Minutes of the GMMMG Clinical Reference Group Meeting
Tuesday May 11th 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							
Dr Jonathan Schofield (JS)	Consultant physician acute medicine & diabetes	Manchester FT	✓	✓							
Lisa Kershaw (LK)	Lead Medicines Optimisation Pharmacist	Manchester FT	A (VR)	✓							
Sarah Boulger (SB)	Medicines Information Pharmacist	Penine Acute	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	✓							
Peter Marks (PM)	LPC Board Member	GM LPC	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)							

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	✓	✓							
Lizzie Okpara (LO)	Lead Pharmacist Medicines Management	RDTC	✓	✓							
Monica Mason (MM)	Head of Prescribing Support	RDTC	✓	✓							
Dan Newsome (DN)	Principal Pharmacist	RDTC	A	✓							
Andrew White (AW)	Head of Medicines Optimisation	JCT	✓	✓							
Andrew Martin (AMart)	Strategic Medicines Optimisation Pharmacist	JCT	✓	✓							
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 following a couple of minor amendments.
1.4	**Action log review** Updates on the action log were noted. The suite of shared care documents in development including the Guidance on Transfer of Prescribing responsibilities and the blank GMMMG shared care template had been approved by MGSG. Final ratification from GMMMG is awaited for these. The azathioprine SCP had been clinically approved by MGSG, however commissioning aspects are to be finalised; JCT and the MGSG commissioning rep are liaising with GM Directions of Commissioning (DoCs) to progress. Regarding the action for the shared care leaflet, it was noted that the background states the leaflet should be amended to emphasise that GPs *have* to accept shared care. This is however incorrect wording as the intention was to highlight that GPs have the choice of whether or not to accept shared. The same wording was also used in the minutes. Minutes and action log to be amended accordingly.
1.5	**Update from MGSG** MM updated the group about plans for GMMMG to hand over delegated authority to MGSG explaining that while there is strong support for this, this is yet to be finalised and the current governance process remains in place at this time. It was also mentioned that the group would be following the MGSG/CRG work plan included in the agenda which would be updated on an ongoing basis with agreed pieces of work, and with ongoing communication between CRG and MGSG. GMMMG will avoid duplication and not work on anything that NICE or RMOC is working on and expected to publish within 12 months. AM raised the point that operational/ commissioning issues need to be considered alongside clinical aspects with the managed entry of medicines. Their organisation is facing significant operational issues with implications for patient access to some NICE approved treatments. A specific example given was the recently NICE approved CGRP inhibitors for migraine prevention (erenumab, fremanezumab, galcanezumab) and the lack of capacity to deliver these treatments. MM noted that this issue has been escalated through MGSG. It was discussed that in general, CRG would consider clinical aspects and commissioning issues such as these would be discussed in depth at MGSG who would also escalate to GMMMG to address whilst they retain delegated authority.
2. Formulary and RAG	

2.1	**Formulary amendments** **TA694: Bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia** Following discussions to assign a RAG status, the group were minded to assign a status of GREEN following specialist initiation or advice. However, they were keen that its position in the treatment pathway in relation to other lipid modification therapy including PCSK9 inhibitors is clarified. Any positioning would need to reflect the recommendations in the NICE TA. It was suggested that an update to the GMMMG PCSK9 inhibitors guidance to incorporate bempedoic acid could be considered. AM and HI agreed to liaise with Trust specialists to advise on the positioning of bempedoic acid ahead of the next meeting. It was also noted that there is a PAS in place, however, there was lack of clarity around how this would be accessed in primary care. **ACTION: AM and HI to seek specialist opinion on positioning of bempedoic acid. PAS accessibility issue to be passed to MGSG.** **NG193: Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain** The group noted that the guideline recommends six different antidepressants as options for the management of chronic primary pain and that all except paroxetine were on formulary. The group did not feel the need to add paroxetine to formulary at this time given the availability of all of the other options. It was noted that the guidance would need to be incorporated in the GMMMG Opioid Prescribing for Chronic Pain: Resource Pack which is approaching its review date. A gabapentinoids resource pack is currently in development and will incorporate this NICE guidance. **NG196: Atrial fibrillation: diagnosis and management** All drugs included in this guideline are on formulary. It was noted that the guideline advocates use of DOACs in preference to warfarin but doesn't specify preference of any particular DOAC. It also recommends the use of the ORBIT bleeding risk score in preference to others e.g. HASBLED. Primary care reps have reported that ORBIT is not available in EMIS or Vision. The NICE guidance does state that "*although ORBIT is the best tool for this purpose [bleeding risk], other bleeding risk tools may need to be used until it is embedded in clinical pathways and electronic systems*." The NICE resource impact estimates the cost impact to GM to be £271k in year 1, rising to £1.4 million in year 5. This includes increased drug costs and reduced costs for anticoagulation clinics. This is to be flagged to MGSG. **ACTION: AMart to look into availability of ORBIT in electronic systems.** **Remdesevir** Addition of remdesevir for patients hospitalised with COVID-19 to formulary as a RED drug was agreed as per NHSE Interim Clinical Commissioning Policy. Sarilumab and tocilizumab for the same indication are already on formulary. **ACTION: To open for consultation** **Tofacitinib safety** Link to letter to healthcare professionals highlighting increased risk of major adverse cardiovascular events and malignancies with use of tofacitinib to be added to formulary pending the availability of more comprehensive safety information. **ACTION: Link to be added to formulary** **Phyllocontin® discontinuation**

	The formulary is to be amended to reflect discontinuation of Phyllocontin®, including adding a link to the Supply Disruption Alert which includes advice on switching to alternatives. **ACTION: Formulary to be amended** **Bisphosphonates for osteoporosis** The addition of ibandronic acid 150mg tablets for osteoporosis as a GREEN drug to formulary was agreed to reflect TA464. Also the RAG status of alendronic acid and risedronate sodium was clarified as GREEN. Alendronate 70mg weekly is to remain first choice bisphosphonate with all others listed as alternatives. This is in line with NICE advice on using the least expensive formulation. **ACTION: To open for consultation** **Inhaled budesonide for COVID-19** The group noted that a CAS alert regarding inhaled budesonide for adults aged 50 and over with COVID-19 was issued on 12th April. The alert included an interim position statement endorsed by the Department of Health and Social Care which recommends considering inhaled budesonide in this population when specified criteria are met. Requests had been received from the Greater Manchester and Eastern Cheshire Strategic Clinical Network and a Respiratory Lead GP that the criteria be extended to include all adult ages, as it is expected that inhaled budesonide would also be effective in younger patients. A reference was made to the STOIC trial mentioned in the position statement which included younger patients (average age 45 years) and demonstrated efficacy of inhaled budesonide. A query was also received from a CCG lead regarding whether patients already receiving an inhaled corticosteroid would require a dose increase to an equivalent of 800mcg BD of budesonide. JCT had completed a scoping of the requests. This highlighted the limited quality of the evidence used to support the treatment. The PRINCIPLE trial which only included patients aged 50 and above reported a 3-day median benefit in self-reported recovery for patients with COVID-19 but impact on hard outcomes such as hospitalisation rates or mortality has not been established. Additionally, the findings of this trial are based on an interim analysis which has not been peer reviewed. The other trial mentioned, STOIC which included younger patients was a phase 2 trial therefore has limited application. There are also no data available to inform increasing the dose to an equivalent of budesonide 800mcg BD for patients already on an ICS). Approximate costings in the scoping report do not suggest a significant cost impact (~£19k). The group heard that MHCC has a home monitoring service where patients with COVID-19 are managed at home and respiratory clinicians are keen to use inhaled budesonide in this group of patients to help them recover faster and stay out of hospital. Other areas (HMR, GMMH) have gone with using in line with recommendations in the position statement. Due to the limited data available, the group agreed that the use of inhaled budesonide for the management of COVID-19 should be in line with the recommendations in the interim position statement and that any use outside of the recommendations would be an individual clinical decision to be taken in conjunction with the patient. **ACTION: Link to CAS alert to be added to chapter 3 of formulary, to annotate to indicate use is supported as per interim position statement.** **Oral semaglutide formulary amendment** The group noted that feedback had been received from Novo Nordisk regarding the current (temporary) formulary status of oral semaglutide i.e. GREEN and GREY restricted to patients who are unable to tolerate injections or where there are barriers to administration and

	annotated to say that an agent with proven CV benefit is preferable in patients with moderate or higher risk of CVD. Points raised included consideration of oral semaglutide in preference to other GLP1RAs, suggestion to remove the restriction to patients unable to tolerate injections/where there are barriers to administration and a change to the annotation wording regarding choice of GLP1RA in patients with CV risk. RDTC had liaised with Dr Schofield to address the points raised and propose recommended actions. CRG agreed to update the oral semaglutide recommendation to reflect NICE NG28's recommendation to consider the individual's preference when choosing drug treatment, as well as ESC guidance which advocates using a GLP1RA with proven cardiovascular benefit in patients with established CVD or *high* CV risk. No change was felt necessary to the positioning of liraglutide as first choice GLP1RA as the greater HbA1c reduction seen with oral semaglutide compared to liraglutide was small and of questionable clinical importance, and liraglutide has proven CV benefit whereas oral semaglutide does not as yet. The agreed revised status for oral semaglutide is GREEN for patients requiring GLP1RA, as per NICE NG28, when an oral option is preferred. And annotated: *Where a patient expresses a preference for the oral option, prescribers should discuss that there are injectable options in the same class with proven cardiovascular benefit.* *An agent with proven cardiovascular benefit would be preferable to oral semaglutide in patients with established cardiovascular disease or high cardiovascular risk. This includes all patients with diabetes of 10 years duration plus one other risk factor (e.g. age over 50, hypertension, dyslipidaemia, smoking, or obesity).* **ACTION: To open for consultation.** **Peanut protein immunotherapy** A new peanut protein immunotherapy product called Palforzia® has been licensed for treatment of peanut allergy. This was picked up by MGSG as a product that may have significant impact in Greater Manchester. However a NICE TA is expected in January 2022 so it was agreed to await the publication of the NICE TA.
3.0 National guidance	
3.1	**RMOC update: Shared care work plan and impact on GM shared care work stream** MM declared that RDTC also support RMOC North. The group was updated on the discussions at MGSG regarding the RMOC shared care work plan and how this would impact the GM shared care work stream. MGSG agreed that to avoid duplication of effort, work should be paused on the development of GMMMG SCPs that are included in the RMOC list and await the RMOC versions. The resource could then be allocated to developing other SCPs that are not on the RMOC list. It is intended that the original authors of these non-RMOC SCPs will be contacted and requested to update their SCP into the new GMMMG template, with the support of RDTC or JCT. MGSG also agreed that any out of date SCPs on the GMMMG website will remain current and have the expiry dates amended to reflect the anticipated date of publication of the new document. However, SCPs would be updated with any new significant clinical or safety information as required. It was noted that the GMMMG lithium SCP while on the RMOC list is nearing the final stages of development and mental health teams are keen to progress with its development given that significant progress has been made and the SCP is currently out of date.

	To inform prioritisation of the non-RMOC SCPs, the group were requested to provide feedback on which SCPs were felt to require urgent review. The paediatric SCPs were mentioned as an area for prioritisation particularly those for mental health drugs. **ACTION: Authors to be contacted and supported by RDTC/JCT; group members to feedback on prioritisation**.
3.2	**SPS/ SFE/ BAD guidance on issuing the Steroid Emergency Card in adults** The group were made aware of this guidance which was published to support the implementation of a National Patient Safety Alert issued in August 2020. The alert was regarding the introduction of a new Steroid Emergency Card to support the early recognition and treatment of adrenal crisis in adults. A number of actions were specified in the alert that organisations need to implement by 13th May 2021. Group members were asked for feedback on the progress of implementation of these actions to provide GMMMG with assurance. It was noted that MHCC, SRFT and MFT have implemented the actions in their organisations. There were discussions around the difficulty for CCGs to obtain feedback from individual organisations, with the expectation being that the onus is on individual providers to action the alert. MM mentioned that this is an issue that can be raised with the IPMO medicines value and medicines safety leads to advise on how assurance can be obtained including advice on thresholds for providing assurance and expectations of what is required and when. **ACTION: MM to raise with appropriate IPMO theme leads.**
4.0 Medicines safety	
4.1	**Boron additives in chloramphenicol eye drops and use in children under 2 years** The group were informed about recent changes to the SPCs of many manufacturers of chloramphenicol eye drops contraindicating use in children under 2 years old due to boron content and concerns about effect on future fertility. The Royal College of Ophthalmologists have produced a statement in response saying that the maximum daily dose of boron is unlikely to be exceeded with conventional eye drop regimens and they believe at this time that the benefits outweigh the risk. The issue has been flagged with the antimicrobial stewardship group who are currently looking into it and any amendments to the antimicrobial formulary as a result will come to CRG for review and approval.
5.0 Work plan and horizon scanning	
5.1	**MGSG and CRG work plan** The current MGSG/CRG work plan was noted; any updates from CRG will be fed back to MGSG and vice versa.
5.2	**Horizon scanning March and April 2021** The horizon scanning document will be added as a standing item on the CRG agenda. Items expected to have significant financial/commissioning impact will be flagged to MGSG. The March and April versions were reviewed at MGSG who picked out deoxycholic acid for the treatment of moderate to severe convexity or fullness associated with submental fat in adults when the presence of submental fat has an important psychological impact for the patient. RDTC are carrying out a scoping of the available data to determine if there is enough evidence to discuss. Some care is needed in considering what status might be given; whilst it may be considered an aesthetic treatment, there is an element of psychological impact on the patient included within its indication.

	ACTION: RDTC to scope for data to inform any further discussions.

6.0 AOB

JS asked about conflicting RAG statuses in different areas and how this is managed. Technically, prescribers could go with the RAG status in their area. However, HI offered some pragmatic advice based on experience that requests are usually more successful when there is clinician to clinician communication.

Date of next meeting: Tuesday 8th June 12:00-14:00 via Teams