PRESCRIBING ERRORS: THE WAY FORWARD?*

A personal perspective

DH Lawson, Chairman, Scottish Medicines Consortium, and Honorary Consultant Physician, Glasgow Royal Infirmary

The perennial topic of prescribing errors has been highlighted in a number of recent media articles in the US and UK. Rightly, patients wish to be reassured that the medical profession (together with those other professions that have recently received extended prescribing privileges) will display the highest standards in selecting and administering an appropriate medicine for their individual needs.

We in Scotland have a long tradition of effort in this regard. Pioneers in the establishment of University Chairs of Clinical Pharmacology (neé *Materia Medica*), we also made a significant number of NHS appointments of clinical pharmacologists in the 1970s and 1980s. The far-sighted efforts of the late Professor James Crooks CBE in developing standardised prescription forms for hospital wards (the Kardex), and the unique contribution of Sir Derrick Dunlop, who instigated a medicines licensing system in the UK, and acted as the Foundation Chairman of the Committee on Safety of Drugs (later Medicines) and then the Medicines Commission, were landmarks in the development of UK clinical pharmacology. More recently, our own former President, the late Professor James Petrie CBE, led the field in evidence-based medicine with his innovative work in the development of the Scottish Intercollegiate Guidelines Network (SIGN) and its role in creating guidelines for rational prescribing.

Despite all these efforts, errors still occur – 'to err is human'.[1] Given the enormous numbers of prescription medicines that are issued daily, perhaps the really surprising fact is the relatively small number of errors of which we are aware.[2, 3] Nevertheless there is clearly a need for renewed efforts to root out this problem by:

- quantifying its magnitude;
- minimising the risks of errors resulting in adverse effects in patients;
- inaugurating and maintaining an active vigilance programme; and
- identifying high-risk categories of medicines and patients requiring special attention.

These approaches are routinely adopted in aviation, the transport industry in general, and the military; in medicine, however, we have been slow to appreciate the problem and unwilling to consider adopting such solutions.

The provision of safe medicines involves many different players:

- manufacturer (pharmaceutical companies);
- regulator (medicines control agencies);
- educator (universities, Royal Colleges);
- prescriber (doctor, dentist, pharmacist, nurse);
- dispenser (pharmacist);
- patient;
- health authority (hospital or primary care trust); and
- lawyer.

Current anecdotal views suggest that there has been a significant deterioration in the quality and consistency of prescribing in recent years. If these views are even partially correct, namely that far from improving, matters are actually deteriorating, this needs to be addressed urgently. Thankfully, there continues to be a rising number of potent effective new medicines produced and marketed by the pharmaceutical industry worldwide. Thus the potential for patients experiencing adverse events is unlikely to decrease in the foreseeable future, unless significant changes are made to our current approach.

Generally speaking, all the evidence suggests that manufacturers, regulators and dispensers have maintained and improved standards during the past decade, so the solution to the problems of prescribing is unlikely to be found in those areas. However, there have been major changes both in undergraduate and postgraduate education in the UK in recent years, and in service provision in the National Health Service (NHS). Prescribers (mainly doctors) are under vastly increased pressure to improve 'efficiency' within significantly reduced hours of work (under the European Working Time Directive). Shift patterns of working are becoming the norm. Patient throughput in hospitals and in out-patient and domiciliary clinics is being enhanced to reduce waiting times. Whilst this has obvious direct benefits for doctors and patients, it is crucial that we maintain and enhance standards of our profession during these developments. This may not be happening in the case of prescribing, given the widespread concerns about increasing errors. Such errors can arise from lack of supervision by senior staff, lack of continuity between staff and patients due to general reduction in hours of working face-to-face with patients, and increasing complexities of rotas worked by staff. These areas are

* Some of the proposals in this article were presented in a Sydney Watson Smith lecture delivered at the Royal College of Physicians of Edinburgh Symposium, 'Moving Points in Medicine', held at Ninewells Hospital, Dundee, on 19 November 2003.

likely foci for any increase in risks from medicines.[4]

UNDERGRADUATE EDUCATION

The General Medical Council (GMC) has been active in devising a new approach to educating young student doctors. For many laudable reasons their recommendations (*Tomorrow's Doctors*) have focused on a more patient-centred, empathic approach to medical education. The initiative has impelled universities to revamp their entire approach towards undergraduate teaching. This, together with the increasing funding crises faced by all universities, has resulted in the recent loss of several key Chairs of Clinical Pharmacology and a major reduction of the teaching of this discipline at undergraduate level in Scotland and indeed in the UK as a whole.[5–7] This interpretation of the cause of poor prescribing, although widely shared by clinicians and clinical pharmacologists, is not universally accepted. In particular, Sir Michael Rawlins feels that the undoubted malaise at the core of poor prescribing is not directly attributable to the GMC-induced curricular changes.[8] Whatever the cause, undergraduates are still taught about medicines as major treatment modalities for disease processes, but the teaching is often disjointed and buried within specialty-based curricula. Thus, albeit unintentionally, the loss of a clearly focused therapeutics course is a major adverse outcome of the recent changes in undergraduate teaching.

Proposals to address this problem urgently have come from the British Pharmacological Society.[5] These proposals are eminently sensible and, if adopted, will go a substantial way towards remedying the deteriorating undergraduate educational situation. If ignored, the future of the medical profession retaining its leading role in the field of therapeutics may be in doubt.

POSTGRADUATE EDUCATION

Clinicians

By addressing the urgent need to enhance undergraduate knowledge of medicines, clinical pharmacology and interactions with patients, we will also be addressing a part of the problem of insuring that safe and effective medicines are delivered to the correct patient at the correct time and in the correct dose and formulation. We will not, however, be solving the problem entirely. For decades it has been true that most young medical postgraduates – at junior and senior house officer level – learn practical prescribing skills from their peers and mentors. The historical grouping in hospital that has provided supervision of this professional skill has been the 'unit'. This comprised a small number of consultants, supported by middle-grade and junior house staff working together for substantial periods of time. It has been under threat from all directions for the past decade and more. Managers, some with little prior knowledge of the NHS, frequently see these 'units' as 'wasteful' and 'inefficient', believing that the disposition of available staff should be evenly spread within a larger grouping (e.g. medicine, surgery). Unfortunately, such an approach greatly inhibits high-quality mentoring and the associated skills derived therefrom. The latest 'hours-of-work' initiatives clearly give added impetus in this direction. The result is that, as a senior physician with special interests in clinical pharmacology and safety in prescribing, frequently I have difficulty in clarifying which staff member has written a prescription for my patient (illegible initials nowadays being the norm rather than legible signatures as legally required).[4] The ability to alter/correct a prescription whilst educating the prescriber is therefore lost. This is the very antithesis of good educational principles. The loss of a clearly focused mentoring system and abandonment of continuity of care in everyday acute situations is a key factor in deteriorating prescribing habits.

What can be done about this sad state of affairs? It is clear that returning to a system that has served us well since the inception of the NHS is neither feasible nor practical. The solution must be a drastic overhaul of the provision of postgraduate education in the field of practical safe prescribing.

Royal Colleges

The Royal Colleges have been at the forefront of greatly increased efforts in postgraduate education, mounting impressive symposia on a wide variety of relevant topics. In our own College, major symposia provide Fellows and Members who cannot attend with CD-ROMs of proceedings. Sadly attendances, although improving, are not as high as justified by the quality of the meetings – presumably because pressures of hours-of-work initiatives come into conflict with increasing patient needs and demands, thereby diminishing the flexibility necessary to permit attendance at meetings. By setting curricula for their examinations, Royal Colleges are keeping up with 'educational theory and practice'. Whether such curricula will prove to be relevant to the everyday practice of medicine I shall leave others to judge. However, by so doing, the Royal Colleges could have a new role in emphasising the importance of prescribing, and improving and enhancing postgraduate knowledge and practice in the area.

The key feature currently lacking is a formal method of ensuring that all prescribers acquire and maintain high-quality prescribing skills, irrespective of the precise point in their careers when this takes place. Initiatives such as the SIGN guidelines are highly welcome and make major contributions to summarising current facts for ready access by prescribers. However, as their founding father, Professor James Petrie, continually emphasised, 'guidelines summarise best practice'. They are not instructions to prescribers, nor are they substitutes for thought! Although a beta-receptor blocking drug is

appropriate to treat hypertension and a beta-receptor stimulating drug is appropriate to treat wheeze, the use of both together in an asthmatic hypertensive patient is manifestly bad practice and highlights the recipe-book approach to prescribing in the first decade of the twenty-first century. Perhaps the time has come for new initiatives from the Royal Colleges in this area, particularly in improving the standards both of record keeping[9] and training at senior house officer levels,[10] and in all cases emphasising the key importance of good prescribing practice.[8] The development of evidence-based guidelines to assist rational prescribing will be effective providing prescribers use guidelines as a structure for thought and not as a substitute for it.

THE FUTURE

I believe the perception that standards of prescribing are falling is correct. Recent initiatives, far from improving matters, will lead to continuing deterioration unless urgent action is taken. Prescribers wish to provide an excellent service to patients, but have difficulty doing so due to several issues: inadequate undergraduate education; inadequate mentoring during junior house officer posts; non-standardised postgraduate training in prescribing; reduced hours of work subtending increasing work load; discontinuity in patient care; increasing recipe-book approach to prescribing; inadequate appreciation of the limitations in patients' ability to cope with multiple prescriptions; inadequate systems alerting prescribers to errors; poor communication with patients; and poor communication with other prescribers involved with the individual patient. All these factors make for an uneasy situation fraught with the potential for error.

Given such developments, the real surprise is that so few errors result in major clinical problems.[2] However, we cannot permit this situation to continue. What is the solution? We could tinker with individual parts of the system, but the recent trends that have brought us to the present state are irreversible. New initiatives are required. The airlines and the military may have identified and put into practice for many years the solution to our problem. Their approach addresses three complimentary areas:

1. Information collection and computerisation

In aviation most routine passenger and flight systems are computerised. The information acquired during everyday use and at service intervals is scrutinised regularly. Thus, for the most part, potential problems can be foreseen, corrected and avoided. The systems in place are user-friendly and relevant to everyday situations.

By contrast, the history of the application and use of information technology to the NHS has been very poor. The technology is currently available to collect routinely, standardised demographic and outcome information on all patients in hospital and in general practice and to link these data with prescriptions issued and dispensed. Such systems are currently available and could be adapted to apply to the NHS. We should by now have automatic exposure and routine measures of outcome for all prescriptions, at costs which are well within practical attainment, given the potential magnitude of the resulting benefits. Pioneering work in this area was initiated by Professor James Crooks and continued by his successors, Professors Denis McDevitt and Tom McDonald in the Medicines Evaluation and Monitoring Organisation (MEMO) at Ninewells Hospital, Dundee. Were this system to be active in 'real time', many types of prescribing mistake could be automatically identified and computerised prescriptions corrected or blocked under certain circumstances (e.g. non-formulary items, incompatibilities, conflicting medicines, interactions with serious consequences). Such developments are easily within the grasp of general practice prescribing where computerisation is penetrating to an ever greater extent. Indeed in some areas such facilities are already *in situ*.[11] By contrast, computerised prescribing in hospitals is woefully underdeveloped in the UK, despite years of effort to achieve this by many individuals including those in the MEMO group. As is usually the case, such delays arise from controversies about the 'best' systems to adopt. In my view it would be much better to decide on a standard system for all hospitals in Scotland and review the position in five years' time, than continue to debate *ad nauseam* whilst delivering little in the way of concrete results. Even now, ironically just at the time when computerisation costs are rendering ambitious systems feasible at realistic costs, such highly desirable initiatives face major additional hurdles from the current overemphasis on patient consent and confidentiality to the exclusion of the real needs of public health surveillance[12] – the very surveillance which will directly benefit the same patients whose data contribute to the common weal! Here surely is an area in need of urgent support.

2. Maintenance of competence

Once qualified, pilots are allowed to fly their planes for a set time interval and always under supervision. To maintain their licence, they need regularly to requalify by demonstrating their continuing skills to a senior colleague during flight simulator activities.

By contrast, to be a prescriber, doctors need only pass their basic qualification (and any higher qualification, such as MRCP, relevant to their intended specialty of interest). No formal demonstration of their continuing skills is then demanded until they retire, save only for their attendance at regular CME courses/sessions. Should we follow the aviation industry example?

In this model, to become an approved prescriber,

doctors would need to undertake and pass a relevant computer-based interactive course in prescribing run by their College each year, at least for the first five or six years post-qualification until attaining a permanent post as a consultant or general practitioner. Thereafter the CME arrangements for all staff may suffice to maintain expertise – this could be reviewed as the initial cohort of certified prescribers passes through the system. Provision of a certificate of competence to prescribe would be a requirement to maintain one's registration with the GMC for all those involved in prescribing practice.

Some may feel this to be a draconian and impractical solution to a problem regarded by many as of relatively minor nature. It is clear, however, that with the major extension of prescribing rights to additional professionals, the near future is going to bring about a revolution in medicines management.[13, 14] The new era could provide a major impetus towards improving public health and patient convenience. It could also prove to be a disaster, were systems not put into place to ensure both complete communication between different prescribers addressing different needs of the same patient, and complete reassurance on the competence levels of all prescribers. This latter aspect is crucial to the safe extension of prescribing rights, which are approved by many doctors[14] and have the support of the Medicines Commission. The key to their successful adoption is to ensure that communications are maintained between prescribers and that the diagnoses treated are well-defined or are symptoms needing relief pending appropriate investigations and targeted therapy. Such developments clearly would be of great potential benefit to patients by reducing the inconvenience many experience in obtaining necessary prescriptions or in achieving optimised dosing of long-term medicines such as anticoagulants, anticonvulsants, hypotensives and many others. They will also be a stimulus to new prescribers to broaden their expertise and rise to the challenges of modern prescribing. Only by adopting similar levels of education for all prescribers will the benefits to patients be maximised and risks minimised. In the long run this will be achieved by running common introductory pharmacology and therapeutics courses for nurses, pharmacists and doctors. In the short term whilst these developments are taking place, it behoves the medical profession to set its prescribing house in order, and not only be achieving the highest standards in this area, but also be seen to be achieving them to the satisfaction of all concerned, patients, other prescribers, and independent advisors alike.[15]

3. Near-miss reporting systems

Continuing the analogy with the airline industry, it is clear that in a complex world, no matter how careful we are, mistakes will continue to occur. Hopefully the frequency of these mistakes will reduce; nevertheless they will not cease. The airlines and the military have for years had a system of confidential reporting of near-misses so that, should mistakes be occurring, they can be identified and hopefully corrected before rather than after a disaster has taken place.

The medical profession already takes advantage of this type of approach by using the spontaneous reporting of suspected adverse drug reactions.[16] Nonetheless it would be appropriate now to extend this approach to include reporting of near-miss incidents in clinical practice. Such reports are already foreseen in the latest developments in the NHS in Scotland and indeed trusts are currently encouraged to develop them. To maximise the benefit to the public at large it would be wise to ensure some standardisation of the methodology being adopted. Routine, unbiased reporting of the resulting information to prescribers will be a crucial part of the success of any such system as it evolves from an exploratory idea to become a widespread and acceptable reality. To achieve this, reporting such incidents will need to gain and retain the support of the professions. This will be paramount and can be achieved as is shown by the experiences both of the airline industry in their version of the system and by the medical profession in its continuing support of the spontaneous adverse drug reaction reporting scheme of the Committee on Safety of Medicines, and the audits of surgical and of maternal deaths published annually. The key ingredient for success is to maintain anonymity of the reporting individual whilst being open and honest about the findings. At issue is not the aim of obtaining a scapegoat to blame for any perceived wrongs in the system, but rather to learn from errors so that they do not recur. To achieve this, reporting should be under the aegis of respected clinicians and not managers – not even clinical managers. The aim is to encourage reports not to deter them. Whilst a voluntary approach to such developments is desirable, the advent of the Clinical Standards Board for Scotland (now part of NHS Quality Improvement Scotland) will no doubt provide an additional impetus to those who lag behind in this area. This Board will also be able to provide both advice on how best to analyse the resulting information in a standardised manner[17] and a venue for publishing the results in their annual report.

Were we to move in the directions outlined above, it will prove to be relatively easy to quantitate the extent of the problem of medication errors and minimise the risks of clinically important adverse effects occurring. The resulting information will update our knowledge in key problem areas. At present, it is well known that the patients at greatest risk of serious drug-induced illness are the young and the elderly, the seriously ill and those with organ impairment, particularly kidney or liver impairment.[18, 19] These groups of patients do receive significant attention during the developmental and

licensing phase of medicines regulation; however it is often not until medicines are released for routine use that the clinical problems become fully appreciated and understood by prescribers. Of major concern are the continuing problems of administration of correct doses of medicines to children, particularly seriously ill young children.[18] Also, with the proliferation of new medicines in the market place, confusion of drug names is a perennial issue which cannot be ignored.[20]

The information regarding those medicines commonly resulting in adverse effects is extensive. Routine surveillance techniques such as those adopted by the Boston Collaborative Drug Surveillance Program, for example, have shown that the most hazardous medicines are the anti-cancer medicines, anticoagulants, anticonvulsants and intravenous fluids.[21] Whilst emphasising that medicines on the whole are remarkably safe,[2] this program has repeatedly highlighted the need for routine monitoring to ensure that commonly used preparations are kept under careful review, foremost among these causing unnecessary ill-health being intravenous fluids.[22] This can only be done by a combination of standardised procedures associated with ongoing routine monitoring of the real-life situation. We can no longer indulge ourselves by ignoring the need to monitor our activities.[23] This can be achieved but will involve expenditure on observational systems. Epidemiology, the science of observational systems, sometimes gets a bad press. In particular it is seen by many as inferior to the gold standard of the randomised controlled clinical trial.[24] This is certainly so when we are studying the efficacy of a medicine. However it is not only an established method for studying rare drug effects,[25–7] but is also the only feasible and practical way to routinely monitor systems and their behaviour under stress, which is where most prescribing errors arise. Collection of routine prescribing information in a standardised manner may even permit detailed comparisons of clinical practice in different countries:[28] a development which could provide clinically-relevant information in the feasible future.

CONCLUSIONS

A large number of changes have recently taken place in our universities and in the NHS. No doubt all have been carefully thought through and were undertaken for the best of reasons. Collectively, they have had the unintended consequence of leading to the widely held perception of a marked deterioration in prescribing skills amongst newly-qualified members of our profession. The absence of routine information collection makes this perception difficult to quantify; nevertheless it is so widely held by experienced teachers and clinicians that it would be folly not to take the matter most seriously. Contemporaneously with this development is the extension of prescribing privileges to a substantially greater number of people, bringing in its wake the need to ensure patient safety in a rapidly changing environment. To ensure this safety we need to review our approach to prescribing both by enhancing undergraduate medical education (bringing it into line with that received by pharmacists and nurses), and by standardising postgraduate medical education (by adopting some of the approaches used in the transport industry). Such views are being increasingly voiced not only in UK but also in US and elsewhere.[29, 30] In particular we will need to improve our routine information collection on prescribing procedures, develop computerised prescribing systems in hospitals, and establish anonymised near-miss reporting schemes. Perhaps more controversially, it is proposed that the Royal Colleges develop prescribing simulators to ensure that trainee prescribers are fully aware of the complexities and pitfalls of the prescribing process, and practice with this simulator at least annually for the first few years after qualification. Such systems could be accessed directly from home computers and skills developed during study periods there. Doctors in training would need to pass an assessment of their relevant prescribing skills annually before having their registration with the GMC renewed. Similarly, other prescribers in training, e.g. nurses and pharmacists, would also need to demonstrate their continued proficiency in this area (were they to wish to be recognised prescribers) before being re-registered with their professional body. Only by adopting such schemes is it envisaged that we will be able to reassure patients of the continuing competence of practitioners to prescribe safely and effectively in the future.

REFERENCES

1 Kohn LT, Corrigan JM, Donaldson MS *et al. To err is human; building a safer health system*. Washington: National Academic Press; 2000.

2 Jick H. Drugs – remarkably nontoxic. *N Engl J Med* 1974; **291:**824–8.

3 Jick H. The discovery of drug-induced illness. *N Engl J Med* 1977; **296:**481–5.

4 Dean B, Schacter M, Vincent C *et al.* Causes of prescribing errors in hospital inpatients: a prospective study. *Lancet* 2002; **359:**1373–8.

5 Maxwell S, Walley T. Teaching safe and effective prescribing in UK medical schools: a core curriculum for tomorrow's doctors. *Br J Clin Pharmacol* 2003; **55:**496–503.

6 Maxwell S, Walley T, Ferner RE. Using drugs safely: undergraduates must be proficient in basic prescribing. *BMJ* 2002; **324:**930–1.

7 Webb DJ, MaxwelL SRJ. A spoonful of sugar? Tomorrow's doctors. *Br J Clin Pharmacol* 2002; **54:**341–3.

8 Rawlins MD. Making tomorrow's doctors better prescribers. *Br J Clin Pharmacol* 2003; **55:**495.

9 Watkins P. Medical records. *Clin Med JRCPL* 2003; **3:**301–2.

10 Royal College of Physicians. *Laying the foundations for good medical practice: generic training programme for senior house officers*. London: Royal College of Physicians; 2003.

11 Lawson DH, Sherman V, HollowelL J. General practice database – a vastly underused information resource. *Q J*

Med 1997; **91:**445–52.
12 Verity C, Nicholl A. Consent, confidentiality and the threat to public health surveillance. *BMJ* 2002; **324:**1210–13.
13 Ferner RE. Medicines management: a sour taste. *Q J Med* 2002; **95:**181–4.
14 Grahame-Smith DG. The demedicalization of prescribing. *Int J Pharm Med* 2002; **16:**233–8.
15 Walley T, Earl-Slater A, Haycox A *et al.* An integrated national pharmaceutical policy for the United Kingdom? *BMJ* 2000; **321:**1532–6.
16 Rawlins MD. Spontaneous reporting of adverse drug reactions I: the data. *Br J Clin Pharmacol* 1988; **26:**1–5.
17 Vincent C, Taylor-Adams SE, Chapman EJ *et al.* How to investigate and analyse clinical incidents. *BMJ* 2000; **320:**777–81.
18 Rowe C, Koren T, Koren G. Errors by pediatric residents in calculating drug doses. *Arch Dis Child* 1998; **79:**56–8.
19 Swift C. The clinical pharmacology of ageing. *Br J Clin Pharmacol* 2003; **56:**249–53.
20 Hoffman JM, Proulx SM. Medication errors caused by confusion of drug names. *Drug Saf* 2003; **26:**445–52.
21 Porter J, Jick H. Drug-related deaths among medical inpatients. *J Amer Med Assoc* 1977; **237:**879–91.
22 Lawson DH. Intravenous fluids in medical inpatients. *Brit J Clin Pharmacol* 1977; **4:**299–304.
23 Ferner RE, Whittington RM. Medical errors and lessons from drug-related deaths. In: *Pharmacovigilance*. Mann RD, Andrews EB, editors. Chichester: John Wiley & Sons; 2002; 509–14.
24 Pocock SJ, Elbourne DR. Randomised trials or observational tribulations? *New Engl J Med* 2000; **342:**1907–9.
25 Jick H, Vessey MP. Case-control studies in the evaluation of drug-induced illness. *Am J Epidemiol* 1978; **107:**1–9.
26 Kaufmann DW, Shapiro S. Epidemiological assessment of drug-induced disease. *Lancet* 2000; **356:**1339–43.
27 Benson K, Hartz AJ. A comparison of observational studies and randomised controlled trials. *New Engl J Med* 2000; **342:**1878–86.
28 Lawson DH, Jick H. Drug prescribing in hospitals: an international comparison. *Amer J Pub Health* 1976; **66:**644–7.
29 Califf RM. The need for a national infrastructure to improve the rational use of therapeutics. *Pharmacoepidemiol Drug Saf* 2002; **11:**319–27.
30 Rawlins MD. Clinical pharmacology and therapeutics into the future. *Br J Clin Pharmacol* 2003; **55:**483–5.