Northern, Eastern and Western Devon
Clinical Commissioning Group

Meeting of the Northern and Eastern Devon Formulary Interface Group

Minutes

Thursday 8th February 2018: 9:00am – 11:00am

Old Heathcoat School, Tiverton

Present:

Susie Harris	Consultant, Elderly Care	RD&E
Carol Albury	Locality MO Pharmacist	NEW Devon CCG
Glen Allaway	GP	NEW Devon CCG
Beverly Baker	Non-Medical prescribing lead	NEW Devon CCG
Emma Gitsham	Joint Formulary Pharmacist	NEW Devon CCG
Andrew Harrison	GP	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Simon Kay	GP	NEW Devon CCG
Matt Kaye	Chief Pharmacist	NDHT
Carole Knight	Formulary Pharmacist	NDHT
Stuart Kyle	DCT Chair / Consultant Rheumatologist	NDHT
Denise Lanyon	MO Pharmacist	NEW Devon CCG
Jess Parker	GP	NEW Devon CCG
Bethan Rogers	Formulary Pharmacist	RD&E
Graham Simpole	Joint Formulary Support Pharmacist	NEW Devon CCG
Darren Wright	Joint Formularies Technician	NEW Devon CCG

Guests:

Lee Dobson	Consultant in Respiratory Medicine	RD&E
Tom Lewis	Consultant Microbiologist	NDHT
Maddie Norbury	Pre-Reg Pharmacist	RD&E
Rob Porter	Consultant Microbiologist	RD&E
Roderick Warren	Consultant Physician	RD&E

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG

1. Welcome and introductions:

Attendees were welcomed to the meeting.

Maddie Norbury attended the meeting as an observer.
Lee Dobson attended for the consideration of Trimbow.
Tom Lewis and Rob Porter attended the meeting for the consideration of oral candidiasis and urinary infection review.
Roderick Warren attended the meeting for the consideration of FreeStyle Libre.

Apologies

Tawfique Daneshmend Consultant Gastroenterologist RD&E

Declaration of Interests

Agenda Item	Company	Agenda Item	Company
Trimbow Any other inhalers for the management of severe to moderate COPD	Chiesi Limited Various	Alprostadil Intraurethral delivery system for the treatment of erectile dysfunction. Alternative treatments: Alprostadil Intracavernosal injection Alprostadil Topical cream	Meda Pharmaceuticals UCB Pharma Limited Pfizer Limited Ferring Pharmaceuticals Ltd
NHSE Consultation Co-proxamol Dosulepin Prolonged release doxazosin Glucosamine and chondroitin Herbal treatments Homeopathic treatments Paracetamol & tramadol combination Perindopril arginine Rubefacients Trimipramine	Various	Urgoclean Pad ® Urgoclean Rope® Alternative treatments for sloughy, diabetic, acute, chronic or cavity wounds	Urgo Limited Various
Eclypse Border and Eclypse Border Oval dressings Alternative treatments for sloughy wounds	Advancis medical Various	Cutimed® Sorbact® Gel Dressings Alternative treatments for dry to low exuding, sloughy, or partly necrotic wounds	BSN medical UK Various

Agenda Item	Company	Agenda Item	Company
Joint hosiery formulary: Duomed® Soft, Mediven® ranges, Medi 2in1® Sigvaris Cotton® ranges Haddenham Microfine® Toe Cap Jobst® Elvarex Plus Foot Cap Alternative hosiery manufacturers	Medi UK Ltd) (SIGVARIS Britain Ltd) (Haddenham Healthcare) (BSN Medical) Various	Hypertension Various medications: ACE inhibitors Angiotensin II reception blockers Calcium-channel blockers Beta-blockers Diuretics Alpha-blockers	Various
Management of oral candidiasis Miconazole, Nystatin, Fluconazole, Itraconazole	Janssen-Cilag Ltd, McNeil Products Ltd, Sandoz Limited, Aurobindo Pharma-Milpharm Ltd, Sandoz Limited, Actavis UK Ltd Various generic manufacturers	Antibiotics for Urinary Tract Infection Any antibiotic used for the treatment of UTI	Various
FreeStyle Libre device for interstitial glucose monitoring in diabetes Alternative treatments: Blood glucose monitoring devices Continuous glucose monitors	Abbott Laboratories Ltd Various Various		

NAME OF ATTENDEE	ROLE	
Lee Dobson	Consultant in Respiratory Medicine	Lecture fees from Chiesi but also other competing companies. ERS meeting sponsorship

2. Minutes of the meeting held on Date, Month, Year and matters/actions arising

The minutes of the meeting held on Thursday 14th December 2018 were approved.

Terms of reference

The group received and approved the updated Terms of Reference.

Summary of actions			
Date	**Action**	**Lead**	**Status**
17/40	AirFluSal MDI: consideration to be given to how the formulary and MO website can provide additional support information. Formulary Team to discuss with MO Team and Lee Dobson.	Formulary Team	Outstanding
17/51	MHRA Drug Updates: Adrenaline – Liaise with MO in East regarding the number of auto-injectors for each patient. Formulary Team to discuss and also consider schools.	Formulary Team	Outstanding
17/52	MHRA Drug Updates: Adrenaline – Liaise with MO in North regarding the number of auto-injectors for each patient. Formulary Team to discuss and also consider schools.	Formulary Team/Louise Greaves	Outstanding
17/53	AOB: Invita D3 50,000IU tablets and oral solution for vitamin D deficiency paper to be brought to a future meeting. Stuart Kyle and Carol will discuss. To be added to the MO work plan.	Stuart Kyle/Mo Team	Outstanding
17/66	Formulary entry for oral nutritional supplements to be updated as per the discussion.	Formulary team	Outstanding
17/68	Antimicrobial and infections: Whether adults should receive antimicrobials for an ear infection to be established and reported back to FIG in February 2018.	Formulary Team	Outstanding
17/71	Antimicrobial and infections: further work to be undertaken on Diverticulitis and if required Diverticulitis to be brought back to FIG. This has been added to the Formulary Team work plan		Complete
17/72	Antimicrobial and infections: further work to be undertaken on Cholecystitis and if required Cholecystitis to be brought back to FIG. This has been added to the Formulary Team work plan.		Complete
17/73	Antimicrobial and infections: Dermatophyte infection – Proximal fingernail or toenail (adults): Note to be added to strengthen advice that patients must commit to completing course of treatment.		Complete

3. Consideration of Trimbow 87 micrograms/ 5 micrograms/ 9 micrograms pressurised inhalation for addition to the formularies

An application was received from Dr Lee Dobson for inclusion of the combination metered dose inhaler (MDI) Trimbow (beclometasone dipropionate 87 micograms, formoterol fumarate dihydrate 5 micrograms, glycopyrronium bromide 9 microgram) in the formulary. It is licensed for maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteriod (ICS)/ long-acting beta2-agonist (LABA). It is not licensed for switching of patients who are stable on triple therapy, or patients not adequately controlled on therapy other than ICS/LABA, such as LABA/long-acting muscarinic antagonist (LAMA) combination therapy. The application suggests that Trimbow will provide a treatment option alongside currently available ICS/LABA and LAMA inhalers. Dr Dobson indicated that Trimbow is suitable for use in adult patients with moderate to severe COPD who require triple therapy and would reduce the number of inhalers. Trimbow may reduce between inhaler variations in technique and potential loss of efficacy. Dr Dobson attended the meeting and contributed to the discussion.

It was noted that the list of specialists contacted in the meeting paper was incorrect. The following specials had been contacted for comment:

<u>Royal Devon and Exeter NHS Foundation Trust</u>

Michael Gibbons, David Halpin, Hugh Bakere, Bip Patel, Chris Sheldon, Tom Whitehead, Nick Withers, Belen Carballido Romero.

<u>Northern Devon Healthcare Trust</u>

Alison Moody, Georgina Hands, Jareer Raza

<u>GPwSI</u>

Simon Kay, Anne Saunders

There was discussion about:

- The potential for a single appliance containing all medicines to increase patient compliance and improve asthma control.
- The current licensing of Trimbow; it was noted that there seems to be a trend in manufacturers not getting licences for switching.
- There is evidence of improvements in outcomes when patients step up from a LABA. The TRIBUTE trial found Trimbow to be superior over a LABA/LAMA combination. In due course, there may be potential for licence expansion based on this trial.
- The potential for Trimbow to be cost saving if it is used for patients stepping up their treatment.

The FIG accepted the proposed formulary entry without amendment.

ACTION: **Formulary Team to add Trimbow 87 micrograms/ 5 micrograms/ 9 micrograms pressurised inhalation to the North and East Devon Formulary.**

4. Consideration of alprostadil urethral sticks for addition to the formulary

A formulary application has been received from Dr Soumya Misra, Consultant in Urology, Northern Devon Healthcare NHS Trust for the addition of alprostadil urethral sticks to the formulary.

MUSE intraurethral sticks are indicated, in adults aged 18 years and above, for the treatment of erectile dysfunction of primarily organic aetiology, and diagnosis of erectile dysfunction adjunct to other tests. They are available as 250mcg, 500mcg, and 1000mcg transurethral delivery systems. It has been suggested that MUSE intraurethral sticks present a less invasive route of administration, for many men who would otherwise be offered alprostadil via intracavernosal injection, but alprostadil cream would be a less invasive route to MUSE intraurethral sticks, which can be painful.

It was noted that alprostadil urethral sticks are already in use. The costs are similar to current alprostadil formulary options, and would offer another choice as patient preference should be considered when deciding treatment plans.

The FIG accepted the proposed formulary entry without amendment.

ACTION: **Formulary Team to add alprostadil urethral sticks to the North and East Devon Formulary**

5. Items which should not routinely be prescribed in primary care

In November 2017 NHS England (NHSE) and NHS Clinical Commissioners (NHSCC) published guidance for CCGs on 18 treatments that these organisations recommend should not be routinely prescribed in primary care. CCGs are “expected to have ‘due regard’ to the guidance in formulating local policies and making decisions about implementation”.

The guidance also states that “in relation to some of the medicines consulted on, the consultation feedback included requests that the particular medicine should be formally placed on the 'blacklist'. NHSCC and NHS England will recommend that the Secretary of State for Health formally consider blacklisting of Co-proxamol, Glucosamine and Chondroitin, Herbal Treatments, Homeopathy, Lutein and Antioxidants, Omega-3 Fatty Acid Compounds, Rubefacients (excluding topical NSAIDs)” as they have been determined to be clinically inappropriate for use in the NHS. It is not known if or when any of these items may be added to the ‘blacklist’.

NHSE/NHSCC recommendations for each of these products advise CCGs that prescribers in primary care should not initiate the product for any new patient and that CCGs should support prescribers in deprescribing of the product/s and where appropriate, ensure the availability of relevant services to facilitate this change.

The FIG was asked to consider adopting recommendations for treatments considered by NHSE and NHSCC and any additional support that may be required to aid deprescribing these items:

Co-Proxamol - Co-proxamol was withdrawn from the UK market in 2007 due to safety concerns and is not currently in the N&E Devon formulary. However it is still being prescribed to up to 61 patients across North and East Devon. It was proposed that an entry be added to the formulary stating that co-proxamol is not recommended for use due to significant safety concerns. Prescribers should not initiate co-proxamol for any new patient.

The FIG considered and accepted the proposed formulary entry for Co-Proxamol with an agreed minor amendment:

- Add the words 'following national guidance from NHS England'.

ACTION: Formulary team to add the agreed formulary entry for co-proxamol.

Dosulepin - Dosulepin is not currently included in the N&E Devon formulary. The current formulary guidance for unipolar depression states "dosulepin should not be initiated and where appropriate its use should be reviewed". However it is estimated that approximately 1,000 to 2,000 patients are treated across North and East Devon.

It was proposed that an entry be added to the formulary stating that dosulepin is not recommended for use in primary care due to significant safety concerns. Prescribers should not initiate dosulepin for any new patient. If, in exceptional circumstances, there is a clinical need for dosulepin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

The FIG considered and accepted the proposed formulary entry for dosulepin with agreed minor amendments:

- Add the words 'following national guidance from NHS England'.
- 'Prescribed' to be changed to 'initiated' in the third line of the entry and a statement that current patients are to be regularly reviewed to be added and alternative treatments considered.

ACTION: Formulary team to add the formulary entry for dosulepin in line with the discussion.

Prolonged-release doxazosin (also known as doxazosin modified release) – NHSE/NHSCC state that prolonged release doxazosin is approximately six times the cost of doxazosin immediate release, and no benefits of prolonged release above immediate release were identified. Doxazosin is not currently included in the N&E Devon formulary. However data suggests that approximately 285 patients are being treated with 4mg and 8mg MR tablets.

The FIG considered and accepted the proposed formulary entry for doxazosin with agreed minor amendments:

- Add the words 'following national guidance from NHS England'.

ACTION: Formulary team to add the formulary entry for doxazosin in line with the discussion.

Immediate release fentanyl - Further work will be undertaken locally in relation to this recommendation.

Glucosamine *and chondroitin* - Glucosamine and chondroitin are not currently included in the N&E Devon formulary, which contains a statement about lack of evidence of efficacy of glucosamine for osteoarthritis, and a NICE "do not do" notification (NICE CG177). However glucosamine and chondroitin are being prescribed in the North and East although it is not clear how many patients this involves.

The FIG considered and accepted the proposed formulary entry for glucosamine and chondroitin with an agreed minor amendment.

- Add the words 'following national guidance from NHS England'.

ACTION: Formulary team to add the formulary entry for glucosamine and chondroitin in line with the discussion.

Herbal treatments - Under a Traditional Herbal Registration there is no requirement to prove scientifically that a product works, the registration is based on longstanding use of the product as a traditional medicine.

Herbal products are not recommended in the N&E Devon formulary. The current formulary guidance on herbal treatments for menopause highlights the unregulated nature of compound bioidentical hormones and that the efficacy and safety of such products is unknown as is the quality and purity of such products.

The proposed formulary entry states that following national guidance from NHSE herbal treatments are not recommended for use in any condition due to lack of scientific evidence required to register these products and prescribers should not initiate herbal treatment for any new patient.

The FIG discussed the current and proposed formulary entries.

The FIG accepted the proposal that 'See Herbal treatments and homeopathy' be added to the entry and that information from NICE be deleted from the current entry for menopause.

ACTION: Formulary team to update the formulary entry for herbal treatments for menopause in line with the discussion.

It was further agreed that a separate section be created for herbal treatments and homeopathy on the formulary information page, and a note be added stating that herbal treatments are still subject to yellow card monitoring (MHRA drug safety update January 2018).

ACTION: Formulary team to create a separate section for herbal treatments and homeopathy on the formulary information page.

Homeopathic treatments - Homeopathic products are not currently included in the North and East Devon formulary.

The proposed formulary entry states that following national guidance from NHSE homeopathy is not recommended for use for any condition due to lack of clear or robust evidence of efficacy. Prescribers should not initiate homeopathic treatment for any new patient.

The FIG discussed and accepted the proposed formulary entry for homeopathic treatment without amendment. It was further agreed that a separate section be created for herbal treatments and homeopathy on the formulary information page.

ACTION: Formulary team to add the accepted formulary entry for homeopathic treatments to the separate section created on the formulary information page, entitled 'Herbal Treatments and Homeopathy'.

Lidocaine plasters - Further work is to be undertaken locally in relation to this recommendation.

Liothyronine (including Armour Thyroid and liothyronine combination products) - Work is being undertaken separately across Devon by the Sustainability and Transformation Plan (STP) footprint. No further work is being undertaken by the formulary team.

Lutein and antioxidants - Further work is to be undertaken locally in relation to this recommendation.

Omega-3 Fatty acid compounds - Further work is to be undertaken locally in relation to this recommendation.

Oxycodone and naloxone combination product - Further work is to be undertaken locally in relation to this recommendation.

Paracetamol and tramadol combination product - NHSE/NHSCC guidance indicates that paracetamol/tramadol combination products are significantly more expensive than the individual components and offer no significant advantages in terms of efficacy or safety over individual products.

Paracetamol and tramadol combination products are not currently included in the N&E Devon formulary. However 12 months (Nov '16 to Oct '17) ePACT data show that approximately 55,300 tablets were prescribed in North and East Devon.

It is proposed that an entry be added to the formulary stating that paracetamol and tramadol combination products are not recommended for use due to significant extra costs and no evidence of efficacy or safety over the individual products. Prescribers should not initiate paracetamol and tramadol combination products for any new patient.

The FIG considered and accepted the proposed formulary entry for paracetamol and tramadol combination products with agreed minor amendment:

- Add the words 'following national guidance from NHS England'.

ACTION: Formulary team to add the formulary entry for paracetamol and tramadol combination products in line with the discussion.

Perindopril arginine - The NHSE/NHSCC guidance notes that "the perindopril arginine salt version was developed as it is more stable in extremes of climate than the perindopril erbumine salt, which results in a longer shelf life. Perindopril arginine is significantly more expensive than perindopril erbumine". No clinical advantage of the arginine salt was identified.

Perindopril arginine is not currently included in the N&E Devon formulary. However 12 months (Nov '16 to Oct '17) e-PACT data suggests that approximately 75 patients are treated across north and east Devon.

It is proposed that an entry be added to the formulary stating that perindopril arginine is not recommended for use due to significant extra costs and no evidence of clinical advantage over perindopril erbumine. Prescribers should not initiate perindopril arginine for any new patient.

The FIG considered and accepted the proposed formulary entry with minor amendment:

- Add the words 'following national guidance from NHS England'.

ACTION: Formulary team to add the formulary entry for perindopril arginine in line with the discussion.

Rubefacients (excluding topical NSAIDs) - The NHSE/NHSCC guideline is clear that the recommendations for rubefacients apply to topical products containing nicotinate compounds, salicylate compounds, essential oils and camphor, but do not apply to topical NSAIDs. There is limited evidence of efficacy regarding rubefacients for treating osteoarthritis and NICE has issued a "do not do" statement.

Currently the North and East Devon formulary contains an entry for rubefacients. It is proposed that Algesal and Balmosa be removed from the formulary. It is also proposed that a new entry be added stating that rubefacients (including topical products containing nicotinate compounds, salicylate compounds, essential oils and camphor) are not recommended for use due to lack of evidence of efficacy. Prescribers should not initiate rubefacients for any new patients.

It is estimated that across North and East Devon the cost of prescribing rubefacients between November 2016 and October 2017 was £9,787. It is not possible to estimate the number of patients treated.

The FIG accepted the proposed formulary entry for rubefacients (excluding topical NSAIDS) with minor amendment:

- Add the words 'following national guidance from NHS England'.

ACTION: Formulary Team to add the formulary entry for rubefacients in line with the discussion.

Once daily tadalafil - Further work to be undertaken locally in relation to this recommendation.

Travel vaccines - The NHSE/NHSCC guidance restates existing regulations with respect to vaccinations which should not be prescribed on the NHS exclusively for the purposes of travel. These vaccines should continue to be recommended for travel but the individual traveller will need to bear the cost of the vaccination. This is in line with current formulary information, with the exception of BCG, which is not currently included.

It is proposed that BCG be added to the current formulary list of "travel immunisations that cannot be given as an NHS service" as well as the statement from NHSE/NHSCC that "for all other indications, as outlined in Immunisation Against Infectious Disease – the green book – the vaccine remains free on the NHS."

The FIG accepted the proposed formulary entry without amendment.

ACTION: Formulary team to add the accepted formulary entry for travel vaccines.

Trimipramine - Trimipramine is not currently included in the North and East Devon formulary; however 12 months (Nov '16 to Oct '17) ePACT data suggest that depending of the number of tablets per day each patient is prescribed a maximum of 173 patients are prescribed trimipramine.

It is proposed that an entry be added to the formulary stating that trimipramine is not recommended for use due to significantly higher costs; more cost-effective tricyclic antidepressants are available. Prescribers should not initiate trimiparmine for any new patient.

The FIG considered and accepted the proposed formulary entry for trimipramine with minor amendment:

Add the words 'following national guidance from NHS England'.

ACTION: Formulary team to add the formulary entry for trimipramine in line with the discussion.

6. Addition of UrgoClean Pad and UrgoClean Rope into the formulary

A proposal has been received from the North and East Devon Tissue Viability Nurse teams for the addition of the UrgoClean Pad and the UrgoClean Rope into the formulary as green (first line) options for the removal of slough in appropriate wounds.

The product has been assessed by both the North and East Devon Tissue Viability Nurse teams. Experience of using the product in other organisations in Devon has also been reported to be positive.

There was discussion about the lack of trial evidence and the cost. It is understood that use of UrgoClean could reduce use of DebriSoft products where a dressing is more appropriate and could present a cost saving.

The FIG accepted the proposed formulary entry without amendment.

ACTION: Formulary Team to add UrgoClean Pad and UrgoClean Rope into the formulary.

7. Addition of Eclypse Border and Eclypse Border Oval dressings into the formulary

A proposal has been received from the North and East Devon Tissue Viability Nurse teams for the addition of Eclypse Border dressings into the formulary as blue (second line) options, for all exuding wounds that require a super absorbent, fixed in place dressing.

Eclypse Border and Eclypse Border Oval dressings are super absorbent dressings with a soft silicone contact layer and border with added hypoallergenic adhesive on the border to ensure the dressing remains in place. These dressings are indicated for all exuding wounds. The current formulary entry contains Eclypse super absorbent dressings as a blue (second line) option, but these do not include an adhesive boarder.

The product has been assessed by both North and East Devon Tissue Viability Nurse teams. Experience of using the product in other NHS organisations in Devon has also been reported to be positive.

There was discussion about the cost of the Eclypse Border and Eclypse Border Oval dressings, which are more expensive than the currently formulary products. At this time, Eclypse Boarder and Eclypse Boarder Oval dressings are being prescribed as non-formulary products. e-PACT data showed that in the last 6 months around 400 dressings have been prescribed at a cost of a little less than £2,000. It was noted that previously shaped dressings have been avoided except where needed for a particular patient. Other methods of adhesion were questioned e.g. tape and standard dressing in consideration of cost.

The FIG suggested that a Tissue Viability nurse be invited to a future N&E FIG meeting in order that the impact of the inclusion into the formulary of Eclypse Border and Eclypse Border Oval dressings be better understood.

The FIG did not accept the proposal for the addition of Eclypse Border and Eclypse Boarder Oval dressings into the formulary.

It was agreed that the addition of Eclypse Border and Eclypse Border Oval dressings into the formulary be brought to a future FIG meeting and that a Tissue Viability Nurse be invited to attend.

ACTION: Formulary team to invite a Tissue Viability Nurse to a future FIG meeting at which Eclypse Border and Eclypse Border Oval dressings will be discussed again.

8. Addition of Cutimed® Sorbact® Gel Dressings into the formulary

A proposal has been received from the North and East Devon Tissue Viability Nurse teams for the addition of Cutimed Sorbac Gel Dressing into the formulary as a green (fist line) dressing option for low exudate wounds.

Cutimed Sorbact gel dressings are coated with a hydrophobic fatty acid derivative, which gives the dressings hydrophobic properties. In the environment of an infected wound, hydrophobic substances and organisms, such as pathogenic wound bacteria and fungi, are attracted to the dressing and bind to each other, and are held together by the surrounding water molecules. Removing the dressing removes the bound bacteria, which cannot multiply once bound to the dressing fibres.

Use of Cutimed Sorbact gel dressings could reduce the need for two individual products to be used. This may present a cost saving but it has not been possible to quantify this. Cutimed Sorbact gel dressings are currently being prescribed as a non-formulary product; e-PACT data show that between May 2017 and October 2017 £5,750 was spent on these dressings making them the 15th most commonly prescribed (by volume) non-formulary dressing over this period.

The product has been assessed by both North and East Devon Tissue Viability Nurse teams. Experience of using the product in other NHS organisations in Devon has also been reported to be positive.

The FIG accepted the proposed formulary entry without amendment.

ACTION: Formulary Team to add Cutimed® Sorbact® Gel Dressings into the formulary

9. Compression hosiery and garments

A new section for compression hosiery and garments has been suggested by the North and East Devon Tissue Viability Specialist Nurses, to simplify the choices of compression hosiery, and make prescribing easer with relevant supporting guidance.

Due to time constraints at the meeting it was agreed that this item would be taken forward via the e-FIG process.

ACTION: Formulary team to initiate the e-FIG process for the proposed formulary entry for compression hosiery and garments.

10. Management of Hypertension

Due to time constraints at the meeting discussion of this item was deferred.

11. Oral candidiasis

The proposed guidance is for the management of acute oral conditions pending review by a dental specialist. Currently there is no guidance for the management of oral candidiasis in the North and East Devon Formulary. The proposed guidance is based on information supplied by microbiology specialists and acute pathways used in secondary care. Tom Lewis, Consultant Microbiologist, NDHT and Rob Porter, Consultant Microbiologist, RD&E attended the meeting and took part in the discussion of oral candidiasis

The guidance has been reviewed by the Antimicrobial Stewardship Committee for North and East Devon.

There was discussion about recurrent candidiasis and the difficulty of treating resistant conditions. It was agreed that more general guidance on the management of oral candidiasis was needed in the formulary.

The FIG considered the proposed formulary entry. It was agreed that Nystatin be included as the first line treatment with green status and that Miconazole be included as the second line treatment with blue status. It was also agreed that the reference to interaction between miconazole and warfarin be emboldened.

ACTION: Formulary Team to make agreed changes to the guidance on oral candidiasis and circulate to Tom Lewis and Rob Porter

ACTION: Following circulation of the proposed formulary guidance to consultants, formulary team to circulate the guidance for comment/approval via the e-FIG process.

12. Urinary tract infections follow up

The Primary Care Antimicrobial Guidance is reviewed annually using the Public Health England Management of Infection Guidance for Primary Care.

An updated formulary entry is proposed. The proposed entry has been reviewed by the Antimicrobial Stewardship Committee for North and East Devon.

The FIG considered the proposed formulary entry for urinary tract infections.

<u>Urinary tract infections (Main page)</u>

The proposed entry was accepted without amendment.

ACTION: Formulary team to add the proposed formulary entry.

Each slider on this page was then discussed.

Asymptomatic bacteriuria

The proposed entry was accepted without amendment.

ACTION: Formulary team to add the proposed formulary entry.

UTI in adults (no fever or flank pain)

Subsequent to the circulation of the meeting papers amendments had been made to the guidance on UTI in adults. An updated paper was tabled at the meeting.

The FIG considered the proposed formulary entry. There was discussion about rates of resistance to treatment, the number of tests being undertaken and management of confused elderly patients and it was noted that most conditions are self-limiting.

It was suggested that a positive test result may not help in determining the treatment for confused elderly patients. It was suggested that pivmecillinam be added to the guidance as a possible treatment for confused elderly patients or where estimated Glomerular Filtration Rate (eGFR) is less than 45mL/min. The proposed formulary entry was accepted subject to minor amendments:

- 1st and 2nd paragraphs of the entry to be reordered.
- Nitrofurantoin – 3rd bullet point to be emboldened.
- Pivmecillinam to be added with 'blue' status at the same dose as in community multi-resistant UTIs.

ACTION: Formulary team to add the proposed formulary entry in line with the discussion.

It was queried whether there is a warning on Script-switch about Clostridium difficile (C-diff). Carol Albury will check.

ACTION: Carol Albury to check whether there is a warning regarding C-diff on script-switch.

Community multi-resistant UTIs

There was discussion about prescribing fosfomycin as Monuril® for both male and female patients and use of repeat doses of fosfomycin in females with complex UTI.

The proposed formulary entry was accepted subject to fosfomycin being prescribed as Monuril for both males and females and the addition of a note stating that the dose of fosfomycin may be repeated (unlicensed) in females if the UTI is complicated.

ACTION: Formulary team to add the proposed formulary entry in line with the discussion.

Catheter associated urinary tract infection (CA-UTI)

There was discussion about the timing of the changing of catheters. It was agreed that catheters should be changed during the course of antibiotics if there is a clinically important UTI, i.e. with systemic symptoms and if inserted for more than one week.

The formulary entry was accepted subject to the replacement of 'Urinary catheters should be replaced at the time of starting antibiotics, if there is a clinically important UTI' with 'Urinary catheters which have been inserted for more than 1 week, should be replaced during the course of antibiotics, if there is a clinically important UTI'.

ACTION: Formulary Team to update the formulary entry for CA-UTI in line with the discussion.

Acute prostatitis

The proposed formulary entry was accepted without amendment.

ACTION: Formulary team to add the proposed formulary entry.

UTI in pregnancy

The proposed formulary entry was accepted without amendment.

ACTION: Formulary team to add the proposed formulary entry.

UTI in children

The proposed formulary entry was accepted without amendment.

ACTION: Formulary team to add the proposed formulary entry.

Acute pyelonephritis

The FIG considered the proposed formulary entry. It was noted that the wrong dose of cefalexin had been included in the paper.

It was agreed that Carol Albury would highlight the changes to prescribing leads and include in the Medicines Optimisation Post Live and that the microbiologists would review highlighting the changes on laboratory notes.

ACTION: Carol Albury to highlight changes to prescribing leads and include in the Medicines Optimisation Prescribing Post Live.

The FIG accepted the formulary entry with minor amendment to the dose of cefalexin.

ACTION: Formulary team to add the proposed formulary entry.

.Recurrent UTI in non-pregnant women, 3 or more UTIs in a year

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

- The definition of recurrent UTI in non-pregnant women; whether it is 3 UTIs in 12 months or 2 UTIs in 6 months. The need to be consistent with DRSS was noted.
- A query was raised as to whether nitrofurantoin should be modified release or not.
- It was agreed that the licensed dose for trimethoprim (100mg) should be used.
- Microbiologist opinion is there was significant unmet need in this group. There is a need to get patients off life long prophylaxis.

Tom Lewis agreed to confirm the additional wording for standby medication in this patient group.

ACTION: Tom Lewis to confirm additional wording for standby medication in this patient group.

ACTION: Formulary team to add the formulary entry in the line with the discussion.

13. Freestyle Libre device for interstitial glucose monitoring in diabetes

The Clinical Policy Committee (CPC) made a recommendation at its meeting in January 2018 that a 6 month trial of the FreeStyle Libre be routinely commissioned for patients with type 1 diabetes meeting certain criteria. Patients will be attending specialist secondary care clinics for their diabetes and have been assessed by their specialist to meet one of a number of agreed criteria set out in the policy. FreeStyle Libre would be continued if the patient demonstrated the applicable continuation criteria at a 6 month clinic assessment. Roderick Warren, Consultant Physician at the RD&E contributed to the FIG discussion of FreeStyle Libre.

The trial is to be initiated only by specialist endocrinologists. The specialist must inform the patient's GP of the indication under which the trial is commenced and the continuation criteria the patient must meet at their six month diabetes clinic review. On completion of the trial, if the patient has achieved the indicated continuation criteria the specialist must inform the patient's GP to allow for continued prescribing in primary care. The FIG was asked to consider whether specialist services or the GP should supply the patient with the FreeStyle Libre sensors for the duration of the six month trial.

The recommendation is now being taken though the CCGs' governance processes.

The FIG considered the proposed formulary entry and whether secondary or primary care should supply patients with sensors during the trial period. Representatives from both primary and secondary care highlighted reasons why they could not fund the sensors during the trial. A suggestion was made that the secondary care fund the sensors during the trial if the cost was refunded by the CCGs.

There was also discussion about GPs experiencing pressure from patients for the device in the first instance and continuation of the device following a trial period. The consultant present stated secondary care would take responsibility for explaining to patients the reasons why they were not eligible for the 6 month trial or continuation of the device following the trial period.

It was agreed that the MO Team would liaise with the Formulary Team and secondary care providers to consider mechanisms for transferring funding to cover the cost of specialist services supplying sensors during the 6-month trial.

ACTION: **MO Team to liaise with the Formulary Team and secondary care providers to consider mechanisms for transferring funding to cover the cost of specialist services supplying sensors during the 6-month trial.**

14. The Devon Formulary and Referral user survey report

At the end of 2017 the Formulary Team undertook a survey of users of the Devon Formulary and Referral website and App to enable the team to understand and improve user experience and satisfaction. The FIG received a report of the Devon Formulary and Referral user survey.

The survey comprised 18 questions. These broadly covered:

- The demographic area in which respondents worked and their primary job role.
- Formulary and referral use.
- General thoughts on content.
- Navigation and the search function.
- The traffic light drug classification system.
- Any additional comments respondents wished to make.

Responses were generally very positive. However a number of next steps have been identified. These include:

- Contacting the design agency to discuss functionality options that can be amended within budget; such as search function spelling errors/auto correct.
- Ask secondary care colleagues to help address issues around requests for primary care prescribing of secondary care only drugs (red drugs).
- Consideration of a FAQs page to include information about applications/reclassifications.
- Feedback to DRSS.
- Determine which trust(s) will not allow personal downloads of the app to trust supplied phones and ask if phones can be supplied with the app already embedded.
- Production of a summary report for publication.
- Quizzes updated and new ones published.

The FIG discussed the survey and results. Several suggestions were made about changes to the formulary website and app including whether search results could be condition based and identification of the top 3 reasons for use. Queries were raised as to whether education on the formulary website and app was undertaken during induction of new employees and whether this should be done as part of department meetings or if a ‘How To’ video could be included on the formulary.

15. Proposed change to process for preferred brand recommendations

The Medicine Optimisation team has put forward a proposal for a revised process for the preferred brand recommendations.

The FIG discussed the proposal. It was agreed that the formulary team and medicines optimisation team would undertake further refining of the proposed process, including secondary care contracts and pricing considerations. A trial of the process will then be undertaken.

ACTION: Formulary team and medicines optimisation team to undertake further work to refine the proposed process for preferred brand recommendations and begin trialling the process.

16. Recent drug decisions (including NICE)

The recent drug decisions were noted.

17. MRHA DRUG Safety Updates: Dec 17, Jan 18

- <u>December 2017</u>
  - Gadolinium-containing contrast agents: removal of Omniscan and iv Magnevist, restrictions to the use of other linear agents. These agents are not included in the formulary therefore no action required.
  - Cladribine (Litak, Leustat) for leukaemia: reports of progressive multifocal encephalopathy (PML); stop treatment if PML is suspected. This is a 'red' drug. No action required.
  - Radium-223 dichloride (Xofigo▼): do not use in combination with abiraterone and prednisone/prednisolone following clinical trial signal of increased risk of death and fractures. This is a 'red' drug. No action required.
  - Eluxadoline (Truberzi ▼): risk of pancreatitis; do not use in patients who have undergone cholecystectomy or in those with biliary disorders. This is a 'red' drug. No action required.
  - Fingolimod (Gilenya▼): new contraindications in relation to cardiac risk. This is a 'red' drug. No action required.
  - Fingolimod (Gilenya▼): updated advice about risk of cancers and serious infections. This is a 'red' drug. No action required.
- <u>January 2018</u>
  - Daclizumab (Zinbryta▼) and risk of severe liver injury: new restrictions to use and strengthened liver monitoring. This is a 'red drug', no action required.
  - Recombinant human erythropoietins: very rare risk of severe cutaneous adverse reactions (SCARs). Add:
    - Be aware of very rare cases of severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TENS), in patients receiving recombinant human erythropoietins (r-HuEPOs); some cases were fatal

        - more severe cases were recorded with long-acting r-HuEPOs (darbepoetin alfa and methoxy polyethylene glycol-epoetin beta)
        - advise patients of the signs and symptoms of severe skin reactions at imitation and instruct them to stop treatment and seek immediate medical attention if they develop widespread rash and blistering; these rashes often occur following fever of flu-like symptoms.
        - Discontinue all r-HuEPOs permanently in patients who develop severe cutaneous adverse reactions such as SJS or TEN.
    - Drug-name confusion: reminder to be vigilant for potential errors. No action required.
    - Co-dydramol: prescribe and dispense by strength to minimise risk of medication error. No action required.
    - Herbal medicines: report suspected adverse reactions via the Yellow Card Scheme. Add to 'Herbal treatments and homeopathy' section on formulary information page.
        - report suspected adverse reactions to herbal medicines, including traditional Chinese medicines, via the Yellow Card Scheme
        - when submitting a Yellow Card for herbal medicines, it is important to provide some extra details to help us to identify the particular product

18. Any Other Business

Change in NICE Guidance for Oral Herpes

Attending microbiologist Rob Porter noted the change in NICE guidance to recommend oral treatment in place of topical treatment. It was unclear why the change had taken place. This will be discussed at FIG at a later date.

Linezolid

Attending microbiologist Rob Porter noted that linezolid is in the South and West Devon Formulary but not in the North and East Devon Formulary. It was requested that this be added as a 'red' drug but only prescribed on the advice of microbiologists.

The Formulary Team will draft a proposed formulary entry based upon the South and West Devon Formulary entry and circulate to the microbiologists for comment.

ACTION: Formulary team to circulate a proposed formulary entry for linezolid to the microbiologists prior to bringing to a future FIG meeting.

Summary of actions

Date	Action	Lead	Status
17/40	AirFluSal MDI: consideration to be given to how the formulary and MO website can provide additional support information. Formulary Team to discuss with MO Team and Lee Dobson.	Formulary Team	Outstanding
17/51	MHRA Drug Updates: Adrenaline – Liaise with MO in East regarding the number of auto-injectors for each patient. Schools can now order and keep adrenaline. It was suggested that guidelines would be useful. Formulary Team will consider.	Formulary Team/Louise Greaves	Outstanding
17/52	MHRA Drug Updates: Adrenaline – Liaise with MO in North regarding the number of auto-injectors for each patient. Schools can now order and keep adrenaline. It was suggested that guidelines would be useful. Formulary Team will consider.	Formulary Team/ Louise Greaves	Outstanding
17/53	AOB: Invita D3 50,000IU tablets and oral solution for vitamin D deficiency paper to be brought to a future meeting. Stuart Kyle and Carol will discuss. To be added to the MO work plan.	Stuart Kyle/Mo Team	Outstanding
17/66	Formulary entry for oral nutritional supplements to be updated as per the discussion.	Formulary team	Outstanding
17/68	Antimicrobial and infections: Whether adults should receive antimicrobials for an ear infection to be established and reported back to FIG in February 2018.	Formulary Team	Outstanding
18/01	Trimbow 87 micrograms/ 5 micrograms/ 9 micrograms pressurised inhalation to be added to the formulary.	Formulary team	Complete
18/02	Alprostadil urethral sticks to be added to the formulary	Formulary team	Complete
18/03	Items which should not be routinely prescribed in primary care - agreed formulary entry for co-proxamol to be added to the formulary in line with the discussion.	Formulary team	Complete
18/04	Items which should not be routinely prescribed in primary care – formulary entry for dosulepin to be added in line with the discussion.	Formulary team	Complete

18/05	Items which should not be routinely prescribed in primary care – formulary entry for doxazosin to be added in line with the discussion in line with the discussion.	Formulary team	Complete
18/06	Items which should not be routinely prescribed in primary care – accepted entry for glucosamine and chondroitin to be added to the formulary in line with the discussion.	Formulary team	Complete
18/07	Items which should not be routinely prescribed in primary care – formulary entry for herbal treatments for menopause to be updated in line with the discussion.	Formulary team	Complete
18/08	Items which should not be routinely prescribed in primary care – create a separate formulary page section for herbal treatment and homeopathy on the formulary information page.	Formulary team	Complete
18/09	Items which should not be routinely prescribed in primary care – accepted formulary entry for homeopathic treatments to be included on the separate section on the formulary information page entitled 'Herbal Treatments and Homeopathy.	Formulary team	Complete
18/10	Items which should not be routinely prescribed in primary care – formulary entry for paracetamol and tramadol combination products to be added to the formulary in line with the discussion.	Formulary team	Complete
18/11	Items which should not be routinely prescribed in primary care – formulary entry for perindopril arginine to be added to the formulary in line with the discussion.	Formulary team	Complete
18/12	Items which should not be routinely prescribed in primary care – formulary entry for rubefacients to be added to the formulary in line with the discussion.	Formulary team	Complete
18/13	Items which should not be routinely prescribed in primary care – accepted entry for travel vaccines to be added to the formulary.	Formulary team	Complete
18/14	Items which should not be routinely prescribed in primary care – entry for trimipramine to be added to the formulary in line with the discussion.	Formulary team	Complete
18/15	UrgoClean Pad and UrgoClean Rope to be added to the formulary.	Formulary team	Complete
18/16	Tissue viability nurses to be invited to a future FIG to discuss Eclypse Border and Eclypse Border Oval dressings.	Formulary team	Complete

18/17	Cutimed® Sorbact® Gel Dressings to be added into the formulary.	Formulary team	Complete
18/18	e-FIG process to be initiated for the proposed formulary entry for compression hosiery and garments.	Formulary team	Complete
18/19	Agreed changes to the guidance on oral candidiasis to be circulated to Tom Lewis and Rob Porter.	Formulary team	Complete
18/20	Following circulation of proposed formulary guidance for oral candidiasis to consultants it will be circulated to the FIG for comment/approval via the e-FIG process.	Formulary team	Complete
18/21	Urinary tract infections – proposed formulary entry to be added to the formulary.	Formulary team	Complete
18/22	Asymptomatic bacteriuria – proposed formulary entry to be added to the formulary.	Formulary team	Complete
18/23	UTI in adults (no fever or flank pain) – formulary entry to be added to the formulary in line with the discussion.	Formulary team	Complete
18/24	Check whether there is a warning regarding C-Diff on Scriptswitch.	Carol Albury	Outstanding
18/25	Proposed formulary entry for community multi-resistant UTIs to be added to the formulary in line with the discussion.	Formulary team	Complete
18/26	Formulary entry for CA-UTI to be added to the formulary in with the discussion.	Formulary team	Complete
18/27	Proposed formulary entry for acute prostatitis to be added to the formulary in line with the discussion.	Formulary team	Complete
18/28	Proposed formulary entry for UTI in pregnancy to be added to the formulary	Formulary team	Complete
18/29	Proposed formulary entry for UTI in children to be added to the formulary	Formulary team	Complete
18/30	Changes to the choice of antibiotic for acute pyelonephritis to be highlighted to prescribing leads and include in the MO Prescribing Post Live.	Medicines Optimisation	Outstanding
18/31	Proposed formulary entry for acute pyelonephritis to be added to the formulary in line with the discussion.	Formulary team	Complete
18/32	Recurrent UTIs in non-pregnant women – additional wording for standby medication to be confirmed.	Tom Lewis	Complete
18/33	Recurrent UTIs in non-pregnant women – formulary entry to be added in line with the discussion.	Formulary team	Complete
18/34	Liaise with the Formulary Team and secondary care providers to consider mechanisms for transferring funding to cover the cost of specialist services supplying sensors during the 6-month trial.	Medicines Optimisation Team	Outstanding

18/35	Further work to be undertaken to refine process proposed for the preferred brand recommendations.	Formulary team/MO	Complete
18/36	MRHA Drug safety update for January 2018: Advice for Recombinant human erythropoietins to be added.	Formulary team	Complete
18/37	MRHA Drug safety update for January 2018: Advice for herbal medicines to be added to the 'Herbal treatments and Homeopathy' section of the formulary information page.	Formulary team	Complete
18/38	Linezolid formulary entry to be developed and brought to a future FIG meeting.	Formulary team	Outstanding