ADTC(M) 16/05
Minutes: 55 - 72

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, 10 October 2016 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Mrs J Watt	Dr S Muir
Dr G Forrest	Dr K O'Neill
Mrs A Campbell	Ms H Lindsay
Mr R Foot	Mrs L Hillan
Mrs Y Semple	Mrs M Ryan
Dr R Hardman	Mr A Crighton
Mr G Gorman	Mr N Lannigan
Dr A Seaton	

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

Ms Megan Trearty.....District Nurse
Miss L Young.....Secretariat Officer

ACTION BY

55. 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.

56. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr J Simpson, Dr A Bowman, Dr K McAllister, Ms A Muir, Dr J Burns, Mrs A Thompson and Prof G McKay.

The Chair welcomed Ms Megan Trearty, District Nurse, who was in attendance to observe proceedings.

57. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 22 August 2016 were approved as a correct record.

NOTED

58. MATTERS ARISING

Item 43 - Supply of Medicines Following Specialist Review or Clinic Appointments

Dr Taylor sought clarification on what changes the GP Out of Hours service had requested. Mrs Hillan informed members that GP OOH requested that it should be clear they should only be contacted if it is a clinical emergency. The final version of the guidance will be shared when available.

Item 53 – Prescribing Management Group Primary Care: Clinical Guidelines Disclaimer Statement

Dr Taylor asked for clarity around the very complex "gold standard" guidelines for care of patients in Care Homes and the inclusion of the guideline disclaimer statement. This was discussed at the last ADTC. Members noted that the statement that had been included was out of date. The updated statement states that documentation of significant deviation is good practice rather than stating this is mandatory.

59. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(1) **Report on SMC Product Assessments**

Dr Forrest 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.

Accepted but not added

(a) paliperidone palmitate 175mg, 263mg, 350mg, 525mg prolonged release suspension for injection (Trevicta®) [1181/16] *[Janssen-Cilag Ltd]**[Abbreviated Submission] [Indication: paliperidone palmitate (Trevicta®), a three-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on one-monthly paliperidone palmitate injectable product]***

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

The Committee noted that the Mental Health D&T asked that this medicine is not added to the Formulary at this stage. They advised that the place in therapy of the three monthly injection was unclear with respect to management of adverse effects and/or relapses..

The Committee agreed that this medicine should not be added to the Adult Formulary.

This medicine is not routinely available as local clinicians do not support at this time.

Major Changes

(b) dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®) [1170/16] *[Bristol-Myers Squibb Pharmaceuticals]**[Full Submission][Indication: for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase]***

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

The Committee noted this has been sent to 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) restricted to specialist use in accordance with regional protocol (in development).

This medicine is available in line with regional guidance.

(c) dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®) [371/07] *[Bristol-Myers Squibb Pharmaceuticals Ltd]* ***[Resubmission][Indication: for the treatment of adult patients with chronic, accelerated or blast phase chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate]***

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

The Committee noted that this replaces a NICE MTA which previously superseded initial SMC advice. 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 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) restricted to specialist use in accordance with regional protocol (in development).

This medicine is available in line with regional guidance.

(d) idarucizumab 2.5g/50mL solution for injection/infusion (Praxbind®) [1178/16] *[Boehringer Ingelheim Ltd]****[Full Submission][Indication: idarucizumab is a specific reversal agent for dabigatran and is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding]***

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

This medicine is available in A&E Departments available for immediate access. The use of this medicine will be monitored via audit. Haematologists and the Thrombosis Committee favour removal of the haematology approval step to reduce the risk of delay in use. The Committee discussed whether the restriction of specialist use should remain. Following discussion members agreed for this medicine to remain restricted to specialist use to ensure use remains within acute hospital.

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

This medicine is available in line with national guidance.

(e) lenvatinib 4mg and 10mg hard capsules (Lenvima®) [1179/16] *[Eisai Ltd]****[Full Submission] [Indication: treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI)]***

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

The Committee noted that small patient numbers are predicted. This has been sent to 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) restricted to specialist use in accordance with regional protocol (in development).

This medicine is available in line with regional guidance.

(f) trametinib 0.5mg and 2mg film-coated tablets (Mekinist®) [1161/16] *[Novartis Pharmaceuticals UK Ltd]* ***[Full Submission][Indication: in combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation]***

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

The Committee noted this has been sent to 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) restricted to specialist use in accordance with regional protocol (in development).

This medicine is available in line with regional guidance.

Minor Changes

(g) aflibercept 40mg/mL solution for injection (Eylea®) [1186/16] *[Bayer plc]****[Full Submission] [Indication: for adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV)]***

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

The Committee noted this new indication. This licence extension offers an alternative to ranibizumab.

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

This medicine is available in line with national guidance.

(h) budesonide 9mg prolonged release tablet (Cortiment®) [1093/15] *[Ferring Pharmaceuticals Ltd]* ***[Resubmission] [Indication: in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient]***

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

The Committee noted this licensed option will replace off-licence use in this indication. Members noted the restriction will be amended to include steroids as rectal budesonide is not on the Formulary.

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

This medicine is available in line with national guidance.

(i) calcipotriol 50 micrograms/g and betamethasone 0.5g/g cutaneous foam (Enstilar®) [1182/16] *[Leo Pharma]* ***[Abbreviated Submission] [Indication: topical treatment of psoriasis vulgaris in adults]***

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

This product offers an alternative formulation. The Committee noted that the gel formulation has the lowest acquisition cost therefore may remain the preferred treatment option due to cost effectiveness.

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

This medicine is available in line with national guidance.

(j) fosfomycin trometamol granules for oral solution (equivalent to 3g fosfomycin) (Monuril®) [1163/16] *[Profile Pharma Ltd]* ***[Abbreviated Submission] [Indication: Treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females. Prophylaxis in diagnostic and surgical transurethral procedures]***

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

This licensed product will displace unlicensed use. Guidelines are in place to support use. Dr Seaton informed members that an educational article will be created for the blog.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to use on the advice of microbiologists or infectious disease physicians.

This medicine is available in line with national guidance.

(k) nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) [1180/16] *[Bristol-Myers Squibb Pharmaceutical Limited]* ***[Full Submission] [Indication: treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults]***

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

The Committee noted the two year clinical stopping rule. There is no cost economics beyond the two years. Members noted that the stopping rule may create local difficulties. This has been sent to 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) restricted to specialist use in accordance with regional protocol (in development).

This medicine is available in line with regional guidance.

(l) progesterone 100mg vaginal tablets (Lutigest®) [1185/16] *[Ferring Pharmaceuticals Ltd]* ***[Full Submission] [Indication: Luteal support as part of an assisted reproductive technology (ART) treatment program for infertile women]***

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

This product offers an alternative formulation at a similar cost.

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

This medicine is available in line with national guidance.

(m) rilpivirine/emtricitabine/tenofovir alafenamide 200mg/25mg/25mg film-coated tablets (Odefsey®) [1189/16] *[Gilead Sciences Ltd]* ***[Abbreviated Submission] [Indication: treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg), infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load HIV-1 RNA ≤100,000 copies/mL]***

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

The Committee noted this new combination for age 12 years and over which appears to have fewer side effects. The Committee noted that generic tenofovir is expected soon. Discussions are taking place within the specialist HIV team.

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

This medicine is available in line with national guidance.

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

(n) bevacizumab (Avastin®) 25 mg/ml concentrate for solution for infusion [1190/16] *[Roche Products Ltd]*
(o) budesonide/formoterol 200 micrograms/6 Inhalation powder and 400 micrograms/12 Inhalation powder (Symbicort Turbohaler®) budesonide/formoterol 200 micrograms/6 micrograms per actuation, pressurised inhalation, suspension (Symbicort®) [1198/16] *[AstraZeneca UK Limited]*
(p) carfilzomib 60mg powder for solution for infusion (Kyprolis®) [1171/16]*[Amgen Ltd]*
(q) cobimetinib (Cotellic®) 20mg film-coated tablets [1191/16] *[Roche Products Ltd]*
(r) golimumab (Simponi®) 50 mg solution for injection [1199/16] *[Merck Sharp & Dohme Limited]*
(s) iron (III) isomaltoside 1000 (contains 50mg iron per mL) (Diafer®), solution for injection [1177/16] *[Pharmacosmos UK Limited]*
(t) liraglutide (Victoza®) 6 mg/ml solution for injection in pre-filled pen [1192/16] *[Novo Nordisk Limited]*
(u) perampanel (Fycompa®) 2mg, 4mg, 6mg, 8mg, 10mg and 12mg film-coated tablets [1200/16] *[Eisai Ltd]*
(v) tocilizumab (RoActemra®) 162mg Solution for Injection in Pre-Filled Syringe [1201/16] *[Roche Products Ltd]*

60. FORMULARY APPEAL: QUETIAPINE MODIFIED RELEASE (MR) TABLETS

Mr Foot presented the appeal received by the Primary Care Prescribing Management Group to remove Quetiapine MR tablets from the NHSGGC Adult Formulary (Total Formulary). The MR (once daily) and IR (twice daily) tablets demonstrate the same therapeutics effects however the MR preparations have a considerably higher acquisition cost. Mr Foot reported that removal of the MR preparation could result in an estimated saving of up to £765,000 per annum. The change in status is supported by the Mental Health Drugs & Therapeutics Committee, Mental Health Interface Group and the Prescribing Management Group Mental Health.

DECIDED:

Following detailed discussion the Committee support the removal of Quetiapine MR (once daily) tablets from the NHSGGC Formulary.

61. FORMULARY APPEAL: INDACATEROL MALEATE/ GLYCOPYRRONIUM BROMIDE (ULTIBRO®)

Mr Foot presented the Formulary appeal to add indacaterol maleate/ glycopyrronium bromide (ultibro®) to the Adult Formulary (Total Formulary). This product was removed during the Formulary Review in 2015. At that time the decision was made that formoterol should be the 1st choice LABA. At that time it was felt that there was a range of other options available. Mr Foot reported that a recent FLAME study was carried out with the results suggesting that there is a strong role for this agent for reducing exacerbation rates in COPD. The manufacturer has addressed the device concerns previously highlighted.

Mr Foot reported that the Prescribing Group and the Respiratory MCN are supportive of adding this option to the GGC Adult Formulary (Total Formulary). This will be added to the Total Formulary and not the Preferred List as existing pathways are retained.

DECIDED:

Following discussion the Committee agreed to add this product to the Adult Formulary (Total Formulary).

62. FORMULARY STRUCTURE REVIEW

The Formulary event on 20th September 2016 was successful, with good representation from across the sectors and good participation and support within the groups. Feedback from delegates highlighted that the Preferred List is viewed as a valued tool. Key themes from the workshops will be collated and a paper to discuss next steps will be prepared. Members noted that national Formulary developments may impact locally.

63. SAFER USE OF MEDICINE SUB-COMMITTEE

Six Monthly Report

Report to be provided at the next meeting.

64. THERAPEUTICS SUB-COMMITTEE

Six Monthly Report

The Committee noted the Therapeutics Sub-Committee 6 monthly report to inform the ADTC of the work of the Sub-Committee.

Mrs Ryan highlighted the work plans that are in place to support prescribing quality in a range of non drug therapeutic areas.

Wound Care Formulary/ Wound Management

Compliance has improved. The Formulary report indicated that compliance was now at 64%.

HTA – Antimicrobial Wound Dressings – Implementation Plan

A National 'Task and Finish' group has formed and an implementation plan in place to drive forward implementation of the HTA recommendations.

Vascular Update

Work is ongoing in the way compression bandages are prescribed.

Podiatry

A new competency framework has been published. This will be discussed at the next Podiatry Forum and will go to the Therapeutics Committee in November.

Stoma Care Formulary/Guidance

A small sub group has formed to discuss Bowel Management Service and prescribing due to the increased use of bowel devices.

Urology Products Formulary including Urosheaths

A Urology Steering Group for NHSGGC will be formed to look at improving Formulary compliance.

Oral Nutrition Sub Group

Changes are being made to the Formulary. A draft version of the new Formulary is due by the end of

the year.

Non Medical Prescribing (NMP)

A national conference was held in Edinburgh on 27th May 2016 which included regional hubs. Mr Gorman informed the Committee that there is high demand for the NMP course, with the next course now fully booked. A lot of activity is taking place, with growing evidence that prescribing is being carried out. The Committee noted that Pharmacists will be prescribing electronically by next year. Dieticians and Radiographers have applied to join.

Antimicrobial Stewardship

The workbook for nursing staff is available for use on the NES website.

PGD Group

There are over 200 PGDs currently in use. Monthly meetings are held to review current/approve new PGDs.

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

65. PRESCRIBING INTERFACE SUB-COMMITTEE

Six Monthly Report

The Committee noted the Prescribing Interface Sub-Committee 6 monthly report to inform the ADTC of the work of the Sub-Committee. The report summarises the work undertaken by the Committee from April 2016 to September 2016 and provides an update on future work.

Dr Hardman reported that following discussion with the Local Medical Committee, new terminology will be used. The documents previously known as Shared Care Protocols (SCPs) will now be known as Shared Care Agreements (SCAs). The terminology will be updated as each existing SCP reaches its review date. Dr Hardman informed the Committee that the web address and mailbox (scp@ggc.scot.nhs.uk) will remain the same in order to preserve existing links within the NHSGGC Formulary.

A number of Shared Care Protocols have been reviewed in the last 6 months. Dr Hardman provided an updated on the following SCPs;

Existing SCPs reviewed and approved
Melatonin for sleep disturbance in children.

New SCPs approved
Voriconazole for treatment of invasive aspergillosis in adults.

New SCPs pending final approval
Acamprosate, Enoxaparin, Methotexate s/c, Somatropin and Apomorphine.

New SCPs under development (not yet approved)
Riluzole and Teriflunomide

New SCPs under development (not yet reviewed)
Pirfenidone for idiopathic pulmonary fibrosis.

Enhanced Service

Dr Hardman informed members that the group that previously dealt with NPT LES no longer exists. The Sub-Committee has concerns regarding this and highlighted the need for new processes to be established.

Dr Taylor informed the Committee that a new group has been set up which David Leese and Catriona Renfrew will attend. The group has met once and is scheduled to meet again.

Sharps containers and disposal

A number of Shared Care Protocols have been discussed for injectable medicines where the supply and disposal of sharps containers is an issue. Members noted that work is being carried out nationally.

The Committee continues to work with directorates and clinical specialists to identify medicines which may be suitable for shared care.

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

66. OTHER ADTC SUB-COMMITTEES

(a) Medicines Utilisation Sub-Committee

No specific update

(b) Antimicrobial Sub-Committee

Dr Seaton provided an update on non medical prescribing. He informed the Committee that 1 in 20 prescriptions are written by Non Medical Prescribers.

Dr Seaton informed members that an antimicrobial kardex may be created in order to provide support with prescribing targets regarding review of IV therapy and overall duration of therapy. Further discussion will take place at the antimicrobial meeting next month.

A large percentage of time is being spent working on the Point Prevalence Survey. This is a mandatory requirement which happens every 5 years.

The Committee noted the update provided.

67. ADTC COLLABORATIVE

The Committee noted the September ADTC Collaborative newsletter.

Mr Foot reported that an annual conference is being held on 24th November 2016 in Glasgow.

68. HOSPITAL ELECTRONIC PRESCRIBING AND ADMINISTRATION (HEPMA)

Prof Lannigan provided an update on recent developments with the implementation of HEPMA in NHSGG&C.

Prof Lannigan covered the background of the initiative, which will result in safer and more effective use of medicines. The Scottish Government has invested £20m to support the implementation of HEPMA across Scotland over the next 5-7 years. This leaves Boards to source the revenue and ongoing costs.

Prof Lannigan reported that there are 2 suitable systems that NHSGGC could use. As capacity is limited it is estimated that work will commence in 3 years time, with a 3 year roll out. It is estimated that roll out will be complete in Greater Glasgow and Clyde by 2022. In the interim work will take place to develop a roadmap towards HEPMA. A basic level will be built and layers can be added at a later stage.

Prof Lannigan reported that a strategic review has been commissioned to establish what the clinical community want to achieve through HEPMA. The ADTC will have a chance to comment on the

strategy.

Dr Taylor suggested consideration is given to the number of pop up alerts that are received when developing the system. He reported that important messages could potentially be missed through pop up "fatigue". Members agreed it would be beneficial if messages could be matched to the patient.

The Committee noted the current position and welcome future updates.

69. TERMS OF REFERENCE

Members noted the Terms of Reference of the Committee which are due for renewal.

Dr Taylor highlighted inconsistency in relation to the election of Chair and Vice Chair. He suggested expanding the appendix. The Committee briefly discussed the membership and agreed that sectors and directorates should be represented. Mr Lannigan suggested strengthening the relationship with Board Clinical Governance. Mr Lannigan will prepare a sentence to be added to the Terms of Reference. **Prof Lannigan**

Mr Foot will revise the Terms of Reference for the next meeting. **Mr Foot**

70. PRESCRIBING MANAGEMENT GROUP REPORT

The Prescribing Management Group last met on 13th September 2016.

Mrs Campbell reported that the new medicines fund is smaller and the number of patients increasing, therefore a deficit will be reported to the Scottish Government.

Work on biosimilars is ongoing.

An event is scheduled for 25th November 2016 to look at HMUD data and refining the process.

The group discussed feedback from the PACS pilot. The output of the review is awaited.

The Committee noted the update provided.

71. ANY OTHER BUSINESS

Members noted the review decision by NICE on prophylaxis for endocarditis in dental patients. The wording has now changed to 'not routinely recommended'. This will be discussed on a Scottish level at SAPG. This item will be added to the November AUC agenda in order to reflect on SAPG discussion.

72. DATE OF NEXT MEETING

Monday, 12 December 2016 – Boardroom, JB Russell House, Gartnavel Royal Hospital