NHS
Devon
Clinical Commissioning Group

Meeting of the Northern and Eastern Devon Formulary Interface Group

Minutes

Thursday 17th September 2020: 9:00am – 11:30 am
Via Microsoft Teams

Present:

Matt Howard (Chair)	Clinical Evidence Manager	NHS Devon CCG
Glen Allaway	GP	NHS Devon CCG
Andrew Harrison	GP	NHS Devon CCG
Matt Kaye	Chief Pharmacist	NDHT
Carole Knight	Clinical Pharmacist (Medicines Information and Formulary)	NDHT
James Leavy	Medicines Information Pharmacist	RD&E
Sarah Marner	Senior MO Pharmacist	NHS Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Graham Simpole	MO Pharmacist	NHS Devon CCG
Darren Wright	Joint Formulary Technician	NHS Devon CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and Announcements:

Welcome and Introductions

Matt Howard welcomed attendees to the meeting. It was explained that Tawfique Daneshmend was unable to chair the meeting on this occasion. FIG members indicated that they were happy for Matt Howard to act as chair.

It was noted that due to another commitment Matt Kaye would leave the meeting at 10.00.

Meeting etiquette

Matt Howard briefly explained the meeting etiquette.

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
NICE antimicrobial guideline: UTI (recurrent)	
Various antibiotics	Various manufacturers
Alternative treatments	Various manufacturers
D-mannose (non-medicinal product)	Various manufacturers
Estriol 0.1% cream (Ovestin cream)	Aspen Pharma Trading Ltd
Estradiol vaginal ring (7.5mcg/24 hrs) (Estring)	Pfizer Ltd
NICE antimicrobial guideline: UTI (catheter-associated)	
Various antibiotics	Various manufacturers
Alternative treatments	Various manufacturers
NICE antimicrobial guideline: Pyelonephritis (acute)	
Various antibiotics	Various manufacturers
Alternative treatments	Various manufacturers
NICE guideline (NG145): Thyroid disease: assessment and management.	
Levothyroxine	Various manufacturers
Liothyronine	Various manufacturers
Carbimazole	Various manufacturers
Propylthiouracil	Various manufacturers
Natural thyroid extracts (non-medicinal)	Various manufacturers
Cluster headache	
Sumatriptan 6mg injection (Imigran Subject)	GlaxoSmithKline UK Ltd, various manufacturers
Sumatriptan 3mg injection	Sun Pharmaceutical Industries Europe B.V.
Sumatriptan nasal spray (Imigran)	GlaxoSmithKline UK Ltd
Zolmitriptan nasal spray (Zomig)	Grunenthal Ltd
Home oxygen	Providers of home oxygen and equipment

Environmental impact of inhalers: consideration of Salamol CFC-free inhaler as the preferred brand of salbutamol pressurised metered dose inhaler (pMDI) Salamol CFC-free-inhaler Alternative brands of salbutamol-pressured metered dose inhalers	 Teva UK Limited Various manufacturers
Vigabatrin safety advice Vigabatrin tablets (Sabril) Vigabatrin oral powder sachets (Sabril)	 Sanofi Sanofi

Apologies

Tawfique Daneshmend	Consultant Gastroenterologist	RD&E
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon CCG
Susie Harris	Consultant, Elderly Care	RD&E
Jess Parker	GP	NHS Devon CCG

Declaration of Interests (DoI)

All participants had completed a DoI prior to the meeting. No declarations were made.

2. Minutes of the meeting held on Thursday 16th July 2020, including action list update

Minutes of the meeting held on Thursday 16th July 2020

The minutes of the meeting held on Thursday 16th July 2020 were approved.

Action list

Summary of actions

Number	Action	Lead	Status
19/84	The need for a system to enable secondary care to prescribe medicines to patients without them having to attend a hospital appointment to be raised with relevant people at RD&E.	Susie Harris	Outstanding

20/01	*Cluster headache – work with Ali Round to develop formulary guidance and liaise with specialists. Proposed formulary guidance to be brought back to future FIG meeting for discussion.* It is hoped that this can be included on the agenda for the meeting scheduled for September.	Formulary team	On agenda
20/04	Develop draft osteoporosis guidance, circulate to specialists for comment and bring to a future FIG meeting.	Formulary Team	Outstanding
20/24	Formulary Team to seek the views of specialists regarding the formulary classification for domperidone, metoclopramide and erythromycin in the context of paediatric GORD. The proposed formulary entry will then be updated and brought back to the next FIG meeting or completed via the e-FIG process. The Formulary team is working with specialists from South and West Devon who would like additional wording. On completion of this work this will be brought back to the N&E FIG.	Formulary Team	Outstanding
20/25	Omeprazole for paediatric patients – respond to Dr Graham regarding the points raised in response to the consultation and patients on long term PPI. This is linked to action 20/24 above.	Formulary Team	Outstanding

Matters Arising

Report of COVID-19 related changes to the formulary – July 2020 to September 2020

- COVID-19 related changes to the formulary – July 2020 to September 2020

  Since the last North & East FIG meeting the Formulary Team has continued to support the development and dissemination of temporary COVID-19 related guidance from various local and national groups.

  The temporary Devon Formulary page, "COVID-19 Updates", remains relevant to the current pandemic status and has been updated with important information related specifically to the COVID- 19 pandemic. This page can be accessed via the Devon Formulary homepages by clicking on the interactive image "Coronavirus – What you need to know".

Guidance has been updated for:

- the management of musculoskeletal and rheumatic conditions with corticosteroids, and
- advice regarding the prevention and treatment of skin damage beneath personal protective equipment (PPE). Specific information regarding the Prevention and Management of Skin Damage beneath PPE from Northern Devon Healthcare NHS Trust has been added to the page. Information from the Royal Devon and Exeter NHS Foundation Trust was added previously and discussed at the last FIG meeting.

3. NICE antimicrobial guideline: Pyelonephritis (acute)

NICE Guideline 111: Pyelonephritis (acute): antimicrobial prescribing is one of a series of NICE antimicrobial guidelines for Urinary Tract Infections (UTIs).

The proposed guidance was presented to FIG members in order to gather early input into the development of the primary care guidelines. Feedback on this guidance is currently being sought from local microbiologists. Following discussion by the FIG and receipt of feedback from specialists the proposed guidance will be brought back to a future FIG meeting for final consideration and agreement.

The proposed guidance includes information on managing acute pyelonephritis, including choice of antibiotic, reassessment, referral and seeking specialist advice. Guidance is included for treatment in pregnancy and for children.

The antibiotic recommendations have been split into non-pregnant women and men over 16 years, pregnant women, and children.

It was noted that the NICE guideline includes trimethoprim as a suitable treatment option in non-pregnant women and men over 16 years. Specialists have suggested during previous reviews of NICE guidance for UTI that Devon has a higher than national average resistance rate for trimethoprim. Variance among the trust recommendations has been raised with the microbiologists.

Feedback from specialists will be included in the proposed guidance which will be brought back to a future FIG meeting.

The FIG considered the proposed formulary guidance. There was discussion about:

- The NICE guideline includes self-care advice. The FIG considered that the term “self-care” was not appropriate in the context of acute pyelonephritis, and the term “supportive advice” should be used in the formulary guidance. It was agreed that a statement be added to the introductory self-care advice at the beginning of the formulary section for UTIs stating that Ibuprofen should not be used for the treatment of pyelonephritis.
- The proposed antibiotics were accepted subject to feedback from specialists. It was agreed that the Formulary team will discuss doses with specialists.
- Trust guidelines should align or at least be in-line with the formulary guidance.

- It was agreed that trust FIG pharmacists will ask antimicrobial pharmacists to review draft guidance and provide feedback.
- Formulary team to seek confirmation that all children under 3 months of age should be referred to specialists in line with the NICE guideline.

ACTION: Trust FIG pharmacists to ask antimicrobial pharmacists to review the draft guidance for pyelonephritis, recurrent UTI and UTI (catheter-associated) and provide feedback.

ACTION: Formulary Team to seek clarification of points raised during the discussion

ACTION: Formulary team to update the proposed guidance in line with the discussion and specialist comments once received.

ACTION: Once updated the Formulary team will bring the proposed guidance back to a future FIG meeting.

4. NICE antimicrobial guideline: UTI (recurrent)

NICE Guideline NG112: Urinary tract infection (recurrent) antimicrobial prescribing is one of a series of NICE antimicrobial guidelines for Urinary Tract Infections (UTIs).

A draft of the proposed guidelines has been submitted to local microbiologists for comments and feedback. It includes information on referral and seeking specialist advice, treatment for women who are not pregnant, reassessment, self-care, behavioural and personal hygiene measures. A definition of recurrent UTI and risk factors is also included.

The current guidance suggests in North Devon, patients with recurrent UTI can be referred to a joint urology / microbiology clinic. This will be checked and included in the proposed guideline if correct.

NICE guidance for recurrent UTI suggests that postmenopausal women may benefit from the use of vaginal oestrogen which is off label for this indication. This also appears to be replicated in University Hospitals Plymouth NHS Trust's guideline. The Eastern referral guidance for UTI states that the use of local vaginal oestrogen cream is often very beneficial in appropriate patients.

NICE antibiotic prophylaxis recommendations suggest nitrofurantoin and trimethoprim as first line options in recurrent UTI, which is in line with current guidance. The NICE committee did suggest that trimethoprim should only be prescribed if a lower risk of resistance is likely; specialists have previously suggested that Devon has a higher than national average resistance rate for trimethoprim

Antibiotic prophylaxis for recurrent UTI with nitrofurantoin is recommended in the NICE Guideline as 100mg single dose when exposed to a trigger, or 50mg to 100mg at night. Currently the Devon Formulary does not have a 50mg formulation, unless administered as an oral solution. The formulary advises that nitrofurantoin suspension is significantly

more expensive than tablets and capsules and should be avoided unless other options are not appropriate.

Second line choices have been added in line with NICE recommendations.

The FIG considered the proposed formulary guidance. There was discussion about:

- The NICE guidance recommends D-mannose which is not a medicine and can be purchased over the counter.
- Following discussions with microbiologists and urology consultants at Northern Devon Healthcare NHS Trust, it has been confirmed that patients with recurrent UTI can be referred to a joint urology /microbiology clinic. The current statement can be retained in the guidance.
- Oestrogen deficiency is a risk factor for recurrent UTI however use of vaginal oestrogens is off label for this indication. The FIG considered re-instating 'presenting recurrent UTI in postmenopausal women' as an off-label indication to topical vaginal oestrogens. It was agreed that Estriol cream be retained as a 'green' first line option for this indication and that estradiol vaginal ring be retained in the formulary as an 'amber' specialist product. The GPs noted that the use of vaginal oestrogens for recurrent UTIs is well established, and they are frequently recommended by gynaecologists.
- Antibiotic prophylaxis for women with recurrent UTI who are not pregnant – the Formulary team will check with urologists and microbiologists on use of prophylaxis as a last resort.
- Nitrofurantoin – (immediate release formulation). The 50mg dose is not included in the formulary unless it is administered as an oral solution. In principle the FIG was happy for this to be added dependent on the views of specialists.
- Trust guidance suggests methenamine hippurate for recurrent UTI. However NICE guidance states that methenamine hippurate is considered less effective than antibiotic prophylaxis with nitrofurantoin, and acknowledges that the BNF considers methenamine hippurate to be less suitable for prescribing. It was noted that GPs are rarely asked to prescribe this. The Formulary team will seek specialist opinion on this.

ACTION: Formulary team to update the proposed guidance in line with the discussion and specialist comments once received.

ACTION: Once updated the Formulary team will bring the proposed guidance back to a future FIG meeting.

5. NICE antimicrobial guideline: UTI (catheter-associated)

NICE Guideline NG113: Urinary tract infection (catheter-associated) antimicrobial prescribing is one of a series of NICE antimicrobial guidelines for Urinary Tract Infections (UTIs).

A draft of the proposed guidelines has been submitted to local microbiologists for comments and feedback.

Current formulary guidance across Devon is limited, the proposed guidance includes information on antibiotic treatment, reassessment criteria, referral and seeking specialist advice, self-care, and prevention. Antibiotic treatment varies according to whether symptoms of an upper UTI are present. The proposed guidance includes a link to the formulary catheter guidance and products and the clinical referral guidelines for each of the localities.

The antibiotic recommendations have been split into non-pregnant women and men over 16 years, pregnant women, and children. NICE guidance includes trimethoprim for non-pregnant women and men over 16 years if a lower risk of resistance is likely; specialists have previously suggested that Devon has a higher than national average resistance rate for trimethoprim.

Fosfomycin was not included in the NICE Guidance, however the formulary team has been asked if this is suitable as it is currently offered as an option in lower UTI infections and it appears to be a choice within some of the trust's guidelines.

For 1st line treatment of upper UTI symptoms the recommendations are the same as acute pyelonephritis.

The FIG discussed the proposed formulary entry:

- Option to add a link to the subsection for acute pyelonephritis (under UTI) as the antibiotic recommendations are the same for catheter-associated UTI with upper UTI symptoms. It was agreed that in this circumstance, duplication of information in the catheter-UTI section was acceptable.
- Antibiotics for pregnant women aged 12 years and over. It was noted that currently there are no recommendations in pregnancy and the only trust that had guidance widely available was Plymouth. NICE recommend Cefalexin, which corresponds with the Plymouth recommendations. This was accepted by the FIG.
- Antibiotics for children and young people under 16 years. GPs present stated that patient numbers are small and that secondary care assistance would be sought. It was agreed that a note be added regarding trimethoprim, in line with previous guidance for children, and for seeking specialist advice.

The Formulary team to update the guidance in line with the discussion and bring back to the FIG with specialist comments and to clarify discussions.

ACTION: The Formulary team to update the guidance in line with the discussion and bring back to the FIG with specialist comments and to clarify discussions.

6. Pelvic Inflammatory Disease (PID): update

The current formulary guidance was recently reviewed in line with the BASHH update by the N&E Devon FIG in July and was due to be reviewed by the S&W Devon FIG in August. Discussions at the N&E Devon FIG raised some questions that required further input from Genito-Urinary Medicine (GUM) Specialists.

The N&E Devon FIG asked the formulary team to gather further advice on *Mycoplasma Genitalium* (M.Gen) testing in primary care and to progress the guidance accordingly.

The Formulary team asked the GUM Specialists the following questions:

- Is M.Gen NAAT (nucleic acid amplification test) an absolute requirement? If this test is not currently widely available in primary care, then GPs cannot routinely request it. This leaves the following options:
  - If M.Gen NAAT is essential, but not available in primary care, all patients would need to be referred to specialist services for testing and management for PID. This would mean all testing (including for gonorrhoea and chlamydia), management and contact tracing would be done by specialist services, and formulary guidance would simply recommend referral to specialist services.
  - If M.Gen NAAT test is desirable but not essential, we would remove reference to it in formulary guidance until it becomes routinely available in primary care. This would mean that patients with suspected PID who are managed by their GP would not be routinely tested for M.Gen

Responses received indicated that M.Gen testing is advised for all suspected cases of pelvic inflammatory disease and a referral into sexual health clinics for full assessment; including testing, contact tracing, and treatment management should be the current recommendation in Devon.

The FIG considered the proposed amendment to PID and whether it wished to refer all patients into sexual health clinics, until such a time that service provisions allow adequate full assessment in primary care, where guidance can then be re-evaluated.

The FIG agreed the PID section should be amended to advise that all patients should be referred into sexual health clinics, until such a time that service provisions allow adequate full assessment in primary care. At this point, the formulary guidance can be reviewed.

There was discussion about whether the guidance should state that an urgent opinion from a specialist should be sought for patients who are unwell. It was considered not necessary to add this to the guidance.

ACTION: Formulary team to update the formulary with the accepted formulary guidance for PID.

7. Environmental impact of inhalers: End of GSK Complete the Cycle scheme

In November 2019, the N&E Devon FIG agreed formulary guidance on the environmental impact of inhalers. This guidance is in keeping with the NHS Long Term Plan and was developed to support a move to dry powder or soft mist inhalers as preferred devices in the absence of a specific clinical or dexterity reason requiring a pressured metered dose or breath actuated inhaler. This guidance also addresses opportunities for recycling or recovery of spent inhalers and highlights the GSK 'Complete the Cycle' scheme. In July 2020, the Pharmaceutical Journal reported that the 'Complete the Cycle' scheme is to close at the end of September 2020. The formulary team confirmed this via personal communication with GSK.

The Devon Formulary guidance on the environmental impact of inhalers therefore requires updating to remove reference to this scheme.

The FIG discussed the end of the GSK 'Complete the Cycle' Scheme, including:

- Disappointment at the end of the GSK 'Complete the Cycle' scheme.
- Knowing which inhalers have the least environmental impact would be helpful. It was noted that Table 2 in the paper by Wilkinson et al provides some information, which may be added to the formulary
- Part of the Primary Care Network Directed Enhanced Service (PCN DES) focuses on the environmental impact of inhalers.

It was agreed that the Formulary team will investigate available resources to help with inhaler choice and their environmental impact.

ACTION: Formulary Team to investigate available resources helping with inhaler choice and adding relevant information from the paper by Wilkinson et al to the formulary.

ACTION: Formulary Team to make the necessary changes to the North and East presentation of the formulary.

8. NICE guideline (NG145): Thyroid disease: assessment and management

The current formulary guidance for thyroid disease is based on guidance for hypothyroidism from the British Thyroid Association and published guidance for hyperthyroidism. NICE guideline NG145 Thyroid disease: assessment and management was issued by NICE. The guideline covers investigating all suspected thyroid disease and the management of primary thyroid disease including:

- Investigation of thyroid dysfunction or thyroid enlargement.
- Treatment and monitoring of:
  - Primary hypothyroidism
  - Thyrotoxicosis
  - Subclinical thyroid dysfunction
  - Non-malignant thyroid enlargement and normal thyroid function.

Areas not covered by the NICE clinical guideline include thyroid disease in pregnant women and thyroid eye disease.

There are differences in coverage between the NICE clinical guideline and the current formulary guidance, the proposed update to the formulary was presented to FIG for initial discussion before consultation with specialists. The paper will be brought back to a future meeting for discussion and agreement on inclusion in the formulary when input from specialists has been received.

The FIG agreed that it was appropriate that NICE guidance should be included in the formulary.

There was discussion about:

- Tests when thyroid dysfunction is suspected. It was agreed to keep the current formulary guide to interpreting test results.
- It was agreed to retain the current subsection for ischaemic heart disease (IHD) and hypothyroidism, and keep this as a separate subsection.
- Referral to specialists. – Add in urgent referral for IHD.
- It was noted that a high proportion of patients with hyperthyroidism are referred to secondary care. The Formulary Team will clarify with specialists which patient groups they want to see.
- Follow-up and monitoring of hyperthyroidism. It was suggested that more information/advice is needed on monitoring of patients after radioactive treatment.
- Hyperthyroidism in pregnancy (current formulary only) – add refer to specialists.

It was agreed to retain the formulary guidance where it is not covered by NICE and that the Formulary Team will seek clarity on referral for GPs.

FIG members were thanked for their comments. The formulary team will take the comments raised to specialists.

ACTION: Formulary team to take the comments raised to specialists.

The Formulary team will bring the proposed formulary section back to the FIG once feedback has been received from specialists.

ACTION: Formulary team to bring the proposed formulary section back to the FIG once feedback has been received from specialists.

9. Cluster headache

The Formulary team has been asked to develop formulary guidance for the management of cluster headache. It is considered that guidance to support prescribers in the treatment of

cluster headaches would be a useful resource to include in the formulary in view of the number of patients in Devon receiving oxygen for cluster headache.

Cluster headache was discussed at the FIG meeting on 19th March to determine current practice for its management. This discussion was used to inform the development of a proposed structure for formulary guidance. In addition, the Formulary team reviewed national guidance and searched for local guidance produced in other areas of the country.

The proposed structure for the formulary guidance section for the management of cluster headache was circulated with the 17th September meeting papers.

A discussion took place:

- It was noted that for GPs the diagnosis of cluster headache is difficult. Specialist involvement and specialist review is needed. Because of the delay in getting a specialist assessment, GPs initiate triptans and patients can remain on triptans if they are not reviewed. GPs should do an early review on whether triptans are working and stop them if they are not.
- The extent of prescribing of sumatriptan injection in Devon was raised. The Formulary team will contact MO regarding prescribing levels of sumatriptan injection at each locality.

ACTION: Formulary team to contact MO regarding prescribing levels of sumatriptan injection at each locality.

- It was agreed that the proposed structure for formulary guidance would be helpful to prescribers.

The formulary team will work with specialists to develop formulary guidance. It will then be brought back to a future FIG meeting for agreement and discussion.

ACTION: Formulary Team to work with specialists to develop cluster headache guidance and then bring back to the FIG for agreement.

10. Environmental impact of inhalers: consideration of Salamol CFC-free inhaler as the preferred brand of salbutamol pressurised metered dose inhaler (pMDI)

Currently, the Devon Joint Formulary does not specify a brand of inhaler for aerosol inhalation of 100mcg salbutamol. Salamol CFC-free inhaler is a pressurised metered dose inhaler (pMDI) containing 100mcg salbutamol per inhalation. It is licenced for the symptomatic treatment of asthma and other conditions with associated reversible airways obstruction in patients aged 4 years and older. The recommended dose is one inhalation as required; this can be increased to two inhalations if required. The use of Salamol CFC-free as the brand choice for prescribing 100mcg salbutamol would have the potential to reduce the carbon footprint of pMDI salbutamol inhaler use in Devon, and result in small cost savings.

The FIG considered and accepted Salamol CFC-free inhaler as the preferred brand of salbutamol pressured metered dose inhaler (pMDI) without amendment.

There was discussion about reducing the environmental impact of inhalers and the move to dry power inhalers. It was agreed that the Salamol CFC-free inhaler should be considered on the basis of environmental impact alone given the estimated reduction in carbon footprint.

The issue of the inhaler nozzle becoming gummed up was raised. It was noted that this had been raised in New Zealand. The New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) conducted a number of tests on Salamol CFC-free inhalers, and concluded that the inhalers are sensitive to cleaning and require cleaning in the manner described in the patient information leaflet.

It was agreed that Graham Simpole request that the MO Team update Scriptswitch to facilitate use of Salamol CFC-free inhaler.

ACTION: Graham Simpole to request that the MO Team update Scriptswitch to facilitate use of Salamol CFS-free inhaler.

ACTION: Formulary team to update the formulary entry with Salamol CFC-free inhaler as the preferred brand of salbutamol pressurised metered dose inhaler pMDI).

11. Vigabatrin safety advice

Vigabatrin is an antiepileptic licenced for treatment in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated, and as monotherapy in the treatment of infantile spasms (West's syndrome). Vigabatrin tablets (500mg) and granules for oral solution (500mg) are currently included in the Devon Formulary as an amber (specialist input) medicine in North and East Devon, and as a red (hospital only) medicine in South and West Devon.

A request has been received from Sarah Marner (Senior Medicines Optimisation Pharmacist, NHS Devon CCG) to consider the reclassification of vigabatrin from 'red' (hospital only) to amber (specialist) in South and West Devon in order to align the recommendations across the county.

No requests have been received from any specialists in Devon for the reclassification of vigabatrin (either from red to amber in South and West Devon, or from Amber to red in North and East Devon).

At this time, specialists have not been specifically asked to comment on proposals to align the Devon formulary recommendations in this way, however initial scoping highlighted the requirement for regular ophthalmological monitoring for safety reasons and very low levels of prescribing.

There are frequent reports of visual fields defects (VFD) ranging from mild to severe in nature in patients receiving vigabatrin. Severe cases are potentially disabling and blindness has been reported. Available data suggests that visual field defects are irreversible even after discontinuation of vigabatrin. The possibility that there may be further deterioration in visual fields after treatment is discontinued has not been excluded. Vigabatrin is not recommended for use in patients with any pre-existing clinically significant visual field deficit. Visual field testing and assessment of visual acuity is required at six month intervals for the duration of treatment. There are specific recommendations on appropriate methods of visual field testing in adults and children.

The risk of ophthalmological adverse effects and the need for regular ophthalmological monitoring was highlighted in the drug entry for South and West Devon, but there is no mention of this in the drug entry for North and East Devon.

It is proposed that the formulary entry for North and East Devon is updated to reflect the requirement for regular visual field testing and visual acuity assessment during treatment with vigabatrin.

The FIG considered the proposed formulary entry. The additional notes for the drug entry proposed in the meeting papers were accepted. It was also agreed that the formulary status of Vigabatrin should be changed from 'amber' specialist input to 'red' hospital only in North and East Devon given the requirement for frequent ophthalmological monitoring of a specialist nature and the very low level of prescribing. It was noted that local specialists have not been specifically consulted on a proposal to reclassify vigabatrin in this way; it was therefore agreed that the Formulary Team will seek additional specialist opinion on the proposal.

The Formulary team will update the North and East Devon drug entry with the drug safety information immediately.

ACTION: Formulary team will update the North and East Devon entry for vigabatrin with the drug safety information immediately.

ACTION: Formulary team to consult specialists on the proposal to reclassify vigabatrin as 'red' (hospital only) drug.

12. MHRA Drug Safety Updates: July and August 2020

MHRA Drug Safety Update – July 2020

The following items were noted:

- Systemically administered VEGF pathway inhibitors: risk of aneurysm
- Liposomal and lipid-complex formulations: name change to reduce medication errors
- Coronavirus (COVID-19) updates
  - Remdesivir for patients hospitalised with COVID-19 (adults and children
- Safety letters
  - Ondexxya
  - Dihydropyrimidine dehydrogenase (DPD) deficiency testing for 5-fluorouracil (iv), capecitabine and tegafur to minimise risk of toxicity

The Formulary had been updated with regard to the MHRA Drug Safety Update for July 2020.

MHRA Drug Safety Update August 2020

The following items were noted:

- Clozapine and other antipsychotics: monitoring blood concentrations for toxicity.

  It was agreed that the reference to the Drug Safety Update will be added to the Formulary and that the Formulary Team will liaise with Chris Sullivan at Devon Partnership NHS Trust (DPT).

ACTION: Formulary Team to add reference to the Drug Safety Update to the formulary and liaise with Chris Sullivan at DPT.

- Denosumab 60mg (Prolia): increases risk of multiple vertebral fractures after stopping or delaying ongoing treatment.
- Baricitinib (Olumiant): increased risk of diverticulitis, particularly in patients with risk factors.
- Isotretinoin (Roaccutane): reminder of important risks and precautions
- Emollients and risks of severe and fatal burns: new resources available

The Formulary will be updated with regard to the MHRA Drug Safety Update for August 2020.

ACTION: Formulary team to update the formulary with regard to the MHRA Drug Safety Update for August.

13. Recent drug decisions (including NICE)

The recent drug decisions were reviewed.

5-mg ulipristal acetate

The EMA Safety Review (September 2020): EMA's safety committee recommends revoking the licence for ulipristal acetate for uterine fibroid. A note has been added to the Formulary. The Formulary team will remove the entry for ulipristal acetate 5mg for uterine fibroids in three months' time.

Single doses for emergency contraception are not affected.

14. Devon Formulary website: update on IT issues with 'contact us' link

The Devon-wide Formulary and Referral Website was experiencing some technical issues with regards to email communications via the contact details pages located on the website. This had resulted in some enquiries not reaching the Formulary and Referral Teams.

This issue has now been resolved; the cause was related to an external NHS system error which incorrectly marked enquiries as spam and deleted them.

It is not known how long the problem existed; the Formulary team has been informed that enquiries sent during this time are not retrievable. The Formulary team therefore asked that any enquiries which have not been responded to are re-sent. This has been highlighted on the Formulary website and via the usual channels for communication to trusts and GP practices etc.

15. Any other business

FIG Merger

The consultation on the merger of the two Devon FIGs has now ended. Responses received have been positive however a small number of issues have been raised. The Formulary team will produce a summary of the responses. There may be further questions for the FIGs to consider with regard to the issues raised in the responses.

H2-Receptor Antagonists (H2RAs)

The FIG discussed the availability of H2RAs, it was noted that shortages are intermittent. The Formulary team has provided an update on the current situation to gastroenterologists and to remind them of the shortages. Specialists were asked that if they consider a patient requires a H2RA, it would be helpful if they could also recommend an alternative treatment in the event that a H2RA is not available.

An update regarding ranitidine has been added to the Formulary website.

Date of next meeting

The next meeting will be held on Thursday 19th of November 2020 from 9:00am to11:30 am via Microsoft Teams/telephone conference

Summary of actions

Number	Action	Lead	Status
19/84	The need for a system to enable secondary care to prescribe medicines to patients without them having to attend a hospital appointment to be raised with relevant people at RD&E.	Susie Harris	Outstanding
20/01	*Cluster headache – work with Ali Round to develop formulary guidance and liaise with specialists. Proposed formulary guidance to be brought back to future FIG meeting for discussion.* It is hoped that this can be included on the agenda for the meeting scheduled for September.	Formulary team	Complete
20/04	Develop draft osteoporosis guidance, circulate to specialists for comment and bring to a future FIG meeting.	Formulary Team	Outstanding
20/24	Formulary Team to seek the views of specialists regarding the formulary classification for domperidone, metoclopramide and erythromycin in the context of paediatric GORD. The proposed formulary entry will then be updated and brought back to the next FIG meeting or completed via the e-FIG process. The Formulary team is working with specialists from South and West Devon who would like additional wording. On completion of this work this will be brought back to the N&E FIG.	Formulary Team	Outstanding

20/25	Omeprazole for paediatric patients – respond to Dr Graham regarding the points raised in response to the consultation and patients on long term PPI. This is linked to action 20/24 above.	Formulary Team	Outstanding
20/29	NICE antimicrobial guideline: Pyelonephritis (acute) – ask antimicrobial pharmacists to review the draft guidance for pyelonephritis, recurrent UTI, and catheter-associated UTI and provide feedback.	FIG Trust pharmacists	Complete
20/30	NICE antimicrobial guideline: Pyelonephritis (acute) – seek clarification of points raised during the discussion.	Formulary Team	Complete
20/31	NICE antimicrobial guideline: Pyelonephritis (acute) – update the proposed guidance in line with the discussion and specialist comments once received.	Formulary Team	Complete
20/32	NICE antimicrobial guideline: Pyelonephritis (acute) – once updated bring proposed guidance back to a future FIG meeting.	Formulary Team	On agenda
20/33	NICE antimicrobial guideline (UTI) recurrent: update the proposed guidance in line with the discussion and specialist comments once received.	Formulary Team	Complete
20/34	NICE antimicrobial guideline (UTI) recurrent: Once updated bring the proposed guidance back to a future FIG meeting.	Formulary Team	On agenda
20/35	NICE antimicrobial guideline: UTI (catheter-associated) – update the guidance in-line with the discussion and bring back to the FIG with specialist comments and to clarify discussions	Formulary Team	On agenda
20/36	Pelvic Inflammatory Disease (PID): update – update the formulary with the accepted formulary guidance for PID	Formulary Team	Complete
20/37	Environmental impact of inhalers: End of GSK Complete the Cycle scheme – investigate available resources helping with inhaler choice and adding relevant information from the paper by Wilkinson et al into the formulary.	Formulary Team	Outstanding
20/38	Environmental impact of inhalers: End of GSK Complete the Cycle scheme – make necessary changes to the North and East presentation of the formulary information.	Formulary Team	Complete

20/39	NICE guideline (NG145): Thyroid disease: assessment and management – take comments raised to specialists.	Formulary Team	Complete
20/40	NICE guideline (NG145): Thyroid disease: assessment and management – bring the proposed formulary section back to the FIG once feedback has been received from specialists.	Formulary Team	Outstanding
20/41	Cluster Headache – contact MO regarding prescribing levels of sumatriptan injection at each locality.	Formulary Team	Complete
20/42	Cluster Headache – work with specialists to develop cluster headache guidance and bring back to FIG for agreement.	Formulary Team	Outstanding
20/43	Environmental impact of inhalers: consideration of Salamol CFC-free inhaler as the preferred brand of salbutamol pressurised metered dose inhaler (pMDI) – request that the MO Team update Scriptswitch to facilitate use of Salamol CFS-free inhaler.	Graham Simpole	Outstanding
20/44	Update the formulary entry with Salamol CFC-free inhaler as the preferred brand of salbutamol pressured metered dose inhaler pMDI).	Formulary team	Complete
20/45	Vigabatrin safety advice – update the North and East Devon vigabatrin entry with drug safety information immediately.	Formulary team	Complete
20/46	Vigabatrin safety advice – Formulary team to consult specialists on the proposal to reclassify vigabatrin as 'red' (hospital only) drug.	Formulary team	Complete
20/47	MHRA Drug Safety Update August 2020 – clozapine and other antipsychotics: monitoring blood concentrations for toxicity. Add referenced to Drug Safety Update to the formulary and liaise with Chris Sullivan at DPT	Formulary Team	Complete
20/48	MHRA Drug Safety Update August 2020 – update the formulary with regard to the MHRA Drug Safety Update for August.	Formulary Team	Complete