RCPCH Progress

Paediatric curriculum for excellence

Paediatric Clinical Pharmacology

Level 3

Paediatrics Sub-specialty Syllabus

Version 1

Approved by the GMC for implementation from 1st August 2018

RCPCH
Royal College of Paediatrics and Child Health
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This document outlines the syllabus to be used by doctors completing completing Level 3 Paediatric Clinical Pharmacology training in the United Kingdom training in the United Kingdom (UK). It accompanies the RCPCH Progress curriculum and assessment strategy.

This is Version 1.0. As the document is updated, version numbers will be changed, and content changes noted in the table below.

Version number	Date issued	Summary of changes

Introduction

This syllabus supports the completion of the RCPCH Progress curriculum, and should be used in conjunction with the curriculum document.

The purpose of the curriculum is to train doctors to acquire a detailed knowledge and understanding of health and illness in babies, children and young people. The curriculum provides a framework for training, articulating the standard required to work at Consultant level, and at key progression points during their training, as well as encouraging the pursuit of excellence in all aspects of clinical and wider practice.

The curriculum comprises of Learning Outcomes which specify the standard that trainees must demonstrate as they progress through training and ultimately attain a Certificate of Completion of Training (CCT). The syllabi support the curriculum by providing further instructions and guidance as to how the Learning Outcomes can be achieved and demonstrated.

Using the Syllabus

Paediatric trainees are required to demonstrate achievement of generic and sub-specialty or General Paediatric Learning Outcomes throughout their training period.

For all level 1 and level 2 trainees, there are 11 generic paediatric Learning Outcomes for each level. At level 3, there are a further 11 generic paediatric Learning Outcomes for all trainees, and several additional Learning Outcomes in either General Paediatrics or the GRID sub-specialty the trainee has been appointed into.

This syllabus contains 5 interlinked elements, as outlined in figure 1 which illustrates how each element elaborates on the previous one.

Elements of the Syllabus

The **Introductory Statement** sets the scene for what makes a Paediatric Clinical Pharmacologist.

The **Learning Outcomes** are stated at the beginning of each section. These are the outcomes which the trainee must demonstrate they have met to be awarded their Certificate of Completion of Training (CCT) in Paediatrics. Progress towards achievement of the Learning Outcomes is reviewed annually at the Annual Review of Competence Progression (ARCP).

Each Learning Outcome is mapped to the General Medical Council (GMC) Generic Professional Capabilities framework. Each trainee must achieve all the Generic Professional Capabilities to meet the minimum regulatory standards for satisfactory completion of training.

The **Key Capabilities** are mandatory capabilities which must be evidenced by the trainee, in their ePortfolio, to meet the Learning Outcome. Key Capabilities are therefore also mapped to the GMC Generic Professional Capabilities framework.

The **Illustrations** are examples of evidence and give the range of clinical contexts that the trainee may use to support their achievement of the Key Capabilities. These are intended to provide a prompt to the trainee and trainer as to how the overall outcomes might be achieved. They are not intended to be exhaustive, and excellent trainees may produce a broader portfolio or include evidence that demonstrates deeper learning. It is not expected that trainees provide ePortfolio evidence against every individual illustration (or a set quota); the aim of assessment is to provide evidence against every Key Capability.

The **Assessment Grid** indicates suggested assessment methods, which may be used to demonstrate the Key Capabilities. Trainees may use differing assessment methods to demonstrate each capability (as indicated in each Assessment Grid), but there must be evidence of the trainee having achieved all Key Capabilities.

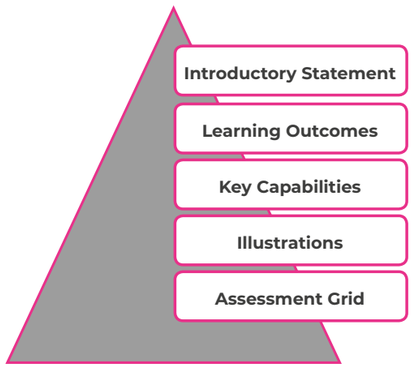

Figure 1: The 5 elements of the syllabus

Using the Syllabus with ePortfolio

Recording evidence in the ePortfolio to demonstrate progression against the learning outcomes and key capabilities can be done from any assessment or event in the ePortfolio.

At the end of any event or assessment, there is an opportunity to add tags, documents and comments. Expanding this by clicking “show more” will enable you to link your assessment to the curriculum items, where you will find the learning outcomes for each domain, key capabilities and example illustrations.

Trainees will therefore be able to track their progress in fulfilling the mandatory learning outcomes and key capabilities.

Paediatric Clinical Pharmacology Introductory Statement

Introductory Statement

A Paediatric Clinical Pharmacologist is a doctor who has expertise in all aspects of the development of medicines and their safe, rational use. This includes research (from early phase clinical trials to translational), ethics, clinical practice, drug regulation and education.

In clinical practice, they provide advice and support locally and nationally regarding the introduction of new medicines, adverse drug reactions, poisoning and toxicity, and prescribing policies. They contribute to the ethical review of research, plus the safe and effective conduct and delivery of drug trials. Additional research skills developed during training include those in drug development, medicine safety and the rational use of medicines in children.

Clinical Pharmacologists play a vital role in many areas that complement the use of medicines in children. Roles within drug regulation include developing local guidelines, advising on pharmacovigilance and serving on national committees. They contribute to the education of undergraduate and postgraduate health care professionals on drug metabolism, formulations and prescribing.

Sub-specialty Learning Outcomes

	Sub-specialty Learning Outcomes	GMC Generic Professional Capabilities
1.	Competently manages patients with adverse drug reactions (ADRs) and acute poisonings.	GPC 1, 3, 5, 6
2.	Designs and plans a clinical trial of a medicine and understands the roles of the study team.	GPC 9
3.	Participates in the design, delivery and interpretation of paediatric clinical trials of medicines.	GPC 2, 6, 9
4.	Understands, advises and teaches on drug metabolism in children.	GPC 3, 5, 6, 8
5.	Contributes to Trust, regional and national paediatric drug policy development and implementation.	GPC 2, 6, 9
6.	Advocates for the safe and effective evidence-based use of medicines in children.	GPC 3, 5, 6, 9

Specialty Learning Outcome 1

Competently manages patients with adverse drug reactions (ADRs) and acute poisonings.	GPC 1, 3, 5, 6

Key Capabilities

Recognises, assesses, advises on and appropriately manages ADRs and acute poisonings in children.	GPC 1, 3, 5, 6, 7

Illustrations

1.	Teaches and advises on the difference between an adverse event and an ADR.
2.	Advises on safeguarding as a factor in poisonings, both accidental and from self-harm.
3.	Recognises, assesses and advises on the clinical presentations of ADRs in paediatric patients of different ages.
4.	Manages cases of common overdose or poisoning and understands the mechanisms of common antidotes and their effective use in practice.
5.	Recognises and advises on maternal drug use and the effects of this on the baby during pregnancy and when breastfeeding.
6.	Advises on the common causes of teratogenicity seen in practice.

Sub-specialty Learning Outcomes 2 and 3

Designs and plans a clinical trial of a medicine and understands the roles of the study team.	GPC 9
Participates in the design, delivery and interpretation of paediatric clinical trials of medicines.	GPC 2, 6, 9

Key Capabilities

Designs a clinical trial of a medicine and understands the roles of the study team.	GPC 2, 6, 9

Illustrations

1.	Advises about sampling and measurement techniques in clinical trials, including early phase clinical trials.
2.	Uses statistical methods, including determination of sample size and population pharmacokinetics, and can guide others on their uses in drug metabolism studies (including pharmacokinetics).
3.	Advises on common methods of drug assay required for paediatric studies.
4.	Evaluates toxicity testing in animals in pre-clinical drug development, and advises on their use in drug development.
5.	Advises on the principles of ethical research in children.
6.	Advises on consent and assent issues in children, including legal aspects and the process of informed consent.
7.	Evaluates the risk involved with a procedure and/or a whole study in drug research.
8.	Evaluates different types of paediatric trial design and advises researchers on their strengths and weaknesses.
9.	Advises researchers during trial protocol development about the recruitment and retention of paediatric patients.
10.	Applies the principles of randomisation and use of controls, placebos and blinding to the investigation of medicinal products in children.

Sub-specialty Learning Outcome 4

Understands, advises and teaches on drug metabolism in children.	GPC 3, 5, 6, 8

Key Capabilities

Is proficient in teaching both at undergraduate and postgraduate levels on drug metabolism, formulations and prescribing.	GPC 3, 6, 8

Illustrations

1.	Advises others on the differences between paediatric patients and adults in relation to drug delivery, metabolism and action.
2.	Uses the principles of pharmacokinetics to optimise drug therapy.
3.	Recognises the differences in pharmacodynamic responses among children of different ages.
4.	Advises on the development of the major metabolic pathways, including P450 enzymes, glucuronidation and sulphation, in relation to age and pharmacogenetic profile from prematurity through puberty.
5.	Assesses the impact of developmental physiology (e.g. absorption, distribution and excretion) on drug disposition across age ranges of life to support prescribing management.
6.	Advises others on the different analytical methods available for determining and monitoring drug concentrations in clinical practice.
7.	Interprets dose–response relationships and determines optimum dose range.
8.	Differentiates between different routes of drug administration and advises on appropriate formulations at different ages.
9.	Alters therapeutic regimens appropriately using an understanding of drug pharmacokinetics.
10.	Teaches paediatric clinical pharmacology to other health professionals and graduates of medicine.

Sub-specialty Learning Outcome 5

Contributes to Trust, regional and national paediatric drug policy development and implementation.	GPC 2, 6, 9

Key Capabilities

Advises at local, regional and national levels on drug-development management policies, the rational use of medicines and pharmacovigilance.	GPC 5, 6, 9

Illustrations

1.	Establishes the need to study medicines scientifically and advises on the process by which this is ensured.
2.	Advises on how to make an application for a research protocol by explaining the structures, functions and processes of the national Research Ethics Committees (RECs) and the National Health Service, Research and Development departments.
3.	Prepares and critically analyses a submission to an ethics committee for a clinical trial in children.
4.	Advises on the role of the pharmaceutical industry in the development of new medicines and can effectively explore in detail the planning of studies in the clinical setting.
5.	Advises about regulatory agencies and their roles, especially in paediatric drug development.
6.	Describes ADR surveillance schemes in relation to children (pharmacovigilance) and liaises with national authorities on their conduct.
7.	Advises and teaches on the licensing of medicines for paediatric patients and unlicensed and off-label use.
8.	Advises on the role of the National Institute of Clinical Excellence (NICE) in the use of medicines and its relation to local prescribing drug policies.
Medicine management in children	
1.	Assists in formulary development, and local and national management.
2.	Assists in the management of medicines in hospital and general practice settings, and at the interface between them, including the challenges of unlicensed and off-label medicine use.
3.	Works with others on committees overseeing the management of medicines.
4.	Assesses the role of drug and therapeutic committees.
5.	Determines how to use drugs rationally within organisations and institutions and supports local and national policies.
6.	Supports trainees and other colleagues in providing effective prescribing and risk management.
7.	Supports trainees and colleagues in the prescribing of drugs, basing choices on efficacy, safety and acceptability.
8.	Advises on how to prescribe drugs cost-effectively and supervises the audit practice.

Sub-specialty Learning Outcome 6

Advocates for the safe and effective evidence-based use of medicines in children.	GPC 3, 5, 6, 9

Key Capabilities

Manages and advises locally, regionally and nationally on prescribing errors and the evidence-based use of medicines.	GPC 2, 3, 5, 6, 9

Illustrations

1.	Manages a prescribing error and its reporting.
2.	Understands and advises on factors affecting the compliance with medicine use.
3.	Understands how childhood diseases can influence drug disposition and recognises the influence this has in clinical practice.
4.	Understands the differences between drug toxicity in the developing child and young person, and advises on this in clinical practice.
5.	Recognises specific age-related drug toxicities in children.
6.	Evaluates the evidence base for the use of medicines in childhood and supports the review of guideline development for clinical practice.

Assessment Grid

This table suggests assessment tools which may be used to assess the Key Capabilities for these Learning Outcomes. This is not an exhaustive list, and trainees are permitted to use other methods within the RCPCH Assessment Strategy to demonstrate achievement of the Learning Outcome, where they can demonstrate these are suitable.

Key Capabilities	Assessment / Supervised Learning Event suggestions									
	Paediatric Mini Clinical Evaluation (ePaed Mini-CEX)	Paediatric Case-based Discussion(ePaed CbD)	Directly Observed Procedure / Assessment of Performance (DOP/AoP)	Acute Care Assessment Tool (ACAT)	Discussion of Correspondence (DOC)	Clinical Leadership Assessment Skills (LEADER)	Handover Assessment Tool (HAT)	Paediatric Multi Source Feedback (ePaed MSF)	Paediatric Carers for Children Feedback (Paed CCF)	Other
Recognises, assesses, advises on and appropriately manages ADRs and acute poisonings in children.	✓	✓		✓						
Designs and plans a clinical trial of a medicine and understands the roles of the study team.	✓	✓				✓				
Is proficient in teaching both at undergraduate and postgraduate levels on drug metabolism, formulations and prescribing.	✓	✓				✓		✓		
Advises at local, regional and national levels on drug-development management policies, the rational use of medicines and pharmacovigilance.		✓				✓				
Manages and advises locally, regionally and nationally on prescribing errors and the evidence-based use of medicines.		✓				✓