Implications of the Crown Report and nurse prescribing

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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. 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 1998 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 campaign and sales force do not automatically

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).
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. 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 19997 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 group recommended that district nurses or health visitors should be allowed to prescribe from a limited formulary. 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 dieticians. One study on an adult dermatology ward found that nurses' topical treatments correlated better with the consultants' choices than did those of junior doctors.8 Pharmacist operated clinics have been described for asthma, hypertension, and anticoagulation,8 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.

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.13 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.
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. 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. They are an excellent resource for clinicians, educators, and consultants.

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