Development and use of an innovative Gap Finding Tool to create a Pharmaceutical Care Model within a paediatric oncology setting

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Abstract
Introduction: A paediatric cancer ward is a setting where pharmacists participate in direct patient care, acting as coordinators between the patient, caregivers and healthcare professionals. The aim of the study was to develop a Gap Finding Tool to support the setting up of a pharmaceutical care model at a Paediatric-Adolescent Cancer Ward.

Methods: The Standards of Practice for Clinical Pharmacy Services by the Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Clinical Pharmacy (2013), the American College of Clinical Pharmacy (2014) and the European Association of Hospital Pharmacists (2014) were used to compile the Gap Finding Tool. The developed Tool was tested for content validity by a panel of experts and subsequently implemented over 2 months.

Results: The Gap Finding Tool comprised of nine sections with an average of eight statements each about pharmacy services that should be provided at ward level. For each statement, the rater indicates whether these contributions are provided. When the Tool was implemented at the Paediatric-Adolescent Cancer Ward, four major gaps were identified, namely, absence of a clinical pharmacist, lack of medicines information, vetting of chemotherapy prescriptions by pharmacist with limited access to patient data and lack of pharmacist-input on medicines availability. Processes requiring optimisation included discharge medication advice and documentation processes.

Conclusion: The developed Gap Finding Tool is an innovative tool which is versatile and can be used in ward or ambulatory clinical settings to identify gaps in pharmaceutical processes and services and compare national or regional practices to international standards.

Keywords
Gap finding tool, pharmaceutical care, paediatrics, oncology

Date received: 17 September 2021; revised: 17 September 2021; accepted: 18 September 2021

Introduction
A high intensity ward such as a Paediatric-Adolescent Cancer Ward (PAW) is a setting where a pharmacist can participate in direct patient care by acting as a coordinator of care between the patient, parents and carers and the healthcare professionals.1–5 When starting a ward-based clinical pharmacy service, the tools required to develop, implement and run the service need to be determined. In this case, one asks what tools are needed to ensure that the pharmacist establishes an innovative, world-class pharmaceutical care model which is tailored for the needs of paediatric patients attending the PAW and supports pharmacy to contribute towards a higher level of care for paediatric oncology patients? This question formed the rationale behind the development and application of a Gap Finding Tool. The purpose of the tool was to determine and document the required interventions of a ward-based clinical pharmacist to enable the identification of gaps and processes necessitating optimisation in ward pharmacy
services. The tool supports comparing pharmaceutical care practices delivered to patients.

The research leading to the implementation of an innovative clinical pharmacy service was carried out at the PAW at Sir Anthony Mamo Oncology Centre (SAMOC). The PAW is a 14-bed ward and treats all types of cancer, including leukaemia, lymphoma, solid tumours, as well as brain and spinal cord tumours, in children and adolescents. Patients are admitted as in-patient or day-patients. Day-case patients attend by appointment every week either for review only, or for review and chemotherapy treatment. At the PAW, the clinical service is provided by a team of consultant paediatric oncologists, medical resident specialists, higher specialist trainees, nurses, a social worker, a psychologist, a speech therapist, a physiotherapist, nutritionist and a teacher. At the time of the study, there was no direct clinical pharmacist working as an integral member of the interdisciplinary health care team to aid in the management of cancer in this patient cohort and the pharmaceutical service development aimed to complement interprofessional service already in place. The aim of the study was to develop and use an innovative Gap Finding Tool to support the setting up of a pharmaceutical care model at the PAW at SAMOC.

**Methods**

The Standards of Practice for Clinical Pharmacy Services put forward by the Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Clinical Pharmacy,6 the American College of Clinical Pharmacy,7 and the European Association of Hospital Pharmacists8 were used to compile the Gap Finding Tool. These standards were chosen namely because they all discuss extensively the roles of ward-based pharmacists which was the focus of the Gap Finding Tool. The developed Gap Finding Tool was tested for content validity by a panel of experts consisting of two consultant paediatric oncologists, a drug information pharmacist, a quality assurance hospital pharmacist and two nursing officers. The panel was given a set of questions assessing the relevance of the sections with the purpose of the Gap Finding Tool and the relevance of the statements for each heading. They were also asked to provide changes or additions to any sections or statements. No major changes were undertaken following the validation process. The Gap Finding Tool was implemented between April and May 2017. During the implementation phase, the PAW was attended by the pharmacist-researcher three times per week to observe the care practice delivered to the patients at the ward whilst completing the Gap Finding Tool.

**Results**

The Gap Finding Tool was presented in tabular format (Appendix). It comprised of nine sections corresponding to a pharmacy service which should be provided at ward level. Each section consisted of an average of eight related statements describing the input of a pharmacist. For each statement, the rater indicates whether these contributions are provided. A ‘Comment’ section was included so that the rater could document any further details in relation to these roles.

When the Gap Finding Tool was implemented at the PAW, four major gaps requiring establishment were identified. These include the absence of a clinical pharmacist as part of the interdisciplinary care team; lack of medicines information at patient bedside; chemotherapy prescriptions not verified by a clinical pharmacist on the ward who is knowledgeable of the patient’s medication condition and drug therapy but rather being vetted by the compounding pharmacist in the central pharmacy with minimal clinical group contact; and lack of pharmacist’s input regarding medication availability and access to medications. The latter two gaps relate to the current medication management process.

The Gap Finding Tool also highlighted processes requiring optimisation. The processes were clinical review, therapeutic drug monitoring, adverse drug reaction (ADR) management, discharge medication and documentation processes, as well as provision of pharmacotherapy counselling to parents. The lacuna highlighted by the Gap Finding Tool to optimise the discharge medication process in tandem with the need for pharmacotherapy counselling to parents as well as the documentation process enables the development of processes which help to improve pharmacist-input at ward level.

**Discussion**

The usefulness of the Gap Finding Tool lies with the identification of gaps in pharmaceutical processes and services in ward or ambulatory clinical settings. In this study, the Gap Finding Tool led to the identification of a number of gaps which were absent or required optimisation through a direct pharmacist intervention at ward level within the PAW. The implementation of the Tool served to elaborate a pharmaceutical care model that addressed the gaps in care required to support a personalised patient care model.

The tool highlighted the gap ensuing from a lack of clinical pharmacist interventions within the interdisciplinary care team. Paediatric cancer patients have special pharmaceutical care needs.9 Drug therapy and disease management of cancer in this patient cohort integrates multiple medications, most of which are high alert medications. Drug therapy includes chemotherapy, supportive care medications and medications for the management of co-morbidities.2 The complex pharmacotherapy carries a high risk of potentially serious pharmaceutical care issues (PCIs) including serious medication errors.1 The consequences of PCIs can not only be irreversible and interfere with the patient’s health outcomes and
reduce the patient’s quality of life but can sometimes result in death.\textsuperscript{2,3} The more complex the drug regimen, the higher is the risk of medication misadventures.\textsuperscript{5,10} The wide variation in size from infancy through adolescence and the associated developing physiological processes affect the drugs’ pharmacokinetics and pharmacodynamics.\textsuperscript{5} In the child suffering from cancer, this will lead to varying levels of exposures and clearance of chemotherapy and related medications, hence, in difficulty to predict efficacy and toxicity. It also leads to the need for frequent individual dosing calculations.\textsuperscript{5}

To meet the need of small doses, in these patients, dosage formulations are often cut, crushed and dissolved by the parents or extemporaneously compounded.\textsuperscript{5,11} The process from selection and prescribing to monitoring chemotherapy and related medications is very complex. These challenges make paediatric cancer patients a high-risk patient population.\textsuperscript{4,5} Clinical pharmacists may focus on the individualisation of pharmacotherapeutic care plans tailor-made to patient needs whilst interacting with the interdisciplinary team and providing carer support to overcome challenges of pharmacotherapy and optimise patient’s therapeutic outcomes.\textsuperscript{12} In collaboration with other healthcare professionals, they are in an ideal position to provide high-quality evidence-based pharmaceutical care to the young patient suffering from cancer, including initial and subsequent therapeutic management, supportive care and survivorship.\textsuperscript{4,9,13–17} Clinical pharmacists play a pivotal role in maximising the benefits of the complex pharmacotherapy involved and minimising its toxicities, ensuring that the drugs are utilised to their fullest therapeutic potential.\textsuperscript{18–22} Identification of the need for physical presence of a pharmacist at the ward was crucial to establish the importance of the pharmacist being actively present at the PAW and subsequently contribute towards establishment of other ward-based pharmaceutical services.

The absence of medicines information provision to healthcare professionals at patient’s bedside was captured during this exercise. It was noted that when healthcare professionals, namely doctors and nurses, had a drug-related enquiry, they either relied on their knowledge, looked up the information themselves, or phoned the medicines information or the dispensary sections of the hospital pharmacy. However, the latter alternative created a weakness in that the discussion ensuing was based on the information request and lacked the individual patient-focus. Accurate and relevant information or advice may be delivered in response to effective verbal or written questioning by the healthcare professional or initiated by the clinical pharmacist to impact the prescribing, administration, monitoring and use of medicines for individual patients.\textsuperscript{6} The contribution aids towards the provision of patient-centred care, optimisation of the quality use of medicines and guarantees an efficient pharmaceutical care service through the use of latest evidence-based medicines information as well as by allowing clinicians and nurses to focus on other patient care issues.\textsuperscript{6}

Gaps within the current medication management process that ensure safe and effective medication use were identified through the Gap Finding Tool exercise. During the implementation phase, it was observed that chemotherapy prescriptions were vetted by pharmacists at the compounding section prior to reconstitution who however was unaware of the individual patient’s needs and co-morbidities. To be able to undertake the chemotherapy prescription vetting process from a patient individualistic point of view, it may be worth suggesting that prescription checking is conducted by clinical pharmacists who have access to all patient data and the rest of the interdisciplinary team, leading to optimisation of patient care. In tandem with active participation in the prescription review process to ensure clarity and validity of prescriptions and appropriateness of all prescribed drugs, clinical pharmacists are in an ideal position to identify challenges relating to medication availability and access and to intervene in order to overcome these challenges. Clinical pharmacists’ actions to overcome these challenges may include coordinating the process for procurement of chemotherapy and associated medicines that are not readily available on the hospital formulary and suggesting alternative methods such as extemporaneous compounding in cases where specific formulations cannot be procured.\textsuperscript{15}

Application of the Gap Finding Tool enabled the development of processes which help to improve pharmacist-input at ward level. During the implementation phase, it was noted that at the discharge stage, discharge medications were written on a small white piece of paper and only the patient identifiers, the name, dosage regimen and duration of the drug were written. Other important information was limited to word of mouth provided by the medical team. Paediatric hospital discharge is a complex transitional care process fraught with risk for information transfer to be suboptimal, which can lead to medication misadventures.\textsuperscript{6,11,23,24} In paediatric cancer, the complex treatment and schedules involved make this process even more intricate.\textsuperscript{25–27} In a study conducted by Walsh et al. (2009) to determine rates and types of medication errors in outpatient adults and children suffering from cancer, it was found that administration errors accounted for more than half of the medication errors, with home administration errors being more common in children than in adults (77% vs. 7%, respectively). A practical suggestion for intervention was improved communication between healthcare professionals and the parents about medicine-related information, particularly home medications.\textsuperscript{11} Pharmacists’ interventions during transitions of care, including provision of education along with communication of complete and accurate information on discharge medications to patients and their families, have been widely described to improve capacity for involvement, encourage the safe and appropriate use of medicines, enhance therapeutic outcomes and reduce the chances of adverse outcomes and hospital readmissions.\textsuperscript{6,23,24,28–32} Information that should be provided
includes but is not limited to the reason why each medication was prescribed, method of administration, duration of treatment, storage, possible side effects and details regarding further supply of medications upon discharge. Supplementation of written instructions to reinforce verbal education enhances knowledge, compliance and adherence. Written instructions or guides could also serve as documentation tools which could be shared as patients move across transitional settings thereby ensuring continuity of care. 

Optimisation of the documentation process was identified. Documentation is central to the provision of high-quality pharmaceutical care. Just as clinicians and nurses document pertinent patient-related information for the purpose of practicing good medicine and good nursing, clinical pharmacists require a standard format to gather and integrate patient, drug and disease information to contribute to good patient-centred pharmacy. Albeit much of the patient, drug and disease related information that is gathered by pharmacists is the same as that documented by clinicians and nurses, pharmacists must process the information in a different context so as to determine what is, and what is not a pharmaceutical care issue. In turn, this leads to pharmacist decisions and interventions to resolve the PCIs identified. Effective clinical reasoning targeting cancer patients necessitates that the pharmacist gathers several components. These include (i) patient-specific details such as age, weight, height, body surface area, medical diagnosis, protocol, presence or absence of a central line and presence or absence of an enteral tube (ii) patient medication history such as family history, past medical history, drug history and ADR/sensitivities (iii) current medications including chemotherapy and related medications as per protocol and other medications and (iv) PCIs. The process of resolving PCIs through pharmaceutical interventions is a dynamic process where pharmaceutical interventions proposed to resolve PCIs may generate secondary PCI. Similarly, documentation by the clinical pharmacist is a sustained process that needs to be prompt, absolute and consistent. Apart from enabling the pharmacist to be fully informed about patient-specific issues, documentation of information and interventions enables pharmacist accountability and continuity of care as well as demonstration of the value of clinical pharmacy service provision to high-quality care and improvement of patient outcomes.

The strengths of the study include the development and implementation of a Gap-Finding Tool which is versatile and can be used in any ward or ambulatory clinical setting to update provision of service and compare national or regional practices to international standards. The Gap-Finding Tool could be used to identify gaps and subsequently provide a pharmaceutical service aimed at closing the gaps. In this study, it provided the evidence for the valid intervention of a ward-based clinical pharmacist. The clinical pharmacist service was started and the impact was assessed which led to a roadmap for the prioritisation of implementing this model in the oncology setting. A limitation of the study is that the tool was validated within a national expert team. Further studies may include the validation and application of the tool within a broader context that considers European and international scenarios.

Conclusion
In this study, the developed Gap Finding Tool led to the identification of pharmaceutical gaps and processes requiring optimisation at the PAW. The application of the tool supports a standardised approach for optimisation of services including the interprofessional focus.

Declaration of conflicting interests
The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding
The authors received no financial support for the research, authorship and/or publication of this article.

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Appendix. Gap Finding Tool – The roles of a Ward-Based Pharmacist.

| 1. Accurate history | Tick | Comments |
|---------------------|------|----------|
| Obtaining and documenting a complete Drug History |       |          |
| Obtaining and documenting a complete Past Medical History |       |          |
| Confirming and documenting adverse drug reactions/sensitivities |       |          |
| Reconciliation of medication therapy |       |          |
| Asking about recently stopped/changed medications |       |          |
| Asking about the use of adherence aids |       |          |
| Asking about storage of current medications at home |       |          |
| Assessing parent's/patient's understanding of their child's/their illness and determining if there is need for further education about the illness |       |          |
| Assessing parent's/patient's understanding and attitude to their child's/their current drug therapy |       |          |
| Assessing parent's/patient's ability to use drugs as prescribed |       |          |
| Assessing the need to refer to medical staff |       |          |

| 2. Current medication management |       |          |
|---------------------------------|------|----------|
| A. Reviewing all prescriptions and treatment charts to ensure clarity and validity |       |          |
| Ensuring prescriber’s intention is clear to enable the safe supply and administration of medicines |       |          |
| Ensuring that prescriptions and treatment charts are comprehensive and unambiguous |       |          |
| Ensuring all drugs are prescribed by their active ingredient |       |          |
| Ensuring that drug names and directions are not abbreviated |       |          |
| Ensuring that the date and time at which medicine administration is to commence and stop are written |       |          |
| Ensuring that the time the dose should be given is endorsed in the relevant section of the treatment chart |       |          |
| Checking that patient identifiers are documented |       |          |
| Ensuring that the order is signed and the prescriber can be identified |       |          |
| B. Reviewing prescriptions and treatment charts to ensure appropriateness of all drugs |       |          |
| Confirming drugs have a clear indication |       |          |
| Confirming drug is prescribed for an approved or recognised indication. If not, ensuring that the necessary forms are filled |       |          |
| Ensuring protocols/guidelines are considered when prescribing |       |          |
| Considering latest evidence regarding drug’s efficacy and toxicity |       |          |
| Ensuring appropriate method of administration is selected |       |          |
| Ensuring infusion solution and concentration are appropriate for IV drugs |       |          |
Appendix (continued).

| Activity                                                                 | Details                                                                                                                                 |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Checking drugs and doses are appropriate                                |                                                                                                                                       |
| Checking dose conversions with changes to route or formulation          |                                                                                                                                       |
| Checking that the drug is achieving therapy goals                       |                                                                                                                                       |
| Checking for duplications                                               |                                                                                                                                       |
| Checking for contraindications                                          |                                                                                                                                       |
| Checking for drug interactions                                          |                                                                                                                                       |
| Ensuring drug units are clear                                           |                                                                                                                                       |
| Tracking cumulative doses of anti-cancer drugs                          |                                                                                                                                       |
| Providing information on extemporaneous oral formulations               |                                                                                                                                       |
| Liaising with the cytotoxic compounding unit to coordinate the timely supply of chemotherapeutics |                                                                                                                                       |
| Ensuring drugs are available at the ward and where necessary are ordered|                                                                                                                                       |
| Checking treatment chart to ensure all doses have been administered     |                                                                                                                                       |
| Annotating treatment charts as required                                 |                                                                                                                                       |
| Ensuring drug is cancelled on treatment chart when stopped              |                                                                                                                                       |
| Checking availability and access to medications                         |                                                                                                                                       |
| Considering cost of drugs to patient and hospital and considering alternatives |                                                                                                                                       |
| **3. Clinical review**                                                  | Reviewing and monitoring patient-specific clinical information to evaluate the response to the drugs and adjust therapy accordingly           |
|                                                                         | Identifying actual and potential drug-related problems                                                                               |
|                                                                         | Performing follow-up evaluations in collaboration with other members of the healthcare team                                          |
| **4. Therapeutic drug monitoring (TDM)**                                | Providing instructions as to when and how TDM must be carried out                                                                       |
|                                                                         | Informing the prescriber of TDM results in a timely manner, including recommended action and future monitoring requirements               |
| **5. Medicines information**                                            | Providing medicines information to healthcare professionals                                                                          |
|                                                                         | Providing medicines information to patients and parents/legal guardians verbally and in writing                                        |
| **6. Adverse drug reaction (ADR) management**                           | A. Detection and prevention of an ADR                                                                                                 |
|                                                                         | Identifying and monitoring susceptible patients: patients on multiple drugs, paediatric patients, patients treated with drugs known to have a high incidence of and serious adverse effects including narrow therapeutic index drugs, previously experienced ADRs, hepatic and renal impairment, multiple disease processes |
B. Suspected ADR
Assessing the details of the ADR in the context of patient-specific and medication-related factors

C. Management of an ADR
Considering the likelihood of the suspected drug having caused the reaction and the clinical significance when assessing whether to continue treatment with the suspected drug.

Recommending treatment options for the ADR and, if appropriate, recommending alternative treatments

Involvement in the management of all cancer and chemotherapy related complications

Developing and implementing pharmacological treatment guidelines on acute and late effects of chemotherapy drugs

7. Participating in interdisciplinary care
Being physically present to participate in ward rounds, clinics and meetings attended by other healthcare professionals

Preparing accurate and comprehensive pharmacy patient profiles

Contributing information about patient’s drugs and their management

Making suggestions for selecting and monitoring medicines

Be fully informed about current patient-specific issues

Prioritising patients requiring further review or education by the pharmacist

Participating in discharge planning

8. Information for ongoing care
A. Managing the patient’s medicines and communicating with them/their parents or legal guardians on transition

Discussing the drugs that need to be supplied or sourced on discharge or transfer

Annotating drugs which need to be supplied on discharge on the patient profile/file

Removing stopped medicines for destruction

Providing patients with drug/s required

Providing information (written and verbal) about discharge medications, including directions, indication, start and stop date, contact name and number, how to identify side effects of new drugs and what to do if they occur

Providing information about adherence aids

Encouraging parents/patients to contact their hospital pharmacist at any time after discharge

B. Liaising with other Health Professionals on Transition

Obtaining consent and then communicating all drug-related information in a timely manner to the patient's General Practitioner community pharmacist, residential care provider or other healthcare professional

9. Documentation
Documenting the medication-related assessment and plan of care to optimise patient outcomes directly in the patient file
Adopted from:
American College of Clinical Pharmacy. Standards of Practice for Clinical Pharmacists. Pharmacotherapy 2014; 34: 794-797.

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