AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 13th December 2018
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Lisa Brownell	BSMHFT
Dr Paul Dudley	Birmingham and Solihull CCG
Prof Mark DasGupta	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Kate Arnold	Birmingham and Solihull CCG
Dr John Wilkinson	Birmingham and Solihull CCG
Jonathan Boyd	Sandwell & West Birmingham CCG
Carol Evans	UHB NHS FT/ Birmingham and Solihull CCG
Gurjit Kudhail	UHB NHS FT
Prof Jamie Coleman	UHB NHS FT
Jeff Aston	Birmingham Women's & Children's NHS FT
Kalpesh Thakrar	Birmingham Community Healthcare NHS FT
Ravinder Kalkat	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU
Daya Singh	Midlands & Lancashire CSU

IN ATTENDANCE:

Dr William Hutton - UHB NHS FT	Observer

No.	Item	Action

1218/01 Apologies for absence were received from:

Dr Sonul Bathla, Sandwell and West Birmingham CCG
Dr Nashat Qamar, Birmingham and Solihull CCG
Katy Davies, UHB NHS FT
Melanie Dowden, Birmingham Community Healthcare NHS FT, deputy attended
Dr Sangeeta Ambegaokar, Forward Thinking Birmingham Partnership
Dr Neil Bugg, Birmingham Women's and Children's NHS FT

It was confirmed that the meeting was quorate.

1218/02 Items of business not on agenda (to be discussed under AOB)

- Direct Oral Anticoagulants discussions for APC away day– Interest amongst clinicians
- Appointment of permanent Chief Pharmacist at member Trust – for information
- Fiasp® supporting document
- Bath emollients feedback from member Trust

1218/03 Declaration of Interest (DoI)

There are some outstanding annual declarations of interest and members were reminded to submit these at the earliest opportunity. There were no interests to declare relating to items on the agenda.

1218/04 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.

The Chair announced that this was Kate Arnold's last meeting. The Chair and members thanked Kate for her valuable contribution to the APC.

1218/05 Cortiment® (Budesonide MMX) data – Ferring Pharmaceuticals Ltd

It was established that there were no Declarations of Interests for Ferring Pharmaceuticals Ltd.

The APC secretary reminded members that budesonide MMX was agreed a RAG status of RED at the October 2016 APC meeting. The reason for the status was that the APC had little information presented to confirm that admissions would be avoided with the use of budesonide MMX. It was agreed that the APC wished to see data in the form of case reports, tracking the patient's journey. The APC secretary directed members to the Decision Support Tool (DST) and the extract of minutes of the meeting.

The APC secretary read out the summary of the data from the Trust. The data was collected for 10 patients, including patients with previous admissions for IV steroids. Out of the 10 patients selected, 1 patient could not receive budesonide MMX as it was contra-indicated due to a peanut allergy. Out of the

remaining 9 patients, 7 patients avoided an admission and further administration of IV steroids.

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

- A member commented that the Trust has presented data in line with they had been asked to do by the APC and the member felt grateful that the Trust had not been prescribing excessive amounts of budesonide MMX.
- It was asked whether the total usage of the drug is 10 patients or whether the APC had asked the Trust to look at 10 patients only. A Trust representative replied and said that it is currently used sparingly.
- A member raised that the review of 10 patients was meant to have been within a year from the date of the original meeting for the application, however the APC secretary explained that the Trust had not achieved the number of patients to complete the review therefore were unable to present the data within the year.
- It was noted from the minutes of the original application that the applicant had proposed a RAG status of AMBER, however, the APC decided on a RED status. A Trust representative responded that the clinicians would like to see an AMBER status or AMBER with an ESCA.
- A member commented that for a very small cohort of 10 patients, a shared care agreement may not be necessary.
- A member pointed out that there is currently no prescribing of budesonide MMX in primary care therefore commended the clinicians who abided by the original APC agreement of a RED status.
- A member referred to the extract of the minutes presented at the meeting in October 2016 and highlighted that the cost of an 8-week course for budesonide MMX is £150, therefore asked who would be making the decision when to initiate the medication? A Trust representative replied that mainly consultants would make the decision when to initiate drug, however, it is a drug that does not necessarily need to be prescribed in clinic. Patients could be referred to the GP for them to prescribe the full 8-week course
- A member also referred to the extract of minutes and highlighted the section where it states “the specialist clarified that budesonide would be initiated in secondary care with two supply and then GP will be expected to prescribe for the remaining 6 weeks only”
- Following on from the above point, a member commented that if the drug is to continue and it is a flare up then the specialist should prescribe the 8-week course without involving another clinician into the treatment. A fellow member agreed with this point and stated it is a discrete course of treatment.
- A member was unsure whether budesonide MMX is the course of action that would be taken if a patient experiences another similar flare if the patient cannot take other steroids. The member stated that a flare up is often based upon symptomology.
- A member expressed concerns over the idea of a specialist prescribing for 2 weeks only and then whether a GP would be able to prescribe the remaining 6-week period for budesonide MMX so swiftly and whether there would be a risk of a patient not having treatment in the intervening period
- It was raised that if budesonide MMX is not regularly prescribed in primary care then pharmacies may not stock the item which may result in a delay in the patient obtaining the medication.
- A member felt that would be logical to allow primary care to prescribe

budesonide MMX if it was the go-to rescue treatment or if it is recurrent treatment for a patient. However, it could cause undue difficulty for the patient if they must obtain a prescription from the GP for the remaining 6 weeks supply and then to find a pharmacy that stock the medication. The member wished for clarity around the prescribing of budesonide MMX and whether the specialist would write a care plan for the GP outlining the management of the patient or whether the specialist would want to see a patient of that level of complexity if they were relapsing.

- A member discussed that as part of the protocol for establishing if there is a flare, the clinician must be absolutely certain there is no evidence of an infection such as campylobacter as steroid treatment would appropriate in these cases. The member referred to three cases where it was all suggested to have been an inflammatory bowel disease flare up however upon following the protocol, it was established that in all three cases, the patient had campylobacter, which can produce blood, mucus and can mimic inflammatory bowel disease. Therefore, budesonide MMX can be the go-to treatment along as the clinician who is initiating the medication has followed protocol. A fellow member was also in agreement with this point.
- A member commented that from a patient centered care view, it would save travelling time to the hospital for patients, however, this does not seem to be reflected in the original application and therefore would require to see a more robust case before changing the RAG status of budesonide MMX
- The Trust representative raised that they will clarify with the applicant whether budesonide MMX should remain as the current Red RAG status or whether they prefer AMBER then a more robust case will need to be presented.
- A member reiterated if the specialist intend budesonide MMX as a go to treatment for a flare up then the GP must ensure before prescribing the drug that they are not dealing with an infected bowel problem which patients with inflammatory bowel conditions are more susceptible to.
- A Trust representative raised that an AMBER status may be needed for patients that have had a previous course of budesonide or are intolerant of other agents and are known to have recurrent flare ups instead of referring patients to secondary care each time a flare up occurs. Further clarification is required from the applicant.

Decision Summary: UHB NHS FT to seek further clarification from applicant and present a more robust case if change in formulary status is desired.

ACTION:

• **Obtain further clarification from applicant regarding preferred RAG rating and intended use of budesonide MMX**	**UHB NHS FT**

1218/06 Primary Care Clinical Pathway for Atrial Fibrillation Detection and Management – for discussion

The chair directed members to the Primary Care Clinical Pathway for Atrial Fibrillation Detection and Management document produced by the West Midlands Academic Health Science Network.

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

- A member felt the document is a good summary for atrial fibrillation detection and management and felt it would be a reasonable addition if published to the BSSE APC website. The member added the document could be a little more detailed around renal function testing as this appears to be an area of contention in primary care. It was suggested that the document can potentially replace the existing RICaDs.
- There was a discussion on local pathways for initiating anticoagulation in primary care for individual CCG areas. It was established that a local pathway had been established within the BSOL CCG area whereas in SWB CCG it is in progress therefore the BSSE APC website would need to have a caveat to inform that the prescribing of anticoagulation is not the same across the APC patch.
- A member commented that there are no explanatory notes within the document. For example in the Determine OAC strategy using SAMe-TT_2-R_2 section regarding interacting drugs. The member assumes this means interacting drugs with vitamin K antagonists however it is not clear.
- Members discussed that they are not familiar with the SAMe-TT_2-R_2strategy whereas the $CH_2ADS_2VAS_C$ and HASBLED strategy is more widely known and used. Fellow members responded that the Time in Therapeutic Range (TTR) is calculated by a computer programme and is reported to the GPs in primary care.
- An example was given using the OAC strategy, that if a patient is a female of less than 60 years of age, with no medical history or smoking history and is of Caucasian race then it is suggested that the patient is more likely to do well with a vitamin K antagonist with a good TTR. The member questioned whether this takes into consideration patient choice. A member agreed and stated that they thought the current view is to actively encourage NOACs when appropriate rather than warfarin. The document is coming across as implying that clinicians should still consider warfarin before NOACs.
- A member raised that most patients who will require anticoagulation will be aware of the risks of warfarin and will be very aware that there are other agents available that do not require the amount of blood tests and monitoring that warfarin requires. There is a risk patients with a significant risk may not comply if offered warfarin. The member expressed that from a logistical and expense point of view, warfarin clinics will become far fewer.
- It was acknowledged that the document is good and has been approved by the West Midlands Cardiovascular and Stroke Clinical Network NHS England, however a member felt that even though the document presents good evidence about safety, this is the only thing it is focusing on rather than patient choice.
- It was discussed whether the APC should adopt the document onto the APC website with additional wording from the APC suggesting that the OAC strategy is useful for determining the safety of different strategies however it should remain a clinical decision based upon a two-way discussion with the patient.

- APC members overall felt that the document was a very good summary but felt that the inclusion of the SAMe-TT_2-R_2algorithm was problematic and are the evidence base behind the document is very unclear.
- A member raised and quoted from a recent systemic review which concluded "the SAMe-TT_2-R_2 score does predict low TTR, but the effect is small. The effect on individual patients is too limited to be clinically useful".

Decision summary: Not approved for publication on BSSE APC website

ACTIONS:

- **Feedback to West Midlands Academic Health Science Network on behalf of APC** — **CCG representative**

1218/07 Process for development and review of ESCAs/RICaDs

The APC secretary informed members the process for development of the supporting ESCA andRICaD documents has been updated. In addition, a process for review of ESCAs/RICaDs has been created due to the number of ESCAs/RICaDs that have reached their review date and will be updated in line with the upcoming away days.

The APC secretary directed members to the updated BSSE APC Workflow and timescales for development of RICaDs and ESCAs.

- Establish the need for an ESCA/RICaD for an AMBER approved drug.
- Add drug to formulary with the RAG status GREY whilst the ESCA/RICaD is produced
- Draft 0.1 is produced by applicant/Trust pharmacist/CCG lead (template sent to them) with a 2-week turnaround
- Draft 0.2 is reviewed by a second pharmacist at the CSU with a one-week turnaround
- Draft 0.2 is then circulated as part of a wide consultation with clinicians. The CSU then receive responses and send back to author (applicant/Trust pharmacist/CCG lead). Draft 0.3 to be produced from the consultation with a 4-week turnaround
- Draft 0.3 is then circulated by the CSU circulate and receive responses and send back to author. Applicant/Trust pharmacist/CCG lead to develop draft 0.4
- Draft 0.5 produced by CSU which includes a check on grammar, layout, formatting, header/footer and use of header/footer
- Draft 0.5 document presented to APC meeting for approval.
- Once approved, the RAG status changes from GREY to AMBER.
- Process should take 3 months.

The APC secretary directed members to the Workflow and timescales for the review of RICaDs and ESCAs.

- APC secretary will identify ESCA/RICaD for review 3 months before expiry or APC members can raise concerns or need for review at any time.

- The APC will be informed at the next scheduled APC meeting and will be discussed whether the supporting RICaD or ESCA is still required.
- If changes are identified, then the process for updating will follow the process described for initial development.
- If no changes required, then the review date at the bottom of the document can be updated and approved at the next scheduled APC meeting.

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

- A member raised shared care documents drafted by clinicians have in the past been presented to the APC and have needed substantial changes to be made in line with what had been agreed by the APC when the application was originally approved. The member was concerned that the supporting document is sent for wide consultation before presenting at the APC meeting then the APC may propose changes are needed at a late stage.
- Members agreed that draft 0.2 should include a check by the second pharmacist to ensure the shared care document reflects what had been agreed by the APC when the application was first approved
- It was agreed that an extract of the minutes and the Decision Support Tool (DST) should be sent to the clinician with the ESCA/RICaD template for the production of draft 0.1 so it reflects the agreement supported at the APC meeting

Decision Summary: It was agreed that subject to the above amendments, the document was approved for internal use

ACTIONS:

- **Make the proposed changes to the processes as discussed** — **APC sec**

1218/08 BSSE Wound Care Group Documents

Urgoclean® wound group evaluation was approved by APC in September 2018. An action required from the meeting was for the wound care sub group to establish the position of Urgoclean® within the wound care pathways.

Decision summary: Approved

ACTIONS:

- **Publish updated BSSE Wound Care Group documents on APC formulary website** — **APC sec**
- **Relay decision to Wound care sub group** — **APC sec**

1218/09 BSSE APC Feraccru® RICaD – For ratification

The chair directed the members to the revised Feraccru® RICaD which was recommended by the APC during the November 2018 APC meeting. The RICaD has been approved by the applicant, Prof Iqbal and a primary care APC representative member.

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

- APC members are satisfied that the contents of the Feraccru® RICaD now reflect how Feraccru® was approved for use by APC

ACTION:

- **Publish Feraccru® RICaD on APC website** **APC sec**

1218/10 Regional Medicines Optimisation Committee recommendations – For discussion

- Midlands and East RMOC November 2018
- RMOC guidance – prescribing of liothyronine
- RMOC guidance: Homely remedies
- RMOC STOMP resources

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

- A member asked whether liothyronine is widely prescribed in primary care. A member responded that the prescribing of liothyronine varies and there are some parts of the country where there is a lot of prescribing.Within BSSE a RED status stands in the APC formulary for very specific indications. The member further explained that the clarification for liothyronine is due to some areas being more robust in their implementation compared to other areas and therefore it was felt that there was need to restate the prescribing guidance around liothyronine.

1218/11 Minutes of the meeting held on Thursday 8th November 2018 – for ratification

The minutes of the meeting held on Thursday 8th November 2018 were discussed for accuracy.

- Page 2: Spelling of lisdexamfetamine and dexamfetamine throughout section 1118/05 to be corrected.

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

It was noted that the clinical effectiveness section of the DST for lisdexamfetamine should read “equal to or superior to other agents”. It was agreed that subject to this change, the DST for lisdexamfetamine is approved for publication.

1218/12 Matters Arising

The Chair moved onto the action table for comments and updates:

The outstanding actions included:

- 1118/09- BSSE APC away day documents – Ciclesonide RICaD to be produced in collaboration with Col Wilson Update: draft RICaD was circulated this morning – representatives were asked to forward on to specialists.
- 1118/AOB – Identified issues with shared care documents – sodium clodronate, denosumab, degarelix and apormorphine - Update: ESCAs were sent out for circulation to specialists last week
- 1018/06 - BSSE APC Dietetic formulary group documents – update the APC formulary with the harmonised formulary section 9.4 enteral feeds and the Guidelines for Prescribing Specialist Infant Formula in Primary Care Wound care documents – Update: uploaded to APC formulary
- 1018/08 – APC Decision to Decline Prescribing form Update: To be published soon
- 0418/08 - APC membership list -for ratification Update: Ongoing
- 1217/09 - NOAC RICaDs Update: to be discussed at away day
- 1017/07 – Pan-Birmingham Respiratory Clinical Network Asthma Guidelines Update: Awaiting updated guidelines from the Respiratory Network.

1218/13 NICE Technological Appraisals (TAs)

In November 2018, there were 3 TAs published; of these, 1 is NHSE commissioned, 1 is CCG commissioned and 1 is not recommended.

The CCG commissioned NICE TA is:

NICE TA 547: Tofacitinib for moderately to severely active ulcerative colitis. Tofacitinib is commissioned by clinical commissioning groups. Providers are NHS hospital trusts.

The NHSE commissioned NICE TA is:

NICE TA 545: Gemtuzumab ozogamicin for untreated acute myeloid leukaemia. Providers are NHS hospital trusts.

Red RAG status was agreed.

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

Any other business:

1. **Direct Oral Anticoagulants (DOAC) discussions for away day – Interest amongst clinicians**

   A Trust representative informed the APC there has been divergent opinions amongst Trust clinicians over the DOACs in preparation for the cardiology chapter review. It was asked whether there will be an opportunity for rationalising the DOACs and looking at the evidence base behind them during the away day. The representative wanted clarification on how a diverse group of DOACs can be rationalised and how the secondary care

clinicians be helpful with what the APC is trying to achieve with the chapter review. The evidence behind the DOACs varies and there are clinicians of various specialities that have vested interest in different ways.

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

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- A Trust representative highlighted that the current APC preferred choices as per APC formulary website are apixaban and rivaroxaban and that the Trust consultants on one site are happy with these choices however highlighted that there are discussions in other sites over whether the RICaDs for these agents are still needed.
- A Trust representative raised that their Trust would like all four DOACs listed without having two listed as the preferred agents and would like to remove the RICaDs.
- A fellow member raised that in primary care, some clinicians are not comfortable with the prescribing these agents therefore if the RICaD is to be removed an alternative document should be produced.
- A member clarified that all four DOACs were listed on the formulary as per their NICE TAs. Due to the agents being new and considered high risk the APC attempted to limit the amount of variability in prescribing by recommending two APC preferred agents.
- A member commented that from a primary care view it is better to use a limited number of agents in order to build up experience with the prescribing of these agents. The overall APC view is to have two preferred agents unless there is a compelling reason to have more.
- It was raised that the APC has two preferred agents in order to build up clinical safety, however all agent are prescribable as per the NICE TAs. The member expressed concern that completing a wholesale switch from all the other DOACs to one specific DOAC on the basis of cost due to a rebate scheme is not keeping in line with the NICE TAs. It was felt that apart from the clinical risk, there is a procedural risk of switching patients from all the DOACs to one specific DOAC as there is potential to be challenged on the implementation of NICE TAs.
- A member commented that the NOACs are considered high risk and they would not want to encourage switching agents for patients already established and maintained on a specific NOAC.
- A member added that the DOACs are prescribed in different specialities within their Trust such as cardiology, stroke, elderly care, and acute medicine and haematology who all have differing views on which DOAC is their preferred based on evidence.
- A member stated that if there are two agents which are preferred, there are likey to be fewer Decline to Prescribe forms.
- There were discussions amongst members whether the APC wording on the two preferred agents on the website is still needed.
- It was noted that specialists may challenge the APC for interfering with NICE guidance if the APC recommends certain agents.

- A member commented that clinicians in their area have now built up expertise with the APC preferred agents.
- Members agreed that all agents are available to prescribe and if the clinician had a strong clinical view to use a particular agent this was acceptable.
- A member confirmed that the APC website states "APC preferred agent: this recommendation must only be taken into account after a patient and prescriber have discussed all treatment options (including warfarin) and only if they have no preference about which medicine they want to use."
- It was agreed that the APC may need to revisit the APC preferred agents in the next twelve months if the other agents begin to be prescribed more.

2. Fiasp® supporting document

The APC secretary reminded members Fiasp® was approved onto the APC formulary for use in gestational diabetes with the RAG status of AMBER with RICaD. The Diabetes Medicines Management Group (DMMAG) have raised whether an ESCA would be more appropriate in view of how Fiasp® will be used and monitored.

The DMMAG stated women who have diabetes in pregnancy will need to remain under the care of their specialist throughout their pregnancy for close monitoring of their glycaemic control. The DMMAG felt it is appropriate for the GP to prescribe/supply the insulin in primary care but wondered if a shared care approach to monitoring would be better as the patient would need specialist support with the switch-over from their existing bolus insulin to Fiasp®. The DMMAG also felt these patients would need specialist input when assessing the effect of changing to Fiasp®, identifying and addressing any new episodes of hypoglycaemia, and providing advice on future dose adjustment etc. The DMMAG felt that the ESCA format potentially allows this to be outlined better than the RICaD which was originally agreed.

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

- A member expressed that the agreed plan was not to switch patients from their existing insulin to Fiasp®. The evidence submitted with the original application showed slight improvement in post-prandial glucose levels therefore Fiasp® was approved for use in gestational diabetes only.
- A member clarified the use of Fiasp® was originally approved as RED for gestational diabetes only. The RAG rating was changed to AMBER due to applicant expressing that these gestational diabetes patients are transferred to primary care and are not seen in secondary care again. There is now expression from DMMAG that gestational diabetes patients will still be under specialist care/monitoring once discharged to primary care.
- A member raised that Fiasp® was only approved as one of the choices if the patient develops gestational diabetes. There is concern patients who are already established on an insulin agent are switched over to Fiasp® once they become pregnant. Another member agreed they did not expect Fiasp® to be used for existing type 1 diabetes patients already established on an insulin agent.
- A member expressed concerns over whether the APC had

inadvertently given a message that they feel Fiasp® is the preferred agent and wondered whether the DMMAG had misinterpreted the APC decision on Fiasp®.

- The APC members were surprised to hear that patients will be monitored by a secondary care specialist once transferred to primary care as the reason this was approved AMBER was due to the APC being given representations that the patients are usually only seen once by the specialist and then transferred to primary care. Members felt that if patients are being monitored by secondary care continually then the original recommendation of a RED status should have stayed in place.
- It was agreed that an extract of minutes should be recirculated to the DMMAG in order to help assist and clarify the decision to produce a RICaD as what was originally agreed.

Decision summary: AMBER with RICaD

ACTION: APC secretary to resend minutes and decision to DMMAG **APC sec**

3. Bath emollients feedback

The APC secretary informed members dermatologists from a member Trust have responded in regard to the BATHE study and the use of bath emollients. They advised that the APC should seek feedback from paediatric dermatologists as their clinical practice is adult dermatology. The Trust also wanted the committee to consider the National Eczema Society's which was circulated to members.

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

- A member raised that the use of bath emollients is now currently part of the national consultation on phase 3 of low priority prescribing "Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs". The decision has now been moved from the APC's remit to a national focus.

ACTION: Inform UHB NHS FT - QE dermatologists that the prescribing of bath emollients has now been moved from the APC remit to a national consultation **APC sec**

The Chair thanked the members for their input today. The meeting closed at 15:30.

Date of next meeting: Thursday 10th January 2019 14:00 – 16:45 Birmingham Research Park.