Nottinghamshire Area Prescribing Committee

Minutes of the meeting held on Thursday 19th September 2019 2:00pm Boardroom, Duncan MacMillan House

All attendees should be aware that public authorities are legally required to comply with the Freedom of Information Act 2000. The minutes and papers from this meeting could be published on the Publication Scheme or internet with all names included, unless notified to the Chair before the meeting commences or included in a pre-agreed confidential section due to the sensitive nature of the topic.

Present:

Steve May (SM) (Chair)	Chief Pharmacist	Sherwood Forest Hospitals NHS Foundation Trust
Tanya Behrendt (TB)	Associate Chief Pharmacist, Medicines Management	NHS Nottingham City CCG
Khalid Butt (KB)	GP	LMC representative
Laura Catt (LC)	Prescribing Interface Advisor	Representing County CCGs
Mark Flanagan (MF)	Advanced Podiatrist, non-medical prescriber	Local Partnerships, Nottinghamshire Healthcare Trust
Esther Gladman (EG)	GP	Nottingham City CCG
Tim Hills (TH)	Interim Assistant Head of Pharmacy	NUH Trust
David Kellock (DK)	Chair SFH Drug and Therapeutics Committee	Sherwood Forest Hospitals NHS Foundation Trust
Jenny Moss-Langfield (JM)	GP	Notts City CCG and LMC representative
Sarah Northeast (SN)	Advanced Nurse Practitioner	CityCare

The meeting was not quorate due to no attendee from Notts Healthcare Trust. Minutes and actions will be reviewed by the Trust before implementation

In attendance:

Deepa Tailor (DT), City CCG Practice Pharmacist
Jill Theobald (JT), Interface Efficiencies Pharmacist, Greater Nottingham CCGs
Shadia Jenner (SJ), Interface/Formulary Pharmacist/Medicines Management Pharmacist Mansfield & Ashfield CCG
Joe Allwood, GP Registrar
Karen Robinson (KR), APC Support Technician Mansfield & Ashfield CCG

1. Apologies

Matt Elswood (ME) Chief Pharmacist, Nottinghamshire Healthcare Trust
Mike Jones (MJ), Community Pharmacist, Local Pharmaceutical Committee (LPC)
Paramjit Panesar (PP), GP, Nottingham North & East CCG

David Wicks (DW), GP, Newark and Sherwood CCG
Amanda Roberts (AR), Patient representative

2. Declarations of interest

None declared.

3. Minutes of the last meeting/matters arising

The minutes from the previous meeting were reviewed and agreed as being accurate subject to an amendment around TB and TH requesting APC representation from NUH DTC.

Glycopyrronium – JT contacted the Parkinson's team in Mid Notts to ask why prescribing of glycopyrronium had increased after adding the Parkinson's indication to the formulary and why prescribing of glycopyrronium was higher in Mid Notts than Greater Notts. The response from the team was that Mid Notts prescribing is likely to be higher due to the lack of a botox clinic. They confirmed that they always try other options as per NICE guideline before glycopyrronium. Initial increase after adding to APC may be because they had a group of patients waiting to go onto it, but expect prescribing to settle down now.
ACTION: JT will continue to monitor and will report back to APC again in six months (March 2020)

Mexiletine hydrochloride, (Namuscla® 167 mg capsules) – Repatriation of prescribing to secondary care has been actioned. NUH DTC meeting yesterday and discussed this being RED. JT checked prescribing data and discovered that there is a small amount of prescribing in Newark and Sherwood CCG.
ACTION: JT to identify practice and request that prescribing is repatriated.

All other actions were either complete or on the agenda.

4. FOR RATIFICATION – Penicillin allergy leaflet (Update)

DT presented the updated 'Is it really Penicillin Allergy' leaflet. Minor changes had been made to the leaflet to bring it in line with current evidence.

Some symptoms that may present as a non-immediate reaction can be a result of the condition itself and not considered true penicillin allergy. Extra information was requested with regards to actions required in cases when patients experience non-immediate or "delayed" reactions as there were concerns that the next reaction could potentially be more severe. Members raised questions around what kind of coding would be required in such patients.

It was suggested that the terminology 'non-immediate reaction' be changed to 'delayed reaction'. It was requested that the paragraph on penicillin re-challenge should be in a stand-alone box.

ACTION: DT to make amendments and to clarify with Viv Weston about what actions prescribers should take with patients experiencing non-immediate reactions. Send for ratification via email.

5. FOR RATIFICATION – Transgender position statement (Update)

TB presented the 'Primary Care Responsibilities in Prescribing and Monitoring Hormone Therapy

for Patients under the Specialist Gender Identity Service for Adults' guidance. The guidance has been updated to reflect the updated NHSE services specification and General Medical Council (GMC) guidance and now contains hyperlinks to relevant documents.

The GPs on the committee felt that more guidance was needed on how to handle requests to prescribe from non NHS clinics. TB informed the group that guidance is available and is on "F12", TB to look into getting it onto GP Net as well and put a comment in the position statement that this guidance is available.

TB highlighted that the document only covered adults and that separate NHSE guidance was available for children and adolescents. The committee asked if the link to this document could be shared and mentioned in the position statement.

Gender identity services are currently out for tender, so the document will be reviewed again in March 2020 once the tender process is complete.

Ratified subject to minor changes.

ACTION: TB to correct typos and add link/reference to guidance on non-NHS clinics and upload to the APC website.
TB to email link for child / adolescent NHSE specification to committee.

6. **FOR RATIFICATION – COPD Exacerbation guidance (Interim update)**

DT presented the updated COPD exacerbation guidance. The guideline was initially ratified in March 2018 and has been updated to bring in line with NICE guidance (NG114) published in December 2018. Changes included reducing antibiotic course length from 7 days to 5 days. EG asked if the prednisolone course could also be reduced to 5 days. JM asked if an OptimiseRx message could be authored to prompt consideration of bone protection with repeated steroid courses. Also a hyperlink was added to MHRA alert for Fluoroquinolones (Mar19).

EG and JM asked if the guidance on considering bone protection and DXA scan could be the same as in the recently updated osteoporosis guideline. DK requested addition of author.

TH mentioned that antibiotics should be started if sputum has increased AND changed colour instead of and/or. This will bring the guidance in line with NICE "Summary of antimicrobial prescribing guidance – managing common infections" September 2019 document.

The committee noted that the guidance was due for a full clinical review in 2021.

ACTION: DT to check NICE COPD guidance and change prednisolone duration if appropriate. To make suggested changes and upload to APC website.
JT to consider Optimise message to prompt consideration of bone protection with repeated steroid courses.

7. FOR RATIFICATION – Emollient formulary (Update)

DT presented the updated emollient formulary. Following MHRA advice (Dec18), the fire hazard symbols have been removed from individual products as **all** emollients can cause a fire risk. Choice of 1st line products reviewed and cost effective choices added.

SM requested that the key was made more obvious.

TB asked that advice be added for care home staff about how long to use an emollient for before disposing to prevent unnecessary wastage once local policies are aligned.

Action: DT to make minor amendments to emollient formulary and upload to APC website. DT to add emollient disposal information once care home policy aligned.

JT to update primary care "Guide to switching formulary choices" document to reflect changes in emollient formulary. To upload link onto APC website once complete.

JT to update OptimiseRx messages to reflect changes in emollient formulary

8. FOR RATIFICATION – UTI prophylaxis guideline (Update)

SJ presented the UTI prophylaxis guideline and patient information which had been updated by Dr Vivienne Weston Consultant Microbiologist and Mr Richard Parkinson Consultant Urologist NUH.
Changes to existing guidelines in line with NICE NG112 as follows:

- Updated conservative measures
- Prophylactic doses updated in line with NG112
- Second line options added
- Patient advice sheet updated to include cranberry tablets and d-mannose (OTC)

Localised variation from NICE NG112:

- Pivmecillinam as a second line option, in place of Amoxicillin. Only on advice of Urology. Local variation due to resistance rates.

The committee made suggestions including the following :

- KB questioned why trimethoprim was recommended for prophylaxis given rates of resistance. TB confirmed that this is because local resistance to trimethoprim is lower than national levels due to successfully restricting its use.
- EG requested that dosing instructions be added for d-mannose and cranberry tablets and that the patient information leaflet (PIL) be updated to include information on TARGET PIL, especially advice on hygiene and washing.
- JM asked if there was an increased risk of UTI associated with menstrual cup usage. SJ to discuss Viv Weston.

ACTION: SJ to clarify above queries and make suggested changes. Send to APC members for ratification via email.

9. FOR RATIFICATION – Prostatitis guideline (Update)

LC presented the updated Prostatitis guideline authored by Annie Joseph also approved by Mr Walton – Urology NUH. The guideline was sent to SFH urology with no response.

Main changes:

- Addition within the Acute section - "Discuss with the Urology on-call Registrar or Consultant".
- Addition of new Chronic Prostatitis section.

Minor wording amendments were suggested

Action: LC to amend the wording and upload the final version.

10. FOR DISCUSSION – Vitamin D maintenance in COPD/Asthma

JT presented the updated adult Vitamin D guideline and patient information leaflet. The committee approved of the changes to the suggested cost effective products for treatment of deficiency. Changes to the patients information leaflet were welcomed as it was easier to read and more informative.

JT asked the committee for their opinion on including advice for patients with COPD and asthma to take vitamin D supplements all year round. There had been a request from the local Integrated Care System (ICS) to include this wording in the APC guideline to support a project to increase vitamin levels for patient with COPD and asthma in the hope that this would reduce the number of respiratory exacerbations. The committee felt there was insufficient evidence to recommend year round vitamin D supplementation for patients with COPD / Asthma, as exacerbation rates were only shown to be reduced in patients with very low vitamin D levels. Furthermore members felt it was difficult to recommend something that is not in national guidance without strong evidence. Local specialists (particularly Prof Charlotte Bolton) were of a similar mind. Therefore, the committee felt it was inappropriate to add in the statement regarding vitamin D supplementation to the Asthma, COPD guidelines or PIL. However, they were not opposed to the project (provided that self-care is promoted) and were happy for the project team to use the wording from the PIL as long as the APC logo was removed from any leaflet they produced.

Action: JT to remove advice about vitamin D supplementation in COPD and asthma. All other changes approved and JT to finalise and upload guideline and PIL to APC website.

11. FOR DISCUSSION – Edoxaban first line for Non Valvular AF

JT sought approval from the committee for creating a position statement naming Edoxaban as the first line DOAC for Non Valvular AF. The reason for the suggestion is cost saving, Edoxaban is part of a rebate scheme which makes it the most cost effective DOAC. TB explained that the CCGs have never before allowed a rebate to influence a clinical decision about which medicine to recommend.

The committee was clear that choice DOAC should be made on clinical grounds and evidence, but that it was reasonable to also consider cost effectiveness. The committee felt that if all other clinical factors were equal then edoxaban could be considered first line. This should be worked into a decision making algorithm in the AF guideline. There are currently no head-to-head studies and NICE identifies them all as equal. All DOACs would remain on formulary as an option to prescribe where clinically appropriate.

Specialist opinion from cardoiologists, stroke and healthcare of the elderly was sought prior to the meeting. The specialists felt very strongly that all DOACs should remain available for prescribing, but most said that if all else was equal then having edoxaban first fine would be acceptable. The committee agreed that the decision to switch existing patients lies with the CCGs and not the APC.

The Derby and Derbyshire CCGs have released a position statement naming edoxaban as first choice DOAC in suitable patients and are very transparent that this is due to the rebate received from the manufacturer. APC agreed that Nottinghamshire would need a similarly transparent position statement.

Action: JT to write a position statement for ratification at the next APC meeting.

12. FOR RATIFICATION – Infant feed, premature infants (Update)

LC presented the Infant feeding guidelines – premature infants, authored by Chris Jarvis – dietitian at NUH. LC was awaiting a response from the author for clarification on several comments at the time of the meeting so no decision could be made.

Action: LC bring back to the next meeting.

13. FOR DISCUSSION – Melatonin

LC presented the paper, Melatonin in under 18s, authored by NS.
The paper was first presented at the JFG in August 2019 and since then an options paper, mapping out the various traffic light status options has been produced and shared. APC were asked to review whether new preparations should be added to the Joint Formulary and whether the current classification is appropriate.

DK fed back comments from SFH consultants who currently use melatonin. They would like melatonin to still be available but moved out to primary care as an Amber medicine. They would support any recommendation to support non-pharmacological sleep interventions and would not support promethazine as an alternative to melatonin.

The committee heard that melatonin is currently classed as RED on the Nottinghamshire Joint Formulary for patients under 18 years old. The medication has been unlicensed in this patient cohort. As a result, the majority of prescribing happens in secondary care where unlicensed immediate release preparations are prescribed for patients and the cost is more predictable. This is becoming increasingly difficult as manufacturers of the unlicensed products have begun to request a 'statement of need' before supply can be made. If all current patients were to be swapped to the licensed preparations (in some cases use would still be off label) the cost impact to the health community would be significant and arguably unaffordable. Engagement in restricting patient cohorts and the amounts being used would be key in limiting this spend, ideally within the current cost envelope. NUH have recently employed a sleep practitioner to offer sleep advice and utilise a prescribing pharmacist for repeat prescribing. There is currently no such service offered from SFH.

A survey undertaken by a Paediatric pharmacist at NUH showed out of 30 regions 5 are red with one allowing pass through, one was green and 23 were amber with or without shared care agreement. However, a further survey would be needed to ascertain whether or not there are plans to change the classification in light of the imminent cost pressure.
Alternative strategies were discussed including:

- Use of Circadin (2mg MR tablets) off-label
- Self care
- Deprescribing or reducing patient doses

Melatonin in the UK is a POM, so advising patients to self-care had previously been dismissed. However melatonin as a food supplement is readily available for as little as £3 for 60 tablets. Self-care for vitamins, minerals and food supplements is actively promoted across the health community. As melatonin is essentially not a medicine, it could be appropriate to refer patients to self-care.

The cost pressure could be contained if Circadin was the only formulary brand in paediatric

population although in most cases this would be off-label and only if restrictions were applied to the dose and number of patients.

JT noted that a neighbouring county advocate the use of Ciradin in paediatric population and advise crushing the tablet. The manufacturer of Circadin note on their website that this would result in an immediate release product. Immediate release products are currently used in paediatric population.

All in attendance agreed that current levels of prescribing would not be sustainable financially if prescribing moved over to the licensed products. Cost impact to primary care if status was moved to amber would also exceed the APC mandate, thus requiring a business case to be submitted to the CCG for commissioning approval. In line with the recent SMC decision on Slenyto, the committee agreed that this could not be considered to be cost effective, and thus should be classified GREY.

The committee worked through their formulary inclusion criteria for melatonin of all formulations to aid sleep in under 18s:

Does the medicine offer advantages over existing therapy?

- Clinical effectiveness – we accepted there was some evidence to show increased sleep time and reduced sleep onset, however we have no formal evidence to show the clinical significance of this
- Safety although melatonin appears safe, trials and available data do not go beyond 2 years
- Cost effectiveness –we felt that the cost is higher than other medications used for sleep and the overall cost does not warrant the limited benefit seen.
- NICE approved - Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges NICE guideline Published: 29 May 2015 - Do not offer medication to aid sleep **unless the sleep problem persists after a behavioural intervention**, If medication is needed to aid sleep, **consider** melatonin. NB NICE state - we use 'offer' to reflect a strong recommendation, usually where there is clear evidence of benefit. We use 'consider' to reflect a recommendation for which the evidence of benefit is less certain'
- Affordability for Nottinghamshire Healthcare Community at current level of use, not affordable. Cost pressure of over £2.2M on top of current spend if moved over to licensed products at same level of use
- Offer significant benefits to patients

The group did not reach a decision as to the appropriate status of melatonin but agreed further actions were required

Action: Interface team to:

- **Determine the degree of restriction required if only Circadin was used and spend was maintained within the cost envelope**
- **Confirm current cost envelope**
- **Invite the specialists to share pathways and guidance to ensure patient numbers are reduced to maintain spend within the current cost envelope**
- **Investigate the self-care option further**
- **Ensure commissioners are aware of the potential financial risk and on-going discussions.**

14. RMOC update

The RMOC update was noted by the committee and TB highlighted the upcoming national RMOC update day in October.

15. Formulary amendments and horizon scanning

a. Formulary amendments

The committee agreed the following formulary amendments:
Glycopyrronium 400micrograms/mL oral solution (Sialanar®) for hypersalivation – first line glycopyrronium preparation for paediatric patients. Note that the Colonis liquid will also remain on the formulary.

Clonidine tablets – do not have a traffic light status on formulary. Different traffic light status may be needed for different indications. EG and JM confirmed that clonidine 25microgram tablets are widely used in primary care for menopausal symptoms e.g. sweating and flushing. The committee agreed that the 25 microgram tablets be given a GREEN traffic light for this indication. Other indications are to be reviewed and presented to the JFG in October.

Linagliptin / metformin combination, Jentadueto® for type 2 diabetes - GREEN for patients on a stable combination of linagliptin and metformin only.

Salicylic acid 40% corn/verruca removal plasters – GREY with note about self-care and link to patient information leaflet on warts and verrucas.

Pregabalin for neuropathic pain in palliative care patients – This item did not go to JFG. Request from Rebecca Harrison, specialist palliative care pharmacist at NUH to use pregabalin in preference to gabapentin for neuropathic pain in palliative care patients. The main reason was reduced tablet burden due to twice daily dosing. Gabapentin is preferred in primary care due to a lower potential for misuse, but this was considered to be a low risk in this cohort of patients. Neuropathic pain guidelines will remain unchanged, but a note will be added to the formulary to state that pregablin may be used in preference to gabapentin in palliative care patients.

MHRA and other safety bulletins were noted.

b. Horizon scanning

Atomoxetine – new generic formulation from Zentiva. NS to review for ADHD and make suggestion as to generic or brand prescribing.

Estriol 50micrograms/g vaginal gel, Blissel® for the local treatment of vaginal dryness in postmenopausal women with vaginal atrophy – GREEN

Botulinum Toxin type A, Xeomin® – new indication for chronic sialorrhea due to neurological disorders. Currently RED for cervical dystonia and post stroke spasticity only. Refer to NUH DTC.

Testosterone 20 mg/g Transdermal gel, Testavan® - GREY. Already have Tostran

on formulary as Amber 2 and the devices are different, APC noted that the Testavan device contained a lot of plastic and was not very environmentally friendly.

Action: JT / KR to update formulary

16. New Submissions

a. VisuXL

Review summarised and outcomes from actions requested by JFG presented. There was insufficient evidence showing that this is a superior product to those currently on formulary. Classification of GREY was given and the interface team were asked to highlight this decision to ophthalmologists and GPs.

Action: SJ to update formulary

b. Testosterone

Paediatric endocrinology teams have requested amber 2 classifications for the following three formulations of testosterone for the use in constitutional delay in growth and puberty and for hypogonadism in children and adolescence.

- Sustanon-250 injection
- Restandol Testocaps
- Tostran gel 2%

Sustanon-250® injection, Nebido® and Tostran® gel are currently on formulary as amber 2, but there is no clarity specified with regards to the cohort of patient i.e. adult and/or children. Restandol® Testocaps are currently GREY.

Concern was raised about the administration of sex hormones to children currently being done in primary care in the absence of shared care or a service specification. As the numbers are small, it was suggested that administration could be done at PCN level as opposed to practice level.

Secondary care is keen to transfer the administration to primary care. This would be more convenient for patients. Administration is required monthly, which often results in time away from school to attend appointments. Training needs of clinicians to administer would need to be met and consultants have expressed willingness to provide such training.

Many committee members were clear that there must be shared care protocol in place and that administration of this should be covered in a LES, so clinicians in primary care would be appropriately remunerated. Leicestershire currently has a shared care protocol in place, which with their permission could be used in the development of one locally. The shared care protocol should contain guidance with regards to children with hypogonadism, transitioning into adulthood.

Traffic light status for all formulations of testosterone in children and adolescence is recommended to be RED pending completion of shared care protocol documentation. Following completion it was considered that Sustanon-250 injection would be amber 1, whilst the Restandol® Testocaps and Tostran Gel 2% would become amber 1 or 2.

Action: DT to produce a shared care protocol with support from paediatric

consultant endocrinologist.
NUH DTC to consider interim RED classification
Interface team to highlight request for inclusion in the LES to commissioners

17. APC forward work plan
Noted

18. Declaration of compliance with NICE TAs
Noted

19. Dates of Future Meeting
Next APC meeting is Thursday 21st November 2019, 2pm – 5pm (Boardroom, Duncan Macmillan House)

20. Any Other Business
SJ Sitagliptin renal dosing update approved.
Action: SJ to upload updated type 2 diabetes guideline to APC website

Stoma accessories formulary update approved. Main change was removal of deodorant sprays.
Action: LC to upload updated stoma formulary to APC website

Kelhale Inhaler – JT informed the committee that this product had been added to the formulary as an alternative to QVAR following reports of shortages with QVAR. Kelhale is therapeutically equivalent to QVAR. TH raised concerns from the respiratory pharmacist at NUH around the colour of the inhaler – the inhaler device body for the 50mcg and 100mcg strengths is white and the only difference was the colour of the caps. The strength on the packaging is highlighted clearly.
Agreed that note could stay on formulary but made clear that Kelhale only to be used in the case of QVAR shortage. The committee requested a formal review so that a decision could be made.
Action: JT to bring review to JFG in October

Earcalm spray – SN asked if anyone had come across supply problems with OTC Earcalm spray. It was suggested that this may be a problem within individual pharmacies only.

Meeting closed at 1700hrs