VicTAG Chemotherapy Audit Toolkit

Quality Framework and Supporting Information

v1.0

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Executive Summary

Summary: In a survey of health services providing chemotherapy in Victoria in 2016, only 27% were found to be retrospectively auditing their prescribing. The Victorian Therapeutics Advisory Group (VicTAG) Chemotherapy Audit Toolkit provides health services with trialed methods of auditing variations that can be implemented to improve quality processes.

Background: In 2015, a serious incident involving under-prescribing of carboplatin for head and neck cancer was detected in NSW. In response to this, the Victorian Department of Health and Human Services (DHHS) audited current quality processes at public and private health services across the state to assess for quality weak points.

Project: The Chemotherapy Audit Toolkit is designed to provide health services with a quality framework for chemotherapy prescribing and a tested methodology for auditing their chemotherapy prescribing variations. These tested methodologies do not represent the only valid approach to auditing of variation and are intended to provide a starting point for services that do not have an established practice.

Scope: The toolkit covers currently implemented electronic prescribing systems in Victoria: CHARM, Cerner Oncology, ARIA and Epic. Additional information has been found for MOSAIQ from users in another state. There is also an approach that is usable for services without an electronic prescribing system.

Introduction

Chemotherapy is a common modality of treatment for cancer patients with a wide range of benefits and side-effects. Optimising the dose of chemotherapy for patients requires consideration of a range of factors including the type of cancer, the agent/s and patient-related factors, particularly relating to a patient's ability to complete a course of treatment or to achieve a particular therapeutic outcome.

There are a large number of chemotherapy protocols used across Victorian hospitals (e.g. there are over 300 protocols listed on EviQ, an Australian reference site managed by Cancer Institute New South Wales), and the type and number of protocols regularly changes as the results of new clinical trials become available. This, coupled with the complexity of dosing for individual patients and the quality processes for getting the right medication/s to the right patient at the right time, requires robust clinical governance processes to be in place to ensure that the various aspects of the treatment process work together to provide the best outcomes for patients.

Change to the dose of chemotherapy agents is a common point where variations to approved chemotherapy protocols occurs. This is typically done by balancing patients' capability to tolerate treatment against established treatment protocols and the desire to give full therapeutic treatment, and may lead to an increase or decrease of the dose and/or changes to the timing and frequency of delivery of chemotherapy. While health services have formal governance approaches in place to approve all new chemotherapy protocols permitted to be delivered to their patients, and also for the chemotherapy delivery process, there are clear variations between services in the way in which they review changes to doses.

This paper provides an overview of this area following recent high profile chemotherapy dosing issues in two Australian jurisdictions, and describes a model governance process around the chemotherapy pathway. The paper also describes the development of a simple electronic tool to assist health services in reviewing dose adjustments, and how this can be used with different chemotherapy management systems as well as paper based approaches.

The VicTAG Chemotherapy Audit Toolkit was supported by the Victorian Government.

Glossary

Chemotherapy: Treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Chemotherapy may be given by mouth, injection, or infusion, or on the skin, depending on the type and stage of the cancer being treated. It may be given alone or with other treatments, such as surgery, radiation therapy, or biologic therapy. For the purposes of this toolkit, immunotherapy is included as chemotherapy but hormonal therapy is not. (Definition from National Cancer Institute)

Credentialing: the formal process used to verify the qualifications, experience, professional standing and other relevant professional attributes of health practitioners for the purpose of forming a view about their competence, performance and professional suitability to provide safe, high-quality health services within specific organisational environments. (Australian Commission on Safety and Quality in Health Care. Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners. Sydney: ACSQHC, 2015.)

Variation: chemotherapy prescribing variation – a change in the prescription of a protocol for a patient usually made on basis of patient specific factors e.g. dose reduction for altered hepatic or renal function.

Background

In response to chemotherapy dosing incidents identified in NSW and SA in 2016, the Victorian Department of Health and Human Services (DHHS) conducted surveys of Victorian's Integrated Cancer Services and all chemotherapy providers to determine the quality processes in place for prescribing and administration of chemotherapy. The results showed that governance procedures across health services were consistent with national guidelines, however retrospective review of dose variations from protocol was comparatively low, with only 27% of public services indicating that they undertook such audits.

Based on these results, and to ensure that Victorian health services are able to be appropriately supported in an area of growing complexity of care, DHHS engaged the Victorian Therapeutics Advisory Group (VicTAG) to consider approaches to improve services' capabilities to self-audit chemotherapy prescribing and administration. The key focus for this was on developing an audit tool that could be used by health services to enable them to have a consistent approach to understanding dose variations at their service.

It is common for chemotherapy doses to cancer patients to be varied from what is recommended in an approved protocol. Typical reasons for these variations include organ dysfunction (especially renal and hepatic), previous toxicity and co-morbidities. In each case, the reasons for dose variations should be recorded, and where variations are made based on unusual or uncommon features/factors, it is appropriate that these be peer reviewed both to inform peer learning/education and to conform with peer review processes as part of overall health service quality of care.

The role of Pharmacy in auditing is well established, with significant roles in Quality Use of Medicines (QUM) activity around Australia as shown by dedicated QUM pharmacists being present at a significant range of health services. In addition, the establishment of various stewardship roles, in conjunction with medical and nursing colleagues, in disciplines such as anti-microbial (infectious diseases), opioid management and anticoagulation shows the breadth of roles pharmacists have been asked to perform.

However, review of chemotherapy dose variations and processes around this is an area that has been little explored in the peer reviewed literature, with few articles able to be identified from a Medline and EMBASE review that described retrospective auditing of protocol compliance. A survey of International Society of Oncology Pharmacy Practitioners (ISOPP) members, with responses from 11 countries apart from Australia, as well as informal correspondence with oncology pharmacists internationally was similarly unable to elicit much evidence of tools or processes for retrospective auditing of chemotherapy dose variations. The one example reported from Mexico is of a similar model to the one utilised in this toolkit. This likely reflects the fact that other jurisdictions have not had the same motivation to focus on this specific aspect of care, as opposed to the broader quality governance processes around chemotherapy.

These broader processes and the context in which they occur are important to note. For example, there are some key differences between centralised and decentralised approaches to pharmacogovernance.

For example, Alberta, Canada, has centralised:

- protocol maintenance and governance, including protocols on their electronic prescribing system.
- formulary listings with indications, including restrictions on medical staff able to prescribe for some agents.
    - formulary listings consider pCODR (pan Canadian Oncology Drug Review) which does have a cost-effectiveness metric in the evaluation.
- a universal electronic prescribing system covering all of Alberta, with harmonised protocols (oncology protocols are harmonised and haematology are moving in this direction).

In contrast, Victoria's current system is a good example of a decentralised system:

- protocol maintenance and governance is the responsibility of individual health services. Whilst EviQ provides a good set of example protocols (that often exist at sites but with small changes to the published protocol), however there is variable use of these protocols across health services.
- a fragmented ecosystem of electronic prescribing systems, including a significant group that have not yet taken up or are implementing an electronic prescribing systems.
- formulary listing is governed mostly by listing on the PBS, with the exception of inpatient treatment which is not funded and is therefore health service dependent.

The decentralised approach requires each institute to develop and maintain their own governance processes and systems, and there is naturally variation across these depending on their mix and size of services. Where new services are developed or implemented, particularly at smaller health services, the development of these systems can be challenging in the absence of support from larger health services or other organisations.

The audit tool and toolkit aims to provide a consistent baseline approach to chemotherapy quality that reflects existing service capabilities.

Evidence review (including published literature)

A literature review was conducted with thanks by Eastern Health Library Service on Medline and EMBASE searching for inappropriate prescribing and antineoplastic agents, including synonyms and subject terms.

The review found little to suggest retrospective auditing was common practice in the oncology sphere. Most of the literature focused on the implementation of CPOE (Computerised Prescriber Order Entry), and whether this reduced and/or altered the types and frequency of errors encountered (Sanchez Cuervo, Rojo Sanchis et al. 2015, Aita, Belvedere et al. 2013, Elsaid, Truong et al. 2013, Nerich, Limat et al. 2010, Small, Barrett et al. 2008). Some studies focused on oral chemotherapy, given that the processes in place do not mirror parenteral chemotherapy but carry similar risks in terms of prescribing (Weingart, Mattsson et al. 2012, Oberoi, Trehan et al. 2014, Taylor, Winter et al. 2006, Collins, Elsaid 2011). For some of these studies, however, errors were detected in the normal processes of operation, with the checks in place (pharmacy and nursing) recording incidents of therapy that were changed as a result of their intervention. Other studies looked at implementation of guidelines (sometimes known as treatment pathways) and compliance, rather than prescribing from a protocol (Wymer, Pearce et al. 2017). Some of the literature focused on the economic costs of errors, and also costs avoided by error prevention (Ranchon, Moch et al. 2012).

Various national and international associations including Clinical Oncology Society of Australia (COSA), Society of Hospital Pharmacists Australia (SHPA), International Society of Oncology Practitioners (ISOPP), British Oncology Pharmacy Association (BOPA), ASHP (formerly known as American Society of Hospital Pharmacists) and American Society of Clinical Oncology (ASCO) have published guidelines[1] to help inform best practice staffing and governance models to prevent error. It is worth noting that prior to the dosing issue in NSW, NSW Therapeutics Advisory Group (NSWTAG) had developed a quality indicator which provided a methodology to verify chemotherapy prescribing utilising retrospective auditing (NSW QUM Indicator 3.6, 2014). Whilst auditing completed by NSWTAG in 2011 does show that the tool was not used widely at that time, the need may not have been as apparent or urgent. The QUM indicator was integrated into the 2014 National Quality Use of Medicines Indicators for Australian Hospitals.

Protocols for use in the treatment of cancer are developed through clinical trials. Whilst they include some ability to individualise treatment (e.g. doses and frequency of anti-cancer agents) to the patient's condition, the real world experience is often more diverse than could be tested in a

[1] **COSA:** Cancer Therapy Medication Safety Working Group. COSA guidelines for the safe prescribing, dispensing and administration of systemic cancer therapy. Sydney: Cancer Council Australia. [Version URL: https://wiki.cancer.org.au/australiawiki/index.php?oldid=183289, cited 2018 Oct 16];
SHPA: The Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Oncology. Standards of practice for the provision of clinical oncology pharmacy services. J Pharm Pract Res 2002; 32: 115–18.;
ISOPP: International Society of Oncology Pharmacy Practicioners Standards Committee. ISOPP standards of practice. Safe handling of cytotoxics. J Oncol Pharm Pract. 2007;13 Suppl:1-81;
BOPA: accessed: http://www.bopawebsite.org/publications/guidelines-standards ;
ASHP: GOLDSPIEL, B., HOFFMAN, J.M., GRIFFITH et al, 2015. ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy. Am J Health Syst Pharm, 72(8), pp. e6.
ASCO: 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology; Michael N. Neuss, Terry R. Gilmore, Kristin M. Belderson, et al. Journal of Oncology Practice 2016 12:12, 1262-1271

SHPA and ISOPP guidelines/standards of practice are currently under review.

controlled environment. Expert opinion replaces controlled trial evidence in these scenarios, and the impact of these changes to the treatment on the outcomes for the patient is not certain. Testing of frequency changes suggest that it is not often known what the optimal treatment is, and protocols that have being used for decades are being trialed with modifications. For example, changing the frequency of chemotherapy administration of common protocols can lead to improvements in treatment (Denduluri, Somerfield et al. 2016) or can lead to greater toxicity with no improvements for patients (Cunningham, Hawkes et al. 2013) many years after the protocols have become mainstream practice. In addition, an incident involving the miscalculation of an Etoposide Phosphate preparation resulted in an 18% overdose in 11 children was evaluated by a medical oncologist that "no harm was done." Variation, whether through intent by personalising treatment or by error, does not necessarily represent a better or worse outcome for a patient, instead, the outcome becomes less certain. For variations that are an alteration to the underlying protocol (e.g. reducing a dose for the whole patient population), until it can be said that the variation is an improvement on existing standard of care therapy (or contributing to that knowledge through inclusion in a clinical trial), it should be avoided to prevent potential reductions in treatment efficacy for patients.

The official reports from the New South Wales (Currow, et al 2016) and South Australia (Marshall, et al 2015) chemotherapy dosing incidents highlight potential vulnerabilities for health services, but focus on deficiencies in governance and the cultures that permit this to happen as the key contributors. The governance failures are different, with SA emphasising the failure of appropriate controls on protocol entry in the electronic environment and NSW being the failure of application of evidence based medicine.

Role of the Chemotherapy Audit Tool and Quality Framework

This toolkit seeks to reduce the risk from unwarranted variations (whether intended or not) that successfully penetrate the "Swiss cheese" model of error prevention (Reason 2000) as applied in standard oncology practice in Victoria. Retrospective auditing to show systematic variations for discussion and review by a peer group that completes the feedback loop into protocol maintenance (and also formalizes what was often an informal and ad-hoc process).

The quality framework is built to support best practice around the journey from evidence to patient, and management of variations from protocol as they appear. The additional audits listed later in the toolkit also help to complete the spectrum of activity covered by assessment and quality measures.

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Model quality framework for protocol approval, localisation and variation management

This quality model will cover chemotherapy treatment, with presumed ability to be applied to biotherapy. It will not cover diagnostic processes.

Guidelines from national and international multi-disciplinary and pharmacy bodies, including COSA (Cancer Therapy Medication Safety Working Group), BOPA, ASHP (Goldspiel, Hoffman et al. 2015), ASCO and ISOPP provide some guidance in this area, but do not fully outline a comprehensive process that could be used as a model. Drawing on these and some real world examples of quality frameworks, a best practice framework has been derived and is described below.

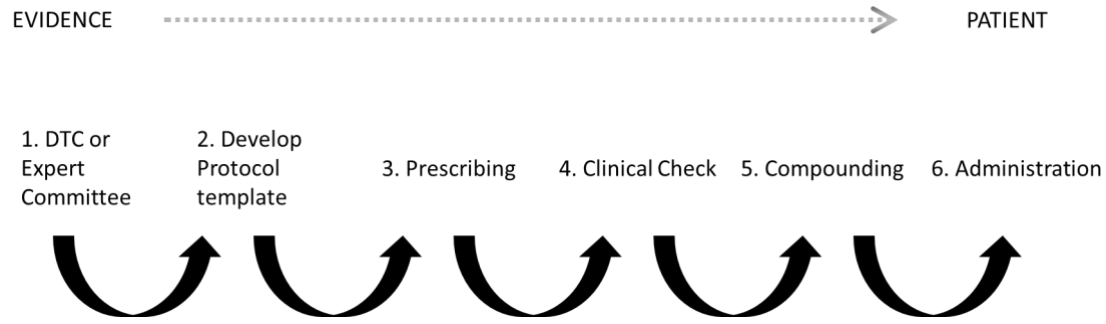

Fig. 1 The Evidence to Patient Journey

1. A submission is made to the hospital Drugs and Therapeutics Committee (DTC) or delegated committees for a new protocol or medication to become part of standard treatment for that health service. This is made by clinicians from the health service and is generally based on the published evidence. Approval is generally based on the strength of the evidence and cost of the agents.
2. The protocol, if approved, is then formally documented to guide use in the health service. This documentation includes the protocol (in institutional format with supportive care and monitoring) as well as either a pre-printed standard order form if used (for health services prescribing on paper) or loading of the protocol into the Electronic Prescribing System (EPS) if the health service utilises these. For all of these documents, multidisciplinary review of the protocol in the final format (loaded on electronic prescribing system, institutional proforma and/or reference protocol) is of paramount importance to prevent mistakes (Goldspiel, Hoffman et al. 2015). It is strongly recommended for this multidisciplinary review to involve medical, pharmacy and nursing staff as these specialties each have different touchpoints with protocols through their roles of prescribing, dispensing and administering.
3. Once a patient has been diagnosed and then an appropriate protocol selected, it needs to be prescribed by a credentialed prescriber for the patient with regard to relevant patient parameters, such as BSA, renal and hepatic function.
4. The prescribed chemotherapy will then undergo a clinical check by a credentialed pharmacist to ensure appropriateness of the therapy for the patient. If a variation to the protocol is detected, a variation pathway can be activated. For specific recommendations covering

variation management, please see the next section. BOPA have standards covering clinical verification. [2]

5. Compounding/dispensing is then completed by pharmacy or external providers as required. This is specifically covered by guidelines produced in the main by pharmacy associations.
6. Administration of the therapy as required according to product information or evidence based guidelines is completed by appropriately credentialed staff.

Relevant Standards/Guidelines for each step in the evidence to patient journey

4. Standards for Pharmacy Verification of Prescriptions for Cancer Medicines, BOPA.
5. SHPA Standards for Compounding (under review)
6. CNSA: https://www.evig.org.au/getmedia/13df577c-f417-4951-a0d6-c18bc84407f1/newlogoApril-01-2c-2010-CNSA-NEC-Minimum-Safety-For-Nurses-re-Anti-Cancer-Drugs-Position-Statement-33b-1.pdf.aspx (Under review for mid 2018)
   ANZCHOG: http://www.anzchog.org/docs/members-documents/anzchog-nursing-anti-cancer-therapy-position-statement.pdf (paediatric association)

7. Variation Management

Incorrect management of variations (usually involving insufficient oversight) can lead to patient harm through over or under dosing of patients, each with their specific set of consequences. Appropriate escalation pathways ensure that all staff are supported to make clinically sound decisions, and will not accept potentially unwarranted variation without due diligence.

A suggested variation quality framework follows, with escalation pathways as appropriate.

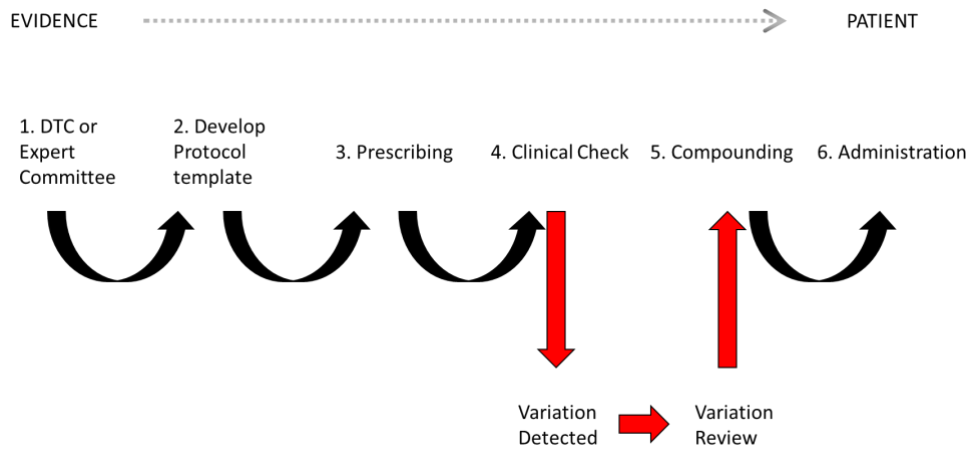

Fig. 2 Variations are most often detected during a clinical check

Medical oncologists will often engage with quality mechanisms in the health service prior to prescription of chemotherapy if considering a significant dose modification. This may occur with a group of clinicians looking after the same tumour stream, or via a director of oncology/haematology as institutional guidelines/norms allow. These may involve an approval mechanism, with evidence to be provided to support a change in practice. Some services mandate information about variations to be provided at the time of booking the patient for chemotherapy at a Chemotherapy Day Unit.

After prescribing, chemotherapy variations will often be detected at a clinical check by a pharmacist, and this will lead to a process for review, listed below (it is important to note that prescribers will often have escalated appropriately before this point and the escalation caused by the variation being detected will simply be a confirmation that this process has occurred).

When a variation is detected at a clinical check, it is important that clear escalation pathways exist for variations to be examined with sufficient rigor to ensure that optimal patient care is being delivered. This will depend on the magnitude and type of deviation from protocolised care detected.

There are a range of standardly accepted reasons for varying chemotherapy doses to patients, and where these have been advised and approved through a health service's clinical governance processes, further review is not warranted (except in rare cases of complex patients where multiple factors can affect dosing). For dose adjustments outside these, retrospective peer review can be an important quality check and for discussion/learning around the reasons for such changes.

Definitions of minor and major variations, and also of how much modification a protocol can undergo before a major variation becomes an unrelated or new protocol need to be defined to give clarity for clinical staff at the coalface. It is also to give some context as to acceptable variations – such as less than 10% for dose rounding or accepted modification for renal and/or hepatic dysfunction, or previous side effects, and resources that may be considered for reference in these scenarios.

A suggested clinical governance process for clinicians who detect a variation (usually either a pharmacist or a nurse) to follow upon identification of a dose variation is provided below. It is important to note that information about the variation once detected should be sought from the prescriber, MDM records and all available documentation to ensure that further steps are completed with full insight, thus preventing rework and inappropriate escalation. This ensures that the process will be followed with the understanding of the quality processes that have previously been undertaken by the prescriber.

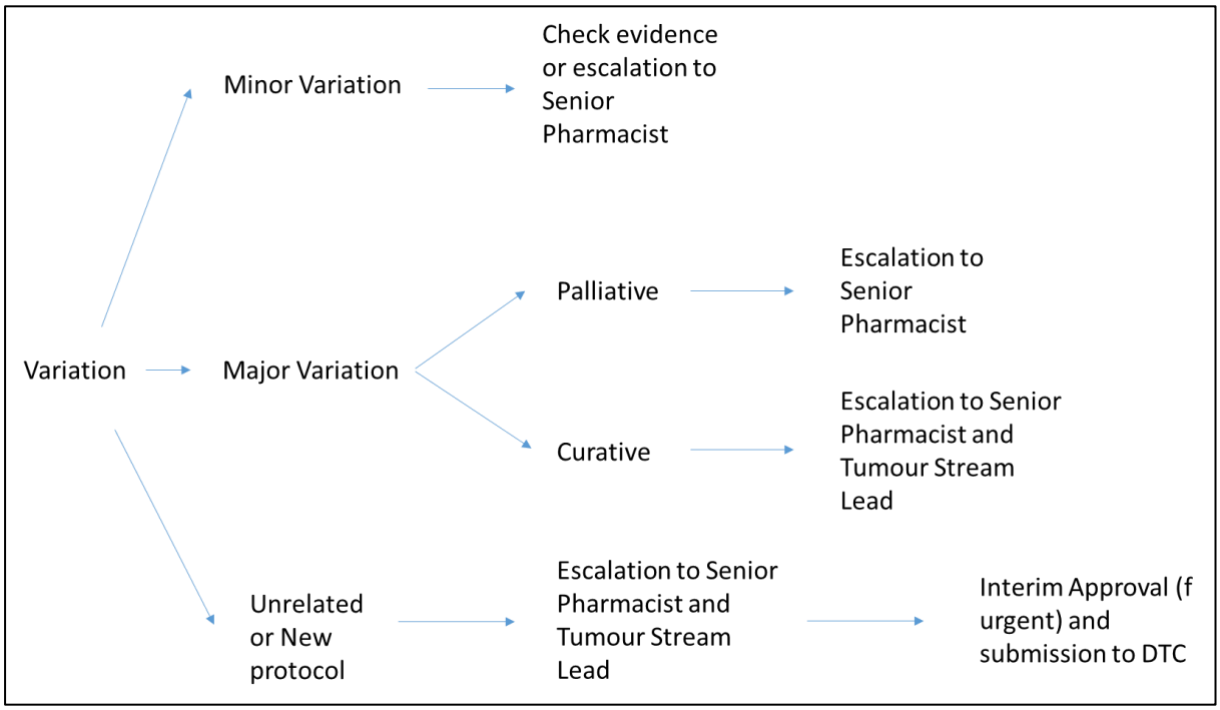

Fig. 3 Model Escalation procedure for a variation once detected (Individual thresholds for minor/major variations and escalation pathways to be set by health service)

Note that this is a suggested model and can be adapted to the personnel available in the health service. For example, in a larger health service "Senior Pharmacist" may refer to the Senior Oncology Pharmacist and in a smaller centre, this may involve external consultation or director of pharmacy involvement as is most appropriate with the personnel available. Heads of Unit may wish to be involved as well in escalation.

The intention of the audit tool is to capture all variations and to filter a subset of these for later oncologist peer review. The audit tool is retrospective and does not form part of this process

Some examples of variations are presented below:

Variation	Classification	Escalation Pathway
Dose rounding (e.g. <5% to full vial)	Minor variation with evidence	No escalation required
25% dose reduction as per EviQ because of reduced Creatinine Clearance	Minor variation with evidence	No escalation required
50% dose reduction of Doxorubicin with genetic heart defect, but normal Left Ventricular Ejection Fraction and no evidence	Major variation	If palliative intent: Senior Pharmacist If curative intent: Senior Pharmacist and Tumour Stream Head
Addition of extra chemotherapy agent	New or unrelated protocol*	Escalation to Senior Pharmacist and Tumour Stream Lead
Changing a protocol from 3 weekly to 2 weekly	New or unrelated protocol*	Escalation to Senior Pharmacist and Tumour Stream Lead
Substitution of chemotherapy agent	New or unrelated protocol*	Escalation to Senior Pharmacist and Tumour Stream Lead
Substitution of anti-nausea agent	Not relevant to escalation pathways	See internal formulary and anti-emetic guidelines

*: there are scenarios when this will be evidence based (e.g. CHOP protocol → CHOEP protocol, changing AC to dose dense version). Please refer to the individual protocol and supporting literature for guidance.

Note: Smaller services with smaller units may have trouble implementing some of these recommendations due to insufficient staff for peer review as suggested above. Strategies for the auditing of these units will need to be developed. Potential solutions may include hub-and spoke models with a regional centre supporting smaller centres (often, the medical practitioners in these situations originate from a hub service) or forming a partnership with a larger tertiary centre for support.

Reference: refer to literature review references.

Audit tool principles

Audit process

The toolkit provides tools that facilitate auditing of chemotherapy prescribing variations using quality structures internal to the health service.

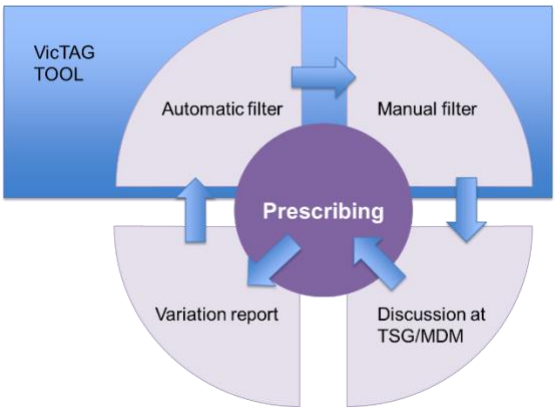

Fig.4 The VicTAG tool

The process for using the tool involves:

1. Creation of a retrospective variation report using the parameters and instructions supporting the tool. This will include health service decisions around scope based upon available resources.
2. Utilisation of a VicTAG tool to automatically filter the report to reduce resources required for manual filtering.
3. Manual filtering of report to identify prescribing variations that require attention from medical prescribers.
4. Discussion at tumour stream meeting/multi-disciplinary meeting and/or report to head of unit. Discussion of variations will lead to changes of prescribing patterns if required.

Note: Health services may choose different quality processes to be put into place for the discussion and analysis. The important function of this process is to feed back variations that would be considered outside of prescribing norms in order to ensure that appropriate oversight has occurred. Health services may also detect administrative issues, such as suboptimal protocol pathways (either electronic or paper) that require modification to match the utilisation of the health service, noting that this would require approval through the relevant pathways of the health service.

Audit parameters

The audit tool has included a number of principles to aid in improving usefulness, efficiency and specificity.

Note: Some of these recommendations have been made to limit the burden of auditing. The restrictions of first cycle inclusion only and excluding clinical trials (due to increased oversight) are recommendations to comply with a resource constrained environment. Ideally, **in an environment**

where resources are available, greater scope is provided by including second and subsequent line treatments as well as clinical trials.

The audit tool will target:

- curative/adjuvant (or neoadjuvant) therapy only – palliative chemotherapy, by intent, is intended to prolong survival, but not cure the patient. As cure cannot be compromised by dose reduction in this scenario, adjusting the dose to patient tolerance and wishes is appropriate for palliative intent chemotherapy, and therefore variation is acceptable.
- the first cycle of treatment only – by removing subsequent treatments, including variations resulting from toxicity, a much cleaner set of data will result with variations sampled of more value in auditing and discussion.
- all chemotherapy agents via all routes (e.g. intravenous, subcutaneous, intramuscular, oral, intraperitoneal, intrathecal etc.) – all chemotherapy regardless of route engenders the same risks and must be treated appropriately. Oral chemotherapy can potentially cause more issues as the patient or carer administers the dose. This removes the additional scrutiny afforded to parenteral therapy via the pharmacist and nursing staff during the processes of therapy preparation and administration. As many routes as possible should be included to ensure that maximal chemotherapy is covered by the audit.
    - A possible approach may be to do a manual audit of a small number of capecitabine patients – these patients currently represent the majority of oral chemotherapy patients outside of leukaemia and will provide a reasonable cross-section of coverage in the absence of an EPS based approach.

The following have been agreed as being outside the scope of the audit tool:

- Patients who have failed first line therapy – patients who have previously had therapy may increase the white noise produced by the audit, as these patients may require genuine dose adjustments for patient specific factors.
- Clinical trials patients – these patients are held to strict protocols where variation and deviations already have their own consequences in ways that standard of care patients do not.
- Supportive agents – dose adjustments to supportive therapies whilst having chemotherapy are excluded. Whilst some of these agents contribute to patient experience and safety, they more than often do not contribute to protocol efficacy, and that is the prime aim of this tool.

Note: not all of these considerations can be included in the automatic phase of tool operation. This is dependent on the information and format of the report from the EPS utilised, and on how the information has been programmed into the EPS.

Audit frequency and scope

Optimal parameters for auditing have been reviewed by the Project Reference Group.

In a setting with an EPS that produces reports for review, auditing of all tumour streams every 3-6 months is optimal. Please note that tumour streams can be audited continuously in a rolling style or processed as a batch.

In settings that operate on paper based prescribing or EPS that don't support audit functionality, some consideration of auditing parameters needs to occur. To guide health services in stratifying their approach:

- Frequency – 3-6 monthly auditing is optimal. Decreased frequency may be used in resource constrained settings, but no longer than annual is advised.
- Tumour Streams – all is optimal, but in resource constrained environments, targeting different tumour streams on a rotational basis may assist (e.g. Breast in this round of audit, Prostate in the next round etc.)

It is important to ensure that there is adequate sampling of tumour streams and prescribers if an approach is chosen that does not sample all activity. This will obviously interact depending on resources available for the audit. Guides to particular systems will inform approaches that can be used for each to maximise effect. General principles that may be used include:

- Limiting tumour streams covered by the audit, rotating through tumour streams each time an audit is done – focusing on one tumour stream (e.g. Breast) will allow better depth of coverage to find systematic deviation from practice.
    - May need to consider ensuring sufficient depth of audit by checking number of patients per prescribers

If a service is able to go beyond the limitations listed above, it is encouraged to do so, especially where electronic prescribing systems support this. Ideally, all chemotherapy cycles should be monitored for changes. More audits are described in the section “Additional audits to support the quality framework”. These fill out some of the gaps that are not met by the use of the tool.

This section provides guidance on how to optimally audit using the tool for the EPS currently in use in Victoria. These approaches have been piloted with the help of health services in Australia in order to provide a practical guide on auditing dose variations at health services.

CHARM Audit Methodology

The CHARM Variation report, as utilised by Barwon Health, forms the basis of this approach. It has been combined with an Excel based tool that streamlines exclusion of approximately 80% of non-first cycle and supportive therapy variations to improve efficiency and reduce the workload on the auditor in the manual phase of the process.

Variation reports, such as the example found in the CHARM EPS, detail changes from pre-programmed protocols loaded in the system by the health service. Whilst the variations captured by these reports include events that won't have a detrimental impact on the effectiveness of a treatment (e.g. the addition of extra anti-emetics for a patient with nausea and vomiting), they provide a starting point for extracting variations that should be re-examined in light of the evidence and the patient's situation.

This report can be further filtered to remove most of the variations that don't require review. This is followed by a manual review, using a list of accepted reasons for variation to provide a very small list for presentation to a group of clinicians working in the tumour stream.

Variation reports as a methodology have many advantages:

- Vastly reduced time in reviewing patient histories
- All modifications are reported

And some disadvantages:

- Variations are deduced from programmed protocols. These programmed protocols may not be consistent with the established guidelines sources such as EviQ. It is recommended that EPS programmed protocols should be assessed against established protocols and any variation approved and documented by the tumour stream.

The CHARM variation report can be produced using the process demonstrated on the Department of Health and Human Services (DHHS) website. This report produces a raw list of all variations made to all chemotherapy prescribed for the chosen tumour stream between listed dates.

The CHARM Audit Tool, also available on the DHHS website, is used to automatically filter the majority of this data, resulting in a smaller set of targeted data for consideration by the auditor.

The variations requiring consideration are then manually evaluated, as guided by the exclusion guide on the website. The resultant list will go to an MDM or appropriate auditing committee for consideration.

ARIA Audit Methodology

Under development.

Please contact projectmanager@victag.org.au for enquiries.

EPIC Audit Methodology

Under development.

Please contact projectmanager@victag.org.au for enquiries.

Cerner Oncology Audit Methodology

Under development.

Please contact projectmanager@victag.org.au for enquiries.

MOSAIQ Audit Methodology

With one implementation project under way in Victoria, but no active implementations, the project did not have a health service to assist with assessing reports or piloting.

However, a health service in NSW contributed their report for use in the toolkit.

This information has been provided on the website to inform utilisation and auditing.

This report is based on the same auditing metholodogy as the CHARM report – it will identify variations in dose against established protocols.

Please contact projectmanager@victag.org.au to consider development of a tool in an active implementation.

Paper Prescribing System Approach

For a paper based prescribing approach to auditing, it is important to acknowledge that auditing will be limited as the resources are not available to health services to fully retrospectively audit all of their chemotherapy prescribing.

The approach is retrospective and focuses on small segments of activity to provide some assurance about prescribing activity whilst being a realistic allocation of resources. It will involve:

- isolation of a particular tumour stream/s to be audited
- a targeted time period to be selected
- audit of variations in the first cycle of patient's current line of treatment (best reflects current practice, whilst minimising individual toxicity/tolerance variations)

The methodology closely mirrors the CHARM approach:

1. Selection of patients for audit from available health service data (suggested sources include clinic appointment list or day unit chemotherapy list[3]).
2. Audit cycle 1 of current chemotherapy regimen for variation and whether it is to be escalated for discussion using guideline for exclusion (due to the need to access patient data to decide if a variation has occurred, it will be more efficient to analyse the variation at this point in time and decide if it will get included for escalation).
3. Submit list for escalation as per the toolkit process

More information and supporting documents can be found on the DHHS website.

[3] The information sources often have nuances about the patient population that can be collected. CDU lists may not have patients that have only oral chemotherapy treatment, whilst appointment lists will contain patients that are not currently on treatment and may miss private patients treated in a public health service. Health services may also have access to documents not considered as part of this guide that can be used to help audit patient populations.

Additional audits to support the quality framework

- Protocol Audit
    - Random audit of protocols against supporting evidence – checking that transcription and translation from the supporting evidence is correct in versions of the protocol used in house (e.g. on the Electronic Prescribing System).
- Audit of toxicity management
    - Some agents require specialised monitoring of side effects that are built into protocols. This monitoring can be important to prevent catastrophic complications. (e.g. ATIII monitoring for L-Asparaginase dosing).
- Audit of cumulative dosing
    - Some agents (e.g. anthracyclines such as Doxorubicin) have lifetime cumulative doses that should not be exceeded in order to prevent complications for the patient.

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