs.

Justification for Recommendation 6

Several studies demonstrated consistent similar (i.e., no difference) or improved patient outcomes with respect to newly diagnosed cancer patients who were post cancer surgery or receiving chemotherapy or radiation therapy for CNSs working in complementary provider roles. The benefits of CNS care exceeded the harms.

Qualifying Statements for Recommendation 6

- No studies evaluated complementary NP roles.
- Patients who may benefit the most from CNS care are unmarried women with breast cancer, and those who have more intensive and complex healthcare needs related to psychological distress, older age, and advanced cancer.
- CNS care focused on the prevention, early detection, and management of health problems following patient discharge from hospital may have contributed to improved survival for patients with advanced stage cancer.

Additional Implementation Considerations

- CNS care involved a package of interventions emphasizing patient self-care through education, provision of information and skill development; coping; symptom assessment and management; care coordination and referral to other supportive care providers and community services; and decision support.
- Most CNS interventions occurred over eight to 24 weeks, took place during scheduled weekly or alternate week and on-demand clinics, telephone or home visit appointments. In one study, patients had access to a CNS seven days per week by telephone, but not for 24 hours each day (42).
- CNSs had extensive training to deliver psychoeducational interventions (36) or had specialized knowledge and skills related to clinical decision making, symptom management, diagnostic and cancer treatment protocols, community resources and negotiation (42).
- The studies by McCorkle et al. (40,42) and Ritz et al. (37) highlight the importance of careful patient assessment to determine subgroup populations who may benefit the most from CNS interventions and also tailoring the intensity of interventions to match the needs of different at-risk patient populations.

SURVIVORSHIP/POST-TREATMENT FOLLOW-UP CARE

RECOMMENDATION 7

For patients with breast and colorectal cancer, CNS- or NP-delivered telephone follow-up may provide a safe and acceptable alternate model to outpatient clinic follow-up care provided mostly by physicians.

Summary of Key Evidence for Recommendation 7

- CNS- or NP-led telephone follow-up for patients with breast and colorectal cancer, respectively, was associated with improved patient satisfaction and achieved similar (i.e., no difference) outcomes including anxiety, psychological well-being, quality of life, self-care, recurrence, and time to detect recurrence (43-45).
- There were no differences in hospitalization, numbers of tests, or contacts between scheduled appointments for CNS or NP telephone follow-up care for patients with breast or colorectal cancer (43,46).
- In one study, the combination of longer consultation times and a 20% increase in consultations, resulted in higher overall per patient costs for CNS care (mean difference £55, 95% CI, £26 to £77) (46). It is unclear whether these costs would generalize to the Ontario context.
- Patients receiving CNS telephone follow-up had lower travel and lost productivity costs (46).

Justification for Recommendation 7

The evidence demonstrated consistent similar (i.e., no difference) or improved patient outcomes with respect to follow-up care of low to moderate risk for cancer recurrence in breast or colorectal cancer patients for NPs and CNSs working in alternate provider roles. There were very few negative outcomes and the benefits of APN-delivered care exceeded the harms.

Qualifying Statements for Recommendation 7

- CNS or NP telephone follow-up is suitable for patients at low to moderate risk for cancer recurrence and those wishing to avoid clinic visits due to long travel distance and/or mobility issues (44,45).
- Standard post-treatment follow-up care for breast cancer was delivered in outpatient clinics and was most often provided by junior doctors (residents), but also by oncologists, CNSs, or a colorectal NP (43,44).

RECOMMENDATION 8

The addition of a complementary and comprehensive assessment and intervention program provided by a NP may be effective for reducing menopausal symptoms in women following treatment for breast cancer.

Summary of Key Evidence for Recommendation 8

- Women receiving the NP-led intervention had significant improvements in menopausal symptoms and sexual functioning compared with those in the attention control/usual care group (47). There were no significant differences in vitality.

Justification for Recommendation 8

The evidence consisted of one randomized controlled trial (RCT) that demonstrated decreased harms or similar (i.e., no difference) or improved patient outcomes, with no reported harms, with respect to menopausal symptoms in women following breast cancer treatment for NPs working in complementary provider roles.

Qualifying Statements for Recommendation 8

- Study participants were female, and between eight months and five years following a diagnosis of stage I or II breast cancer. They had completed chemotherapy or radiation therapy at least four months prior to study participation, but could be taking tamoxifen (47).
- Study participants had at least one menopausal symptom (hot flashes, vaginal dryness, or stress urinary incontinence) of moderate to severe intensity (47).

Note:

One study evaluated CNS-performed flexible cystoscopy for the follow-up care of patients with bladder cancer (48). Based on the results of this one study, there is insufficient evidence to make recommendations about the use of CNS or NPs as alternate providers to physicians in performing follow-up flexible cystoscopy for patients with bladder cancer.

PALLIATIVE CARE

RECOMMENDATION 9

The complementary addition of CNS care to cancer services may improve HRQL and mental and social well-being for patients with advanced cancer or cancer-related pain while providing similar or improved outcomes related to healthcare utilization.

Summary of Key Evidence for Recommendation 9

- Three studies evaluated very different models of complementary CNS care in providing proactive palliative care services for patients with advanced cancer in oncology settings (49,50) and coaching for cancer pain management (51).
- No studies evaluating NPs were identified.
- The early introduction of CNS palliative care services did not lead to improved HRQL, symptoms, or mood but was associated with increased survival and fewer hospital admissions (49).
- In contrast, Bakitas et al. (50) found higher HRQL and less depression but no differences in symptom severity, survival, hospital days, and intensive care unit days for patients receiving a CNS-delivered self-care program.
- Similarly, a CNS coaching intervention using motivational interview techniques also led to better HRQL, mood, and psychosocial well-being (reduced pain interference) but no improvement in pain attitudes or symptoms (pain relief, pain intensity) (51). Health service utilization outcomes were not evaluated in this study.

Justification for Recommendation 9

The addition of CNS care was similar to usual care for most patient and health system outcomes. No harms were reported for CNS care. In select studies, CNS care led to improved patient outcomes for survival, HRQL, mental well-being, and pain interference and improved health system outcomes related to reduced hospitalization.

END-OF-LIFE CARE

RECOMMENDATION 10

No evidence-based recommendations can be made about the utilization of APN roles for end-of-life care owing to a lack of data at this time.

Summary of Key Evidence for Recommendation 10

- No comparative studies about the effective use of advanced practice nurses related to end-of-life care were identified.

Justification for Recommendation 10

There is insufficient evidence currently available on which to make a recommendation regarding the use of advanced practice nurses in cancer end-of-life care.

RESEARCH QUESTION #2

What specific patient, provider, or health system outcome indicators are associated with CNS or NP roles?

RECOMMENDATION 11

For those involved in planning, implementing, and evaluating CNS and NP roles (e.g., healthcare administrators, researchers, and advanced practice nurses), careful selection of outcomes that are the target of specific CNS and NP interventions is required.

Summary of Key Evidence for Recommendation 11

- In many studies included in this systematic review, there were findings of no differences between CNS or NP care and usual care for a variety of outcomes. It is possible that the outcomes are, in fact, similar. Other factors noted in this review may also explain these results including poor intervention design and/or failure to select outcomes that are sensitive or responsive to CNS and NP interventions. The selection of outcomes should be driven by the type of CNS or NP intervention and the need or problem it aims to address.
- Patient outcomes evaluated in studies of CNS or NP roles include HRQL, pain and symptom management, mental health, physical function, performance status, self-care, information needs, satisfaction with care, and survival (Table 9A). Of these, HRQL, symptoms, and mental health were the most frequently reported outcomes.
- Health systems outcomes evaluated in studies of CNS and NP roles related to indicators of care quality, healthcare costs, and health service utilization including hospital length of stay, hospital readmission, emergency department visits, number of advanced practice nurse consultations, and number of physician visits (Table 9B). Quality of care indicators were the most frequently reported outcome.

RECOMMENDATION 12

No recommendations can be made about the effectiveness of CNS or NP roles for improving healthcare provider outcomes owing to a lack of data at this time.

Summary of Key Evidence for Recommendation 12

- No comparative studies about the effective use of advanced practice nurses for improving healthcare provider outcomes, such as job satisfaction, workload, or team functioning, were identified.

Justification for Recommendation 12

There is no evidence currently available on which to make a recommendation regarding the use of advanced practice nurses for improving healthcare provider outcomes.

RECOMMENDATION 13

No recommendations can be made about the cost-effectiveness of CNS or NP roles in cancer control.

Summary of Key Evidence for Recommendation 13

- No studies identified for this review conducted an economic analysis. In the few studies measuring costs, only a direct cost comparison is provided, rather than a comprehensive assessment of the incremental costs and benefits of APN care (37,46,48).
- One study reported on health utilization outcomes for NPs (43). There were no differences in the number of tests ordered but NPs had longer consultation times.
- Longer consultation times were also reported for CNSs (35,46).
- Overall, CNS outcomes related to healthcare utilization including hospital length of stay, hospital readmission, emergency department visits, consultations, physician visits, and tests and investigations were equivalent to standard care and costs were either similar or reduced (Section 2, Table 11 and 9B).
- Increased costs may be associated with the time required for CNSs to develop cystoscopy skills and experience (48) with the increased number and length of CNS consultations (46).

Justification for Recommendation 13

There is insufficient evidence on which to make a recommendation regarding cost-effectiveness of advanced practice nurses in alternate or complementary provider roles in cancer control.

FUTURE RESEARCH

Several recommendations regarding future research were developed by the Working Group as follows:

- Further research about the cost-effectiveness of CNS and NP roles in cancer control is required, particularly within the context of the Ontario and Canadian healthcare systems.
- Further research to evaluate innovative models of CNS and NP care is required across all phases of the cancer journey, but particularly for prevention, palliative care, and end-of-life care.
- Beyond screening and diagnosis, future research should evaluate alternate and complementary models of NP care in other phases of the cancer journey.
- In addition to patient outcomes, future research should examine the impact of CNS and NP roles in cancer control on families and family caregivers, healthcare teams and providers, productivity and efficiency, quality of care and evidence-based practice, and access to care.
- Future research should provide decision-makers with guidance about the appropriate use of RNs, CNSs, and NPs in alternate and complementary models of care for specific patient populations and phases of the cancer journey.

- To build capacity to conduct timely and meaningful evaluations of innovative models of CNS and NP care in Ontario that permit comparison across regional cancer programs, practice settings, and patient populations, Cancer Care Ontario should provide leadership and support to:
 - develop an evaluation framework with associated tools to examine the structures, processes and outcomes associated with CNS and NP care;
 - establish an agreed-upon template of priority patient, provider and health system outcome indicators and measures; and
 - strengthen the use of technology and data management support to collect and analyze administrative data relevant to CNS and NP roles.
- To improve the quality of research and generalizability of the results, researchers should address the following methodological issues:
 - use of mixed-method study designs and relevant evaluation theories and concepts to evaluate and understand how CNS and NP roles impact on outcomes;
 - provide more detailed reporting of key study methods (i.e., randomization, randomization concealment, power calculations, and outcome assessment);
 - explicitly report the type of APN role being evaluated (i.e., CNS or NP) and details about APN education and training and the package of APN interventions provided; and
 - measure and evaluate the impact of the APN intervention dose (timing, frequency, intensity, duration of advanced practice nurse-patient interactions) for different at-risk or vulnerable populations.

Important Considerations for the Uptake of Practice Guideline Recommendations

This practice guideline identifies the potential for introducing new models of cancer care delivery that expand the use of CNSs and NPs and maximize their expertise to improve access, quality of care, and health outcomes for patients and families in Ontario. The introduction of new care delivery models, especially those requiring the optimization or expansion of existing nursing roles or the introduction of new roles, is a complex process necessitating thoughtful planning and strategic implementation to ensure successful achievement of expected outcomes.

Research-based approaches and strategies to promote the successful integration of CNS and NP roles in Canada provide important guidance for the application of practice guideline recommendations (52,53). Key considerations for planning, implementing, and evaluating the introduction of CNS and NP roles in cancer control include, but are not limited to, the following:

- Decisions to expand the role of CNSs and NPs for Ontario cancer services should be based on established patient, healthcare team, organization, and healthcare system needs, and assessment of existing health human resources and expertise (15).
- Substantive planning and use of change management strategies to identify and address potential barriers to optimal role implementation. Frequently reported or common issues include:

- allocation and/or reallocation of healthcare funding dollars for new CNS and NP roles, especially with those roles that are aligned with strategic provincial priorities for improving cancer care;
 - current physician funding models and reimbursement policies do not make it attractive for institutions to substitute advance practice nurses for physicians
 - regulatory and legislative barriers and the need for new organizational structures, policies, and other strategies to support enhanced or expanded scopes of practice (e.g., medical directives, referral policies, documentation systems);
 - engagement of the healthcare team and other key stakeholders in the role design and planning process and targeted education and marketing to ensure role clarity and to foster stakeholder understanding and support for the role;
 - physician concerns about liability, especially for alternate CNS and NP roles;
 - need for CNS or NP education, training, and mentorship;
 - need to increase the pool of CNSs and NPs; and
 - mechanisms and resources for appropriate role supervision and support.
- Given the paucity of information about the use of CNS and NP roles in Canada, the introduction of these roles in new models of care should be evaluated to determine their impact on patient and family, healthcare team and provider and health system outcomes.
 - Use of the PEPPA Framework, a Participatory, Evidenced-Informed, and Patient-Centred Process for APN Role Development, Implementation and Evaluation. This framework is a best practice approach outlining systematic steps and strategies to guide activities and inform decision making about the introduction and effective use of CNS and NP roles in cancer control (54,55). In Canada and internationally, the framework has been used to successfully introduce and evaluate CNS, NP, and other advanced healthcare provider roles. *Designing Innovative Cancer Services and APN Roles - Toolkit* (56) is a research-based resource that was developed and tested in Ontario regional cancer centres. It provides guidance, tools, and resources for PEPPA framework application and is freely available at:
<https://www.cancercareontario.ca/sites/ccocancercare/files/assets/PEPPAToolkitOverview.pdf>

Funding

The PEBC is a provincial initiative of Cancer Care Ontario supported by the Ontario Ministry of Health and Long-Term Care. All work produced by the PEBC is editorially independent from the Ontario Ministry of Health and Long-Term Care.

Updating

All PEBC documents are maintained and updated as described in the PEBC Document Assessment and Review Protocol.

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Evidence-Based Series 16-4: Section 2**A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)****Effective Use of Advanced Practice Nurses in the Delivery of
Adult Cancer Services in Ontario: Evidentiary Base**

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Report Date: May 11, 2015

INTRODUCTION

Increasingly, provincial ministries of health and cancer agencies across Canada are challenged to meet the rising demands for cancer services within the context of finite human and financial resources. Over the past 30 years, a growing and aging Canadian population has led to a steady increase in cancer incidence and this trend is expected to continue for the foreseeable future (1). By 2020, the number of new cancer cases in Canada will increase to 290,000 per year. It is estimated that in 2014, Ontario alone will have almost 73,800 new cancer cases (1). The number of cancer survivors is also increasing at twice the rate of new cases owing to improvements in early detection and treatment (2). In 2009, there were over 838,000 cancer survivors who had been diagnosed in the previous 10 years, making up 2.5% of the Canadian population (1). The rise in cancer incidence and prevalence has significant implications for meeting associated increased needs for screening, diagnostic, treatment, and supportive care services, and the long-term health needs of cancer survivors. Up to 50% of cancers may also be preventable (3), suggesting the need for stronger emphasis on primary prevention services to reduce the cancer burden.

New and more sustainable, cost-effective models of cancer care delivery that optimize the expertise of all healthcare providers are required to meet demands for cancer care. In Ontario and other provinces, advanced practice nursing (APN) roles have been identified as an important and yet underutilized resource for improving access to timely, high-quality, patient-centred care (4-6).

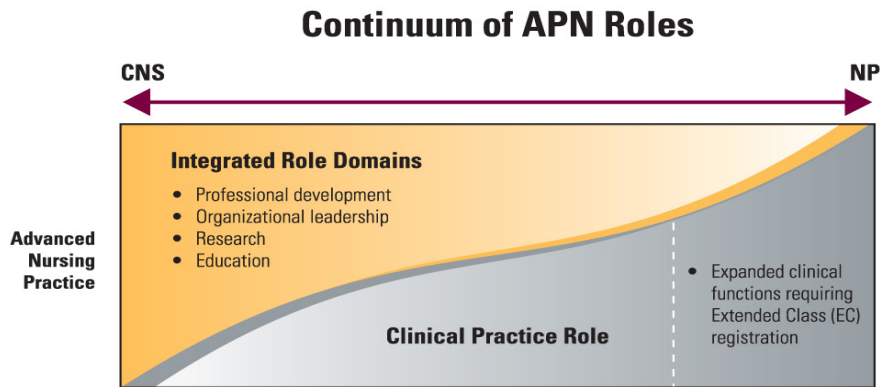
Canada recognizes two types of APN roles: the nurse practitioner (NP) and the clinical nurse specialist (CNS). Both roles have existed in Canada for over 50 years. According to the Canadian Nurses Association, CNSs and NPs provide *“an advanced level of clinical nursing practice that maximizes the use of graduate educational preparation, in-depth nursing knowledge and expertise in meeting the health needs of individuals, families, groups, communities and populations. It involves analyzing and synthesizing knowledge; understanding, interpreting and applying nursing theory and research; and developing and advancing nursing knowledge and the profession as a whole”* (7).

CNSs have a graduate degree in nursing and practice experience in a specialty area such as oncology or palliative care. They have the same scope of practice as a registered nurse (RN). CNSs provide solutions for complex healthcare issues and are leaders in the development of clinical practice guidelines, promoting the use of evidence, and facilitating system change (8). The title, CNS, is not protected in legislation. As a result, any nurse can identify him/herself as a CNS without legal or regulatory repercussion. This often makes it difficult to identify nurses in legitimate CNS roles (9,10).

NPs are RNs with an expanded regulatory scope of practice that requires completion of an NP-specific education program and competency examination and, in Ontario, Extended Class registration (i.e, RN-EC). NPs are able to autonomously diagnose a disease or disorder, order and interpret diagnostic tests, prescribe pharmaceuticals, and perform specific procedures within their legislated scope of practice (8). The title, NP, is also protected in legislation. Only nurses in the Extended Class can use this title. In Ontario, there are three NP categories in the Extended Class: NP-Primary Health Care, NP-Pediatrics, and NP-Adult (11).

Figure 1 illustrates the overlapping and complementary nature of CNS and NP roles. The term 'advanced nursing practice' refers to work responsibilities or what CNSs and NPs do in their roles. Defining features of advanced nursing practice include clinical practice (direct and indirect patient/family care), professional development (of oneself, nurses, and the nursing profession), organizational leadership, education of nurses and other health professionals, and leading or participating in research and evidence-based practice. Of these activities, clinical practice is the primary or core domain of CNS and NP roles. However, the ways in which CNSs and NPs operationalize these role activities can vary.

Figure 1: Clinical Nurse Specialist and Nurse Practitioner Roles



Bryant-Lukosius, D. (2004 & 2008). *The continuum of advanced practice nursing roles*. Unpublished document.

CNSs tend to have less clinical practice and greater role responsibilities related to education, research and evidence-informed practice, organizational leadership, and professional development. In contrast, NPs have an expanded scope of clinical practice and tend to have greater clinical practice responsibilities and less involvement in other role activities. However, as the wavy line in Figure 1 suggests, CNS and NP roles are very fluid.

The balance of clinical and other role responsibilities for CNSs and NPs are contextually driven in response to the needs of patient populations they serve and the practice settings in which they work. For example, an examination of Canadian APN roles found that CNSs working in oncology or palliative care were more likely to report higher concentrations of direct clinical care responsibilities compared with CNSs in other specialties (12). There is a high degree of variability in how CNS and NP roles are implemented within

and across practice settings (13).

Several systematic reviews on the effectiveness of APN roles have been conducted, but none have specifically focused on APN roles in cancer control. Newhouse et al. (14) recently completed a systematic review on the outcomes of CNS and NP roles in the United States (US). There was high evidence indicating that compared with standard care, CNSs achieve equivalent or better outcomes related to patient satisfaction, hospital length of stay, and hospital costs. There was moderate evidence that CNS care leads to reduced complication rates. Similarly, there was high-quality evidence that NPs achieve outcomes equivalent to other providers (mostly physicians) related to patient satisfaction, patient health outcomes, emergency department visits, hospital length of stay, and mortality rates (14). These findings are similar to a scoping review of the international APN literature demonstrating that compared with standard care, CNS and NPs provide equal or better outcomes related to patient health status, health-related quality of life (HRQL) and satisfaction with care; and quality of care, health provider satisfaction, healthcare costs, and hospital length of stay (12).

Nurses working in oncology make up a small (1.5%) proportion of all RNs in Canada (15). In 2013, there were 497 RNs (including CNSs), 55 NPs, and 138 registered practical nurses working in oncology in Ontario (16). A 2013 survey conducted by Cancer Care Ontario's APN Community of Practice identified 82 advanced practice nurses including NPs (59%) and CNSs (41%). Over 50% of these advanced practice nurses worked in regional cancer centres and hospital inpatient units, with fewer advanced practice nurses working in hospital outpatient or community settings. The majority of oncology advanced practice nurses cared for patients with hematological, breast, and gastrointestinal cancers during the treatment, post-treatment, or palliative phases of the cancer journey. Similar to an earlier survey in 2006, the results suggest that there is considerable opportunity to maximize the use of oncology advanced practice nurses through expanded deployment across the cancer journey from prevention to end-of-life care and to a broader mix of high-incidence and high-need patient populations (17). Healthcare administrators report the need for evidence-based information to make effective decisions about patient populations at different stages of the cancer continuum who may benefit the most from expanded use of advanced practice nurses (5,18).

To further inform cancer care planning and decision making about the utilization of APN roles in cancer control, an APN Working Group was established. The task of the Working Group was to conduct a systematic review as the evidentiary basis for recommendations made as part of an organizational practice guideline. Based on the objectives of the guideline, the Working Group developed the research questions outlined below.

RESEARCH QUESTIONS

- (1) For which patient populations and in which situations (types of needs, practice settings, phase of the cancer journey) have APN roles demonstrated equivalence or improved outcomes or reduced harms in appropriate controlled comparative studies of cancer care?
- (2) What specific patient, provider, or health system outcome indicators are associated with CNS or NP roles?

METHODS

This evidentiary base was developed using a planned two-stage method, summarized here and described in more detail below.

1. Search and evaluation of existing systematic reviews: If one or more existing systematic reviews are identified that address the research questions and are of reasonable quality, then those systematic reviews would form the core of the evidentiary base.
2. Systematic review of the primary literature: This review would focus on those areas not covered by existing reviews if any are located and accepted.

The Program in Evidence-Based Care is supported by the Ontario Ministry of Health and Long-Term Care. All work produced by the Program in Evidence-Based Care is editorially independent from the Ministry.

Search for Existing Systematic Reviews

An overall search strategy was developed and implemented that captured both existing systematic reviews and the primary literature in the following databases: MEDLINE, EMBASE, CINAHL, and HealthSTAR (Appendix 1). Any systematic reviews identified using this search strategy were evaluated for relevancy. Identified systematic reviews requiring further consideration would be assessed using the AMSTAR tool (19). AMSTAR evaluates reporting and not quality. It is provided for information purposes only.

Primary Literature Systematic Review

Assuming that no existing systematic reviews were identified, or that identified reviews were incomplete in some fashion, a systematic review of the primary literature was also planned. This review would be reduced in scope, such as a reduction in subject areas covered, time frames covered, etc., based on the scope of incorporated existing reviews. The criteria described below were written assuming no existing reviews would be incorporated.

Literature Search Strategy

The MEDLINE (1980 through November [week 2] 2012), EMBASE (1980 through week 46 2012), HealthSTAR (1980 through October 2012), and CINAHL (1982/01/01 through 2012/11/31) databases were searched for relevant evidence. The full literature search strategies can be found in Appendix 1. The reference lists from retained articles were also searched for additional relevant studies.

Study Selection Criteria and Protocol

Inclusion Criteria

Articles were included if they were fully published English-language reports of randomized trials, prospective comparative studies with historical or contemporaneous controls, or comparative nonrandomized trials that compared specific tasks in the delivery of cancer care performed in the standard way or by the standard people to those same tasks done by advanced practice nurses and reported on at least one of the outcomes of interest. Studies had to be published from 1980 onwards and have a minimum sample size of 30. If more than one study evaluated the same data set, only the most recent paper was selected for inclusion.

There is high variability in APN role titles internationally as well as inconsistent reporting to determine whether an APN role is the focus of a study. To ensure that all

relevant studies met the criteria for inclusion in the guideline related to advanced practice nurses, several methods, in the following order, were employed:

- The information about the specific type of APN role (CNS or NP) and completion of graduate nursing or NP-specific education was provided in the publication itself.
- Authors of a given paper were emailed and asked to provide the information either by:
 - the research assistant of another systematic review of advanced practice nurses being conducted by the lead author of the current guideline, or
 - the lead author of the current guideline
- The lead author used the information provided in the paper along with the year of publication and the country of origin of the research to determine the likelihood that the nursing intervention in a given study was provided by advanced practice nurses that met our definition. If it was determined that the advanced practice nurses in a given study likely met our definition, that study was included. If it was determined that the advanced practice nurses in a given study likely did not meet our definition that study was excluded.
- The lead author (DBL) and one other author (DB), who is a nursing professor/nurse clinician, reviewed the papers independently to determine whether the advanced practice nurses in the study met the necessary requirements. Their agreement was 88% (seven of eight papers). Disagreements were resolved by a third author (BF) who is an experienced advanced practice nurse.
- Any study for which a determination could not be made with any kind of certainty was not included in the current guideline.

Exclusion Criteria

Abstract reports from conference proceedings were excluded. Letters, editorials, notes, case reports, commentaries, and nonsystematic reviews were not eligible. Any reports of procedures that are no longer recommended (e.g., clinical breast examination or breast self-examination) were also excluded.

A review of article titles and abstracts resulting from the search was completed by one person (RC). Articles warranting a full-text review were assessed by one reviewer (RC). Any questionable papers, where it was not clear whether the intervention was a true APN intervention, were reviewed by the Working Group to determine eligibility.

Data Extraction and Assessment of Study Quality and Potential for Bias

Data were extracted by one member of the Working Group (RC). Ratios, including hazard ratios, were expressed with a ratio <1.0 indicating that patients receiving an intervention delivered by an advanced practice nurse had a lower probability of experiencing an event. All extracted data and information were audited by an independent auditor.

The internal validity of included studies was assessed using a modified version of the Cochrane risk of bias tool (20,21), which has not been validated. We did not assess for blinding of participants and personnel as per the Cochrane criteria because it is usually not possible to do so in studies of APN roles. Another modification was that objective and subjective outcomes within a study were analyzed separately for outcome assessment and completeness of outcome data. Finally, if outcomes had more than 20% missing data, the study was determined to be at risk of bias due to incomplete outcome data. Studies were assigned a high, low or unclear risk of bias related to criteria for: 1) random sequence generation (e.g., random number table, computer random number generator); 2) allocation concealment sequence (e.g., sequentially numbered, opaque, sealed envelopes; central allocation office); 3) assessment of objective outcomes (objective measures, blinding of assessors, trained data extractors); 4) assessment of subjective outcomes (blinding of

outcome assessors, use of reliable, validated measurement tools); 5) completeness of outcome data for subjective and objective measures (i.e., complete for $\geq 80\%$ of sample; missing data balanced between groups; missing data imputed using appropriate methods); 6) selective reporting (all outcomes described in the methods section of the study are reported in the results, all key outcomes reported); and 7) other sources of bias (e.g., contamination, co-intervention). To provide a global summary of study quality, an overall risk of bias was assigned to each study using these investigator-determined categories: low risk of bias (at risk in zero or one category), moderate risk of bias (at risk in two or three categories), high risk of bias (at risk in four to six categories), and very high risk (at risk in seven or eight categories) (20). When the risk of bias was unclear, it was captured as a risk in the overall assessment. In studies with low risk it is unlikely that potential bias, if present, would impact the results. With increasing levels of risk there is greater uncertainty about the results. For example, with high risk there is a strong likelihood that bias may seriously influence the results (21). Internal validity was also examined in relation to sources of bias not part of the Cochrane criteria including sample size and adequate power. Data related to risk of bias were extracted by RC. Risk of bias assessments were only based on the information provided in the published studies. Authors were not contacted to provide further information.

In addition to confirming that APN roles were the focus of all included studies, data were collected to assess the numbers, training, and experience of advanced practice nurses evaluated in each study. This information is important for assessing potential threats to internal validity related to intervention fidelity and also for determining external validity or the generalizability of study findings to similar APN roles in other practice settings. Training and maturation issues can impact on intervention fidelity or the extent to which expected APN role activities are completely implemented (22). Outcomes of APN roles may not be fully achieved for novice advanced practice nurses with less than two years of experience, when advanced practice nurses lack role specific training, and/or when advanced practice nurses are in new roles that have been established for less than two years (17). A common limitation of studies reported in other systematic reviews of APN roles is the small number of nurses (often as few as one) involved in delivering the intervention (20). Studies involving one or just a few advanced practice nurses limit our confidence in generalizing the results to other advanced practice nurses in similar roles (e.g., are the results due to the nurse in the role, or the APN role itself). To address this limitation, we pragmatically considered the external validity of study findings to be low for studies involving less than 10 advanced practice nurses (20).

Synthesizing the Evidence

Research Question #1: For which patient populations and in which situations (types of needs, practice settings, phase of the cancer journey) have APN roles demonstrated equivalence or improved outcomes or reduced harms in appropriate controlled comparative studies of cancer care?

To address Research Question #1, studies selected for review were categorized into groups according to the focus of the APN role related to phases of the cancer journey. These phases included prevention, diagnosis, treatment, survivorship/post-treatment follow-up, palliative, and end-of-life care as defined by Cancer Care Ontario (23). Prevention studies focused on APN interventions aimed at reducing the risk of developing cancer. Studies during the diagnosis phase examined APN activities related to the early detection of cancer through screening and other diagnostic tests, procedures, or services. Studies during the treatment phase involved APN interventions for patients receiving surgical, systemic, and/or radiation

therapies. Palliative care was defined as APN interventions designed to improve the HRQL of patients and their families with life-threatening cancer conditions through the early detection and management of pain and/or other physical, psychosocial, and spiritual problems (WHO). Studies related to palliative care were distinguished from those involving end-of-life care or APN interventions provided to dying patients and their families in the terminal stages of illness in the last few weeks or months of life (24).

Data were then extracted from each paper into a spreadsheet or tables to summarize study details for each phase of the cancer journey related to country, practice setting, patient population, cancer type, underlying need or rationale for the APN role, type and characteristics of the APN role as the intervention under examination, characteristics of the comparator intervention, outcomes, and outcome results. The APN role was identified as either CNS or NP based on inclusion criteria for study eligibility as outlined above. Based on information about rationale and characteristics, APN roles were further classified as alternate or complementary to the comparator intervention. Alternate APN roles were defined as those introduced as a replacement or substitute for another provider, most often a physician. The purpose of alternate roles is to provide services that reduce cost or address workload or workforce shortages while maintaining or improving the quality of care (25). Studies of alternate roles compare the advanced practice nurse to standard (physician) care and are usually designed to assess for equivalent outcomes. In contrast, complementary APN roles were defined as those introduced to augment the services of existing healthcare provider roles with the goal of improving quality of care (26). Studies of complementary roles compare APN plus standard care with standard care alone and are designed to assess for improved outcomes.

Research Question #2: What specific patient, provider, or health system outcome indicators are associated with CNS or NP roles?

To address Research Question #2, data were extracted to identify and describe the outcomes and impact of APN roles. Identified outcomes were categorized as being specific to patients and families, healthcare providers, or the health system. Patient and family outcomes related to HRQL, varied indicators of health, and satisfaction with care. Healthcare provider outcomes related to acceptance and satisfaction with the APN role. Health system outcomes related to quality of care, service utilization, and costs. In terms of impact, the results of each study outcome were further grouped in relation to the comparator intervention as being equivalent, worse, or improved.

For both Research Questions #1 and #2, narrative and descriptive analysis were used to examine the frequency, pattern and variation of study features, APN role characteristics, and outcomes for each phase of the cancer journey. Study patient populations and outcome measures were too varied to conduct any meta-analyses.

RESULTS

Search for Existing Systematic Reviews

Nine systematic reviews were considered and subjected to full-text review. None of these reviews were considered appropriate for inclusion and, therefore, none were evaluated using AMSTAR.

Primary Literature Systematic Review

The original literature search strategy described above was adequate and no changes were needed in response to the existing reviews that were found.

Literature Search Results

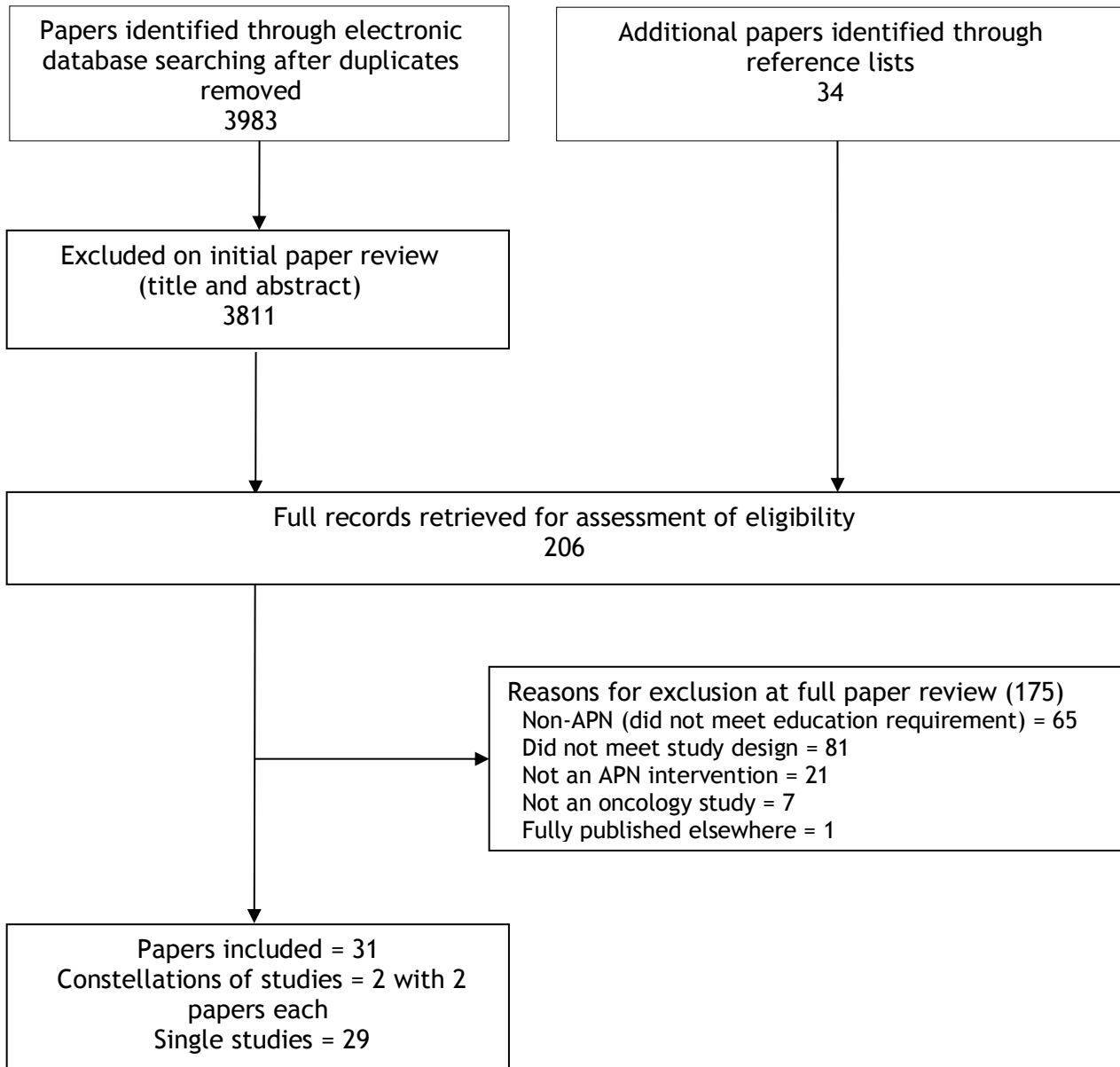
The MEDLINE search yielded 1087 hits, of which 100 were potentially relevant and were fully reviewed. Fifteen papers were retained (Table 1, Figure 2 and Appendix 2). The EMBASE search yielded 1686 hits of which 51 papers were potentially relevant and fully reviewed. Nine of these papers were retained. The HealthSTAR search yielded 1206 hits of which 21 were potentially relevant and fully reviewed. One paper was retained. For the CINAHL search it was possible to exclude all previously identified MEDLINE records. As a result, there were only four hits, of which none were relevant. The reference lists of included papers were also searched (i.e., reference mining) and resulted in 34 papers being fully reviewed with six being retained. In total, there were 31 included papers (27-57) representing 29 unique studies. One study had a separately published economic analysis and a second study published separate papers on HRQL and healthcare utilization with respect to their intervention.

Table 1. Studies selected for inclusion.

Database	Dates Searched	Hits	Fully Reviewed	Retained
MEDLINE	1980 - November [week 2] 2012	1087	100	15
EMBASE	1980 - week 46 2012	1686	51	9
HealthSTAR	1980 - October 2012	1206	21	1
CINAHL	1980/01/01 - 2012/11/31	4	0	0
Reference mining	NA	NA	34	6

NA=not applicable

Figure 2: Identification and Screening of Relevant Studies



APN=advanced practice nursing

Overview of Study Characteristics

Study Design

The study designs of the included studies were as follows: randomized controlled trials (RCTs; 15 studies published in 17 papers), prospective comparison (one study), non-randomized trial (one study), before/after studies (five studies), descriptive studies (six studies including five chart reviews and one survey), and an audit (one study). One of the RCTs included an economic analysis (Table 2).

Quality Assessments

Based on Cochrane criteria (21), 12 studies had high risk of bias, 16 had moderate risk of bias and only one study had low risk of bias (Table 2). The most common limitation was selection bias due to lack of randomization or inadequate reporting of random sequence generation and allocation concealment. Many of the studies may not have been sufficiently powered to detect statistically significant differences. Study sample sizes were relatively small, ranging from 43 to 2675 participants, and most studies had not established adequate power (Table 2). Only Beaver et al. (53) were explicit in reporting that a power calculation was not performed because it was an exploratory RCT.

The majority of studies (20 of 29) provided adequate descriptions of specialized advanced practice nurse education or training relevant to specific aspects of the role under evaluation. However, few studies provided information about the level of advanced practice nurse experience in nursing, oncology nursing, or in their current role (i.e., novice, expert) (Table 3). Only four studies offered information indicating that the advanced practice nurses were in well-established roles that had been operating for two to three years, and/or that the nurses in the role were seasoned advanced practice nurses with substantive experience and expertise (29,31,41,48).

In terms of external validity, only one study involved 10 or more advanced practice nurses. This study by Mandelblatt et al. (27) evaluated 20 NPs. Seven studies did not report the number of advanced practice nurses evaluated and the majority of studies (18 studies) involved only one to three advanced practice nurses; three studies involved five to seven advanced practice nurses.

Table 2: Design and quality of included studies. design and quality

Phase of Cancer Journey	Study	Study Design	N	ITT Analysis	Power Calculations	MODIFIED RISK OF BIAS/QUALITY ASSESSMENT TOOL*								OVERALL RISK OF BIAS=
						SELECTION BIAS		DETECTION BIAS		ATTRITION BIAS		REPORTING BIAS	OTHER BIAS	
						Random Sequence Generation	Allocation Concealment	Outcome Assessment: Objective Measures	Outcome Assessment: Subjective Measures	Complete Outcome Data: Objective Measures	Complete Outcome Data: Subjective Measures	No Selective Reporting	Other Sources of Bias	
Prevention	No studies	---	---	---	---	---	---	---	---	---	---	---	---	---
Screening	Mandelblatt 1993 (27)	Controlled Pre/Post	673	No	Yes	High	High	High	NA	Low	NA	Low	Low	Moderate
	Curtis 1999 (28)	Chart Review	176	No	No	High	High	Unclear	NA	Low	NA	Low	Low	Moderate
	Thommasen 1996 (29)	Chart Review	149	No	No	High	High	Low	NA	Low	NA	Low	Low	Moderate
	Schroy 1988 (30)	Audit	100	No	No	High	High	Low	NA	Low	NA	Low	Low	Moderate
	Limoges-Gonzalez 2011 (31)	RCT	150	No	Yes	High	Low	High	High	Low	Low	Low	Low	High
	Wildi 2003 (32)	Prosp Comparison	43	No	No	High	High	Low	NA	Low	NA	Low	Unclear	Moderate
Diagnosis	Gage 2006 (33)	RCT	2675	No	No	Unclear	Unclear	Low	NA	Low	NA	Low	Low	Moderate
	Kilic 2012 (34)	Chart Review	455	No	No	High	High	Unclear	NA	High	NA	Low	Low	High
	Morris 1998 (35)	Chart Review	762	No	No	High	High	High	NA	Low	NA	Low	Low	Moderate
Treatment	Wengstrom 1999 (36)	RCT	134	No	No	Unclear	Unclear	Unclear	Unclear	Low	Low	Low	Low	High
	Osborne 2010 (37)	Descriptive survey	119	No	No	High	High	NA	Low	NA	Unclear	Low	Low	Moderate
	Ritz 2000 (38)	survey	211	No	No	Unclear	Unclear	Unclear	Unclear	High	High	Low	Low	High
	McCorkle 2009/2011 (39,40)	RCT	149	No	No	Low	Unclear	Low	Low	Low	Low	Low	Low	Low
	Wells 2008 (41)	Pre/Post	43	No	No	High	High	High	High	Low	Low	Low	Low	High
	McCorkle 1989 (42)	RCT	166	No	No	Unclear	Unclear	Unclear	Unclear	High	High	Low	Low	High
	McGlynn 2004 (43)	Pre/Post	131	Unclear	No	High	High	Unclear	Unclear	Low	Low	Low	High	High
	Weintraub 1990 (44)	RCT	56	No	No	Unclear	Unclear	NA	Unclear	NA	High	Low	Low	High
	Faithfull 2001 (45)	RCT	115	No	Yes	Unclear	Unclear	Low	Low	Low	Low	Low	Low	Moderate
	Rawl 2002 (46)	RCT	120	No	No	Low	Unclear	NA	Unclear	NA	Unclear	Low	High	High
Survivorship/ Follow-Up	McCorkle 2000 (47)	RCT	375	No	No	Unclear	Low	Unclear	Low	Low	Unclear	Low	Low	Moderate
	Radhakrishnan 2006 (48)	Chart Review	722	No	No	High	High	Unclear	NA	Low	NA	Low	Low	Moderate
	Ganz 2000 (49)	RCT	76	Yes	Yes	Unclear	Unclear	NA	Unclear	NA	Low	Low	Low	Moderate
	Beaver 2009a/2009b (50,51) ^	RCT/Economic Evaluation	374	Yes	Yes	Low	Low	Low	Low	High	Low	Low	High	Moderate
	Koinberg 2006 (52)	Non-rand Trial	96	No	Yes	High	High	NA	Unclear	NA	Low	Low	Low	Moderate
Palliative Care	Beaver 2012 (53)	RCT	65	Yes	No†	Low	Low	Low	Low	High	Unclear	Low	Unclear	Moderate
	Prince-Paul 2010 (54)	Pre/Post	101	No	No	High	High	Unclear	Unclear	High	High	Low	Low	High
	Bakitas 2009 (55)	RCT	322	Yes	Yes	Unclear	Unclear	Unclear	Unclear	Low	Low	Low	Low	High
	Thomas 2012 (56)	RCT	318	No	Yes	Low	Unclear	NA	Unclear	NA	High	Low	Low	Moderate
End-of-Life	No studies	---	---	---	---	---	---	---	---	---	---	---	---	
Other	Hardie 2010 (57)	Pre/Post	50	No	No	High	High	NA	Unclear	NA	High	Unclear	Low	High

*evaluation of risk of bias based only on that part of the study for which data were extracted

=Low = at risk of bias in ≤1 categories; Moderate = at risk of bias in 2-3 categories; High = at risk of bias in 4-6 categories; Very High = at risk of bias in 7-8 categories

^two papers reporting on different outcomes for the same RCT

†This was a pilot study; authors state it was not powered to detect statistically significant differences

ITT=intent-to-treat; N=number of participants; NA=not applicable; Prosp=prospective; rand=randomized; RCT=randomized controlled trial

Table 3 - Advanced practice nurses role according to education and experience.

Phase of Cancer Journey	Study	CNS	NP	Number of Advanced Practice Nurses	Education	Experience		
					Special Training	No. Years as an RN	No. Years in Oncology	No. Years as an Advanced Practice Nurse
Screening	Mandelblatt 1993 (27)		X	5	NR	NR	NA	NR
	Curtis 1999 (28)		X	20	NR	NR	NA	NR
	Thommasen 1996 (29)		X	1	Pap smear technique taught theoretically followed by observation, questions, and trial and error practice. Also trained in bimanual examination. Advanced practice nurse trained by physicians in the office.	NR	NA	>3 years
	Schroy 1988 (30)		X	1	Prior to this study, the NP had performed approximately 25 examinations with a 35 cm scope, but had received no formal training in the use of the 40 cm video endoscope.	NR	NA	NR
	Limoges-Gonzalez 2011 (31)		X	1	The GI-NP completed an intensive training program in which she demonstrated competence with completion of 140 directly observed colonoscopies and 40 snare polypectomies before independently performing screening colonoscopies. By the time the study was initiated she had performed a total of approximately 1000 colonoscopies.	NR	NA	NR
	Wildi 2003 (32)		X	1	The training for the NP consisted of 150 supervised, complete esophagoscopies with an SVE and 10 "supervised" sedated esophagoscopies with the BPE, which were followed by SVE performed by the gastroenterologist.	NR	NA	NR
Diagnosis	Gage 2006 (33)		X	NR	The NPs received training that encouraged additional biopsy-taking.	NR	NA	NR
	Kilic 2012 (34)		X	NR	The NPs training involved understanding the indication for colposcopy, patient counselling, formation of a colposcopic impression, and taking cervical biopsies. NPs were required to perform a minimum of 50 colposcopies to become certified.	NR	NA	NR
	Morris 1998 (35)		X	6	Advanced NPs were recognized by the Texas Board of Nurse Examiners, had completed a didactic curriculum specific to the evaluation and treatment of cervical dysplasia, had received clinical supervision for a minimum of 40 colposcopies, routinely performed a minimum of four colposcopies per month, and practiced without a physician on site.	NR	NA	NR
Treatment	Wengstrom 1999 (36)	X		NR	NR	NR	NR	NR
	Osborne 2010 (37)	X		1	A background in breast cancer care and experience in theatre and ward-based practice. They also underwent a period of supervised practice, working with a plastic surgeon and spent time in the clinics, the operating theatre, and the breast and plastic surgery wards.	NR	NR	NR
	Ritz 2000 (38)	X		2	NR	NR	NR	NR
	McCorkle 2009/2011 (39,40)	X		NR	NR	NR	NR	NR
	Wells 2008 (41)	X		1	NR	NR	NR	NR
	McCorkle 1989 (42)	X		NR	Trained to give personalized care to persons with advanced cancer and to their families including knowledge of symptom management, cancer treatments, pain management, physical assessment, psychosocial assessment, grief and mourning theory, communications systems, community resources and agencies, systems analysis, self-support, professional role development, pathophysiology of death, and research theory and methodology.	NR	NR	NR
	McGlynn 2004 (43)	X		1	NR	NR	NR	NR

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	Weintraub 1990 (44)	X		2	NR	NR	NR	NR
	Faithfull 2001 (45)	X		NR	NR	NR	NR	NR
	Rawl 2002 (46)	X		3	Nurse specialists were trained intensively, focusing on delivery of the intervention protocol and use of the computer-based nursing intervention system.	NR	NR	NR
	McCorkle 2000 (47)	X		NR	Interventions based on specialized knowledge in clinical decision making, symptom management, diagnostic and cancer treatment protocols, community resources, and interpersonal skills in negotiating.	NR	NR	NR
Survivorship/ Follow-Up	Radhakrishnan 2006 (48)	X		2	NPs had a formal training period under supervision, in accordance with the nationally agreed guidelines that include theoretical knowledge and observational skills. The nurses must have passed a FC in a patient under general anesthetic in the theatre in 10 patients within a predetermined time, and must have performed ≥50 consecutive surveillance FCs, with the accuracy of findings confirmed by the supervising urologist.	NR	NR	>3 years
	Ganz 2000 (49)		X	1	NP was trained by one of the study physicians over 6 months to provide the comprehensive menopausal assessment intervention. Training included systematic readings on the topics of breast cancer, its psychosocial impact, and menopause, as well as careful review of specific assessment and management strategies for the nine pilot subjects who completed the baseline assessment, six of whom were followed over the course of 4 months.	NR	NR	NR
	Beaver 2009a/2009b (50,51)	X		7	Four half-day training sessions on the administration of the telephone intervention with subsequent feedback and debriefing sessions throughout the study period.	NR	NR	NR
	Koinberg 2006 (52)	X		1	NR	NR	NR	NR
	Beaver 2012 (53)		X	1	Four half-day sessions on the administration of the intervention were given, with regular feedback and de-briefing sessions throughout the study period.	NR	NR	NR
Palliative Care	Prince-Paul 2010 (54)	X		1	NR	NR	NR	NR
	Bakitas 2009 (55)	X		2	Advanced practice nurses had palliative care specialty training in problem solving and group medical appointments (20 hours). It was provided by one of the study team psychologists.	NR	NR	NR
	Thomas 2012 (56)	X		1	Trained extensively in motivational interviewing and change theory by a cognitive psychologist and then in procedures related to the specific coaching protocol.	NR	NR	NR
Other	Hardie 2010 (57)	X		1	NR	NR	NR	NR

BPE=battery-powered esophagoscope; CNS=clinical nurse specialist; FC=flexible cystoscopy; GI=gastrointestinal; NA=not applicable; No.=number; NP=nurse practitioner; NR=not reported; Pap=Papanicolaou; RN=registered nurse; SVP=standard videoendoscopy

Research Question #1

Geographic location, practice setting, patient population, health need or issues, cancer journey and type of APN role

Most studies were conducted in the US (19 papers representing 18 studies) or the United Kingdom (UK) (nine papers representing eight studies). Two studies came from Sweden and one from Canada. Almost all studies took place in an outpatient clinic in a hospital, cancer centre, or community oncology setting (27 papers representing 25 studies). The practice settings of remaining studies included primary care (two studies), a combination of primary care and outpatient clinics (one study), and home care (two studies). No studies occurred in an acute care setting (Table 4). The studies took place in mostly urban communities with only three studies involving patients in rural or remote locations.

The studies included patient populations with varied types of cancer as follows: breast (eight papers representing seven unique studies), gynecological (seven papers representing six unique studies), urological (three studies), colorectal (three studies), gastrointestinal (one study), lung (one study), and head and neck (one study); seven studies included patients with more than one type of cancer (Table 4). Owing to the number of studies (n=13) related to breast and gynecological cancers, women were the dominate focus of APN interventions in almost one-half of the studies. Only two studies were specific to men (43,45). In 10 studies involving non-gender-specific cancers, which reported gender, there were variable proportions of male and female participants. However, across these studies the total number of participants reflect the slightly higher incidence of some cancers (i.e., colorectal, lung) in men, with more male than female participants (813 versus 618) (30,31,41,42,46,47,53-56). In four studies, patient participants were identified as average risk for developing cancer (31) or low to moderate risk for cancer recurrence (49-52). A larger number of studies (16 of 29) involved more vulnerable or at-risk populations. This included five studies of patients at risk for developing cancer due to age, family history, or symptoms (27,32-35), of which two studies focused on underserved populations with low socioeconomic status (27,35). Another 11 studies focused on vulnerable cancer populations at risk for poor outcomes due to age (47), treatment side effects (36,39,41,43-45), or advanced disease (42,54-56).

The majority of studies examined APN interventions related to the screening (six studies), treatment (11 studies), and post-treatment (five studies) phases of the cancer journey. Fewer studies focused on diagnosis (three studies) or on palliative care (three studies), and no studies included APN interventions related to cancer prevention or end-of-life care. One study involving patients receiving adjuvant treatment, palliative care, or post-treatment follow-up for breast cancer was not specific to any phase of the cancer journey (57) (Table 4). Addressing patient needs related to psychosocial well-being, symptom management, and/or self-care was the underlying impetus for the APN role in more than one-half (16) of the studies (36,38-47,49,50,52,53,55,56). Improving access to care was the reported need for introducing an APN role in over one-third of the studies (27,29-32,34,35,37,46,48,54).

A greater number of studies evaluated CNS (18 studies) than NP (11 studies) roles. Over one-half of the studies (18 studies) evaluated CNS or NPs in alternate roles. There were a similar number of CNS studies involving a complementary (10) or alternate (eight) role. Of the 11 NP studies, 10 involved an alternate role with a predominant focus (eight studies) on evaluating the effectiveness of NPs in performing diagnostic tests or procedures compared with physicians (Table 5).

Table 4: Study characteristics - country, population and setting.

Phase of Cancer Journey	Study	Country	Patient Population	Need or Rationale for APN Role	Setting
Screening	Mandelblatt 1993 (27)	US	Underscreened African American women of low SES, ≥65 years	Access, improve screening for breast/cervical cancer	PC, urban
	Curtis 1999 (28)	US	Women	Quality of cervical cancer screening	PC, OPC
	Thommasen 1996 (29)	CA	All presenting women	Access to cervical screening	PC, remote
	Schroy 1988 (30)	US	Patients at risk for CRC (age >50 years or age >40 years with family history of cancer)	Access to screening sigmoidoscopy	Cancer centre, urban
	Limoges-Gonzalez 2011 (31)	US	Patients with average risk for CRC ≥50 years	Access to screening colonoscopy	OPC, urban
	Wildi 2003 (32)	US	Patients at risk for esophageal cancer	Access to esophagoscopy	OPC, urban
Diagnosis	Gage 2006 (33)	US	Women, 18-75 years, with cervical dysplasia	Sensitivity of colposcopy biopsies	OPC, urban
	Kilic 2012 (34)	US	Women with cervical dysplasia	Access/quality of colposcopy biopsy	OPC, urban
	Morris 1998 (35)	US	Women, 14-81 years, with cervical dysplasia. NPs served mostly low-income women in medically underserved communities	Access/quality of evaluation and treatment of cervical dysplasia	OPC, urban, rural
Treatment	Wengstrom 1999 (36)	SW	Women, 37-83 years, receiving curative radiation treatment for breast cancer	Self-care, emotional stress, treatment side effects, HRQL	OPC
	Osborne 2010 (37)	UK	Women undergoing mastectomy for breast cancer	Access to information about breast reconstruction surgery	OPC
	Ritz 2000 (38)	US	Women, 30-85 years, with newly diagnosed breast cancer	HRQL, uncertainty, mood disturbance	OPC
	McCorkle 2009/2011 (39,40)	US	Women, ≥21 years, post abdominal surgery planned to receive chemotherapy for ovarian cancer or cancers with metastasis to ovaries/abdomen	Self-care, HRQL, depression, uncertainty, symptom distress	Hospital, cancer centre OPC
	Wells 2008 (41)	UK	Patients with head and neck cancer receiving radiotherapy	Self-care, symptom management, HRQL	OPC
	McCorkle 1989 (42)	US	Homebound patients with ≥ stage II lung cancer	Psychosocial well-being, pain and symptom management	Home care
	McGlynn 2004 (43)	UK	Men undergoing radical prostatectomy	Pre and postoperative education needs and urinary function	OPC
	Weintraub 1990 (44)	US	Patients receiving external beam radiation therapy	Self-care, anxiety, side effects	OPC, urban
	Faithfull 2001 (45)	UK	Men, 49-83 years, receiving radical radiation therapy for prostate and bladder cancer	Symptom management, HRQL	OPC
	Rawl 2002 (46)	US	Patients with newly diagnosed breast, colon, or lung cancer receiving chemotherapy	Psychosocial function, depression, anxiety	Cancer centre, urban
	McCorkle 2000 (47)	US	Patients ≥60 years, post-cancer surgery	Improve recovery/health outcomes (survival, depression, symptom distress, functional status)	Home care
	Survivorship/ Follow-Up	Radhakrishnan 2006 (48)	UK	Patients with known bladder cancer undergoing check (follow-up) flexible cystoscopy	Access to diagnostic cystoscopy, reduce physician workload
Ganz 2000 (49)		US	Women with stage I/II breast cancer, post chemotherapy or radiation therapy, with menopausal symptoms	Reduce menopausal symptoms, HRQL	OPC
Beaver 2009a/2009b (50,51)		UK	Women post-primary treatment for breast cancer with low/moderate risk for recurrence	Information, psychosocial, follow-up care needs	OPC
Koinberg 2006 (52)		SW	Women with stage I/ II breast cancer, post-surgery	Self-care, coping, HRQL	OPC
Beaver 2012 (53)		UK	Patients with colorectal cancer, post treatment, in remission	Information needs, psychosocial well-being	OPC
Palliative Care	Prince-Paul 2010 (54)	US	Patients with advanced (stage III/IV) cancer	Early integration of palliative care on patient health outcomes	Community oncology
	Bakitas 2009 (55)	US	Patients with advanced lung, breast, GI or prostate cancer soon after diagnosis, concurrent with cancer treatment	Palliative care needs, psychosocial well-being, symptom management, physical function, HRQL	Cancer centre, rural
	Thomas 2012 (56)	US	Patients with cancer-related pain	Pain management, HRQL	OPC, community oncology
Other	Hardie 2010 (57)	UK	Women, 34-86 years, receiving adjuvant or palliative treatment or follow-up for breast cancer	Patient experience, satisfaction with care	Outpatient

APN=advanced practice nursing; CA=Canada; CRC=colorectal cancer; GI=gastrointestinal; HRQL=health-related quality of life; NP=nurse practitioner; PC=primary care; OPC=outpatient clinic; SES=socioeconomic status; SW=Sweden; UK=United Kingdom, US=United States

Table 5: Intervention characteristics.

Phase of Cancer Journey	Study	CNS	NP	Provider Role		Type of Intervention		
				Alternate Provider	Complementary Provider	Diagnostic Test	Clinical Intervention	Service or Care Delivery Model
Screening	Mandelblatt 1993 (27)		X	X			X	
	Curtis 1999 (28)		X	X		X		
	Thommasen 1996 (29)		X	X		X		
	Schroy 1988 (30)		X	X		X		
	Limoges-Gonzalez 2011 (31)		X	X		X		
	Wildi 2003 (32)		X	X		X		
Diagnosis	Gage 2006 (33)		X	X		X		
	Kilic 2012 (34)		X	X		X		
	Morris 1998 (35)		X	X		X		
Treatment	Wengstrom 1999 (36)	X			X		X	
	Osborne 2010 (37)	X		X			X	
	Ritz 2000 (38)	X			X		X	
	McCorkle 2009/2011 (39,40)	X			X			X
	Wells 2008 (41)	X		X				X
	McCorkle 1989 (42)	X		X				X
	McGlynn 2004 (43)	X		X				X
	Weintraub 1990 (44)	X			X		X	
	Faithfull 2001 (45)	X		X				X
	Rawl 2002 (46)	X			X		X	
Survivorship/ Follow-Up	McCorkle 2000 (47)	X			X			X
	Radhakrishnan 2006 (48)	X		X		X		
	Ganz 2000 (49)		X		X			X
	Beaver 2009a/2009b (50,51)	X		X				X
	Koinberg 2006 (52)	X		X				X
Palliative Care	Beaver 2012 (53)		X	X				X
	Prince-Paul 2010 (54)	X			X			X
	Bakitas 2009 (55)	X			X		X	
Other	Thomas 2012 (56)	X			X		X	
	Hardie 2010 (57)	X			X			X

CNS-clinical nurse specialist; NP=nurse practitioner

Outcomes According to Phase of the Cancer Journey

Prevention

No studies were identified that compared advanced practice nurses with other healthcare providers in the delivery of cancer prevention services.

Screening

Six studies (27-32) examined NPs in alternate provider roles for breast, cervical, gastrointestinal, and esophageal cancer screening (Table 2). All six studies were assessed as having moderate or high risk of bias.

a) Breast Cancer

A controlled pre- and postintervention study evaluated the effectiveness of NP recruitment compared with chart reminders for improving breast cancer screening with mammography (27). In this study, five NPs provided an alternate intervention. Study participants were elderly black women of low socioeconomic status attending a primary care clinic in two public hospitals. In one hospital, acting as the control group, a reminder for providers was put on all the charts of eligible women attending the clinic. At a second hospital, intervention group participants were approached by NPs at their clinic visit regarding screening mammography and Papanicolaou (Pap smear) tests for cervical screening. Baseline annual mammography rates were similar in both groups (intervention, 18.3%; control, 18.1%). Following the intervention, the screening rate for the intervention group increased significantly compared with the control group (40.0% versus 18.2%, $p < 0.01$). Cervical screening rates are reported in the section below.

b) Cervical Cancer

Three studies evaluated advanced practice nurses related to cervical screening (27-29). In one study, the NP acted as an alternate to a reminder intervention (27) and in two studies, the NP was evaluated as an alternate to other healthcare providers (28,29). The study by Mandelblatt et al. (27), assessed screening uptake in poor elderly black women. In this controlled pre and post study, cervical screening rates as well as breast screening rates (see section above) were evaluated. In the control group, women had a reminder put on their chart, and in the intervention group, women were approached by one of five NPs. Baseline annual Pap smear test rates were similar in both groups (intervention, 17.8%; control, 11.8%). Following the intervention, the screening rate for the intervention group increased significantly compared with the control group (56.9% versus 18.2%, $p < 0.01$).

Two studies used chart review methods to evaluate the quality of Pap smear tests performed by various healthcare providers (28,29). One NP and eight physicians participated in the Thommasen et al. study (29) and 20 NPs and 156 physicians/physician assistants participated in the Curtis et al. study (28). Both studies found the technical competence of NPs to be similar, or in some cases superior, to other medical practitioners in terms of satisfactory smears and ability to obtain smears with endocervical cells (Table 6).

Table 6. Studies of cervical screening comparing nurse practitioners with other healthcare providers

Study	Provider	N	% Unsatisfactory Smears	% Smears with Endocervical Cells
Thommasen 1996 (29)	Nurse practitioners	55	0.0	100
	Physicians	94	8.5 p=NR	91.5 p=NR
Curtis 1999 (28)	Nurse practitioners	1147	22.2	83.7
	Obstetrician-Gynecologists	NR	NR	82.5
	Family practitioners	NR	NR	74.5
	General practitioners	385	38.4	62.5
	Internists	NR	NR	60.1*
	Physician assistants	NR	NR	83.9
	Total	21833	p=NR	

NR=not reported

*Internists compared with nurse practitioners, physician assistants, and obstetrician-gynecologists, p=0.009

c) Gastrointestinal Cancer***Flexible Sigmoidoscopy and Colonoscopy***

Two studies evaluated the use of NPs in performing colonoscopy or flexible sigmoidoscopy (FS) to screen for colorectal cancers (30,31). In both studies, the NP was evaluated as an alternate healthcare provider. The study by Schroy et al. (30) was unique in that it was the only study to compare NPs with physician endoscopists related to screening concordance, sensitivity, and specificity. In this study, 100 patients underwent FS by one NP. The procedure was videotaped and independently reviewed by one physician endoscopist. Any discordant cases were subsequently reviewed by the NP and the physician together to try and reach consensus. Using the physician endoscopists' findings as the gold standard, the sensitivity and specificity of the NPs investigations were 75% and 94%, respectively. Of the 100 cases independently reviewed, there were 12 discordant cases, giving a near-excellent concordance ($\kappa=0.72$, $p<0.0001$). Ten of these discordant cases were resolved following the joint review.

The other study (31) compared one NP with two gastroenterologists in performing FS or colonoscopy on various clinical measures in a RCT. Limoges-Gonzalez et al. (31) reported on depth of insertion and found no difference in reaching the cecum/terminal ileum when comparing the NP with gastroenterologists (100 versus 99%, $p>0.999$) (Table 7). There was also no significant difference between providers for duration of the procedure, or for procedural pain. However, the NP group had a higher adenoma detection rate (42% versus 17%, $p=0.0001$) and patients whose procedure was performed by the NP were significantly more satisfied than those whose procedure was performed by a gastroenterologist (31).

Esophagoscopy

One study evaluated the accuracy of esophagoscopy performed by a NP as an alternate provider (32). In this prospective and blinded study, patients underwent sedated esophagoscopy performed by one NP with a battery-powered endoscope followed by standard video-endoscopy performed by one gastroenterologist. The NP and the gastroenterologist were blinded to the findings of the other provider. Using the endoscopy performed by the gastroenterologist as the gold standard, the sensitivity and specificity of endoscopy performed by the NP, for all lesions, were 75% (95% confidence interval [CI], 67% to 82%) and 98% (95% CI, 96% to 99%), respectively (32).

Table 7. Studies of flexible sigmoidoscopy and/or colonoscopy comparing nurse practitioners with other healthcare providers on clinical outcomes.

Study	Procedure	Provider	N	Mean Depth of Insertion (cm)	Mean Duration of Procedure (minutes)	Procedural Pain	Adenoma Detection Rate	Patient Satisfaction
Schroy 1988 (30)	Flexible sigmoidoscopy	Nurse practitioner Physician endoscopist	100 100	NR	NR	NR	NR	NR
Limoges-Gonzalez 2011 (31)	Colonoscopy	Nurse practitioner Gastroenterologists	50 100	Cecal intubation rate 100% 99% p>0.999	19.6 18.8 p=0.774	14.6 13.9 p=0.847	42% 17% p=0.0001	5.9 8.6 p=0.042*

NR=not reported

*those whose procedure was done by the NP were significantly *more* satisfied than those whose procedure was done by a gastroenterologist

Diagnosis

Three studies evaluated the NPs as alternate providers for the diagnosis and management of cervical cancer in women with cervical dysplasia. Two studies had moderate risk of bias (33,35) and one study had high risk of bias (34) (Table 2).

a) Cervical Cancer

Two studies compared colposcopy performed by NPs as an alternate to other healthcare providers (33,34). In a RCT, Gage et al. (33) compared the sensitivity of colposcopy performed by NPs with general gynecologists, gynecologic oncology fellows, and gynecologic oncologists for 2675 patients with cervical dysplasia. There were 35 providers in total but the number of each type of provider is not reported. They found no significant differences in colposcopy sensitivity among the various healthcare providers (Table 8). However, they did report that sensitivity was significantly greater ($p<0.01$) when two or more biopsies were taken by the colposcopists. NPs were significantly more likely to take more than one biopsy compared to the other healthcare providers ($p<0.01$). Kilic et al. (34) conducted a retrospective chart review of 455 colposcopic examinations performed by NPs and gynecologists (the number of each type of provider is not reported). Sensitivity of the procedure, in the subset with high-grade cervical dysplasia, using excisional biopsy as the gold standard, was not significantly different between these two groups of healthcare providers (Table 8). Moreover, they report no significant differences between gynecologists and NPs with respect to agreement between colposcopic and cone biopsy ($p=0.2867$).

Table 8. Studies of colposcopy performed by nurses compared with other healthcare providers.

Study	Patients (N)	Provider	Sensitivity (%)
Gage 2006 (33)	934	Nurse practitioners	70.0
	385	General gynecologists	76.4
	639	Gynecologic oncology fellows	67.3
	717	Gynecologic oncologists	68.6
			$p=0.640$
Kilic 2011 (34)	308	Nurse practitioners	82.4
	147	Gynecologists	77.1
			$p=0.1231$

One study evaluated NPs as an alternate provider to gynecologists for the diagnosis of cervical dysplasia (35). This was a retrospective chart review of 284 patients seen by 11 gynecologists and 478 patients seen by six NP colposcopists. Compared with the gynecologists, NPs had significantly fewer discrepancies between the Pap smear test and the biopsy (5.9% versus 12.3%, $p=0.002$), performed more endocervical curettages (98.1% versus 77.1%, $p<0.001$), had fewer patients lost to follow-up (35.8% versus 43.0%, $p=0.049$), had fewer patients with abnormal Pap smear tests after treatment (16.9% versus 33.6%, $p<0.001$), and had lower surgical intervention rates (11.1% versus 27.5%, $p<0.001$). There were no significant differences in the rates of insufficient biopsies/endocervical curettages, unsatisfactory colposcopy or missed invasive cancers. NPs were more likely than physicians to document the adequacy of the examination (i.e., whether the transformation zone of the cervix was visualized) (98.3% versus 83.5%, $p=0.0001$). Overall, NP practice fell within the same range as that of the gynecologists and when they were statistically significantly different, the NPs were more consistent with generally accepted standards of care (35).

Treatment

a) Breast Cancer

One RCT compared conventional medical care with conventional care plus APN care for women with newly diagnosed breast cancer related to HRQL and cost outcomes (38). This complementary role, generically titled as an advanced practice nurse, is consistent with that of a CNS as a master's-prepared RN with in-depth knowledge and skill in the care of patients with breast cancer. The Cost-Quality Model of APN Transitional Care provided the framework for the intervention (58). Two CNSs initiated care within two weeks of diagnosis and continued to provide care through preoperative, postoperative, on-treatment and post-treatment phases. The CNSs provided information about breast cancer and what to expect during physician appointments, decision-making support, answers to patients' questions, and general support. Patients had access to the CNS seven days a week but not 24 hours a day. Patient-CNS interactions occurred on an as-needed basis, during clinic appointments and home visits, and by telephone. Conventional care was not described. Participants in both groups were followed for two years after enrolment. HRQL was measured using the Mishel Uncertainty in Illness Scale (MUIS), the Profile of Mood States and the Functional Assessment of Cancer Therapy-Breast scale (FACT-B).

The APN group showed significantly lower levels of uncertainty than the control group at one ($p=0.001$), three ($p=0.026$), and six ($p=0.011$) months following enrollment but not at 12 months. The beneficial effects were greater for unmarried women than for married women ($p=0.017$). With respect to mood, there were no significant group differences on any of the Profile of Mood States subscales. However, compared with the control group, unmarried women in the intervention group had significantly lower levels of distress related to tension-anxiety ($p=0.027$), depression-dejection ($p=0.004$), and anger-hostility ($p=0.028$). HRQL as measured by the FACT-B was not significantly different between the two groups except for unmarried women who had higher levels of HRQL in the intervention compared with the control group ($p=0.036$). Overall costs did not differ between the two groups of the study, nor did length of stay for definitive surgery, length of stay for admissions following definitive surgery, or number of visits to healthcare providers. The mean CNS time and cost per patient was 1377 minutes and \$629, respectively. The majority (75%) of CNS time occurred during clinic or telephone visits and was greatest in the first six months of the intervention (38).

Radiation

One RCT evaluated the complementary role of a CNS for enhancing patient self-care and improving symptom management and HRQL for patients with breast cancer undergoing radiation treatment (36). Orem's Self-Care Theory (59) provided the framework for the intervention that consisted of five 30 minute sessions during treatment and two sessions following completion of treatment delivered by one CNS. Patients randomized to the control group received standard nursing care involving an information session on treatment and its side effects delivered just after treatment simulation. There was no assessment of the nursing care needs of the patient; nursing care only took place during the 15 minutes the patient was at the centre for their radiation treatment, and there was no follow-up nursing care after radiation treatment was completed. The aim of the CNS intervention was to enhance the patient's self-care ability and decrease their dependence on the nurse. Each session was individualized to the patient's education and informational needs with respect to managing treatment side effects. Patients in the intervention group had less perceived distress than those in the control group ($p<0.05$). The intervention had no significant effect on either perceived side effects of treatment or on HRQL (36).

Reconstruction

One study evaluated patient-reported outcomes related to preparation for breast reconstruction provided by one CNS compared with one consultant surgeon (37). As such, the CNS was evaluated as an alternate healthcare provider. This descriptive study included 119 patients; 60 who had an information session with the surgeon and 59 who had an information session with the CNS. Patients were then asked to complete a validated questionnaire to evaluate their satisfaction with the information they received. Response rates in the two groups were similar (70% versus 71%). Overall satisfaction with the information session was high in both groups. There were no significant differences on any of the questions except whether the patient had been offered contact with a patient advocate. Significantly more patients in the CNS group had been offered this service compared with the surgeon group (54% versus 22%, $p=0.004$).

b) Gynecological Cancers

Two papers involving one RCT reported on the complementary role of an advanced practice nurse for women who had undergone surgery for ovarian cancer or cancers with metastasis to the ovaries and abdomen (39,40). The generically titled oncology APN role evaluated in this study was implemented by a master's-prepared RN in a role consistent with that of a CNS. The first paper (39) reported on HRQL outcomes and the second paper (40) reported on healthcare utilization outcomes. Patients were randomized to either an intervention provided by the CNS or an attention control group. Following discharge from hospital and over a six-month period, patients randomized to the intervention group received standard care plus specialized tailored care delivered by the CNS through 18 contacts visits in their home or by telephone. Initial contacts were more frequent and intensive during the first month to prevent and monitor postoperative complications. The intervention included symptom management, symptom monitoring, emotional support, patient education, coordination of resources, referrals, and direct nursing care. In addition, women who scored ≥ 4 using the Distress Thermometer were evaluated by a psychiatric consultation-liaison nurse. Patients in both groups received the Symptom Management Toolkit (SMT). It contained information on 16 commonly experienced symptoms post-surgically or while on chemotherapy. Patients in the attention control group received standard care plus nine contacts by telephone from a research assistant trained in the use of the SMT. The research assistant provided instruction on the use of the SMT and made inquiries about the presence of symptoms and the utility of the strategies provided in the SMT. If a patient had questions outside the content of the SMT they were instructed to contact their oncologist. Emotional distress was measured by the Distress Thermometer, depression by the Center for Epidemiological Studies-Depression Scale (CES-D), uncertainty by the MUIS, symptom distress by the Symptom Distress Scale (SDS) and overall HRQL by the Short-Form Health Survey (SF-12) (39). All HRQL measures were administered four times (at baseline, and one, three, and six months after baseline).

Over time, the rate of improvement in uncertainty (MUIS) was significantly greater in the intervention group ($p=0.0006$), but the control group performed better related to CES-D, SDS, and SF-12 physical scores. However, women with high distress scores in the intervention group who received CNS plus psychiatric consultation-liaison nurse care had less uncertainty (MUIS) ($p=0.0181$), less symptom distress (SDS) ($p<0.0001$), and better HRQL (SF-12) related to mental ($p=0.0001$) and physical ($p<0.001$) well-being compared with the total attention control group. In terms of healthcare utilization (40), patients receiving the CNS intervention reported fewer primary care appointments ($p=0.0003$) but there were no significant differences in hospitalizations ($p=0.4319$), emergency room visits ($p=0.0852$), or oncology outpatient visits ($p=0.5359$).

c) Head and Neck

One paper evaluated CNS-led treatment review for patients undergoing head and neck cancer radiation as an alternate model to physician care (41). This was a pre/post comparison study. The preintervention group included 20 patients undergoing standard care or weekly treatment review by their physician. The postintervention group included 23 patients undergoing weekly review by a CNS using evidence-based clinical protocols to guide symptom management related to mucositis, pain, skin reactions, and nutritional problems. Patients were also provided instruction on self-care procedures to help minimize their symptoms. HRQL was assessed using the EORTC QLQ-C30 (core questionnaire) and the EORTC QLQ-H&N37 (head and neck specific). Data were collected at the beginning, during, and after treatment as well as in the three months following treatment completion. The patients' general practitioner also completed a questionnaire to evaluate the communication they received from the clinic.

Patients in the CNS group had significantly more consultations (six versus four, $p=0.006$) and significantly longer consultations (16 min versus 4 min, $p<0.001$) compared with those in the physician group (41). Joint CNS-physician review of the patient at the beginning or end of treatment occurred in 13% of consultations. The CNS managed 83% of remaining patient consultations without referral to an oncologist. Patients in the CNS group were significantly less likely to be kept waiting than those in the physician group (2 min versus 9 min, $p=0.001$). There were no significant differences between the two groups on any HRQL measure evaluated. General practitioners were receptive to the idea of CNS-led review and overall were more positive about the content and timing of information they received from the CNS-led clinic.

d) Lung Cancer

One study evaluated CNS home care as an alternate model of care for patients with lung cancer (42). This was a RCT in which patients with at least stage II lung cancer were randomized to either specialized oncology home care (OHC) involving a CNS, standard home care (SHC) or office care (OC). The number of oncology CNSs who participated in the study was not reported. The OHC was delivered by master's-prepared nurses trained to provide personalized care to patients with advanced cancer and their families. The SHC was provided by a multidisciplinary health team and the OC was provided by patients' physicians. Psychosocial and healthcare utilization outcomes were measured at five time points over a six-month period. For the psychosocial outcomes, the OHC and SHC groups were analysed together, although measurements are reported separately.

Consistent with the nature of progressive lung cancer, patients in all groups reported increased symptom distress and increased dependency over time (42). However, patients in the OC group had higher levels of symptom distress ($p=0.03$) and experienced elevated distress six weeks sooner compared with the OHC and SHC groups. Patients in the OHC and SHC groups also remained independent for a longer period of time compared with the OC group ($p=0.02$). There were no significant differences in symptom distress, social dependency, or health perceptions between the OHC and SHC groups. The OHC group had fewer hospitalizations (2.08, versus 2.82 for the SHC group and 2.62 for the OC group) and shorter hospital lengths of stay (258 days, versus 317 days for SHC and 272 days for OC) but these differences were not statistically significant.

e) Prostate

One study evaluated an alternate model of CNS care delivery designed to improve the preoperative process for men contemplating radical prostatectomy and the postoperative management of urinary incontinence (43). This was a pre/post audit study with 25 patients evaluated prior to the intervention and 106 patients evaluated following implementation of the CNS intervention. The number of CNSs who delivered the intervention was not reported. Preintervention, patients were given a one-month review appointment with the urologist following biopsy. At that appointment, which averaged eight minutes, patients were informed of their diagnosis, treatment options, possible side effects, and prognosis. In addition, staging investigations were also booked at this time. Patients waited up to approximately three months for a definitive treatment plan to be developed. In the new CNS-led program, all patients received their diagnosis from the CNS at a scheduled 30-minute appointment. The CNS organized necessary staging investigations and scheduled a further appointment with patients to go over the staging results. Patients were given written and verbal information about their treatment options and a number to contact the CNS if they required further information. Patients who opted for surgery were then referred for preoperative assessment by the continence and physiotherapy team. Patients were taught strategies to alleviate stress incontinence following surgery. A telephone survey of all participants occurred one year following surgery using a validated continence severity index and HRQL questions from the International Prostate Symptom Score Questionnaire. The results for the pre- and postintervention groups are provided but it does not appear that statistical tests of comparison were conducted because p-values are not reported.

Preintervention, only 32% of men having radical prostatectomy were seen by the continence team preoperatively whereas postintervention, all men were either seen preoperatively or on the day of hospital admission (43). Following removal of the urethral catheter, 72% of men in the preintervention group had poor urinary control compared with 49% of men in the postintervention group. Men in the postintervention group also regained total continence more quickly with discharge from the continence clinic at two months compared with eight months in the preintervention group. With respect to HRQL, 68% of men in the preintervention group were pleased, happy or delighted with their bladder control compared with 97% of men in the postintervention group. Overall, 99% of patients in the postintervention group were satisfied with their cancer diagnosis by a nurse.

f) Radiation

Two RCTs evaluating the effectiveness of CNS care for patients undergoing radiation therapy were identified (44,45). Weintraub and Hagopian (44) randomized 56 participants to control, health education, or nursing consultation groups and measured anxiety, severity of side effects as well as the number and effectiveness of self-care strategies used by participants. The number of patients allocated within each group was not reported. Outcomes were measured using the Side Effects Profile and the State-Trait Anxiety Inventory (STAI). Those in the control group received usual care consisting of weekly physician visits while on treatment. The intervention groups received complementary care. Patients in the health education intervention group received usual care plus general health information regarding nutrition, stress reduction, and relaxation provided by an RN. Patients in the nursing consultation intervention group received usual care plus weekly individualized consultation sessions provided by one CNS to deal with side effects and self-care strategies. There were no significant differences between the groups on all outcomes measured.

Faithfull et al. (45) conducted a RCT to evaluate an alternate model of CNS-led follow-up care for patients receiving pelvic radiation therapy. Men (n=115) receiving radical radiation therapy (>60 Gy) for either prostate or bladder cancer were randomized to standard

physician or CNS-led follow-up. One CNS and six physicians participated in the study. The CNS made initial contact just prior to the start of treatment to provide information and answer questions and continued for 12 weeks. Written information was provided on healthy eating, radiation, and the management of urinary symptoms during radiation. Clinic appointments occurred during the first and last weeks of treatment and telephone contact was maintained between clinic visits. A protocol used for medications and symptom management was approved by the attending physicians. Standard follow-up care consisted of weekly (for bladder cancer) or two-weekly (for prostate cancer) 10-minute appointments at the urology outpatient clinic throughout the duration of treatment. Toxicity, symptoms, HRQL, patient satisfaction, and healthcare costs were measured. There were no differences in HRQL at week 1 following the start of radiotherapy but there were significant differences in seven of the symptom scores.

Compared with men in the CNS group, those in the control group had significantly more nocturia ($p < 0.006$), impact on activity from bladder symptoms ($p < 0.01$), constipation ($p < 0.001$), cramps or abdominal pain ($p < 0.04$), fatigue ($p < 0.04$), sickness ($p < 0.01$), and feeling of unwellness ($p < 0.01$) (45). These differences were unexpected at this early stage of treatment and were believed to be due to education the CNS provided at the pretreatment appointment. These differences were not maintained; there were no differences in symptom self-assessment or observer-rated symptoms at three, six, or 12 weeks. There was a difference at 12 weeks on the HRQL physical functioning scale ($p = 0.05$) such that those in the intervention group were less physically impaired. With respect to patient satisfaction, participants in the intervention group were significantly more satisfied with their follow-up care compared with the participants in the control group ($p < 0.002$). Moreover, service costs were 31% lower in the intervention group ($p < 0.001$). The reduced costs in the CNS group related to lower costs for the nurse, replacement of clinic visits with telephone calls, and lower microbiology and medication costs.

g) Chemotherapy

One RCT evaluated the use of a complementary nursing intervention involving a CNS to improve psychological functioning in newly diagnosed cancer patients undergoing chemotherapy (46). Fifty-five participants were randomized to receive a computer-based nursing intervention and 54 participants were randomized to conventional cancer care. The computer-based nursing intervention was provided by three CNSs over an 18-week period and consisted of five in-person and four telephone contacts. Topics covered included symptom management, disease and treatment information, emotional support, and coordination of resources. The CNSs also provided information and counselling during each session. The computer-based nursing intervention was a menu-driven program that guided the nurses through clinical assessment, identification of problems, intervention selection, and outcome measurement. Conventional cancer care consisted of any education normally delivered during chemotherapy. This included verbal information on what to expect from chemotherapy and symptoms that should be reported to the physician. Psychosocial functioning was measured using the Medical Outcomes Study 36 Short Form (SF-36), depressive mood was measured using the CES-D-20 scale, and anxiety was measured using the STAI. These outcomes were measured at three time points: study entry, midway through the intervention, and one month postintervention. Psychosocial functioning improved over time regardless of treatment group and there were no group differences related to anxiety. However, patients in the intervention group had lower depression scores compared with those in the control group when comparing scores from baseline to the midway point of the intervention, although this difference did not quite reach significance ($p = 0.05$).

h) Surgery

One RCT evaluated a complementary model of specialized home care for older postsurgical cancer patients delivered by master's-prepared oncology CNSs (47). The number of CNSs who participated in the study was not reported. The specialized home care intervention was initiated within 24 hours after hospital discharge and consisted of three home visits and five telephone calls by a CNS over a four-week period. Guidelines were used to assess and monitor patient physical, emotional and functional status, provide direct care, facilitate obtaining other community resources or services, and to provide teaching, counselling, and support during the recovery period. Care was individualized to patient needs. The CNSs were available on a 24-hour basis and they consulted with physicians and intervened immediately when complications arose. Patients in the control group received standard postoperative care in the hospital and routine follow-up in outpatient clinics upon discharge. Despite randomization to control and intervention groups, there were significantly more late-stage patients in the intervention group (38% versus 26%, $p=0.01$).

The main outcome was survival. There were no survival differences between the groups when they were compared without stratification by stage (47). Given that there was a difference in the two groups with respect to stage, a stratified analysis was done. There were no survival differences between the groups for early stage patients. However, survival was significantly greater for patients with later-stage cancer in the intervention group compared with the control group (two-year survival, 66.7% versus 39.6%, $p<0.05$). There were no group differences related to depressive symptoms, symptom distress, or functional status. During the first six months after surgery, more patients in the intervention group (32%) compared with the control group (27%) were rehospitalized. During the first three months after surgery, more patients in the control group (eight patients) died of postoperative complications compared with the intervention group (one patient). Earlier CNS interventions to identify and manage postoperative complications, especially for patients with more advanced disease, may have contributed to the improved survival rates in the intervention group.

Survivorship and Post-treatment Follow-Up

a) Bladder

A chart review study on CNS-led check flexible cystoscopy (FC) in patients with known bladder tumours was identified (48). Two master's-prepared urology CNSs with >10 years of nursing experience were formally trained as alternate providers to perform FC. It was noted that once the CNSs were performing FC independently, the wait list for FC declined but there were more referrals for general anesthetic (GA) procedures after FC. Therefore, an audit was conducted to compare the outcomes of CNS-led FC with physician FC and impact on GA cystoscopy referrals for patients receiving follow-up examinations. The first audit compared data from initial CNS FC patient charts with that of physician FC patient charts over a four-month period when the CNSs were not working. After the CNSs had obtained one year of experience in conducting independent examinations, a second similar audit was conducted using new CNS data but the same physician chart data.

When first practicing independently, urology CNSs referred significantly more check FC cases for GA procedures than did physicians (26.7% versus 9.3%, $p<0.0001$) (48). One year later, they referred only 15.9% of check FC cases, which was statistically nonsignificant when compared with physicians' referrals ($p=0.063$). For both groups, suspicious areas and suspected papillary tumours were the primary reason for referral. Nurses' referrals for GA procedures included significantly more cases where results were normal in the GA procedure

than did physician referrals for GA procedures in both the first (27.8% versus 16.1%, $p=0.002$) and second audits (33.3% versus 16.1%, $p=0.032$). There were extra costs associated with the increased number of GA procedure referrals. The extra costs incurred by the nurse-led clinics were £48,002 in the first audit and £29,122 in the second audit.

b) Breast

Four papers representing three studies evaluated APN care during the survivorship phase of the cancer journey for women with breast cancer (49-52). Ganz et al. (49) conducted an RCT to evaluate a complementary and comprehensive menopausal assessment (CMA) intervention program for breast cancer survivors with at least one severe target menopausal symptom (hot flashes, vaginal dryness, and stress urinary incontinence). In this study, 76 postmenopausal breast cancer survivors were randomized to the CMA intervention or an attention control group receiving usual care. Usual care was not specifically described but patients in this group were phoned by the research assistant once and asked about any therapies they used to manage their symptoms. This was an effort to control for the attention the CMA group received. The CMA intervention was delivered by a master's-prepared primary care NP who received six months of special training to deliver the intervention. The CMA intervention consisted of an assessment of the three target symptoms and an individualized plan of education, counselling, interventions, psychosocial support, referrals, and follow-up with the goal of providing patients with the tools necessary to manage their symptoms effectively. Menopausal symptoms were measured with the Menopausal Symptom Scale (adapted from the Breast Cancer Prevention Trial Symptom Checklist), HRQL was measured with the Vitality Scale of the SF-36, and sexual health was measured using the Sexual Summary Scale from the Cancer Rehabilitation Evaluation System. Intervention group participants had significant improvements in menopausal symptoms ($p=0.004$) and sexual functioning ($p=0.04$) compared with those in the attention control/usual care group. There were no significant differences in vitality.

Beaver et al. (50) conducted a randomized equivalence trial comparing traditional hospital follow-up with an alternate model of telephone follow-up provided by CNSs for 374 patients with breast cancer who were at low or moderate risk of recurrence. Traditional hospital follow-up involved 10 minute appointments and consisted of consultations, clinical examinations, and mammography as per hospital policy. Consultations were provided by consultant surgeons, consultant oncologists, registrars, junior doctors or CNSs. However, junior staff usually conducted these visits. Telephone follow-up provided by CNSs consisted of consultations using a structured intervention and mammography according to hospital policy. Patients were asked about any changes in their condition including new symptoms and were provided with information on spread of disease, treatment, side effects, sexual attractiveness, self-care, and family issues. Telephone appointments were allotted 30 minutes; 20 minutes for the consultation and 10 minutes for dictation. Seven CNSs received 4.5 days of training to deliver the intervention, although four CNSs conducted most of the telephone appointments. Psychological morbidity was measured using the Spielberger STAI and the General Health Questionnaire-12 (GHQ-12). There were no statistically significant differences between treatment groups with respect to psychological morbidity at any of the time points measured (beginning, middle, and end of the trial). There was little difference between the groups related to information needs, although statistical evaluation of this is not provided. At the beginning of the study, there were no statistically significant group differences with respect to satisfaction with the information received. However, by the middle and end of the study, patients receiving telephone follow-up were significantly more satisfied ($p<0.001$ for both time points) compared with those receiving usual care. Similar results were found related to 'helpfulness in dealing with concerns at their appointment'.

There were no group differences at the onset of the study but significantly higher 'helpfulness' scores by the middle ($p<0.001$) and end of the study ($p=0.001$) for patients receiving telephone follow-up. In addition, there were no significant group differences with respect to the clinical investigations ordered as a result of appointments at any of the three time points. Finally, there was no statistically significant group difference for the time to detection of recurrence. Only 17 participants had a confirmed recurrence.

Beaver et al. (51) performed an economic evaluation of this follow-up intervention. They reported that patients in the telephone follow-up group had 20% more consultations than those in the hospital follow-up group (634 versus 524). Telephone consultations were longer than hospital consultations but hospital appointments were usually conducted by junior staff. There were no group differences in mean costs for diagnostic tests, but women receiving telephone follow-up were more likely to have documented referrals to a general practitioner, hospital doctor or nurse, or clinical psychologist. Combined, the costs of nursing training, the length and frequency of telephone consultations, and referrals resulted in higher routine total costs for the telephone consultations (£179 versus £124, mean difference £55, 95% CI, £26 to £77, p -value not reported). There were no significant group differences in terms of the costs of treating recurrences. Women in the hospital follow-up group had significantly higher travel and productivity costs, with a mean difference of £47 (95% CI, £40 to £55, p -value not reported).

Koinberg et al. (52) conducted a nonrandomized comparison of two methods of follow-up in patients with recently diagnosed stage I or II breast cancer: a multidisciplinary educational program (MP) and traditional follow-up by a physician program (PP). The MP focussed on health as a means to promote the self-care ability of women with breast cancer. It consisted of four sessions led by an oncology CNS but also included a physiotherapist, social worker, physician, and a local breast cancer patient advocate. Each session was followed by a discussion and relaxation exercises. Women in the MP group were also provided with the names of oncology nurses whom they could contact if required and were referred to the routine mammography screening program. Women in the traditional follow-up group were examined by an oncology specialist or a surgeon semiannually in the first two years after surgery and then annually up to five years. They also underwent yearly mammograms. Participants were evaluated at the time of diagnosis (baseline) and again one year later using the FACT-General scale (FACT-G), the Self-Care Aspects Questionnaire and the Sense of Coherence Scale. No statistically significant differences were found between the two groups at one-year follow-up. However, those in the MP group did display significant improvements in both physical ($p<0.01$) and functional well-being ($p<0.01$) from baseline to one-year follow-up. Those in the PP group also showed significant improvements in functional well-being ($p<0.01$) but significant decreases in social/family well-being from baseline to one-year follow-up. There were no differences between the two groups in self-care. No significant differences were reported between the two groups with respect to sense of coherence. However, those women in the PP groups demonstrated a significant decrease in their sense of coherence between baseline and one-year follow up ($p<0.001$).

c) Colorectal

Beaver et al. (53) evaluated an alternate model of NP-led telephone follow-up after colorectal cancer treatment. This was a phase III exploratory RCT in which 65 patients were randomized either to regular hospital outpatient follow-up or NP-led telephone follow-up. Both treatment groups had the same number of follow-up appointments on the same schedule (i.e., at six weeks post-treatment, every six months for two years, and then every year for another three years). Hospital follow-up focused on routine monitoring for detecting a recurrence. The NP who provided the telephone follow-up had completed Master's degree in

clinical nursing and had knowledge and expertise in clinical assessment and providing nurse-led care. Telephone follow-up included a structured intervention to determine patients' informational needs. Patients were asked about any changes in their condition including new symptoms and were provided with information on spread of disease, treatment, side effects, sexual attractiveness, self-care, and family issues. The outcomes included psychological morbidity using the STAI and the GHQ-12. Questionnaires were administered at baseline and at one additional time point that was individualized for each patient in order to maximize the number of appointments received between completed measurements.

There were no statistically significant group differences in STAI or GHQ-12 scores at follow-up (53). The study was not powered to detect such differences. Both groups had similar information needs at baseline but at follow-up, patients in the telephone group had been able to raise more information needs than those in the hospital group (30 versus 16). Satisfaction with the most recent appointment was higher in the telephone group ($p=0.029$). There were no group differences in the number of follow-up tests ordered. The median length of appointment was shorter for hospital follow-up compared with telephone follow-up (14.0 minutes versus 28.9 minutes, $p=0.001$ [Mann-Whitney U test]).

Palliative Care

Three studies regarding the integration of advanced practice nurses in palliative care for cancer patients were identified (54-56). Prince-Paul et al. (54) evaluated the addition of a palliative care advanced practice nurse to a community cancer centre. A pre and post study was conducted to assess patient outcomes and resource utilization for 101 patients with advanced cancer (stage III/IV). The preintervention or usual care group included 52 patients and the postintervention APN group had 49 patients. Data were collected at enrollment and four months post-enrolment. The complementary APN role in this study was consistent with that of a CNS. The advanced practice nurse worked collaboratively with the oncologists at the cancer centre. Their responsibilities included physical assessments, pain and symptom management, advanced care planning, education about medication side effects, emotional support, assessment of spiritual needs, and discussions about goals of care. When required, the advanced practice nurse also made patient referrals to nutritionists and social workers. The advanced practice nurse saw patients during clinic visits and provided follow-up telephone calls. There were no statistically significant group differences related to comorbid conditions, performance status, symptom assessment, mood, spirituality, social well-being, or HRQL. However, patients in the APN group were 67% less likely to be hospitalized compared with patients in the usual care group (odds ratio [OR], 0.33; 95% CI, 0.12 to 0.87; $p=0.03$). Patients in the APN group were also 9.6 times more likely to be alive four months after enrollment than those in the usual care group (OR, 9.56; 95% CI, 1.14 to 80.05, $p=0.04$).

Bakitas et al. (55) conducted a RCT to evaluate the early introduction of a complementary multicomponent palliative care intervention for 322 patients with newly diagnosed advanced cancer in a rural comprehensive cancer centre. Participants were randomized to usual care or to an enhanced psychoeducational intervention based on the Chronic Care Model. The intervention involved a telephone-based curriculum that included four formal sessions and monthly follow-up until the patient's death to provide ongoing assessment, coaching, advance care planning, symptom management, and crisis prevention. The intervention was delivered by two advanced practice nurses with palliative care speciality training in roles similar to that of a CNS. The patient's clinical team was responsible for medication and inpatient care management. Patients randomized to usual care had access to all oncology and supportive services with no restrictions. All participants completed questionnaires at enrollment, one month after baseline, and every three months thereafter. At baseline, there were no significant group differences related to HRQL,

symptom intensity, and mood. Longitudinal analysis over the length of the study demonstrated higher HRQL ($p=0.02$) and lower depression scores ($p=0.02$) in the intervention group compared with the usual care group. There was no statistically significant group difference over the course of the trial with respect to symptom intensity. In addition, there were no significant group differences with respect to number of days in hospital, number of days in intensive care, or in the number of visits to the emergency room. A post hoc survival analysis revealed no statistically significant group differences in survival.

Thomas et al. (56) conducted an RCT comparing three methods to improve cancer pain management in 318 adult patients with various cancers and various types of cancer-related pain. Patients were randomized to one of three groups: control/usual care, education, or intervention/coaching. Patients in the usual care group were shown a video on cancer. Patients in the education group were shown a video on managing cancer pain and were given a consumer version of a clinical practice guideline on managing cancer pain. Coaching group participants received the same intervention as the education group plus four telephone sessions about pain and pain management provided by a CNS trained in motivational interviewing techniques. Usual care participants also received four telephone calls on the same schedule as the coaching participants for attention control purposes. All participants completed the same questionnaires at enrollment and 12 weeks postrandomization. There were significant group differences with respect to mean pain interference at the end of the study as measured by the Brief Pain Inventory ($p=0.01$). Patients in the CNS coaching group had the lower pain interference scores compared with the education and control groups ($p=0.3$ and $p=0.02$, respectively). Based on the SF-36, the CNS coaching group also had significantly better general health ($p=0.015$) and vitality ($p=0.02$) compared with the education group, better mental health (0.042) compared with the education and control groups, and better mental functioning ($p=0.035$) compared with the control group. There were no group differences on attitudinal barriers as measured using the Barrier Questionnaire or HRQL as measured using the FACT-G.

End of Life

No studies evaluating advanced practice nurses related to the end-of-life care of cancer patients were identified.

Non-Phase-Specific Within the Cancer Journey

One paper did not fall within a specific phase of the cancer journey (57). Hardie et al. (57) evaluated the introduction of a complementary model of breast cancer care provided by a CNS in one centre in the UK. In this model, patients were receiving adjuvant or palliative treatment or follow-up care. This was a repeated measures pre/post design in which 50 patients attending the outpatient breast cancer clinic were surveyed prior to the introduction of the CNS and the same patients were surveyed one year later. Descriptions of the care provided pre and post CNS implementation are not reported. In general, the CNS role for patients with breast cancer involved providing education; complex care management; managing physical, psychological and social problems; engaging patients in treatment decision making; and facilitating referral to community resources. Prior to the introduction of the CNS, 38% of respondents described their satisfaction with the cancer care they received as excellent, whereas post-CNS implementation, 56% of respondents described their satisfaction with the cancer care they received as excellent. Following implementation of the CNS role, more patients reported receiving enough support compared with preimplementation (82% versus 71%). No statistical comparisons were reported.

Research Question #2 - Summary

Patient outcomes associated with APN roles include HRQL, pain and symptom management, mental health, physical function, performance status, self-care, information needs, satisfaction with care, and survival (Table 9A). HRQL, symptoms, and mental health were the most frequently reported outcomes.

None of the studies included in the review evaluated APN outcomes specific to family members or other healthcare providers.

Health systems outcomes associated with APN roles related to indicators of care quality, healthcare costs, and health service utilization including hospital length of stay, hospital re-admission, emergency department visits, number of advanced practice nurse consultations, and number of physician visits (Table 9B). Quality of care indicators were the most frequently reported outcome.

There was a similar pattern of results across patient and health systems outcomes (Tables 10 and 11) with few studies reporting harmful or negative outcomes associated with APN roles. Overall, APN roles in cancer control are associated with no differences or improved outcomes. Across 29 studies reported in 31 papers, a total of 150 outcomes were measured. Of these outcomes, 88 were assessed as not different, 53 were found to be superior in the APN group, and nine were found to be superior in the control group.

Table 9A - Overall patient outcomes.

Result	HRQL N=10 studies	Symptoms N=11 studies	Mental Well-being N=12 studies	Physical Function N=5 studies	Performance Status N=1 studies	Self-Management N=2 studies	Information N=1 study	Satisfaction N=7 studies	Other N=9 studies
No. Worse Outcomes	1	1	1	1	0	0	0	0	1*
No. No Difference Between Outcomes	8	15	13	2	1	2	2	4	11**
No. Improved Outcomes	1	9	6	3	0	0	0	5	7***

HRQL=health-related quality of life; No.=number

*Health perceptions

**survival for early stage patients; vitality; helpfulness at the beginning of study; time to detection of recurrence; functional well-being; social/family well-being; sense of coherence; comorbidities; survival; attitudinal barriers; support

*** survival for late stage patients; sexual functioning; helpfulness at the middle of study; helpfulness at the end of the study; survival at 4 months; general health; vitality

Table 9B - Overall provider/health system outcomes.

Result	Provider Satisfaction N=0 studies	Adverse Events N=0 studies	Meets Quality Indicators N=7 studies	Hospital Length of Stay N=3 studies	Hospital Readmission N=3 studies	ED Visits N=2 studies	Number of Advanced Practice Nurse Consults N=1 study	Number of MD Visits N=2 studies	Costs N=4 studies	Other N=8 studies
No. Worse Outcomes	0	0	0	0	0	0	0	0	2	2*
No. No Difference Between Outcomes	0	0	10	5	2	2	0	2	2	7**
No. Improved Outcomes	0	0	11	0	1	0	1	1	2	6***

ED=emergency department; MD=medical doctor; No.=number

*At beginning of study more general anesthetic (GA) procedures requesting by advanced practice nurse; results of GA studies at beginning of study and at 1 year

** Procedure duration; seen by continence team preoperatively; GA requests at 1 year; clinical investigations ordered; more consultations; longer consultations; follow up tests ordered

*** breast screening rate; cervical screening rate; offered services of a patient advocate; longer consultations; amount of time kept waiting; length of appointments

Table 10 - Overall summary of advanced practice nursing role outcomes.

Result	HRQL N=10 studies	Patient Health N=16 studies	Patient Self-Care & Information Needs N=3 studies	Patient Satisfaction N=7 studies	Provider Satisfaction N=0 studies	Quality of Care N=7 studies	Health Service Use N=6 studies	Costs N=4 studies	Other N=16 studies	Total N=29 studies
No. Worse Outcomes	1	3	0	0	0	0	0	2	3	9
No. No Difference Between Outcomes	8	31	4	4	0	10	11	2	18	88
No. Improved Outcomes	1	18	0	5	0	11	3	2	13	53
Total No. of Outcomes	10	52	4	9	0	21	14	6	34	150

HRQL=health-related quality of life; No.=number

Patient Health = symptoms, mental health physical function, performance status

Quality of Care = adverse events, achievement of quality indicators

Health Service Use = hospital length of stay, hospital readmissions, emergency department visits, number of advanced practice nurse consults, number of medical doctor visits

Table 11: Summary of advanced practice nursing outcomes according to role aim, cancer journey phase, and type of advanced practice nursing role.

Role Aim	Phase of Cancer Journey	Study	APN Role		APN Outcomes
			CNS	NP	
Alternative	Screening	Mandelblatt 1993 (27)		X	Breast screening rate - improved Cervical screening rate - improved
		Curtis 1999 (28)		X	Unsatisfactory Pap smears - no difference Smears with endocervical cells - improved (one comparison) Smears with endocervical cells - no difference (another comparison)
		Thommasen 1996 (29)		X	Unsatisfactory Pap smears - no difference Smears with endocervical cells - no difference
		Schroy 1988 (30)		X	Flexible sigmoidoscopy sensitivity and specificity - no difference
		Limoges-Gonzalez 2011 (31)		X	Patient satisfaction with screening colonoscopy - improved Adenoma detection - improved Colonoscopy procedural pain - no difference Colonoscopy depth of insertion - no difference Colonoscopy procedure duration - no difference
		Wildi 2003 (32)		X	Eosophagoscopy sensitivity and specificity - no difference
	Diagnosis	Gage 2006 (33)		X	Overall sensitivity of colposcopy-guided cervical biopsies - no difference Sensitivity of colposcopy-guided cervical biopsies >2 biopsies - improved
		Kilic 2012 (34)		X	Colposcopy-guided cervical biopsy sensitivity - no difference
		Morris 1998 (35)		X	Fewer discrepancies between Pap smear and colposcopy-guided cervical biopsy - improved More ECCs performed - improved Fewer patients lost to follow up - improved Fewer patients with abnormal Pap smear after treatment - improved Lower surgical intervention rates - improved Insufficient cervical biopsies/ECCs - no difference Unsatisfactory colposcopy - no difference Missed invasive cervical cancers - no difference Documents adequacy of examination - improved
	Treatment	Osborne 2010 (37)	X		Patient satisfaction with preparation for breast reconstruction surgery - no difference Offered services of a patient advocate - improved
		Wells 2008 (41)	X		All HRQL measures for patients undergoing radiotherapy for head and neck cancer - no difference Consultations - improved (more) Longer consultations - improved (more) Kept waiting - improved
		McCorkle 1989 (42)	X		Home care of patients with lung cancer - symptom distress, independency - improved Health perceptions - worse Hospital length of stay - no difference Hospital readmission - no difference
		McGlynn 2004 (43)	X		HRQL following radical prostatectomy - no difference Urinary control and urinary symptoms - no difference Seen by continence team preoperatively - no difference Patients satisfied with CNS care (no comparison)
		Faithfull 2001 (45)	X		HRQL at 1 week after radiation begins for patients receiving radiation therapy for bladder and prostate cancer - no difference Physical functioning and constipation at 12 weeks - improved Patient satisfaction - improved Symptoms at 1 week after radiation begins - improved on 7 separate symptoms Symptoms at weeks 3, 6, 12 - no difference on 7 separate symptoms Costs - improved
	Survivorship/ Follow-Up	Radhakrishnan 2006 (48)	X		Costs at beginning and at 1 year - worse At beginning more GA procedures requested by advanced practice nurse - worse At 1 year GA requests - no difference At beginning and 1 year - results of GA procedures normal - worse
		Beaver 2009a/2009b (50,51)	X		Psychological morbidity - no difference Satisfaction at beginning - no difference Satisfaction at middle - improved Satisfaction at end - improved Helpfulness at beginning - no difference Helpfulness at middle - improved

					<p>Helpfulness at end - improved Time to detection of recurrence - no difference Costs in the APN group - worse Costs of treatment recurrence - no difference Travel and productivity costs - improved Clinical investigations ordered - no difference More consultations - no difference Longer consultations - no difference</p>
		Koinberg 2006 (52)	X		<p>Emotional well-being - no difference Physical functioning - no difference Self-care - no difference Functional well-being - no difference Social/Family well-being - no difference Sense of coherence - no difference</p>
		Beaver 2012 (53)		X	<p>Anxiety - no difference Information needs at baseline - no difference Information needs at follow up - no difference Satisfaction with most recent appointment - improved Follow up tests ordered - no difference Length of appointments - improved</p>
Complementary	Treatment	Wengstrom 1999 (36)	X		<p>HRQL for patients receiving curative radiation therapy for breast cancer - no difference Perceived distress - improved Side effects - no difference</p>
		Ritz 2000 (38)	X		<p>Uncertainty at 1, 3, 6 months for women with newly diagnosed breast cancer - improved Uncertainty at 12 months - no difference Mood - no difference on all subscales Well-being - no difference Hospital LOS for definitive surgery - no difference Hospital LOS for admissions after definitive surgery - no difference Number of MD visits - no difference Costs - no difference</p>
		McCorkle 2009/2011 (39,40)	X		<p>Symptom distress for postsurgical women with gynecological cancers - worse Uncertainty - improved Depression - worse Physical functioning - worse Hospital readmission - no difference Emergency department visits - no difference Number of primary care visits - improved Number of oncology physician visits - no difference</p>
		Weintraub 1990 (44)	X		<p>Anxiety for patients receiving radiation therapy - no difference Self-management - no difference Side effects/symptoms - no difference</p>
		Rawl 2002 (46)	X		<p>Psychosocial functioning for newly diagnosed patients with cancer - no difference Anxiety - no difference Depression - no difference</p>
		McCorkle 2000 (47)	X		<p>Survival of early stage patients for older postsurgical cancer patients - equivalent Survival of late stage patients - improved Symptom distress - no difference Depression - no difference Social dependency - no difference</p>
		Survivorship/ Follow-Up	Ganz 2000 (49)		X
	Palliative Care	Prince-Paul 2010 (54)	X		<p>HRQL - no difference Symptoms - no difference Mood - no difference Spirituality - no difference Social well-being - no difference Performance status - no difference Comorbidities - no difference Survival at 4 months - improved Hospital readmission - improved</p>
		Bakitas 2009 (55)	X		<p>HRQL - improved Symptoms - no difference Depression - improved Survival - no difference</p>

				Hospital length of stay - no difference ICU length of stay - no difference Emergency department visits - no difference
	Thomas 2012 (56)	X		HRQL - no difference Mental health - improved Mental component scores - improved Pain interference - improved General health - improved Vitality - improved Attitudinal barriers - no difference
	Other	Hardie 2010 (57)	X	Patient satisfaction - no difference Support - no difference

APN=advanced practice nursing; CNS=clinical nurse specialist; ECC=endocervical curettages; GA=general anesthetic; HRQL=health-related quality of life; ICU=intensive care unit; LOS=length of stay; MD=medical doctor; NP=nurse practitioner; Pap smears=Papanicolaou smears

Ongoing, Unpublished, or Incomplete Studies

There were no ongoing, unpublished, or incomplete studies.

DISCUSSION

Quality and Scope of the Evidence

Inclusion criteria related to study design were deliberately broad, permitting RCTs and other comparative designs, in order to gain understanding about how APN roles have been implemented and evaluated across the cancer journey. Overall, there are few RCTs of APN roles in cancer control. Regardless of type of study design, the overall quality of studies was poor. Of the 15 RCTs reported in 17 papers, only one study had low risk of bias. There was moderate to high risk of bias across all studies designs, which dampens our confidence in the overall results. Common and substantive methodological limitations of this body of evidence include the risk for selection bias, inadequate reporting of key study methods, inadequate descriptions of the APN role (type of role, role activities) as the intervention, and small sample sizes with lack of power to detect small, but clinically important, group differences. Similar methodological limitations have been reported in other systematic reviews of CNS and NP roles not specific to cancer control (14,20). The implementation of APN roles, especially those that are newly established, can be challenged by provider, patient, organization, and health system factors even in well-controlled study conditions (12,17). Poor reporting of advanced practice nurse (e.g., education, experience), and APN role (e.g., new versus established role) characteristics and role implementation issues (e.g., timing, frequency and intensity of APN interventions; barriers to implementation) in many studies make it difficult to assess intervention fidelity, interpret results, and draw definitive conclusions about role outcomes. The results of some studies may not be readily generalizable to APN roles in other practice settings due to inadequate descriptions of the APN role and the few number of advanced practice nurses (n=1 to n=7) evaluated.

Significant gaps in the evaluation of APN roles in cancer control are noted. There is a paucity of research about Canadian APN roles in cancer control and the outcomes of APN roles related to cancer prevention and end-of-life care. The challenges of conducting comparative studies of end-of-life care and the recent recognition of this unique phase of the cancer journey may contribute to the lack of research in this area. Prevention to reduce risks for developing cancer is a Cancer Care Ontario (60) priority for improving cancer control. It is possible that relevant studies on APN roles and the primary prevention of chronic diseases including cancer (e.g., health promotion/healthy lifestyle interventions related to diet, exercise, smoking cessation, alcohol use) were missed because our literature search strategies focused on cancer. However, the absence of research about APN roles in primary prevention was also noted in a recent non-cancer-specific systematic review of CNSs and NPs (20). Health promotion and illness prevention is an important aspect of NP roles in primary care, but research on these roles has focused on the management of episodic conditions, secondary prevention, and chronic disease management (20). In Canada, there may be limited use of APN roles related to primary prevention, particularly in public health settings where much of this work and research may take place (61).

There is also limited research evaluating APN roles in other areas of strategic priority in the Ontario Cancer Plan (60), such as improving access and quality of care for high-volume and resource-intensive populations with lung, colorectal, prostate, and hematological cancers. No studies evaluated APN roles for patients with high-cost, complex care needs related to multiple chronic conditions, long-term adjuvant therapy, concurrent or multi-modality therapies, bone marrow transplantation, personalized medicine, or cancer genetics. In addition, there were no studies evaluating important healthcare provider outcomes such as acceptance and satisfaction with the APN role, job satisfaction, workload, or team function. There are also no studies evaluating APN interventions related to the nonclinical dimensions of the role (i.e., education, leadership, research/evidence-based practice). The lack of evidence about nonclinical APN activities may be due to the review's search strategy and

emphasis on patient care across the cancer journey. The lack of research in this area has been identified in other international reviews of the APN literature (12).

Finally, for every one study included in this review, at least two studies (n=65) were excluded because they involved RNs but not advanced practice nurses (Figure 1). This suggests there is a substantive body of research about generalist and specialized oncology nurses in cancer control. The findings of this review do not inform decision making about the effective use of RNs as opposed to advanced practice nurses. Only one study compared RNs and advanced practice nurses related to the home care of patients with lung cancer (42).

APN Roles and Outcomes

NPs have been evaluated more widely as alternate providers to physicians, particularly for services related to cancer screening and diagnosis. In contrast, CNSs have been evaluated in alternate and complementary roles concentrated at the treatment and post-treatment phases of the cancer journey. Patients with breast and gynecological cancers and those at increased risk for poor health outcomes owing to socioeconomic status, age, or treatment complications were the most frequent target populations of APN roles. The need to improve access to care and/or to improve symptom management or psychosocial well-being was cited most often as rationale for the APN role. As a result, the most frequent patient outcome indicators evaluated in this systematic review were related to HRQL, symptoms, and mental health. The most frequently examined health system outcome indicators were related to quality of care, hospital length of stay, and costs. Interestingly, although wait time reduction was a prominent driver for APN role introduction, no studies evaluated indicators relevant to access to care such as wait times. Other relevant outcomes indicators that were absent in this systematic review related to healthcare providers and family caregivers.

The results of individual studies in this review must be interpreted with caution owing to methodological limitations and the risk of bias. However, the consistent pattern of results demonstrating improved or no difference in quality of care and patient health outcomes for different types of APN roles across varied patient populations, geographic jurisdictions, and phases of cancer is compelling (Table 10). There were very few negative outcomes associated with APN roles. No conclusions can be drawn about the cost-effectiveness of APN roles in cancer control because our review did not identify studies providing an economic analysis. In the few studies measuring costs, only a direct cost comparison was provided, rather than a comprehensive assessment of the incremental costs and benefits of APN care (38,48,51). Further discussion of the outcomes now follows.

Summary of Outcomes by Phase of the Cancer Journey

Screening

Across six studies (all with moderate or high risk of bias), there are consistent findings that NPs, working as alternate providers to physicians, may improve breast and cervical cancer screening rates and improve access to quality screening services for cervical and gastrointestinal cancers for average and at-risk patient populations. NPs providing same-day services in primary care clinics for underscreened patients had improved breast and cervical screening rates compared with physician chart reminders (27). Two studies demonstrated that the quality of Pap smears conducted by NPs was no different and, in some cases, superior to physicians (28,29). The sensitivity and specificity of NP-conducted sigmoidoscopy and esophagoscopy was found to be similar (i.e., no difference) to that of physicians (30,32). Compared with physicians, NP-led colonoscopy was found to provide no difference in quality of care related to procedural pain, duration of the procedure and depth of insertion, and improved care related to patient satisfaction and detection of adenomas (31).

Maximizing the scope of practice and skills sets of all healthcare providers is necessary for the efficient and effective delivery of cancer care services. While NPs may be appropriate providers for cancer screening, duplication or overlap with services already provided by RNs should be avoided. In Canada, NPs are authorized to perform Pap smears, as are RNs who have received appropriate training. Most RNs complete a Pap smear training module developed by Alberta Health Services (2012) (personal communication, P. Allen, manager, Integrated Cancer Screening, Juravinski Cancer Centre). A national study suggests that RN roles in primary care are underutilized in this regard, and that RNs are more likely to perform Pap tests and other enhanced role activities in settings where NPs and physicians are not present (e.g., northern, rural, and remote communities; sexual assault clinics; mobile screening services) (62). In addition, RN-performed flexible sigmoidoscopy is the standard of care in 14 sites across Ontario, so expansion of NPs to this service would not be appropriate (63).

Diagnosis

Three studies provide consistent results demonstrating that NPs in alternate roles provide high quality, safe, and effective care related to the diagnosis and management of cervical cancer and may improve access to care for women with cervical dysplasia, especially in underserved communities. Two studies, one with moderate risk of bias (33) and one with high risk of bias (34), found the sensitivity and specificity of colposcopy-guided cervical biopsies conducted by NPs to be similar to physicians. NPs were also more likely to take two or more biopsies and this was associated with improved sensitivity (33). In a third study (moderate risk of bias), there was greater consistency between Pap smear and biopsy results for NPs compared with physicians, providing further evidence about the high quality of NP-performed colposcopy-guided cervical biopsies. The study by Morris et al. (35) suggests that compared with physicians, NP practices are less variable and more consistent with accepted standards of care, and NPs achieved higher rates of patient follow-up and had better quality of care related to documentation (moderate risk of bias).

Noted absences in this review are studies evaluating advanced practice nurses in performing transrectal ultrasound (TRUS)-guided biopsies for patients with suspected prostate cancer. We identified one RCT from the UK, but were unable to confirm from the authors whether the NP met the criteria as an advanced practice nurse (64). Owing to the lack of standardized APN education at the graduate level, variability in urology-specific training and inconsistent use of role titles among urological nurses in the UK, we did not include this study (65). NP-led TRUS prostate biopsies have been performed in the UK as early as 1998. A recent international survey found that a substantive proportion of urological nurses (9.4% to 13.2%) were performing advanced procedures such as prostate and bladder biopsies and cystoscopies in North America, the UK, Australia, and Europe (66). Similar results were found in a survey of US NPs (67). The European Association of Urological Nurses recently published evidence-based guidelines for TRUS-guided prostate biopsies, recommending that nurses performing this procedure be advanced practice nurses with graduate education and additional training (65). One UK study published after 2012 (i.e., after our search time period), comparing physician and NP prostate cancer biopsies for 222 consecutive patients, suggests that NPs may provide equivalent care related to cancer detection and complication rates, but further research is required (68). A major barrier to expansion of APN roles internationally related to the diagnosis and management of urological cancers is the absence of formal training programs for invasive procedures such as TRUS-guided prostate biopsies (66,67).

Treatment

Only CNS roles were evaluated during the treatment phase of the cancer journey (Tables 5 and 11). There were consistent findings of either no differences or improved patient and health system outcomes from 11 studies of CNSs in alternate (five studies) and complementary (six studies) roles (low, moderate, and high risk of bias). The main aim of the CNS role in these studies was to improve patient outcomes related HRQL, symptoms, and psychosocial well-being and/or health system outcomes related to health service use. Patients were satisfied or more satisfied with alternate models of CNS care compared with usual care (37,43,45). In general, there was no impact of CNS care on HRQL and variable impact on symptom management, physical function, psychosocial well-being, and mental health. Improved survival was observed in one study of elderly postsurgical cancer patients (47). Vulnerable populations (e.g., unmarried women, new cancer diagnosis, psychological distress) and those at risk for poor outcomes (advanced cancer, older adults) may benefit the most from CNS care. Healthcare utilization related to hospital length of stay, readmissions, and emergency department visits was similar for CNS and usual care groups. Lower costs may be achieved through CNS care due to reductions in diagnostic tests, prescriptions, and clinic visits (45).

Alternate Roles

Across five studies (moderate and high risk of bias), alternate CNS care was found to have either no differences or improved patient and health system outcomes when compared with usual physician-based models of care (Table 11). CNSs in alternate roles provided care to women with breast cancer considering reconstructive surgery (37), patients with lung cancer receiving home care (42), patients undergoing radical prostatectomy (43), and patients receiving radical radiation therapy (41,45). Studies of alternate roles are designed to demonstrate equivalent outcomes.

For patient outcomes, there were no differences in HRQL between CNS and usual care groups for head and neck cancer (41), or for bladder and prostate cancer (45). The only exception was better HRQL related to physical function and constipation at 12 weeks in the CNS group for patients receiving radiation for bladder and prostate cancer (45). At one week following the start of treatment, these patients also had less-severe symptoms due to nocturia, activity and bladder symptoms, constipation, cramping, fatigue, sickness, and feeling unwell (45). This early and surprising finding was believed to result from CNS pretreatment interventions focused on patient education, coping, and managing symptoms. Improved symptom severity was not sustained because there were no group differences in symptom scores at three, six, and 12 weeks post treatment. The large amount of missing data at later assessments makes it difficult to draw conclusions about the longer-term benefits of CNS care.

The McCorkle et al. (42) study is noteworthy because it is one of few published studies providing a direct comparison of RN and APN roles. Lack of power may account for the finding of no differences in most outcomes between RN and CNS patient groups. Despite increased symptoms of progressive lung cancer across all groups over time, when compared with patients receiving office-based physician care, those in the RN and CNS groups experienced longer and clinically important delays (six weeks) in symptom development and functional dependency. However, patients in both nurse groups had more negative perceptions of their health compared with those receiving physician care (even though they had earlier symptom distress and dependency). How nurses and physicians communicate information to patients about illness severity and prognosis may account for these differences in health perceptions. Since 1989, when this study was published, the treatment for lung cancer has become substantially more aggressive and complex and is associated with greater

side effects (69,70). Further evaluation of CNS home care of this patient population may be even more relevant today.

Patients were also satisfied or more satisfied with alternate CNS care (37,43,45). Aspects of CNS care associated with patient satisfaction included receipt of understandable information, feeling well-informed, inclusion of family members, continuity of care, and communication (37,45). The emphasis of these roles was on providing patient education and support, care coordination, and symptom management, and not medical care. In only two studies did CNSs provide substantive medical care related to providing a cancer diagnosis, discussing treatment options and/or ordering of diagnostic tests and referrals (37,43).

In terms of health system outcomes, patients receiving CNS care were more likely to be referred to a patient advocate for peer support (37), have shorter clinic visit wait times (41), and more frequent and longer clinic appointments (41). There were no differences between CNS and usual care related to hospital lengths of stay or readmission rates (42) but the costs for CNS care for patients receiving radiation for bladder and prostate cancer was 31% less compared with physician care (45). Cost savings were related to lower costs of the nurse and fewer outpatient clinic appointments, prescriptions and microbiology tests.

Complementary Roles

Six studies (reported in seven papers) compared usual nursing and/or medical care to CNSs in complementary roles providing for patients with newly diagnosed cancer (38,46), undergoing radiation therapy (36,44), and post cancer surgery (39,40,47). The aim of complementary APN roles is to improve outcomes, and for these studies the primary focus was to improve HRQL and psychosocial well-being. Interventions emphasized self-care through patient education, provision of information and skill development; coping; symptom assessment and management; care coordination and referral to other supportive care providers and community services; and decision support. No studies reported on patient satisfaction. In most cases, the addition of CNS care to usual care did not lead to improvements in HRQL. There were no group differences in HRQL in three studies (all high risk of bias), largely involving women with a new diagnosis of breast cancer receiving radiation and/or chemotherapy (38,44,46). The only exception was improved HRQL and mood in the CNS group for unmarried women receiving treatment for breast cancer (38). There were also no differences in symptom distress (moderate risk of bias) (47) or radiation treatment side effects for patients who did or did not receive CNS care (high risk of bias) (36,44). Several psychosocial outcomes were measured with varying results. CNS care was associated with less psychological distress (high risk of bias) (44) and less uncertainty about the meaning of the cancer experience (MUIS) (low, high risk of bias) (38,39). In contrast, there were no differences in anxiety as measured by the STAI in patients with a new diagnosis of cancer or those receiving radiation therapy (both high risk of bias) (44,46). CNS care had variable impact on mood and depression. In newly diagnosed patients, mood or depression was either not different or improved in the CNS group (high risk of bias) (38,46). There was no improvement in depression or social dependency for elderly postsurgical cancer patients (moderate risk of bias) (47).

In the study by McCorkle et al. (39), CNS care for postsurgical women with gynecological cancers was associated with heightened depression and symptom distress, and poorer HRQL related to physical well-being compared with the attention control group (low risk of bias). When CNS care was augmented by collaboration with a psychiatric liaison nurse for patients with high psychological distress, outcomes were improved for uncertainty, symptom distress, and HRQL, but not for depression.

For the treatment phase of the cancer journey, the study by McCorkle et al. (47) provides the only evaluation of CNS care on survival. For elderly postsurgical cancer patients,

there were no survival differences between the CNS and usual care groups for those with early stage cancers. In contrast, patients with advanced cancer in the CNS group had improved survival at two years (67% versus 40%, $p=0.001$; CI, 1.33 to 3.12). Patients in the CNS group had fewer deaths related to postoperative complications. Improved survival was believed to be due to CNS interventions to prevent, assess, and manage health problems following discharge from hospital.

In this cluster of studies about complementary roles, unmarried women or those with no previous diagnosis of breast cancer, patients with high levels of psychological distress, and elderly patients with advanced cancer benefited the most from CNS care. The studies by McCorkle et al. (39,47) and Ritz et al. (38) highlight the importance of careful patient assessment to determine subgroup populations who may benefit the most from CNS interventions, and tailoring the intensity of interventions to match the needs of different at-risk patient populations.

Few studies evaluated health system outcomes. The addition of CNS care to usual care did not lead to reduced (i.e., improved) health service use but, importantly, was not associated with increased costs. In two studies (low, high risk of bias), there were no differences in hospital length of stay (38), rehospitalization (40), emergency department visits (38,40), outpatient clinic visits (38), oncology physician visits (40), or costs (38). Patients receiving CNS care post cancer surgery were more likely to follow up with their primary care provider (40).

Survivorship/Post-treatment Follow-Up

There are consistent results across four studies (all moderate risk of bias) demonstrating that compared with usual care, alternate models of CNS or NP post-treatment follow-up care achieve equivalent patient health outcomes and improved patient satisfaction with care. Patient costs were lower and healthcare utilization was similar for telephone-based models of CNS or NP follow-up care. Increased numbers and the duration of consultations, and time to develop procedural experience may result in higher healthcare costs for CNS follow-up care. One study (49) (moderate risk of bias) found that the addition of a complementary NP role improved menopausal symptoms and sexual function, but not HRQL for breast cancer survivors.

Alternate Roles

Four studies compared usual care (mostly hospital-based follow-up by physicians) with alternate APN roles performing flexible cystoscopy for bladder cancer (48), providing telephone follow-up for patients with breast or colorectal cancer (50,51,53), or leading a multidisciplinary follow-up education program (52). Three studies involved CNSs (48,50,52) and one study involved a NP (53). CNS- or NP-led telephone follow-up was associated with improved patient satisfaction and achieved no difference in outcomes related to anxiety, psychological well-being, recurrence, and time to detect recurrence. There were no differences in HRQL, self-care, or sense of coherence for women treated for breast cancer who had telephone access to a CNS following education and referral to a traditional screening program, compared with those who received hospital follow-up (52).

In terms of health service utilization, consultation time was longer but there were no differences in hospitalization, numbers of tests, or contacts between scheduled appointments for CNS or NP telephone follow-up care for patients with breast or colorectal cancer (51,53). Patients receiving telephone follow-up also had lower travel and productivity costs. In one study, the combination of longer consultation times and a 20% increase in consultations, resulted in higher overall costs for CNS care (51). Increased patient referral for cystoscopy under general anaesthetic was also associated with higher costs for follow-up flexible

cystoscopies performed by CNSs (48). The number of patient referrals declined as the CNSs became more experienced in performing flexible cystoscopies, with no differences compared with physicians at one-year.

Complementary Roles

The addition of NP-led care to usual care for the management of menopausal symptoms for breast cancer survivors led to improved symptoms and sexual function, but had no impact on HRQL (49).

Palliative Care

The benefits of augmenting usual care with complementary CNS roles providing palliative care services are uncertain. There were inconsistent results for patient and health utilization outcomes for three studies (moderate, high risk of bias) evaluating complementary CNS roles providing proactive palliative care services for patients with advanced cancer in oncology settings (54,55) and coaching for cancer pain management (56). Patient education, problem solving, and self-care were a prominent focus of CNS interventions in all three studies. Two studies also provided ongoing follow-up with more intensive patient assessment, symptom management, and care coordination (54,55). The early introduction of CNS palliative care services did not lead to improved HRQL, symptoms, or mood but was associated with increased survival and fewer hospital admissions (54). The estimated differences in survival and hospitalization were imprecise but clinically important. Patients receiving CNS care were 24.6 times more likely to be alive at four months (OR, 24.6; 95% CI, 1.62 to 374.96) and had a 84% decrease in odds of being hospitalized (OR, 0.16; 95% CI, 0.04 to 0.59). In contrast, Bakitas et al. (55) found higher HRQL and less depression but no differences in symptom severity, survival, hospital days, or intensive care unit days for patients receiving CNS-delivered self-care program. Similarly, a CNS coaching intervention using motivational interview techniques also led to better HRQL and psychosocial well-being (reduced pain interference) but no improvement in pain attitudes or symptoms (pain relief, pain intensity) (56).

Nonspecific Phase of the Cancer Journey

Hardie et al. (57) evaluated the complementary role of the CNS for women with breast cancer receiving adjuvant or palliative treatment, or routine follow-up care. Patient satisfaction and perceived support in the CNS group were high. Differences in outcomes before and following the introduction of the CNS role cannot be interpreted because statistical analyses were not reported.

Systematic Review Strengths and Limitations

The strengths of this review include the comprehensiveness of the search strategy, the use of independent assessors and standardized quality assessment using the modified Cochrane Risk of Bias tool, the criteria and methods used to identify and determine consensus on study eligibility with respect to APN roles, and the audit to ensure accuracy and completeness of extracted data. Multiple attempts were made to contact authors to determine or confirm study eligibility related to APN. Despite these efforts, for eight studies, author confirmation could not be obtained. It is possible that with our rigorous methods to ensure inclusion of APN-only studies, some relevant studies have been excluded. Studies may also be missed from our review because of the variability in how APN roles are titled and how APN studies are catalogued in different databases. Given the research team's in-depth knowledge of oncology and the APN literature, we are confident the number of any excluded or missed studies, if any, is small and would not significantly impact on the review results. A

final limitation is that the quality of the evidence for each recommendation has not been assessed. The Cochrane *Handbook for Systematic Reviews of Interventions* recommends the use of GRADE (Grading of Recommendations, Assessment, and Evaluation) to provide a clear assessment of the strength of the recommendations for each outcome. In a recent systematic review of the cost-effectiveness of CNS and NP roles, application of GRADE often downgraded the strength of recommendations to low quality (71). Indirectness of evidence and imprecision were frequent reasons for downgrading the evidence. Similar downgrading of study recommendations might apply to this review, given the overlap of content fields and the similarity in findings and methodological limitations between this and the Donald et al. (71) review.

CONCLUSIONS

The overall quality of the evidence reported in this systematic review is poor (moderate to high risk of bias in all but one study with low risk of bias) and the results of individual studies must be interpreted with caution. However, the consistent pattern of results demonstrating reduced harms, improved or equivalent quality of care, and patient health outcomes for different types of APN roles across varied patient populations, geographic jurisdictions, and phases of cancer is compelling.

CONFLICT OF INTEREST

Information regarding conflict of interest declarations can be found at the end of Section 3.

ACKNOWLEDGEMENTS AND AUTHORSHIP

The APN Models of Care Guideline Development Group and the Working Group would like to thank the following individuals for their assistance in developing this report:

- Michelle Acorn, Melissa Brouwers, Mary Jane Esplen, Dr. Bill Evans, Sheila McNair, Hans Messersmith, Krista Rawson, Dr. Rebecca Wong, Patsy Yates for providing feedback on draft versions.
- Elizabeth Chan for conducting a data audit.
- Sara Miller for copyediting.
- Lindsay Yuille for providing feedback

A complete list of the members of the APN Models of Care Guideline Development Group and the Working Group, with their affiliations and conflict of interest information, is provided in Section 3, Appendix 1.

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Appendix 1. Literature search strategy.**MEDLINE**

1. exp Advanced Practice Nursing/
2. Advanced Practice Nursing.mp.
3. nurse practitioners.mp. or exp Nurse Practitioners/
4. nurse specialist.mp.
5. nurse consultant.mp.
6. nurse led.mp.
7. or/1-6
8. neoplasm.mp. or exp Neoplasms/
9. cancer.mp.
10. oncology.mp.
11. palliative care.mp. or exp Palliative Care/
12. hospice care.mp. or exp Hospice Care/
13. terminal care.mp. or exp Terminal Care/
14. or/8-13
15. 7 and 14
16. comment.pt.
17. letter.pt.
18. editorial.pt.
19. or/16-18
20. 15 not 19
21. limit 20 to english language
22. limit 21 to yr="1980 - 2012"

EMBASE

1. Advanced Practice Nursing.mp. or exp advanced practice nursing/
2. nurse practitioner.mp. or exp nurse practitioner/
3. advanced practice nurse.mp. or exp advanced practice nurse/
4. advanced practice nurs*.mp.
5. clinical nurse specialist.mp. or exp clinical nurse specialist/
6. nurse specialist*.mp.
7. nurse consultant.mp. or exp nurse consultant/
8. nurse led.mp.
9. nurse practitioner*.mp.
10. or/1-9
11. neoplasm.mp. or exp neoplasm/
12. cancer*.mp.
13. cancer.mp.
14. exp oncology/ or oncology.mp.
15. palliative care.mp.
16. terminal care.mp. or exp terminal care/
17. hospice care.mp. or exp hospice care/
18. or/11-17
19. 10 and 18
20. letter.pt.
21. editorial.pt.

22. conference abstract.pt.
23. or/20-22
24. 19 not 23
25. limit 24 to english language

HealthSTAR

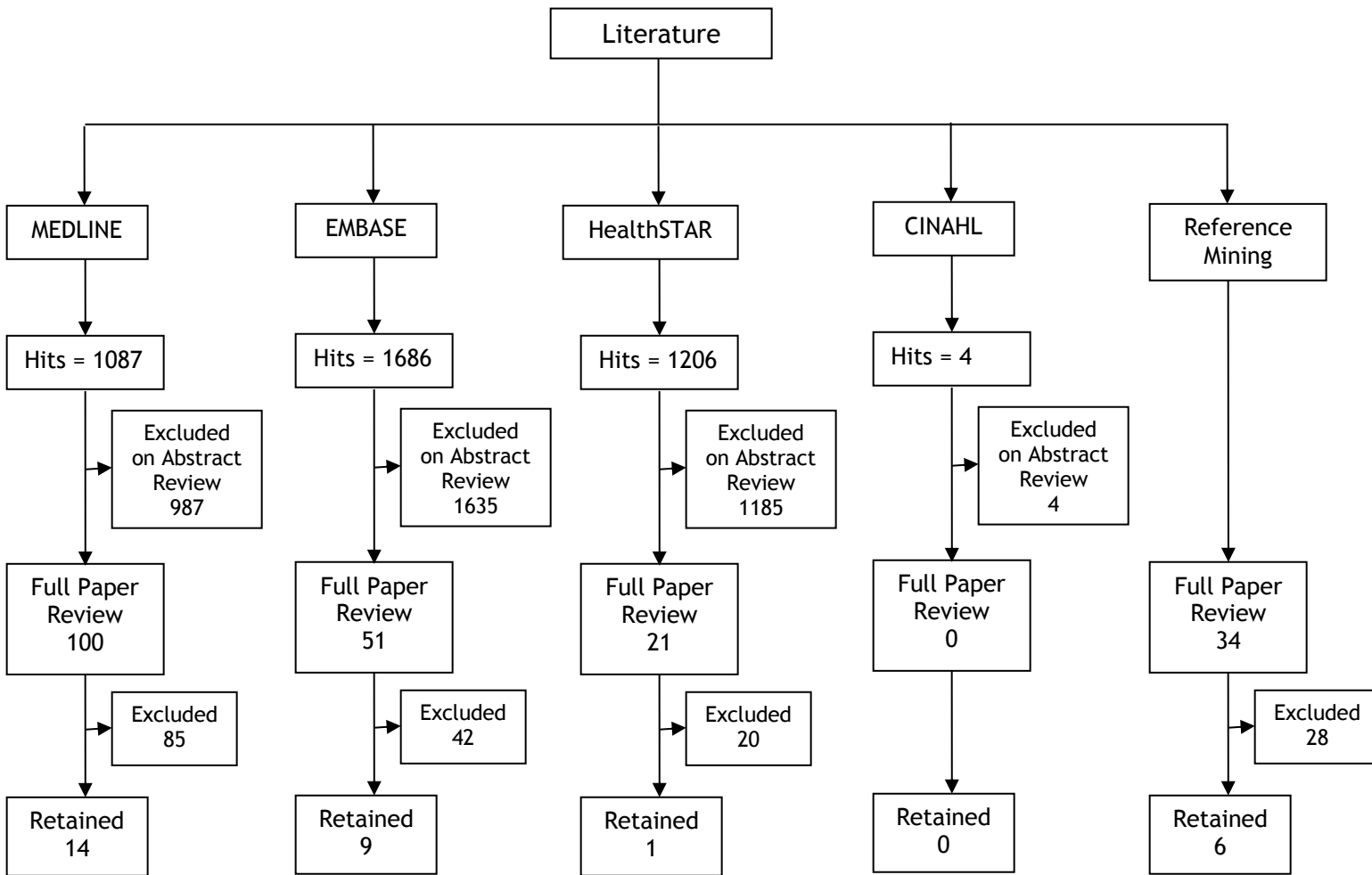
1. exp Nurse Practitioners/
2. nurse practitioner*.mp.
3. nurse specialist*.mp.
4. advanced practice nurs*.mp.
5. advanced nursing practice.mp.
6. nurse consultant*.mp.
7. nurse led.mp.
8. or/1-7
9. exp Neoplasms/
10. cancer*.mp.
11. oncology.mp.
12. palliative care.mp. or exp Palliative Care/
13. Hospice Care.mp. or exp Hospice Care/
14. Terminal Care.mp. or exp Terminal Care/
15. or/9-14
16. 8 and 15
17. comment.pt.
18. letter.pt.
19. editorial.pt.
20. or/17-19
21. 16 not 20
22. limit 21 to english language
23. limit 22 to yr="1980 - 2012"

CINAHL

- S1. MH "Advanced Practice Nurses+"
- S2. MH "Advanced Nursing Practice+"
- S3. MH "Clinical Nurse Specialist" or MH "Nurse Specialist Service"
- S4. S1 or S2 or S3
- S5. MH "Nurse Midwives"
- S6. S4 not S5
- S7. MH "Neoplasms+"
- S8. "cancer"
- S9. MH "Oncology+" or "oncology"
- S10. MH "Palliative Care"
- S11. MH "Hospice Care"
- S12. MH "Terminal Care"
- S13. S7 or S8 or S9 or S10 or S11 or S12
- S14. S6 and S13

With Limiters as follows: Published Date from 19820101-20121131; English Language;
Research Article; Exclude MEDLINE records; Evidence-Based Practice; Publication Type
Journal Article

Appendix 2. Literature search results flow diagram.



Evidence-Based Series 16-4: Section 3

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Effective Use of Advanced Practice Nurses in the Delivery of Adult Cancer Services in Ontario: Development Methods, Recommendations Development and External Review Process

*D. Bryant-Lukosius, R. Cosby, D. Bakker, C. Earle, B. Fitzgerald, V. Burkoski,
and the Advanced Practice Nursing Guideline Development Group*

Report Date: May 11, 2015

THE PROGRAM IN EVIDENCE-BASED CARE

The Program in Evidence-Based Care (PEBC) is an initiative of the Ontario provincial cancer system, Cancer Care Ontario (1). The PEBC mandate is to improve the lives of Ontarians affected by cancer through the development, dissemination, and evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer care.

The PEBC supports a network of disease-specific panels, termed Disease Site Groups, (DSGs), as well as other groups or panels called together for a specific topic, all mandated to develop the PEBC products. These panels are comprised of clinicians, other healthcare providers and decision makers, methodologists, and community representatives from across the province.

The PEBC produces evidence-based and evidence-informed guidelines, known as Evidence-based Series (EBS) reports, using the methods of the Practice Guidelines Development Cycle (1,2). The EBS report consists of an evidentiary base (typically a systematic review), an interpretation of and consensus agreement on that evidence by our Groups or Panels, the resulting recommendations, and an external review by Ontario clinicians and other stakeholders in the province for whom the topic is relevant. The PEBC has a formal standardized process to ensure the currency of each document, through the periodic review and evaluation of the scientific literature and, where appropriate, the integration of that literature with the original guideline information.

This EBS is comprised of the following sections:

- *Section 1: Guideline Recommendations.* Contains the clinical recommendations derived from a systematic review of the clinical and scientific literature and its interpretation by the Group or Panel involved and a formalized external review in Ontario by review participants.
- *Section 2: Evidentiary Base.* Presents the comprehensive evidentiary/systematic review of the clinical and scientific research on the topic and the conclusions reached by the Group or Panel.

- *Section 3: Development Methods, Recommendations Development, and External Review Process.* Summarizes the EBS development process, the recommendations development process, and the results of the formal external review of the draft version of the EBS.

FORMATION OF GUIDELINE DEVELOPMENT/WORKING GROUP

The Models of Care clinical program asked the PEBC to develop a guideline on the effective use of advanced practice nurses in the delivery of adult cancer care services in Ontario. In consultation with the Models of Care clinical program, a Working Group was identified by members of the clinical program. These experts were then invited to become members of the Working Group. This Working Group consisted of four nurses (one PhD who is a former oncology clinical nurse specialist [CNS] and current oncology nurse researcher and faculty; one PhD and current Professor Emerita; one previously practicing nurse practitioner [NP]-Primary Health Care; and one former oncology CNS in a Chief Nursing Executive position), one medical oncologist, and one methodologist (Section 3, Appendix 1). The Working Group in conjunction with members of the Models of Care clinical program then identified other experts who could provide feedback on the document when it was developed. These people were contacted and invited to join the Expert Panel (Section 3, Appendix 2). The Working Group and the Expert Panel formed the Advanced Practice Nursing Guideline Development Group. This group would take responsibility for providing feedback on the guideline as it was being developed and acted as Expert Panel for the document at Internal Review, reviewing the document and requiring changes as necessary before approving it.

OBJECTIVES AND RESEARCH QUESTIONS

This Working Group developed the following objective(s) for this guideline in consultation with the Models of Care clinical program.

- **OBJECTIVE 1** - To make evidence-based recommendations about the roles of advanced practice nurses (i.e., CNS, NP) for optimizing patient, provider, and health system outcomes across the cancer journey.

From these objectives, the following research questions were derived to direct the search for available evidence to inform recommendations to meet the objectives.

- **QUESTION 1** - For which patient populations and in which situations (types of needs, practice settings, phase of the cancer journey) have advanced practice nursing (APN) roles demonstrated equivalence or improved outcomes or reduced harms in appropriate controlled comparative studies of cancer care?
- **QUESTION 2** - What specific patient, provider, or health system outcome indicators are associated with CNS or NP roles?

EVIDENTIARY BASE DEVELOPMENT

Using the research questions described above, a search for existing systematic reviews and a systematic review of the primary literature was conducted, as described in Section 2 of this EBS.

INITIAL RECOMMENDATIONS

Using the evidentiary base in Section 2, the Working Group developed a set of initial recommendations. These initial recommendations were developed through a consideration of the aggregate evidence quality and the potential for bias in the evidence and the likely

benefits and harms of APN interventions in either alternate or complementary roles. The Working Group considered the values they used in weighing benefits compared with harms, and then made a considered judgement. This process is described in detail for each topic area described below.

Overall Aggregate Evidence Quality and Potential for Bias

This section describes the overall aggregate evidence quality and potential for bias for most of the recommendations; specifically, Recommendations 2 to 9, and 11. Information regarding the aggregate evidence quality and potential for bias for Recommendations 1, 10, 12, and 13 are provided separately in the sections that follow that cover these recommendations specifically.

There are few randomized controlled trials of APN roles in cancer control. There was moderate to high risk of bias across all studies designs for the identified studies with the exception of one study that had a low risk of bias (3,4). Poor reporting of advanced practice nurse (education, experience) and APN role characteristics (e.g., new versus established role) and role implementation issues (e.g., timing, frequency, and intensity of APN interventions; barriers to implementation) in many studies make it difficult to assess intervention fidelity, interpret results, and draw definitive conclusions about role outcomes. The results of some studies may not be readily generalizable to APN roles in other practice settings owing to inadequate descriptions of the APN role and the few number of advanced practice nurses (often only one advanced practice nurse) evaluated. Given the evidence that does exist, there is a consistent pattern of results demonstrating improved or no difference in quality of care and patient health outcomes for:

- NPs working in alternate provider roles for cancer screening (Recommendations 2 and 3)
- NPs working in alternate provider roles for colposcopy-guided cervical biopsies (Recommendation 4)
- Quality of care and patient health outcomes for CNSs working in alternate and complementary provider roles for outpatient cancer treatment (Recommendations 5 and 6)
- Quality of care and patient health outcomes for CNSs and NPs working in alternate provider roles in providing post-treatment follow-up care; specifically, delivering telephone follow-up as an alternate to outpatient clinic follow-up usually provided by physicians or with NP interventions for reducing menopausal symptoms in women following breast cancer treatment. There was no evidence supporting the use of advanced practice nurses in performing follow-up flexible cystoscopy for patients with bladder cancer (Recommendations 7 and 8)
- The addition of CNS care for most patient and health system outcomes. There were no reported harms (Recommendation 9)
- Quality of care and patient health outcomes for advanced practice nurses working in alternate and complementary provider roles for specific patient outcomes (Recommendation 11).

Overall Values of the Working Group

This section describes the overall values of the Working Group for most of the recommendations; specifically, Recommendations 2 to 9, and 11. Information regarding the values of the Working Group for Recommendations 1, 10, 12, and 13 are provided separately in the sections that follow that cover these recommendations specifically.

The Working Group considered the values of patient-centred care as well as the consistency of the evidence. The Working Group strongly believed that similar or improved outcomes or decreased harms with respect to quality of care and patient health outcomes for different APN roles across various patient populations and in various screening settings were important values to consider. Moreover, the value of the right care by the right provider and, thus, optimal use of expertise within the healthcare team was considered. These values in conjunction with values specific to each recommendation were combined and considered judgements were made in developing the recommendations for each topic area.

Values the Working Group considered during the development of specific recommendations included the following:

- NPs and registered nurses (RNs) are already authorized to perform certain screening tests (e.g., Papanicolaou [Pap] smears). Although provision of these services by alternate providers is a standard of care, it is currently an underutilized standard of care (Recommendations 2 and 3).
- The Working Group strongly believed that similar or improved outcomes or decreased harms were important to consider, with respect to:
 - quality of care and patient health outcomes, for APN roles in colposcopy-guided cervical biopsies (Recommendation 4).
 - quality of care and patient health outcomes, for APN roles in outpatient cancer treatment (Recommendations 5 and 6).
 - quality of care and patient health outcomes, for APN roles in providing telephone follow-up compared with outpatient clinic follow-up usually provided by physicians, and reducing menopausal symptoms in women following breast cancer treatment (Recommendations 7 and 8).
 - quality of care, and patient and health system outcomes, for APN roles in providing palliative care (Recommendation 9).
 - quality of care and patient health outcomes, for APN roles in improving patient-specific outcomes (Recommendation 11).

Overall Considered Judgement

This section describes the considered judgement of the Working Group for most of the recommendations; specifically, Recommendations 2 to 9, and 11. Information regarding the considered judgement of the Working Group for Recommendations 1, 10, 12, and 13 are provided separately in the sections that follow that cover these recommendations specifically.

The Working Group recognized that some may believe that the overall quality of the evidence would preclude the development of recommendations. However, the Working Group believed that the totality of the evidence and the consistency within that evidence warranted the development of recommendations. The benefits of the utilization of advanced practice nurses outweighed the harms in the case of:

- Cancer screening (there were no reported harms) (Recommendations 2 and 3)
- Cancer diagnosis with colposcopy-guided cervical biopsies (there were no reported harms) (Recommendation 4)

- Outpatient cancer treatment (there were very few reported harms) (Recommendations 5 and 6)
- Cancer post-treatment telephone follow-up delivered by advanced practice nurses rather than outpatient clinic follow-up usually provided by physicians, and the use of NPs for reducing menopausal symptoms in women following breast cancer treatment, (there were no reported harms) (Recommendations 7 and 8)
- The complementary provision of palliative care delivered by advanced practice nurses, (Recommendation 9)
- Several patient-specific outcomes (Recommendation 11)

Topic Area 1- Patient populations in which APN roles have demonstrated equivalence or improved outcomes or reduced harms with respect to cancer prevention.

Key Evidence for Benefits and Harms

No comparative studies about the effective use of advanced practice nurses related to the primary prevention of cancer were identified.

Aggregate Evidence Quality and Potential for Bias

There is no evidence regarding APN roles with respect to primary cancer prevention.

Values of the Working Group

As there was no evidence regarding APN roles with respect to primary cancer prevention, the Working Group did not believe it was appropriate to make any recommendations on this topic.

Considered Judgement

The Working Group made no recommendations owing to the lack of any evidence with respect to cancer prevention.

Initial (DRAFT) Recommendations

PREVENTION

RECOMMENDATION 1

No recommendations can be made about the utilization of APN roles for cancer prevention. Future research should: i) examine the broader international literature about the effectiveness of primary prevention strategies delivered by advanced practice nurses in the non-cancer literature that may be relevant to cancer; and ii) assess the need to optimize APN role involvement in cancer primary and secondary prevention services.

Qualifying Statements for Recommendation 1

- Up to 50% of cancers may be preventable (5). Increased emphasis on primary prevention may help to reduce the cancer burden.
- Relevant studies on the primary prevention of chronic diseases including cancer (e.g., health promotion/healthy lifestyle interventions related to diet, exercise, smoking cessation, alcohol use) may have been missed in this review because of the cancer-specific focus of the literature search strategies. The absence of research about APN roles in primary prevention has been noted in a non-cancer-specific systematic review of CNSs and NPs (6). Health promotion and illness prevention is an important aspect of NP roles in primary care, but research on these roles has focused on the management of episodic conditions, secondary prevention, and chronic disease management (6). Primary prevention services commonly take place in public health settings where few APNs roles have been implemented (7).
- People with a history of cancer may be at risk for developing a second cancer and other chronic conditions including cardiovascular disease, pulmonary disease, diabetes, and hypertension (8-10). Efforts to improve the long-term health of cancer survivors through secondary prevention strategies are required.

Topic Area 2 - Patient populations in which APN roles have demonstrated equivalence or improved outcomes or reduced harms with respect to cancer screening.

Key Evidence for Benefits and Harms

Several studies demonstrated the effective use of NPs working in alternate provider roles in breast and cervical screening as well as in the performance of esophagoscopy, flexible sigmoidoscopy, and colonoscopy for screening purposes. There were no reported harms.

SCREENING

RECOMMENDATION 2

In primary care and community-based settings, NPs working in alternate provider roles can be utilized to improve access breast and cervical cancer screening.

Qualifying Statements for Recommendation 2

- No studies compared RNs and NPs in performing Pap smears.
- In Canada, RNs (who have acquired competency through additional training) and NPs are authorized to perform Pap smears.
- Maximizing the efficient use of skill sets and the scope of practice of RNs, NPs, and other members of the healthcare team, should be taken into consideration when making decisions about who is the best provider for cervical screening.
- Quality of Pap smear is defined as the proportion of satisfactory smears and the proportion of smears with endocervical cells.

RECOMMENDATION 3

As alternate providers to physicians, NPs can provide safe and effective care in performing esophagoscopy, flexible sigmoidoscopy, and colonoscopy for cancer screening.

Qualifying Statements for Recommendation 3

- No studies were identified that compared RNs with NPs in performing flexible sigmoidoscopies.
- In Ontario, RN-performed flexible sigmoidoscopy is the standard of care in 14 sites across the province and has been found to be a safe and effective model of care (11). Based on the findings of this review, the advantages (if any) for introducing NPs as an alternate provider to RNs in performing flexible sigmoidoscopy are unknown. The need for NP-led flexible sigmoidoscopy is likely small, given perceptions that this role is adequately performed by RNs.
- In Ontario, the need to consider alternative provider roles, such as NPs, for the delivery of services such as esophagoscopy and colonoscopy for cancer screening has not been established.
- Schroy et al. (12) included patients who were at average risk for colon cancer and were referred because they were ≥ 50 years of age as well as at-risk patients who were ≥ 40 years of age and had a first-degree relative with any cancer.
- Wildi et al (13) included patients who were at risk for esophageal cancer and who had an indication for esophagoscopy.
- Limoges-Gonzalez et al. (14) included patients who were at average risk for colon cancer and were referred because they were ≥ 50 years of age.

Topic Area 3 - Patient populations in which APN roles have demonstrated equivalence or improved outcomes or reduced harms with respect to cancer diagnosis.

Key Evidence for Benefits and Harms

Several studies demonstrated the effective use of NPs working in alternate provider roles in performing colposcopy-guided cervical biopsies. There were no reported harms.

DIAGNOSIS

RECOMMENDATION 4

For women with cervical dysplasia, NPs are an appropriate alternate provider to physicians in performing colposcopy-guided biopsies to diagnose cervical cancer and may improve access to care, especially for women in underserved communities.

Topic Area 4 - Patient populations in which APN roles have demonstrated equivalence or improved outcomes or reduced harms with respect to cancer treatment.

Key Evidence for Benefits and Harms

Several studies demonstrated the effective use of CNSs working in alternate provider roles with respect to outpatient management for newly diagnosed patients undergoing surgery or radiation therapy. In addition, several studies demonstrated the effective use of CNSs working in complementary roles added to usual care with respect to the improvement of psychological and mental well-being and survival for newly diagnosed patients who are post cancer surgery or receiving chemotherapy or radiation therapy. There were very few reported harms compared with the many reported benefits.

TREATMENT

RECOMMENDATION 5

CNS-led care may provide a safe and acceptable alternate model to outpatient management provided by physicians, especially for newly diagnosed patients undergoing surgery or radiation therapy. The focus of care in this model is to address patient needs related to treatment decision making, self-care management, psychosocial support, assessment and management of treatment side effects and disease-related symptoms, and care coordination.

Qualifying Statements for Recommendation 5

- Patients with lung cancer who received oncology CNS care, were aged 18 to 89 years with newly diagnosed stage II or greater disease, recruited mostly from radiation treatment facilities, and not able to use public transportation on a routine basis without assistance (15). Participants in both intervention groups experienced progressive disease over the course of the study. The primary reason (30% of admissions) for hospitalization was to receive cancer treatment (chemotherapy). Advances in the treatment of lung cancer necessitate further evaluation of this model. Since 1989, when this study was published, the treatment for lung cancer has become more complex and associated with greater side effects (16,17). Patients are also less likely to be admitted to hospital for treatment and more likely to receive chemotherapy, often concurrently with radiation therapy, as an outpatient. The need for CNS-led care for patients receiving treatment for lung cancer may be even more relevant today.

- Lack of statistical power may account for findings of no difference in patient and health utilization outcomes between RN- and CNS-led home care (15).
- The study by Wells et al. (18) was not sufficiently powered to detect clinically important differences in health-related quality of life (HRQL).
- In general, CNS care involved a package of interventions or services that included comprehensive and holistic patient assessments, provision of information, development of patient self-care management skills, symptom management, psychosocial support, and care coordination with patient referral to other healthcare providers and services, including physicians as required (15,18-21). Patients also had on-demand access to the CNS as needed via telephone and ad hoc clinic appointments (18-21). The specific nature of CNS interventions must be tailored to each patient population and to individual patients. These interventions require a CNS with highly specialized oncology nursing expertise and experience and strong clinical reasoning and decision-making skills, who is comfortable working independently and yet collaboratively with other members of the healthcare team.
- It is not possible to make specific recommendations about the package of services that should be included in alternate models of CNS-led care for patients receiving cancer treatment, because of the small number of studies and variability of patient populations and needs examined. The development of CNS-led interventions requires careful assessment of unmet patient population health needs and integration of clinical practice guidelines for the assessment and management of specific disease and treatment-related symptoms and side effects.
- In some instances, CNSs provided medical care outside of their scope of practice such as communicating a diagnosis (20), discussing treatment options (20,21), and ordering diagnostics tests (19,20) or symptom-management medications (18-19). In these cases, CNSs used predetermined and physician agreed-upon protocols or medical directives (18-20) and had completed additional training (18,21).

RECOMMENDATION 6

The addition of complementary CNS care to usual care may improve psychological and mental well-being and survival for patients with a new diagnosis of cancer who are post cancer surgery or receiving chemotherapy or radiation treatment. Patients who may benefit the most from CNS care are unmarried women with breast cancer and those who have more intensive and complex healthcare needs related to psychological distress, older age, and advanced cancer. The addition of CNS care did not reduce or increase healthcare costs.

Qualifying Statements for Recommendation 6

- The primary goal of complementary CNS roles during the treatment phase was to improve HRQL and psychosocial well-being. The CNSs provided a package of interventions emphasizing patient self-care through education, provision of information and skill development; coping; symptom assessment and management; care coordination and referral to other supportive care providers and community services; and decision support.
- One CNS intervention included a computer-based program to assess and monitor patient health needs and the effectiveness of interventions (22).
- Most CNS interventions occurred over eight to 24 weeks, took place during scheduled weekly or alternate week and on-demand clinics, telephone or home visit appointments. Depending on patient need, appointments took 15 to 45 minutes. In one study, patients were followed for 24 months but patient need for CNS care was minimal after 12 months

(23). In another study, patients had access to a CNS seven days a week by telephone, but not for 24 hours each day (24).

- CNSs had extensive training to deliver the psychoeducational intervention (22) or had specialized knowledge and skills related to clinical decision making, symptom management, diagnostic and cancer treatment protocols, community resources, and negotiation (24).
- The studies by McCorkle et al. (3,24) and Ritz et al. (23) highlight the importance of careful patient assessment to determine subgroup populations who may benefit the most from CNS interventions, and also tailoring the intensity of interventions to match the needs of different at-risk patient populations.

Topic Area 5 - Patient populations in which APN roles have demonstrated equivalence or improved outcomes or reduced harms with respect to cancer survivorship/post-treatment follow-up care.

Key Evidence for Benefits and Harms

Several studies demonstrated the effective use of CNSs and NPs working in alternate provider roles in performing post-treatment follow-up care; specifically, telephone outpatient follow-up and NP interventions for reducing menopausal symptoms in women following breast cancer treatment. There were no reported harms.

SURVIVORSHIP/POST-TREATMENT FOLLOW-UP CARE

RECOMMENDATION 7

For patients with breast and colorectal cancer, CNS- or NP-delivered telephone follow-up may provide a safe and acceptable alternate model to outpatient clinic follow-up care provided mostly by physicians. CNS or NP telephone follow-up is suitable for patients at low to moderate risk for cancer recurrence and those wishing to avoid clinic visits due to long travel distance and/or mobility issues. Telephone follow-up care may reduce patient costs but not result in cost savings for cancer centres. Telephone follow-up may help to reduce clinic wait times for other patients with urgent healthcare needs by reducing clinic workload and freeing up appointment schedules.

Qualifying Statements for Recommendation 7

- Patients with breast cancer were at low to moderate risk of recurrence (25) or had stage I or II disease according to the Union for International Cancer Control (UICC) classification (26).
- Stage of disease or risk for recurrence was not reported for patients with colorectal cancer, but they were in remission post cancer treatment (surgery, chemotherapy, or radiation therapy) (25).
- There were few cancer recurrences in control or intervention groups (25,27).
- Standard post-treatment follow-up care for breast cancer was delivered in outpatient clinics and was most often provided by junior doctors (residents), but also by oncologists, CNSs, or a colorectal NP (25,27).

RECOMMENDATION 8

The addition of a complementary and comprehensive assessment and intervention program provided by a NP may be effective for reducing menopausal symptoms in women following treatment for breast cancer.

Qualifying Statements for Recommendation 9

- Study participants were female, and between eight months and five years following a diagnosis of stage I or II breast cancer. They had completed chemotherapy or radiation therapy at least four months prior to study participation, but could be taking tamoxifen (28).
- Study participants had at least one menopausal symptom (hot flashes, vaginal dryness, or stress urinary incontinence) of moderate to severe intensity (28).

Topic Area 6 - Patient populations in which APN roles have demonstrated equivalence or improved outcomes or reduced harms with respect to palliative care.

Key Evidence for Benefits and Harms

In one study, the early introduction of CNS palliative care services did not lead to improved HRQL, symptoms, or mood but was associated with increased survival and fewer hospital admissions (29). In contrast, Bakitas et al. (30) found higher HRQL and less depression but no differences in symptom severity, survival, hospital days, or intensive care unit days for patients receiving a CNS-delivered self-care program. Similarly, a CNS coaching intervention using motivational interview techniques also led to better HRQL and psychosocial well-being (reduced pain interference), but no improvement in pain attitudes or symptoms (pain relief, pain intensity) (31).

PALLIATIVE CARE**RECOMMENDATION 9**

The complementary addition of CNS care to cancer services may improve HRQL and mental and social well-being for patients with advanced cancer or cancer-related pain, while providing similar or improved outcomes related to healthcare utilization.

Topic Area 7 - Patient populations in which APN roles have demonstrated equivalence or improved outcomes or reduced harms with respect to cancer end-of-life care.

Key Evidence for Benefits and Harms

No studies evaluated the use of NPs working in alternate provider roles in cancer end-of-life care.

Aggregate Evidence Quality and Potential for Bias

There is no comparative evidence regarding APN roles with respect to cancer end-of-life care.

Values of the Working Group

As there was no evidence regarding APN roles with respect to end-of-life care, the Working Group did not believe it was appropriate to make any recommendations on this topic.

Considered Judgement

The Working Group made no recommendations owing to the lack of comparative evidence with respect to cancer end-of-life care.

END-OF-LIFE CARE

RECOMMENDATION 10

No evidence-based recommendations can be made about the utilization of APN roles for end-of-life care.

Topic Area 8 - Specific patient outcome indicators associated with APN roles.

Key Evidence for Benefits and Harms

Evidence demonstrated the effective use of NPs working in alternate provider roles resulting in equivalent or improved patient outcomes particularly related to satisfaction with care, breast and cervical screening rates, and quality of care. Other evidence demonstrated the effective use of NPs working in complementary provider roles resulting in improvement in outcomes related to symptoms, sexual functioning, and information needs. CNS interventions are most likely suited to equivalence or improvements with respect to symptoms and psychological well-being as well as HRQL, physical functioning, meeting informational needs, satisfaction with care, and survival.

RECOMMENDATION 11

For those involved in planning, implementing, and evaluating CNS and NP roles (e.g., healthcare administrators, researchers, and advanced practice nurses), careful selection of outcomes that are the target of specific CNS and NP interventions is required.

Topic Area 9 - Specific healthcare provider outcome indicators associated with APN roles.

Key Evidence for Benefits and Harms

No comparative studies regarding the effective use of advanced practice nurses for improving healthcare provider outcomes such as job satisfaction, workload, or team functioning were identified.

Aggregate Evidence Quality and Potential for Bias

There is no comparative evidence regarding APN roles for improving healthcare provider outcomes.

Values of the Working Group

As there was no evidence regarding specific provider outcome indicators associated with APN roles, the Working Group did not believe it was appropriate to make any recommendations on this topic.

Considered Judgement

The Working Group made no recommendations owing to the lack of comparative evidence with respect to improving healthcare provider outcomes.

RECOMMENDATION 12

No recommendations can be made about the effectiveness of CNS or NP roles for improving healthcare provider outcomes.

Topic Area 10 - Specific healthcare system outcome indicators associated with APN roles.

Key Evidence for Benefits and Harms

No studies regarding the effective use of advanced practice nurses for improving healthcare system outcomes were identified.

Aggregate Evidence Quality and Potential for Bias

There is no comparative evidence regarding APN roles for improving healthcare system outcomes (e.g., economic analyses).

Values of the Working Group

As there was no evidence regarding specific system outcome indicators associated with APN roles, the Working Group did not believe it was appropriate to make any recommendations on this topic.

Considered Judgement

The Working Group made no recommendations owing to the lack of evidence with respect to improving healthcare provider outcomes, specifically, economic analyses.

RECOMMENDATION 13

No recommendations can be made about the cost effectiveness of CNS or NP roles in cancer control.

INTERNAL REVIEW

Almost all PEBC documents undergo internal review. This review is conducted by the Expert Panel and the Report Approval Panel (RAP). The Working Group was responsible for incorporating the feedback and required changes of both of these panels, and both panels had to approve the document before it could be sent to External Review.

Expert Panel Review and Approval

The Advanced Practice Nursing Guideline Development Group acted as the Expert Panel for this document. The members of this group were required to submit conflict of interest declarations prior to reviewing the document. These declarations are described in Section 3 in the section labelled “Conflict of Interest” on page 92. The document must be approved by formal vote. To be approved, 75% of the Advanced Practice Nursing Guideline Development Group membership must cast a vote or abstain, and of those that voted, 75% must approve the document. At the time of the voting, the Advanced Practice Nursing Guideline Development Group members could suggest changes to the document, and possibly make their approval conditional on those changes. In those cases, the Working Group was responsible for considering the changes, and if those changes could be made without substantially altering the recommendations, the altered draft would not need to be resubmitted for approval again.

The Advanced Practice Nursing Guideline Development Group reviewed the document during September and October 2014. The document was distributed by email and comments were returned by email. During this review, the Advanced Practice Nursing Guideline Development Group provided the following key feedback.

- 1) Studies of NPs in primary care were not included in the document.
- 2) Policy recommendations should be included in the document or as a supplementary document.
- 3) With respect to managed care and complementary care there is no comparison of CNSs to RNs.
- 4) A suggestion that the definition of the NP role is too simplified in the introduction.
- 5) Add Directors of Interprofessional Practice to the list of intended users.
- 6) Indicate how many of the general class RNs are CNSs.
- 7) Some confusion regarding the meaning of the term ‘alternative role’.
- 8) Several small editorial and grammatical changes were suggested.

In response to this feedback, the Working Group made the following changes.

- 1) The role of NPs in primary care is beyond the scope of this project; therefore, no change was made.
- 2) Policy recommendations are beyond the scope of this project. However, this guidance document can be used by policy makers to develop such recommendations.
- 3) The Working Group believed it was important to look at the competencies of each type of provider. This will was included under Future Research in Section 1.
- 4) The Working Group added information regarding the NP competency framework.
- 5) Directors of Interpersonal Practice were added to the list of intended users.
- 6) It is unknown how many of the general class RNs are CNSs; therefore, no change was made.
- 7) ‘Alternative role’ was changed to ‘alternate role’.
- 8) Editorial and grammatical changes were made.

Of the nine members of the Advanced Practice Nursing Guideline Development Group, nine members cast votes by email and zero abstained, for a total of 100% response. Of those that cast votes, nine approved the document (100%).

Report Approval Panel Review and Approval

The purpose of the Report Approval Panel (RAP) review is to ensure the methodological rigour and quality of PEBC documents. The RAP consists of nine clinicians with broad experience in clinical research and guideline development, and the Director of the PEBC. For each document, three RAP members review the document; the Director and two others. RAP members must not have had any involvement in the development of the guideline prior to Internal Review. All three RAP members must approve the document, although they may do so conditionally. If there is a conditional approval, the Working Group is responsible for ensuring the necessary changes are made, with the Assistant Director of Quality and Methods, PEBC, making a final determination that the RAP's concerns have been addressed.

In September to November 2014, the RAP reviewed this document. The RAP approved the document. Key issues raised by the RAP included the following:

- 1) There is a lot of repetition in Section 3. Instead of having 'aggregate evidence quality and potential for bias', 'values of the Working Group' and 'considered judgement' sections for each topic area, construct an 'overall aggregate evidence quality and potential for bias', 'overall values of the Working Group' and 'overall considered judgement' sections.
- 2) Add in a statement in Section 1 that guides the reader as to the number of questions and how the evidence is organized.
- 3) A suggestion to shade the recommendation boxes in Section 1 to make the recommendations stand out better.
- 4) Add the outcomes of interest to Section 1.
- 5) Add more information to the definitions of NP and CNS in Section 1.
- 6) A suggestion that the term 'CNS-managed care' was confusing.
- 7) Reorder and group the statements about the factors that were taken into consideration in formulating the guideline recommendations in Section 1.
- 8) A suggestion to add a summary page to the beginning of Section 1 to highlight the recommendations.
- 9) Expand the search strategy so studies on smoking cessation will be accessed.
- 10) A suggestion to keep only the summary tables for Question 2 in Section 2.
- 11) Several small editorial changes were suggested.

The Working Group made the following changes in response to the RAP review:

- 1) The repetition in Section 3 was removed. An 'overall aggregate evidence quality and potential for bias', 'overall values of the Working Group' and 'overall considered judgement' section was generated instead.
- 2) Statements were added to Section 1 indicating that there were two questions and the evidence was structured by the phases of the cancer journey.
- 3) The recommendation boxes in Section 1 were shaded.
- 4) A list of the outcomes of interest was added to Section 1.
- 5) More information was added to the definitions of NP and CNS in Section 1.
- 6) The term 'CNS-managed care' was changed to 'CNS-led care'.
- 7) The statements about the factors that were taken into consideration in formulating the guideline recommendations in Section 1 were reordered and grouped.

- 8) A summary page was added to the beginning of Section 1 that highlights the recommendations.
- 9) The search strategy would have found smoking cessation studies by advanced practice nurses if such studies existed.
- 10) All of the individual tables by phase of the cancer journey were removed for Question 2 in Section 2. Only the summary tables were retained.
- 11) Suggested editorial changes were made.

External Review by Ontario Clinicians and Other Experts

The PEBC external review process is two-pronged and includes a targeted peer review that is intended to obtain direct feedback on the draft report from a small number of specified content experts and a professional consultation that is intended to facilitate dissemination of the final guidance report to Ontario practitioners.

Following approval of the document at Internal Review, the Advanced Practice Nursing Working Group circulated the draft document with recommendations modified as noted under Internal Review, above, to external review participants for review and feedback. Appendix 3 (Section 3) summarizes the draft recommendations and supporting evidence developed by the Advanced Practice Nursing Working Group as submitted for External Review.

Methods

Targeted Peer Review: During the guideline development process, seven targeted peer reviewers from Ontario, Alberta and Australia considered to be clinical and/or methodological experts on the topic were identified by the Working Group. Several weeks prior to completion of the draft report, the nominees were contacted by email and asked to serve as reviewers. Five reviewers agreed and the draft report and a questionnaire were sent via email for their review. The questionnaire consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a guideline. Written comments were invited. The questionnaire and draft document were sent out on February 18, 2015. Follow-up reminders were sent at two weeks (email) and at four weeks (telephone call). The Advance Practice Nursing Working Group reviewed the results of the survey.

Professional Consultation: Feedback was obtained through a brief online survey of health care professionals who are the intended users of the guideline. The Oncology Nursing Program at Cancer Care Ontario was able to provide us with a comprehensive list of professionals from Ontario to contact by email to inform them of the survey. These included healthcare administrators, nurses (APNs and RNs), those in nursing leadership roles, nurse educators, physicians including palliative care physicians, allied health professionals, directors of clinical programs, provincial program heads, clinical leads, patient and family advisors, models of care steering committee members and chief nursing executives. Participants were asked to rate the overall quality of the guideline (Section 1) and whether they would use and/or recommend it. Written comments were invited. Participants were contacted by email and directed to the survey website where they were provided with access to the survey, the guideline recommendations (Section 1) and the evidentiary base (Section 2). The notification email was sent on February 18, 2015. The consultation period ended on March 23, 2015. The Advance Practice Nursing Working Group reviewed the results of the survey.

Results

Targeted Peer Review: Four responses were received from five reviewers. Key results of the feedback survey are summarized in Table 1.

Table 1. Responses to nine items on the targeted peer reviewer questionnaire.

Question	Reviewer Ratings (N=4)				
	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the guideline development methods.				1	3
2. Rate the guideline presentation.				2	2
3. Rate the guideline recommendations.				1	3
4. Rate the completeness of reporting.				1	3
5. Does this document provide sufficient information to inform your decisions? If not, what areas are missing?				2	2
6. Rate the overall quality of the guideline report.					4
	Strongly Disagree (1)	(2)	Neutral (3)	(4)	Strongly Agree (5)
7. I would make use of this guideline in my professional decisions.					4
8. I would recommend this guideline for use in practice.					4

9. What are the barriers or enablers to the implementation of this guideline report?

Barriers stated included the funding issues to support alternate models, professional barrier to changes to scope of practice, the need for more CNSs and NPs in Canada, and the need for a champion for this model.

Enablers stated included the ministry and their urgent need to address capacity issues and gaps in care and access, and taking the document forward to administrators and professional practice leads in cancer across Canada to enlist their help.

Summary of Written Comments

The main points contained in the written comments along with the modification(s) made by the working group (*in italics*) were:

- i. A concern that it might be perceived that evidence demonstrating NP ability to do a task means a CNS cannot or vice versa. *On page 4 it was clarified that the guideline focuses only of the evidence specific to CNS and NP roles and does not include evidence for roles that could be provided by other healthcare professionals.*
- ii. A concern that Recommendation 5, taken on its own without looking at the Key Evidence, may be interpreted that newly diagnosed patients need not see a physician. *Recommendation 5 was reworded so that it was clear that it was related to outpatient supportive care only.*
- iii. A suggestion that the no recommendation statements be reworded so that it was clear that the lack of recommendation was owing to a current lack of data. *This modification was made.*

Professional Consultation: Fifty-four responses were received. Key results of the feedback survey are summarized in Table 2.

Table 2. Responses to four items on the professional consultation survey.

General Questions: Overall Guideline Assessment	Number (%)				
	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the overall quality of the guideline report.		1(2)	6(11)	28(52)	19(35)
	Strongly Disagree (1)	(2)	(3)	(4)	Strongly Agree (5)
2. I would make use of this guideline in my professional decisions.	2(4)	3(6)	8(15)	17(32)	23(43)
3. I would recommend this guideline for use in practice.	2(4)	2(4)	4(7)	19(35)	27(50)

4. What are the barriers or enablers to the implementation of this guideline report?

Barriers noted by respondents included the need for buy-in from institutions/organizations and/or senior leadership, length of the document and the difficulty in disseminating it, focussing on only one type of healthcare provider, expense of APNs in conjunction with the current funding models, cultural barriers within organizations to fully understand and embrace the role of CNSs and NPs, lack of cost-effectiveness data, weak data, larger expert panel was needed, resistance to changing historical practices, need to increase the pool of CNSs and NPs

Enablers noted by respondents included comprehensiveness of the document, the ability of document to be used to inform discussions about the role of CNSs and NPs, being able to use the evidence in the guideline to support decisions around the use of CNSs and NPs, methodological rigour used in the development of the guideline, wide distribution in order to facilitate the use of the guideline, using the guideline to drive the future research agenda, clear indications of how APNs can be used at the various stages of the cancer journey, and the success stories seen in the evidence collected,

Summary of Written Comments

The main points contained in the written comments along with the modification(s) made by the working group (*in italics*) were:

- i. A concern that the provision of care by other healthcare provides (e.g., physician assistants, RNs, etc.) were not included in the guideline. *The guideline was meant to focus on CNSs and NPs. All other healthcare providers were beyond the scope of this guideline.*
- ii. A concern that there was a lack of evidence in some stages of the cancer journey. *The Working Group shares this concern. Perhaps future research will fill this gap in knowledge.*

- iii. The need for wide dissemination of the guideline and guideline recommendations. *The Working Group agreed this is important; however, dissemination is beyond the prevue of the PEBC.*

CONCLUSION

This EBS report reflects the integration of feedback obtained through the external review process with final approval given by the Advance Practice Nursing Panel and the Report Approval Panel of the PEBC. Updates of the report will be conducted in accordance with the PEBC Document Assessment and Review Protocol.

CONFLICT OF INTEREST

In accordance with the PEBC Conflict of Interest (COI) Policy, the guideline authors, Advanced Practice Nursing Guideline Development Group members, and internal and external reviewers were asked to disclose potential conflicts of interest. All authors declared they had no conflicts of interest. For The Expert Panel, eight members declared they had no conflicts of interest. One expert panel member declared a conflict in that when she was president of the Nurse Practitioners' Association of Ontario she had been interviewed by a television news network regarding NP access to narcotics. Each of the three RAP reviewers declared no conflicts of interest. All Targeted Peer Reviewers declared no conflicts of interest.

The COI declared above did not disqualify any individuals from performed their designated role in the development of this guideline, in accordance with the PEBC COI Policy. To obtain a copy of the policy, please contact the PEBC office by email at ccopgi@mcmaster.ca.

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Appendix 1. Members of the Advance Practice Nursing Working Group Panel.

Member Name	Affiliation	Conflict of Interest Declaration
Denise Bryant-Lukosius, RN, CON(C) PhD, former oncology CNS (lead)	School of Nursing, McMaster University Dept. of Oncology McMaster University	No conflicts of interest.
Debra Bakker, RN, PhD, Professor Emerita	School of Nursing, Laurentian University	No conflicts of interest.
Vanessa Burkoski, RN, MScN, DHA, former NP	London Health Sciences Centre	No conflicts of interest.
Roxanne Cosby, BSc, MA	Cancer Care Ontario's Program in Evidence-based Care Dept. of Oncology, McMaster University	No conflicts of interest.
Craig Earle, MD	Medical Oncologist, Odette Cancer Centre	No conflicts of interest.
Barbara Fitzgerald, RN, MScN former oncology CNS	Chief of Interprofessional Practice, Juravinski Hospital and Cancer Centre	No conflicts of interest.

Appendix 2. Members of the Advance Practice Nursing Expert Panel.

Member Name	Affiliation	Conflict of Interest Declaration
Beth Cowper-Fung	Nurse Practitioner Georgina Nurse Practitioner Led Clinic	When president of Nurse Practitioners' Association of Ontario, interviewed by a television news network regarding NP access to narcotics.
Tannice Fletcher-Stackhouse	Nurse Practitioner NorWest Community Health Centre	No conflicts of interest.
Mark Hartman	Interim Regional Vice President, North East Regional Cancer Program	No conflicts of interest.
Cathy Kiteley	Clinical Nurse Specialist Trillium Health Partners, Credit Valley Site	No conflicts of interest.
Gail Macartney	Director, Nursing Research & Knowledge Translation Children's Hospital of Eastern Ontario	No conflicts of interest.
Maurene McQuestion	Clinical Nurse Specialist Princess Margaret Hospital Adjunct Lecturer Faculty of Nursing, University of Toronto	No conflicts of interest.
Ralph Meyer	President, Juravinski Hospital and Cancer Centre Regional Vice President, Cancer Care Ontario Professor, Dept of Oncology, McMaster University	No conflicts of interest.
Shari Moura	Clinical Nurse Specialist Princess Margaret Hospital	No conflicts of interest.
Janice Wright	Nurse Practitioner Hotel Dieu-Shaver Health & Rehabilitation Centre	No conflicts of interest.

Appendix 3. Recommendations submitted for external review.

DRAFT RECOMMENDATIONS (approved for external review February 12, 2015)

PREVENTION

RECOMMENDATION 1

No recommendations can be made about the utilization of APN roles for cancer prevention.

Future research should: i) examine the broader international literature about the effectiveness of primary prevention strategies delivered by advanced practice nurses in the non-cancer literature that may be relevant to cancer; and ii) assess the need to optimize APN role involvement in primary and secondary cancer prevention services.

Summary of Key Evidence for Recommendation 1

- No comparative studies about the effective use of advanced practice nurses related to the primary or secondary prevention of cancer were identified.

Justification for Recommendation 1

There is no evidence currently available on which to make a recommendation regarding the use of advanced practice nurses in cancer prevention.

Qualifying Statements for Recommendation 1

- The lack of research studies related to cancer prevention was a surprising finding given that health promotion and illness prevention are important aspects of APN and, in particular, NP roles in primary care (16-18).
- Relevant studies on the primary prevention of chronic diseases including cancer (e.g., health promotion/healthy lifestyle interventions related to diet, exercise, smoking cessation, alcohol use) may have been missed in this review because of the cancer-specific focus of the literature search strategies. The absence of research about APN roles in primary prevention has been noted in a non-cancer-specific systematic review of CNSs and NPs (14). Research on these roles has focused on the management of episodic conditions, secondary prevention and chronic disease management (14).
- People with a history of cancer may be at risk for developing a second cancer and other chronic conditions including cardiovascular disease, pulmonary disease, diabetes, and hypertension (19-21). Efforts to improve the long-term health of cancer survivors through secondary prevention strategies are required.

SCREENING

RECOMMENDATION 2

In primary care and community-based settings, NPs working in alternate provider roles can be utilized to improve access to breast and cervical cancer screening.

Summary of Key Evidence for Recommendation 2

- NPs providing same-day services in primary care clinics for underscreened patients had improved breast and cervical screening rates compared with physician chart reminders (22).
- Two studies demonstrated that the quality of Papanicolaou (Pap) smears conducted by NPs was not detectably different and, in some cases, was superior to physicians (23,24).

Justification for Recommendation 2

The evidence demonstrated consistent results with similar or improved patient outcomes, and no reported harms, with respect to breast and cervical cancer screening for NPs working in alternate provider roles.

Qualifying Statements for Recommendation 2

- No studies compared RNs and NPs in performing Pap smears.
- Quality of Pap smear is defined as the proportion of satisfactory smears and the proportion of smears with endocervical cells.

Additional Implementation Considerations

- In Canada, RNs (who have acquired competency through additional training) and NPs are authorized to perform Pap smears.

RECOMMENDATION 3

As alternate providers to physicians, NPs can provide safe and effective care in performing esophagoscopy, flexible sigmoidoscopy, and colonoscopy for cancer screening.

Summary of Key Evidence for Recommendation 3

- The sensitivity and specificity of NP-conducted sigmoidoscopy and esophagoscopy was found to be no different to that of physicians (25,26).
- Compared with physicians, NP-led colonoscopy was found to provide equivalent quality of care with respect to procedural pain, duration of the procedure and depth of insertion, and improved care related to patient satisfaction and detection of adenomas (27).

Justification for Recommendation 3

The evidence demonstrated consistent similar (i.e., no difference) or improved patient outcomes, with no reported harms, with respect to esophagoscopy, flexible sigmoidoscopy, and colonoscopy for cancer screening for NPs working in alternate provider roles.

Qualifying Statements for Recommendation 3

- The studies included patients at average risk for colorectal cancer and at above-average risk for colorectal cancer and esophageal cancer.

Additional Implementation Considerations

- In Ontario, RN-performed flexible sigmoidoscopy is standard care in 14 sites and has been found to be a safe and effective model of care (28). No studies were identified that compared RNs with NPs in performing flexible sigmoidoscopies.

DIAGNOSIS**RECOMMENDATION 4**

For women with cervical dysplasia, NPs are an appropriate alternate provider to physicians in performing colposcopy-guided biopsies to diagnose cervical cancer.

Summary of Key Evidence for Recommendation 4

- Two studies found the sensitivity and specificity of colposcopy-guided cervical biopsies conducted by NPs to be no different than those conducted by physicians (29,30). NPs were more likely to take two or more biopsies and this was associated with improved sensitivity (29). These results are based on randomized controlled trial and chart review data.
- One study found that compared with physicians, there was greater consistency between Pap smear and biopsy, less variability and greater consistency with standards of care, higher rates of patient follow-up, and better documentation by NPs.

Justification for Recommendation 4

The evidence demonstrated consistent similar (i.e., no difference) or improved patient outcomes, with no reported harms, with respect to colposcopy-guided biopsies to diagnose cervical cancer performed by NPs working in alternate provider roles.

Additional Implementation Considerations:

- NPs may be particularly effective at improving access to care for women with cervical dysplasia in underserved communities.

TREATMENT

RECOMMENDATION 5

CNS-led care is an appropriate alternative model to outpatient management provided by physicians, particularly for newly diagnosed patients undergoing surgery or radiation therapy.

Summary of Key Evidence for Recommendation 5

- CNS-led care was evaluated in five studies involving patients considering reconstructive surgery due to breast cancer (31), receiving homecare for lung cancer (32), undergoing radical prostatectomy for prostate cancer (33), and receiving radical radiation therapy for head and neck, bladder, or prostate cancer (34,35).
- CNS-led care is associated with similar or improved patient health outcomes and satisfaction with care including:
 - delay in symptoms and physical impairment for lung cancer patients
 - reduction in early urinary and gastrointestinal symptoms, less fatigue, and better physical functioning for patients receiving pelvic radiation
 - reduction in urinary symptoms, improved continence for prostate cancer patients
- Substitution of physician care with CNS management did not lead to unnecessary duplication of services for patients receiving radiation therapy.
- CNS-led care is not associated with reduced healthcare utilization (e.g., hospital length of stay, readmissions, and emergency department visits) but may lead to a reduction in diagnostic tests, prescriptions, and clinic visits.
- No studies of NPs related to the treatment phase of the cancer journey were identified.

Justification for Recommendation 5

Several studies demonstrated consistent reduced harms, or similar (i.e., no difference) or improved patient outcomes, with very few reporting negative outcomes with respect to patients undergoing surgery or radiation therapy for CNSs working in alternate provider roles. The benefits of CNS care exceeded the harms.

Qualifying Statements for Recommendation 5

- It is not possible to make recommendations about the specificity of interventions to be included in the package of services offered in alternate models of CNS-led care for patients receiving cancer treatment. Overall, the studies are small and heterogenous.

Additional Implementation Considerations

- In general, CNS care most commonly involved a package of interventions or services that included comprehensive and holistic patient assessments, provision of information, development of patient self-care management skills, symptom management, psychosocial support, and care coordination with patient referral to other healthcare providers and services, including physicians as required (31-35). Patients also had on-demand access to the CNS as needed via telephone and ad hoc clinic appointments (31,33-35).
- Developing CNS care interventions requires careful assessment of unmet patient population health needs and integration of clinical practice guidelines for the assessment and management of specific disease- and treatment-related symptoms and side effects.

- In some instances, CNSs provided medical care outside of their regulated scope of practice such as communicating a diagnosis (33), discussing treatment options (31,33), and ordering diagnostics tests (33,34) or symptom management medications (34,35). In these cases, CNSs used predetermined and physician agreed-upon protocols or medical directives (33-35), and had completed additional training (31,35).

RECOMMENDATION 6

The addition of complementary CNS care to usual care may improve psychological and mental well-being and survival for patients with a new diagnosis of cancer who are post cancer surgery or receiving chemotherapy or radiation treatment.

Summary of Key Evidence for Recommendation 6

- Complementary CNS care was evaluated in six studies for patients receiving chemotherapy and/or radiation therapy (36,37), undergoing radiation therapy alone (38,39), or who were post cancer surgery (40-42).
- The studies included patients with breast, gynecological, head and neck, gastrointestinal, lung, or urological cancers.
- The addition of CNS care to usual care did not improve HRQL for patients receiving radiation or chemotherapy (36-38), except for unmarried women with breast cancer who had improved HRQL and mood (37).
- There were no differences in symptom distress (42) or radiation treatment side effects for patients who did or did not receive CNS care (38,39).
- There were variable results related to psychosocial and mental health outcomes.
- One study evaluated the impact of CNS care on survival (42). There were no survival benefits for elderly patients post cancer surgery who had early stage solid tumour cancers. Patients with advanced stage cancer in the CNS group had improved survival at two years (67% versus 40%, confidence interval [CI], 1.33 to 3.12; $p=0.001$) due to fewer deaths from postoperative complications.
- The addition of CNS care to usual care did not lead to reduced health service use, but importantly, was also not associated with increased healthcare costs.

Justification for Recommendation 6

Several studies demonstrated consistent similar (i.e., no difference) or improved patient outcomes with respect to newly diagnosed cancer patients who were post cancer surgery or receiving chemotherapy or radiation therapy for CNSs working in complementary provider roles. The benefits of CNS care exceeded the harms.

Qualifying Statements for Recommendation 6

- No studies evaluated complementary NP roles.
- Patients who may benefit the most from CNS care are unmarried women with breast cancer, and those who have more intensive and complex healthcare needs related to psychological distress, older age, and advanced cancer.
- CNS care focused on the prevention, early detection, and management of health problems following patient discharge from hospital may have contributed to improved survival for patients with advanced stage cancer.

Additional Implementation Considerations

- CNS care involved a package of interventions emphasizing patient self-care through education, provision of information and skill development; coping; symptom assessment and management; care coordination and referral to other supportive care providers and community services; and decision support.
- Most CNS interventions occurred over eight to 24 weeks, took place during scheduled weekly or alternate week and on-demand clinics, telephone or home visit appointments. In one study, patients had access to a CNS seven days per week by telephone, but not for 24 hours each day (42).
- CNSs had extensive training to deliver psychoeducational interventions (36) or had specialized knowledge and skills related to clinical decision making, symptom management, diagnostic and cancer treatment protocols, community resources, and negotiation (42).
- The studies by McCorkle et al. (40,42) and Ritz et al. (37) highlight the importance of careful patient assessment to determine subgroup populations who may benefit the most from CNS interventions and also tailoring the intensity of interventions to match the needs of different at-risk patient populations.

SURVIVORSHIP/POST-TREATMENT FOLLOW-UP CARE

RECOMMENDATION 7

For patients with breast and colorectal cancer, CNS- or NP-delivered telephone follow-up may provide a safe and acceptable alternate model to outpatient clinic follow-up care provided mostly by physicians.

Summary of Key Evidence for Recommendation 7

- CNS- or NP-led telephone follow-up for patients with breast and colorectal cancer, respectively, was associated with improved patient satisfaction and achieved similar (i.e., no difference) outcomes including anxiety, psychological well-being, quality of life, self-care, recurrence, and time to detect recurrence (43-45).
- There were no differences in hospitalization, numbers of tests, or contacts between scheduled appointments for CNS or NP telephone follow-up care for patients with breast or colorectal cancer (43,46).
- In one study, the combination of longer consultation times and a 20% increase in consultations resulted in higher overall per patient costs for CNS care (mean difference £55, 95% CI, £26 to £77) (46). It is unclear whether these costs would generalize to the Ontario context.
- Patients receiving CNS telephone follow-up had lower travel and lost productivity costs (46).

Justification for Recommendation 7

The evidence demonstrated consistent similar (i.e., no difference) or improved patient outcomes with respect to follow-up care of low to moderate risk for cancer recurrence in breast or colorectal cancer patients for NPs and CNSs working in alternate provider roles. There were very few negative outcomes and the benefits of APN-delivered care exceeded the harms.

Qualifying Statements for Recommendation 7

- CNS or NP telephone follow-up is suitable for patients at low to moderate risk for cancer recurrence and those wishing to avoid clinic visits due to long travel distance and/or mobility issues (44,45).
- Standard post-treatment follow-up care for breast cancer was delivered in outpatient clinics and was most often provided by junior doctors (residents), but also by oncologists, CNSs, or a colorectal NP (43,44).

RECOMMENDATION 8

The addition of a complementary and comprehensive assessment and intervention program provided by a NP may be effective for reducing menopausal symptoms in women following treatment for breast cancer.

Summary of Key Evidence for Recommendation 8

- Women receiving the NP-led intervention had significant improvements in menopausal symptoms and sexual functioning compared with those in the attention control/usual care group (47). There were no significant differences in vitality.

Justification for Recommendation 8

The evidence consisted of one RCT that demonstrated decreased harms or similar (i.e., no difference) or improved patient outcomes, with no reported harms, with respect to menopausal symptoms in women following breast cancer treatment for NPs working in complementary provider roles.

Qualifying Statements for Recommendation 8

- Study participants were female, and between eight months and five years following a diagnosis of stage I or II breast cancer. They had completed chemotherapy or radiation therapy at least four months prior to study participation, but could be taking tamoxifen (47).
- Study participants had at least one menopausal symptom (hot flashes, vaginal dryness, or stress urinary incontinence) of moderate to severe intensity (47).

Note:

One study evaluated CNS-performed flexible cystoscopy for the follow-up care of patients with bladder cancer (48). Based on the results of this one study, there is insufficient evidence to make recommendations about the use of CNS or NPs as alternate providers to physicians in performing follow-up flexible cystoscopy for patients with bladder cancer.

PALLIATIVE CARE

RECOMMENDATION 9

The complementary addition of CNS care to cancer services may improve HRQL and mental and social well-being for patients with advanced cancer or cancer-related pain while providing similar or improved outcomes related to healthcare utilization.

Summary of Key Evidence for Recommendation 9

- Three studies evaluated very different models of complementary CNS care in providing proactive palliative care services for patients with advanced cancer in oncology settings (49,50) and coaching for cancer pain management (51).
- No studies evaluating NPs were identified.
- The early introduction of CNS palliative care services did not lead to improved HRQL, symptoms, or mood but was associated with increased survival and fewer hospital admissions (49).
- In contrast, Bakitas et al. (50) found higher HRQL and less depression but no differences in symptom severity, survival, hospital days, and intensive care unit days for patients receiving a CNS-delivered self-care program.
- Similarly, a CNS coaching intervention using motivational interview techniques also led to better HRQL, mood, and psychosocial well-being (reduced pain interference) but no improvement in pain attitudes or symptoms (pain relief, pain intensity) (51). Health service utilization outcomes were not evaluated in this study.

Justification for Recommendation 9

The addition of CNS care was similar to usual care for most patient and health system outcomes. No harms were reported for CNS care. In select studies, CNS care led to improved patient outcomes for survival, HRQL, mental well-being, and pain interference and improved health system outcomes related to reduced hospitalization.

END-OF-LIFE CARE

RECOMMENDATION 10

No evidence-based recommendations can be made about the utilization of APN roles for end-of-life care.

Summary of Key Evidence for Recommendation 10

- No comparative studies about the effective use of advanced practice nurses related to end-of-life care were identified.

Justification for Recommendation 10

There is insufficient evidence currently available on which to make a recommendation regarding the use of advanced practice nurses in cancer end-of-life care.

RESEARCH QUESTION #2

What specific patient, provider, or health system outcome indicators are associated with CNS or NP roles?

RECOMMENDATION 11

For those involved in planning, implementing, and evaluating CNS and NP roles (e.g., healthcare administrators, researchers, and advanced practice nurses), careful selection of outcomes that are the target of specific CNS and NP interventions is required.

Summary of Key Evidence for Recommendation 11

- In many studies included in this systematic review, there were findings of no differences between CNS or NP care and usual care for a variety of outcomes. It is possible, that the outcomes are, in fact, similar. Other factors noted in this review may also explain these results including poor intervention design and/or failure to select outcomes that are sensitive or responsive to CNS and NP interventions. The selection of outcomes should be driven by the type of CNS or NP intervention and the need or problem it aims to address.
- Patient outcomes evaluated in studies of CNS or NP roles include HRQL, pain and symptom management, mental health, physical function, performance status, self-care, information needs, satisfaction with care and survival (Table 9A). Of these, HRQL, symptoms, and mental health were the most frequently reported outcomes.
- Health systems outcomes evaluated in studies of CNS and NP roles related to indicators of care quality, healthcare costs, and health service utilization including hospital length of stay, hospital readmission, emergency department visits, number of advanced practice nurse consultations, and number of physician visits (Table 9B). Quality of care indicators were the most frequently reported outcome.

RECOMMENDATION 12

No recommendations can be made about the effectiveness of CNS or NP roles for improving healthcare provider outcomes.

Summary of Key Evidence for Recommendation 12

- No comparative studies about the effective use of advanced practice nurses for improving healthcare provider outcomes, such as job satisfaction, workload, or team functioning, were identified.

Justification for Recommendation 12

There is no evidence currently available on which to make a recommendation regarding the use of advanced practice nurses for improving healthcare provider outcomes.

RECOMMENDATION 13

No recommendations can be made about the cost-effectiveness of CNS or NP roles in cancer control.

Summary of Key Evidence for Recommendation 13

- No studies identified for this review conducted an economic analysis. In the few studies measuring costs, only a direct cost comparison is provided, rather than a comprehensive assessment of the incremental costs and benefits of APN care (37,46,48).
- One study reported on health utilization outcomes for NPs (43). There were no differences in the number of tests ordered but NPs had longer consultation times.
- Longer consultation times were also reported for CNSs (35,46).
- Overall, CNS outcomes related to healthcare utilization including hospital length of stay, hospital readmission, emergency department visits, consultations, physician visits, and tests and investigations were equivalent to standard care, and costs were either similar or reduced (Section 2, Table 11 and 9B).
- Increased costs may be associated with the time required for CNSs to develop cystoscopy skills and experience (48) with the increased number and length of CNS consultations (46).

Justification for Recommendation 13

There is insufficient evidence on which to make a recommendation regarding cost-effectiveness of advanced practice nurses in alternate or complementary provider roles in cancer control.