POSTSCRIPT REACHES ITS 50TH EDITION!

PostScRxipt
from the
NHSGGC Area Drug & Therapeutics Committee
Issue 50 March 2009

To celebrate the 50th edition of PostScript, *we thought it might be interesting to review changing patterns in prescribing since our launch in October 1998. Back then, the* Glasgow Formulary *was in its fifth edition, clopidogrel had just been reviewed for* Formulary *inclusion, co-amoxiclav side effects were discussed and the clinical effectiveness of donepezil was under the spotlight. Congratulations to Dr Andrew Power, who is the only one of the committee still closely involved with every edition and who continues to develop and maintain our website.*

There have been some significant changes in prescribing patterns over the last ten years. Although recent changes in generic pricing have driven down the cost of many products, annual primary care prescribing costs have risen by almost 80% to £240 million in NHSGGC. With almost 22 million scripts annually, each resident of the Board's area has an average of 17 prescription items dispensed per year.

In the last five years, prescribing of drugs for cardiovascular disease has risen by 20% with lipid lowering drugs increasing by 50%. Even with this large increase in prescribing rates, the overall prescribing cost for these medicines has substantially reduced. We should probably not be surprised that prescribing of NSAIDs has reduced by 15% over the past five years; however, a 10% increase in analgesic prescribing has offset this.

Costs in acute care have risen more sharply, doubling over the last decade to £79 million in the last financial year. Acute care prescribing costs now account for almost 28% of overall prescribing; an increase from 22% in 1998-99. The major costs are in oncology (up to 25% of total), anti-TNFs, antiretrovirals, antibacterials and treatments for multiple sclerosis. Cost pressures for the near future come from the same group of therapies and treatments for macular degeneration.

In this issue . . .

Website
http://www.ggcformulary.scot.nhs.uk

We asked local experts and leaders in Formulary management to provide us with their thoughts on progress in prescribing and therapeutics over the last decade. ***Dr Keith Beard*** *is the NHSGGC Hospital Prescribing Adviser and a consultant physician. He developed the concept of an ADTC newsletter and was the first editor of* PostScript. *Here he reflects on his national and international work on medicines regulation.*

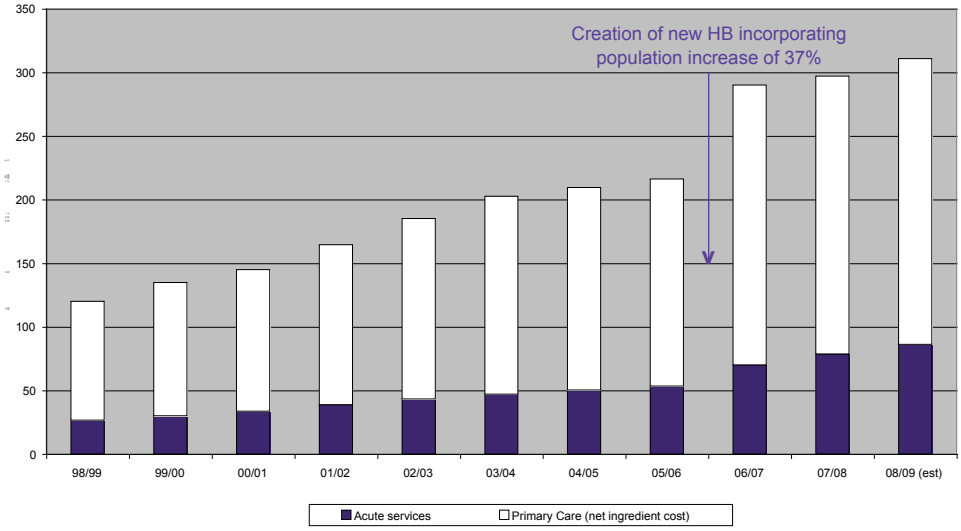
Does it work, is it safe, is it worth it? These linked key questions have recently been at the heart of medicines evaluation. *"Does it work, is it safe?"* are issues that require effective regulation. Significant developments in the last few years include:

• **Clinical trials:** The EU Clinical Trials Directive has codified and tightened aspects of pre-licensing clinical trials. It is a difficult balance between stimulating innovation and ensuring patient safety. While there is some concern about 'research bureaucracy', the phase 1 TGN 1412 incident at Northwick Park serves to remind us of the importance of this.

• **Safety and post-marketing surveillance:** Drug regulation has embraced the concepts of risk management and pharmacovigilance planning. The required risk management plan for a new medicine must lay out what is and is not known about safety, and how knowledge can be extended as a product becomes more widely used. Implementation poses a challenge including appropriate sanctions should standards

contd on page 3

Trends in medicines expenditure



Alphabetical list of most recent ADTC decisions

For full details of SMC advice, visit **www.scottishmedicines.org** For NICE advice, visit **www.nice.org.uk** For previous ADTC decisions, visit **www.ggcformulary.scot.nhs.uk**

Drug	Indication under consideration (There may be other licensed indications)	NHSGGC decision	
Adalimumab (Humira®)	Active polyarticular juvenile idiopathic arthritis in adolescents aged 13-17 years who have an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.	(S) Total *Formulary*. Acknowledge new indication.	✓
Aliskiren (Rasilez®)	Essential hypertension.	Non-*Formulary*.	x
Buprenorphine transdermal patches (BuTrans®)	Severe opioid responsive pain conditions which are not adequately responding to non-opioid analgesics.	Non-*Formulary* for this formulation.	x
Docetaxel (Taxotere®)	Induction treatment of patients with resectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil.	(S) Total *Formulary*. Acknowledge new indication. Restricted to use in accordance with regional protocol.	✓R
Doripenem (Doribax®)	Complicated intra-abdominal infections in adults.	(S) Total *Formulary*. Restricted to use on the advice of local microbiologists or specialists in infectious diseases as a second or third line treatment of complicated intra-abdominal infections resistant to current conventional treatment.	✓R
Etonogestrel/ Ethinylestradiol vaginal ring (Nuvaring®)	Contraception.	Non-*Formulary*.	x
Etravirine (Intelence®)	Treatment of human immunodeficiency virus type 1 infection in antiretroviral treatment-experienced adult patients.	Non-*Formulary*.	x
Fosaprepitant (Ivemend®)	Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.	Non-*Formulary* following consultation with the Regional Cancer Advisory Group.	x
Lacosamide (Vimpat®)	Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older.	(S) Add to Total *Formulary*. Restricted to patients with refractory epilepsy.	✓R
Lapatinib (Tyverb®)	In combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2) and who have progressive disease following prior therapy including anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting.	Non-*Formulary*.	x
Morphine extended release epidural (Depodur®)	Relief of post-operative pain following major orthopaedic, abdominal or pelvic surgery.	Non-*Formulary*.	x
Pemetrexed (Alimta®)	In combination with cisplatin for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.	Non-*Formulary* for this indication.	x
Rivaroxaban (Xarelto®)	Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.	(S) Total *Formulary*. Restricted to use in accordance with local protocol.	✓R
Rivastigmine capsules, oral solution and patches (Exelon®)	Mild to moderately severe Alzheimer's disease.	(S) Total *Formulary*. Restricted to use according to local protocol. Use of the transdermal patch is further restricted to patients for whom rivastigmine is an appropriate choice and in whom a transdermal patch is an appropriate choice of formulation.	✓R
Salmeterol/fluticasone (Seretide 500 Accuhaler®)	Symptomatic treatment of patients with chronic obstructive airways disease (COPD) with a forced expiratory volume in one second (FEV_1) <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.	Non-*Formulary* for this indication. Use in COPD patients should continue to be in accordance to current NHSGGC COPD guidelines.	x
Stiripentol (Diacomit®)	In conjunction with clobazam and valproate as adjunctive therapy of refractory generalised tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI, Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate.	Non-*Formulary*.	x
Sugammadex (Bridion®)	Immediate reversal of rocuronium-induced neuromuscular blockade.	(S) Total *Formulary*. Restricted to use in the immediate reversal of rocuronium-induced neuromuscular blockade in adults only, according to protocol. A register of use is to be maintained by specialists.	✓R
Zoledronic acid infusion (Aclasta®)	Treatment of osteoporosis in men at increased risk of fracture, including those with a recent low-trauma hip fracture.	Non-*Formulary* for this indication.	x

✓ =*Formulary* ✓R =*Formulary* (restricted) x =non-*Formulary* ? = awaiting final decision (S) =specialist initiation only (S) =specialist use only

***PostScript's* 50th edition** *contd from page 1*

not be met. Rofecoxib brought much of this into sharp focus.

• **Paediatrics:** The EU regulation on paediatric medicines use came into force in 2007. This is a major step in ensuring that children's medicines are properly researched and evaluated. Companies must design studies in children where appropriate for new drugs, and assessment of data on older drugs is to be pursued. A dedicated EU committee on paediatric medicines is now at work. Progress has been brisk, with several hundred paediatric investigation plans considered.

"Is it worth it?" is addressed by health technology assessment, discussed by others in this edition. The safe, effective, economic and appropriate use of medicines is a continuum which can only be pursued by an integrated approach involving all arms of the advisory and regulatory structures. The examples illustrate how the picture has matured over the last few years to the continuing benefit of public health.

Professor Ken Paterson *worked on the very first mock-up of an ADTC bulletin with Dr Beard and even came up with the name* PostScript! *He is a consultant diabetologist and Chair of the Scottish Medicines Consortium. Here he gives his perspective on how that work links with ADTC.*

The introduction of the *Glasgow Formulary* in 1994 led to a requirement to assess new drugs to decide whether to add them to the *Formulary*. The ADTC New Drugs Sub-Group was formed and a two-stage process introduced, with critical appraisal and assessment by the New Drugs Sub-Group and a final decision on *Formulary* status made by the ADTC. To ensure a consistent approach, all new drugs were reviewed at the time of launch in the UK; a considerable workload even for a large health board.

In the late 1990s it was apparent that other health boards were experiencing similar (or greater) problems and the concept of a single assessment of comparative effectiveness and cost-effectiveness for all Scottish health boards was born. The Scottish Medicines Consortium (SMC), an informal consortium of all ADTCs in Scotland, was formed in 2001 and has since offered more than 500 pieces of advice on new drugs to NHS boards. This has removed the need for boards to undertake reviews of primary evidence, though the final decision on *Formulary* inclusion remains with the local ADTC and its clinicians.

In forming the SMC, the two-stage approach pioneered by Glasgow was adopted – the New Drugs Committee looks in detail at the scientific and health economic data, while SMC itself also factors in wider healthcare and societal perspectives. The tight timelines (submission to decision in 16-18 weeks) are onerous but clinicians and patients need to have rapid advice and, where accepted for use, rapid access to new and cost-effective therapies.

SMC reviews and decisions are all on the website and attract considerable interest from outwith Scotland, including the rest of the UK, Europe and North America. This is leading to Scotland's involvement in discussions between similar health technology assessment bodies in Europe, Canada and Australia. Glasgow is hosting a three-day workshop this summer on 'The Managed Introduction of New Medicines' with colleagues from Eastern Europe and beyond. Even the NICE Single Technology Assessment process bears more than a passing resemblance to the work of SMC!

All the SMC's work over the last seven years has been based on the firm foundations upon which it was established. The experience of the Greater Glasgow ADTC and New Drugs Sub-Group was crucial to this. Those who set up local procedures in the 1990s could not have foreseen where we would be 15 years later.

contd on page 4

***PostScript's* 50th edition** *contd from page 3*

PostScript is an important part of the SMC process; it is the route by which SMC decisions, and decisions on *Formulary* inclusion, are disseminated to prescribers in NHSGGC. SMC therefore warmly congratulates *PostScript* on its 50th edition.

***Dr Jonathan Fox** is the current chair of ADTC and a renal physician. He has the distinction of having been the last Chair of both the Stobhill Hospital and North Glasgow DTCs before taking over as Chair of the ADTC.*

The current ADTC structure was established in response to the formation of NHSGGC, with its specialty-based directorates, in 2006. The previous Trust-based DTCs were replaced by each directorate having its own prescribing group. The ADTC role is to deal with issues which involve the whole of the Health Board, or cross more than one directorate. Membership of the ADTC and its sub-committees encompasses a wide range of professionals, from primary care and hospitals, and has broad geographical representation.

With each of the amalgamations of Trusts have come concerns that DTCs might become increasingly bureaucratic, unresponsive to local needs. I hope this is not true of the current ADTC. Many processes are now more streamlined than in the past. For example, an appeal against a *Formulary* decision requires only review by the Formulary & New Drugs Sub-committee and then ratification of the decision by ADTC, rather than also having to be considered by a local DTC. Decisions relevant to the whole Health Board, eg changes in antimicrobial guidelines, can be swiftly translated into practice across the organisation, rather than having to be considered at local DTCs.

The establishment of the SMC has also had a significant impact on the work of the ADTC. NHSGGC is well represented on the main SMC committee and its New Drugs Committee. The ADTC's Formulary & New Drugs Sub-committee considers SMC advice very soon after (indeed, often before) publication. [For full details of how SMC advice influences *Formulary* status, see *PostScript* 42.]

I believe that processes surrounding prescribing have improved considerably over the last decade. One disappointment to me has been the lack of substantial progress towards an electronic prescribing and administration system in Scottish hospitals. I am frustrated by the uncertainties and errors that still occur at the interfaces between primary and secondary care which are often crucial points for patient care. Much effort has gone into improving the transfer of information about medicines, but I think that a major advance will only be possible with a properly integrated electronic system. This would also bring other advantages, such as decision support and accurate information about medicines usage.

One vital aspect of the work of the ADTC is communication with prescribers throughout the Health Board. *Postscript* is a very important part of this process and I congratulate Audrey and her team for their excellent work as they reach the 50th edition.

***Dr Kate McKean,** Head of Pharmacy and Prescribing Support Unit, has been involved with DTC processes at hospital, Trust and area level for many years. Here, she considers the work that has been undertaken by pharmacy staff to support prescribers and other clinicians.*

I think the ADTC of 1998 would be impressed with the breadth and depth of work now undertaken to support prescribers. We wanted to improve the ADTC systems and processes; but I'm not sure we envisaged the amount of work and time it would take!

I think there are two major achievements over the last decade which have helped to support the implementation of ADTC work. Firstly, the creation of a single system approach allowed us to streamline the use of professional expertise from primary and acute care, prevent duplication of effort and release time to develop new roles. This improved use of resources allowed the refocusing of ADTC on to a wider range of medicines governance issues such as:

- the safe use of medicines
- the management of antimicrobials
- the analysis of medicines utilisation data
- development of educational resources for prescribers
- development of non-medical prescribing
- development and implementation of policies and procedures to ensure effective and efficient use of resources.

The second achievement is the creation of a single repository of information and guidance on medicines use. The formation of the new Health Board gave an opportunity to review processes. The NHSGCC *Formulary* first edition was published in 2007 with a new format of Preferred List and Total *Formulary*. The production of *PostScript* in 1998 (and specialist publications such as *PostScript Oncology*) and, more recently, a single *Therapeutics Handbook* for prescribers in acute care has developed this work stream. A current priority is the development of Staffnet to include a repository for all clinical guidelines, although ADTC will remain focussed on those relating to medicines use.

In the background, work goes on to ensure the underpinning processes that support the work of the committees are relevant and support development of best practice.

What do you think is the most important change in prescribing since* PostScript *was launched? We have asked local opinion leaders for their views and will publish a selection in the next edition. Send your suggestions to audrey.thompson@nhs.net

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