The Society of Hospital Pharmacists of Australia

Australian **Medicines Information** Procedure Manual

shpa

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Websites cited throughout this document may be accessed by hyperlink from the PDF, however URLs are not visible when the document is printed.

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ABBREVIATIONS

ADR	Adverse Drug Reaction
APPF	Advanced Pharmacy Practice Framework
APPFSC	Advanced Pharmacy Practice Framework Steering Committee
CoDEG	UK Competency Development and Evaluation Group
COSP	Committee of Specialty Practice
DTC	Drug and Therapeutics Committees
DUE	Drug Use Evaluation
EBM	Evidence Based Medicine
EBP	Evidence Based Practice
MI	Medicines Information
MIC	Medicines Information Centre
NDIS	National Drug Information Service
NWAU	National Weighted Activity Units
QA	Quality Assurance
QUM	Quality Use of Medicines
RSS	Really Simple Syndication
SAS	Special Access Scheme
SHPA	Society of Hospital Pharmacists of Australia
TGA	Therapeutic Goods Administration
UK MHRA	United Kingdom Medicines and Healthcare Regulatory Agency
UK Mi	United Kingdom Medicines Information
US FDA	United States Food and Drug Administration

1•INTRODUCTION

This manual provides information about the resources and skills required to establish, operate and maintain a medicines information (MI) service. In this manual, medicines information (MI) refers to information or advice provided in response to a request from a health professional, organisation, or consumer and may relate to a specific patient, or consists of general information promoting the safe and effective use of medicines. It contributes to high quality patient care and public health by promoting the quality use of medicines. Medicines information supports judicious, appropriate, safe and efficacious use of medicines to optimise health outcomes.

A medicines information service describes activities undertaken by pharmacists to provide MI. The term includes, but is not limited to, the specialised service offered by MI pharmacists.

A medicines information centre (MIC) refers to a facility specifically set aside for, and specialising in, the provision of medicines information.[1]

Although providing MI is an essential part of pharmacy practice[2], a clinical pharmacist may not have the necessary skills, knowledge, or time to utilise additional resources which are often required to answer clinical questions in an optimal manner. According to SHPA's standards of practice[1], a medicines information pharmacist is defined as 'a pharmacist who has extensive knowledge and skills in medicines information, a sound knowledge of evidence-based medicine and therapeutics, completed training in medicines information and specialises in providing medicines information'.

Medicines information pharmacists guide safe, effective, and efficient use of medicines by providing tailored clinical advice about the care of patients. The MI pharmacist utilises a wide range of medicines-related resources and can also be a pharmacy representative on drug and therapeutics related committees. Medicines information pharmacists usually work in an MIC which is a knowledge hub within their host organisation.

Providing reliable information on the appropriate use of medicines is an essential component of pharmacy practice and patient care.[1] High quality information support is as necessary as good manufacturing practice, efficient distribution, appropriate prescribing and accurate dispensing. Medicines information pharmacists work with other health professionals to enhance the quality use of medicines.

The history of MI

Primary medical and drug literature expanded considerably following the controlled trials in the 1950s with subsequent development of many new pharmaceuticals. This resulted in an information explosion which continues today, with ensuing evolution of bibliographical indexing systems for medical literature and later, the concept of evidence-based practice and introduction of electronic decision support for prescribers. These developments have aimed to make better use of a vast body of knowledge. Accessing this array of information and using it to improve health continues to be a challenge for all practitioners.

The development of MI has paralleled the evolution of clinical pharmacy services as part of the profession's movement toward patient-centred practice.[3] The first centre specialising in MI was established at the University of Kentucky Medical Centre, USA in 1962.[4] In the UK the first MI centres were established in 1969 at the London Hospital and the Leeds General[5] with national coordination at the regional level of the National Health Service from 1975.[6] In Australia, the first MIC was established at the Royal Melbourne Hospital in 1968.[7]

In 1977, the Australian Commonwealth Department of Health established the National Drug Information Service (the NDIS) to promote the rational use of medicines in the treatment of patients. One of the objectives of NDIS was to ensure uniformity in the provision of MI in Australia. By 1985 major State centres were established and networked under the coordination of NDIS. These centres provided MI resources for smaller centres and

communities without access to a centre. NDIS was disbanded by the Commonwealth Government in 1987 but major centres continued to function in some states.

In 2000, the National Prescribing Service (now known as NPS MedicineWise) established the Therapeutic Advice and Information Service, a consortium of six established MI services, to provide MI for health professionals in Australia. However, funding for the service was withdrawn in 2010.[8]

In 2010 the name of SHPA's Committee of Specialty Practice (COSP) in Drug Information was changed to Committee of Specialty Practice in Medicines Information. The name change was considered appropriate to reflect the therapeutic use of the substances about which the services provided information. Committee of Specialty Practice in Medicines Information maintains standards of practice[1] and promotes liaison between MI pharmacists. The Committee also encourages communication and co-operation between MI practitioners internationally. However, some medicines information centres (MICs) across Australia are still referred to as drug information centres.

The value and need for MI services

Research about the value of MI services is limited. One study in a US hospital indicated a positive benefit in terms of costs based on a cost avoidance model.[9] Positive effects on patient care (mainly in terms of medication safety) were found in a survey of health professionals using MI centres in England.[10] The lack of similar studies may reflect the challenge of isolating the economic effects of advice received from an MI service about the care of an individual patient. Patient outcomes are invariably confounded by numerous other factors within a healthcare environment. This is particularly true for patients receiving complex therapy and information support and advice is more likely to be requested for such patients.

Medicines information is an essential component of the clinical services provided by a hospital. MI services have a major role in providing support for clinical pharmacists and other health professionals. An MI service provides information and advice which is beyond the scope of standard sources available to clinical staff, and integrates a range of resources to increase the net value of those resources used in isolation. Medicines information is differentiated from library services because it links the provision of information with clinical interpretation: it includes providing, evaluating and interpreting information. Clinical pharmacy and MI have evolved together and support each other.[11]

An MI service should contribute to improved therapeutic outcomes as well as enhancing patient safety. The National Safety and Quality Health Service Standards require that 'current and accurate medicines information and decision support tools are readily available to the clinical workforce when making clinical decisions'.[12] An MI service can provide direct patient-related advice and support the development and deployment of decision support tools to enhance safety. The Standards also require that information be available to hospital staff on how to contact an MI service, either within a hospital or externally.[13]

Medicines information centres/services have traditionally been hospital-based and designed to provide information to medical, nursing and pharmacy staff. However, some of these also provide advice to consumers and/or support other activities such as toxicology services.

Further reading:

Malone PM, Kierj KL, Stanovich JE. Drug Information: A Guide for Pharmacists. 4th ed. New York: McGraw-Hill; 2012

Ascione FJ, Manifold CC, Parenti MA. Principles of Drug information and Scientific Literature Evaluation. 1st ed. Illinois: 1994

Robson AS, Bawden D, Judd A. Pharmaceutical and Medicines Information Management: Principles and Practice. 1st ed. China: Harcourt Publishers; 2001

2 ESTABLISHING A CENTRE OR SERVICE

The following factors should be considered when establishing a new centre/service as well as maintaining a current centre/service:

- justification of the need for the centre
- services offered see *RESPONSIBILITIES AND SERVICES* on page 9
- staffing
- resources (non-human, facilities and maintenance)
- budget
- location
- key operating requirements.

All centres should develop a strategic plan. It should include a mission statement, goals and objectives, an operational plan with performance indicators, details of budget and methods of evaluating and improving the service.

2.1 Justification

The goals and objectives of having an MI service have to be clearly defined to justify allocating necessary funding.

It is difficult to fully isolate the financial impact of improved patient care occurring as a result of the provision of MI.[14-16] Workload statistics, enquirer assessment and peer review may not provide adequate justification for the service. Methods of evaluating the clinical impact of the service must be developed and implemented as part of quality assurance (QA) activities.[17-20]

Instances where the MI service contributes to formulary review or DUE may be quantified in terms of cost savings relating to the promotion of rational use of medicines. It is more difficult to evaluate cost impact of education programs, however, these may result in cost savings relating to rational prescribing and early detection or prevention of adverse drug reactions (ADRs).[21]

2.2 Staffing

It is desirable that pharmacists specialising in MI have:

- a postgraduate qualification such as a Master of Clinical Pharmacy or studies in other relevant disciplines such as epidemiology, public health and statistics, and
- at least 3 years of postgraduate experience in clinical pharmacy, including areas of specialty practice relevant to the service.[1]

A centre should be adequately staffed during its operating hours, with on-call support if required. The number of MI pharmacists required to staff a hospital based centre is approximately one equivalent full time per 25,000 National Weighted Activity Units (NWAUs). Additional staff may be required for specialised centres and for services available to consumers. For non-hospital based services, staff requirements should reflect the scope and workload of the service.[1]

Adequate clerical assistance may also be required. Clerical duties may include indexing, filing, and other data management, but not receiving verbal requests or communicating responses.

2.3 Resources

Human resources

- salaries and on-costs for pharmacists and support staff
- funding for conferences, training and continuing education.

Access to a medical library with interlibrary loan facilities is also required as well as access to consultation with specialists in various fields.

Non-human resources

For all non-human resources local purchasing procedures require consideration. Non-human resources include:

- office space, furnishings and fittings. These include ergonomic desks, chairs, filing cabinets and book shelves
- computers and software compatible with database requirements
- scanning, printing and photocopying facilities
- computer networking, internet access and security (reliable and of appropriate bandwidth)
- telecommunications equipment such as telephones, facsimile machine and answering machine
- MI resources (relevant texts, journals and databases)
- stationery and graphic design.

2.4 Budget

There must be adequate funding available to meet the capital and operating costs of the centre to ensure that the service is sustainable. This includes maintenance and repairs of equipment, on-going subscription costs, acquisition of new texts and resources, and replacing resources. Resources should be reviewed at least annually and updated as appropriate.

Hospital-based MI services have traditionally been funded by their institution or government authorities. Charging a fee for service may occur when hospital funded resources are being used to respond to enquiries generated from external sources. Overseas, a few services have successfully implemented fee for service on a subscription basis or set fee per enquiry. In general, fees are charged for legal consultations, for information to private corporations, for newsletters, external contracts or for research projects rather than for individual patient care.[22-25] Grants or donations are another possible source for additional funding.

2.5 Location of the centre

An MIC should be readily accessible to all prospective users, either physically or remotely. Regardless of its physical location, the service should establish an electronic profile and offer communication options to encourage clients to use the service. This could include a website, email access, and options to leave messages or contact an MI pharmacist for urgent enquiries.

Locating a hospital-based centre within or near the pharmacy department can provide pharmacists with direct access to information resources and advice. This allows pharmacists to answer simple enquiries using basic resources and for the MI staff to keep in touch with the functions and requirements of the pharmacy and its clinical services. The centre should be located in an area which allows quiet study and confidential communication with clients.[1]

As the quality use of medicines (QUM) movement has evolved, services have been built in areas outside of the traditional location of the pharmacy department, e.g. in Clinical Pharmacology departments, QUM and other independent units.

There may be advantages in locating a centre that it is accessible to medical, nursing, and allied health staff, which raises its profile. Face-to-face communication (initially or occasionally) can help to overcome the limitations of non-verbal communication when indirect methods are used for enquiries. Direct access to the centre also promotes the activities of the service and its resources can be more readily used by all staff.

2.6 Key operating requirements

Data maintenance

Data generated should be retrievable so that it can be used as an in-house resource and for archival purposes. The following information should be kept in a manner that will enable it to be readily accessed:

- personnel providing the service, e.g. daily or weekly rosters
- a catalogue of information resources, including books and subscriptions
- search strategies
- addresses for web sites of common interest
- details of previous enquiries
- reference material sourced from external sites and not readily available for review
- subscription payments.

Storage of paper copies of documents should be minimised. Details of enquiries should be recorded electronically and documents archived as computer files where possible. Enquiries can be indexed by sequence number and a suitable indexing approach created for other documents. Data storage and indexation can also assist with data retrieval that may help current enquiries.

The length of time that records are retained must take into consideration legal and local policy requirements and be detailed in the centre's Operating or Procedure manual. The recording system used should maintain integrity and security of the record. Electronic systems for recording enquiries should be housed on a secure server and password protected to prevent fraudulent electronic access.

Job description

A current job description outlining duties and responsibilities of all staff should be maintained.

Work health and safety

Furniture, equipment and the office environment must comply with local work health and safety standards. Repetitive or forceful movement or both and/or the maintenance of constrained or awkward postures arising from tasks undertaken must be identified, assessed and controlled in order to prevent risk.[26, 27]

Operating/policy and procedure manual

The MI policy and procedure manual for each MIC should include information and guidelines appropriate to the services provided. This document should include priorities, procedures and the format for requests and responses. It should also define the centre's responsibilities with respect to any other activities undertaken.

This manual should be reviewed regularly and include:

- aims and objectives
- clientele (nature and scope; health professionals, other clients e.g. patients, carers, other organisations)
- range of services provided
- access to, and availability of, the service (including hours of service)
- contact details
- procedures for enquiries; receipt, searching, answering, referencing, logging, storage, statistics
- filing systems: indexing, storage, archiving, and retrieval
- referral of enquiries to other information providers

- resource availability and updating procedures for book purchases or journal subscriptions. This includes ordering/renewal procedures, receipt procedures, records kept
- a catalogue of all books/resources held
- QA procedures
- training guidelines for new staff
- position descriptions for all staff.

Procedures for other functions must be included, if provided.

Examples of these include:

- training of intern pharmacists and pharmacists (note that SHPA's Medicines Information Training Workbook is a useful resource for this)
- training of other healthcare professionals
- Drug and Therapeutics Committee (DTC) information
- formulary information
- bulletin information.

Quality assurance (QA)

Quality assurance measures, as outlined in *QUALITY ASSURANCE AND SERVICE IMPROVEMENT* on page 55, must be established and implemented. In addition, workload statistics including sufficient detail to assess the level and nature of activity should be maintained to assist in the evaluation and cost justification of the service.

Training

Staff employed in the MIC are required to have appropriate experience and training in the field of MI, see *TRAINING* on page 12 for further details. SHPA's Medicines Information Training Workbook should also be referred to.[11]

3•RESPONSIBILITIES AND SERVICES

The principal role of an MI service is to optimise patient care by supporting QUM. This is achieved by providing current, evidence-based, accurate, timely and objective information about medicines and pharmacotherapy.[1] Information is often tailored to the needs of specific patients.

The scope of the service provided should be clearly defined and documented in a departmental or service-based operating/policy and procedure manual. See *2.6 Key operating requirements* on page 7.

The primary role of an MI service is to respond to medicines-related enquiries from doctors, nurses, pharmacists, other healthcare professionals and possibly patients and the public, depending on the scope of service. The following activities may be provided or supported:

ADR reporting (pharmacovigilance)

An MI service should be active in promoting ADR reporting. The service can be used in the identification and documentation of possible ADRs, methods of treatment, assessment of outcome and incidence and also provide an educative program for the early detection and prevention of ADRs. Details of suspected adverse reactions should be recorded and, where appropriate, reported to the Therapeutic Goods Administration (TGA).

Clinical trials/ethics committees

An MI service can provide a literature retrieval service; assist with clinical trial design and evaluate clinical trial submissions.

Drug and therapeutics committees (DTCs)

An MI service may provide a pharmacy representative on drug and therapeutics related committees. Alternatively, they may provide to the committee product or document review, literature appraisal, assist with requests for formulary applications or raise agenda items for formulary management or review.

Electronic decision support/clinical informatics

Electronic medication management systems may require the input of specialist MI advice.

Formulary management

An MI service can influence usage and promote rational prescribing by providing objective reviews of medicines for formulary inclusion or deletion.

Medication-related audits

Drug Utilisation Evaluation (DUE) programs were developed in the 1990s. These programs were led by pharmacists, with organisational support, to ensure the safe, rational and cost-effective prescribing and use of medicines. Since then, medication-related audit opportunities have evolved where pharmacists are part of a larger team tasked to improve hospital and prescriber performance on quality indicators in areas such as venous thromboembolism and antimicrobial stewardship. Medicines information resources may be used for literature retrieval and evaluation to support DUE and other clinical audit activities. An MI service can be instrumental in promoting medication-related recommendations and encouraging compliance with the recommendations through publication in a newsletter or bulletin.

Medication safety

Medicines information pharmacists have an important role in enhancing patient safety. Providing appropriate advice on the correct use of medicines is an important element in reducing the risk of errors. Clinical Governance units may also require assistance in analysing medication incidents.

Therapeutic drug monitoring (TDM)

Medicines information pharmacists can contribute to or run therapeutic drug monitoring, pharmacokinetic and/or dose calculation programs.

Education and training
Medicines information staff may take an active role in education programs within or outside the hospital by lecturing, providing in-services and publishing relevant topics including teaching MI skills. The service may also provide MI training to other health professionals e.g. pharmacists, doctors, nurses or students. The role may include academic detailing.

Medico-legal
Specialist input may be required for the delivery of medico-legal advice to external agencies such as the coroner, police or health professional governance organisations.

Publications and review
Staff may be involved in publication of a pharmacy bulletin, patient information, journal articles, editorial comments for books or other publications, contractual reviews for third parties, or may be involved in publications in the capacity of a referee. Providing information on new drugs, horizon scanning for drugs in development or reviews about newly marketed drugs is another important feature of the MI service. See *5.4 Medical writing* on page 26 for further details.

Research
Where resources exist, there may be opportunities for participation in collaborative, or individual, research in medication safety and related topics.

Support for other services and/or other healthcare professionals
Specialised services or larger centres may have resources not generally available to other MI services.

3.1 Provision of MI to consumers
Also see *9.4 Communicating with patients* on page 52 in *ETHICAL AND LEGAL ISSUES*.

The general public increasingly choose to seek information to support their health decisions, beyond the traditional patient-practitioner face-to-face encounter.[28] Personal health and medicines information seeking has transformed in response to societal changes such as improvements in health and education, increased lifespan, urbanisation, increased personal wealth and leisure. People are demanding a bigger say in their own healthcare; and their perceived needs, expectations and behaviours are influencing healthcare systems.[29, 30]

The frequency of patients seeking health and medicines information has exponentially increased due to widespread access to health information mass media and the Internet. [31, 32] As early as 2001, Newby's group found approximately 10% of medicine users expressed potential unmet need for medicines information.[33] In 2012 a Pew Research Center study of 3014 adults living in the United States found that one-third of U.S. adults use the internet as a diagnostic tool, with 52% of smartphone owners using their phone to find health information.[34] Family and friends also represent an important source of information for patients.[35, 36] Sources may be available to patients, but there are barriers to accessing relevant information such as deficiencies in reliable, credible information and Internet search skills.[36-41]

Health information seeking is associated with higher education, poorer health status, female gender, younger age and higher income.[32, 42] However, there is also convincing evidence that uncertainty plays a role in motivating health information seeking[43-45] as a coping strategy in health decision-making[46]; and that consistent information from a credible authority reduces uncertainty.[47] Uncertainty within a medical encounter could be due to a lack of or too much information and/or multiple interpretations of information.[48] Patients first try to cope with uncertainty via empowerment behaviours to improve their medical encounters, including actively seeking health information, participating in medical decisions, and expressing their concerns and feelings.[48, 49] Patients then try to reduce uncertainty and gain agency by increasing their understanding of disease aetiology, treatment options, self-management knowledge, and sense of control. Research shows positive correlations between health

information seeking and patient follow-up conversations with their doctors or other health professionals, as well as patient self-management.[32]

Improved health outcomes have been demonstrated where patients and their primary health carers work together to identify and adequately address their patients' medicines information needs.

Implications for practitioners

Health information seeking is now an integral part of the healthcare management experience, with patients likely to be seeking health information outside of the healthcare visit. Identifying consumer information needs and their favoured information sources are critical in order to provide patients with current and relevant information and, to assist them in making informed decisions concerning their healthcare. If we fail to satisfy patients' information needs, they will turn to other sources of information to satisfy those information needs.

Before providing health or medicines information, consider:

- what does the patient know about the issue/s concerning them
- the extent to which they have engaged in a search for information
- their motivations to seek help
- sources used
- their opinion or evaluation of the information obtained, and importantly, how they intend to act on the results of their information search.

Consumers expect medicines information to be accessible, accurate, clear and concise.[50] The evidence based medicine (EBM) movement has created an environment where people are encouraged to question the evidence that supports medication efficacy in disease management.[51] Knowledge gaps have therefore become more overt to the consumer; encouraging information seeking and scepticism when therapies change or appear ineffective.[52] To assist consumers, pharmacists providing medicines information should consider these principles:

- **Keep it simple.** Harris and Dewdney[53] suggest that *"… information (for consumers) should be physically, psychologically, and intellectually accessible."* Information overload may lead patients to incorrectly process information, delay processing of information, accept lower quality information or give up the search for needed information.[54, 55]
- **Make credible information accessible.** People tend to seek information that is readily available[55]; so provide patients with credible, accessible medicines information to support counselling or address their information gaps.
- **Be willing to provide information when patients need it rather than when it is convenient for health professionals to provide it.** Studies of cancer patients have highlighted the critical importance of correct timing in providing patients with medicines information to minimise anxiety[54] and to facilitate decision-making.[56] Qualitative studies have also found that information provided by health professionals to patients with a range of comorbidities could be redundant or counterproductive if given when they were physically unwell or emotionally unwilling to receive it.[57] Consumers would therefore be more motivated to use information services able to provide medicines information when they perceive *they* need it. Medicines call centres and the internet have the flexibility and location independence to respond to these consumer-timing needs.
- **Provide patients with education** about medication issues likely to generate uncertainty. An example is counselling patients about the time lag in drug action when they are commencing an antidepressant and explaining that in this period they may, in fact, feel worse and to provide them with strategies to use if required.

4•TRAINING

Providing MI is a specialist area of practice within pharmacy. Medicines information pharmacists should understand the complexities of patient care. Therefore adequate clinical experience should be a prerequisite for appointment as an MI pharmacist. Ideally this experience should be relevant to the range of information services offered and include any relevant specialties.

In addition to clinical experience and expertise, technical skills for searching and managing data, communication and time management skills are all required. An MI pharmacist also needs a sufficient understanding of statistics, research methods, and methods of evaluating evidence to support clinical practice.

The Australian Medicines Information Training Workbook provides a sound introduction to medicines information.[11] Its contents are assumed knowledge for an MI pharmacist.

4.1 Formal, informal and local training

Where possible MI pharmacists should complete formal training in MI. There is currently no national course however there are a few training courses available periodically in some states.

MI pharmacist training should cover:

- scope and limitations of information services in Australia
- role of the MI pharmacist
- translation of a request for information into an appropriate answerable question
- necessary background information required for the type of enquiry
- MI resources – text, web-based, free access, subscription-based, general and specialised (including resource limitations)
- bibliographic database searching
- systematic searching
- evidence-based medicine principles
- critical literature evaluation, including an understanding of statistics and research methods
- search skills and resources for specialised enquiries e.g. drug use in pregnancy, lactation, paediatrics, organ impairment, ADRs, drug interactions etc.
- formulating and communicating a response
- enquiry answering standards and quality assurance
- writing and communication skills
- when to refer or seek expert opinion
- copyright
- legal and ethical considerations.

Other training

Some of these skills may be included in postgraduate courses in epidemiology, public health and statistics, or within postgraduate clinical pharmacy courses.

While training in MI practice and computer-based information systems may be provided within an MI service under the supervision of experienced pharmacists, valuable training may also be provided or acquired within the pharmaceutical industry, research settings, drug use evaluation, conducting literature or systematic reviews, library courses etc.

Counselling skills may be relevant for services which provide information to non-medical enquirers.

Local training

Medicines information services should develop local training for their staff, which should be documented in the local operating or policy and procedure manual. This should cover local resources, use of equipment and databases, documentation of enquiries and replies, specific duties e.g. production of newsletters or bulletins, support for drug and therapeutics related committees. Specific local training for a new MI pharmacist should cover:

- aims, objectives and scope of service, e.g. clients, hours of operation, extent of service
- role of the MI pharmacist within the context of the centre and its clients
- layout and resources available, including library services
- operating or procedure manual and organisational procedures, e.g. safety and security
- related activities, e.g. ADR reporting, medication safety, formulary management
- procedures for phone, email, paging etc.
- computer networking, data locations and managing web addresses
- deadlines, priorities and workload sharing
- programs for managing enquiries and recording responses
- standard search strategies for common enquiries
- storage and retrieval systems (including regular backup of critical data and verification).

4.2 Current awareness and skill maintenance

An MI pharmacist should maintain a high level of awareness of trends and issues relating to medicines use and public health. Medical news, national regulatory bulletins and advisories from both Australia and overseas (e.g. the US FDA, UK MHRA) and core medical/pharmacy journals should be monitored. Alerting services, RSS feeds, Table of Contents (TOC) subscriptions, email discussion networks and automated searches may assist in maintaining current awareness. Information should be sought about newly registered drugs, new marketed products, Special Access Scheme (SAS) and trial drugs, drug shortages, and ADRs.

Education and training are required to provide and/or maintain skills associated with the use of centre resources.

4.3 Advanced practice and competencies

Training and experience may lead pharmacists to work with extended or advanced practice competence in a scope of practice beyond their initial registration.

The definition of advanced pharmacy practice adopted by the Advanced Pharmacy Practice Framework Steering Committee (APPFSC) which is now the Pharmacy Practitioner Development Committee (PPDC), and endorsed by all participating pharmacy organisations is: 'advanced practice is practice that is so significantly different from that achieved at initial registration that it warrants recognition by professional peers and the public of the expertise of the practitioner and the education, training and experience from which that capability was derived'.[58]

'Advanced practice is practice that is so significantly different from that achieved at initial registration that it warrants recognition by professional peers and the public of the expertise of the practitioner and the education, training and experience from which that capability was derived'

The Advanced Pharmacy Practice Framework (APPF) is intended to provide a basis for the development of pharmacists but it also provides a process whereby pharmacists undertake a professional journey from Level 1 (transition) to Level 2 (Consolidation) to Level 3 (Advanced).[58]

An advanced practice pharmacist needs to demonstrate they have achieved Level 3 across a number of competencies within five domains:

1. expert professional practice
2. communication, collaboration, teamwork
3. leadership and management
4. professional and ethical practice
5. critical analysis, research and education.

The APPF has combined aspects of the UK Competency Development and Evaluation Group (CoDEG)[59] and the The National Competency Standards Framework for Pharmacists in Australia[60] (the 'National Framework') to reflect progression towards an advanced practice pharmacist.

The primary purpose of the APPF is to support and assist the professional development and growth of pharmacists (regardless of whether their scope of practice is broad or narrow) and of the profession as a whole.

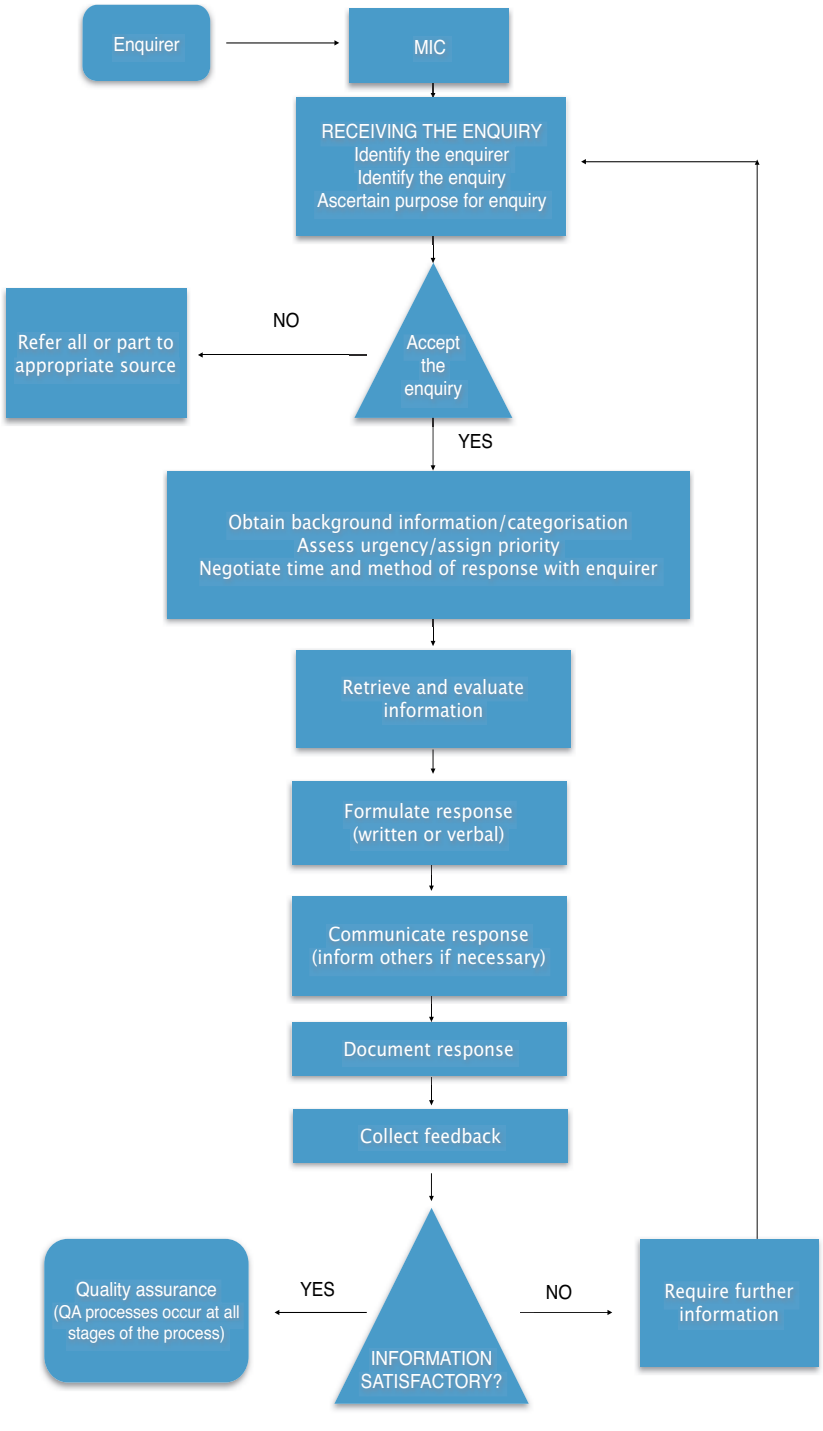
The APPF can be adapted to specific areas of practice such as MI by customising the standards in the Expert Professional Practice. All the other competency standards can be applied to any area of advanced pharmacy practice.

5•GUIDELINES FOR PRACTICE

Enquiries to an MI service may vary from a simple uncomplicated query to a complex query requiring a thorough literature search and evaluation. Regardless of the nature of the enquiry, the same fundamental practice guidelines should be applied.

5.1 Enquiry processing and flow chart

The following flow chart is designed to act as a memory prompt to ensure all phases of enquiry processing are met, to maximise use of the information available and thus lead to the provision of an optimum response.



5.2 Explanatory notes for the flow chart

Receiving the enquiry

An enquiry may come directly from the enquirer or via a third party. Whichever the case, the manner in which the enquiry is received is fundamental to effective communication.

Telephones should be answered promptly and pleasantly. In answering the telephone it is appropriate to clearly identify the MI service. A suggested approach would be to answer the telephone in a positive tone with 'Medicines Information' and your name, so the enquirer knows with whom they are speaking. Visitors to the centre should be acknowledged and welcomed promptly.

An enquirer is entitled to your full attention whilst making their enquiry. Noise/distractions must be minimised or eliminated where possible when receiving an enquiry. Use noise elimination devices and/or headphones if needed.

Enquiries may also be received electronically or via facsimile. These enquiries should be acknowledged according to local guidelines.

In the situation of an emergency or distress, remain calm and, if necessary, reassure the enquirer. If unable to handle the situation with the required skill or speed immediately refer the enquiry in a professional manner.

Identify the enquirer

The identity of the enquirer and the reason for the enquiry should be established early in the communication as it may influence subsequent action. Identification includes name, specialty, and contact details. If the enquiry is being conveyed via a third party, both the source and the messenger must be identified. If the enquiry originates from the media (see *9.2 Special circumstances* on page 50), a member of the public, pharmaceutical company or legal firm, the nature of your response or authority to release information may be different from responding to health care professionals within your institution.

Identify the enquiry

The MI pharmacist is often required to formulate the actual enquiry and articulate the precise needs of the enquirer. Enquirers often do not specifically request the information they really want or need in order to completely address the complexities surrounding their question.

Enquirers often do not specifically request the information they really want or need.

Care is required to identify a complex enquiry if the MI pharmacist is unfamiliar with the subject of an enquiry. While most people are receptive to questions for clarification and fact-finding, sometimes you will be confronted with an impatient enquirer. In these cases an explanation of the logic of your questions to justify the value of obtaining background information may be required. A variety of questioning techniques may be required: open-ended, closed, direct, indirect or probing.

Active listening is essential and the following points are useful:

- allow the enquirer to talk without interrupting
- concentrate on the answers provided, rather than thinking about your next question
- effective listening and speaking skills must be employed
- confirm your understanding.

Taking notes during a verbal enquiry may be useful to avoid omitting details of the conversation later on. It is recommended that a standard MI enquiry form (*Figure 1. Information required for the MI enquiry record* on page 17) and/or enquiry prompts for specific types of enquiries be used as a memory prompt.

Paraphrasing is a necessary technique for establishing what a person has meant. Reiterating and summarising of your interpretation of the question gives the enquirer the opportunity to confirm, provide additional details or correct any misunderstandings. Lengthy enquiries should be summarised to the client at the end of the conversation.

Figure 1. Information required for the MI enquiry record

Name and designation of the enquirer
How to contact the enquirer
Details of enquiry
Person/pharmacist who received the enquiry
Date and time of receipt of enquiry
When response is needed by and mode of response
Reason for enquiry
Patient details
Relevant medication history (current and past; include over the counter medications and complementary and alternative medicines)
Relevant medical history
Relevant laboratory results
Other details (pregnancy, allergies etc.)

Ascertain purpose of the enquiry

A clear understanding of the purpose of the enquiry is required to assign appropriate priority, provide an appropriate degree of detail in the response and provide a response which meets the enquirer's needs and comprehension.

The following information may assist in ascertaining the purpose of the enquiry:

- what prompted the question
- the urgency of the question
- how the response is intended to be used.

Accepting the enquiry

The MI pharmacist must be familiar with the resources and expertise available and decide if an alternative information source may be more appropriate. In the latter instance the MI pharmacist is required to be familiar with a wide spectrum of information sources including Government Departments, Poisons Information Centres, Alcohol and Drug Dependence Units, sports medicine facilities and specialist advice and put in place strategies to maintain currency.

Be mindful that it is not a failure to refer an enquiry that cannot be appropriately answered by the MI service. It is in the best interest of both the enquirer and the MI service if staff can quickly identify that the enquiry lies outside their expertise or resources. If the enquiry or enquirer is outside the scope of the service refer the enquirer to a suitable source of information.

Relevant background information / categorisation

The type of background information required will vary depending on the nature of the enquiry and the purpose for which the response is intended. Obtain details of the reason for the enquiry. For example: is the enquiry patient specific? Is it for research, publication or for a protocol etc.?

In the case of patient-specific requests, a medical and medication history often gives insight into the true nature of the enquiry and/or significantly affects the focus of the literature search or response. Patient identifiers are often required to consult pertinent information such as pathology results and medical notes.

Categorising the question by subject area (enquiry type) will also assist in determining what additional patient-specific background information might be required and what information sources and search strategy might be useful in formulating a response.

Common examples of enquiry types include:

- ADRs*
- comparison
- complementary and alternative medicines (CAM)*
- contraindications
- cost
- dosage
- drug administration*
- drug availability and identification*
- drug interaction*
- efficacy
- forensic (legal)
- formulation or stability (pharmaceutical chemistry)
- geriatrics
- in-vitro compatibility*
- indications
- laboratory interference
- lactation*
- liver impairment*
- paediatrics*
- patient counselling/education
- pharmacodynamics
- pharmacokinetics*
- pharmacology
- poisoning, overdose (consider immediate referral)
- pregnancy*
- public health (travel, vaccinations etc.)
- renal disease/dialysis*
- source (manufacturer, distributor)
- switching therapy
- therapeutic equivalent
- warnings, precautions.

*Many of the above types of enquiries and appropriate background questions to ask/consider are discussed in tutorials located in SHPA's Australian Medicines Information Training Workbook.[11]

Urgency of the enquiry

It is particularly important to ascertain the urgency of the problem, both to establish workload priority and to satisfy the needs and expectations of the enquirer. The timing, format and mode of delivery of response should be negotiated and communicated with the enquirer at the initial time of enquiry; assumptions should not be made regarding any aspect. Some urgent enquiries require an immediate response, but this may necessitate further research and investigation so two responses are necessary: one to address the immediate need and the other for future application. Even in urgent situations you must always ensure that your answer can be justified.

The urgency of a request can dictate the nature of the search and response. If a treatment decision regarding a specific patient needs to be made quickly, the time available to spend on your search may be limited. This time limitation should be stated when delivering the answer. Other limitations may include your other patient care priorities i.e. if there are issues to resolve for multiple patients, each query must be prioritised and managed.

If the deadline for the response cannot be met it is important to inform the enquirer of the delay (with a reason) and negotiate and communicate a revised deadline. For example, delays may occur if more urgent queries are received by the centre or if there are unexpected delays receiving information from external sources.

Assigning priority

Priority should be assigned to all enquiries and activities and frequently reviewed to maintain optimum service. Priority should be allocated according to the urgency of the enquiry as follows:

- acute clinical problems (most urgent)
- non-acute clinical problems
- specific events; lectures; DTC meetings
- research
- general interest (least urgent).

Some modification to priority rating may be required in relation to other duties and functions of the MI service, the resources immediately available and, on occasions, in accordance with the enquirer's perceived urgency. Non-urgent enquiries may be answered according to relative importance.

Retrieve and evaluate information

Familiarity with the subject

Prior to attempting to answer an enquiry it is essential to be familiar with the subject. Basic subject knowledge may be obtained from the enquirer, colleagues, specialists in the field, a basic literature search, and appropriate texts.

Resources

See SHPA Australian Medicines Information Training Workbook, Section D: Resources Used in Medicines Information[11] for additional information about types of resources (primary, secondary or tertiary) and specific resources.

The resources available and knowledge of their uses and limitations will determine the quality and depth of the response which can be provided. Currency of the resources should also be considered and out-of-date resources should be avoided unless information of a historic nature is required. In addition, the urgency of the response may affect the number of resources used.

Past MI enquiries can be most useful and time-saving for similar enquiries. As information extracted from previous enquiries may not be up-to-date, this resource should not be a substitute for a thorough search and the applicability of prior responses to the current enquiry must always be carefully considered.

Dependent upon the enquiry, tertiary resources are useful for general knowledge about a subject, including terminology and standard treatment guidelines. This knowledge can be used when searching secondary resources to determine keywords, text words or phrases and to ensure appropriate context. Be mindful of limitations of tertiary resources; especially that content should be supported by appropriate documentary evidence (usually from primary literature). Primary resources will always be required for in-depth or extensive answers and for ensuring clinical currency of practice. They are also desirable when tertiary resources conflict or are not appropriately authoritative for a specific enquiry. Note that primary resources will also require interpretation and evaluation for applicability and reliability.

The use of secondary information sources such as MEDLINE and EMBASE provide access to the primary literature in an efficient manner. See *INFORMATION RESOURCES* on page 27.

Information for simple enquiries such as dosage recommendations, compatibilities, and route of administration may generally be found in tertiary resources such as drug compendiums. However, information about new drugs, recent developments, or more complex enquiries requires more detailed searching.

The use of search strategies for specific types of enquires can assist in the thorough and efficient utilisation of available resources. See *5.3 Search strategies* on page 22.

Once the information has been collected it must be interpreted and evaluated. This requires the knowledge of clinical trial design, statistics, pharmacology, pharmacokinetics, disease pathology, and critical appraisal skills. See *8.3 Literature evaluation* on page 38 as well as SHPA's Australian Medicines Information Training Workbook: Tutorial 5 Critical Evaluation and Tutorial 2 Pharmacokinetics.[11]

Replies should not be formulated on the basis of abstracted information alone as this information may be misleading and open to misinterpretation. However, in rare circumstances this may be necessary. For example, where information is required urgently and the primary source is not immediately accessible, or where the primary data is in a foreign language and alternative resources are limited or unavailable. When formulating a written response to an enquiry, information extracted from abstracts should be clearly identified. Specifying the type of the reference, for instance, as an abstract in the list of references is one way of identification.

External sources of information such as other MICs, government departments, clinical expertise and pharmaceutical manufacturers may provide useful and relevant information. When using information from an external source, document the information. Written rather than verbal recommendations are preferred to ensure clarity of meaning and assign responsibility for the information. If written details from an external source are not available then details of verbal communications should be carefully documented, and include date, time and name of person providing the information.

Formulation of a response

A concise, relevant, and logical summary of the information noting points that may be emphasised or further explained to the enquirer should be prepared. All references should be cited and available if requested. Inexperienced staff should discuss their conclusions and proposed response with a supervisor, and from feedback received, modify or expand the search and reformulate the response if required.

In deciding the depth and detail of your response consider:

- who the enquirer is (e.g. patient, doctor, etc.)
- how the information will be used
- the level of detail/complexity required to support the response.

Prediction of possible questions as a result of the information communicated is often required. Proactive collection of information to assist with these questions can be most useful to reduce additional workload.

For patient-specific enquiries, information to support a management plan may be requested. In these circumstances, suggestions should be based on the information located, patient-specific factors, and the purpose of the enquiry (as well as anticipated further questions).

Following a thorough search of available resources, there may be inadequate information available to provide a definitive answer and further discussion with the enquirer may be advisable.

The nature of the enquiry and the availability of the enquirer will determine the most appropriate method of response. Verbal replies may be given over the telephone or in person to the enquirer. This method is suitable for conveying simple information. It may also be used as a method for discussing the response prior to supplying documentation. Written replies are preferred for complex or detailed replies or where documentation is requested. Written replies may be delivered electronically (email) or in hard copy format (i.e. post or facsimile) according to local policies and the enquirer's preference.

An explicit statement highlighting limitations that could affect the accuracy, comprehensiveness, or time efficiency of the response should be included.

Written response format

A written response should follow a standard format. See additional information about writing skills and examples are located in Section C: Answering Enquiries in SHPA's Australian Medicines Information Training Workbook.[11]

Action to inform others

Matters arising from the enquiry and response should be discussed with other members of the patient's care team, such as the ward pharmacist. Enquiries received may also identify safety signals that may be useful to share with other health organisations such as the TGA, pharmaceutical manufacturer, publishers (e.g. Australian Medicines Handbook, Therapeutic Guidelines) or authors of references. Confidentiality of the enquirer and patient must be respected. The enquirer must be consulted before any information is given to a third party.

Documentation of the enquiry

All enquiries must be accurately and comprehensively documented in a standard format as a legal record of activities and as a potentially useful resource for future enquiries. In addition, documentation provides information for workload statistics and QA programs.

Documentation should contain information as per *Figure 1. Information required for the MI enquiry record* on page 17, plus:

- additional patient details (not known at time of initial enquiry)
- enquiry category and search pattern (if available)
- details of the response including resources used, content of response and conclusions
- keyword indexing terms to enable retrieval
- unique enquiry identification number or code for the service
- name of MI pharmacist responding
- time taken to respond
- date, time and mode of delivery of response.

Feedback and follow-up

Whenever possible, enquiries should be followed up either directly or by using a standard feedback form. This helps to determine the outcome and relevance of the information provided and to check if any additional information is required. Feedback is important as a QA measure and also in terms of professional responsibility, assessment of enquiry impact, healthcare personnel collaboration and education.

Clinicians involved with direct patient care usually see the results of an intervention and learn from the experience. However, this opportunity for education through experience is usually not available to MI pharmacists unless actively sought after the event.

Feedback may be collected in the following ways:

- verbally, either at the time of delivering the response to the enquiry or at a later time
- hard copy or electronic user satisfaction survey.

Also see *QUALITY ASSURANCE AND SERVICE IMPROVEMENT* on page 55.

5.3 Search strategies

A search strategy is a prioritised list of resources available for researching a particular type of enquiry. Search strategies provide an efficient and systematic approach to searching for the most common types of enquiries. A search is usually commenced with general references and progressed to more detailed references if necessary. Using general references first provides an overview of the topic. It may also improve efficiency as, should an answer be readily found in these resources, a more involved search might not be needed. Nevertheless, in some cases it might be immediately evident that specialised references would be most appropriate initially. Search strategies cannot be created for every potential type of enquiry; so often the strategy will only approximate the best course to follow. Strategies should only be followed to the extent that the problem is satisfactorily resolved, that is, there is no need to consult all the references listed and the exact nature of the question or time constraints may require deviations from the general strategy.

Local search strategies should be developed according to resources and scope of practice.

Examples of search strategies

The following examples provide a suggested pattern of resources to consult for specific enquiry types. Not every resource needs to be checked for every enquiry and other resources may also be appropriate. The order that these, or alternative, resources are searched should be considered and based on the complexity and depth of information required and available resources. If appropriate information is not located consider consulting or referral to a specialised centre or clinician. Strategies should also be developed for enquiry types other than those listed according to the needs of individual services.

The following search strategies should be used in conjunction with the information in SHPA's Australian Medicines Information Training Workbook.[11] Additional information about book or online resources listed in this manual is included in Appendix 4: Resources .

Table 1: Suggested search strategies

Enquiry	Search strategy
Administration of medicines - enteral	Previous enquiries Product information SHPA Don't Rush to Crush Handbook Handbook of Drug Administration via Enteral Feeding Tubes The NEWT Guidelines Manufacturer Embase/Medline/Pubmed
Administration of medicines - parenteral	Previous enquiries Local administration guidelines/protocols Product information SHPA Australian Injectable Drugs Handbook Injectable Drugs Guide (Gray et al) UCL Hospitals Injectable Medicines Administration Guide ASHP Handbook of Injectable Drugs Embase/Medline/Pubmed
Adverse drug reactions	Product information Previous enquiries AMH Micromedex (Drugdex) Meyler's Side Effects of Drugs AHFS AusDI Interactions & Safety Lexicomp Reactions Weekly Embase/Medline/Pubmed TGA Database of Adverse Event Notifications (DAEN) Medsafe Suspected Medicine Adverse Reaction Search (SMARS) UK Committee on Safety of Medicines (CSM) Drug Analysis Prints Canada Vigilance Adverse Reaction Online Database Danish Medicines Agency Drug Analysis Prints (Lægemiddelstyrelsen) European Database of Suspected Adverse Drug Reaction Reports Manufacturer Livertox (US NLM)
Complementary and alternative medicines	Previous enquiries Natural Medicines Herbal Medicines Herbs & Natural Supplements The Review of Natural Products National Centre for Complementary and Alternative Medicines (NCCAM) Memorial Sloan Kettering Cancer Centre: About Herbs, Medicines and Natural Products Stockley's Herbal Medicines Interactions Embase/Medline/AMED/Pubmed AusDI Interactions & Safety

Table 1: Suggested search strategies

Enquiry	Search strategy
Compatibility	SHPA Australian Injectable Drugs Handbook Previous enquiries Product information IV Compatibility (Micromedex) ASHP Handbook on Injectable Drugs Injectable Drugs Guide (Gray et al) King Guide to Parenteral Admixtures Stabilis.org The Teddy Bear Book: Pediatric Injectable Drugs RCH Melbourne Paediatric Injectable Guidelines Embase/Medline/Pubmed
Drug interactions	Product information Previous enquiries Stockley's Drug Interactions Micromedex Drug Interactions MIMS Drug Interactions Lexi-interact (via Lexicomp) Top 100 Drug Interactions (Hansten P, Horn J) AusDI Interactions & Safety AMH YouScript Clinical Manual of Drug Interaction Principles for Medical Practice CredibleMeds (QT prolongation) HEP Drug Interactions (University of Liverpool) HIV Drug Interactions (University of Liverpool) Drug Interaction Tables, Toronto Immunodeficiency Clinic Embase/Medline/Pubmed
Drugs in breastfeeding	Previous enquiries Pregnancy and Breastfeeding Medicines Guide LactMed (US NLM) Drugs in Pregnancy and Lactation (Briggs) Hale, Medications and Mothers Milk Drugs during Pregnancy and Lactation (Schaefer) Therapeutic Guidelines Embase/Medline/Pubmed
Drugs in pregnancy	Previous enquiries Pregnancy and Breastfeeding Medicines Guide Drugs in Pregnancy and Lactation Drugs during Pregnancy and Lactation Product information Micromedex (Reprorisk) Embase/Medline/Pubmed UK Teratology Information Service (UKtis)
Drugs in liver disease	Previous enquiries Drugs and the Liver (North-Lewis) High-Risk IV Medications in Special Patient Populations Embase/Medline/Pubmed

Table 1: Suggested search strategies

Enquiry	Search strategy
Drugs in renal disease	Previous enquiries Product information AMH Therapeutic Guidelines Renal Drug Database / The Renal Drug Handbook Micromedex (Drugdex) The Renal Drug Reference Guide (Cervelli) Seyffart's Directory of Drug Dosage in Kidney Disease Drug Prescribing in Renal Failure: Dosing Guidelines for Adults and Children (Aronoff) Sanford Guide to Antimicrobial Therapy Kucers' The Use of Antibiotics High-Risk IV Medications in Special Patient Populations Dialysis of Drugs Embase/Medline/Pubmed
Paediatrics	Previous enquiries AMH Children's Dosing Companion BNF for Children Pediatric and Neonatal Dosage Handbook (Lexicomp) NeoFax and Pediatrics (Micromedex) Embase/Medline/Pubmed
Palliative care	Previous enquiries The Syringe Driver Palliative Care Formulary Palliative Care Syringe driver: Eastern Metropolitan Region Palliative Care Consortium Resources Symptom Management in Advanced Cancer (Twycross et al) Embase/Medline/Pubmed
Pharmacokinetics	Previous enquiries Product information Micromedex (Drugdex) Basic Clinical Pharmacokinetics (Winter) Clinical Pharmacokinetics (Murphy) Clinical Pharmacokinetics and Pharmacodynamics (Rowland and Tozer) Applied Clinical Pharmacokinetics (Bauer) Applied Pharmacokinetics and Pharmacodynamics (Burton et al) Embase /Medline/Pubmed
Psychiatry	Previous enquiries The Maudsley Prescribing Guidelines in Psychiatry Psychotropic Drug Directory (Bazire) Clinical Handbook of Psychotropic Drugs (Procyshyn et al) Stahl's Essential Psychopharmacology Embase / Medline/Psychinfo Drug-Drug Interaction Primer (Sandson) Embase/Medline/Pubmed

Table 1: Suggested search strategies

Enquiry	Search strategy
Toxicology	Previous enquiries TOXBASE (UK) database TOXINZ database POISINDEX (Micromedex) National Poisons Register (NPR) TOXNET (US NLM) Toxicology Handbook (Murray et al) Therapeutic Guidelines – Toxicology and Wilderness Embase/Medline/Pubmed
Travel	Previous enquiries Travel Health Advisor Manual of Travel Medicine (Yung) Centre for Disease Control and Prevention. Travelers' Health Embase/Medline/Pubmed

5.4 Medical writing

Medical writing involves the production of high-standard scientific content about diseases and drugs aimed at various target audiences. It is paramount that any medical document is presented and communicated effectively. Clear and accurate presentation of MI is required for interpretation, validation and clinical use.

Professional writing is not necessarily limited to journal articles or books. It also includes written responses to enquiries, evaluations of medicines for formulary submissions, newsletters, policies and procedures, training material, written reports etc. Writing gives the author the opportunity to share knowledge and ideas.

Before writing, it is necessary to consider the audience and to adapt both the writing style and depth of information to cater to the audience. Regardless of the format, the goal is to prepare a document that is accurate, clear, concise, complete, balanced and presented appropriately.

Particular advice and general rules of writing can be found in Section C: Answering Enquiries of the SHPA Australian Information Training Workbook[11], and other resources (see Further reading). In addition, it is imperative that all statements be referenced appropriately. This is usually provided according to the Vancouver style guide.

Further reading:
Stuart M, ed. The Complete Guide to Medical Writing. UK: Pharmaceutical Press; 2007
Goodman N, Edwards M, Langdon-Neuner E. Medical Writing. A Prescription for Clarity. 4th ed. Cambridge, UK: University Printing House; 2014
Taylor, R. The Clinician's' Guide to Medical Writing. New York: Springer; 2006
Gopen G, Swan J. The Science of Scientific Writing. American Scientist 1990;78:550-558.

6•INFORMATION RESOURCES

Medicine Information Resource Checklist - minimum requirements

The checklist below outlines recommendations for minimum resource holdings according to the type of MIC. Editions and publication dates are not specified. The most recent edition should be held. Electronic versions of any of the listed resources are acceptable.

M = mandatory text, Pharmacy Board of Australia (as specified in Guideline on practice-specific issues - Guideline 1 (List of reference texts for pharmacists), issued 2.9.15. Due for revision September 2020.

MI centre/service category	**Key**
Group 1 = state centres Group 2 = major teaching hospital Group 3 = other hospitals	S = specialist services E = essential R = recommended Alt = alternative resource Ad = additional resource

Table 2: Pharmacy Board of Australia Mandatory Resources*

Resource	Group 1	Group 2	Group 3
Australian Pharmaceutical Formulary and Handbook (APF)	M	M	M
Australian Medicines Handbook (AMH)	M	M	M
Australian Don't Rush to Crush Handbook	M	M	M
Therapeutic Guidelines series (complete set in hardcopy) or eTG	M	M	M
A current source of Australian product information and consumer medicine information • MIMS Annual with MIMS Abbreviated • e-MIMS • MIMS Online, or • AusDI Advanced/AusDI	M	M	M
Drug interaction resource (updated at least quarterly) • AusDI Advanced/AusDI • Drug Interaction Facts – Facts and Comparisons • eMIMS • MIMS Online • Micromedex • Stockley's Drug Interactions Online, or • Lexicomp Interactions.	M	M	M
AMH Children's Dosing Companion	M	M	M

Table 2: Pharmacy Board of Australia Mandatory Resources*

Resource	Group 1	Group 2	Group 3
An evidence-based reference work on complementary and alternative medicines • Herbs and Natural Supplements: An evidence-based guide. Braun and Cohen • Herbal Medicines. Barnes, Anderson and Phillipson • Herbal Medicines and Dietary Supplements package (each resource can be independently accessed through Medicines Complete) • MedlinePlus: Drugs, Supplements, and Herbal Information (available free online) • Natural & Alternative Treatments: EBSCO, or • Natural Medicines	M	M	M
Copies of the legislation controlling the practice of pharmacy: • the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law) • Drugs, medicines and poisons legislation • Standards, codes and guidelines relevant to pharmacy practice for each jurisdiction (including information published by relevant government departments and jurisdictional pharmacy premises registering authorities) • Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).	M	M	M
The Australian Immunisation Handbook (available free online)	M	M	M
The professional practice standards and guidelines published by the Pharmaceutical Society of Australia (PSA) and The Society of Hospital Pharmacists of Australia (SHPA)	M	M	M
The Pharmacy Board of Australia guidelines	M	M	M
The Merck Manual (Professional Version, Merck)	M	M	M

* Where multiple resources are listed in the same category only one is required. Resources may be held elsewhere in the pharmacy.

Table 3: MI Resources Version 1.0 July 2016

Resource	Group 1	Group 2	Group 3
Adverse drug reactions			
Meyler's Side Effects of Drugs	E	E	E
Side Effects of Drugs Annuals	R	R	
Litt's D.E.R.M (database or text – database includes references)	Ad		
Pharmacovigilance Insight (database) or Reactions Weekly	E	R	
Adverse Drug Reactions, Lee	Ad		
Textbook of Adverse Drug Reactions, Davies	Ad		
Medications and nutrition, a quick reference for busy clinicians	R	R	
Antimicrobials / infectious diseases			
Kucers' The Use of Antibiotics	E	R	R
Sanford Guide to Antibiotic Therapy (or database)	R	R	
Sanford Guide to HIV/AIDS Therapy (or database)	R	Ad	
Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases	R		
A major textbook about medical microbiology: Jawetz, Melnick & Adelberg's Medical Microbiology	R		
Bibliographic databases			
Medline	E	E	E
PubMed	E	E	E
Embase	E	E	R
Cochrane Library	E	E	E
CINAHL	R	R	R
PsycINFO	E	E	R
AMED	R	R	
International Pharmaceutical Abstracts (IPA)	R		
Chemical information			
Merck Index	E	R	R
PubChem (free)	R	R	R
DrugBank (free)	R	R	R
INCHEM (free)	R	R	R
ChemIDPlus (free)	R	R	R
Compatibility & stability of parenteral products			
Australian Injectable Drugs Handbook	E	E	E
A major reference on drug compatibility: • ASHP Handbook on Injectable Drugs • King Guide to Parenteral Admixtures, or • IV Compatibility (via Micromedex or Lexicomp)	E	E	E
Stabilis (free online compatibility resource, French)	Ad	Ad	Ad

Table 3: MI Resources Version 1.0 July 2016

Resource	Group 1	Group 2	Group 3
Injectable Drugs Guide (Gray)	Ad	Ad	Ad
Injectable Medicines Administration Guide, UCLH NHS	Ad	Ad	Ad
Extended stability for parenteral drugs, Bing	Ad	Ad	Ad
Complementary & alternative medicines			
Natural Medicines database	E	R	R
Herbal Medicines, Barnes	R	R	
Stockley's Herbal Drug Interactions	Ad		
IM Gateway (database)	Ad	Ad	
About Herbs, Botanicals & Other Products, Memorial Sloan-Kettering (free)	R	R	R
NIH National Centre for Complementary & Integrative Health (free)	Ad	Ad	Ad
MedlinePlus Herbs & Supplements (free)	Ad	Ad	Ad
Contraception & hormonal treatment			
Contraception: an Australian clinical practice handbook (Family Planning NSW, Qld, Vic)	E	R	
Contraception: Your Questions Answered (Guillebaud, MacGregor)	Ad	Ad	
Critical care (or emergency & critical care)			
Oh's Intensive Care Manual or Marino's The ICU Book	Ad	Ad	
Dermatology			
Clinical Dermatology: A Color Guide to Diagnosis and Therapy (Habif)	Ad		
Drug abuse			
Drugs of Abuse (Wills)	Ad		
Drug administration			
Don't Rush to Crush	E	E	E
The Syringe Driver	E	E	
Handbook of Drug Administration via Enteral Feeding Tubes or The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties	Ad	Ad	
Drug interactions			
A major reference about drug interactions: Stockley's Drug Interactions	E	R	E
YouScript	E	E	
Drug Interaction Facts (Tatro)	Ad		

Table 3: MI Resources Version 1.0 July 2016

Resource	Group 1	Group 2	Group 3
An online drug interaction checker: • via Micromedex • via MIMs • via AusDI • Lexicomp Interactions	E	E	E
Evidence based medicine & critical literature evaluation			
Users Guides to the Medical Literature (JAMA) or How to Read a Paper (Greenhalgh, BMJ)	E	R	R
Foreign drug identification			
Index Nominum	R		
Martindale or Micromedex	R	R	
General drug references			
Micromedex (DrugDex database) – detailed monographs	E	R	R
AHFS Drug Information	R	R	R
Martindale: The Complete Drug Reference	E	E	R
BNF (British National Formulary)	Ad	Ad	Ad
General medicine			
Harrison's Principles of Internal Medicine (or similar)	R	R	R
General references			
A medical dictionary e.g. Steadman's, Dorland's	E	E	E
Geriatrics			
AMH Aged Care Companion	E	E	R
Laboratory tests			
Basic Skills in Interpreting Laboratory Data (ASHP)	Ad		
Use of Laboratory Test Data (Hughes)	E	E	E
Lactation			
Drugs in Pregnancy and Lactation: a Reference guide to Fetal and Neonatal Risk (Briggs)	E	E	R
Pregnancy & Breastfeeding Medicines Guide	E	E	R
Medications and Mothers' Milk (Hale)	E	R	R
LactMed (free)	E	E	E
Drugs During Pregnancy and Lactation (Schaefer)	Ad		
Liver impairment			
Drugs and the Liver (North-Lewis)	Ad		
Ophthalmic preparations			
Moorfields Eye Hospital NHS Foundation Trust Pharmacists Handbook	E	R	

Table 3: MI Resources Version 1.0 July 2016

Resource	Group 1	Group 2	Group 3
Extemporaneous Ophthalmic Preparations	E	R	
Ophthalmic Drug Facts	E	R	
Paediatrics			
AMH Children's Dosing Companion	E	E	E
BNF-C	R		
Pediatric & Neonatal Dosage Handbook (Lexicomp)	Ad	Ad	
NeoFax (for specialist paediatric centres with neonatal units)	R		
Palliative care			
Palliativedrugs.com / The Palliative Care Formulary (PCF)	E	R	
Symptom Management in Advanced Cancer or Palliative Care Guidelines Plus	R	R	
Parenteral & enteral nutrition			
AUSPEN Guidelines	E	E	
ASPEN Pediatric Nutrition Support Core Curriculum	R	R	
ASPEN Adult Nutrition Support Core Curriculum	R	R	
ASPEN Parenteral Nutrition Handbook	R	R	
ASPEN Enteral Nutrition Handbook	R	R	
ACI Parenteral Nutrition Pocketbook: For adults	R	R	
Pharmaceutics (including compounding, sterile manufacture)			
Remington – the Science & Practice of Pharmacy	E	R	
Handbook of Pharmaceutical Excipients	E		
Ansel's Pharmaceutical Dosage Forms & Drug Delivery Systems	R		
Pharmaceutical Compounding & Dispensing OR Handbook of Extemporaneous Preparation	Ad	Ad	
Trissel's Stability of Compounded Formulations	E		
Disinfection, Sterilization and Preservation (Block)	R	R	
Pharmacokinetics			
Advanced pharmacokinetics texts: • Clinical Pharmacokinetics and Pharmacodynamics (Rowland & Tozer) • Clinical Pharmacokinetics (Murphy) • Applied Clinical Pharmacokinetics (Bauer) • Drug Disposition and Pharmacokinetics (Curry, Whelpton)	E	R	
Basic pharmacokinetics texts: • Basic Clinical Pharmacokinetics (Winter) • Concepts in Clinical Pharmacokinetics (ASHP) • Introduction to Pharmacokinetics and Pharmacodynamics (Rowland, Tozer)	Ad	Ad	R

Table 3: MI Resources Version 1.0 July 2016

Resource	Group 1	Group 2	Group 3
Pharmacology			
Goodman & Gilman's The Pharmaceutical Basis of Therapeutics	E	R	R
Alternative pharmacology texts: Rang & Dale's Pharmacology Pharmacology for Health Professionals (Bryant, Knights) Basic and Clinical Pharmacology (Katzung, Trevor) Melmon and Morelli's Clinical Pharmacology Oxford Textbook of Clinical Pharmacology and Drug Therapy	Ad	Ad	
Pharmacotherapeutics			
Pharmacotherapy, a Pathophysiological Approach (DiPiro)	R	R	
Applied Therapeutics (Koda-Kimble)	R	R	
Clinical decision support databases: • BMJ Best Practice • UpToDate • DynaMed	R	R	R
Clinical decision support databases: PEMSoft (Paediatric)	R	Ad	
Poisoning & toxicology			
POISINDEX	R	R	
TOXINZ	R	R	
Toxicology Handbook (Murray et al)	E	R	R
Goldfrank's Toxicologic Emergencies Casarett and Doull's Toxicology: The basic science of poisons Medical Toxicology (Dart), or Baselt's Disposition of Toxic Drugs and Chemicals in Man	R	R	
Australian National Poisons Register	E	R	
TOXBASE (UK)	R	R	
TOXNET (free)	E	R	R
INCHEM (chemical toxicology)(free)	R	R	R
Pregnancy			
Drugs in Pregnancy and Lactation (Briggs et al)	E	E	R
Pregnancy and Breastfeeding Medicines Guide	E	R	R
Drugs During Pregnancy and Lactation (Schaefer et al)	R		
Therapeutics in Pregnancy and Lactation (Lee et al)	Ad		
Micromedex (Reprorisk)	E	R	R
Product information & CMI			
Product information: • TGA (free) • MIMs • AusDI • Medicines Australia (free)	E	E	E

Table 3: MI Resources Version 1.0 July 2016

Resource	Group 1	Group 2	Group 3
CMI: • TGA (free) • Medicines Australia (free)	E	E	E
Psychotropics			
The Maudsley Prescribing Guidelines in Psychiatry	E	E	
Psychotropic Drug Directory (Bazire)	E	E	
Stahl's Prescribers Guide	E	R	
Clinical Handbook of Psychotropic Drugs (Procyshyn et al)	R	R	
Renal impairment			
The Renal Drug Handbook or Database (Ashley, Dunleavy)	E	E	R
The Renal Drug Reference Guide (Cervelli)	E	E	R
Seyffart's Directory of Drug Dosage in Kidney Disease	R	R	
Travel			
Travel Health Advisor (online)	R		
Manual of Travel Medicine (Yung et al)	Ad	Ad	
Centre for Disease Control and Prevention Travelers' Health	E	E	R
Wound management			
The Wound Care Manual (Carville)	Ad		

7•BIBLIOGRAPHIC DATABASES

Bibliographic databases are used to rapidly access and retrieve articles from journals. Some databases include a summary of the published work in the form of an abstract and a link to full-text journal articles which can either be accessed free of charge ('open access') or restricted to subscribers.

PubMed and the Cochrane Library are available for free on the internet in Australia. Other databases commonly used by MI pharmacists include PreMEDLINE, MEDLINE, Embase, CINAHL, PsycINFO, AMED, MEDLINE Ovid Nursing Database, Informit, ProQuest Central, Scopus, Journals @ Ovid Full Text and The Joanna Briggs Institute EBP Database. These require subscriptions which may be state-wide, group (consortia), organisational, or individual.

Curated databases (e.g. MEDLINE, Embase) are indexed into a structured thesaurus specific for the database (e.g. MeSH for MEDLINE, EMTREE for Embase). Indexing terms are applied to references according to a strict policy, although there is some variation in how terms and subheadings are indexed. Note that terms used in one database are often not directly transferable to another database. The depth of indexing also varies between databases depending on the number of terms available and how these terms are structured within the index. This has particular relevance to controlled searching for drugs.

Many databases are accessible to clinicians and the public but these are often used without an understanding of the underlying processes and the results of inexperienced use can be inadequate when a more comprehensive search is required. MI pharmacists should be familiar with the scope, limitations and database specific user instructions for each of the resources available to them. Database-specific training and extensive experience is required in order to optimise a search.

The SHPA Australian Medicines Information Training Workbook contains an introduction to bibliographic databases (MEDLINE, EMBASE etc.). It explains indexing, explosion, focus, subheadings, limits, supplementary concepts and the use of Boolean operators.[11] Advanced searching requires a thorough knowledge of these concepts and other techniques such as proximity or adjacency, truncation, wildcards, hedges, filters, multi-database searching. Standard search strategies can be prepared and applied to recurring questions in medicines information. See Appendix 4: Resources for information about database training materials.

Searching databases

To ensure that an appropriate search is conducted a specific and focused question is required. This will enable the development of relevant keywords and effective search strategy. It will often be necessary to use more than one database to improve the comprehensiveness of a search.

Initial searching of an individual database should usually be broad with a combination of text word, MeSH/EMTREE, word variants and wild cards to search for occurrences in the title, abstract and subject heading fields of articles. When results of a search are examined, terms are narrowed or filters are used if the amount of information is prolific. Medicines information pharmacists often need to design their own hedges (search 'filters') dependent upon the enquiry, however, search results can also be limited by applying filtering provided in the database e.g. articles of a particular level of evidence (e.g. randomised controlled trial, systematic reviews) or a specific population (e.g. paediatrics).

Pre-validated search filters are also available to improve retrieval of scientifically sound and clinically relevant study reports from large bibliographic databases such as MEDLINE, EMBASE and PsycINFO.

Some pre-validated search filters for different databases can be copied and pasted directly to a search and are available from SIGN which may assist to identify the higher quality evidence in Ovid implementations of Medline, Embase and CINAHL for:

- systematic reviews
- randomised controlled trials
- observational studies
- diagnostic studies
- economic studies
- patient issues.

Note that these filters are undated.

See the following resources for further information:

- Centre for Reviews and Dissemination
- National Clinical Guideline Centre (navigate to appendix of guideline)
- McMaster University Hedges Project.

Constructing a search can be considered an exercise in risk management in that every decision involves a risk of retrieving too much or of missing relevant articles. This applies to decisions at the level of selecting the best database, using indexing terms, explosions (and at what level), subheadings and applying filters.

Grey literature

Grey literature is not controlled by commercial publishing. It may be produced by government, academics, business, industry, advocacy or others that disseminate information in the form of reports or working papers rather than by publishing scholarly articles in commercial journals.

Conference abstracts and other grey literature have been shown to be sources of approximately 10% of the studies referenced in Cochrane reviews.[61] Examples of grey literature can include bulletins, policy statements, course materials, fact sheets, patents, government documents, press releases, essays, questionnaires, book chapters, lectures, interviews, speeches etc. Some grey literature may be searched by using web access portals such as:

- Google Advanced Search
- MedNar
- Trove
- The Grey Literature Report
- The Agency for Healthcare Research and quality
- Open Grey
- Grey Literature Network Service
- National Technical Information Service (NTIS)

Use of .org, .gov domains or restricting to PDF documents may assist with searching for grey literature. Some grey literature databases are only available on a subscription basis, for example Healthcare Management Information Consortium (HMIC) via Ovid PsycEXTRA (EBSCO, Ovid or ProQuest)

Critical appraisal of grey literature is important. Unpublished studies and randomised controlled trials should be appraised using the same tools as their black (published) counterparts. Checklists that examine the Authority, Accuracy, Coverage, Objectivity, Date and Significance (AACODS) have been developed to assist with evaluation.

8•LITERATURE EVALUATION AND CLINICAL TRIALS

This section offers some guidelines about points to look for while reading journal articles or other biomedical literature. This chapter should be read in addition to the information in Tutorial 5: Critical Evaluation and Tutorial 19: Clinical Trials and Regulatory Processes in the SHPA Medicines Information Training Workbook.[11] Due to the importance of this work for an MI pharmacist this section includes significant detail.

An MI pharmacist must be able to critically evaluate and interpret scientific literature for general populations as well as for individual patient care. By their practise, MI pharmacists conduct evidence-based practice (EBP). Evidence-based medicine (EBM) was coined in the early 1990's by David Sackett, to describe the concept of 'integrating individual clinical expertise with the best available external clinical evidence from systematic research'. EBP covers a wider scope of healthcare than just EBM. If clinical practice is about making choices, then EBP is about the process of rationalising the evidence for making them. The purpose of EBP is to:

- recognise uncertainties of clinical practice
- use research information to reduce uncertainties
- discriminate between strong and weak evidence
- quantitate and communicate uncertainties with probabilities.

The MI pharmacist uses the principles of EBP to assist clinicians in their clinical decision-making by:

- formulating an answerable question
- locating the best evidence of outcomes available
- critically appraising the evidence
- applying the evidence by integrating results with clinical expertise and patient values
- evaluating the effectiveness and efficiency of the process.[51]

Most published work will conform to accepted standards for content and style but the overall quality of the research and the relevance to local populations must be carefully considered.

8.1 Standards for biomedical publications

In 1978 a small group of editors from major biomedical journals met in Vancouver and created the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. The 'Vancouver Group' evolved into the International Committee of Medical Journal Editors and this group is responsible for maintaining these standards. They meet annually to refine its *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals*.[63]

The 'Vancouver Guidelines' include requirements for:

- ethical considerations – including authorship, peer review, conflicts of interest, privacy and confidentiality, protection of human and animal rights
- publishing and editorial issues – including obligation to publish negative studies, corrections, restrictions, copyright, overlapping publications, correspondence, electronic publishing, advertising, relation to general media, obligation to register clinical trials
- manuscripts – preparation and sending.

8.2 Clinical trials

Prior to gaining marketing approval the efficacy and safety of a drug must be thoroughly evaluated by clinical trials. A clinical trial is an experiment conducted in humans in order to assess the effects, efficacy and/or safety of a drug or drug product. This includes pharmacokinetics and pharmacodynamics studies. Clinical trials are usually classified according to the development phase of the drug. See SHPA Medicines Information Training Workbook[11] for development phases. Note that individual phases may not be clearly delineated and not all phases are relevant to some classes of drug. Standards and processes used in the conduct of clinical trials are outlined in the SHPA Standards of Practice for Pharmacy Investigational Drug Services.

Some tools used to ensure appropriate protocols and adequate reporting occur include:

CONSORT statement
The Consolidated Standards of Reporting Trials (CONSORT) Statement provides a minimum set of recommendations for reports/summaries of randomised trials. These cover:

- title
- authors
- trial design
- methods: participants, interventions, objective, outcome, randomisation, blinding
- results: numbers randomised, recruitment, numbers analysed, outcome, harms
- conclusions
- trial registration
- funding.

It is a standard approach for authors to report trial results in a manner which facilitates critical appraisal and interpretation. CONSORT consists of a 25-point checklist and flow diagram which authors are expected to address within the publication.

SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) is another checklist that is recommended when drafting clinical trial protocols. It consists of 33 item checklist and figure. The checklist can be used to evaluate a clinical trial publication.

STROBE (STrengthening the Reporting of OBservational studies in Epidemiology and RECORD (REporting of studies Conducted using Observational Routinely-collected health Data) guidelines and checklists for conduct of observational studies - where health data have been collected for service purposes and used in epidemiological or observational studies.[64, 65]

PRISMA provides an evidence-based minimum set of items for reporting systematic reviews and meta-analyses.

8.3 Literature evaluation

A paper requires examination for validity, importance and applicability. There are large volumes of literature written about this topic and many aspects of evaluation are required. These are also dependent on the types of study being analysed. An MI pharmacist must interpret the validity and applicability of the literature to their specific enquiry prior to formulating a response if it is to be used to support their recommendations.

When evaluating the literature the following aspects should be considered:

Reputation of the journal

Some weighting on the potential quality of the article may depend on the reputation of the journal in which it is published. In general, well established and reputable journals publish the results of well conducted research. Publications sponsored by pharmaceutical companies may demonstrate bias.

Reputable journals usually demonstrate the following characteristics:

- the editorial policy specifying types and format of articles accepted for publication is published regularly
- text exceeds pages of advertising or promotional material
- articles undergo peer review.

Peer review

Peer review is the evaluation of the manuscript by consultants recognised as experts in the field. Peer reviewers recommend whether a submitted article is suitable for publication and if so provide any recommendations to improve its content or presentation. Referees' names are confidential and are consequently not published with the article. However, there should be notation of the date of submission for publication and date of acceptance. The process of peer review with manuscript evaluation and modification usually takes some weeks to be completed. Thus, it is unlikely that an article published quickly following submission to the journal has undergone a stringent review process. Journals without a peer review process may have less rigid criteria for accepting manuscripts.

Open access journals

Open access journals are journals that are digital, online, free of charge, and free of most copyright and licensing restrictions. The possible ethical inequity of access to literature is removed by availability of open access and it is often viewed as providing access to knowledge as a 'public good'. Directories of open access journals (e.g. publishers A-Z lists, DOAJ) are available and peer review is usually required. Many business models are used for open access journal publishers. For example they may be either a profit (BioMed Central or BMC) or non-profit organisation (Public Library of Science or PLoS). As with all reputable journals critical evaluation of articles is required. One way to be assured of the quality of the open access journal is that reputable journals, e.g. *BMJ Open*, provide not only public access to the published paper but also paper's review history, including pre-publication reviewer critique.

Relevance and scope of the journal

Researchers usually submit their manuscripts to reputable journals within their specific field, e.g. emergency medicine, clinical pharmacy, pharmacogenetics. Alternatively, they may choose to communicate their results to a broader population in a less specialised but highly reputable journal, e.g. Lancet or The New England Journal of Medicine. If not accepted for publication by these journals the author may then submit the manuscript for publication in a journal with less stringent acceptance criteria.

Impact factors

The impact factor is a very crude measure of a journal's impact in a discipline. A journal's impact factor is based on a two-year period and involves dividing the number of times articles were cited by the number of articles that are citable. High impact factor journals are often sought after by authors due to their article's possible higher visibility, however, this should be only one of many considerations.

Researchers and Facilities

The quality of research can be considered in terms of:

- are the researchers known and respected in the field?
- do the researchers appear to have the appropriate qualifications and experience to conduct a study in this field?
- has a statistician been included or mentioned by the authors?
- do the authors have an obvious connection with a pharmaceutical company?
- are the authors from the same research facility or is the study a multi-centre study? If the latter, possible inconsistencies in methodology may be present in the study.
- was the research performed at an appropriate medical facility? Research in a

specialised field may be best conducted in a specialised setting. However, large institutions offer the researcher access to a broad range of patients and facilities.

Sponsorship

The source of financial support for the research should be clearly defined. Independent support is preferred but financial support from a pharmaceutical company does not preclude good quality research.

Manuscript

In general, an article may be considered within the sections listed below. It is recommended that an article be initially read or scanned to establish a feel for the content and layout and then, except for the abstract, each section should be more closely scrutinised. The abstract should be read after the main text to confirm that it provides a valid summary of the article.

- title
- abstract/summary
- introduction
- methods
- results and data analysis
- discussion/conclusions
- references.

Title

Does the title provide an adequate description of the content?

The title of a paper ideally provides a succinct description of the research and or results of the study. Cute and gimmicky titles may attract attention, alternatively they may trivialise the value of the work presented. Titles may be inaccurate and not reflect the content of the paper at all. The title alone should not be relied upon to determine if the paper is worth reviewing or discarding.

Abstract

Does the abstract provide an accurate synopsis of the paper?

The abstract provides a synopsis of the paper. It should outline the purpose of the study, the method (including patient population, interventions and evaluations), the results and authors' conclusions (based on the results). The abstract should not be used alone to evaluate the study as it does not provide a full description of the methods and results, and consequently it is not possible to determine if the authors' conclusions are appropriate.

When assessing an abstract, be alert for lack of clarity and contradictions, particularly discrepancies between the number of patients entering the study and the number actually evaluated. Also be alert for inappropriate use of statistical terminology such as 'significant' (without an indication of the precision of the estimate (preferably a confidence interval). Also ensure that p-values correlate with confidence intervals.

Introduction

Does the Introduction provide the background and rationale for the study?

The introduction should include a brief outline of the problem being addressed and a justification to conduct the study. Clinical trials consume health resources and are likely to entail some degree of risk and inconvenience to participants. These factors must be justified based on the significance of the problem being addressed and confidence that the study is warranted to improve healthcare rather than an academic exercise.

The study objectives or hypothesis should be clearly defined and raise questions for the reader as to the type of patient selected, appropriateness of interventions and outcome measures and possible sources for error or bias.

Study design and methods

Is the study design appropriate for the question being investigated? The following points should be assessed:

Study sample

Power

Clinical studies require an appropriate sample size for the differences in measured effect between tested drugs or interventions to permit statistical tests to determine the probability that significant differences exist. The probability that a statistical test will reveal a true difference in outcomes where one exists is called the *power* of the test. This depends on the size of the study group and the size of the measurable difference in outcome. Researchers must ensure that the sample size of the study is large enough to ensure a true statistical difference can be detected.

Patient selection

The information on patient selection should enable the reader to determine if the subjects are representative of the population for whom the drug is intended for use and if they were chosen appropriately without possible bias. The type of patient chosen for a study and the means by which they were selected should be well defined:

- patient demographics such as age, gender and race should be clearly defined and, the diagnostic procedures used to identify the medical condition of the patients included in the study described.
- details of both inclusion and exclusion criteria should be presented. Examination of these criteria enable the reader to determine if the population studied is representative of the population with the disease and consequently if the results obtained can be extrapolated to the broader population. Strict adherence to inclusion and exclusion criteria during patient selection helps to avoid the criticism of selection bias.
- it should be noted that clinical trials are generally conducted in patients without significant co-morbidities, risk factors or confounding factors including medications. Thus study results may not be readily extrapolated into the general population.
- the settings from where the patients are selected should be described. Patients selected from a hospital inpatient setting may differ in degree of disease severity than those selected from hospital outpatient, research institution or general practice settings. Alternatively it should be clear if subjects were recruited on a self-selection or volunteer basis.

Study design

The study design should be clearly stated and described. The following are some of the terms used when describing the design of a study.

Clinical trial: in a clinical trial patients are assigned to a treatment or control group by the investigator. Clinical trials may be single or double blinded, controlled or not, randomised or not.

Controlled: in a controlled study, effort is made to keep the study groups as similar as possible so they differ only in the variable under study.

Placebo controlled: subjects in the control group receive a placebo, i.e. inactive agent that is otherwise identical to the study treatment.

Single-blind: in a single-blind study subjects do not know if they are in the treatment group or the control group i.e. if they are receiving the investigational drug or placebo.

Double-blind: in a double blind study neither subject nor investigator knows to which group the subjects have been assigned.

*Open study***:** in an open study both investigator and subjects are aware to which group the subjects are allocated.

Randomised study: in a randomised study subjects are assigned to treatment and control groups by random allocation. A randomised, double-blind controlled trial will yield the strongest and most direct evidence on which to base a judgement of whether an observed association is one of cause and effect.

Retrospective study: retrospective studies begin after the subjects have developed the condition under study. Patients are assigned to the study as a result of a condition not directly controlled by the investigator. These studies include case controlled studies, cohort studies and case reports.

Prospective study: prospective studies are initiated before subjects receive a treatment or develop an outcome to that treatment. These studies include clinical trials, cohort studies, before and after studies, crossover studies, studies using historical controls and case reports.

Case report: case reports provide detailed description of one or more persons exhibiting a response to an unusual treatment or an unusual reaction. Case reports may be indicative of possible outcome but they are difficult to evaluate as they are not controlled.

Case-controlled: a case-controlled study compares subjects who have developed a condition with a similar control group who do not have the condition. The objective is to determine the common factor which is the possible cause of the disease. A case-control design is well suited to the evaluation of diseases with long latent periods, and rare diseases, but cannot directly compare incidence rates. A temporal relationship between exposure and disease may be difficult to establish, and this design is particularly prone to bias compared with other analytical designs.

Cohort studies: a cohort study identifies subjects who share a common characteristic and compares them with a similar group who do not show that characteristic. Both groups are followed through time to determine who develops the outcome of interest. A cohort design can elucidate a temporal relationship between exposure and disease. It allows direct measurement of incidence of disease in the exposed and non-exposed groups. However, it is inefficient for the evaluation of rare diseases, and can be expensive and time consuming. The validity of results can be affected by losses to follow up.

Historical control: in these studies the results of a study group are compared with results of a previous study group.

Before and after studies: patients may be used as their own controls, i.e. a before and after study where in the same patient the response to one therapy is compared to the response to an alternative therapy with an appropriate washout period intervening.

Crossover: in a crossover study subjects are divided into two groups. One group receives drug A the other drug B. After a period of time the groups cross over and receive the alternative treatment arm. An appropriate period of time must be allocated to washout of each therapy. Patient drop out or natural fluctuation in disease state may affect the results of these studies.

Drug Usage Evaluation: an evaluation of drug therapy and drug therapy outcomes by comparison of practice with predetermined criteria and standards.

Economic Evaluation: the systematic analysis of alternative courses of action (e.g. alternative ways of addressing a particular clinical problem), which compares the costs (e.g resource use) and consequences (e.g. benefits) of each alternative in order to facilitate decision making. Studies that do not make explicit comparisons of costs and consequences of alternatives are considered partial economic evaluations, and may, for example, include cost analyses.

Secondary research designs include:

Meta-analysis: combining the results of a number of independent yet similar studies using a quantitative statistical approach to develop a single conclusion that has greater statistical power.

Systematic review: a review of the evidence on a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant primary research, and to extract and analyse data from the studies that are included in the review.[66]

Group assignment
Generally patients should be assigned to treatment groups in such a way that each subject has an equal chance of being assigned to any of the groups. To minimise the risk of selection bias and ensure random allocation, investigators should use random numbers to distribute patients to different arms of the study.

Controls
Study investigators must control extraneous factors, i.e. confounding variables, to ensure that the study outcomes are a result of the factor/ drug under investigation rather than some other influence. These confounding variables may include factors such as age, gender, severity of disease, concomitant disease or drugs.

Some methods to achieve control and ensure equivalence in patient groups are:

- matching with respect to variables
- stringent adherence to inclusion and exclusion criteria
- randomisation in selection
- blinding
- crossover control studies.

Study methods and measurements

Are the methods employed in the study appropriate? The following topics should be considered when evaluating a study:

Were appropriate doses and regimens used for treatment of the condition under investigation?

When reviewing a study establish that the dose, route of administration and dosage schedule are appropriate for the condition under investigation. If inappropriate doses, routes of administration and dosing schedules are used the outcomes may not be credible, i.e. if the doses chosen for the study are too low or the dosage interval too great the therapy may not be beneficial or the incidence of adverse drug reactions lower than expected. If the dosage is too high or interval too short the incidence and severity of toxicities observed may be unrealistically increased.

When comparing two therapies it is essential to select the right comparator and regimen to ensure that the results are applicable into practice and attributable to intrinsic differences between the two therapies rather than a lack of comparability between the two dosage regimens.

Was the length of the study adequate to observe the outcome under investigation?

The duration of the study and follow-up must be long enough for outcome measurement, i.e. for both beneficial and adverse effects to become apparent. The length of the study will be determined by both the type of drug and disease being investigated.

Was the length of the washout period adequate?

For a crossover study an appropriate washout period must be employed to prevent any carryover effect from one treatment to the next. The condition under study should remain constant over the duration of the study at least. Modification of the disease process or spontaneous remission occurring during the time of the study will bias the results. A random crossover design may control for this.

Was patient compliance ensured?

If patients are not compliant with their medication the study results may be erroneous. For studies conducted in an inpatient setting the risk of this error is minimised. However, when

studies are conducted in a less restricted setting, methods to ensure patient compliance must be instigated. Appropriate means of monitoring patients include tablet counts, measurement of drug levels, observation of expected adverse effects, etc.

Were effects of concomitant medication observed or controlled?

This parameter should be controlled by adherence to the inclusion and exclusion criteria and random allocation to study groups.

Does the study medication affect the blinding?

Trial blinding is not possible if the drugs under investigation produce distinct adverse effects which are recognisable by the patient or doctor.

Were the methods used to measure outcome appropriate?

The methods employed to measure the study outcome should be either well established or substantiated as appropriate e.g. through validation. In quantitative studies, all methods of measurement should be standardised, i.e. reproducible and sufficiently sensitive to detect the outcome being measured. In qualitative studies when the qualitative method is employed and a standardised data collection method, there may be markedly different interpretation of results. Measurements should be conducted at intervals of appropriate frequency. It would be expected that methods usually employed in the clinical setting to evaluate the disease state under investigation be employed in a study. In addition, any special measurements as determined by the hypothesis should be employed.

Were the methods used to measure adverse drug reactions appropriate?

The criteria recommended for measurement of outcome should also be met for measurement of adverse drug reactions.

Were effects measured or assessed by appropriate persons?

Ideally drug effects should be measured by persons who have appropriate training or experience in conducting these assessments.

How were variations in observations controlled?

Substantial variation in assessment and measurement may be expected if observations or measurements are conducted by different persons, for example in a multicentre study. Methods should be employed to minimise discrepancies by the use of objective measures and standardised measuring techniques.

Study results and analysis

Data presentation

The data collected from the study is presented in the results section. Data should be presented clearly so it is easy for the reader to interpret and evaluate the results independently. In addition, all data collected should be presented for analysis not just that which substantiates the authors' hypothesis.

Where a large volume of data is generated it is frequently presented diagrammatically in the form of graphs, charts or tables to make relationships among the data more apparent. When interpreting graphical presentations of data the following points should be observed:

- are the axes appropriately labelled?
- do both axes start at zero or at another point?
- the latter practice may lead to erroneous conclusions by magnification of small effects
- be alert for graphical distortions where the pictorial presentation is interrupted ostensibly to save space on the page. This technique does not permit visualisation of the relative proportions of the data presented
- in graphical presentations the scatter about the mean (i.e. error bars) should be present

- when an average or mean value is presented confidence limits should be noted as an estimate of variance
- check the contents of graphs and tables against the text. Discrepancies or omissions in the data may be found
- are the data presented in a way that the reader is able to analyse them independently or, are only the results of the investigators' analysis available?
- are all patients and data accounted for?

Patient dropouts and data collection
All patient dropouts and errors in patient collection should be accounted for in the results. Patients may drop out of a study for a variety of reasons, i.e. due to patient characteristics or for reasons attributable to the study. When a subject does drop out of a study the overall characteristics of the group for analysis may change. These dropouts should be followed up to determine the reason for withdrawing from the study and included in final study results. An intention to treat analysis includes study dropouts in the data analysis in the group to which they were originally allocated.

In the event of patient dropouts as a result of adverse effects, information on the incidence and nature of the adverse effects should be documented.

Errors in data collection such as the inclusion of ineligible patients, inadequate sample size, non-comparable study groups and protocol deviation should be reported.

Adverse events
Adverse events including ADRs should be monitored throughout the study. The nature and incidence of adverse events occurring during the study should be presented as well as the methods used for detecting such adverse events. For example, consider whether adverse reactions were formally and systematically sought throughout the study or were spontaneous or voluntary reporting methods used. Presentation of these data enables the reader to assess the risk/benefit of the study medication.

Statistical evaluation
After the raw data is collected it should be organised into a useable form with patient characteristics and responses described numerically.

In quantitative research, this process is referred to as descriptive statistics. Descriptive statistics involve the classifying of data, examining the distribution of the data, providing measures of group characteristics and identifying degree of variation in the data. Investigators use a wide variety of statistical tests to evaluate data. Misleading conclusions can be drawn from the data when inappropriate statistics are used.

Standard texts should be consulted for further information on statistics. However, when reviewing a paper the following should be kept in mind:

- were the statistical tests chosen prior to gathering of the data? For statistical testing to be valid the acceptable level of significance must be established prior to the study.
- was the study hypothesis developed prior to the beginning of the research? The initial study hypothesis or null hypothesis should be statistically evaluated rather than an hypothesis developed once the study has commenced i.e. post hoc hypothesis.
- be alert for type 1 and type 2 errors. Type 1 (alpha errors) occur when the null hypothesis is rejected when it is actually true and should be accepted, a false negative result. Type 2 (beta errors) occur when the null hypothesis is accepted when it is actually false and should be rejected a false positive result. Type 2 errors are more likely when the sample size is small.
- were appropriate statistical procedures chosen? *Parametric tests* (t-test or analysis of variance) may be used if populations are normally distributed and if both study groups

are drawn from populations with equal variance and measure of patient response is independent and not related in any manner. *Non Parametric tests* (Chi-square, Mann-Whitney Rank Sum or Wilcoxon signed-rank test) should be used if the distribution of the data is not known or does not meet the criteria for a parametric test.

- were there any factors that would influence the power of the statistical test and thus the interpretation of the results, e.g. sample size, within sample variability or size of observable difference?

Qualitative research

Qualitative research is designed to reveal a target audience's range of behaviour and the perceptions that drive it, with reference to specific topics or issues. It uses qualitative methods to gather data that serve as evidence for their distilled descriptions. Qualitative data are gathered primarily in the form of spoken or written language rather than in the form of numbers. Possible data sources are interviews with participants, observations, documents, and artefacts.

The data produced from the various sources are assembled into a single text for the final analytic work, with the subunits of the text made up of the data that relate to each participant. These data are usually transformed into written text for analytic use to guide and support the construction of hypotheses, themes or models. The results of qualitative research are descriptive rather than predictive.

Economic evaluation

Clinical trials often concurrently collect data about resource use and report on the costs and benefits of new therapies to assist with information about cost-effectiveness in resource allocation. Full economic evaluations can be broadly categorised into cost-minimisation, cost-effectiveness, cost-utility and cost-benefit analyses. Cost effectiveness studies focus on a single effect of interest, common to the two alternatives but achieved to different degrees. The outcome is measured in natural units or clinical units such as units of blood pressure reduction. The user of a cost effectiveness study should ask the following questions:

- did the authors provide a meaningful, reasonable, and realistic statement of the clinical problem their analysis was intended to address?
- did they accurately identify, describe, and characterise all of the important ways that this problem might be addressed?
- did they accurately identify, measure and value all of the important costs and consequences of each of these strategies?
- did they adjust these measures to reflect differences in the timing of costs and consequences?
- did they give explicit consideration to the marginal costs and marginal consequences of the alternatives that they examined?
- did they examine the robustness of their findings through the use of alternative assumptions and estimates?

Discussion and conclusion

In the final part of the paper an evaluation and interpretation of the results is presented. The conclusions of the study should be supported by the data presented. One should consider if there is a factor other than the drug under investigation that could have caused the observed effects. That is, the discussion should demonstrate how the presented results answer the study hypothesis. Strengths and weaknesses of the study should also be explored in the discussion.

The clinical significance of results, as distinct from statistical significance, should be discussed in the conclusion. It should be recognised that statistical significance does not always imply clinical significance.

Over-extrapolation of results to situations or populations not adequately addressed in the study may occur. Note that the study population is controlled by inclusion and exclusion criteria not present in the general population. This limits the usefulness of extrapolating study results to a broader population.

Finally some discussion of the results in the light of previous work should be presented, particularly if contradictions occur. The implications of these results with regard to future research should also be recognised.

References

Important points raised in the paper should be substantiated by a reference. A sequentially numbered reference list such as the Vancouver style of referencing is most commonly used in biomedical journals.

8.4 Critical appraisal tools

Some critical appraisal tools (CAT) and resources include:

- CASP appraisal tool: A methodological checklist providing key criteria relevant to randomised controlled trials, systematic reviews, qualitative studies, case control studies and cohort studies
- The JADAD Score: assesses quality of published randomised controlled trials based methods relevant to random assignment, double blinding and the flow of patients
- DISCERN: A brief questionnaire providing users with a valid and reliable way of assessing the quality of written information on treatment choices for a health problem
- McMaster Critical Review Form: A generic quantitative study appraisal tool
- Centre for Evidence-Based Medicine. Critical appraisal tools of worksheets for various types of studies as well as Patient/Intervention/Comparator/Outcome (PICO) worksheet
- KT Clearing House Centre for Evidence Based Medicine Toronto. Critical appraisal worksheets for diagnosis, prognosis, therapy, harm and systematic reviews
- What is series. What is critical appraisal?

Literature evaluation checklist			Y/N
JOURNAL Is the journal reputable?	Y/N	Were control groups appropriate?	Y/N
Is the journal appropriate for the subject of the publication?	Y/N	Was the study appropriately blinded?	Y/N
AUTHORS AND SETTING Do the author's qualifications appear appropriate for this type of study?	Y/N	Was the study appropriately randomised?	Y/N
Are the research settings/facilities appropriate?	Y/N	METHODS Was the drug therapy, duration of therapy and washout period appropriate?	Y/N
SPONSORSHIP Who is the study sponsor?		Was patient compliance assessed?	Y/N
Is there a potential conflict of interest with the sponsorship i.e. financial or prestigious remuneration?	Y/N	Were the methods used to measure outcome and ADRs appropriate? i.e. precise, reproducible, sufficiently sensitive and clinically relevant?	Y/N
TITLE Does the title reflect the contents of the article?	Y/N	Were appropriate persons employed to minimise discrepancies in outcome measurements?	Y/N
ABSTRACT Does the abstract concisely discuss all major aspects of the study?	Y/N	RESULTS Was the data presented clearly to allow independent evaluation?	Y/N
INTRODUCTION Is there a brief literature review to provide background information on the topic?	Y/N	Were figures, graphs and tables used appropriately and reflect the text?	Y/N
Does the question of the study follow logically from the available evidence?	Y/N	Were patient dropouts and protocols deviations accounted for?	Y/N
Is the study objective/hypothesis clearly stated and appropriate?	Y/N	Were ADRs appropriately reported?	Y/N
STUDY DESIGN Were the patients selected using appropriate criteria?	Y/N	Were the statistical tests employed appropriate?	Y/N
Were the study subjects representative of the population with the disease?	Y/N	CONCLUSIONS Are the conclusions supported by the data?	Y/N
What was the study design?		Are the conclusions of clinical significance?	Y/N
Was it stated clearly and correctly?	Y/N	Were the conclusions appropriately extrapolated to the broader community?	Y/N
Is the study design appropriate for evaluating the therapy or study subjects?	Y/N	REFERENCES Is the article appropriately referenced?	Y/N
Did the patient selection process minimise study variables?	Y/N		

9•ETHICAL AND LEGAL ISSUES

An MI pharmacist must comply with the legal and ethical principles for the profession of pharmacy and health professionals.[60, 67-69] Codes, standards and guidelines adopted by the Pharmacy Board of Australia take on the force of law and are part of the regulation applicable to professional practice. Domain 1 of the National Competency Standards Framework[60] outlines professional and ethical practice and Domain 8 contains specific performance criteria and evidence examples for the retrieval, analysis and synthesis of information. The SHPA Standards of Practice for Medicines Information Services also outline specific ethical and legal considerations when answering enquiries.[1]

All MI work should be undertaken according to the guidelines set out in this manual while adhering to basic ethical principles. The best interests of the patient are paramount, and encompass provision of good care, confidentiality, privacy, and sensitivity to social, cultural and economic factors.

Enquirers are to be dealt with in an open, honest and professional way. Individual pharmacists need to be aware of their capabilities and competence, and work within them. Enquiries can be refused or referred to a more suitable resource if appropriate.

The MI pharmacist takes full responsibility for the quality of information and advice provided. Information resources used must be current and appropriate to the type and level of service provided. Complete and accurate record keeping is essential.

All pharmacists have a professional obligation to maintain appropriate and current knowledge, and competency - only practicing when fit to do so and with adequate professional indemnity. Professional obligations also include provision of on-going training and supervision of junior staff, and avoidance of any conflicts of interest, real or perceived.

"The best interests of the patient are paramount, and encompass provision of good care, confidentiality, privacy, and sensitivity to social, cultural and economic factors."

9.1 Negligence and liability

The MI pharmacist must be satisfied that an enquirer is *bona fide*. The identity of the enquirer and the reason for the enquiry should be established prior to provision of information and deemed to be legitimate. If it is believed that the enquirer is asking for information that is unethical or illegal, the MI pharmacist can refuse to take the enquiry or seek advice from a superior or legal counsel.

In providing MI the pharmacist must recognise that the enquirer receiving the information is relying on the pharmacist's expertise and judgment. Information provided must be current, accurate and complete, supported by the literature or documented current practice. Any limitations or extrapolations of data on which the answer is based, including use of animal or *in-vitro* studies, or abstract only reports, should be made clear to the enquirer. Professional opinion can be given, but must be acknowledged as such. The information provided must be at a level appropriate to the enquirer and their medical understanding.

If information provided is inaccurate, incomplete or potentially dangerous, the pharmacist may be held liable for the consequences. Where a pharmacist is working for an organisation then both will be jointly liable. The claimant will then have the option to claim damages from any one of them or both. The enquirer can also be contributory negligent if they have contributed to the adverse results and in this case there will be a reduction in the apportionment of liability.[70]

The potential for liability for advice given negligently exists regardless of how the response is given i.e. verbally or written or whether the service is provided without a charge or for a fee.

All staff working in an MI service should be aware of, and adhere to current codes of practice and professional guidelines. They should be appropriately trained and skilled in the field of MI (see also SHPA Standards of Practice for Medicines Information Centres).[1]

Current duty statements describing responsibilities of staff should be available within the centre and followed by all staff.

Accurate records must be maintained as they may support the defence if a claim against the service arises.

Advice from the hospital legal services, insurer or other appropriate legal sources should be available and sought if a situation of concern arises.

9.2 Special circumstances

Providing MI in some circumstances may require additional precautions.

Use of drugs outside approved indications (i.e. unregistered or 'off-label')

In some circumstances medicines are used for indications, in dosages, or administered via routes of administration, other than those approved by the TGA. In providing this information to an enquirer it is the pharmacist's responsibility to inform the enquirer that this is not an approved use of the drug in Australia. The enquirer should be reminded of his/her responsibilities if they choose to prescribe the medicine for a non-approved indication, including the need to obtain informed consent from the patient. Also see CATAG Guiding Principles for the quality use of off-label medicines.[71]

Medicines information for legal purposes

Requests for information, or interpretation of data for legal purposes, should be handled with due care. Interested parties requesting such information include the coroner, police or health professional governance organisations. In providing a response in these circumstances the pharmacist is functioning as an 'expert witness' and may be required to provide evidence at any resulting court hearing. In handling requests for information concerning a patient's therapy the patient's confidentiality must be respected. If the information is required to support an expert witness it may be preferable to provide the information directly to them. Care should be taken to avoid any conflict of interest.

Every MI service should have a policy, approved by management, about how to deal with enquiries that have overt legal overtones. This policy should make clear the types of enquiry, the situations and conditions under which the service may become involved and any charges associated with provision of such a service. The department's policy should be made clear at the time of the initial request. If the enquiry does not meet the criteria for acceptance, it is helpful to be able to direct the enquirer to an alternative resource if one is available.

If this work is to be undertaken, it should be ensured that the provision of information for legal proceedings is included in the job description. This will ensure that the activity is covered by employers' liability if work of this nature is conducted in work time. The individual pharmacist should also ensure they are covered by their professional indemnity insurance. It may also be appropriate to discuss this kind of work with the employer's legal team before accepting the enquiry. In addition, the medication-related expert statement needs to be accompanied by an expert evidence statement that includes:

- the name and primary professional address (including email) of the MI pharmacist, their qualifications and areas of expert knowledge related to the report (e.g. pharmacology)
- their curriculum vitae
- the sources of information relied upon at the time of writing this report e.g. the deceased's medical records, autopsy reports, pathology results (including drug levels), and extensive bibliographic and other drug information resources

- acknowledgement for the purpose of Rule 31.23 of the Uniform Civil Procedure Rules 2005[72], that he/she has read the expert witness code of conduct in Schedule 7 to the said rules and agree to be bound by it
- acknowledgement, by virtue of section 110A(6C)(c) of the Justices Act 1886 (or the package of legislation that is appropriate to the state where the MIC presides) that:

  - the written statement by the MI pharmacist dated xxxx and contained in the pages numbered xxxx is true to the best of their knowledge and belief; and

  - he/she makes this statement knowing that, if it were admitted as evidence, he/she may be liable to prosecution for stating in it anything he/she knows as false.

Providing MI to the police

Enquiries from the police are usually concerned with identifying drugs or medication. Providing information from sources within the public domain, such as the AMH or MIMS, is not a breach of confidentiality. However, when dealing with enquiries of this nature, or any enquiry concerning a third party, the legitimacy of the request should be considered along with the best interests of the patient. In the absence of patient consent it is reasonable to ask for written confirmation that the information is needed in connection with a crime. Note that police have legal rights to subpoena health professionals to provide requested written reports and/or appear as an expert witness in court.

Also see the SHPA Medicines Information Training Workbook Tutorial 6: Ethical Dilemmas.

Providing MI to the media

The media may request general background information or a professional opinion on any medicines or poisons related issue. On the other hand, the MI may wish to use the media to convey a message to the outside world.

In general, dealing with the media is the responsibility of the employer's public relations department. It is important to be aware of the employer's policy on dealing with the media and to adhere to it. If requested to provide information to the media, local procedures with regard to prior approval of the hospital administration or equivalent should be followed.

Social media

If the MI service wishes to publish information using social media (such as Facebook, Twitter, Instagram or YouTube), all legal and ethical principles and codes of conduct relating to pharmacy must be upheld. See Pharmacy Board of Australia Social media policy. Patient and institution confidentiality must also be adhered to. Any material that is posted on social media should be publicly available and within the pharmacist's range of expertise. The service should be very cautious about or refrain from taking medicines information queries via social media due to the limitations in gathering all required data and risk of third party enquiries. See *9.4 Communicating with patients* on page 52.

Providing MI to pharmaceutical companies

Pharmaceutical companies may occasionally request information about a particular drug – who prescribes it and how much is dispensed over a period of time. These requests potentially breach prescriber and institution confidentiality and should be politely declined or referred to the Director of Pharmacy, hospital executive or approved delegate.

Bulletins and publications

Local procedures should be in place for the research, compilation, production and checking of such publications. The process should aim to minimise any risk of error and include documentation that such a procedure has been followed. If an error occurs in a publication originating from an MI service the concept of negligence may apply (i.e. if a patient suffers injury as a result of an error the author may be held legally responsible), whether or not a disclaimer has been used in the publication. Measures should be taken to withdraw the publication, correct the error and minimise the risk associated with the error as soon as it becomes apparent. Management and the insurance provider should be made aware of the error and it may be

appropriate to report it as an adverse event, or risk of such, according to the institution's policy.

9.3 Ethical dilemmas

Ethical dilemmas are not uncommon in the course of MI, particularly with regard to patient confidentiality, enquiries from patients and those that potentially impact on the relationship between the patient and medical, nursing or allied health staff responsible for their care. It is important to adhere to the basic ethical principles outlined above. Time should be taken to consider any ethical issues. If necessary, advice from more experienced colleagues, managers or legal input should be sought.

See also SHPA Medicines Information Training Workbook Tutorial 6: Ethical Dilemmas.[11]

9.4 Communicating with patients

Enquiries from patients generate the majority of ethical dilemmas. Members of the public may be unable to provide all the information needed or explain their problem in a way that is readily understood. Conversely, they are often unfamiliar with medical concepts such as risk, regulatory issues and healthcare politics and may have difficulty interpreting information received. See *3.1 Provision of MI to consumers* on page 10 for additional information.

It is important to be aware that they may be seeking a second opinion on information provided by another healthcare professional, and may withhold some details of their case. Caution is advised, as there is an obligation not to undermine the relationship between the patient and their treating physician or other healthcare staff.

Public domain information

Much of the information used in MI is in the public domain and therefore not confidential and essentially available to everyone. However, there should be consideration of the fairness of providing such information, the appropriateness of providing it, and sensitivity to the consequences of the patient being made aware of the information. The patient may be referred to their treating physician or other healthcare professional if deemed more appropriate.

Patient confidentiality

A breach of patient confidentiality occurs when a healthcare professional caring for a patient reveals privileged medical or personal information to a third person who is not involved with the healthcare of the patient. Breaches of confidentiality are very serious disciplinary offences and so it is important to understand this definition and its implications.

Confidentiality is breached if the privileged position of a pharmacist is used to divulge information from the patient's notes or data provided by a fellow professional caring for the patient. It may also be breached by indiscriminately sharing information from pharmacy dispensing software about an individual patient's discharge or outpatient prescription.

While information gained from public domain resources does not breach confidentiality, this does not endorse the routine answering of these types of enquiry. It needs to be determined whether, it is fair that the enquirer should know this information and if it is in the best interest of the patient.

Third party enquiries

Third party enquiries are those where one member of the public asks a question about medication being taken by another person. Generally, the rule should be not to answer an enquiry about a third party, unless the enquirer is a healthcare professional caring for the patient. There are rare exceptions. If it is judged that the circumstances justify providing information to a third party, supporting reasoning should be documented.

For some examples of considerations with regard to third party enquiry scenarios refer to the SHPA Medicines Information Training Workbook Tutorial 6.[11]

9.5 Healthcare professional/patient relationship

There is a duty to protect a patient's relationship with other healthcare professionals. The personal interplay between professional and patient is a vital part of many successful healthcare interventions. As soon as there is mistrust, this relationship could collapse, perhaps to the patient's detriment. Other professionals should not be overtly criticised, however apparent mistakes or misunderstanding must be corrected in the best interests of the patient. Pharmacists should never assist healthcare professionals to deceive or lie to a patient.

Enquiries from hospital inpatients and outpatients

These could effectively be a 'check' upon a hospital doctor's competence. For anything more than simple enquiries patients should be advised to raise queries with the team treating them in the first instance; the team can then refer on to MI if appropriate. Involvement of all three parties in this type of enquiry is ideal.

Enquiries from patients involving legal action

It is prudent to take advice before becoming involved in this type of enquiry. See *9.2 Special circumstances* on page 50.

Clinical trials

Requests for information from clinical trial participants concerning any aspect of the clinical trial should be referred back to the trial co-ordinator. Clinical trial protocol covers informed consent and information provision to participants, any supply of information outside of this process may compromise informed consent and breach clinical trial protocol.

9.6 Confidentiality

Information such as that supplied by pharmaceutical manufacturers including formulation data, in-house ADR data or investigational drug data, provided for the benefit of an individual patient should be treated as confidential. That is, information provided in confidence should be used for the situation it was provided for and not used for publication or disseminated further without specific approval. The MI pharmacist has a responsibility to convey the confidential nature of the information to the enquirer for whom the data was obtained.

Information relating to patients should be treated as confidential. When using patient specific information, other than in relation to the treatment of that patient, such as in-house lectures, the patient's identity should be withheld. Patient consent is required for publications.

Similarly the identity of an enquirer should be treated as confidential or withheld from a second party unless specific approval obtained from the enquirer first.

9.7 Acceptance of gifts or benefits

Acceptance of gifts or benefits, other than tokens of minimal value such as flowers or chocolates, may place the MI pharmacist in a position of actual, potential or perceived conflict of interest.[67] Declaration of competing interests are required in many situations. Pharmacists must always exercise professional autonomy, objectivity and independence and manage actual and potential situations of conflict of interest.[69] It may be misconstrued that accepting a gift allows the giver to receive preferential treatment in the future. Some organisations may have local policies offering guidance to staff to avoid actual or perceived conflicts of interest from gifts of a non-token nature.

9.8 Copyright law

Copyright law covers a broad range of material with the purpose of protecting the creator's creativity or intellectual effort. It enables the creator to exercise some control over possible exploitation of material they have created. Copyright law seeks to protect the creator's need to be rewarded or recognised when their work is reproduced while still enabling access to the material by potential users.

For copyright protection to be conferred in Australia, one of the following conditions need to be met:

- the creator must be a citizen or resident in Australia or a country to which our Act extends, or
- the work must be first published in a country to which our Act extends.

The material must be original but not necessarily unique or novel. Copyright protection is free, automatic, and material is protected from the time it is first written or recorded. Creators do not need to make application for copyright protection.

Guidelines

A copyright owner is entitled to take legal action against a person who infringes their copyright. Unauthorised copying may infringe the copyright of that work unless it is otherwise permitted by the Copyright Act.[73] However, where it is considered 'fair dealing' under the Act, the making of that copy is not an infringement.

With regard to the provision of MI; copying work, issuing copy of work or adapting original works without permission, licence or an exemption such as 'fair dealing' may be an infringement of copyright. 'Fair dealing' means that the creator would not be unfairly deprived of a reasonable financial or creative return on their work which was copied or disseminated.

It is considered 'fair dealing' to make a copy for the purpose of research or study under the following circumstances:[74]

- one or more articles on the same subject matter in a periodical publication
- in the case of any other work a 'reasonable portion' of that work. For published work greater than ten pages a 'reasonable portion' is considered to be 10% of the total number of pages, or one chapter if the work is divided into chapters
- for more extensive copying, clarification should be sought as to whether requirements of 'fair dealing' are being met.

Commonwealth, State and Territory Government departments and agencies (the Crown) **are eligible** to copy and communicate under the Statutory Government Licence provided the activity is for the services of the Commonwealth or State and/or Territory.[75]

With regard to the provision of medicines information and complying with copyright requirements the following guidelines may be useful:

- copies of published material should be supplied only when specifically requested for the purposes of private study or research. Research means 'diligent and systematic enquiry or investigation into a subject in order to discover facts or principles…'
- the requirements of 'fair dealing' as described above must be adhered to when making a copy of work
- when making a copy of an article for an enquirer or other person only one copy may be made, i.e. a second copy should not be made for the file or vice versa
- multiple copies should not be made without permission of the publisher or copyright holder
- copying or adapting computer programs without permission is an infringement of copyright. Adhere to licence agreements with regard to networking or sharing resources
- when using licensed e-resources, confirm the digital rights associated with the e-resource.

Information about copyright can be obtained from the Australian Copyright Council.[76] All librarians should also be able to provide advice and guidance on matters of copyright or provide a copy of the current Copyright Act and Regulations.[73, 76, 77]

10•QUALITY ASSURANCE AND SERVICE IMPROVEMENT

Quality assurance (QA) is a management technique used to ensure the quality of practice and outcome. It defines expectations and creates an awareness of quality and establishes a process of accountability. An MI service aims to achieve quality use of medicines by providing and communicating timely, accurate, balanced and comprehensive information about medicines and their usage. MI services and the use of QA and service improvement aligns well with the Australian Safety and Quality Framework for Health Care's second core principle of 'driven by information'.[78]

To ensure best practice, a systematic process for quality monitoring, development and problem solving is required. Activities should focus on improving the current standards, not merely maintaining them. Identified problems should be documented and reported. Routine quality activities can highlight areas of concern that require further investigation. A quality improvement program should be implemented by all services to ensure that practice standards are met and regularly evaluated.

A QA program should be proactive, encouraging routine collection and analysis of data, and providing a systematic ongoing process of review of the centre's work and functions. It is ideal that QA has both internal and external input.

The procedures in this section should be read in conjunction with the Australian Commission on Safety and Quality in Health Care (NSQHS) - *National Safety and Quality Health Service Standards* Version 2 which includes discussion of quality assurance objectives.[79]

The Australian Commission's standard includes the Standard GS: Governance for safety and quality which states that the '*leaders of a health service organisation implement governance systems to set, monitor, and improve the safety and quality performance of the organisation. Leaders of a health service organisation communicate the importance of partnering with consumers and ongoing quality improvement. The workforce uses the governance systems.*' The intention of the standard is to '*create integrated governance systems that maintain and improve the reliability, safety and quality of health care, and improve health outcomes for consumers.*'[79]

In addition to these standards and this section in the procedure manual, the United Kingdom Medicines Information (UKMi) has a QA program in place to ensure a high quality service is delivered by all UK MICs to their service users. UKMi is the UK National Health Service pharmacy based service which aims to support the safe, effective and efficient use of medicines by the provision of evidence-based information and advice on their therapeutic use. Their QA program includes UK national standards for enquiry answering, education and training, clinical governance, publications and risk management in MI. These standards are available at www.ukmi.nhs.uk.

Quality assurance programs should be viewed as advising, enabling and a lever for service improvement.

The objectives of a QA program are to:

- identify key areas of MI practice
- identify key performance indicators for these areas
- establish minimum acceptable levels of performance for these indicators
- identify opportunities for improvement
- develop and implement plans for improvement.[1]

10.1 Procedures

Assessment of quality can be divided into structure, process and outcome.

Key areas of MI can be identified within these divisions:

Structure	Process	Outcome
Resources (including staff)	Documentation (verbal and written replies)	Provision of response
Facilities	Receiving enquiries	Patient outcome
Organisation	Resource searching	
	Data collection	
	Evaluation and assessment of available information	
	Formulation of response	

Structure assessment examines the organisation, facilities and resources (including staff) involved in providing MI services. Process assessment reviews the activities involved in providing MI and outcome assessment reviews the end results of the process. Performance indicators for the process and outcome of MI are required.

STRUCTURE ASSESMENT

Staffing numbers, office equipment and resources are determined by the size of the institution where the centre is based and the clientele using the service.[1]

Resources

See *2.2 Staffing* on page 5 for staff qualifications and experience and *4.1 Formal, informal and local training* on page 12 and *4.2 Current awareness and skill maintenance* on page 13 re training of staff.

Reference material

See *INFORMATION RESOURCES* on page 27. In developing a reference library, services should be guided by availability of an individual resource, the nature and scope of the service they provide, and any regulatory requirements in their jurisdiction of practice.

Facilities

See *2.5 Location of the centre* on page 6 and for other non-human resources see *2.3 Resources* on page 5.

Organisation

Staff requirements should reflect the scope and workload of the service. See *2.2 Staffing* on page 5 and SHPA Medicines Information Standards of Practice for additional information.[1]

Policy and procedure manual

See *2.6 Key operating requirements* on page 7.

PROCESS ASSESMENT

Process assessment reviews activities involved in the provision of MI. These include:

- documentation
- receipt of enquiries
- resource search
- data collection
- evaluation and assessment of data
- formulation of replies.

Audits to review the quality of enquiry answering should be held.

Process assessment criteria used in UKMi audits are based upon scores for documentation, analysis, coverage and enquiry answer.[62]

The following table is from the UKMi audit tools:

	CORRECT – score 5	INCOMPLETE – score 1-4	INCORRECT – Score 0
Document-ation (Standards are the same for all levels of complexity)	Record is complete *i.e.* • legible; with correct spelling and no unfamiliar abbreviations; • enquirer details complete (full name, address/contact). • patient's details are present if relevant, • the question is documented to allow a third party to tackle it without further contact with the enquirer; • details of resources are complete; • names of others contacted with regard to the enquiry are recorded; • there is a concise summary of the answer.	Record is complete to the extent that • it is legible, • enquirer details are sufficient to permit the enquirer to be traced, or a statement that enquirer wished to remain anonymous is present. • a summary of the answer is present, but there are one or more deficiencies, e.g. as follows: • enquirer details are incomplete, e.g. first name and department only, • patient details (if appropriate) are missing or incomplete, • documentation of resources used is incomplete.	There are key omissions *i.e.* • the record is illegible • contact name and/or means of contact are missing. • the question and/or answer cannot be understood.
Analysis (As above)	The form shows evidence that the question has been fully understood, and that sufficient, relevant background information has been obtained.	Some relevant information (useful but not essential) is missing which may have assisted in providing a more comprehensive answer. Implications of enquiry not fully understood.	Question does not appear to have been understood, no background information. Omissions in enquiry.
Coverage (Standards depend on level of complexity)	**Level 1** – ***Simple enquiries - answered using data from one or two standard sources.***		
	Shows evidence of use of relevant authoritative resources or (if appropriate) accurate and up-to-date personal knowledge.	Accurate but not comprehensive personal knowledge used. Answer might have been improved by use of additional/alternative resources.	Inaccurate personal knowledge used. Answer not supported by relevant resources.
	Level 2 – *Complex enquiries – requiring the use of multiple and more specialist sources where the available evidence provides a reasonably clear answer or course of action.*		
	Relevant authoritative general resources have been used. In addition, databases, in-house files and more specialised resources have been used where appropriate. It is unlikely further useful information would be gained by further resource use.	There is evidence appropriate resources have been used but omissions are apparent, and/or resources have not been used in a systematic fashion (*i.e.* authoritative references first, then more specialised resources if needed). Useful information may have been missed.	Key texts appear to have been omitted. It is likely that important information has been missed.
	Level 3 – ***Complex enquiries – in the absence of a clear answer or course of action from available sources, professional judgement is used to provide advice to the enquirer. This may require the specialist evaluation of multiple sources and the evaluation of primary literature.***		
	As for level 2. In addition, where necessary, a thorough search of the literature has been conducted.	As for level 2, and/or incomplete use of bibliographic databases where use of these was necessary.	Key resources omitted. It is likely that *important* information was missed.
Answer (Standards depend on level of complexity)	**Level 1** – ***Simple enquiries - answered using data from one or two standard sources.***		
	Evidence that the answer is accurate and based on comprehensive knowledge supported by appropriate resources where necessary. The answer has been communicated at a suitable level (use of language) and by an appropriate method.	The answer appears to be accurate and supported, but there may have been some problems, *e.g.* as follows: • level of detail inadequate; • inappropriate level/ method of communication.	The answer is inaccurate, or the enquiry has not been answered at all, and/or there has been a serious failure in communication.
	Levels 2 and 3– *Complex enquiries – multiple sources and professional judgement*.		
	Evidence that comprehensive knowledge and thorough consideration of the issues have been used. The information has been evaluated in a logical fashion. Skill in interpreting the information and application to individual circumstances are demonstrated. Calculations are correct. The answer has been communicated at a suitable level (use of language) and by an appropriate method.	Accurate information has been supplied but there are deficiencies *e.g.* in one or more of the following areas: • some issues relevant to the answer have been overlooked; • the information has been passed on without evaluation, or insufficient evaluation; • level of detail inadequate; • inappropriate level/ method of communication.	The answer is inaccurate, or the enquiry has not been answered at all, and/or there has been a serious failure in communication.

OUTCOME ASSESMENT

Outcome assessment reviews the results of providing MI. Feedback forms and surveys will give an indication of the service provided. It is recommended that enquirers, i.e. people using the service, be given the opportunity to provide feedback or their assessment of the service provided.

Feedback forms include questions on the usefulness, timeliness, presentation of replies and how the information was used can be used to survey the perceived quality of the service for both telephone and written replies. In addition, enquirer feedback forms assist in assessing the impact of the service on patient care.

It is recommended that feedback forms may be included with written replies. The data provided can be used during the review process (see below). An appropriately designed electronic survey tool may provide a suitable alternative to paper-based systems.

Follow-up of verbal replies via survey is also recommended. These data can be used during the review period and will also provide a more continuous indication of the quality of the service provided. Sample selection may be performed a number of ways (e.g. a percentage of enquiries (every 10th enquiry) or a quarterly survey carried out on enquiries received during one week of the quarter).

A copy of the UKMi Medicines Information User Survey is shown at Appendix 1: Medicines information user survey. User Survey Guidance advice is also available on the Clinical Governance section of the UKMi website to assist with the use of their validated tool.

10.2 Service reviews

Workload statistics

Workload statistics are useful to determine the number of enquiries handled by the centre, who the enquirers are, the types of enquiries, the resources used to formulate a response and the time taken to reply. These data should be reviewed or assessed regularly. In addition, statistics should be reviewed annually to assess trends in activities.

Quantity of work is not an indicator of quality and impact on patient care and thus workload statistics cannot be used alone as a quality or outcome measure.

Peer review

Peer review is an essential method of assessing the quality and effectiveness of the service. It also provides ideas for improvement and future development of the service.

This topic is comprehensively covered by the UKMi **-** Clinical Governance Working Group Peer Review Good Practice Guidance document which we have adapted below.

PEER REVIEW GOOD PRACTICE GUIDANCE

The purpose of this section is to provide guidance about how systems of peer review could be implemented. Internal and external peer review models will be discussed.

See Table 2 for advantages and disadvantages of each model.

All services require a systematic process for quality monitoring, development and problem solving to promote high quality service delivery. Quality assurance (QA) activities should improve rather than maintain current standards with identified issues documented and reported. Routine quality activities may highlight areas of concern that require further investigation.[1]

Each centre's QA activities are a part of a risk management strategy to ensure minimum standards are being met for enquiry answering and other regular activities.

Internal and external peer review

Peer review is one way of monitoring the standard of enquiry answering provided by MI services against agreed enquiry answering standards. It is recommended that as part of the QA program all MICs undertake regular peer review as this provides an additional tool to reduce the risks associated with the enquiry answering processes.

Peer review in MI primarily focuses on the enquiry answering process, but may be an opportunity to discuss other areas of the MI service provision in relation to the SHPA Standards of Practice for Medicines Information and National Safety and Quality Health Service Standards.[1, 79] The scope of a peer review should be clearly defined before it is undertaken. The aim of peer review is to encourage the sharing of experience, knowledge and expertise amongst MI staff. The spirit of the discussions should be non-judgemental and focus on professional support of colleagues.

It allows:

- regular objective feedback on performance
- feedback and suggestions on improving the quality of service
- sharing of ideas and learning from colleagues
- development of own practice and service
- identification of learning needs.

UKMi provide the following tools for conducting peer review of an enquiry answering service:

- Definition for ranking enquiries
- Summary of criteria for grading answers to enquiries using documented evidence
- Enquiry assessment form.

These tools focus on four aspects of the enquiry answering process- documentation, analysis, coverage, and answer. Centres may choose to use similar tools for assessment to ensure standardisation and appropriate documentation of peer review.

Some suggested models for internal peer reviews are:

a) Manager led

1. The MI manager selects a sample of completed enquiries for assessment - either a set number of enquiries or percentage of enquiries. The sample selected could be such that enquiries done by every individual staff member are included.
2. The MI manager assesses the enquiries against the tools for peer review described above.
3. For enquiries that the MI manager has completed themselves - other members of the MI team could assess these enquiries or where the MI manager is the only staff member in MI – colleagues outside of MI such as clinical directorate pharmacists could be asked to assess the enquiries, using the set documentation, relevant to their clinical expertise. Non-MI staff may need training on how to assess enquiries using the tools for peer review described above.
4. The comments and scoring of the enquiries are documented on the standard enquiry assessment forms .
5. The results are reviewed by the MI manager and can be fed back to individuals as a way to provide personal learning points and/or incorporated into a report that is circulated to the team which would provide a way of monitor performance of the MI service over time.
6. Enquiry peer review could be carried out at regular monthly or 3 monthly intervals depending on staffing and enquiry numbers.

b) Team involvement

1. All MI staff will receive training on how to assess enquiries using the tools for peer review described above during their induction programme. This increases awareness of standards throughout the MI team.
2. The MI manager selects a random sample of completed enquiries for assessment - either a set number of enquiries or percentage of enquiries could be used. The sample selected could be such that enquiries done by every individual staff member are included.
3. The MI manager then allocates the sample of enquiries to the MI team or other members of the wider pharmacy team who answer MI enquiries; ensuring that individuals are not asked to assess their own enquiries. This approach provides an opportunity for MI team members to learn from their colleagues' enquiries.
4. Enquiries are assessed against the tools for peer review described above.
5. The comments and scoring of the enquiries are documented on the standard enquiry assessment forms and given back to the MI manager.
6. The results are reviewed by the MI manager and can be fed back to individuals as a way to provide personal learning points and/or incorporated into a report that is circulated to the team which would provide a way to monitor performance of the MI service over time.
7. Enquiry peer review could be carried out at regular monthly or 3 monthly intervals depending on staffing and enquiry numbers.

c) Service user feedback

An extension of models a and b would be for the MI manager to also send out a user satisfaction survey to all the enquirers involved in the sample of enquiries selected for peer review. The results of the returned surveys could be compared to the results from the internal assessment to provide an added dimension to the feedback provided to individuals and also provide a way to monitor performance of the MI service over time. Centre-specific user satisfaction surveys can be used or other published surveys such as the UKMi user satisfaction survey may be used.

Group discussion

Each member of the MI team selects a set number of his or her own enquiries to bring to a peer review session. Selection criteria could be left to the individual or pre-set by the manager - for example interesting enquiries, enquiries that were challenging, enquiries about specific topics such as adverse drug reactions, pregnancy etc.

The MI team will assess the enquiries against expected standards through group discussion, using tools for peer review described above.

The comments and scoring of the enquiries are then documented on the standard enquiry assessment forms.

The peer review session could be carried out at regular monthly or 3 monthly intervals depending on staffing and enquiry numbers.

External Peer review

External peer review involves staff from different local MI centres within a region peer reviewing their colleagues. The following are suggestions of how systems of external peer review could be implemented by regional MI centres. This list is not designed to be exhaustive and should be adapted to suit the geography of the region, the set-up of the individual MI centres, and according to the staffing and time available. See Appendix 2 for examples of these models that are already in place.

1) Peer review visits

A lead person would need to be responsible for overseeing this process and MI centres within a reasonable travelling distance should be involved; this would require the agreement of the Senior Pharmacy managers. Ideally groups and pairings would be changed on a periodic basis so centres have the chance to visit different MI centres to increase sharing of practice and give the MI managers a wider perspective.

Paperwork used, schedule and procedure that should be followed should be produced by the lead person and used as a standard for all centres.

- Each MI manager or suitably qualified member of the MI team visits another MI centre for half a day once a year to peer review the centre, and if possible, each MI manager receives a visit from a different manager or suitably qualified member of the MI team each year.
- The main focus of the visit is to assess a random sample of enquiries - either a set number or a set percentage of the year's enquiries could be used.
- The enquiries should be assessed by the two managers together against the standards using tools for peer review described above.
- The comments and scoring of the enquiries are documented on standard enquiry assessment forms.
- If time allows, the rest of the visit should be a general discussion/sharing of ideas about the service provided including resource holdings, standard operating procedures in place, staffing, training etc.
- After the visit, the visiting MI manager collates results of the enquiry assessment and notes from the discussion into a standard report form. Copies of these reports are then sent to the host MI manager for comment. An additional approach (if a number of centres were using peer review visits), would be a discussion about results within the SHPA Committee of Specialty Practice (Medicines Information) as there are possible similarities between those and other centres. This may be especially useful for ongoing unresolved issues.

This approach allows greater collaboration giving services and opportunities to share practice and ideas whilst closely monitoring the quality of the service.

2) Regional meetings

Peer review sessions could be incorporated into the agenda of a regional network or medicines information special interest group. These sessions would probably need to be at least an hour in length.

- Each MI staff member attending would bring a set number of enquiries to the meeting that they would like to have reviewed/discussed by other people. Selection criteria could be left to the individual or pre-set for example interesting enquiries, enquiries that were challenging, those that were on a specific topic such as adverse drug reactions, pregnancy etc. The questions for review/discussion would be distributed at least one week prior to the meeting.
- Explanation of the documentation involved and how to assess enquiries may need to be covered depending on how often these sessions are done and if there are new staff present.
- Depending on the number of attendees the staff would be split into small groups for the purposes of review and discussion. These groups could also be identified prior to the meeting to allow the staff to share their enquiries with their small groups before the meeting. This would allow them to have more time for discussion at the meeting itself.

- The groups would then assess the enquiries against accepted standards by discussing them, using tools for peer review and assigning scoring.
- The comments and scoring of the enquiries would be documented on the standard enquiry assessment forms.
- If there are multiple groups an open feedback session could be used for sharing learning points/problems/questions etc.

These sessions could be included in the network meetings on a regular basis depending on how often the meetings usually take place and number of attendees. Alternatively a similar process may be incorporated into a national meeting. The length of time allocated to the session would be determined by how often they were included in the meeting and the number of attendees.

The advantage of this approach is that it should increase awareness of standards across regions or the nation, and provides an opportunity for learning/practice sharing with colleagues.

Table 4. Advantages and disadvantages of various models of peer review

Model		Advantages							Disadvantages		
		Provides Individual learning points/feedback/development of own practice	Can monitor performance of MI service over time – allows review between audit visits.	Increased awareness of standards throughout the team	Feedback from the users of the service	Learn from colleagues' enquiries/ sharing of ideas/practice amongst colleagues and across centres	Allows focus on a clinical topic	Allows development of the service	Not random – problem enquiries may not be selected	Staff can feel that they are being criticised	Time consuming for the manager
Internal Peer Review	1a) Sample enquiries: Manager Led	√	√			√		√			√
	1b) Sample enquiries: Team involvement	√	√	√		√		√			
	1c) Sample enquiries: User feedback	√	√	√	√	√		√			√
	2) Group discussion	√		√		√	√		√	√	
External Peer Review	Peer Review visits	√	√			√		√		√	√
	Regional Network Meeting	√				√	√		√	√	

11•EPILOGUE

Pharmacists provide medicines information to health professionals or patients to ensure the safe, rational and cost-effective use of medicines. While most pharmacists are equipped with a basic knowledge regarding the practice of medicines information, the ever-expanding list of pharmaceuticals, as well as the overwhelming amount and varying presentation of clinical data, makes it difficult for practitioners to remain up-to-date with many advanced concepts and developments. Skills to enable critical analysis of the vast quantity, quality and variety of information now available may also be inadequate. Therefore, MI as a service and practitioner specialty is a highly differentiated area contained within clinical pharmacy practice.

More advanced problem-solving skills and access to specialist resources are required to respond to complex questions that challenge practitioners today. This requires collaborative work between MI pharmacists and other healthcare professionals in order to provide appropriate responses. The use of an MI pharmacist's retrieval, analytical and dissemination skills enables systematic, practical and timely input to complex and often unique clinical questions. MI pharmacist's input remains invaluable to direct patient care at an individual and population level, for medication use policies, medication safety, medical writing, informatics and other quality use of medicine initiatives.[9, 10, 14-20]

Appendix 1: Medicines information user survey

UKMi
UK Medicines Information

Medicines Information User Survey

Enquiry number:_____

Summary of enquiry:

_____

Your enquiry

1. Were you able to contact us easily by phone, email or in person? Yes ☐ No ☐
2. Did our staff interpret your needs correctly? Yes ☐ No ☐
3. Was a deadline agreed for a reply? Can't recall ☐ N/A ☐ Yes ☐ No ☐

Our response

4. Did you receive the answer by the agreed time? N/A ☐ Yes ☐ No ☐
5. Did our response answer your question? Yes ☐ No ☐
6. Did we offer practical advice where appropriate? N/A ☐ Yes ☐ No ☐
7. Did we give you enough detail? Yes ☐ Not enough ☐ Too much ☐
8. Were you confident in the answer we gave you? Yes ☐ No ☐

Outcome

9. Did our answer contribute to patient care? N/A ☐ Yes ☐ No ☐
10. Would you use the service again? Yes ☐ No ☐

Overall rating

11. Overall, what is your opinion of the Medicines Information service provided at this centre? Please circle the number that most closely represents your view.

Poor	1	2	3	4	5	6	**Excellent**

12. What can we do to improve the enquiry answering service? Please give us your ideas or any comments you may have below:

_____

_____

_____

Appendix 2: Internal peer review, examples of models used locally

These examples may be useful to either adopt or adapt, dependent upon service requirements.

Site	Model
Austin Hospital MI	All enquiries are reviewed by a second MI pharmacist.
Drug & Therapeutic Information Service (DATIS)	Monthly peer review audits of a random selection of 10% of the total number of enquiries answered over the prior month are undertaken by DATIS staff. An audit form is utilised with some data prefilled for the reviewer such as enquiry ID, audit date, pharmacist's name, time received, patient related, time spent, enquiry answered, call-back and documentation. The reviewer's audit documentation includes information about whether animal or in-vitro information is used, timeliness, irrelevant information and scores for background information, search strategy and response. The QA program also seeks feedback via survey from the enquirers of these randomly selected enquiries with respect to satisfaction, timeliness and patient outcomes.
Hunter Drug Information Service (HDIS)	All enquiries are reviewed by another MI pharmacist. All enquiries are reviewed at a weekly QA meeting within the Department of Clinical Pharmacology. User Satisfaction Surveys are emailed to every tenth enquirer and every new user.
South Australia MI	Meet fortnightly with the Royal Adelaide Clinical Pharmacology Unit for review of completed MI enquiries. The meeting is attended by at least one pharmacology consultant (up to 3) and 2 pharmacology registrars, in addition to MI staff. A few days prior to the meeting, the titles of all of the MI questions are sent to the invited attendees. During the meeting, clinical pharmacology select enquiries for review based upon the title of the enquiry and then review the response. All levels of enquiries are included for review and it is intended that at least 10% of all level 3 enquiries be reviewed each month. Level 3 enquiries are defined as those requiring any degree of interpretation or advice in addition to either a thorough literature search (in a database such as Medline or Embase) or more than 8 resources used for the response.

Site	Model
Westmead Hospital MI	All enquiries are reviewed by a second MI pharmacist. An additional internal peer review process utilising departmental pharmacists as reviewers is used. This review process occurs preferably monthly. An enquiry suitable for review when its number is randomly generated from the month's enquiries is: • an enquiry that has been completed and filed AND • has taken over 20 minutes to complete AND • has been completed by one of the MI pharmacists. Exclusions of enquiries from this process include: • article retrieval • article or publication/guideline writing. A printout of the reply as well as screen shots of all aspects of enquiry (e.g. statistics) is included for information to the reviewer. Hard copies of all attachments or additional information files associated with the enquiry are given to the reviewer. All enquirer, responder, clinical advice and patient details are de-identified, however titles such as intern, nurse, consultant etc. are retained/ included. An answer assessment form that has been adapted from the UKMi audit tools and weighted appropriately is used for scoring. This also provides an additional guide to assist reviewers with their detailed analysis. The use of this process enables both qualitative and quantitative feedback to be obtained.

Internal Peer Review: examples of models used overseas

London MI Service (Northwick Park Hospital)

The following section explains the responsibility of the MI Manager:

1. In the first week of each month, divide the total number of enquiries for the previous month by 20 to obtain a random sample of enquiry numbers. e.g. 100 enquiries for the previous month will mean every 5th enquiry is used for the internal QA.
2. The total number of enquiries for the required month can be obtained using MiDatabank search function – date range tab.

   a. Enter the start & end date using the drop down calendars i.e. 1st and last day of the month for which you are going to QA .
   b. Use the figure given as the total to randomly select the QA sample.
3. Find the 20 completed enquiries from the list displayed according to the numbers worked out above.

   a. Completed enquiries will have a letter A next to the title. If the enquiry that should be selected is not completed go to the next sequential enquiry.
   b. View each completed enquiry on screen by double clicking on the enquiry line.
4. Assign 5 enquiries to each member of the MI team. The member of staff assessing the completed enquiry *must not* have had any involvement in the enquiry itself and the enquiries should be assigned as such. Where this is not possible, a member of the MI team who has not been working in the area for the month in question should be approached for assistance in assessing the enquiry.
5. The relevant MI staff should then be emailed indicating which 5 enquiries they are to assess. The email must include a master copy of the assessment form for electronic use and the link to this procedure.

6. Once the enquiries have been assessed and returned if an enquiry is returned with a low score, a second opinion should be obtained; a senior pharmacist should re-assess the enquiry in question and discuss the outcome with the original assessor.
7. It is at the MI Managers discretion to follow up enquiries that fall short of the UKMi enquiry answering standards.
8. The MI Manager will aim to circulate the final report to the MI team within a week of receiving all the completed assessment forms.

The following section explains the responsibilities of the MI Staff – Assessor:

1. Staff rotated to complete the internal QA for a particular month will receive an email informing them of the deadline for this to be completed. In the majority of cases it will be 2 weeks from the date of the email being sent.
2. Locate the 5 assigned enquiries on MiDatabank by using the 'search function' - enquiry number tab. View each one on screen by double clicking on the enquiry number in the search results field.
3. Complete the assessment form attached to the email and return the completed form to the MI Manager by the deadline indicated in the email.

South West Regional MI Service Peer Review Scheme

The aim of the scheme is to encourage the sharing of experience, knowledge and good practice amongst members of the MI team. It also acts as an additional checking mechanism for enquiry answering. The scheme should support clinical governance and improve the quality of our work.

Procedure:

- Each person in the group should bring with them an enquiry of their own to discuss. Topics may be specified in advance by email.
- Examine each enquiry record and assign level of complexity as per "Definitions for ranking enquiries"
- The enquiries should be discussed using the UKMi QA tool – "Summary of criteria for grading answers to enquiries using documented evidence"
- Judge each enquiry against the columns "Correct", "Incomplete" and "Incorrect" and assign a score.
- Enter the scores and any comments in the spaces provided on the recording sheets.

The spirit of any discussion should be non-judgemental and focus on professional support of colleagues.

Appendix 3: External peer review, examples of models used in the UK

These examples may be useful to either adopt or adapt dependent upon the MICs requirements.

London MI Service (Northwick Park)

Peer Review Visits

Background

An annual Peer Review visit of each MIC within the London (Northwick Park) network forms part of the QA program in place to monitor the standard of MI services against the UKMi QA Standards. All MICs also receive an audit visit from the regional team at least every three years. The main focus is the enquiry answering service, but discussion of Education and Training in MI, and Clinical Governance (including risk management) issues is also included, as well as more general discussion.

Participation

All MICs are required to participate.

The centre makes the statement that they appreciate that workload and staffing situations can make participation difficult but consider peer review an essential part of ensuring the quality of MI services and development of MI staff. If participation is difficult for reasons such as long term sickness of the MI manager or long-standing recruitment difficulties it is discussed with the Senior Pharmacy Manager initially and then the lead at the regional centre to determine a suitable way forward.

Benefits of annual peer review

The aim of the peer review visits is to encourage the sharing of experience, knowledge and expertise amongst MI staff. The spirit of the discussions should be non-judgemental and focus on professional support of colleagues.

- √ Regular objective feedback on performance
- √ Improved quality of service
- √ Sharing of ideas and learning from colleagues
- √ Development of own practice and service.

Requirements for conducting a visit

The individual conducting a peer review visit must meet the following criteria:

- √ an MI Pharmacist who has at least 2 years MI experience and/or who has attended the National Introductory Medicines Information Training Course and/or who has attended an orientation visit at the regional centre
  OR
- √ a UKMi Accredited Medicines Information Technician.

Schedule for visits

All visits should be undertaken according to the Peer Review Visits Schedule. All visits should be planned well in advance at a mutually convenient time.

Time required

When conducting a visit at another MI service, it should be borne in mind that time is required prior to the visit for preparation, writing the report after the visit as well as the time required for the visit itself. The total amount of time required is therefore approximately 1½ to 2 working days. Less time is required when being visited.

Terminology

During the rest of this example, the following terminology will be used:
Reviewer = the individual conducting the visit
Host = the host

The Peer Review Visit

A. Preparation before the visit

The host should ensure that the following have been completed or are available:

- action points from the most recent QA report are revisited and a copy of the report is emailed to the visiting pharmacist one week before the visit, and made available during the visit.
- action points from the most recent Peer Review report are revisited and a copy of the report is emailed to the visiting pharmacist one week before the visit, and made available during the visit.
- a copy of the procedure for dealing with enquiries in the absence of the MI pharmacist
- the essential resources checklist using the most recent 'UKMi list of essential resources for MI services' which can be found at: http://www.ukmi.nhs.uk/Policy_product/CGEnquiryAnswering.asp. A list of the resources not held should be prepared prior to the visit and made available on the day of the visit
- a workload report detailing the total number of enquiries for the last 2 financial years or a more recent comparative timescale. This should also include a breakdown by enquiry category, enquirer status etc
- a copy of the results from the most recent user survey
- details of any service developments
- a list of any points for discussion or concerns about the MI service.

The reviewer should undertake the following:

- read the most recent QA and Peer Review Reports. The host should have provided these
- familiarise themselves with the content of the report to be completed after the visit
- take a copy of these guidance notes and the report template to complete at the visit.

B. The visit

The visit will take approximately 2.5 to 3 hours, and will therefore take up the majority of a morning or afternoon session.

During each visit there should be discussion of the specified enquiry answering elements of the UKMi QA Standards as detailed below.

The Record of Peer Review Visit template should be used to record all discussions, recommendations and action points during the visit using the following guidance. It is suggested that the record of peer review template could be completed electronically during the visit, as this may help to save time.

A copy of procedures should be available for the reviewer to see. This should be noted in the record sheet. A suitable review date should be included. Arrangements for ward/annual leave cover should also be discussed. Make a note of any action points.

The review will determine that the centre holds the appropriate resources (information, IT and office equipment, staff) including:

- all resources designated as essential in the 'UKMi Essential Resources List for MI Services' are held. Any omissions would be discussed and appropriate actions agreed. Currency of editions should be included
- a selection of supplementary resources appropriate to the enquiry types commonly handled is held
- all websites/web-based resources on the 'UKMi Essential Resources List for MI Services'
- included in internet favourites or similar list, such that all MI staff can access these for enquiry answering.

IT and office equipment.

Assessment of the availability of appropriate IT, office equipment and health and safety equipment will occur.

All discussions and actions should be noted in the record of the visit.

Re: meeting the requirements of its users

The results of the most recent user survey should be noted and discussed, along with any issues raised/addressed since the last user survey. Make a note of any action points in the record of the visit.

Determination of the use of professional expertise and judgement in processing MI requests is the focus of the peer review visit and will take approximately 1.5 to 2 hours if you aim to spend 5 minutes on each enquiry. The most useful element about this section is the discussion generated during the process.

A sample of enquiries is audited against national standards using UKMi audit tools

n = 20 for peer review (locally agreed) from any level of enquiries. These are divided into level 1 (simple enquiries), level 2 (intermediate complexity) and level 3 (complex enquiries).

Documentation and analysis of enquiry must meet the standard (100%), search coverage and answer must meet the standard (95%).

The reviewer will need to be shown how to retrieve enquiries and should pick 20 at random from the previous 6 to 12 months depending on when the last visit took place (the host should help to retrieve the selected enquiries to save time). The reviewer and host should then go through each enquiry together using the following method and recording the levels, scores and comments as they go along:

- assign a level of complexity (level 1, 2 or 3)
- judge the enquiry form against the columns 'Correct', Incomplete' and 'Incorrect' and agree a score for each category
- enter any comments on why a particular score was assigned in the comments box for each enquiry next to the relevant category: D (documentation), A (analysis), C (coverage), and Ans (answer). This should include reasons for marks deducted and positive comments. Detailed notes, including a summary of the enquiry title will increase the usefulness of the report.
- calculate the scores for the 20 enquiry forms as a percentage of the possible maximum and record on the table provided and calculate the % of enquiries at each level (these calculations can be done after the visit).

Current systems used in the MIC should permit easy access to enquiry records and accurate identification of individual records with storage complying with local procedures.

Changes in parameters such as enquiry category breakdown, or enquirer status, and any service developments should be discussed during the review with comments and action points recorded.

Any proactive MI activities undertaken by the MIC is discussed with comments and action points recorded.

Additional discussions during the peer review may include:

- any action points raised at the last QA visit and/or peer review visit
- use of the competency framework
- staffing
- MI Training commitment
- training needs of MI staff
- clinical Governance issues
- risk management issues
- out-of-hours enquiries
- primary care support
- access to medical library
- involvement with local ADR reporting
- involvement with formulary work
- involvement with D & T Committee
- involvement with local PCT Prescribing CommitteesiInvolvement with Medicines Management programmes
- clinical involvement
- involvement with Patient Group Directions.

C. After the visit

- The Record of Peer Review Visit template should be used to complete the final report.
- The reviewer should complete the first draft of the report as quickly as possible after the visit (preferably within 2 weeks of the visit). This should reflect all the major points discussed during the visit.
- The draft report should be sent to the host for comments/discussion and a final version agreed. The final report should reflect the views of both the reviewer and the host.
- A copy of the final report should be sent to the lead at the Regional MIC within ONE month of the visit so that the data can be incorporated into the annual Peer Review report and support or actions required by the regional team can be addressed.
- If there are major problems or disagreements regional support should be sought.
- If it is necessary to contact someone at the regional, then the person who undertook the most recent QA visit should be the initial contact person (as they will be familiar with the MI service), although the lead for peer review can be contacted directly if necessary.
- Reports and action plans should be discussed with the relevant manager and/or SPM.
- Action points or issues of concern should be followed up/addressed as soon as possible.
- Feedback should be provided to other members of the MI team and/or the pharmacy department where appropriate.

Results of review

Following review of the service, a report should be prepared presenting the results, who carried out the assessment, suggestions for improvement and actions to be taken. Issues should be discussed with staff and a quality action plan developed. These discussions, plans, implementation and outcomes should be documented.

An annual report on the service may be appropriate. The report may include a comparison with the previous year's reviews, evidence of improving performance, priorities, responsibilities, and resolved and unresolved issues.

Appendix 4: Resources

Alphabetical collated resource list, title & format only.

Notes:

- An e-book is an online version of a book with no added functionality.
- Only title and author or online publisher are given. Medicines Information centres and units are expected to have the most recent version or any resource held.

- A.S.P.E.N Adult Nutrition Support Core Curriculum. [Online]
- A.S.P.E.N Parenteral Nutrition Handbook. (Ayers P, Guenter P, Holcombe B, Plogsted S, eds.) [Text,e-book]
- A.S.P.E.N Pediatric Nutrition Support Core Curriculum. (Corkins MR, ed.) [Text, e-book]
- A.S.P.E.N Enteral Nutrition Handbook. (ASPEN. Boullata J, Nieman C, Guenter P, eds) [Text, e-book]
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