Minutes of the GMMMG Clinical Reference Group Meeting
Tuesday June 8th 2021, 12:00-14:00
via MS Teams

Name	Title	Organisation	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Dr Connie Chen (CC)	GP Lead Medicines Optimisation	Manchester Health and Care Commissioning	✓	✓	✓						
Dr Hina Siddiqi (HS)	GP		A	A	A						
Dr Jonathan Schofield (JS)	Consultant physician acute medicine & diabetes	Manchester FT	✓	✓	✓						
Lisa Kershaw (LK)	Lead Medicines Optimisation Pharmacist	Manchester FT	A (VR)	✓	A						
Sarah Boulger (SB)	Medicines Information Pharmacist	Penine Acute	A	✓	A						
Suzanne Schneider (SS)	Medicines Information Pharmacist	Bolton FT	A	A	✓						
Gary Masterman (GM)	Associate Director of Pharmacy	Wrightington, Wigan and Leigh FT	A	A	✓						
Andrea Marrosu (AM)	High cost medicines and home care pharmacist	Salford Royal FT	A	✓	A						
Peter Marks (PM)	LPC Board Member	GM LPC	A	A	A						
Keith Pearson (KP)	Head of Medicines Optimisation	Heywood, Middleton & Rochdale CCG	✓	✓	✓						
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	Bury CCG	✓	A (SK)	✓						
Helen Isherwood (HI)	Medicines Optimisation Pharmacist	Manchester FT	✓	✓	✓						
Jane Wilson (JW)	Director of pharmacy	GM Mental Health FT	A	✓ (SB)	✓ (SB)						

Or Steven Buckley (SB)	Deputy director of pharmacy										
Faduma Abukar (FA)	Head of medicines management	Stockport CCG	✓	A	✓						
Zoe Trumper (ZT)	Assistant director of medicines management	Wigan Borough CCG	✓	✓	✓						
Faisal Bokhari (FB)	Deputy Head of Medicines Optimisation	Tameside & Glossop CCG	A	A	✓						
Jennifer Bartlett (JB)	Team Leader Neighborhood Integrated Practice Pharmacists	Salford Royal FT	A	✓	✓						
Aleksandra Houghton (AH)	Senior Medicines Optimisation Adviser	Manchester Health and Care Commissioning	✓	✓	A (CF)						
Lizzie Okpara (LO)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓						
Monica Mason (MM)	Head of Prescribing Support	RDTC	✓	✓	A						
Dan Newsome (DN)	Principal Pharmacist	RDTC	A	✓	A						
Andrew White (AW)	Head of Medicines Optimisation	JCT	✓	✓	✓						
Andrew Martin (AMart)	Strategic Medicines Optimisation Pharmacist	JCT	✓	✓	A						
Karina Osowska (KO)	Medicines Optimisation Pharmacist	JCT	A	✓	✓						

1. General Business	
1.1	Welcome and apologies (See register for apologies). The meeting was chaired by Andrew White (JCT).
1.2	**Declarations of interest** None declared.
1.3	**Minutes of the last meeting** The minutes were agreed as a true record.
1.4	**Action log review** Updates on the action log were noted. Some feedback had been received confirming that the ORBIT bleeding risk tool recommended in NG196 is not available on EMIS or Vision. This is recognised in the guidance which states "*other bleeding risk tools may need to be used until it is embedded in clinical pathways and electronic systems*". This was flagged to MGSG. Following the request made in the May meeting, some feedback had been received by email regarding the prioritisation of the development of non-RMOC SCPs with the suggestion of prioritising the SCPs for modafinil and mental health medicines. This adds to feedback received in the May meeting suggesting prioritisation of paediatric SCPs particularly those for mental health drugs. This feedback will be used to inform the development of these SCPs. The action relating to providing assurance to GMMMG on the implementation of safety alerts had been passed on to the Integrating NHS Pharmacy and Medicines Optimisation (IPMO) programme lead for medicines optimisation and safety and this is likely to be picked up as part of the work stream.
1.5	**Update from MGSG** The draft minutes for the May MGSG meeting were enclosed for information. AW updated the group on some key discussions that had taken place. The group discussed the implications of the recent NICE AF guideline including the potential for reconsidering the current model for anticoagulant services in GM given that DOACs are now being recommended first line with a shift away from vitamin K antagonists. There were also initial discussions around aducanumab for treating mild dementia in Alzheimer's disease. A NICE TA is expected for this treatment around May 2022 however, discussions have been initiated at this stage as if approved there is likely to be significant commissioning and financial implications. MGSG plan to flag these issues to GMMMG.
2.0 Matters arising	
2.1	**Consultation feedback on Dec 20 to Apr 21 actions** The group noted the consultation feedback on decisions made between Dec 20 and Apr 21 and discussed and agreed the following: The proposed merging of the GREEN specialist initiation and GREEN specialist advice categories is not to go ahead at this time. Feedback received raised concerns that merging the categories may promote shifting of workload to primary care without additional resource. Also where baseline monitoring is required for drugs currently assigned a GREEN specialist

	initiation RAG, it was felt strongly that this should be carried out by the specialist and not by primary care. There were also comments stating that the term “specialist initiation or advice” was confusing as it wasn’t clear which of the two applied. Further, it was also noted that some drugs may specifically need to remain specialist initiation for example where specifically recommended by NICE. The group discussed the points raised and identified that there is still a role for the specialist initiation category specifically. It was also discussed that with the planned reform in elective care and anticipated changes in patient management pathways, there would need to be consideration on how these might affect RAG categories and there should be communication with teams involved in this work. **ACTION**: JCT to engage with teams involved in elective care and patient management pathways reform. The group agreed that the RAG status for ulipristal (Esmya®) for uterine fibroids should be changed to RED. Following a safety review of serious liver injury with Esmya, the product license which was suspended in March 2020 has been reinstated with restricted use as a result of cases of serious liver injury. Esmya can now only be used for intermittent treatment of moderate to severe uterine fibroids symptoms before menopause and when surgical procedures are not suitable or have failed. Prior to the license suspension, Esmya was assigned a GREEN specialist inditiation status for this indication. However, the group felt that given the restricted use, the concerns around serious liver injury and liver failure and the close monitoring required for this drug that it was safer that prescribing and monitoring of clinical and safety outcomes should remain the responsibility of the specialist team. **ACTION**: RDTC to open ulipristal decision for GM wide consultation. All other decisions were approved and would be submitted to MGSG for ratification.
3.0 Formulary and RAG	
3.1	**Formulary amendments May 2021** Suggested formulary amendments were noted and approved as follows: Andexanet alfa for reversing anticoagulation from apixaban or rivaroxaban to be added to chapter 2 of the formulary as a RED drug along with the link to NICE TA697. The NICE resource impact template estimates that using the list price, the cost impact in GM will be £530k in year 1, increasing to £1.3m in year 5. A confidential commercial access agreement is in place but this price is unknown. This is to be flagged to MGSG. Ravulizumab for treating paroxysmal nocturnal haemoglobinuria (NICE TA698) to be added to the RAG list with a RED status. This is an NHSE commissioned PbRe drug. Ofatumumab for treating relapsing multiple sclerosis to be added to chapter 8 of the formulary as a RED drug and for specialist use only along with the link to NICE TA699. This is an NHSE commissioned PbRe drug. Demeclocycline for hyponatraemia associated with SIADH to be RED pending further information and guidance from specialists regarding place in therapy to inform a full RAG review. **ACTION**: RDTC to open the above decisions for GM wide consultation. The group also approved the addition of an annotation to the RAG entry for glycopyrronium oral solution to highlight the non-interchangeability of oral solutions due to differences in bioavailability and advise prescribers to state the specific product to be dispensed. **ACTION**: RDTC to amend RAG entry for glycopyrronium oral solution.

3.2	**Bempedoic acid with ezetimibe RAG status** The group discussed NICE TA694 for bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia at the May meeting but requested specialist feedback on its place in therapy to inform the decision on the RAG status. Feedback received from SRFT specialists was noted which suggested that bempedoic acid would likely be used in patients who did not meet the eligibility criteria for PCSK9 inhibitors. It was also suggested that initiation in primary care would be appropriate if there were guidelines advising when to consider bempedoic acid and when to consider PSCK9 inhibitors. The group heard that MFT would be reviewing an application for bempedoic acid soon and that the proposed place in therapy was in line with the NICE TA and matches that predicted by the SRFT specialists. JS pointed out that the licensed indications for bempedoic acid as per the SPC/BNF are wider than that approved by NICE. Bempedoic acid is licensed to be used in combination with statins whereas this use is not approved by NICE. This opens the possibility of the medicine being used outside the approved indications if going strictly by the SPC/BNF. Also, the NICE TA leaves open to interpretation when bempedoic acid could be considered as one of the criteria for use is if ezetimibe alone does not control LDL cholesterol *well enough*. JS explained that adequate cholesterol control would differ from patient to patient and depend on individual circumstances e.g. risk factors for CVD. Taking the above points into consideration the group felt that appropriate patient selection for this treatment and initiation best sits with lipid specialists and agreed to assign bempedoic acid a GREEN following lipid specialist initiation status as per NICE TA694. The group also felt that it would be helpful for the current GMMMG PCSK9 inhibitor guidance to be updated to include the pathway for use of bempedoic acid. It was suggested that the working group who produced the PCSK9i guidance could be approached to take this forward. **ACTION**: RDTC to open decision for GM wide consultation. A Martin to liaise with working group for PCSK9i guidance regarding update to include bempedoic acid.
3.3	**Sativex RAG status** In line with recommendations given in NG144 regarding the use of Sativex spray, the group agreed to add Sativex spray for treating moderate to severe spasticity in adults with multiple sclerosis to the formulary as a RED drug. It was recognised that the NICE guidance suggests shared care may be appropriate. However, there are ongoing operational/ commissioning issues which need to be resolved before this could be done safely/ effectively. Therefore a RED RAG was agreed at this time. The operational issues are to be flagged to MGSG. **ACTION:** RDTC to open decision for GM wide consultation.
3.4	**Deoxycholic acid for submental fat evidence scoping** The group noted the evidence scoping document for deoxycholic acid for treatment of moderate to severe convexity or fullness associated with submental fat (“double chin”) in adults when the presence of submental fat has an important psychological impact for the patient. Four clinical trials were identified, all of which use a subjective measure (change in patient and clinician judgement of submental fat) as their primary outcome. Deoxycholic acid was superior to placebo for this outcome; there were no active comparators. The group felt that the indication falls within cosmetic use and should be considered for a DNP status. While the indication includes psychological impact, it was felt that this factor alone would not be sufficient grounds to consider its use. It was agreed that a DNP assessment should be completed ahead of the next meeting. It was also discussed that a referral should be made to the EUR steering group for them to consider this product.

	ACTION: RDTC to complete DNP assessment for the next meeting. JCT to liaise with EUR steering group to consider this product.
4.0 Pathways and Clinical Guidelines	
4.1	**COPD management plan** The group reviewed the draft updated GMMMG COPD management plan. AW explained that review was triggered by developments in the therapeutic area and an increased focus on environmental sustainability and reducing the carbon footprint of inhalers. As well as updating the clinical content, the update has involved highlighting information on three key areas including carbon impact, cost and required inhaler technique to assist prescribers in making informed decisions about inhaler choice for patients. Dry Powder Inhalers (DPIs) are recommended as the preferred option due to substantially lower environmental impact with less prominence given to Metered Dose Inhalers (MDIs). Charts include an indication of the carbon impact of individual inhalers through colour coding. AW proposed the use of descriptions of carbon impact that would be relatable to patients such as the equivalent number of miles which was welcomed. Charts also include information on cost per dose and the inhalation resistance for each product. The addition of a key explaining the different symbols in the charts was requested. It was noted that the RDTC would be calculating the carbon and cost impact of the recommendations for submission to MGSG. AW sought feedback from the group regarding the time frame it might take to implement the recommendations in the updated management plan including active switching of patients to low carbon options. The feeling was that this would be a long term process likely to take a few years, bearing in mind that changes to COPD patients' regimens should be avoided in winter. However, there may be some groups of patients who could be targeted more quickly e.g. patients who are clinically unstable requiring review of their treatment anyway or harmonising inhaler type for patients who are stable but prescribed different types of inhalers. Overall, the group were supportive of the updated COPD management plan and agreed to its submission to MGSG for ratification following any necessary amendments, along with the carbon and cost impact produced by RDTC. **ACTION**: JCT to make any necessary amendments and submit to MGSG for ratification. RDTC to calculate cost and carbon impact.
5.0 Shared care	
5.1	**Lithium in Adults** The group noted a draft updated lithium SCP to replace the current version which expired in December 2020. The SCP has been transferred to the updated template and mental health teams have worked together to agreed this final draft. Cluster headache prophylaxis had been added to the indications list; this indication had been approved with an AMBER RAG status with SCP pending for some time. A clinical check had been completed by the RDTC. The group gave approval to open the SCP for consultation. It was noted that the RMOC lithium SCP consultation was still open and due to close in a few days. To avoid any potential confusion, the GMMMG version will open for consultation after the RMOC consultation is closed. **ACTION**: RDTC to open for GM wide consultation.

5.2	**Hydroxychloroquine in adults** The group reviewed the post consultation version of the hydroxychloroquine SCP. Consultation comments were provided for information. Some minor amendments had been made in response to consultation feedback. The document was clinically approved for submission to MGSG to consider financial/commissioning implications and final ratification. **ACTION**: JCT to work up commissioning/financial implications for submission to MGSG.
5.3	**Shared care information leaflet for patients and carers** This document was first reviewed at April CRG with feedback suggesting the use of less complex language and to make sure it's clear that agreement is needed from GPs for shared care. A similar document used by MFT rheumatology was kindly shared and this was used to build on the GMMMG version. The updated version was kindly reviewed by the MHCC communications team who made a minor suggestion which was accepted. The group gave approval to open the leaflet for GM wide consultation however a minor suggestion was made to review the wording used regarding GP acceptance prior to opening for consultation. **ACTION**: RDTC to open for GM wide consultation.
6.0 National and regional guidance	
6.1	**GMMMG response to consultation on ACBS policy on standard adult ready-to-drink oral nutritional supplements** The group were made aware of a consultation currently running on the ACBS policy for oral nutritional supplements. GMMMG plan to submit a response to the consultation. To facilitate this, group members were requested to submit their responses and to share with relevant colleagues, in particular those from dietetic services and procurement. The consultation questions had been complied in an enclosed Word document. Responses are required by the 1st of July to allow enough time to collate and to be reviewed by MGSG/GMMMG before final submission. **ACTION**: Group members to submit feedback on consultation to RDTC by 01/07/2021.
6.2	**RDTC QAA: Private Healthcare providers requesting prescriptions from GP services** The group reviewed the draft of a document being produced by the RDTC addressing points that that primary care prescribers need to be aware of when they receive requests to prescribe medicines from private healthcare providers. The document has been reviewed and commented on by colleagues in the North East, and RDTC would are also seeking feedback from GM colleagues. Group members were requested to share any feedback or suggestions on the document and to share with relevant colleagues; comments would be appreciated by the end of June. Initial feedback given during the meeting was that the document is helpful. It was suggested that it might be useful to include some real life scenarios. It was noted that there is a GMMMG document on this topic which expired in 2013 and is due for review. The group supported reviewing of the local document in light of the RDTC document and considered this to be a priority. A suggestion was made to engage with various societies to raise awareness of the guidance and to help to cut down inappropriate requests from private healthcare providers. **ACTION:** JCT to review GMMMG guidance on prescribing following a private consultation.

7.0 Work plan and horizon scanning	
7.1	**Horizon scanning May 2021** The group noted the May Horizon Scanning document and that MGSG had identified a levofloxacin eye drop product to be flagged to the antimicrobial working group. No further action was identified by CRG.
7.2	**MGSG and CRG work plan** The group noted the current work plan and that it had been updated with some items being scoped by MGSG. The work plan will be updated with any additional items from CRG as appropriate.

8.0 AOB

JP asked about horizon scanning for SGLT2 inhibitors and their use in patients with CKD for improved renal outcomes. He noted that significant financial implications are expected with this use. It was noted that NICE are looking at this as part of the update to NG28; the expected date of publication is not certain but some information previously received suggests that it could be within the next couple of months. Any significant developments will be picked up in the horizon scanning and highlighted to the group.

FB asked if any group members had noticed an increase in the prescribing of methenamine for UTI prophylaxis in their areas. His area had noticed a spike in prescribing over the past year with requests being made to GPs to prescribe. Other group members were not aware of this. It was suggested that a referral could be made to the antimicrobial stewardship group if this was becoming a problem.

Date of next meeting: Tuesday 13th July 12:00-14:00 via Teams