CARDIFF AND VALE UNIVERSITY HEALTH BOARD
NOTES OF THE MEDICINES MANAGEMENT GROUP MEETING
HELD ON TUESDAY23rd JULY 2013

Present: [redacted]

ACTION

1. Apologies
[redacted]

2. Declarations of interest
None.

3. Minutes of last meeting – 17th June 2013
These were accepted as an accurate record.

4. Matters arising

a) *Mental Health prescribing issues*
- Discussions were ongoing about the appropriateness of switching existing aripiprazole patients
- Memantine policy has now been completed and will go to the MHSOP Q&S meeting before being presented to the August MMG meeting [redacted]
- ECG guidelines for patients on psychotropic medication have been approved by [redacted] following consultation across primary and secondary care. They will be disseminated by Mental Health. The issue of competency of mental health clinicians to interpret ECGs is being discussed with input from Cardiology [redacted]
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b) *Safe sedation – Guidelines for clinical staff*
[redacted] noted that minor formatting changes to the guidance document are being made before circulation. [redacted] queried the specific issues identified within adult cardiac service and it was noted that several directorates would need to consider a local appendix to the guidelines.

c) *Drug Tariff - Appliances*
[redacted] has written to Clinical Boards as agreed to remind prescribers that appliances that are in the Drug Tariff are not formulary unless approved. The situation will be monitored.

d) *Outpatient dispensing*
[redacted] noted that he had formally replied to Bro Taf LMC regarding the issues they had raised around WP10HPs. Following discussion within the UHB it has been agreed to delay the implementation of those changes until an electronic prescribing system was available for outpatients.
The appropriate use of the existing prescription/recommendation (yellow) forms is being promoted. A significant proportion of forms

presented to hospital pharmacy do not fit the agreed criteria i.e. hospital only or urgent (within 48hours). Feedback on practice will be provided to Clinical Boards, directorates and individual consultants. Support to address this safety and workload issue was requested from Clinical Boards.

e) *Internal Audit*

[redacted] reported that a recent audit exercise had confirmed significant improvement with "reasonable (previously adequate) assurance". Concerns about key holding in mental health and temperature monitoring of fridges are being addressed. Audit within the Dental hospital was included for the first time and some issues there will be addressed.

[redacted] raised concerns about security of medicines deliveries to smaller sites. Whilst a meeting with WAST is arranged for 12th August, the pharmacy logistics team are trying to address as a matter of urgency in the interim.

5. Delivering O4E – medicines management project

[redacted] noted progress with this project which aims to reduce medicines spend whilst maintaining access to effective evidence based treatment. [redacted] explained that the discussion document circulated to MMG had been the focus of discussion at a recent Leaner & Fitter group meeting. Following subsequent discussion it had been agreed that the previous focus on individual medicines savings and cost containment plans would be changed to a focus on transformational change in the medicines related processes. These will include:

- strengthening formulary management particularly first line v second line usage
- e prescribing in secondary care
- support development of effective prescribing to align with care pathways as these are developed/commissioned
- support CBs to deliver the meds man savings targets 2013/14 focusing particularly on switching in secondary care and areas where we have agreed to restrict or limit use
- develop meds management plan to align with 2014/15 integrated business plan (including horizon scanning, financial parameters and and benchmarking) by end of September, plan by mid November
- develop and implement a communications plan particularly across primary and secondary care but also for cross-cutting practice e.g. microbiology
- ensure effective reporting against the workstream, both financially and against milestones
- reshape MMG (and its sub groups if necessary) and review reporting arrangements to support this agenda

The project outline document is being redrafted to reflect this change in focus with project support from [redacted] (PMO). The Leaner & [redacted] Fitter group will consider proposals on Thursday 25th July and the executive management team will do so on Monday 29th July. The document will be widely circulated for comment when ready.

6. Terms of Reference

To reflect the changes described in the above project the Health System Management Board had requested transformation of the medicines management group (and potentially its sub groups).

The following were raised during discussion on the terms of reference:

- Consideration of clinical effectiveness and prioritisation are key roles of the group
- Membership must reflect and support engagement of clinical boards (it was noted that several CBs have an MMG- others should consider?)
- The format of the agenda will focus on:
  a) statutory functions and safety
  b) prescribing performance
  c) strategic planning for medicines management

- Equity and consistency of access to medicines across the UHB needs debate
- The prioritisation framework discussions led by [redacted] will be considered in terms of its application to medicines
- A decision on reported arrangements is required. Options are; remain with Q&S group, move to HSMB or PPD groups.

In response to a question about the role of MMG in managing "early adopters" [redacted] noted that the group should aim to facilitate good clinical consensus around best practice in cost effective and affordable prescribing. It was noted that robust cost and clinical effectiveness consideration takes place at AWMSG and NICE appraisal, prior to implementation discussions at MMG.

During discussion it was noted that whilst the implementation planning document had proven useful in managing the introduction of new drugs, some format changes e.g. WHSSC funding agreements and an executive summary sheet should be incorporated. In addition, as [redacted] Clinical Board authorisation freedoms are progressed it is feasible that in future a CB-specific IPD could be signed off by the CB (with only cross-CB implications being discussed through MMG)

Any further comments on the Terms of Reference should be forwarded to [redacted] by the end of July. As the medicines management strategic project evolves these ToR may need to be updated. A redraft will be circulated for comment prior to the next meeting. When the reporting arrangements have been agreed the ToR will be submitted there for [redacted] approval.

7. NICE/AWMSG implementation

a) *IPD – Perampanel (Fycompa®)*

[redacted] presented the IPD and noted that this anti epileptic drug has AWMSG approval as adjunctive treatment of partial onset seizures with or without secondary generalised seizures. The annual cost impact compared with current alternative is minimal (£4 per patient per annum). The impact on primary care will be to replace existing third line options in eligible patients.

Clarity on recommendation and initiation will be requested from the epilepsy service (post meeting note – the drug would be specialist

recommended. GPs may be required to up-titrate the dose in accordance with clear directions on a yellow outpatient form or clinic letter, but would not be expected to assess response, any concerns should be referred back to secondary care; lack of ministerial endorsement of AWMSG recommendation was noted).
It was agreed that following this the IPD would be forwarded to [redacted] for Primary Care approval before sign off.

b) *IPD – Ranibizumab*
[redacted] noted that discussions on funding of Ranibizumab for diabetic macular oedema had reached stalemate. This NICE approved indication will be a potential £1m cost pressure. [redacted] suggested that discussions needed to continue including options to reduce spend in other areas of the directorate to ensure this guidance is implemented.

c) *IPD – Ivacaftor*
[redacted] presented this IPD for the treatment of cystic fibrosis (CF) in patients aged 6 years and above with the G551D mutation (approximately 4% of the CF population in the UK). It was noted that whilst AWMSG did not recommend the drug the Health Minister subsequently agreed that it should be made available for eligible patients in Wales. Funding will be made available via WHSSC, supported by strict audit/stopping criteria. [redacted] requested that all appropriate costing should be incorporated in the central funding. It was noted that Homecare service should be put in place as soon as possible. Implementation was approved.

d) *IPDs in Cystic Fibrosis*
The UK Cystic Fibrosis Trust Antibiotic Working Group – May 2009, state that all patients with chronic pulmonary infection with Pseudomonas aeruginosa should have long term anti-pseudomonal therapy unless contraindicated.

Currently licensed antibiotics include nebulised colistimethate sodium (Colomycin® or Promixin®), nebulised Tobramycin (TOBI® or Bramitob®), nebulised Aztreonam Lysine (Cayston®) and inhaled dry powder Tobramycin (TOBI® Podhaler®) and inhaled dry powder colistimethate sodium (Colobreathe®). Only nebulised colistimethate sodium and nebulised Tobramycin are currently available through routine prescribing in Wales.

[redacted] outlined the content of Implementation Planning documents for Aztreonam Lysine (Cayston®), inhaled dry powder Tobramycin (TOBI® Podhaler®) and inhaled dry powder colistimethate sodium (Colobreathe®). The proposed treatment options (taking account of NICE guidance and cost implications are:

1st line: Continuous nebulised/dry powder colistimethate sodium as per NICE guidance

2nd line: An alternating monthly regimen of nebulised/dry powder colistimethate sodium and nebulised/dry powder Tobramycin as per

NICE guidance.

3rd Line: An alternating monthly regimen of either nebulised/dry powder colistimethate sodium or nebulised/dry powder Tobramycin with nebulised Aztreonam Lysine (AZLI) - Cayston®

It is anticipated that the dry powder therapies will be offered to patients intolerant to nebulised therapies prior to trialling Cayston based on cost. The availability of these treatments may reduce the need for Cayston® as patients who are intolerant of nebulised tobramycin +/or colistimethate sodium will be trialled on the dry powder alternatives when made available in Wales.

These proposals form the basis of a business case being submitted to WHSSC and were approved contingent upon all costs being covered by them.
Parallel IPDs for child health and in progress and it was agreed that an appendix to the adult IPDs detailing patient numbers in child health would be passed to the Board Director and then Medical Director for sign off.

Due to involvement of a Patient Access scheme for each drug, supply will need to be managed through secondary care (ideally homecare).

e) *IPD – Fidaxomicin(Difficlir®)*
[redacted] presented this IPD for Fidaxomicin which is recommended by AWMSG as an option within NHS Wales, restricted to:
- Patients with severe Clostridium difficile infection (CDI)
- Patients with recurrence of CDI.

Local specialist opinion is that the drug should be reserved for first recurrence of CDI (15-30% of patients). There are several options for how these patients are currently managed. Evidence suggests an absolute risk reduction of 12% i.e. NNT of 8 patients with Fidaxomicin to prevent further recurrence (compared with vancomycin). The drug would be Consultant microbiologist recommended only (Category C antimicrobial)
It was noted that individual Clinical boards had not yet had the opportunity to consider affordability and also that [redacted] (Medicine) is completing some patient level costing work in *Cdiff* patients with [redacted].
On the basis of the significant cost impact (£1620 per course) it was felt that individual Clinical Boards may take differing views on the prioritisation of this option. This raises potential concerns about equity of access. It was agreed that a short paper should be provided for HSMB consideration. In the meantime the drug would be treated as non-formulary.
It was noted that an IPFR request might be an option.

8. Items for approval
a) *Guideline for maintenance of warfarin and management of a high INR*
The draft has been developed by [redacted]

[redacted] for primary care and mirrors the guidance available to secondary care for several years. Any comments on the guideline should be sent to [redacted] by the end of July who will forward to [redacted].

b) *Guidelines for symptom-triggered alcohol detoxification in UHW & UHL*

[redacted] noted that the guidelines have been updated to include a medical review at cumulative diazepam dose of 200mg or every 24 hours. The guidance was approved for implementation.

c) *Interim guidance for use of codeine in children and breastfeeding mothers*

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMEA) and the US regulator (FDA) has recommended restrictions on the use of codeine. They include:-

- restricting use of codeine to children over 12 years of age
- avoiding the use of codeine in all children (under 18) who undergo tonsillectomy or adenoidectomy (or both) for obstructive sleep apnoea.

Since the evidence base is limited and in line with statements made elsewhere in the UK, recommendations have been drafted by the Safe Medication Practice Group for use within Cardiff and Vale UHB. This document covers inpatient and discharge use in children and use of codeine in breastfeeding mothers.

The guidance was approved for dissemination. It will be reviewed in light of any change nationally (or in 6 months if nothing further is issued). [redacted]

d) *SOP - stopping probiotic preparations, such as VSL#3 and acidophilus*

The procedure is to review all patients with VSL#3 probiotics on repeat prescription, with the aim of stopping treatment in patients without a diagnosis of chronic relapsing or refractory pouchitis relapsing rapidly after (or failing to respond to) courses of antibiotics (specialist initiated indication).
VSL#3 should not be continued unless there is clear evidence of symptom improvement on the therapy.

The SOP was approved for implementation. [redacted]

9. Items to note
None

10. Any other business
None

11. Date of next meeting
1.30 – 3.30, Monday 19th August, Seminar Room 5, Cochrane Building, UHW