ADTC(M) 15/06
Minutes: 39 - 52

NHS GREATER GLASGOW AND CLYDE

Minutes of a Meeting of the Area Drugs and Therapeutics Committee held in the Boardroom, JB Russell House on Monday, 14 December 2015 at 2.00 p.m.

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P R E S E N T

Dr J Gravil (in the Chair)

Mrs A Campbell	Dr S Muir
Dr R Hardman	Dr A Taylor
Dr A Bowman	Mrs M Ryan
Dr A Crighton	Mr G Gorman
Mr R Foot	Mrs A Thompson
Mrs Y Semple	Mrs J Watt
Dr K McAllister	Mrs L Hillan
Ms A Muir	Dr C Harrow
Dr J Burns	Ms H Lindsay

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

Ms Y Gourlay.....	Lead Pharmacist Antimicrobial Management Team
Mr M Mitchell.....	Clinical Pharmacist
Miss L Young.....	Secretariat Officer

ACTION BY

39. 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.

She also reminded Members that they should make relevant declarations of interest in line with Board policy.

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.

40. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Prof G McKay, Dr A Seaton, Dr J Larkin, Dr G Forrest, Dr J Simpson, Dr J MacKenzie, Dr G MacPhee, Mr A Crawford, Dr A Petrie, Dr G Simpson,

The Chair welcomed Mr Michael Mitchell, Pharmacist, to the meeting who was in attendance to observe proceedings.

41. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 19 October 2015 were approved as a correct record subject to the following minor amendment:.

Page 1, Ms Helen Lindsay was in attendance. The file copy will be amended.

NOTED

42. MATTERS ARISING

The Chair contacted the Scottish Paediatric Epilepsy Network to suggest a national response to prescribing valproate in female children. No response has been received to date. The Chair will provide an update at the next meeting. **Chair**

The Chair informed the Committee that Dr MacPhee is due to retire at the end of December. The Chair thanked Dr MacPhee in his absence for his valued support and contribution to the Committee over a number of years.

43. FORMULARY AND NEW DRUGS SUB-COMMITTEE

Report on SMC Product Assessments

Dr Muir gave a brief resume of the SMC reviews and the Formulary and New Drugs Sub-Committee's recommendations.

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.

(1) insulin degludec/liraglutide 100 units/mL / 3.6mg/mL solution for injection pre-filled pen (Xultophy®)[1088/15] *[Novo Nordisk A/S]*

The Formulary decision on this medicine had been deferred from the last meeting. The above product was accepted by SMC however the insulin component was not recommended by SMC and not included on the Formulary. The MCN was approached to seek clarification on place in therapy. Clinicians have indicated that there is a place in practice for a small number of patients. The MCN are supportive of the product being available with clear reference to SMC restrictions and sequence of use (GLP-1 agonist added to basal insulin). The MCN suggested that initiation should be by a consultant and prospective audit would be helpful controls.

DECIDED:

The Committee discussed the pros and cons and agreed that the above product should be added to the Formulary, restricted to consultant initiation and in line with SMC advice.

The Committee agreed that further consideration of the role and purpose of the Formulary is required. The Chair requested that the Formulary and New Drugs Sub-Committee lead on this piece of work. **Dr Muir**

Major Changes

(a) ceritinib 150mg hard capsules (Zykadia®)[1097/15]*[Novartis Europharm Limited]**[Full Submission][Indication: Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib]***

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

The Committee noted that the SMC advice takes account the views from a PACE meeting and benefits from a Patient Access Scheme (PAS).

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use in accordance with regional protocol (in development).

(b) edoxaban tosilate15mg, 30mg and 60mg film-coated tablets (Lixiana®)[1090/15]*[Daiichi Sankyo UK Limited]****[Full Submission][Indication: Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults]***

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

The Committee noted the above 4th new agent for the treatment of DVT/PE. Apixaban is the preferred choice for this indication but this could be an alternative option, noted to be at lower cost.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary).

(c) edoxaban tosilate15mg, 30mg and 60mg film-coated tablets (Lixiana®)[1095/15]*[Daiichi Sankyo UK Limited]****[Full Submission][Indication: Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA)]***

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

The Committee noted the additional indication for the above product.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary).

(d) gefitinib 250mg film-coated tablets (Iressa®)[615/10]*[AstraZeneca UK Limited]****[Resubmission][Indication: Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK)].***

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

The Committee noted the above medicine benefits from a Patient Access Scheme (PAS).

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use.

(e) ivermectin, 10mg/g, cream (Soolantra®)[1104/15]*[Galderma (U.K) Ltd]****[Full Submission][Indication: Topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients]***

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

The Formulary and New Drugs Sub-Committee discussed the positioning of this medicine. The preferred topical option is metronidazole. Dr Taylor confirmed that metronidazole would be used 1st line in practice and the favoured brand in GGC (highlighted in ScriptSwitch) is lower cost than this new product. The above product would be seen as an alternative topical option. There is a concern that mild presentations may be treated with the above product but that is outwith SMC advice. The Committee noted the SMC restriction for moderate to severe rosacea. The Committee supported positioning this medicine after other topical preparations. Mrs Thompson suggested a blog could be posted to describe place in therapy.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to the treatment of moderate to severe rosacea where other topical treatments are unsuitable or not effective.

(f) naloxegol 12.mg and 25mg film-coated tablets (Moventig®)[1106/15]*[AstraZeneca UK Ltd]****[Full***

Submission][Indication: Treatment of opioid-induced constipation in adult patients who have had inadequate response to laxative(s)]

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

The Committee noted a potentially high number of patients may be suitable for this medicine, which could have an impact on the medicines expenditure. The Formulary and New Drugs Sub-Committee discussed defining the restriction further to patients on at least 30mg morphine equivalent in line with the clinical trial population. The Committee agreed not to impose a dose limit however agreed that it should be emphasised that at least two other laxatives at sufficient dose should be tried first.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to use in patients who have failed to respond to at least two classes of laxative.

(g) pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®)[1086/15]*[Merck Sharp and Dohme Ltd]****[Full Submission][Indication: Monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab]***

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

The SMC advice takes account the views of a PACE meeting and the benefits of a Patient Access Scheme (PAS). This has been sent to the West of Scotland Prescribing Advisory Sub-Group (WoSPASG) for development of protocol.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) pending protocol, restricted to specialist use in accordance with regional protocol (in development).

Minor Changes

(h) atazanavir/cobicistat 300mg/150mg film-coated tablets (Evotaz®)[1098/15] *[Bristol-Myers Squibb Pharmaceuticals Ltd]****[Abbreviated Submission][Indication: In combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir]***

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

This product may be useful in a particular group of patients however it is predicted to have a limited role in practice.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to use by HIV specialists.

(i) atomoxetine oral solution 4mg/mL (Strattera®)[1107/15]*[Eli Lilly and Company Limited]****[Abbreviated Submission][Indication: Treatment of attention-deficit/hyperactivity disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme (See SMC advice for full details of indication)].***

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

The Committee noted this liquid oral solution is more expensive than capsules however would offer a treatment option for patients unable to swallow capsules.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist initiation where patients unable to swallow capsules.

(j) bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) [806/12]*[Roche Products Limited]****[Resubmission][Indication: In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube or primary peritoneal cancer].***

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

The Committee noted that SMC advice takes account the views from a PACE meeting. This medicine will be restricted to use in patients with stage IV disease.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) pending protocol, restricted to specialist use in accordance with regional protocol.

(k) glatiramer acetate 40mg/mL solution for injection prefilled syringes (Copaxone®)[1108/15]*[Teva UK Limited]****[Abbreviated Submission][Indication: Treatment of relapsing forms of multiple sclerosis (MS)].***

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

This preparation supports less frequent administration, reducing from daily dosing to 3 times per week. The Committee noted the patent for glatiramer is due to expire in 2016.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use

(l) lenalidomide, 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg capsules (Revlimid®)[1096/15]*[Celgene Europe Limited]****[Full Submission][Indication: Treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant]***

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

Small patient numbers are predicted.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use in accordance with regional protocol (in development).

(m) tiotropium/olodaterol 2.5 microgram/ 2.5 microgram inhalation solution (Spiolto® Respimat®)[1099/15]*[Boehinger Ingelheim Ltd]****[Abbreviated Submission][Indication: Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)].***

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

This combination product was not considered as part of the recent inhaler review however the single agents are included on the Formulary.

The Committee agreed that this combination should be added to the Adult Formulary (Total Formulary).

Not recommended: the following medicines/indications were all not included in Formulary as not recommended by SMC

(n) anakinra (Kineret®) 100mg solution for injection in a pre-filled syringe [1116/15]*[Swedish Orphan Biovitrum Ltd]****[Non Submission][Indication: Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above (See SMC advice for full details of indication).]***

(o) co-careldopa (levodopa 20mg/mL and carbidopa monohydrate 5mg/mL) intestinal gel (Duodopa®)[316/06]*[Abbvie Ltd.]****[Resubmission][Indication: Treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.]***

(p) denosumab (Xgeva®) 120mg solution for injection [1119/15] *[Amgen Ltd]****[Non Submission][Indication: Adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity]***

(q) everolimus (Certican®) 0.25mg, 0.5mg and 0.75mg tablets [1117/15] [Novartis Pharmaceuticals UK Ltd]***[Non Submission][Indication:- Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a cardiac transplant- Prophylaxis of organ rejection in patients receiving a hepatic transplant]***

(r) pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®)[1087/15] *[Merck Sharp and Dohme Ltd]****[Full Submission][Indication: Monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously treated with ipilimumab.]***

(s) regorafenib (Stivarga®) 40mg film-coated tablets [1118/15]*[Bayer Plc]****[Non Submission][Indication: Adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies.]***

The following medicines were referred for consideration in the Paediatric Formulary and all were added in line with SMC advice

(t) raltegravir granules for oral suspension 100mg (Isentress®) [1102/15]*[Merck Sharp & Dohme Limited]****[Abbreviated Submission][Indication: In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents, children, toddlers and infants from the age of 4 weeks].***

(u) raltegravir chewable tablets 25mg, 100mg (Isentress®)[1113/15] *[Merck Sharp & Dohme Limited]****[Abbreviated Submission][Indication: In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in children from the age of 4 weeks to <2 years].***

(v) triamcinolone hexacetonide 20mg/mL suspension for injection [1103/15]*[Intrapharm Laboratories Limited]****[Abbreviated Submission][Indication: Juvenile idiopathic arthritis (JIA)].***

(w) efavirenz 50mg, 100mg and 200mg hard capsules and 600mg film-coated tablets (Sustiva®)[1125/15]*[Bristol Myers Squibb]****[Abbreviated Submission][Indication: Antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected children aged 3 months to 3 years and weighing at least 3.5kg].***

44. COMMUNICATIONS SUB-COMMITTEE

Six Monthly Report

The Committee noted the Communications Sub-Committee six monthly report to inform the ADTC of the work carried out by the Sub-Committee.

Mrs Thompson informed the Committee that lay involvement on the Sub-Committee was considered. Taking into account the aims of the Sub-Committee and the target audience for the Medicines Updates, the Sub-Committee were unable to clearly define a role for lay involvement at the moment. The Sub-Committee acknowledged lay involvement in other areas of NHSGGC therefore would be willing to review involvement in 12-18 months.

The report provided an update on website viewing figures from 1st June – 30th November 2015. An increase in page views corresponds with the circulation of email alerts. The report highlights the top and bottom pages viewed. The pages with the lowest number of views are those which were published before 2015. The report highlights the top 15 single articles viewed from 1st January 2015-30th November 2015, which includes governance concerns with high strength insulins.

Twitter and Facebook pages for Medicines Update will be launched late December 2015. These

channels will be used to highlight new materials on the website and to refer back to older articles which are still relevant. A further update will be provided in 6 months time.

The Committee acknowledged the 6 monthly report submitted and noted the developments.

45. ANTIMICROBIAL SUB-COMMITTEE

The Committee noted the 6 monthly report to inform the ADTC on work the Antimicrobial Utilisation Committee and NHS GGC Antimicrobial Management Team have carried out. Ms Gourlay highlighted in particular;

- An increase in use of antibiotics in Secondary Care. This is in line with other Health Boards in Scotland. Increasing resistance to antibiotics is a particular concern. Steps are being taken to reduce antibiotic use within GG&C.
- Meropenem use in GG&C is the highest in Scotland. This remains a main focus for the Antimicrobial Sub-Committee and promotion of Aztreonam and Temocillin continues.
- The number of patients receiving IV is increasing. Better promotion of the IV to oral switch policy is taking place and a meeting has been scheduled with a Lead Nurse to discuss further.
- Antibiotic use in Primary Care is decreasing. The "4C" antibiotics are being targeted in particular.
- An administration and monitoring form for Vancomycin prescribing is under review. Following feedback on the form, the Antimicrobial Utilisation Committee is piloting an updated version in the RAH and GRI. A pilot will be carried out in the Orthopaedics department in January.
- GG&C is continuing to meet CDI targets, with 30.2 cases, which is below the Scottish mean target of 32. The national mean target for SAB is 24, with GG&C above that target at the moment, sitting at 33 cases.

Ms Gourlay informed the Committee that a letter of advice has been received from the manufacturers of micafungin, Astellas, in regards to a new checklist which highlights toxicity. The Committee discussed the letter and agreed that further information was required. MI will be asked to search if there is any new evidence regarding toxicity **Ms Gourlay**

The Committee discussed the prescribing of antibiotics and how to highlight the importance of reducing antibiotic use. Mr Foot suggested a Medicines Information article to highlight the general principles. The Committee agreed that regular communication from the Antimicrobial Utilisation Committee would be helpful and key prescribing messages could be circulated.

The Committee acknowledged the 6 monthly report submitted and noted the developments.

46. POLYPHARMACY SUB-COMMITTEE

The Committee noted the six monthly Polypharmacy Sub-Committee six month report submitted for information. The vast amount of ongoing work was acknowledged by the Committee.

Mrs Semple reported that medicines reconciliation and interface issues were discussed at the last medicines utilisation sub-committee meeting. It was suggested that this could be a topic for a future Medicines Update Extra bulletin; to highlight feedback and update on the work being carried out across NHS GGC.

47. OTHER ADTC SUB-COMMITTEES

(a) Medicines Utilisation Sub-Committee

No update.

(b) Prescribing Interface Sub-Committee

Prescribing Interface Sub-Committee

Dr Hardman circulated a proposal to update the Outpatient Prescribing Medication protocol (2012) in order to refine the process and promote consistent practice across NHS GG&C when a patient is seen by a specialist service or clinic and the reviewing clinician recommends the initiation of a new medicine or a change to existing therapy.

Dr Hardman highlighted some common issues, for example some specialist services not being hospital based, eg. Mental Health. Also HBP Prescription Pads may only be available to some specialist clinics. Dr Hardman informed the Committee that work is being carried out to improve paper based systems.

The Committee discussed the paper submitted in detail and agreed that an improvement in communication is required to ensure the policy is applied consistently across NHS GG&C. Mrs Watt suggested communicating with Chiefs of Medicine and the Non-Medical Prescribing Lead to disseminate the policy and promote a common understanding about the supply of medications for outpatients. A blog could also be posted on the website to highlight the policy.

The Committee approved the policy.

48. BNF ERRORS

A number of errors have been identified in the latest British National Formulary (BNF 70) and British National Formulary for Children (BNFC 2015-2016) since publication. The Committee noted that both online and printed versions of the BNF publication have been re-designed with the first new look printed issue published in September 2015. Since then 10 errors have been identified. A joint statement was issued from UKMi, NPPG and BNF and the correction documents were attached. The electronic versions of the BNF and BNFC and being updated and corrected, therefore the digital version remains the most accurate and up to date version.

Mrs Semple informed the Committee that a risk awareness notice was prepared and disseminated across the Board. This was circulated by urgent email to the appropriate people and departments. In Acute care stickers will be placed on the front covers of the printed copies. These will include a table of the drugs affected and their corresponding page numbers. This will be facilitated by Pharmacy at each Hospital site. A further notice will be issued in Primary Care and notes will be added to ScriptSwitch to highlight the errors to prescribers. An email will be sent to Community Pharmacy and an article will be included in the CP bulletin.

The Committee noted that in time, printed copies will be phased out with a move towards electronic only access. Prescribers are encouraged to use the electronic version to ensure they are accessing the most up to date information.

The Committee noted the paper submitted.

49. RCAG PRESCRIBING ADVISORY SUBGROUP: GUIDELINE FOR THE PREVENTION OF SKELETAL RELATED EVENTS IN ADULTS WITH CANCER

The Committee noted the report submitted with new recommendations on the prevention of skeletal related events in adults with cancer. These recommendations supersede SMC advice. The availability of generic zoledronic acid has reduced the cost significantly, making it a cost effective treatment option. A review of the regional guidelines was initiated which addressed the impact of the generic price on the economic case for licensed treatments. A new guideline was then produced merging the existing Bisphosphonate Guideline and denosumab protocol. This guideline was endorsed by the RCAG PASG. The key recommendations include restricting denosumab to when zoledronic acid is not appropriate and widen the guideline to include access to zoledronic acid in other solid tumour types. The Committee noted that service implications have been discussed and will be managed

locally.

The Committee supported the recommendations submitted. Mr Foot will update the Formulary and communicate the decision with the other formulary decisions. **Mr Foot**

50. PRESCRIBING MANAGEMENT GROUP REPORT

The key points and actions from the Prescribing Management Group which took place on 10th November 2015 were circulated to the Committee.

The paper highlights the prescribing expenditure from April to September 2015. Mrs Campbell highlighted that the budget planning process for 2016/17 is underway. A report on the background and current activity of new medicines for HCV treatment was reviewed. Planning for HCV treatments in 2016/17 was also discussed.

The Committee noted the paper submitted by the Prescribing Management Group.

51. ANY OTHER BUSINESS

Changes to SMC System for Approving New Medicines

The Health and Sport Committee has sought written evidence on the effectiveness of the changes made to the SMC system for approving new medicines. There are specific questions for which a Board response is required. The questions will be circulated to the Chair for input. A response will be submitted by the deadline date of 20th January 2016.

Near Patient Testing LES Processes

Dr Hardman informed the Committee that Shared Care Protocols with primary care monitoring requirements are being submitted to the Prescribing Interface Committee for review without going through the process of inclusion in the near patient testing enhanced service. Dr Hardman highlighted that the SCP checklist should be used prior to submitting a Shared Care Protocol. The importance of considering inclusion of the medicine in the LES if monitoring requirements are significant for primary care is a rate-limiting step in the review and approval process, and can delay progress. Dr Hardman highlighted that there is no easily visible process for common medicines to be added on. Mr Foot suggested that the 5 questions/principles could be better highlighted in the guidance.
It was agreed that this issue would be included in the ADTC report to PMG (on behalf of PIC), requesting clarity around the processes and funding arrangements for inclusion of medicines in the NPT LES. Following discussion, the Committee are supportive of the Prescribing Interface Sub-Committee having a facilitative role.

52. DATE OF NEXT MEETING

Monday, 22 February 2016 – Boardroom, JB Russell House, Gartnavel Royal Hospital