TAYSIDE PRESCRIBER

ADTC Supplement, No. 9

Issue 9 **June 2000**

In this issue:

TREATMENT OF ERECTILE DYSFUNCTION

There is continuing confusion over the method of referral of male patients whose GPs consider might qualify for (any) treatment of erectile dysfunction at NHS expense but, in particular, sildenafil (Viagra®) under the "extreme distress" criterion. Such treatments are currently allowed on GP10 prescriptions for stated categories (neurological disease, diabetes, prostate cancer, renal failure, etc) and may be prescribed by GPs on private prescription for others. What constitutes "severe distress", just how it should be assessed, and by whom is proving to be a difficult issue to resolve.

The New Drugs Sub-Group that first reviewed sildenafil in September 1998 will be reconvened. It is hoped to produce a definitive statement on the method of referral and assessment of this group of patients in the near future.

LINKING DRUG & THERAPEUTICS COMMITTEES ACROSS TAYSIDE

The TUHT has now established a Drugs & Therapies Committee set up *to advise the Trust on issues relating to the use of medicines and other technologies which impact on patient care in TUHT hospitals*. Representatives of the PCT and Health Board are members of this Committee. Discussions are ongoing about how best to link the work of this Committee with the PCT in order to ensure continuity of care across the hospital/community interface and also how best to link up with the established ADTC structure which advises Tayside Health Board on related issues. A re-organisation of the ADTC has taken place to ensure full representation from the Tayside Trusts. Early communication of decisions between these different organisations will be vital to achieve effective medicines and technologies management and to resolve issues on funding and implementation and review of new (and current) therapies across the area.

NEW DRUGS SUB-GROUP

ETANERCEPT (Enbrel®) and INFLIXIMAB (Remicade®) in RA

These are two anti-tumour necrosis factor (anti-TNF) monoclonal therapies for rheumatoid arthritis - only etanercept is licensed for this indication at present. Both drugs appear to be more effective than standard DMARD treatment but, as there may be safety issues concerning their use and also significant cost implications, they must be introduced in a systematic way. To this end the British Society of Rheumatology (BSR) have produced guidelines on who should receive the new drugs and this should serve as the basis for their use in Tayside. Those who might be considered for treatment include the following.

Patients with highly active RA, calculated by a composite disease activity score including those who have failed on standard therapy for advanced disease (e.g. methotrexate + cyclosporin + low dose steroid).

The BSR considers that a central register should be established in order to monitor use, benefit and adverse effects of etanercept and infliximab. Since both are new in clinical practice, the need to address long term safety (in particular the development of infections and malignancies) is stressed. Specialists using the treatments must be advised accordingly.

Category 2a - prescribed by specialists in secondary care

CELECOXIB (Celebrex®) - a new selectice COX-2 NSAID

This is the second drug (rofecoxib, Vioxx® being the first) in a new series of NSAIDs that are highly specific for pro-inflammatory cyclooxygenase type 2 (COX-2). Their arrival brings the promise of safer NSAID therapy for those at risk of serious GI events due to inappropriate COX-1 inhibition resulting in compromised mucosal protection. It remains to be seen whether or not celecoxib (and others like it) will provide a cost-effective alternative to standard NSAIDs in practice. Meanwhile celecoxib should be reserved for those at highest risk of major GI events.

An osteoarthritis treatment algorithm, which covers risk groups, will soon be published in Tayside Prescriber and circulated as a guide to prescribers.

Only celecoxib is currently licensed for rheumatoid arthritis and there is generally more data available for this drug than for rofecoxib. Most evidence on safety has been based on endoscopic studies and long term outcomes in relation to the effects of treatment on major GI events (bleeds, ulceration, etc) is still awaited. Note that dyspepsia is still a reported side effect of treatment.

Prescribing category 1 (prescribed in both primary and secondary care settings) – *in patients who require an NSAID and are at high risk of GI complications and unable to tolerate the co-prescription of misoprostol or acid suppression.*

FORMULARY SUB-GROUP

The 5th edition of the Tayside Area Drug Formulary (TADF) will be issued in August 2000. A number of new Appendices have been added, including: Tayside Advisory Notes on the Management of Acne, Anticoagulant Advisory Notes, and ADTC New Sub-Group Recommendations.

Clearly, there is much work to be done on the monitoring and implementation of the TADF in the coming year, and the Trust Drug and Therapeutics Committees are expected to play a key role in this.

FUTURE EVALUATION OF NEW DRUGS

In future, new and (where appropriate) existing drug therapies will be reviewed by a Drug Evaluation Panel formed from the previous New Drugs and Treatment Review Sub-Groups. Information and advice will then be passed to the Health Board, as before, for decisions on funding and prioritisation. Such decisions will be taken in consultation with senior representatives of each of the Tayside Trusts. This process should enable Trusts to act promptly when planning the application of new or existing therapies within their organisations.

In order to provide a comprehensive drug evaluation programme and avoid duplication of effort, methods of sharing workload across Scottish centres (ADTCs) are currently being investigated. Clearly the new Heath Technologies Board of Scotland (HTBS) will play a key role in providing guidance in areas of major therapeutic relevance. Future cooperation between HTBS and ADTCs will be essential in ensuring that standards are applied consistently across Scotland in line with the spirit of Clinical Governance.