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Information requirements for a PBS electronic Chemotherapy Medication chart – A literature scan

Final Report

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Abbreviations

ADR	Adverse drug reaction
ASCO	American Society of Clinical Oncology
ASHP	American Society of Health-System Pharmacists
BSA	Body surface area
CDS	Clinical decision support
COSA	Clinical Oncology Society of Australia
CPOE	Computerised provider order entry
eCMC	Electronic chemotherapy medication chart
EHR	Electronic health record
EMR	Electronic medical record
ePBS HMC	Electronic pharmaceutical benefits scheme hospital medication chart
ID	Identification
ONS	Oncology Nursing Society
PBS	Pharmaceutical benefits scheme

Executive summary

Context

The work described here comprises an environmental scan and literature review to support development of the information requirements on the Pharmaceutical Benefits Scheme (PBS) electronic Chemotherapy Medication Chart (eCMC) and provide clarity around key safety and quality issues shaping contemporary chemotherapy medication management in Australian hospitals.

Project aims

1. Identify and describe any safety and quality gaps that have been documented around chemotherapy medication management (in particular prescribing, dispensing and administration processes) and the mitigating workflows that have been put in place to address these gaps.
2. Identify and describe any aspects of chemotherapy medication management documentation that have been recommended to support safety and quality and best practice.
3. Identify and summarise the legislative and policy requirements that support chemotherapy medication management documentation within each Australian state and territory.

Method

A search strategy was developed by the authors to capture the three concepts of interest (chemotherapy, medication management, and safety and quality). Databases Medline, EMBASE and PubMed were searched on 14 November 2020. We included English papers published from 2015 and excluded conference papers, commentaries and editorials. To find legislation, policies and/or guidelines related to chemotherapy medication management documentation, a grey literature search was completed in OpenGrey and relevant government websites.

Findings

Safety and quality gaps around chemotherapy medication management

We identified two review papers and 14 original papers that focused on safety and quality gaps in chemotherapy medication management. The most frequent safety risk reported in papers was medication errors, in particular, **prescribing errors**, occurring in up to **25% of chemotherapy orders**.[1] Voluntary incident reports and pharmacy intervention studies reveal chemotherapy medication errors occur at a rate of **3-4 errors per 1000 orders in paper-based sites and 1.5-2 errors per 1000 orders in settings with computerised provider order entry (CPOE)**.[2] Chart review studies also show that 5-10% of inpatients experience an adverse event as a result of chemotherapy medication errors.[2] In both settings using paper-

based chemotherapy charts and settings using electronic chemotherapy charts, **wrong dose** was the most frequently occurring error type.

We identified only one Australian study on safety and quality gaps in chemotherapy medication management. This paper focused specifically on the role that CPOE plays in potentially facilitating medication errors and risks in oncology.[3] In an analysis of incident reports in a children's cancer centre in Australia, a number of oncology-specific incident types were identified including protocol-related errors, errors related to coordination, verification and activation of chemotherapy. Use of CPOE was also determined to be a factor in approximately 50% of incidents.[3] The authors identified technical issues with the CPOE (e.g. ceased medications remaining on activation screens), user experience with the CPOE (e.g. the need to scroll through a plan to determine where a patient is up to), unanticipated problems with CPOE workflow (e.g. medications becoming automatically overdue if not ceased when a patient is transferred from another location), and missing CPOE safety features (e.g. decision support alerts) as factors contributing to errors.[3] Lessons learnt from incident reports were incorporated into CPOE training so that users are aware of CPOE automatic behaviours and downstream consequences of their actions on other CPOE users.

Mitigating workflows to address safety and quality gaps around chemotherapy medication management

We identified six review papers and 21 original papers that focused on strategies or interventions to address quality and safety gaps around chemotherapy medication management. Thirteen papers described or evaluated computerised interventions and the remaining eight papers described or evaluated non-computerised strategies, typically intervention bundles.

The most frequently studied computerised intervention was **CPOE or electronic health records**. Four review papers focused on CPOE or computerised decision support (CDS) for oncology,[4-7] with three summarising evidence on the impact of CPOE and CDS on medication safety, patient outcomes or the chemotherapy process.[4,5,7] The fourth CPOE-focused review identified and classified the specifications of CPOE and CDS for cancer patients.[6]

Two original papers described the process of implementing a CPOE system for chemotherapy,[8,9] and four papers described evaluations of chemotherapy CPOE/electronic medical records (EMRs), including impact on safety and work.[10-13] Two papers also evaluated computerised interventions as part of multi-intervention bundles.[14,15]

Overall, implementation of CPOE or EMR was shown to reduce medication errors[8,13] improve error detection,[10] and result in a greater number of pharmacy interventions.[10] One study found no change in the number or types of incident reports submitted before and after implementation of an EMR.[11] The three systematic reviews were consistent in their conclusion, all concluding that **CPOE with CDS can result in significant reductions in chemotherapy prescribing errors, most markedly in dose errors.**[4,5,7] However the authors also noted that this conclusion is based on small-scale studies with short follow-up periods and highlighted a

need for further work on the impact of systems on safety and quality, particularly patient outcomes.[4,5]

Although there was some variability in the computerised interventions described and evaluated in papers, there were some key components or design elements that frequently featured in technology to support chemotherapy medication management. For example, **order sets or templates** were often used to minimise prescribing errors and ensure chemotherapy orders were complete. To mitigate dosing errors, **automatic dose calculations and adjustments** were a common form of computerised decision support, as were **computerised alerts.** To facilitate review and verification of chemotherapy by pharmacists and nurses, many systems also included a **verification tool**.

The two most common non-computerised strategies described in papers to address quality and safety gaps around chemotherapy medication management were the use of **paper-based standardised chemotherapy order forms**, and **education or training for clinicians**.

Aspects of chemotherapy medication management documentation recommended to support safety and quality and best practice

We identified five papers that described or evaluated aspects of chemotherapy medication management documentation. In all papers, an intervention bundle (e.g. education and a guideline) was implemented to improve documentation of chemotherapy medication management.[16-19] Many aspects of chemotherapy medication management documentation were described in the five papers including **patient information (e.g. allergies, diagnosis), medication information, and patient instructions and informed consent.**

We identified six guidelines from our grey literature search that provided consensus-based recommendations for chemotherapy medication management documentation. Collectively they recommend **over 35 elements be documented** to support safety, quality and best practice in chemotherapy medication management.

Legislative and policy requirements that support chemotherapy medication management documentation within each Australian state and territory

There appear to be limited legislative requirements specific to chemotherapy medication management documentation across Australian states and territories, however, chemotherapeutic agents are high risk medicines and as such, their management should adhere to best practice standards for other high risk drugs.

Project context and scope

The Australian Commission on Safety and Quality in Health Care (the Commission) was established to contribute to improved health outcomes and experiences for all patients and consumers, and improved value and sustainability in the health system by leading and coordinating national improvements in the safety and quality of health care.

The Commission has been engaged by the Australian Commonwealth Government Department of Health (the Department) to develop information requirements for a Pharmaceutical Benefits Scheme (PBS) electronic Chemotherapy Medication Chart (eCMC). This work follows on from the development of the electronic Pharmaceutical Benefits Scheme Hospital Medication Chart (ePBS HMC) which allows hospital services to electronically prescribe, dispense and claim PBS items using electronic medication management systems, instead of using paper-based prescriptions.

The work described here comprises an environmental scan and literature review to support development of the information requirements on the PBS eCMC and provide clarity around key safety and quality issues shaping contemporary chemotherapy medication management in Australian hospitals.

Project aims

The environmental and literature scan aimed to:

1. Identify and describe any safety and quality gaps that have been documented around chemotherapy medication management (in particular prescribing, dispensing and administration processes) and the mitigating workflows that have been put in place to address these gaps
2. Identify and describe any aspects of chemotherapy medication management documentation that have been recommended to support safety and quality and best practice.
3. Identify and summarise the legislative and policy requirements that support chemotherapy medication management documentation within each Australian state and territory.

Method

Information sources and search strategy

A search strategy was developed by the authors to capture the three concepts of interest (chemotherapy, medication management, and safety and quality). Databases Medline, EMBASE and PubMed were searched on 14 November 2020. Database search terms are provided in Appendix 1.

To find legislation, policies and/or guidelines related to chemotherapy medication management documentation, a grey literature search of OpenGrey and the websites in Table 1 was completed, using the terms chemotherapy and antineoplastic.

Table 1. Websites searched for legislation, policies and/or guidelines related to chemotherapy medication management documentation.

Organisation	URL
American Society of Clinical Oncology/Oncology Nursing Society	https://www.asco.org
Association of Cancer Physicians (United Kingdom)	https://www.theacp.org.uk/
The Clinical Oncological Society of Australia (COSA)	www.cosa.org.au
The Australian Commission on Safety and Quality in Health Care	https://www.safetyandquality.gov.au
Government of South Australia: SA Health	https://www.sahealth.sa.gov.au/
Government of Western Australia: Department of Health	https://ww2.health.wa.gov.au/Home
New South Wales Government: Clinical excellence commission	https://www.cec.health.nsw.gov.au
New South Wales Government: eviQ	https://www.eviq.org.au
New South Wales Government: Ministry of Health	https://www.health.nsw.gov.au/

Australian government: Federal register of legislation	www.legislation.gov.au
New South Wales Government: Agency for clinical innovation	https://aci.health.nsw.gov.au
Open Grey	http://www.opengrey.eu
Queensland Health	www.health.qld.gov.au
Tasmanian Government: Department of health	https://www.health.tas.gov.au
Cancer Australia	https://www.canceraustralia.gov.au
Northern Territory Government: Department of Health	https://health.nt.gov.au
Australian Capital Territory Government: Health	https://health.act.gov.au
Victorian State Government: The Department of Health and Human Services	https://www.dhhs.vic.gov.au
New South Wales legislation	https://www.legislation.nsw.gov.au
Queensland legislation	https://www.legislation.qld.gov.au
South Australia legislation	https://www.legislation.sa.gov.au
Tasmanian legislation	https://www.legislation.tas.gov.au
Victorian legislation	https://www.legislation.vic.gov.au
Western Australia legislation	https://www.legislation.wa.gov.au
Northern territory	https://legislation.nt.gov.au
Australian Capital Territory	https://www.legislation.act.gov.au

Eligibility criteria

We included English papers published from 2015 that reported safety and quality gaps and/or mitigating workflows related to chemotherapy medication management, papers related to legislative and policy requirements, and papers reporting aspects of chemotherapy medication management documentation. Both reviews and primary studies were included.

We excluded:

- Conference abstracts, commentaries or editorials
- Papers that reported outcomes not related to safety and quality gaps and/or mitigating workflows (e.g. efficiency, time to treatment, cost, patient adherence, counselling, quality of life and patient reported outcome measures)
- Papers that focussed on chemotherapy manufacturing, compounding or preparation, and no other aspect of chemotherapy medication management.

Study selection

The study selection process is depicted in Figure 1. Covidence[20] was used to manage screening results from Medline, EMBASE and PubMed. Papers were imported into Covidence[20] and duplicates were removed, resulting in 10,779 papers for screening. All titles and abstracts were screened by at least one researcher, with 167 'possible' included papers screened by a second researcher prior to full-text review. This resulted in 77 full-text papers being reviewed. Full-text papers were reviewed by one researcher with any difficult or unclear papers reviewed by and discussed with a second researcher.

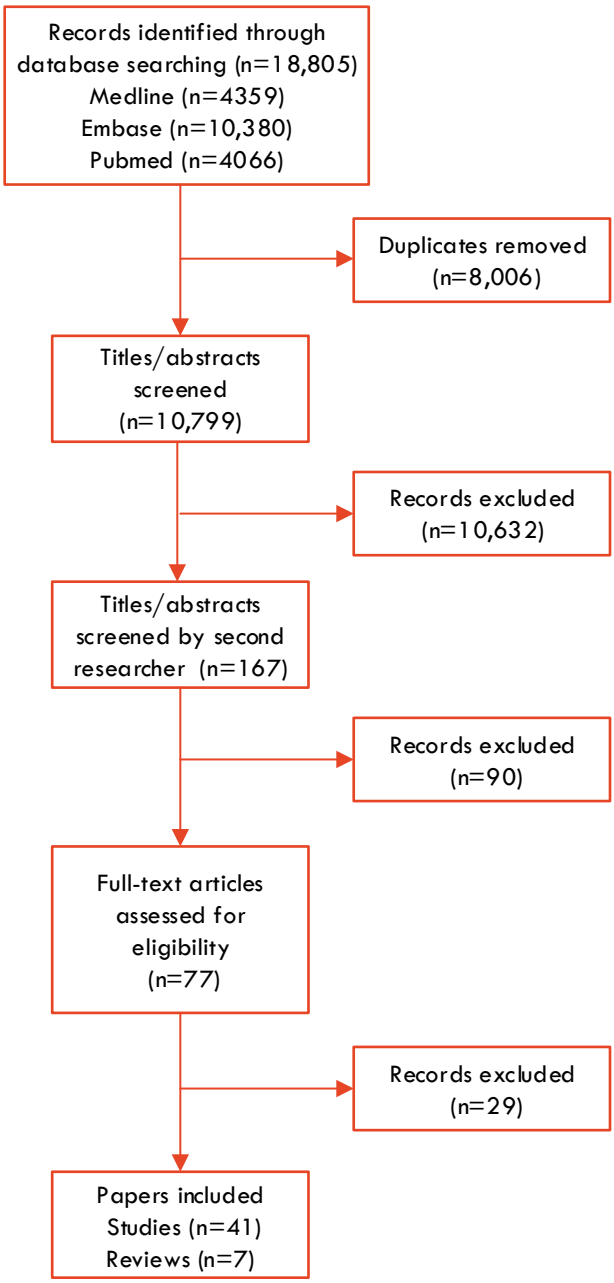

Figure 1. Study selection process

Data extraction

Seven review papers, 41 studies, six guidelines and five legislation/policy documents were included for data extraction. Review papers and studies were read in full and key features of papers, including country of origin, setting, aim, method and main findings were extracted and summarised in tables (see Appendices). All safety and quality gaps, mitigating workflows or strategies, and key aspects of chemotherapy medication management documentation were extracted from papers and summarised in tables. For computerised interventions, design

requirements or features to address safety and quality gaps around chemotherapy medication management were also extracted and tabled.

Guidelines, policies and legislation were read in full and aspects related to chemotherapy medication management documentation were extracted and summarised in a table.

Findings

Safety and quality gaps around chemotherapy medication management

We identified two review papers that focused on safety and quality gaps in chemotherapy medication management. In a systematic review that aimed to determine the frequency of chemotherapy errors among cancer patients, the authors identified 11 studies that quantified the rate of errors during prescribing, preparation, dispensing and administration.[1] Prescription errors were most frequent, occurring in up to 25% of orders. Rates of preparation, dispensing and administration were reported to be low, occurring in less than 1% of prescriptions and patient days.[1]

The review's aim was to determine the frequency of errors at each medication management stage, and no results were included on types of errors or factors contributing to errors. This review also did not differentiate between studies where paper charts were in use and sites where a computerised provider order entry (CPOE) system was in place for chemotherapy management, although the authors acknowledged the potential of CPOE to reduce medication errors.[1]

The second review was a narrative review that aimed to understand the extent and nature of medication errors related to chemotherapy as well as strategies for improvement.[2] We summarise the identified strategies for improvement below (see Table 4). With respect to extent and nature of errors, the authors reported that the variability in methods and measures of medication errors limited their ability to form firm conclusions about chemotherapy medication errors. They reported that in studies utilising voluntary incident reports and pharmacy interventions to identify errors, errors occurred at a rate of 3-4 errors per 1000 orders in paper-based sites and 1.5-2 errors per 1000 orders in settings with CPOE.[2] A number of chart review studies were also described, and these showed that 5-10% of inpatients experience an adverse event as a result of chemotherapy medication errors.[2] In ambulatory care, different denominators and measures were used, making it difficult to estimate error and harm rates.

The authors of this review highlighted a number of "special risks" associated with chemotherapy medication management including inadvertent intrathecal chemotherapy,

potential drug-drug interactions between chemotherapy and non-chemotherapy agents (usual and supportive care medications) and the use of oral chemotherapy. The review described a number of papers that explored patient medication administration errors, including examples of missed or wrong doses as a result of patients misunderstanding doses and schedules.[2]

We identified six papers that described safety and quality gaps in paper-based sites, most (n=4) focusing on medication errors. The details of these papers, including setting, method and key findings, appear in Appendix 2. Three papers utilised chart review (+/- interviews) to identify errors and risks, one used a survey[21] and two papers described a prospective risk assessment.[22,23] Only one of the papers we identified was also included in the two reviews summarised above. Table 2 shows the most frequent types of medication errors and other safety risks reported in papers.

Table 2. Top five medication errors and other safety risks reported in the papers where paper chemotherapy charts were in use

Paper (country) and setting	**Top five error types**	**Other safety or quality gaps**
Barakat, 2016[24] (Egypt) Chemotherapy clinic	Unspecific stage Dose error BSA calculation error Intention of treatment inconsistent with protocol choice Wrong dose time	
Kurgat, 2020[23] (Kenya) Inpatient and outpatient oncology unit	Dose miscalculation Inadvertent intrathecal administration of vincristine	Out-dated weight and height on the treatment sheet Past history inconclusive in determining last date of administration Obscure prescription/medication order Inadequate labelling Medication spillage Failure to adequately confirm vital information before administration Vincristine leaks to adjacent tissues (Extravasation) Doctor fails to notice exosmosis has occurred
Mathaiyan, 2016[25] (India) Day care unit	Incomplete orders Use of brand names Use of abbreviations Incomplete premedication Time of infusion missing	
Mathaiyan, 2015[26] (India) Day care unit	Incomplete orders Use of brand names Use of abbreviations Poor legibility Drug dose unclear or incorrect	
Ulas, 2015[21] (Turkey) N/A	Prescribing wrong dose Not following the chemotherapy sequence during multi-chemotherapy administration	

	Prescribing wrong medication Not following the administration duration Errors during labelling of chemotherapy serums	
Wang, 2017[22] (China) Inpatient department	Prescribing errors Dispensing errors Transportation errors Administration errors	

Note: BSA; Body surface area, N/A; Not available

We identified eight papers that described safety and quality gaps in sites using a CPOE system. Two of these papers utilised chart review to identify errors and risks,[27,28] four described pharmacy interventions to reduce medication errors,[29-32] and two papers reported an analysis of incident reports.[3,33] As shown in Table 3, the most frequently reported error type was wrong dose.

Table 3. Top five medication errors and other safety risks reported in the papers where electronic chemotherapy charts were in use

Paper (country) and setting	**Top 5 error types**	**Other safety gaps**
Azim, 2019[27] (Pakistan) Health institutes	Wrong dose Lack of treatment effectiveness Wrong drug Monitoring error Wrong time/schedule	
Battis, 2017[28] (USA) Chemotherapy clinic	Failure to discontinue therapy Drug without indication Inappropriate regimen Incorrect direction	Lost to follow-up (not returning for another appointment) Non-adherence to oral chemotherapy ADRs to chemotherapy
Hamel, 2018[29] (France) Paediatric oncology department	Wrong dose Wrong administration volume Wrong administration date Drug interaction No justified indication	
Han, 2016[30] (Korea) Cancer Hospital	Wrong dose Instability and incompatibility Discrepancy with protocol Reimbursement or cost saving issue Wrong admixture solution volume	
Lennes, 2016[33] (USA) Cancer Centre	Wrong dose Height/weight issue Laboratory issue Drug preparation issue Documentation issue	
Lichtner, 2019[3] (Australia) Cancer Centre		Risks during patient transfers Lack of or outdated chemotherapy protocols Failures in chemotherapy coordination Errors in the handling or storing of medication

		Issues related to patients' use of medication Technical issues with the CPOE User experience with the CPOE Unanticipated problems with CPOE workflow Missing CPOE safety features
Reinhardt, 2019[31] (Germany) Medical Centre	Wrong dose Incorrect timing Chemotherapy not ordered Incorrect chemotherapy Incorrect trial arm	
Suzuki, 2017[32] (Japan) Cancer Hospital	Wrong dose Error in premedication/ supportive medication Error when adding/stopping a drug Error in chemotherapy interval Error in chemotherapy regimen choice	Reasons for change in the chemotherapy regimen were unclear Difference between physicians' chemotherapy records and their chemotherapy prescriptions

Note: ADR; Adverse drug reaction, CPOE; Computerised provider order entry.

Factors contributing to medication error and safety gaps

A number of papers went further than identifying error types to explore causes or factors contributing to error occurrence. In a survey of 200+ oncology nurses in Turkey, factors reported to have contributed to medication administration errors were high workload, insufficient staffing and tiredness and stress.[21] In an in-depth analysis of over 400 chemotherapy prescribing errors in Germany, it was determined that over half could have been prevented if clinicians had consulted the previous chemotherapy order.[31] Finally, in a Pakistani study of poorer quality, where the data collection methodology was less clear, the most frequent cause leading to medication errors was found to be human factors (i.e. performance deficits, dosage miscalculations), and frequent contributory factors were reported to be staff training and the system covering patient care.[27]

The two papers that undertook prospective risk assessments identified a range of factors contributing to error occurrence, such as heavy workload and missing features in the CPOE (see Appendix 2).

One paper focused specifically on the role that CPOE plays in potentially facilitating medication errors and risks in oncology.[3] In an analysis of incident reports in a children's cancer centre in Australia, use of CPOE was determined to be a factor in approximately 50% of incidents.[3] The authors identified technical issues with the CPOE (e.g. ceased medications remaining on activation screens), user experience with the CPOE (e.g. the need to scroll through a plan to determine where a patient is up to), unanticipated problems with CPOE workflow (e.g. medications becoming automatically overdue if not ceased when a patient is transferred from another location), and missing CPOE safety features (e.g. decision support alerts) as factors contributing to errors.[3] Lessons learnt from incident reports were incorporated into CPOE training so that users are aware of CPOE automatic behaviours and downstream consequences of their actions on other CPOE users.

Mitigating workflows to address safety and quality gaps around chemotherapy medication management

We identified six reviews that synthesised the evidence on strategies or interventions used to address quality and safety gaps around chemotherapy medication management. Four reviews focused on CPOE or computerised decision support (CDS) for oncology,[4-7] with three summarising evidence on the impact of CPOE and CDS on medication safety, patient outcomes or the chemotherapy process.[4,5,7] See Table 4 for the components/features of the computerised interventions evaluated in included studies. These three reviews were consistent in their conclusion, all concluding that CPOE with CDS can result in significant reductions in chemotherapy prescribing errors, most markedly in dose errors.[4,5,7] However the authors also note that this conclusion is based on small-scale studies with short follow-up periods and highlight a need for further work on the impact of systems on safety and quality, particularly patient outcomes.[4,5]

The fourth CPOE-focused review aimed to identify and classify the specifications of CPOE and CDS for cancer patients.[6] The authors identified 58 papers and outline 30 specifications for systems. A summary of these is shown in Table 4.

Table 4. Design requirements or features of computerised interventions to address safety and quality gaps around chemotherapy medication management, as reported in four reviews and nine papers

	CPOE/ EMR with CDS (in general)	CDS alerts	Automatic dose adjustment	Automatic dose calculation	Preparation or admin instructions	Order sets, treatment plans or templates	Entry fields (e.g. for cycle)	Guidelines	Clinical pathways/ protocols	Access to Patient Reported Outcomes	Chemotherapy verification tool	Pharmacy review bucket	Data entry boundaries (e.g. max body weight)
Elsaid, 2015[4] (review paper)	✓	✓	✓	✓	✓	✓	✓	✓					
Pawloski, 2019[5] (review paper)	✓	✓						✓	✓	✓			
Rahimi, 2019[7] (review paper)	✓												
Rahimi, 2018[6] (review paper)	✓	✓	✓	✓		✓	✓	✓	✓				
Chung 2018[8] (USA)					✓	✓			✓		✓		
Finn 2017[10] (USA)						✓						✓	
Hess, 2020[11] (USA)	✓												
Lichtner, 2020[12] (Australia)		✓		✓		✓			✓		✓		

Valencia 2018[9] (Peru)		✓		✓		✓					✓		✓
Vosters 2018[13] (Belgium)				✓		✓					✓		
Walsh 2020[34] (USA)								✓					
Huertas-Fernandez, 2017[15] (Spain)	✓												
Weiss, 2017[14] (USA)									✓				

Note: EMR; Electronic medical record, CDS; Clinical decision support, CPOE; Computerised prescriber order entry.

We identified two review papers that outlined strategies or interventions to address quality and safety gaps around chemotherapy medication management but did not specifically focus on computerised interventions.[1,35] In the narrative review outlined above (see section 'safety and quality gaps around chemotherapy medication management'), four general strategies to reduce chemotherapy medication errors are described: safe practice standards and guidelines, prospective risk assessment, information technology, and patient engagement.[2] Examples of these appear in Table 5. The authors conclude that these interventions have merit, but are typically supported by expert opinion or small-scale single-centre studies, rarely evaluated across multiple settings and populations.[2]

The second review was a synthesis of education and safety practice requirements for safe nursing administration of chemotherapy.[35] As shown in Table 5, it described five key types of requirements: governance, process safeguards, communication, interdisciplinary collaboration, and education.

We identified 21 papers that described or evaluated mitigating workflows or strategies to address safety and quality gaps around chemotherapy medication management. Three of these papers[36-38] were captured in the systematic reviews described above, so have been excluded from our discussion here and appendices. The details of original papers (n=18), including setting, method and key findings, appear in Appendix 3.

Computerised interventions to address safety and quality gaps around chemotherapy medication management

Two papers described the process of implementing a CPOE system for chemotherapy,[8,9] one described the development of a 'chemotherapy-induced nausea and vomiting' dashboard,[39] and four papers described evaluations of chemotherapy CPOE/EMRs, including impact on safety and work.[10-13] Two papers also evaluated computerised interventions as part of multi-intervention bundles.[14,15]

Overall, implementation of CPOE or EMR was shown to reduce medication errors[8,13] improve error detection,[10] and result in a greater number of pharmacy interventions.[10] One study found no change in the number or types of incident reports submitted before and after implementation of an EMR.[11]

Although there was some variability in the computerised interventions described and evaluated, as shown in Table 4, there were some key components or design elements that frequently featured in technology to support chemotherapy medication management. For example, order sets or templates were often used to minimise prescribing errors and ensure chemotherapy orders were complete. To mitigate dosing errors, automatic dose calculations and adjustments were common forms of computerised decision support, as were computerised alerts. To facilitate review and

verification of chemotherapy by pharmacists and nurses, many systems also included a verification tool.

Table 5. Strategies to reduce chemotherapy medication errors and safety risks, as identified in two review papers

	Strategy	**Examples**
Coyne, 2019[35]	Governance	Risk assessment policy Standardised assessment tools
	Process safeguards	Standardised orders Electronic orders Protocols and guidelines Time out
	Communication	Handover Standard documentation Patient education
	Interdisciplinary collaboration	Clear documentation and accountability
	Education	Blended learning modules
Weingart, 2018[2]	Practice standards and guidelines	Unambiguous packaging and labelling Tall man lettering Order set templates Checklists No verbal orders No ambiguous abbreviations Double checking Patient and family education
	Prospective risk assessment	FMEA
	Information technology	CPOE Decision support BCMA Smart pumps
	Patient engagement	Medication and allergy lists Teamwork training System to report errors or treatment-related symptoms

Note: BCMA; Barcode medication administration, CPOE; Computerised provider order entry, FMEA; Failure modes and effects analysis.

Non-computerised interventions to address safety and quality gaps around chemotherapy medication management

Eleven papers described or evaluated non-computerised interventions, often in bundles of multiple interventions, to mitigate medication error and safety risks. These are summarised in Table 6. The two most common strategies described in papers were the use of paper-based standardised chemotherapy order forms,[40-42] and education or training for clinicians.[15,43-45]

Studies on paper-based standardised chemotherapy order forms showed that these were not consistently used by oncologists[40] or nurses,[41,42] and even if used, could still result in prescribing errors due to errors in dose calculations.[41,42]

Studies on education/training typically evaluated this intervention as part of an intervention bundle, making it difficult to determine the impact of this single strategy on chemotherapy medication management. In the one study that evaluated a stand-alone training program, an electronic health record (EHR) simulation training program was implemented in response to the identification of chemotherapy ordering errors that were the result of new workflows demanded by the EHR.[44] The researchers reviewed IT help-desk enquiries, voluntary incident reports, and held discussions with key stakeholders to identify aspects of the EHR which posed a safety risk. These included, for example, ordering inappropriate infusion doses and durations, issues with 'releasing' chemotherapies, and notifying pharmacy of signed chemotherapy orders. Using these examples, the researchers designed scenarios for their simulation-based training and found that delivery of this training improved providers' ability to identify and mitigate EHR safety risks (5.5 vs. 7.4/10 risks).[44]

In the only other study to evaluate a single intervention, implementation of a nursing time-out process led to an initial increase in medication administration errors (from 1.3/100 patients to 1.6/100 patients), but when examined again 3 years post-implementation, error rates had declined (to 0.7/100).[45] The authors note that error rates were very low initially, making it challenging to detect an impact of the time-out process, but also note that this process allowed 28 errors to be detected prior to administration of chemotherapy.[46]

In examining the studies of intervention bundles, although large variability existed in mitigating workflows or strategies implemented and outcomes measured, these bundles were shown to improve compliance to policy/guidelines[43,45], reduce medication errors,[14,15] and improve error detection (see Appendix 3).[15]

Table 6. Non-computerised strategies to reduce chemotherapy medication errors and safety risks, as identified in 11 papers

	Standardised chemotherapy order form	Staff education & training	Audit & feedback	Standardised lab parameters	Checklist	Manual	Standardised procedure	Nursing time out	Error reporting system	Chemotherapy safety zone	Patient strategies (e.g. education, consent)
Asgarian, 2017[40] (Iran)	✓										
Bryant-Bova, 2016[43] (USA)		✓		✓							
Crandell, 2018[47] (USA)					✓						
Huertas-Fernandez, 2017[15] (Spain)		✓				✓	✓				
Jazieh, 2019[45] (Saudi Arabia)		✓	✓								
Kalo, 2019[46] (USA)								✓			
LeFebvre, 2016[48] (USA)											✓
Mousavi, 2020[41] (Iran)	✓										

Rouhani, 2018[42] (Iran)	✓										
Weiss, 2017[14] (USA)									✓	✓	
Wyatt, 2020[44] (USA)		✓									

Aspects of chemotherapy medication management documentation recommended to support safety and quality and best practice

We identified five papers that described or evaluated aspects of chemotherapy medication management documentation. One paper focused on paper-based documentation,[16] one on the implementation of CPOE to improve documentation,[17] and the remaining three papers on documentation within a CPOE or EMR.[18,19,49] In all papers, an intervention bundle (e.g. education and a guideline) was designed to improve documentation of chemotherapy medication management and in all cases improvements in documentation were observed following implementation of the interventions.[16-19] The details of these papers, including setting, method and key findings, appear in Appendix 4.

Table 7 outlines the aspects of chemotherapy medication management documentation which were the focus of the papers we identified.

Table 7. Aspects of chemotherapy medication management documentation recommended to support safety and quality, as identified in five papers

	Dos Santos, 2020[16] (Brazil)	Enright, 2015[17] (Canada)	Harle, 2017[18] (Canada)	Raney, 2020[19] (USA)	Turner, 2015[49] (Australia)
Paper focus:	**Nursing**	**Treatment plan**	**Advance care planning**	**Patient adherence**	**Nursing**
Medication allergies	✓				✓
Assessment of access device required for administration	✓				✓
Premedication/ pre-hydration	✓				✓
Chemotherapy administration according to protocol	✓				✓
Post medication/ Post hydration	✓				✓
Treatment related toxicities and side-effects	✓				✓
Self care instructions for patients post-administration	✓	✓			✓
Duration of cytotoxic precautions	✓				✓

Patient diagnosis	✓				✓
Recent blood results have been checked and actions taken	✓				✓
Treatment plan has been checked	✓				
Physical assessment of patient	✓				✓
Psychosocial assessment to patient					✓
Patient education	✓	✓			✓
Informed consent or approval to proceed	✓				✓
Verification of the treatment plan, chemotherapy order and patient ID by 2 qualified staff	✓				✓
Care plan details (e.g. dose, administration schedule, treatment intent, toxicity, assessment schedule)		✓			
Goals of care			✓		
Patient's adherence to prescribed chemotherapy regimen				✓	
Follow up appointment/ next appointment					✓
Referrals to services					✓

Note: ID; Identification.

We identified six guidelines from our grey literature search that provided consensus-based recommendations for chemotherapy medication management documentation. Five Australian guidelines are summarised, and we also included the 2016 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards, as these form the foundation of the Australian guidelines.

The Clinical Oncology Society of Australia (COSA) guidelines[50] provide recommendations for the safe prescribing, dispensing and administration of systemic cancer therapy. General recommendations related to documentation requirements to support safe provision of cancer therapy include:

- Documentation must be legible and organised in a standardised format

- Documentation (protocols, procedures etc.) stored electronically should be in a read-only format.
- Patient data should be easily accessible, and printing copies of electronically available data should be minimised to avoid out-of-date information being accessed.
- When a patient's care is transferred, documentation should be transmitted accurately and confidentially
- A standardised clinical handover process and documentation for patients receiving cancer therapy should be adopted (Australian Commission on Safety and Quality in Health Care, 2012).
- A treatment plan must be completed for all patients receiving cancer therapy and be available in a patient's health record at all times. Deviations from accepted protocols and changes in treatments must be documented and justified.
- Medication labels should be presented in a consistent manner ensuring easy identification of medication, route, dose and patient.

The National Safety and Quality Health Service Standards User Guide for Medication Management in Cancer Care for Clinicians[51] includes general recommendations related to documentation requirements:

Before treatment

- Medical history documented
- Document patient's expectations, concerns and goals for treatment
- Treatment plan based on evidence-based protocol

During treatment

- Written informed patient consent
- Document and justify deviations from protocol in patients' healthcare record
- Prescribe using evidence-based protocols
- Use approved anti-cancer medication charts
- Apply COSA guidelines[50] when applicable
- Use electronic prescribing when possible

We identified five guidelines that outlined specific recommendations for chemotherapy medication management documentation. These are presented in Table 8.

Table 8. Aspects of chemotherapy medication management documentation recommended to support safety and quality, as identified in guidelines.

	2016 updated ASCO/ ONS chemotherapy administration safety standards, including standards for pediatric oncology[52]	COSA guidelines for the safe prescribing, dispensing and administration of systemic cancer therapy[50]	ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy[53]	WA country health services chemotherapy administration clinical practice standard[54]	Standards for chemotherapy services in South Australia[55]
Relevant section in guideline:	**Chart documentation, clinical encounter documentation, treatment planning, and chemotherapy orders**	**Information in medication order and treatment protocol**	**Content of medication orders and medication profiles for cancer patients**	**Prescription documentation for parenteral cytotoxic agents**	**Chemotherapy planning, prescribing and assessment/monitoring of patients**
Drug dose	✓	✓	✓	✓	✓
Height, weight and body surface area	✓	✓	✓	✓	✓
Medical history	✓	✓	✓	✓	✓
Cycle number and day	✓	✓	✓		✓
Rate and duration of administration (where applicable)	✓	✓	✓	✓	
Treatment related reactions/ toxicities	✓	✓	✓		✓
Allergies	✓	✓	✓		✓
Patient name and unique identifier	✓	✓	✓	✓	
Reference sources supporting use of protocol or variations	✓	✓	✓		✓
Patient's written consent	✓	✓	✓		✓
Age	✓		✓	✓	
Dose calculation (methodology, variables, frequency)	✓	✓		✓	
Medication names (generic)	✓	✓	✓		
Patient/ caregiver's comprehension of disease and treatment plan	✓		✓		✓
Route of administration	✓	✓	✓		
Date of administration	✓	✓	✓		
Date order is written	✓	✓		✓	
Diagnosis	✓	✓	✓		
Pathology/ radiology results		✓	✓		✓

Regimen/ protocol name and number	✓	✓	✓		
Sequencing of drug administration, when applicable	✓	✓	✓		
Supportive care treatments	✓	✓	✓		
Cancer stage/ current status	✓	✓			
Other medications used by patient	✓				✓
Pain assessment	✓				✓
Psychological assessment	✓				✓
Cumulative amount of drug administered for medications with established limits	✓		✓		
Potential interactions with medicines, foods and other agents to be avoided	✓	✓			
Expiration date/ time	✓		✓		
Additional ingredients and diluting agents and the amounts used			✓		
An explanation of time limitation, such as the number of cycles for which the order is valid.	✓				
Expected side effects, likelihood of onset and management		✓			
Number of refills (oral chemotherapy)	✓				
Parameters that would require holding/modifying dose	✓				
Pre-treatment investigations and future investigations scheduled		✓			
Product manufacturer's identity, product lot numbers			✓		
Treatment contraindications and precautions		✓			
Vital signs	✓				
Ward/ clinic where administration is planned				✓	

Note: ASCO; American Society of Clinical Oncology, ONS; Oncology Nursing Society, COSA; Clinical Oncology Society of Australia, ASHP; American Society of Health-System Pharmacists, WA; Western Australia.

Legislative and policy requirements that support chemotherapy medication management documentation within each Australian state and territory

Australian Capital Territory

Canberra Hospital and Health Services Clinical Procedure Intrathecal Chemotherapy Administration including Lumbar Puncture (Adults Only)[56]

- Outlines the expected practice for safe administration of intrathecal chemotherapy
- Requirements related to chemotherapy medication management documentation include:
    - Staff involved in chemotherapy must be provided with this document, accompanying protocols and guidance
    - Administering Medical Officer must check the relevant treatment protocol which includes the intrathecal therapy for the individual patient and be educated in the standard doses of intrathecal chemotherapy.
    - The drug, dose and route of administration must be clearly written in full on the CHARM prescription
    - The route of administration must be written as 'INTRATHECAL' (not abbreviated).
    - Intrathecal chemotherapy is provided by Pharmacy in small volume syringes (each syringe is usually made up to 2mLs) and will be delivered in distinctive specially labelled containers not used for any other purpose.
    - The pharmacist, the administering doctor, and the nurse will all confirm the patient name and URN, the drug, the dose and the intrathecal route and sign the CHARM order. The syringes must also be matched against the written drug orders for name of patient and drug, URN, dose, route of administration and also checked for the expiry date

New South Wales

Private Health Facilities Regulation 2017[57]

- Legislation for chemotherapy class private health facilities
- Facilities must have written policies and procedures for
    - Provision of information and counselling to patients and their relatives
    - Admission, discharge, continuing care and review
    - Management of side effects
    - Access to relevant specialists for consultation
- Clinical records for patients must include
    - Treatment plan

    - Signed record of patient consent
    - Details of drugs and doses prescribed and administered to patient
- Facility must comply with Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy published by COSA in November 2008

- **High Risk Medication Policy**[58]
- Applicable to all public health facilities in NSW.
- Facilities must maintain a high-risk medication register (which includes chemotherapeutic agents) and employ strategies to mitigate risk of medications on the registers.
- Local protocols must be developed for all identified high-risk medicines specified on the register. The protocols are to be developed in consultation with relevant specialists and overseen and approved by the District or Health Service Drug and Therapeutics Committees.
- Protocols must include a timeframe for review and patient monitoring which is relevant and appropriate for the patient's clinical circumstances.
- Adverse incidents involving high-risk medications must be reported and reviewed.
- Policy includes specific standards regarding use of Vincristine. Local vincristine protocols must be approved by The District or Health Service Drug and Therapeutics Committee.
- Standards for prescribing and administering high-risk medicines specific to documentation include:
    - Accurate patient weight should be documented on the medication chart for all patients
    - Route of administration must be clearly identified.
    - Where required, strengths of medicines must be clearly visible in terms of the dosage unit or dose per volume of liquid,
    - The prescriber should complete the 'Indication' for use box on the National Inpatient Medication Chart (NIMC) for high-risk medicines
    - Where Electronic Medication Management systems are in use, the indication for use should be documented according to local Electronic Medication Management guidelines
    - Dose adjustments must be considered when prescribing for patient groups such as overweight, obese or underweight patients, and patients with existing clinical conditions (such as renal or hepatic impairment) that may affect drug metabolism and excretion
    - Therapeutic guidelines should be followed where dosing is complex and duration of therapy substantially increases the risk of toxicity
    - Medication reconciliation processes should be prioritised for these patients

South Australia

Cancer Service – State-wide Cancer Chemotherapy Policy Directive[59]

- Policy defines a state-wide, quality assured framework for development, approval and review of cancer chemotherapy protocols and prescribing tools for use within SA Health hospitals and health services.
- Policy outlines the use of eviQ treatments online as the primary resource for adult cancer chemotherapy protocols.

Western Australia

High Risk Medication Policy[60]

- Applicable to inpatient care facilities in WA.
- Facilities must maintain a list of high-risk medications (which includes chemotherapeutic agents) and periodically review this list to identify risks and mitigation strategies for each medication class.
- Clinical incidents involving high-risk medications must be reported and reviewed.
- Each facility must have its own local high-risk medication policy supported by protocol, procedures and/or guidelines.
- Guideline recommendations[61] related to chemotherapeutic medication management documentation include:
    - Oral chemotherapy should be clearly identified as cytotoxic to all staff that may handle the medication. A cytotoxic purple sticker can be placed on the dispensed medication container and/or the medication administration chart to identify this risk.
    - All staff should have access to information applicable to the patient and the treatment including diagnosis, patient's history, patient's weight and height, pathology results and the treatment plan.
    - All chemotherapy and targeted therapy should be prescribed on the basis of a documented, referenced protocol and a treatment plan. Protocols should outline all therapy, dosages and scheduling relevant to the treatment. Dose adjustments should be clearly documented in the treatment plan and duplicated on the order and/or prescription.
    - All prescriptions for oral chemotherapy and targeted therapy should include a start and stop date for intermittent therapy.
    - Patients should be given access to both written and oral information about their treatment which is to include all medications, expected side effects, how to take supportive medication and who to contact in the event of an emergency or severe adverse events.

Queensland

None

Tasmania

None

Victoria

None

Northern Territory

None

Conclusion

Prescribing errors, specifically dose errors, are a key safety issue shaping contemporary chemotherapy medication management in hospitals. CPOE systems are the most frequently implemented strategy to improve medication safety. CPOE introduction has been shown to lead to fewer chemotherapy prescribing errors, including dose errors, however research has also shown that CPOE systems can lead to new error types.

It is recommended that a large number of information elements be documented to support safe and high-quality chemotherapy medication management, including data related to the patient, the treatment plan, chemotherapy administration, and patient education (i.e. self-care instructions, patient consent, patient/caregiver's comprehension of disease and treatment plan). Although there appear to be limited legislative requirements specific to chemotherapy medication management documentation across Australian states and territories, chemotherapeutic agents are high-risk medicines and as such, their management should adhere to best practice standards for other high-risk drugs.

Limitations of studies and papers should be taken into account when interpreting these conclusions. There was large variability in methods used across studies and measures of medication errors and risks. The majority of studies we identified that focused on error/risk identification were also undertaken in countries with health care systems and processes likely to differ significantly from those in Australia (e.g. India, Korea, Turkey).

Papers on interventions to mitigate errors and risks were primarily descriptive, and in those where an evaluation was presented, no controlled designs were employed. Many interventions also comprised intervention bundles, limiting our ability to draw conclusions about effectiveness of individual elements or strategies.

Overall, we identified very few studies, papers and reports focusing on chemotherapy medication management in Australia, and as such, can draw limited conclusions about Australian specific policies and practices (e.g. PBS chemotherapy funding).

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Appendices

Appendix 1

Databases and associated search terms

Database	Search terms
MEDLINE	1. "chemotherap*".ab,ti. 2. "prescrib*".ab,ti. 3. "order*".ab,ti. 4. "preparation*".ab,ti. 5. "dispens*".ab,ti. 6. "administ*".ab,ti. 7. documentation.ab,ti. 8. 2 or 3 or 4 or 5 or 6 or 7 9. safety.ab,ti. 10. quality.ab,ti. 11. "error*".ab,ti. 12. adverse drug event.ab,ti. 13. "workaround*".ab,ti. 14. "harm*".ab,ti. 15. "workflow*".ab,ti. 16. "incident*".ab,ti. 17. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 18. 1 and 8 and 17 19. limit 18 to (english language and yr="2015 -Current")
EMBASE	1. "chemotherap*".ab,ti. 2. "prescrib*".ab,ti. 3. "order*".ab,ti. 4. "preparation*".ab,ti. 5. "dispens*".ab,ti. 6. "administ*".ab,ti. 7. documentation.ab,ti. 8. 2 or 3 or 4 or 5 or 6 or 7 9. safety.ab,ti. 10. quality.ab,ti. 11. "error*".ab,ti. 12. adverse drug event.ab,ti. 13. "workaround*".ab,ti. 14. "harm*".ab,ti. 15. "workflow*".ab,ti. 16. "incident*".ab,ti. 17. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 18. 1 and 8 and 17 19. limit 18 to (english language and yr="2015 -Current") 20. exp chemotherapy/ 21. 8 and 17 and 20 22. limit 21 to (english language and yr="2015 -Current")

PubMed	("safety"[Title/Abstract] OR "quality"[Title/Abstract] OR "error*"[Title/Abstract] OR "adverse drug event*"[Title/Abstract] OR "workaround*"[Title/Abstract] OR "harm*"[Title/Abstract] OR "workflow*"[Title/Abstract] OR "incident*"[Title/Abstract]) AND "chemotherap*"[Title/Abstract] AND ("prescrib*"[Title/Abstract] OR "order*"[Title/Abstract] OR "preparation*"[Title/Abstract] OR "dispens*"[Title/Abstract] OR "administ*"[Title/Abstract] OR "documentation"[Title/Abstract]) AND 2015/01/01:3000/12/31[Date - Publication] AND "English"[Language]

Appendix 2

Papers that described safety and quality gaps around chemotherapy medication management

Author, year (country)	Setting	Paper or CPOE	Aim	Method	Main findings
Barakat, 2016 (Egypt)	Chemotherapy clinic	Paper	To identify incidence and severity of prescribing errors, including risk factors associated with these	Chart review (500 patients)	100% of prescriptions contained an error, with protocol type, number of cycles, toxicity type, tumour type and total number of medications shown to be predictors of errors.
Kurgat, 2020 (Kenya)	Inpatient and outpatient oncology unit in a teaching and referral hospital	Paper	To identify risks associated with use of Vincristine	HFEMA including doctors, pharmacists, nurses and pharmaceutical technologist	Identified 11 failure modes and multiple causes for each. Example modes included outdated weight and heights on treatment sheets, past history not including last date of administration, and dose miscalculation. Example causes included lack of clear guidelines, heavy workload and lack of adequate space to affix a label.
Mathaiyan, 2016 (India)	Day care unit of a regional cancer centre	Paper	To estimate the prevalence and types of prescription, transcription and administration errors	Chart review and direct observation (500 patients)	42% of patients experienced a medication error. 56% of errors were in prescribing, 25% in transcribing and 21% medication administration. The majority of the prescription errors were due to missing information (46%) and administration errors were mainly due to errors in drug reconstitution (56%).
Mathaiyan, 2015 (India)	Day care unit of a regional cancer centre	Paper	To estimate the prevalence, type and severity of prescription errors in patients receiving chemotherapy	Chart review (1500 orders)	4253 prescribing errors were found, 47% were omissions. Use of brand names was also common.

Ulas, 2015 (Turkey)	N/A	Paper	To identify medication errors and underlying factors during chemotherapy preparation and administration	Survey of oncology nurses (n=206)	83% of nurses reported experiencing an error while preparing or administering chemotherapy. Nurses reported errors during prescribing and ordering were more common, especially wrong doses and wrong medications. Common administration errors included errors during labelling of chemotherapy serums and not following the chemotherapy sequence during multi-chemotherapy administration. Contributing factors included high workload, insufficient staffing and stress/tiredness.
Wang, 2017 (China)	Department of chemotherapy in a tertiary university hospital	Paper and CPOE	To demonstrate the application of a FMEA to complex chemotherapy management	FMEA including doctors, nurses, IT staff, pharmacy and medical management. Prescribing errors measured (method not reported)	Identified 10 failure modes and multiple causes for each. Example modes included prescription errors, dispensing error and errors in administration timing. Examples causes included errors in dose calculations, missing warning signs on label, and information system lacking a reminder. Error rate decreased after implementation of a CPOE system.
Azim, 2019 (Pakistan)	2 non-government health institutes	CPOE and paper	To evaluate the incidence of medication errors among cancer inpatients along with causes and contributing factors	Chart review (151 patient charts)	Medication errors occurred at a rate of 0.25 per 1000 orders. Frequent error types with CPOE included wrong dose, lack of treatment effectiveness and wrong drug. Frequent errors with paper-based charts included wrong dose, monitoring errors and wrong timing errors. Human factors (e.g. performance deficit, miscalculation) was reported to be the most common cause of incidents and staff training the most common contributing factor. More errors were intercepted prior to reaching the patient at the site using CPOE than the paper-based site.

Battis, 2017 (USA)	Oral chemotherapy monitoring clinic, VA Sierra Nevada Health Care System	CPOE	To detect gaps and deficiencies in current practice in a new pharmacy-managed oncology clinic, with chemotherapy-directed electronic order sets.	Chart review, patient interviews, patient follow-up, clinical dashboard (31 patients)	The clinic identified problems with oral chemotherapy in 45% of patients including non-adherence, lost to follow-up, medication errors and adverse drug events.
Hamel, 2018 (France)	Paediatric oncology department in a major oncology hospital	CPOE	To describe drug related problems (DRPs) identified during review of IV chemotherapy prescriptions that led to pharmacy interventions, and to identify risk factors associated with these	Review of pharmacy interventions, as documented in a database (18 months)	102 pharmacy interventions per 10,000 prescriptions were found. 61% of interventions related to dose. More pharmacy interventions were found when standardised protocols were used, than when non-standardised protocols were used.
Han, 2016 (Korea)	Tertiary cancer hospital	CPOE	To evaluate the clinical and economic impact of pharmacist interventions	Review of pharmacy interventions, as documented in the pharmacy information service (12 months)	15.9 interventions per 1000 chemotherapy prescriptions were found. 61% of interventions related to dose. The majority of pharmacy interventions were rated as 'significant' or 'somewhat significant' and most (72%) were accepted by oncology physicians. The cost-benefit analysis showed a clear cost benefit with a net cost-benefit of $116,493.
Lennes, 2016 (USA)	Multidisciplinary cancer centre in a general hospital	CPOE	To summarise chemotherapy-related safety events that have occurred over a 5-year period and make recommendations to	Review of incident reports (5 years)	330 chemotherapy safety evets were reported, 89 reached the patient, 10 had the potential for serious harm but did not cause harm. The most common incident types related to patient height/weight and laboratories.

			standardise reporting and analysis		
Lichtner, 2019 (Australia)	Children's cancer centre within a tertiary paediatric hospital	CPOE	To explore medication safety issues related to use of CPOE in paediatric oncology	Review of incident reports (18 months)	Approx. 35% of incidents occurred during prescribing, 25% during administration and 27% were coded as 'other'. Use of CPOE was determined to be a factor in approx. 50% of incidents. Common themes in incident reports included patient transfers, information on chemotherapy protocols, chemotherapy coordination, handling or storing of medication and patients' use of medication. CPOE related issues included technical issues with the CPOE, user experience with the CPOE, unanticipated problems with CPOE workflow, and missing CPOE safety features.
Reinhardt, 2019 (Germany)	University medical centre	CPOE	To identify the relative frequency, root causes, and potential consequences of chemotherapy prescribing errors and to determine whether errors identified could be prevented using an upgraded CPOE tool.	Review of errors detected by the chemotherapy surveillance team, as documented in the CPOE (24 months)	2% of chemotherapy orders contained an error. The most frequent causes of errors were overlooked dose modifications in previous orders and modification to/missing protocols. 51% of errors were considered preventable by consulting the previous chemotherapy order, 38% by knowing the chemotherapy protocol and 35% by checking the patient's medical records. Using updated software with increased safety features would have prevented 61% of prescribing errors.
Suzuki, 2017 (Japan)	Cancer hospital	CPOE	To evaluate the interventions that were conducted by pharmacists.	Review of pharmacy interventions, as documented in a data base (12 months)	Pharmacists intervened in 1% of chemotherapy administrations and 53% of interventions were accepted by prescribers. The most common reason for intervening was that the reason for a change the chemotherapy regimen was unclear and the most frequent error detected was wrong dose.

Note: CPOE; Computerised provider order entry, HFMEA; Healthcare failure modes and effects analysis, N/A; Not available

Appendix 3

Papers that described or evaluated mitigating workflows that have been put in place to address safety and quality gaps around chemotherapy medication management

Author, year (country)	Setting	Mitigating workflow or strategy	Aim	Method	Main findings
Chung, 2018 (USA)	Health district	CPOE	To describe the strategies, challenges and lessons learnt in the development and implementation of a CPOE	Paper describes process taken, including a small-scale evaluation	Lessons learned: - Optimise workflow before CPOE implementation - Engage all interprofessional stakeholders - Include a CPOE verification tool - Consolidate similar or identical protocols for different diagnoses - Deliver ongoing training and support Medication ordering errors decreased post CPOE implementation.
Finn, 2017 (USA)	Cancer centre in a medical university	EMR	To evaluate the effect of an EMR-based pharmacist-managed oral chemotherapy program in pharmacist interventions	Chart review of pharmacy interventions 3 months before and 3 months after EMR (n=240 patients)	Over 660% more pharmacy interventions were documented after EMR implementation and over 500% more chemotherapy order errors were detected.
Hess, 2020 (USA)	Cancer hospital, part of a University medical centre	EMR	To evaluate trends in medication error reporting before and	Review of incident reports 5 months before and 5 months after EMR	No change in the number of medication reports submitted pre and post EMR, with most reports describing no patient harm. Most errors occurred during prescribing and the most frequently reported error was wrong dose.

			after implementation of a new EMR system		
Lichtner, 2020 (Australia)	Children's cancer centre within a tertiary paediatric hospital	CPOE	To identify the strategies clinicians apply to safely manage the interdependencies in paediatric oncology and how CPOE affects these.	Review of incident reports post CPOE (18 months), interviews with clinicians (n=19)	Two types of interdependencies were identified: those related to the organisation of clinical activities and independencies inherent to chemotherapy regimens. Clinicians reported strategies to address chemotherapy risks including rigid rules and 'no go' contexts for treatment to proceed, and multiple checks. The CPOE supported these strategies through automation, access to information and standardised protocols.
Valencia, 2018 (Peru)	Referral tertiary cancer centre	CPOE	To describe the implementation process of a CPOE at a Latin American Hospital	Paper describes process taken	Key recommendations: - Ensure you have adequate policies in place - Leadership is critical - Crucial to have protected time to develop the project - Multidisciplinary teamwork is required - Before migration to CPOE undertake process mapping and redesign - Use phased implementation and continuous training and monitoring The authors report the CPOE is usable, accessible, secure, has a high degree of concurrence, and is highly configurable.
Vosters, 2018 (Belgium)	Academic hospital with ambulatory facility	CPOE	To evaluate the impact of a new CPOE for managing chemotherapies and to identify residual risks or	FMEA before and after CPOE, including oncologists, nurses, pharmacists and quality assurance specialists, chart review, and	38 potential failure modes were identified, most commonly in prescribing, followed by transmission, validation, preparation, administration, delivery and pricing. 21 risks were rated as not acceptable. Following CPOE, all risks were prevented, controlled or eliminated. There was a 39% reduction in medication errors post-CPOE, with many error types eliminated. The satisfaction

			critical points that need addressing	clinician satisfaction survey (n=24)	survey showed that hospital pharmacists and doctors were less satisfied by the software than nurses, mostly in terms of task achievement and time savings.
Walsh, 2020 (USA)	Children's hospital	Dashboard	To describe the creation of a chemotherapy-induced nausea and vomiting dashboard to encourage clinical practice guideline compliance	Paper describes process taken to design and implement dashboard	Key features: - Chemotherapy medications and antiemetic drugs are colour coded to allow easy and quick identification of whether antiemetics provide guideline-consistent care - Daily review of the dashboard allows identification of patients who may require a change to the antiemetic medication regimen
Asgarian, 2017 (Iran)	Teaching medical centre	Standardized chemotherapy order form (paper-based)	To design and evaluate a standard form for treatment of gastric cancer.	Paper describes how the form was developed. Chart review (54 patients, 249 chemotherapy courses)	22% of sessions of chemotherapy contained errors, with most occurring during prescribing. The approved regimens on the standard form were used in only 41% of sessions.
Bryant-Bova, 2016 (USA)	Outpatient infusion centres in Texas	Intervention bundle: education, same day lab work, standardized lab parameters, and audit and feedback	To decrease the number of chemotherapy order forms that deviated from chemotherapy order policy	Used Plan, Do, Study, Act improvement methodology	Intervention bundle resulted in a 19% reduction in chemotherapy order forms that deviated from chemotherapy order policy. The authors attribute this to the one-on-one education provided to clinicians.
Crandell, 2018 (USA)	N/A	Checklist	To describe a checklist that can be used by pharmacists to	Paper describes checklist (does not include an evaluation)	Checklist (PRONTO) includes 6 steps: - Patient: gain an overview of the patient

			standardize review of chemotherapy orders		- Regimen: verify that the chemotherapy regimen matches a published regimen and applies to the specific patient - Organ function: evaluate whether the patient's organ function and labs warrant full dose treatment - Numbers: dose calculations, dose tracking, admixture and administration numbers - Toxicity: reconcile a prescribed supportive care regimen with the expected toxicities of a regimen - Order verification: independent double check, check chemotherapy labels and staff communication.
Huertas-Fernandez, 2017 (Spain)	Oncology outpatient unit of a tertiary university hospital	Intervention bundle: training, standardized procedures, CPOE, pharmaceutical validation, bar coding and a DDI manual	To evaluate the effectiveness of safeguards introduced to increase the safety of oncology patients	Review of anonymous error reports, chart review, then interviews with patients, 1 year before and 1 year after intervention bundle (total 500 patients)	Implementation of the interventions was associated with a significant reduction in medication errors (43% vs. 27% of patients). 13% more errors were also detected before reaching the patient, with CPOE leading to >90% of errors being detected during pharmacy verification.
Jazieh, 2019 (Saudi Arabia)	Oncology department	Intervention bundle: Education and audit and feedback	To improve adherence to lung cancer guidelines	Used Plan, Do, Study, Act improvement methodology, Chart review (160 patients)	Histological subtype identification improved from 94% to 100%. Presentation of new cases at the tumour board improved from 35% to 82%. Testing for epidermal growth factor receptor mutation for nonsquamous cell lung cancer improved from 77% to 100%. The staging was documented in 100% of the cases.
Kalo, 2019 (USA)	Hospital-based cancer units	Nursing time-out	To examine the rate of chemotherapy	Review of incident reports, review of	Errors increased from 1.3/100 patients to 1.6/100 patients following implementation of time-out, but then declined to 0.7/100 3-years

			administration errors that occurred before and after implementation of the chemotherapy time-out process	chemotherapy infusions and subcutaneous administrations from a pharmacy data base, at 3 time periods: pre, immediately post and 3 years after	post implementation. There were no errors causing harm after implementation of the time-out process.
LeFebvre, 2016 (USA)	N/A	Safety standards including patient assessment and education, informed consent, and dose verification prior to administration	To learn about the application of safety standards in relation to oral anticancer drugs across a variety of settings and identify gaps	Survey of Oncology Nursing Society nurses (n=160)	A large number of settings did not have the processes in place to support safety standards and ensure patient safety, particularly with respect to patient assessment, consent, education, drug verification and monitoring.
Mousavi, 2020 (Iran)	Outpatient oncology wards of two teaching hospitals	Standardized chemotherapy order form (paper-based)	To evaluate the effect of a chemotherapy standard form on the rate and types of medication errors in patients with Hodgkin's and non Hodgkin's lymphomas	Chart review (62 patients)	160 medication errors were found, 65% of which were dose errors. Administration errors (incorrect duration of infusion) were also common (56/206 courses). All regimens were selected according to the standard guideline, errors occurred during dose calculations.
Rouhani, 2018 (Iran)	Two outpatient oncology centres, one in a	Standardized chemotherapy	To evaluate the effects of a chemotherapy	Chart review (84 patients)	89 medication errors were found, 63% were prescribing errors and the remainder administration errors. The most common error was

	teaching hospital and one in a private clinic	order form (paper-based)	standard form on rates and types pf medication errors in relation to early detection of toxicity and ADRs in patients with breast cancer		wrong dose, followed by incorrect duration of infusion. All regimens were selected according to the standard guideline, errors occurred during dose calculations.
Weiss, 2017 (USA)	Paediatric medical centre	Intervention bundle: cancer error reporting system, safety huddle, chemotherapy safety zones, use of headphones, electronic chemotherapy protocols	To describe the development and early results from a chemotherapy error prevention project.	Review of incident reports, including near-misses over the 6-year period where the quality improvement initiative was implemented.	Improvement project resulted in a significant decline in errors that reached the patient, from 3.8 to 1.9 per 1000 doses.
Wyatt, 2020 (USA)	Division of paediatric hematology/ oncology in a clinic	Simulation-based training	To reduce the proportion of safety hazards within the EHR through the implementation of an EHR training program.	Used incident reports, help-desk enquiries and discussions to identify patient safety events to include in training. Measured proportion of safety risks that providers (n=8) could identify and mitigate before	Simulation-based training improved providers' ability to identify and mitigate EHR safety risks (5.5 vs. 7.4/10 risks).

				and after the training	

Note: CPOE; Computerised provider order entry, EHR; Electronic health record, EMR; Electronic medical record, N/A; Not available

Appendix 4

Papers that described or evaluated aspects of chemotherapy medication management documentation recommended to support safety and quality and best practice

Author, year (country)	Setting	Intervention	Aim	Method	Main findings
Dos Santos, 2020 (Brazil)	Bone Marrow Transplant unit, paper based records	Intervention bundle: staff education, checklist, nursing documentation guidelines	1) To determine the current adherence with evidence- based criteria regarding antineoplastic chemotherapy nursing documentation 2) To identify barriers and facilitators for achieving adherence and to develop strategies to address areas of nonadherence. 3) To improve knowledge and adherence with evidence-based criteria regarding antineoplastic chemotherapy nursing documentation.	Audit of evidence-based documentation before and after intervention bundle implementation	Improved documentation was observed post-implementation of the bundle, with some items completed 100% of the time. However, compliance with some items (e.g. patient education) remained low.
Enright, 2015 (Canada)	2 cancer centres in a mixed community and academic hospital, paper based records initially	Intervention bundle: standardised nursing flow sheet and CPOE	Undertake a rapid-cycle quality improvement project, with the aim of increasing the number of components of an oral chemotherapy care plan documented in the medical record	Used a plan-do-act-cycle, with chart audit to examine impact of interventions	Found a sustained improvement in the number of components of oral chemotherapy care plans documented in the medical record, from 67% to 92% of components.

Harle, 2017 (Canada)	Academic cancer centre, used an EMR	Intervention bundle: guideline and a standardised form in the EMR	To outline the steps taken to improve the rates of goals of care discussion and documentation	Used a plan-do-act-cycle, with chart audit to examine impact of interventions	Implementation of the intervention was feasible and improved goals of care documentation
Raney, 2020 (USA)	Children's Research hospital ana affiliated clinics, used an EMR	Intervention bundle: standardizing the format (content and location) of documentation in the EMR and staff education.	To increase compliance with oral chemotherapy documentation	Administered a burnout survey to clinicians, then used a plan-do-act-cycle, with chart audit to examine impact	Compliance with adequate documentation of oral chemotherapy increased from 13% to 87% following implementation of the intervention
Turner, 2015 (Australia)	Inpatient and outpatient oncology/ hematology units, used a CPOE	Intervention bundle: education and documentation guidelines	To improve documentation of chemotherapy administration by nursing staff	Audit of evidence-based documentation before and after intervention bundle implementation	Follow-up audit showed improved practices across both the inpatient and outpatient setting (inpatient improvement in 12/18 criteria, outpatient improvement in 10/18). Greater compliance was observed in the outpatient setting, most likely because of the availability of drop down notes in the CPOE system.

Note: CPOE; Computerised provider order entry, EMR; Electronic medical record

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