AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 12th February 2015
Birmingham Medical Institute, 36 Harborne Rd, Birmingham, West Midlands B15 3AF.

PRESENT:

Dr Paul Dudley	PD	Chair, Birmingham CrossCity CCG
Alima Batchelor	AB	Birmingham South Central CCG
Dr Adnan Masood	AM	Birmingham CrossCity CCG
Dr Jamie Coleman	JC	UHB NHSFT
Dr Lisa Brownell	LB	BSMHFT
Dr N Shaheed	NS	Birmingham South Central CCG
Dr Timothy Priest	TP	HEFT NHS FT
Elizabeth Walker	EW	Sandwell and West Birmingham CCG
Inderjit Singh	IS	UHB NHSFT
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Jonathan Horgan	JH	Midlands & Lancashire CSU
Kate Arnold	KA	Solihull CCG
Mark DasGupta	MD	Birmingham CrossCity CCG
Nigel Barnes	NB	BSMHFT
Satnaam Nandra	SN	Birmingham CrossCity CCG
Tania Carruthers	TC	HEFT NHS FT

IN ATTENDANCE:

Patricia James	PJ	APC Secretary, Midlands & Lancashire CSU (minute taker)
Dr Das Pillay	DP	Birmingham Antibiotic Advisory Group, Consultant Microbiologist, Public Health England, for item 0215/10
Dr Farida Shah	FS	Consultant Dermatologist, UHB NHSFT, for item 0215/11

No.	Item	Action
0215/01	**Apologies** Apologies for absence were received from: • David Harris, Birmingham Community Healthcare NHST • Mandy Matthews, NHS England • Prof Robin Ferner, S&WB Hospitals NHST • Tony Green, Patient Representative	
0215/02	**Items of business not on the agenda (for AOB)** The Chair circulated proposed dates for the APC away days for June, September and December 2015 and asked members to pass round sheets to give clearer indication on availability to the APC Secretary. • APC membership to be published on website • Email from Inderjit Singh re: tapentadol • Doodle poll dates for June, Sept and Dec • Chapters for discussion at March away day	
0215/03	**Declaration of Interest (DoI)** There were no new interests to be declared. There was one outstanding declaration confirmed. APC secretary to email form for completion. MD sought clarification of whether the declarations of interest already declared were sufficient from members. It was agreed the CSU would audit the DoI and feedback. **Action: CSU to audit DoI and feedback.**	**CSU**
0215/04	**Welcome and introductions** The Chair welcomed the members	
0215/05	**Minutes of the meeting (8th January 2015)** The minutes of the meeting held on Thursday 8th January, were discussed for accuracy. IH confirmed that there had been one amendment from SN which had been incorporated. The Chair stated therefore that the minutes should be approved as a true and accurate record.	
0215/06	**Matters arising – Actions Table** **0115/07 NICE technology Appraisals (TAs)** To invite the DPHs to the next meeting to advise on nalmefene; IH confirmed that Directors of Public Health were contacted. Dennis Wilkes, (Birmingham) is aiming to attend the March APC meeting. KA and MD confirmed they would contact with their DPHs and request input at the same meeting. The Chair confirmed that it would be ideal to have all 3 representatives attending the meeting.	

Open

0115/09 New drug application: alogliptin (Vipidia®) Dr Basu – SWB NHST

Contact the diabetes network for views for the away day in March; ***Closed***

Decision to be relayed to Dr Basu by the APC secretary by 15th January 2015 in line with the APC policy; ***Closed***

0115/11 Any Other Business

Ratification of Chapter 3 (SN);

Add Chapter 3 ratification to the February APC meeting agenda ***Closed***

Circulate electronic copies of updated Chapt 3, colours in line with RAG status ***Closed***

Melatonin

Add melatonin to the January APC away day agenda ***Closed***

Feedback from poll for date of March APC away day;

Send out doodle poll dates for June, September and December; ***Closed***

1214/03 Declaration of Interest

Contact the non-attendees;

JH advised that he had contacted Anthony Sinclair from BCH about attendance. He was unable to attend today's meeting but has suggested a separate meeting is set up outside this group to discuss how this impacts on the BCH formulary. AB had also met with Anthony Sinclair and discussed attendance.

JC expressed his concerns around developing a subgroup or separate process for BCH and highlighted that the formulary for Children should complement the adults formulary recognising that patients progress from one to other.

JH and AB to liaise further with Anthony Sinclair in relation to their representation and input to the APC and feedback at the next meeting. ***Open***

1214/06 Matters Arising – Action table

Review appeal section of the policy**;**

This is to be discussed on agenda. ***Open***

Email Dr Kaur appeal process form;

JH confirmed that Dr Kaur no longer wishes to proceed ***Closed***

Circulate appeal template to members;

Done ***Closed***

1214/09 Feedback and actions from the November Away Day

Review "restricted form" terminology, consider RICaD;

LB advised that BSMHFT have some medicines that they manage as restricted use and they were considering whether some of these needed a RICaD to remove internal processes. This would be considered at the March away day as part of the work around RICaDs. ***Open***

1214/12 ESCAs and RICaDs templates for ratification

Update: ESCA template approved, RICaD template and completed documents to be ratified for the March Away Day;

SN confirmed that these are to be reviewed at the March away day ***Open***

1214/13 Lubiprostone

RICaD to be developed;
To be discussed at the March Away day ***Open***

1114/08 Decision to decline prescribing of medicines recommended by hospital specialist.

Email revised form to all CCG members for dissemination within own organisation and implementation;

SN confirmed contact links are still required for SWB and BCH. ***Open***

There was a group discussion about the processes for this form. Individual Trusts can decide that the form should go to the hospital specialist as well as the agreed central contact point; however UHB want to continue with their process of a single contact point which works well and is efficient.

It was agreed the form should not be the process for resolving any immediate continuity of care patient issues. The form needs to advise GPs that they should contact the Clinician directly wherever possible. To support audit and understanding of the quality of referrals or decisions to decline prescribing the forms should be submitted to each Trust separate to any clinical discussion. It was noted that this is a voluntary process.

1114/09 ESCAs: Azathioprine for IBD, oral methotrexate in adult patients (gastroenterology).

APC Branding and formatting to be finalised.
To be discussed at the March Away day ***Open***

1114/11 New drug application: Brimonidine 3mg/g topical gel (Mirvaso®)

Update APC formulary website
As Dr Kaur is not proceeding with an appeal, this has now been published on APC website. ***Closed***

Review APC policy to clarify process around drugs approved as RED status by Trusts DTC/Formulary groups;
Update: Make amendments as per January minutes and recirculate to members for ratification at February meeting**.** ***Closed***
See further discussion below.

1114/13 Antibiotic harmonisation by regional group:
Invite Chair to come to the APC;
Share our RAG Rating information with the regional group

Dr Das Pillay attending for item 0215/10 on today's agenda. ***Closed***

Revised APC Policy- enclosure 2b

JH outlined updates to the Policy in relation to Red drugs and the Appeal process.

It was confirmed that the word 'senior' would be removed from the section 12.6.

IS raised concerns that section 7.3.6 did not sufficiently clarify that the red status relates only to drugs prescribed and maintained by Trusts. Wording to be amended to "Drugs will be included as red formulary status where NHS Trusts maintain prescribing for patients to take home or are taken by the patient in the community outside the hospital."

Action: Amendments to be made and the document circulated to members. **CSU**

0215/07 **Nice Technology Appraisals (TAs)**

IH confirmed there were no new relevant NICE TAs for discussion.

0215/08 **Trust Chairs non Formulary approvals**

The Chair confirmed that these had been circulated with the papers to the APC members.

0215/09 **Chapter 3 Ratification**

Page 3 Section 3.2

IH sought confirmation from SN that it was agreed to remove Seretide evohaler from the formulary, as minuted at the December APC meeting. MD advised that this was also minuted by the Respiratory Network to remove.

It was noted the formulary relates to new patients or those not controlled/ stepping down from high dose ICS requiring a review. JH questioned whether it was misleading to use the word 'switch' and it was agreed that this actually means review and consider switch if appropriate.

Action: SN to amend wording in master document, and change Seretide to BLACK (non-formulary) **SN**

MD raised a potential issue with Symbicort turbohaler, or more specifically generic prescriptions for budesonide/formoterol dry powder inhalers as these can be dispensed as either Symbicort ® turbohaler or a new preparation DuoResp Spiromax ®.These are completely different devices and there is a significant difference in costs. There is potential for device switching without the prescriber's intention with generic prescriptions. A suggestion to prescribe by brand was made. It was agreed MD would raise a question of the respiratory network on the use of DuoResp Spiromax ®.

Action: MD to discuss variations in devices for budesonide/ formoterol dry powder inhalers with respiratory network. **MD**

Page2, section 3.1

IS raised concern that tiotropium is the only long acting muscarinic antagonist (LAMA) licensed for asthma. Aclidinium and glycopyrronium are only licensed for COPD. There was discussion on the effect on the formulary positioning.

KA highlighted that the new draft asthma guideline, although supporting the use of tiotropium, places it well along the treatment pathway, so a Green RAG status does not fit well for asthma.

It was confirmed that tiotropium should be green for COPD, amber for asthma. The other LAMAs should be green used in accordance with COPD guidance.
Action: SN to amend master document as minuted. **SN**

IS requested that Methotrexate , although not listed in this section, be linked from elsewhere in the BNF as it is used as a steroid sparing agent/ in difficult to manage asthma.

SN confirmed that the interstitial lung disease section, together with nebulised antibiotics for non-CF patients would be reviewed by the Respiratory network and comments brought to the APC.

Ciclesonide
IS highlighted that this was marked as 'on hold'.
RF had requested more evidence to be presented to the group on the place in therapy and steroid sparing effect.

Action: IS to request Col. D. Wilson to attend or identify a suitable representative to present evidence for ciclesonide. **IS**

IH commented she had received an email from Dr Alice Turner (Consultant Respiratory Medicine HEFT) detailing the progress of the Respiratory network with the new COPD guideline and giving advance notice to the APC of forthcoming new drug applications to support the guideline. SN/MD confirmed that the network has already undertaken a systematic evidence-based review of the new drugs licensed for COPD, compared them to current drugs and considered cost –effectiveness and device consistency. The 6 drugs they will apply for are:

1) Indacaterol
2) Ultibro – indacaterol/glycopyrronium in one inhaler
3) Relvar – vilanterol/fluticasone furoate
4) Duaklir – aclidinium/formoterol
5) Anoro – vilanterol/umeclidinium
6) Incruse – umeclidinium

The Respiratory network has shared out the formulary requests to be developed and reviewed locally.
Concerns were expressed in relation to the influence of pharmaceutical industry on these submissions. Any submissions will follow the APC process and policy.
It was suggested that the 3 LABA/LAMA combination inhalers be put forward to a single Trust DTC so that they could be assessed as a group, rather than at individual DTCs.
JC summarised the members view as: the APC heard the Respiratory network was looking at these agents and was pleased they were considering splitting up the work with drug applications across the 3 Trusts. However the APC suggests it would be better to hear common combination inhalers similarly, either by presenting to the same Trust's DTC, or across the Trusts but brought to a common APC meeting. It would be up to the Respiratory network to plan this. IH to feed back to Alice Turner the views of the group.
Action: IH to respond to Alice Turner **IH**

Nebulised Dornase alpha/ tobramycin/ colomycin
MD requested clarity on the ESCAs in line with advice from Mandy Matthews. No ESCA is required for new patients as prescribing is retained in secondary care. These are only required for existing patients (started before April 2013) until repatriated to NHS England.

Action: SN to amend wording around ESCAs **SN**

0215/10 **Birmingham Antibiotic Advisory Group: Dr Das Pillay**
Consultant Microbiologist, Public Health England

Dr Pillay was welcomed by the Chair and thanked the members for inviting him to the meeting. He explained that he is a consultant microbiologist working with the Antibiotic stewardship team at HEFT. The BAAG was founded in around September 2014 with the aim to report to APC. The group has a good deal of credibility as it represents the antibiotics stewardship from UHB, Heartlands and City and Sandwell. They have had 2 meetings to date. The next meeting will be held at City Hospital on 24 March 2015 where they are hoping to finalise the draft proposal for the APC. The BAAG has representation from all 5 CCGs. The BAAG has reasonable expertise in formulary production.

The main aim was to support formulary discussions. A secondary aim was to support stewardship of antibiotics. This needs more development. The BAAG also wants to be involved in harmonising guidelines across the Area. Work has progressed on guidance for management of cellulitis to date.

There is already a joint formulary for primary care for Heartlands and UHB with CrossCity and Solihull CCGs. The group is comparing these documents and the latest PHE advice and aims to harmonise and agree this guideline. This will be sent to the APC for review and ratification. They have reviewed the RAG formulary definitions and are able to incorporate these into the new guidelines.

There are some difficulties, mainly with the variance in use of home IV antibiotics across the 3 Trusts. The use of these drugs in private organisations also adds to the complexity, and needs to be considered.

Dr Pillay then discussed some of the concerns with multi-drug resistant organisms, namely carbapenemase-producing enterobacteriaceae, and highlighted that a range of new drugs will be coming out soon to address this. He requested that the BAAG are part of the process to support the APC review these drugs.

He raised concerns about Green RAG status from an antibiotic point of view and requested a tier method to discourage first line prescribing of antibiotics which were second line options.

Dr Pillay requested that the APC is vigilant to APC formulary requests bypassing the BAAG advice.

It was confirmed that the advice does cover paediatrics.

There was discussion around the use of the RAG formulary status and the difficulties it caused as the use of antibiotics was condition-specific. A drug may be first line for a specific condition, second-line for another and not approved for a third. MD proposed to leave it to the BAAG to decide how to portray this to GPs, rather than the APC impose the RAG system which has never worked in the past for antibiotics. JC was concerned a different ranking system would cause confusion. KA proposed that commonly used antibiotics in Primary care would be classified as Green and clearly annotated "when used in line with the antibiotic guidelines".

CCG leads confirmed that primary care teams monitor and audit antibiotics locally to support stewardship.

JC asked whether we make the BAAG a more formal subgroup. It was agreed that more formal arrangements were not required and that there was a range of groups or clinical experts that the APC can seek advice from on different drugs. The APC supports the BAAG in its aims and would ensure the BAAG was consulted in any antimicrobial drug applications.

There were questions about the attendance and quorate of the BAAG meetings. Dr Pillay confirmed that members are part of the network and can be consulted on any applications or questions. Dr Pillay reassured the APC that the BAAG also recorded Declarations of Interest. IS proposed that the local DTCs are informed by members that there is a BAAG which can provide expert advice in this area.

Dr Pillay advised that they would be able to present antibiotic recommendations to the APC following their meeting of 24th March 2015.

Dr Pillay was thanked by the Chair for attending then left the meeting.

Dr Farida Shah joined the meeting.

0215/11 **New drug application: Dr Farida Shah, UHBFT**
Ingenol mebutate gel (Picato gel®)

The Chair welcomed Dr Shah to the meeting. She presented the new drug application for ingenol mebutate gel (Picato gel®) to the group.

She outlined that they would like the option to use this drug, particularly for elderly patients, patients in care homes in view of the shorter course of treatment. GPs may wish to prescribe this agent prior to referring to secondary care for cryotherapy.

One advantage of this drug compared to others for this condition is the short course of treatment (2-3 days). Solaraze® (diclofenac 3% gel) is used for 60-90 days, Efudix ® (fluorouracil 5% cream) is used for 3-4 weeks. Localised skins reactions do occur but as the duration of treatment is short severity is usually not significant.

Dr Shah confirmed there hadn't been any comparative studies with other treatments published although studies are underway.

PD enquired about the formulary status. Dr Shah proposed a Green RAG status to allow GP prescribing would be suitable; this would avoid referral to specialists to then be advised to use Picato®. If there was doubt over the diagnosis (i.e. squamous cell carcinoma) then patients could be referred in.

NICE have not carried out any healthcare technology appraisals on topical patient-applied actinic keratosis treatments, however both SMC and AWMSG had accepted Picato® for use within Scotland and Wales respectively.

Dr Shah was asked why two products would be needed, what the difference was between them and whether it filled a gap in the current treatment options. Dr Shah highlighted that two options are usual to support;

- Fluorouracil cream is useful for hyperkeratotic lesions or where only one or two lesions present.
- Ingenol gel would be a better option if field change or for elderly patients/ patients unable to comply with long treatment.

Dr Shah felt this was a better first line treatment compared to diclofenac gel.

JC clarified that the localised skin reaction was a necessary/on target reaction, causing the inflammation that gets rid of the keratoses.

The Chair thanked Dr Shah for her time and advised that the group would deliberate and relay their decision by email within a week. Dr Shah left the meeting.

The members used categories from the APC Decision Support Tool to support discussion;

Patient Safety;
No specific additional concerns over other agents.

Clinical effectiveness;
Effective against placebo. No direct comparative data, but this is not unusual in this therapeutic area.

Strength of evidence;
Similar evidence to other agents for this condition.

Cost effectiveness or resource impact;
Acquisition cost is higher than current treatment options on formulary. No evidence of cost-effectiveness data over other agents. However SMC concluded that the economic case for ingenol mebutate had been demonstrated.

Place of therapy relative to available treatments;
Treatment pathway provided. Would be used in preference to other agents in patients with field change issue, less than 25cm^2, not hyperkeratotic. Also more suitable for elderly patients/ patients where compliance with lengthy treatments is an issue.

National guidance and priorities;
Accepted for use within Scotland and Wales by SMC and AWMSG respectively.

Local health priorities;
Option for treatment to be initiated in Primary care would reduce referrals to Dermatology clinics. This relies on confidence in diagnosis. Still able to refer to secondary care if Squamous Cell Carcinoma is suspected.

Equity of access;
Available for all

Stakeholder views;
Not applicable

Implementation requirements;
Not applicable

Decision Summary;
GREEN in line with treatment pathway provided (highlight cost/ £)

Action: Inform Dr Shah of APC decision, update APC website **IH**

0215/12 **Feedback from the January away day**

The Chair confirmed that tapentadol has been tabled to be discussed under Any Other business.

AP stated that there were some points for BWH that were agreed and not captured in the notes. AP to relay these points to IH for inclusion in notes from away day. **IH**

7.4.2 - Drugs for urinary frequency, enuresis and incontinence
IS raised concerns that solifenacin was to be removed. He highlighted that he hadn't been present at the away day for the discussions. KA advised that it was agreed that, in line with NICE clinical guidelines, oxybutynin standard release would be the first option, and then 1 or 2 additional drugs with lowest cost would be chosen. IS pointed out that the NICE guideline was only relevant to women with incontinence, and did not cover men with/without incontinence or women without incontinence. NICE had also been significantly challenged on this guideline. IS highlighted that all three trusts use solifenacin and leads had raised objections to its removal from formulary.

IS to request a formulary review and presentation from the consultants via Mr Belal from UHBFT. MD proposed a defined question to be answered: Is there a justification for solifenacin to remain on the formulary given the costs and evidence base compared with other similar agents. **IS**

MD highlighted a personal conflict of interest which he had raised at the away day which hasn't been cited. There was discussion and agreement that members should raise individual conflicts of interest with items but they will be recorded within the DoI register.

It was confirmed that the notes from the Away Day which cover harmonisation of the formularies are not published on the APC website.

Melatonin:
TC raised a question why melatonin used for sleep disorders in adults had not been considered at the away day. It was confirmed that this use was not on any of the Trust formularies and so was not subject to the harmonisation process during the Away day. A formulary application would be required to consider this for the formulary.

7.4.5 Drugs for erectile dysfunction (ED)
IS questioned the harmonisation of drugs for ED and the formulary position of tadalafil in respect of vardenafil and avanafil which had been proposed as second line. UHB urologists do not use these agents. It is their view that tadalafil is a more appropriate second line agent as it offers a lower dose, longer half-life and better patients outcomes. HEFT urologists use tadalafil after prostatectomy. LB confirmed that generic sildenafil was first line and then subsequent drugs choices were based on cost effectiveness (as opposed to lowest acquisition cost) and it was confirmed at the Away day that a review was requested of the second line drugs. IS suggested Dr Foster at Good Hope hospital would review these drugs.

Action: TC to request Urologists at HEFT to provide evidence review of drugs for ED. **TC**

6.7.2 Danazol (page 8)
IH sought clarification from the members as to who was tasked with submitting an application for danazol in benign fibrocystic breast disease. AP confirmed it was not BWH. The conclusion was that the application should come from HEFT as it was only listed for this indication in the HEFT formulary.

Action: TC to feed back to specialists at HEFT need for formulary application for danazol in benign fibrocystic breast disease. **TC**

0215/13 **Any Other Business:**

- **Email from Inderjit Singh re: tapentadol**

IS raised concerns from UHB in relation to the removal of tapentadol from the formulary. He highlighted that UHB is one of the pain centres in the region and there has been controlled and appropriate use of tapentadol at the Trust. It is currently an Amber drug with an agreed ESCA in place. To date, UHB have 20 patients stabilised on tapentadol, managed under shared care. He questioned the notion of creep. They would recommend Amber for secondary care initiation, supported by an ESCA.

UHB has been conservative in its approach and has reserved the use of tapentadol to isolated cases. All patients commenced on tapentadol are initially assessed by Consultants. The primary care practitioners are involved in the decision making process and the ESCA is agreed prior to commencing treatment.

From a clinical perspective all UHB patients had multiple medication trials prior to tapentadol, including several opioid drugs. Some patients had evidence of high/abnormal opioid drug use or were utilising opioid combinations (morphine and oxycodone in both MR and IR formulations). They remain stable on tapentadol only.

UHB is in the process of setting up a designated medicines management clinic to support these patients. JC confirmed the rationale for the use of tapentadol was in line with SMC's recommendation.

TP raised concerns about the limited evidence base for benefit with this drug compared to standard opioids. It was only ever compared to oxycodone, and primarily placed in the management of musculoskeletal pain, which is poorly responsive to opioids, with high rates of discontinuation. He also commented on the risk of rapid

dispersion of another opioid into the community. The point of experience in use over evidence base was also questioned.

NB questioned the move away from morphine, which is accepted as gold standard.

MD enquired who had commissioned the designated medicines management clinic. He raised concerns about growth in the levels of prescribing in the CCG and acknowledged that the increase may be due to prescribing initiated outside specialists but wanted to manage this within the formulary. He also observed that the majority of prescribing was for the very low strength preparations (50-100mg), which is equivalent to 12.5-25mg morphine.
LB confirmed that at the Away day, HEFT and City did not want this on the formulary and CCGs were not supportive. The process for harmonisation requires that if only one Trust wants a drug on the formulary then they should place an application. At the Away day it was requested that if UHB wanted to make an application then this would be reviewed. It was agreed that UHB would review and present their application and a consultant would be invited to present the case.

ACTION: UHB to forward the application form and information it considered at the DTC and arrange for a consultant to attend an APC meeting to discuss the use of the agent. **IS**

- **APC membership to be published on website**

JH highlighted that organisations were getting in touch requesting details for the APC membership and asking the Secretary to check their lists. Members were being targeted by companies for APC information. JC also highlighted that members may be subject to false surveys purporting as official bodies to obtain information.

As an NHS organisation information is available as freedom of Information. These will be published on the website. It was confirmed member name and organisation will be listed but not email address. Also add a statement on the website any queries are to be submitted to the APC secretary via the APC email listed on the site and to not be contacted directly.
Action: Publish membership list with name and organisation only. Add statement for queries to be submitted via APC email. **CSU**

- **Doodle poll dates for June, Sept and Dec**

These were circulated for completion at today's meeting

- **Chapters for discussion at March away day**

IH requested agreement for the topics for the Away day.
It was agreed that the following would be covered;

  - ESCAs and RICaDs- for approval subject to any comments presented at the away day or by email prior to the event.
  - Chapter 6: Diabetes section supported by clinician representation from the network.
  - Chapter 11: Eye
  - HRT and OCP – if sufficient time, and cost analysis available (currently underway) **SN/ CSU**

Action: Circulate information for away day as soon as possible

- **APC website and branding**

JH displayed the website and the format to present the formulary status clearly against each product. The website was commended and the branding was also commended. LB proposed clarification on wording for drugs with proposed RAG status not matching current commissioning arrangements.

Action: IH to amend website wording for these drugs. **IH**

The meeting closed at 16:47 pm

Date of Next Meeting:

Thursday 12th March 2015 - Birmingham Medical Institute,
36, Harborne Road, Edgbaston, Birmingham B15 3AF
Solomon Wand Room, 1st Floor