ADTC(M) 15/03
Minutes: 26 - 38

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, 8 June 2015 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Mrs A Campbell	Mrs L Hillan
Dr G Forrest	Dr S Muir
Dr R Hardman	Dr A Taylor
Mrs A Thompson	Dr A Seaton
Dr A Petrie	Mrs M Ryan
Dr K McAllister	Dr G Simpson
Dr A Bowman	Mrs J Watt
Dr A Crighton	Dr G MacPhee
Mr R Foot	

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

Dr Campbell Tait.....Consultant Haematologist
Dr John Farley.....GP
Dr Nigel Pexton.....GP
Miss L Young.....Secretariat Officer

ACTION BY

26. 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.

27. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr J MacKenzie, Dr J Burns, Dr J Larkin, Dr J Simpson, Prof G McKay and Dr C Harrow.

The Chair welcomed Dr Campbell Tait to the meeting who was in attendance for minute 29a. The Chair also welcomed Dr John Farley and Dr Nigel Pexton who were in attendance for minute 29b.

28. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 20 April 2015 were approved as a correct record.

NOTED

29. MATTERS ARISING

(a) apixaban in DVT/PE treatment and prophylaxis

Dr Campbell Tait attended the meeting to provide a summary of the key points relating to safe introduction of apixaban for treatment and prophylaxis of DVT/PE. Dr Tait consulted the Thrombosis Committee to seek their views on selecting a preferred choice NOAC. Dr Tait received sixteen replies which unanimously supported the view of a preferred drug. Half of the responses were of no strong opinion between rivaroxaban and apixaban as a preferred option, one member had a preference towards rivaroxaban and seven members favoured apixaban due to better safety data. SMC advice for apixaban supported use in both short and long term but rivaroxaban was not recommended where indefinite anticoagulation was indicated. Apixaban would therefore need to be the preferred agent if a single agent was selected for both short and long term use. Draft clinical advice and a sample GP letter for apixaban were included in the papers.

Patients will receive a pack of 56 tablets from the hospital which will cover the first three weeks of treatment including the first dose change. If a patient is to receive long term treatment there will be a further dose reduction required at 6 months, to be managed by the patient's GP.

The Committee noted no cost difference. Dr Taylor raised a point in relation to the clinical advice and it was confirmed that Acute services would have responsibility to provide patient education The paperwork provided supported implementation. A discussion took place in regards to guidance and a FAQ document. Mrs Watt informed the Committee that the Medicines Information Team are reviewing the structure of the current FAQ document, developed for stroke prevention in AF indication and reviewing overlapping information. Mrs Watt will provide an update to the Committee when this has been fully reviewed.

The Committee agreed to add apixaban to preferred list of the Total Formulary (Adult Formulary) for the treatment and prevention of DVT/PE however agreed that patient or clinician still has the option to opt for an alternative if apixaban was not suitable.

(b) Respiratory Inhaler Review

(1) Review Recommendations

Dr John Farley and Dr Nigel Pexton attended the meeting to answer questions in relation to the recommendations following the Respiratory Section Formulary Review.

Draft Primary and Secondary Care Inhaler Device Guides for Asthma and COPD were included in the papers. The aim of the device guide is to bring flexibility to treatment and dosing by clarifying step up/down rules, deal with new device dexterity issues, long term patient safety and to highlight cost, shelf lives etc. Mr Foot clarified that the proposed changes would not impact on GP compliance with LES and highlighted that there is no intention to switch patient's devices if they were clinically stable and managing well. The Committee provided comments on the device guides and noted in particular the asthma table appears to be clear and concise. Dr Farley will report the Committees comments and feedback to the MCN subgroup developing the guidance. The Committee noted that the device guide will be submitted to Medicines Utilisation Sub-Committee for review in due course.

The Committee approved the Respiratory Section Formulary Review Recommendations.

(2) Branded Inhaler Devices

Mr Foot presented a paper to the Committee to support the recommendation from the Respiratory Review to prescribe inhaler devices by brand name. The Committee discussed the recommendations in the paper and agreed to move to branded prescribing with the exception of Salbutamol MDI. The Committee noted that this would be implemented alongside the section review changes

(c) biosimilar infliximab

Mrs Campbell summarised previous discussions regarding selection of a preferred biosimilar infliximab product as agreed by ADTC in April 2015. SMC accepted two biosimilar infliximab products. Mrs Campbell reported that since the investigation all three companies, the reference and two biosimilars, have been asked to review their price. The companies have a two week deadline in which to submit their new prices. To avoid further delay Mrs Campbell proposed that the Acute Services Prescribing Management Group make the final decision at its meeting late June, when the outcome of national procurement activity would be available. The Committee agreed to this proposal.

30. 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.

No declarations of interest were made.

Major Changes

(a) *apremilast 10mg, 20mg, 30mg tablets (Otezla®)[1053/15] *[Celgene Ltd]* ***[Full Submission] [Indication: Alone or in combination with disease modifying anti-rheumatic drugs (DMARDs), for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy]***

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

Dr Muir reported that this new line of therapy is seen as good option if escalating treatment. Description of the place in therapy for this new treatment within a clinical guideline would be helpful.

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

(b) *apremilast 10mg, 20mg and 30mg film-coated tablets (Otezla®)[1052/15]*[Celgene Ltd]****[Full Submission][Indication: Treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA)]***

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

A treatment ladder has been described by local specialists: inclusion of this medicine within a clinical guideline which includes start/stop rules would be helpful.

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

(c) ofatumumab 100mg and 1,000mg concentrate for solution for infusion (Arzerra®)[1037/15]*[Novartis]****[Full Submission] [Indication: In combination with chlorambucil or bendamustine for the treatment of patients with chronic lymphocytic leukaemia (CLL) who have not received prior therapy and who are not eligible for fludarabine-based therapy]***

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

The Committee noted the advice took account of the views of a PACE meeting and the benefits of a Patient Access Scheme (PAS). Dr Muir reported that this product would be of particular value to older patients who are less fit and have co-morbidities and whose treatment options are limited. An increase in symptom free period was noted.

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

(d) *ombitasvir 12.5mg / paritaprevir 75mg / ritonavir 50mg (Viekirax®) film-coated tablet and dasabuvir 250mg (Exviera®) film-coated tablet [1051/15]*[Abbvie]**[Full Submission] [Indication: - Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with dasabuvir (Exviera®) with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults - Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with ribavirin for the treatment of genotype 4 CHC in adults]***

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

Dr Muir reported that the dosing for this 5th new agent for Hepatitis C is twice daily. More drug interactions are noted however it would currently be preferred option on basis of cost; ongoing national procurement activity in this area to achieve best prices may change preferences.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use in accordance with local protocol which will be more restrictive than SMC advice, and in line with previous agents.

(e) *secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®)[1054/15]*[Novartis Pharmaceuticals]**[Full Submission] [Indication: Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy]***

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

The Committee noted the above product for patients who have failed to respond to standard systemic therapies.

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

(f) vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®)[1045/15]*[Takeda]**[Full Submission] [Indication: Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFC) antagonist]***

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

The Committee noted that a regional guideline is in development which will include criteria for start/stop rules. The specialists welcomed this advice along with the recent NICE guidance which accepted the use of biologics in ulcerative colitis.

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

Minor changes

(g) budesonide, 3mg, gastro-resistant capsules (Budenofalk®)[1043/15]*[Dr Faulk Pharma UK Ltd]**[Full Submission] [Indication: Autoimmune hepatitis]***

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

Dr Muir informed the Committee that this is frequently selected in preference to standard corticosteroids for various clinical reasons, including fewer side effects for patients and reduced attendance for monitoring.

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

(h) dexamethasone 700 micrograms intravitreal implant in applicator (Ozurdex®)[1046/15]*[Allergan]****[Full Submission] [Indication: Treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy]***

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

The Committee noted specialists would like to have this available. It is most likely to be used in patients with an artificial lens as intravitreal steroids tend to lead to cataract formation. Patients with their own lens can still be considered for treatment in cases where other treatment options as not suitable.

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

(i) idelalisib, 100mg and 150mg film-coated tablets (Zydelig®)[1039/15]*[Gilead Sciences Ltd]****[Full Submission][Indication: Monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment]***

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

Dr Muir reported that studies show this 3rd line therapy shows a quick response rate and can prolong life and offer a better quality of life. The SMC advice takes account of the benefits of a Patient Access Scheme (PAS) and the views of a PACE meeting.

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

(j) *levonorgestrel (Levosert®) 20 micrograms/24 hours intrauterine delivery system[1058/15]*[Actavis UK Ltd]* ***[Abbreviated Submission] [Indication: Contraception. Heavy menstrual bleeding]***

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

The Committee noted that gynaecologists would like to have this product available. A discussion took place around relative costs as the licence currently only supports the use of this product over a 3 year period whereas Mirena can be left in place for up to 5 years. Mr Foot reported that an ongoing study could provide evidence to extend the licence.

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

(k) linagliptin 5mg tablet (Trajenta®)[850/13]*[Boehringer-Ingelheim]* ***[ReSubmission]][Indication: the treatment of type 2 diabetes mellitus to improve glycaemic control in adults in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control]***

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

Low use of this particular combination of treatments is predicted by clinicians. Linagliptin was recently selected as a preferred list DPP-IV inhibitor.

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

(l) *linagliptin 2.5mg plus metformin 850mg and linagliptin 2.5mg plus metformin 1000mg film-coated tablets (Jentadueto®)[1057/15]*[Boehringer-Ingelheim]*[**Abbreviated Submission] [Indication: for the treatment of adult patients with type 2 diabetes mellitus in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control when insulin and metformin alone do not provide adequate glycaemic control.]***

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

The Committee noted the minor extension to the licence of the above product to use in combination with insulin. As with other combination anti-diabetic agents in GGC use is to be restricted to where there are compliance issues which is more restrictive than SMC advice.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to where there are compliance issues with taking separate agents.

(m) liraglutide 6mg/mL prefilled pen for injection (3mL) (Victoza®)[1044/15]*[Novo Nordisk]*[**Full Submission] [Indication: For the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with basal insulin when this, together with diet and exercise, does not provide adequate glycaemic control.]***

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

The Committee noted the new indication for this product for use alongside insulin: specialists indicate there has been some use in this positioning.

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

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

(n) cangrelor (Kengraxel®)[1070/15]*[The Medicines Company]* ***[Non Submission] [Indication: Co-administered with acetylsalicylic acid for the reduction of thrombotic cardiovascular events in adult patients with coronary artery disease undergoing percutaneous coronary intervention who have not received an oral P2Y12 inhibitor prior to the PCI procedure and in whom oral therapy with P2Y12 inhibitors is not feasible or desirable.]***

(o) collagenase clostridium histolyticum (Xiapex®)[1059/15]*[Swedish Orphan Biovitrum Ltd]* ***[Non Submission] [Indication: treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy]***

(p) insulin degludec (Tresiba®)[1060/15]*[Novo Nordisk Limited]* ***[Non Submission] [Indication: Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year.]***

(q) paclitaxel albumin (Abraxane®)[1071/15]*[Celgene Ltd]* ***[Non Submission] [Indication: in combination with carboplatin for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.]***

Other Formulary Decisions

(r) Erythropoiesis Stimulating Agents

NICE MTA advice states that ESA's are recommended as options to treat anaemia in people with cancer who are having chemotherapy. Dr Muir reported that clinician's view these agents would not be an option frequently used. The Committee noted that regional guidance will not be produced. This product will continue to be managed via non-Formulary processes.

The Committee agreed that these products should not be added to the Formulary as there is no support from clinicians.

(s) adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (Humira®)[1050/15]*[AbbVie Ltd]* ***[Abbreviated Submission]***

This medicine has been passed to Paediatric D&T to consider inclusion in the GGC Paediatric Formulary.

(t) entecavir,0.5 and 1mg film-coated tablets and 0.05mg/mL oral solution (Baraclude®)[1049/15]*[Bristol Myers Squibb Pharmaceuticals Ltd]* ***[Abbreviated Submission]***

This medicine has been passed to Paediatric D&T to consider inclusion in the GGC Paediatric Formulary.

(2) Aprepitant

Mrs Campbell submitted a paper to the Committee proposing a change to the wording in the Formulary entry for aprepitant. The licence specifically refers to highly emetogenic cisplatin- based chemotherapy however there are regimens in use which are assessed to be highly emetogenic but not cisplatin based. In practice aprepitant has been used in patients who have had an inadequate response to standard anti-emetics during first cycle chemo or if 1st line treatments may not be suitable: this is essentially off-label use. In the past these requests have been approved through the IPTR route, this is usually retrospectively.

Mrs Campbell highlighted that the CIVN guideline includes use of aprepitant in this particular group of patients. This guideline was endorsed by the Regional Prescribing Advisory Group. The Committee was asked to acknowledge the CIVN guideline and amend the wording in the Formulary. Mrs Campbell asked the Committee to consider amending the wording to "use in accordance with regional CIVN guideline". The wording that use in moderately emetogenic chemo is excluded should be retained (in line with SMC advice). Mrs Campbell reported that there will be no financial implications and this would reduce the need for IPTR's.

The Committee agreed to amend the Formulary entry for aprepitant.

31. 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 articles are now posted as blogs of shorter, individual articles. Email alerts are sent on a fortnightly basis and Mrs Thompson reported that this format appears to be working well. The team discussed various options of presenting the bulletins and agreed to present articles through headings that link to the document. Mrs Thompson presented website access statistics which show an increase in page views on the day the alert email is circulated. The top 20 articles viewed from 01/01/2015 to 21/05/15 were highlighted in the report. A regular statistical review will be carried out to evaluate topics that have low levels of readership and the information used to inform developments.

Mrs Thompson informed the Committee that work is being carried out to set up social media accounts following approval by the Board. The team is considering setting up Twitter, Facebook and possibly Linkedin accounts.

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

32. 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. Dr Seaton highlighted in particular;

- An increase in prescribing of Aztreonam, which is driven by guidelines aiming to preserve effectiveness of carbapenems. There is support from across Scotland however stock is in short supply and we may see increasing use of temocillin as an alternative which has cost implications.
- A large increase in prescribing of Levofloxacin
- Progress is being made against the national prescribing indicator targets in Primary and Secondary care.
- Audit data show that there is an improvement in prescribing of gentamicin, Datix reports for this medicine have reduced dramatically although some caution is advised in interpreting this observation.
- The Health Board is sitting below the national average for CDI and SAB

Dr Seaton highlighted figures on antimicrobial resistance. Dr Seaton informed the Committee that an audit has been carried out on ScRAP. He highlighted that 31% of practices have completed the audit and it is expected that more than 50% will have this delivered in the next round.

Dr Seaton informed the Committee that HAI Standards were issued in February 2015.

The Antimicrobial Utilisation Sub-Committee minutes of a meeting held on 29th April 2015 were circulated for information.

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

33. POLYPHARMACY SUB-COMMITTEE

Dr MacPhee informed the Committee that work is ongoing to inform patients on the purposes and benefits of polypharmacy reviews including development of patient information. The national polypharmacy guidance has been published. Dr MacPhee informed the Committee that a six monthly report and the 2014/15 LES report will be reported at the next meeting.

34. OTHER ADTC SUB-COMMITTEES

Medicines Utilisation Sub-Committee

Dr Simpson informed the Committee that following the resignation of the current vice chair, Mrs Janice Watt, the Sub-Committee is seeking to appoint a replacement. This process will be carried out within the Sub-Committee.

Safer Use of Medicines Sub-Committee
No specific items to report

Therapeutics Sub-Committee
No specific items to report

NOTED

35. EARLY ACCESS TO MEDICINES SCHEME

Mrs Watt provided the Committee with information on the Early Access to Medicines Scheme (EAMS) which is a formal programme that offers patients access to medicines that are not yet authorised. The Medicines and Healthcare products Regulatory Agency (MHRA) will assess the risks/benefits of the medicine and will offer an opinion based on the data available.

Promising Innovative Medicine (PIM) status will provide an early marker that a product may be available for EAMS based on early clinical data. Mrs Watt informed the Committee that there have been 7 medicines offered PIM status to date.

A national approach is supported and operational guidance is awaited from Scottish Government: issues that need considered include:

- management of patients commenced on a medicine via EAMS, post-licensing
- patient information for EAMS medicines

The Committee highlighted that the medicine identified to date were primarily cancer medicines but there was also one medicine for the treatment of heart failure.

The Committee noted the above update provided for information.

36. ABPI COLLATION OF LOCAL FORMULARY DECISIONS

Mr Foot informed the Committee that the Head of PPSU received a letter from ABPI which shared on collated information from NHS Boards public websites regarding implementation of SMC accepted medicines including whether this information was in the public domain within the 90 day target timescale. Mr Foot reported that the spreadsheet was largely accurate but some variances had been noted. There were seven entries where ABPI indicated there was no information available: Mr Foot reported that four medicines were included in the Adult Formulary, two within the Paediatric Formulary within the timescale and one medicine had not been added to the Formulary but this decision and rationale had been communicated within the target timescale.

Mr Foot informed the Committee that Prof Norman Lannigan has formally responded following a meeting with ABPI representatives therefore no further action is required.

37. PRESCRIBING MANAGEMENT GROUP REPORT

The key points and actions from the Prescribing Management Group which took place on 21st April 2015 were circulated to the Committee.

A paper had been discussed regarding the proposal for new HCV treatments for 2015/16. Mrs Campbell highlighted that the MCN have developed clinical guidance to support the national strategy which indicates that patients with the greatest clinical need should be treated first. In addition a series of control measures have been put in place to support delivery of the agreed programme of activity within budget.

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

38. ANY OTHER BUSINESS

Dr Taylor highlighted that on occasions GPs can be asked to prescribe a medicine with which they may be unfamiliar. The Committee acknowledged that improvements in communication of this information would be helpful.

39. DATE OF NEXT MEETING

Monday 17 August 2015, 2:00pm, Board Room, JB Russell House, Gartnavel Royal Hospital