ADTC(M) 12/01
Minutes: 1 - 14

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, 13 February 2012 at 2.00 p.m.

P R E S E N T

Dr G McKay (in the Chair)

Dr A Bowman	Dr G J A Macphee
Professor S Bryson	Dr C E McKean
Mrs J Camp	Dr P Moultrie
Mrs A Campbell	Mrs M Ryan
Mr R Foot	Dr G Simpson
Ms L Hillan	Mrs A Thompson
Dr J MacKenzie	Mrs J Watt

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

Ms L Wolfson .. Board Infant Feeding Co-ordinator *[for Minute 6 only]*
Mrs E Watt .. Secretariat

ACTION BY

1. CHAIR'S STATEMENT

Dr McKay 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.

He 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.

2. APOLOGIES

Apologies for absence were intimated on behalf of Dr J Burns, Mr A Crawford, Dr G Forrest, Dr J Gravil, Dr R Hardman, Dr H Hopkinson, Dr J Larkin, Dr H Macdonald, Dr A Seaton, Dr N Smart and Dr A Taylor.

Dr McKay welcomed Dr Patricia Moultrie, GP, to her first meeting of the Committee. Dr Moultrie had replaced Dr Colin Brown as one of the LMC GP representatives on the Committee.

ACTION BY

3. MINUTES

The Minutes of the meeting of the Area Drugs and Therapeutics Committee held on 12 December 2011 [ADTC(M) 11/06] were approved as a correct record.

NOTED

4. MATTERS ARISING

Medicines Reconciliation in Hospital Good Practice Guidance

Professor Bryson advised that Mr MacLaren had given an overview of the above document at the last meeting. This set out standards for medicines reconciliation in hospital and provided guidance for implementing safe and reliable processes across NHSGGC.

A number of comments had been raised at the last meeting and the Committee accepted the principle of the document and felt that this was good practice.

Mr MacLaren had taken on board the Committee's comments and had recirculated a revised paper to members. Positive comments had been received.

Professor Bryson commended the paper and outlined that this should be disseminated widely, with an ADTC endorsement. It was noted that this was an evolving programme.

NOTED

5. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(1) SMC Evaluations / NICE/QIS Guidance

Dr Macphee gave a brief resume of the 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. 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 new prescribing 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.

One declaration of interest was made.

The following was highlighted:-

Linagliptin, 5mg film-coated tablet (Trajenta®) [746/11] ***[Indication: Treatment of type 2 diabetes mellitus to improve glycaemic control in adults (as monotherapy and as combination therapy]***

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

The SMC cannot recommend the use of linagliptin as monotherapy or in combination with metformin and a sulphonylurea as the company's submission related only to its use in combination with metformin.

This may have clinical advantages for some patients and was expected to be cost neutral.

ACTION BY

A GP questioned the specialist initiation. It was noted that this was the current position for all gliptins and if the specialist initiation was changed for linagliptin it would require to be changed for all gliptans.

It was agreed that the specialist initiation restriction remain but that this be discussed at the next section review for this therapeutic area. **Mr R Foot**

Apixaban 2.5mg film-coated tablet (Eliquis®) [741/11] ***[Indication: Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery]***

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

Local clinicians were content with current Formulary choices and did not wish to use this medicine, therefore, the Formulary and New Drugs recommendation was not to add to the Formulary.

Fentanyl 50, 100, 200 microgram single dose nasal spray (Instanyl®) [750/11] ***[Indication: For the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain]***

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

Feedback from advisers indicates that single dose presentation may have advantages, however, note they are not currently using intra nasal fentanyl – sublingual/buccal formulations are preferred.

The Formulary and New Drugs recommendation was that this should not be added to the Formulary following consultation with the Palliative Care MCN.

Rivaroxaban 15 and 20mg film-coated tablets (Xarelto®) [755/12] ***[Indication: The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack]***

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

The Sub-Committee's recommendation was to acknowledge new indication (Total Formulary) restricted as per SMC restriction and in accordance with the National Consensus Statement for dabigatran, available on the NHS HIS website, which is also valid for this medicine.

The ADTC agreed to add rivaroxaban to the Formulary, with the restriction to patients currently receiving warfarin who have poor INR control despite evidence that they are complying, or patients with allergy or intolerable side effects from coumarin anticoagulants. Use in other patient groups remained non-Formulary. Further information can be found in the National Consensus Statement for dabigatran on the NHS HIS website.

Further work was presently being undertaken with the Heart MCN on a pathway for the use of both dabigatran and rivaroxaban in the patient group not currently on warfarin. This was hoped to be available for the April meeting of the Committee.

DECIDED:

That decisions made by the Formulary and New Drugs Sub-Committee at their meeting on 3 February 2011 be ratified by the Committee, noting the outstanding work in relation to rivaroxaban.

ACTION BY

(2) Appeals

(a) Budesonide nasal spray (Rhinocort Aqua®)

Mr Foot advised that an appeal for Budesonide nasal spray (Rhinocort Aqua®) had been received from Ms Joanna Johnson, Respiratory Support Pharmacist, PPSU. Ms Johnson had no interests to declare. He gave a summary of the appeal. The main points were as follows:-

- There was sufficient evidence to support the use of intranasal corticosteroids as first line therapy for moderate to severe persistent symptoms of rhinitis. Meta-analysis shows that intranasal corticosteroids are superior to antihistamines and act by suppression of inflammation at multiple points in the inflammatory cascade. All intranasal corticosteroids have similar clinical efficacy but bioavailability varies considerably.
- Systemic effects of nasal corticosteroids may occur, especially when prescribed at high doses for prolonged periods. However, no clinically relevant systemic exposure resulting from intranasal administration of fluticasone, mometasone, budesonide had been observed. The metabolism of budesonide was primarily mediated by CYP3A4 and interactions with enzyme inhibitors could therefore increase systemic exposure to budesonide. However, use of enzyme inhibitors such as itraconazole or ketoconazole concomitant with Rhinocort® Aqua for periods up to two weeks treatment appeared to be of limited importance.
- Rhinocort® Aqua was a lower acquisition cost than the current second line choice Nasonex® (mometasone).

The Sub-Committee's recommendation was that Rhinocort Aqua represents a cost-effective alternative and the appeal to move this preparation into the Preferred List should be upheld. It should replace mometasone furoate which would move into the Total Formulary.

A discussion ensued and it was

DECIDED :

1. That the Committee ratify the Formulary and New Drugs Sub-Committee's decision to uphold this appeal.

2. That a response be sent to the appellant. **Dr G McKay**

(b) Carmellose Sodium (Celluvisc®)

Mr Foot advised that an appeal for Carmellose sodium (Celluvisc®) had been received from Ms Nicola McElvanney, Chair of GGC Area Optometric Committee. Ms McElvanney had no interests to declare. The appeal was for first line treatment option for atopic dry eyes.

In a Formulary Section Review in October 2010, Carmellose Sodium (Celluvisc®) was added to the Total Formulary for tear deficiency and dry-eye conditions. This was restricted to use only in those patients with severe dry eyes in addition to external eye or corneal conditions who demonstrate intolerance to preservatives.

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

- The main reference to support the appeal was the DEWS report which stated that the single most critical advance in treatment for dry eye disease was the elimination of preservatives such as benzalkonium chloride (BAK). Optometrists and ophthalmologists following the recommendations to avoid preservatives in moderate to severe dry eye conditions would therefore deviate from the current GGC Formulary Preferred List. It was claimed that administering preservative containing eye drops may worsen the symptoms leading to extra appointments and the need for

ACTION BY

other anti inflammatory or anti allergy medication to treat a situation that may have been avoidable.

The one supporting evidence paper was a consensus paper from USA – which highlighted that absence of BAK or use of less toxic preservatives seem to achieve better tolerance of eye lubricants. However, the strength of the evidence for its recommendations remained uncertain.

Ophthalmology opinion confirmed that preservatives, and BAK specifically, can cause or exacerbate symptoms used for dry eye treatment. However, hypromellose was still considered to be a viable first line option for dry eye conditions.

The current Preferred List offers a range of eye lubricants which either contain a different preservative or are preservative-free. The estimated budget impact of a modest switch from hypromellose to Celluvisc was considerable. It was important that optometrists were discouraged from routinely suggesting these preparations without full consideration of alternative Preferred List options.

It was noted that a pilot whereby optometrists review and directly supply patients with dry eye treatments was to be undertaken in a single CHP in April this year. This in part explained the submission of this appeal from the Area Optometry Committee.

The Sub-Committee's recommendation was that this appeal to move Celluvisc® into the Preferred List should not be upheld due to insufficient evidence provided and the potential cost implications.

DECIDED:

1. That the Committee ratify the Sub-Committee's recommendation not to uphold this appeal.

2. That a response be sent to the appellant. **Dr G McKay**

(3) Section Reviews – Outcomes : Chapter 3 : Respiratory, Section 7.3 : Contraceptives and Chapter 12 : Skin (Part 2) Dermatology.

Mr Foot advised that section reviews had been undertaken on the above. There were a number of changes in content and prescribing notes and this had been reviewed in detail at the Sub-Committee meeting and recommended approval for the changes. The following was highlighted:-

- **Contraceptive Review** - The GGC Formulary had previously referred to the BNF, with the exception of those preparations that had been not recommended by SMC, so in effect nearly all contraceptives were considered Formulary. The review focused on limiting this list.

  The NHSGGC guideline for contraception in primary care would be updated to reflect the changes.

- **Skin Review** - Preparations for psoriasis - There were two additional entries to the Total Formulary [Salicylic acid in aqueous cream 5%, 10% and salicylic acid in yellow soft paraffin 5%, 10%] which were specials (unlicensed medicines). Use of these medicines were accepted practice.

NOTED

ACTION BY

(4) Erectile Dysfunction associated with Severe Distress

Mr Foot advised that following advice from the Scottish Government on medicines for erectile dysfunction associated with severe distress, the entries for the medicines tadalafil, vardenafil, sildenafil had been amended on the Formulary to make them in line with the agreed local referral pathway.

NOTED

(5) Six Monthly Update

Dr Macphee gave a brief summary of the work which had been carried out by the Formulary & New Drugs Sub-Committee. A paper had been presented which outlined information on membership, web access for the Formulary, presentation of information to ADTC, pending Formulary status, patient access schemes, NICE single technology appraisals, Formulary upkeep, high priority medicines, formalisation of protocol development, cancer medicines and productivity and efficiency work streams.

The Sub-Committee had changed the format of presentation of new medicines advice to ADTC. It was agreed that a clear summary would suffice. If Members wished to see the full SMC DAD they should contact the Secretary.

The Sub-Committee would work with Primary Care colleagues to highlight newly launched medicines which could result in high budget impact or where additional advice was required to manage the introduction. A short list of these medicines would be monitored at Practice level to improve early signals of unexpected uptake.

NOTED

(6) Review of Medicines Accepted by the Scottish Medicines Consortium (SMC) but not Added to the NHS Greater Glasgow & Clyde Drug Formulary : 2011

Mrs Campbell gave a summary of the above paper which considered all medicines assessed during the full calendar year of 2011.

During 2011, out of a total of 54 medicines accepted by SMC, there were six occasions (11%) when NHSGGC ADTC decided, on initial review, not to add to the Formulary. This was similar to the rate observed in the 2010 review (seven of 51 occasions; 14%) a slightly higher proportion than observed in the 2008 and 2009 reviews.

The “acceptance rate” had varied over time with no particular trend. Reasons for accepted medicines not added to the Formulary in 2011 were:-

- 83% no plans to use, on advice from specialist colleagues
- 17% combination class not on the Formulary.

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

NOTED

6. CLARIFICATION OF PRESCRIBING GUIDANCE IN NHSGGC BREASTFEEDING POLICY

Ms Wolfson gave an overview of the above policy. Attached with the policy was a paper which outlined the context, issues, proposal, topics to be included and summary. The aim of this was not solely to give information on the appropriate medications but to reduce inappropriate medication usage and to signpost to the appropriate care and sources of information.

ACTION BY

NHS Greater Glasgow and Clyde has had a Board wide Policy document since 1990. Individual areas had their own guidelines but by 2003 these were amalgamated into one document to ensure that patients and staff were able to provide a seamless service, reduce duplication of effort and to reduce conflicting information.

The document was updated every three years and each update takes about a year to complete since the document was actually a set of guidelines that required to be ratified by a number of different groups.

For the 2009 version all mention of medications was omitted. However, this had proved to be unpopular with Health Visiting teams, GP's, Midwifery teams and Infant Feeding Advisors.

Currently the Board has been using UNICEF UK training materials which mention some of the medications and they have a new e learning package for GP's which makes recommendations on medications.

A discussion ensued and the following comments/suggestions were made:-

- It was noted that there were no prescribers on the guidelines development group.
- Useful document but education required for midwives *[It was pointed out work was ongoing]*.
- Off label use – It was important that prescribers understand in which circumstances they may be prescribing outwith the product license for the medicine (off label). A comment should be added where this was the case.
- WHO guidance was 2000 – references may not be up to date.
- Fungal infection of the breast – Reword the first sentence as no medicine can be considered completely safe and fluconazole is excreted in breast milk in similar concentrations to that found in the mother.
- Galactagogues – The domperidone dose is above the recommended dose.
- Advice on antimicrobials should be reviewed by the Antimicrobial Management Team.
- Guideline, when complete, should be reviewed by the Medicines Utilisation Sub-Committee.

Ms Wolfson advised that this was work in progress and she would take on board the Committee's comments.

Dr McKay thanked Ms Wolfson for attending to present her paper.

DECIDED:

That any further comments should be sent to Ms Wolfson at Linda.Wolfson@ggc.scot.nhs.uk. **Members**

7. MEDICINES UTILISATION SUB-COMMITTEE

(a) General Update

Dr Simpson gave an update on the types of work carried out by the Sub-Committee. This included the following:-

- Feedback from ADTC meetings
- Reviewing guidelines and policies
- Utilisation reports
- Non-Formulary Use
- Clinical Effectiveness Pharmacists reports.

A brief summary of the work of the Sub-Committee would be produced on a six monthly basis.

NOTED

ACTION BY

(b) List of Approved Guidelines

Attached with the agenda papers was a list of all guidelines/policies reviewed by the Sub-Committee from 2011 to date. This list included when the guideline was considered, whether approved and when posted in the clinical information repository on StaffNet.

The Clinical Governance Department are in the process of taking over responsibility for the upkeep and adding clinical guidelines to StaffNet.

NOTED

(c) Guidelines for the Supply of Medication at Hospital Out-Patient Clinics

Mrs Ryan gave an overview of the above guidelines which outlined the overview, principles, guideline and further advice, along with draft letters from the GP to the consultant and a draft letter to all prescribers that would be signed by the Chief Executive and Board Medical Director.

These guidelines are intended to promote consistent practice across NHS Greater Glasgow & Clyde (NHSGGC) when a patient is seen at a hospital out-patient appointment by a hospital doctor who recommends initiation of a new drug or a change to existing drug therapy. It was important that hospital prescribers, GPs and patients have a common understanding about supply of medications for hospital out-patients. Although procedures may vary between different out-patient departments, the overall policy should be consistent across NHSGGC.

A discussion ensued which included comments submitted by a member who could not be present. The following comments were highlighted:-

- Clarification required on what constitutes 48 hours if patient is seen at an out-patient clinic on a Friday.
- It would be useful to have the name of the clinic and contact number on the slip used to ask the GP to prescribe from the clinic.
- Implementation would be more difficult in electronic format.

A form had been developed previously which could be reconsidered to support this process. **Mr R Foot/ Mrs M Ryan**

DECIDED:

That the Committee endorse the above guideline subject to minor comments being taken on board.

(d) Individual Patient Treatment Request (IPTR)

Mr Foot gave a summary of his paper which outlined the purpose of the paper, background, issues and proposals for revised system.

This paper proposed amendments to the process for Level 2 IPTRs in the acute sector of NHS Greater Glasgow and Clyde for all specialties excluding specialist oncology services.

Scottish Government circulars CEL(2010)17 and CMO(2011)3 are explicit that all requests for medicines not recommended by SMC or NHS HIS should be considered by a core panel and approved before use. NHSGGC currently do not apply this guidance to Level 2 medicines in light of the logistics in managing such a system.

With many of these medicines being for long-term conditions requiring ongoing prescription in primary care, there are direct implications for GPs. It was important that clinicians in acute care were aware of the Formulary status of medicines and are able to explain to their GP colleagues the reasons for using an SMC not recommended medicine instead of those on the NHSGGC Formulary.

ACTION BY

The paper outlined two options for managing Level 2 IPTRs:-

(i) Process applicable to all SMC not recommended medicines where medicine is being newly initiated.
(ii) Target a small number of SMC not recommended medicines with a requirement for recording all use (new initiations and continuations) with variance on approval dependent on origin.

A detailed discussion ensued.

It was highlighted that NHSGGC was required to give a six monthly report to the Scottish Government on IPTRs .

DECIDED:

That Option 2 above be taken forward as the process for IPTR2s.

8. PRESCRIBING MANAGEMENT GROUP

Professor Bryson advised that there had been no meeting of the PMG since the last ADTC. He outlined that there would be change of Chair and Vice Chair. Dr John Dickson, current Chairman, had resigned from the Committee. His replacement would be Dr Richard Groden, Clinical Director, Glasgow City CHP and the Vice Chair would be Dr Rachel Green, Associate Medical Director Diagnostics / Clinical Director, SNBTS. This had still to be formalised.

NOTED

9. ANTIMICROBIAL UTILISATION SUB-COMMITTEE

An update would be given at a future meeting.

NOTED

10. SAFER USE OF MEDICINES SUB-COMMITTEE

Dr McKay intimated that an update would be given at a future meeting.

NOTED

11. COMMUNICATIONS SUB-COMMITTEE

(a) General Update

Mrs Thompson advised that PostScript had a new format with a new mailing list and dedicated PostScript address.

NOTED

(b) PostScript

Issue 67 (January 2012) was attached with the agenda papers for information. This edition included articles on HbA1c: change to reporting units, web watch, dabigatran, voluntary ban on methotrexate 10mg tablets, actinic keratosis and new Formulary treatment option and a case study on dopamine agonist withdrawal syndrome in Parkinson's disease.

ACTION BY

Mrs Thompson gave a summary of items to be included in the next edition.

NOTED

12. FORMULARY RESTRICTION OF NRT FORMULATION

Professor Bryson gave a summary of the above paper which outlined the purpose, background, progress and implementation.

A new tender had taken place and GSK has been awarded the contract as the preferred supplier of NRT formulations for NHS GGC patients, starting from 1 March 2012 until 28 February 2015. This would replace the Nicorette range (McNeil products contract expires on 29 February 2012). The new range does not include an inhalator.

The Committee was asked to approve the proposed initiative, with a focus on change to the wording in the GGC Formulary as follows:-

'Niquitin CQ' 24 hour patches are the Nicotine Replacement Therapy (NRT) formulation of choice. See BNF and product literature for dosing information. If 'Niquitin' patches are unsuitable or if combination NRT is deemed the approach of choice, only alternative products from the GSK range should be considered (i.e. lozenge or gum).

A discussion ensued and it was

DECIDED:

That the Committee give its approval to the above initiative and change of wording in the Formulary for NRT products when the contract changes over.

13. ANY OTHER BUSINESS

(a) New Terminology for Formulary Decisions

Mr Foot advised that there was new Scottish Government guidance which outlined specific terminology for local Formulary decisions following advice from SMC. This new terminology would be used in future minutes and communication of Formulary decisions.

NOTED

(b) West of Scotland Regional Planning Group : Efficiency & Productivity Workstream Prescribing Group - Guidance on the Cost Effective Treatment of Depression where Drugs are Indicated

Mrs Campbell advised that the above guidance had been received from the West of Scotland Regional Planning Group. The guidelines were an attempt to harmonise practice across the West of Scotland and were sent to ADTCs as a mechanism for ensuring they are implemented. NHSGGC had several representatives on this group.

It was noted that an NHSGGC Depression Guideline had been approved recently by the Medicines Utilisation Sub-Committee and there were no major conflicts between the two documents. Dr Simpson highlighted that there could be confusion around a perceived order of first line agents.

A discussion ensued and it was

ACTION BY

DECIDED:

That the Committee acknowledge West of Scotland guideline (subject to clarification on the order of first line agents) and note there was no major conflicts to the NHSGGC guideline.

14. DATE OF NEXT MEETING

The next meeting of the Area Drugs and Therapeutics Committee would be held on Monday, 16 April 2012 at 2.00 p.m. in the Conference Room, Management Building, Southern General Hospital, 1345 Govan Road, Glasgow.