ADTC(M) 12/05
Minutes: 59 - 75

NHS GREATER GLASGOW AND CLYDE

Minutes of a Meeting of the
Area Drugs and Therapeutics Committee
held in the Conference Room
Management Building
Southern General Hospital
on Monday, 8 October 2012 at 2.00 p.m.

P R E S E N T

Mrs J Watt (in the Chair)

Professor S Bryson	Dr J Larkin
Mrs J Camp	Dr J MacKenzie
Mr R Foot	Dr G McKay
Dr G Forrest	Mrs M Ryan
Dr R J Hardman	Dr G K Simpson
Ms L Hillan	Dr A Taylor
Dr H Hopkinson	Mrs A Thompson

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

Ms B Campbell .. Non Medical Prescribing Adviser
Ms L Watret .. Non Medical Prescribing Adviser
Mrs E Watt .. Secretariat

ACTION BY

59. 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.

60. MATTERS ARISING

Public Partners

Mrs Watt intimated that the public partners who had attended the last meeting had indicated that it had been a positive experience and they may have something to offer the Committee. A discussion should take place with the Chair of the Committee on how to structure input from the public partners.

ACTION BY

61. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr A Bowman, Dr J Burns, Mrs A Campbell, Dr J Gravil, Dr G J A Macphee, Dr C E McKean, Dr P Moultrie and Dr A Seaton.

Mrs Watt welcomed Ms Lynne Watret and Ms Bernadette Campbell, Non Medical Prescribing Advisers, who were attending as observers as part of their induction into the Central Prescribing Team.

62. MINUTES

The Minutes of the meeting of the Area Drugs and Therapeutics Committee held on 13 August 2012 [ADTC(M) 12/04] were approved as a correct record.

NOTED

63. MATTERS ARISING

Position Statement for Ticagrelor

Professor Bryson spoke on his paper on the above which outlined the situation, background, assessment and recommendation. He indicated that this remains work in progress. The GGC process with regard to the above had been followed in that this was received from the SMC, the ADTC referred this to the Heart MCN, who passed it to the West of Scotland Cardiac Prescribing Group, who, in turn, referred it to national level.

Ticagrelor had been discussed at the last meeting and in the absence of a regional/national consensus the ADTC had decided that this medicine should be included the Total Formulary for the indication in question 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. The ADTC had written to the regional group to encourage the development of regional advice. This was anticipated shortly but no timescales had been given.

The Committee would be kept advised of developments.

NOTED

64. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(1) SMC Evaluations / NICE/QIS Guidance

Dr Forrest advised that the Formulary and New Drugs Sub-Committee meeting on 28 September 2012 had been inquorate due to the absence of a clinician. The meeting went ahead and an email of the recommendations made had been sent to the clinicians not in attendance at the meeting requesting their comments. Comments received back were in agreement with the recommendations made at the meeting.

Dr Forrest 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.

ACTION BY

No interests were declared.

The following was highlighted:-

Colecalciferol 800 international units, equivalent to 20 micrograms vitamin (Fultium D3®) [801/12] ***[Indication: In adults, the elderly and adolescents for the prevention and treatment of vitamin ~D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency]***

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

There was no evidence of superiority in severe disease therefore this group of patients was excluded.

This was the first licensed vitamin D monotherapy preparation and was double the dose recommended by the Scottish Government for at risk groups.

Feedback from local advisers indicated that most patients with vitamin deficiency would still get Calcium and Vitamin D. Fultium-D_3 would be the preferred therapy for hyperparathyroidism. Primary Care were concerned about potential for high uptake.

Two guidelines have been developed by endocrinologists for specific patient groups (osteoporosis and hyperparathyroidism).

It was recommended that a PostScript article on the place in therapy of this medicine be considered to support introduction.

A discussion ensued and it was suggested that an article be included PostScript outlining that guidance was being produced and when this would be available.

It was agreed that a Prescribing Note be included in the Formulary entry for this medicine. Mr Foot would draft this and email to Members for comment. **Mr R Foot**

Velaglucerase alfa 400 units powder for solution for infusion (VPRIV®) [681/11] ***[Indication: Long-term enzyme replacement therapy in patients with type 1 Gaucher disease]***

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

This was low volume high cost medicine.

Mr Foot advised that the other two medicines for this therapeutic area had not previously been included in the Formulary – imiglucerase pre-dated SMC was not added due to low numbers and migulstat was accepted by SMC but not added to the Formulary due to it being an orphan product and, at that time, orphan products were not routinely added to the Formulary. To ensure consistency, Mr Foot asked if these could be added to the Formulary. This was agreed.

Fingolimod (as hydrochloride), 0.5mg hard capsules (Gilenya®) [763/12] ***[Resubmission] [Indication: As single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: (1) Patients with high disease activity despite treatment with a beta-interferon; or (2) Patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year, and with one or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI Treatment of moderate to severe manic episodes associated with bipolar 1 disorder in adults]***

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

The SMC restriction was for use as single disease modifying therapy in highly active RRMS in adult patients with high disease activity despite treatment with a beta-interferon

ACTION BY

with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.

It was noted that there was significant interest from patient groups about this medicine. It was pointed out that there was some funding in the 2012/13 Financial Plan for this.

Mr Foot advised that there was a protocol in development for its use.

Strontium ranelate (Protelos®) 2g granules for oral suspension [816/12] *[Servier Laboratories Limited]* ***[Indication: Treatment of osteoporosis in men at increased risk of fracture]***

The SMC decision was that in the absence of a submission from the holder of the marketing authorisation the above medicine was not recommended for use within NHS Scotland.

It was pointed out that this was a useful medicine for use in men.

As this was not accepted by SMC, any use would require completing an IPTR form.

DECIDED:

That recommendations made by the Formulary and New Drugs Sub-Committee at their meeting on 28 September 2012 be ratified by the Committee.

(2) SMC Update

Eslicarbazepine acetate (Zebinix)

The SMC published advice for eslicarbazepine acetate (Zebinix) in November 2010 and accepted for restricted use within NHS Scotland as adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation. The SMC advice took account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eslicarbazepine acetate and is contingent upon the continuing availability of the PAS in Scotland.

The Manufacturer, Eisai, has withdrawn the Patient Access Scheme for eslicarbazepine acetate (Zebinix) as the list price of the product has been reduced. However, the SMC advice remains valid as the list prices is now lower that the price SMC made its decision on.

NOTED

(3) Appeal – Oral Typhoid Vaccine (Vivotif®)

Mr Foot advised that an appeal for Oral Typhoid Vaccine (Vivotif®) had been received from Dr R Walker, GP, Bearsden. No interests had been declared.

Mr Foot gave a summary of the appeal. Three supporting evidence papers were provided by the appellants.

The main points mooted by the appellants were:-

- Typhoid injection was poorly immunogenic and antibody levels wane rapidly over 3 years.
- Re-vaccination with intra-muscular (i.m.) injections does not have a “booster” effect but results in raising antibody levels to those achieved with primary immunisation.
- Evidence was available that re-vaccination with i.m. preparation produced progressively lower increases in antibody levels. Therefore, travellers with high risk destinations and a recent i.m inoculation (eg 1 year ago) could be eligible for top-up with oral typhoid vaccine.

ACTION BY

- Oral preparation would also be available as treatment option in case of the injection not being available on the market.

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

- There remains uncertainty when and why current Formulary exclusion of the oral vaccine was imposed
- Oral vaccine required three doses to be administered to complete a course and was restricted to patients six years and older.
- Currently low prescription levels are anticipated for the oral vaccine.
- Public Health Consultant was not aware of evidence for administration of oral vaccine in-between injectable type to improve / boost immunity. He still sees the polysaccharide injections as first line choice; the oral vaccine might be used due to patient's preference or supply issues with the injectable vaccine.

The Sub-Committee's recommendation was not to uphold this appeal as there was insufficient evidence of benefit over existing Formulary choices. Following consultation with Public Health, there was no compelling evidence to support the use of the oral vaccine to boost immunity in-between typhoid vaccine injections.

A discussion ensued and the comments included the following:-

- There was no prescribing of this in PRISMS.
- Typhoid vaccine was not routinely given on its own, but rather in combination with Hepatitis A vaccine.
- This was more expensive that alternatives by approximately 50%.
- It was suggested that most prescribing would be on private prescriptions, however, in "The Green Book" there was a sentence which outlines that the vaccine can be prescribed on the NHS in specific circumstances.
- Vaccination with the oral preparation would consist of three doses taken by the patient, with the risk that the course would not be completed.

DECIDED:

1. That the Committee ratify the Formulary and New Drugs Sub-Committee's decision not to uphold this appeal.

2. That a response be sent to the appellant outlining the Committee's reasons for not upholding the appeal. **Mrs J Watt**

65. WEST OF SCOTLAND CANCER NETWORK PRESCRIBING ADVISORY SUB-GROUP – SUMMARY OF ADVICE TO NHS BOARDS ADTCs – SEPTEMBER 2012

A summary of advice was tabled with the agenda papers from the Regional Cancer Advisory Group Prescribing Advisory Sub-Group. This outlined local implementation of SMC Guidance and NICE/QIS MTAs.

Mr Foot advised that this had come direct to the ADTC and the medicines with new protocols had been included in a tabled paper for insertion in the New Drugs Recommendation table discussed earlier in the meeting and were highlighted below.

(a) Everolimus, 5mg, 10mg tablets (Afinitor®) [777/12] ***[Indication: Treatment of unresectable or metastatic, well or moderately differentiated neuroendocrine tumours of pancreatic origin (Pnet) in adults with progressive disease]***

The SMC decision was "Accepted for Use in NHS Scotland".

A decision on this medicine had been previously deferred pending consultation with the Regional Cancer Advisory Group for development of a protocol.

ACTION BY

DECIDED:

That the above medicine be included in the GGC Total Formulary for the indication in question restricted to specialist use in patients who have received only one prior chemotherapy regimen and used in accordance with protocol.

(b) Abiraterone acetate 250mg tablets (Zytiga®) [764/12] ***[Resubmission] [Indication: With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen]***

The SMC decision was "Accepted for Restricted Use in NHS Scotland".

A decision on this medicine had been previously deferred pending consultation with the Regional Cancer Advisory Group for development of a protocol.

DECIDED:

That the above medicines be included in the GGC Total Formulary for the indication in question restricted to specialist in accordance with regional protocol.

66. SAFER USE OF MEDICINES SUB-COMMITTEE

Six Monthly Update

Dr McKay gave an overview on the work the Sub-Committee. The following was highlighted:-

- Ongoing work *[Medicines Reconciliation prescribing charts for gentamicin/vancomycin, in-patient setting for Surgery and Anaesthetics Directorate and work in the medical wards with regard to errors]*.
- Work Plan/ Strategy *[A copy would be included on the agenda for the next meeting of this Committee]*.

A detailed discussion ensued on IT advice for junior doctors in that they have to write lists of drugs three ways. It was pointed out that junior doctors can access the E-summary through the clinical portal (and can also use ECS) which would cut down on this and possible potential errors.

Dr McKay advised that it was important to note that this was a consultant led process and junior doctors require time to carry out medical reconciliation. How medicines should be arranged on list, ie alphabetical etc was discussed.

Dr Hopkinson outlined that access to PCs for junior doctors in South Glasgow was an issue. Mrs Watt advised that this was on the IT agenda.

A GP raised concerns regarding the discharge summary provided through Trackcare in that it was hard to read.

Mrs Watt advised that she had attended a Health Improvement Scotland conference re improving the use of medicines in Scotland, electronic prescribing and how Drugs and Therapeutics Committees were involved in shaping this agenda within NHS Boards.

A Member highlighted an issue of recurring out of date information on StaffNet with no governance for removing it and no system for checking. This should be added to the Sub-Committee's agenda.

DECIDED:

That Dr McKay write to Dr David Stewart, Lead Director of Acute Medical Services, with regard to some of the issues raised by Members. **Dr G McKay**

ACTION BY

67. THERAPEUTICS SUB-COMMITTEE

Six Monthly Update

Mrs Camp gave a summary of her paper which asked the Committee to review the work of the Sub-Committee. The paper outlined information on the process under development for products to be included in the Dressings and Sundries Formulary, Wound Formulary for the West of Scotland Acute Services, wound dressings, wound dressing order form, Urinary Catheter Formulary, nutritional products, a safe prescription peer reviews, Non Medical Prescribing Policy, PGD Group and Symptomatic Relief Policy.

The following was highlighted:-

- Process for products to be included in the Dressing and Sundries Formulary *[The Sub-Committee had a role to support the development of Formularies that are single system and advantageous to the organisation no matter the care setting. This raised challenges due to the differences in costs between the acute supply chain which was determined by national contract prices and the community supply through prescription and the Scottish Drug Tariff. Processes and flowcharts were in the final stages of development and would be brought to the Committee for final approval in December 2012. A Member raised the question of why the national contract could not include both primary and acute care. Mrs Camp gave an explanation of why this was a separate contract, including that some dressings were for hospital only].*
- Would Formulary for the West of Scotland Acute Services *[As a result of the national contract awards, a West of Scotland Group had met to agree a Regional Dressing Formulary which would form the list of dressings available for use within the Acute services].*
- Urinary Catheter Formulary *[Care homes practice would pilot the switching of catheters and supplies. This would identify criteria for patients who need review prior to switching. Prescribing of long term catheters would be led by Ms N Downes and Dr G Macphee in terms of the polypharmacy agenda].*

NOTED

68. PRESCRIBING MANAGEMENT GROUP (PMG) – KEY POINTS OF THE MEETINGS HELD ON 19 JUNE 2012 AND 11 SEPTEMBER 2012

Professor Bryson advised that the remit of the PMG was to promote access to innovative medicines and managing finance. He gave a brief update of the key points for the above meetings. This included information on the following:-

- Polypharmacy
- Parenteral Methotrexate in RA
- Anti-VEGF usage in eye disorders
- HEPMA *[Endorsed by NHSS HEPMA Short Life Working Group & e-Health Board. This aligns with commitment to medicines reconciliation and single shared medication record across the patient journey. An outline business case was in development at local level, based on an enhancement of Ascribe, essentially a "HEPMA light" option which was undergoing evaluation. This proposal had been supported by the Acute Services IT Strategy Group. A discussion ensued on whether "HEPMA light" would make a difference and what it would mean for patients. Professor Bryson answered Members questions indicating that this was a genuine way forward. It was suggested that Mr Norman Lannigan give a report to the Committee. Professor Bryson would take this forward].* **Prof S Bryson**
- Management of delirium in the acute setting *[Mrs Watt advised that this guideline had not been reviewed by the Medicines Utilisation Sub-Committee because it made very limited reference to medicines. More general information including drug treatment for management of acutely disturbed patients was available in the Therapeutics Handbook].*
- Finance Report *[Total expenditure for medicines in NHSGGC for April 2011 – March 2012 was £348.0M - This represented an increase of £4.8M (1.4%) compared to 2010/11 and an adverse variance of £2.4M (1.4%) versus budget. This was broken down as follows:*

ACTION BY

- Acute Services *[£109.4M - which was on budget. This represented an increase of £1.4M (1.3%) compared to 2010/11.*
- *Primary Care spend was £230.1M. This represented an increase of £3.5M (1.5%) compared to 2010/11 and an adverse variance of £2.7M (1.2%) versus budget. Areas of growth include respiratory disease and diabetes.*
- *Mental Health medicines spend was similar to 2010/11 – on budget].*

➢ Horizon scanning for 2011/12
➢ PMG Finance Reporting to CMT
➢ Mental Health PMG
➢ ADTC Report
➢ PMG Reports: Priorities.

NOTED

69. MEDICINES UTILISATION SUB-COMMITTEE

(a) Dual Therapy Smokefree Pregnancy Proposal

Dr Simpson advised that two Health Improvement Officers had been in attendance to present a case to consider the use of using dual NRT products concurrently for suitable pregnant smokers, stopping with NHSGGC Smokefree Pregnancy Service.

Pregnant women engaging with the Smokefree Pregnancy Service are often particularly nicotine dependant and it is suggested may require a higher dose of NRT. The Smokefree Pregnancy Service across GGC uses current guidance re NRT. Pregnant women should try to stop smoking without NRT, and, if unable to do so, they could be offered NRT following discussion of the risks and benefits of NRT. Intermittent forms of NRT are first line and if not tollerated a patch can be used which was removed overnight. This guideline proposed that if individuals were unable to quit using a single product they would be offered dual therapy with a patch and another product such as Microtabs.

Anecdotal evidence suggested that many were experiencing significant nicotine withdrawal which might be explained by pregnant women metabolising nicotine faster compared to smokers who are not pregnant. There was limited evidence that nicotine clearance increased during pregnancy when compared to non-pregnancy.

The Sub-Committee were reluctant to give its approval to this guideline due to there being no evidence to confirm the efficacy and safety of dual NRT therapy and use would be outwith its licence.

A detailed discussion ensued on all aspects of this proposal.

The ADTC acknowledged that smoking in pregnancy was difficult to treat but concluded that it could not endorse a guideline which had no evidence base. It was also noted that use would be outwith the licence.

DECIDED:

That the authors of the above proposal be advised of the Committee's views. **Mrs J Watt**

(b) Update of Current Palliative Care Subcutaneous Infusion Prescription and Monitoring Chart

Mrs Watt advised that the above update had been submitted by Ms Carolyn Mackay, Specialist Pharmacist, Palliative Care, NHSGGC, and outlined the background with regard to review of this chart which would replace previous versions.

The background was that Continuous Subcutaneous Infusion (CSCI) Prescription & Monitoring Charts for Palliative Care have been in use in NHSGGC since 2007. They were introduced to standardise the documentation for these infusions across all sectors of care, ie primary care, secondary care and hospices. Historically there were two fairly

ACTION BY

similar versions (one used in Greater Glasgow and one used in Clyde area) but with a few differences including colour of chart.

The amendments aim to enhance the safe use of these infusions and result from previous experience using the original chart, identified gaps, awareness of clinical incidents and feedback from the previously mentioned pilot.

Mrs Watt highlighted that there was a Hospital Records Committee that reviewed and approved charts for use across Acute care. It was agreed that as this chart would be used in both Acute and Primary Care it should be reviewed by ADTC. Mrs Watt was unsure whether this should be reviewed by the main Committee or by the Safer Use of Medicines Sub-Committee.

A discussion ensued and the following was highlighted:-

- The chart replaces separate charts for Glasgow and Clyde
- Clarify compatibility on page 1 of the chart.
- Require the background of how to use the chart.
- There is uncertainty about the role of the Hospital Records Committee and of its membership.

DECIDED:

The chart be approved by ADTC and that there would be further discussion at the next meeting about the relative roles of ADTC and the Hospital Records Committee in reviewing prescription charts. **Mrs J Watt**

70. ANTIMICROBIAL UTILISATION SUB-COMMITTEE (AUC)

(a) Minutes of a Meeting held on 22 August 2012

The above minutes were attached for information. Mrs Ryan advised that the GP Antibiotic Audit Toolkit may require local promotion for effective implementation. She would liaise direct with Dr Seaton in this regard. **Mrs M Ryan**

NOTED

(b) Minutes of the Fidaxomicin Discussion held on 22 August 2012

The notes of the above minutes were attached for information.

Professor Bryson advised that the Formulary status of Fidaxomicin had been discussed at the last meeting and a decision had been deferred until this had been discussed by the Antimicrobial Utilisation Sub-Committee for a consensus between the microbiologists and the ID consultants on final positioning within the protocol. This had been a helpful review and Fidaxomicin had now been added to the Formulary.

NOTED

71. POLYPHARMACY PRESCRIBING SUB-COMMITTEE

Mrs Ryan advised that national guidance on polypharmacy was awaited. Pilots in NHSGGC were being started.

NOTED

ACTION BY

72. COMMUNICATIONS SUB-COMMITTEE

PostScript

Issue 71 (September 2012) was attached with the agenda papers for information. This edition included articles on developments in hepatitis C treatment, a safety update on simvastatin, dabigatran and ondansetron, a table of ADTC decisions, information on the new TOBI podhaler, and an update on PPIs and hypomagnesaemia and antibiotics.

A Member asked if local advice on MHRA safety warnings could appear on the front page. Mrs Thompson advised that safety alerts from MHRA are monitored and it was not always possible to be definitive when advice was coming and when expected. It was suggested that the email alerts to Postscript readers could be used to highlight new and forthcoming safety advice..

A discussion ensued and a number of other suggestions for highlighting alerts were made including that a "current alerts" link could be set up on the front page of the GGC Prescribing website. Mrs Thompson would take on board the suggestions made. **Mrs A Thompson**

NOTED

73. ANY OTHER BUSINESS

Protocols

Dr MacKenzie enquired as to what the procedure was for approving protocols. Mrs Watt advised that the procedures for guidelines/protocols were detailed in the Clinical Guideline Framework which had been reviewed and approved by the Medicines Utilisation Sub-Committee in January 2012. She outlined the circumstances which would dictate when guidelines would be reviewed by individual directorates, Primary Care Prescribing Management Group and the Medicines Utilisation Sub-Committee.

A discussion regarding the Orthopaedic Thromboprophylaxis Guideline ensued. This guideline had been submitted to the Medicines Utilisation Sub-Committee in September where it was recognised that there was a degree of urgency to get the guideline approved, and it was subsequently agreed to circulate to Members by email following the meeting with a view to a final sign off rather than delay until the next Sub-Committee meeting. The Sub-Committee, having reviewed the guideline, had approved subject to some minor changes and clarifications. They were of the view that the guideline largely reflected current practice.

A discussion ensued around the level of consultation with Primary Care, as there was a perceived shift in emphasis of care. It was considered by General Practitioners that this was a creeping development that had never been formally approved and that there were potential budgetary and service implications (if patients could not administer the injection themselves). The Acute Care specialists had made the point that the guidance had been developed to standardise and improve the quality of care for this patient group.

It was agreed that the Medicines Utilisation Sub-Committee would approve the guideline and that the budgetary implications would be discussed at the Primary Care Prescribing Management Group to resolve any outstanding issues. It was noted that any cost implications in relation to the medicine itself were likely to be modest.

NOTED

74. MEETING DATES FOR 2013

Mrs Watt advised that the meeting dates for 2013 had been agreed. These would all be held in the Board Room, J B Russell House, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12. A schedule of the meeting dates would be sent out with the minutes. **Secretary**

NOTED

ACTION BY

75. DATE OF NEXT MEETING

The next meeting of the Area Drugs and Therapeutics Committee would be held on Monday, 10 December 2012 at 2.00 p.m. in Board Room, J B Russell House, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12.