ADTC(M) 12/06
Minutes: 76 - 86

NHS GREATER GLASGOW AND CLYDE

Minutes of a Meeting of the
Area Drugs and Therapeutics Committee
held in the Board Room
J B Russell House
Gartnavel Royal Hospital
on Monday, 10 December 2012 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Dr A Bowman	Dr H Hopkinson
Professor S Bryson	Dr J Larkin
Dr J Burns	Dr J MacKenzie
Mrs J Camp	Dr G J A Macphee
Mrs A Campbell	Dr P Moultrie
Dr G Forrest	Mrs M Ryan
Dr R J Hardman	Dr A Seaton
Ms L Hillan	Dr A Taylor

Mrs J Watt

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

Ms N Downes .. Lead Clinical Pharmacist Medicines for the Elderly/Care Homes *[For Minute 80 only]*
Ms K Greschner .. Formulary Pharmacist *[Deputising for Mr R Foot]*
Mrs E Watt .. Secretariat

ACTION BY

76. CHAIR'S STATEMENT

Mrs Watt 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.

She 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.

77. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Mr R Foot, Dr H Hopkinson, Dr G McKay, Dr C E McKean, Dr G K Simpson and Mrs A Thompson.

The Chair welcomed Ms Kathrin Greschner, Formulary Pharmacist, who was deputising for Mr R Foot.

ACTION BY

78. MINUTES

The Minutes of the meeting of the Area Drugs and Therapeutics Committee held on 8 October 2012 [ADTC(M) 12/05] were approved as a correct record.

NOTED

79. MATTERS ARISING

Relative Roles of ADTC and the Hospital Records Committee re Reviewing Prescriptions Charts

Mrs Watt intimated that at the last meeting the Committee had reviewed a prescription and monitoring chart which related to both primary and secondary care. It had been pointed out that there was a Hospital Records Committee which reviewed acute care prescription charts and she had undertaken to contact the Chair of this Committee to clarify the relative roles of the ADTC and the Hospital Records Committee in reviewing prescriptions charts. Mrs Watt would give an update on this at the next meeting. **Mrs J Watt**

NOTED

80. POLYPHARMACY SUB-COMMITTEE

(a) GGC Mindful Prescribing Strategy – Polypharmacy

Ms Downes/Dr Macphee advised that the Scottish Government Health Department (SGHD) National Polypharmacy Guidance CEL 36 (2012) had been launched on 1 November 2012 providing guidance for clinicians undertaking face to face medication reviews.

NHSGGC had been provided with details of approximately 9,000 patients aged over 75 years with a SPARRA risk score of 40-60% considered high priority for review. NHS Boards would be asked to regularly report on supportive activities as part of the SGHD Quality and Efficiency Programme.

A draft Mindful Prescribing Strategy - Polypharmacy and associated work plan to address the SGHD requirements had been developed. This recognised that a number of services across NHSGGC already provide polypharmacy reviews. The strategy aimed to support engagement with prescribers and patients to encourage a collaborative, mindful approach to the use of medication. An extensive consultation process had been undertaken with input from acute services, partnerships and primary care.

Initial pilot polypharmacy medication reviews by GPs for the SGHD priority cohort are in progress and evaluation was underway.

Mechanisms to support delivery of regular face to face multidisciplinary polypharmacy reviews in the primary care setting in 2013/14 were in development with consideration of a Local Enhanced Service.

Dr Taylor welcomed this joint approach to ensure good communication across the interface to avoid inadvertent reversal of agreed changes. There was a QOF for polypharmacy at a national level.

In response to a question from Dr Larkin, Ms Downes outlined that this strategy was aimed at all involved in prescribing medicines and would have an impact on patients, carers and clinicians. Work was ongoing to develop clinical tools and patient information to support the service. The Sub-Committee would lead the activities to address eight recommendations.

Professor Bryson advised that the strategy had been presented to the PMG and had been well received. An update report would be received once or twice a year.

ACTION BY

A discussion ensued and it was

DECIDED:

That the Committee give its endorsement to the Mindful Prescribing Strategy – Polypharmacy.

(b) Minutes of the meeting held on 7 November 2012

The minutes of the meeting of the Polypharmacy Sub-Committee held on 7 November were for information only.

NOTED

81. 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. Recommendations made by the Committee are summarised in an Appendix to these Minutes and would be further publicised in PostScript and in the Formulary update available on the GGC 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.

Three interests were declared.

The following was highlighted:-

- Ferric carboxymaltose 50mg iron/mL solution for injection/infusion (Ferinject®) [463/08] ***[Indication: Treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests]***
  Iron isomaltoside 1000, 100mg/mL solution for injection/infusion (Monofer®) [697/11] ***[Indication: Treatment of iron deficiency anaemia in the following conditions: When oral iron preparations are ineffective or cannot be used; and where there is a clinical need to deliver iron rapidly]***

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

  There had been concern that this may be used widely and a decision on these medicines being added to the Formulary had been deferred to allow consultation with the relevant specialists. This had now been received.

  Professor Bryson enquired if there were financial implications. Mrs Campbell advised that modest uptake had been predicted but the specialties had been invited to submit development bids for 2013/14 if a more extensive change in practice was planned.

- Ustekinumab, 45mg solution for injection (Stelara®) [572/09] ***[Indication Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and psoralen and UVA treatment (PUVA)]***

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

ACTION BY

A decision on this medicine had been deferred until implementation plans for the relevant Patient Access Scheme were in place. This had now been confirmed.

Dr Larkin asked how long Patient Access Schemes last for. Companies are obliged to continue these for at least five years but there was no expectation that PAS would be withdrawn. It was pointed out that this was a complex PAS but the majority now introduced are simple discounts which are easier for the NHS to implement.

- Olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide (Sevikar HCT®) [823/12] ***[Indication: In adult patients whose blood pressure is not adequately controlled on the combination of Olmesartan medoxomil and amlodipine taken as dual-component formulation]***

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

  Amlodipine is a Preferred List medicine but olmesartan and hydrochlorothiazide are non-Formulary medicines. This type of combination is generally not added to the Formulary.

  The Formulary and New Drugs recommendation was that this medicine should not be included in the GGC Total Formulary for the indication in question because the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the Formulary.

- Ranibizumab, 10mg/mL solution for injection (Lucentis®) [732/11] ***[Indication: For the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults]***

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

  The SMC restriction is for use in patients with macular oedema secondary to central retinal vein occlusion (CRVO). Use in BRVO is not recommended.

  A decision on this medicine being added to the Formulary had been deferred for the development of a clinical protocol. This protocol had now been reviewed and endorsed by the Medicines Utilisation Sub-Committee.

- Argatroban, 100mg/ml, concentrate for solution for infusion (Exembol®) [812/12] ***[Indication: Anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy].***

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

  Mrs Watt advised that she had spoken to Dr C Tait about this medicine and he had indicated that in some circumstances there may be no suitable alternative and this medicine may need to be used in an emergency. Stock of this medicine had been ordered and the IPTR paperwork would need to be completed retrospectively.

  Dr Burns advised that SMC recognised the practical difficulties for Boards given the lack of alternatives and emergency medical situation which may require specific local processes to be put in place, without setting a precedent for not recommended medicines.

  The Committee gave its approval to the above.

- Zopiclone replace temazepam on the Preferred List of the GGC Adult Formulary. There have been supply problems with temazepam which are not expected to be resolved in the near to medium-term, and this medicine is now considerably more expensive than zopiclone, ie five times the costs which is expected to rise to 10 times the cost - this would have considerable cost implications.

  A discussion ensued on various ways in which this could be highlighted without a direct switch on the Formulary but ultimately it was agreed to go with the Formulary and New

ACTION BY

Drugs recommendation. These agents are recommended for short term use only. Mrs Ryan advised that GPs have been advised of the problems of temazepam through PostScript Primary Care.

DECIDED:

That recommendations made by the Formulary and New Drugs Sub-Committee at their meeting on 30 November 2012 be ratified by the Committee.

(3) Appeal – Trospium Modified-Release (Regurin XL®) Capsules

Ms Greschner advised that an appeal for Trospium (Regurin®XL) capsules had been received from Dr V Granitsiotis, Consultant Urologist and Dr K Guerrero, Consultant Urogynaecologist, Southern General Hospital. Dr Granitsiotis declared a non-personal interest.

Ms Greschner gave a summary of the appeal. Four supporting evidence papers were provided by the appellants.

The important points highlighted by the appellants were as follows:-

- Potential for interaction (inhibition or induction) with concomitantly administered drugs is minimal for Trospium chloride, in contrast to all other anticholinergics used for the same indication; this is particularly significant for elderly patients with co-morbidity and consequent poly-pharmacy.
- Regurin® XL does not cross the blood brain barrier meaning that it is less likely to impair cognition or the patient's ability to drive or operate machinery whilst being treated, and unlike the other anti-cholinergics it does not have a label 3 BNF warning about dizziness and confusion.
- Regurin® XL has proven efficacy for OAB patients irrespective of BMI or symptom severity. Regurin® XL is the only anti-cholinergic that has evidence of treating OAB in obese patients, this is becoming an increasing problem and is a predisposing risk for those who have OAB.
- Regurin® XL is the least expensive once daily anti-cholinergic available.

The important points highlighted by the Formulary Team were as follows:-

- The cost data provided in the appeal could not be confirmed but new cost data was presented in the summary.
- Clinical effectiveness for this medicine seemed to be limited to placebo controlled studies only. Available clinical guidelines do not suggest that there are significant differences in clinical effectiveness between the currently available medicines for urinary incontinence.
- Trospium XL could be cost-saving if it were to replace one of the more expensive Formulary choices.
- The appellants position the medicine as Preferred List option. The Formulary Team suggested that, if included there, it should replace one of the more expensive treatment options such as solifenacin or tolterodine. The replaced medicine could be moved into the Total Formulary.

The Sub-Committee's recommendation was to uphold this appeal and that Trospium (Regurin®XL) capsules should be included in the Preferred List and solifenacin should be moved to the Total Formulary.

A detailed discussion ensued and Members had concerns about moving solifenacin from the Preferred List to the Total Formulary. It was outlined that solifenancin was used frequently and removal from the preferred list would have significant implications in primary care.

ACTION BY

DECIDED:

1. That the Committee agreed that Trospium (Regurin®XL) capsules should be added to the Total Formulary but no further changes.

2. That a response be sent to the appellants. **Chair**

82. ANTIMICROBIAL UTILISATION SUB-COMMITTEE (AUC)

(a) Six Monthly Report

Dr Seaton gave an overview of some of the work carried out by the Sub-Committee in the last six months. This included secondary care antibiotic (AB) use : "4C", meropenem, gentamicin/ vancomycin, Primary Care "4C" use and quinolone use/PC prescribing, hospital point prevalence summary, HAI: CDI, AB Prescribing indicators underlying CDI HEAT target for acute medical and surgical admissions and surgical prophylaxis, vancomycin status report and HIV post exposure prophylaxis.

There was a series of graphs on HAI in GGC on the undernoted issues

- "4C" antibiotics in hospitals. *[There was a sustained reduction in secondary care]*.
- Meropenem *[There was 140% increase in use but prescribing was deemed appropriate and was on advice of microbiologists. The AMT were discussing different strategies to limit the prescribing of meropenem. It was noted that there was an alternative to meropenem which predated SMC and is currently non-Formulary: this would be submitted to the Formulary and New Drugs Sub-Committee as an appeal]* .
- Gentamicin and vancomycin *[Prescribing had plateaud. A GP asked if an end date could be put on the monitoring sheet]*.
- 4C antibiotics in primary care *[Large reduction in prescribing]*.
- Quinolones in Primary Care *[In the table of seasonal variations in quinolones by NHS Boards, NHSGGC had 9.1% against the expected Scottish figure of 5.5%.. A letter would be sent by CHCP Clinical Directors to all practices outlining the variation in quinolone prescribing in CH(C)Ps. An audit had been carried out in Inverclyde. Dr Seaton outlined that if the guideline was followed, the target would be met]*.
- Summary of hospital antibiotic point prevalence surveys *[Every month members of the AMT would visit one hospital for one or two days. Findings of the studies would be fed back to directorates through relevant clinical governance groups. Dr Burns advised that communication of this data to clinicians appeared incomplete. Dr Seaton would look into this]*. **Dr A Seaton**
- HAI CDI *[This had now reduced to 20 cases a month with no ward closures]*.
- Prescribing Indicators in hospitals *[These were all in the region of 95% compliance]*.

(b) Drug Regimen Choice for HIV Post-Exposure Prophylaxis – October 2012

Dr Seaton gave an overview of proposed changes to the above guideline which had been received by Dr A Winter, Consultant Physician, Sexual Health and HIV, Sandyford Initiative. The HIV PEP was indicated following significant exposure. An initial three day supply was provided by emergency departments with the remainder of the 28 day course supplied following review by an HIV specialist. The current regimen was associated with potential serious drug-drug interactions and had a high rate of adverse events (gastrointestinal) which comprises compliance. The three day supply was often insufficient prior to review by HIV specialist therefore double supplies are frequently used. Neither the current nor proposed antiviral treatments are licensed for PEP. The HIV specialists have agreed to change the PEP regimen to Truvada (Tenofovir and FTC) and Raltegravir. The initial regimen was five days rather than three days.

This change to the guideline was approved by the Sub-Committee on 20 November 2012.

ACTION BY

A discussion ensued including the unlicensed status and comparative adverse effect profiles. Dr Seaton advised that these changes are in line with National practice.

Dr Seaton asked whether the Sub-Committee were able to approve this type of guideline without bringing to the ADTC. It was agreed that in line with the Medicines Utilisation Sub-Committee, the Antimicrobial Utilisation Sub-Committee had been delegated authority to approve guidelines on behalf of ADTC.

NOTED

(c) Minutes of the meeting held on 20 November 2012

The minutes of the meeting held on 20 November 2012 were attached for information.

NOTED

83. COMMUNICATIONS SUB-COMMITTEE

(a) Six Monthly Report

Mrs Watt gave an overview of Mrs Thompson's six monthly report which gave an update on the work of the Steering Group. The paper described some proposed changes to the format and production of PostScript Acute and PostScript Safety and some possible actions to further promote the bulletins to healthcare professionals within the acute sector.

Recent research was conducted to determine what proactive medicines information junior doctors want and how they would like to receive it. A survey was sent to all FY1s and FY2s in NHSGGC acute hospitals followed by a focus group for interested individuals.

The key findings from the focus group included that there was a very low awareness of the PostScript bulletins, however, there was an awareness of some of the recent key messages. Also, the email cascade systems appeared to be ineffective. The focus group participants thought the bulletin content was relevant, interesting and rated positively.

The following actions would be undertaken.

- Format and Frequency of Bulletins *[PostScript Safety would be discontinued and key messages would be incorporated into other bulletins - this had been agreed with the Safer Use of Medicines Sub-Committee. PostScript Acute would be issued on a bi-monthly basis]*.
- Advertising and Promotion *[A proposal with Strathclyde University Marketing Department was work in progress]*.
- Therapeutics Handbook and Clinical Info App *[Junior doctors were keen to have an app. Mr Foot had submitted a Business Case to the CMT which had now been approved. PostScript bulletins and the Formulary could be included in the app]*.

NOTED

(b) PostScript 72

Issue 72 (November 2012) was attached with the agenda papers for information. This edition included articles on levomepromazine: patient safety in palliative care, antibiotics and medicines for hospital use only, ticagrelor update, new drug: colecalciferoL (vitamin D3), PostScript Extra: new oral anticoagulants, ADTC decisions, safety updates and new guidelines: Antiplatelet therapy in secondary prevention of stroke and TIA: thromboprophylaxis for orthopaedic patients..

NOTED

ACTION BY

84. THERAPEUTICS SUB-COMMITTEE

Mrs Camp gave an overview of her paper asking the Committee to endorse the Therapeutics Sub-Committee processes related to the Therapeutics Formulary. This was based on the Formulary and New Drugs Sub-Committee processes.

She outlined that new (non-medicine) products are constantly being developed and added to the Scottish Drug Tariff and therefore can be prescribed in the community. Historically a Formulary has only been established for medicines and SMC advice has provided guidance to NHS Boards in developing their Formularies to direct doctors and prescribers on appropriate cost effective medicines. There is no equivalent organisation for these other prescribable products and medical devices. Requests have often been directed from acute service specialists to GPs. In addition patients may request this type of product from GP surgery staff who will be unable to determine suitability.

The process by which new products are managed must be transparent, consistent and explicit to ensure clinicians, managers and the public have confidence in the process and the decisions made.

A detailed discussion ensued and comments included the following:-

- The process needs to clarify the categories that would be included so as not to overlap with the Dressings and Sundries Formulary group.
- Outline what crosses over from acute sector to community.

DECIDED:

That Mrs Camp take on board the Committee's comments and a revised copy be sent to the Chair and Mrs J Watt for final approval.

85. PRESCRIBING MANAGEMENT GROUP (PMG) – KEY POINTS OF THE MEETINGS HELD ON 11 SEPTEMBER 2012 AND 13 NOVEMBER 2012

Professor Bryson advised that a verbal report on the key points from the meeting of the PMG held on 11 September 2012 had been given at the last meeting and they were attached for information. He gave a brief update of the key points form the meeting on 13 November 2012.

This included information on the following:-

- HEPMA.
- Finance Report
- Polypharmacy
- Ticagrelor *[See below *]*
- Revision to Risk Threshold for Primary Prevention of CVD – the rationale for changing GGC policy for initiation of statin therapy to align with national guidelines and practice standard (≥ 20% 10 year risk) *[GGC were currently out of step with national standard. The PMG had discussed the pros and cons of the proposed threshold reduction from ≥30 to ≥20% 10 year risk, and had agreed to support the MCN proposal. This would have an estimated budget impact of around £1M p.a. This was included in the budget projections for 2013/14].*
- ADTC Report
- PMG Reports: Priorities

* This had previously been included the Total Formulary restricted to specialist initiation only for patients who are either allergic or intolerant to clopidogrel or have a stent thrombosis on clopidogrel. Use in other patient groups currently remained non-Formulary until the regional/national position was clarified.

ACTION BY

Professor Bryson advised that consensus at a national level was not anticipated and regional consensus was not yet achieved. The GGC MCN advocate the use of ticagrelor for all patients with diagnosis of STEMI (requires regional agreement) and nSTEMI (can be progressed at GGC level). Regional support was expected at their meeting on 19 December 2012.

GPs raised the issue of stop dates for these medicines and emphasised the importance of good communication. Mrs Campbell advised this would follow same process as currently in place for clopidogrel but the concerns would be highlighted to the MCN to be considered in their implementation plans.

The Committee gave its support in principle to the MCNs suggestion and await the regional advice and identify an implementation date before the next ADTC meeting. The regional decision would be brought back to the next meeting for information.

NOTED

86. DATE OF NEXT MEETING

The next meeting of the Area Drugs and Therapeutics Committee would be held on Monday, 18 February 2013 at 2.00 p.m. in Board Room, J B Russell House, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12.