CURRENT TOPIC

Implications of the Crown Report and nurse prescribing

Terence Stephenson

Surgeons operate and physicians prescribe. However, some paediatricians know less about drugs, their prescription, and the legislation governing medicines than their surgical counterparts about anatomy and operative technique. For the first half century of its existence, the British Paediatric Association did not have a Medicines Committee. Yet it is now becoming clear that thirty years after the thalidomide disaster and the ensuing Medicines Act (1968), children remain disadvantaged compared to adults in the development of new drugs and in the scrutiny of old drugs.^{1,2} The two recent Crown Reports add to the complexities of prescribing for children but also represent opportunities for innovation to improve the quality of the service we can offer families.

Background to the Crown Committee

The Government established a review of prescribing, supply, and administration of medicines in 1997 chaired by Dr June Crown. The review grew out of a desire to make greater use of the skills and experience of the various professions working in primary and secondary care and to determine in what circumstances non-medical health professionals could undertake new roles with regard to the prescribing, supply, and administration of medicines. There already exist situations where a doctor signs a prescription even though the assessment has been undertaken by a non-medical colleague, for example, gaiters recommended by a paediatric physiotherapist to aid walking. This is unsatisfactory in clarity of responsibility and accountability.

The first Crown Report and group protocols

The first Crown Report published in April 1998³ was concerned with the supply and administration of medicines by group protocols. A group protocol is a specific written instruction, drawn up locally by doctors and pharmacists, for the supply or administration of named medicines by other health professionals in an identified clinical situation. It applies to a group of patients who need not be individually identified before they present for treatment and may include several medicines, a range of doses, or a variable number of doses. Current examples in paediatrics would be group protocols for the nurse led immunisation

or for adjustment of drug doses for outpatient asthmatics. A group protocol should not be confused with “standing orders” under which a nurse can give a drug without a doctor’s prescription but where there is no flexibility. For example, in our hospital midwives give 10 units intramuscular Syntocinon injection to all mothers once the anterior shoulder is delivered under a “standing order” signed annually by all the obstetricians. The report concluded that group protocols should specify clear arrangements for professional responsibility and accountability. The report recommended that the law should be clarified to ensure that health professionals who supply or administer medicines under group protocols are acting within the law.

THE FIRST CROWN REPORT AND UNLICENSED MEDICINES

For a medicine to be marketed in the United Kingdom it must first receive a Product Licence, now called a Marketing Authorisation. It is then said to be licensed. The licence will only cover the specific indications, doses, routes of administration, age groups, etc for which the Medicines Control Agency, advised by the UK Committee on Safety of Medicines, is satisfied by the pharmaceutical company’s data on safety, quality, and efficacy. For example, cisapride is licensed for gastro-oesophageal reflux in adults but not infants; vitamin K was originally licensed for parenteral use but not by mouth. Some of the apparent limits imposed by a licence may be rather artificial. For example, the company can choose the age groups in which it wishes to market the drug and for perfectly sound commercial reasons may decide not to seek a licence for children. This does not necessarily mean the drug is ineffective or dangerous in children. Alternatively, there are many drugs being used in children for which the triad of safety, quality, and efficacy have not been formally shown but for which long experience suggests they work and do more good than harm. For example, paraldehyde has no Product Licence in the UK. In relation to children, the limits which a licence places on a pharmaceutical company’s advertising campaign and sales force do not automatically extend to the actions of medically qualified prescribers (*infra vide*).

Academic Division of
Child Health, School
of Human
Development, Queen’s
Medical Centre,
Nottingham NG7 2UH,
UK
T Stephenson

Correspondence to:
Prof. Stephenson
email: Terence.Stephenson@
nottingham.ac.uk

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The first Crown Report stated that the following should “not normally” be included in group protocols: “new drugs under intensive monitoring, unlicensed medicines, medicines used outside their licence indications, medicines being used in clinical trials”. Within paediatrics, group protocols may be used for the initiation of drugs and intravenous fluids by, for example, advanced neonatal nurse practitioners. Many of the drugs approved by paediatricians for initiation by advanced neonatal nurse practitioners include examples of both unlicensed medicines and medicines that are used outside their licence indication. In the newborn, both morphine and caffeine are unlicensed medicines.⁴ The joint Medicines Committee of the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists’ Group drew attention to this potential problem. The Crown Review Team’s view was that the caveat “not normally” allowed the use of unlicensed and off-label medicines under group protocols in exceptional circumstances.

Finally, this first report recommended that “the law should be clarified to ensure that health professionals who supply or administer medicines under approved group protocols are acting within the law”. The law has not been amended but legal advice is that any group protocol which meets the criteria set out in the first Crown Report would accord with current standards on good medical practice. It is very unlikely in these circumstances that any judge would find against the health professional following the group protocol (personal communication with Dr Crown). It is therefore important that paediatricians and children’s nurses check that any existing group protocols which they are using satisfy all these criteria.

The second Crown Report

The second Crown Report published in March 1999⁵ dealt principally with the question of professionals other than doctors initiating and prescribing drugs outside the narrow use of group protocols. The government announced an intention to train 20 000 nurses and health visitors over the next two years to make nurse prescribing a reality, following the current period of consultation. The report stated that “any changes to existing roles must at the very least maintain, and preferably enhance, patient safety. The changes also need to bring about demonstrable benefits to patient care and be cost effective”. Some of the government’s enthusiasm for non-medical prescribing may reflect anticipated cost savings. Research suggests that nurse practitioners tend to prescribe less than physicians,⁶ and the greater involvement of pharmacists can save resources.⁷

POM, P, AND GSL MEDICINES

Under the Medicines Act 1968, a written prescription is required for certain medicines called prescription only medicines (POMs). For example, in the UK, all oral antibiotics are POMs. Certain other medicines can be ob-

tained from a pharmacist without a prescription (for example, topical antifungals). Finally, drugs on the General Sales List can be obtained without the supervision of a pharmacist (for example, paracetamol from the supermarket). For many years the only prescribers of POMs for human use were fully registered doctors and dentists. In 1989 an advisory group recommended that district nurses or health visitors should be allowed to prescribe from a limited formulary.⁸ The necessary legislation came into force in 1994. However, the main recommendations of the second Crown Report need further primary legislation before implementation. The pressures on parliamentary time make rapid enactment unlikely.

EXPERIENCE OF PRESCRIBING BY NURSES AND PHARMACISTS

While many countries allow prescribing by nurses under defined circumstances, published evidence is limited. Even less information is available about other potentially relevant professions such as physiotherapists and dietitians. One study on an adult dermatology ward found that nurses’ topical treatments correlated better with the consultants’ choices than did those of junior doctors.⁹ Pharmacist operated clinics have been described for asthma, hypertension, and anticoagulation,¹⁰ but none of these were specifically for children. It is possible that a teenage girl wishing to obtain the oral contraceptive pill would be less intimidated by a family planning nurse prescriber than her own general practitioner, but there is no proof of this. The second Crown report concluded that “current arrangements fail to make the fullest use of the skills of many professionals”. The review recommended that “the legal authority in the UK to prescribe should be extended beyond currently authorised prescribers” to include new groups of healthcare professionals in specific therapeutic areas with expertise in these areas. Because of long standing concerns about the differences in training of doctors, nurses, and pharmacists in relation to using the history and examination to arrive at a diagnosis, the report recommended a distinction between:

- Independent prescribers—professionals responsible for initial assessment of the patient and devising the treatment plan
- Dependent prescribers—professionals authorised to prescribe certain medicines for patients whose condition has been diagnosed by an independent prescriber and within an agreed treatment plan. For example, a dependent prescriber could have authority to adjust doses of anticoagulants, antiasthma drugs, or anti-diabetic regimes according to patient needs.

However, the report also recommended that “newly authorised groups of prescribers should not normally be allowed to prescribe medicines in the following categories”:

- Drugs over which there is continuing professional concern, for example, drugs

used to treat children and young people with mental health problems

- Drugs which on public health grounds should be subject to particular safeguards, for instance antibacterial antibiotics
- Unlicensed drugs, or drugs used outside the licence indication.

For much of paediatric practice it is common practice to prescribe unlicensed medicines and medicines outside their licence.^{11 12} The consensus and authority for their use is set out in the new formulary, *Medicines for children*. The Medicines Committee's view was that there should be a further development of the role of specialist nurse practitioners and other health professionals to afford them the authority to prescribe drugs for children, including those which are unlicensed and used outside their licence, where clear guidance existed.

A licence is a legal requirement for a company to market or promote a drug. However, it is not a legal requirement for a doctor to prescribe a drug. Even if the drug has a licence for certain indications or age groups, it is not illegal for a doctor to prescribe the drug for a different indication or for a different age group ("off-label prescribing"). In my view, the professional requirements to prescribe a licensed or unlicensed drug are very similar and would also apply if prescribing was extended to other professionals. These are that the prescriber should have clinical involvement with the patient they are prescribing for, prescribe the correct dose, be aware of the side effects, and advise on these in advance when appropriate. In general, it should not be necessary to take additional steps, beyond those taken when prescribing licensed medicines, to obtain the consent of parents or the child to prescribe or administer unlicensed medicines or licensed medicines for unlicensed applications. One of the strengths of *Medicines for children* is that it provides a consensus view on the correct dose of a drug for children of different ages where that dose is not available in the company's summary of product characteristics. It will therefore be an invaluable resource for other professional groups if and when the legal authority to write prescriptions is extended to those groups.

THE CROWN REPORTS: AN OPPORTUNITY TO REVIEW EXISTING PRESCRIBING ARRANGEMENTS

If legal authority is given for other professions to prescribe, there will need to be:

- An education and training programme for those already in post
- Changes to the syllabuses of those still in training
- Regular review of the approved list of drugs which can be prescribed
- A monitoring system to detect any sudden increase in drug related incidents
- Clear lines of accountability for independent prescribers and their related dependent prescribers in terms of drug budgets and legal liability

Nurses and pharmacists who prescribe will be as vulnerable as doctors to complaints and

litigation. Over a six year period, errors in prescribing, monitoring, or administering drugs accounted for 25% of settled medical negligence claims against general practitioners who belonged to the Medical Defence Union.¹³ In most situations, a nurse's employer will retain liability but many community pharmacists are self employed.

The scrutiny currently being given to other potential professional groups of prescribers should cause paediatricians to reflect on their own practices. Nurses and pharmacists often have rigorous procedures for staff training, for detecting errors, and to remedy practitioners' deficits; no doubt these safeguards would be extended to their prescribing. In contrast, doctors embark on relatively unsupervised prescribing soon after qualifying. One safety net is that every doctor's outpatient prescriptions will be seen by a pharmacist.¹⁴ However, errors with inpatient prescriptions and administration of drugs can more easily go undetected. Arithmetical errors could be reduced by stipulating that all children's drug doses be calculated using a palm top computer containing software for automatically checking the prescription. However, the "Psion" cannot weigh the baby or detect that the wrong weight has been entered into the keypad! Administration of excessive doses of intravenous and intrathecal drugs would be less likely if all children's drugs were in vials containing doses appropriate to paediatric patients.¹⁵ For instance, it would then be obvious that the dose of morphine prescribed was 100-fold too great if the nurse was required to open 100 vials to draw up this amount.

Conclusions

The authority to prescribe certain drugs in certain conditions is likely to be extended to other health professionals. Early applications to become independent prescribers are expected from family planning nurses, tissue viability nurses, and optometrists. New dependent prescribers might include specialist nurses in the fields of diabetes, asthma, and palliative care and some groups of pharmacists.¹⁶ Potentially, this is an opportunity to improve the quality of care to children but adequate resources for training, implementation, monitoring, insurance, and assessing benefits to children must accompany any changes.

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TRANSATLANTIC TOPIC

Developmental dysplasia of the hip (DDH): an evolving science

Over the past decade, the term congenital dislocation of the hip has been changed to developmental dysplasia of the hip (DDH). This change has occurred because of the important recognition that some infants will have a normal hip examination at birth, but develop hip disease during the first year of life. The American Academy of Pediatrics recently released a guideline for DDH based upon an extensive review of the literature.¹ The guideline was prompted by concerns that some children with DDH are being recognised late in infancy. I have recently been involved in a number of law suits that have resulted from cases of children who were recognised to have DDH well beyond the newborn period, and thus had extensive surgery. This guideline focuses on detection rather than treatment. Highlights include the following:

- DDH refers to a spectrum of disease, including hips that are unstable, subluxated, dislocated, and/or have malformed acetabula
- The incidence of true dislocation is approximately 1–2/1000
- Girls, infants with a positive family history of DDH, and infants in breech presentation are at increased risk
- If a positive Ortolani or Barlow sign is found on newborn examination, the infant should be referred to an orthopaedic specialist (no ultrasonography is necessary)
- If the newborn exam is equivocal (soft click, mild asymmetry) then a follow up hip examination at two weeks is recommended

- If results of the physical examination at two weeks are positive, referral to an orthopaedic specialist is recommended
- Physical examination should be performed regularly during scheduled routine visits. Important aspects of the hip exam as infants age include leg length discrepancy, asymmetry of the gluteal folds, and a positive Galeazzi sign (relative shortness of the femur with the hips and knees flexed).

The objective of this guideline is to reduce the number of dislocated hips detected later in infancy. Almost all clinicians become skilled at performing Ortolani and Barlow manoeuvres during their training, and it is equally important that we recognize other signs and symptoms of hip pathology in older infants.

This guideline and the technical report that accompanies it contain a great deal of important information, including a wonderful review of the literature.² They are an excellent resource for clinicians, educators, and consultants.

H BAUCHNER
US Editor

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