

Minutes of the GMMMG Clinical Reference Group Meeting Tuesday November 8th, 2022, 12:00-14:00 via MS Teams

Name	Title	Organisation	June	July	Aug	Sept	Oct	Nov
Dr Peter Budden (PB) Chair	GP	St Andrews Medical Practice	✓	✓	✓	✓	A	✓
Dr Helen Burgess (HB)	GP	NHS GM IC (Manchester)	✓	A	✓	✓	✓	✓
Dr Jonathan Schofield(JS)	Consultant Physician Acute Medicine & Diabetes	Manchester FT	A	A	A	✓	✓	✓
Suzanne Schneider (SS)	Medicines Information Pharmacist	Bolton FT	✓	✓	✓	✓	✓	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
Peter Marks (PM)	LPC Board Member	GM LPC	A	A	A	A	A	A
Keith Pearson (KP)	Head of Medicines Optimisation	NHS GM IC (Heywood, Middleton & Rochdale)	A (MC)	A (MC)	A	A (MC)	A	A (MC)
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	NHS GM IC (Bury)	A	✓	A	✓	✓	✓
Steven Buckley (SB)	Director of Pharmacy	GM Mental Health FT	A	A	A	✓	✓	✓
Faduma Abukar (FA)	Head of Medicines Management	NHS GM IC (Stockport)	✓	A	✓	A	✓	✓
Zoe Trumper (ZT)	Assistant Director of Medicines Management	NHS GM IC (Wigan)	✓	A	✓	A	✓	✓
Faisal Bokhari (FB)	Deputy Head of Medicines Optimisation	NHS GM IC (Tameside)	✓	A	✓	A	A	A
Jennifer Bartlett (JB)	Team Leader Neighborhood Integrated Practice Pharmacists	Salford Royal FT	✓	✓	A	A	✓	✓
Claire Foster (CF)	Senior Medicines Optimisation Adviser	NHS GM IC (Manchester)	✓	✓	✓	✓	✓	A (ZP)
Jole Hannan (JH)	CCG Interface Pharmacist	NHS GM IC (Bolton)	✓	✓	A	✓	✓	✓
Jacqueline Coleman (JC)	Medicines Optimisation, Interface Pharmacist	NHS GM IC (Stockport)	A	A	A	A	A	A
Charlotte Atkinson	Specialist Pharmacist	Manchester FT	✓	A	✓	✓	LL	LL
Consultant Rheumatologist Audrey Low Ben Parker Charlie Filer Dipak Roy Louise Mercer		SRFT MFT Stockport TGH Stockport	✓ DR	A	✓ SN	A	✓ (SW)	✓ (AL)

Meghna Jani Sahena Haque Anindita Paul		SRFT UHSM Bolton							
Dan Newsome (DN)	Principal Pharmacist	RDTC	✓	✓	✓	✓	✓	✓	✓
Nancy Kane (NK)	Senior Medical Information Scientist	RDTC	✓	✓	✓	✓	✓	✓	A
Conor McCahill (CM)	Senior Pharmacist	RDTC	✓	✓	✓	✓	✓	✓	A
Andrew White (AW)	Head of Medicines Optimisation	JCT	A	✓	✓	✓	✓	✓	
Andrew Martin (AMart)	Strategic Medicines Optimisation Pharmacist	JCT	✓	✓	✓	✓	✓	✓	✓
Karina Osowska (KO)	Medicines Optimisation Pharmacist	JCT	✓	A	A	A	✓	✓	✓

1. General Business	
1.1	Welcome and apologies The chair welcomed Dr Manju Navani who was in attendance for item 4.1
1.2	Declarations of interest Previously declared where relevant. No further declarations of interest were made.
1.3	Draft October 2022 CRG Minutes The October 2022 CRG Minutes were accepted as a true record with some minor amendments to note the correct TA number for upadacitinib and NG numbers for NICE diabetes guidance documents.
1.4	Action log review Most items had no updates, the action owners will be approached for updates. Some items have full agenda items. Others have progress as follows: <ul style="list-style-type: none"> • 02223.2 Steroid eye drops review. Feedback now received from MFT ophthalmology consultants on review intervals for these medicines, the formulary amendments can now be updated, and a primary care prescribing leaflet be produced to support the change to Green (specialist initiation) • 082202 Osteoporosis metabolic agents pathway—a draft pathway has now been received, and will be discussed at the December meeting pending further info on patient numbers. • 102203 First generation typical antipsychotics – A proposal is being drafted and will be shared with the secretariat when ready
1.5	Update from GMMM There is still uncertainty regarding the formal governance route for approval of medicines decisions by the GM ICB. The ICB Clinical Effectiveness and Governance Committee has been tasked with receiving GMMM decisions, but this group also has no delegated authority to approve decisions. Separately to this ICB Finance has now approved the outstanding decisions from the September CEGC, and this group is meeting again on Thursday 9 th November, after not meeting in October, and will consider GMMM decisions from October. The GMMM chairs and Professional Secretariat will continue to seek clarity on the process for ratification of GMMM decisions by the ICB.
2.0 Matters arising	
2.1	CRG Consultation September 2022

	<p>Two comments were received regarding the proposed change from RED to Amber for quetiapine when used in line with NICE Guidance (NG71). There is some clarity needed about when this is appropriate to transfer as NICE guidance on dementia does not recommend the use of antipsychotics as this may worsen motor features of the disease and may contribute to a higher risk of stroke.</p> <p>CRG then discussed quetiapine's inclusion in the shared care protocol as item 5.1 which excludes patients for whom the drug is being used to treat behavioural and psychological symptoms of dementia (BPSD). It was explained that patients may have 2 conditions but the antipsychotic may be being used to treat the mental health condition rather than the dementia, or in fact both. Feedback to CRG was that this isn't always clear in communications received by primary care. This indication is RED on the GMMM RAG list but feedback from members was that it may be being treated as Amber in some GM localities. CRG heard this may historically be based on the availability of MH services rather than safety. This is due to variation in commissioned services across GM (see also item 5.1).</p> <p>CRG noted the reservations but agreed to assign an amber status as per the updated SCP in line with the recommendations in NG71, where there is no cognitive impairment.</p> <p>No other comments were received.</p> <p>All proposed actions were approved.</p> <p>Action: RDTC to submit actions to GMMM for approval.</p>
<p>3.0 Formulary and RAG</p>	
<p>3.1</p>	<p>Formulary Amendments October 2022</p> <p>CRG approved the formulary amendments to open for consultation and noted the following:</p> <ul style="list-style-type: none"> • TA828 Ozanimod for ulcerative colitis: The GM IBD pathway will include ozanimod as part of the current update • TA832 Relugolix-estradiol-norethisterone (Ryeqo) for uterine fibroids: CRG noted the requirements for DXA at initiation if patients have risk factors for osteoporosis, and for DXA at 12 months for all patients. Questions were raised about length of treatment as NICE does not specify duration. The SPC for Ryeqo recommends discontinuation at menopause but that in practice surgical intervention may happen prior to this. CRG agreed this should be proposed as Green (specialist advice) <p>Action: RDTC to open formulary amendments for GMMM consultation</p>
<p>3.2</p>	<p>Glucagon pre-filled pen (Ogluo) formulary assessment tool</p> <p>A formulary assessment tool prepared by the RDTC was discussed and CRG agreed that there may be benefits associated with the use of pre-filled pens rather than the reconstitution process required with Glucagen Hypokit. To replace the existing product would add around £383k per year to the prescribing budget for GM with little evidence to support the product being safer or more effective for any patient, however CRG members found it was very difficult to define which groups are most likely to benefit from the product.</p>

It was proposed that due to licensing and the availability of a 0.5mg pre-filled injection, that patients aged 2-6 years old who have a weight of less than 25kg could be considered eligible to reduce the potential for dosing errors with Glucagen.

It was recognised that a clear GM-wide position is required to enable use in the groups which stand to benefit the most and to ensure fair access. For this reason, it was agreed that a proposal is required on which GM ICS can be consulted. JS suggested he can obtain specialist consensus through the MFT insulin safety group and PB agreed to liaise with specialist services in Salford. DN will approach the SCN for advice on a GM position.

Decision: Members as above to seek specialist input to enable CRG to propose a GM-wide position prior to consultation. This is planned to return to CRG in January 2023.

4.0 Pathways and Clinical Guidelines

4.1 HRT Guidance

Due to the attendance of Dr Navani this item was discussed prior to item 2.1

KO outlined the changes that had been made to the document since the consultation in Dec-Feb 22, and that the document had undergone extensive clinical check. The changes include addition of a glossary and definitions table, updated recommendations for patients aged 60 years and over and to remove first line products from the formulary so that a wider range of treatments will be available. Plus, the inclusion of further information and guidance on the prescribing of testosterone in primary care for which a Green specialist advice status is requested.

Further comments were received from a GM oncoplastic breast surgeon regarding the cancer risks and the process for referral to the breast cancer family history clinic.

There was considerable discussion about the definition of a specialist with regard to the initiation of testosterone. Dr Navani advised that the BMS are providing training from next year to facilitate primary care prescribers to initiate testosterone and could individuals who had undertaken and been certified in this training be considered within the RAG definition of a specialist? DN advised that the current definition is sufficiently permissive to incorporate GPwSI and specialist nurses, however prior to seeing the content and CRG being assured that it was sufficient to enable each trainee to consider themselves a specialist in the area, CRG could not commit to adding this note to the formulary.

It was noted that testosterone in primary care has caused problems in the past, and that knowing when discontinuation is appropriate is a concern for primary care prescribers. Dr Navani highlighted BMS guidance which recommends discontinuation after 3-6 months if no improvement in symptoms is observed or if intolerable side effects are present (which is contained in the guidance).

A question was raised about lab reference ranges for testosterone and whether testing is available in all GM localities. Dr Navani believed it was and that though there may be differences in reported reference ranges the aim would be to maintain testosterone levels in the pre-menopausal range set locally.

CRG asked for information on testosterone dosing to be added to section 14.5 which currently states that doses for women are 1-8th - 1/10th of those used for men, which is insufficient.

Decision: Pending the addition of the requested information on testosterone dosing for each product, CRG approved the guidance and formulary changes.

<p>4.2</p>	<p>SCN Hypertension guidance</p> <p>CRG considered a draft of the Greater Manchester and Eastern Cheshire Strategic Clinical Network advice on diagnosing and managing hypertension, which is designed to augment NICE guidance.</p> <p>DN explained this had received a clinical check by the RDTC and the suggested amendments communicated to the SCN working group, however some remain unaddressed.</p> <p>CRG noted and supported the intention of improving the management of hypertension in GM and wholly agreed with the need to reduce heart attack and strokes in the ICS. However, the proposed financial savings of £13.2m over 3 years were questioned as this was not supported within the document.</p> <p>CRG recognised the innovation within the and welcomed a new way of managing hypertension but suggested that the significant commissioning requirements may need to be addressed prior to the implementation of the proposed strategy. These include use of community hypertension services and urine testing for compliance.</p> <p>Unfortunately, CRG did not agree that there is sufficient evidence base to recommend the use of “polypill” therapies. There is an assumption in the strategy that underpins the financial savings associated with its implementation that CRG believed to be a non-sequitur. If GM clinicians can identify the non-compliant patients it does not follow that moving these to a single dose treatment will increase compliance and reduce BP to within the target range. There is insufficient evidence to support the assumption that a patient who is non-compliant with 3 separate tablets will be compliant with a single dose containing 2 or 3 agents, this is of greater importance where there is a cost associated with this recommendation as there is here. The guidance proposes a move from lisinopril to perindopril as the first choice ACEi, which comes with a cost increase of around 50%. The proposed preferential use of a single product (Sevikar HCT) places a great deal of faith in the supply chain for that particular medicine, which, as has been observed recently for other medicines often cannot be relied upon to be robust. For this reason CRG would prefer the use of generic products and those where viable clinical alternatives are available.</p> <p>CRG believed that the guidance was not suitable for GMMM consideration and approval based on the number of commissioning and financial questions raised and that there may be a better route for the proposed strategy to be considered by the ICB if the issues noted above regarding the single pill approach can be addressed.</p> <p>Decision: CRG’s comments will be communicated to the SCN to facilitate further discussion.</p>
<p>4.3</p>	<p>Hypersalivation pathway</p> <p>CRG discussed whether this document, received by the committee after a consultation adequately captures the comments made through the consultation and by CRG.</p> <p>CRG agreed that it did but asked for some additional wording on atropine eye drops to state that the minims product may be more cost effective and should be used in preference to the bottle if appropriate. The group also asked for a small change to the flow chart in appendix 1 to move an</p>

	<p>arrow to better demonstrate the likely decision-making route when initiating antimuscarinic medicines.</p> <p>Decision: DN to make amendments and check with Authors before submitting for GMMMG ratification.</p>
<p>4.4</p>	<p>CPMA Guidelines – clinical incident review</p> <p>In October 2022 the RDTC were notified of an incident involving a product that is listed on the GM CPMA guidance (GMMMG cow’s milk protein allergy guideline), Similac alimentum which was subject to a product recall in February 2022 due to microbial contamination.</p> <p>The practice involved, have conducted a review into the incident whereby a child received this product after it was prescribed and then dispensed by a pharmacy, fortunately no harm occurred. The had requested that GMMMG remove the product from the guidance.</p> <p>CRG heard that a review by RDTC and JCT noted the recall and the actions for community pharmacy (here) included returning all affected products to the wholesaler, there was a warning on the GP clinical system not to prescribe, the product has not been discontinued and it is not normal practice to remove products from guidelines unless there is a discontinuation.</p> <p>CRG agreed with the recommendation that the guideline should not be amended at this time.</p> <p>Decision: No change to guidance. RDTC to feedback to practice involved</p>
<p>5.0 Shared care</p>	
<p>5.1</p>	<p>Oral atypical antipsychotics SCP</p> <p>CRG were asked to review this updated SCP to include 2 new medicines, oral lurasidone and paliperidone. The process has been fast-tracked due to a request from Mental Health, supported by a MO lead to enable transfer of prescribing into primary care. A number of patients are currently required to receive prescriptions from their mental health provider as these medicines are not catered for in the existing SCP, which is due for review.</p> <p>The presented document was in the old format and now contains 7 medicines and was thought to be too long and unwieldy for it to be useful in primary care, and concern was raised regarding how well it would be received by those intending to use it.</p> <p>Further discussion was had on the appropriateness of primary care taking on prescribing of oral antipsychotics for indications which include management of dementia symptoms. SB confirmed that oral antipsychotics are sometimes used for patients who have dementia, but that this is commonly for the other mental health indication such as schizophrenia or bipolar illness. The SCP protocol doses state that patients for whom the prescribing is to treat behavioural and psychological symptoms of dementia (BPSD) would be excluded. CRG did not think that this was clear enough to approve the document and requested further information be provided</p> <p>There are references to the Care Programme Approach which is no longer applicable and should be deleted.</p> <p>As noted under item 2.1, CRG heard there are long-standing variations in the application of the RAG status in GM of these medicines which are linked to the commissioning of MH services. If services were equitable across all GM localities many of these shared care issues would not exist.</p>

	<p>Decision CRG were not assured that the document provided a safe framework under which transfer of prescribing to primary care could take place and asked for more work before it returns to CRG</p> <p>Action: RDTC to liaise with MH leads to update before resubmitting to CRG for approval.</p>
5.2	<p>GM Shared Care Update</p> <p><i>There was no standalone update to this item.</i></p>
6.0 Work plan and horizon scanning	
6.1	<p>Horizon scanning October 2022</p> <p>CRG noted the contents of the document, and the following items were discussed.</p> <ol style="list-style-type: none"> 1. Dienogest. An oral treatment for endometriosis, no action agreed at present. 2. Baricitinib: new indication for alopecia areata. TA in development (expected April 2023). It was noted that although auto immune driven this condition is mainly cosmetic and approval from NICE would represent a change from existing principles of not routinely funding treatment for cosmetic diseases. Await NICE TA 3. Although not in the MHSD for October, Tirzepatide for use in T2DM and obesity is likely to have a significant impact and demand will be high. CRG asked for a statement on the formulary the request that prescribing does not take place until the NICE TAs are published. These are expected in April 2023 for T2DM and TBC for the obesity indication.
7.0 AOB	
None raised	
Date of next meeting: Tuesday 13th December 2022 12:00-14:00 via Teams	