Clinical Standards Board

Minutes of the meeting held on
Thursday 9th August 2018
1-3.30 pm
St James House, Pendleton Way, Salford

Present:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Organisation</th>
<th>Representing</th>
<th>Feb</th>
<th>Apr</th>
<th>Jun</th>
<th>Aug</th>
<th>Oct</th>
<th>Dec</th>
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<tr>
<td>Dr Helen Burgess (HB)</td>
<td>GP MO Prescribing lead</td>
<td>NHS Manchester CCGs</td>
<td>Chair/GPs</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Dr Phillip Burns (PhB)</td>
<td>GP and Chair of MHSCC</td>
<td>GM AGG</td>
<td>AGG</td>
<td>✔</td>
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<tr>
<td>Dr Pete Budden (PB)</td>
<td>GP Prescribing lead</td>
<td>Salford CCG</td>
<td>FMESG</td>
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<td>Jane Brown (JB)</td>
<td>Chair of the GM Pharmacy LPN</td>
<td>GM Pharmacy LPN</td>
<td>NHSE Local Professional Network</td>
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<tr>
<td>Petra Brown (PeB)</td>
<td>GM MH Medicines Optimisation Strategic Lead</td>
<td>GM MH</td>
<td>GM Mental Health Organisations</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Dr Richard Darling (RD)</td>
<td>GP Prescribing Lead</td>
<td>Heywood, Middleton and Rochdale CCG</td>
<td>PaGDSG</td>
<td>A</td>
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<tr>
<td>Alison Dwyer (AD)</td>
<td>Consultant Pain Nurse</td>
<td>SRFT</td>
<td>Secondary care specialist</td>
<td>✔</td>
<td>A</td>
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<tr>
<td>Siobhan Farmer (SF)</td>
<td>Public Health Consultant &amp; Screening and Immunisation Lead</td>
<td>Greater Manchester Health &amp; Social Care Partnership</td>
<td>GM Public Health</td>
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<tr>
<td>Ben Galbraith (BG)</td>
<td>CFO</td>
<td>Oldham CCG</td>
<td>CCG finance leads</td>
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<tr>
<td>Jay Hamilton (JH)</td>
<td>Programme Development Lead</td>
<td>GM AHSN</td>
<td>Health Innovation Manchester (HIM)</td>
<td>✔</td>
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<tr>
<td>Lindsay Harper (LH)</td>
<td>Director of Pharmacy</td>
<td>Salford Royal FT</td>
<td>FMESG</td>
<td>✔</td>
<td>A</td>
<td>A</td>
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<tr>
<td>Dr Ann Harrison (AH)</td>
<td>GP MO Prescribing lead</td>
<td>Trafford CCG</td>
<td>GPs</td>
<td>✔</td>
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1. General Business

1.1 Apologies
Apologies had been received in advance as noted above. Two new members were welcomed to the CSB; Siobhan Farmer (Public Health Consultant & Screening and Immunisation Lead at Greater Manchester Health & Social Care Partnership) will take the seat for GM Public Health following Vicci Owen-Smith’s retirement. Ben Galbraith (Chief Finance Officer at Oldham CCG) will represent CCG finance leads following Jackie Murray’s departure.

1.2 Declarations of Interest
There were no interests raised that were relevant to this agenda.

1.3 Minutes and actions from the June meeting
The minutes were agreed as a true and accurate record of the meeting.

CSB was updated on the following actions from the June meeting:

*Response to the Medicines Implementation Strategy:* KO’B thanked CSB for the comments received on the Medicines Implementation Strategy and explained that that these were being considered for inclusion. It was understood that this strategy would be communicated from the Medicines Strategy Board, the Joint Commissioning Board and the Provider Federation Board. As a live document updates will be made as required.

2. **GMMMG reporting structure**

CSB considered the comments with regards how recommendations made by CSB are taken forward across the GM economy for implementation as policy. It was acknowledged that improvements had been made to this reporting structure with support from Directors of Commissioning, Finance and AGG representation, however in light of the conclusion of AGG, progress to date has been limited. Increased influence from the GM HSCP but a lack of formal meeting schedule of the GM Strategy Board posed difficulties for CSB output reporting.

Following on from June CSB meeting where a review of the CSB terms of reference were instigated changes to the reporting section of the ToR had been proposed, however CSB members were asked to discuss this content further now in order that GM commissioners can take these comments forward in their discussions with the Joint Commissioning Board. It was felt that the membership of CSB had been expanded sufficiently to enable the discussion of an enhanced level of delegated authority to CSB to be taken forward. AGG membership on CSB was intended to support this development. It was agreed that representation from the Provider Federation Board on CSB was required, alongside a GM local authority representative.

**Action:** MO’D to lead a task and finish group to support the development of an improved governance structure which would enable a more efficient route for approval of GMMMG outputs and support the development of GM policy rather than guidance.

3. **GMMMG Engagement with the Pharmaceutical Industry**

Updates to the GMMMG Policy on Engagement with the Pharmaceutical Industry were accepted by GMMMG in December 2017. Recently the GM Health and Social Care Partnership had asked that GMMMG consider this policy and whether it supports the MoU between GM and the Pharmaceutical Industry (Securing productive partnership working between Greater Manchester and the Pharmaceutical Industry to deliver a transformation in population Health and Wealth, attached). In particular GMMMG was asked that the statement “*Industry can comment on factual inaccuracy only*” be removed from all GMMMG website consultations, thus enabling Industry to comment on draft GMMMG recommendations. This was carried forward by Chair’s action and comments had been received in for the asthma pathway consultation and the May formulary consultations amongst others. As per GMMMG process the RDTC will consider these comments against the evidence available and suggest an action to the authors/subgroup as appropriate. Where the information submitted is unpublished it will be graded accordingly. Primarily this is expected to lead to an increase in work at the RDTC and for the working groups and subgroups, and may slow down the production time for pathways and guidelines whilst the additional comments are processed.

CSB acknowledged that whilst the request to consider information from Industry was reasonable, it was important that GMMMG adhered to their approved policies and procedures with regards to engagement with Industry, and development of GMMMG guidance, to ensure that all decisions were made appropriately and were supported by a robust evidence base.

**Action:** MM to update the working with Industry policy to reflect the above change as appropriate

4. **Output from wAMD treatment options working group**

At its April meeting, CSB requested that a task and finish group be formed to undertake a review at GM level as to the potential for commissioning bevacizumab (an unlicensed “Special”) as an option in ophthalmological conditions where anti-VEGF (anti vascular endothelial growth factor) drugs are
currently used. An update from the T&F group was communicated to CSB, with a recommendation that it would be prudent to await the outcome of the current judicial review (JR), the group agreed to reconvene once the outcome of the JR is known. CSB supported this proposal from the T&F group.

**Action:** No further action pending the outcome of the JR, following which the task and finish group will reconvene if so directed by CSB.

### 5. Report from the Formulary and Managed Entry Subgroup

CSB considered a report from the July FMESG meeting and approved the following decisions, pending the outcomes of GM consultation after which the formulary and associated lists will be updated accordingly:

<table>
<thead>
<tr>
<th>Agent</th>
<th>Decision</th>
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<tbody>
<tr>
<td>Ciprofloxacin ear drops (Cextraxal®)</td>
<td>Recommended for formulary inclusion (green RAG status) and grey list inclusion (for use in cases of proven pseudomonas otitis externa only).</td>
</tr>
<tr>
<td>Toujeo® (insulin glargine 300U/mL)</td>
<td>Not recommended for formulary inclusion. In the absence of a defined population for use, there was insufficient evidence to support the routine use of Toujeo® over other analogue insulins</td>
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<tr>
<td>GLP-1s</td>
<td>Formulary amendment: The group agreed liraglutide should replace lixisenatide as the GMMMG first choice GLP-1 agent, on the basis of evidence that liraglutide presents the more cost-effective option for reducing cardiovascular outcomes. Liraglutide costs approximately 26% more than lixisenatide.</td>
</tr>
<tr>
<td>SGLT2s</td>
<td>On the basis that there is no robust evidence supporting the use of any one SGLT2 over the others in patients with CV disease or additional risk factors, the group recommended that no change is required to the formulary at present</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>Agreed that pending TA publication, there was no need to assess ertugliflozin for formulary inclusion as it was assumed that in the absence of a cost, it would be a less cost effective option that established treatment.</td>
</tr>
<tr>
<td>Semaglutide</td>
<td>Agreed that there was no reason to assess semaglutide for formulary inclusion as it was assumed that in the absence of a cost, it would be a less cost effective option than established treatment.</td>
</tr>
<tr>
<td>Tadalafil</td>
<td>Formulary amendment: tadalafil to replace avanafil as the alternative choice PDE5 inhibitor for the treatment of erectile dysfunction</td>
</tr>
<tr>
<td>Ulipristal (Esmya®)</td>
<td>Formulary amendment: Ulipristal with new restrictions and monitoring advice to be reinstated in the formulary following CHMP/MHRA safety review</td>
</tr>
<tr>
<td>Insulin lispro biosimilar</td>
<td>Formulary amendment: Biosimilar to replace insulin lispro as the first choice formulary option in patients requiring a rapid-acting insulin analogue.</td>
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<tr>
<td>Raloxifene-chemoprevention of breast cancer</td>
<td>RAG review: Status to remain unchanged (Green following specialist initiation) in light of its inclusion in NICE guidance, along with tamoxifen for this indication.</td>
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<tr>
<td>Donepezil, galantamine, rivastigmine and memantine</td>
<td>RAG review: following recent update of NICE guidance which recommends these agents may be started by GPs if they have a specialist expertise in Alzheimer’s. The group agreed the RAG should be changed to Green</td>
</tr>
<tr>
<td>Triptorelin embonate (Savacyl®) to decrease sexual drive in men with severe sexual deviations</td>
<td>RAG review: recommended that the RAG status should remain unchanged i.e. RED as the indication was specialist and forensic in nature and so the management of these patients would fall beyond the scope of primary care</td>
</tr>
<tr>
<td>Paravit-CF® multivitamin for patients with CF was considered – compared with existing options</td>
<td>Recommended for formulary and grey list inclusion (green following CF specialist recommendation). Paravit-CF® reduces medication burden, is a less costly alternative and offers supplementation in line with clinical recommendations.</td>
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TheraBite®  | DNP assessment: Recommended for DNP inclusion on the basis of poor evidence base for the management of trismus.
---|---
Bath additives  | DNP assessment: Based on the results of the BATHE RCT, FMESG recommend that bath additives without antimicrobials should be DNP, and those with antimicrobials should be grey for infected eczema.

CSB also noted that:

- FMESG supported the development of a GM diabetes pathway for the prescribing of insulin to reduce variation in prescribing across GM CCGs, and that PaGDSG would lead on this work.
- FMESG acknowledged the recently published RMOC guidance on safety factors to consider when adding a new insulin preparation to a local formulary.
- FMESG had reviewed the diabetes horizon scanning report for drugs with launch dates within the next 2 years. It was agreed that the group with review Suliqua®, a GLP-1 + long-acting insulin analogue for type 2 diabetes, which is due to launch this year.
- In response to consultation feedback on the proposed switch of RAG status of naltrexone for opioid and alcohol dependent patients, FMESG agreed that a paper will be raised with CSB and then AGG/Strat board to challenge the practice of commissioning without considering prescribing provision.
- A letter has been agreed for distribution to hospitals, opticians and LOC regarding adherence to Chapter 11 of the formulary. The GM Primary Eyecare Conditions Service (MECs) would also be contacted in regards to updating and aligning their formulary with Chapter 11 of the GMMMG formulary.

**Action:** FMESG proposed actions to be taken forward as approved by CSB

### 6. GM OTC Policy

CSB considered a paper resulting from the June FMESG meeting which had been dedicated to this topic. The paper sought approval from CSB that CCGs implement the NHSE guidance on Prescribing of Over the Counter (OTC) items (issued 29th March 2018), and that a draft policy had been produced that would require local amendments and formulation into local policy. The paper explained that enquiries have been made of the Shared Service Head of Engagement as to the level of local Consultation required and NHS England has advised that:

- CCGs were encouraged to go out to consultation or at least engage with their local population at the time of the national consultation, so they could feed into the national process and then they may not need to repeat it once the guidance was published. Some CCGs may have already done this so it’s not a one size fits all approach. It may also depend on how CCGs currently prescribe for and treat these conditions.
- CCGs would be expected to take the guidance into account in formulating local polices. This would include taking account of local circumstances and their own impact assessment and legal duties to advance equality and have regard to reduce health inequalities. Whether this requires a formal consultation would need to be a decision taken by the CCG.

An enquiry was also made regarding the possibility of a GM-wide Public Consultation. However, given that the CCGs are at different stages of implementation of the NHSE guidance, this may not be the appropriate mechanism to go forward. There may not be capacity to do this at GM level unless funding for capacity and materials are provided.

NHSE also stated that CCGs would need to conduct a local equality impact assessment, as they are best placed to assess the impact on their local populations.

It was acknowledged that whilst consistency of approach across GM would be preferred, GM CCGs have different priorities and are progressing with this work at different paces. There was a risk that by trying to implement a GM approach that the whole economy may risk moving at the pace of the slowest adopter. It was agreed that the 4-page guidance from the BMA be added to the draft policy, after which this policy could be published to the GMMMG website and the steps presented in the
paper be taken forward by individual CCGs through AGG (or equivalent) direction. Quarterly reporting to CSB would be required to demonstrate that all CCGs had implemented this policy and were showing signs of a reduction in the prescribing of OTC items.

**Action:** AM to amend policy as discussed prior to website publication. DoCs (in the absence of AGG), to direct their CCGs to implement this policy as per NHSE direction. MM to add to a quarterly reporting schedule.

**Post meeting note:** As CCG MO leads have requested this topic be re-opened for discussion, the policy remains as draft and has not yet been published to the website.

7. **Report from the Pathways and Guidelines Development Subgroup**

CSB considered a report from the July PaGDSG meeting and approved the following decisions:

**Neuropathic pain guideline** - It was agreed that the neuropathic pain guidance be opened for review and has been added to the PaGDSG work plan.

The group approved the **GMMMG Sacubitril/valsartan information sheet** for a further three years, and confirmed that no changes were required. It will be refreshed and added to the GMMMG website. It was noted that this document is regularly used by the heart failure clinics.

**Draft pathway for extended dual antiplatelet therapy following myocardial infarction** – The group considered an alternative version of the GMMMG information leaflet which had been submitted by a GM cardiologist. It was agreed that the two documents would be merged, but that as there was no content change and this was simply a reformatting issue formal approval shouldn't be required, but that CSB are asked to note this change.

**STOMP project scoping** – PaGDSG queried the prioritization of this work, it was agreed that the scoping template would be completed and submitted to CSB for prioritization in due course.

**GMMMG guidelines requiring review** – it was agreed that a GMMMG document control policy would be produced, and that all pathways/guidelines/SCPs should have a 3 year review date as standard, but that in addition monthly horizon scanning should pick up all potential changes to current documents. The group agreed a review schedule for all guidelines currently on the website.

The group approved shared care protocols for sulfasalazine for IBD (new SCP), domperidone for paediatric GORD (updated SCP) and disulfiram in the treatment of alcohol dependence (update).

CSB noted that the following SCPs will be opened for GM wide consultation:

- Hydroxychloroquine for dermatology and rheumatology (UPDATE, pending some additional amendments)
- Apomorphine use in Parkinson’s Disease
- Azathioprine for Interstitial lung disease
- Oral methotrexate for IBD
- Goserelin in breast cancer

**Action:** PaGDSG to take forward actions as approved by CSB

8. **GMMMG Opioid Prescribing for Chronic Pain: Resource Pack**

CSB considered the “Opioid prescribing for chronic pain: resource pack” which has been reproduced from the guidance developed by Wigan Borough CCG. This was acknowledged by the group as a very good and useful piece of work, the purpose being to establish in part a GM wide strategy to tackle the inappropriate prescribing of opioids. The paper highlighted the levels of opioid prescribing across GM, showing a two-fold variation in spend per patient between CCGs, and an almost two-fold variation in prescribing frequency. It was recognised that CCGs would have different priorities based on their patterns of prescribing and would be able to use the most useful parts of this resource as required. A “pain diary” was still in development and approval was sought for this to be added to the pack post approval (following the necessary clinical checks). CSB approved the resource pack for publication to the GMMMG website. CSB will monitor opioid prescribing patterns using the recently developed Epact2 dashboard, and accepted the initial target proposed by PaGDSG of “any GM CCG with an opioid prescribing frequency above that of the England average aims to reduce below the England average in the next twelve months”.

It was agreed that this work should be highlighted to the JCB and Provider Federation Board, KO’B offered to aid this communication as initial conversation had been undertaken. However formal route of communication to JCB from GMMMG was pending confirmation of governance structures.
9. Report from the High Cost Drugs Subgroup

CSB considered a report from the June HCDSG and approved the recommendations from HCDSG which included addition of guselkumab to the GM biologics pathway as per NICE TA511. This is likely to have cost implications as treatment options for patients are extended but this is not able to be quantified as yet, as patient numbers are unknown. A full review of this pathway is being planned because whilst many agents had a positive NICE TA, there was still a need for the pathway to consider the appropriate number of treatment options received by the patient, as in some cases 5th or 6th line biologics were being requested through Individual Funding Requests. It was agreed that GMSS would investigate the variation in IFR approval rates between GM CCGs and identify any areas for action to improve IFR equity across GM.

CSB considered the June progress report from the GM biosimilar adalimumab working group. HCDSG reminded CSB that the GM target for uptake of the adalimumab biosimilar will not commence from day 1 of the biosimilar product being launched in October 2018. Whilst GM would still aim to achieve the targets set, the timeline for this may not be as quickly as first anticipated. Although there was no July HCDSG meeting CSB are asked to note that the GM biosimilar project is progressing as per plan. In particular Trusts’ assurance checklists have been introduced to facilitate reporting to HCDSG. There are no major issues reported in July 2018 that require CSB consideration.

**Action:** HCDSG to continue with the work being undertaken as detailed

10. Biosimilar assurance report

An updated report on the current status of biosimilar uptake across GM was presented by the HCDSG. Following the approval and adoption of the GM gain share principles and biosimilar uptake agreement at the start of the year, this report demonstrated an improvement in biosimilar uptake and demonstrated that a number of local health economies are now working together to improve uptake and maximize potential savings. However, it also showed that some localities have not engaged with this exercise, and this lost opportunity was communicated to CSB. The lack of engagement within some organisations was raised as a concern given the upcoming arrival of biosimilar adalimumab.

Some improvements to the report were suggested, and it was agreed this report would return to HCDSG for further development prior to returning to CSB.

**Action:** MM to add this item to the HCDSG agenda for further discussion to aid its development.

11. The Agreement of Prescribing Responsibilities between Primary and Secondary/Tertiary Care’ (Shared Care) and the Impact on the Mental Health Acute Care Pathway.

CSB considered the above paper which had been presented to the Adult Mental Health Board (AMHB) to describe the Greater Manchester (GM) system for production and approval of prescribing pathways and medicines suitable for shared care. This paper had not been produced by GMMMG but rather the GM mental health trusts. PB explained that key elements of discussion from this paper had been an explanation of RAG status to MH Trusts, who were often unfamiliar with the concept. There was discussion around the variation between CCGs as to how shared care is accepted and adhered to across GM, and that this wasn’t unique to mental health. It was noted that FMESG have agreed to write a similar paper highlighting the issues with commissioning of services without a prescribing provision, although this work has been delayed due to capacity of the group. SD explained that RMOC are looking to support a national shared care project, and agreed to link in with PB outside of the meeting. PB asked for support from the PaGDSG for support around this agenda.

**Action:** Paper to be shared with PaGDSG and FMESG in due course

12. Rebate Schemes

A rebate scheme for Januvia (sitagliptin) was noted as complying with the approved rebate framework
13. GM Antimicrobial improvement plan: progress report
A progress report on the 2018/19 antimicrobial workstream was presented which demonstrated the current position for the 2018/19 prescribing indicators and describes the final position achieved by CCGs for the 2017/18 indicators. This report was noted by CSB who asked that the full antimicrobial improvement plan be brought before CSB for consideration.

Action: KG to return the full antimicrobial improvement plan to CSB

14. NHS operational productivity: unwarranted variations in Mental health services and Community health services. Lord Carter of Coles (Carter 2 report)
A quick overview of this report was presented. It was noted that the content was directed to community services and mental health providers; however there may be some aspects which would require the attention of CCG MO teams.

Action: no action from CSB, CCGs and mental health teams should take this report through their forums.

15. Royal Pharmaceutical Society Utilising Pharmacists to improve the care of people with mental health problems.
It was requested that this report be directed to the LPN for further consideration of the use of community pharmacists to better support the mental health agenda.

Action: MM to forward to RMcD

16. Communication from Subgroups and Associated Committees
Minutes and work plans from the GMMMG subgroups were noted.

GM CCG Lead Pharmacists: PH updated CSB on recent discussions at CCG MO leads meetings. There was some discussion around the need for a consistent approach to funding of homecare, which would be directed to HCDSG. There was some concern around the roll out of CURE without appropriate cost modelling for CCGs. It was thought that the pilot scheme had been approved through a public health board without any consultation with the CCG finance teams.

Action: BG and SF to support this discussion around CURE financial modelling as appropriate outside of CSB

GM Chief Pharmacists: Concerns regarding the medicines supply chain and the effect of Brexit were raised, the current advice was not to stockpile and the CMU would update in due course. A centralised procurement function is being presented to CFOs later in the week

Mental Health: Updated under items 14 and 15

Local Professional Network: No update

Health Innovation Manchester: No update

17.0 AOB
KO'B updated on the cannabis oil working group, and agreed to forward a statement to GMMMG for website publication

Date of next meeting: Thursday 11th October 2018, 1-3.30pm. St James House, Salford, M6 5FW