AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 9th July 2015
Birmingham Medical Institute, 36 Harborne Rd, Birmingham, West Midlands B15 3AF.

PRESENT:

Dr Lisa Brownell	LB	BSMHFT (Chair)
Dr Paul Dudley	PD	Birmingham CrossCity CCG
Alan Pollard	AP	Birmingham Women's NHS FT
Alima Batchelor	AB	Birmingham South Central CCG
Prof Robin Ferner	RF	Sandwell & West Birmingham Hospitals NHST
Elizabeth Walker	EW	Sandwell & West Birmingham CCG
Inderjit Singh	IS	UHB NHS FT
Prof Jamie Coleman	JC	UHB NHS FT
Mark DasGupta	MD	Birmingham CrossCity CCG
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
Tania Carruthers	TC	HEFT NHS FT
Nilima Rahman-Lais	NR	Solihull CCG
Tony Green	TG	Patient representative
Brian Smith	BS	The ROH NHS FT
Carol Evans	CE	HEFT NHS FT/Solihull CCG
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Jonathan Horgan	JH	Midlands & Lancashire CSU

IN ATTENDANCE:

Kalvinder Bansal	KB	Minute taker, Midlands & Lancashire CSU
Dr Das Pillay	DP	Consultant Microbiologist for Item 0715/11
Rakhi Aggarwal	RA	Interface Pharmacist, BCC CCG for Item 0715/11

No.	Item	Action
0715/01	**Apologies for absence were received from:** • Dr John Wilkinson • Kate Arnold • Mandy Mathews • Maureen Milligan • Nigel Barnes • Dr Timothy Priest • Patricia James	
0715/02	**Items of business not on agenda (to be discussed under AOB)** No items were raised.	
0715/03	**Declaration of Interest (DoI)** The Chair reminded the members to submit their annual declarations to the APC Secretariat. The Chair also asked the committee to declare any interest that may be relevant to the business to be discussed at the meeting. No declarations were raised.	
0715/04	**Welcome and Introductions** The Chair welcomed those present to the Area Prescribing Committee. Introductions were not deemed necessary.	
0715/05	**Minutes of the Meeting held on Thursday 11th June 2015** The minutes of the meeting of 11th June 2015 were discussed for accuracy. The minutes were approved with no further amendments and the Chair asked the recording of this meeting to be deleted in accordance with the procedures.	
0715/06	**Matters arising – Action Table** The Chair asked if there were any matters arising not on the table. TC asked if there was a timetable for the release of the ESCAs and RICaDs; IH confirmed that the drafts were now ready and would be circulated following this meeting. This had been delayed to prevent confusion on the papers for today. MD reminded the members that these were final drafts and would be published on the website unless there were objections or comments. It was agreed that if significant comments or concerns were raised by members on an ESCA then this would be brought back to the APC otherwise they would be published. **Action:** • **IH to circulate final drafts of ESCAs and RICaDs** — **IH** • **Members to relay comments to secretariat on any documents that should NOT be uploaded by 23rd July** — **All** • **Upload documents to APC website by first week in August** — **IH** RF highlighted an issue with the quantity and size of emails from the APC secretariat, which were causing problems due to the limited capacity of his inbox. He enquired if a cloud-based system could be used to access the files rather than attach them to emails. BS is aware that NHS IT teams ban the use of a cloud drop-box due to lack of security. JH mentioned Office 365. DH stated his Trust use links to an internal shared drive, but this is not	

accessible by all the members so not appropriate.
Action: JH to investigate alternative delivery of / access to APC documents than email attachments and report back in September. **JH**

0615/03 Declaration of Interest **On-going**
Members to submit their annual declarations for 2015/16 to APC secretary.

0615/06
RiCaD for Rivaroxaban in ACS – Circulate to specialists for comments. **Closed**
Update: IH circulated to Dr W. Lester, Dr C. Kartsios and Dr R. Davis on 1st July 2015. No comments received to date.

HRT and OC review – Circulate CSU's document to members. **Open**

RICaD for Grazax – **Open**
Dr J. North has responded to IH and sent a guideline for immunotherapy selection for use in grass pollen allergy. He has also asked if the APC was considering which specialist centre would be most appropriate to initiate Grazax. It was agreed that IH would send him the RICaD template and ask him to complete the RICaD for approval without which amber status cannot be supported. IH to advise him that it is not the role of the APC to advise on which centres should provide services as this was a commissioning decision.
Action: IH to send RICaD template to Dr North and relay comments from APC members. **IH**

0615/07 NICE TAs –
- Add 3 NICE TA approved drugs to APC website as Grey status (apixaban, ustekinumab, vedolizumab) **Closed**
- Draft Rifaximin RICaD is on the agenda

0615/10 Insulin degludec RICaD
To be discussed on the agenda

0615/11 Utrogestan caps 100mg
AP is liaising with Miss L Robinson. **Ongoing, due Sept.**

0615/12 Eslicarbazepine
- Inform Dr McCorry of APC decision **Closed**
- Liaise with Dr McCorry to revise ESCA as discussed **Closed**
- Circulate revised ESCA to APC members for ratification **Open, due Sept**

0615/13 Generic Sildenafil for digital ulceration
Add generic sildenafil to APC website as Red status. **Open**
IH confirmed this would be published shortly. It was confirmed that this would be published under rheumatology and a signposting message would be placed with the other Chapters relevant for this drug as this does not usually appear in the rheumatology chapter.

0615/14 Stiripentol & BCH **Open**
AB outlined that A Sinclair has emailed concerns about the principles of BCH attendance and the joint formulary. It was agreed that LB, PD, AB and JH would review and engage BCH to discuss further.

0615/16 Ciclesonide **Open**

IH to request further evaluation from the Respiratory Network/Col Wilson. Referred to September.

0615/15 Any other business

Mycophenolate: use in connective tissue disease. **Open**

IH confirmed a new drug application is not required as this is in tariff and is standard therapy in connective tissue disease. It would therefore be included as Red on the Trust formulary. However, the APC needs to consider if shared care is appropriate before reviewing the RAG status. It was agreed that a draft ESCA would be discussed at the September meeting.

Action: IH to circulate draft ESCA prepared by UHB NHS FT. **IH**

0715/07 **NICE Technology Appraisals (TAs)**

IH presented the enclosures 3a and 3b.

- **NICE TA adherence checklist**

Confirmed that ofatumumab, obinutuzumab, omalizumab would be listed as Red status, as commissioned by NHS England.

Ustekinumab for PA and vedolizumab for UC are commissioned by CCGs but supplied in secondary care only, so would be listed as Red status.

Apixaban in DVT or PE: amber with a RICaD, in line with other NOACs already on the formulary.

Action: Update RAG status of formulary entries as per minutes **IH**

There was further discussion about the NOACs in general. It was agreed that there would be a review of NOACs to identify if there were any preferences or recommendations that would be in line with NICE and improve the safe use of these agents whilst maintaining cost-effectiveness across the health economy. MD stated that it was public knowledge that rebates on dabigatran and rivaroxaban were available to CCGs. BS also pointed out that NHS Trusts can negotiate favourable rates in secondary care but this information is commercially sensitive. It was agreed therefore that a piece of work was required to look at acquisition cost, indications, special precautions, horizon scan availability of antidotes. IS suggested updating a previous document presented to APC members. BS proposed adding availability of PAS or rebates but withholding details.

Action: Schedule review of NOACs for October. **CSU team**

- **Rifaximin RICaD for ratification**

Dr Holt has enquired if CCGs were planning to draw up a list of specialists / Trusts approved to initiate rifaximin and issue the RICaD. In line with the previous discussion around Grazax, this was not the role of the APC.

JC proposed further minor amendments: under agreed indications, remove the word *named* in front of Consultant Gastroenterologist and add the words"*or a Consultant Gastroenterologist with a recognised interest in liver disease*" after reference to a Consultant Hepatologist throughout the document. Subject to these amendments this is approved for publication and sharing with MM.

Action:

- **IH to make final amendments and publish** **IH**
- **Send final version to MM to share with Worcestershire Trust and CCGs** **IH**

0715/08 **Trust Chairs non Formulary approvals**

UHB NHS FT has submitted their recent approvals. No further submissions have been received.

0715/09 **Feedback from Away Day, 26th June 2015.**

The draft notes of the away day were reviewed for accuracy by the members.

The following amendments were agreed;

Page 4, amend wording at end of paragraph 8 to: *RF requested information about usage of PF eye drops at UHB.*

Action: all Trust leads (including BMEC) to report prescribing data on PF eye drops as percentage of total eye drops to APC secretary by 31st August to be reviewed in September. **Trust leads**

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Page 9, remove action. Change to: Note: a new drug application for ciclosporin eye drops (Ikervis®) may well be forthcoming once launched.

Page 11, delete sentence: Requests for new additions… and amend to note as above.

Add **Action: IH to inform LT and SR that new drug applications will be required for any new ocular lubricants and other products such as Ikervis to be considered for addition to the formulary.** **IH**

Page 12, actions are listed. IH to ensure these are added to the APC Action table.

Page 13, delete drugs from "The following are not…to " and replace with this paragraph when writing to BMEC clinicians:
The APC noted that novel ocular lubricants and second line anti-infective eye drops (list them) were included in the documentation you circulated but are not on any formulary. This is a reminder that you would need to submit new drug applications in the usual way.

Page 14, typo 2nd line- change to antifungals.
Page 14, under section 11.8.2, typo, and change to apraclonidine.
Page 14, nepafenac- change last sentence to read: *Application from UHB to be forwarded to APC for a future meeting.*

Page 15, section 8.1 Cytotoxic drug. Typo, change to Cyclophosphamide.

Page 15, delete action at the bottom of the page and change to: *NOTE: develop/ review ESCA. This will be considered when the relevant BNF chapter is reviewed.*

Page 16, fulvestrant, noted as: UHB to confirm if remove is appropriate. IS has confirmed at today's meeting that removal from formulary is appropriate as this is historic prescribing, initiated pre NICE.

MD commended IH and JH for producing such a comprehensive set of notes in such a quick time from an Away day and asked that this was minuted.

IH sought confirmation that the Away Day notes are not published on the website. This was confirmed by the members.

Action: add all Actions from Away day notes to main Action table. **IH**

0715/10 **COPD – applications for 6 new inhalers, ratification of Decision Support Tools.**

IH presented the DSTs for the 6 inhalers discussed on the Away day for ratification. It was noted that the membership was not quorate on the Away Day due to only one non specialist trust being represented. Ratification is required at the Committee today.

The members reviewed the Draft DSTs presented by IH.

Subject to amendments these were ratified.

Action: IH to inform the Respiratory Network consultants, update formulary and publish the DSTs. **IH**

0715/11 **BNF Chapter 5 – Antibiotics**

Dr Das Pillay, Consultant Microbiologist, PHE
Rakhi Aggarwal, Interface Lead, BCC CCG

The Chair welcomed Dr Pillay and Ms Aggarwal to the meeting.

Dr Pillay presented the enclosures to the group.
He reminded the group that he was working with the Birmingham Antibiotics Advisory Group (BAAG) which had representation from CCGs and antibiotic stewardship committees of Trusts such as UHB, HEFT, Sandwell and West Birmingham Hospitals and Birmingham Children's Hospital.

The first document was a summary of the recommended RAG ratings for the various drugs included in BNF chapter 5, based on the APC criteria.
The second document was a draft Primary Care antimicrobial guideline. It is based on national PHE guidance, with collaboration from BAAG representatives, and presents a harmonised approach to antimicrobial prescribing.

The Chair asked for any comments or questions from the members.

IH reminded the members of a suggestion put forward previously: agents to be rated as GREEN if used in line with antimicrobial guideline. DP suggested this may not be appropriate as it would be difficult to ascertain the indication for which it was prescribed, unless retrospective audits were carried out.

IS asked for confirmation of stakeholders from each Trust who attended the BAAG. DP confirmed that the members included; Dr M Gill (UHB), Dr D Pillay (HEFT), Dr M Patel (BCH) and Dr N Wickramasinghe (SWB Hospitals) as

well as other members of Antimicrobial stewardship committees from Primary Care (CCG and GP).

There was discussion about the proposed formulary status of the drugs.
SSN sought clarification on the drugs labelled RED Remove and just wanted to confirm the intended status was not BLACK.

It was agreed that all the agents currently listed as RED and RED remove would stay on the list as RED, unless the APC members were certain that these agents would never be used or were not appropriate, in which case BLACK would be used. JC felt more comfortable with this decision as it would cover all clinical scenarios, including Out Patient Antibiotic Therapy (OPAT).

RF commented on the potential for confusion by having a similar colour scheme in the Primary Care guidelines (Green for first line option, Amber for second line option) to the RAG ratings on the APC formulary which had different definitions.

TC asked about the status for antimicrobials used for dermatology indications such as dapsone: currently listed as RED, but is currently AMBER with an ESCA at HEFT when used for dermatitis herpetiformis. DP advised that BAAG would take advice from dermatologists and it doesn't don't have the expertise to advise on these specialist areas.

As further example, JC quoted demeclocycline and its use in endocrinology (Chapter 6) for SIDH, and reminded the Committee that rifaximin had recently been approved as AMBER with a RICaD.

The conclusion was that the RAG rating needs to correctly reflect the use of the drug in chapter 5, but also cross-reference to other chapters if necessary where it may have a different RAG rating. Links to other chapters can be included on the website.

JC sought clarification on the terminology used in the BAAG comments column, specifically on the difference between infection specialist and specialist in general. A clinician would use sensitivity reports and not necessarily need recommendation from a microbiologist.
DP and RA will review these.

RF further suggested the comments "in line with formulary" be changed to "in line with Primary Care guideline".

DP confirmed that the draft Guidance is based on PHE's last published update (Nov 2014), however their latest update has only recently been released into the public domain. BAAG has reviewed the draft guideline to ensure it is aligned with this latest advice from PHE, but this was too late to circulate to APC members. An updated document will be circulated in due course.

The most significant change in the PHE guidance relates to recommendation for prescribing of antibiotics for UTI. This is no longer trimethoprim first line. Medicines management implementation tools can be used to support the advice in primary care and RA confirmed a one page summary has already been developed to support this.

LB queried the amber status for benzathine benzylpenicillin, cefotaxime and ceftriaxone injections and wondered if transfer to primary care prescribing was intended. DP referred to various models of delivery of parenteral antibiotics in the community which may involve GP prescribing.

MD enquired on the status of fidaxomicin (section 5.1.7). DP confirmed this was primary therapy for relapsing *C.Diff,* and an option for patients with severe *C.Diff.* IS confirmed it was included on UHB formulary. JC commented on the cost (£1,400 for 10 days).

DP was happy to defer decisions on RAG status for non-infection related indications (e.g., dapsone, demeclocycline) to the appropriate speciality.

Actions: BAAG to

- **Change all RED remove to RED, unless not recommended at all, in which case BLACK.** **BAAG**
- **Review colours to identify first line and second options in Primary Care Antimicrobial Guidance, and avoid duplication of RAG rating colours to avoid confusion.** **BAAG**
- **Clarify differentiation between specialist and infection specialist in comments column.** **BAAG**
- **Change wording to "in line with Primary Care antimicrobial guideline" instead of "formulary".** **BAAG**
- **Confirm RAG status of benzathine benzylpenicillin, cefotaxime, and ceftriaxone injections.**

The Chair thanked DP and RA for their support today and they left the room.
It was confirmed that the documents once finalised would need to be ratified at the September meeting if available. Further attendance of DP or RA would not be required for this.

0715/12 **New Drug Application: Niquitin oral strips 2.5mg.**

PD was of the view Nicotine Replacement Therapy (NRT) is already included on the APC formulary, IH also advised that the Committee had previously decided that there was no need to review similar brands of formulary approved products unless there was a clinical or safety issue to be considered.
IH reminded the members that an abbreviated application had been requested for this product but as a full application had already been prepared, this has been shared.

IH summarised the information as follows:

- NICE Public Health Guidance"Smoking Cessation Services in Primary Care" makes no distinction between NRT products.
- It is an established licensed product. Available data support the bioequivalence of 2.5mg oral strips to 2mg nicotine lozenges, for which efficacy has been determined.
- Niquitin strips are more costly than 2mg nicotine lozenges and gum; however they are less costly than nicotine inhalator, sprays and sub-lingual tablets.
- No evidence it is less safe than alternative NRT products.

It was confirmed this was approved as Green. Rationale: NRT is already

included on APC formulary; NICE makes no distinction between NRT products/ delivery systems. LB completed the DST accordingly.
Action: IH to inform clinician of the decision, update formulary and publish DST. **IH**

0715/13 **Insulin degludec-RICaD**

IH brought this back to the Committee once again. Although it had been approved in June subject to amending the title and removing the recurrent DKA indication, further discussion with the Diabetes clinicians had confirmed that recurrent episodes of DKA in otherwise compliant patients would be far more in keeping with the NICE guidance.

A number of further amendments were discussed and agreed:
AP – typo: demonstrate
RF – reworded discontinuation criteria to read: Where there is no significant reduction in the frequency of nocturnal and/ or severe hypoglycaemia episodes after 6 months of treatment, insulin degludec will be stopped.
OR Where there is no significant reduction in frequency of hospital admissions after 6 months of treatment, insulin degludec will be stopped.
MD – remove any reference to trade name Tresiba, and only use generic name, insulin degludec.
Action: IH to make final amendments and publish **IH**

0715/14 **Lidocaine 5% Plasters – draft RICaD**

IH has circulated the first draft RICaD prepared by TP. LB requested comments to APC secretary by email, and this be brought back in September.
Action: members to email comments on draft RICaD to APC secretary **All**

0715/15 **Prioritisation of next BNF chapters for harmonisation**

The members agreed to harmonise Chapters 9 (Nutrition) and 12 (ENT) at the September Away Day; Chapter 13 (Dermatology) at the December Away Day.

0715/16 **Any other business**

- Dates of APC meetings in 2016: the members requested this information.

Action: circulate list of APC meeting dates for 2016 **CSU**

LB thanked the members for their input today. The meeting closed at 16:15.

The members were reminded that there will be no meeting in August.

Date of next meeting
Thursday 10th September 2015 14:00 – 16:00
Birmingham Medical Institute,
36, Harborne Road, Edgbaston B15 3AF
Solomon Wand Room, 1st Floor.