

SHPA Standards of Practice for Drug Use Evaluation in Australian Hospitals

SHPA Committee of Specialty Practice in Drug Use Evaluation

These are standards of professional practice and not standards prepared or endorsed by the Standards Association of Australia. They are not legally binding.

INTRODUCTION

Drug use evaluation (DUE) is a systematic quality improvement activity. The purpose of DUE is to improve the quality and cost-effectiveness of drug (medicine) use, and thereby improve patient care.

DUE may be applied to a drug, therapeutic class, disease state or condition, a drug use process or specific outcomes.¹ It may be applied in various practice settings, including hospitals, other health facilities, and community practice environments.² DUE is an essential component of pharmacy service provision, clinical pharmacy practice and pharmacy quality assurance and management programs.

These standards supersede the previously published SHPA Standards of Practice for DUE in Australian hospitals.³

DEFINITIONS

In Australia, the terms drug use evaluation and drug use review have been used interchangeably. DUE is the preferred term and is the term used in this document.

When DUE activities become routine or ongoing, and become an integral part of the overall patient care review system, they are recognised as part of a DUE program.⁴

A DUE program can be defined as an authorised, structured, ongoing system for improving the quality of drug use within a healthcare organisation. Drug use is evaluated by using pre-determined standards and efforts are initiated to correct patterns of use which are not consistent with these standards. It includes a mechanism for measuring the effectiveness of these corrective actions.^{4,5}

OBJECTIVES

A DUE program is a comprehensive and cyclical process of review, evaluation and intervention, which should operate as part of a broader hospital program of quality management. The goal of a DUE program is to improve the quality, safety and cost-effectiveness of drug use by:

- facilitating multidisciplinary consensus on drug use;
- conducting regular audits to assess concordance with best practice in drug use;
- providing feedback of results to prescribers and other stakeholders;
- promoting judicious, appropriate, safe and cost-effective therapy through provision of information, advice and education;
- minimising variations in practice that contribute to suboptimal clinical outcomes; and
- enhancing opportunities, through standardisation, to assess the value of drug use practices.

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EXTENT AND OPERATION

Program Authority and Responsibility

DUE should be part of a systematic and multidisciplinary approach. All those involved in the drug use process (prescribers, pharmacists, nurses, hospital managers, consumers) are important to the success of a DUE program. Attention must be given to the relationships between all interested parties.

For DUE to operate effectively in the institutional context, it must have legitimacy and must operate with institutional authority. The program should be authorised by the Chief Executive Officer, Medical Director or nominee.

Responsibility for program implementation should reside with prescribers, in cooperation with pharmacists and other interested groups. In the majority of cases there will be opportunities for pharmacist leadership of DUE programs and this should be encouraged.

There should be oversight of the DUE program by the institutional committee responsible for regulating drug use (e.g. Drug and Therapeutics Committee). There should be clear lines of communication with other quality improvement committees within the organisation.

The optimum administrative design for a DUE team may vary depending on the environment in which the team operates. The model proposed by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists provides a useful guide (Figure 1).⁶

Drug Use Evaluation Process

DUE is a cyclical, dynamic and iterative process (Figure 2). It is described by Dartnell as follows: 'The DUE cycle has two main phases operating in an iterative cycle. The first phase is investigative: measuring and defining drug use, identifying drug use problems and measuring the impact of interventions. The second phase is interventional: problem solving, consensus building and activity implementation towards improving drug use.'⁴

The DUE model for achieving improvement is similar to other clinical practice improvement methods.⁷ Similarities exist between the Institute for Healthcare Improvement plan-do-study-act methodology and DUE.⁸ Both result in the development of similar activities: identifying desired practice, measuring current practice, developing and implementing changes and feeding back into the process, using iterative cycles. Both are successful tools for improving patient care, but each has different points of emphasis. The Institute's approach is to collect data in small samples over many cycles, with less emphasis on comprehensive data collection and more emphasis on rapid improvement.

POLICIES AND PROCEDURES

The DUE process involves a number of clearly defined steps:⁴

1. Identification of drug use process for evaluation.
2. Assembling the DUE team.
3. Design of the study.

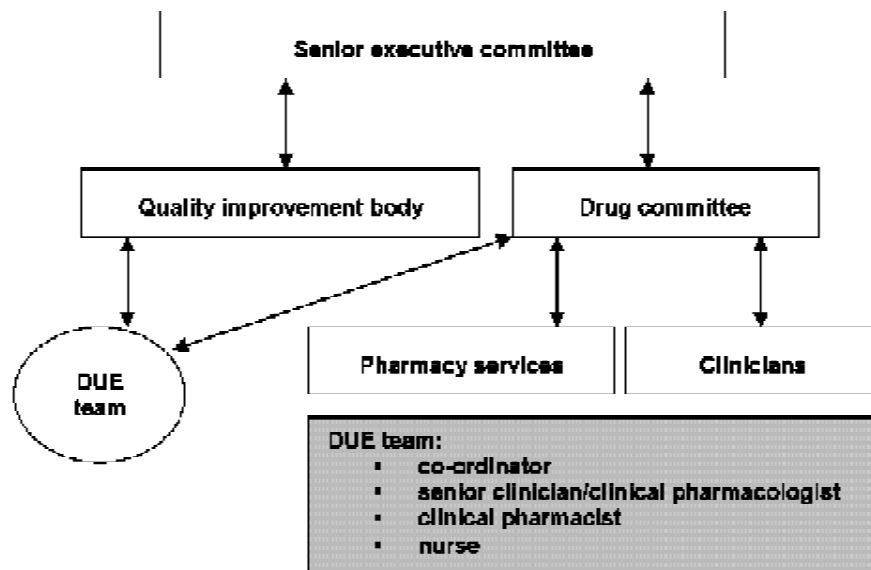


Figure 1. Drug use evaluation team model⁶

4. Approval of the study.
5. Development of criteria and measurement instruments.
6. Data collection.
7. Evaluation with pre-determined criteria and analysis of results.
8. Reporting and feedback.
9. Design and implementation of intervention strategies.
10. Reassessment and revision of problem.

1. Identification of Drug Use Process for Evaluation

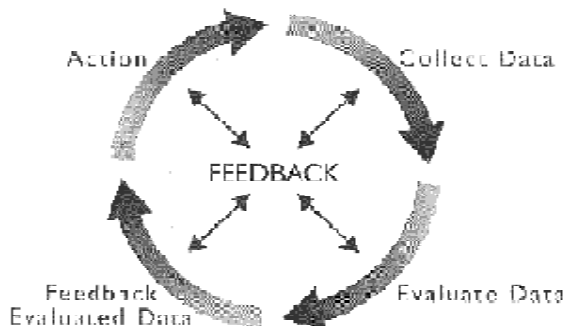


Figure 2. Drug use evaluation process²

Target areas for evaluation may include individual drugs, drug classes, or components of clinical procedures or disease state management. DUE should be considered when new drugs are added to a formulary or as part of drug usage guidelines at the time of ratification.

Certain drugs or events serve as indicators of potential problems in the drug use process and may highlight potential target areas for DUE. They may include:

- drugs known to be associated with adverse events or poor patient outcomes;
- drugs used in high-risk patients;
- drugs with high-unit or high-volume cost;
- drugs or processes where suboptimal use is likely to have a negative effect on patient outcomes or system cost;
- adverse medication events (actual or averted); and
- signs of treatment failure (e.g. bacterial resistance).

2. Assembling the Drug Use Evaluation Team

Relevant experts should be recruited to assist with assessment of practice performance. There will usually be a need to include different team members for different studies, to ensure appropriate expertise.

3. Design of the Study

The objectives and study method will be dependent on the nature of the project. Reviews may be quantitative or qualitative, or combine both elements. They may be descriptive without the use of pre-determined criteria or may involve criteria-based audits. Reviews may range in scope from routine screening activities to expansive reviews of all aspects of drug therapy. Reviews may be conducted retrospectively, concurrently or prospectively.

Retrospective reviews are performed after patient separation, usually by perusal of case notes. This method is the most convenient, and therefore the most commonly used method. However, data availability is limited by the accuracy and completeness of documentation. Retrospective review may benefit future patients but has no direct impact on the patient under review.

Concurrent reviews are performed concurrently with patient treatment, usually within 48 hours of starting therapy.

Prospective reviews occur at the time of treatment initiation and sometimes even before treatment commences. Prospective reviews should be considered where possible, as data collection is more robust.

The latter two methods are more disruptive of daily activities but provide opportunities for direct education and intervention and changes to drug therapy during or before the course of treatment.

A decision on appropriate sampling methods should be made before the commencement of each review. Assessing the therapy of every patient during a review may be neither desirable nor feasible. The time, effort, human resources and expense of retrieving and evaluating every record may be prohibitive.

The project design should be documented prior to commencement of the study and should include background, aims, patient selection, data collection methods, and proposed method of analysis. The project design should be endorsed by the Drug and Therapeutics Committee or other authoritative committee.

4. Approval of the Study

Approval for access to patient data should be obtained from the institutional ethics committee where appropriate.⁹ In some facilities blanket approval may be provided for all quality activities including DUE. In other cases, approval may be required on a project-by-project basis. Prior approval must be sought before access can be gained to patient medical records.

All DUE programs must be mindful of ethical and privacy considerations. Ethical issues must be addressed prior to any pilot data collection and may require identification of patient-specific data.

5. Development of Criteria and Measurement Instruments

Careful consideration should be given to the formulation and use of audit criteria. Audit criteria must be: valid, explicit, pre-determined, easily measured, relevant to the practice environment, and outcome oriented. They should also be scientifically based, supported by clinical or research literature and be periodically reviewed to maintain currency with developments in medicine, pharmacology and pharmacy practice.

Where possible, audit criteria should be based on recognised standards and can be derived from systematically developed clinical practice guidelines. If these are not available or appropriate, criteria development should occur in the same way as the development of clinical guidelines.

Criteria should be explicitly agreed by the project team with input from expert clinicians, prior to commencement of data collection.

6. Data Collection

Data collection instruments should be unambiguous and 'user friendly'. They should be simple and focused to answer the specific question under study. They should include only relevant demographic, clinical or drug therapy information that will help in answering the question posed.

Where possible, data collection should take advantage of existing automated information systems. Collecting data for later review and assessment should be avoided. Data collection instruments should be tested in pilot studies to ensure they are suitable for the purpose.

The extent and limitations of data sources must be understood. Confidentiality of data must be ensured.

7. Evaluation with Pre-determined Criteria and Analysis of Results

Drug use will usually be compared with pre-determined audit criteria and areas of divergence identified and documented. Audit criteria should be evidence-based and should be developed in consultation with expert clinical advice. They may be developed locally, nationally or internationally, but should be explicit, practical, relevant and measurable. They should be endorsed locally before the DUE is commenced.¹⁰ Treatment courses not matching the audit criteria should be reviewed with clinicians to determine if there is valid clinical justification for divergence from criteria.

8. Reporting and Feedback

A mechanism should be developed for feedback of audit results to prescribers and other relevant stakeholders. A conciliatory environment for the feedback of audit results to prescribers should be established. Feedback should be

undertaken constructively with prescriber education as the primary motive. This should be in a manner that engenders support for the program, and encourages acknowledgment and a means to improve drug use.

Wide and constructive feedback of positive and negative findings is fundamental to the success of DUE programs. Dissemination of study results should include summaries to relevant committees and to the service under review. Short articles in the pharmacy or drug committee bulletins or other hospital publications, and presentation at medical grand rounds and other meetings may be useful.

Study results and recommendations should be reported in writing as a comprehensive report to the appropriate body of authority.

9. Design and Implementation of Intervention Strategies

An appropriate intervention plan should be developed to address drug use problems and issues identified in the investigative phase of the DUE process. Factors influencing prescribing are complex.^{4,11} Nevertheless, there is a range of interventions that can be effective in changing prescribing practice.¹¹⁻¹³ Multifaceted interventions appear to have the greatest chance of improving drug use.¹³

Since the factors influencing prescribing decisions are multifactorial, so should be the strategies to change prescribing practice.¹² Interventions should be as simple as possible and directed at specific problems that are amenable to change.⁷ Approaches may include formulary changes, procedure modifications, additional pharmacy services, publication of therapeutic guidelines and a variety of educational activities.

Strategies to influence prescribing and improve drug use may take a number of forms:^{11,13}

- Re-educative strategies are those where the relatively unbiased presentation of fact is intended to provide an impetus for change (e.g. circulation of guidelines, distribution of bulletins or newsletters, reminders at the point of prescribing).
- Persuasive strategies attempt to bring about change partially through reasoning, urging and inducement (e.g. memoranda, academic detailing, rewards or incentives, small group educational activities).
- Facilitative strategies recruit the services of others to assist in changing the behaviour of an individual or group (e.g. endorsement by key opinion leaders).
- System-based strategies change the drug use process (e.g. procedural change, formulary restrictions, automatic stop orders).
- Combined strategies use two or more of the above simultaneously or sequentially.

Evaluation of the effectiveness of interventions should be undertaken. This will provide information on the process itself, the impact of the review on drug utilisation rates and the cost of review against benefits achieved. Short-term and long-term effects should be measured, and hospital, medical, departmental and individual performances reported where appropriate.²

10. Reassessment and Revision of Problem

DUE is a cyclical process—lessons learned from one cycle of study should be incorporated into subsequent study cycles. The program should allow flexibility to rapidly incorporate changes in medical knowledge and practice.

Re-evaluation of specific projects or the overall program can be achieved in a number of ways, determined according to the nature of the problems identified and

the corrective actions implemented. These include:

- Simple monitoring of utilisation data for a drug or group of drugs.
- Exception or threshold analysis, i.e. examining more closely drug use trends which fall outside certain pre-defined limits.
- Periodic screening of one or more aspects of drug use for which specific interventional activities were introduced.
- Reassessment of areas or target groups where inappropriate use was identified previously.
- Comprehensive re-evaluation of the database(s) targeted during the initial review processes.

SURVEILLANCE

The international unit of drug utilisation is the defined daily dose (DDD). For regional drug use, this is usually measured as DDDs per thousand inhabitants per day. In hospitals, the denominator may be bed days or separations, e.g. DDDs per 100 bed days or DDDs per 100 separations. The DDD was established by the Nordic Council on Medicines and the World Health Organization Drug Utilization Research Group on the basis of the assumed average dose per day of the drug, used for its main adult indication.¹⁴ This unit is used by the Drug Utilisation Subcommittee of the Australian Pharmaceutical Benefits Advisory Committee in its ongoing surveillance of the Australian Government subsidised medicines.

This indicator allows for comparison of drug utilisation, adjusted for activity, between services, facilities, states and countries. It may be a useful indicator for surveillance of drug use as part of a comprehensive DUE program.

PHARMACIST'S ROLE

Pharmacists, by virtue of their expertise and mission of ensuring quality use of drugs, should play a leadership role in DUE programs and work collaboratively with other members of the healthcare team. Suggested roles and responsibilities include:

- Recommendation and promotion of the goals and objectives of DUE.
- Program development, supervision and coordination.
- Education of hospital staff about the theory and practice of DUE.
- Coordination of development and/or review of audit criteria, guidelines, study protocols and other educational material.
- Coordination of development of data collection instruments, field testing, data collection, analysis, development of recommendations for intervention, and report writing.
- Documentation of program outcome, effectiveness and cost benefit.
- Participation as a member of hospital committees concerned with quality assurance in general and DUE in particular.
- Presentation of DUE results at meetings and conferences.

RESOURCES

The cost and availability of suitably trained personnel will determine the scope of the DUE program. Staffing levels should be adequate to achieve project goals and objectives. Medical, nursing, quality and/or pharmacy staff may be involved in various aspects of DUE projects.

Specific allocation of professional staff to DUE functions is preferable, although some aspects of data collection, monitoring, intervention and education may be incorporated into the daily routine of clinical, dispensary or other pharmacy staff and/or medical or nursing staff. Non-professional staff, research associates and students may be recruited for prescription or data screening, data collection and collation. Review, interpretation and analysis of drug use will generally require professional input.

Other resources should be adequate to ensure that program goals can be achieved. These include access to reference texts, journals and information sources, data retrieval resources, office space, furniture and space for storage of project documentation. Computer hardware, peripherals and application software, including internet access, should be available and appropriate for management data entry, analysis and reporting by project personnel. Relevant occupational health and safety regulations should be observed.

TRAINING AND EDUCATION

Pharmacists coordinating DUE programs should have wide-ranging clinical knowledge, supported by several years post-registration experience and should have skills in literature retrieval and interpretation and computerised data management. Good communication skills (written and verbal), interpersonal skills and project management skills are essential. Post-graduate qualifications in pharmacoepidemiology, change management, adult education, or other relevant areas may be desirable.

DOCUMENTATION

Documenting the results of individual DUE projects is an important task. Activities should be documented as they are completed. Copies of study audit criteria, agreed guidelines, data collection tools, memoranda and correspondence, tabulated data and feedback reports, committee minutes, intervention plans, project reports and resultant publications should be maintained.²

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