Clinical Standards Board

Minutes of the meeting held on
Thursday 12th April 2018
1-3 pm
St James House, Pendleton Way, Salford

Present:

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<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>
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<tr>
<td>Dr Helen Burgess (HB)</td>
<td>GP Prescribing Lead and GMMMG</td>
<td>NHS Manchester CCGs</td>
<td>Chair/GPs</td>
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<td>Dr Phillip Burn (PhB)</td>
<td>GP and Chair of MHSCC</td>
<td>GM AGG</td>
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<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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<td>Petra Brown (PeB)</td>
<td>GM MH Medicines Optimisation Strategic Lead</td>
<td>GM MH</td>
<td>GM Mental Health Organisations</td>
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<td>Dr Richard Darling (RD)</td>
<td>GP Prescribing Lead</td>
<td>Heywood, Middleton and Rochdale CCG</td>
<td>PaGDSG</td>
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<td>Alison Dwyer (AD)</td>
<td>Consultant Pain Nurse</td>
<td>SRFT</td>
<td>Secondary care specialist</td>
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<td>Jay Hamilton (JH)</td>
<td>Programme Development Lead</td>
<td>GM AHSN</td>
<td>Health Innovation Manchester (HIM)</td>
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<td>Lindsay Harper (LH)</td>
<td>Director of Pharmacy</td>
<td>Salford Royal FT</td>
<td>FMESG</td>
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<td>Dr Ann Harrison (AH)</td>
<td>GP</td>
<td>Trafford CCG</td>
<td>GPs</td>
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<td>Robert Hallworth (RH)</td>
<td>Specialist Cancer Pharmacist</td>
<td>NHSE</td>
<td>PaGDSG</td>
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<td>Peter Howarth (PH)</td>
<td>Head of Medicines Management</td>
<td>Tameside &amp; Glossop CCG</td>
<td>CCG MO leads</td>
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<td>Adam Irvine (AI)</td>
<td>CEO</td>
<td>GM LPC</td>
<td>GM Community Pharmacists</td>
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<td>Leigh Lord (LL)</td>
<td>Locality Lead Pharmacist</td>
<td>NHS Trafford CCG</td>
<td>CCG MO leads</td>
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1. General Business

1.1 Apologies
Apologies had been received in advance as noted above.

1.2 Declarations of Interest
Ben Woodhouse attended in place of Leigh Lord, referred to the declarations held on the GMMMG register (as a consultant to a GP federation and a law firm) but stated that these DOI did not relate to any of the items on the agenda for this meeting, and so no further action was required. There was some discussion surrounding the COI training e-learning package available from NHSE, it was suggested that this information may be useful for members to access from NHSE. It was confirmed that all DOI are recorded on the GMMMG DOI register which is held on file at the RDTC. All members were reminded that to comply with the GMMMG DOI policy they should declare any interests at every meeting and the meeting minutes will reflect the action taken.

1.3 Minutes from the February meeting
The following amendments were requested after which the minutes were agreed as a true and accurate record of the meeting:
• Under 1.3 – the reference to Philip Burn as Chair of AGG to be corrected to “member” of AGG
• Throughout the document reference to DFOs be corrected

2.1 GMMMG CSB work plan
The group considered the revised work plan presented by GMSS, SJ explained that the three priority areas identified at the February meeting as antimicrobial stewardship, optimisation of best value biologics and COPD had been further developed as presented and that KG was communicating with KO’B to align the lead areas with the medicines strategy.

Whilst there was some agreement that progress had been made on these priorities MO’D asked that the rationale for the three priorities be communicated to AGG in more detail, along with the expected benefits that these work streams will deliver. CSB queried the lack of information in some fields of the work plan and asked that named leads be identified to take ownership of these projects. It was agreed that this would be discussed further at the upcoming Chairs of the GMMMG subgroups meeting with an aim for an executive summary to be submitted to AGG.

The need for this work to pick up pace was raised, it was agreed that the Chairs of the subgroups should drive the projects through the subgroups, but it was also recognised that strategic direction was required from CSB and from the Medicines Strategy Board. The delay in the publication of the medicines strategy was discussed and that this had hindered the development of the CSB work plan.

There was further discussion on the rationale for the priorities selected, there was a request for the COPD work stream to be replaced with treatment options for wet AMD, and that more emphasis should be placed on tackling the deprescribing of drugs of low clinical value. It was agreed that this discussion would continue and actions would be agreed at the meeting of the Chairs on the 30th April 2018.

Action: Work plan to be tabled for discussion at the Chairs meeting

2.2 GMMMG website development group: propose changes to the GMMMG website
SJ communicated the changes to the GMMMG website as proposed by the website task and finish group, with an aim to improve accessibility of content by introducing a common indexing system across the website and improving the search functions. There was a mixed opinion on the current website format, and it was agreed that the proposed changes seemed appropriate, particularly as they were being delivered without any additional funding resource. CSB were encouraged that GP feedback had been sought during this project, as the primary users of the website. It was suggested and agreed that the merger of the RAG and DNP lists would not happen until the current work following the NHSE Drugs of Low Clinical value was completed.

Action: SJ/MM to communicate CSB approval for changes to the task and finish group

2.3 GM reporting and monitoring: DLCV and DNP and Grey lists
Dashboard reports from the GMSS BI tool were provided to aid discussion around the continued drive to reduce prescribing of Drugs of Low Clinical Value. It was recognised that the data presented didn’t yet reflect the revisions proposed to the Do Not Prescribe and Grey Lists but that they would in the near future.

CSB noted the variation between CCGs, and the issue of equity for GM patients. There was comment that the Model Hospital data showed similar patterns of variation. It was agreed that Stockport CCG should be applauded for their success in the continued reduction in prescribing of drugs of low clinical value.

CSB members requested that in future a recommendation paper be presented to CSB rather than the dashboards to aid a more structured discussion with delivery of a GM strategy to resolve the issue presented. GMSS to produce these papers on a regular basis as required by the priorities identified at the Chairs meeting.
3 Subgroup outputs

3.1 January minutes

These were noted by CSB

3.2 Report from March 2018 meeting

CSB were updated on recent March 2018 FMESG meeting and in particular that:

- FMESG noted that no significant comments had been received from the GM wide consultation on changes to chapter 11 of the formulary and seek permission from CSB to update the formulary.
- FMESG had reviewed the revised GMMMGG DNP and Grey lists which had been updated to reflect the NHSE Drugs of Low Clinical Value Guidance and criteria. Items which have been considered by GMMMGG but not NHSE have been added to the March FMESG consultations to ensure that all items have undergone consultation either by NHSE or by GMMMGG. The revised list will be submitted to AGG for implementation as policy. FMESG will monitor prescribing of DNP and Grey list items on a six monthly basis, but request that CSB liaise with Trusts to highlight DNP and Grey lists.
- Review of GMMMGG Drugs in diabetes recommendations: The group agreed that the recommendations for insulin degludec and degludec + liraglutide would remain unchanged. The DPP-4 inhibitor, SGLT2 inhibitors and GLP-1 agonists recommendations would be archived as they had now been superseded by NICE guidance, and the formulary would include a link to the NICE algorithm. The statement on insulin biosimilars would be updated and re-issued.
- Primary care prescribing data highlighted significantly higher than expected prescribing of insulin glargine 300U/mL (Toujeo®), it was agreed that local audit would aid understanding as to why prescribing was so much higher than envisaged at the time of issuing the GMMMGG statement and whether the statement required re-clarification or whether additional work needed to be done to redress this issue via diabetes prescribers. It was agreed that GMSS would draft an audit tool to share with HOMMs and the data would return to the July meeting.
- The group agreed that pitolisant for narcolepsy be added to the RAG list as a RED drug, prescribing of this agent was anticipated to occur in less than ten patients across GM per year and so no formal position statement would be issued, as the care of this small group of patients would remain with specialists within the tertiary centre.
- No comments were received on the proposal that sildenafil for digital ulcers be given a green plus statement (with an accompanying information sheet), rather than a red drug, therefore this change will be taken forward
- The March formulary amendments will be opened on the website for GM consultation and intend to revise the formulary to reflect NICE TA497 to TA510, with the addition of lesinurad to the DNP list in light of its negative TA. The formulary will be updated to reflect MHRA guidance from January and February, with the resulting removal of daclizumab. Deodorants for stoma use will be assessed for the DNP list

3.3 Metformin for diabetes prevention – for approval

FMESG presented a paper to CSB proposing that:

- the formulary is updated to reflect NICE PH38 which covers the prevention of Type II diabetes in people at high risk, and includes recommendations on the use of metformin to support lifestyle programmes when HbA1C or fasting blood glucose test results have deteriorated despite their use or patients are unable to participate in a lifestyle programme.
• that the authors of the GM diabetes strategy focus the majority of their efforts to address the prevention of T2DM in people at high risk in the diabetes as per PH38 within the GM strategy
• that GMMMG include the prevention of T2DM in people at high risk in the diabetes plan to be presented to CSB in Q2

CSB asked if there had been any further progress with the GM diabetes strategy and heard that it was now intended to be issued as a best practice guidance rather than a strategy. CSB supported the proposal by FMESG and agreed that this proposal be communicated to the authors of the GM diabetes strategy/guidance. If there is no appetite for this to be taken forward under the strategy then it will be brought back into CSB.

**Action:** MM to obtain a contact for the GM diabetes strategy to communicate this proposal too.

4  The Pathways and Guidelines Development Subgroup

4.1 January minutes
These were noted by CSB

4.2 Report from March 2018 meeting
CSB noted the update from the March meeting where PaGDSG had discussed their role and remit going forward under CSB. The group had accepted the work directed to them by CSB which included monitoring the outcomes of implementation of the COPD pathway, but had also prioritised the development of a pathway to manage the reduction of high dose opioids, the GM development of a number of dermatology pathways and a review of the headache pathway to encompass a number of high cost drugs tabled for consideration by the HCDSG.

5  High Cost Drugs Subgroup

5.1 January minutes
These were noted by CSB

5.2 Report from the March 2018 meeting
CSB were updated on the recent March 2018 meeting where HCDSG had been updated on the progress of the HCDSG position statement on dupilumab for atopic dermatitis. Dupilumab is a specified high cost drug and CCGs will be the responsible commissioners for dupilumab for this indication. Dupilumab costs £1,264.89 for 2 x 300 mg pre-filled syringes. The recommended dose regimen is an initial dose of 600 mg followed by 300 mg given every other week, with a review of efficacy after 16 weeks. The annual cost per patient is therefore around £16,450, and the cost of an initial 16 week trial is approximately £6,300. In the UK, it is estimated there are 14 adults per 100,000 population with moderate AD, and 6 with severe AD who may be eligible for treatment with dupilumab. If it is assumed that 50% of the patients with severe AD are treated at a cost of £16,450 per year this would represent an estimated cost pressure of £49,300 per 100,000 population (£1.38 million annually across GM based on a 2.8 million population). The group noted feedback from GM specialists who had reported that about 30 to 50 patients had been identified as candidates for dupilumab but that further patients may be identified and that this number may rise to 150 patients across GM. IF 150 patients were to receive dupilumab for a year this would cost the GM health economy about £2.55 million. Following its first Committee meeting NICE published an appraisal consultation document “not recommending” dupilumab, as the cost effectiveness estimates range from £30k to £78k per QALY. We now expect any positive approval from NICE to be dependent on a patient access scheme to ensure cost effective access to this treatment. HCDSG will continue to liaise with GM dermatologists to further define a place in therapy for this agent, should this information be required to support implementation of a positive NICE TA which is currently expected in August 2018.

5.3 Adalimumab implementation plan – for approval
CSB considered for approval the GM adalimumab biosimilar implementation project plan, and supported HCDSG in agreeing that delegated authority be given to the adalimumab biosimilar working group for updates to be made to the plan spreadsheet as required. The group were made aware of the need for commissioners to hold their Trusts to account for this work to be successful. The lack of CSB input into the Provider Board was raised, it was reemphasised that engagement
with speciality clinicians was a key component of this work and communication throughout the Trusts could support this. The working group were thanked for their progress to date with this work, updates will be brought to each HCDSG and CSB meeting.

5.4 Commissioning framework for biological medicines: defining “best value”

HCDSG considered and approved for submission to CSB an update on the implementation of the NHSE “Commissioning framework for biologic medicines”, and what will be considered when evaluating best value biologics. This item was approved for addition to the website.

Action: MM to format and add to the website

6 Reports from Associated Committees

There had been no CCG leads meeting in March, however at the April meeting there had been discussion around a folic acid PGD for maternity services, the NHSE OTC draft guidance and how this would be implemented across GM. The CCG leads had met with the NHSE Care Homes Lead however expressed confusion around this agenda and whether there was a need for this work in GM as the CCGs felt it had already been done.

The GM Chief Pharmacists had met to discuss the aseptic preparation work stream and the standardisation of OPAT.

The GM Mental Health representative explained that the three mental health trusts were to meet with providers and commissioners to discuss shared care. CSB commented that the commissioning of services without appropriate provider of services/prescribing facility needed attention. Carter 2 which focused on mental health and community services was also to be discussed by mental health teams.

7 AOB

It was agreed that Health Innovation Manchester (HIM) be added to the agenda to communicate regularly with CSB, as an update on the paliperidone project was expected soon.

Date of next meeting: Thursday 14th June 2018, 1-3pm. St James House, Pendleton Way, Salford, M6 5FW