

Development of an algorithm for evaluating Individual Patient Use (IPU) requests

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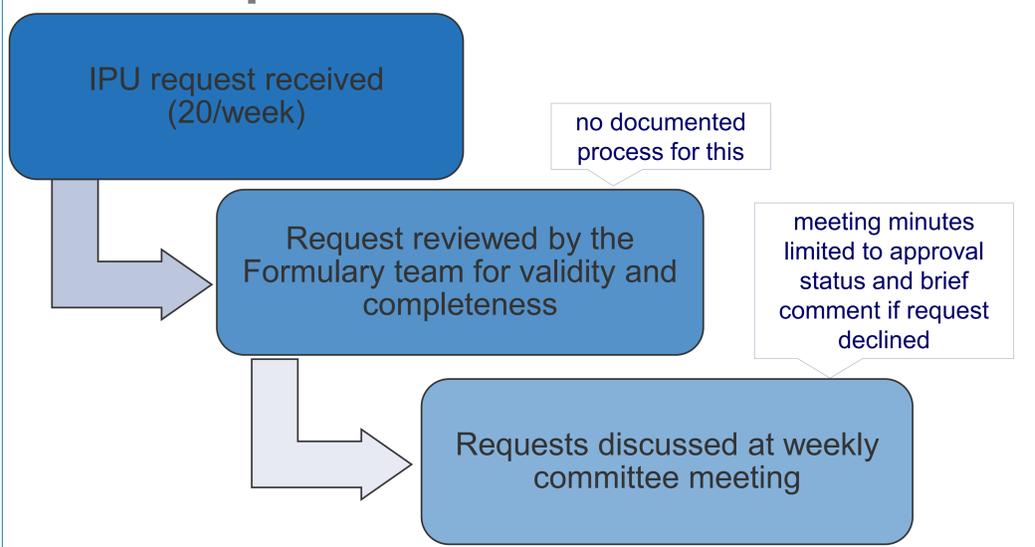
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Introduction

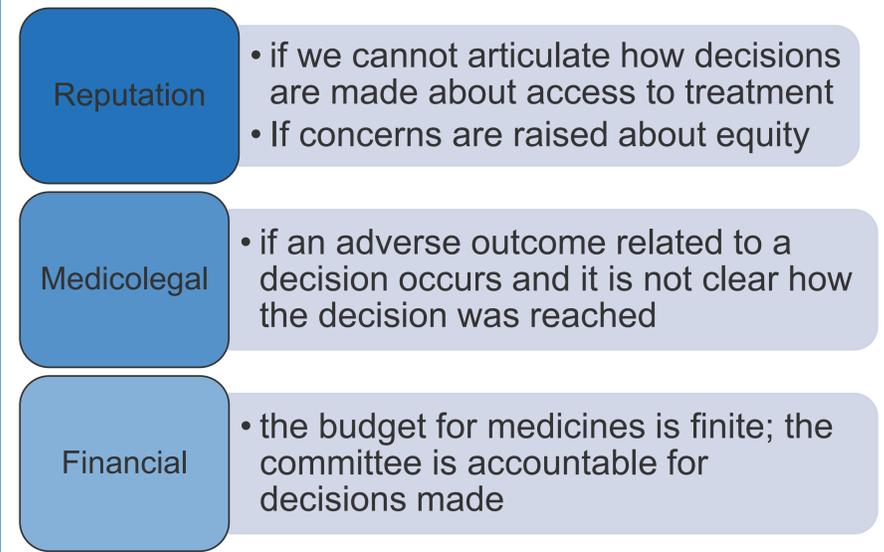
The multidisciplinary Single Patient Use (SPU) Committee review requests to use medicines outside of the medicines formulary. Requests are often for high-cost medicines that are not funded by other means (i.e. Pharmaceutical Benefits Scheme, Medicines Access Programs, clinical trials). The committee need to ensure that the allocation of finite resources (i.e. medicines spend) is equitable and sustainable.

The committee reviews requests as they are received, considering the clinical picture, response to standard therapies, likelihood of benefit and risks of the proposed treatment as well as the cost of the medicine. Aside from precedent, no measures have previously been in place to ensure that decisions made by the committee were consistent and ensuring equity of access.

Baseline process



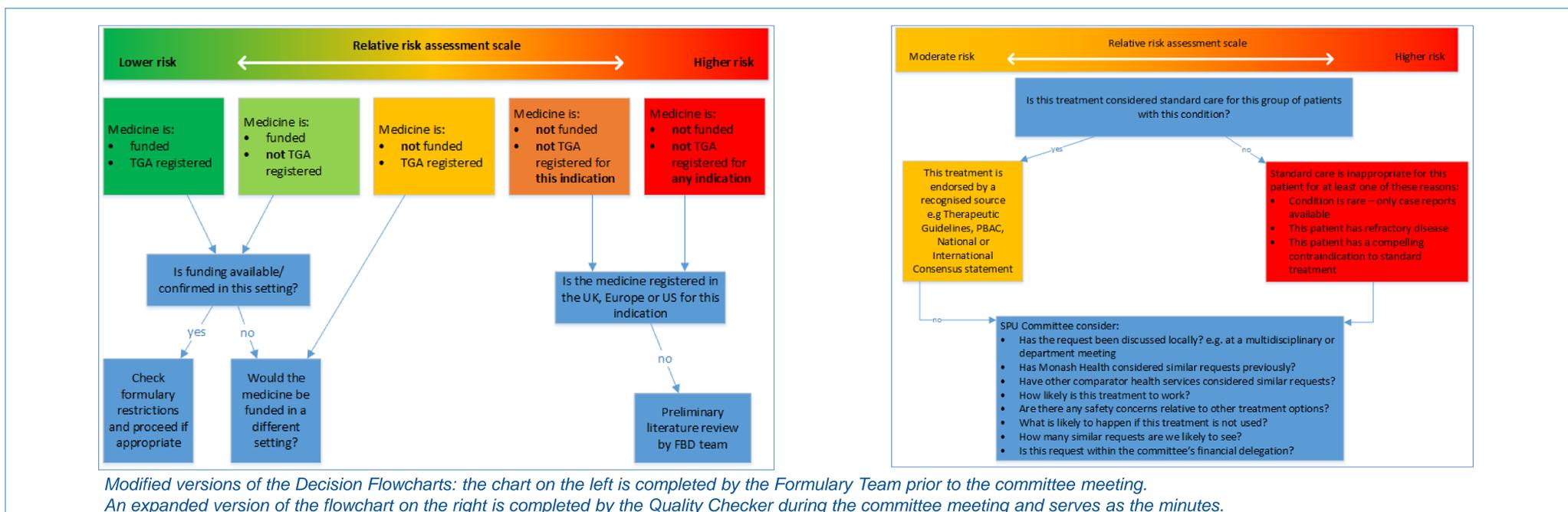
Risks



What have we done about it?

Benchmarking was conducted with Therapeutics Committees around Australia (n=7). Many did not have a formal process (n=4) despite agreeing that the lack of demonstrably consistent decision making was a concern. A review of national and international guidelines identified useful principles¹⁻⁶.

A decision flowchart was developed for use at committee meetings. One member acts as Quality Checker, completing the tool and prompting if a section has not been addressed in the discussion of a complex request. The flowchart is used as the minutes of the discussion.



How do we know it makes it better?

The tool has been used for 10 complex requests (one per month) since introduction. Notably when the tool has been used, the Quality Checker has not needed to prompt the group to consider a section, indicating that committee discussions generally address relevant points organically. The tool ensures that information is consistently considered and handed over across the approval process. It has been used to facilitate timely review of complex requests, particularly those outside of the committee's delegation that are escalated to the approving Executive.

Failure to demonstrate fairness in decision making raises ethical and reputational risks for the health service. The decision flowchart addresses this issue by providing a concise, standardised record of the discussion. It is particularly useful in the event of an appealed decision. The flowchart enables application of concepts that are well described in the literature but challenging to interpret in practice.

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5. McCabe C et al. The NICE Cost-Effectiveness Threshold. What it is and What that Means. *Pharmacoeconomics* 2008; 26 (9): 733-744
6. McDougall JA et al. Understanding the global measurement of willingness to pay in health. *Journal of Market Access & Health Policy* 2020, VOL. 8, 1717030