FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 28th May 2019
12:30 - 2:30 pm
Pharmacy Dept MFT-ORC (formerly known as CMFT)

Present:

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	✓	✓	A	✓	✓	A					
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A (LB)	✓	A	✓	✓	A					
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	✓	✓	A	✓	A						
Aoidin Cooke (AC)	Medicines Management and Medicines Information Pharmacist	MFT-ORC	✓	A (LH)	✓	A (LH)	✓						
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓	✓	✓	✓	A						
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	A (AH)	A	✓	✓	A						
Rachel Macdonald (RM)	Pharmacist	Community pharmacy	A	✓	A	A	A						
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	A	✓	✓	✓	A						
Prof Peter Selby (PS)	Consultant Physician	MFT-ORC	✓	✓	A	A	✓						
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓	✓	A	A						
Dr Hina Siddiqi (HS)	GP		✓	A	A	✓	A						
Lindsay Harper (LH)	Director of Pharmacy	SRFT	A	A	✓	A	A						

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
Anna Swift (AS)	Snr. Assistant Director Medicines Management	Wigan Borough CCG				✓	A						
Jonathan Schofield (JS)	Consultant Physician	MFT-ORC	✓	✓	✓	✓	A						
Faisal Bokhari (FB)	Deputy Head Medicines Optimisation	T&G CCG	✓	✓	A	✓	✓						
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	✓	✓	✓						
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	A	A	A	A	A						
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓	✓						
Nancy Kane (NK)	Senior Medical Information Scientist	RDTC				✓	A						

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above. Although there were a number of apologies, attendees present represented a balanced group and therefore considered quorate.

PS was in attendance until item 4.6

1.2 Declarations of Interest:

No new declarations of interest were received in advance or made at the meeting.

1.3 Draft minutes – April 2019

The minutes from April's meeting were agreed as an accurate record.

1.4 Matters Arising

1.4.1 Consultation feedback:

Items from the April meeting were out for consultation; closing 10th of June. Consultation comments received on actions from the March meeting were discussed and actions recommended as follows:

- Benralizumab for treating severe eosinophilic asthma be RED (in line with TA565)
- Pentosan (Elmiron®) be GREEN (following specialist initiation) and GREY (criterion 3) for use as a second-line treatment option for bladder pain syndrome, where conservative measures have failed.

• Ciclosporin 0.1% eye drops (Verkazia®) to be added to paediatric RAG list as GREEN (following specialist initiation) for treatment of vernal keratoconjunctivitis in patients aged 4 to 18 years old and who are subject to active follow-up (e.g. reviewed every 6 months).

ACTION: FMESG to action these recommendations.

1.4.2 Epidiolex- request to review status

The group considered comments from Dr Paul Cooper, consultant neurologist SRFT, regarding the recently agreed RAG status for Epidiolex in adults. The group discussed issues around access to this product in the absence of a patient access scheme; however it was felt that the current positioning of RED was ultimately still appropriate and this reflected feedback from the original consultation on this item. No action to be taken on this item.

The group did feel that a review of positioning of stiripentol was however warranted, particularly as the current RED only for paediatrics may restrict access for existing patients when they reach adulthood. Additionally it was felt that there may be a very small cohort of patients who are diagnosed with SCN1A variant epilepsy in adulthood for stiripentol may be considered a treatment choice. It was noted that the license for this product is only for children and adolescents and the product SPC highlights a lack of long-term safety information in the adult population

ACTION: FMESG recommend Stiripentol be revised to RED and GREY for use in Dravet Syndrome/ SCN1A variant epilepsy (Criterion 3). RDTC to open the recommendation for GM wide consultation and seek pre-support to action from June's CSB.

1.4.3 Action Log

Updates on the action log were noted. The group heard that approval was pending from DoCs on the FMESG recommendations for Xonvea, and NHSE funding arrangements for flash glucose monitoring- these would be actioned upon response from DoCs. Additionally the group requested that an update on the progress of the GMMMG Wound Care Formulary review be brought to June's FMESG.

The group agreed that comments received on the proposed positioning for rivaroxaban in CAD/PAD should come back as a full agenda item to June's meeting, along with prescribing figures across GM to-date. It was noted that there had been minimal response on this so far, and although the proposal aimed to target the most high risk patients, it was unclear how these patients would be identified and monitored appropriately in primary care.

Additionally, the group heard that CSB had requested further refinement of the proposed liothyronine status to include 'under annual review by an NHS endocrinologist'; RDTC to action this.

1.4.4 Monitoring log

The monitoring log was noted by the group. No action was required on this item.

2.0 Medicines Optimisation

2.1 LMMG Out of Area Prescribing- Position Statement

The group noted a policy from the Lancashire Medicines Management Group on out of area prescribing. Whilst FMESG understood the aim of this document, the group expressed concerns that it would not be practical for GM specialist services to meet its requirements. Additionally it was proposed that other localities may follow suit and develop similar policies which would create additional interface issues for those patients referred into GM services from elsewhere. It was suggested that a statement should be drafted outlining a GM position for specialist services provided to out-of-area localities.

2.2 GM Antimicrobial Guideline Update- June 2019

FMESG considered the quarterly update to the GM antimicrobial guidelines and supported their upload to the GM site, pending a minor annotation to the metronidazole recommendation in bacterial vaginosis.

ACTION: RDTC to liaise with working group requesting annotation that metronidazole 400mg tablets should be prescribed, rather than 500mg tablets, for the treatment of BV. Amended version to be uploaded to the site thereafter.

3.0 FMESG Work Plan 2019

3.1 Consideration of items for FMESG work plan

The group discussed the items for consideration and recommended the following actions:

- Triamcinolone injection (Kenalog®) to be made GREEN (following specialist advice) and GREY for use in all licensed indications with the exception of allergic rhinitis. Use for allergic rhinitis is not recommended in line with BSACI guidance.
- Removal of the gender specification in the current GM status of prucalopride, in line with the product license.

ACTION: RDTC to open these recommendations for GM wide consultation and seek pre-support to action from June's CSB.

It was also agreed that diclofenac topical patches for 'tennis elbow' or ankle sprain (e.g.Flector®) be considered for DNP, in line with NHSE OTC Guidance. To be brought back as part of the GMMMG OTC Guide/ Self-Care Policy work, unless this work is delayed unexpectedly.

4.0 Formulary and RAG

4.1 Formulary amendments May 2019

The suggested formulary amendments were noted and approved by the group.

ACTION: RDTC to open these recommendations for GM wide consultation and seek pre-support to action from June's CSB.

4.2 Formulary application- Levosert ® / review of formulary choice IUS

At April's meeting, FMESG considered scoping for addition of a formulary application for Levosert® IUS to the FMESG workplan. The group agreed that this should come back as a full agenda item, but that this item should also include a review of all intrauterine delivery systems, since several are now available and all have slightly different characteristics.

At May's meeting, FMESG considered a formulary inclusion tool for Levosert, a new drug application to MFT for Kyleena, and an IUS comparison table which had been provided to help support decision making. The group acknowledged that the current formulary choice Mirena, has specific niche use in patients who require endometrial protection during oestrogen HRT and agreed should be assigned a GREEN, and GREY (criterion 2) status. On the basis of smaller frame size, cost efficacy and feedback from sexual health services of reduced incidence of pain on insertion and cervical shock, FMESG recommend Kyleena as first line, and Levosert as the alternative choice in patients with heavy menstrual bleeding. A link to the IUS comparison chart to be added to the formulary.

ACTION: RDTC to open the above recommendations for GM wide consultation and seek pre-support to action from June's CSB.

4.3 RAG assessment- dexamfetamine for narcolepsy

At April's meeting, FMESG considered scoping for a RAG assessment for dexamfetamine in narcolepsy. In view of the monitoring requirements of dexamfetamine, and recognition that only the

liquid preparation is licensed for this indication, the group agreed that this should come back as a full agenda item to May's meeting.

At May's meeting, FMESG considered a RAG assessment form for this item. The group discussed the GM status of other medicines for narcolepsy and note the AMBER status of dexamfetamine in ADHD. Given the dosing ranges and monitoring requirements are similar for use in ADHD versus narcolepsy, the group agreed that an AMBER status would be most appropriate but that a RED status should be assigned until a SCP is developed and approved.

ACTION: RDTC to open this recommendation for GM wide consultation and seek pre-support to action from June's CSB.

4.4 RAG Assessment – Testosterone

At April's meeting, FMESG considered scoping for a RAG assessment for testosterone products used within licensed indications in men. These are currently positioned GREEN (following specialist advice). A request for review had been raised on the basis of the level of monitoring required for these products in hypogonadism, and whether an AMBER status would be more appropriate. The group agreed that this should come back as a full agenda item along with details of the required monitoring, to allow for an updated assessment of the RAG status.

A RAG assessment tool was considered by the group at May's meeting. Monitoring recommendations from the British Society for Sexual Medicine (BSSM) were reviewed- this was noted to differ from previous guidance from the British Society of Endocrinology (BSE) which has been withdrawn, pending review. However an American clinical practice guideline which is signposted to by the BSE recommends less prescriptive monitoring to the BSSM guidance. Additionally, it was noted that the RAG status for these items differ across other localities in England, but no formal shared care was required by the other areas.

The group agreed that the monitoring required would not be unreasonable or unmanageable to be undertaken within primary care and that AMBER status was not necessary. However the group agreed that development of supportive information may be helpful. It was suggested that an information leaflet be drafted for this purpose, similar to other GM green (following specialist initiation) documents.

ACTION: RDTC to draft information leaflet detailing monitoring requirements for primary care and bring to June's meeting.

4.5 RAG Assessment- Hydrocortisone Granules (Alkindi®) for doses <5mg

At April's meeting, FMESG considered scoping for a RAG assessment for Hydrocortisone granules (Alkindi®) for treatment of adrenal insufficiency in patients aged <18 years. The group agreed that this should come back to a future meeting as a full agenda item for doses of hydrocortisone <5mg.

At May's meeting the group agreed that Alkindi possesses value in obtaining dose increments <5mg, offering a licensed alternative to the manipulation of 10mg tablets, or unlicensed liquid specials. The group felt the cost-benefit of the preparation in doses ≥5mg was less favourable and the degree of variation in bioequivalence of higher doses limited the clinical relevance of the product. Additionally, it was noted that these preparations are not recommended for administration via enteral feeding tube, hence the unlicensed liquid may be more suitable for some patients. FMESG recommend Alkindi be added to the paediatric RAG list as GREEN (specialist initiation) for doses <5mg.

ACTION: RDTC to open this recommendation for GM wide consultation and seek pre-support to action from June's CSB.

4.6 RAG Assessment- Glycopyrronium oral solution for severe sialorrhoea

At April's meeting, FMESG considered scoping for a Paediatric RAG assessment for Glycopyrronium bromide 320mcg/ml solution (Sialanar) for severe sialorrhoea in children &

adolescents aged 3 and older with chronic neurological disorders. The group agreed that this product should be considered for addition to the adult RAG list too.

At May's meeting the group considered some additional information on the cost impact of the new product (Sialanar) versus the existing product (Colonis Pharma). It was noted that the comparison of the cost of each was limited by the different strengths of the products and their licensed dose increment by patient weight. The group agreed that the product should be assigned a RAG status but that this should also apply to adults, in light of NICE recommendation for use to manage drooling of saliva in people with Parkinson's disease. FMESG recommend glycopyronnium oral solution is made GREEN (specialist initiation) and annotated 'chose product with the lowest acquisition cost'.

ACTION: RDTC to open this recommendation for GM wide consultation and seek pre-support to action from June's CSB.

4.7 Query re. paediatric versus adult RAG list

The group heard about a query submitted via the website around the RAG status of valganciclovir in paediatrics. This was in response to a request from secondary care for a GP to prescribe for an infant with CMV. Valganciclovir is RED for CMV and is included in the adult list, but the RED status would also apply to paediatric use, however the recommending specialist had not found this to be clear. Given the safety risks associated with this scenario, it was brought to the group for consideration as to how to mitigate similar misunderstandings going forward.

The group re-discussed a potential merge of the RAG list into a single point of reference, where entries that only applied to adults or paeds would be annotated accordingly. FMESG recommended a draft proposal be developed and presented at June's meeting.

ACTION: RDTC to draft a proposal to merge the adult and paediatric RAG lists and bring to June's meeting.

5.0 Horizon Scanning and work plan

5.1 Monthly horizon scanning documents May 2019

The RDTC monthly horizon scanning document for May was considered by the group. The group recommended no additional action was required at present on the basis of this document. It was agreed that a RAG assessment should be submitted for sodium zirconium cyclosilicate in September, pending the outcome of the NICE TA.

5.2 Work plan

It was noted that the GMMMG Work Plan was being updated. A final version would be considered at a future meeting, once agreed by CSB.

6.0 AOB

Nil.

The next meeting will be held on 25th June 2019, 12.30-2.30pm, MFT-ORC (formerly known as CMFT).