



The Royal Australasian
College of Physicians

Clinical Pharmacology

Advanced Training Curriculum

Adult Medicine Division
Paediatrics & Child Health Division





The Royal Australasian
College of Physicians

Physician Readiness for Expert Practice (PREP) Training Program

Clinical Pharmacology Advanced Training Curriculum

TO BE USED IN CONJUNCTION WITH:

Basic Training Curriculum - Adult Internal Medicine
Basic Training Curriculum - Paediatrics & Child Health
Professional Qualities Curriculum

ACKNOWLEDGEMENTS

Fellows, trainees and RACP staff have contributed to the development of this curriculum document.

The College specifically thanks those Fellows and trainees who have generously contributed to the development of these curriculum documents, through critical comments drawn from their knowledge and experience and the donation of their time and professional expertise.

The following Fellows deserve specific mention for their contribution:

- Prof Evan Begg, FRACP
- Dr Matthew Doogue, FRACP
- Dr Ingrid Hopper
- Prof David Horowitz, FRACP
- Prof Kathleen Knights, FRACP
- Prof David Le Couteur, FRACP
- A/Prof Jennifer Martin, FRACP
- Dr David Reith, FRACP
- Dr Scott Twaddell, FRACP

Special contribution by:

- A/Prof Noel E Cranswick, FRACP
- A/Prof Peter I Pillans, FRACP
- Dr Sepehr Shakib, FRACP
- Prof Ian M Whyte, FRACP

The RACP gratefully acknowledges the contribution of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists to the development of this curriculum.

The process was managed by the Curriculum Development Unit within the College's Education Deanery, who designed the document, drafted content material, organised and facilitated writing workshops, developed resource materials, and formatted the final document.

CONTACT DETAILS

THE ROYAL AUSTRALASIAN COLLEGE OF PHYSICIANS

AUSTRALIA

145 Macquarie Street
Sydney
NSW 2000
Australia

Tel: (+61) (2) 9256 5444
Fax: (+61) (2) 9252 3310

Email: racp@racp.edu.au
Website: www.racp.edu.au

AOTEAROA NEW ZEALAND

Level 10
3 Hunter Street
Wellington 6011
New Zealand

Tel: (+64) (4) 472 6713
Fax: (+64) (4) 472 6718

Email: racp@racp.org.nz
Website: www.racp.edu.au

COPYRIGHT

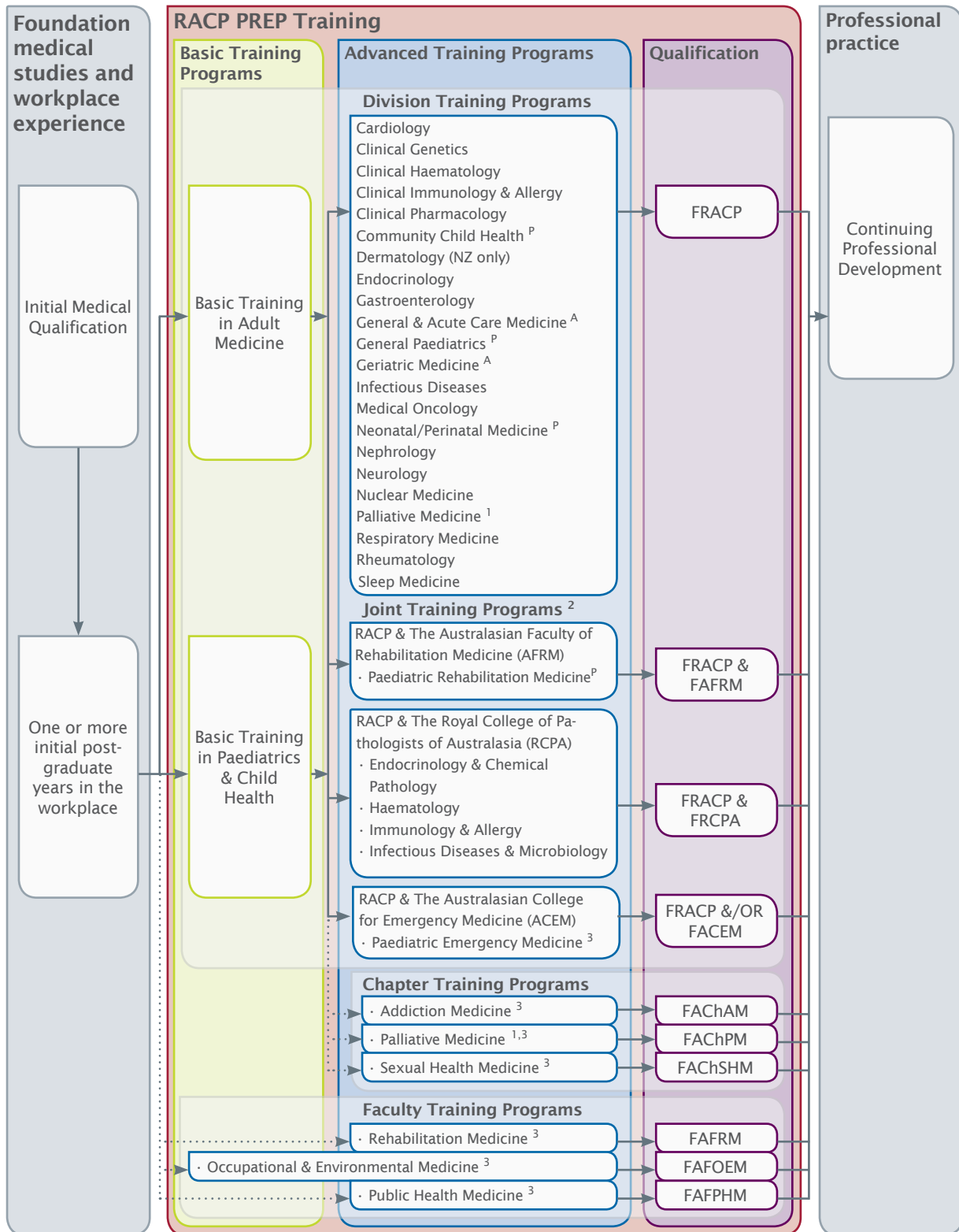
1st edition 2010 (revised 2013).

Please note: No Domains, Themes or Learning Objectives have been updated for this edition; design changes ONLY.

Copyright © 2013. The Royal Australasian College of Physicians (RACP). All rights reserved. Published December 2013.

This work is copyright. Apart from any fair use, for the purposes of study or research, it may not be reproduced in whole or in part, by any means electronic or mechanical, without written permission from The Royal Australasian College of Physicians

RACP FELLOWSHIP TRAINING PATHWAYS AND THE CONTINUUM OF LEARNING



^P Trainees must complete Basic Training in Paediatrics & Child Health to enter this program.

^A Trainees must complete Basic Training in Adult Medicine to enter this program.

¹ Trainees who have entered Advanced Training in Palliative Medicine via a RACP Basic Training Program will be awarded FRACP upon completion and may subsequently be awarded FACHPM. Trainees who have NOT entered Advanced Training in Palliative Medicine via a RACP Basic Training Program will only be awarded FACHPM upon completion.

² The Child & Adolescent Psychiatry Joint Training Program with the Royal Australian and New Zealand College of Psychiatrists (RANZCP) is currently under review by the RACP and RANZCP and closed to new entrants at present.

³ Alternative entry requirements exist for these training programs; please see the corresponding PREP Program Requirements Handbook for further information.

NB1: This diagram only depicts training programs that lead to Fellowship. Please see the RACP website for additional RACP training programs.

NB2: For further information on any of the above listed training programs, please see the corresponding PREP Program Requirements Handbook.

OVERVIEW OF THE SPECIALTY

Clinical pharmacology is the study of the principles and process of rational prescribing and involves the complex interaction between the patient and the drug.

The importance in the wider context is the key role that clinical pharmacologists play in the quality use of medicines (QUM) program, one of the four arms of Australia's National Medicines Policy. The guarantee of quality, safety and efficacy of medicines, of a viable pharmaceutical industry, and of equity of access to medicines (the other three arms) do not guarantee high quality use.

QUM may be defined as the judicious, appropriate and safe use of medicines with the specific objectives of improving patient outcomes and cost effective drug use. QUM focuses on all aspects of drug use, including:

- the statutory milieu and regulatory processes
- safe drug use, minimising adverse reactions and interactions
- promotion of rational prescribing/education on the principles of QUM
- development and implementation of drug treatment guidelines
- development of local and national formularies or standard drug lists
- drug usage evaluation (DUE)
- the appropriate use of drug assays (therapeutic drug monitoring)
- promotion of cost-effective drug use
- QUM research.

Clinical pharmacologists play a key role in drug regulation, serving on national committees such as the Advisory Committee on the Safety of Medicine (ACSOM) or New Zealand Medicines Assessment Advisory Committee (MAAC), and in safe drug use with input into the Australian Adverse Drug Reactions Advisory Committee (ADRAC) or New Zealand Medicines Adverse Reactions Committee (MARC). They have played a central role in the National Prescribing Service's (NPS) development of both an undergraduate and postgraduate national prescribing curriculum, the development of the Australian Medicines Handbook, and the development and implementation of prescribing guidelines, and are involved in hospital, state and national drug and therapeutic committees.

Clinical pharmacologists provide academic leadership in teaching and research in universities, hospitals, government departments and industry, promote the undertaking of drug utilisation evaluations in hospitals and community practice, and provide important input into therapeutic drug monitoring use and interpretation (as opposed to measuring). All these activities ultimately promote rational, evidence-based, cost-effective prescribing.

Current strengths and challenges of the specialty

In common with other medical professionals, clinical pharmacologists face the challenges of managing an ever increasing, more demanding workload. This relates to: a growth in consumer demand; responding to the changing patterns of health and illness within our society; incorporating advances in medical technology; maintaining professional standards; assimilating and utilising new knowledge, information and workplace practices; responding to changing legislative and funding requirements; and working within a multisystem/multidisciplinary/multi-team environment.

Current strengths of this specialty include: expertise in drugs relevant to all medical disciplines; the ability to combine clinical pharmacology expertise with practise in another discipline; and a wide range of job opportunities, including clinical practise, academia, research, industry and drug regulation. Particular challenges include: improving prescribing practices; promoting the judicious and evidence-based use of medicines in the face of counter pressures from the pharmaceutical industry and governmental groups; and making efforts to ensure that quality control is maintained at the same level expected of doctors.

About the Clinical Pharmacology Advanced Training Program

- The current program is flexible, depending on the prior training and experience of each trainee, although a prerequisite is that clinical pharmacology Advanced Trainees have good experience in general medicine.
- The precise manner in which knowledge and experience are acquired varies with the facilities available in individual training units.
- The proportion of time spent in each form of activity varies with the unit and with the interests and requirements of the supervisor.
- It is expected that two years are spent in a department of clinical pharmacology, but periods of training in another subspecialty may also be approved, provided there is a continuing component of clinical pharmacology.
- A core year of Advanced Training should be undertaken in Australia or New Zealand.
- Higher research degrees are particularly encouraged.

Evolving developments and future directions of the specialty

As with any other profession, clinical pharmacologists need to be cognisant of, and sensitively able to respond to, evolving societal, workplace, legislative and technological development.

Some of the currently identified emerging developments within the field include: the extension of prescribing rights to practitioners other than medical practitioners (e.g. nurses, pharmacists, podiatrists); electronic prescribing; computerised databases; and maintaining knowledge perspective in the face of the wide availability of information via the internet.

CURRICULUM OVERVIEW

Clinical Pharmacology – Advanced Training Curriculum

This curriculum outlines the broad concepts, related learning objectives and the associated theoretical knowledge, clinical skills, attitudes and behaviours required and commonly utilised by clinical pharmacologists within Australia and New Zealand.

The purpose of Advanced Training is for trainees to build on the cognitive and practical skills acquired during Basic Training. At the completion of the Clinical Pharmacology Advanced Training Program, trainees should be competent to provide at consultant level, unsupervised comprehensive service in clinical pharmacology.

Attaining broad competency across this curriculum is expected to take three years of training. It is expected that all teaching, learning and assessment associated with the Clinical Pharmacology Advanced Training Curriculum will be undertaken within the context of the physician's everyday clinical practice and will accommodate discipline-specific contexts and practices as required. As such it will need to be implemented within the reality of current workplace and workforce issues and the needs of health service provision.

There may be learning objectives that overlap with or could easily relate to other domains; however, to avoid repetition, these have been assigned to only one area. In practice it is anticipated that within the teaching/learning environment, the progression of each objective would be explored.

Note: The curricula should always be read in conjunction with the relevant College Training Handbook available on the College website.

Professional Qualities Curriculum

The Professional Qualities Curriculum (PQC) outlines the range of concepts and specific learning objectives required by, and utilised by, all physicians, regardless of their specialty or area of expertise. It spans both the Basic and Advanced Training Programs and is also utilised as a key component of the Continuing Professional Development (CPD) program.

Together with the various Basic and Advanced Training Curricula, the PQC integrates and fully encompasses the diagnostic, clinical, and educative-based aspects of the physician's/paediatrician's daily practice.

Each of the concepts and objectives within the PQC will be taught, learnt and assessed within the context of everyday clinical practice. It is important, therefore, that they be aligned with, and fully integrated into, the learning objectives within this curriculum.

EXPECTED OUTCOMES AT THE COMPLETION OF TRAINING

Graduates from this training program will be equipped to function effectively within the current and emerging professional, medical and societal contexts. At the completion of the Clinical Pharmacology Advanced Training Program, as defined by this curriculum, it is expected that a new Fellow will have developed the clinical skills and have acquired the theoretical knowledge for competent clinical pharmacology practice. It is expected that a new Fellow will be able to:

- predict the pharmacology and possible effects of a drug from an understanding of its mechanism of action
- understand and apply pharmacokinetic principles
- perform complex medication reviews and provide advice on judicious prescribing
- provide in-depth advice on prescribing in special patient groups, including older people, children, pregnant and nursing mothers, and patients with renal or hepatic disease
- describe clinically important genotypes that produce atypical patient responses to medications
- predict and recognise potential drug interactions
- provide advice on therapeutic drug monitoring, including dose prediction calculations
- provide pharmacological leadership on hospital, state or regulatory national drug committees, e.g. Therapeutic Goods Administration (TGA)
- teach clinical pharmacology at both undergraduate and postgraduate level
- describe the process of drug development and the ability to assess the efficacy, safety and quality of medicines
- explain basic research principles and undertake drug-related research
- explain the principles of good laboratory and clinical research practice
- design and conduct clinical trials
- perform drug utilisation evaluations
- assess adverse drug reactions and determine causality, and have awareness of national and international pharmacovigilance systems
- diagnose and manage adverse drug reactions
- extract and critically evaluate drug information
- interpret and develop evidence-based prescribing guidelines
- diagnose and manage poisoning and drug overdose
- explain pharmacoeconomic principles and advise on cost effective drug use
- describe pharmacology of drug dependence
- integrate other disciplines with clinical pharmacology.

CURRICULUM THEMES AND LEARNING OBJECTIVES

Each of the curriculum documents has been developed using a common format, thereby ensuring a degree of consistency and approach across the spectrum of training.

Themes

The themes identify and link specific aspects of learning into logical or related groups.

Learning Objectives

The learning objectives outline the specific requirements of learning. They provide a focus for identifying and detailing the required knowledge, skills and attitudes. They also provide a context for specifying assessment standards and criteria as well as providing a context for identifying a range of teaching and learning strategies.

Colour coding in the learning objective tables

The various components within the learning objective tables have been shaded to differentiate between common and paediatric specific material as follows.

Theme 1	Basic Pharmacology	
Learning Objective 1.1	Evaluate the pharmacology of essential drug groups	
Knowledge	Skills	
White: Common material	White: Common material	
Green: Paediatric specific material	Green: Paediatric specific material	

LEARNING OBJECTIVES TABLES

Theme 1	Basic Pharmacology
Learning Objectives	
1.1	Evaluate the pharmacology of essential drug groups
1.2	Define the principles of pharmacokinetics and their clinical application
1.3	Define the principles of pharmacodynamics and their clinical application
1.4	Apply the principles of pharmacokinetics and pharmacodynamics in special circumstances in pharmacology: children, geriatrics, pregnancy, lactation, pharmacogenetics, renal disease and hepatic disease

Theme 2	Drug Research
Learning Objectives	
2.1	Explain good laboratory practise
2.2	Perform drug related research
2.3	Recognise drug development(s) and evaluate efficacy, safety, quality and cost effectiveness
2.4	Explain the ethical aspects of drug related research
Theme 3	Quality Use of Medicine
Learning Objectives	
3.1	Describe drug safety, including assessment and management of adverse drug reactions (ADRs), adverse drug events (ADEs) and drug error
3.2	Diagnose and manage drug interactions
3.3	Interpret drug concentrations and give advice on dose individualisation
3.4	Access, evaluate and provide drug information
3.5	Develop drug policies and actively contribute to drug-related committee activities
3.6	Describe, practice and advise on quality use of medicines (QUM)
3.7	Assess and manage issues related to compliance/adherence/concordance
3.8	Critically review medications and prescribe rationally
3.9	Explain and critically appraise the use of complementary and alternative medicines (CAMs)
Theme 4	Addiction and Overdose
Learning Objectives	
4.1	Recognise clinical and legislative issues relating to drugs of dependence/abuse
4.2	Explain toxicological principles and diagnose and manage poisoning/overdose
Theme 5	Teaching
Learning Objectives	
5.1	Teach pharmacology effectively at all levels, including undergraduates and postgraduates across all disciplines

Theme 1	Basic Pharmacology
Learning Objective 1.1	Evaluate the pharmacology of essential drug groups
Skills	
<ul style="list-style-type: none"> • evaluate the basis behind all aspects of the drug profile • explain that drugs need to be modified according to patient requirements • tailor an individual drug to the individual patient 	
<ul style="list-style-type: none"> • adapt drugs to paediatric requirements. 	
Teaching and Learning Methods	
<ul style="list-style-type: none"> • preparation of drug profiles and patient information leaflets (at least five drug profiles should be prepared, in some form, and presented) • participation in medication rounds • drug profiles should be discussed with supervisor and others in team. 	

Theme 1	Basic Pharmacology	
Learning Objective 1.2	Define the principles of pharmacokinetics and their clinical application	
Knowledge	Skills	
<ul style="list-style-type: none"> • describe the following concepts: <ul style="list-style-type: none"> • clearance • volume of distribution • half-life • bioavailability and first pass effect • drug metabolism and elimination • plasma protein binding and free drug concentrations • drug transport • non linear kinetics • identify variability in pharmacokinetics e.g.: <ul style="list-style-type: none"> • hepatic disease • renal disease • age and gender • pharmacogenetics • explain basic pharmacokinetic equations 	<ul style="list-style-type: none"> • analyse concentration/time data • use pharmacokinetic equations to derive basic pharmacokinetic parameters • use pharmacokinetic concepts to determine rational drug dosing regimen • communicate and teach pharmacokinetic principles to other staff and apply to specific patients 	
<ul style="list-style-type: none"> • describe the development of renal and hepatic drug elimination from preterm-neonates through to adolescence. 	<ul style="list-style-type: none"> • use pharmacokinetic concepts to determine paediatric drug dosing regimens. 	

Theme 1	Basic Pharmacology
Learning Objective 1.2	Define the principles of pharmacokinetics and their clinical application
Teaching and Learning Methods	
<ul style="list-style-type: none"> • participation in research projects, e.g. bioavailability studies • dissemination of information supporting concepts, e.g. preferred medicines lists and educational bulletins • involvement in a drug information service • evidence of active use and promotion of these concepts in research projects, teaching, and patient care, e.g. applied therapeutic drug monitoring (TDM) • publication of research/review papers • evidence of report/bulletin generation • review drug information answers • presentations at conferences, continuing professional development (CPD) and grand rounds illustrating these concepts. 	

Theme 1	Basic Pharmacology	
Learning Objective 1.3	Define the principles of pharmacodynamics and their clinical application	
Knowledge	Skills	
<ul style="list-style-type: none"> • describe mechanisms of drug action, e.g. receptor pharmacology • describe variability in drug action • recognise concentration-effect relationships and factors that may alter these • describe potency vs. efficacy • describe tolerance 	<ul style="list-style-type: none"> • predict the pharmacology and possible effects of a drug group from an understanding of its mechanism of action • analyse concentration-effect data • assess pharmacodynamic variation over time and how this impacts on clinical decisions 	
<ul style="list-style-type: none"> • describe mechanisms of action in relation to paediatric age groups. 	<ul style="list-style-type: none"> • adapt concentration effect data to paediatric patients. 	
Teaching and Learning Methods		
<ul style="list-style-type: none"> • participation in research projects, e.g. concentration response studies • involvement in active dissemination of information supporting the concepts, e.g. preferred medicines lists and educational bulletins • involvement in a drug information service • evidence of active use and promotion of these concepts in research projects, teaching, and patient care, e.g. applied TDM • publication of research/review papers • evidence of report/bulletin generation 		

Theme 1	Basic Pharmacology
Learning Objective 1.3	Define the principles of pharmacodynamics and their clinical application
<ul style="list-style-type: none"> • review drug information answers • presentations at conferences, CPD and grand rounds. 	

Theme 1	Basic Pharmacology	
Learning Objective 1.4	Apply the principles of pharmacokinetics and pharmacodynamics in special circumstances in pharmacology: children, geriatrics, pregnancy, lactation, pharmacogenetics, renal disease and hepatic disease	
Knowledge	Skills	
<ul style="list-style-type: none"> • recognise how pharmacokinetics and pharmacodynamics are affected in these patient groups, and how these may affect therapeutics 	<ul style="list-style-type: none"> • apply principles of pharmacokinetics and pharmacodynamics to drug dosing regimens for these patient groups 	
<ul style="list-style-type: none"> • recognise how pharmacokinetics and pharmacodynamics are affected in preterm neonates, neonates, infants, children, and adolescents • recognise how pharmacokinetics and pharmacodynamics are affected in the intrauterine environment • recognise how pharmacokinetics and pharmacodynamics are affected in lactation. 	<ul style="list-style-type: none"> • apply principles of pharmacokinetics and pharmacodynamics to drug dosing regimens for preterm neonates, neonates, infants, children, and adolescents • advise on drug dosing regimens in pregnancy and lactation. 	
Teaching and Learning Methods		
<ul style="list-style-type: none"> • use of dose tailoring strategies e.g. Cockcroft and Gault formula • TDM rounds • teaching students/post graduates • development of guidelines/formularies and other resources • evidence of active use and promotion of these concepts in research projects, teaching, and patient care, e.g. applied TDM • publication of research/review papers • evidence of report/bulletin generation • review drug information answers • presentations at conferences, CPD and grand rounds. 		

Theme 2		Drug Research
Learning Objective 2.1		Explain good laboratory practise
Knowledge		Skills
<ul style="list-style-type: none"> outline principles and codes of good laboratory practice (GLP) explain the principles of common drug assay methodology and quality control outline principles of assay performance and analysis of assay results 		<ul style="list-style-type: none"> act as a liaison between laboratory scientists and clinicians on matters related to drug concentrations develop a collegial relationship with laboratory scientists
<ul style="list-style-type: none"> explain the principles of collecting samples and performing drug assays in paediatric age groups. 		<ul style="list-style-type: none"> interact with laboratory scientists in matters relating to paediatric drug concentrations.
Teaching and Learning Methods		
<ul style="list-style-type: none"> participation in research familiarity with analytical techniques e.g. liquid chromatography-mass spectrometry (LCMS) liaison with TDM/toxicology laboratory site visit to a GLP facility application of principles of GLP in own research documented records of all aspects of research, and especially quality control evidence of active involvement in TDM hands-on laboratory experience in TDM. 		

Theme 2		Drug Research
Learning Objective 2.2		Perform drug related research
Knowledge		Skills
<ul style="list-style-type: none"> discuss principles of research methodology, including: <ul style="list-style-type: none"> hypothesis development and testing basic biostatistics, including power analysis principles of good clinical research practice role of ethics, and ethics committees 		<ul style="list-style-type: none"> design, conduct and complete a research study including full report and/or publication prepare an ethics application for a drug study review clinical trial protocols
<ul style="list-style-type: none"> discuss principles of consent and other ethical issues specific to paediatric age groups. 		<ul style="list-style-type: none"> design, conduct and complete a research study in the paediatric age group, including ethics application, full report and/or publication.
Teaching and Learning Methods		
<ul style="list-style-type: none"> active participation in research evidence of involvement in research: hypothesis generation, preparation of protocols, ethics applications, grant applications. 		

Theme 2	Drug Research	
Learning Objective 2.3	Recognise drug development(s) and evaluate efficacy, safety, quality and cost effectiveness	
Knowledge	Skills	
<ul style="list-style-type: none"> describe the process of drug development evaluate new drug applications for efficacy, safety and quality identify the working and role of the Australian/New Zealand regulatory authorities explain generic medicines, including drug patents and bioequivalence studies recognise the opposing viewpoints and the pressures involved to market and subsidise new drugs 	<ul style="list-style-type: none"> contribute to the evaluation of a new drug application provide expert clinical/scientific reports contribute to drug evaluation committees illustrate an awareness of sources and influence of bias. 	
<ul style="list-style-type: none"> discuss the process of paediatric drug development, including European and North American guidelines evaluate new drug applications for, or extension of indications to, the paediatric age for efficacy, safety and quality. 		
Teaching and Learning Methods		
<ul style="list-style-type: none"> secondment to drug regulatory agency and/or industry attendance at drug evaluation committee meetings preparation of written reports evaluation of written reports/manuscripts evidence of involvement in pharmacopolitics, including interactions with regulatory bodies and drug companies. 		

Theme 2	Drug Research	
Learning Objective 2.4	Explain the ethical aspects of drug related research	
Knowledge	Skills	
<ul style="list-style-type: none"> discuss the principles of ethics surrounding the process of research describe the safety requirements of research subjects 	<ul style="list-style-type: none"> write a submission to an ethics committee. 	
<ul style="list-style-type: none"> discuss the principles of ethics as applied to research in children. 		
Teaching and Learning Methods		
<ul style="list-style-type: none"> preparation, under supervision, of an ethics application evidence of completion of a written ethics application. 		

Theme 3	Quality Use of Medicines	
Learning Objective 3.1	Describe drug safety, including assessment and management of adverse drug reactions (ADRs), adverse drug events (ADEs) and drug error	
Knowledge	Skills	
<ul style="list-style-type: none"> recognise ADEs and the difference between ADRs and ADEs explain methods of evaluating and classifying ADRs, ADEs and drug errors explain the contribution of ADRs and drug error to morbidity and mortality identify sources of information on ADRs recognise the role of postmarketing surveillance/ pharmacovigilance promote the importance of considering risks as well as benefits of drugs recognise health professionals responsibility to contribute to the national database of ADRs 	<ul style="list-style-type: none"> assess ADRs to determine degree of likelihood of causality report an ADR appropriately diagnose and manage ADRs evaluate and act upon ADEs detect and assess drug error 	
<ul style="list-style-type: none"> recognise how detection of ADRs and ADEs differs in children explain the contribution of medication errors, including prescribing, dispensing, administration and monitoring error, and ADEs to morbidity and mortality in children. 		

Theme 3	Quality Use of Medicines
Learning Objective 3.1	Describe drug safety, including assessment and management of adverse drug reactions (ADRs), adverse drug events (ADEs) and drug error
Teaching and Learning Methods	
<ul style="list-style-type: none"> • participation in ADR/ADE activities, including drug information, causality assessment, reporting of ADRs and ADEs, and teaching about drug safety • participation in national pharmacovigilance activities • active involvement in ADR and ADE assessment and reporting • active involvement in a drug information service • evidence of answers and reports generated. 	

Theme 3	Quality Use of Medicines	
Learning Objective 3.2	Diagnose and manage drug interactions	
Knowledge	Skills	
<ul style="list-style-type: none"> • describe the importance of drug interactions as a cause of variability, morbidity and mortality • explain the following interactions: <ul style="list-style-type: none"> • pharmaceutical • pharmacokinetic • pharmacodynamic 	<ul style="list-style-type: none"> • assess a possible drug interaction in terms of causality, and classify according to type • manage drug interactions 	
Teaching and Learning Methods		
<ul style="list-style-type: none"> • participation in drug information and teaching about drug interactions • involvement in formulary activities, patient information leaflet (PIL) preparation and drug profile preparation • preparation of case reports • active involvement in assessment of drug interactions • active involvement in dissemination of information about drug interactions. 		

Theme 3	Quality Use of Medicines	
Learning Objective 3.3	Interpret drug concentrations and give advice on dose individualisation	
Knowledge	Skills	
<ul style="list-style-type: none"> describe the indications, usefulness and limitations of TDM in patient management identify the therapeutic ranges for commonly assayed medications. 	<ul style="list-style-type: none"> review a patient's drug concentration in light of the patient's clinical condition, dosing history, and other factors that may affect the interpretation of the drug concentration advise on aspects related to measured drug concentrations interpret laboratory data 	<ul style="list-style-type: none"> interpret drug concentrations in children and advise upon dosing modifications.
Teaching and Learning Methods		
<ul style="list-style-type: none"> involvement in TDM rounds preparation of TDM profiles/reports involvement in legal and other reports audit of TDM results involvement in laboratory activities, e.g. governance involvement in TDM rounds preparation of TDM profiles/reports. 		

Theme 3		Quality Use of Medicines
Learning Objective 3.4		Access, evaluate and provide drug information
Knowledge		Skills
<ul style="list-style-type: none"> describe literature, computer and institutional sources of drug information explain principles of evidence-based medicine recognise different levels of evidence recognise gaps between lay, paramedical and medical understanding of research methodology and evidence 		<ul style="list-style-type: none"> assess important drug information critically evaluate a journal article critically evaluate information presented regarding a medicine source and apply principles of evidence-based medicine communicate relevant information/issues to others
<ul style="list-style-type: none"> describe sources of drug information for paediatric age group recognise limitations of available information for drugs in children recognise the appropriate methods for extrapolating adult data to children and the limitations of these methods. 		<ul style="list-style-type: none"> advise on off-label and unlicensed medication use.
Teaching and Learning Methods		
<ul style="list-style-type: none"> participation in drug information, patient medication list (PML) and database activities use of evidence based medicine sources participation in journal clubs/CPD promotion of PMLs and drug databases evidence of output in drug information activities reviews/bulletins written. 		

Theme 3		Quality Use of Medicines	
Learning Objective 3.5		Develop drug policies and actively contribute to drug-related committee activities	
Knowledge		Skills	
<ul style="list-style-type: none"> evaluate drug policy at various levels, including national, state, and local explain formularies recognise the role and functioning of drug committees explain the competing factions, e.g. drug companies, government regulatory committees 		<ul style="list-style-type: none"> contribute to the working of a drug committee assist in developing local drug policy 	
<ul style="list-style-type: none"> recognise the role of paediatric formularies. 		<ul style="list-style-type: none"> participate in the development or maintenance of paediatric formularies. 	
Teaching and Learning Methods			
<ul style="list-style-type: none"> member of drug committees observer at national drug committees experience within a drug company and governmental agencies involvement in committees related to drug policy evidence of assistance in local drug policy development or function preparation of reports for local and wider committees. 			

Theme 3		Quality Use of Medicines	
Learning Objective 3.6		Describe, practice and advise on quality use of medicines (QUM)	
Knowledge		Skills	
<ul style="list-style-type: none"> recognise the principles of drug use evaluation (DUE), in particular the audit loop recognise the importance of, and evaluate, sustainability discuss the principles of pharmacoeconomics explain the principles of pharmacoepidemiology describe the wider aspects of QUM, including costs to country and to the individual 		<ul style="list-style-type: none"> conduct/evaluate a drug utilisation study review a medication chart and make suggestions in order to reduce polypharmacy, drug interactions and ADRs apply the principles of pharmacoeconomics develop evidence-based prescribing guidelines evaluate controversial issues and make effective decisions which balance efficacy, safety, ethics, and cost. 	
<ul style="list-style-type: none"> recognise the principles of orphan drug designation. 			

Theme 3	Quality Use of Medicines
Learning Objective 3.6	Describe, practice and advise on quality use of medicines (QUM)
Teaching and Learning Methods	
<ul style="list-style-type: none"> involvement in DUE activities involvement in pharmaco-economic activities participation in reviews of medication charts involvement in teaching involvement in drug utilisation review projects involvement in pharmaco-economic analyses completion and writing of reports related to these. 	

Theme 3	Quality Use of Medicines	
Learning Objective 3.7	Assess and manage issues related to compliance/adherence/concordance	
Knowledge	Skills	
<ul style="list-style-type: none"> recognise the principles behind compliance/adherence with medicines, and methods to improve this explain the benefits of compliance aids 	<ul style="list-style-type: none"> take a comprehensive drug history talk to patients about their drugs use and advise about compliance aids, e.g. PILs, unit dose packaging. 	
<ul style="list-style-type: none"> recognise the principles of paediatric formulations and administration of medicines to children. 	<ul style="list-style-type: none"> talk to parents about drug administration to children. 	
Teaching and Learning Methods		
<ul style="list-style-type: none"> teach compliance principles use of patient drug lists, e.g. 'yellow cards', pill dispensers and PILs preparation of PILs promotion of good history taking encouragement of compliance by keeping prescriptions simple development of a standard approach to talking to patients about their drugs preparation of and active use of PILs. 		

Theme 3		Quality Use of Medicines
Learning Objective 3.8		Critically review medications and prescribe rationally
Knowledge		Skills
<ul style="list-style-type: none"> evaluate the basis of a good prescription – complete, detailed, unambiguous, generic where possible, prescriber identifiable recognise the principles of prescribing behaviour discuss prescribing errors 		<ul style="list-style-type: none"> write a complete, correct and legal prescription perform complex medication reviews and provide advice on judicious prescribing promote better prescribing
<ul style="list-style-type: none"> recognise the principles of prescribing to children, including mg/kg dosing and the concentrations of liquid formulations. 		<ul style="list-style-type: none"> promote safe prescribing for children.
Teaching and Learning Methods		
<ul style="list-style-type: none"> teach compliance principles use of patient drug lists, e.g. 'yellow cards', pill dispensers and PILs preparation of PILs promotion of good history taking encouragement of compliance by keeping prescriptions simple development of a standard approach to talking to patients about their drugs preparation and active use of PILs. 		

Theme 3		Quality Use of Medicines
Learning Objective 3.9		Explain and critically appraise the use of complementary and alternative medicines (CAMs)
Knowledge		Skills
<ul style="list-style-type: none"> recognise CAMs and their prominence in the population explain the benefits and limitations of CAMs, including their side effects and interactions 		<ul style="list-style-type: none"> recognise the existence, inevitability and place of CAMs in therapeutics extract a history of CAM taking
<ul style="list-style-type: none"> recognise the extent of CAM use in children explain the benefits and limitations of alternative remedies in the paediatric age group. 		<ul style="list-style-type: none"> recognise the age-based limitations of herbal remedies in children.
Teaching and Learning Methods		
<ul style="list-style-type: none"> involvement in drug information activities related to CAMs answering drug information questions regarding CAMs taking full and complete history related to CAMs. 		

Theme 4		Addiction and Overdose
Learning Objective 4.1		Recognise clinical and legislative issues relating to drugs of dependence/abuse
Knowledge		Skills
<ul style="list-style-type: none"> • identify drugs/classes involved, including legal/illegal • outline the principles of diagnosis and management of dependence and overdose • explain the legislative and regulatory controls for drugs of abuse 		<ul style="list-style-type: none"> • diagnose and manage patients with legal or illegal drug dependence • advise on drug abuse in medicolegal settings
<ul style="list-style-type: none"> • outline the principles and diagnosis of neonatal abstinence syndromes • outline the principles of management of adolescent substance misuse. 		<ul style="list-style-type: none"> • diagnose and manage children and adolescents with substance misuse • diagnose and manage neonatal abstinence syndromes.
Teaching and Learning Methods		
<ul style="list-style-type: none"> • treatment of patients with addiction • involvement in research related to addiction • teaching the pharmacology of addiction • generation of reports (legal etc) related to addiction • answering drug queries • active involvement in treatment of patients with addiction • involvement in research projects related to addiction • involvement in teaching of the pharmacology of addiction • generation of reports (legal etc) related to problems of addiction • answering drug information questions related to addiction. 		

Theme 4		Addiction and Overdose
Learning Objective 4.2		Explain toxicological principles and manage poisoning/overdose
Knowledge		Skills
<ul style="list-style-type: none"> explain principles of toxicokinetics and toxicodynamics describe common poisonings and their diagnosis and management identify poisonings where specific interventions, above and beyond standard supportive care, may affect outcome recognise basic principles of forensic toxicology and postmortal kinetics recognise basic principles of occupational toxicology recognise basic principles of environmental toxicology 		<ul style="list-style-type: none"> diagnose and manage poisonings/overdoses access and interpret the literature on more complex issues
<ul style="list-style-type: none"> explain the principles of diagnosis and management of paediatric poisons exposures recognise the principles and management of intentional poisoning of children. 		<ul style="list-style-type: none"> provide poisons advice for paediatric poisons exposures.
Teaching and Learning Methods		
<ul style="list-style-type: none"> treatment of patients with overdose involvement in research related to overdose teaching related to overdose answering drug queries preparation of forensic reports, e.g. coroner's reports related to overdose display a non-judgmental approach to patients who self-harm provision of care to patients who deliberately self-harm active involvement in the treatment of patients with overdose involvement in research projects related to overdose involvement in teaching related to overdose answering drug information questions related to overdose preparation of forensic reports, e.g. coroner's reports, related to overdose. 		

Theme 5	Teaching	
Learning Objective 5.1	Teach pharmacology effectively at all levels, including undergraduates and postgraduates across disciplines	
Knowledge	Skills	
<ul style="list-style-type: none"> recognise different modes of teaching, and their advantages/disadvantages. 	<ul style="list-style-type: none"> prepare, deliver and evaluate teaching in a variety of different modes teach clinical pharmacology at both undergraduate and postgraduate level 	
	<ul style="list-style-type: none"> teach paediatric clinical pharmacology at undergraduate and postgraduate level. 	
Teaching and Learning Methods		
<ul style="list-style-type: none"> involvement in undergraduate and postgraduate teaching involvement in CPD development of new teaching aids, e.g. problem based learning (PBL) cases involvement in teaching at undergraduate and postgraduate levels preparation of portfolio indicating teaching performed evidence of development of new teaching aids, e.g. PBL cases. 		

Glossary of Acronyms and Initialisms

ADE	adverse drug event
ADR	adverse drug reaction
ADRAC	Adverse Drug Reactions Advisory Committee
ACSOM	Advisory Committee on the Safety of Medicines
CAMs	complementary and alternative medicines
CPD	continuing professional development
DUE	drug usage evaluation
FRACP	Fellow of the Royal Australasian College of Physicians
GLP	good laboratory practice
LCMS	liquid chromatography-mass spectrometry
MAAC	Medicines Assessment Advisory Committee
MARC	Medicines Adverse Reactions Committee
TDM	therapeutic drug monitoring
TGA	Therapeutic Goods Administration
NPS	National Prescribing Service
PBL	problem based learning
PIL	patient information leaflet
PML	patient medication list
QUM	quality use of medicines