

6.4 Percentage of submissions for formulary listing of new chemical entities for which the drug and therapeutics committee has access to adequate information for appropriate decision making

Purpose

This indicator addresses the effectiveness of processes that promote systematic and consistent decision-making by area or hospital-based drug and therapeutics committees (DTCs).

Background and evidence

A structured approach to formulary additions encourages evidence-based decision making and promotes consistency and equity of access to medicines.¹

Formulary decisions should take into account objective and appropriately detailed information including relative efficacy, safety and cost-effectiveness in comparison with current alternative therapies. Information about local clinical needs, intended use, potential safety issues and potential cost impacts will also be required if an informed decision is to be made. In some hospitals, the DTC may not make formulary decisions but will act as an advisory body to clinical units. In such cases, the same level of information is required.

A study of Australian paediatric DTCs² found that the quality of submission by applicants was variable and that only one of eight hospitals described the information provided by applicants as generally adequate.³

Use of a standard application form for formulary submissions that includes prompts for information requirements can assist in ensuring that adequate information is provided and that consistent and transparent formulary decisions can then be made by the area- or hospital-based DTCs. A template form for formulary submissions has been prepared by the NSW Therapeutic Advisory Group¹ and is available at www.nswtag.org.au.

Key definitions

Formulary refers to the list of pharmaceutical products which have been approved by the DTC for use in the hospital or area health service.

Adequate information means objective comparative information about clinical efficacy and safety, economic analysis and assessment of local clinical need.

Objective comparative information about clinical efficacy and safety includes clinical trial data from well designed (blinded randomised controlled) studies which compare the new medicine with an appropriate comparator. The context of the clinical trial should be consistent with expected clinical practice.

Economic analysis includes clinical trial data that include economic endpoints or modelling of economic data. The analysis may take a societal or institutional perspective and should include a sensitivity analysis, explanation of assumptions.

Assessment of local clinical need may include any of the following:

- therapeutic alternatives to the new drug
- medicine utilisation information
- relevant medication error and adverse drug reaction reports
- readmission rates due to drug related problems
- local antimicrobial resistance patterns
- case mix and specialty services
- local community health needs.

Data collection for local use

Please refer to the section *Using the National Quality Use of Medicines Indicators for Australian Hospitals* for guidance on sample selection, sample size, measurement frequency and other considerations.

Inclusion criteria: Submissions to the DTC for formulary listing of new chemical entities.

Exclusion criteria: Nil.

Recommended data sources: DTC minutes and relevant meeting papers.

The data collection tool for QUM Indicator 6.4 assists data collection and indicator calculation.

Data collection for inter-hospital comparison

This indicator may be suitable for inter-hospital or inter-service comparison. In this case, definitions, sampling methods and guidelines for audit and reporting need to be agreed in advance in consultation with the coordinating agency.

Indicator calculation

$$\frac{\text{Numerator}}{\text{Denominator}} \times 100\%$$

Numerator = Number of submissions for formulary listing of new chemical entities for which the DTC had access to adequate information for appropriate decision making

Denominator = All formulary submissions for new chemical entities in sample

Limitations and interpretation

This indicator measures the percentage of decisions for which information was available but does not measure the quality of the information available or the quality of the DTC decision process.

Further information

Decision tools for drug and therapeutics committees have been produced by NSW Therapeutic Advisory Group and are available at www.nswtag.org.au

Medication Safety Self Assessment for Australian Hospitals⁴ (MSSA) can help identify potential strategies for improvement with this and other indicators. MSSA encourages development of robust systems for safe prescribing, dispensing, administration and monitoring of medicines. MSSA is available at www.cec.health.nsw.gov.au

This indicator can be used to assist hospitals in meeting the National Safety and Quality Health Service Standard 1 [items 1.2.1, 1.2.2, 1.5.2, 1.6.1, 1.6.2] and Standard 4 [items 4.1.1, 4.1.2, 4.2.2, 4.5.1, 4.5.2].⁵

References

1. Hospital formulary submission template: A decision tool for Drug and Therapeutics Committees. NSW Therapeutic Advisory Group, 2009.
2. Sinha YK, Craig JC, Barclay P, et al. Drug approval processes in Australian Paediatric Hospitals. *Arch Dis Childhood* 2010; 95: 739–744.
3. Personal communication. Dr Yashwant Sinha, Centre for Kidney Research, The Children's Hospital at Westmead, 22 Feb 2012.
4. Medication Safety Self Assessment for Australian Hospitals: Institute for Safe Medication Practices USA (Adapted for Australian use by NSW Therapeutic Advisory Group and the Clinical Excellence Commission), 2007.
5. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. Sydney, ACSQHC, 2012.