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

PRESENT:

Dr Paul Dudley	PD	Chair and Birmingham Cross City CCG
Alan Pollard	AP	Birmingham Womens NHS FT
Alima Batchelor	AB	Birmingham South Central CCG
David Harris	DH	Birmingham Community Healthcare NHST
Dr Jamie Coleman	JC	UHB NHS FT
Dr John Wilkinson	JW	Solihull CCG
Prof Robin Ferner	RF	Sandwell & West Birmingham Hospitals NHST
Elizabeth Walker	EW	Sandwell & West Birmingham CCG
Inderjit Singh	IS	UHB NHS FT
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Kate Arnold	KA	Solihull CCG
Mandy Matthews	MM	NHS England (West Midlands)
Mark Dasgupta	MD	Birmingham Cross City CCG
Nigel Barnes	NB	B&SMHFT
Satnaam Nandra	SN	Birmingham Cross City CCG
Sumaira Tabassum	ST	Sandwell and West Birmingham CCG
Tania Carruthers	TC	HEFT NHS FT
Dr Timothy Priest	TP	HEFT NHS FT
Brian Smith	BS	Interim Chief Pharmacist, attending on behalf of Maureen Milligan, ROH NHS FT

IN ATTENDANCE:

Davina Mistry	DM	Secretary, Midlands & Lancashire CSU
Dr Andrew Holt	AH	Hepatology UHB NHS FT in attendance for item 0415/07

No.	Item	Action
0415/01	**Apologies** Apologies for absence were received from: • Jonathan Horgan • Maureen Milligan • Dr Dennis Wilkes • Patricia James • Dr Lisa Brownell	
0415/02	**Items of business not on the agenda** • IH confirmed dates for the next APC Away Days; 26th June 2015, 29th September 2015, and she proposed 2nd December (amended date). Views on the 2nd December to be emailed to IH in the next week.	**All**
0415/03	**Declaration of Interest** No new declarations were raised.	
0415/04	**Welcome and introductions** The Chair welcomed those present to the Area Prescribing Committee and members introduced themselves.	
0415/05	**Minutes of the last meeting** The minutes of the meeting of 12th March 2015, were discussed for accuracy. These had been circulated by email during the month, and an amendment proposed by KA has been incorporated. . The draft minutes were approved with no further amendments.	
0415/06	**Matters Arising – Action Table**	
0315/07	**NICE Technology Appraisals (TAs)** IH has amended TA 329 and 323 as per minutes	**Closed**
0315/09	**Nalmefene** IH confirmed this has been published on the APC website. IH has amended the name of the specialist service from CRI to 'Reach Out Recovery' as instructed by John Denley. The service is still part of CRI. IH also published their 24 hour/7 days a week single point of contact number. IH will add the contact numbers for Swans well and SIAS (Solihull) when she is notified of these. IH has also amended the front page of the website to include an update that the nalmefene formulary position has been clarified. There is a link to the relevant section.	**Closed**
0315/11	**Chapter 2 update the formulary entries for fibrates RAG rating** This has been actioned by IH	**Closed**
0315/12	**Any other business** **Emails from pharmaceutical industry regarding published minutes and formulary progress** IH has responded to the companies and actioned the amendments.	**Closed**

Wound Formulary Network
KA and ST to liaise on contact details for the wound care leads. **Closed**

DH raised a question whether Solihull was going to be part of this network and who was leading the set up. ST confirmed that Sandeep Prahal, SWB CCG is leading this work and is contacting relevant leads currently. ST highlighted that this work will take some months so it was agreed that the action would be closed for now and for the network to feedback updates at a suitable time.

Six drug applications in support of draft COPD guidelines
Confirmation has been received that Dr A Turner will attend the June Away Day in the afternoon. UHB NHSFT has also nominated Dr Simon Gompertz to attend the June Away Day.
IH will circulate the six drug applications with evidence reviews for review at least 6 weeks prior to the meeting to enable members to discuss locally.

Action: IH to circulate by email the COPD drug applications and guideline. **IH**

Updated Action Table from previous meeting.

0215/03 **Declaration of Interest** **Open**
IH to liaise with MD re audit.

0215/06 **Matters arising: Revised APC Policy – Encs 2b**
IH has recirculated the updated Policy and requested any further comments prior to publishing. No further comments were received. The updated APC Policy has now been published. **Closed**

0215/09 **Chapter 3 Ratification**

- Discuss variations in devices for budesonide/formoterol dry powder inhalers with respiratory network; This is on the agenda, item 0415/10 **Closed**

0215/13 **APC membership to be published on website**
IH to action next month **Open**

Website and Branding

- Amend website wording for drugs with proposed RAG status not matching current commissioning arrangements; **Open**

IH has updated enoxaparin but is not aware of any other amendments required. There was discussion about the range of drugs affected and clarity is required. IH to liaise with LB and review previous minutes to confirm what the position is for each drug affected by commissioning arrangements.
Action: IH to liaise with LB **IH**

1214/03 **Declaration of interest**
It was agreed at the last meeting that LB would contact the Birmingham Childrens Hospital regarding representation. **Open**

0415/07 **NICE Technology Appraisals (TAs)**

Rifaximin for overt hepatic encephalopathy (TA337)
The Chair welcomed Dr Andrew Holt from UHBFT hepatology department who has attended to discuss Rifaximin (TA337).

AH advised that rifaximin is not a new drug and for many years an early iteration of the drug was used to treat travellers' diarrhoea. The preparation has been developed further and tested on hepatic encephalopathy (HE).

Initially in the UK it was marketed as an orphan drug. However liver disease is the third most common cause of death in the under 65s, and the fifth most common cause of death in the UK overall. Prevalence is increasing annually.

HE presents as a transient fluctuating clinical state e.g. with confusion, which is not easily diagnosed with tests and requires a clinical diagnosis. Traditionally it has been treated with antibiotics that are not absorbed in the intestine e.g. neomycin, and with lactulose which acidifies the colonic flora and reduces the absorption of ammonia. Rifaximin is a non-absorbed antibiotic and affects the bacterial flora in the intestine. NICE has approved this drug for HE. There is no competitor product and it has robust evidence published in the NEJM to show that the drug reduces the incidence of Overt HE and at 6 months reduces the admission rates to hospital. As hospital admissions can be prolonged, there is a good cost argument for this drug.

The Chair asked AH what formulary status would be most appropriate for this drug. AH advised that the guidance does not clarify where the drug should be prescribed. He outlined that it was helpful to consider the range of drugs available. Lactulose can be used with neomycin. However neomycin has significant adverse effects such as ototoxicity and is not recommended for routine use. Rifaximin has a potentially safer profile although it does have side effects. The two products have not been tested head to head in trials.

TP questioned whether it had been tested against lactulose alone and highlighted that he was aware of a review that found similar results. AH confirmed that this drug does add to the effectiveness of lactulose.

BS advised of his experience in an NHS Trust that was involved in a small trial involving around 9 patients. The trial over 1 year demonstrated considerable reduction in admissions with the use of rifaximin from around 40 to 5 admissions. Patients were able to continue with lactulose in this trial. This demonstrated patient benefits and cost effectiveness for the NHS.

MM asked for clarification on the management in UHBFT. AH confirmed that UHBFT was a tertiary centre for liver disease and they had taken steps to control the appropriate use of this drug prior to NICE. He also highlighted that not all patients respond to the drug. The liver unit at QEHB was best placed to recommend which patients are most likely to benefit from the use of the drug and would be able to evaluate the clinical response. He emphasised that the diagnosis of HE (which can be subtle) and initiation of the drug needs to be made by, or with input from, the treating specialist. He also mentioned that, in some patients, the specialists at UHBFT might adjust the dosage regimen to the one stated in the Summary of Products Characteristics (SPC): 550mg once daily or when required, as opposed to 550mg twice daily (SPC dose).

It was confirmed that the drug can be continued for life or until liver transplant. AH advised that longitudinal studies recognised that patients with Overt HE generally have advanced disease. This emphasised the importance of patients being evaluated in a specialist centre, as, for many patients, the evolution of

encephalopathy symptoms is a harbinger of more advanced/end-stage disease.

MM confirmed that NHSE does not fund this drug, and that it is funded by CCGs.

RF asked about the incidence of ototoxicity with neomycin and questioned whether it was a significant problem if it isn't absorbed. AH confirmed it can be an issue and steps are taken to minimise the ototoxic risk for example by issuing small amounts on prescription. Absorption does vary with the stage of liver disease and therefore ototoxicity would be more likely in advanced disease due to increased systemic absorption due to increased gut permeability. RF questioned why, if neomycin works for some patients and if ototoxicity can be managed and is more cost effective than rifaximin, it would not be the preferred agent. AH confirmed that the evidence was best for rifaximin.

KA asked whether HE can result from conditions other than cirrhosis and highlighted that the NICE costing template commences from cirrhosis. AH responded by saying this was a good question and confirmed that HE can result from other causes, but that these are rare disorders. This would result in an underestimate from the costing model.

AH recommended that there be a process for patient review with the specialist prior to commencement of the drug and he would expect a Consultant Hepatologist (or at the very least a Gastroenterologist with a declared interest in Hepatology) to initiate it. It was recognised that liver services are very limited in many areas of Birmingham. Once a clinical response had been confirmed over a 4 week period the responsibility for continuing the prescription would pass to primary care and the GP could continue to issue the drug. These patients would remain under some form of specialist review in hospital clinics due to the seriousness of their underlying condition. A typical interval for follow up would be every 6 months for ultrasound and blood work. The utility of continuing the Rifaximin prescription could be made at that time.

The Chair asked about whether there would ever be a review of the patient to stop the drug. AH confirmed that with the nature of liver disease with Overt HE, most patients would not be stopped unless they experienced side effects. It might be possible to reduce the frequency of the prescription in some patients however, and it should not be assumed that all patients would need the drug all of the time.

The Chair thanked AH for his specialist input and AH left the meeting.

The members discussed the proposed formulary status. MM pointed out that rifaximin is not PbR excluded, and would be within tariff. It was agreed that rifaximin should be at Amber with a RICaD. The RICaD needs to be developed or agreed by the specialists with interest in liver disease, and include a statement from hepatologists/ gastroenterologists in Trusts covered by the APC with regards to different dose regimen. MD suggested specialists provide first 2 months' supply as mentioned by BS, and transfer to Primary Care once they are satisfied it is working and suitable for the patient. Secondary Care follow up should be 6 monthly at least. IH to contact AH to take this work forward and to include pharmacy leads at UHB NHSFT.

Action: IH to liaise with UHB NHSFT to develop a RICaD for rifaximin. **IH**

Rivaroxaban for ACS (TA335)
This was agreed as amber with a RICaD.

Action: KA/Solihull CCG medicines team to develop a draft RICaD for rivaroxaban. **KA**

Empagliflozin (TA336)
This was confirmed as formulary status green.

0415/08 **Trust Chairs non Formulary approvals.**
No comments were raised

0415/09 **Updated BNF Chapters**

Chapter 4, Central Nervous System

MD raised a query from the March Away Day with UHB NHSFT with regards to eslicarbazepine, and whether it should have been included in the harmonisation process as he didn't recall it being approved at the MMAG. . IS confirmed that it had been reviewed some time ago at UHB NHSFT but that the MMAG committee had not had the opportunity to consider the views of the CCG. It was agreed that the formulary review process needs to be completed to ensure it had gone through proper scrutiny. It was agreed that the original application can be resubmitted if felt appropriate. The members would aim to complete this at the 11th June meeting, subject to specialist availability. It was confirmed that it would be removed from the draft harmonised chapter pending a formulary application.

It was confirmed that oxycodone m/r and naloxone (Targinact®) should be listed as black remove.

Chapter 6, Endocrine

IH highlighted that KA had discussed armour thyroid at the January Away Day. It was agreed that this should be listed as black as it had not been approved for trust formularies.

Section 6.3.2, glucocorticoid therapy.
Methylprednisolone tablets: RF advised that they had only issued three prescriptions for these tablets in the last year or so. The members agreed to list these as Black remove.

Betamethasone parenteral: to be changed to red.

Section 6.4.1.2:
Ulipristal (Esmya ®)
AP raised a question on the interest to extend the use beyond the 3 month treatment course following the recent change to the SPC allowing a repeat of this treatment course. The current ESCA only supports one treatment course. It was confirmed that if there was interest, a further application would be required to amend the formulary. AP to discuss this outside the meeting.

Utrogestan®
BWH to consider putting in an APC application.

Section 6.4.2 : Testosterone undecanoate capsules:
It was confirmed that clarification was required for this from urologists at HEFT.

Section 6.4.3: Oxandrolone: MD confirmed this was unlicensed in the UK and is a 'special'. It was confirmed this would be formulary status Red.

Chapter 7: Obstetrics, gynaecology, and urinary-tract disorders

The Chair confirmed that Urologists from HEFT would provide the evidence review for drugs for erectile dysfunction (shown in blue) at the May meeting.

IH asked if the evidence for the solifenacin / tamsulosin combination had been discussed. The Chair confirmed that it had previously been declined from formulary and so was not listed.

Chapter 10: Musculoskeletal

KA requested that the reference to the relevant NICE technology appraisals is included for anti-TNFs or similar. IH confirmed these are included in the APC website.

10.3.2 Capsaicin cream is listed as 0.025% green, and 0.075% amber for neuropathic pain (licensed). It was confirmed that 0.025% should appear in Chapter 10 and 0.075% in Chapter 4 to avoid confusion for prescribers in relation to licensed use. A note can be added in each section.

It was confirmed that Algesal® is no longer available.

IS requested that the updated tables are circulated to go to formulary leads.

Action: SN/IH to amend Chapters 4, 6, 7 and 10 and reissue to all to forward to formulary leads within their Trusts/ CCGs. **SN/ IH**

0415/10 **Feedback from the Respiratory network**

SN confirmed that a consultant would come back to the APC in June with regards ciclesonide. There was discussion regarding fluticasone and paediatric use. The Respiratory Network will go back to the Paediatric Lead to clarify the position on paediatric use and the possible impact of the proposed removal of fluticasone from the formulary. The Chair pointed out that this highlights the need for BCH input.

There was discussion about the need to bring applications for combination or new devices for approved products. There was a consensus that the APC needs to a take view as the patents may apply to individual devices. RF proposed that the APC need oversight of the devices and a rationale for inclusion however a full APC application may not be required as the drug(s) had already been approved. MD highlighted when these are generically prescribed then they are interchangeable at pharmacies which may cause problems for patients. It was noted that many more customised inhalers would be expected to be made available with developments in technology. It was confirmed that it would be appropriate to list an order of preference for GPs in the use of different types of inhalers or technologies and to develop this from an abbreviated application or letter.

Action: IH to contact Jonathan North, Consultant Immunologist at City Hospital re Grazax® and the need for supplementary documentation. **IH**

0415/11 **View of APC members re applications for NRT products**

IH had received an email from Carol Evans, formulary lead at HEFT, asking whether an application was required for niquitin oral strips. It was confirmed that nicotine replacement preparations are green on the formulary however these may come in different devices and so should follow the same process as inhalers.

Action: IH to feedback to CE that an abbreviated application would be required. **IH**

0415/12 **Any Other Business- Agenda for June Away Day**

IS enquired which chapters were going to be reviewed at the June Away Day. IH confirmed COPD will be discussed in the afternoon. Chapter 8 and feedback from ophthalmologists to be covered in the morning session. A representative from NHS England will also be required at the Away Day (MM to follow up representation). Chapter 9 to be covered if time permits.

PD thanked the members for their input today. The meeting closed at 16.10pm

Date of next meeting

Thursday 14th May 2015. Birmingham Medical Institute,
36, Harborne Road, Edgbaston, Birmingham B15 3AF
Solomon Wand Room, 1st Floor