EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST

NEW DRUG AND INTERFACE GROUP

MINUTES OF THE MEETING HELD ON WEDNESDAY 10th AUGUST 2016
IN PINK ROOM, GROUND FLOOR, B BLOCK, ST HELIER HOSPITAL

Present:
Dr S Patel (Chair) **SP**
Dr P O'Mahony (Consultant Stroke Physician) **PO**
Dr V De Silva (Consultant Nephrologist) **VDS**
Dr L Mulleaue (Consultant Anaesthetist) **LM**
Anne Davies (Chief Pharmacist) **AD**
Sharon Kitcatt (Consultant Nurse – Acute Pain Service) **SK**
Dr R Scott (Joint Medicines Management Lead – GP Sutton CCG) **RS**
Niel Kenny (Senior Primary Care Pharmacist, Sutton CCG) **NK**
Clare Johns (Lead Commissioning Technician, Surrey Downs CCG) **CJ**
Anne Lowson (Secretary) **AL**

In attendance:
Vanya Slavova Boneva (Medicines Management Pharmacist) **VSB**
Susie Strange (Administration Coordinator) **SS**
Sophie Bye (Senior Primary Care Pharmacist, Sutton CCG) **SB**
Dr Noreen Cowley (Consultant Dermatologist) **NC**
Dr Angela Tewari (Senior Registrar, Dermatology) **AT**

No	Item	Responsible for Action
1.	**Apologies for Absence** Dr A Mahmood (Consultant Gastroenterologist) **MH** Dr R Shephard (Consultant Neonatologist) **RS** Dr M Gardner (Consultant Anaesthetist) **MG** Susie Mallinder (Lead Renal Nurse) **SM** Dr A Pitsiaeli (GP, Surrey Downs CCG) **AP** Liz Clark (Lead Commissioning Pharmacist, Surrey Downs CCG) **LC** Sarah Taylor (Chief Pharmacist, Sutton CCG) **ST** Sumbo Adeyemo (Medicines Management Pharmacist) **SA**	
2.	**Declarations of Interest** Nil declared for this meeting. No declarations of interest declared from the new drug presenters.	
3.	**Minutes of the Meeting held on the 15th June 2016** Page 3 Change Surrey PCN to PCN as area covered is not just Surrey. VDS requested a copy of the draft minutes when documented rather than just prior to the meeting.	**SS** **SS**
4.	**Matters Arising**	
a)	**Ranibizumab Switching Policy** AD has requested Michelle Barnard arranges a meeting with Mr Saeed to finalise this work.	**AD**
b)	**SWL - Pathway for Melatonin** Agreed with Sutton and Merton CCG's that the Trust will adopt the SWL & St George's Mental Health Trust shared care document. This will allow shared care of the melatonin tablets but no the liquid currently. Discharge from the service	

	and how patients may be able to obtain liquid preparations from GP's in future to be discussed as a separate issue.	**AL/NK**
5.	**New Drug Requests**	
a)	**Levosimendan for short term maintenance of cardiac output (Orion Pharma)** Levosimendan injection requested by Dr Beaumont as an alternative or adjunctive agent to dobutamine/milrinone or mechanical support in patients with low cardiac output with: • myocardial stunning with decreased organ perfusion • acute decompensated chronic heart failure with reversible cause • bridging therapy prior to a definitive surgical procedure • undesirable adverse effects due to dobutamine therapy LM presented the case (as Dr Beaumont was not available) explaining it is a calcium sensitizing agent that increases myocardial contractility without significantly increasing oxygen consumption or affecting diastolic function. Dobutamine would remain first line as levosimendan is currently unlicensed in the UK. It would be used as a single dose 24 hour infusion which produces prolonged haemodynamic effects for up to 7-9 days. The evidence suggests improved survival in certain patient cohorts with low cardiac output secondary to acute decompensation of heart failure (ADHF) cardiac surgery or in profound sepsis. A protocol for use would be required and it may be possible to adapt Guys and St Thomas' document with their agreement. Concern was expressed regarding hypotension when patients are transferred out of intensive care to ward areas and this should be included in the protocol. **Decision** The committee agreed the addition of levosimendan injection (unlicensed medicine) to the Trust formulary subject to the development of a Trust protocol which includes statements to address interface issues on transfer to ward areas. Dr Al-Subaie (Clinical Lead) to be approached to ensure there is support across the division.	**Sonia Moore**
b)	**Metaraminol a peripheral vasopressor to support BP (Torbay & South Devon NHS Foundation Trust)** LM presented the case on behalf of Dr Beaumont explaining metaraminol is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has both alpha and beta-adrenergic activity, the former being predominant and is used to treat acute hypotension due to loss of vasoconstrictor tone e.g. during spinal anaesthesia. The Trust have used phenylephrine as the peripheral vasopressor of choice in patients with hypotension refractory to other measures as there was no licensed version of metaraminol. However there is now a licensed version of metaraminol which is currently less expensive than phenylephrine. There are a small number of studies showing that metaraminol can be used peripherally as a vasopressor agent and efficacy appears similar to phenylephrine. Anaesthetists often come from other local hospitals and it may be safer to have a drug that they have used elsewhere to use in the emergency situations. It was recognised that there would be an ODA training issue to address and that there have been availability issues with phenylephrine injection but these are not current. **Decision** The committee felt there was no major advantage in terms of efficacy and that the Trust should have a 'centre approach' and ensure all staff are familiar with the use of phenylephrine for the treatment of acute hypotension due to loss of	

	vasoconstrictor tone. If supply issues occur with phenylephrine this decision will be reconsidered.	**Sonia Moore**
c)	**Ivermectin 1% Cream for inflammatory lesions of rosacea (Galderma (UK) Limited)** Dr Cowley presented the case for the use of ivermection cream for the topical treatment of inflammatory lesions of rosacea (papulopustular) in adults. The topical treatments for this condition are limited to metronidazole and azelaic acid (AZA). NICE have recently produced an evidence summary which advises it was better than vehicle cream alone in terms of reduction in lesions and superior to metronidazole 0.75% cream. Other studies have shown that it is better tolerated than AZA 15% gel. It was recognised that studies have been supported by the manufacturer. It is applied once daily rather than twice daily for metronidazole cream and this should be considered in terms of compliance and when looking at the increased cost of a tube compared with metronidazole cream. It has the potential to reduce the use of systemic antibiotics in patients who are currently failing topical treatments. Treatment is used for up to 4 months and the course can be repeated. If there is no improvement after 3 months treatment should be stopped. Dr Cowley felt GP's could be involved in treatment with this medication and provide repeat courses if required. GP information would be required around response and when to consider another course in the discharge letters. Dr Cowley advised ivermectin would be used after treatment with topical metronidazole had failed and in moderate to severe rosacea only. **Decision** To agree to the addition of ivermectin 1% cream to the formulary for moderate to severe rosacea (papulopustular) in adults after treatment with topical metronidazole cream has failed. Treatment success criteria and information regarding repeat courses to be documented in GP letters. It was noted that the PCN discuss the drug next month therefore decision awaited.	**VBS**
d)	**Clindamycin 1% and Tretinoin 0.025% gel for acne (Meda Pharmaceuticals)** Dr Tewari presented the case for Treclin® which is a combination gel containing clindamycin and tretinoin for treatment of acne vulgaris when comedones papules and pustules are present in patients 12 years or older. There are several treatment guidelines for acne and generally antibiotic and retinoid topical preparations are used 2nd line for moderate acne with comedones papules and pustules present. The data comes from a Canadian product equivalent to Treclin®. It has low levels of skin irritation possibly because it is a water based gel. Tolerability of any treatment is important as it affects compliance. A direct comparison with clindamycin plus benzoyl peroxide (similar to Duac®) suggested this combination may be more effective than the individual components in Treclin® applied separately. Studies have shown that Treclin® is more effective than its individual components. An indirect comparison with Epiduo® showed similar efficacy with Treclin® but Treclin® was better tolerated. There is no published comparison with Isotrexin® (isotretinoin/erythromycin). Treclin® is cheaper than Epiduo® and Duac® but neither alternative are currently on the Trust formulary although felt to be used in primary care. There may be benefits in reviewing the formulary options overall and Dr Cowley agreed this would be useful. Consider also linking with microbiology with regards to use of topical antibiotics. **Decision**	

	To add clindamycin 0.1% and tretinoin 0.025% gel Treclin® to the Trust formulary for use in treatment of acne vulgaris when comedones papules and pustules are present in patients 12 years or older. Review of formulary options for treatment of acne to be done in conjunction with Dr Cowley and primary care. Links to be made with microbiology regarding the use of topical antibiotics treatments.	**SA**
6.	**Six Month New Drug Reviews** Nothing for this meeting.	
7.	**NICE Guidance**	
	Updates	
a)	**Updated - Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease – TA217** Awaiting response from CCG's with regards to commissioning.	**LC/NK/ST**
	Technology Appraisals Updated	
b)	**Updated - Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen – TA259** TA259 re-issued after a change to the commercial arrangements. On formulary following initial publication.	**AL/SS**
c)	**Updated - Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated – TA387** Abiraterone will be added to the Trust formulary in line with this NICE TA, however as these patients would not be initiated on treatment by the Trust it will only be available for patients admitted to the Trust already on treatment.	**AL/SS**
	Technology Appraisals for Discussion	
d)	**Adalimumab for treating moderate to severe hidradenitis suppurativa – TA392** The dermatologists do have a small number of patients who are reaching the limits of conventional therapy and may be suitable for treatment with adalimumab. Funding via specialist centres only.	
e)	**Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia – TA393** These agents will be added to Trust formulary for initiation by the lipid specialists only. Currently the Trust is obtaining free of charge stock which CCG's have supported. Homecare options for these preparations to be reviewed. Funding via Blueteq forms to CCG's.	**AD**
f)	**Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia – TA394** These agents will be added to Trust formulary for initiation by the lipid specialists only. Currently Trust obtaining free of charge stock which CCG's have supported. Homecare options for these preparations to be reviewed. Funding via Blueteq forms to CCG's.	**AD**
g)	**Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer – TA395** Ceritinib to be added to the Trust formulary for patients admitted on treatment only as treatment would not be initiated by the Trust.	**AL/SS**
h)	**Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma – TA396** These agents will be added to the Trust formulary for patients admitted on treatment only as treatment would not be initiated by the Trust.	**AL/SS**
i)	**Belimumab for treating active autoantibody-positive systemic lupus erythematosus – TA397** Belimumab to be added to the Trust formulary for treatment of active	

	autoantibody-positive systemic lupus erythematosus. Patient numbers are small and need to consider place in therapy relative to rituximab. Currently the rheumatologists are not routinely using the listed activity score Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI).	**AL/SS**
j)	**Nivolumab in combination with ipilimumab for treating advanced melanoma – TA400** To be added to the Trust formulary for use by patients already on treatment. The Trust will refer patients to the Royal Marsden Hospital for initiation if appropriate.	**AL/SS**
	Technology Appraisals Not Recommended	
k)	**Lumacaftor–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation – TA398** Not recommended for use currently.	
l)	**Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts – TA399** Not recommended for use currently.	
	Clinical Guidelines Updated	
m)	**Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures – CG64** This clinical guideline will be discussed at the Trust's Antimicrobial Steering Group.	**Donna Francis**
n)	**Cardiovascular disease: risk assessment and reduction, including lipid modification – CG181** Amended to clarify the advice on saturated and monosaturated fat. Dr Wilcox advised Trust are working with GP's to implement this guidance.	
o)	**Type 2 diabetes in adults: management – NG28** Reworded to clarify the role of the GP's in referring people for eye screening.	
p)	**Type 1 diabetes in adults: diagnosis and management – NG17** Reworded to clarify the role of the GP's in referring people for eye screening.	
q)	**Familial hypercholesterolaemia: identification and management – CG71** Trust lipid clinicians aware of the guidance. Ezetimibe and statins available in Trust formulary.	
	Clinical Guidelines for Discussion	
r)	**Non-alcoholic fatty liver disease (NAFLD): assessment and management – NG49** Gastroenterologists response awaited.	**AL**
s)	**Cirrhosis in over 16s: assessment and management – NG50** Gastroenterologists response awaited.	**AL**
t)	**Sepsis: recognition, diagnosis and early management – NG51** This guideline links to the Trust CQUIN being led by Dr Clark. Crisis team may also be able to support implementation.	
u)	**Non-Hodgkin's lymphoma: diagnosis and management – NG52** The haematologists have advised that not all subtypes have been discussed and some of the newer treatments being reviewed for NICE TA's not included e.g. bendamustine and ibrutinib. Funding for rituximab for asymptomatic patients with advanced stage follicular lymphoma to be clarified. They support the discharge of patients in complete remission for 3 years after treatment of diffuse large B cell non-Hodgkins lymphoma.	
	Quality Standard for Information	
v)	**Bronchiolitis in children – QS122**	

	To seek the views of Dr Kundu on these quality standards.	**AL**
w)	**Diabetes in children and young people – QS125** To seek the views of Dr Kundu on these quality standards.	**AL**
x)	**Motor neurone disease – QS126** Neurologists aware of this QS and no additional formulary drugs required.	
	MHRA Guidance	
y) **z)**	**June 2016** **July 2016** The relevant sections of the guidance have been circulated to Trust clinicians.	
8.	**Patient Safety Alert** Nothing for this meeting.	
9.	**Operational Issues**	
a)	**3M Tegaderm IV securement dressing for central venous and arterial catheter insertion sites** No update for this meeting.	**AD**
b)	**Anticoagulant Cards for Patients on DOAC's** There is a need for a single standardised anticoagulant patient safety card that is recognised by all healthcare professionals across South London and Surrey. This document could be used as part of the implementation plan once finalised. The project has been supported by the stroke physicians, haematologists and cardiologists. The committee supported the principal and use of the anticoagulant cards which if used for DOAC's would need an entry stating 'not required for this drug' in the therapeutic range (INR) box. Small typographical errors will be corrected. Once final version available this will be circulated with a supply of the cards.	**AL/SS**
c)	**Referral to Allergy Clinic** These guidelines have been written by the immunologists and circulated via the GP liaison network. GP's have found the document useful however there are some drugs listed which are not currently on the Trust formulary e.g. desloratidine or are being used off label e.g. montelukast and ranitidine. Dr Bansal is happy to discuss and will forward national guidelines/key references to the committee. Update at next meeting. Document currently removed from the Trust website.	**AD/AL**
d)	**NSTE-ACS Risk Stratification and Management Guideline** These guidelines have been previously discussed and concern raised by Surrey Downs CCG over the place in therapy of ticagrelor and whether it is appropriate for eGFR to be used as a risk factor. The place in therapy of ticagrelor is now supported by the CCG's and agreed appropriate to use eGFR as a risk factor rather than CrCl. Document agreed.	**AL**
e)	**Regional Medicines Optimisation Area Prescribing Committees** AD provided an update on the plans for the implementation of Regional Medicine Optimisation Committees (RMOC's) which aim to reduce duplication of effort, improve uptake of biosimilars, implementation of dose banded chemotherapy, licensed medicines for unlicensed indications and support the decommissioning of outdated medicines. Currently it is not clear how the work programme will be decided or the exact membership. The work will be divided between the 4 regions (RMOC – North, South, Midlands and East and London). RMOC outputs will be advisory not mandatory. There will be formal consultation over the summer and all Trust and CCG members are encouraged to input into this.	**ALL**
10.	**Feedback from CCGs and Trust Committees**	

a)	**<u>Respiratory Working Group</u>** The aim the Respiratory Working Group (RWG) has been to try and get clarity around the devices the local health economy will support. Sutton CCG have been doing work on patient pathways and trying to clarify the place of the inhalers with Dr Medvescky. This work will take into consideration the Trust documents agreed at the RWG although greater detail may be provided with regards to patient management. A further meeting of the Surrey working group is planned for late September and Trust clinicians and pharmacists have been invited.	
b)	**<u>DOAC's</u>** **I. DVT/PE** This DVT/PE pathway has been devised by Dr Appiah-Cubi and is supported by the Trust MMC. Dr Stern has raised one concern regarding the wording on the 'offering choice of anticoagulation with' and the proposal is to amend this to: Dalteparin (for at least 5 days) and warfarin OR Dalteparin alone for the whole period of anticoagulation OR This will be confirmed with Dr Appiah-Cubi on her return from leave and the final version of the document circulated to the committee. **II. Atrial Fibrillation (South London Documents)** The committee discussed the general issues over the documentation and communication across the interface. St George's have all DOAC's with the initiation and transfer of care documents managed by the anticoagulant team. This will be raised again with Dr Appiah-Cubi but it was recognised this is resource dependant. The calculator for the $CHA_2DS_2VAS_c$ score and HASBLED score have been removed from the forms to allow prescribing information on all four currently marketed DOAC's to be included. Request made to see if these can be added to the Trust intranet. The committee agreed the: • Position statement for prevention of atrial fibrillation (AF) related stroke 16/17. • Prescribing information for apixaban, edoxaban, rivaroxaban and dabigatran for stroke prevention in (non-valvular) AF. • Screening checklist and notification of initiation to GP and the transfer of prescribing responsibility forms for DOAC's in (non-valvular) AF. **III. Acute Coronary Syndrome (South London Documents)** The committee discussed the general issues over the documentation and communication across the interface. As stated above St George's have all DOAC's with the initiation and transfer of care documents managed by the anticoagulant team. This will be raised again with Dr Appiah-Cubi but it was recognised this is resource dependant. The committee agreed the: • Prescribing information for rivaroxaban for acute coronary syndrome (ACS). • Screening checklist and notification of initiation to GP and the transfer of prescribing responsibility forms for DOAC's in acute coronary syndrome (ACS).	**AL/SS**
c)	**<u>South London Cardiovascular Medicines Working Group</u>** **I. Terms of Reference** Terms of reference for information but this is supported by the committee.	
d)	**<u>SWL Sutton & Merton CCG's</u>**	

	I. Minutes – May 2016 For information. **II. South London Algorithm for Lipid Management for the Primary and Secondary Prevention of CVD** Awaiting the final version of this document which will be discussed at a future meeting. **III. 2017 18 SWL Care Pathway – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis** **IV. 2017 18 SWL Care Pathway – Psoriatic Arthritis** **V. 2017 18 SWL Care Pathway – Rheumatoid Arthritis** These pathways have been supported by the Trust Rheumatologists and were supported by the committee.	
e)	**<u>Surrey Prescribing Clinical Network</u>** **I. Minutes – June 2016** **II. Minutes – July 2016** For information. **III. Treatments for Erectile Dysfunction (updated at PCN on 6th July 2016)** The Trust Urologists are aware of this document and have supported the erectile dysfunction treatment pathway. Regular once daily tadalafil continues to be considered black on the traffic light system. **IV. Spiolto Respimat® (tiotropium 2.5 micrograms (LAMA)/olodaterol 2.5micrograms (LABA) for the treatment of chronic obstructive pulmonary disease (COPD)** The Trust support Spiolto Respimat® as an option for the treatment of COPD**.** **V. Striverdi Respimat® (olodaterol 2.5micrograms (LABA)) for the treatment of chronic obstructive pulmonary disease (COPD)** The Trust have not yet reviewed Striverdi Respimat® but it is on the work schedule for the Respiratory Working Group. **VI. Midodrine (Bramox®) for the treatment of orthostatic hypotension due to autonomic dysfunction** The Trust cardiologists and care of the elderly consultants support this statement. **VII. Sacubitril/Valsartan (Entresol®) for treating symptomatic chronic heart failure with reduced ejection fraction** The Trust cardiologists support this statement and are working together with the CCG's to develop an implementation plan which will include the use of notification of initiation and transfer of care forms. **VIII. Anoro Ellipta® (umeclidinium/vilanterol) combination inhaler to relieve symptoms in adults with COPD*(To replace PCN 173-2015)*** The Trust support Anoro Ellipta® as an option for the treatment of COPD**.** **IX. Duaklir Genuair® (formoterol fumarate dihydrate/aclidinium bromide) combination inhaler to relieve symptoms in adults with COPD *(To replace PCN174-2015)*** The Trust support Duaklir Genuair® as an option for the treatment of COPD**.** **X. Ultibro® Breezhaler (indacaterol/Glycopyrronium) combination inhaler to relieve symptoms in adults with COPD *(To replace PCN 175-2015*)** The Trust support Ultibro® Breezhaler as an option for the treatment of COPD**.** **XI. Ciclosporin (Ikervis®) eye drops for the treatment of severe keratitis in adult patients with dry eye disease that has not**	

	improved despite treatment with artificial tears The ophthalmologists support the use of Ciclosporin 0.1% (Ikervis®) however the formulary will continue to have Ciclosporin 0.05% - for patients unable to tolerate higher strength preparation. Supplies for the lower strength will be hospital only prescription. **XII. Dymista (azelastine hydrochloride/fluticasone propionate) Nasal Spray for perennial and seasonal allergic rhinitis (12 years and over)** The Trust have received a request to review the formulary status of Dymista which will be considered at a future meeting. **XIII. Guanfacine (Intuniv) for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old** This medication will be initiated and maintained by specialists in Surrey & Borders Partnership NHS Foundation Trust until review. **XIV. Spondyloarthritis Biologic Drug Treatment Pathway (NICE TA383)** The Trusts Rheumatologist support this pathway for Surrey patients.	
11.	**Any Other Business** Sutton CCG sought suggestion on how the patients who have been recommended or started on vitamin B12 for chronic fatigue by the immunologists should be managed following its rejection by the NDAIG meeting recently. It was felt patients should be assessed individually and managed in primary care or referred back to the chronic fatigue clinic as appropriate.	
12.	**Date of Next Meeting:** Wednesday 12th October 2016, 12.30-2.00pm, Boardroom, Ground Floor, Rowan House, Epsom Hospital.	