

Indicators
for
Drug and Therapeutics Committees

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Chapter 1

Introduction

Why Performance Indicators for Drug and Therapeutics Committees are needed

Expenditure on drugs in public hospitals exceeds \$250 million in Australia per annum. Given this large allocation of money, it is essential that the community, individual hospitals, Area Health Boards and government are confident that cost-effective, efficient and high quality drug therapy is achieved.

An active and effective Drug and Therapeutics Committee (DTC) is important to ensuring funds are used properly. Hard clinical and financial decisions must be made when DTCs choose between therapies. It is important to have an organised and well planned mechanism for making choices and maximising rational drug use.

The first concern for a DTC is to ensure high quality therapeutics for all patients in the health care setting for which it has responsibility. This task becomes more difficult in times of economic rationing when increasing demands for improved health care outcomes are countered with requirements for containment or reduction of costs. In such an economic environment the drug committee is responsible for ensuring that drug use in its organisation is safe, of high quality and equitably distributed.

While an effective DTC is of great value to an institution, substantial hospital resources are required for it to function. Provision of these resources by the hospital has two important implications, the hospital is demonstrating a commitment to DTC activities and the DTC becomes accountable to the hospital (and its patients) for the outcome of those activities.

It is evident that DTCs vary in the role they play in their institution and in their ability to promote quality drug use. Limited financial and human resources, lack of hospital commitment, the local politics and culture and the capability of the DTC will all affect its ability to perform.

Hospitals are focusing on patient outcomes and the cost-effectiveness of services, DTCs also need to evaluate their performance against these parameters in order to remain relevant and influential and to justify their use of resources.

Performance indicators will help to:

- monitor progress in the implementation of DTC policies;
- evaluate performance objectively; and
- revise strategies on the basis of systemic assessment.

These indicators are designed for use by hospitals which have a formal drug therapeutic committee which meets at least once each year.

How the Performance Indicators Were Developed

Development of performance indicators in this project has been a staged process which has involved qualitative data collection, quantitative data collection, field testing and consultation.

Qualitative Data

Focus groups were held to determine what people with an interest in hospital drug use thought should be the goals, objectives and strategies of a DTC. Three broad stakeholder groups were represented in the focus group discussions:

- Clinicians - specialist medical officers, training medical officer, general practitioners, clinical pharmacists, nurses.
- Consumers - consumer advocates and representation from self-help groups.
- Administrators - State government bureaucrats, hospital administrators, pharmacy managers and clinical unit managers.

The focus groups identified a number of goals for DTCs which referred to the effect of drug use on patient and economic outcomes. A very large group of objectives were identified but these could generally be grouped under the headings of quality drug use, affordable drug use and equity of access. Similarly many strategies were identified including authority and credibility of the DTC, decision making processes, educational activities, policy development, cost containment and best practice in therapeutics.

Quantitative Data

The data collected in the focus groups was used to develop a survey which was sent to 303 hospitals, represented by 287 drug and therapeutics committee, throughout Australia. A response was received from 148 committees (52%).

This survey was designed to document the composition, role and activities of DTCs as they currently exist in Australia. Some of the key findings:

- The most commonly cited goals for a DTC were to create an environment that produces quality use of medicines and to improve patient and economic outcomes.
- The major issues addressed by DTCs in the previous 12 months were quality use of medicines, drug policies, medication errors, high cost drugs, cost-effectiveness and adverse drug reactions.
- Guidelines, restriction policies and clinical monitoring were the major strategies used to implement DTC policies.
- The mix of members on representational committees inadequately represented major stakeholders in some hospitals.
- Attendance rates at committee meetings was a problem for about 40% of DTCs.
- Almost half of the DTCs surveyed had no appeals mechanism.
- Many committees were under-resourced in terms of expertise, access to information and material resources.
- The quality of information used by DTCs in making decisions on formulary changes was sometimes inadequate.

The survey provided an insight to the great potential of DTCs and their most pressing problems. This information, together with the qualitative data previously collected allowed us to develop a set of candidate performance indicators.

Field Testing

The candidate indicators were field tested in the hospitals listed below:

TEACHING HOSPITALS

Woden Valley	Canberra
Royal Brisbane	Brisbane
St Vincent's	Sydney
Royal Adelaide	Adelaide
Austin	Melbourne
Central Coast	Gosford

METROPOLITAN NON-TEACHING HOSPITALS

Campbelltown	Sydney
Modbury	Adelaide
Dandenong	Melbourne

REGIONAL AND BASE HOSPITALS

Illawarra	Wollongong
Gippsland Base	Sale
Wagga Wagga	Wagga Wagga

PRIVATE HOSPITALS

John James	Canberra
Wesley	Brisbane
St John of God	Sydney
The Avenue	Melbourne

The objectives of the field tests were to:

- View the spread of results to the indicator questions.
- Validate the selection of indicators.
- Assess each indicator for clarity, ease of collection, validity and usefulness for action.
- Identify indicators that should be discarded or new ones that should be added.
- Identify a set of core indicators for use by all hospitals and complementary indicators that may be useful to only some sites.

A Data Collection Booklet was used to standardised data collection.

Consultation

Each DTC was invited to send a representative to a consensus meeting together with representatives from interested organisations and stakeholder groups to discuss the candidate indicators for:

- Usefulness.
- Validity.
- Acceptance/Rejection.
- Coverage of key issues.
- Relative priority.

The set of indicators presented in this manual reflects decisions reached at that meeting.

Fundamental Principles

The performance indicators described in this manual are based on the following premises:

Goals of Drug and Therapeutics Committees

- To improve the health and economic outcomes of hospital care particularly those related to drug use.

Objectives of Drug and Therapeutics Committees

- Availability of safe, efficacious and cost-effective medicines in the hospital.
- Affordability of medicines to the hospital.
- Quality (judicious and appropriate) use of medicines in the hospital.

Strategies for Drug and Therapeutics Committees

- Policies for Availability, Affordability and Quality of Use of Medicines
- The Committee and its Decisions
 - an active, credible and sustainable committee.
 - sound and transparent decision-making processes.
 - efficient management of resources.
- Promotion of Quality Therapeutics
 - standards of care.
 - educational and behavioural interventions.

How to use the manual

For consistency, the indicators in this manual have been documented in the same format as the National Manual of Indicators to measure the effect of initiatives under the Quality Use of Medicines arm of the Australian National Drug Policy¹. Each indicator is set out in the following way:

- **Indicator number: Indicator question**
- **Definition** of key terms
- **Purpose** of the indicator
- **Description** of the scope of the indicator and how the results can be interpreted

- **Sources and methods of data collection** which describe what data should be used and how the indicator should be calculated
- **Limitations** of the indicator

The indicators are grouped into three categories, Process Indicators, Impact Indicators and Outcome Indicators. Within these groupings are general headings that describe desirable strategies (for process indicators), objectives (for impact indicators) or outcomes (for outcome indicators) for DTCs².

Core indicators appear at the front of each section followed by complementary indicators. Core indicators are suitable for inter-hospital comparisons while complementary indicators are valid for intra-hospital comparison over time.

¹ National Manual of Indicators for Quality Use of Medicines. Department of Human Services and Health, Australia, November 1994.

² The methods for arriving at these strategies, objectives and outcomes are described in the preceding Introduction.

Chapter Two

Performance Indicators

Process Indicators

What is a Process Indicator

These indicators provide mainly qualitative information on the activities or infrastructure necessary to achieve the objectives of a DTC. The indicators are designed to reflect the extent to which an activity or infrastructure has been developed and implemented, by a series of graduated responses. They do not evaluate the functioning or effect of the activities or structures. For example, these indicators check whether a restricted drug list exists but not whether it is effective.

Format of the Indicators

Process Indicators will be expressed in the form of a series of questions which relate to specific strategies which have been identified as important for DTC performance³. These strategies are:

- Policies for Availability, Affordability and Quality of Use of Medicines
- The Committee and its Decisions
 - an active, credible and sustainable committee
 - sound and transparent decision-making processes
 - efficient management of resources.
- Promotion of Quality Therapeutics
 - standards of care
 - educational and behavioural interventions.

Format for Data Collection

Each of the indicator questions is answered by responding with:

- I. A graduated response
 - a) Not yet planned
 - b) Planned but not yet implemented
 - c) Implementation commenced but not yet fully developed
 - d) Fully developed and regularly reviewed; the process is visible and sustainable

OR

- II. Numerical values (ratios, rates, volumes or frequencies), providing quantitative measures of specific aspects of DTC activities.

OR

- III. Yes / No

³ The methods for arriving at these strategies, are described in the preceding Introduction.

Policies for availability, affordability and quality of use of medicines

PR1 Does the DTC have an established place in the organisational structure, including clear lines of authority and accountability?

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definitions

An *established place* is indicated by reference to DTC roles, lines of responsibility and reporting mechanisms in organisational policy and procedure manuals or other official documentation.

Accountability includes the DTC reporting responsibilities.

Purpose

To assess the organisation's commitment to the DTC. A written statement not only provides a structured framework for the DTC activities, but also explicitly demonstrates the commitment and endorsement of the organisational administration.

Description

The DTC's place in the organisation should not be defined in terms of a single department (eg Pharmacy Department) but in terms of its role in overseeing therapeutics within the organisation. The section dealing with the DTC in the policy and procedure manual should be reviewed at least every 3 years. Lack of documentation or a scant description of the DTC roles, responsibility and accountability may reflect a lack of commitment to or understanding of the potential value of the DTC to the organisation.

Sources and Methods of Data Collection

Documentation must be in an official policy document held by the Executive of the organisation. This would be preferably a document that complies with the requirements of the ACHS accreditation process.

Limitations

Although the DTC authority and accountability are documented, the DTC performance may also be affected by material (financial and human resources) and political support from hospital administration.

Process Indicators

Policies for availability, affordability and quality of use of medicines

- PR2** Does the DTC have a documented:
1. Mission statement (goals and objectives)?
 2. Terms of reference?
 3. Strategic plan?

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definitions

The *mission statement* states the goals of the DTC and how it will fulfil these.

The *terms of reference* are the areas of concern referred to the DTC, including boundaries and scope of authority.

The *strategic plan* will address the planned objectives and activities of the DTC in the short term (1-3 years).

Purpose

To assess the commitment and capability of the DTC to define the mission, goals, objectives, terms of reference, and plan for future activities. A written statement provides a structured framework for the DTC activities which explicitly describes what the DTC aims to achieve and how it will do this. It helps to ensure that all DTC members understand the aims, aspirations and general business of the committee.

Description

This indicator refers to the mission, terms of reference, and strategic plan which have been developed and documented by the DTC. It does not refer to policy documents of individual departments.

Sources and Methods of Data Collection

Documentation must be in the DTC policy and procedure manual, business plan or another official record. This document should be readily available for review by all members of the DTC or by other relevant people.

Limitations

Although the mission, terms of reference, and strategic plan are documented, the DTC may not have undertaken the necessary activities or have the necessary resources to achieve these.

Policies for availability, affordability and quality of use of medicines

PR3 Do the DTC terms of reference include provision for the following:

1. Authority to make decisions on the availability and use of drugs in the organisation.
2. Processes for implementation and evaluation of drug policy in the organisation.
3. Mechanism for appeal of DTC decisions.
4. Policy and procedure for declaration of conflicts of interest for individual members.
5. Regular meetings (all matters of business addressed to the committee should be considered by the DTC within 3 months of receipt).

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definitions

Availability and use of drugs concerns which drugs are bought and distributed by the organisation, prescribing guidelines (formulary, restricted drug policies, consensus or evidence based guidelines) and policies on drug administration.

Processes for implementation and evaluation of policy will include activities that complete the quality improvement cycle including feedback, education and review.

A mechanism for appeal allows individuals or groups to appeal to the DTC or another authority against a decision made by the DTC.

Purpose

To ensure the terms of reference supports the authority and credibility of the DTC to promote quality use of drugs.

To ensure the terms of reference supports timely, ethical and transparent decision making.

Description

This indicator assumes the terms of reference provide the basic framework for the daily activities of the DTC. It is important that this framework promotes the authority and credibility of the DTC. The five points listed in this indicator address some of the key determinants for achievement of this - ability to influence drug availability and use, willingness to review drug policy, an ethical and transparent decision-making process and a timely response to submissions made to the committee.

Sources and Methods of Data Collection

Terms of Reference of the DTC.

Limitations

Documentation in the terms of reference alone will not ensure that the DTC has credibility and authority. The activity and performance of the DTC also will be influential in these respects.

Process Indicators

Committee and its decisions: An active, credible, authoritative and sustainable committee

PR4 Are resources specifically allocated to the DTC.

Response Yes / No

Definitions

The *resource allocation* is designated funds budgeted as a separate line item to the DTC for a one year period. The allocation will support the processes of the DTC such as meetings, educational activities and formulary management. It may be part of a departmental budget or administered directly by the DTC, however, the allocation will not form part of the drug budget.

Purpose

To measure the material support provided by fundholders to the DTC.

Description

This indicator measures the material support given by fundholders to the work of the DTC. A resource allocation or either funds or personnel (eg secretarial support) is desirable to ensure that the activities of the DTC can be sustained by a membership which is generally voluntary. A lack of resource allocation could be interpreted as a lack of understanding by fundholders of the amount of work undertaken by the DTC or of its value to patient care.

Sources and Methods of Data Collection

The fundholder financial records for the survey financial year. This may be the hospital general ledger if funding is provided directly to the DTC or it may be the accounts of one or more clinical units.

Limitations

Lack of resource allocation may also reflect a general lack of resources in the hospital.

Committee and its decisions: A sound and transparent decision making process

PR5 Are representatives from the following groups either members of the committee or available for dialogue and collaboration to assist decision making:

1. Prescribers from a variety of units in the organisation?
2. Nursing?
3. Pharmacy?
4. An expert in therapeutics?
5. A person who brings a community health perspective (eg GP, Community Pharmacist)?

OR

A person who brings the perspective of “the common good “ or societal values?

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definitions

The *person who brings the perspective of “the common good “ or societal values* may be an academic, consumer, consumer advocate, minister of religion or other person who is able to take a societal perspective on DTC issues.

Purpose

To assess that the decision making process is sound by ensuring that representative groups are available to assist decision making.

Description

Developing and implementing strategies for quality use of medicines requires a partnership between all those who are involved in the use of medicines. This indicator assesses whether key groups are either represented on the committee or available to the committee in an advisory role. It does not measure whether all stakeholder groups are represented although it would be possible to extend the indicator in future editions of the manual. A positive response to questions 1-3 would be considered essential for any DTC while progress towards questions 4-5 would be highly desirable.

Sources and Methods of Data Collection

DTC minutes or Policy and Procedure Manual.

Limitations

This indicator does not measure whether all stakeholder groups are available for consultation but a subset of these; nor does it measure the quality of consultation, only the opportunity for that consultation.

Process Indicators

Committee and its decisions: A sound and transparent decision making process

PR6 Is the rationale for individual decisions clearly documented and available to stakeholders?

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definitions

The *rationale* includes the analysis of arguments for and against the decision.

Stakeholders include:

- those who take or consider taking medicines;
- those who prescribe medicines;
- those who dispense, facilitate and monitor their use;
- those who make, market, distribute and sell the medicines; and
- the organisation administration or the government who, in the public interest, monitors safety and efficacy and provides equity of access to medicines.

Purpose

To assess the willingness of the DTC to make decision making a transparent process.

Description

A transparent process should freely provide information on how and why decisions are made, commenting on the data available and the decision maker's understanding of clinical need in the specific situation addressed. The provision of this information to stakeholders should be in a 'user friendly' format that encourages feedback to the DTC where appropriate. This indicator assumes that a mechanism for communication of such information exists which in its simplest form could be a letter to the people who have made a submission to the committee. A negative response to this indicator may be inferred to mean that the DTC is operating without the understanding and hence support of stakeholders. Decisions made by the DTC may appear unreasonable and be subject to undue criticism.

Sources and Methods of Data Collection

Documentation available from DTC Policy and Procedure Manual and DTC minutes.

Limitations

This indicator only measures that the DTC conveys information to stakeholders, not that it is prepared to act upon feedback.

Committee and its decisions: A sound and transparent decision making process

PR7 Does the DTC have guidelines on the information required in submissions for formulary additions?

Response Yes/No

Definition

Submission guidelines would include the minimum information required by the DTC to assist decision making on formulary additions. For the purposes of this indicator only submissions for addition of a new chemical entity to the formulary should be considered.

Purpose

To assess commitment to a transparent system by defining and making known the information required for DTC decisions.

Description

This indicator recommends the availability of written application guidelines or a checklist that facilitate:

- consistent retrieval of adequate information by the DTC and
- clinician understanding of what information is required to make the decision.

If application guidelines are not available, the DTC may spend unnecessary time accessing the required information and the original applicant may not be given the opportunity to comment on the relevance of the additional data.

Sources and Methods of Data Collection

Application guidelines may be documented in the DTC Policy and Procedure Manual or a similar document. Alternatively the application guidelines may be published as a separate document.

Limitations

This indicator does not measure the quality of the guidelines only that they are available to individuals applying for a formulary addition.

Process Indicators

Committee and its decisions: A sound and transparent decision making process

PR8 Are requests for availability of non-formulary drugs for individual patients dealt with through a standard mechanism that is overseen, reviewed and ratified by the DTC?

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definitions

Availability of non-formulary drugs may be for an individual patient in extenuating circumstances; use for a non-formulary indication; or for use of a new or investigational drug which would not be considered by the research ethics committee.

Purpose

To assess the ability of the DTC maintain a sound and transparent decision making process in extraordinary situations.

Description

A mechanism for consideration of individual non-formulary requests will help to ensure that the DTC is able to respond to the special or urgent needs of individual patients. A standard process, including documentation of the rationale for the decision and reporting at a subsequent DTC meeting will promote a sound, consistent and transparent approach to decisions not made at a full meeting of the committee. A poor response to this indicator may be interpreted to reflect ad-hoc and erratic decision making in extraordinary circumstances.

Sources and Methods of Data Collection

Documentation must be in the DTC Policy and Procedure Manual or a similar document that is readily available for review by all members of the DTC and other relevant people.

Limitations

The indicator does not measure how well or how often this process is used. An excessive number of individual patient requests may indicate a break down of the usual committee decision making processes. This indicator cannot determine if this is the case but subsequent revision of this manual may include an indicator able to assess such an effect.

Committee and its decisions: To ensure efficient use of resources

PR9 Has the formulary been critically reviewed in the last 12 months?

Response Yes / No

Definitions

The *formulary*, in this case, refers to the list of drug which the DTC has agreed will be available for use in the hospitals.

Critical review included review of the list for out-dated or duplicated therapies which would be deleted and for therapies not represented for which the DTC may seek submissions.

Purpose

To assess the DTC commitment to efficient use of resources by

- removing unnecessary or out-moded drugs from the formulary.
- adding drugs for which a clinical need has been identified.

Description

Efficient management of the formulary will include not only a mechanism for addition of new drugs but also a mechanism for deletion of drugs which:

- are replaced by safer, more effective or more cost-effective agents.
- have intolerable safety profiles.
- are ineffective.

Sources and Methods of Data Collection

DTC minutes and/or hospital formulary.

Limitations

This indicator measures if a critical review has been undertaken. It does not measure the rigour or effectiveness of that review.

Process Indicators

Promoting good therapeutics: Standards of care

PR10 Is there a DTC-endorsed policy on drug promotion by pharmaceutical industry which has been implemented and evaluated?

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definitions

Drug promotion is defined as activities undertaken by the pharmaceutical industry, the effect of which is to induce the prescription, supply, purchase and/or use of drugs. It can target doctors, nurses, pharmacists, other health professionals and the general public.

A *DTC-endorsed policy* may have originated from another committee or department in the organisation but is supported by the DTC.

Purpose

To assess if policies for control of drug promotion are in place.

Description

Regulation of pharmaceutical promotion in the hospital is important for preventing irrational use of drugs. Promotion should provide information which is reliable, accurate, truthful, informative, balanced and up-to-date. Lack of a policy on drug promotion may mean the DTC is unaware of or uninterested in promotional activities. However as the industry is a major source of drug information for most prescribers this may place the DTC at a significant disadvantage in any educational initiatives it undertakes.

Sources and Methods of Data Collection

Documentation will be in the Policy and Procedure Manual or a similar document of the DTC and/or the department who originally wrote the policy.

Limitations

This indicator does not assess the quality or effectiveness of the policy only that it exists.

Promoting good therapeutics: Standards of care

PR11 Does the DTC support implementation of policies that assist discharged patients maintain their medication regimen?

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definition

Policies to assist discharged patients... may include policies for provision of information to GPs and community pharmacist or full discharge liaison services.

Purpose

To promote a continuum of therapeutic care as patients return to the community.

Description

The DTC may not be directly responsible for writing or implementing these policies. In its role of overseeing quality therapeutics, however, it is desirable that the DTC consider patient care not only in hospital but also at the hospital/community interface. The DTC may encourage other groups to develop and implement policies or may ratify such policies. A negative response to this indicator could be inferred to mean that the DTC is solely interested in inpatient care, ignoring both how well patients are transferred back to the community and the educational role the DTC may play in its local community.

Sources and Methods of Data Collection

DTC Minutes; organisation or departmental Policy and Procedure Manuals.

Limitations

This indicator measures the intentions of the DTC but not the vigour or effectiveness of their support for discharge policies.

Process Indicators

Promoting good therapeutics: Standards of care

PR12 Has the DTC ensured that it (or another body in the organisation) has implemented and evaluated a policy on unregistered and alternative drug use?

Response Yes / No

Definition

Unregistered and alternative drug use refers to use of a licensed drug for indications not registered by the Therapeutic Goods Administration (off-label use), use of unlicensed drugs and use of alternative medicines.

The *policy* may address issues such as doing more good than harm and informed consent for use of a drug.

Purpose

To ensure that drug use for unlicensed indications is safe, efficacious and ethical.

Description

While the DTC may not be directly responsible for unlicensed drug use it is responsible for ensuring that the issue is addressed within the organisation. In some hospitals the Ethics Committee may have responsibility for this but the DTC should keep a watching brief and support/endorse recommendations made by another body. The policy would not necessarily relate to all investigational drug use (eg clinical trials). A negative response to this indicator may mean that the DTC is unaware of or unable to influence an important area of drug use in its hospital.

Sources and Methods of Data Collection

DTC, hospital or other committee/departmental Policy and Procedure Manuals or similar documents.

Limitations

This indicator does not measure how well such a policy is implemented or monitored, nor whether it is adhered to.

Promoting and monitoring the outcomes of therapeutics

- PR13** Does the DTC review all cases of mortality thought to be due or partly due to:
1. preventable adverse drug reactions?
 2. medication errors?

Response Yes / No

Definitions

Adverse drug reactions are noxious and unintended effects that occur at doses of a drug normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

Medication errors are the accidental prescribing, administration, omission or dispensing of an incorrect drug, route of administration or dose.

Purpose

To determine if the DTC reviews drug related deaths in the organisation. Ideally such a review would form part of an overall quality improvement program.

Description

The DTC is responsible for supporting best practice in therapeutics. Adverse consequences of medication will not be eliminated under best practice but they will be minimised. This process indicator flags that the DTC is reviewing sentinel events of drug related mortality.

Sources and Methods of Data Collection

DTC minutes, coroners' reports, organisational 'death reports.

Limitations

The coding of patient records to identify adverse consequences of medication use is currently under reported in most hospitals. This indicator measures only if the cases are reviewed not what action is subsequently taken.

Process Indicators

Promoting good therapeutics: Educational and behavioural strategies

- PR14** Were any of the following activities supported or endorsed by the DTC:
1. Provision of educational material (eg drug bulletin) to health professionals?
 2. Detailing of objective information to prescribers?
 3. Audit and feedback of data to health professionals?
 4. Presentations on quality use of medicines issues?

Response

- a) Not yet planned
- b) Planned but not yet implemented
- c) Implementation commenced but not yet fully developed
- d) Fully developed and regularly reviewed; the process is visible and sustainable

Definitions

Detailing of objective information may be delegated/endorsed by the DTC when it requests clinical pharmacists or nurses to promulgate and discuss therapeutic guidelines or literature reports with prescribers.

Audit and feedback data may include data on prescribing, adverse reactions, medication incidents, infection rates, etc.

Presentations may include lectures at forums such as medical meetings, inservice programs, hospital seminars or grand rounds.

Purpose

To assess the commitment of the DTC to rational drug use through the provision of educational activities.

Description

Educational and behavioural interventions which have been shown to influence quality use of medicines should be promoted by DTCs when possible. The selection of such interventions, however, should be made within the context of the priorities and needs of each institution. A negative response to this indicator may be justified by the provision of other proven educational strategies. A mix of strategies, targeted at a range of groups and individuals who prescribe, administer, manage or take medicines is recommended in all hospitals.

Sources and Methods of Data Collection

DTC minutes and other organisational documentation.

Limitations

This indicator measures if educational activities were supported/endorsed but not if they were attended or had an impact.

COMPLEMENTARY INDICATOR 1

Committee and its decisions: An active, credible, authoritative and sustainable committee

$$\frac{\text{Number of DTC members who attend more than 50\% of meetings}}{\text{Total number of DTC members}}$$

Response Ratio

Purpose

To assess the credibility of the DTC by measuring the commitment of the members to DTC processes

Description

If the DTC is to be credible in the institution, it must firstly be credible amongst its own membership. A strongly supportive membership will attend meetings and facilitate implementation of DTC decisions in the hospital.

Sources and Methods of Data Collection

DTC minutes for the 12 month survey period.

Limitations

This indicator does not measure the willingness of DTC members to publicly and practically support the implementation of DTC decisions.

Process Indicators

COMPLEMENTARY INDICATOR 2

Committee and its decisions: To ensure efficient use of resources

Number of chemical entities on formulary in an ATC group
Total number of chemical entities in an ATC group

Calculate For:

1. General anaesthetic agents
2. Parenteral cephalosporins

Response Ratios

Purpose

To assess the DTC commitment to efficient use of resources through formulary management.

Description

In some classes of drugs a large number of products with very similar safety and efficacy profiles are marketed. As part of their formulary management most DTCs limit the number of products available within the hospital in a particular chemical class where no advantage can be shown for individual products. The primary effect of this is to assist inventory control procedures and reduce wastage. An important secondary effect is that educational interventions and appropriate prescribing may be assisted by selection from a less extensive list of medications. A ratio approaching one may indicate that the DTC does not actively seek to contain costs through formulary management.

Sources and Methods of Data Collection

Formulary or hospital drug list / catalogue.

Limitations

This indicator does not assess whether the most appropriate products have been selected only that some selection process has been undertaken by the DTC. This indicator will require further testing in the future.

COMPLEMENTARY INDICATOR 3

Promoting good therapeutics: Standards of care

$$\frac{\text{Number of drug usage guidelines received by health professionals}}{\text{Total number of health professionals surveyed}}$$

Calculate For:

1. Doctors
2. Nurses

Response Ratios

Definitions

Drug usage guidelines may include consensus or evidence based recommendations on use, accepted indications and dosage, place in therapy and approved prescribers. They may also include therapeutic guidelines that recommend appropriate treatments for a particular condition. These guidelines will be endorsed although not necessarily written by the DTC. The guidelines will be published for distribution in the hospital.

Purpose

To assess the availability of drug usage guidelines or therapeutic guidelines which are intended to promote ‘best practice’.

Description

Drug usage guidelines are one tool used by DTCs to improve the quality of health care, with the efficient use of resources usually an inherent by-product. Guidelines will preferably be consensus or evidence based and will be developed in collaboration with the expected users. However, these guidelines cannot be effective unless they are received by those making drug use decisions.

A low ratio may indicate that a better distribution mechanism is needed or that the guidelines are forgotten/ignored because no other measures have been used to facilitate their use.

Sources and Methods of Data Collection

Numerator: Number of surveyed health professional who report receiving a copy of the guideline.

Denominator: Total number of health professionals surveyed.

The survey should include 10-20 individuals randomly selected from relevant target groups, that is prescribers and nurses. In a small hospital, it would be acceptable to survey 30-50% of staff who fall into these categories.

The survey should be undertaken for a guideline which has been produced within the survey year, preferably within the last 6 months.

Limitations

This indicator does not measure if or how drug use indicators are used, nor their impact on quality of drug use. The small sample size will affect the sensitivity of this indicator. Sample size will be reviewed with the next edition of the manual.

Impact Indicators

What is an Impact Indicator?

These indicators provide quantitative information on the function of activities and infrastructure used by the DTC to achieve its objectives. Impact indicators can be used to assess and quantify changes over time and progress in specific areas.

Format of the Indicators

Impact Indicators will be expressed in the form of a series of questions which relate to specific objectives which have been identified⁴ as important for DTC performance. These objectives are:

- Availability of safe, efficacious and cost-effective medicines in the hospital
- Affordability of medicines to the hospital.
- Quality (judicious and appropriate) use of medicines in the hospital.

Format for Data Collection

Impact indicators will generally be expressed in the form of numerical values (ratios, rates, volumes or frequencies), providing quantitative measures of specific aspects of DTC activities.

⁴ The methods for arriving at these objectives are described in the preceding Introduction.

Availability of safe, efficacious and cost-effective medicines for hospitals

IMI Percentage of submissions for addition of a new drug (new chemical entity) to the formulary for which the DTC had access to the following information:

1. Balanced, comparative information on clinical efficacy and safety
2. Economic analysis
3. Assessment of clinical need

Response Percentage

Definitions

Balanced comparative information includes :

Clinical trial data from well designed (blinded, randomised, controlled) studies which compares the new drug with placebo and/or the current gold standard for the indication(s) under consideration. The data should be published in a peer reviewed journal and the context of the clinical trial should be consistent with expected clinical practice. Both positive and negative outcomes of therapy should be given equal emphasis.

Economic analysis includes:

Clinical trial data that includes economic endpoints or modeling of economic data. The analysis would include a sensitivity analysis, explanation of assumptions and may take a societal or institutional perspective.

Assessment of clinical need may include any of the following:

- The therapeutic alternatives to the new drug
- Drug utilisation information
- Relevant medication error and adverse drug reaction reports
- Readmission rates due to drug related problems
- Local anti-microbial resistance patterns
- Casemix / specialty services
- Local community health needs

Purpose

To assess the type of information used to inform decisions on additions to the hospital formulary.

Description

Decisions made on formulary changes should be based on objective information including the relative efficacy, safety and cost-effectiveness of the drug. In addition the DTC needs to be aware of how the drug is likely to be used in the local setting, what problems it may solve or create and which clinical needs it will address. In some hospitals, the DTC may not make formulary decisions but will act as an advisory body to clinical units. In these cases, please apply this indicator to how the DTC reaches recommendations to be made to clinical units on new drugs.

Impact Indicators

IM1 (cont.)

Sources and Methods of Data Collection

DTC minutes and agenda papers

Numerator: Data should be collected for all applications for addition of a new drug to the hospital formulary. Do not include applications for new indications for drugs already on the formulary. Calculate for all DTC meetings held in the first 6 months of the survey year. The information may have been provided by the sponsor or may have been supplemented by the DTC. The decision of whether the information was available will be made on all information available to the committee before a decision was taken.

Denominator: Data should be collected for the number of applications made for addition of a new drug to the hospital formulary. Do not include applications for new indications for drugs already on the formulary. Calculate for all DTC meetings held in the first 6 months of the survey year.

Limitations

This indicators measures the percentage of decisions for which information was available but does not measure the quality of the information.

Availability of safe, efficacious and cost-effective medicines for hospitals

IM2 Percentage of drug use policies which were adopted?

Response Percentage

Definitions

Drug use policies are policies or protocols which provide standards for how, when and where drugs should be used in the hospital. This may include policies on administration guidelines; nurse initiated medications; cytotoxic handling practices, etc.

Purpose

To assess the capacity of the DTC to adopt decisions.

Description

A DTC requires authority, credibility and resources to adopt its decisions. This indicator measures the success of the DTC in adopting policy. Drug use policies should form the framework for all drug use in the hospital and consequently their implementation is a fundamental step in ensuring quality use of medicines in the hospital. A low percentage for this indicator would indicate that the DTC is not effective in influencing drug use in the hospital.

Sources and Methods of Data Collection

Numerator: DTC minutes of other hospital documentation . Of the drug use policies decided in the 12 month survey period how many have been adopted as organisational policy.

Denominator: DTC minutes for the 12 month survey period. How many drug use policy decisions were made by the DTC in the 12 month survey period.

Limitations

This indicator measures whether a policy has been adopted. It does not measure how complete the implementation is or if the policy has resulted in desired outcomes.

Impact Indicators

COMPLEMENTARY INDICATOR 4

Availability of safe, efficacious and cost-effective medicines for hospitals

Expenditure on non-formulary drugs as a percentage total drug expenditure

Response Percentage

Definitions

Non-formulary drugs for the purposes of this indicator will include only registered drugs. Drug available through the Special Access Scheme should not be included.

Purpose

To assess the affordability of drug treatment within the facility.

Description

An important objective of many DTCs is to ensure that drug use in the institution is affordable. Drugs are added to the formulary depending on relative effectiveness, cost and clinical need. A large expenditure on non-formulary drugs indicates that the formulary system is not successful as a means to achieve affordable drug therapy.

Sources and Methods of Data Collection

General ledger and pharmacy computer system for the survey period.

Limitations

This is a fairly crude and indirect indicator of drug affordability to the institution. It measures the success of systems that are aimed at achieving affordable drug therapy.

COMPLEMENTARY INDICATOR 5**Quality use of medicines: Judicious, appropriate and safe use of medicines in the hospital**

Percentage of health professions who report using a drug usage guideline?

Calculate for:

1. Doctors
2. Nurses

Response Percentage

Definitions

Drug usage guidelines may include consensus or evidence based recommendations on drug use, identifying accepted indications and dosage, place in therapy and approved prescribers. They may also include therapeutic guidelines that recommend appropriate treatments for a particular condition. These guidelines will be endorsed although not necessarily written by the DTC. The guidelines will be published for distribution in the hospital.

Purpose

To assess the use of drug usage guidelines by health professionals.

Description

Drug usage guidelines are one tool used by DTCs to improve the quality of health care, with the efficient use of resources usually an inherent by-product. Guidelines will preferably be consensus or evidence based and will be developed in collaboration with the expected users. This indicator measures how well guidelines are used by the target group for which they were developed.

If no drug use guidelines have been developed or endorsed by the DTC during the survey period, the response to this indicator will be zero. A low percentage may indicate problems in the process of developing the guideline (lack of ownership by the users) or inadequate distribution and promotion of the guideline by the DTC.

Sources and Methods of Data Collection

This indicator should be calculated from the second part of the survey required for Complementary Indicator 3.

Numerator: Number of surveyed health professional who report having used a copy of the guideline in the past 2 months.

Denominator: Total number of health professionals surveyed.

The survey should include 10-20 individuals randomly selected from relevant target groups, that is prescribers and nurses. In a small hospital, it would be acceptable to survey 30-50% of staff who fall into these categories.

The survey should be undertaken for a guideline which has been produced within the survey year, preferably within the last 6 months.

Limitations

This measures that the information was used but it does not measure how it affected the behaviour of those involved.

Impact Indicators

COMPLEMENTARY INDICATOR 6

Quality use of medicines: Judicious, appropriate and safe use of medicines in the hospital

Drug utilisation for key conditions/indications post DTC intervention
Drug utilisation for key conditions/indications pre DTC intervention

Response Ratio

Definitions

DTC interventions may include one or more of the following: an article in the drug bulletin, distribution of a therapeutic guideline, promotional campaign for how to prescribe for a particular indication, prescriber audit and feedback, etc. The *key condition /indication* is defined in the ‘Sources and Methods of Data Collection’ section below.

Purpose

To assess the impact of DTC interventions to change drug utilisation.

Description

Educational and behavioural interventions are an important activity of DTCs. The aim of these activities is usually to influence drug use in the hospital by changing the practices of doctors, nurses, pharmacists or patients. This indicator measures the impact of an intervention or series of interventions to change drug utilisation for a specified condition. If the DTC cannot provide utilisation data, the response will be zero. In such a case it would appear that the DTC does not have good quality information drug utilisation data available to it. A ratio of > 1 indicates some success with the intervention program.

Sources and Methods of Data Collection

Numerator: Drug utilisation for a selected indication (key condition/indication) following an educational or behavioural intervention undertaken, endorsed or coordinated by the DTC. Drug usage for each patient survey will either comply or not comply with the guideline; partial compliance should be treated as ‘not comply’ for the purposes of this data collection. Drug utilisation will be expressed as percentage compliance of observed drug use : recommended drug usage.

Denominator: Drug utilisation for a selected indication (key condition/indication) before the educational or behavioural intervention was undertaken, endorsed or coordinated by the DTC. Drug utilisation will be expressed as percentage compliance of observed drug use : recommended drug usage.

The *key condition* which is selected by your DTC should be a condition/indication which has been of concern to the DTC in recent times (the last 1-3 years).

The DTC would have undertaken an educational intervention promoting the preferred treatment for the condition/indication, within 3 months of the post intervention measure of utilisation.

COMPLEMENTARY INDICATOR 6 (cont)

Sources and Methods of Data Collection (cont.)

Drug utilisation will be assessed for compliance with the recommendations of the educational intervention. If your DTC or pharmacy has undertaken a DUE in the past year which fulfils these criteria you may choose to use these data to calculate the indicator.

Limitations

This indicator will require a significant amount of data collection for those hospitals which do not routinely undertake DUE. The indicator provides data for a point in time, it does not show if the effect is maintained over time.

COMPLEMENTARY INDICATOR 7

Quality use of medicines: Judicious, appropriate and safe use of medicines in the hospital

Adverse drug reaction (ADR) reports forwarded to the national database (ADRAC) per annum?

Calculate for

1. Number of reports per 1000 beds

Response Number

Definitions

Adverse drug reactions are noxious and unintended effects that occur at doses of a drug normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

ADRAC is the Adverse Drug Reaction Advisory Committee of the Therapeutic Goods Administration, Department of Health and Family Services.

Purpose

To assess the impact of the ADR reporting mechanism by measuring the number of reporters and the rate of reporting ADRs to a national database (ADRAC).

Description

Information about the number and type of adverse drug reactions is needed to facilitate the optimal use of medicines. In a hospital the DTC is usually the central body which promotes reporting of and provides information about ADRs. A good level of reporting indicates an awareness that ADRs occur and an understanding of the importance of reporting adverse effects and reporting mechanism.

Sources and Methods of Data Collection

Secretary, Adverse Drug Reactions Advisory Committee, Therapeutic Goods Administration, Department of Health and Family Services.

The department can provide this data for a 12 month period for individual hospitals.

Limitations

The indicator is reliable only if the monitoring system is reliable. An increase or decrease in the rate of reporting may be multi-factorial and not only attributable to the DTC mechanism.

What is an Outcome Indicator

These indicators seek to measure the progress toward the stated goal of the DTC.

Format of the Indicators

Outcome Indicators will be expressed in the form of a series of questions which relate to specific outcomes which have been identified as important for DTC performance⁵. These outcomes are:

- To improve the health and economic outcomes of hospital care particularly those related to drug use.

Format for Data Collection

Outcome indicators will generally be expressed in the form of numerical values (ratios, rates, volumes or frequencies, providing quantitative measures of the desired outcomes.

⁵ The methods for arriving at these outcomes are described in the preceding Introduction.

Outcome indicators

To improve the health and economic outcomes of hospital care particularly related to therapeutics

- OT1** Hospital morbidity due to:
1. Preventable adverse drug reactions?
 2. Medication errors

Response Percentage

(Number of cases of ADRs or medication errors causing patient morbidity during the survey period as a percentage of the total number of patients surveyed)

Definitions

Adverse drug reactions are noxious and unintended effects that occur at doses of a drug normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

Medication errors are the accidental prescribing, administration, omission or dispensing of an incorrect drug, route of administration.

Morbidity would include increased length of hospital stay, need for additional therapeutic or diagnostic procedures, increased length of stay in high dependency units, need for additional medications or permanent disability.

Purpose

To measure the rate of patient morbidity due to the adverse consequences of medication use.

Description

If the DTC is to improve health outcomes of the patients in its hospital, it would be expected to do so by ensuring high quality therapeutics or 'best practice' in therapeutics. Adverse consequences of medication will not be eliminated under best practice but they will be minimised. Patient morbidity is an important health outcome measure of medication use. It is also often an important economic outcome measure of medication use. A high percentage for this indicator may reflect a lack of effectiveness of DTC policy and activities, although it is recognised that influences on this indicator are multifactorial.

Sources and Methods of Data Collection

Numerator: No. patients experiencing morbidity that is believed to be definitely or probably due to an adverse drug effect.

Patients admitted over a one month period will be followed prospectively for the duration of that single admission to hospital. Data should be collected for a cohort of at least 250 randomly selected patients admitted during the recruitment period.

Denominator: Number of patients in the study cohort.

Limitations

This indicator will be time consuming to calculate as most hospitals will not routinely collect this data. The small sample size will affect the sensitivity of this indicator. The sample size may need to be reviewed in the next edition of the manual.

Chapter Three

Glossary

Glossary

Anatomical Therapeutic Chemical classification (ATC)

Drug and Therapeutics Committee (DTC)

A multi-disciplinary committee whose role can incorporate:

- i) **Advisory Functions**
to formulate policies regarding evaluation, selection and therapeutic use of drugs and related services.
- ii) **Educational Functions**
to recommend or assist in the formulation of programs designed to meet the needs of professional staff for complete, current knowledge on matters related to drugs and drug use.

Drug utilisation evaluation (DUE)

Is a structured, ongoing and outcome oriented programme which uses pre-determined criteria and standards to monitor, evaluate and improve the quality of drug therapy.

Educational and behavioural interventions

Are activities that aims to change behaviour or educate. This may include:

- raising the level of awareness;
- influencing attitudes;
- improving the level knowledge;
- providing information.

Formulary

Is the list of drugs which the DTC has agreed will be available for use in the hospitals.

Performance Indicator

Are a range of objective criteria by which DTC initiatives may be evaluated in relation to their goals and objectives.

Quality use of medicines (QUM)

Is defined by the World Health Organisation in 1987 as:

“Drugs are often required for prevention, control and treatment of illness. When a drug is required, the “rational use of drugs demands that the appropriate drug be prescribed, that it be available at the right time at a price people can afford, that it be dispensed correctly, and that it be taken at the right dose at the right intervals and for the right length of time. The appropriate drug must be effective, and of acceptable safety and quality.”

