FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 23rd April 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	✓							
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)	✓	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	A							
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	A	✓	✓	✓							
Prof Peter Selby (PS)	Consultant Physician	MFT-ORC	✓	✓	A	A							
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓	✓	A							
Dr Hina Siddiqi (HS)	GP		✓	A	A	✓							
Lindsay Harper (LH)	Director of Pharmacy	SRFT	A	A	✓	A							

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	✓	✓								
Anna Swift (AS)	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	A							
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓							
Nancy Kane (NK)	Senior Medical Information Scientist	RDTC				✓							

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above.

Lorna Hand (LH) attended on behalf of Aoidin Cooke.

1.2 Declarations of Interest:

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

1.3 Draft minutes - March 2019

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

1.4 Matters Arising

1.4.1 Consultation feedback:

Items from the March meeting were out for consultation; closing 20th May. Consultation comments received on actions from the February meeting were discussed and actions recommended as follows:

- Actipatch to be added to the DNP list (criterion 1).

- Licensed and off-label topical anaesthetics for management of premature ejaculation to be added to the DNP list (criterion 1)
- Menthol in aqueous cream: brand names to be removed from formulary. Preparations to be listed generically, with a statement added to recommend choosing the product with the lowest acquisition cost and prescribe by brand name.
- VSL#3 and Vivomixx to be added to the DNP list (criterion 1), following removal of these products from the Drug Tariff. The group discussed consultation comments both in support and opposed to this action. One comment suggested that the DNP listing should apply to all indications, and not be restricted to pouchitis. It was concluded that, due to a lack of evidence of effectiveness or any national guidance recommending use, these products should be added to the DNP list for all indications.

These actions received pre-support from the April meeting of CSB.

Actions: RDTC to update the formulary and RAG list in line with these recommendations.

1.4.2 GMMMG Antimicrobial Guidelines- response to FMESG's comments

Following discussion at the March meeting of FMESG, the GM Antimicrobial Task and Finish group had been approached to provide further clarity on the issue of treatment of LUTI in men and children. The group responded that:

- Nitrofurantoin had been recommended for children due to local resistance patterns. While it was acknowledged that there may be a considerable cost attached to use of nitrofurantoin liquid, it was felt that this was not adequate grounds to recommend use of less clinically appropriate drugs.
- Trimethoprim had been recommended for men on the basis that this is more effective when there is prostate involvement, and that sensitivity testing should be conducted in these patients as a good practice point.

FMESG agreed that cost should not be a barrier to appropriate anti-microbial prescribing. FMESG requested that the recommendation for children be amended to include additional wording from the NICE guidance around patients with low risk of resistance, to add clarity for the reader.

There was a discussion around process, and FMESG queried whether the Task and Finish group have any Terms of Reference. If not, FMESG suggested that these could be developed, and could include a requirement to take cost into consideration when making recommendations.

Action: RDTC to feedback the group's discussion to the Antimicrobial Task and Finish group.

1.4.3 Action log

Updates to the action log were noted. This included progress of the GM OTC policy, for which an engagement process was currently underway. A list of drugs to be designated DNP under this policy would be brought to a future meeting of FMESG for approval.

Actions: LB to bring OTC policy to FMESG once available.

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 Diabetes chapter

2.1.1 Draft Toujeo recommendation

The group reviewed a draft update of the FMESG recommendation on Toujeo. The draft was approved with two minor amendments:

- The wording on injection pain to be updated to state “There is pain as a consequence of high injection volumes of standard-strength insulin”.
- The wording on Toujeo DoubleStar pen devices to be updated to note that this device delivers doses in increments of two units.

Discussion followed regarding how this item will be monitored, and it was agreed that this item should be added to the FMESG monitoring log and reviewed in six months to assess any prescribing growth for this item.

Action: RDTC to amend the draft statement as above and circulate to the group for approval. RDTC to add this item to the FMESG monitoring log and review prescribing in six months.

2.1.2 Draft insulin degludec recommendation

The group reviewed a draft update of the FMESG recommendation on insulin degludec. It was agreed that the draft statement should be updated to apply to type 1 diabetes only, with a statement added to the end to highlight that degludec should not be used in type 2 diabetes, in line with the NICE guideline development group’s recommendation from NG28. The group recommended that insulin degludec should also be added to the grey list for use in type 1 diabetes only, and that the current recommendation on insulin degludec + liraglutide (Xultophy) should be updated to bring it in line with the new recommendations for insulin degludec.

Action: RDTC to re-draft the statements on insulin degludec, and insulin degludec + liraglutide, and circulate to the group for approval. Recommendation to add insulin degludec to the grey list for use in T1DM only to be opened for GM-wide consultation.

2.2 Draft guidance for the Covert Administration of Medicines

The group heard that guidance on the Covert Administration of Medicines had been written by Wigan Borough CCG and updated by Trafford CCG. The guidance had been written to ensure that guidance was in place for all settings where covert administration may occur, but was not intended to replace any individual organisation’s existing policy. The authors felt it would be useful to have the guidance adopted for GM-wide use, and it had been brought to FMESG to seek support from the group.

The group felt that this document represented a good support for medicines optimisation policy, and supported bringing it into GMMMG process. It was noted that the language in the document would benefit from simplification in places. The group also noted that the document would benefit from further detail on the use of unlicensed and off-label medicines, and specials, and that reference to an existing UKMi document on covert use of medicines in care homes may be useful.

Action: RDTC to add the draft guidance document to the FMESG workplan and progress the work in line with GMMMG process.

3.0 FMESG Work Plan 2019

3.1 Consideration of items for FMESG work plan

The group discussed the items for consideration and accepted all items for addition to the agenda at future meetings, as capacity allows. The group also made the following recommendations:

- Sodium oxybate should be referred to HCDSG for any future monitoring requirements, since it has now been added to the list of specified High Cost Drugs in the 2019/20 National Tariff. The group were supportive of expanding the current GM positioning to include adult patients, but recognised that there was a commissioning impact for CCGs and would await further direction from HCDSG.
- Glycopyrronium liquid should be considered for addition to the adult RAG list as well as the paediatric list. Additional information on the commissioning impact of these products would be required, along with more detail on the place in therapy.

- The Levosert application should be expanded to include a review of all intrauterine delivery systems, since several are now available and all have slightly different characteristics. RDTC to engage with relevant clinical services on this topic.

Additionally, the group requested a RAG review of dexamfetamine for narcolepsy, with a view to assigning an AMBER status for all formulations.

Action: RDTC to draft RAG tools for hydrocortisone granules (Alkindi) for doses <5mg, testosterone products, glycopyrronium oral liquid, and dexamfetamine, and a formulary tool for Levosert IUS, including comparisons to other available IUS.

4.0 Formulary and RAG

4.1 Formulary amendments April 2019

The suggested formulary amendments were noted and approved by the group, with the exception of a request to add ropinirole 3 mg & 6 mg modified-release tablets to formulary, since this request was not supported by any clinicians.

The group recommended that ertugliflozin should be added to formulary as an alternative treatment option, and review this position once cardiovascular outcome data become available.

Action: RDTC to open these decisions for GM-wide consultation and feed back to the applicant for ropinirole tablets.

4.2 Rivaroxaban license extension- CAD/PAD

At the March meeting, the group reviewed consultation comments on the proposed addition of rivaroxaban to the DNP list (Criterion 1) in this indication. The group had also requested additional detail from the working group, who suggested the following:

"Following consideration of individual factors for bleeding risk, rivaroxaban in combination with aspirin may be considered for the prevention of atherothrombotic events in the following adult patient populations with coronary artery disease, or symptomatic peripheral artery disease, who are at high risk of ischaemic events:

(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 15-60 mL/min)*
- *Heart Failure (NYHA I or II, plus ejection fraction >30%)*
- *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

** Peripheral vascular disease defined as either of:*

1. ABPI <0.9 or TBPI <0.7 (toe brachial pressure index)

2. Stenosis of peripheral artery >50% on Duplex/CTA/MRA/DSA"

The group appreciated this additional clarification, but were concerned that there may not be sufficient evidence to support use of rivaroxaban in these populations. Additionally, the group felt there was a need to assess bleeding risk annually. It was felt that more input was needed from primary care, since prescribing may end up being transferred to GPs following initiation by surgical teams. The group requested a brief summary paper and a copy of the original evidence summary reviewed by FMESG be circulated to group members, who would then seek input from primary care prescribers.

Action: RDTC to circulate brief summary paper and evidence summary; group members to seek input from primary care colleagues.

4.3 RAG status review: oral sodium fusidate

During routine review of the RAG list, and following GM-wide consultation, non-formulary drugs with GREEN status have been removed from the RAG list. One of the removed items was sodium fusidate. However, comments received during consultation queried whether this was appropriate for oral formulations of sodium fusidate, given the potential for uncommon but serious adverse effects. It was therefore proposed that oral formulations of sodium fusidate should remain on the RAG list as GREEN (microbiologist advice, non-formulary). The group reviewed this comment and agreed that, given low prescribing in the region and a lack of any national guidance on use, this positioning would be appropriate.

Action: FMESG recommend oral sodium fusidate be positioned GREEN (following microbiologist advice) and non-formulary. This recommendation to be opened for GM-wide consultation.

4.4 New Medicines review: Suliqua for treatment of Type 2 Diabetes

The group reviewed a summary of evidence for a novel product comprising insulin glargine + lixisenatide in a single pre-filled pen (Suliqua®▼). The group noted that lixisenatide is not currently a first choice formulary option in GM, and that the only other comparable product (insulin degludec + liraglutide, Xultophy®) is not recommended for use in GM. The group acknowledged that Suliqua is less costly than Xultophy but felt that there did not appear to be an appetite to use long-acting insulin analogue/GLP-1 receptor agonist combination products. There was also concern that the availability of two strengths may lead to dispensing or dosing errors.

The group recommended that Suliqua should be added to the existing statement for Xultophy, which is currently being updated as per item 2.1.2 above.

Action: RDTC to update the statement on Xultophy, and circulate to the group for approval.

4.5 New Medicines review: Slenyto for treatment of insomnia in ASD and SMS

The group reviewed a summary of evidence for newly-launched melatonin 1 mg & 5 mg modified-release tablets (Slenyto®) for use in children and adolescents aged 2-18. The group raised concerns regarding the quality of the evidence, and the degree of polypharmacy in the target population.

The group noted that there is an existing shared care protocol for melatonin in use in GM, but were concerned that the review and stopping criteria in this document are not currently being well-followed. It was proposed that the shared protocol should be updated to include Slenyto, and that this topic should also be referred to the Pathways and Guidelines Development Subgroup for consideration since the group were aware there may be a relevant piece of work.

Action: RDTC to contact author of melatonin shared care protocol and arrange for review and update of this document.

5.0 Horizon Scanning and work plan

5.1 Monthly horizon scanning documents April 2019

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

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 a future meeting.

6.0 AOB

PCSK9 inhibitors for treatment of hypercholesterolaemia: the group heard that the FMESG statement on evolocumab and alirocumab is now due for review, but noted that these drugs have been added to the list of specified High Cost Drugs in the 2019/20 National Tariff. The group agreed that this topic should be referred to the High Cost Drugs Subgroup for consideration.

Action: RDTC to refer this topic to the High Cost Drugs Subgroup for consideration.

The next meeting will be held on 28th May 2019, 12.30-2.30pm, MFT-ORC (formerly known as CMFT).