MEDICATION SAFETY

SUMMARY

- Prescription of medicines is the commonest healthcare intervention
- Prescribing is controlled by legislation
- Adverse drug reactions and medication errors are the commonest cause of preventable iatrogenic disease
- The ICGP and NMIC have developed medication record cards to promote medication safety.

INTRODUCTION

The prescribing of medicines is the commonest healthcare intervention in developed countries. However, drug-related adverse effects (so-called ADRs) are a significant cause of morbidity and/or mortality. It has been estimated that up to 98,000 deaths from medical error occur in the US each year and a recent UK study has shown that ADRs were responsible for >6% of hospital admissions. Rational prescribing may be defined as the appropriate use of medicines, using best available clinical evidence. This bulletin outlines the rules of prescribing, the risks for developing ADRs and specifically looks at a recent joint initiative between the Irish College of General Practitioners (ICGP) and the National Medicines Information Centre (NMIC) aimed at improving medication safety and anticoagulant use.

PRESCRIPTION REGULATION

The EU has laid down rules on the classification of medicines that have been incorporated into national legislation. The supply of medicines to the marketplace in Ireland is controlled by The Medicinal Products (Prescription and Control of Supply) Regulations, 2003. The Regulations outline several different classifications (“Schedules”) relating to the supply of medicines to the market. The First Schedule (S1) lists all medicines subject to prescription control; this is further subdivided into three classes (S1A, S1B, S1C) which have implications for the way a prescription should be written and dispensed. Table 1 gives examples of the various sub-divisions in the First Schedule. The dispensing of a prescription for a S1A medicine is restricted to one occasion only unless the prescriber specifically states that it can be dispensed on more than one occasion. It is not sufficient to write “repeat” on the prescription for S1A medicines; specific dosages, and either the number of occasions or the intervals of supply (e.g. weekly / monthly) must be clearly specified. S1B contains those medicines for which a prescription may be repeated for up to six months from the date of issue, unless the prescriber specifically limits the number of repeats or the amount to be dispensed. S1B includes most medicines for chronic use. S1C indicates a prescription that may only be dispensed in a hospital setting (e.g. radio-pharmaceuticals) and therefore is not used in the primary care setting. Table 2 outlines the basic requirements of a prescription.

The Regulations also cover the following areas: medicines which are exempt from prescription control (i.e. for over-the-counter sale) and the circumstances of their sale and supply (e.g. NSAIDs and anti-fungal agents for topical use); the controls for hormonal preparations, including corticosteroids for topical use; the mechanism for the emergency supply by a pharmacist of prescription-only medicines without a prescription. The complete text of the Regulations, including a full listing of all prescription-only medicines is available at: www.dohc.ie/legislation/statutory_instruments/2003 (look for SI 540, 2003).
PRESCRIPTION OF CONTROLLED DRUGS

The Misuse of Drugs Regulations (1988; 1993) set out the conditions under which controlled drugs may be produced, possessed, supplied, imported or exported. Controlled drugs are classified into five schedules with different controls applying to each. Opiates and synthetic narcotics for medicinal use (e.g. pethidine, methadone and buprenorphine) are contained in Schedule 2 and are termed CD2 drugs.

Prescriptions for controlled drugs carry additional requirements to those outlined in Table 2. These include the following:

- The prescription must be in ink or otherwise to be indelible. Certain minimum information must be in the prescriber’s own handwriting such as the name and address of the patient, the dose to be taken, the form (in the case of preparations), the strength (when appropriate) and, in both words and figures, either the total quantity of the drug or preparation or the number of dosage units to be supplied. The prescription must also be signed and dated by the prescriber in his own handwriting. A prescription for controlled drugs cannot be repeated but may be dispensed in installments by the direction of the prescriber. Computer-generated prescriptions without the above information in the prescriber’s own handwriting are not acceptable.

ADVERSE DRUG REACTIONS/MEDICATION ERRORS

Medicines not only have the ability to produce therapeutic benefit (the rationale for their prescription), they can cause unwanted or unexpected adverse reactions. The EU definition of an adverse drug reaction (ADR) is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

The majority of ADRs are predictable (i.e. from the pharmacological profile) and are commonly dose-dependent (Type A). Type A reactions account for up to 80% of ADRs. Type B reactions are idiosyncratic, unpredictable and usually independent of dose; they tend to have greater morbidity and potential mortality. Factors that are known to increase the risk of an ADR include: 1) extremes of age, 2) underlying poor health status, 3) female gender and 4) polypharmacy (defined as the concurrent use of five or more medicines) which results in increased potential for drug-drug interaction.
ADRs that occur in the primary care setting can result in hospital admissions / Accident and Emergency consultations or use of other healthcare services. The exact number of ADRs experienced by patients is unknown but a recent study involving two large UK hospitals reported that 6.5% of admissions were related to ADRs, which was the direct cause of admission in 80% of these cases. Most reactions were either definitely or possibly avoidable. Drugs most commonly implicated included warfarin, diuretics, low dose aspirin and NSAIDs, with gastrointestinal bleeding being the commonest adverse reaction.

Medication errors may be defined as any error in the prescribing, dispensing or administration of a drug, whether there are adverse consequences or not. They are reported to be the commonest preventable cause of patient injury. In one US study the rate of serious medication error (i.e. preventable ADRs plus potential adverse drug events) was recorded at 7.3%. Medication errors have been reported to account for approximately 10-20% of legal claims against general practitioners. Prescribing errors may arise from incorrect drug selection for a patient in terms of dose, strength, route, quantity or contra-indications. A recent Irish study showed that 5% of prescriptions reviewed were illegible, another major source of medication error. Table 3 outlines ways of reducing prescribing errors.

### Table 3. Points to remember when writing a prescription

- Check dosing, contraindications and potential side effects (e.g. from the Summary of Product Characteristics or in a recognised formulary, such as the BNF) prior to issuing prescription
- Check what other medicines the patient is taking, including non-prescription items, which may interfere with the new medicine
- Refer to the list of common drug-drug interactions, when patients are taking several medicines
- Ensure that the prescription is legible – it may be misinterpreted if it cannot be read
- Advise patients of possible, likely and probable side effects and encourage them to report back any problems
- Respond promptly (either reducing dose / discontinuing drug) to a patient’s concern / ADR
- In the event of any side effect, consider reporting it to the regulatory authority (www.imb.ie for downloadable form)

**IMPROVING MEDICATION SAFETY**

The number of patients on complex medication regimens is increasing. Many currently approved regimens demand that patients should take several medicines with differing modes of action (e.g. combined therapy for hypertension; use of several medicines in the secondary prevention of cardiovascular disease). This increases the risk of developing ADRs. In addition, it is often difficult to keep accurate records if a patient attends both primary and secondary care facilities, or if a patient has more than one prescribing doctor. Patients may be unaware of the name or type of medicine prescribed by another physician and this can lead to the risk of an ADR or medication error.

Involving patients in their own drug treatment has been shown to increase compliance. Advising patients, in advance, that they may experience a side effect, inviting them to report such side effects promptly and having a planned course of response is important and will help to reduce the impact of ADRs.

**COMBINED ICGP/ NMIC SAFE MEDICATION INITIATIVE**

To address the issue of improving medication safety, a joint initiative was undertaken recently by the ICGP and the NMIC. The objective of this initiative was to produce two simple, user-friendly cards, chiefly with a view to improving communication between different prescribers / care-givers in the management of patients requiring several medications or anticoagulation therapy. The cards are designed to be handbag / inside-pocket size and are not designed as a complete record of patient information.
Every effort has been made to ensure that this information is correct and is prepared from the best available resources at our disposal at the time of issue. Prescribers are recommended to refer to the drug data sheet or summary of product characteristics (SPC) for specific information on drug use.

**MEDICATION CARD**

These cards may be obtained from the ICGP at (01) 6763705 (small fee applies). They are particularly relevant in the care of older patients, on polypharmacy, who are at significantly greater risk and more vulnerable to toxicity from prescribing errors. A simple rule-based approach could be introduced into primary care practices, in instances where patients are prescribed five or more medicines. Such patients (or their carer) might be issued with a card. It should be noted that issuing the card initially involves a time cost; however once set up, the card is easy to maintain, and greatly reduces the time taken to subsequently review medications during later consultations. The introduction of these cards will also be of benefit at outpatient visits, to colleagues on call and to practice locums.

**SUMMARY**

Improving safety in the prescribing, dispensing and administration of medicines is a priority for health services throughout the world and many countries have put in place strategies to deal with this issue. Many of these provide good practice recommendations in areas that are known to be error prone. The use of the ICGP/NMIC medication and anticoagulation cards aims to tackle these two main areas of potential problems in prescribing. In addition, by involving patients, these cards will increase patients’ awareness of their medicines which should increase compliance and improve medication safety.

References available on request.

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