ADTC(M) 11/02
Minutes: 13 - 25

NHS GREATER GLASGOW AND CLYDE

**Minutes of a Meeting of the
Area Drugs and Therapeutics Committee
held in the Conference Room
Medical Block C Conference Room
Clock Tower Building
Southern General Hospital
on Monday, 18 April 2011 at 2.00 p.m.**

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P R E S E N T

Dr J Gravil (in the Chair)

Dr K Beard	Dr R J Hardman
Dr A Bowman	Dr H Hopkinson
Dr C Brown	Dr G J A Macphee
Professor S Bryson	Dr C E McKean
Mrs J Camp	Dr A Power
Mrs A Campbell	Mrs A Thompson
Mr R Foot	Mr J Wallace
Dr G Forrest	Mrs J Watt

I N A T T E N D A N C E

Mrs E Watt .. Secretariat

ACTION BY

13. CHAIR'S STATEMENT

The Chair reminded Members that papers and proceedings relating to SMC advice were, in some cases, confidential and should not be disclosed before the relevant embargo dates stated in the agenda.

The Chair also reminded Members that they should make relevant declarations of interest in line with Board policy as agenda items arose.

Members were advised not to speak with members of the press on ADTC business but to refer such enquiries to the Board press liaison office.

14. APOLOGIES

Apologies for absence were intimated on behalf of Dr J Burns, Mr A Crawford, Ms L Hillan, Dr J Larkin, Dr J MacKenzie, Dr G McKay, Mrs M Ryan, Dr A Seaton, and Dr A Taylor.

ACTION BY

15. MINUTES

The Minutes of the meeting of the Area Drugs and Therapeutics Committee held on 21 February 2011 [ADTC(M) 11/01] were approved as a correct record.

NOTED

16. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(1) SMC Evaluations / NICE/QIS Guidance

Dr Macphee gave a brief resume of the undernoted SMC reviews, and the Formulary and New Drugs Sub-Committee's recommendations. These had been divided into sections for ease of understanding as outlined in the Appendix to this Minute.

Members were asked to consider and, if appropriate, ratify decisions by the Sub-Committee at their meeting on 1 April 2011. Decisions made by the Committee are summarised in an Appendix to these Minutes and would be further publicised in PostScript and in the cumulative Formulary update available on the website and StaffNet.

Members were asked to declare any interests specific or non-specific, personal or non-personal, on any of the drugs being discussed on an individual basis.

No declarations of interest were declared.

Detailed discussions ensued and the following items were highlighted:-

Botulinum toxin type A 50 unit, 100 unit and 200 unit powder for solution (Botox®) [80/03] **[2nd Resubmission]** ***[Indication: Focal spasticity, including the treatment of wrist and hand disability due to upper limb spasticity associated with stroke in adults]***

The SMC decision was "Accepted for use within NHS Scotland".

The Sub-Committee's recommendation was that this new indication should be acknowledged on the Total Formulary restricted to specialist use only.

Dr Macphee intimated that all referrals would be made to Dr Chris Roy. It was unclear how this advice impacted on the use of phenol injection. Dr Macphee would contact Dr Roy in this regard. It was noted that different botulinum toxins units are not interchangeable from one product to another. The local adviser did not see any problems with this.

Dalteparin sodium 5,000IU/0.2mL, 7,500IU/0.3mL, 10,000IU/0.4mL, 12,5000IU/0.5mL, 15,000IU/0.6mL, 18,000IU/0.72mL solution for injection (Fragmin®) [683/11] ***[Indication: Extended treatment of symptomatic venous thromboembolism (VTE) and prevention of its recurrence in patients with solid tumours]***

The SMC decision was "Accepted for restricted use within NHS Scotland".

The SMC restriction is for initiation by healthcare professionals experienced in the treatment of DVT.

The Sub-Committee's recommendation was that this new indication be acknowledged on the Total Formulary restricted to specialist initiation by healthcare professionals experienced in the treatment of VTE.

There were some safety issues. Clarity was required as to who would be supervising the patient's anticoagulation. Respective responsibilities are detailed within the local protocol.

ACTION BY

A discussion ensued on reducing dose, administration, and the problem communicating with GPs, along with DVT nurses. The Chair would pursue the issue of communication with DVT nurses. **Chair**

It was agreed that the key issues be highlighted in PostScript. **Mrs A Thompson**

Extended release nicotinic acid/laropiprant, 1000mg/20mg modified release tablets (Tredaptive®) [614/10] ***[Indication: The treatment of dyslipidaemia as monotherapy where statins not appropriate/tolerated].***

The SMC decision was "Accepted for restricted use within NHS Scotland".

The Sub-Committee's recommendation was that this new medicine should not be added to the Formulary following consultation with the Heart MCN due to the potential financial impact for limited clinical benefit. The potential budget impact is also influenced by the recent removal of ezetimibe from the Formulary.

There was concern that a change in the Formulary status might give the impression that this is a new effective treatment which is being actively advocated rather than a drug of last resort for use only when statins are absolutely not tolerated.

Denosumab pre-filled syringe (Prolia®) [651/10] ***[Indication: Treatment of osteoporosis in postmenopausal women at increased risk of fractures. Denosumab significantly reduces the risk of vertebral, non vertebral and hip fractures]***

The SMC decision was "Accepted for restricted use within NHS Scotland".

A decision on this medicine had been deferred for consultation with the Osteoporosis Sub-Group for defining patient group and how the service would be delivered. A protocol had now been prepared which reflected the SMC restriction. The service implications of where it would be delivered had yet to be agreed. This had primary care implications.

The Sub-Committee's recommendation was that addition to the Formulary would be deferred until the protocol implementation plan was completed. When finalised, this protocol should be reviewed by the Medicines Utilisation Sub-Committee.

Cannabinoid oromucosal (Sativex®) [703/11] ***[Non Submission] [Indication: As an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy]***

The SMC decision was "Not recommended for use in NHS Scotland".

The ADTC had issued advice to prescribers through PostScript on the non-Formulary status of this medicine at the time of launch given the high media/patient interest. There was no requirement to highlight this further. Non-Formulary processes were being untaken in the Acute Sector for use of this medicine.

A suggestion was made this be included in the non-Formulary Target List. Mr Foot intimated that this had already been done.

DECIDED:

That decisions made by the Formulary and New Drugs Sub-Committee at their meeting on 4 February 2011 be ratified by the Committee.

It was confirmed that we could continue with business as usual with regard to SMC advice during the election period for the Scottish Parliament.

ACTION BY

(2) West of Scotland Cancer Network Prescribing Advisory Sub-Group – Summary of Advice To NHS Boards ADTCs – April 2011

A summary of advice was tabled with the agenda papers from the Regional Cancer Advisory Group Prescribing Advisory Sub-Group. This outlined local implementation of SMC Guidance and NICE/QIS MTAs, protocol update, regional guidance (including clinical management guidelines) and current work programme.

The local implementation of SMC advice had been undertaken by the Formulary and New Drugs Sub-Committee and was included in the New Drugs Recommendation table discussed earlier in the meeting..

The remainder of the advice would be processed locally via the Cancer Therapeutics Group.

(a) Paclitaxel albumin powder for suspension for infusion (contains 100mg paclitaxel as paclitaxel albumin) (Abraxane®) [607/10] ***[Indication: Treatment of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard anthracycline containing therapy is not indicated]***

The SMC decision was "Accepted for restricted use within NHS Scotland".

A decision on this product had been deferred to the Regional Cancer Advisory Group. Relative cost-effectiveness has changed considerably since the SMC advice was issued due to availability of generic docetaxel. Their recommendation was that this medicine should remain non-Formulary. There may be a small sub-population of patients where docetaxel or the original paclitaxel formulation are contraindicated. The treatment can be accessed for these patients through local non-Formulary processes.

A discussion ensued.

DECIDED:

That this new formulation should not be added to the Formulary.

(b) Pazopanib 200mg, 400mg film-coated tablets (Votrient®) [676/11] ***[Indication: First-line treatment of advanced cell carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease]***

The SMC decision was "Accepted for restricted use within NHS Scotland".

A decision on this product had been deferred to the Regional Cancer Advisory Group.

A regional protocol was now available which was in line with the SMC recommendation and provided additional specific guidance on eligibility criteria.

It was noted that this medicine was included in the NHS Board's 2011/12 Medicines Expenditure Plan.

DECIDED:

That a decision on this new medicine be deferred until the NHS Board's 2011/12 Medicines Expenditure Plan had been approved and confirmation that local arrangements are in place to implement the PAS.

ACTION BY

(c) Rituximab, 100mg in 10mL, 500mg in 50mL, concentrate for solution for infusion (MabThera®) [675/11] ***[Indication: Rituximab maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy]***

The SMC decision was "Accepted for restricted use within NHS Scotland".

A decision on this product had been deferred to the Regional Cancer Advisory Group.

A regional protocol was now available which was in line with the SMC recommendation and provided additional specific guidance on eligibility criteria.

It was noted that this medicine was included in the NHS Board's 2011/12 Medicines Expenditure Plan.

DECIDED:

That a decision on this new indication be deferred until the NHS Board's 2011/12 Medicines Expenditure Plan had been approved.

ACTION BY

(3) Review of Medicines Accepted by the Scottish Medicines Consortium but not added to the NHS Greater Glasgow & Clyde Drug Formulary : 2010 Update

Mrs Campbell gave a summary of the above paper which considered all medicines assessed during the full calendar year of 2010.

During 2010, out of a total of 51 medicines accepted by SMC, there were seven occasions (14%) when NHSGGC ADTC decided, on initial review, not to add to the Formulary. This is a slightly higher proportion than observed in the 2008 and 2009 reviews, which indicated 9% and 5% of accepted medicines were not added to the local Formulary.

The "acceptance rate" has varied over time with no particular trend. Reasons for accepted medicines not added to the Formulary in 2010 were sufficient alternatives already on the Formulary, limited clinical benefit and no plans to use.

On three occasions, ADTC added medicines to the Formulary but conferred additional restrictions to the SMC advice to define a more limited place in therapy.

A number of medicines are currently deferred for further consultation with specialists/MCNs of which some may not be added to the Formulary in due course. Monitoring of drugs in this category will continue. The ongoing low level of appeal suggests that the originally agreed non-Formulary status has largely been appropriate and that Formulary choices meet the requirements for the majority of patients.

This report was thought to be very useful and can be used for media enquiries.

NOTED

17. PRESCRIBING MANAGEMENT GROUP (PMG) – KEY POINTS OF THE MEETING HELD ON 8 MARCH 2011

Professor Bryson gave an update of the key points for the above meeting. He highlighted the following items of interest:-

- Finance Report - *Total expenditure for medicines in NHSGGC for April – December 2010 was £257M - £1.8M over budget (0.7%) variance. This was broken down as follows:*

  - Acute Services *[£79.2M - £788k over budget (1.06%) reflecting a £5.2m (7.0%) increase compared to 2009]*.
  - *Partnerships and Public Health [£6.3M]*.
  - *Primary Care [£171.5M - £1.3M over budget (0.8%) reflecting a £3.0M (1.8%) increase compared to 2009]*.

- Licensed or Unlicensed Therapy – Management of LE Myasthenic Syndrome *[Professor Bryson had given a report at the February meeting of the Committee. There were two therapeutic options, one unlicensed and well established in clinical practice, the other newly licensed and not recommended by SMC. Comparative cost were £971 and £65,743 respectively; specialists cannot identify clinical benefits from the latter. The MHRA position is clear (reflected by ADTC Policy) that no unlicensed medicine should be prescribed where an licensed alternative exists. Dr S Roger, Associate Medical Director, had attend the PMG meeting highlighting a dilemma for the management of this condition and the wider repercussions for NHSGGC practice. It had been agreed that the status quo should prevail with preference for the unlicensed product for all patients, pending clarification of national advice]*.

  A discussion ensued and the following comments were made:-

  - There was a letter in the British Medical Journal from a specialist making a case for

ACTION BY

using the unlicensed indication.

- MHRA advice should be adhered to unless a rigorous risk assessment is carried out and has senior management approval to use an unlicensed medicine over a licensed one. A position statement should be used robustly.

- A consultation from the General Medical Council (GMC) about this situation was out for views. It was highlighted that the wording in the consultation was not the same as the wording in the proposed guidance. The GMC should be made aware of this.

Professor Bryson indicated that this discussion had been helpful. The Regional Services Directorate wished representation when this was next discussed at the PMG.

- ADTC Report *[Update from items referred to PMG from ADTC meeting on 21 February 2011]*.

NOTED

18. MEDICINES UTILISATION SUB-COMMITTEE

(a) General Update

Dr Beard gave a general update on the work of the Sub-Committee. This included:-

- **Dronedarone.**
- **IV Zoledronic Acid**.
- **Oxycodone in acute pain management** *[The aim was to define prescribing patterns of oxycodone in the Surgery and Anaesthetics Directorate]*.
- **IV PPI audit** *[Use of PPIs in Surgery Directorate was audited. This was subsequently audited in the Medical Directorate]*.

He asked if the Committee would be interested in looking at some of the Sub-Committee's reports in the future. The Chair indicated that some of these projects would be interesting and a selection could come to the Committee in due course.

Dr Beard advised that he was retiring in mid May and the Sub-Committee would require a new Chairman.

NOTED

(b) Preferred List Adherence Report

These data relate to adherence with the Preferred List within primary care for quarter 3 2010-11 with data from previous quarters included for comparison. Mr Foot gave a brief overview of the paper which outlined the executive summary, breakdown of sections 2.5 : ACE inhibitors and Angiotensin-II receptor antagonists, 2.6 : Nitrates, calcium channel blockers and other anti-anginals, 2.9 : Antiplatelet drugs and 2.12 : Lipid-regulating drugs.

Mr Foot outlined that this was a positive report with the proportional use of Preferred List ACE Inhibitors and Angiotensin-II receptor antagoinists increasing steadily. The Preferred List helps with cost efficiencies and effectiveness in the NHS Board.

The main points were as follows:-

- 5.9 million prescriptions were dispensed in the third quarter of 2010-11, of which 76.3% were for preparations included in the Preferred List. *[This was steadily increasing]*.
- The proportion of the Preferred List ARBs has increased gradually over the last five

ACTION BY

years (comparing the same financial quarter in each year) and, at the same time, the amount of prescribing of non-Formulary ARBs has declined.

- Losartan is off patent and it is planned to increase prescribers' awareness of the price difference between ARB preparations via publications such as PostScript , both in the acute sector and primary care.
- Over the last five years, the proportion of ISMN prescribed as the normal release preparations has increased substantially.
- Over the past two years amlodipine prescribing has increased slightly most likely due to a related primary care prescribing indicator.
- Aspirin still remains the most used Antiplatelet agent accounting for more than 85% of all prescriptions.
- With the exception of dipyridamole MR, where prescribing has increased slightly over the last five years, and prasugrel, which has only recently been launched, proportions of these prescribed antiplatelets have not changed substantially over the last five years.
- The GGC Antiplatelet Guidelines are currently being revised, and in line with NICE/QIS advice, there may be a more prominent role for clopidogrel in the secondary prevention of stroke.
- A primary care prescribing indicator is being considered to encourage the prescribing of Preferred List statins ahead of rosuvastatin.
- Ezetimibe was removed from the GGC Formulary in 2010 and the trend on prescribing in primary care decreased from July – November but rose again in December. *[Mr Foot advised that this could have been caused by GPs changing their system and the Christmas period where duplicate prescriptions were given. A GP disagreed with the cause of the GPs changing their systems. It was agreed that this report be brought back to a future meeting and would include stats for January – March 2011].*
- Amended versions of this report will be presented to the ADTC, Acute Services PMG, Primary Care PMG and Lead Directorate Pharmacist for Emergency Care and Medical Services.

NOTED

(c) Guidelines

(i) Management of Drug Misusers in Glasgow and Clyde Acute Hospital

This guideline had been reviewed approximately two years ago. The guideline on the management of pain in patients on substitute prescriptions had also been reviewed in 2010 and comments made but this had not been processed as it had been decided that this would be incorporated into the above guideline.

The Sub-Committee reviewed the guideline and minor comments had been made. This was a comprehensive guideline but there had been some concern about the complexity of the information and questions about how such detailed information might be used in clinical practice. It was suggested that it might be useful to include an overall table/flow chart to signpost which appendix would be used in which clinical situation. These comments had been sent to the authors and an updated guideline would be considered at the next meeting of the Sub-Committee on 23 May 2011.

NOTED

(ii) BMT Vaccinations

This guideline was designed to cover all patients transplanted by Adult BMT services in GGC who are referred throughout Scotland. This was unlicensed use of vaccines

Mrs Watt advised that the Sub-Committee reviewed the above guideline. This had implications for primary care. Minor edits had been suggested which included that

ACTION BY

changes to the previous policy should be highlighted for GPs.

The Sub-Committee recommended approval of the guideline subject to minor edits being taken on board.

DECIDED:

That the Committee ratify the Sub-Committee's recommendation.

19. ANTIMICROBIAL UTILISATION SUB-COMMITTEE : KEY POINTS OF THE MEETING HELD ON 9 MARCH 2011

Professor Bryson gave an update of the key points for the above meeting. He highlighted the following items of interest:-

- Primary Care Prescribing *[This has now become a standard report to the Committee and would include infection control reports, unintended consequences of prescribing antibiotics and risk benefit. There had been a gradual increase in overall DDDs but a progressive downturn in 4C antibiotics in particular, with GGC below the national average. There was a plan for an executive summary of this report with community acquired HAI data, for presentation to ADTC (at June meeting) and GPs. Information from these reports would be highlighted to GPs. Mrs Watt asked if this could be sent out under PostScript Primary Care. This was agreed. There was a microbiology initiative to promote mecillinam as an alternative to fosfamycin for treatment of UTIs resistant to standard therapy]*.

- Paediatric Prescribing *[Royal Hospital for Sick Children Sub-Group to finalise presentation content for approval by the Sub-Committee and guideline would be on the agenda for the ADTC in June 2011]*.

NOTED

20. NON MEDICAL PRESCRIBING SUB-COMMITTEE

Mrs Camp gave an update on the work of the Sub-Committee as follows:-

PGDs – Report of 1 April 2010 – 31 March 2011 approved. There were 127 PGDs on the database. 93 were approved, 17 not approved *(required major amendment or were not appropriate)* and a number were not being renewed.

Non-Medical Prescribing Strategy – A Quality Impact Assessment had been carried out by the Scottish Office. A favourable outcome had been given with particular noting of good quality practice and bilingual pharmacy prescribers.

The Chair asked if nurses who have attended a course to become a prescriber use this qualification in their job. Mrs Camp advised that the number of nurse prescribers using their qualification was improving. Job roles have changed and in future this would form part of planning career pathways.

A discussion ensued on non-medical prescribers accessing electronic records. It was pointed out that electronic records are accessible to practice nurses and community pharmacists but it was more difficult for district nurses to access computer systems.

Dr Brown pointed out that the integrity of the ECS records lies with the GP and this can be a burden. Mrs Camp advised that it should be the prescribers who should enter the information on the ECS record.

Mrs Camp and Dr Brown would liaise outwith the meeting with regard to non-medical **Mrs J Camp/**

ACTION BY

prescribing being inserted on the ECS record . **Dr C Brown**

NOTED

21. COMMUNICATIONS SUB-COMMITTEE

PostScript - Issue 62 (March 2011) was attached with the agenda papers for information. This edition included articles on chronic non-cancer pain, latest ADTC decisions, Formulary news, erectile dysfunction, and new chair for ADTC.

Mrs Thompson advised that proactive contact would be made with MCNs asking about their areas of work and if there were changes they may wish to publicise. She gave a summary of articles which would be included in the next edition.

Mrs Thompson indicated that the Sub-Committee were always trying to improve the circulation of PostScript. This was available on StaffNet, the ADTC website and by internal CHP circulation. The Chair asked if hard copies were sent to individual wards. Mrs Thompson replied indicating that this was not done. A survey had been carried out some time ago on the best way to access PostScript and the results indicated that most people who responded to the survey wished this electronically.

A discussion ensued on handheld devices which would be able to access applications including PostScript. It was noted that handheld devices were being used at St John's Hospital, NHS Lothian. These devices were not available in NHSGGC.

NOTED

22. TERMS OF REFERENCE

Professor Bryson advised that the revised Terms of Reference for the Committee had been discussed at the ADTC Executive but had still to be reviewed by the Head of Board Administration at the NHS Board.

The main changes were the process for appointment of Vice Chair of the Committee and Chair and Vice Chairs of the Sub-Committees.

It was noted that the appointment process was very detailed but also that this would align the Committee to that of the SMC.

A discussion ensued and the following comments were made:-

- Clarification was required on the relationship between the roles of the ADTC and the PMG.
- In Appendix 1, first paragraph, the phrase "representing a different area of clinical practice" be made more explicit.

DECIDED:

That the above comments be taken on board and the Committee await the comments of the Head of Board Administration. **Prof S Bryson**

23. POLICIES RELATING TO THE MANAGEMENT OF MEDICINES

- **POLICY FOR THE MANAGEMENT OF INDIVIDUAL PATIENT TREATMENT REQUESTS (IPTR)**
- **INDIVIDUAL PATIENT TREATMENT REQUEST (IPTR) APPEAL PROCESS**

ACTION BY

Mr Foot gave a summary of the above papers. These were part of a compendium of policies relating to the management of medicines. He gave the background in that standardised non-Formulary processes were introduced to all acute sites in NHS Greater Glasgow and Clyde in 2008. The processes were then amended in 2010/2011 to reflect guidance from the Scottish Government Circular CEL (2010)17 and CMO (2011)3 regarding the introduction and availability of newly licensed medicines and non-Formulary requests for medicines in the above categories were renamed Individual Patient Treatment Requests. All NHS Boards had similar arrangements under Scottish Government guidance.

The NHS Board had been adhering to the processes outlined in the papers from October 2010.

NOTED

24. ANY OTHER BUSINESS

Retiral of Dr Keith Beard

The Chair advised that Dr Beard was retiring in May 2011 and this would be his last meeting of the Committee. Dr Beard had been an integral part of the ADTC and had been a member since its inception in 1989. His role had been Vice Chair for many years and Hospital Prescribing Adviser since 1998. He had also been Chairman of Medicines Utilisation Sub-Committee since its inception in September 2006 and previously the Formulary and New Drugs Utilisation Sub-Group (FONDU).

Dr Beard, along with others, had the vision and was instrumental in convincing the Health Board that a Glasgow Area Medical Evaluation Unit (known as GAMEU) was required. This was approved and in 2002 and contracts for four pharmacists were given for a 1½ year period. Due to the good work and outcome data carried out by GAMEU, full time positions were given to the pharmacists now known as "The Clinical Effectiveness Team".

The Chair gave thanks to Dr Beard for all the work and dedication he had given to the work of the Committee and wished him well in his retirement.

Dr Beard responded outlining that he had enjoyed his time on the Committee and the significant progress it had made. He gave examples of changes which had taken place over the years emphasising that some issues are still discussed today. He thanked a number of people including Mrs Watt and Mrs Semple for the Clinical Effectiveness Team, Mr Foot and the Formulary Team and the Secretary.

NOTED

25. DATE OF NEXT MEETING

The next meeting of the Area Drugs and Therapeutics Committee would be held on Monday, 13 June 2011 at 2.00 p.m. in the Conference Room, Management Building, Southern General Hospital.