ADTC(M) 11/01
Minutes: 1 - 12

NHS GREATER GLASGOW AND CLYDE

**Minutes of a Meeting of the
Area Drugs and Therapeutics Committee
held in the Conference Room
Management Building
Southern General Hospital
on Monday, 21 February 2011 at 2.00 p.m.**

P R E S E N T

Dr J Gravil (in the Chair)

Dr K Beard	Dr G J A Macphee
Dr A Bowman	Dr J MacKenzie
Professor S Bryson	Dr C E McKean
Mrs A Campbell	Dr A Power
Mr R Foot	Dr A Taylor
Dr G Forrest	Mrs A Thompson
Ms L Hillan	Mrs J Watt
Dr R J Hardman	Professor D Wray

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

Mrs E Watt .. Secretariat

ACTION BY

1. CHAIR

Dr Jane Gravil advised Members that she had been appointed Chair of the Committee, taking over from Dr J Fox who had resigned due to his new appointment as Chairman of the New Drugs Committee of the Scottish Medicines Consortium.

2. 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.

3. APOLOGIES

Apologies for absence were intimated on behalf of Dr J Burns, Mrs J Camp Mr A Crawford, Dr H Hopkinson, Dr H Macdonald, Dr G McKay, Mrs M Ryan and Dr A Seaton.

ACTION BY

The Chair welcomed Ms Linda Hillan, Lead Directorate Pharmacist, Emergency Care and Medical Services Directorate, to her first meeting of the Committee. Ms Hillan was replacing Dr Norman Lannigan who had resigned due to other work commitments.

4. MINUTES

The Minutes of the meeting of the Area Drugs and Therapeutics Committee held on 13 December 2011 [ADTC(M) 10/06] were approved as a correct record.

NOTED

5. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(1) New Joint Chair of the Sub-Committee

Dr Macphee advised that with Dr Gravil being appointed as Chair of the ADTC, this left a vacancy for a Joint Chair of the Sub-Committee. Dr Gordon Forrest had been appointed as Joint Chair.

NOTED

(2) 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 4 February 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:-

Lenalidomide 5mg, 10mg, 15mg and 25mg Capsules (Revlimid®) [441/08] ***[Indication: In combination with dexamethasone, for the treatment of multiple myeloma patients who have received at least one prior therapy]***

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

A decision on this medicine had been deferred to allow consultation with the Regional Cancer Advisory Group for development of a protocol.

A regional protocol was now available which was in line with SMC guidance and provided information on budget and service impact. The budget impact was far in excess of earlier estimates and would require approval by PMG.

The Sub-Committee's recommendation was that this new indication should be added to the Total Formulary (subject to PMG approval) restricted to specialist use and use in accordance with regional protocol.

Professor Bryson indicated that this was an appropriate decision and the PMG were aware of this new medicine.

ACTION BY

Dronedarone 400mg film-coated tablets (Multaq®) [636/10] ***[Indication: In adult clinically stable patients with a history of, or current non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate]***

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

This had been discussed at the last meeting but the day after the meeting the SMC advised that the original wording within the advice box was noted to be ambiguous and had caused some confusion therefore, the wording of the restriction has been modified to provide greater clarity and reflect in more detail the original decision made by SMC, however the status of SMC advice remains unchanged.

SMC restriction: for the prevention of recurrence of AF in patients in whom beta-blockers, class 1c drugs or amiodarone are contra-indicated, ineffective or not tolerated**.** Treatment should be initiated on specialist advice only.

Consultation had taken place with the Heart MCN who outlined that they wished an additional restriction "… or not tolerated ***and who do not have a diagnosis of heart failure***". The MCN asked to be informed about prescribing data and may review guidance with time.

The Sub-Committee discussed the use of the word "or" rather than "and" in the list of medicines ….. "*patients in whom beta-blockers, class 1c drugs* ***or*** *amiodarone*" and took the view that the intention was that all of these should be excluded prior to prescribing dronedarone and therefore preferred the use of the word "and". This had been confirmed with Dr David Murdoch, Heart MCN Chair.

It had been pointed out that some safety concerns had recently been highlighted with this medicine.

A discussion ensued and it was thought that clinicians should be made aware of these concerns. An article on dronedarone would be included in the next edition of PostScript.

Capsaicin, 179mg, cutaneous patch (Qutenza®) [673/11] ***[Indication: Treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain***]

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

A local adviser had indicated that there would be cases outwith the SMC restriction (this would be non-Formulary use).

The Sub-Committee had written to the clinicians asking for a plan for service delivery to ensure economies of scale and an audit tool which could evidence compliance with the restriction.

It was noted that the patches could be cut and used in more than one patient. The cost for each patch was £210.

The Sub-Committee's recommendation was that this new formulation should be acknowledged on the Total Formulary restricted to specialist use in the treatment of adults with post-herpetic neuralgia (PHN) who have not achieved adequate pain relief from, or who have not tolerated, conventional first and second-line treatments, subject to the additional requests to the specialists re service delivery and audit tool. Treatment should be under the supervision of a specialist in pain management.

Dr Macphee advised that confirmation was awaited and asked that a decision on this medicine be deferred until a response was received from the specialists. This was agreed.

ACTION BY

Trastuzumab 150mg powder for concentrate for solution for infusion (Herceptin®) [623/10] ***[Resubmission] [Indication: In combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herceptin is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 over expression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay]***

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

It was noted that this new indication had been recommended in NICE STA 208. STAs have no standing in Scotland.

Fentanyl 100 microgram/dose and 400 microgram/dose nasal spray solution (PecFent®) [663/10] ***[Indication: Management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain]***

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

The Sub-Committee's recommendation was that a decision on this new formulation be deferred to allow consultation with the Palliative Care MCN.

It was noted that other short acting Fentanyl preparations are non-Formulary awaiting Palliative Care MCN advice on preferred options. The MCN had indicated that they did not have enough experience of these medicines to express a preference. The Sub-Committee would be pressing the MCN for a choice (ideally looking for one oral and one spray).

Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular event (review of technology appraisal guidance 90) ***[NICE MTA 210]***

Dr Macphee advised that with regard to the above NICE MTA 210 there was no change in the Formulary status of these medicines but it would prompt a change in the anti-platelet guideline. The Heart and Stroke MCNs were aware of this NICE guidance and discussions are underway.

DECIDED:

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

(3) Cefixime 200mg tablets (Suprax®)

Mr Foot advised that an appeal for Cefixime 200mg tablets (Suprax®) had been received from Dr Andrew Winter, Joint Clinical Director and Acting Lead Clinician, Sexual Health (Sandyford Initiative). Dr Winter had no interests to declare.

Mr Foot gave a summary of the appeal. The main points were as follows:-

- Cefixime is recommended for oral treatment of acute uncomplicated gonorrhoea in national (and international) guidelines.
- The only Formulary alternative is ceftriaxone injection.
- Cefixime is listed in the BNF as a treatment option for uncomplicated gonorrhoea.
- Careful monitoring of resistance patterns is required for this condition.

ACTION BY

Cefixime is currently a nationally and internationally recommended treatment choice for 1st line treatment of uncomplicated gonorrhoea. It is already incorporated in the local guideline and has been used, in combination with azithromycin, as empirical treatment option.

An oral formulation is often preferred by patients.

Unlicensed indications have previously been included in the GGC Formulary (eg amitriptyline and minocycline) and could also be considered for this indication.

The Sub-Committee's recommendation was that this medicine be added to the Total Formulary restricted to prescribing by specialists in accordance with the Sandyford Treatment Protocol. The preference was that prescribing should be undertaken by Sandyford. In addition, a prescribing note should be included noting that this is an unlicensed indication of cefixime.

A discussion ensued and the following comments were made:-

- If, in exceptional circumstances, a patient did not wish to be referred to the Sandyford Clinic, the GP should be able to contact the Sandyford for advice on prescribing.

- The laboratory tests reported to GPs advise that gonorrhoea is diagnosis but does not include sensitivity.

DECIDED:

1. That the Committee ratify the Formulary and New Drugs decision to uphold this appeal.

2. That a response be sent to Dr Winter outlining the Committee's decision. **Chair**

6. WEST OF SCOTLAND CANCER NETWORK PRESCRIBING ADVISORY SUB-GROUP – SUMMARY OF ADVICE TO NHS BOARDS ADTCs – NOVEMBER 2010

A summary of advice was attached 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, regional guidance (new developments and clinical management guidelines) and current work programme.

Mrs Campbell advised that 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.

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

NOTED

7. PRESCRIBING MANAGEMENT GROUP (PMG) – KEY POINTS OF THE MEETING HELD ON 14 DECEMBER 2010

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

- Finance Report *[Expenditure for medicines in NHSGGC for April – September 2010 was*
  - Acute Services *[£52.7M - £326k over budget (0.6%) reflecting a 7.2% increase compared to 2009 (excluding plasma products)]*.

ACTION BY

- *Partnerships and Public Health [£4.2M].*
- *Primary Care [£113.7M - £2M over budget (1.8%) reflecting a £2.7M (2.4%) increase compared to 2009].*

Total expenditure £170M - £2.1M over budget (1.25% variance)].

- ADTC Report *[Update from items referred to PMG from ADTC meeting on 13 December 2010].*

- NHGGGC Lipid Guidelines *[Heart MCN confirmed guidance related to both new and existing patients. Professor Bryson gave acknowledgement to the PostScript Group for highlighting prescribing changes in PostScript].*

- Licensed or Unlicensed Therapy – Management of LE Myasthenic Syndrome

  This therapy is used in a small number of patients. The unlicensed medicine had been used for a number of years. Cost was £1,000 per patient per annum. A new licensed product (preparation not exactly the same) was now available at a cost of approximately £65,000 per patient per annum. Specialists were of the opinion that there was little or no added benefit on grounds of safety or effectiveness.

  There was strong opinions from:-

  (1) MHRA and ADTC – No unlicensed medicine should be prescribed where a licensed alternative exists.

  (2) The Regional Services Directorate – No grounds to change.

  A compromise had been reached at PMG (December 2010) in that existing patients could remain on unlicensed medicine and new patients receive the licensed medicine. Advice had been sought from the Central Legal Office via the NHS Scotland Directors of Pharmacy. QIS have asked the same questions to these organisations.

  A detailed discussion ensued and the following comments were made:-

  - The new licensed product was not recommended by SMC (the holder of the marketing authorisation had not made a submission to the SMC regarding this product). Prescribing of this product would be through the non-Formulary system.

  - It would be exceptional to use an unlicensed product when a licensed product was available.

  - It may be helpful to consult with the Medical Defence Union/Pharmaceutical Society.

  - Orphan drugs are in the main very expensive.

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

  The Committee would be kept advised of developments.

NOTED

8. MEDICINES UTILISATION SUB-COMMITTEE

(a) General Update

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

ACTION BY

Projects and Education Briefs

- **Oxycodone in acute pain management**. *[The aim was to define prescribing patterns of oxycodone in the Surgery and Anaesthetics Directorate. Data had been gathered and the finalised report would be brought to this Committee]*.

- **IV PPI audit** *[Use of PPIs in Surgery Directorate was audited. This was subsequently audited in the Medical Directorate. Data had been gathered and the finalised report would be brought to this Committee]*.

- **Inhaler wastage project**. *[This audit was an attempt to rationalise and limit inhaler wastage. A pre-registration pharmacist was carrying this out under the supervision of the Clinical Effectiveness Team]*.

- **PostScript Extra – Statins and Cholesterol Lowering Targets**. *[This was being updated and included information on the switch from prescribing atorvastatin to simvastatin. The bulletin would be distributed shortly. GPs were keen for an information Roadshow with specialists explaining the rationale for prescribing. It had been suggested that the PC PMG contact the Heart MCN in this regard]*.

- **Therapeutics Handbook** *[A survey on the handbook had been undertaken with users. There had been a sight increase in the number of respondees from last year. A better response rate had been received. Comments received included the need for a written version, along with electronic versions. Mobile applications were suggested for smart phones but a charge would be required to use this by the staff member]*.

- **StaffNet** *[Mrs Campbell and Mrs Watt have been working with the IT Department on the Clinical Information box on the front of StaffNet. The Clinical Governance Department are now able to provide administrative support for the guideline repository. A site for trainee doctors was in the process of being set up. Mrs Watt would arrange to meet with the group responsible for this site to ensure a cohesive approach]*. **Mrs J Watt**

NOTED

(b) Preferred List Adherence Report

These data relate to adherence with the Preferred List within primary care for quarter 2 2010-11 with data from previous quarters included for comparison. Mr Foot gave a brief overview of the paper which outlined the executive summary, overall preferred list adherence by financial year, Health Board adherence by BNF chapter over the last five financial years, breakdown of Section 1.3 Oral proton pump inhibitors and breakdown of subsection 1.5 Chronic bowel disorders.

Mr Foot advised that the Sub-Committee had agreed that the information in the bar charts had been changed to highlight the last five years rather than the last four quarters.

The main points were as follows:-

- 5.8 million prescriptions were dispensed in the first quarter of 2010-11, of which 76.7% were for preparations included in the Preferred List.

- This report focused on prescribing and Preferred List Adherence in Chapter 1: Gastro-intestinal tract. **Formulary Team**

- Despite the overall increase in PPI prescribing, the associated cost has been decreasing. This can most likely be attributed to preparations becoming available generically and a successful switch strategy to prescribe the most cost-effective formulations within primary care.

ACTION BY

- Omeprazole and Lansoprazole remain the two most commonly prescribed PPIs. Prescribing of esomeprazole remains low.

- Standard sulfasalazine tablets as well as the enteric-coated formulation can be used for the treatment of inflammatory bowel disease. The standard formulation is currently £1.74 cheaper for 112 tablets compared to the enteric-coated formulation.

- The Formulary recommends prescribing by brand name but does not specify specific drugs or formulations.

- Though current advice is to prescribe mesalazine by brand names, there is still some generic prescribing (eg mesalazine 400mg tablets) occurring.

- A recent UKMI publication summarised the similarities and differences between the different available mesalazine preparations. It includes a statement from the North Central London Formulary and Medicines Management Group highlighting that there does not appear to be any significant disparity between Asacol MR and Mesren MR with regards to clinical, pharmaceutical, pharmacokinetic and manufacturing profile. The publication also highlights that the British Society of Gastroenterology guidelines do not differentiate between different brands of mesalazine for the treatment of inflammatory bowel disease. Efficacy of treatment was related more to the adherence with a prescribed dose rather than the delivery system.

- Mesren MR is considerably less expensive than Asacol MR 400mg and in view of the above information cost savings could be realised within GGC if patients were to be prescribed the cheaper preparation. However, there have so far no published trials to compare Asacol MR and Mesren MR preparations directly. Discussions are ongoing with specialists to explore the potential for rationalisation of prescribing in this area.

- More detailed reports would be presented to the Acute Services PMG, Primary Care PMG AND Lead Director Pharmacist for Emergency Care and Medical Services.

NOTED

9. ANTIMICROBIAL UTILISATION SUB-COMMITTEE

Professor Bryson gave a brief update on the work of the Sub-Committee. An update of the meeting of 23 November 2010 had been given at the last meeting and the next meeting would be held on 9 March 2011. The following was highlighted:-

- Acute Presentations and Reports *[The Antimicrobial Team had given a number of presentations and reports to the Board's Medical Director. Ms S Galbraith, Prescribing Adviser, would give a primary care perspective as a follow-up to this on the presentations and reports to the next PPSU Executive Group. This would be reported to the next meeting of the Antimicrobial Sub-Committee and the ADTC]*.

- Paediatric Guideline *[This was work in progress]*.

- Scottish Antimicrobial Prescribing Group Audit *[A small group of interested GPs have participated and a report will be available in due course]*.

NOTED

ACTION BY

10. COMMUNICATIONS SUB-COMMITTEE

PostScript - Issue 61 (January 2011) was attached with the agenda papers for information. This edition included articles on the new guidelines on Anti-TNF Therapy in Adult Crohn's Disease, latest ADTC decisions, case notes on an error in an opioid case, "if I could change on thing" and Formulary news.

Mrs Thompson advised that positive feedback had been received on the case study re opioid dose. She gave a summary of articles in the next edition which included dronedarone and the safety issues, prescribing charges, opioids and update to unlicensed medicines policy.

A discussion ensued on future articles, which included:-

- Dabigatran for AF and Stroke Prevention –- This has a potentially significant budget impact if accepted by SMC and would require a carefully managed introduction. At present the medicine remains unlicensed for this indication. Discussions have begun across directorates, the Heart MCN and primary care on how GGC manages the impact of this medicine.

- Use of Methadone in Hospital – Discharge Arrangements.

- Treatment for Erectile Dysfunction : Patients with Severe Distress : Planning and Service Change - A redesign of this service was being implemented. The Scottish Government policy change delivers that the current restriction on GP prescribing can be removed following assessment of advice by relevant consultants.. Work was ongoing with the Sexual Health Planning Group and no changes would be made until the new arrangements were finalised.

NOTED

11. TERMS OF REFERENCE

Professor Bryson advised that the Terms of Reference for the Committee were being revised. The main changes would be the process for appointment of Chair and Vice Chair of the Committee and Sub-Committees. The Terms of Reference would be discussed at the ADTC Executive meeting and a finalised report would be on the agenda for the April meeting.

NOTED

12. DATE OF NEXT MEETING

The next meeting of the Area Drugs and Therapeutics Committee would be held on Monday, 18 April 2011 at 2.00 p.m. in the **Med C Conference Room, Clock Tower Building, Southern General Hospital.**