FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 30th October 2018
12:30 - 2:30 pm
Pharmacy Dept MFT-ORC (formerly known as CMFT)

Present:

Name	Title	Organisation	Jan	Mar	May	July	Aug	Sept	Oct
Elizabeth Arkell (EA)	Medicines Management Lead	MFT-WH	✓	LA	A	✓	A	✓	✓
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	✓	✓	✓	A	✓ (RR)	✓	✓
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A	✓	✓	✓	✓	✓	A
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	✓	✓	A	A	✓	A	✓
Dr Paul Chadwick (PC)	Consultant Microbiologist and Chair of Meds Management Committee	SRFT	✓	A					
Lorna Hand	Medicines Management and Medicines Information Pharmacist	MFT-ORC	✓	✓	✓	✓	✓	✓	✓
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓	✓	✓	✓	✓ (FA)	✓	✓
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	✓	A	A	A	✓ (AH)	✓	✓
Rachel Macdonald (RM)	Pharmacist	Community pharmacy	A	A	A	✓	✓ (AI)	✓	✓ (AI)
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	✓	✓	A	✓	✓	✓	✓
Prof Peter Selby (PS)	Consultant Physician	MFT-ORC	✓	A	✓	A	A	A	A

Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓	✓	A	A	✓	A
Dr Hina Siddiqi (HS)	GP	Trafford CCG			✓	A	A	✓	✓
Lindsay Harper (LH)	Director of Pharmacy	SRFT	✓	A	A	✓	A	A	✓
Jonathan Peacock (JP)	Deputy Chief Pharmacist	WWL	✓	✓	✓	A	✓	✓	✓
Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	✓	✓	✓	A	✓	✓
Jonathan Schofield (JS)	Consultant Physician	MFT-ORC							✓
Faisal Bokhari (FB)	Deputy Head Medicines Optimisation	T&G CCG							✓
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	✓	✓	✓	✓	✓
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	✓	✓	✓	✓	✓	✓	✓
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC				✓	✓	A	✓

1. General Business

1.0 Apologies

Apologies had been received in advance as noted above.

Dr Hussain Contractor, Consultant Cardiologist, attended for item 2.1.

Dr Ian O'Connell, Consultant Endocrinologist attended for item 3.2

LH chaired the meeting until item 3.2. JP chaired thereafter. JS was in attendance until item 2.2.

1.2 Declarations of Interest:

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

1.3 Draft minutes (September 2018)

The minutes were agreed as an accurate record, following a minor grammatical amendment.

1.4 Matters Arising

1) Consultation feedback:

All items from the September meeting were out for consultation at time of meeting; closing 14th November. Consultation comments received on actions from the August meeting were discussed.

Penicillamine for RA: the group recommended that a shared care protocol be developed, to reflect the AMBER RAG status of the drug. It was proposed that this could be added in to the new SCP for penicillamine in Wilson's disease which is currently under development.

Action: RDTC to contact author of SCP and request adaptation to include RA as an indication.

RAG status haloperidol and chlorpromazine for psychiatric indications: The group agreed that a shared care protocol for these agents should be developed or an existing SCP amended to include them. Comments received from mental health services regarding a lack of capacity for existing patients to be repatriated back to mental health services were acknowledged. It was emphasised that the proposed change in RAG would apply to new patients only and existing patients should continue with their current management. Additionally, although comments were received that all bar one CCG in England have positioned these drugs as GREEN, a check of various formularies highlighted at least 3 areas for which AMBER positioning exists for psychiatric indications. It was suggested that other oral 'typicals' also be considered for inclusion (e.g. trifluoperazine) however haloperidol and chlorpromazine are the only oral typicals listed in the formulary at present.

Action: RDTC to contact author(s) of existing MH SCPs and request development/ amendment of SCP.

Toujeo: A large number of comments were received on this item. The citation of helpful references, advantages of the 3 hour administration window, and feedback on improved stability vs BD basal regimens were noted by FMESG. Remarks around the appropriateness of the original NTS recommendation in relation to injection volumes were also acknowledged. However- despite most of the comments received relating to use in Type I diabetes- the group recognised that audit data for use of Toujeo across GM demonstrates a significant use in the Type II population, which emphasises the need for clarity regarding the appropriate place in therapy. Recognising that work is currently underway to develop GM-wide diabetes pathways, it was agreed that a summary from FMESG be sent to this working group, along with the consultation comments and audit data for Toujeo, in order that the working group define its positioning. Review of the current NTS statement to be put on hold until the pathway(s) have been developed.

Action: RDTC to feedback to diabetes pathways working group accordingly.

No other comments were received on the actions proposed from August's meeting.

Action: RDTC to seek CSB approval and update the formulary, and RAG/DNP list to reflect these actions.

2) Action log:

Updates to the action log were noted.

3) Paediatric RAG/DNP:

Following September's meeting, FMESG members were requested via email to approve by simple majority a proposal to review the current format of the paediatric RAG/DNP list and consider either:

1. Combining the paediatric and adult lists, to give a single point of reference and provide clarity
2. Preserving the current format, but make clearer the wording on the paediatric list which indicates users should check the adult list for items considered DNP

An insufficient number of responses were received via email to permit approval prior to the meeting. The group members in attendance were therefore asked to respond by 'show of hand'. A majority vote in favour of option 2 was received.

Action: RDTC to propose amended wording for inclusion on the paediatric RAG list and circulate to group via email for approval.

4) Draft letter to dental services

At September's meeting, the group noted that there was a lack of clarity regarding prescribing of prescription-only toothpaste and mouth washes. It was agreed that prescribing should be restricted to dentists, who have the necessary skills to detect and manage the risk of fluorosis. RDTC were to draft a letter clarifying this position to be sent to dental hospitals, the Christie, LDCs and chief pharmacists. This draft has now been approved by the chair of CSB.

It was agreed that the letter should be sent to Dympna Edwards (GM Consultant in Dental Public Health) and Deborah Moore (GM Specialist Registrar in Dental Public Health), to make them aware of its existence prior to GM wide dissemination.

Action: RDTC to send to Dympna Edwards and Deborah Moore, then for GM-wide distribution.

2. Medicines Optimisation

2.1 Rivaroxaban for prevention of CV events

The license for rivaroxaban was extended by the EMA in July 2018. It is now indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events; administered at dose of 2.5mg twice daily taken in combination with aspirin 75-100mg daily. The group considered a review document produced by RDTC which presents the clinical evidence for this from the COMPASS study.

Dr Hussain Contractor (HC) Consultant Interventional Cardiologist MFT-ORC attended to provide the group with some specialist cardiology background to help the group assess the appetite for prescribing from a cardiology point of view. The group recognised that the license extension presents a novel intervention for patients at ongoing risk of ischaemic events by targeting thrombin generation, noting the broad inclusion criteria of the study and that it was stopped early after the superiority endpoint was reached. HC expressed that an appetite to prescribe within cardiology exists- primarily in outpatient clinics for patients that have been referred by their GPs with ongoing symptoms, but uptake would be expected to be slow.

The group expressed concerns that the new 2.5mg strength may introduce dosing/ prescribing/ dispensing errors within primary care and that education would be required to mitigate this risk. The group acknowledged that it was unknown whether a pathway is in development within GM.. It was agreed that some scoping would be necessary across the relevant specialities to identify the potential place in therapy and expected patient numbers.

Action: RDTC to contact GMMMG chief pharmacists to commence scoping process.

2.2 FreeStyle Libre Audit

In line with the GMMMG approved recommendation, there was an agreement that FreeStyle Libre is audited annually to ensure it is being prescribed in line with the agreed criteria. AM

presented a proposal for this audit to the group, and highlighted limitations of using ABCD audit forms for this purpose. AM also explained that engagement from all CCGs would be necessary for such an audit to be successful.

It was agreed that the current level of prescribing of FSL should be brought to CSB to ascertain whether such an audit is needed at this point.

Action: AM to write summary paper for submission to CSB

2.3 OTC Policy Update

LB updated the group on the formation of a 'task and finish group' due to meet shortly after FMESG that day to begin drafting of a position statement and policy. NHSE had been approached for support and confirmed that they will feed in and provide advice where requested. FMESG will be updated in due course.

2.4 GM Antimicrobial Guideline

The group reviewed the most recent update to the GM antimicrobial guideline, noting that the most significant change was in the positioning of doxycycline for acute exacerbation of COPD. FMESG approved this version for upload to the website. It was suggested that the route for continuous consultation be made clearer within the document- either by inclusion of an email address for contact, or a hyperlink to the 'Contact Us' page on the site. Additionally, the GMMMG positioning of methenamine was questioned in relation to its inclusion in PHE guidance but not within the GM document.

Action: RDTC to add updated document to website and request authors to consider clarifying how readers can submit feedback on each version.

3.0 Formulary and RAG

3.1 Formulary amendments October 2018

The suggested formulary amendments for October 2018 were noted and approved by the group.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval.

3.2 Semaglutide – New Medicine Request

A RDTC new drug evaluation of semaglutide was considered at July's meeting. In the absence of a cost or release date, the group agreed at that time that there was no reason to assess semaglutide for formulary inclusion. Semaglutide is now expected to launch Q4 2018/ Q1 2019 and pricing is comparable to other marketed GLP1s. A new medicine request had now been received by the group for consideration.

Dr Ian O'Connell, consultant endocrinologist attended for this item, to support his application. The group noted evidence that semaglutide had greater effects on glycaemic parameters and body weight than most comparators, including exenatide and dulaglutide in a large clinical trial, and that it is associated with a reduction in cardiovascular events comparable to that observed with liraglutide in the LEADER trial. The advantage of once weekly administration versus the current formulary first choice agent (daily liraglutide) was highlighted.

On the basis of the evidence presented, the group recommended that semaglutide should replace dulaglutide in the formulary as the first choice weekly preparation, with GREEN RAG status to align with the other formulary choice GLP1s. It was acknowledged that patent expiries would be borne in mind going forward, as this may further influence positioning of agents within GMMMG. In recognition of the current diabetes pathway work being undertaken, the group agreed that a summary be sent to the working group to update them on the discussion.

Action: RDTC to contact diabetes pathways working group, open these decisions for GM-wide consultation and seek CSB pre-approval

3.3 Noqdirna- New Medicine Request: Update

At May's FMESG, a New Medicines Request for Noqdirna for idiopathic nocturnal polyuria was considered by the group. The lack of GM patient numbers within the application meant that the group were unable to assess a GM impact, and it was agreed that this item should remain non-formulary as a routine use across GM was not demonstrated. The group referred to a recent Drug and Therapeutics Bulletin that highlighted a 0.2 to 0.4 reduction in night time voids with Noqdirna, and that the clinical significance of this outcome was negligible. FMESG group agreed that feedback should be sought from the application regarding the definition of the improvement expected, and target population/ anticipated prescribing figures for GM.

Some further data was submitted by the applicant for October's meeting. The group noted patient numbers were much higher than expected and that data supplied did not support the applicants statement that 'the vast majority of these patients would already be in the system and potentially being treated with expensive 2nd or 3rd line antimuscarinics. The group recommended that more work would be required to identify the potential cohort for GM, and firm-up proposed place in therapy. It was suggested that the working group currently reviewing and updating the OAB pathway be contacted to help establish this information, in order to adequately assess Noqdirna for formulary inclusion.

Action: RDTC to contact OAB pathways working group with aim to identify potential place in therapy/ patient cohort.

3.4 Dapoxetine- DNP assessment

The group considered a proposal to change the current status of dapoxetine from its current positioning to DNP. Prescribing figures across GM are low with estimated ~2,000 items dispensed annually at a cost of £60,000. Current GMMG positioning is: *Grey (Green RAG) Criterion 1: Only for use in patients whose condition is medically related or as part of a fertility programme, however more cost effective options should be considered first.* CD explained that it was not clear from past minutes/records where the suggested restriction relating to fertility programmes originated, and that premature ejaculation is not covered by NICE guidance on fertility problems (CG 156). LB was able to provide some background that this recommendation was aimed at providing an alternative option for patients in whom the next step would be referral for IVF. The group considered the evidence-base presented and noted that there had been no new favourable data. It was recommended that dapoxetine is added to DNP as Criterion 1.

Action: RDTC to open this decision for GM-wide consultation and seek CSB pre-approval

3.5 VSL#3 DNP/Grey List Assessment

The group were asked to agree on formulary positioning of VSL#3. VSL#3 is a food supplement with ACBS approval for maintenance of remission of ileo-anal pouchitis. Recommendations for the use of VSL#3 for this indication are derived from the European evidence-based consensus on ulcerative colitis' diagnosis and management (ECCO) and are referred to in NICE Evidence Summary on Pouchitis: rifaxamin (2014). As surgery may be considered as a last resort for people whose pouchitis does not respond to other treatment options, VSL#3 may be considered a non-invasive strategy in the management of this condition. GM primary care prescribing figures for July 2017- June 1018 demonstrate that there is some prescribing in all CCGs totalling 500 items (~£31,500).

Evidence for VSL#3 for other indications (including prevention of *C. Diff*, improvement of hepatic encephalopathy, and remission of ulcerative colitis) are conflicting and/or lacking in quality. NTS issued a GMMMG position statement on probiotics (review date June 2017) which states that GMMMG does not recommend the use of probiotics for the prevention and treatment of diarrhoea of any cause.

The group recommended VSL#3 be assigned Grey (GREEN following specialist initiation) status, Criterion 3: Nutritional supplement (ACBS) for the maintenance of remission of ileoanal pouchitis induced by antibacterials in adults.

Action: RDTC to open this decision for GM-wide consultation and seek CSB pre-approval

4.0 Horizon Scanning and work plan

The RDTC monthly horizon scanning document from October was provided to the group. The group recommended that scoping should be undertaken for the new oro-dispersible budesonide tablet which is indicated for the treatment of eosinophilic oesophagitis in adults. Additionally, the new licensed status of Pentosan was noted, with a request to bring back to November's meeting for assessment for formulary positioning.

Action: RDTC to update the work plan and action log accordingly.

4.0 AOB

HS updated the group on October's hypertension SCN meeting. Although this had been an initial 'path-finding' meeting, there had been discussion regarding fixed-dose dual therapy preparations. HS highlighted that attendees were not all aware of the potential cost-saving to patients by prescribing combination preparation. Reluctance from GPs to start 2 antihypertensive drugs at the same time was noted, strengthening the need for a pathway to be developed to position these agents. The next meeting is the 15th of November. There is a plan for the SCN protocol to follow the GMMMG processes and come through FMESG/PaGDSG in due course.

The next meeting will be held on 27th November 2018 12.30-2.30pm, MFT-ORC (formerly known as CMFT).