AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 14th February 2019
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Paul Dudley	Birmingham and Solihull CCG
Prof Mark DasGupta	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Jonathon Boyd	Sandwell & West Birmingham CCG
Dr Sonul Bathla	Sandwell & West Birmingham CCG
Satnaam Singh Nandra	Sandwell & West Birmingham CCG
Dr Angus Mackenzie	Sandwell & West Birmingham NHS Trust
Prof Jamie Coleman	UHB NHS FT
Gurjit Kudhail	UHB NHS FT
Dr Sangeeta Ambegaokar	Forward Thinking Birmingham Partnership
Dr Neil Bugg	Birmingham Women's and Children's NHS FT
Alison Tennant	Birmingham Women's and Children's NHS FT
Ravinder Kalkat	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU
Daya Singh	Midlands & Lancashire CSU

IN ATTENDANCE:

Asma Ghani (Observer)	Sandwell & West Birmingham CCG
Hanadi Ghannam Alkhder for item 0219/06	Birmingham and Solihull CCG
Professor Wasim Hanif for item 0219/06	UHB NHS FT

No.	Item	Action

0219/01 Apologies for absence were received from:

Melanie Dowden, Birmingham Community Healthcare NHS Trust
Kalpesh Thakrar, Birmingham Community Healthcare NHS Trust
Dr John Wilkinson, Birmingham and Solihull CCG
Dr Mark Pucci, UHB NHS FT
Dr Dhiraj Tripathi, UHB NHS FT
Carol Evans, UHB NHS FT
Katy Davies, UHB NHS FT

The meeting was not quorate.

0219/02 Items of business not on agenda (to be discussed under AOB)

- Levodopa with carbidopa and entacapone (Stalevo®)
- Evolve HA® and Hylo-Forte®
- APC Meeting dates 2019

0219/03 Declaration of Interest (DoI)

The Chair reminded members to submit their annual declarations of interest to the APC Secretariat.

Dr Nashat Qamar declared interest in item 0219/06 as a member of the Diabetes Medicines Management Group (DMMAG).

0219/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today. Introductions around the table were carried out for the benefit of a new attendee.

The Chair reminded members, that the meeting is digitally recorded for the purpose of accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.

0219/05 Xonvea® gastro-resistant tablets (doxylamine/pyridoxine) – New drug application – Alliance Pharmaceuticals Ltd

The application is deferred and will be resubmitted with further information on the place in therapy and expected usage.

0219/06 DMMAG Type 2 Diabetes prescribing guideline – For discussion / ratification

The Chair welcomed members of the Diabetes Medicines Management Advisory Group (DMMAG); Hanadi Ghannam Alkhder, Birmingham and Solihull CCG and Professor Wasim Hanif, UHB NHS FT to the meeting and invited them to present the diabetes prescribing guidance. Dr Saqib Mughal was acknowledged for his input into the guidance.

Hanadi delivered a presentation on the DMMAG Type 2 diabetes guideline with input from Professor Hanif.

The Birmingham and Solihull CCG multidisciplinary virtual clinic model is moving 90% of diabetes management into primary care. GPs are asking for a guideline that simplifies how to individualise treatment. The guideline

produced by DMMAG considers NICE NG28 *Type 2 diabetes in adults: management*, American Diabetes Association and European Association for Study of Diabetes consensus report published in December 2018 and the relevant NICE TAGS for individual drugs.

The guideline aims to provide clarity about how to individualise treatment when selecting drugs and provide advice on optimal drug combinations in context of NHS. It takes into consideration the latest evidence, rationalisation of drug options, de-escalation and intensification of treatment and sign-posts to useful guides e.g. renal dosing, sick day rules. The treatment algorithm has been deliberately kept on one page. It includes extensive guidance on prescribing in frailty. The guidance aims to be applied across all care settings.

Hanadi presented 5-year prescribing data from Birmingham and Solihull CCG for newer antidiabetic agents which shows increased growth in prescribing of sodium-glucose co-transporter-2 (SGLT2) inhibitors, Dipeptidyl peptidase-4 (DPP4) inhibitors agents glucagon-like peptide (GLP-1) receptor agonists. The data shows DPP4i agents are prescribed more than any of the others and this was taken into consideration when developing the treatment algorithm.

Cardiovascular disease (CVD) is addressed within the guidance. Treatment options after metformin are limited for people with cardiovascular disease (CVD) usually to oral agents, SGLT2 and DPP4 inhibitors. DPP4 inhibitors are currently the default option for prescribing because in terms of CVD, they are generally noninferior to placebo except saxagliptin and to some extent alogliptin. This is, reflected in the prescribing data.

Hanadi outlined the CVD evidence and practice. The evidence for SGLT2 inhibitors comes from CVD outcome trial, EMPA-REG trial for empagliflozin. Almost all patients in this trial had CVD on enrollment. The trial demonstrated significant improvement in CV outcomes and reduction in mortality. Arguably, evidence for CVD benefit has been derived from triple therapy rather than dual therapy use. 48% people in EMPA-REG were on dual therapy when enrolled, 29% were on monotherapy. Most people who develop CVD will already be on dual therapy. If SGLT2i's not included as an option at dual therapy stage, the default option usually will be to add in DPP4i's. DMMAG feel the DPP4's at this stage do not add clinical benefit over SGLT2s and are cost-similar to the SGLT2is. However, a new SGLT2i will be launched in January 2019 (ertugliflozin, £29). Patent expiry of sitagliptin is expected in 2022. It is important to clarify the guidance does not advocate the use of SGLT2is for primary prevention but as an option for improving HbA1c and CV outcomes for those with existing CVD which are anticipated as a smaller cohort, with supporting evidence provided.

Hanadi moved onto triple therapy options. Most patients with CVD, if they follow the guideline pathway, will go on SGLT2i, unless contra-indicated/not tolerated. Patients with raised body mass index (BMI) can have either SGLT2i, GLP1 or a weight neutral agent. In *NG28*, the GLP1 is described as third line in a specific group of patients i.e. those with BMI > 35 (or co-morbidities that would benefit from weight loss). Therefore, GLP1 were positioned third line for patients with a high BMI. If CVD benefit is required, the GLP1 with CVD benefit is proposed option i.e. liraglutide. Evidence for this comes from the LEADER trial. In order not to conflict with NICE, the addition of GLP1-RA is not included as a dual therapy option. The use of GLP1 and SGLT2i together is

discouraged.

Hanadi ended by directing members to the algorithm “Antihyperglycaemic treatment options for adults with type 2 diabetes”.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- Members commended DMMAG for the comprehensive presentation and guidance produced.
- A member asked if there is any outcome data at launch for ertugliflozin. Prof Hanif answered there are NICE technology appraisals forthcoming for ertugliflozin. He is aware of an outcome study which should conclude towards the end of the year. New evidence will be reviewed and applied to the DMMAG guideline as it becomes available.
- A member asked if DMMAG are aware the regional medicines optimisation committees (RMOC) are going publish a position statement regarding liraglutide. Prof Hanif stated there was a cut off point for consideration of new evidence of November 2018 for input into the DMMAG guidance.
- It was clarified the guidance presented is a working document and as new evidence emerges, this will be considered.
- A member suggested the second point within the guidance be re-worded to read “Use slow-release metformin if ongoing GI intolerance”.
- It was clarified that DMMAG have rationalised the diabetes section of the APC formulary in line with this guidance. Amendments to the formulary will be proposed at the next APC away day in February. The cost-effectiveness and usage of agents has been considered.
- A member asked if type 2 diabetes in pregnancy had been considered within this guidance and if not, where should primary care clinicians i.e. general practitioners (GPs) be directed for information on the management of these patients. DMMAG acknowledged there is a need for further guidance for subsections of diabetes management, such as pregnancy, type 1 diabetes, insulins and are considering these as part of their work plan. Members agreed primary care clinicians would currently garner specialist input for the management of these subgroups.
- A member asked what the next steps are for this guidance. Hanadi confirmed the formulary amendments will be proposed at the away day, then governance processes sought at the separate organisations.
- Prof Hanif asked members for input on the layout of the 1-page algorithm. The CCG representative suggested approaching the internal communications team.

The Chair thanked Hanadi and Prof Hanif for attending the meeting and for answering all the questions from the APC members.

There were no further discussion points in the absence of the specialists.

ACTIONS:

- **Amend guidance and seek approval by individual organisation’s governance processes** — **DMMAG/APC sec**

0219/07 BSSE APC Primary Care Clinical Pathway for Atrial Fibrillation Detection and Management – For discussion/ratification

The Chair directed members to the West Midlands Academic Health Science Network (WMAHSN) Primary care atrial fibrillation pathway. The document includes details of authors and references as requested by the APC.

The Chair directed members to the draft BSSE APC Primary care atrial fibrillation pathway adapted from the WMAHSN version.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- There was concern raised of the usefulness of the SAMe-TT_2R_2. A member asked if further evidence was submitted. It was clarified there was a large paper submitted.
- The SAMe-TT_2R_2 section has been removed. A member stated SAMe-TT_2R_2 approach is not widely known or used.
- The document should refer to the term NOAC rather than DOAC.
- The document should be more explicit with regards to how renal function is measured.

ACTIONS:

- **Amend the document as discussed** — **APC sec /BSOL CCG**

0219/08 Low Molecular Weight Heparins – For discussion

The Chair directed members to the draft enoxaparin effective shared care agreement (ESCA) which was circulated with the papers for the meeting.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- There have been shortages for the various brands of LMWHs recently. There is a national group looking at which secondary care trust uses which LMWH product to manage the supply.
- The Commercial Medicines Unit (CMU) has instructed UHB NHS FT to switch patients from tinzaparin to the Inhixa® brand of enoxaparin. UHB NHS FT aims to switch patients from tinzaparin to Inhixa® by 27th March 2019.
- A member asked if the ESCA can be clearer to indicate the first prescription comes from secondary care. E.g. 14 days supply from secondary care.
- A member sought clarity regarding GP responsibilities with regard to monitoring for heparin induced thrombocytopenia after 14 days. In addition, felt more information was required for platelet monitoring and potassium monitoring including frequencies. A member responded it may be difficult to pinpoint frequency of monitoring due to lack of evidence particularly for side effects which occur over a prolonged period.
- There was a discussion surrounding the side effects included in the draft ESCA. It was confirmed the listed side effects were taken from the British National Formulary (BNF).
- A UHB NHS FT representative stated the weight-based dosing guidance is being reviewed to make it practical for use with Inhixa®

syringe i.e. move towards whole syringe dosing. The Inhixa® syringe is not marked with clear graduations that work with the current dosing guidance.

- UHB NHS FT request more time to input onto this section of the ESCA due to the complexity of switching from tinzaparin to Inhixa®.
- A member stated clarity is required regarding the responsibility for monitoring required for thrombocytopenia and hyperkalaemia for the first 14 days of treatment as it is stated under both specialist and general practitioner responsibilities sections of the ESCA.
- A CCG representative stated the shared care arrangements can be agreed by APC however its implementation is pending commissioning arrangements.
- A member stated providers need to consider additional provisions for patients beyond supply of the product itself. E.g. pre-packs or district nurse involvement.
- There was a discussion surrounding timescales for secondary care providers within BSSE to switch to the designated LMWH products.
- BWCH NHS FT are using Inhixa® currently. The pharmaceutical company provides a suite of materials for distribution.

0219/09 **BSSE APC Rationales for initiation, continuation and discontinuation** – For review

The Chair directed members to the ivabradine and ranolazine rationales for initiation, continuation and discontinuation (RICaDs) which were circulated with the papers for the meeting.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- There was a proposal from the recent APC away day from secondary care representatives to withdraw the ivabradine and ranolazine RICaDs but retain the Amber RAG ratings.
- A primary care representative felt there is useful crucial information within the RICaD that supports primary care clinicians when care is transferred to them. Ivabradine is prescribed infrequently and has extensive monitoring requirements.
- The primary care representative added an audit was undertaken within practice which showed some discrepancies in prescribing ivabradine within primary care.
- There was a discussion surrounding the suitability of Amber RAG rating for ranolazine and ivabradine.
- It was clarified the RICaDs were due for review in May 2018.
- Members agreed to retain the ivabradine and ranolazine RICaDs. The next step is for the RICaDs to be sent to specialists for review.

Decision summary: Retain ranolazine and ivabradine RICaDs.

ACTION:

- **Circulate ivabradine and ranolazine RICaDs for specialist review.** **APC sec**

0219/10 **Summaries for Decline to prescribes -** For information

The Chair directed members to the Summaries for Decline to prescribe (DtP) received from UHB NHS FT – HGS and SWB NHS FT included in the papers

circulated for the meeting.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member highlighted melatonin was commonly declined to prescribe by primary care.
- Members recalled a Red RAG status was agreed for melatonin prolonged release tablets (Circadin®) due to lack of evidence presented.
- There was a discussion surrounding need for clinician awareness of formularies within primary and secondary care.

0219/11 DTC Chairs Non-formulary approvals – For information

The Chair directed members to the Non-formulary approvals from UHB NHS FT HGS, UHB NHS FT QE, and SWB NHS FT included in the papers circulated for the meeting.

No comments were made.

0218/12 Regional Medicines Optimisation Committee recommendations – For discussion

The Chair directed members to the RMOC Midlands and East Update 2019 Issue 1.

No further comments were made.

0218/13 Minutes of the meeting held on Thursday 10th January 2019 – for ratification

The minutes of the meeting held on Thursday 10th January 2019 were discussed for accuracy.

It was confirmed that the minutes are approved, can be uploaded to the APC website and the recording deleted

0218/14 Matters Arising

The Chair moved onto the action table for comments and updates:
(See separate document attachment for updated version). Consider actions closed if not discussed.

The outstanding actions include:

- 0119/07 BSSE APC Valproate medicines ESCA Amend ESCA and bring to future meeting – **Update:** The ESCA has been amended and circulated for comments.
- 0119/07 BSSE APC Ciclesonide RICaD **Update:** Now accessible on formulary website. Close action.
- 1218/05 Cortiment (Budesonide MMX) data Obtain further clarification from applicant regarding preferred RAG rating and intended use of budesonide MMX. **Update:** UHB NHS FT now support RED rating as originally approved with a maximum of 20 courses over a 12 month period. The team will continue to collect data on these patients and especially on those patients which end up on continuous courses of

Budesonide MMX, if any. They will review this use in 12 months' time. Close action.

- 1118/08 BSSE APC Dermatology ESCAs **Update:** Scheduled April meeting
- 1119/AOB Identified issues with shared care documents – **Update:** Comments received from specialists. Amendments in progress. Scheduled for April meeting.
- 1217/09 NOAC RICaDs **Update:** Close action
- 1017/07 Pan-Birmingham Respiratory Clinical Network Asthma Guidelines **Update:** scheduled for March meeting.

0218/15 NICE Technological Appraisals (TAs)

In January 2019, there were 5 TAs published; of these, 4 are NHSE commissioned and 1 is not recommended.

ACTION: Update APC formulary with decisions on NICE TAs. **APC sec**

Any other business:

1. **Levodopa/carbidopa/entacapone**

There is a switch from Stalevo® to an alternative brand currently underway in Solihull. The current APC effective shared care agreement (ESCA) is brand-specific to Stalevo®. The representative asks APC to remove the brand name from the ESCA now other brands are available. The ESCA is due for review from July 2018.

Members agreed to review the ESCA at the upcoming April away day in line with the other Chapter 4 - Central Nervous System ESCAs and RICaDs.

2. **Evolve HA® and Hylo-Forte®**

UHB NHS FT stated there is resistance from ophthalmologists to switch to Evolve HA®. It was clarified that Evolve HA® has not replaced Hylo-Forte® on the APC formulary. Evolve HA® was agreed as an addition to the formulary in January 2019.

3. **Meeting dates 2019**

The meeting dates have been circulated to members. A poll will determine the date and location for the APC meeting in September 2019.

The Chair reminded members the next away day is on Thursday 28th February 2019 covering formulary chapter 6 - Endocrine, chapter 7 – obstetrics, gynaecology and urinary tract disorders and chapter 4 – pain section only.

The Chair thanked the members for their input today. The meeting closed at 15:50.

Date of next meeting: Thursday 14th March 2019 14:00 – 16:45 Birmingham Research Park.