ADTC(M) 11/05
Minutes: 51 - 64

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, 10 October 2011 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Dr A Bowman	Dr J Larkin
Dr J Burns	Dr J MacKenzie
Mrs J Camp	Dr G J A Macphee
Mrs A Campbell	Dr G McKay
Mr R Foot	Dr C E McKean
Dr G Forrest	Dr A Seaton
Dr R J Hardman	Dr N Smart
Ms L Hillan	Dr A Taylor
Dr H Hopkinson	Mrs A Thompson

Mrs J Watt

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

Ms S Tennant	..	Lead for Prescribing and Clinical Pharmacist, North West Sector (deputising for Mrs M Ryan)
Mrs E Watt	..	Secretariat

ACTION BY

51. 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.

52. APOLOGIES

Apologies for absence were intimated on behalf of Dr P Beardon, Mr A Crawford, Dr A Crighton, Mrs M Ryan and Professor S Bryson.

The Chair welcomed Ms Sheila Tennant (who was deputising for Mrs Ryan) to the meeting.

ACTION BY

53. MINUTES

The Minutes of the meeting of the Area Drugs and Therapeutics Committee held on 8 August 2011 [ADTC(M) 11/04] were approved as a correct record.

NOTED

54. ADTC APPOINTMENTS

(a) Second ADTC Vice Chair Appointment

The Chair advised that further to the retiral of Mr James Wallace at the end of September 2011 an email had been sent out to members seeking nomination of the second Vice Chair of the Committee. This would preferably be a GP or a pharmacist as both the Chair and other Vice Chair (Dr McKay) were acute services doctors. The closing date for nominations was 18 October 2011.

NOTED

(b) ADTC Dental Representative

The Chair advised that further to the retiral of Professor David Wray from the Committee, Dr Alex Crighton, Consultant, Glasgow Dental Hospital, has agreed to be the dental representative on the Committee.

NOTED

(c) Chair of Medicines Utilisation Sub-Committee

The Chair advised that after the nomination process, Dr Graeme Simpson, Consultant Physician, Royal Alexandra Hospital had been appointed as Chairman of the Medicines Utilisation Sub-Committee.

NOTED

55. MATTERS ARISING

(a) Single Prescription and Administration Record for Scotland – Consultation – ADTC Response

Mr A MacLaren had given an overview of the above consultation document at the last meeting. Attached with the agenda papers was the response which had been sent on behalf of GGC.

There was broad agreement with the majority of the standards, most of which are reflected in the current inpatient prescription chart used in GGC. However, there were suggestions for further amendments.

Dr Taylor raised the issue of documentation of why medicines have been stopped. It was agreed that this could be fed back to the authors.

(b) The Use of Unlicensed Medicines in Preference to their Licensed Alternative on Grounds of Cost Effectiveness

Further to a discussion at the last meeting of the Committee on the off label use of Triptorelin, which was included in a Clinical Management Guideline endorsed by the Regional Cancer Advisory Committee, and further discussion about the use of off label/

ACTION BY

unlicensed medicine, Mrs Watt had undertook to produce a paper on the various approaches to the approval of the use off label medicines/unlicensed medicines.

Mrs Watt advised that the Greater Glasgow and Clyde Unlicensed Medicines (ULM) Policy was approved by this Committee in December 2010. This policy provides a governance structure for prescribers, nurses and pharmacists under which medicines can be prescribed and administered. The current version of the UMP states that "no unlicensed or off label medicine should be used routinely in preference to a licensed alternative solely because of cost". However, it has been recognised that in some circumstances to maximise the health gain for the whole population from available resources it may be appropriate to prescribe an unlicensed or off label medicine in preference to a licensed one because it is more cost effective. This approach has been approved, in principle, by the GGC Corporate Management Team but should only be undertaken where a full risk assessment has been carried out and where the use of the unlicensed medicine does not result in any additional risk for the patient. It is also expected that the use of an ULM will be undertaken with the patients' fully informed consent.

Mrs Watt gave a summary of the paper which outlined the background, categories of unlicensed/off label medicines (general medicines, off label use of a medicine from the same class, licensed medicines used in an unlicensed formulation/presentation, use of an unlicensed medicine in preference to a licence medicine), proposed approach and conclusion. She focused on the categories of unlicensed/off label medicines.

The Committee was asked to consider the revised process highlighted in the paper and agree a future approach and approve/amend a proposed change to the wording of the ULM Policy to cover the scenarios described in the paper.

A wide ranging discussion ensued and the following comments were made:-

- Unlicensed/off label medicines should only be used when there is no additional risks to patients.
- There could be a heavy reliance on pharmacy procurement for licensed medicines purchased as unlicensed formulations and clinical pharmacist and clinical director's input would be essential.
- Use of medicines off label should be picked up through guidelines either by local directorates or the Medicines Utilisation Sub-Committee for guidelines considered GGC wide.
- Comment/clarification of the proposed revision of wording of ULM policy.

Dr Seaton outlined that this would have implications for infectious diseases with medicines of the same class commonly being use off-label. The Chair indicated that this policy revision would help this situation.

DECIDED:

That the Committee gave its approval to a change in the wording to the Unlicensed Medicines Policy as described in Mrs Watt's paper. Mrs Watt would amend the Policy incorporating revised wording as suggested by Committee members. **Mrs J Watt**

56. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(1) SMC Evaluations / NICE/QIS Guidance

Dr Forrest gave a brief resume of the SMC reviews, and the Formulary and New Drugs Sub-Committee's recommendations with the exception of Dabigatran where Mrs Campbell gave an overview. These had been divided into sections for ease of understanding as outlined in the Appendix to this Minute.

ACTION BY

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 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.

Three declarations of interest were made.

The following was highlighted:-

Tapentadol 50, 100, 150, 200 and 250mg prolonged-release tablets (Palexia® SR) [654/10] ***[Indication: The management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics]***

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

A decision on this new medicine had previously been deferred to allow consultation with the Chronic Pain MCN. The MCN agreed to a third line position after morphine and oxycodone. This was more restrictive than SMC advice.

The Sub-Committee's recommendation was to add to the Total Formulary restricted to patients who have failed to respond or tolerate both morphine and oxycodone.

ADTC members indicated that further restricting to pain specialists was appropriate, at least initially until some experience had been gained with this medicine.

A detailed discussion ensued and the Committee amended the Sub-Committee's decision to:-

"Add to the Total Formulary restricted to initiation by, or on the advice of pain specialists only in patients who have failed to respond or tolerate both morphine and oxycodone".

The prescribing status would be looked at after six months.

Golimumab 50mg solution for injections prefilled pen (Auto-injector) or prefilled syringe (Simponi®) _ ***[Indication: Treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy]]***

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

The Sub-Committee's recommendation was to add to the Total Formulary restricted to specialist use in accordance with the British Society for Rheumatology (BS) guidelines of July 2004. Use of the 100mg dose has not been accepted by SMC and remains non-Formulary.

There was debate on whether the July 2004 were the correct guidelines this referred to. Mr Foot undertook to find this out and would amend the restriction if required. **Mr R Foot**

Olmesartan medoxomil/amlodipine/hydrochlorothiazide (Sevikar HCT®) [706/11] ***[Indication: As substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine, and hydrochlorothiazide taken as a dual component (olmesartan medoxomil and amlodipine or olmesartan medoxomil and hydrochlorothiazide) and a single formulation (hydrochlorothiazide or amlodipine)].***

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

ACTION BY

The Sub-Committee's recommendation was that this new combination should not be added to the Formulary as antihypertensive combinations are not added to the Formulary.

Vardenafil 100mg orodispersible tablet (Levitra®) [727/11] ***[Indication: Treatment of erectile dysfunction]***

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

There was no enthusiasm from the specialists for this new formulation to be added to the Formulary and it was more expensive than standard vardenafil.

The Sub-Committee's recommendation was not to add this new formulation to the Formulary.

Dabigatran etexilate 110mg and 150mg hard capsules (Pradaxa®) [672/11] ***[Indication: For the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more of the following risk factors: previous stroke, transient ischaemic attack, or systemic embolism; left ventricular ejection fraction <40%, symptomatic heart failure; ≥ New York Heart Association (NYHA) Class 2; age ≥75 years age ≥65 years associated with one of the following; and diabetes mellitus, coronary artery disease or hypertension]***

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

A national conference was held on 21 September 2011 with representations across all sectors. A consensus statement would be sent to ADTCs. Feedback from the MCN indicated that NHSGGC would follow the national consensus which was expected to advise that warfarin should remain first choice for patients with INR in therapeutic range > 60% of time (excluding non-compliance as reason) and patients not on warfarin should be reconsidered for this before considering dabigatran.

There would be significant cost implications for NHSGGC.

Boceprevir 200mg capsule (Victrelis®) Treatment experienced patients [722/11] ***[Indication: Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who have failed previous therapy]***

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

Another agent, telaprevir, would be coming through SMC in November 2011. The Hepatitis MCN would await this advice before making a decision on Boceprevir for treatment experienced patients and treatment naïve patients. There would be significant cost implications for GGC.

DECIDED:

That decisions made by the Formulary and New Drugs Sub-Committee at their meeting on 30 September 2011 be ratified by the Committee subject to the change in restriction to tapentadol.

(2) Appeals

(a) Buprenorphine/naloxone sublingual tablets (Suboxone®)

Mr Foot advised that an appeal for Buprenorphine/naloxone sublingual tablets (Suboxone®) had been received from Dr Saket Priyadarshi, Senior Medical Officer/Lead Clinician, Addiction. Dr Priyadarshi had no interests to declare.

ACTION BY

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

- Appeal proposes a change to the restriction from specialist initiation to allow specifically trained GPs to initiate directly with the support of local addiction services. Currently the short initiation phase is undertaken by the Community Addiction Teams and patients are then transferred back to GPs for continued prescribing.
- Prescribing note to reflect change in name of what is now the NHSGGC Specialist Addiction Services.
- Restriction change does not infringe on current SMC prescribing restrictions.
- Current Suboxone prescribing in GG&C addiction services is in the region of 320-40 patients.
- The proposed Formulary change will allow an increase in these numbers to utilise financial capacity previously agreed for this treatment (as agreed by PMG in December 2009).
- Although prescribing/initiation will take place in primary care this will be as a constituent component of the Locally Enhanced Services (LES) Shared Care scheme and initiation will be restricted to prescribers who have completed appropriate training and will be supported by specialist advice and access to social and psychological support.

The change in restriction will simply make the initiation of suboxone more straightforward, with specially trained and endorsed GPs initiating treatment with the support of Addiction Services.

The Sub-Committee's recommendation was to uphold the appeal for the change in restriction and Buprenorphine/naloxone sublingual tablets restriction in the Formulary would be amended to read:-

"Initiation is restricted to addiction services or specialist GPs who have received appropriate training and authorisation from Addiction Services, for those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate".

A discussion ensued and it was

DECIDED:

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

2. That the Chair write to the authors of the Committee's decision. **Chair**

(b) Pravastatin Sodium Tablets

Mr Foot advised that an appeal for Pravastatin Sodium tablets had been received from Ms Sheila Tennant, Lead for Prescribing and Clinical Pharmacy, Glasgow City CHP – North West Sector. Ms Tennant had no interests to declare. Ms Tennant was in attendance at the meeting in another capacity.

Pravastatin was previously on the Formulary but following a Drug of Choice report the decision was made to remove pravastatin from the GGC Formulary. Since then the price of pravastatin has dropped.

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

- Pravastatin is recommended to be positioned for use when patients are on medicines which interact with simvastatin or atorvastatin because of route of metabolism.
- Appeal suggests that pravastatin replaces rosuvastatin on Formulary.
- Reduces coronary morbidity and mortality when used for primary and secondary prevention.

ACTION BY

- NICE CG67 recommends pravastatin as alternative to simvastatin if potential drug interactions or contraindications.
- SIGN 97 also recommends an alternative statin, such as pravastatin if interactions
- NHSGGC primary and secondary prevention guidelines recommend simvastatin 40mg as the first line statin.
- Rosuvastatin is currently the only Formulary statin which is water soluble and where interactions from cytochrome p450 metabolism are not expected.

The MCN are broadly in support of the addition of pravastatin to the Formulary for the patient group but their view on the removal of rosuvastatin was not yet known.

The Sub-Committee's recommendation was to uphold the appeal .

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

- The GPs on the Committee had some concerns about the removal of rosuvastatin from the Formulary. It would limit GPs prescribing for patients who don't reach target. *[Remove the word "intolerant" in the rosuvastatin entry in the Formulary]*.

- Clarification of drug choice would be helpful. *[Mrs Thompson would highlight this in an article in PostScript]*. **Mrs A Thompson**

DECIDED:

1. That the Committee ratify the Sub-Committee's recommendation to uphold the appeal.

2. That Pravastatin sodium tablets will be added to the Total Formulary restricted to use only in patients in whom drug interactions might pose a problem or for patients who are intolerant of simvastatin and atorvastatin. The restriction of rosuvastatin be amended to exclude the word "intolerant".

3. That the Chair inform the authors of the Committee's decision. **Chair**

57. PRESCRIBING MANAGEMENT GROUP (PMG) – KEY POINTS OF THE MEETING HELD ON 13 SEPTEMBER 2011

The key points of the above meeting were noted. Dr McKean gave a brief update and highlighted the following items of interest:-

- Dabigatran for stroke prevention in AF *[Discussion was informed by input from them Lead Clinician for Heart MCN who supported cautious approach and use in selected patients (existing and new). This was going to be a cost pressure for the NHS Board]*.
- Horizon Scanning for prescribing pressures and efficiency savings (forecast for 2012/13) *[A forward look would take place at the end of the month which would focus on the financial year]*.

NOTED

58. MEDICINES UTILISATION SUB-COMMITTEE

(a) Buprenorphine Utilisation Report

Mrs Watt advised that arising from discussion on the Preferred List Adherence Report at the Sub-Committee meeting it had been agreed to research buprenorphine patches. Patch formulations are the most commonly prescribed formulation and show an increase in prescribing figures over the past 12 months but are not on the Formulary.

ACTION BY

Unfortunately this information was not yet available and would be discussed at the next meeting of the Sub-Committee in November.

NOTED

(b) Primary Care Depression Guideline

Mrs Watt advised that after some amendments the Sub-Committee gave its approval to the guideline and this would go on the ADTC website.

A discussion ensued on whether updates on guidelines which this Committee had not seen were relevant. It was noted that the ADTC had devolved the approval of guidelines to the Medicines Utilisation Sub-Committee and only those guidelines which required ADTC input should be brought to the Committee. The guidelines should state the approving Committee. This was noted.

Dr Taylor asked how guidelines fit in with the GP Sub-Committee of the LMC. He asked if this and other guidelines, as a matter of course, be sent to that Committee. It was pointed out that this guideline was seen by the Primary Care PMG which is the primary prescribing advisory Committee to the Board. The GP Sub-Committee should liaise directly with the Primary Care PMG with regard to having sight of any guidelines which have a primary care input. Dr Taylor would pursue this with the GP Sub-Committee. **Dr A Taylor**

NOTED

(c) Diabetes Ketoacidosis Care Pathway

Mrs Watt advised that the above protocol, disseminated by the Scottish Diabetes Group to all Diabetes MCNs in Scotland, had been discussed at the last meeting and minor comments were made on the implementation from the acute units.

Dr Hopkinson advised that she had liaised with Dr McGrane. Specialist Registrar, Gartnavel Royal Hospital, on the Committee's comments. She advised that implementation was underway.

A number of comments had been fed back to the national group including that there was still a need for kardex, useful for fluid chart to be larger and separate sheets were required for infusion.

NOTED

(d) Treatment Selection for Fracture Risk Reduction

Mrs Watt advised that the above guideline had been discussed previously and an algorithm for treatment had been produced. This main focus was that Denosumab (now added to the Formulary) would be prescribed third line.

The Sub-Committee gave its approval to the guideline subject to minor comments and this would go on the ADTC website.

Dr Taylor asked what happens to patients in the longer term (after the three years). Mrs Watt was unsure but would check with Mrs L Hendry from Osteoporosis Group. Dr Hardman advised that he had contacted Dr S Gallacher with the same point and an ongoing review was planned.

NOTED

ACTION BY

59. ANTIMICROBIAL UTILISATION SUB-COMMITTEE

The Minutes of the meeting of the above Sub-Committee were attached with the agenda for information.

Dr Seaton gave an update as follows:-

- Staffing – There had been staffing challenges over the last few months which had impacted on the AMT work programme, including significant time commitment to fulfill the requirements of the Healthcare Association Point Prevalence Study.

- Guideline implementation – Intensive Care and Antifungal Prescribing Policy. These were about efficacy and cost efficiency and had been approved by the AMT.

- Revised Primary Care Guidelines – Dr H Macdonald, Primary Care Prescribing Adviser, and Ms S Galbraith had revised the Primary Care guidance for adults. This had been taken to the Primary Care PMG for review.

- Paediatrics – A Primary Care Paediatric Antibiotic Guideline had been produced. This would go the Primary Care PMG for approval.

- Datix – the top themes related to Gentamicin. If the guidelines were followed rigorously this would reduce incidents.

NOTED

60. THERAPEUTICS SUB-COMMITTEE

Mrs Camp advised that the above Sub-Committee had not yet had its first meeting. This would take place in November.

NOTED

61. COMMUNICATIONS SUB-COMMITTEE

PostScript - Issue 65 (September 2011) was attached with the agenda papers for information. This edition included articles on opiate substitution therapy, latest ADTC decisions, SIGN guidelines app for iPhone, individual patient treatment requests, smoking cessation and effects on drug metabolism and web watch.

Mrs Thompson requested ideas for articles on “If I could change one thing”.

Mrs Thompson advised that the process for PostScript bulletins would be revamped and she was looking at how to improve the co-ordination of the PostScript bulletin “family”, co-ordinate this more effectively.

A summary of items in the next edition was highlighted which included an article on dabigatran and also an adverse effect of a medicine use in Parkinson’s Disease.

NOTED

62. MEETING DATES FOR 2011

Attached with the agenda papers was a schedule of meetings for 2012. This was agreed. The venue had still to be confirmed.

ACTION BY

DECIDED:

That the meeting dates for 2012 were agreed. An updated schedule would be sent out once venue had been confirmed. **Secretary**

63. ANY OTHER BUSINESS

GGC Prescribing Website

Mr Foot gave an presentation and overview of the new GGC Prescribing website which would replace the current ADTC website. A soft launch would take place shortly with a direct link to StaffNet and a larger launch would take place when the site was up and running and could be accessed on the internet. The website address was *www.ggcprescribing.org.uk*.

Mr Foot demonstrated the e-Formulary and updates from ADTC meetings would be put directly on the website.

Mr Foot gave examples of searching for Formulary items. Other information on the website included PostScript bulletins, link to clinical guidelines (NHS address required), medicines policies, other Formularies, Therapeutics Handbook, mobile app etc.

Mr Foot responded to Members' comments including information on SharePoint and the Clinical Portal.

This was thought to be an exciting development and thanks were given to Mr Foot for all the work he had carried out developing this website.

NOTED

64. DATE OF NEXT MEETING

The next meeting of the Area Drugs and Therapeutics Committee would be held on Monday, 12 December 2011 at 2.00 p.m. in the **Board Room, J B Russell House, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12.**