Leading article

Patient packs and the prescribing of antimicrobial agents

J Antimicrob Chemother 1996; 38: 329-331

Unlike most other pharmaceutical products, antibiotics are usually prescribed for a defined period. This varies from a few days in the case of treatment of an acute bacterial infection, to several months for tuberculosis. There is considerable variation in the duration of treatment of common infections largely because the optimal course is not known. This is reflected in the section of The British National Formulary dealing with anti-infectives; for most conditions specific agents and dosages are recommended but advice as to duration is given for only a minority and, where it is provided, is often imprecise, e.g. 10–21 days for syphilis (British Medical Association & Royal Pharmaceutical Society of Great Britain, 1995). New developments in the dispensing of drugs, arising from legislation enacted by the European Community, are likely to challenge this vagueness of much antibiotic prescribing.

Throughout most of Europe prescribed medicines are dispensed with patient information leaflets provided by the manufacturer. In the UK, Ireland and the Netherlands, however, many medicines are bought in bulk by pharmacists and then dispensed in individually labelled bottles with little or no information provided for the patient. A new European Community directive, which came into force in early 1994 and which is geared towards a high degree of consumer protection, requires all member states to move to dispensing drugs in a patient pack of approved size with improved labelling and an approved patient information leaflet (Council Directive 92/27 EEC, 1992). In the UK, the move towards patient pack dispensing will take place in 12 phases, starting from December 1995 but the majority of antimicrobial agents will not be affected until Phase 10, due in March 1998. Patient pack dispensing will have its greatest effect outside hospitals where 90% of all drugs are dispensed and should ensure that patients are better informed about the medicines they take. For many drugs used chronically, this initiative will result in little change; the pack size will be for 28 days' treatment and doctors will prescribe a pack rather than specify the number of days of treatment. In the UK, antibiotic packs are likely to be for 5 to 7 days but these may vary elsewhere in Europe according to local practice.

There are four main arguments in favour of patient pack prescribing: improved compliance, patient and medical assurance, enhanced drug safety and more effective use (Association of the British Pharmaceutical Industry, 1995). Improved compliance should follow as patients better understand why and how they should take their medications. Patients and medical staff can be assured of the quality and integrity of the product; this may also reassure patients about any differences in the appearance of generic products. Patient safety should be improved by the provision of information on dosage recommendations, adverse effects, contraindications, details of storage and the expiry date. Finally, medicines should be used more effectively by informing the patient of their correct use, e.g. a patient or carer will be able to identify which tablet is for which condition, and special instructions for use in children, the elderly, and pregnant or breast-feeding women will be included. This initiative will have practical implications for patients, pharmacists and doctors. It will also involve patients more in decision-making, requiring information leaflets that are clear, up-to-date and consistent (Anonymous, 1995). Antimicrobial agents are most commonly prescribed for the treatment of urinary tract infection (UTI) and lower respiratory tract infection (LRTI) and some aspects of prescribing for these conditions are ill-defined and illustrate some of the issues that need to be addressed.

The optimal duration of treatment for uncomplicated UTI, once considered to be 7–10 days, is now 3–5 days following studies such as those of Charlton conducted in the 1970s (Charlton et al., 1976). Exceptions to this include infections involving the upper renal tract, infections of the prostate and the acute
urethral syndrome' (Lerner, 1987). Single dose therapy with some drugs has been popular as it is cheap and convenient for the patient; rapidly excreted agents such as nitrofurantoin and \( \beta \)-lactams are unsuitable whereas those with a longer half-life, e.g. fosfomycin trometamol are preferred (Greenwood, 1994). Before the introduction of patient pack dispensing, the pack size (i.e. number of days' treatment) will have to be decided and this will be influenced by the duration of treatment, type of infection and the agent to be used. This applies particularly to those agents, often referred to as urinary antiseptics such as nitrofurantoin, trimethoprim, nalidixic acid and norfloxacin.

Prescribing patterns are even more variable in LRTI. The treatment of acute exacerbations of chronic obstructive airways disease is complicated by the uncertainty whether antimicrobial agents are even necessary, but the introduction of precise guidelines regarding their prescription, agreed locally, does not have a detrimental effect on outcome (Boyter, et al., 1995). One recent review of LRTI suggested that "... antibiotics should be used in adequate doses for a specified period of time, then stopped . . ." (Hosker, Jones & Hawkey, 1994). This apparently vague statement simply reflects the absence of more precise advice following relevant clinical trials. In a North American review of community-acquired pneumonia (CAP), which compared the British and American Thoracic Society guidelines regarding therapy, there was considerable similarity in the approach to the choice of agent recommended for uncomplicated CAP, and advice on dosages was included, but there was little guidance on duration of treatment (Bartlett & Mundy, 1995). The authors, however, suggested that parenteral therapy should be continued for at least 24 h after the patient had become afebrile and that 5–10 days is satisfactory in most cases, except for infections caused by Mycoplasma pneumoniae, Chlamydia pneumoniae and Legionella spp., where up to 21 days is preferred (Bartlett & Mundy, 1995). It seems likely that for the treatment of community LRTI, the issuing of a 7 day course or pack would satisfy most needs even if 5 days' treatment may be adequate.

A recent survey in England and Scotland has revealed a steady annual increase in the number of prescriptions for antimicrobial agents in the community, especially for new drugs (Davey et al., 1996). With the dispensing of antimicrobial agents and the accompanying information leaflet, there will be an opportunity to educate patients on the importance of the correct use of antibiotics. While there will be some initial difficulties for pharmacists, e.g. what to do with a request for an unusual pack size, and some drug companies, e.g. different pack sizes required according to country and infection (5 and 7 days for UTI and LRTI, respectively), there should be opportunities to rationalise aspects of antimicrobial prescribing. There is considerable concern over the emergence and spread of resistant bacteria, especially in hospitals, and improving antimicrobial prescribing is seen as essential in combating this threat (Goldmann et al., 1996).

Patient pack dispensing should ensure greater consistency in the duration of antibiotic treatment with shorter courses helping to ensure more cost-effective prescribing and lessening the pressures on new resistant microbes emerging. As we prepare for the implementation of this important initiative, it is essential that all those involved in the prescribing of antimicrobial agents work with the pharmaceutical industry in ensuring that information packs, dosages and dose duration reflect what is considered to be good prescribing.

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References


