AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 12th July 2018
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Paul Dudley	Birmingham and Solihull CCG (Chair)
Prof Mark DasGupta	Birmingham and Solihull CCG
Satnaam Singh Nandra	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Dr John Wilkinson	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Carol Evans	UHB NHS FT/ Birmingham and Solihull CCG
Katy Davies	UHB NHS FT
Inderjit Singh	UHB NHS FT
Prof Jamie Coleman	UHB NHS FT
Dr Angus Mackenzie	Sandwell and West Birmingham Hospitals NHSFT
Hannah Peach	Sandwell and West Birmingham CCG
Dr Sangeeta Ambegaokar	Birmingham Women's & Children's NHS FT
Nigel Barnes	BSMHFT
Ravinder Kalkat	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU
Daya Singh	Midlands & Lancashire CSU

IN ATTENDANCE:

Jagvir Garcha	Midlands & Lancashire CSU (observer)
Maliha Mir	Midlands & Lancashire CSU (observer)

No.	Item	Action

0718/01 Apologies for absence were received from:

Jonathan Boyd, Sandwell & West Birmingham CCG, deputy attended
Melanie Dowden, Birmingham Community Healthcare NHS FT
Mary Johnson, South East Staffordshire & Seisdon Peninsula CCG
Dr Neil Bugg, Birmingham Women's & Children's NHS FT
Jeff Aston, Birmingham Women's & Children's NHS FT
Liz Thomas, Birmingham and Solihull CCG

It was confirmed that the meeting was quorate.

0718/02 Items of business not on agenda (to be discussed under AOB)

- Unavailability of Modecate® (fluphenazine)

0718/03 Declaration of Interest (DoI)

There are no outstanding annual declarations of interest from members and there were no interests to declare relating to items on the agenda.

0718/04 Welcome and Introductions

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

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 Dr C. Kartios and Tania Carruthers have stood down from APC. Members of APC would like to thank them for their contribution.

0718/05 Budenofalk® foam enema – abbreviated application form – Dr Falk Pharma UK Ltd.

It was established that there were no Declarations of Interests for Dr Falk Pharma UK Ltd.

The Chair introduced an abbreviated application for Budenofalk® (budesonide 2mg/dose foam enema). Predfoam® enema was discontinued and its generic alternative is significantly costlier. The APC recommended Colifoam® (hydrocortisone foam enema) as an alternative, however, there is now a supply issue with this.

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

- A member asked whether the Colifoam® shortage had resolved as it had initially been anticipated for there to be a shortage until the middle of 2018. The APC secretary has confirmed with the manufacturer that stock is expected to arrive either later this year or early 2019.
- It was clarified that Budenofalk® is more cost effective compared to the generic prednisolone foam enema.

- A CCG representative stated the application has been discussed and supported within their organisation.
- Completion of the Decision Support Tool (DST) was not deemed necessary.

Decision Summary: Budenofalk® accepted onto the formulary

ACTIONS:

- **Relay decision to the applicant by Thursday 19th July 2018.** **APC sec**
- **Add Budenofalk® to the formulary as AMBER** **APC sec**

0718/06 Abbreviated or full applications – for discussion

The Chair informed members of APC that the use of the abbreviated or full application form was discussed at the away day on 3rd July. It was felt that the APC needed to revisit the criteria for use of the abbreviated application form, in light of recent applications to the APC. Members were directed to the proposal document.

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

- A member stated that it is beneficial to have the option of an abbreviated application form and set guidance for the use of the form, particularly for acute trusts.
- A member highlighted *The screening pharmacist/APC secretary is to determine if an abbreviated application is suitable at the point of request, in conjunction with the APC Chairs.* The proposal states *APC Chairs* in the plural and asked whether, in light of the current joint Chair arrangement, approval from one of the Chairs was sufficient to sanction the use of an abbreviated application form. It was agreed that approval from one Chair was acceptable.
- The Chair stated if there was uncertainty about whether an abbreviated application is suitable then they would seek advice from members.

Decision Summary: APC approved the proposal

0718/07 Decision making process – for discussion

The Chair directed members to the decision making process proposal document and the revised Decision Support Tool (DST).

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

- A member asked whether the decision making process proposal document is simply clarifying what the APC are currently doing in bullet points or whether there have been any changes to the process. The Chair responded that there have been no major changes.
- A member disagreed with the word 'personal' in the proposal and stated that the word professional would be more appropriate.
- Members largely agreed with the two part process detailed in the proposal.
- The Chair highlighted that the proposal was not a response to any formal criticism regarding the current deliberation process. However, members have raised concerns with how applications are being deliberated.
- A member agreed and stated that this proposal strengthens the current decision making process.

- A new member sought clarification regarding how the DST is being used by the APC currently. The Chair explained that members record their decision and rationale on the DST when the application is assessed at the meeting. The DST is published on the APC website.
- Another member asked whether only one members fills out the DST on behalf of all members or whether each organisation completes the form. The Chair responded that the APC agree the wording of the DST and either the APC secretariat or the Chair will fill out the form during the meeting. This is then distributed to the members and ratified at the following meeting.
- A member agreed with the proposal that there should be a patient focused approach as part of the initial review and approved the addition of this element to the DST as published patient factors.
- A discussion ensued surrounding the acquisition of a lay APC member and members agreed that it would be beneficial to have lay member input.
- The APC secretary directed members to the part of the proposal recommending an extract of the minutes from the drug and therapeutics committee (DTC) where the application is originally discussed is included with applications forwarded to the APC. A discussion ensued regarding the practicalities of doing this.
- A secondary care representative member stated that when the application comes to the DTC, the DTC is considering if the evidence is presentable and the application has been completed to an appropriate standard for forwarding to the APC. The application is not challenged at the DTC in the same way it is at APC.
- Members agreed that the minutes of the DTC meeting would not be useful to the APC unless there was a parallel process occurring between the DTC and the APC. Endorsement of applications by the Chair of the DTC is sufficient and this is what currently happens.
- A member asked whether having minutes from the DTC would benefit the APC particularly in cases where an application has been rejected at several DTC but accepted at one DTC.
- Members agreed that Trust DTCs inform the APC when an application has not been accepted for consideration at APC.

Decision Summary: APC approved the decision making process minus the requirement for extract of DTC minutes. The revised Decision Support Tool (DST) was approved.

0718/08 Exceptional circumstances – for discussion

The Chair directed members to the proposed wording on the BSSE APC formulary website homepage which covers prescribing in exceptional circumstances.

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

- A member mentioned that the wording in the second paragraph *'A change should only be considered where the patient will gain clinical benefit; for example, if the non-formulary drug is less effective or has poor adherence'* should be amended as it is unclear.
- A member raised that the national policy covering medicines of limited clinical value should be mentioned. The policy states that certain medication should not be routinely prescribed in primary care. For new patients, these should not be initiated and for existing patients, deprescribing should occur.

ACTION: **APC secretariat to amend the proposed wording as discussed** **APC sec**

0718/09 Formulary chapters and ESCA/RICaD review

The Chair directed members to the proposal for the process the APC will undertake to review the formulary chapters and ESCA/RICaDs.

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

- A member highlighted that certain chapters may require numerous clinicians to attend.
- Members agreed that the term specialist can be misleading as multi-disciplinary input for most chapters is required.
- It was proposed that *'specialists are given 6 weeks to review the formulary chapter'* should be amended to *'departments are given 6 weeks to review the formulary chapter'*
- A member stated that from previous experience, the level of organisation can vary between departments. Therefore, a programme of work should be made for clinicians so that they can use this to liaise with their counterparts.
- APC members agreed for the ophthalmology, respiratory and possibly dermatology chapters to be reviewed at the away day scheduled for October 2018.
- The APC secretary informed members that the first away day is scheduled for Thursday 25th October 2018. Due to half-term, it was decided to amend the date to the week before which still gives clinicians more than 6 week's notice.

ACTION:

- **APC secretary to circulate a timetable for the chapter review away days** **APC sec**

0718/10 Membership and Quorum

BSSE APC Terms of Reference

The Chair directed members to the revised APC Terms of Reference document. The APC secretariat explained that the following changes have been made:

- Page 1: Last bullet point under responsibilities has been amended to 'on a rolling three-year programme'
- Page 3: List of organisations have been amended to reflect the recent mergers of trusts.
- Page 6: Updated the Chairman and Vice-Chairman section with the addition of a footnote to reflect the current Joint Chair arrangement.

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

- Member suggested the statement *'The chair cannot have a casting vote which would bind a non-consenting CCG to the decision'* should to be removed under voting rights on page 6 as there is covered in the paragraph following it.
- A member highlighted at the recent away day it was agreed the membership of the APC would reflect the make up of the organisations when the APC was first formed. This should be reflected adequately in the Terms of Reference.

- University Hospitals Birmingham NHS Foundation Trust consists of Queen Elizabeth, Heartlands, Good Hope and Solihull Hospital which constitutes to 4 members.
- Birmingham Cross City CCG, Birmingham South Central CCG and Solihull CCG have all merged to form Birmingham and Solihull CCG which constitutes to 6 members.
- Birmingham Women's Hospital NHS FT and Birmingham Children's Hospital NHS FT has merged to form Birmingham Women's and Children's Hospital NHS Foundation Trust (incl. Forward Thinking Birmingham) constituting to 4 members.
- A member raised that the term of office of Chair has a minimum of 2 years but does not have a maximum value. It was agreed the Terms of Reference should be amended to state, '*The term of office for both Chair and Vice-Chair will be determined every 2 years and not usually reappointed for more than two consecutive terms.'*
- It was raised that there has been no participation by Public Health or by the Council representatives for a period of time.
- It was agreed to remove the reference to The CCG Chief Executives Forum on page 6 as they do not exist anymore. The amended version should read 'The Chair and Vice-Chair may either be elected from the core membership of the committee or proposed by the membership organisations.'
- It was agreed that voting membership should be restricted to organisations that use the APC formulary as their main formulary.

ACTION: APC secretary to amend the Terms of Reference as above.

BSSE APC Policy

The Chair directed members to the proposal document for Terms of Reference. The APC secretariat explained that the following changes have been made:

- Page iii: List of organisations amended to reflect mergers
- Page 2: Footnote added to reflect that the core principles listed are based on the CCG's Commissioning Policy: Ethical framework for priority setting and resource allocation 2013.
- Page 5: Changes made to responsibilities regarding RMOC recommendations
- Page 6: Amendment to the information regarding the use of the full application form and abbreviated application form to reflect the proposal discussed earlier
- Page 8: Additional paragraph on advice if there is an immediate clinical need in primary care
- Page 12: New section added on how RMOC recommendations are to be reviewed. RMOC recommendations from the previous month will now be a standing agenda item.

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

- A member raised the APC does not have an RMOC representative as suggested in the new paragraph surrounding feedback to RMOC. There are members of the RMOC which sit on the APC committee therefore this should be amended.

- It was suggested that the APC Chairs should contact the RMOC when the APC feels it is necessary to feedback to them.
- After discussion, members agreed to remove the additional paragraph regarding feedback to RMOC. It was agreed that feedback could be provided when felt necessary by the APC.
- Members agreed to amend the title of this section to *'RMOC recommendations'*.

ACTION: APC Secretary to amend the APC Policy as above. **APC sec**

0718/11 Insulin preparations: RMOC recommendations of safety considerations for formulary decision making

The APC secretary informed members of APC that Midlands and East Regional Medicines Optimisation Committee held a meeting on 18th April 2018 and reviewed issues pertaining to safety considerations when adopting any insulin preparation onto a local formulary. The RMOC programme as now issued guidance to Area Prescribing Committees on this subject. The guidance is also available as a checklist which is intended to be completed as part of the evidence-gathering process alongside clinical and cost-effectiveness data.

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

- A member commented that the APC already largely considers the points highlighted by the RMOC guidance however if a new insulin is being considered then the APC should bear the checklist in mind.
- A member stated that the checklist would not need to be used retrospectively to evaluate insulin preparations currently on the formulary.
- A member raised that risks may vary from organisation to organisation. For example, the risks in an acute setting may be different to risks in a mental health setting therefore a risk assessment at this stage may be difficult. The risk assessment may not apply to all the organisations in equal measure.
- A member suggested that the completed checklist is submitted with any new applications for insulin preparations.
- A member raised that DMMAG should have sight of the checklist for their review of the formulary chapter. Furthermore, a local risk assessment tool for high strength insulins was approved by APC in October 2017.

0718/12 Minutes of the meeting held on Thursday 14th June 2018 – for ratification

The minutes of the meeting held on Thursday 14th June 2018 were discussed for accuracy.

- Page 13: To be amended to read "EAMS recommendation".
- Page 14: Date of next meeting to be updated to Thursday 12th July 2018

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

The DST for Eclypse® was also approved for publication.

0718/13 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:

- 1618/06- Wound Care Group Documents. Update: Feedback from APC given to Wound Care Group and are now awaiting the final amendments.

- 1618/09- European Medicines Agency safety update Esmya® (ulipristal acetate): Contact gynecology colleagues to seek views regarding a change of RAG rating to RED. Update: The APC secretariat has received feedback from UHB NHS FT, SWB NHS FT and BWCH NHS FT who agree with the proposed change from AMBER with ESCA to RED status.

ACTION: Update formulary status of Esmya® to RED **APC sec**

- 1618/10- Emollient Bath Additives: Approach dermatologists to comment on the article and summarise their position on the use of bath emollients. Update: Ongoing

- 0518/A05- Novel Oral Anticoagulants in Atrial Fibrillation – abbreviated application form: To contact AHSN regarding their work into the anti-coagulation pathways. Update: Ongoing

- 0518/10- Feedback from Midlands & East Regional Medicines Optimisation Committee- Secondary care representatives to report back regarding Ethambutol 400mg in 5ml, Pyrazinamide 500mg in 5ml and Isoniazid 50mg in 5ml. Update: No feedback received. Ongoing.

- 0518/11- Palliative care proposal: to ask the local palliative care community to convene a subgroup Update: Ongoing

- 0418/08- APC membership list. Update: Require information from UHB NHS FT. Ongoing.

- 1117/AOB- Formulary for patients in transition from paediatric to adult services. Update: Ongoing

0718/14 NICE Technology Appraisal (TAs)

In June 2018, there were 7 TAs published; of these, 6 are NHSE commissioned, 1 is CCG is commissioned which is:

- Guselkumab for treating moderate to severe plaque psoriasis.

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

Any other business:

1. **Unavailability of Modecate® (fluphenazine)**
   Modecate® will be discontinued by the UK manufacturer by the end of 2018.

A representative from BSMHFT stated the Trust plan to import Modecate® from a European manufacturer for existing patients stabilised on Modecate®. Modecate® will not be newly initiated for any patients. The same manufacturers that will be accessed by BSMHFT can be accessed by community pharmacies, therefore the trust representative is willing to share the details with primary care.

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

- A member asked if it is known how much Modecate® is prescribed by primary care. A representative stated that within the BSOL CCG area, there are 55 people who have had prescriptions for this in the last 6 months.
- A CCG representative anticipates that there may be some uncertainty among GP to prescribe an unlicensed medicine.
- A member expects that the majority of the patients have been stable on Modecate® for a long period of time. The BSOL CCG representative stated that the majority of patients identified are aged 50 and over.
- A member stated that most patients are likely to have been discharged to primary care by now. Some of these patients may need a dose review and therefore referral back to secondary care.
- A member expressed caution against a wholesale transition from Modecate® to an alternative product due to the risk of destabilising patients.
- A member highlighted that the recommendation of surrounding APCs has varied.
- A member asked secondary care representatives how many patients are there potentially on Modecate® within the trust. A member responded that figure may be between hundreds to thousands.
- Primary care representative members were asked how they would feel about prescribing an unlicensed preparation of Modecate® and if they would refer them back to secondary care. The consensus was that they would refer to secondary care as there would be concerns of patients destabilising. Another concern was that GPs would have to communicate to community pharmacies to order through a specific supplier. A primary care representative stated in this instance they would refer back to secondary care for a review of the agent and if required the trust could source the product through their channels. There was a question as to whether these long-standing patients still require a depot injection as compliance may now be poor.
- A member anticipated that referring large number of patients to secondary care may cause operational problems within the mental health Trusts as waiting times are increasing.
- It was clarified that manufacturing of the product had already ceased. It is estimated that an impact may be felt in the next three to four months.
- A secondary care representative stated that when supply issues occurred with trifluoperazine, the supplier details were made available to primary care and issues were circumvented; GP were able to continue to prescribe this for their patients.
- A member asked whether advice and guidance can be created and disseminated to primary care colleagues to avoid large number of referrals back to secondary care.
- A member suggested secondary care liaise with the Local Pharmaceutical Committee (LPC) regarding how community pharmacies can source the product.

- It was agreed that CCG representatives will highlight to the identified primary care prescribers that there are supply issues with Modecate®.
- CCGs to liase with BSMHFT to resolve issues as they arise.

The Chair thanked the members for their input today. The meeting closed at 15:55.

Date of next meeting: Thursday 13th September 2018 14:00 – 16:45
Birmingham Research Park