FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 26th March 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
Elizabeth Arkell (EA)	Medicines Management Lead	MFT-WH	✓	A	A								
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	✓	✓	A								
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A (LB)	✓	A								
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	✓	✓	A								
Aoidin Cooke (AC)	Medicines Management and Medicines Information Pharmacist	MFT-ORC	✓	A (LH)	✓								
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓	✓	✓								
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	A (AH)	A	✓								
Rachel Macdonald (RM)	Pharmacist	Community pharmacy	A	✓	A								
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	A	✓	✓								
Prof Peter Selby (PS)	Consultant Physician	MFT-ORC	✓	✓	A								
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓	✓								
Dr Hina Siddiqi (HS)	GP		✓	A	A								

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
Lindsay Harper (LH)	Director of Pharmacy	SRFT	A	A	✓								
Jonathan Peacock (JP)	Chief Pharmacist	T+G	A	A	A								
Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	✓	✓								
Jonathan Schofield (JS)	Consultant Physician	MFT-ORC	✓	✓	✓								
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								
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓								

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above.

Lindsay Harper deputised as chair.

It was noted that the meeting was not quorate. The members present agreed that actions would be circulated around the group for approval prior to them being progressed.

1.2 Declarations of Interest:

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

1.3 Draft minutes- February 2019

Following minor amendments, the minutes of February's meeting were agreed as an accurate record.

1.4 Matters Arising

1.4.1 Consultation feedback:

Items from the February meeting were out for consultation; closing 16th April. Consultation comments received on actions from the January meeting were discussed and actions recommended as follows:

- Oxis Turbohaler to be added to formulary as an alternate choice LABA. This recommendation to be submitted to April's CSB as part of the respiratory chapter update agreed at January's FMESG.
- GREEN NF drugs to be removed from the RAG list. Oral sodium fusidate to be brought back for RAG assessment at April's meeting.
- Tofacitinib to be added to chapter 1 in line with NICE TA547.
- Darvadstrocel to be added to DNP list (criterion 1) in line with NICE TA556.
- Clarification of guidelines for RAG listing of GREEN (specialist advice)- following further discussion and consideration of consultation comments, the group agreed that the current wording of *'can be initiated following written or verbal advice from a specialist'* should stand i.e no change would be made to the current version of the document
- Rivaroxaban for risk reduction in CAD/PAD to be made DNP. This item was discussed in full as a designated agenda item- see item 4.2

Actions: FMESG to seek support from CSB (April's meeting) to action these recommendations.

1.4.2 GMMMG Antimicrobial Guidelines- response to FMESG's comments

Comments from February's FMESG meeting had been submitted to the GM Antimicrobial Task and Finish Group, requesting consideration of amendments relating the inclusion of nitrofurantoin as a treatment option for LUTI in children (given the high cost of the suspension versus other options) and relating the substitution of nitrofurantoin for LUTI in men with trimethoprim (in the context of local concerns re. trimethoprim resistance).

A response from the author was considered by the group. Whilst the group acknowledged that these recommendations were in line with NICE, further discussions took place about the implications of recommending use of nitrofurantoin in the paediatric population. It was highlighted that the high cost of the liquid preparation may result in an increase in recommendations to crush tablets/ open capsules; the risks of which had not been adequately assessed. The group concluded that further scoping of the issue was warranted. FMESG also highlighted that the recommendation regarding trimethoprim conflicted with previous local advice to minimise use, and further clarity on this recommendation was requested from the Antimicrobial Task and Finish Group.

Action: AC to liaise with colleagues at CMFT regarding the concerns raised re. nitrofurantoin and bring comments back to April's FMESG. RDTC to relay queries to author of the guideline.

1.4.3 Action log

Updates on the action log were noted. This included a review of the GMMMG positioning of antipsychotics, and how this item could be progressed.

Actions: LH to liaise with MH services regarding request to review RAG status of antipsychotics. CD to liaise with CMFT to identify potential specialists to provide opinion on the new drug evaluation for Slenyto® ahead of April's meeting.

1.4.4 Monitoring log

The monitoring log was noted by the group.

2.0 Medicines Optimisation

2.1 GMMMG Management of RED listed drugs in primary care- technical update

A technical review of the current version of this policy was scheduled in January 2018. The group considered a technical update of this document, and associated appendices. Following a discussion regarding the implications of RED drugs not being recorded within the patient record, and noting the progression of work towards shared records across GM, the group approved the updated version, pending some minor typographical amendments. It was noted that the policy does not make reference to shared care records and that this should be considered for inclusion in the next full scheduled review of the document.

Action: FMESG approve update with suggested amendments. RDTC to feed-back to author.

2.2 Diabetes Chapter- items for FMESG consideration

The group discussed a number of items relating to the current diabetes section of chapter 6:

2.1.1- Proposed Positioning of Toujeo

Following an application to formulary in July 2018 for the addition of Toujeo, FMESG had undertaken some scoping regarding existing use of this product across GM. It was noted that year-on-year there had been a significant uptake in the prescribing of this product and that available audit data suggested prescribing was largely not in line with existing NTS recommendations. The group ultimately agreed that there was insufficient evidence to support routine use of Toujeo over other analogue insulins and did not recommend formulary inclusion. The safety implications associated with prescribing and dispensing of high strength insulins was also highlighted. Recognising that work was underway to develop GM-wide diabetes pathways, FMESG agreed that the working group should be approached to help define an appropriate GREY and GREEN following specialist advice' list positioning for Toujeo.

The positioning proposed by the working group was considered at the March meeting and approved by the group pending a minor amendment regarding Toujeo Doublestar® which allows more units to be administered per dose than the existing product:

Toujeo is a **high-strength insulin*** preparation**.** It may be considered as an option in people with Type 1 or Type 2 diabetes when one or more of the following criteria are met:

- **i)** **There is a requirement for flexible timing of injection (+/-3 hours) due to reliance on 3rd party assistance to administer insulin.**
- ii) **There is pain related to high injection volumes of standard-strength insulin.** (High insulin dose alone is not a reason to switch).
- iii) **There are unacceptable nocturnal hypoglycaemic episodes despite intensive management on other basal analogues.** This must be supported by appropriately recorded data (e.g. glucose monitoring device/blood glucose diaries).

***Toujeo preparations must always be prescribed by brand** to minimise the risks associated with the prescribing, dispensing, and administration of high strength insulins.

Action: FMESG recommend that proposed positioning be applied to Toujeo, and the existing NTS statement updated accordingly. FMESG seek support from CSB (April's meeting) to progress these actions

2.2.2- GMMMG Insulin Degludec Recommendation- review

The group acknowledged a request to review the current GMMMG recommendation for insulin degludec in patients with type 2 diabetes. This was in light of updated NICE Guidance (NG28) which states 'The GDG agreed that there was strong evidence to indicate that insulin degludec was not cost-effective and therefore was confident that this option should not be recommended'.

Action: RDTC to re-draft the NTS statement accordingly and bring back to April FMESG for approval.

2.2.3- Chapter 6: Additional notes

The 'Additional notes' appendix to chapter 6 was taken down from the GMMMG site at the end of November. The document was last reviewed in 2014 and a number of aspects were noted to be out of date. The group considered if there would be an appetite to review this document and how best to progress this work as some aspects would be considered outside the scope of FMESG's work stream. It was agreed that keeping the document in its current format would require regular review for accuracy and updating of referencing, and highlighted that none of the other formulary chapters have an additional notes section. However the group felt there was a need for this information to continue to be available as it was thought to be very useful.

Action: RDTC to liaise with the diabetes pathways working group about incorporating relevant diabetes information within a short prescribing aid (in line with existing work requested by PaGDSG). RDTC to propose which sections would align with GMMMG pathways in development (e.g neuropathic pain), propose which information could be included in the formulary chapter, and propose which information could be cut. To be added to the action log and returned to FMESG as work progresses.

2.3.4 GMMMG diabetes pathways (drafts)

Copies of the draft pathways were provided for information. The group noted that these were in alignment with current formulary positioning and that no significant changes / review work was anticipated for FMESG as a result of their development.

2.3 NHSE Funding Arrangements for Flash Glucose Monitoring.

The group acknowledged the newly issued NHSE funding arrangements for flash glucose monitoring, and the criteria for reimbursement detailed within. For 2019/20, CCGs will be reimbursed for each set of sensors prescribed for up to 20% of their type 1 diabetic population. Breakdowns of maximum CCG reimbursement figures were noted.

Whilst the current GMMMG positioning is currently aligned with RMOC guidance, the group noted a number of ways in which the NHSE reimbursement criteria differ; in particular the inclusion of the following populations:

- people with any form of diabetes on haemodialysis and on insulin treatment who are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months
- people with diabetes associated with cystic fibrosis on insulin treatment
- pregnant women with type 1 diabetes for 12 months total, inclusive of post-delivery period, irrespective of insulin regimen. (GM guidance says pregnant patients will be expected to return to previous method of blood glucose testing once they have given birth)
- people with type 1 diabetes for whom the specialist team determines they have occupational or psychosocial circumstances that warrant a 6 month trial of Libre with appropriate adjunct support.

FMESG agreed that the GM positioning should be updated to bring in line with these populations, and to align with the NHSE document as a whole. The group also highlighted that relevant information around DVLA requirements within the document requires updating in line with recent change in legislation

Acknowledging the additional cost pressure to CCGs, it was proposed that the following populations continue to be included in the GMMMG guidance, but would not be reimbursed by NHSE:

- Pregnant type 2 patients on a basal bolus insulin regimen
- Type 1 patients actively trying to conceive

The group felt that recommendations for follow-up and cut-off criteria for de-prescribing were overlooked within the NHSE criteria. Concern was also highlighted regarding the lack of definition of 'psychosocial circumstances' and how this was to be assessed in the absence of clear criteria. FMESG agreed that the GM recommendation should include wording to indicate that this should apply to patients who had 'warranted formal assessment for psychosocial support as a result of their diabetes'. It was acknowledged that there are variations in the provision of specialist diabetes psychosocial support within the commissioned services across GM

Finally, the group noted that reimbursement will occur based upon primary care (FP10) prescribing data, and this would introduce a commissioning implication for those secondary care services that retain prescribing for the initial 3 to 6 months. The group agreed that the GM recommendation should be updated to direct transfer of prescribing to primary care following the first month's supply.

Action: RDTC to re-draft the GM recommendations accordingly and circulate round the group for approval. AM to prepare a paper for April's CSB detailing the potential commissioning implications of the NHSE arrangements, and of the wider GM criteria proposed.

3.0 FMESG Work Plan 2019

The group acknowledged that the CSB work plan for the 2019 was pending and would be considered by the group when available.

3.1 Consideration of items for FMESG work plan

Owing to time constraints this item was deferred to a future meeting.

4.0 Formulary and RAG

4.1 Formulary amendments March 2019

The suggested formulary amendments for February 2019 were noted and approved by the group. '

Action: RDTC to open these decisions for GM-wide consultation.

4.2 Rivaroxaban license extension- CAD/PAD

The license extension for rivaroxaban in CAD/PAD was first considered by FMESG in October 2018. The group reviewed a summary of evidence from the COMPASS trial which highlighted a similar NNT to NNH, and expressed concern regarding the risk of major bleeds vs. potential cardiovascular benefits. Additionally, a NICE Evidence Commentary published in July 2018 that questioned the relevance of the trial data to the UK population, was also acknowledged by the group.

FMESG felt that a GMMMG position should be recommended ahead of the NICE TA being published in August 2019. It was recommended that a position of DNP be issued (Criterion 1) and the decision opened for GM-wide consultation, with a footnote that this recommendation would be reviewed once NICE has published guidance. Additionally, an ongoing need to scope for the potential GM target population was highlighted and a working group of relevant specialist clinicians from across GM was identified to aid with this scoping.

At March's meeting, the group considered consultation comments on this item. And the following target GM population that had been proposed by the working group:

(A) Patients who have had a Previous Myocardial Infarction (as opposed to those who simply have a history of coronary artery disease) who are currently on optimised medical therapy and have no current indication for dual antiplatelet therapy who also have 2 of the following risk factors

- *Diabetes*

- *Chronic Kidney Disease (eGFR < 60)*
- *Heart Failure*
- *Peripheral Vascular Disease*
- *Previous ischaemic strokes of presumed atheroembolic origin*
- *Age over 65*

(B) Patients with Peripheral Vascular Disease who have had previous surgical or percutaneous intervention who are currently on optimised medical therapy and have no current indication for dual antiplatelet therapy

The group heard that whilst there was an appetite within the specialists of the working group to prescribe rivaroxaban under the new license extension, this would be in the most high-risk groups (as above) where the cost-benefit ratio would be most favourable. FMESG acknowledged that the proposed positioning was pragmatic and noted that the working group had engaged very positively with GMMMG processes to progress this work. It was felt that work to refine the potential positioning should continue in the event that the NICE TA is published later than scheduled.

FMESG supported the proposed positioning in principle, pending some further clarification from the working group on the relevant definitions of heart failure, CKD and PVD within (A) and inclusion of recommendations on the assessment of bleeding risk using a validated tool.

Action: RDTC to liaise with the working group accordingly and return updated positioning to April's meeting.

4.3 New Drug Evaluation: Pentosan for the treatment of bladder pain syndrome

At February's meeting, FMESG considered a summary of evidence for the newly licensed pentosan preparation (Elmiron®). The group noted that the quality of the evidence was limited by the relatively small patient numbers; however this was reflective of the low prevalence of the condition. It was noted that that pentosan is not recommended in RCOG/BSUG guidance, but is included in EAU guidance, however historical use of unlicensed pentosan preparations is established across GM. The financial implications of the licensed product would be challenging to determine as there was wide variation in the exact product used across GM, however an increased spend was expected.

The group felt that the best course of action would be to contact urology services to clarify pentosan's place in therapy, in order that that GMMMG positioning be appropriate. If this could not be clarified then FMESG would consider a restrictive positioning based on the high cost of the product and limited evidence base associated with the low patient numbers in trial data.

In response to this request, Prof Ian Pearce, Consultant Urological Surgeon provided a review article on BPS written by himself and colleagues that had been published in the Journal of Obstetrics, Gynaecology and Reproductive Medicine, 2018. He also provided the following background: '*Bladder pain Syndrome (Interstitial Cystitis), is a tremendously difficult condition to treat and manage, with most therapies offering a 50% success rate at best, and many offering very much less. From a purist perspective, PPS (Elmiron®) should be second line treatment after lifestyle modification as a consequence of its efficacy, high level of evidence and tolerability. In addition, the longer patients take PPS, the greater the positive impact, and it is duration rather than dose that has the greatest influence*.

FMESG discussed the response from Dr Pearce, and issues around recommending off-label use of alternatives for BPS (eg. tricyclic antidepressants) ahead of a licensed product.

Action: FMESG recommend Elmiron® be positioned GREEN (following specialist initiation) and GREY (criterion 3) – for use as a second-line treatment option for BPS, where conservative measures have failed. This recommendation to be opened for GM-wide consultation.

4.4 Formulary Application: Verkazia® for vernal keratoconjunctivitis in 4 to 18 years of age

At February's FMESG, the group scoped a formulary application for Ciclosporin 0.1% eye drops emulsion (Verkazia®) for vernal keratoconjunctivitis/ severe allergic eye disease in 4 to 18 years of age. The group noted that a formulary application had requested this item be positioned as GREEN following specialist initiation on the PAED RAG list. This would be in line with the positioning of ciclosporin 0.1% eye drops in adults.

The group requested that the formulary application come back as a full agenda item at March meeting- this was reviewed by the group, along with a corresponding formulary inclusion tool completed by RDTC. The group noted the lack of long-term safety data and the need to ensure adequate follow up.

Action: FMESG recommend Verkazia® be added to the paediatric RAG list as GREEN (following specialist initiation) and annotated 'in patients subject to active follow up e.g. reviewed every 6 months'.

5.0 Horizon Scanning and work plan

5.1 Monthly horizon scanning documents March 2019

The RDTC monthly horizon scanning document for March was considered by the group. The group recommended no additional action was required at present on the basis of these documents.

5.2 Work plan

It was noted that the GMMMG Work Plan was being updated following February's CSB. An update version would be considered at March's FMESG.

6.0 AOB

No other items were raised.

The next meeting will be held on 23rd April 2019, 12.30-2.30pm, MFT-ORC (formerly known as CMFT).