The minimum education and safety requirements for the nursing administration of cytotoxic drugs: an integrative review protocol

*** Elisabeth Coyne** • RN, MN Hons, PhD
Senior Lecturer, School of Nursing & Midwifery, Menzies Health Institute Queensland, Griffith University, QLD, Australia
Email: e.coyne@griffith.edu.au

Sarah Northfield • RN, BN, GradCert (Cancer Nursing)
Clinical Nurse (Research), Cancer Care Services, Royal Brisbane and Women's Hospital, Herston, QLD 4029, Australia

Kylie Ash • RN, MN
National Project Manager, School of Nursing, Queensland University of Technology, Kelvin Grove, QLD 4059, Australia

Leisa Brown-West • RN, BN, Cert Chemo Reconstruction, Grad Cert Onc, GDip AdVocEd, MN (Cancer Nursing)
Clinical Implementation Manager, ICON Integrated Cancer Centre, North Lakes, QLD 4509, Australia

Corrie Miles • EN
Ambulatory Oncology, Townsville Cancer Centre, Townsville Hospital, Douglas, QLD 4814, Australia

Karen Munton • RN
Clinical Practice Development Nurse, Day Oncology Unit, Sunshine Hospital, St Albans, VIC 3021, Australia

Catherine Barratt • RN
Staff Development Educator, WA Cancer & Palliative Care Network, System, Policy & Planning Division, Department of Health, East Perth, WA, 6004, Australia

* Corresponding author

Abstract

Background: This protocol describes the steps taken to develop an integrative review to identify current research on the minimum education and safety requirements for nurses to administer cytotoxic drugs. The review will provide evidence to underpin a Cancer Nurses Society of Australia (CNSA) position statement on the same topic.

Methods: An integrative review of literature will be conducted within the following databases: CINAHL, PubMed, the Cochrane Library and Embase. Methodological quality of the included studies will be assessed using the Mixed Methods Appraisal Tool.

Discussion: The completion of an integrative review will ensure CNSA takes a leadership role in the provision of evidence to inform cancer nurses about the minimum education and safety requirements when administering cytotoxic drugs in any setting.

Conclusion: A systematic approach to the development of a CNSA position statement will provide transparency on the supporting evidence. Gaps in the current literature will be identified, highlighting future directions for research.

Keywords: Safety, education, cytotoxic drugs, protocol.

Background

The Cancer Nurses Society of Australia (CNSA) aims to provide resources which support and contribute to cancer nursing practice. The CNSA has previously provided a position statement outlining the minimum education and safety requirements for nurses to administer cytotoxic drugs in any setting. To maintain the currency and rigour of this document, a literature review will be conducted using the current integrative review protocol. It is important for nurses to understand the minimum safety and education requirements when administering cytotoxic drugs and the evidence supporting these recommendations.

To ensure patient safety, nurses must receive appropriate education on cytotoxic drug administration. The Antineoplastic Drug Administration Course (ADAC) offered by EviQ[1] provides standardised education for the safe administration of antineoplastic drugs and handling of related waste via online modules, a skills workshop and competency assessments in the clinical setting. The evidence that informed the development of the ADAC modules, along with a systematic, integrative review will be used to update the CNSA position statement for the minimum education and safety requirements for the nursing administration of cytotoxic drugs.

It is important for the minimum standards to be based on current evidence and for the development of these standards to be replicable[2]. Specialist knowledge, competencies and skills are required by health care professionals to administer cytotoxic drugs[3]. Standards of practice provide guidelines for education and safety, to ensure nurses have the essential knowledge to administer cytotoxic drugs in a way which is safe for both the patient and the nurse[4]. Cytotoxic drugs are intended primarily for the treatment of cancer and have a highly toxic effect on cells[5]. In the context of this integrative review, "cytotoxic drugs" will refer to all chemotherapies except for targeted therapies, such as biotherapy agents or monoclonal antibodies.

Cancer nurses are required to have knowledge about the pathophysiology of cancer and mechanism of actions for cytotoxic drugs[2,6]. The nurse administering the cytotoxic drugs needs to have assessment skills to complete a situational assessment of the patient and the venous access point to ensure safe administration and prompt identification of adverse reactions[4]. The nurse should also be able to assess the patient and family across the domains of health, including physical and psychosocial, to ensure best patient and family outcomes during treatment and into survival[7,8]. A minimum education standard for nurses administering cytotoxic drugs provides clear guidelines to ensure nurses are equipped with the essential knowledge to administer drugs safely for their own safety and that of others.

The safe administration of cytotoxic drugs has been a contentious issue with differing practices across institutions and countries; however, a minimum standard provides a guideline for best evidence-based practice[4,9]. Detailed information about safe administration should include safe handling, accidental exposure and provision of patient and family safety education to ensure they have an understanding of side effects/toxicities and are able to make informed decisions and manage their own health care[10,11]. The complexity of cytotoxic drug administration increases the potential for errors. The variations of medications, administration routes and the co-morbidities of patients adds to the complexity which the cancer nurse must navigate to provide safe cytotoxic drug administration and reduce potential errors and negative outcomes for the patients[12]. The development of evidence-based, high-quality standards of practice work towards providing nurses with guidance to aim for best and safe practice for patients and nurses.

The purpose of developing a protocol ensures methodological decisions, search terms, data extraction and synthesis are considered, justified and replicable. This process improves the quality of the literature review and enables the final product to be based on current available evidence[13]. A well-developed protocol provides a baseline for future literature reviews, which in the case of a position statement will inform revisions and updates of the document to ensure it is based on current evidence[13].

Methods

The current integrative review protocol was developed by the project team who are members of the CNSA Education Committee. All research questions should be specific and well articulated to identify relevant research on the topic of interest[14]. One approach to construct a research question is the PICO format, which employs the following components: (P) the patient, population or problem being addressed; (I) the intervention or area of interest; (C) the comparison intervention (if applicable); (O) the outcomes of interest[14,15]. The project team worked collaboratively to develop search terms using the PIO format (population, interest, outcomes) (refer to Table 1). A review protocol enables consistency in the data extraction, critique and synthesis, reducing the ambiguity of staying focused on the research question. This review framework was developed to guide an integrative review across two key areas — minimum education and safety requirements for nursing administration of cytotoxic drugs. This review will inform the development of the 2018 CNSA position statement on the minimum standards for education and safety requirements for nursing administration of cytotoxic drugs in any clinical setting.

An integrative review design guided by the Whittemore, Knafl[16] framework will be used to explore qualitative, quantitative and mixed method, ensuring a comprehensive review of research. The Whittemore, Knafl[16] framework includes problem identification, literature search, data evaluation, data analysis and synthesis.

Problem identification

The research question was developed in the process of identifying the aims and focus of the new CNSA position statement. Education and safety requirements were combined in the research question after literature identified the connected nature of these key requirements when administering cytotoxic drugs[4]. A range of keywords were identified during the scoping and preliminary literature search phase. These were further refined during completion of the literature review, resulting in the following key terms, which provided a comprehensive review of literature exploring the minimum education and safety requirements for nurses to administer cytotoxic drugs.

Inclusion and exclusion criteria

The inclusion criteria for this integrative review will be peer-reviewed primary research published during 2006–2017 using quantitative, qualitative or mixed methods, which report research findings on *education and safety requirements for nursing administration of cytotoxic drugs in any setting* (refer to Table 2). Grey literature will be reviewed for best practice recommendations for nursing administration of cytotoxic drugs made by cancer-focused Australian and international health care professional societies/associations/organisations to inform the background of this review. Papers that describe nursing administration of targeted therapies, such as biotherapy agents

Table 1: PIO search terms — integrative review

Question component	Key term	Search synonyms	Final search synonyms
Population	Nurses registered with AHPRA	**Nurses** Nurs* "registered nurse" "enrolled nurse" "Oncology nursing" "Cancer care nursing" "Cancer nurs*"	**Nurses** "Nurs*"
Interest	Minimum safety and education requirements for the nursing administration of cytotoxic drugs	**Safety** "safe practice" "cytotoxic safety" "safe handling" "cytotoxic waste" "workplace health and safety" "occupational health and safety" "cytotoxic exposure" "cytotoxic-related waste" "occupational exposure" **Education** "training" "educat*" "competen*" "skill*" "standards of practice" "guidance" "preparation" "recommendations"	**Safety** "safe practice" "safe handling" **Education** "educat*" training "skill*" preparation recommendations
Outcome measures	Nursing administration of cytotoxic drugs	**Administration** "chemotherapy administration" "cytotoxic drug administration" "anti-neoplastic drug administration" "anti-cancer drug administration" **Cytotoxic drugs** Chemotherapy "Anti-cancer drug*" "anti-neoplastic drug*" Cytotox* "cancer medication" "anti-cancer medication" "cancer treatment" Mutagenic Carcinogenic Teratogenic Genotoxic	**Administration** Administration "chemotherapy administration" **Cytotoxic drugs** Chemotherapy "cancer treatment"

and monoclonal antibodies will be excluded. In addition, operational clinical guidelines and papers describing legislative requirements and registration requirements outside Australia will be excluded. Only research articles published in English, where full text-article is available will be included.

Table 2: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• English language only • Full-text article available • All patient diagnostic and age groups • All health care settings • Provides primary evidence supporting any education or safety requirement for the nursing administration of cytotoxic drugs by all routes • All study designs • Studies published in 2006 – June 2017 • Peer-reviewed primary research or grey literature articles, including quality improvement reports	• Papers that describe nursing administration of targeted therapies, such as biotherapy agents or monoclonal antibodies • Papers that provide operational clinical practice guidelines • Papers describing legislative requirements and registration requirements in settings outside Australia

Literature search

A comprehensive literature search will be conducted across the following databases: CINAHL with full-text EBSCO Nursing and Allied Health; PubMed (which includes Medline and Pre-Medline) Health Sciences; The Cochrane Library and Embase using a combination of key words and MeSH terms (Table 1). For each database, a specific search strategy will be developed. In PubMed, terms will be combined as MeSH and title/abstract, in EMBASE and PsycINFO as subject heading and keyword, in CINAHL as subject heading and title/abstract, in CENTRAL as MeSH and title/abstract/keyword, and in Web of Science as topic.

In addition to these electronic database searches, a grey literature search will be conducted (using Google) to identify relevant practice recommendations, key guidelines, position statements, educational resources, competency and professional standards related to nurse administration of antineoplastic drugs made by international and Australian cancer-focused health care professional societies/associations/organisations. Findings from the grey literature search will be used to inform the background section of the integrative review. After literature searches have been completed, reference lists of ADAC will be hand searched to identify any additional relevant papers. Hand searching the reference lists of relevant articles will also be performed, to ensure all articles that met the inclusion criteria are screened as part of the integrative review process. A spreadsheet will be developed to track the article retrieval process and direct uploading of included articles into an online EndNote Library© to maintain an up-to-date reference list.

Literature searches, screening of search results and articles will be completed across the selected databases and secondary searches completed from reference lists. Decisions on whether to include studies will be made based on the inclusion and exclusion criteria (Table 2). For journal articles where relevance cannot be determined by reviewing the title and abstract, the full article will be retrieved for further evaluation. Challenging decisions regarding the inclusion of an article will be resolved through discussion with the project team. All relevant primary quantitative, qualitative and mixed method studies will be included in the integrative review.

The position statement will be based on the best available evidence, using the hierarchy of evidence provided by the National Health and Medical Research Council (NHMRC). The position statement will be supplemented with references to expert opinion or secondary sources (that is to say, key guidelines, position statements, educational resources, competency and professional standards made by professional societies, associations or organisations). Relevant background articles identified during the search process will be saved separately from included studies for use during the synthesis phase.

Data evaluation

Whilst the importance of using critical appraisal tools to determine the quality of research is widely acknowledged, no "gold standard" tool for assessing the quality of quantitative, qualitative and mixed method research currently exists[17]. As the integrative review will include research from a diverse range of study designs, a critical appraisal tool that assesses a broad range of methodological issues was selected by the project team.

Data evaluation of quantitative, qualitative and mixed method research will be conducted using the Mixed Methods Appraisal Tool (MMAT) which consists of five scoring systems to evaluate the quality of the research studies. This quality appraisal assessment tool was developed from thematic analysis of quality appraisal procedures employed in 17 systematic mixed studies reviews[18]. The MMAT has been validated, pilot-tested and revised to determine separate scoring systems for qualitative, mixed method, randomised controlled, non-randomised and descriptive quantitative studies[17,18]. The MMAT was chosen as the framework to guide the quality assessment process for this integrative review as it provides a systematic, reproducible, descriptive and numerical method of simultaneously critiquing the quality of a diverse range of study designs[18].

The quality appraisal process enables scoring of quality of qualitative, mixed method and quantitative studies in relation to their methodological quality to address the research question. A minimum of two reviewers will independently assess all studies to be included in the integrative review using the MMAT[17]. Any discrepancies will be resolved by consensus or by employing a third independent reviewer. Each reviewer will provide a score

of yes (1), no (0), or not applicable for each of the four listed criteria. The score for all four methodological quality criteria for each domain will be tallied to provide the overall assessment score for each research article[17]. The overall quality appraisal score for each article can be presented numerically or using descriptors, as outlined in the MMAT tutorial[18]. Papers that receive an average score of 75% (quality appraisal score range: 0–100%) will be considered high quality. The relative quality of all included studies will be reported in the integrative review.

Data analysis and synthesis

Data extraction will be completed using the Matrix Method© to enhance the rigour of this stage of the review[19]. This data-extraction method provides a clear framework to systematically extract relevant data from each of the included studies and populate each section of the review matrix. The included studies will be summarised in tabular form and then quality appraised to aid data synthesis. Data from the studies were extracted relating to the research approach, context, sample and key findings. The table headings will include: author (year, country); design; sample; intervention; measures; main findings; limitations; and MMAT score.

To date, integrative review methods for data analysis and synthesis have been poorly articulated and infrequently applied[16]. Consequently, this creates several challenges when combining and synthesising data from a wide range of research designs[16]. Writing an integrative review without a synthesis framework (based on systematic methods) increases the likelihood of error and bias influencing the findings of the review[16]. Thus, the data analysis and synthesis framework plays an integral role, by providing guidance to the author during one of the most difficult aspects of the review — the synthesis of qualitative, quantitative and mixed methods research findings[16]. Ultimately, the chosen synthesis framework should aim to enhance the rigour and accuracy of reporting, as well as reduce bias in the presentation of findings[16]. Once the included studies have been identified, the project team will be able to consider the study designs and select the most suitable synthesis framework.

Ethical considerations

The proposed review will critique and summarise the findings of primary research studies relevant to the topic of interest. Thus, there are no ethical issues of concern.

Discussion

This protocol presents the steps that will be taken to conduct an integrative review of literature, exploring the minimum education and safety requirements for nursing administration of cytotoxic drugs in any setting. The completed review and analysis will inform the development of the CNSA position statement. As the leading organisation for cancer nurses in Australia, CNSA aims to inform nurses about the evidence supporting safety and education requirements for administering cytotoxic drugs, as well as the negative consequences of unsafe practice. The CNSA position statement will be an evidence-based educational resource that outlines the minimum education and safety requirements for nursing administration of cytotoxic drugs. The position statement will also act as an important reference document for health care organisations, providing a summary of current evidence to inform policies and procedures and the provision of a safe workplace environment when administering cytotoxic drugs in any clinical setting. Nurse managers and educators may also use the position statement to guide or update their educational curriculum, ensuring the minimum educational and safety requirements for nursing administration of cytotoxic drugs are met.

The completion of this integrative review of literature will provide current evidence to enable CNSA to achieve its strategic goals of developing and disseminating resources which contribute to advances in cancer nursing practice. The completed body of work (including an integrative review protocol, literature review and position statement) will ensure CNSA takes a leadership role in the provision of evidence to inform cancer nurses about the minimum education and safety requirements when administering cytotoxic drugs in any setting. It is anticipated that this review will identify knowledge gaps in the current literature on this topic and provide direction for future research in this area.

Limitations

There were several limitations for the current review process. The lack of clarity as to the best term to use when referring to drugs administered primarily for the treatment of cancer and have a highly toxic effect on cells, influenced the choice of key words. Both "chemotherapy" and "cytotoxic drug" were used as key terms; however, chemotherapy was the most commonly used term within current studies. The terms for "nurse", "cancer" or "oncology nurse" were used within all articles where the keyword "nurse" was used, providing a clear rationale to refine the list of search terms. The inclusion of different study methodologies enabled a range of research to be explored; however, there was a lack of high-level quantitative research.

Conclusion

This integrative review protocol provides a systematic approach to guide the development of an evidence-based CNSA position statement on the minimum safety and education requirements for the nursing administration of cytotoxic drugs. This protocol will ensure future updates of this document employ a consistent process to provide nurses with up-to-date, evidence-based information over time.

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