ViP bDMARDs
STAKEHOLDER REPORT

CATAG activities and recommendations

The Council of Australian Therapeutic Advisory Groups (CATAG) is an authoritative, expert, consensus-based collaboration of representatives from all Australian State and Territory Therapeutic Advisory Groups or their jurisdictional committee equivalents.

CATAG contributes to the equitable, safe, cost-effective and quality use of medicines primarily (but not exclusively) in the hospital sector across Australia.

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CATAG
Council of Australian
Therapeutic Advisory Groups

Contents

+TARGETED THERAPIES ALLIANCE

Helping consumers and health professionals make safe and wise therapeutic decisions about biological disease-modifying antirheumatic drugs (bDMARDs) and other specialised medicines. Funded by the Australian Government Department of Health through the Value in Prescribing bDMARDs Program Grant.

EXECUTIVE SUMMARY

CATAG is a consortium member of the Targeted Therapies Alliance (TTA) convened to work on the Value in Prescribing (ViP) – Biological Disease Modifying Anti-Rheumatic Drugs (bDMARDs) Program. This program aims to help consumers and health professionals make safe and wise therapeutic decisions about biological disease modifying antirheumatic drugs and other specialised medicines.

CATAG undertook a survey to gain an understanding of current formulary and individual patient use (IPU)/ individual patient approval (IPA) activities and QUM issues with regards to the use of biologicals and biosimilars in hospital and health services. Results of the survey informed the development of resources as part of the ViP bDMARDs program.

Thirty-three responses were received in the survey, representing all jurisdictions. Gaps in practice were identified around the governance of biologics; therapeutic drug monitoring in inflammatory bowel disease; the requirements for handling low-dose methotrexate in hospitals.

Through the ViP bDMARDs program **CATAG** developed a range of interventions to support good governance and decision-making for health service organisations, medicines governance committees and health professionals that respond to the clinical and practice complexities identified.

Interventions developed include:

- **Biologics and biosimilars best practice:** Guiding principles for the governance of biologics and their biosimilars in Australian hospitals.

- **Facilitating the translation of evidence into best practice:** Optimising the pharmacological management of inflammatory arthritis

- **Facilitating the translation of evidence into best practice:** Therapeutic drug monitoring in inflammatory bowel disease

- **Supporting safe practices for low-dose methotrexate:** Position Statement on the use of low-dose methotrexate

- **Navigating high-cost medicines:** Guiding principles for the governance of high-cost medicines in Australian hospitals

All resources were endorsed by representatives from the **CATAG** member organisations and published on the **CATAG** website ***www.catag.org.au.*** These resources were distributed by **CATAG** to the member organisations for dissemination to their local networks through state-wide, local health district and hospital DTCs, along with external stakeholders.
Future work, on adopting new practices for low-dose methotrexate and high-cost medicines, was identified by **CATAG**.

CONTEXT

CATAG is a consortium member of the Targeted Therapies Alliance (TTA) convened to work on the Value in Prescribing (ViP) – Biological Disease Modifying Anti-Rheumatic Drugs (bDMARDs) Program. This program aims to help consumers and health professionals make safe and wise therapeutic decisions about biological disease modifying antirheumatic drugs and other specialised medicines. The Targeted Therapies Alliance is led by NPS MedicineWise and includes Arthritis Australia, Australia and New Zealand Musculoskeletal (ANZMUSC) Clinical Trials Network, Australian Rheumatology Association, Cochrane Musculoskeletal, Council of Australian Therapeutic Advisory Groups, Pharmaceutical Society of Australia, Quality Use of Medicines and Pharmacy Research Centre (University of South Australia) and Society of Hospital Pharmacists of Australia.

BACKGROUND

CATAG aims to improve medicines management and use within the framework of the National Medicines Policy as it applies to clinical practice in Australian hospitals and at the interfaces of care. It promotes the equitable, safe, cost-effective and quality use of medicines (QUM), to optimise medicines management and use in the public sector and wider community, with the objective of realising the best possible health outcomes for all Australians. **CATAG** supports national information sharing, advice and advocacy for the hospital sector on strategic medicines issues. **CATAG** has published several resources addressing medicines governance within public hospitals.

CATAG seeks opportunities to influence the QUM in the community through appropriate governance and treatment decisions made in public hospitals.

CATAG comprises representatives from all Australian State and Territory Therapeutic Advisory Groups or their jurisdictional committee equivalents:

- Canberra Health Services
- NSW Therapeutic Advisory Group (NSW TAG)
- Northern Territory Drug and Therapeutics Committee
- Queensland Health Medicines Advisory Committee (QHMAC)
- South Australian Medicines Advisory Committee (SAMAC)
- Tasmanian Medication Access and Advisory Committee (TMAAC)
- Victorian Therapeutics Advisory Group (VicTAG)
- Western Australian Therapeutics Advisory Group (WATAG).

SURVEY

AIM

The aim of the survey was to gain an understanding of current formulary and individual patient use (IPU)/ individual patient approval (IPA) activities and QUM issues with regards to the use of biologicals and biosimilars in hospital and health services to inform CATAG's contribution to the ViP bDMARDs program.
Results of the survey will inform the update of CATAG's Guiding principles for the governance of biological and biosimilar medicines, along with the development of position statements for the use of medicines in inflammatory arthritis and inflammatory bowel disease (IBD) to support QUM and good medicines governance for Drug and Therapeutics Committees (DTCs) or equivalent.

METHODS

As a consortium member of the TTA for the ViP bDMARDs program, CATAG committed to develop resources and tools that would assist hospital, district or jurisdictional DTCs in the good governance of bDMARDs and other specialised medicines. To obtain additional information to inform CATAG's interventions, it was determined the most appropriate pathway was to survey hospitals through its members' networks. An online survey utilizing Survey Monkey™ was conducted from the 17th June until 10th July 2020 . The survey template is available on request. Respondents were able to skip questions if they wished; as a result, the number of responses may vary with each question.

RESULTS

Jurisdictional, health district and institutional representation.

Participation in the survey was requested from DTCs across Australia. Queensland, South Australia, Tasmania and Northern Territory operate state-wide formularies although hospitals within these jurisdictions also have DTCs to locally implement formulary decisions and manage medicine requests for individual patients. The number of eligible DTCs is estimated to be 107 across all states and territories. Table 1 indicates the types of DTCs that responded to the survey. All jurisdictions were represented in the survey, 45% responses were from Victoria, 18% from NSW and 12% from Queensland.

Drug and Therapeutics Committee description	Response Count (n=33)
State-wide	3
Metropolitan health district/network	10
Regional health district/network	6
Rural health district/network	3
Individual metropolitan hospital	5
Individual regional hospital	6

Table 1: Jurisdictional, district and institutional Drug and Therapeutics Committee representation n=33

Seventy percent (23/33) of respondents stated their DTC was responsible for both the organisation's formulary and individual patient usage approvals.

Criteria used in the decision-making process for formulary additions of biologics

The following criteria, in no particular order, were mostly or always used for more than 75% of DTCs in the decision-making criteria to add a biologic (either reference biologic or biosimilar) to the organisation's formulary:

- The cost of the medicine
- PBS listing
- Direct and indirect costs associated with harms and benefits
- Comparison with existing therapies
- Medication safety issues (e.g. adverse drug reactions, heightened potential for error)
- Opinion of local specialist prescribers
- Pharmaceutical industry support (such as clinical nurse, top-up doses)
- Clinical effectiveness of the medicine
- Place in therapy and alternate treatments
- TGA registered indications
- Cost effectiveness of the medicine

The decision to add a biologic to an organisations formulary, most prevalently depends upon the cost or whether the medicine is listed on the Pharmaceutical Benefits Scheme (PBS). Support from the pharmaceutical industry was considered a driver particularly for infliximab (25% of respondents 7/24).

To determine the utilisation of CATAG's *Guiding Principles for the governance of biological and biosimilar medicines version 2,(Guiding Principles)* respondents were asked a series of questions regarding their implementation and impact. Ninety percent of respondents had implemented the *Guiding Principles* in their hospital or health service. This indicates their wide acceptance; the following comments were received in support:
"State-wide guiding principles were developed based on the CATAG Guiding Principles".
The CATAG Guiding Principles *"provided structure for assessing the suitability of biosimilar use in different indications and for switching"*.

Gaps in practice, identified by the survey

Survey respondents were requested to identify what they considered to be gaps in practice in the management of biological medicines. Three major gaps were identified: guidance around switching and substitution; policy regarding communication of the active ingredient and trade name; and, governance gaps, particularly around avoidance of multiple switching.

Switching and substitution

Switching is defined as changing between two brands of the same medicine. This could be changing from the reference biologic to a biosimilar, or vice-versa or between biosimilars. The majority (76%, 22/29) of hospitals or health

services did not have protocols for switching between biologics. Respondents noted it was dependent on the individual biological medicine. The responses showed there was variation in the way in which organisations planned and implemented switching. Substitution is defined as the practice of dispensing one brand of a biologic instead of the prescribed brand of the biologic when both brands have been endorsed as equivalent and substitutable by an appropriate body e.g. Pharmaceutical Benefits Advisory Committee. The majority of respondents (86%, 24/28) noted their organisation does not have a written protocol/rule for substitution between biological medicines.

Communication of active ingredient and trade name

Figures 1 and 2 indicate that respondents reported varying approaches to when the active ingredient and trade name are communicated and whether the batch number is recorded during the medication management cycle.

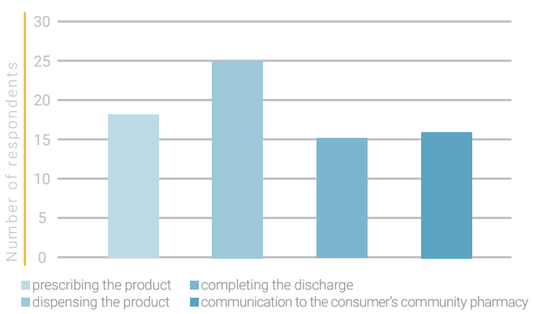

Figure 1: Communicating the active ingredient and trade name of the biologic or biosimilar medicines, n=26

Organisations may communicate at all points, across this medicines management pathway or only at one or two points. Communication to the community pharmacy could be either verbal or written communication.

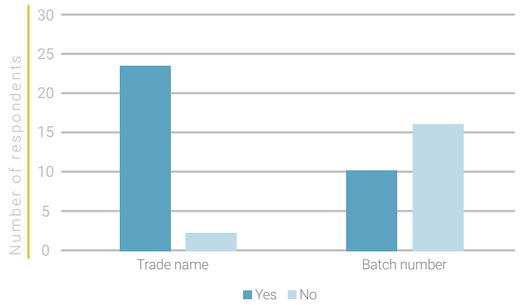

Figure 2: Recording of trade name and batch number when dispensing a reference biologic or biosimilar, n=26

Governance

Respondents were asked what they perceived were the gaps in good medicine governance regarding the use of biologics and biosimilars. Almost 60 percent (15/26) of respondents noted there were gaps in governance regarding methods to reduce multiple switching. Figure 3 demonstrates the identified gaps in good medicines governance of biologics and their biosimilars.

Other responses included the following comments:

"clear guideline allowing clinicians to be well informed to switch patients"

"evidence whether multiple switching is harmful or whether it could lead to reduced efficacy"

"ongoing communication is also key to good governance in this space".

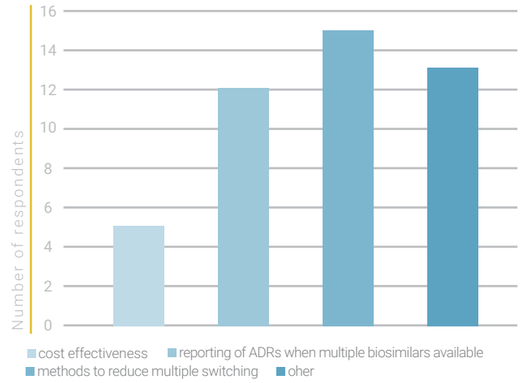

Figure 3: Gaps in good medicine governance of biologics and biosimilars, n=24

Other issues related to biological medicine use

Survey participants were requested to provide information regarding therapeutic drug monitoring, dose escalation, QUM and safety issues related to biological medicines and low-dose methotrexate.

Therapeutic Drug Monitoring

CATAG sought to determine the number of organisations who utilised therapeutic drug monitoring (TDM) to monitor specific drug levels of bDMARDs for rheumatoid arthritis. Eight respondents reported that TDM was available for one or more of the following medicines: abatacept, adalimumab, etanercept, infliximab, rituximab and tocilizumab. Infliximab therapeutic levels was the most common biologic to be monitored (75%, n=6/8).

TDM for biologics in patients with inflammatory bowel disease (IBD) was more common than in those with rheumatoid arthritis. Just over half of respondents (52%, n=13/25) used TDM for biologics in patients with IBD. The following medicines were monitored, infliximab was the most monitored medicine.

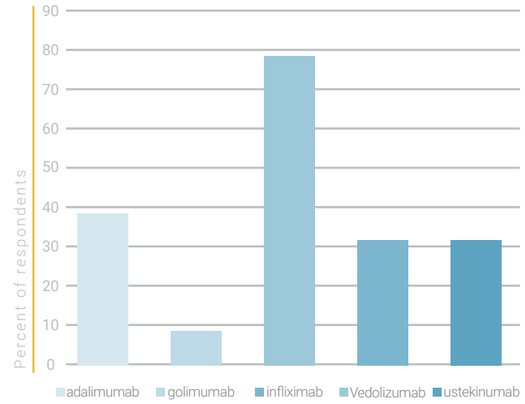

Figure 4: Respondents using therapeutic drug monitoring for inflammatory bowel disease, n=13

Dose escalation of biologics

CATAGs members have previously identified complexities of dose escalation of biologics in patients with IBD, which commonly occurs outside the PBS. Survey questions sought to understand the practices behind dose escalation and how the additional doses were funded. Seventy percent of DTC respondents (n=18/26) received requests for dose escalation of biologics for patients with IBD. These requests were most frequently or always approved for both ulcerative colitis and Crohn disease.

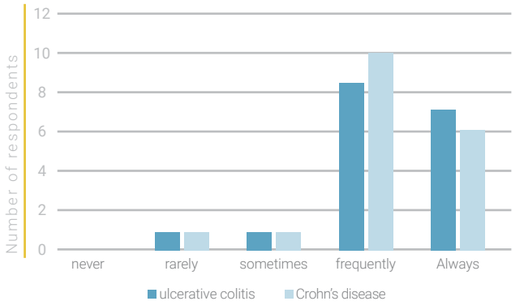

Figure 5: DTC approval of biologics dose escalation requests, n=18

For both ulcerative colitis and Crohn disease, 78% (14/18) of DTCs implemented a written protocol or accepted dose escalation of biologics as an accepted standard of practice. The 'top up doses' were funded through a range of mechanisms. The most common source of funding was through a pharmaceutical company program or sponsorship, followed by hospital funding.

Access to biological medicines using Medicines Access Programs

Pharmaceutical companies may provide cost-free or subsidised mechanisms for accessing medicines not listed on the Pharmaceutical benefits Scheme (PBS) and when hospital funding is required to access medicines usually through Individual Patient Use (IPU) requests to the DTC. These mechanisms fall under a variety of Medicines Access Programs (MAPs) which include, but are not limited to, compassionate use programs, expanded access programs, product familiarisation programs and cost share programs. The MAPs facilitate deferred cost, cost-free or subsidised medicines supply to hospital patients (usually outpatients) before the implementation of relevant funding arrangements such as funding through the PBS. CATAG's Guiding principles for the governance of Medicine Access programs in Australian Hospitals have facilitated the implementation of consistent good governance and promote the quality use of medicines including biological medicines within the various types of MAPs available in Australian public hospitals.

In IBD, escalated doses of biologics are indicated for patients who lose clinical response to standard doses. The current approved dose of these medicines on the PBS does not allow for escalated doses and therefore is not subsidised by the PBS. The cost for these escalated doses is then borne by either the hospital, the patient or sponsored via the pharmaceutical company. Survey respondents indicated that the most common sponsored pathways were by provision of free medicine stock to hospitals (100%, n=17), by providing a reduced price of stock (47%, n=8/17) or by indirectly supporting the provision of nursing services (18%, n=3/17). CATAG also sought to understand whether DTCs have oversight of the use of compassionate stock of biologics for outpatients with IBD. Only 54% (n=14/26) of DTCs have oversight of the use of compassionate stock. It was reported that prescribers often organise compassionate stock. DTCs were not directly aware of the number of patients accessing compassionate stock and there were individual agreements made between the pharmaceutical company and the individual prescribers.

Quality use of medicine or medication safety concerns about the use of biological/targeted synthetic DMARDS (b/tsDMARDs) in ulcerative colitis, Crohn disease and rheumatoid arthritis

Survey respondents raised a number of QUM and medication safety concerns. These included:

- Acceptance of interchangeability of reference and biosimilar brands by clinicians
- The risk of compassionate stock being discontinued by pharmaceutical companies
- The difference between the PBS listing of b/tsDMARDs and the doses being used and accepted practice
- Lack of guidance for dose escalation
- The role of therapeutic drug monitoring
- Biosimilar cost effectiveness assessments

Low-dose methotrexate

CATAG sought to understand whether hospitals or health services had written policies or procedures specifically to handle oral or subcutaneous low-dose methotrexate. Sixty-two percent of participants (n=16/26) responded they had a policy. Respondents provided eight policies for review. Notable issues included the variance in definition of low-dose methotrexate, which ranged from 2.5mg to 30mg. There was also a lack of consistency regarding the requirements for handling low-dose methotrexate with staff required to wear a mix of personal protective equipment (PPE), ranging from gloves only to full PPE including gloves, gown, and mask. Similarly, there was lack of consistency with regards to the handling of patients' blood and body fluid.

Fifty-two percent of respondents (n=12/23) supply subcutaneous methotrexate as prefilled syringes (Trexject), 48% supply compounded syringes through external providers and 35% supply compounded syringes, which are compounded on site. Some sites may have more than one option available for supply.

DISCUSSION

The changing landscape for biologic supply and use

CATAG published *Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals* in 2013. When first published, there was less known about this new group of medicines, clinicians were unfamiliar and there were several concerns such as switching and immunogenicity. The *Guiding Principles* were to provide guidance on good governance and decision making for medicine governance committees on an increasingly important and relevant area of emerging practice. The *Guiding Principles* were subsequently updated in September 2016 to reflect changes in evidence and practice.

Since 2016, the biologic and biosimilar landscape has changed. There is now increased availability of biosimilars, and they are one of the fastest growing sectors within the pharmaceutical industry. The PBS has introduced 'a' flagging of biosimilars, which allows automatic substitution at the point of dispensing by pharmacists. There is also now greater acceptance and confidence by prescribers and patients in the use of biosimilars. The evidence and experience around their use especially with regards to switching and substitution between the reference biologic and its biosimilars and immunogenicity has also increased. The survey of medicines governance committees identified that the *Guiding Principles* informed the approach, discussions and clinical governance of these medicines in hospitals. The *Guiding Principles* assisted hospitals to introduce biosimilars with confidence and provided structure for assessing the suitability of biosimilar use for different indications and provided guidance on switching between biosimilars.

However, the survey identified that there are complexities which need guidance, particularly for multiple switching and ADR reporting. Key informant interviews with medical specialists and pharmacists, as part of the program, undertaken by NPS MedicineWise, identified knowledge gaps regarding the evidence behind the safety and efficacy of biosimilars for both medical specialists and pharmacists and the consequences when pharmacists dispensed biosimilars[1].

1: NPS MedicineWise. Value in Prescribing bDMARDs Program: Rheumatology program design January 2020

Guiding down-titration of bDMARDs in inflammatory arthritis

CATAG identified via the survey only one respondent had a protocol for the down-titration of bDMARDs in inflammatory arthritis.

As part of the ViP bDMARDs Program, the 'Australian Living Guideline for the Pharmacological Management of Inflammatory Arthritis' (mskguidelines.org) was developed to present the best available, current scientific evidence for pharmacological management of the most common forms of inflammatory arthritis, namely rheumatoid arthritis (RA), psoriatic arthritis (PsA) and axial spondyloarthritis (SpA), including choice of disease-modifying antirheumatic drug (DMARD), switching, combination therapy and down-titration of treatment. These key elements were identified during key informant interviews during the ViP bDMARDs Program design and given the findings from the CATAG survey will immediately fill a gap related to biologic medicines use.

Appropriate therapeutic drug monitoring of biologics in inflammatory bowel disease

During the program design undertaken by NPS MedicineWise, gastroenterologists identified that there was a lack of confidence in escalating or de-escalating biologic doses.[2] Similarly, pharmacists reported feeling unconfident about dose adjustments of biologics, particularly around providing advice and recommendations to gastroenterologists regarding de-escalation, dose modification and whether therapeutic drug monitoring is indicated for specific biologics. Gastroenterologists also expressed concerns about reducing the dose of biologics given concerns about risk of disease flares and loss of drug antibodies.

These findings were also identified in the CATAG survey where approximately 50% (13/25) of hospital/health services undertake TDM of biologics for inflammatory bowel disease. Approximately 22% of respondents had protocols for dose escalation and only 1 (5%) had a protocol for dose reduction. It was also identified that TDM is being conducted for medicines such as vedolizumab and ustekinumab without good evidence.

2: NPS MedicineWise. Value in Prescribing bDMARDs Program: Gastroenterology program design August 2020

Issues related to low-dose methotrexate usee

Several barriers that prevent the optimal prescribing and adherence to low-dose methotrexate were identified. Concerns were identified regarding the safety and adverse effects of low-dose methotrexate and the safe handling low-dose methotrexate for nurses, pharmacists and patients.
In some Australian hospitals, there is no discrimination with regard to handling recommendations for methotrexate, and the dose being used. Handling of antineoplastic (or cytotoxic) medicines is considered an occupational risk to workers. Exposure may occur during preparation, administration, transportation, waste disposal and when handling bodily fluids/waste or in the event of a spill.(1) Local hospital policies may outline precautions intended for handling antineoplastic medicines and when dispensing and administering methotrexate, without discriminating between low (immune-modulatory) doses and higher (antineoplastic/cytotoxic) doses.

In community pharmacy, methotrexate oral tablets and pre-filled injections are received in a separate package labelled: 'Caution cytotoxic.' The Quality Care Pharmacy Program requires any antineoplastic medicine to be flagged on the dispensary shelf by a 'Cytotoxic' label. These requirements can potentially add to the confusion that low-dose methotrexate is harmful and result in pharmacists taking unnecessary precautions when handling low-dose methotrexate tablets or pre-filled subcutaneous injections. Pharmacists usually apply cautionary advisory label 21: 'Special handling and disposal required – ask your pharmacist' to the dispensed prescription.(2) In the acute care setting, pharmacists usually annotate methotrexate prescriptions on medication charts with a warning 'cytotoxic'. This may also perpetuate the notion of low-dose methotrexate being a hazardous medicine to dispense and administer.

Most importantly, these warnings and processes can have a detrimental effect on a patient's adherence to low-dose methotrexate, the first line therapeutic option for conditions such as rheumatoid arthritis. The use of handling precautions intended for antineoplastic doses can promote alarm and concern for people being treated with low-dose methotrexate (and their carers), stigmatisation and impede its acceptance. Health professionals, either due to lack of familiarity or as a result of notifications relating to dosing errors, may also contribute to this fear.(3) It is imperative to provide clear directions and written information, emphasising the importance of once weekly dosing to people being treated with low-dose methotrexate

CATAG INTERVENTIONS

CATAG developed a range of interventions to support good governance and decision-making for health service organisations, medicines governance committees and health professionals that respond to the clinical and practice complexities described above.

INTERVENTION 1.
Biologics and biosimilars best practice:
Guiding principles for the governance of biologics and their biosimilars in Australian hospitals.

These Guiding Principles provide guidance for good governance and clinical decision making in relation to use of biologics in Australian hospitals. They contain guiding principles to:

- promote and support the safe, effective and consistent use of biologics.
- promote enhanced cost-effectiveness of biologics.
- provide guidance on implementing the use of biosimilars.
- promote prescriber confidence in using biosimilars.
- support a shared decision-making approach between the health professional and patient.
- encourage a nationally consistent approach.
- recognise the potential savings that can be achieved by the use of biosimilars.(4)

INTERVENTION 2.
Facilitating the translation of evidence into best practice:
Optimising the pharmacological management of inflammatory arthritis

This guidance facilitates and supports the translation of best available evidence into practice for the management of inflammatory arthritis. It applies to the care of those patients who have been diagnosed with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and axial spondyloarthritis (SpA) and adapts the Living Guidelines for consideration by medicines governance committees. It can be used in conjunction with formulary decisions and recommendations.

INTERVENTION 3.
Facilitating the translation of evidence into best practice:
Therapeutic drug monitoring in inflammatory bowel disease

Therapeutic drug monitoring of biologic therapy in inflammatory bowel disease is being increasingly utilised as a helpful tool to optimise remission rates and prevent relapse. (5) TDM of biologics involves the measurement of serum drug concentrations and anti-drug antibody titres.(6) TDM comprises just one aspect of patient monitoring and should be

interpreted alongside other relevant clinical, endoscopic, imaging and biomarker findings to aid clinical decision making.
This CATAG-developed document facilitates and supports the translation of best available evidence into practice for the management of patients with inflammatory bowel disease. The document summarises the evidence on the use of therapeutic drug monitoring of biologics as of May 2021.

INTERVENTION 4.
Supporting safe practices for low-dose methotrexate:
Position Statement on the use of low-dose methotrexate

This Position Statement provides guidance on dispensing and administering low-dose methotrexate (oral and subcutaneous dosage forms). It aims to provide clear information on safety for those dispensing and administering low-dose methotrexate and assists them with providing reassurance to people undergoing treatment with low-dose methotrexate.

INTERVENTION 5.
Navigating high-cost medicines:
Guiding principles for the governance of high-cost medicines in Australian hospitals

The purpose of these *Guiding Principles* is to provide a framework to assist medicines governance committees, including Drugs and Therapeutics Committees (DTCs) to assess and make good decisions about the quality use of high-cost medicines.
More specifically, the objectives of these Guiding Principles are to promote:
- fair process and equity of access to high-cost medicines in public hospitals.
- the assessment of high-cost medicines using the best available evidence.
- the cost-effective utilisation of medicines within the public hospital system; and,
- a reduction in the duplication of effort and foster consistent and efficient decision-making.

IMPLEMENTATION

Following development and endorsement by representatives from the CATAG member organisations, the documents were published on the CATAG website www.catag.org.au.
The documents were also distributed to CATAG member organisations for dissemination to their local networks through state-wide, local health district and hospital DTCs, along with external stakeholders.

Presentation:
National Medicines Symposium May 2021.
Supporting safe practices for low-dose methotrexate. Society of Hospital Pharmacists of Australia February 2022. Translating evidence into practice through evidence-based resources for the management of inflammatory bowel disease.

RECOMENDATION FURTHER WORK

Low-dose methotrexate

CATAG supports further efforts to provide clear information on safety for those dispensing and administering low-dose methotrexate. This could be achieved by incorporation of the messages from the Position Statement into reference materials that are regularly used by health practitioners, e.g. Australian Medicines Handbook, Therapeutic Guidelines, Australian Pharmaceutical Formulary, Product Information and Consumer Medicines Information.
CATAG also recommends that the Quality Care Pharmacy Program QCPP reviews the information regarding low-dose methotrexate and incorporates messages from the CATAG position statement.

High-cost medicines

One of CATAG's stated objectives is to promote fair process and equity of access for all patients. This requires transparency and standardisation in decision making, evaluation and review between jurisdictions to improve equity and patient centrality within these processes.
Establishment of national processes is recommended. This could be achieved by formalising and promoting the already established network for sharing resources, through CATAG, whereby anonymised information is shared, rather than the informal process currently in use. The information would ideally include supporting information used to inform decisions, the resultant decisions (whether positive or negative), outcome data, and medicine use evaluations. This would require resourcing for infrastructure such as interoperable electronic IPUs and DTC tools, in addition

to resourcing to maintain and analyse data. Further supporting information could then be developed including high-cost medicine evaluation resources, standardised templates and nationally consistent guidance to support cost effectiveness reviews. This would facilitate 'network learning' between DTCs and allow sharing of information between sites to reduce duplication of effort and improve transparency and consistency based on the latest research evidence. It could be used to inform the possible development of a national hospital high-cost medicine formulary.

A local example of sharing of information is the National Paediatric Medicine Forum hosted by Children's Healthcare Australasia. The Forum is developing high-cost medicine evaluation resources, networking and sharing information between sites to reduce duplication of effort and improve transparency and consistency based on the latest research evidence in paediatric medicine decision making.

Should it be possible to share the outcomes of DTC deliberations, other organisations, such as Therapeutic Guidelines, could also benefit from the information. It could be used, for example, to identify issues for clinicians and hospitals, prioritise tasks, and fast-track updates when necessary. Therapeutic Guidelines has established an interim updates team to respond to significant changes in evidence and practice between scheduled guideline revisions; and would welcome partnering with CATAG to support this strategic priority.

Enabling greater transparency and reporting of high-cost medicine funding to a broader range of stakeholders (e.g. hospitals, the Therapeutic Goods Administration (TGA), pharma, consumer peaks) would assist in highlighting opportunities for systemic improvements. Encouraging a more collaborative contribution to the collection and reporting of outcome data, could assist in publication and gathering evidence for those medicines and conditions, for which there is limited evidence available. This information could also serve to inform the PBAC's future deliberations.

Benchmarking considerations against previous decisions, with a view to ensure both internal and external consistency, and for interhospital and inter-health service collaboration on this issue, to ensure expertise and manage conflicts of interest.

Currently there is no standardised training available for members of Drug and Therapeutics Committees, nor is there a minimum standard required. CATAG recommends that having all DTC members undertake similar training would assist in 'good decision making', and also work towards a consistent approach throughout Australia, further contributing to the goal of equitable access. Evaluating the financial and economic aspects of high-cost medicines use remains a major challenge for DTCs and there is an urgent need for greater training in health economics/ pharmacoeconomics of DTC members and aspirants. Resourcing of CATAG to run training workshops on cost-effectiveness is recommended.

LIMITATIONS

As CATAG sent the survey to its member jurisdictions to disseminate through their networks to individual public hospitals and health networks, a response rate is unable to be determined. All jurisdictions were represented in the survey.

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