Opening the MAB Gates: Rituximab Use in a Quaternary Hospital Following Relaxation of PBS Restrictions

Poppy Savage, Daniel O'Brien, Brett Anderson, David Harris, Paul Toner

Pharmacy Department, The Royal Melbourne Hospital

Background

Rituximab is a TGA registered immunomodulating monoclonal antibody that is routinely used for off-label indications.

In September 2022, the Pharmaceutical Benefits Scheme (PBS) listing of rituximab was changed to an unrestricted benefit. The aim was to provide subsidised access to treatment for patients with conditions where there are few alternative PBS medicines.

Following this, The Drugs and Therapeutics Committee (DTC) at The Royal Melbourne Hospital (RMH) reviewed the formulary restrictions for rituximab. Unrestricted prescribing was approved for selected medical units which had established previous use of rituximab both on and off-label. This was based on the rationale that rituximab was prescribed by experienced senior medical staff and screened by experienced pharmacists; plus, the organisation's extensive experience with Rituximab use in these areas.

Ongoing monitoring and governance of rituximab prescribing was mandated to ensure patient safety in off-label prescribing. Individual Patient Use (IPU) requirement remained for other units.

Aim

To review:

1. Rituximab prescribing patterns following the relaxation of formulary restrictions.
2. If prescribing habits of rituximab are in line with the quality use of off-label medicines (ie evidence based and guideline driven)
3. The need for updated hospital guidelines based on current and evidence based dosing for these indications.

Primary endpoints:

- Frequency of rituximab prescriptions at RMH that meet the formulary criteria
- The proportion of rituximab use at RMH for TGA listed indications

Secondary endpoints:

- Dosing regimens for off-label indications
- Appropriate of doses used for TGA or hospital guideline approved indications

Methods

A medicine use review was undertaken by a group of supervised fourth year pharmacy students as a research project.

Patients receiving rituximab were identified via a report generated from the pharmacy dispensing system of rituximab orders for the period of ten months following relaxation of the formulary listing.

Inclusion Criteria	Exclusion Criteria
Patients aged 18 years or older	Rituximab administered as part of a clinical trial
Prescribed and administered rituximab via an IV infusion	

A Redcap® tool was designed to collect data. The electronic medicines record was used to perform a retrospective review of administrations to identify the prescribing units, indications and dosing regimens prescribed.

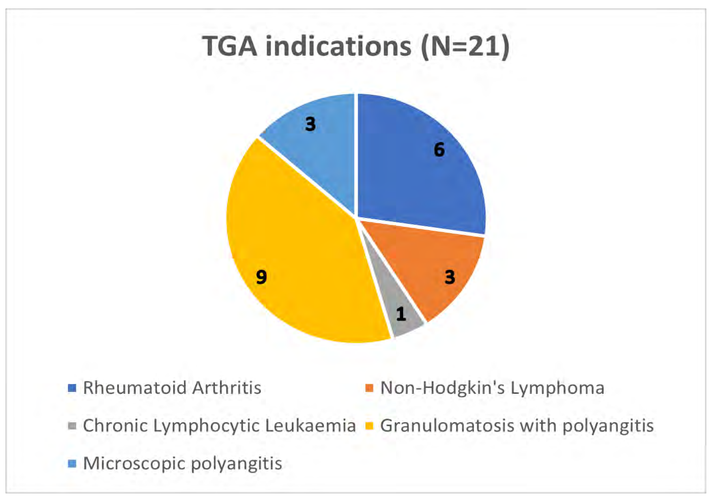
Data on location of infusions, pre-infusion screening, previous use of rituximab and previous treatment for condition was also collected.

The data was exported to Excel® and pivot tables were created to analyse trends.

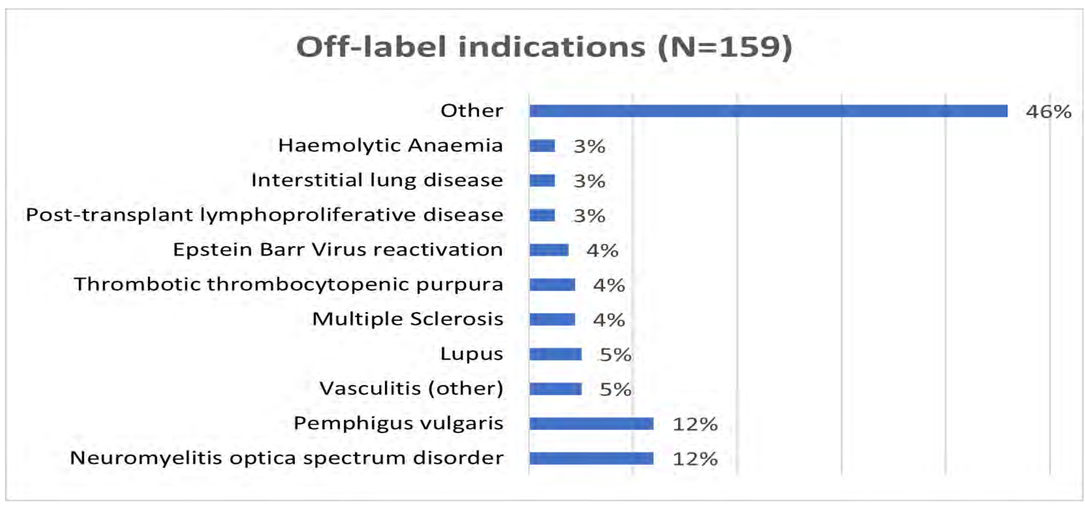
Results

A total of 180 rituximab administrations were evaluated during the collection period.

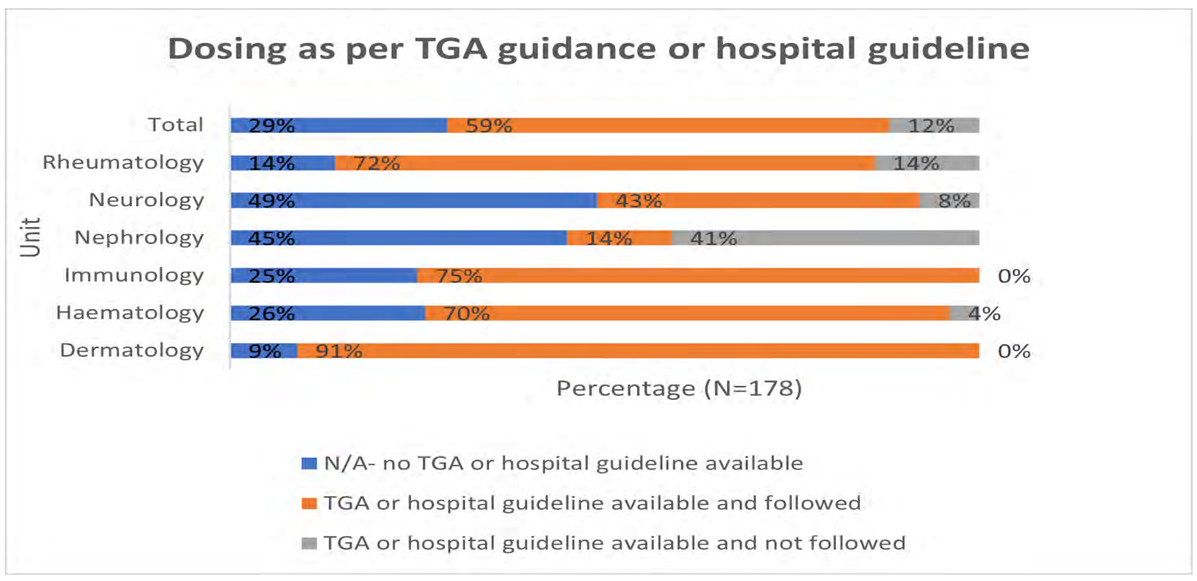
- Of the 180 administrations, 178 met formulary criteria and 2 were prescribed via an IPU
- TGA indications accounted for 21 of the administrations:



- Of the off-label administrations (159 in total) there were 46 distinct indications recorded, with the top ten described below:



- Of 178 formulary rituximab administrations, 29% did not have TGA or hospital guidance available for prescribing advice.
- The Dermatology unit utilised TGA or hospital guidelines the most (91% administrations).
- Nephrology utilised guidelines the least (14%) however they had a large proportion of rituximab administrations for indications not covered by the TGA or hospital guidelines (45%).



- The most commonly administered dose across all units was 1000mg (63%).
- The current hospital guideline suggests nephrology should use 375mg/m2 dosing however in this study 82% of nephrology patients received 1000mg doses.

Discussion

This evaluation has highlighted significant variation in prescribing of rituximab across the hospital. Evidence-based decisions are made with regards to off-label prescribing of rituximab in the majority of cases, however accessible guidance does not exist for around a third of administrations.

There is a significant volume of prescribing happening outside of the evidence sphere. The research has helped to highlight this and will act as a catalyst for robust discussions and better patient care as we respond to emerging evidence. This will ensure safe and appropriate prescribing for rituximab and standardise practice across the organisation.

With use of rituximab in novel indications growing worldwide, there is scope for future audits of use and continuing monitoring of the hospital guideline against emerging evidence.

There is also scope for similar evaluations of other commonly used but off-label monoclonal antibodies to promote guideline driven prescribing (such as infliximab and adalimumab).

Contact: Poppy Savage, Pharmacy Dept, The Royal Melbourne Hospital, poppy.savage@mh.org.au

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