

Minutes of the GMMMG Clinical Reference Group Meeting Tuesday August 10th 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				
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				
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	✓				
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				
Keith Pearson (KP)	Head of Medicines Optimisation	Heywood, Middleton & Rochdale CCG	✓	✓	✓	✓	A				
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	Bury CCG	✓	A (SK)	✓	✓	✓				
Helen Isherwood (HI)	Medicines Optimisation Pharmacist	Manchester FT	✓	✓	✓	✓	✓				
Steven Buckley (SB)	Director of pharmacy	GM Mental Health FT	A	✓ (SB)	✓ (SB)	A	✓				

Faduma Abukar (FA)	Head of medicines management	Stockport CCG	✓	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		SRFT MFT Stockport TGH Stockport SRFT UHSM					✓ AL					
Lizzie Okpara (LO)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓	✓					
Monica Mason (MM)	Head of Prescribing Support	RDTC	✓	✓	A	A	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	✓	✓	A	✓					

1. General Business	
1.1	<p>Welcome and apologies (See register for apologies).</p> <p>The meeting was chaired by Andrew White (JCT).</p> <p>The group welcomed Audrey Low who attended for the first time.</p>
1.2	<p>Declarations of interest</p> <p>None declared.</p>
1.3	<p>Minutes of the last meeting</p> <p>The minutes of the July 2021 meeting were agreed as an accurate record.</p>
1.4	<p>Action log review</p> <p>Updates were noted as recorded in the action log. The item for the PCSK9i guidance update to include bempedoic acid was closed as it was agreed there doesn't seem to be a need for a pathway for its use at this time.</p>
1.5	<p>Update from MGSG</p> <p>DN provided a summary of discussions and decisions made at the July MGSG meeting. Draft minutes were enclosed which contain further details of the discussions. AW also gave a verbal update on alignment of shared care commissioning noting that there was a positive response from GM Chief Financial Officers (CFOs) to progressing the work, however, there was a request from CFOs to see the GMMMG QIPP plan. AW had prepared a paper highlighting current issues with shared care across GM and recommended next steps which was due to be discussed at the upcoming joint DoCs and CFOs meeting to obtain the mandate to progress the work. He shared the document with the group and welcomed any additional comments or suggestions from group members.</p>
2.0 Matters arising	
2.1	<p>Consultation feedback on June 21 actions</p> <p>The group noted consultation comments received on the actions from the June 2021 meeting. With regards to the RED status assigned to demeclocycline and Sativex, comments indicated that some patients currently receive these items in primary care. AMart pointed out that Sativex prescribing had previously been looked into by CCG leads and there has been a low level of prescribing of this item in GM for a long time (12 items in the past year). Prescribing data suggests an estimate of 92 patients per year are receiving demeclocycline in primary care across GM. The RAG status of these agents is likely to be revisited in the future; for Sativex once operational issues in delivery are resolved and for demeclocycline once information is available from specialists to inform a full RAG review. There was also a comment regarding the arrangements for the commercial discount for bempedoic acid (+/- ezetimibe) and whether this was acceptable to primary care clinicians. CRG has previously noted information from NHSE confirming that a central rebate scheme is in place which applies equally across primary and secondary care. No further action was felt to be required following the comments at this stage and it was agreed to submit the recommendations to MGSG for ratification.</p> <p>ACTION: RDTG to submit June actions to MGSG for ratification.</p>

3.0 Formulary and RAG

3.1 Formulary amendments July 2021

Suggested formulary amendments were noted and approved as follows:

Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed to be RED with link to TA715 added to the formulary. All agents already on formulary as RED in line with NICE TAs for use in treating severe rheumatoid arthritis in adults (DAS28 >5.1). This guidance extends the eligible population to include those with moderate disease (DAS28 3.2 to 5.1). It was mentioned as part of the MGSG update that a GMMMGM moderate RA pathway will be developed which will provide guidance on the use of these agents in this patient population.

NICE anticipates that this guidance will lead to the overall proportion of the eligible population receiving biological DMARDs or targeted synthetic DMARDs increasing from 15% to 30%. The overall resource impact of the guidance was difficult to calculate using the template provided by NICE due to requiring information on current use patterns. However DN noted that MGSG will be requesting figures on the cost impact and this is something that the working group for the moderate RA pathway will need to consider as part of the pathway development.

Ixekizumab for treating axial spondyloarthritis to be RED. This is a PbRe drug within the scope of the GMMMGM ankylosing spondylitis pathway.

Secukinumab for treating non-radiographic axial spondyloarthritis to be RED. This is a PbRe drug within the scope of the GMMMGM ankylosing spondylitis pathway.

NG199: Clostridioides difficile infection: antimicrobial prescribing was noted. This guideline is within the scope of the GMMMGM antimicrobial guidance and will be flagged to the working group. There is also a GMMMGM HCD recommendation on the use of fidaxomicin which will need to be reviewed for alignment with the NICE guidance.

The group also noted the update to NG17: Type 1 diabetes in adults: diagnosis and management which includes updated recommendations on long-acting insulin therapy for adults with T1DM. Insulin detemir is recommended as the first choice basal insulin and insulin glargine and degludec are alternatives depending on the specific situation as described in the guidance. Insulin detemir and glargine are both on formulary. Insulin degludec isn't listed on the formulary but is the subject of a recommendation from 2014 which outlines the patient population it may be considered in i.e. GREY. It was agreed that rather than updating the document, it could be retired and the recommendations incorporated within the formulary/RAG list instead. RDTC to submit changes required to formulary/RAG list.

MHRA safety advice on the use of chloramphenicol eye drops containing borax or boric acid buffers in children under 2 years was noted. At a previous meeting, CRG heard that some UK manufacturers were in the process of updating their SPCs to include a contraindication to chloramphenicol eye drops in children under 2 due to boron content. The MHRA have since completed a review and concluded that the benefits outweigh the potential risks and that chloramphenicol eye drops can be safely administered to children under 2 years.

The group also noted a recent National Patient Safety alert on inappropriate anticoagulation in patients with mechanical heart valves. The alert included actions for practices and other providers of anticoagulant services that should have been completed no later than 28th July 2021. There was some discussion around obtaining assurance that these actions have been completed. However there was agreement that responsibility for completing the actions lies with individual organisations who will have received the alert directly. It was also noted that this

	<p>alert came via the Central Alerting System and individual organisations are required to report back directly to the system which in itself provides an assurance system.</p> <p>ACTION: RDTC to open decisions for GM wide consultation, flag NG199 to antimicrobial working group including requirement to review fidaxomicin recommendation and submit formulary/RAG amendments required for insulin degludec for next CRG meeting.</p>
<p>3.2</p>	<p>DNP assessment: Gabapentinoids in pain</p> <p>The group considered a DNP assessment for gabapentinoids in pain. With the recent publication of the GMMM gabapentinoids resource pack, the working group proposed that the RAG list be updated to reflect a DNP status for gabapentinoids in certain types of pain in line with NICE Do Not Do recommendations. These include:</p> <p>NG193:</p> <ul style="list-style-type: none"> Do not initiate any of the following medicines to manage chronic primary pain in people aged 16 years and over: <ul style="list-style-type: none"> antiepileptic drugs including gabapentinoids, unless gabapentinoids are offered as part of a clinical trial for complex regional pain syndrome. <p>NG59:</p> <ul style="list-style-type: none"> Do not offer gabapentinoids for managing sciatica as there is no overall evidence of benefit and there is evidence of harm. Do not offer gabapentinoids or antiepileptics for managing low back pain. <p>Concerns were raised about assigning a DNP status particularly for use in chronic primary pain. It was felt that while a move to reduce the inappropriate use of medicines such as gabapentinoids is positive, a complete ban would mean that patients are left with limited options to treat their pain, taking into consideration that there is currently a lack of access to non-pharmacological treatments recommended in the NICE guideline on chronic pain. The group felt that there needs to be engagement with local pain teams to discuss their plans for managing patients in view of the NICE recommendations before a DNP can be issued. There is likely to be a population of patients who based on their individual circumstances may still require treatment with a gabapentinoid. Concerns were also raised about patients accessing treatments on the black market in desperation to manage their pain. It was agreed that a DNP status should not be issued at this time and a GREY status may be more appropriate. There should be consultation with specialist pain teams to determine the patient population that would remain suitable for treatment with gabapentinoids which would define the conditions of the GREY listing.</p> <p>ACTION: JCT to liaise with pain specialists; group members to forward contact details of local pain teams to LO who will forward these on to JCT.</p>
<p>3.3</p>	<p>Review of Chapter 13.6 of formulary to reflect NG198: Acne vulgaris management</p> <p>As requested at the July meeting, AMart submitted proposed changes to the acne section of the GMMM formulary to bring it into alignment with NICE recommendations. The formulary still maintains that mild acne should be managed by self-care in line with NHSE guidance. The options for topical treatment have been amended to match how these are presented in the NICE guideline. Notably, NICE does not recommend any particular treatments in preference to others. A significant difference is that for oral treatment options the first choice on the GMMM formulary is currently oxytetracycline whereas the NICE guidance does not include oxytetracycline at all, therefore this was removed. A GREY status is proposed for co-cyprindiol which NICE recommends only in people with acne and polycystic ovary syndrome where first line treatments are ineffective. There is an existing GMMM guidance on management of acne in primary care which was noted to require updating to reflect NICE recommendations. The group considered whether this could now be retired, if superseded by NICE guidance.</p>

	<p>However, it was felt that the local guidance provides more specific advice including recommendations on specific types of acne and is easier to navigate than the NICE guidance; an updated version would be helpful and welcome. The review also identified that the rosacea section requires an update. In the absence of NICE/ local guidance this will need to involve clinicians. It was agreed to approach clinicians for input on the update of the GMMMGM acne guidance in line with NICE and the update to the rosacea formulary section simultaneously. An annotation will be included on the website to indicate that the GMMMGM acne guidance is under review.</p> <p>ACTION: AMart to work with AM to liaise with dermatology team for progressing above items.</p>
<p>4.0 Pathways and Clinical Guidelines</p>	
	<p>None for this meeting.</p>
<p>5.0 Shared care</p>	
<p>5.1</p>	<p>GMMMGM Shared Care Protocol for Modafinil in adults</p> <p>The group noted the first draft of a new SCP for modafinil in adults for excessive sleepiness associated with narcolepsy and Parkinson’s disease in the updated GMMMGM SCP template. This SCP had been pending since 2015 when an AMBER RAG was assigned to modafinil. This RAG was revisited in 2019 by the former FMESG who agreed that the status should be maintained. The neurology team at SRFT developed a draft last year in the previous GMMMGM SCP template which progressed up until the point of being opened for consultation. However, its development was stalled due to the impact of COVID and the review of GMMMGM shared care processes. The draft has now been transferred to the new template in conjunction with the neurology team and has been clinically checked by the RDTC. The group were in support of opening this draft for GM wide consultation.</p> <p>The group also noted and supported a minor amendment to the GMMMGM SCP template to include patient identifier details following feedback received. As the first section of the template comprises the request to the primary care prescriber, inclusion of patient details will provide confirmation of the specific patient the request relates to.</p> <p>ACTION: RDTC to open for GM wide consultation</p>
<p>5.2</p>	<p>GMMMGM shared care protocol for melatonin in children and adolescents</p> <p>A draft of the updated GMMMGM SCP for melatonin in children and adolescents was considered by the group for clinical approval. The update was started late 2019 with the main change being to include Slenyto® which is a licensed preparation of melatonin for insomnia in children and adolescents with autism spectrum disorder and Smith-Magenis Syndrome. A draft in the previous GMMMGM SCP template was opened for GM wide consultation between 17/12/19 to 29/01/2020. Following this, progress was affected by COVID and the GM shared care review. The SCP had now been updated to the new template with consultation comments incorporated as appropriate and a further clinical check has been completed by the RDTC. The updated draft was also sent to CAMHS teams for their input to ensure that all relevant clinical information is reflected. The updated SCP clarifies that Circadin remains the preferred agent for most patients with Slenyto use mainly reserved for patients meeting the licensed indication. It was questioned why there was a need to include the unlicensed liquid special since Circadin can be crushed for administration to patients with swallowing difficulties or enteral tubes. The SCP currently states that the liquid should only be used on an exceptional basis but it was reported that in practice there are significant numbers of patients on liquids. CC reported that MHCC have noted a high spend on melatonin liquid and have been doing</p>

	<p>some work to tackle this. The group also heard that the RMCH do not keep melatonin liquid and would use crushed Circadin instead. It was requested that the CAMHS teams are asked for specific examples of when the use of liquids may be considered and this included in the SCP which is to be brought back to the next meeting.</p> <p>ACTION: RDTTC to contact CAMHS teams to request information on use of liquid specials.</p>
<p>5.3 & 5.4</p>	<p>Methotrexate and mycophenolate for ILD</p> <p>The group reviewed two SCPs used by the Interstitial Lung Disease (ILD) service – methotrexate and mycophenolate.</p> <p>The ILD team started the updates of these SCPs in 2019 but progress had been significantly affected by the impact of COVID. With the restart of GMMM activity it was decided to pause development of SCPs on the RMOC schedule which includes methotrexate and mycophenolate. This means that the availability of updated GMMM approved versions will be further delayed for some months.</p> <p>The major change made with the updates was the amendment of monitoring recommendations to bring in line with the recommendations of the British Society for Rheumatology which are applied across most GMMM SCPs for DMARDs. The recommendations in the existing SCPs are now out of date. The ILD team have reported having to write separate letters to explain what monitoring is required in primary care rather than what is included in the SCPs and noted that some GPs are refusing to agree to shared care due to the SCPs being outdated.</p> <p>As an interim measure, it was proposed to update the monitoring sections specifically of the existing SCPs, to bring them in line with current recommendations while awaiting RMOC versions to become available. MGSG previously agreed that SCPs that have passed their review date would remain valid but updates would be performed to address clinically urgent issues as necessary. It is hoped that this update would provide some assurance for primary care prescribers. The updated blood monitoring recommendations are not expected to have significant financial/ commissioning implications.</p> <p>The group were in support of proceeding with this update but noted that the duration the patient is prescribed treatment by the specialist team should be aligned with the duration the specialist team monitors the patient during dose stabilisation before transferring to primary care.</p> <p>ACTION: RDTTC to clarify with ILD team regarding time to transfer, amend accordingly and submit to MGSG for noting.</p> <p><i>Post meeting note: ILD team clarified patient is transferred once they have been on a stable dose for 6 weeks (this can take up to 3 months but depends on the individual patient). Draft amended and checked with Chair prior to submitting to MGSG.</i></p>
<p>5.5</p>	<p>Shared care information leaflet for patients and carers</p> <p>The group reviewed the post consultation draft of the shared care information leaflet for patients and carers for approval. The draft had been updated to incorporate consultation comments as appropriate. The group approved the draft following some minor amendments including amendments to the FAQs on how patients can find out if monitoring results are normal and what they can do if they find it difficult to afford prescription charges. It was agreed these amendments can be agreed with the Chair and then submitted to MGSG for approval.</p> <p>ACTION: RDTTC to amend document and check with Chair prior to submitting to MGSG</p>

7.0 Work plan and horizon scanning

7.1 RDTC Monthly Horizon scanning June 2021

The biosimilars for bevacizumab (launched) and ranibizumab (EMA positive opinion) were noted; the latter is within the scope of the GMMM wet AMD pathway in development. No other items were noted to be of interest.

7.2 MSG and CRG work plan

The current work plan was noted. The work plan will be continually updated with items from MSG/CRG as these are agreed.

8.0 AOB

It was mentioned that the position of Vice Chair remains vacant and it would be helpful for this position to be filled. AW asked group members to consider volunteering for this position.

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