TAYSIDE PRESCRIBER

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NHS in SCOTLAND RE-ORGANISATION – FUTURE ROLE OF THE ADTC

Clarification of the role of Area Drug & Therapeutics Committees in relation to SHTAC - which is to be re-named the Health Technology Board for Scotland (HTBS) - is emerging. Discussions are ongoing between the future HTBS and representatives of local D & T Committees to ensure continuity of advice on therapies, including the managed entry of new drugs in practice, across Scotland. Formation of a consortium from Health Board Areas is anticipated. Further information will be available by the time of the next meeting of ADTC in June. Meanwhile – watch this space.

REPORT FROM THE NEW DRUGS SUB-COMMITTEE

Three new drugs likely to impact upon prescribing across the Tayside trusts have now been reviewed. The following is a summary of the evidence on which the ADTC has based its advice to Tayside Health Board.

INFLIXIMAB *(RemicadeÒ)*

This is a chimeric monoclonal antibody (MAB), currently licensed for the treatment of Crohn's disease in which context it was reviewed by the Sub-Group who took into account the opinions of the local specialists.

MABs are new in clinical practice and the need to address long term safety issues with this class of compound, as experience of their use in practice increases, is stressed.

It is recommended that up to six patients per year in Tayside may meet the current criteria for treatment with infliximab. This includes patients with very severe disease, assessed both medically and surgically via the IBD Clinic, with fistulas and vulval/perineal disease, who have failed to respond to intensive medical therapy and for whom there are limited surgical options. Such patients are otherwise likely to require prolonged periods of hospitalisation and parenteral nutritional support.

The cost implications for treatment of six patients per annum with a single course of infliximab (there is currently no basis to support re-treatment) is £32,500.

Specialists involved in the management of patients referred to the IBD Clinic will be requested to draw up concise guidelines on referral, assessment, criteria for introduction of infliximab and subsequent monitoring of treatment and outcomes.

Category 2(a) – prescribed only by specialists in secondary care

PALIVIZUMAB (Synagis*Ò*)
This too is a monoclonal antibody (MAB) designed to *prevent* infection with respiratory syncytial virus (RSV) which annually places premature babies and infants under 2 years of age, who have required prior ICU care due to respiratory disease, at risk from the end of October to beginning of March.

The same considerations for long term safety apply as for other MABs including infliximab, above.

The evidence in support of palivizumab is very limited and relevant only to hospitalisation rates. It suggests that the drug is *not very cost effective* in these terms.

The neonatologists will be requested to draw up concise guidelines on the use of palivizumab, which are consistent with practice at neonatal units around the country. It is envisaged that only two or three patients per year will be considered for treatment in Tayside at a maximum cost of £20,000 per annum.

Category 2(a) – prescribed only by specialist neonatologists in secondary care.

ROFECOXIB *(Vioxx*Ò*)*
This is the first of a new series of non-steroidal anti-inflammatory drug (NSAIDs) which has been introduced with the "promise" of fewer gastrointestinal side effects. However, the relevance of this in practice is still far from clear. In particular, there is no evidence to suggest that drugs of this type *are not* associated with other (non-GI) side effects attributed to NSAIDs. This includes renal impairment, and rhinitis and wheeze in "at risk groups" such as asthmatics. On the other hand, rofecoxib does not appear to be any more effective than standard NSAIDs in managing painful inflammatory conditions.

The following should also be noted.

Rofecoxib is currently licensed only in osteoarthritis, a condition in which simple analgesics (e.g. paracetamol) have been shown to be as effective as standard NSAIDs and should be considered as first line. *(Evidence level Ib)*

Those at risk of NSAID-induced gastrotoxicity include the over 65s and patients with a history of peptic ulceration/bleeding. However, misoprostol (most frequently prescribed in combination with diclofenac) is the only drug which has been shown to prevent serious NSAID associated gastric events. *(Evidence level Ib)*

It is, however, recognised that acid suppression therapy with H_2 blockers or PPIs is licensed for prevention of GI complications in NSAID users. Rofecoxib might be considered an alternative in "at risk" groups who are unable to tolerate misoprostol or acid suppression therapy but for whom a NSAID is nevertheless strongly indicated.

It is intended to publish guidelines on new NSAIDs which are highly selective Cox-2 inhibitors in relation to GI risk and to provide an algorithm to assist prescribers on selection of these drugs in an early edition of *Tayside Prescriber*.

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 therapy.

REPORT FROM THE FORMULARY SUB-GROUP

The Formulary sub-group met late March 2000 to discuss the annual revision of the core formulary. The membership of this sub-group includes representation from both Acute and Primary Care Trusts. Likewise, other sub-groups relating to the Primary Care Anti-Infective Advisory Notes and Tayside Dyspepsia Guidelines have also recently met. The TUHT Antibiotic policy is in the process of being revised to replace the original policies of the former trusts. Implementation of the formulary and associated guidelines has been identified as a key area that is required to be addressed. It is hoped that Edition 5 of the TADF will be available from August 2000.

REPORT FROM THE TREATMENT REVIEW SUB-GROUP

At present two treatment guidelines are being reviewed. The Donepezil subgroup is examining the use of donepezil in Tayside in the year since the guideline was approved by the ADTC. The group agreed that they should also include guidance on the use of rivastigmine. In view of this, the name of the group has changed to Drugs in Alzheimer's Disease subgroup. A report will be submitted to the ADTC at the September meeting.
The Hepatitis C subgroup met to review the guidance published by the ADTC last year. New consensus guidelines have been produced in the US since then. In addition, new pegylated formulations of interferon-alfa are expected to be licensed shortly. The group therefore felt that the guidelines require to be updated, and this work is in progress.

NOTIFICATION OF NEW DRUGS FOR REVIEW BY ADTC

A comprehensive list of drugs which are likely to be licensed in the near future or for which new and potentially important indications have emerged is to be drawn up by the Drug Information Service in conjunction with the Primary Care Trust Prescribing Team. It is anticipated that a mechanism for sharing the workload when reviewing those drugs likely to have significant impact on prescribing in either the primary care or secondary care setting, or both, will be agreed across the Scottish Health Board areas.

Correspondence arising out of the above proceedings of the meeting of the ADTC in Tayside on March 24th 2000 or other relevant issues for the attention of ADTC should be addressed to Mr Peter Clough, Professional Secretary, Area Drug & Therapeutics Committee, Department of Pharmacy, Ninewells Hospital, Dundee, DD1 9SY.