RCPCH Progress+

Paediatric training for excellence

Paediatric Clinical Pharmacology

Sub-specialty Syllabus

Version 3
Approved by the GMC for implementation from 1 August 2023

RCPCH
Royal College of Paediatrics and Child Health
Leading the way in Children's Health

This document outlines the syllabus to be used by doctors completing Paediatric Clinical Pharmacology training in the United Kingdom (UK). It accompanies the RCPCH Progress+ curriculum and Assessment Strategy.

This is Version 3. 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
Version 2	September 2021	Document reviewed as part of the Shape of Paediatric Training review. 'Using the Syllabus with ePortfolio' (page 5) updated. Learning Outcomes and Key Capabilities updated. Original Learning Outcomes (LOs) 2 and 5 removed and replaced with new LOs 5 and 6. One new illustration (number 2) added to LO 1. LO 2 (previously known as LO 3) moved and Key Capability (KC) amended. LO 3 (previously known as LO 4) moved and one new KC added. LO 4 (previously known as LO 5) moved; two new KC added; six new illustrations (number 17 - 22) added. LO 5 and LO 6 newly added.
Version 3	August 2023	Updated from Progress to Progress+. Using the syllabus (page 3) updated: reference to Level 1, 2 and 3 removed and replaced with Core and Specialty training.

Introduction

This syllabus supports the completion of the RCPCH Progress+ curriculum and should be used with the curriculum document and Assessment Strategy.

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 through 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 Learning Outcomes specifying the standard trainees must demonstrate to progress in training and attain a Certificate of Completion of Training (CCT). The syllabi supports the curriculum by providing further instructions and guidance on how the Learning Outcomes can be achieved and demonstrated.

In the context of clinical training and service the term “babies, children and young people” is a common term used by those working in paediatric and child health areas to mean any of those instances in context with clinical training or service. Therefore, in relation to the assessment, the trainee needs to achieve the capabilities for either a baby, child or young person.

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 core trainees (ST1 – 4), there are 11 generic paediatric Learning Outcomes. For specialty training (ST5 – 7), there are a further 11 generic paediatric Learning Outcomes and several additional Learning Outcomes in either General Paediatrics or the sub-specialty to which the trainee has been appointed.

This syllabus contains five 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.

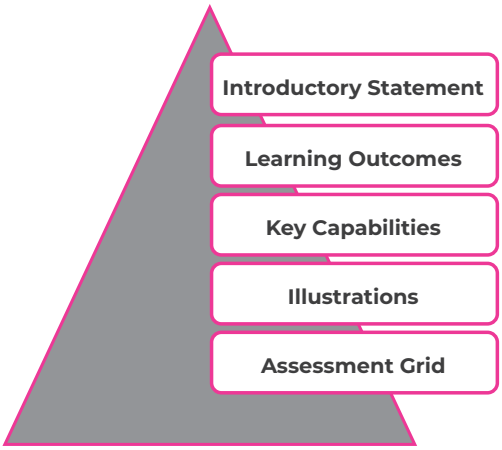

Figure 1: The five elements of the syllabus

Using the Syllabus with ePortfolio

The ePortfolio is used to demonstrate a trainee's progression using assessments, development logs and reflections. Events should be linked to the Progress+ curriculum specifically against the key capabilities at the appropriate level.

Further guidance on using the ePortfolio is available on our website: https://www.rcpch.ac.uk/resources/rcpch-eportfolio-guidance-doctors

Paediatric Clinical Pharmacology 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, as well as managing in-patient and out-patient care, they provide advice and support locally and nationally regarding the introduction of new medicines, adverse drug reactions, poisoning and toxicity as well as 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 and young people.

Clinical Pharmacologists play a vital role in many areas that complement the use of medicines in children and young people. 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.	Manages patients with adverse drug reactions (ADRs) and acute poisonings.	GPC 1, 3, 5, 6
2.	Participates in the design, delivery and interpretation of paediatric clinical trials of medicines.	GPC 2, 6, 9
3.	Understands, advises and teaches on clinical pharmacology in children and young people.	GPC 3, 5, 6, 8
4.	Advocates for the safe and effective evidence-based use of medicines in children and young people.	GPC 3, 5, 6, 9
5.	Contributes to an acute paediatric service, with particular focus on the safe and effective use of medicines in the team and the trust. This will include managing emergency situations including: resuscitation, stabilisation and treatment of acutely unwell children and young people, delivering inpatient care and ensuring that systems are in place for the safe and effective use of medicines in acute care situations.	GPC 2, 6, 9
6.	Contributes to the management of children and young people with a range of chronic health problems, including direct patient management and ensuring systems are in place for the safe and effective use of medicines in chronic disease.	GPC 3, 5, 6, 9

Sub-specialty Learning Outcome 1

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 and young people.	GPC 1, 3, 5, 6, 7

Illustrations

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

Sub-specialty Learning Outcome 2

Participates in the design, delivery and interpretation of paediatric clinical trials of medicines.	GPC 2, 6, 9

Key Capabilities

Contributes to the design of a clinical trial of a medicine and understands the roles of the study team.	GPC 2, 6, 9
Demonstrates understanding of the role of an investigator on a clinical trial and their responsibilities for performing medical assessments and reporting of adverse events.	GPC 2, 3, 8, 9

Illustrations

1.	Advises about sampling and measurement techniques in clinical trials, including early phase clinical trials, as they apply to children and young people.
2.	Uses statistical methods, including determination of sample size and population pharmacokinetics and provides guidance to 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 and young people.
6.	Advises on consent and assent issues in children and young people, 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 and young people.

Sub-specialty Learning Outcome 3

Understands, advises and teaches on clinical pharmacology in children and young people.	GPC 3, 5, 6, 8

Key Capabilities

Proficient in teaching both at undergraduate and postgraduate levels on drug pharmacodynamics, pharmacokinetics, formulations and prescribing.	GPC 3, 6, 8
Advises on clinical pharmacology aspects of the medical care of children and young people.	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 and young people 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 (eg 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 4

Advocates for the safe and effective evidence-based use of medicines in children and young people.	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 3, 6, 9
Manages and advises locally, regionally and nationally on prescribing errors and the evidence-based use of medicines.	GPC 3, 5, 6, 9
Undertakes audit and quality improvement projects to develop evidence-based and rational use of medicines.	GPC 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 the national Research Ethics Committee (NRES) and the Health Research Authority.
3.	Prepares and critically analyses a submission to an ethics committee for a clinical trial in children and young people.
4.	Advises on the role of the pharmaceutical industry in the development of new medicines and effectively explores 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.

9.	Assists in formulary development and local and national management.
10.	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.
11.	Works with others on committees overseeing the management of medicines.
12.	Assesses the role of drug and therapeutic committees.
13.	Determines how to use drugs rationally within organisations and institutions and supports local and national policies.
14.	Supports trainees and other colleagues in providing effective prescribing and risk management.
15.	Supports trainees and colleagues in the prescribing of drugs, basing choices on efficacy, safety and acceptability.
16.	Advises on how to prescribe drugs cost-effectively and supervises the audit practice.
17.	Manages a prescribing error and its reporting.
18.	Understands and advises on factors affecting the compliance with medicine use.
19	Understands how childhood diseases influence drug disposition and recognises the influence this has in clinical practice.
20.	Understands the differences between drug toxicity in the developing child and young person and advises on this in clinical practice.
21	Recognises specific age-related drug toxicities in children and young people.
22.	Evaluates the evidence base for the use of medicines in childhood and supports the review of guideline development for clinical practice.

Sub-specialty Learning Outcome 5

Contributes to an acute paediatric service, with particular focus on the safe and effective use of medicines in the team and the trust. This will include managing emergency situations including: resuscitation, stabilisation and treatment of acutely unwell children and young people, delivering inpatient care and ensuring that systems are in place for the safe and effective use of medicines in acute care situations.	GPC 2, 6, 9

Key Capabilities

Leads a team in the resuscitation of acutely unwell children or young people.	GPC 2, 3, 5, 6, 9
Assesses, investigates and manages acutely unwell children or young people.	GPC 2, 3
Ensures adequate ongoing training for staff involved in acute prescribing and oversight of guidelines related to acute prescription of medicines.	GPC 1, 2
Leads the assessment of new medicines for children and young people in a general paediatric team, including incorporation into local guidelines.	GPC 3, 5, 6

Illustrations

1.	Recognises, investigates and manages children and young people (including discharge or onward referral as appropriate) with the following: • brief resolved unexplained event (previously acute life-threatening event) • coma • dehydration • head injury • pain • poisoning • sepsis • shock • sudden unexpected death
2.	Newborn resuscitation and stabilisation (term and preterm).
3.	Develops and delivers medicine related quality improvement projects.
4.	Develops or updates medication related trust guidelines.

Sub-specialty Learning Outcome 6

Contributes to the management of children and young people with a range of chronic health problems, including direct patient management and ensuring systems are in place for the safe and effective use of medicines in chronic disease.	GPC 3, 5, 6, 9

Key Capabilities

Assesses, investigates and manages children and young people referred to outpatient care clinics with a full range of nonspecific and specific symptoms and signs.	GPC 2
Oversees and co-ordinates the care of children and young people with complex health conditions.	GPC 2, 5, 6
Contributes meaningfully to hospital trust drugs and therapeutics committee, improving access to new medicines for children and young people.	GPC 2, 3, 4, 6, 9
Contributes to assessments of reported risks and events that relate to medicines in children and young people.	GPC 3, 5, 6, 7
Improves management of medicines prescribed to children and young people, including issues related to polypharmacy, rational prescribing, dose optimisation and drug-drug interactions.	GPC 3, 5, 6

Illustrations

1.	Manages a general paediatric outpatients' clinic.
2.	Membership of trust/hospital drugs and therapeutics committees.
3.	Provides a point of contact for local and regional healthcare professionals with medicine related queries about children and young people (eg Hospital Pharmacists, GPs, Community Pharmacists, School nurses, etc).
4.	Involvement in the process for reviewing prescribing and/or medication errors in children and young people.

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 (Mini-CEX)	Paediatric Case-based Discussion (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 (MSF)	Paediatric Carers for Children Feedback (Paed CCF)	Other
Recognises, assesses, advises on and appropriately manages ADRs and acute poisonings in children and young people.	✓	✓		✓						
Contributes to the design of a clinical trial of a medicine and understands the roles of the study team.	✓	✓				✓				
Demonstrates understanding of the role of an investigator on a clinical trial and their responsibilities for performing medical assessments and reporting of adverse events.		✓				✓				✓
Proficient in teaching both at undergraduate and postgraduate levels on drug pharmacodynamics, pharmacokinetics, formulations and prescribing.	✓	✓				✓		✓		
Advises on clinical pharmacology aspects of the medical care of children and young people.	✓	✓								✓
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.		✓				✓				
Undertakes audit and quality improvement projects to develop evidence-based and rational use of medicines.						✓				✓
Leads a team in the resuscitation of acutely unwell children or young people.	✓	✓		✓		✓				
Assesses, investigates and manages acutely unwell children or young people.	✓	✓		✓		✓	✓	✓		
Ensures adequate ongoing training for staff involved in acute prescribing and oversight guidelines related to acute prescription of medicines.	✓	✓				✓				✓

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	Paediatric Mini Clinical Evaluation (Mini-CEX)	Paediatric Case-based Discussion (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 (MSF)	Paediatric Carers for Children Feedback (Paed CCF)	Other
Understand how to access, interpret and implement new information about medicines for children provided by national agencies (eg MHRA, NICE, BNFc).	✓			✓		✓	✓			
Leads the assessment of new medicines for children and young people in a general paediatric team, including incorporation into local guidelines.	✓			✓		✓	✓			
Assesses, investigates and manages children and young people referred to outpatient care clinics with a full range of nonspecific and specific symptoms and signs.	✓	✓			✓			✓		✓
Oversees and co-ordinates the care of children and young people with complex health conditions.	✓	✓			✓	✓				✓
Contributes meaningfully to hospital trust drugs and therapeutics committee, improving access to new medicines for children and young people.	✓					✓				✓
Contributes to assessments of reported risks and events that relate to medicines in children and young people.		✓				✓				✓
Improves management of medicines prescribed to children and young people, including issues related to polypharmacy, rational prescribing, dose optimisation and drug-drug interactions		✓				✓				✓