Commissioner's Comment

A baby harmed by poor prescribing and dispensing

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A recent investigation by HDC into the services provided by a doctor in general practice and a pharmacist is an unfortunate and unusual case where two separate errors resulted in an adverse event for a baby. The drug Maxolon (metoclopramide) was inappropriately prescribed and then inappropriately dispensed to the baby. The case also raises interesting issues about the supervisory arrangements for international medical graduates (IMGs) working in New Zealand and the standard of care expected of them, and the responsibility of pharmacists to query unusual prescriptions.

Baby A's history

Baby A, a six-month-old baby suffering from a cough, raised temperature, vomiting and diarrhoea, was taken to a medical centre by her parents. She was seen by Dr C, who noted mild eczema, a facial rash, white papules in the mouth, and suprapubic tenderness. Dr C diagnosed a urinary tract infection, impetigo, oral thrush and gastroenteritis. She prescribed various medications, including antibiotics (amoxycillin for a urinary tract infection, and flucloxacillin and Fucidin for impetigo), antifungal medication (nystatin for oral thrush), ibuprofen for pain and fever, and Maxolon, 3ml of 5mg/5ml oral solution three times daily, to relieve the vomiting associated with gastroenteritis.

Baby A's parents presented the prescription to a pharmacy where pharmacist Mrs D was on her own, on a Sunday after normal closing time. Mrs D commented that usually she would consider *'the combination of medications extreme'*, but it was not unusual for Dr C.

Mrs D typed the full prescription as presented and then discovered that there was no Maxolon solution in stock. She contacted Dr C and asked whether the Maxolon could wait until the next day. Dr C confirmed that Maxolon was needed that day to stop baby A from vomiting. Mrs D then prepared the medication in tablet form and showed baby A's parents (for whom English was a second language) how to crush the tablet before giving it to baby A.

Mrs D miscalculated the dose of Maxolon. She gave ten 10mg tablets and replaced the previous label with instructions to give half a tablet. (Baby A would thus receive 5mg of Maxolon instead of the prescribed 3mg.) *'In the confusion'*, Mrs D omitted to include the frequency on the retyped label. She initialled every medicine she dispensed as having been checked against the prescription, according to pharmacy procedures, with the exception of the Maxolon.

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Baby A was given the medications at home. Two hours later, a further dose of Maxolon was administered to baby A because she had vomited after the first dose. Baby A developed a fixed upward gaze with hyperextension of the neck, and her body shook for an hour. Baby A was taken to hospital and diagnosed as having an acute dystonic reaction. Staff at the paediatric department also made the diagnosis of gastroenteritis, but none of Dr C's other diagnoses was confirmed. Baby A was treated and discharged the following day.

Dr C's circumstances

Dr C, a UK-trained doctor, had recently moved to New Zealand and initially spent six months as a registrar in cardiology at a provincial hospital. Dr C had worked as a hospital house officer in the United Kingdom for several years, which included work as a paediatric senior house officer. She had taken several years off clinical practice and her experience of general practice prior to seeing baby A was limited to three months.

Dr C was registered with the Medical Council within a provisional general scope of practice to work in general practice and was required to work under supervision. This was undertaken by two GPs at the medical centre, Dr E and Dr F.

She was attending the RNZCGP seminar programme to sit Primex (Primary Membership Examination).

The pharmacy's concerns

The owner/manager of the pharmacy became concerned about Dr C's prescribing practice, particularly the large amounts of antibiotics, codeine, and Maxolon for children. The pharmacy contacted Dr C directly as concerns about individual prescriptions arose, including an inappropriately high dosage of Maxolon to a child a few weeks before the baby A incident. Pharmacy staff were alert to any anomalies with Dr C's prescribing. Subsequently (but before being aware of the baby A incident), based on their Intervention Report (recording several contacts with Dr C to query prescriptions), the pharmacy broached their concerns with the medical centre.

Complaint to HDC

The paediatric registrar at the hospital where baby A was admitted was concerned that baby A had been prescribed a higher than recommended dose of Maxolon, and that Maxolon is not usually recommended for viral gastroenteritis in children. She was also concerned that baby A's parents were given insufficient instructions about the administration and side effects of Maxolon. The registrar commendably reported her concerns to HDC, leading to the investigation.

After obtaining independent general practice advice from Dr Jim Vause and pharmacy advice from Mr John Fraser, HDC concluded that both Dr C and Mrs D had breached the Code of Patients' Rights. Dr C breached Right 4(1) by inappropriately prescribing Maxolon to baby A, and not providing care to baby A with reasonable skill and care. Dr C also breached Rights 5(1) and 6(1) by failing to inform baby A's parents about the side effects associated with Maxolon.

Dr Vause advised that there was no reason to prescribe Maxolon to baby A, and that it was prescribed at a higher than indicated dose. Dr Vause criticised Dr C's multiple prescribing for baby A. He concluded that Dr C's diagnostic skill was poor and would have expected her to understand the hazards of multiple diagnoses.

The pharmacist breached Right 4(2) by failing to comply with professional standards in dispensing the medication. Mrs D had dispensed a dose of Maxolon above the prescribed amount and failed to note the frequency of dosage on the label.

Expected standard of care for a locum in general practice

Dr C was relatively inexperienced in general practice, and was working under supervision, as required by the Medical Council for an IMG new to New Zealand. This raises the interesting question, whether Dr C should be held to a lower standard of care. In McKenzie,[1] the High Court stressed the objective approach to the relevant professional standard: *'It cannot be correct that where a failure to meet proper standard is concerned that a doctor should be able to excuse herself on the basis that she lacked expertise or experience.'* HDC also takes this objective approach in determining whether a health provider breached the Code of Patients' Rights. Patients can hardly be expected to accept a lower standard of care simply because a practitioner is inexperienced in a role. However, an individual's circumstances are then considered by HDC in determining the appropriate penalty (e.g. a referral to the Director of Proceedings).

HDC endorsed Dr Vause's view that judgement problems rather than inexperience was the source of Dr C's difficulties. Dr C should have been aware that prescribing Maxolon was not appropriate, notwithstanding her relative inexperience in general practice.

Supervision of Dr C

Supervision is a condition of registration for all new doctors working in New Zealand. The Medical Council provides guidance on supervisory arrangements.[2]

Dr C believed that she was not adequately supervised or given a proper orientation by the medical centre. She claimed that she was unaware of any concerns about her practice until two months after the baby A incident. The medical centre strongly disputed Dr C's criticisms, noting that Dr C had had a comprehensive orientation to the centre, did not always attend planned supervision sessions or accept alternative supervision offered, and was reluctant to approach her supervisors. Shortly after the pharmacy raised their concerns about Dr C, both Dr E and Dr F spoke to Dr C about her prescribing practice and advised her to make use of the prescribing information available. However, Dr C continued to prescribe medications contrary to the advice given by her supervisors.

With the benefit of hindsight, Dr C required a closer level of supervision. It would have been prudent for the centre to ensure that Dr C was adequately supported, particularly after it became apparent that Dr C was becoming professionally isolated and concerns about her prescribing arose. However, Dr C had a commensurate responsibility to participate and engage in the supervisory process, and to be honest and up-front with her supervisors about any concerns that had been raised with her about her practice.

Responsibility of pharmacists

The pharmacy commented that although it is the responsibility of a pharmacist to check a drug dose, *'if every slight concern were to be related to the prescriber we would be "pharmacops" not fellow professionals.'*

Commentators have remarked on the level of responsibility pharmacists have for the medicines they dispense. Professor John Shaw, Head of the School of Pharmacy, Auckland University, has stated:[3]

'[P]harmacists of the future will be more than 'dispensors' of medicine, rather they would fulfil a societal role of "managers" of medicine in ensuring optimum outcomes for individual patients.'

Dr Fiona McCrimmon, former senior lecturer in healthcare law and ethics, Otago University, has stated:[4]

'[P]harmacists increasingly act in the role of guardians and not mere vendors of medicines, providing products and services on the basis of the knowledge they have and the advice they can provide.'

According to the Pharmacy Council's Code of Ethics, pharmacists have a responsibility to assess the suitability of a prescription and can be expected to confer with the prescriber on unusual prescriptions, and document the details and outcome.[5]

HDC concluded that Mrs D realised that Dr C had prescribed an *'extreme'* combination of medications, and the fact that Mrs D knew it was *'common practice'* for Dr C to prescribe Maxolon for young children did not excuse her failure to specifically query the suitability of the prescription for baby A. In hindsight, Mrs D acknowledged that her dispensing was obviously *'not accurate or adequate'*. HDC stated that pharmacists can be expected to specifically query unusual prescriptions of common medications known to have serious side effects; it is not sufficient simply to query the dosage. This is responsible, rather than simply 'ideal' pharmacy practice.

Improvements to practice

As a result of this incident, the pharmacy's checking pharmacist now circles the date of birth of the child prescribed for, to alert the pharmacist to any possible overdose prescribing. The pharmacy's updated computer system now allows staff to fully record interventions. Mrs D reviewed and adapted her dispensing practice.

No disciplinary proceedings

Dr C escaped disciplinary proceedings. When a doctor breaches the Code of Patients' Rights, and in doing so has provided 'woeful' care, a referral to the Director of Proceedings (to consider whether to bring disciplinary proceedings) may well be indicated. In this case, HDC concluded that the public interest (including the interest in accountability of health practitioners via disciplinary proceedings) did not require a referral of Dr C for possible further proceedings. In making this decision, HDC considered the views of baby A's parents (who did not support further proceedings), submissions from Dr C's lawyer, and confirmation from the Medical Council that Dr C would be required to undergo a competence review should she return to practice. HDC noted that Dr C needs significant retraining and support before returning to practice.

Conclusion

This case vividly illustrates the risk to patients from poor prescribing and dispensing practices. A major initial error by a relatively inexperienced doctor in general practice was compounded by a second error made by a pharmacist. New Zealand is increasingly reliant on IMGs for its medical workforce, and the supervision of IMGs plays a significant requirement for medical registration. This case highlights the responsibilities of both the doctor and his or her supervisor in the supervisory arrangements. It also highlights the duty of care owed by pharmacists to review the suitability of unusual prescriptions before dispensing them.

Competing interests

None declared.

An anonymised version of the full report (05HDC07953) may be viewed at www.hdc.org.nz.

References

1. K A McKenzie v The Medical Practitioners Disciplinary Tribunal [2004] NZAR 47 (HC), paras 73-74.
2. Medical Council of New Zealand, Guidance for doctors working in supervised practice and their supervisors (August 2004).
3. Pharmacy Today, December 2000, p 24.
4. McCrimmon, F, 'Health Care Law and the Interface Between Pharmacy and Medicine', Conferenz, 9th Annual Medico-Legal Conference, Wellington (21-22 February 2001).
5. Pharmacy Council of New Zealand, Code of Ethics (2004), Principle 3.10, available at http://www.pharmacycouncil.org.nz/pharmacists/standard/documents/CODEofEthics20044preps.pdf.

GPs and palliative care

'Altruism is the unselfish devotion to the welfare of others and is greedy of the demands it makes on the individual. It emphasises the point that medicine is a vocation and not just a job. This is at odds with the shift systems in medical training, which adversely effect continuity of care. And yet, one of the great skills we have as GPs is being able to listen, provide symptom relief and follow up where a patient has an illness that cannot be cured. The plight of dying patients has reached a watershed in the UK despite all the valiant efforts of the late Dame Cicely Saunders, founder of St Christopher's Hospice in 1967. We need to reflect on our role as GPs where the ultimate challenge remains the care of someone who is terminally ill.'

Charlton R. The Demise of Palliative Care. Br J Gen Pract http://www.rcgp.org.uk/journal_/bjgp/free_content/previous_free_content_mar07.aspx Accessed 27 March 2007.