

APC meeting 19th November 2020, due to the COVID-19 Pandemic the meeting took place as a web conference using Microsoft Teams.

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)	Senior Medicines Optimisation Pharmacist	NHS Nottingham & Nottinghamshire CCG
Khalid Butt (KB)	GP	LMC representative
Laura Catt (LC)	Prescribing Interface Advisor	NHS Nottingham & Nottinghamshire CCG
Matt Elswood (ME)	Chief Pharmacist	Nottinghamshire Healthcare NHS Foundation Trust
Susan Hume (SH)	Advanced non-medical prescriber	Nottinghamshire Healthcare NHS Foundation Trust
Tim Hills (TH)	Assistant Head of Pharmacy	Nottingham University Hospitals NHS Trust
David Kellock (DK)	Chair SFH Drug and Therapeutics Committee	Sherwood Forest Hospitals NHS Foundation Trust
Esther Gladman (EG)	GP – City ICP	NHS Nottingham & Nottinghamshire CCG
Amanda Roberts (AR)	Patient representative	
Jennifer Moss Langfield (JML)	GP	LMC representative
Sarah Northeast (SN)	Advanced non-medical prescriber	Nottingham CityCare
Asifa Akhtar (AA)	GP – South Notts ICP	NHS Nottingham & Nottinghamshire CCG

Interface support:

Lynne Kennell (LK), Specialist Interface & Formulary Pharmacist for SFH – Joined 1545hrs Shary Walker (SW), Specialist Interface & Formulary Pharmacist for NUH Hannah Godden (HG), Specialist Mental Health Interface and Efficiencies Pharmacist – Left 1430hrs Irina Varlan (IV), Specialist Interface Efficiencies Pharmacist – Joined 1520hrs Jill Theobald (JT), Specialist Interface Efficiencies Pharmacist Karen Robinson (KR), APC Interface Technician

Apologies:

David Wicks (DW), GP - Mid Notts ICP, NHS Nottingham & Nottinghamshire CCG



1. Declarations of interest (DOI)

None declared.

2. Minutes of the last meeting/matters arising

The minutes from the previous meeting were reviewed and one minor amendment on section 13 was noted that it should read 'SFHT currently do not have a specialist <u>haemostasis</u> haematologist". With this exception the minutes were agreed as being accurate.

Adult ADHD shared care

The Adult ADHD shared care protocol has been slightly amended and HG will bring this to January APC for final ratification.

ACTION: HG to share the update and bring to APC

Ibandronic acid for adjuvant treatment of breast cancer

Ibandronic acid for adjuvant treatment of breast cancer was approved clinically at July's APC, but due to the significant cost associated with the intervention, further commissioning approval needed to be sought as it exceeded the threshold for the APC's financial mandate. A business case has been written and the contracting team has been contacted, but there has been no further progress to date. The Nottingham and Nottinghamshire CCG senior pharmacy team has been made aware and other options for a resolution are being sought.

ACTION: TB to continue to seek resolution

Narcolepsy Shared Care Protocol (SCP) and information sheets

An Amber 1 classification for methylphenidate, dexamfetamine and modafanil for narcolepsy was supported by APC in previous meetings. However, on reflection LK suggested that Amber 2 may be more appropriate because narcolepsy is a lifelong condition and, once stabilised, patients are discharged to the care of their GP. The neurology specialists do continue to offer phone advice if required, but as patients will not be under the long-term care of a neurologist, the criteria for shared care is not met. Monitoring requirements are minimal; 6 monthly blood pressure monitoring. Nationally there are very few specialist centers for narcolepsy patients and some of these consider the medication as shared care rather than the condition.

ME asked the committee to consider if mental health patients, who require the same medication under a shared care agreement, were being discriminated against. It was felt that ADHD treatment was different to narcolepsy in that the ultimate goal was to become medication-free with only a small number of patients remaining on long term medication.

Amber 2 classification was agreed; restricted to initiation by a neurologist. The information sheets will be adapted. A two year review will be applied.

ACTION: LK to amend the formulary and information sheets and upload to the APC website

All other actions were either complete or on the agenda

3. FOR RATIFICATION - Lamotrigine in Bipolar Disorder (update)

HG presented the updated Lamotrigine in Bipolar Disorder information sheet. Minor amendments were highlighted including clarification of the requirements of baseline and annual physical health check in line with NICE CG185 (Bipolar disorder: assessment and management).

Pregnancy advice had been updated in line with UK Teratology Information Service (UKTIS)



lamotrigine monograph (updated January 2020).

ME commented that the guidance on initiation by consultant psychiatrists only was inaccurate; lamotrigine for bipolar disorder may also be initiated by specialist mental health non-medical prescribers within NHCT. The information sheet will be updated to incorporate this.

ACTION: HG to update and upload and provide a link to the patient information sheet on the use of lamotrigine in pregnancy.

4. FOR RATIFICATION – End of Life (EoL) Guideline (Update)

JT presented the interim update to EoL guidance. Changes included:

- Changed conversion from SC fentanyl to oral morphine from 1mg:150mg to 1mg:100mg
- Clearer dosing information for opioid naïve patients
- Updated palliative care stockist links (appendix 1e)
- Changed the interval of haloperidol to 1 hourly in renal failure

EG asked that the fentanyl dose in the conversion could be expressed as MICROgrams as GPs were more used to working in micrograms for fentanyl.

The guidance suggested that, for difficult to manage symptoms, the specialist palliative care team should be contacted for advice. The GPs at the meeting felt that it would be more appropriate to contact a GP in the first instance. JT to amend the wording.

The update of the guideline was agreed subject to a few amendments which include acknowledgement of the APC and price update. When the update is published a reminder of the acceptability of electronic prescription charts will be included.

ACTION: JT to make the minor amendments and upload to the APC website

5. FOR RATIFICATION – End stage heart failure pocket book (New)

LC explained that the pocket book had been developed by Dr. Christina Sharkey, who requested the views of the APC prior to taking it to the ICS wide EOL group. The target audience for the booklet will be General Practitioners and Community staff, however it is relevant for any health care professional caring for a patient with palliative needs including secondary care colleagues.

DK asked that the acronym DNA be replaced by ReSPECT and that the term "drug" be replaced with "medicine" (applies to all documents presented at the meeting). JML requested that the formatting of the diagram be reviewed to make it easier to read and the whole document be more compatible with online viewing. The Green Book was suggested as an addition to the references.

ACTION: LC will feed the comments back and update the APC of any changes following review by the ICS EOL group

6. FOR RATIFICATION – Dermatology SCP and information sheets (Update)

SW presented the Management of Dermatological Conditions with Disease-Modifying Anti-rheumatic Drugs in Adults Shared Care Protocol and the information sheets (Azathioprine and Methotrexate), which are expiring this November. The Azathioprine information sheet had its interaction with dairy products highlighted and the MHRA guideline regarding prescribers specifying the day of methotrexate intake on the prescription was the update for the methotrexate.

Wording was updated to reflect that eosinophilia is commonly seen in patients with eczema and therefore not "unexplained".



DK commented about the use of "medicines" rather than "drugs".

ACTION: Approved with minor changes. SW to amend and upload

7. FOR RATIFICATION - IBD SCP and information sheets (Update)

SW presented the Management of Inflammatory Bowel Disease in Adults Shared Care Protocol and information sheets (azathioprine, 6-mercaptopurine and methotrexate). SW mentioned about the new measure in place by the European Medicines Agency to specify the methotrexate day on the prescription. Additionally, as of the recent BSG IBD guideline (2019), additional information about pregnancy was added. The interaction between methotrexate and PPI was highlighted with H2-receptor antagonists used as an alternative.

ACTION: Approved with minor amendments. SW to amend and upload to APC website. JT to formulate OptimiseRx messages where possible

8. FOR RATIFICATION - Neuroinflammatory conditions SCP and info sheet and Patient Information Leaflet (PIL) Update

LC presented the Neuroinflammatory SCP and azathioprine information sheet update (PIL no changes). NUH provide the neurology service so no wider consultation was required, NUH neurologists are supportive of the update.

Dairy products interaction and version control will be added. The clinicians felt eGFR was acceptable for on-going monitoring of U&Es, unless a change is seen in which case calculation of creatinine clearance (CrCl) would be used.

Clarification around the ideal body weight versus actual body weight for the CrCl calculation was raised; the general consensus was that a specific APC statement needed to be developed. This will be raised with Medicine Information at SFHT and the Medicines Safety Officers.

SCP, PIL and information sheet approved with minor changes.

ACTION: SM to discuss CrCl with Medicines Information. LC to draft a statement of appropriate renal function calculation use. LC to amend SCP and information sheet and upload all documents to APC website.

9. FOR RATIFICATION - Opioid patient leaflet (New)

LC presented the opioid patient leaflet, historically this was an NUH leaflet but it was felt it would be useful across the wider health care community in Nottinghamshire.

LC was asked to add more detail about the helpline numbers e.g. whether they go through to Medicines information. ME suggested that the leaflet be made more accessible to all e.g. other languages or in a speaking format. SM pointed out that this would apply to all of the documents on the APC website.

The leaflet referred to Primary Integrated Community Pain Services (PICS) this needed further clarification as PICS was previously county-wide only, City used MOSAIC.

The leaflet was accepted with minor amendments; changing drug to medication and consider removal of the trade mark to aid readability. Version control will also be added

ACTION: Approved subject to minor amendments / clarification. LC will feed back and upload to the APC website in the Patient Information section and link to the Joint Formulary.

*Post meeting note - the APC website has been checked for accessibility and there are email



addresses and a phone number for people to get in touch if they are struggling to access content*

10. FOR RATIFICATION - Fludrocortisone prescribing information sheet (New)

SW presented the new information sheet for Fludrocortisone, this had been requested by the primary care team for orthostatic hypotension.

The format for the information sheets was based on the APC's Midodrine for Orthostatic Hypotension information sheet. NUH, SFH consultants, and HCOP community geriatricians had been consulted.

There have been concerns raised about monitoring not being followed properly and that this guideline is overdue. Information was requested regarding how monitoring is being carried out during the first month after initiation by the specialist. It was also advised to seek the community geriatrician's opinion on the appropriate setting for early monitoring, due to having experience on both primary and secondary care. There was a suggestion to highlight Fludrocortisone monitoring as a safety concern to the CCG MSOs, and conduct a safety piece of work.

The need for a steroid card was discussed as Fludrocortisone is a mineralocorticoid not a glucocorticoid. SW confirmed it is in the SPC.TH established that NUH issue steroid card and that it is also implied on the BNF.

Finally, it was recommended to contact medicines information to query the implication of stopping the medication abruptly and to determine the dose equivalence against prednisolone.

An OptimiseRx message was advised to point people to the direction of the guidelines to remind about monitoring.

ACTION: JT to author OptimiseRx message if possible. SW to clarify the points raised and bring back to January APC

11. FOR RATIFICATION - Hyperlipidaemia guidelines (Update)

TB presented the updated hyperlipidaemia guidelines. Only minor changes to layout and addition of a comment to >40% reduction box "If baseline non-HDL-C is not available, use target <2.5mmol/L. This is in accordance with the guideline from NHSE which has been endorsed by NICE". More detail added about the patient cohort suitable for PCSK9 inhibitors.

The update had been approved by consultants at both SFHT and NUH

ACTION: Approved TB to upload

12. FOR RATIFICATION - Infant feeds - premature infants (Update)

LC presented the updated guideline. Since the last update there has been an accruing literature on the additional needs of the late or moderately preterm infant, with particular emphasis on nutrition and feeding, defining:

- late preterm as 34 weeks of gestation and <37weeks and
- the moderately preterm infant as ≥32 weeks of gestation and <34 weeks

The most significant change in the recent updated Nottingham University Hospital NHS Trust is that preterm infants will not automatically receive a nutrient enriched preterm formula on discharge from hospital. Use of such formulas will be based on individual patient need.

DK asked that acronyms be written in full the first time they are mentioned in the document; the reference numbers also needed correcting.

ACTION: Approved with minor amendments as above. LC to feedback to the author and upload to the APC website when completed



13. FOR RATIFICATION - Melatonin and Sleep Guideline (New)

LC introduced the new Melatonin and sleep guideline and noted there were differences between the trusts for accessing sleep services. The guideline will incorporate a title, an author and version control.

NUH DTC met on the 18th November to discuss the document and comments had been fed back to the authors. The document had previously been reviewed at NUH DTC in the summer and at SFH DTC with comments fed back.

Generally the primary care flow chart was disliked as it was not user friendly or easy to follow.

It was noted by ME that NHCT are to write their own guidance and so he felt the CAHMs appendix should be removed.

TH felt de-prescribing could be better addressed to support the disuse of melatonin and the cost containment.

ACTION: LC to highlight the suggested amendments to the author(s), with discussion from TH and ME and bring back to the APC for ratification.

14. FOR RATIFICATION - Limited clinical value medicines (Update)

IV presented the limited clinical value medicines and appliances list. This document was due for renewal Oct 20 although NHSE had not added anything since the last interim review Nov 19. The main changes to the document were detailed as follows:

- Links updated to ensure that they now refer to new N&N CCG;
- Note added that subscription is needed to access PrescQIPP articles;
- Added perindopril arginine and minocycline (for acne): already Grey on the formulary but not mentioned in the document.
- Added dronedarone listed as Amber 1 on the formulary

Currently our list contains 5 medications that are not listed on the NHSE, Sativex, Co-danthramer/Co-danthrusate, Dapoxetine and Eflornithine

Sativex for MS favorable by NICE but not recommended for pain and nausea and more research is recommended for its use in epilepsy. To change the formulary classification a neurology submission would be required. Sativex has recently been brought up at the high cost drugs meeting and neurology are currently reviewing it to establish its place in therapy.

Eflornithine was not added to the formulary as the evidence was limited and fell towards the cosmetics usage. There was a small amount of prescribing and it was felt this should be highlighted to the MOT for further investigation.

Dapoxetine also required further investigation as some prescribing was occurring

Co-danthramer/Co-danthrusate will remain on the limited clinical value list

Liothyronine is currently on the never prescribe list, however according to the NHSE list it may be prescribed in some exceptional circumstances. This was discussed at DTC because it creates issues and the exceptions make it unsuitable to be placed on the never prescribe list.

The clinicians felt more engagement was required for partnership working e.g. district nurses being made aware of the lists.

Rubefacient prescribing was raised as an expenditure concern. JT reported she is currently working on producing a SOP around this.

It was noted that Derbyshire are changing their traffic light classifications and will include a clear "Do not prescribe" message for some medications. The group felt that the current APC traffic light list with supporting information added was suitable as it stands.



Amiodarone is currently Amber 2 and not currently on the low value list. NHSE recommend shared care due to the monitoring requirements. Safety issues will be fed back to the MSOs ahead of their safety meeting in December.

ACTION: IV to remove Sativex from the limited list, and leave as grey on the formulary. Highlight the Ethlornithine and Dapoxetine prescribing to the MOT for further investigation. Amiodarone safety concerns will be raised with the MSOs

15. Formulary amendment and Horizon Scanning (KR/LK)

Formulary amendments

LK gave a brief overview of the medications considered at JFG that warranted further discussion. The APC agreed the following amendments:

- Lithium (Camcolit & Essential Pharma) reverted to GREY as Priadel discontinuation is suspended. OK for existing patients to continue.
- Tranylcypromine RED (was GREY) as an alternative to phenelzine which has been discontinued.
- Lecicarbon C Temporary reclassification to GREEN for paediatric patients currently using bisacodyl suppositories (supply problem).
- Ceftriaxone added to local meningitis guideline as an option for treatment due to supply problem with cefotaxime.
- Sumatriptan 6mg injection clarification of formulary entry to ensure they are prescribed as "pre-filled disposable devices" cost effective.
- Clonidine Amber 2 for Tourette's syndrome (new indication).
- Adrenaline 1 in 1000 topical solution Amber 2 (was RED) for use on palliative care advice (unlicensed, but in PCF).
- Lacosamide, brivaracetam, eslicarbazepine and perampanel (epilepsy medicines) Removed
 the restriction that adult patients need to be stabilised prior to transfer to primary care with the
 caveat that clear guidance on dose titration and maximum doses should be provided by the
 Neurologist. JFG had recommend removal of restriction subject to LK ensuring that there are
 no complicated requirements for the dose titration. LK had consulted the manufacturers'
 SPCs and confirmed that the dose titration is not onerous.
- Methadone injection deferred to DTC for consideration of RED classification (was unclassified)
- Esomeprazole injection GREY
- Combined Hormonal Contraceptives (CHC) Advice added to formulary about tailored regimens. FSRH suggests using one of the following tailored regimens: (note this is offlicensed and only applies to monophasic 21-day COC) Shortened hormone-free interval (HFI), Extended use (tricycling), Flexible extended use or Continuous use.
- Methylphenidate MR (Ritalin XL) Added Ritalin XL brand to formulary as an option in addition to Equasym XL and Medikinet XL. Licensed for adult ADHD (Equasym XL is not licensed) and absorption not affected by food (Medikinet XL and Equasym XL are affected).
- Acidex oral suspension GREEN 2nd line to Peptac in case of supply problems.
- Lofexidine (opioid detoxification) GREY (was Amber2) as now discontinued.
- Metformin (new indication) Amber 2 as adjunct to attenuate or reduce weight gain resulting from treatment with antipsychotic medication.
- Rivaroxaban GREY (awaiting assessment) for post TAVI procedure. Deferred to DTC for consideration of RED classification.
- Testosterone gel GREY (no formal assessment) for low libido in post-menopausal women.
- Testosterone replacement therapy Discussed if there was a more cost effective option than Tostran 2% gel. Testogel pump was selected as the preferred option by the JFG as being the most cost-effective and environmentally friendly. Testavan, although cheaper, is packaged in



rigid plastic making it less environmentally friendly. Brand prescribing should be encouraged due to the differing dosages that are not interchangeable. SW updated the group on an action she had around establishing the environmental impact of containers and the potential for recycling and stated that all medication containers will be incinerated and converted to electricity and used as heating to homes and some business establishments. The APC agreed with the decision for Testogel to be included in the formulary as the preferred testosterone product locally.

Post-meeting note- it had been clarified that this will apply to adult patients only. The national guidance on which the SCP for use in children and adolescents is based refers to the previous formulation of Testogel in sachets. This will be reviewed once the national guidance is updated.

- Horizon scanning:
- Added as GREY no formal assessment: Bempedoic acid (Nilemdo) tablets, bempedoic acid/ezetimibe (Nustendi) tablets, lefamulin (Xenleta) oral/IV and vardenafil orodispersible tablets.
- SGLT2 inhibitors are about to become licensed for preventative heart failure and delaying the progression of CKD (NICE TAs expected 2021) GREY awaiting further assessment
- Added as GREY non-formulary: Melatonin 3mg film coated tablets, pridinol (Myopridin)

ACTION: KR to update the formulary

16. New applications

• Fluticasone furoate/ vilanterol Ellipta (Relvar, GSK) for asthma

A formulary application had been received from respiratory physicians for Relvar to be re-considered for adults with asthma. The Specialist Asthma service wish to have it as a once daily treatment option for patients where multiple day regimes have failed to achieve asthma control. Relvar is a Dry Powder Inhaler that needs minimum inspiratory flow rate and requires minimum dexterity to use effectively. If effective it may prevent the need to step up to more expensive monoclonal antibody treatment. When used in this way, it is most likely the patient will start on a high intensity regime and step down to 92/22 if their asthma remains under control for at least 6 months. After the initial prescription, it is requested that this would be prescribed by GPs, but this patient group would remain under the care of the Specialist asthma service so regular review will ensue.

Since previously reviewing Relvar for asthma there have not been any new substantial blinded randomised control trials, but there has been a real world open label study that found Relvar to be more effective than standard care in less severe asthma patients and a study that has shown that the systemic potency of fluticasone furoate is less than other corticosteroids, but with much higher airway potency.

APC noted this was a re-submission which had previously been rejected for asthma due to the lack of a step down option. The committee were assured through updated evidence that this was not a significant problem in practice.

These patients will remain under respiratory care and the submission is expected to be cost neutral.

ACTION: Agreed as Amber 2 classification for patients with severe asthma being treated at Step 4 of the BTS guidance. LK to inform the submitter and update the formulary

 Grazax® (timothy grass pollen allergen), (ALK-Abello Ltd) oral lyophilisates for seasonal allergic hay fever due to grass pollen.



The JFG had concluded that its use was a sensible step going forward but its potential classification and appropriateness of prescribing in primary care was discussed in depth with a RED classification being favored.

SW shared how the paediatric service at NUH managed their Grazax patients in terms of monitoring and issuing their prescriptions.

Discussions were made regarding the appropriateness of prescribing in primary care. There were concerns raised about expectations to GPs issuing the prescriptions and taking responsibilities with no input on any monitoring or review.

The decision tree was used in order to form an agreement. A red classification was favored due to the medication use being uncommon and unlikely for the GP to be familiar, specialist assessment required to enable patient selection, initiation & ongoing treatment and Investigations and a specialist need to monitor efficacy.

ACTION: SW to feed back to the submitter and inform the NUH DTC of the submission to be reviewed there

 Naldemedine ▼ (Rizmoic[®], Shionogi Ltd) for treating opioid-induced constipation- NICE TA651)

A slight price advantage was offered against naloxegol and consultants from NUH and SFHT felt it would be another option for opiate induced constipation although de-prescribing opioids would be first line

ACTION: Add to JFG action log, to monitor prescribing levels in 8 months. SW to add to the formulary as Amber 2

17. FOR INFORMATION - APC forward work plan

Noted

18. AOB

- For information, SM has volunteered SFHT to be a national pilot site at for electronic prescribing. This was received positively by the committee.
- Alprostadil (Caverject®) is currently in short supply which is likely to continue until February 21. It
 was agreed to add a note to the formulary that Viridal Duo could be used if Caverject was
 unavailable.

ACTION: JT to update the formulary, add an Optimise Rx message and add to the shortages database

Sodium Docusate – Shortage. NUH have sent a memo to ask consultants not to prescribe as it
is no longer available in primary care, macrogols and senna recommended as an alternative for
constipation, in primary care self-care is the first line option

ACTION: JT to highlight on the formulary and through Hints and Tips newsletter

19. Date of next meeting – 21st Jan 2021

Meeting ended at 1650hrs