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MOTea -SAVE THE DATE!!

- ➤ Our next MOTea (webinar for PCN pharmacists) session will be on Tuesday 25th May 1-2pm. It is open to all PCN pharmacists in Frimley CCG. Information on formulary choices may be individual to Berkshire, however other information will be applicable.
- ➤ We are being joined by Cathy Macqueen, our CCG Prescribing Support Dietitian, who has been doing lots of work relating to infant feeds, their prescribing and support that can be offered to parents.
- It promises to be a really useful session and we hope you can join us. Email tim.langran@nhs.net for further information.

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A welcome note from Frimley CCG Medicines Optimisation (MO) Team

From 1st April 2021 East Berkshire (EB) CCG, North East Hants & Farnham (NEHF) CCG and Surrey Heath (SH) CCG merged to form Frimley CCG. We are still here as your Medicines Optimisation Team, advising and supporting primary care prescribing, including MOCH and our prescribing support dietitians.

We are currently reviewing and refreshing our existing policies and guidelines. These will take on the new Frimley CCG badging. We plan to expand the range of supportive documents available across the area. For now, existing NEHF CCG MO documents remain on the GP intranet here. Former East Berkshire CCG MO documents may be found on the policy and procedure pages on the Frimley CCG website here. Former Surrey Heath documents may be accessed via the PAD. Once rebadged they will be posted on the Frimley CCG website here.

The Medicines Optimisation Teams can be accessed as before. For the NEHF area these contacts are <u>here</u> and at the end of this newsletter, along with EB and SH.

The Frimley formulary has not changed and remains available here.

We plan to continue to work together with you to improve training and support available to you locally, benefiting us all. Providing good outcomes for patients through the provision of evidence based healthcare delivery (clinical effectiveness), which minimises harm (patient safety) and provides the patient with a positive, personal experience of care (patient experience), all within our available resources (cost effectiveness).

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COVID-19 RELATED GUIDANCE UPDATE

Contraindication and special warning with respect to AZ COVID-19 Vaccine

Contraindication: Patients who have experienced major venous and/or arterial thrombosis occurring with thrombocytopenia following vaccination with <u>any</u> COVID-19 vaccine should not receive a 2nd dose of COVID-19 Vaccine with the AZ vaccine.

Special warnings: Risk factors which predispose patients to clotting have not been identified. As a precautionary measure, the AZ Vaccine in patients with a history of cerebral venous sinus thrombosis or antiphospholipid syndrome should only be considered when the benefit outweighs any potential risks.

Summary: No data are currently available on the mixing of vaccines, but for those who have suffered clots after <u>any</u> 1st Covid-19 vaccine dose must not receive the AZ vaccine as the 2nd dose. Because a history of cerebral venous sinus thrombosis or antiphospholipid syndrome could be a potential risk factor, an

alternative to the AZ vaccine for the 2nd dose would be preferable. Such use would not be contraindicated, but only considered when the benefit outweighs any potential risks.

Patients should seek immediate medical attention if four or more days after vaccination they develop new onset or worsening severe or persistent headaches with blurred vision, which do not respond to simple painkillers or if they develop new symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, any neurological symptoms or signs (such as confusion or seizures) or unusual skin bruising and/or petechiae.

COVID-19 Vaccine AstraZeneca UK (publishing.service.gov.uk)

Action: Be aware of the contraindications and special warnings for the Astra Zeneca Covid-19 vaccine.

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Interim Position Statement: Inhaled budesonide for adults (50 years and over) with COVID-19

Recommendation - Inhaled budesonide is not currently being recommended as standard of care but can be considered (off-label) on a case-by-case basis for symptomatic COVID-19 positive patients aged 65 and over, or aged 50 or over with co-morbidities, in line with the published Interim Position Statement. CAS-ViewAlert (mhra.gov.uk)

Supporting Evidence - Inhaled budesonide can reduce recovery time by a median of 3 days in symptomatic COVID-19 positive patients aged 65 and over or aged 50 or over with co-morbidities. A benefit in self-reported early sustained recovery at 28 days was also identified. The analysis has not established whether budesonide can reduce hospital admissions or reduce mortality. Results — PRINCIPLE Trial; STOIC Phase 2, open label, RCT

Prescribers are asked to:

- Consider prescribing inhaled budesonide (off-label, on a case-by-case basis) for symptomatic COVID-19 positive patients in line with the published Interim Position Statement <u>CAS-ViewAlert (mhra.gov.uk)</u>, where supply allows. Prescribers will be advised if there are any national supply restrictions.
- Note that the recommended product is the Pulmicort 400 Turbohaler, studied within the PRINCIPLE
 and STOIC trials. A single inhaler should be used for a maximum of 14 days (or until the inhaler is used
 up, if sooner) with two doses, twice a day (a total daily dose of 1,600 micrograms). Please see the
 Supply section in the alert for details of alternative products.
- Note that supplementary information for patients is available here including links to video resources.

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COVID-19 vaccine Moderna

The MHRA has granted regulatory approval to the third COVID-19 vaccine. More information on the Moderna vaccine may be found <u>here</u>.

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Public Health England Vaccine Key Differences Guide-Which COVID-19 vaccine?

Public Health England has produced a guide summarising the key differences.



GUIDANCE UPDATE

Antibiotic Guidelines: SCAN MicroGuide Latest Updates

Version 4.3 (April 2021)

• Major updates to Scarlet fever as per the box below:

1st Line: phenoxymethylpenicillin 500mg po QDS for 10 days

If phenoxymethylpenicillin is not tolerated or compliance is a concern, amoxicillin 500mg po BD for 10 days can be considered as an alternative (off-label)

<u>Penicillin allergy</u>: (NICE recommend on compliance grounds) azithromycin 500mg po OD for 5 days

Or

Clarithromycin 250mg - 500mg po BD for 5 days

In pregnancy: Erythromycin 250mg - 500mg po QDS for 5 days

 Alert added to cautions section for female UTI treatment (<u>pregnant</u> and <u>non pregnant</u>) - as per BNF cautions that treatment with pivmecillinam in late pregnancy or early post natal period can cause false positives in newborn screening results for isovaleric acidaemia (and to avoid pivmecillinam until newborn screening result) and false positives in urinary glucose test (if tested for reducing substances).

Version 4.4 (April 2021)

 <u>Paediatric conjunctivitis</u> update, as per SPS and Royal College of Ophthalmologists guidance on chloramphenicol, due to boron excipients. Information has also been added to the <u>Antimicrobial</u> <u>alerts</u> section. The updated Infective Conjunctivitis (CHILDREN) guideline now reads as below:

Children under 2 years:

Chloramphenicol eye ointment 1% may be considered, however many of the products are not licensed for use in children under 2 years old.

AVOID chloramphenicol eye drops. There may be occasions where chloramphenicol eye drops are required in preference to eye ointment and no suitable alternative product exists. To support this prescribing decision, see the SPS document discussed in alert section Paediatric conjunctivitis - chloramphenicol eye preparations in children under 2 years old - last updated 30/4/21

Also see more detailed information in MHRA update, below. **Version 4.5 (May 2021)**

- Major change, the creation of a new <u>COVID-19</u> folder developed from NICE guideline 191 COVID-19 rapid guideline: managing COVID-19 and the MHRA CAS alert: COVID-19 Therapeutic Alert Inhaled Budesonide for Adults (50 Years and Over) with COVID-19.
 There are 3 sub folders within the COVID-19 folder (1. <u>Management</u>, 2. <u>Treatment</u>, 3. <u>Treatment for community-acquired pneumonia OR bacterial pneumonia secondary to COVID-19</u>).
- Major update to <u>Lyme Disease</u> page.

Action: Please take note of the major changes and safety alerts. Click on the links to take you to the updated page.

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NICE Update

<u>NICE</u> have published new or updated guidance for the month of April 2021. This month there are four guidelines and one technology appraisal that impact upon primary care.

The Chronic pain (primary and secondary) in over 16s guideline. It covers assessing all chronic pain (chronic primary pain, chronic secondary pain, or both) and managing chronic primary pain in people aged 16 years and over. Chronic primary pain is pain with no clear underlying cause, or pain (or its impact) that is out of proportion to any observable injury or disease.

The Neonatal infection: antibiotics for prevention and treatment guideline. It covers preventing bacterial infection in healthy babies of up to and including 28 days corrected gestational age, treating pregnant women whose unborn baby is at risk of infection, and caring for babies of up to and including 28 days corrected gestational age with a suspected or confirmed bacterial infection. It aims to reduce delays in recognising and treating infection and prevent unnecessary use of antibiotics.

The Postnatal care guideline. It covers the routine postnatal care that women and their babies should receive in the first 8 weeks after the birth. It includes the organisation and delivery of postnatal care, identifying and managing common and serious health problems in women and their babies, how to help parents form strong relationships with their babies, and baby feeding. The recommendations on emotional attachment and baby feeding also cover the antenatal period.

The Atrial fibrillation: diagnosis and management guideline. A summary may be found below.

The Bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia technology appraisal. This treatment recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if:

- statins are contraindicated or not tolerated,
- ezetimibe alone does not control low-density lipoprotein cholesterol well enough, and
- the company provides bempedoic acid and bempedoic acid with ezetimibe according to the commercial arrangement

It is noted that bempedoic acid with ezetimibe can be used as separate tablets or a fixed-dose combination.

Action: Clinicians should be aware of this month's new guidance and implement any necessary changes to practice.

Update to NICE Atrial Fibrillation guidelines (NG196)

NICE has published updated guidelines for the diagnosis and management of AF. The full guideline can be found here. A summary algorithm can be found here.

Some key points from the guidance:

- ORBIT score is now being recommended for assessing bleeding risk (not HAS-BLED). Access the tool here.
- Remember to review modifiable risk factors for bleeds: uncontrolled hypertension, poor INR control, alcohol consumption, anaemia and medication e.g. antiplatelets, SSRIs, NSAIDs.
- CHA2DS2-VASc score remains the tool to use to assess stroke risk:
 - o Score > 2, offer an anticoagulant
 - Males Score = 1, consider an anticoagulant
 - Males Score = 0, do not offer an anticoagulant
 - Females Score = 0 or 1, do not offer an anticoagulant
- Discuss risks and benefits of anticoagulants when they are offered
- DOACs are first choice anticoagulant
- Warfarin recommended if DOACs are contraindicated or not tolerated
- For people already stable on a vitamin K antagonist, discuss switching at their next routine appointment, taking into account time in therapeutic range (TTR).
- Review anticoagulation at least annually.
- Rate control strategy using standard beta-blocker (<u>not</u> sotalol) or a rate-limiting calcium-channel blocker should be offered as first-line treatment, unless:
 - AF has a reversible cause
 - o the person has heart failure thought to be caused by AF
 - o the person has new-onset AF
 - o the person has atrial flutter and their condition is suitable for ablation
 - o a rhythm control strategy is more suitable based on clinical judgement

Action: Please be aware of the guidance above and note that edoxaban remains first choice DOAC within the area, with dabigatran as an alternative if required.

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SAFETY

Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus

There has been a serious incident reported by BHFT (not East Berks area) regarding unrecognised clozapine induced constipation.

BHFT are working on a GP factsheet, but meanwhile they are identifying all patients prescribed clozapine. These patients may then be reviewed to see how many patients have access to laxatives. In addition, because of the lack of recognition of clozapine induced constipation, BHFT have changed the questions they ask the patient at the clinic, and now ask about type and frequency of bowel movements, aiming for 1 per day.

Constipation is reported to not be recognised by up to 50% of patients. This is because paralytic ileus, accompanied by bowel dilation reduces the ability to feel the need to pass a stool, not dissimilar to the cases described with patients with learning disability.

If constipation occurs during treatment with clozapine (Clozaril, Denzapine, Zaponex), it is vital that it is recognised and actively treated. Details of the MHRA warning can be found here. <u>Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus – GOV.UK (www.gov.uk)</u>

Advice to healthcare professionals:

- the antipsychotic drug clozapine has been associated with varying degrees of impairment of intestinal peristalsis; this effect can range from constipation, which is very common, to very rare intestinal obstruction, faecal impaction, and paralytic ileus
- exercise particular care in patients receiving other drugs known to cause constipation (especially
 those with anticholinergic properties), patients with a history of colonic disease or lower abdominal
 surgery, and in patients aged 60 years and older
- clozapine is contraindicated in patients with paralytic ileus
- advise patients to report constipation immediately
- actively treat any constipation that occurs

Action: Be aware of the advice to professionals contained within the MHRA warning (2017) and review patients as necessary.

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MHRA Drug Safety Update – April 2021

The Medicines and Healthcare products Regulatory Agency (MHRA) has published Drug Safety Update for April 2021.

Clinicians are advised of the greater risk of aspiration when polyethylene glycol (PEG)-based laxatives are thickened with a starch-based thickener. The efficacy of the thickener is reduced by the laxative so it is recommended to avoid combining these products. It may be more appropriate to use a gum-based thickener or a different laxative.

A comment from Cathy Macqueen the Prescribing Support dietitian: The majority of patients are now prescribed gum based (rather than starch based) thickeners, as per SLT recommendation. The gum based thickeners all have the word 'Clear' in their name e.g. Nutilis Clear®, Resource Thicken Up Clear® The **starch based ones do not include** 'Clear' so are more likely to be those patients still using e.g. the original 'Thick and Easy'® powder

This issue also contains an update on COVID-19 vaccines and medicines that includes information on the extremely rare risk of blood clots that are associated with the AstraZeneca COVID-19 Vaccine as well as updated information on patients who should now not receive this vaccine.

Action: Clinicians should be aware of this month's new guidance and implement any necessary changes to practice.

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Valproate Pregnancy Prevention Programme- East Berkshire Update

Valproate (Epilim, Depakote and other generic brands) is associated with a significant risk of birth defects and developmental disorders in children born to women who take valproate during pregnancy. Valproate is contraindicated in women of childbearing potential unless they meet the conditions of Valproate Pregnancy Prevention Programme and only if other treatments are ineffective or not tolerated, as judged by a specialist ('Prevent' MHRA 2018).

What are GPs' responsibilities?

GPs are responsible for ensuring continuous use of highly effective contraception in all women of childbearing potential (consider the need for pregnancy testing if not a highly effective method), checking that all patients have an up to date, signed, <u>Annual Risk Acknowledgement Form</u> each time a repeat prescription is issued, ensuring the patient is referred back to the specialist for annual review, and referring to the specialist urgently in case of unplanned pregnancy or where a patient wants to plan a pregnancy.

BHFT have set up a secure trust wide database of all women with childbearing potential who are open to any service in the Trust and are taking Valproate. The database is regularly monitored by the Medication Safety Officers who work closely with the psychiatrists to ensure all requirements of the Pregnancy Prevention Programme are met.

Action: GPs who have patients of childbearing potential on Valproate for a mental health diagnosis and are <u>not</u> already on the Pregnancy Prevention Programme and <u>not</u> seeing a specialist annually, please refer them to the Common Point of Entry in Berkshire Healthcare NHS Foundation Trust on 0300 365 2000 or email <u>gateway@berkshire.nhs.uk</u>

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Valproate Pregnancy Prevention Programme- Surrey Heath and NEHF Update

SABP PRISM (Pathway Redesign for the Improvement of Safer Valproate Medication prescribing) Project starting on 5th May 2021

As part of the Surrey Heartlands Medicines Safety Programme a multidisciplinary team from Surrey and Borders Partnership NHS Trust (SABP), local CCG representatives and the Surrey Heartlands Medicines Safety Group have been working to redesign the pathway for safer valproate prescribing for mental health conditions.

Females of child bearing age (11-55) who are prescribed valproate for a mental health condition must be enrolled in a Pregnancy Prevention Programme and have an annual review by their specialist where the Annual Risk Acknowledgment Form (ARAF) is completed.





SABP GP Referral Valproate annual form for Sod Valp S risk reviews for won

Action: If your female patient of child bearing age is taking valproate for a mental health condition and due their annual review – act now and refer them to SABP immediately using the attached referral form. Following your patient's referral, they will then be recalled annually without the need for further GP referral. The referral form will be available on DXS.

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Chloramphenicol Eye drops- impaired fertility due to boron contents

Due to an associated future risk of impaired fertility, the European Medicines Agency (EMA) has published an update to They state that all preparations containing boric acid or borates above a threshold level must include a warning in their package leaflet.

EMA threshold levels for children under 2 years old: a warning in the packaging leaflet should be included for any product with potential to result in exposure to more than:

- 1mg daily of boron; or
- 5.7mg daily of boric acid

Implications for use: any product that would result in exposure to more than 1mg daily of boron, should not be used in children under 2 years old.

Most UK manufacturers of chloramphenicol eye drop preparations have now updated their SPCs to include a warning contraindicating use in children less than 2 years old, due to boron content.

Advice from the Royal College of Ophthalmologists

- Chloramphenicol eye preparations have been widely used in children of all ages for many years with no documented adverse effects on fertility. To our knowledge there is no new scientific data from human studies to support this change to the product licence.
- There are circumstances where chloramphenicol eye drops are required in preference to eye ointment and no suitable alternative product exists. Other antibiotic eye drops may also contain boron e.g. gentamicin. Commonly available non-boron containing products suitable for young children, such as fusidic acid and azithromycin, have a much narrower spectrum of activity compared to chloramphenicol, and may not be a suitable replacement in some cases. Use of quinolone or broad-spectrum cephalosporin drops (some of which contain no boron) should be reserved for severe eye infections such as keratitis and endophthalmitis to maintain their effectiveness and not used routinely for simple bacterial conjunctivitis.
- Most manufacturers do not list boron content for their products but those that do give a range of 1.1mg/ml-2.9mg/ml. Given that the maximum volume that can be accommodated in the conjunctival sac is between 10-20µL, a typical regime of one drop to either eye four times daily would result in a daily exposure well below 1mg/day, even if 100% absorption is assumed.
- It is unlikely that formulations of boron-containing eye drops will be changed to remove boron in the near future.
- Antibiotic stewardship remains of primary importance to the College. There is a risk that avoiding all
 use of antibiotic eye drops with boron-containing excipients in children will result in increased
 prescribing of second or third-line antibiotics and encourage the development of microbial resistance.

Action: Please be aware of the new safety advice on chloramphenicol eye drops in the under 2 year olds. And read the <u>SCAN</u> update above.

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Steroid Emergency Card- Action by 13th May 2021

A reminder that the National Patient Safety Alert: Steroid Emergency Card to Support Early Recognition and Treatment of Adrenal Crisis in adults should be implemented by May 13th 2021. The full alert may be read <u>here</u>.

<u>Prescqipp</u> have produced resources to support pharmacists implement this in primary care. Please register with Prescqipp to access this information which you will find under the Hot topics section> Implementing the NHS Steroid Emergency Card National Patient Safety Alert, there you will find searches, PIL, PIL protocol for EMIS and the Hot topic document.

In East Berkshire, searches will also be found in the East Berkshire Reporting folder> MOT> MOT general>May 2021 Prescribing Newsletter.

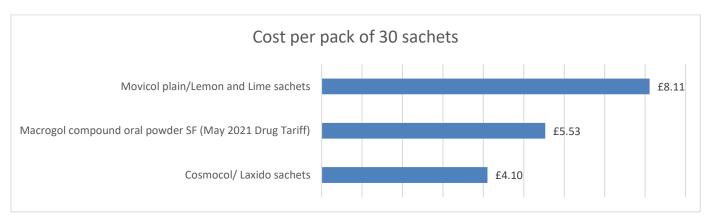
Action: Implement the Patient Safety Alert if you have not already done so.



SAVINGS

Cosmocol®/ Laxido® sachets

Prescribing Laxido® or Cosmocol® instead of macrogol compound oral powder or Movicol is significantly better value by approximately £50 per patient per year, based on the dose, one sachet per day.



Action: Use the better value brands. Perform a G/T switch to macrogol compound oral powder and G/T switch to Laxido[®] and Cosmocol[®].

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MEDICINES OPTIMISATION BOARD UPDATE

Frimley CCG Good Practice Guidance: Repeat medication ordering using Proxy Access in Care Homes

The guidance document written for use by care home staff was noted and agreed to adopt. A copy of the document has been made available to care homes and will be uploaded onto the Frimley CCG website in due course.

Action: For information. Contact your MOCH pharmacist contact for a copy.

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Frimley CCG Medicines Optimisation Position Statement: Adrenaline Autoinjectors

The former position statements from the 3 organisations, SH, EB and NEHF have been merged and rebadged for Frimley CCG. Prescribers are advised to supply no more than 2 adrenaline packs to an individual.

Action: Please follow the guidance in the position statement. This will be uploaded onto the frimley website in due course.

Joint Catheter Formulary Surrey Heath and North East Hants and Farnham Updated April 2021

The joint catheter formulary has now been updated by the medicines optimisation team in conjunction with the urology nurse specialist Frimley Health NHS Foundation Trust and local community continence nurse specialists. In addition to the formulary choices for catheters, leg bags and associated products the document also includes updates on key prescribing points, information on recommended quantities to be prescribed and a catheter care action plan.



Action: Relevant to NEHF and SH places only.

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Vigranon B liquid change to "non-formulary" status

In line with the OTC policy, it was agreed to remove <u>Vigranon B[®]</u>, a liquid vitamin B product, from the Frimley Formulary.

Action: For information.

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SUPPLY ISSUES

Elleste Solo MX® 40 and 80 transdermal patches - being discontinued

- Elleste Solo MX[®] 40 and 80 transdermal patches are being discontinued and remaining supplies are expected to be depleted by October 2021 and July 2021, respectively.
- Alternative brands of estradiol transdermal patches of different strengths remain available

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Estradot® 75micrograms/24 hours patches- out of stock

- Estradot® 75micrograms/24 hours patches are out of stock until w/c 31 May 2021.
- Evorel® 75 patches and Estraderm MX 75® patches remain available and can support an increase in demand (each patch contains 75micrograms of estradiol).
- Please note that a Serious Shortage Protocol was issued on 29/04/2021, which provides
 pharmacists with procedures to follow in providing either Evorel® 75 or Estraderm MX 75® instead
 and thereby help reduce the number of patients having to return to their prescriber for a
 replacement prescription for Eastradot®

For prescriptions (NHS or private) requesting:	Supply permitted under SSP012:
Estradot® 75 microgram patches	Evorel [®] 75 microgram patches OR Estraderm MX [®] 75 microgram patches

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Medicines Optimisation in Care Homes (MOCH) Corner

Keeping Care Homes Up to date with the PEG laxatives and starched-based thickeners Safety Update April 2021

The MHRA's Drug Safety Update for April 2021 has highlighted an increased risk of aspiration in patients with dysphagia when a polyethylene glycol (PEG) laxative (e.g. Movicol™, Macrogol 3350, Laxido™ and Moviprep™) is added to a liquid, which has been thickened with a starch-based thickener (e.g. Thick & Easy™).

Constipation and dysphagia co-exist more commonly in the elderly and in those with disabilities that affect swallowing. Many care home residents are often prescribed both PEG laxatives and thickeners. Addition of a PEG laxative to a liquid that has already been thickened with a starch-based thickener counteracts the thickening action - resulting in a mixture that is thin and watery, so increasing the risk of aspiration, which can be life threatening.

Co-administration of the above is potentially harmful for patients with dysphagia. Care home staff must be informed of these risks and to avoid directly mixing together PEG laxatives and starch-based thickeners to reduce any potential risks in this vulnerable group of patients.

The Frimley CCG Medicines Optimisation in Care Homes (MOCH) team have communicated this alert to the Care Homes in the Frimley ICS MOCH Care Homes Newsletter this month.

For any care home residents who require a PEG laxative to be administered with a thick liquid consistency, a gum based thickener e.g. Nutilis Clear™ or Resource® ThickenUp® Clear should be prescribed or clinically appropriate alternative laxative. Gum based thickeners are recommended first line and should be initiated following referral and advice from a Speech and Language Therapist (SLT).

The MHRA has requested that manufacturers of UK PEG laxative products should add information about the interactive effect to the Summary of Product Characteristics and the Patient Information Leaflet. All suspected adverse drug reactions (ADRs) should be reported through the <u>Yellow Card Scheme</u>.

Action: For information and review any care home patients on PEG laxatives co-prescribed with a starch-based thickener.

East Berkshire MO Team

King Edward VII Hospital, St Leonards Rd, Windsor SL4 3DP
Main office phone number 01753 636845
Generic in box email: eastberksccg.prescribing@nhs.net

	Mobile	E: mail
Catriona Khetyar	07500 606169	catriona.khetyar@nhs.net
Director of Medicines Optimisation		
Tim Langran	07775 010727	tim.langran@nhs.net
Place Lead Medicines Optimisation		
Pharmacist Slough		
Melody Chapman	07826 533736	melody.chapman@nhs.net
Place Lead Medicines Optimisation		
Pharmacist Bracknell		
Dawn Best	07825 691163	dawnbest@nhs.net
Place Lead Medicines Optimisation		
Pharmacist Windsor, Ascot & Maidenhead		
Caroline Pote	07824 476439	caroline.pote@nhs.net
Medicines Optimisation Pharmacist		
Pharmacist		
Caroline Hailstone	07768 020809	caroline.hailstone@nhs.net
Medicines Optimisation Pharmacist		
Cathy Macqueen	07825 437041	catherine.macqueen@nhs.net
Medicines Optimisation Dietitian (Part time)		
Care	Home Team (MOCH)	
Sundus Jawad	07909 505658	sundus.jawad@nhs.net
ICS Lead Medicines Optimisation Care		
Homes (MOCH) Pharmacist		
Sally Clarke	07747 007934	sally.clarke6@nhs.net
Medicines Optimisation Care Homes (MOCH)		
Pharmacist		
Dhara Thacker	07776244842	dhara.thacker2@nhs.net
Medicines Optimisation Care Homes (MOCH)		
Pharmacy Technician		

North East Hants and Farnham MM Team

Aldershot Centre for Health, Hospital Hill, Aldershot, Hants GU11 1AY

Main office phone number 01252 335160 (not currently monitored during pandemic remote working)

Generic in box email: NEHFCCG.medicinesmanagement@nhs.net

	Mobile	E: mail
ennie Fynn	07795 857584	jennifer.fynn@nhs.net
Associate Director of Medicines		
Optimisation		
Sarah Ellis-Martin	07717 779366	sarah.ellis-martin@nhs.net
Place Lead Medicines Optimisation		
Pharmacist NEHF		
(covers Aldershot and Fleet practices)		
Sarah Sneath	07833 094102	sarah.sneath@nhs.net
Medicines Optimisation Pharmacist		
(covers Farnborough practices)		
Clare Carter	07584 204875	clare.carter3@nhs.net
Medicines Optimisation Pharmacist		
(covers Farnham and Yateley practices)		
Simon Smith	07795 335076	simon.smith22@nhs.net

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Medicines Optimisation Pharmacy Technician		
Laura Sexton Medicines Optimisation Dietician	07423 238239	laura.sexton@nhs.net
Alison Carr Medicines Optimisation Dietician	07342 067927	a.carr@nhs.net
	Care Home Team	
Simi Mudhar Medicines Optimisation Care Homes Pharmacist	07425 634218	s.mudhar@nhs.net
Zoe Lewis Medicines Optimisation Care Homes Pharmacy Technician	07774 334737	zoe.lewis9@nhs.net

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Surrey Heath MM Team			
Surrey Heath House, Knoll Road, Camberley, Surrey, GU15 3HD			
	Mobile	E: mail	
Leena Nanavati Primary Care Pharmacist (including support to Care Homes)	07917 211006	leena.nanavati@nhs.net	
Naeed Hussain Primary Care Pharmacist	07595 087855	naeed.hussain@nhs.net	
Noreen Devanney Primary Care Pharmacist	07894 599647	noreen.devanney@nhs.net	
Dr Nicky Townsend Clinical Prescribing Lead	07894 209111	nickytownsend@nhs.net	

OTHER USEFUL CONTACT DETAILS

Controlled Drugs Accountable Officer (CDAO): CDAO (Julie McCann) can be contacted via england.southeastcdao@nhs.net, noting that all general CD concerns, incidents and authorised witness requests should always be raised via www.cdreporting.co.uk. For non-CD medicines safety issues, use julie.mccann3@nhs.net