Paediatric clinical pharmacology training programmes in Canada and the UK: a comparison

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The discipline concerned with evaluation and use of medicines in children is known as paediatric clinical pharmacology and is a relatively new sub-specialty of paediatrics. Two countries which have a formal training programme are Canada and the UK. We have compared the programmes in these two countries in relation to both the duration of the programme and the content. The training programmes are remarkably similar between the two countries suggesting that there is international agreement on the key issues in this area.

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Introduction

Few medicines have been adequately scientifically evaluated in children and even fewer are developed specifically to treat children's diseases[1]. In order to address this important issue there is widespread recognition that more paediatric clinical pharmacologists are required worldwide to facilitate the conduct of research into medicines specifically designed and evaluated in children and translation of this into clinical practice. Traditionally, paediatric clinical pharmacologists have organised their own training, frequently training in paediatrics or a subspecialty before undertaking adult clinical pharmacology research. This is not ideal, however, and the concept of a formal training programme in paediatric clinical pharmacology has been under development for several years.

A worldwide survey of paediatric clinical pharmacology training programmes[2], undertaken in 1988 via the paediatric subcommittee of the International Union of Pharmacology, revealed that Canada and the USA had been most active in training paediatric clinical pharmacologists. It also revealed, however, a significant problem in defining the term paediatric clinical pharmacology with respect to programme content. The survey's Canadian authors considered a formal course in pharmacokinetics, a therapeutic drug monitoring service, a poison control centre, an adverse reaction consultation programme and a teratology information service as key parts of a training programme in paediatric clinical pharmacology. However, of the 11 programmes that had trained three or more medical trainees in the preceding three years, only two had all of these elements. Subsequently, an International Network of Pediatric Pharmacology Training

Programmes was founded[3] with one of its stated aims to create a set of criteria defining content and quality of programmes.

A European survey of training programmes was carried out in 2005 via the European Network for Drug Investigation in Children (ENDIC)[4]. This survey also recognised problems with defining the term paediatric clinical pharmacology and identified that its survey might exclude some paediatric subspecialists with training in pharmacology as well as paediatric pharmacists who were capable of a significant contribution to paediatric drug development. It is clear from these surveys that formal training programmes in paediatric clinical pharmacology have a significant role in defining the subspecialty as well as in producing pharmacologists.

In 2004, the Royal College of Paediatrics and Child Health (RCPCH) in the UK established a formal training programme and curriculum in paediatric clinical pharmacology[5], which has recently produced its first graduate. In addition, the Toronto Hospital for Sick Children and the Children's Hospital of Western Ontario in Canada have recently formalised their residency programmes and learning objectives in paediatric clinical pharmacology. We compared the programmes in these two countries with respect to entry point and duration and content.

Overview of postgraduate paediatric training

Canada

Postgraduate medical training, or residency, in Canada prepares medical graduates for independent practice in their chosen specialty. Length of residency varies for different specialties. In paediatrics, residents complete three years of core paediatric training before a year of general paediatrics or two to three years of subspecialty training, of which paediatric clinical pharmacology is an example (Figure 1). The core paediatric training includes rotations in critical care paediatrics, emergency paediatrics and neonatology. Training is overseen by the corresponding medical school under the umbrella authority of the Royal College of Physicians and Surgeons of Canada.

UK

Postgraduate medical training in the UK has recently been restructured. Under the new system entitled "Modernising Medical Careers", or MMC, medical graduates will first complete two Foundation Years where they will rotate four-monthly through various hospital and primary care specialties. Following this, those pursuing a career in paediatrics will enter a 7–8 year paediatric Specialty Training (ST) grade,

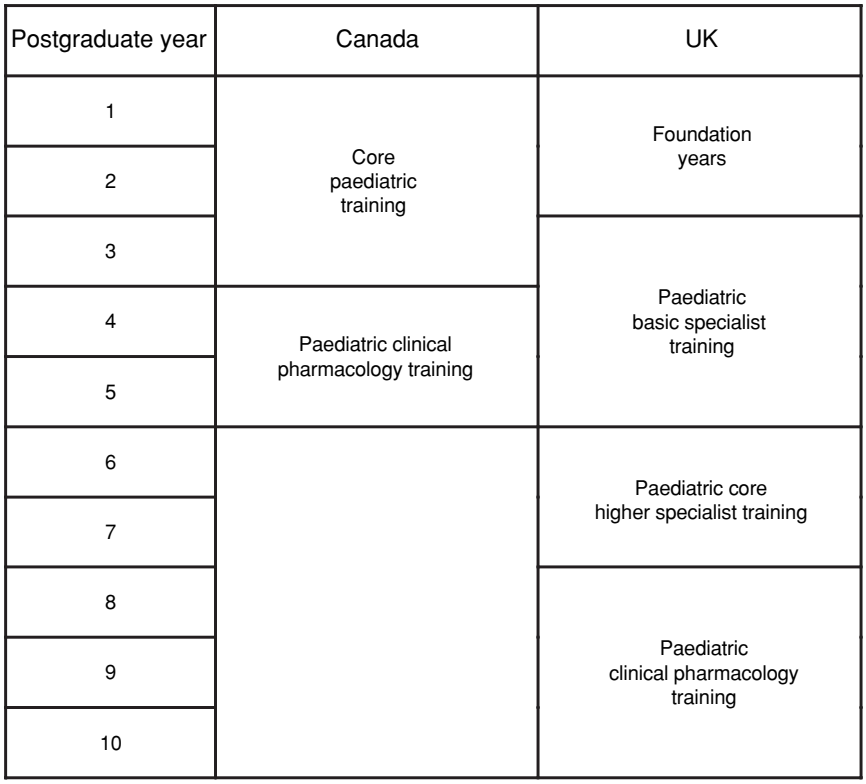

Figure 1 Postgraduate paediatric clinical pharmacology training overview.

the first 4–5 years of which will encompass core paediatric training at two levels of responsibility (Figure 1). These include rotations in general paediatrics, neonatology and community paediatrics. The remaining years are set aside for either subspecialty training (e.g. paediatric clinical pharmacology) or further general paediatrics. Training is overseen by the RCPCH and certification is dependent upon regular assessment of competence and completion of the Royal College's membership examination.

Structure of training programmes

Canada

Paediatric clinical pharmacology training in Canada is a two year programme comprising 6–9 months paediatric clinical pharmacology, three months clinical pharmacology in a different age group, 6 months elective and 6 months research. Residents may elect to spend extra time in related areas, e.g. the pharmaceutical industry or regulatory agency experience. On-call commitments consist of in-patient paediatric clinical pharmacology and toxicology consultations, reproductive toxicology consultations and medical toxicology on-call via a regional poison control centre. Consistent with training in other sub-specialties in Canada, on-call duties are usually restricted to being on-call for clinical pharmacology.

UK

The duration of training in paediatric clinical pharmacology is three years. One year of research in clinical pharmacology (either adult or paediatric) is required. During this period, comprehensive training in investigational skills relevant to clinical pharmacology and therapeutics are obtained. At least one of the remaining two years must be spent in a District General Hospital (DGH) or a teaching hospital with DGH facilities (i.e. having acute paediatrics including emergency admissions), undergoing training for equal periods in general paediatrics and paediatric clinical pharmacology. Trainees are expected to undertake a full acute paediatric on-call commitment during this time.

Content of training programmes

Learning objectives were derived from the Toronto Hospital for Sick Children Overall Goals and Objectives Paediatric Clinical Pharmacology Residency Training Program and the RCPCH Training Programme in Paediatric Clinical Pharmacology.

The learning objectives of both programmes are very similar and can easily be grouped under the following key areas in paediatric clinical pharmacology (Table 1). The UK objectives, on the whole, are more detailed and specific.

Ethics of clinical trials in children

Both programmes require trainees to have an understanding of the principles of ethical issues relating to drug research in children and how it is regulated. The UK programme is more specific and has objectives relating to consent and assent, use of healthy volunteers and use of placebo.

Pharmacokinetic studies in children

Both programmes contain objectives relating to pharmacokinetics, with particular regard to therapeutic drug monitoring, effects of age and disease on drug metabolism and distribution and the use of population pharmacokinetics.

Drug action and effect in paediatric patients

The programmes have common objectives relating to drug concordance/adherence and dose-response relationships. The Canadian programme mentions pharmacogenetics more overtly in its objectives relating to this area. The UK programme has a specific objective relating to paediatric formulation and drug delivery devices, including teaching from paediatric pharmacists.

Drug toxicity

Both programmes expect trainees to be able to detect, interpret and manage adverse drug reactions in paediatric patients as well as to be able to manage and advise cases of overdose and poisoning.

Table 1 Content of paediatric clinical pharmacology training programmes

	Canada	UK
Ethics of clinical trials in children	✓	✓
Pharmacokinetic studies in children	✓	✓
Drug action and effect in paediatric patients	✓	✓
Drug toxicity in children	✓	✓
Socio-political and regulatory aspects of use of medicines	✓	✓
Rational and cost-effective use of medicines	✓	✓
Practical challenges of conducting clinical trials in paediatrics	✓	✓
Education	✓	✓

Socio-political and regulatory aspects of medicines

Both programmes have objectives relating to legal issues relating to drug development and therapy. The UK programme contains more specific objectives relating to knowledge of licensing (labelling), regulatory agencies and the role of the pharmaceutical industry.

Rational and cost-effective use of medicines

Both programmes contain specific objectives relating to rational use of drugs, including assessment of the evidence-base, cost-efficacy and safety. Knowledge of formulary management is also specified and experience of a hospital drug and therapeutics/formulary committee is included.

Practical challenges of conducting clinical trials in children

Both programmes stipulate that trainees should be able to design and conduct a clinical trial for children, including knowledge of statistical analysis.

Education

Both programmes contain generic objectives relating to education and teaching proficiency. In addition, trainees are expected to acquire skills in critical appraisal, including review of papers submitted to journals and review of trial protocols submitted to ethics boards.

Despite the different style of each of the curriculum documents, it was possible to pair off all but a few specific Canadian learning objectives with UK counterparts. The major significant differences relate to:

- A requirement for Canadian residents to "…have an appreciation of important issues related to drug toxicity, substance abuse and drug therapy in pregnancy" which is not mentioned in the UK programme.
- A specific Canadian objective relating to gaining experience of clinical pharmacology issues in adult patients which is indirectly inferred in the UK programme.

Certification

Canada

Pharmacology training in Canada is currently accredited without certification, due to the fact that a nationwide exit examination has not yet been approved. Those with a certificate from the Royal College of Physicians and Surgeons of Canada in one of the five specialties (anaesthesia, emergency medicine, internal medicine, paediatrics, or psychiatry) receive an official letter from the Royal College attesting their completed training in clinical pharmacology. The nationwide certifying examination in clinical pharmacology will be implemented in a few years, and will encompass both adult and paediatric clinical pharmacology. At present, residents conclude their training with a multi-university examination and a clinical assessment.

UK

Paediatric clinical pharmacology trainees in the UK keep a written record of their training experiences to confirm satisfactory fulfilment and acquisition of the competences outlined in the syllabus. They undergo annual assessments throughout the training period, including evaluation by a paediatric clinical pharmacologist from outside their geographical training region. Satisfactory completion of this series of assessments results in the issue of a certificate of completion of training in paediatric clinical pharmacology and general paediatrics.

At present, there is no arrangement for a reciprocal agreement allowing accreditation in one country to be recognised in the other.

Discussion

Directly comparing medical training programmes in two countries is intrinsically complex, given the different roles expected of graduates on completion of the training programme. This is highlighted particularly by the variation in organisation and duration of the two programmes compared above. Graduates of the UK programme would, in general, be expected to practise at consultant level in general paediatrics as well as in paediatric clinical pharmacology. This, combined with current restrictions on weekly working hours in Europe, explains to some extent the longer postgraduate training time and the emphasis on UK trainees maintaining a full "on call" commitment in general paediatrics.

Setting a syllabus for paediatric clinical pharmacology is also inherently difficult. Not only is the subject matter broad in its scope, it is also limitless in its detail. As the original international survey of training programmes[2] noted, agreement on a minimum set of learning objectives is complicated. It is reassuring to note, therefore, that despite the fact that the content of the UK and Canadian programmes have been set independently, they are very similar. This ensures that paediatric clinical pharmacologists in both countries are

being trained to the same high standards and also provides a model for the content of future programmes in other countries. These learning objectives are also a significant step forward in defining the specialty of paediatric clinical pharmacology more clearly which will assist significantly with recruitment and provide a drive towards safer medicines for children.

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