Minutes of the GMMMG Clinical Reference Group Meeting
Tuesday Sept 14th 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	A	A	A			
Dr Jonathan Schofield (JS)	Consultant physician acute medicine & diabetes	Manchester FT	✓	✓	✓	A	A	✓			
Lisa Kershaw (LK)	Lead Medicines Optimisation Pharmacist	Manchester FT	A (VR)	✓	A	A	A	A			
Sarah Boulger (SB)	Medicines Information Pharmacist	Penine Acute	A	✓	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	✓	A	✓	A			
Andrea Marrosu (AM)	High cost medicines and home care pharmacist	Salford Royal FT	A	✓	A	✓	A	✓			
Peter Marks (PM)	LPC Board Member	GM LPC	A	A	A	A	A	A			
Keith Pearson (KP)	Head of Medicines Optimisation	Heywood, Middleton & Rochdale CCG	✓	✓	✓	✓	A	A			
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	Bury CCG	✓	A (SK)	✓	✓	✓	A			
Helen Isherwood (HI)	Medicines Optimisation Pharmacist	Manchester FT	✓	✓	✓	✓	✓	✓			
Steven Buckley (SB)	Director of pharmacy	GM Mental Health FT	A	✓ (SB)	✓ (SB)	A	✓	A			

Faduma Abukar (FA)	Head of medicines management	Stockport CCG	✓	A	✓	A	✓	A			
Zoe Trumper (ZT)	Assistant director of medicines management	Wigan Borough CCG	✓	✓	✓	✓	A	✓			
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)	✓	A	✓			
Jole Hannan (JH)	CCG Interface Pharmacist	Bolton CCG				✓	✓	✓			
Consultant Rheumatologist Audrey Low Ben Parker Charlie Flier Dipak Roy Louise Mercer Meghna Jani Sahena Haque Anindita Paul		SRFT MFT Stockport TGH Stockport SRFT UHSM Bolton					✓ AL	A			
Lizzie Okpara (LO)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓	✓	A			
Monica Mason (MM)	Head of Prescribing Support	RDTC	✓	✓	A	A	A	A			
Dan Newsome (DN)	Principal Pharmacist	RDTC	A	✓	A	✓	✓	✓			
Conor McCahill (CM)	Senior Pharmacist	RDTC						✓			
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	✓	✓	A	✓	✓			

1. General Business	
1.1	Welcome and apologies (See register for apologies). The meeting was chaired by Andrew White. The group welcomed Conor McCahill who attended for the first time.
1.2	**Declarations of interest** None declared.
1.3	**Minutes of the last meeting** The minutes of the August 2021 meeting were agreed as an accurate record.
1.4	**Action log review** See action log
1.5	**Update from MGSG** DN provided an update regarding the GM shared care work. Following discussions at GMMMG, MGSG were disappointed to hear it was declined to be taken forward, apparently on a financial basis, despite the known safety issues. MGSG were keen for the safety issues to be flagged and asked for consideration for addition to corporate risk registers. CRG noted that AW is taking the working group forward to explore solutions to the issue of a single GM-wide shared care position. A paper was written for GMMMG and was made available to members of CRG. AW explained that there is an upcoming meeting with finance and commissioning representatives to hopefully progress the safety concerns. Though without a full mandate GMMMG are unlikely to get unanimous agreement from commissioners prior to April 2022 to progress to a single GM approach due to incoming ICS changes. DN informed the group that MGSG agreed to pause the GM shared care protocol updates, except where there is an urgent clinical need for an update. This is to align with RMOC work. DN noted that shared care information leaflet developed from work done by MFT and supported by MHCC has been approved, will be put online when acknowledged by GMMMG. DN advised the wet AMD pathway working group is in progress, to contact MHCC and Kenny Li if interested. DN noted rebate scheme for freestyle libre “not in line with current recommendations”, and that horizon scanning updates were discussed and are on the agenda for today
2.0 Matters arising	
2.1	**Consultation feedback on July 21 actions**

	The group noted the consultation comments received on the actions from the July 2021 meeting. It was noted by AW and DN that there were only a small number of individuals commenting on actions from July 2021 meeting. HI raised a point that they no longer receive reminder emails (in MFT, from the RDTC), which previously were a prompt. They could also cascade these to other staff/departments for comments. These emails stopped a few months ago, so perhaps reduced comments are as a result of this. DN not aware of them being stopped, advised not clear if oversight or deliberate but will investigate. Comments received so far include one on melatonin (and difference in rankings for indication, ADHD vs sleep disorder, and financials). This refers to NG71 (NICE Guidance Parkinson's Disease), and there is a need to assign a RAG rating but it is an area of low prescribing. No further comments have been made on deoxycholic acid for do not prescribe. One comment on haloperidol, comment left requesting that it remains on the formulary. It was asked by why we are simply removing it from the formulary, and why not adding to the do not prescribe (DNP) list too. It was noted it's a very high cost (see section 3.6). Suggestion to go through DNP criteria next month to confirm this. The updates to the acne guidelines will be reviewed by KO The July 2021 comments were actioned, with exception of haloperidol which is to be reviewed for DNP next month. **ACTION**: **Haloperidol for DNP consideration in October CRG meeting.**
3.0 Formulary and RAG	
3.1	**Formulary Amendments September 2021** **NG201: Antenatal care**; links addition to formulary in chapters 1.3 and 4.6—approved **NG202: Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s**; links addition to formulary in chapters 3.4.1 and 12.2.1—approved **NG203: Chronic kidney disease: assessment and management**; removal of old links (to CG182, CG157, and NG8) approved, replaced with new link to this document. It was noted that the recommendations are likely to increase prescribing costs, and that this is the first in a number of similar proposed updates recommending SGLT2 inhibitors for conditions other than diabetes mellitus. Another update from NICE for T2DM is coming later in the year which is likely to have a significant cost impact, however a lot of these agents (i.e. SGLT2 inhibitors) are already used in practice. **MHRA Letters and medicine recalls sent to healthcare professionals in July 2021 (16/08/2021)**—Link to March 2021 letter replaced with link to this letter, approved. Insulin degludec formulary amendment—Recommendation 2009, should have RAG grey/green. It was noted that whilst it seems fair, this shouldn't be the first line basal insulin, should just be for patient subgroups as noted.
3.2	**Dapsone for PCP prophylaxis – RAG Review (For decision)** This request came from MFT, and has been considered by their medicines management committee to confirm support before submitting to CRG. The proposal has also been approved by their internal antimicrobial stewardship committee. This request has come from the Renal team who have a small subset of patients with a co-trimoxazole allergy who need Pneumocystis jirovecii pneumonia (PCP) prophylaxis. Dapsone is already on RAG list as

	green following specialist advice (for other indications), this is an expansion request to include the above subset of patients. GPs would otherwise be asked to prescribe co-trimoxazole, this would not mean any expected workload as they would be asked to prescribe dapsone instead. This would affect five patients per year, and it was pointed out that we usually wouldn't make changes for such a small sub-group, however challenges facing specialist teams in pandemic were noted. It was noted that with smaller groups we don't typically *add* to formulary but a RAG status amendment would be reasonable. No additional monitoring requirements for GP to consider with Dapsone (similarly to co-trimoxazole). It was clarified this wouldn't split prescribing where it is not already split; i.e. specialist medications with monitoring will still be under specialist, but antimicrobial prophylaxis will be under care of GP. There was agreement, that the application could cover other immunosuppressive patients where co-trimoxazole is not tolerated or appropriate. **APPROVED for consultation as Green specialist advice**
3.3	**Isoniazid for TB – RAG Review (For decision)** Circumstances similar to those covered in 3.2: Dapsone. This request is to expand indications to cover set duration of therapy (noted as typically six months) for renal patients. It was noted that it would affect approximately 50 patients per year, and was noted that the cost is slightly more expensive in primary care than in circulated documented, ~£75 per 28 days for isoniazid. No dissenting opinions, on basis of previous discussion and similar request. **APPROVED for consultation as Green specialist advice**
3.4	**Testosterone for delayed puberty – RAG Review (For decision)** Discussion initially passed over then returned to so that the author of the request could join for discussion, but they were unable to. The MFT paediatric service have noticed a few challenges with requesting the primary care *initiation* of testosterone (for children). In the past, it has "not been an issue" according to member(s) of paediatric team, but now as more options with RAG status that can be assigned, consultant has noticed it says primary care can prescribe after specialist *initiation*, they would like it to be specialist *advice* (i.e. advising primary care team to initiate this themselves) due to location of child patients that attend service. The number of affected patients was not clear, and it was noted from primary care that these requests are reasonably rare. GP representative accepted there is a rationale for primary care prescribing if patients are being asked to attend RMCH (Royal Manchester Children's Hospital) from very far-flung reaches of GM, but expressed surprise that so many GP colleagues have been accepting of this until recently. It was asked how other formularies manage this, and why this isn't already decided on a case-by-case basis with rarity. It was suggested that LK liaises with the consultant in question to come back to CRG with numbers and scale of the problem. It was also noted, with regards to safety and monitoring.

	Action: BNFc provides monitoring recommendations but the request states "no monitoring required". LK to clarify with consultant/team numbers of patients this affects, level of monitoring expected and scope of the issue with primary care. Decision made to **defer** this decision and return to CRG when more information is available
3.5	**Duloxetine capsules 90mg & 120mg review (For decision)** There are two new formulations of duloxetine capsules. (90mg and 120mg capsules.) In terms of dosing, they would be rarely used, and they are noticeably more expensive than existing (lower strength) capsules. Suggested it would be reasonable to give them a DNP based on other products being more cost effective. (DNP Criteria 2.) It was asked if the extra £/month/patient would be worthwhile if it improved compliance. Noted tablet burden a factor for some individuals, especially on higher doses of medicines like duloxetine. It was emphasised that the proposal is DNP; whilst there is a pragmatic view (as above), there is also a financial view we cannot ignore. It was asked if we do this for other medications—we do, for Atorvastatin 30mg and 60mg tablets, and are due to discuss a *similar* situation with haloperidol *form* (not strength) in this meeting. It was, however, noted that the cost difference here is much smaller [Note; from document attached in agenda, price range is <£10 for even the most expensive of the duloxetine capsule options, the price was alluded to here but not included within the discussion explicitly.] It was highlighted that few patients on larger doses of duloxetine take it as a single daily dose, so might not be a large cohort. If there are price changes CRG would need to react and review the DNP status Following a discussion at was agreed that a grey status would be more appropriate and that wording to support the rationale for this would be agreed via chairs action Decision made to put out to **consultation** as Green and Grey (criterion 2) **Action**: DN and AW to describe criteria for duloxetine 90mg and 120mg capsules as grey list preparations.
3.6	**Haloperidol for TIC disorders – RAG review (For decision)** July CRG asked for Green (following specialist advice) An estimated 20 patients per year will receive this drug for this condition. Currently managed with combination of GPs / specialists prescribing, but an alternative, practical consideration is to update the RAG to add this to the current wording which relates to use of haloperidol in palliative care. This would not be for specialist management long-term. However it was pointed out that standard monitoring for antipsychotics would apply which then lends itself more to having a shared care status. No one from a MH trust was present, nor anyone with clinical background in mental health to provide comment. SmPC states for this condition this medication requires assessment every 6-12 months, which would suggest it would be a specialist, therefore a concern was raised regarding prescribing in primary care with no review. CRG were reminded that this applies to a relatively small number of patients.

	With regards to adding alongside palliative care on RAG rating, CRG noted that we do not add every drug on there if it is licensed. If it is not on the formulary, the implication is green. Noted that shared care was put into place for safety reasons, if this antipsychotic requires similar monitoring to others, why is it not being recommended as a shared care indication? If we make this Green+, do we create a precedent for other drugs? RMOC *might* be going to be producing shared care documentation on antipsychotics (though suspected not due to differences in management between areas), though this would be drug-specific, not indication-specific. One opinion given that Tourette's syndrome should be managed in specialist care. DN checked North of Tyne (NOT) formulary and advised it is a green drug in this formulary for TIC disorders, but that antipsychotics have the equivalent status of green specialist initiation in the region. It is not clear if the number of patients (20) is referring to those patients referred to a specialist neurology tertiary care centre. It was suggested that a recent increase in referrals for younger adults with tics and other motor disorders is due to social media in pandemic. This was disputed, and questions raised in turn about organisational strain that may have prompted this. (i.e. waiting list management as a concern, rather than clinical appropriateness.) Concern was raised that the application refers to haloperidol and tetrabenazine being "rather dark ages" as the only options for GPs to prescribe. [Note; this is in reference to considering moving other antipsychotics to amber for TIC disorder] If the opinion is that atypical antipsychotics are more appropriate, should we be questioning this request (i.e. moving haloperidol to green)? Not clear if this was a flippant comment on form, or a serious point that needs addressed. **Decision**: More information required (on patient count, clarity on appropriateness of therapy, and what licensed options are). To return to CRG with this information
4.0 Pathways and Clinical Guidelines	
4.1	**GMMMG Vitamin D Guidance (for approval)** DN presented the document which has been in development for 2-3 years, and has had multiple authors so far. It was previously opened for consultation in October to December 2018. It was not approved due to commissioning questions being raised, and no consistent responses from CCG medicines optimisation leads, though it was clinically approved. There are well documented issues at present concerning blood testing due to ongoing shortage of test tubes. This guideline supports reduced Vit D testing. Noted also that prescribing of OTC products may clash with NHS England guidance for the provision and prescribing of OTC products. Problems with children doses was also highlighted. DN noted that there may be ongoing commissioning questions as we go forward, but for now CRG being asked to look at this *clinically*. The proposal has been suggested that, rather than consultation, this document goes via CRG, then MGSG for commissioning and financing considerations, then to population health IPMO group, and only *then* open for consultation. Concern was raised around pregnancy and breastfeeding. RCOG previously provided some guidance but this was "hastily" retracted. This document advises 40,000 units weekly for seven weeks, but then states SPC recommends against this. If making recommendations these need to be clear. It is not clear what happened with RCOG Scientific Impact Paper No.43 which

	discussed this. The RDTC has sought clarification. It was suggested that NICE refers to RCOG guidance (for 1,000 units daily), but the RCOG guidance was withdrawn and refers to NICE (circular reference). **Following the meeting this was noted to be an error: NICE does not refer to RCOG but many locally developed guidelines do.** A discrepancy with existing information was pointed out, because the North West SCN has recently published guidance leaflets with a recommended dosing in pregnancy of 800 units (20micrograms) colecalciferol daily. This is higher than NICE who recommend 400 units daily. CRG heard that some pregnant patients do not complete the course by the time their child is born at which time they are then breastfeeding and the recommendations differ. It was noted that some groups suggest double-dosing for pregnant women 'at risk' (i.e. darker and/or covered skin). Was asked if infographics could be shared with wider group and agreed. It was suggested that most people would be utilising the flowcharts at the end of the guidance in clinical practice and could these be brought to the top. The size of the document was a concern; and a quick reference was preferable with a suggestion that if sections such as breast feeding were complicated, readers could be referred to the longer form if required. It was noted MO teams and clinicians have received many queries regarding vitamin D lately. A standard consensus/preparation would be ideal, particularly with regards to what dose to give and for how long. The options presented in the document may increase error risk; e.g., 4,000 units daily, or 40,000 units weekly. CRG asked if a standard recommendation for loading dose and a schedule was possible. The authors explained that the products and licensing vary and there is no clinical consensus on what a standard regime should be. It was asked if there is scope (and any agreement) to putting patient choice ahead of licensing and simplifying guidance. It was suggested this is done somewhat with ACE inhibitors and ARBs where licensing doesn't necessarily align. An evidence base would need to be clear to do this is unlicensed/ off label products were being given prominence over licensed products. Clarification given as to why the document is broken into sections; in part this is due to different recommended doses for ages/patient groups, in part due to different licensing around products and the desire for recommended treatment courses to be listed for each group. Also noted that breaking into subsections for treatment means they can standalone for that group, and futureproofs this against changes in licensing or dose recommendations in future. Recent deaths within the Greater Manchester area due to vitamin D deficiency noted, and the preference for some guidance to be decided as soon as feasibly possible. It was noted that the health and inequalities group has been involved in this, and was asked whether it is worthwhile in aligning their views. Primary care explained the MFT PGD avoids the need for GP prescribing. CRG heard this is a complicated issue, and agreed it be helpful to look at what other areas have done, especially Leeds who have an easy to follow guideline. Given the known health inequalities across GM such as access to OTC products, and healthy start vouchers, could the guideline include information on how to access these? A pilot project in Manchester is currently running to provide healthy start multivitamin tablets and drops to all mothers and babies. The chair recommended that this document is not ready for consultation, the authors agreed that the document requires further work to enable it to be used GM-wide. **Action**: The RDTC will get in touch with the GM Population Health group for guidance on how to proceed.

4.2	**Sacubitril/Valsartan GP Info Sheet (for approval)** **Decision:** CRG approved the technical update to this document.
5.0 Shared care	
5.1	**GMMMG and RMOC Shared Care Protocols review** (Discussion) A summary of the shared care protocols (SCPs) that are in use in GM but have not yet been considered for a national template by RMOC was presented to CRG. The group agreed that the exercise was useful in demonstrating what is currently in place in GM and how it aligns are may be outside the RMOC criteria for defining a shared care medicine. The decision by MGSG to pause all SCP development except where clinically urgent revisions are required was acknowledged. It was suggested that if there are any medicines which may no longer warrant a SCP a further RAG review could be conducted, but CRG were reminded that this had already been done at the end of 2020. Only goserelin for breast/endometrial cancer was suggested as being unsuitable for ongoing shared care, however the group agreed that all should be submitted to RMOC for consideration in the next stages of the national shared care development work stream, with the exception of dexamethasone and fluorometholone eye drops. In order for GM to effectively manage shared care locally, indicative timescales are required for future work. RDTC agreed to provide these when available. Once GM are aware of what SCPs will need to be updated/developed locally these can be done, otherwise there is a risk of duplicating work, undermining some of the principles of why RMOC are doing this work. **Action: RDTC to Submit GM shared care drugs to RMOC for consideration**
6.0 Work plan and horizon scanning	
6.1	**Horizon scanning August 2021 (for discussion** The publication of a NICE FAD for inclisiran was discussed. AMart is planning to table a paper for discussion at the October meeting regarding lipid pathways. There are now 3 more licensed biologic products for atopic dermatitis, all of which are undergoing NICE evaluation (publication date TBC). A HCD pathway was suggested which AM will be asked to complete a scoping document for. It was noted that current tariff discussions for 2022-23 strongly suggest that all ICS-commissioned HCDs will remain within the block portion of the contract payments, only Specialised Commissioning drugs will be on a variable cost and volume payment mechanism. **Action: AM to complete scoping for atopic dermatitis HCDs pathway**
6.2	**MGSG work plan (for information)** Not discussed
7.0 AOB There is concern within primary care there are more patients on specialist medicines that have been passed over from secondary care to primary care as a result of the pandemic. If income were to be lost from changes to shared care planning/funding there will be further pushback from primary care,	

CRG noted this and agreed that the paper which explains the problems with shared care addresses this issue. The shortage of BD blood bottles is not yet impacting on some parts of GM due to the use of alternative brands in some laboratories.
Date of next meeting: Tuesday 12th October 12:00-14:00 via Teams