

JOINT FORMULARY COMMITTEE (JFC) – MINUTES
Minutes from the meeting held on 2 June 2020

Present:	Dr R Sofat	NCL JFC Chair	(Chair)
	Dr M Kelsey	WH, DTC Chair	
	Ms G Smith	RFL, DTC Chair	
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Mr P Gouldstone	Enfield CCG, Head of Medicines Management	
	Mr A Dutt	Islington CCG, Head of Medicines Management	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	
	Dr K Tasopoulos	NMUH, DTC Chair	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Dr A Sell	RNOH, DTC Chair	
	Ms R Clark	Camden CCG, Head of Medicines Management	
	Ms P Taylor	Haringey CCG, Head of Medicines Management	
	In attendance:	Mr A Barron	NCL MEP, Project Lead
Ms M Kassam		NCL JFC, Support Pharmacist	
Mr G Grewal		NCL JFC, Support Pharmacist	
Ms SY Tan		NEL, Commissioning Pharmacist	
Ms S Amin		UCLH, Formulary Pharmacist	
Ms A Fakoya		NEL, Senior Prescribing Advisor	
Ms H Thoong		GOSH, Formulary Pharmacist	
Mr D Abdulla		NMUH, Critical Care and Formulary Pharmacist	
Dr P Bodalia		UCLH, Principal Pharmacist	
Mr J Hartwell		UCLH, Formulary Pharmacist	
Ms P McCormick		WH, Lead Pharmacist Integrated Medicine	
Mr J Flor		WH, Formulary Pharmacist	
Ms Ai-nee Lim		WH, Antimicrobial Pharmacist	
Dr N Harper		WH, Consultant Anaesthetist	
Apologies:	Dr P Taylor	NCL CCG, GP Clinical Lead for Evidence-Based Interventions	
	Mr C Daff	Barnet CCG, Head of Medicines Management	
	Ms L Reeves	C&I, Chief Pharmacist	
	Mr S Semple	MEH, Chief Pharmacist	
	Ms K Delargy	BEH, Deputy Chief Pharmacist	
	Dr A Bansal	Barnet CCG, GP Clinical Lead Medicines Management	
	Prof A Tufail	MEH, DTC Chair	
	Mr A Shah	RNOH, Chief Pharmacist	
	Mr S Tomlin	GOSH, Chief Pharmacist	
	Mr A Shah	RNOH, Chief Pharmacist	
	Mr T Dean	Patient Partner	
	Dr A Stuart	Camden CCG, GP Clinical Lead Medicines Management	
	Mr S Richardson	WH, Chief Pharmacist	

2. Meeting observers

The Chair welcomed Dr Harper (WH, Consultant anaesthetist), Ms A Lim (WH, Antimicrobial Pharmacist) and Dr Taylor (NCL CCG, GP Clinical Lead for Evidence-Based Interventions) as observers of the meeting.

3. Matters arising

4. Nebulised prostacyclin (iloprost or epoprostenol) for respiratory failure

The NCL position statement on the use of prostacyclin in ARDS has been updated to reflect the recommendation made in the NHSE 'Clinical guide for the management of critical care for adults with COVID-19 during the coronavirus pandemic'. A clinical trial to investigate the effectiveness of pulmonary vasodilators for COVID-19 associated ARDS is still encouraged.

5. Members declarations of conflicts of interest

Dr Sell informed the Committee of a declaration of interest in Gilead; the Committee did not consider the declaration to impact the outcome of the remdesivir application.

6. New Medicine Reviews

6.1 EAMS: Remdesivir

The Committee considered an Early Access to Medicine Scheme for remdesivir for the treatment of hospitalised adults or adolescents with suspected or laboratory-confirmed SARS-CoV-2 infection and severe disease. To support the clinical decision making of which patients should access the limited supply, a set of access criteria have been defined by the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA). It is expected that these criteria will be amended as further evidence is made available and as experience in use of the medicine increases.

The Adaptive COVID-19 Treatment Trial (ACTT-1) is an international, double-blind, randomised, placebo-controlled trial of remdesivir in adults hospitalised with COVID-19 with evidence of lower respiratory tract involvement. The primary outcome was the time to recovery. Preliminary data reported a reduced 'time to recovery' for patients in the remdesivir arm; median 11 days vs. 15 days respectively (RR = 1.32; 95% CI [1.12 to 1.55]). However, the rate ratio varied across important subgroups with little benefit observed in patients requiring 'High-flow oxygen or Non-invasive mechanical ventilation' or 'Mechanical ventilation or ECMO' at baseline. There was no significant difference in mortality at day 14 although the trend was favourable. The most common adverse events reported in the remdesivir group were anaemia, renal dysfunction, pyrexia, hyperglycaemia and increased aminotransferase levels. Grade 3 or 4 adverse events were similar in both arms. The EAMS public assessment report states that the main concern regarding unfavourable effects relate to hepatic disturbances.

The Committee heard that patients treated with remdesivir under the EAMS remain eligible for RECOVERY and REMAP-CAP trials; confirmation of concurrent use with other clinical trials are still pending.

The Committee agreed remdesivir had a favourable risk:benefit profile and agreed to add remdesivir EAMS to the NCL Joint Formulary for the proposed indication. The Committee considered the DHSC stock rationing criteria and requested clarification as to which patients should have treatment extended to 10 days. It was agreed Dr Sofat would ask the COVID-19 Therapeutics Advice & Support Group to provide guidance.

Decision: Approved

Prescribing: Secondary Care

Tariff status: N/A

Funding: FoC via EAMS

Fact sheet or shared care required: No

Post meeting note: *The NHS implementation plan was updated on the 3rd June with additional information when to extend treatment for an additional 5 days*

7. Ranitidine shortage update

Planning is underway to reduce disruption caused by the removal of ranitidine from the European market.

Intravenous PPIs will broadly replace appropriate use of intravenous ranitidine however the following challenges were identified (intravenous only):

1. WH has pantoprazole on formulary only, which is not licensed for paediatrics use
2. Many Trusts use omeprazole prior to C-section as this was the PPI used in most clinical studies.

To point 1, omeprazole and esomeprazole are licensed in paediatrics with omeprazole being the most cost-effective choice. The Committee recommended WH added omeprazole IV for this indication.

To point 2, the Committee noted omeprazole must be given via infusion and this administration technique may not be suitable prior to emergency surgery. Pantoprazole however can be given via bolus and is used for this indication at other large Trusts in London. The Committee asked for a consensus view as to the appropriate PPI for this indication.

Oral PPIs will broadly replace appropriate use of oral ranitidine however a newly licensed omeprazole suspension would create a significant cost-pressure. Lansoprazole orodispersible is the preferred non-solid oral PPI whilst unlicensed formulations of omeprazole suspension are currently used in circumstances where lansoprazole orodispersible is unsuitable.

The Committee agreed that newly licensed formulations should not automatically replace unlicensed use (e.g. specials or imports) or off-label use (e.g. crushing and dispersing) of medicines unless specifically recommended by the Committee. This view is consistent with practice at SMC and AWMSG who review all licensed medicines and assess the cost-effectiveness, where relevant, against unlicensed or off-label use of medicines.

The Committee therefore agreed to review the licensed omeprazole suspension at the next meeting.

Actions for JFC Support:

- ***Determine if there have been any concerns in practice of administering IV pantoprazole in patients prior to C-section at other Trusts in London.***
- ***Liaise with NCL Trusts to determine the most practical IV PPI for patients prior to C-section.***
- ***Present an evaluation of the newly licensed omeprazole suspension at the next meeting.***

8. Next meeting

Thursday 18th June 2020

9. Any other business

Nil