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US SAFETY BRIEFS

Fewer suicide attempts

In 1998, legislation was passed in the UK that has restricted the package size of paracetamol available in pharmacies to 32 tablets/capsules. In shops other than pharmacies, the package limit is 16 tablets/capsules. The legislation allows one to purchase up to 100 tablets from a pharmacy, but in practice, voluntary restrictions often limit the number of packages that can be purchased. According to a recent study <bmj.bmjournals.com/cgi/reprint/bmj.38253.572581.7Cv1> these smaller packages have helped reduce the number of suicides caused by overdoses in Britain by 22%. Also, the number of liver transplants necessitated by paracetamol poisoning dropped by 30%. The number of overdoses with ibuprofen, not covered by the legislation, increased, but there was no effect on deaths. Although the laws do not stop anyone from purchasing multiple packages from more than one retailer, self-poisoning is often impulsive, involving tablets that are readily available in the household. The researchers suggested making packages even smaller, saying it would further help to reduce the number of deaths. FDA's Drug Safety and Risk Management Committee met in September 2002 to discuss over-the-counter analgesic drug safety (including paracetamol). New overdose warnings were later added to labelling. We are unaware of pending actions that would restrict package size in the US.

Australian comment: Has anyone attempted to buy multiple packets from an Australian supermarket?
[*Medication Safety Alert! November 4, 2004*]

FDA must be more responsive for a safer healthcare system

Without reproducing the whole alert, a section of this article of relevance to the Australian market follows: Dangerous, sometimes fatal, overdoses continue to occur due to confusion between lipid-based products and their corresponding conventional forms (e.g. amphotericin, doxorubicin). Similar nomenclature is the most common cause of mix-ups between these products, yet nothing has changed in the years since our first national alert in August 1998.

[*Medication Safety Alert! November 4, 2004*]

Truth about hospital formularies

What does the term 'formulary' mean in a hospital? If you are a pharmacist, do you consider the formulary a continuously changing list of preferred drug products that reflects clinically proven pharmacological improvements available in the marketplace? Or is it merely an administrative device for identifying the drugs that can be ordered through a group purchasing agreement or just a subset of the *real* formulary when you consider the frequency with which physicians prescribe 'non-formulary' drugs? If you are a physician, do you feel the hospital formulary is a tacit representation of the full

universe of pharmaceuticals in the marketplace, even if it excludes some of the medications you prescribe on paper? Or do you view the formulary as a means for hospital administration, pharmacists, and/or the Pharmacy and Therapeutics Committee to dictate your practice and control your choice of medications? Do you groan and cringe at the mere mention of the term because you believe you can render better care with unfettered access to any medication? Do you think that the formulary is merely the hospital's means of cutting costs? If you're a nurse, do you view the formulary as simply a list of all drug inventories available in the pharmacy? If you are the Chief Medical Officer or the Chief Executive Officer, does the formulary primarily represent a means for restraining drug costs and utilisation to achieve economic goals? If you are a pharmaceutical manufacturer, do you consider the hospital formulary an inconvenience that can hamper and potentially nullify your drug promotion activities? The term 'formulary' can have assorted meanings and conjure up many different feelings, depending on the person's point of view. Too often, the term is employed indiscriminately to suit the convenience of various individuals, organisations, or companies to describe a particular list of drugs and related medical products. Perhaps these inconsistencies represent an even bigger problem. Health professionals and industry tend to deny or downplay the most fundamental and important purpose of a hospital formulary: To delineate the *drugs of choice* as determined by *clinical efficacy* and relative *safety* (including adverse drug reactions, side effects, interactions, as well as error potential and risk of patient harm). Most of the responses to the term 'formulary' cited above do not allude to drug efficacy, and none reflect safety as a goal. Ideally, a carefully selected drug formulary provides a foundation to guide clinicians in choosing the *safest*, most *effective* agents for treating particular medical problems. But full realisation of this potential has been thwarted by misconceptions, according to a 1990 article (Rucker TD, Schiff G. Drug formularies: myths-in-formation. *Medical Care* 1990; 28: 928-42. Reprinted in *Hosp Pharm* 1991; 26: 507-14). During a 3-year period (1987-89), Rucker and Schiff compiled statements made by physicians during Pharmacy and Therapeutics Committee deliberations pertaining directly to the formulary concept. Sadly, they found that the deliberations centered less on critical evaluation of scientific data and more on the purpose, design, and the need for a formulary, *per se*. Rather than debating the relative merits of the drug, the formulary concept itself was often subject to review. In the end, debates about a particular drug were really disagreements about fundamental assumptions related to formularies. These disagreements occurred both within the Committee and with staff physicians who came to support the addition or deletion of a particular drug. After contrasting these statements and other published misconceptions with the basic objectives and operational requirements

of an effective formulary, the authors classified the comments into frequently occurring myths about formularies. It's been well more than a decade since this article was first published, so has much changed with hospital formularies since then? A survey following, describes the formulary myths initially identified by Rucker and Schiff in 1990. We'll report our findings in an early 2005 issue of the newsletter.

[Medication Safety Alert! November 18, 2004]

Why home meds should be inspected

An 82-year-old patient with unstable angina was admitted to the hospital. Per physician's order, the patient was allowed to use her medicines from home after a pharmacist inspected them. The patient was supposed to be taking 'lisinopril 5 mg bid' at home. However, the prescription bottle sent to pharmacy was labelled '10 mg tablets'. The pharmacist also noticed that all the pills were not quite the same color. Upon further inspection, she found that the product imprint code on the pink oval tablets was E101 (lisinopril 10 mg, Eon Labs) and E102 on the peach, oval tablets (lisinopril 20 mg, Eon Labs). The bottle also contained both full and half tablets. The medicine was not approved for administration in the hospital due to these discrepancies. A nurse reviewed the discrepancies with the patient and learned that her lisinopril dose had been changed from '20 mg bid' to '10 mg bid'. The patient had emptied the remainder of an old bottle of 20 mg tablets into the new bottle of 10 mg tablets after splitting each tablet in half. More recently, her dose had been further reduced to '5 mg bid'. The patient had then tried to find all the 10 mg tablets to split them in half, but some of the 10 mg tablets remained whole. The pharmacist separated the different dosages and labelled them correctly for the patient before discharge. Remember to warn patients about mixing the contents of prescription bottles, even if they contain the same drug but different doses. If a medication dose is changed, patients could also bring the prior prescription bottle back to the pharmacy so the patient's physician can be contacted and a new label with correct directions can be applied. Pharmaceutical companies could also use distinct colors for different strengths of the same medication.

[Medication Safety Alert! November 18, 2004]

When the Fax is not factual

If you are using fax machines or scanners to communicate prescriptions or medical orders, it is critically important to create a system of regular equipment maintenance and platen (roller in a fax machine or glass surface of a scanner) cleaning to avoid medication errors. The following order, originally mistaken as 250 mg of Flagyl (metronidazole), was correctly interpreted as 500 mg once the original order was viewed. Since fax machines are connected to telephone lines, significant line 'noise' can obliterate important information, such as portions of a drug name or even the dose. Transmissions via fax machines or proprietary image scanners can show streaks or fadeouts when dirt, dust, stuck paper, correction fluid, and even holepunches interfere with the scanned image. One frequent problem occurs when unit coordinators affix small stickers to orders, such as a 'sign here' arrow for prescribers, then forget to remove them when they scan or fax. The stickers can get caught in the machine, causing a black line across every order sent until it's cleared, or obscure information on scanned documents. A related

problem: prescribers sometimes write on the very edge of the order form, making it impossible for fax machines and scanners to 'read' the entire order. Thus, an order for 'Lomotil qid prn' may appear as 'Lomotil qid' if the 'prn' is in the extreme right margin. In addition to ensuring regular maintenance, those who transmit orders need to be aware of the above stated conditions that could impeded communication, and when recognised, corrected them immediately.

Australian comment: In view of the need to use fax machines or scanners with the new national medication chart, this warning is timely for all Australian hospitals. Few of us will have the capacity for order entry at ward level for some time yet and even if we do, this will only relocate the current undesirable transcription step. Ultimately, we will all be recipients of electronic prescribing messaging, directly into our dispensing systems however as we move towards this, we need to take absolute care not to introduce other sources of error.

[Medication Safety Alert! December 16, 2004]



Flagyl dose was initially seen as 250 mg on fax transmission (above), and then clearly seen as 500 mg on the original order (below).



Separate innies and outies

Dakin's solution (dilute sodium hypochlorite solution), sometimes utilised for wet-to-dry dressings, is often prepared using 1000 mL irrigation bottles of sterile water or saline that are relabelled. These are often stored in the patient's room with the dressing supplies. At the same time, nurses often use sterile water to dilute crushed medications for administration to patients via feeding tubes. This also may be stored in patient rooms. One hospital recently reported a near miss when the sterile water bottle and the Dakin's solution were stored next to each other on a counter in the patient's room. The Dakin's solution was used to dilute crushed medications, but fortunately, the mistake was noticed prior to drug administration. Extemporaneously prepared irrigation solutions of any type should be prepared in the pharmacy and labeled in a way that clearly differentiates the product from those that might be used systemically (orally or by injection). For irrigations, one hospital affixes white labels and the word 'irrigation' appears in a giant font size in red type. This incident should also serve as a reminder of the importance of having pharmacy staff regularly observe the location of medications and solutions outside the pharmacy to uncover potentially hazardous conditions.

[Medication Safety Alert! December 16, 2004]

Still SR and XL confusion

Teva's Budeprion SR, a branded generic bupropion, is labelled 'extended-release', similar to Wellbutrin XL, labelled for once daily administration. We have noted that Budeprion SR might be confused with Wellbutrin SR, a sustained-release product labelled for twice a day administration. However, Budeprion SR, although labeled extended release, is in fact generically equivalent (ABRrated) to the sustained-release product, Wellbutrin

SR. The manufacturer, Teva, confirmed this rather confusing but critical piece of information. This lends further support to our contention that, if drug name suffixes must be used, FDA needs to standardise them in order to prevent medication errors. The United States Pharmacopeia has specific recognised dosage formulations for modified release tablets: delayed release or extended release.

Australian comment: Although this is a US example we are familiar with a large range of extended and sustained release products within Australia. A new entry into the Australian market is Reminyl prolonged release capsules abbreviated as Reminyl prc which on a medication chart could become Reminyl pr. This could be interpreted as the rectal route. The recommendation for standard suffixes is one that also applies in Australia.

Suffix confusion

With a wide range of drug name suffixes used in the US for various dosage forms (CD, CR, ER, LA, SA, SR, TD, XL), frequent errors occur right here due to the lack of standardisation. If obtaining a product with a drug name suffix from a foreign country, errors seem inevitable, even if the active ingredient is the same in branded US and foreign medications! Next, while verbal orders are less likely when importing drugs from abroad, look and sound-alike brand names can also play a role in errors. For example, Amyben is one branded product for amiodarone in the UK. A supply of Amyben in place of Ambien (zolpidem) in the US could have disastrous results! Perhaps a thorough failure mode and effects analysis (FMEA) on drug importation is a critical first step before further consideration of this seemingly cost-effective alternative. With all the political discussions on the topic, we need to step back and really look at safety. How could these issues go unnoticed until now? An FMEA might reveal a host of additional safety issues.

A TACTical error

A dermatologist recommended 'TAC 0.1%, apply tid to affected areas' for a hospitalised patient with a skin disorder. The patient's physician misinterpreted the recommendation as TAC (tetracaine/adrenalin/cocaine) and submitted a non-formulary drug request form to obtain the medication for the patient. The pharmacist intervened and clarified the order with the prescribing dermatologist as triamcinolone cream 0.1%. A few months later, a hospitalised nursing home patient was referred to the same dermatologist for a rash unresponsive to hydrocortisone cream. This time, a different physician interpreted the dermatologist's 'TAC' prescription as tacrolimus 0.1%, and again submitted a non-formulary drug request. The clinical pharmacist realised the similarity to the previous request and called the dermatologist, who again verified that the intended medication was triamcinolone 0.1%. Obviously, we would suggest that 'TAC' be added to your unapproved abbreviation list, but chances are, physicians, pharmacists and nurses are still going to see it from time to time. To prevent misinterpretations, it's best to not accept any order in which the drug name is abbreviated; contact the prescriber to clarify the order.

Australian comment: A similar issue could occur with ALA (Adrenaline, Lignocaine, Amethocaine) solution which is a contract manufactured item. It is used as a topical anaesthetic to be applied to superficial wounds

and lacerations. ALA has also been used as an abbreviation for aminolevulinic acid, an SAS product used by dermatologists in photodynamic therapy. There is a potential for the two to be confused and therefore ALA should be banned as an abbreviation unless used as the unique Brand name.

International traps

Brand name medications that may contain different active ingredients in another country may be problematic. A patient who was travelling to Serbia ran out of Dilacor XR (diltiazem extended-release), marketed by Watson Labs in the US. A Serbian pharmacist filled the prescription with digoxin 0.25 mg. In Serbia, Dilacor, marketed by a local company, is a brand name for digoxin. The patient continued to take digoxin without realising it and was hospitalised after his return to the US with life-threatening toxicity. We suggested reminding patients who are travelling abroad to carry an adequate supply of medications along with a list of their medications by both generic and brand name so they could confirm that the correct drug has been dispensed if supplies become depleted. As we further investigated this problem, we quickly learned that the circumstances leading to this patient's harm have wider implications. There are a number of instances where brand names for US medications exist in some countries with totally different ingredients. Table I provides a few examples of US branded medications that represent different ingredients in Europe. Keep in mind: the problem is far more widespread than represented in the table. Many other examples are listed in *Index Nominum* and *Martindale* (available by subscription through *Micromedex*). Furthermore, the brand name used for a foreign product may be available simultaneously in several countries, or it may represent additional unique medications in countries other than those listed. For example, while Dilacor is a brand name for diltiazem in the US and digoxin in Serbia, it's also a brand name for barnidipine in Argentina and verapamil in Brazil. As a result, this problem adds complexity and danger to drug re-importation. Companies planning to market a drug only in the US might not perform a comprehensive search worldwide to assure that the proposed brand name isn't used elsewhere. If marketing the drug outside the US, most large companies will perform searches in the major markets served because there's an interest in adopting a single global brand name. However information may not be available. On occasion, generic names of products in another country might be different than those used in the US. However, there are world authorities, like the World Health Organization's International Nonproprietary Name system, that control these situations and offer ongoing efforts to harmonise generic names worldwide. This is not so with brand names. Once a brand is marketed in certain countries, there is no universal system to monitor or prevent the same brand name from being used in other countries for different products. As such, the problem is larger than not recognizing a foreign, unfamiliar generic name. That, by itself, would likely stimulate further research. More importantly, the problem with brand names that represent different active ingredients rests squarely on the shoulders of patients (who may have no idea that the wrong drug has been dispensed) and their healthcare providers (who may not know what their patients are really taking). This issue is also of importance when overseas patients are admitted to Australian hospitals with their own medication.