North Central London
Joint Formulary Committee

JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on Thursday 26 May 2016
Room 6LM1, Stephenson House, 75 Hampstead Rd

Present:	Dr R Sofat	UCLH, Consultant Clinical Pharmacologist	**(Chair)**
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Mr P Gouldstone	Enfield CCG, Head of Medicines Management	
	Dr A Stuart	Camden CCG, GP Clinical Lead Medicines Management	
	Ms P Taylor	Haringey CCG, Head of Medicines Management	
	Mr C Daff	Barnet CCG, Head of Medicines Management	
	Mr A Shah	RNOH, Chief Pharmacist	
	Dr C McGuinness	Patient Partner	
	Mr T James	MEH, Chief Pharmacist	
	Mr A Dutt	Islington CCG, Head of Medicines Management	
	Dr V Thiagarasah	Enfield CCG, GP	
	Ms W Spicer	RFL, Chief Pharmacist	
	Dr R Breckenridge	UCLH, DTC Chair	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Prof D Robinson	UCLH, Consultant in Respiratory Medicine	
In attendance:	Mr J Minshull	NCL JFC, Support Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Mr P Bodalia	UCLH, Principal Pharmacist	
	Mr A Barron	NCL JFC, Support Pharmacist	
	Ms S Sanghvi	UCLH, Formulary Pharmacist	
	Ms H Mehta	NMUH, Formulary Pharmacist	
	Mr E Hindle	MEH, Formulary Pharmacist	
	Ms A Fakoya	NEL CSU, Assistant Director Acute Services	
	Ms H Amer	UCLH, Clinical Pharmacology Registrar	
Apologies:	Prof R MacAllister	NCL JFC Chair	
	Prof L Smeeth	NCL JFC Vice-Chair	
	Mr I Man	WH, Interim Deputy Chief Pharmacist	
	Dr M Kelsey	WH, Chair DTC	
	Mr G Kotey	NMUH, Chief Pharmacist	
	Ms H Taylor	WH, Chief Pharmacist	
	Mr B Sandhu	NEL CSU, Assistant Director Acute Services	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	
	Mr TF Chan	RFL, Deputy Chief Pharmacist	
	Ms R Clark	Camden CCG, Head of Medicines Management	
	Ms K Landeryou	Patient Partner	
	Dr R Fox	RNOH, DTC Chair	
	Dr R Kapoor	UCLH, Consultant Neurologist	
	Ms L Reeves	C&I, Chief Pharmacist	

1. Pre-meeting Note

Mr Bodalia informed the Committee that both Prof MacAllister and Prof Smeeth were unable to Chair the meeting due to work commitments. Given the variety of members and stakeholders involved in the running of each JFC meeting it is difficult to cancel or reschedule. It was proposed that two additional Vice-Chairs be established from the membership, one from secondary care and one from primary care. Dr Sofat agreed to fulfil the secondary care position; the Committee agreed.

Action: Mr Minshull to liaise with primary care members to fill the primary care position

2. Meeting observers

Dr Sofat welcomed Dr S Ishaq as a new member of the Committee and explained the role of Joint Formulary Committee in NCL.

3. Minutes of the last meeting

The title for item 7.2 should be updated to "Testosterone gel for poor libido post menopause or due to premature ovarian insufficiency".

The minutes were otherwise accepted as an accurate record of the meeting.

4. Matters arising

There were no matters arising.

5. Declarations of relevant conflicts of interest

No conflicts of interest were declared by the Committee members.

6. Local DTC recommendations / minutes

6.1 Approved by DTC

DTC site	Month	Drug	Indication	JFC outcome
RFL	Apr-16	Anakinra	Familial Mediterranean Fever, Pericarditis and DIRA	RFL only
UCLH	Apr-16	Ixazomib (compassionate use)	In combination with lenalidomide and dexamethasone for relapsed multiple myeloma (having received two or more prior therapies and had not been shown to be refractory to lenalidomide or proteasome inhibitor previously)	UCLH only
UCLH	Apr-16	Nivolumab (compassionate use)	Locally advanced or metastatic PD-L1+ non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy	UCLH and RFL
UCLH	Apr-16	TAS-102 (compassionate use scheme)	Last-line metastatic colorectal cancer	Added to NCL Joint Formulary

6.2 Not approved by DTC

DTC site	Month	Drug	Indication	JFC outcome
NMUH	Feb-16	Misoprostal vaginal insert (Mysodelle®)	Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated	Not recommended in NCL
RFL	Apr-16	Peg-Interferon-alpha 2a	Chronic Enteropathy	Not recommended in NCL
RFL	Apr-16	Tenofovir alafenamide (TAF) as F/TAF, R/F/TAF and E/C/F/TAF (compassionate use)	HIV triple combination treatment for patients with osteoporosis or bone-related toxicity	Not recommended in NCL

7. New Medicine Reviews

7.1 Apremilast for plaque psoriasis (Applicant: Dr B Esdaile, WH)

The Committee reviewed an application for apremilast for moderate to severe plaque psoriasis.

NICE recommends biologics (etanercept, adalimumab, ustekinumab and secukinumab) for patients with a Psoriasis Area and Severity Index (PASI) > 10 and a Dermatology Life Quality Index (DLQI) > 10 if they have failed to respond to phototherapy and two standard therapies (e.g. ciclosporin, methotrexate or acitretin). The current use of biologics varies slightly across NCL however the consensus is 1st line adalimumab, especially if the patient has joint involvement, or ustekinumab for patients with a high body weight, 2nd line ustekinumab and 3rd line secukinumab. The specific ordering of biologics is subject to change as more data becomes available.

NICE issued a negative Technology Appraisal (TA) for apremilast in 2015. The recommendation was made on the grounds of cost-effectiveness; there were no concerns surrounding the efficacy or safety of apremilast. The manufacturer has submitted a Patient Access Scheme and NICE are undertaking a rapid review of the TA. The manufacturer is anticipating a positive TA in July or September 2016. The eligibility criteria are likely to be identical to the existing biologics.

The manufacturer and the applicant have positioned apremilast within its marketing authorisation, before biologics and after other systemic therapy. This is consistent with the current NICE pathway for 'Systemic therapy for psoriasis' however NICE pathways are not mandatory to implement.

The Committee reviewed the evidence from two randomized, double-blind, placebo-controlled, 16-week studies (ESTEEM 1 and ESTEEM 2), both with extension periods to investigate ongoing efficacy and safety. Patients aged ≥18 years with moderate-to-severe chronic plaque psoriasis for ≥12 months, defined as PASI ≥12 and body surface area involvement ≥10% were eligible. Exclusion criteria were clinically significant uncontrolled disease, significant infection, active or history of incompletely treated tuberculosis (testing for latent tuberculosis was not required) or recent biologic, active topical agent or ultraviolet treatment. Patients were randomised 2:1 to receive apremilast or placebo. The primary outcome in both studies was the proportion of patients who achieved PASI-75 from baseline to week 16. Results from both studies showed apremilast had a greater proportion of patients with PASI-75 at week 16 compared with placebo (ESTEEM 1: 31% vs. 5.3% (treatment difference vs. placebo was 28% [95% CI: 23 to 32%]; ESTEEM 2: 29% vs. 5.8% (treatment difference vs. placebo was 23% [95% CI: 16 to 30%]).

A subgroup analysis of ESTEEM 2 found apremilast was less effective when used in patients with prior biologics compared with no prior biologics (PASI-75 achieved by 22.8% and 33.3% respectively) which is likely to reflect that 'post-biologic' patients had more refractory disease.

The Committee reviewed preliminary results from a third study evaluating the efficacy of apremilast or etanercept, compared with placebo for the treatment of biologic-naïve patients with moderate to severe plaque psoriasis. The study was not powered to detect differences between apremilast and etanercept. Results at week 16 showed PASI-75 (primary endpoint) was significantly greater with apremilast (39.8%) or etanercept (48.2%) vs. placebo (11.9%) and not significant for apremilast vs. etanercept ($p>0.05$, post-hoc). Apremilast had a more rapid improvement in DLQI score compared to etanercept, although scores are week 16 were numerically similar. A post-hoc analysis of pruritus VAS identified similar findings to the DLQI.

A network meta-analysis submitted by the manufacturer to NICE found response rates with apremilast were lower than for the biological therapies; this difference was statistically significant for comparisons with all biological therapies except with etanercept.

The most commonly reported adverse drug reactions were GI disorders, upper respiratory tract infections, headache, and tension headache. Insomnia and depression were more frequently seen with apremilast compared with placebo.

The list price of apremilast is £7,170 per annum however the manufacturer has submitted a confidential Patient Access Scheme. Apremilast is not cost-effective (ICER of £28,574 per QALY gained) using the list price however the Patient Access Scheme reduces the ICER to below the cost-effectiveness threshold. The manufacturer has submitted a 'Zero cost scheme' for patients who are initiated on apremilast before the NICE rapid review is published. The scheme will fund patient's treatment pre-NICE, up to 90 days post-NICE, and will honour ongoing funding in the event of a negative TA.

The Committee discussed the proposed eligibly criteria and agreed that the same criteria used for biologics should be applied in the pre-NICE period. The Committee heard from the patient representative that the oral route of administration was likely to beneficial for some patients. The Committee supported

this view and added that the novel mechanism of action and lower risk of infection was likely to be clinically valuable.

The Committee heard anecdotally that etanercept was no longer used in NCL due to inferiority over other available agents, a view supported by the results of the network meta-analysis. The Committee therefore expressed concern that apremilast should not become an additional treatment step prior to use of superior biologics. Although post-hoc data suggests apremilast is less effective when used post-biologics, it is unknown what impact apremilast will have on the efficacy of the biologics. The Committee did not agree that apremilast, with a comparatively unknown long-term adverse effect profile, should routinely displace biologics (e.g. adalimumab) for which there is extensive long-term safety data.

In summary the Committee agreed that apremilast within the confines of the 'Zero cost scheme' should be included on the NCL Joint Formulary, in patients who meet the NICE criteria for biologic use in plaque psoriasis (PASI >10 and a DLQI >10 if they have failed to respond to phototherapy and two standard therapies [e.g. ciclosporin, methotrexate or acitretin]) and one of the below criteria:

- Failed to respond to, or not tolerated, all biologics available under NICE TAs (etanercept, adalimumab, ustekinumab and secukinumab)
- Treatment with biologics is cautioned or contraindicated (e.g. latent tuberculosis, malignancy)

Treatment should be discontinued in patients whose psoriasis has not responded adequately within 16 weeks. An adequate response is defined as:

- a 75% reduction in the PASI (PASI-75) or
- a 50% reduction in the PASI (PASI-50) and a 5-point reduction in the DLQI

Decision: Restricted approval in line with criteria outlined above
Prescribing: Secondary care
Tariff status: Excluded form tariff
Funding: Free of charge supply pre-NICE, CCG funding >90-days post positive NICE TA
Fact sheet or shared care required: No
Audit required: No

7.2 Collatamp for Osteomyelitis including Brodie abscess (Applicant: Mr Atkinson, NMUH)

The Committee reviewed an application for Collatamp (collagen implant impregnated with gentamicin) for osteomyelitis (including Brodie abscess) where anatomical access precludes the use of gentamicin PMMA cement beads, or where the second operation to remove gentamicin beads would be associated with an unfavourable risk profile.

Collatamp is a CE marked medical device indicated for local haemostasis of capillary, parenchymatous and seeping haemorrhages in areas with a high risk of infection. The implant delivers high levels of gentamicin (ranging from 381 to 5,117mg/L) at the surgical site that is maintained for 2 to 5 days. By comparison, gentamicin PMMA cement beads provide lower levels that are maintained for 2 to 3 weeks.

The Committee reviewed the evidence from one retrospective cohort study of 50 patients with chronic osteomyelitis, and compared this to a historical cohort from 2001. All patients were treated with marginal resection, followed by insertion of Collatamp into area of resection. Post-operatively patients received intravenous antibiotics during admission and converted to oral therapy on discharge (typically 6 weeks total treatment). The most commonly affected bones were femur and tibia. Of the 50 patients, 12% suffered a recurrence of infection and 10% underwent further surgery for the infected focus. The reinfection rate is reported to be lower than the historical cohort (30% reinfection rate) that received marginal resection of infected tissue, followed by 6 weeks of intravenous administration of antibiotics and 6 weeks of oral antibiotics.

A single centre, open label, randomised controlled trial to assess the impact of Collatamp on surgical outcomes after minor amputation in diabetic patients. Inclusion criteria were non-healing foot ulceration with signs of osteomyelitis and were suitable for closed wound healing. Patients were randomised 1:1 to Collatamp applied to the wound before closure or 'no Collatamp'. Systemic antibiotics were administered for all patients. Of the 50 patients, 5 were lost to follow-up. Results found that the group randomised to Collatamp had a shorter median wound healing duration (3.0 vs 4.9 weeks, $p<0.05$). There was no significant difference in the median hospitalisation stay (11 days [range 9-36] vs 15 days [range 7-38]) or re-amputation rates (3 vs 4).

A systematic literature review and meta-analysis assessed the effectiveness of Collatamp at preventing sternal wound infections (SWI) in patients who undergo cardiac surgery through median sternotomy.

Study inclusion criteria were randomised controlled trials investigating Collatamp versus either placebo or 'no intervention'. Three trials were identified (n=3994) and all studies used background systemic antibiotics in both arms. Results found no significant reduction in 'any SWI' or 'deep SWI' in the whole population, but did identify a statistically significant reduction in 'deep SWI' in patients who were overweight and/or diabetic (OR: 0.62 [95% CI: 0.39 to 0.98]).

Reporting for adverse effects is limited because Collatamp is a medical device. One cohort study reported toxic gentamicin levels in patients with total hip arthroplasties who endured an acute surgical site infection. In these cases 4 to 6 Collatamp implants were used which is above the 1 to 2 implants suggested by the applicant.

Collatamp costs £110.40 + VAT per 10 x 10cm implant compared to £192.00 + VAT for gentamicin PMMA cement beads.

The Committee heard that RNOH currently uses Collatamp in a restricted manner, supplying to a small number of patients (30 annually, with 1 or 2 implants per patient) in absence of a DTC review. The microbiologists at RNOH / RFL are in principle supportive of the application as there is a concern about IV gentamicin induced nephrotoxicity.

The Committee expressed strong doubts that the difference in osteomyelitis recurrence with Collatamp versus the historical control was solely due to the Collatamp and therefore were unable to draw a conclusion about the Collatamp treatment effect. Additionally the randomised controlled trial data in diabetic foot amputations and cardiac surgery did not show that Collatamp reduced re-amputation rates or sternal wound infections compared with placebo. The Committee was also concerned that clinicaltrials.gov listed two randomised controlled studies in non-cardiac surgeries; 1 was terminated and one was completed in 2010 and has not reported, suggesting that the results are likely to have been negative.

On consideration of the evidence, the Committee was not satisfied that Collatamp was superior to placebo, when used in combination with systemic antibiotics. Collatamp was therefore not approved for use in NCL for osteomyelitis (including Brodie abscess) where anatomical access precludes the use of gentamicin PMMA cement beads, or where the second operation to remove gentamicin beads would be associated with an unfavourable risk profile.

Decision: Not approved

7.3 Ropivacaine via PainBuster for colorectal surgery and incisional hernia (Applicant: Dr Ishaq, WH)

The Committee reviewed an application for ropivacaine to be administered via continuous surgical wound infiltration (CSWI) using the Painbuster® Device (On-Q) in patients undergoing open colorectal surgery or incisional hernia repair surgery who cannot have an epidural inserted. The CSWI technique involves infiltrating the surgical wound continuously with local anaesthetic via an elastomeric pump (Painbuster®). Continuous delivery of the ropivacaine is regulated by the elastomeric device, allowing infiltration to occur for up to 60 hours from the same device. It was noted that the Committee approved use of the Painbuster On-Q Device to deliver ropivacaine as post-operative CSWI in patients undergoing live-donor nephrectomy or DIEP flap breast reconstruction in July 2015, and that evidence presented with this application was the same as discussed at the July 2015 meeting: 2 large systematic reviews and meta-analyses and one prospective, placebo-controlled trial of patients undergoing open nephrectomy.

It was agreed that this approach is effective, with the meta-analyses discussed demonstrating either improvement in pain score compared to control groups (Liu *et al* 2006) or similarity to pain scores achieved when compared to use of epidural (Ventham *et al* 2013). Opioid use was demonstrated to be lower when compared to control groups (Liu *et al* 2006) and lower when compared to epidural (Ventham *et al* 2013). No significant harms from use of CSWI were identified. There was some question over whether infection rates were more common when CSWI was used, with almost a quarter of patients in one study (23.9%, n=16) receiving CSWI following colorectal surgery experiencing a post-operative surgical site infection (Frustran *et al* 2015).

Catheters will be inserted in a sterile surgical environment to avoid the risk of infection. The device should not be manipulated post-operatively to ensure no additional risk of contamination.

Dr Ishaq explained to the Committee that it would be normal to use epidural as a first line option for these patients, so CSWI would be reserved for those who cannot use this. The trend towards lower doses of opioid analgesics was of clinical interest because it is always desirable to protect bowel function in

patients who have undergone bowel surgery. Dr Ishaq reassured the Committee that there is no concern about toxicity from ropivacaine occurring. She suggested that if patients begin to mobilise sooner, there may be the opportunity for earlier discharge, with devices being removed in the ambulatory care setting.

Overall, the Committee agreed that ropivacaine CSWI represented a safe and effective option for management of pain following surgery in this cohort of patients.

Decision: Approved
Prescribing: Secondary care prescribing only
Tariff status: In tariff
Funding: Hospital budgets
Fact sheet or shared care required: NA
Audit required: No

7.4 Pembrolizumab for NSCLC – Early Access Scheme (Applicant: Dr Foster, UCLH)

The Committee reviewed an application for the PD-1 inhibitor pembrolizumab for non-small cell lung cancer (NSCLC) under an Early Access Medicine Scheme approved by the MHRA. Under this scheme pembrolizumab is approved for monotherapy of adults with NSCLC whose tumours express PD-L1 and can be used:

- 1st line where patients are negative for the other biomarkers EGFR and ALK
- Or 2nd/3rd line where patients have progressed after platinum-containing chemotherapy.

The Committee reviewed the phase I study KEYNOTE 001 (n=495). Patients received IV pembrolizumab at one of three doses: (1) 2mg/kg every 3 weeks, (2) 10mg/kg every 3 weeks, or (3) 10mg/kg every 2 weeks. The response rate was 18.0% in treatment experienced patients and 24.8% in treatment naïve patients, representing an overall response rate of 19.4% (95% CI 16.0 to 23.2). Median progression free survival (PFS) was 3.7 months for all patients (95% CI 2.9 to 4.1), 3.0 months for treatment experienced and 6.0 months for treatment naïve patients. Median overall survival was 12.0 months (95% CI 9.3 to 14.7); with 9.3 months for treatment experienced versus 16.2 months for treatment naïve patients.

The results showed the cohort of patients with PD-L1 ≥ 50% was associated with a higher overall response rate and PFS compared to patients with a PD-L1 <50%; thus suggesting the PD-L1 pathway could be successfully targeted. In patients with a PD-L1 ≥ 50%, the median PFS was approximately double that for the overall population. The median overall survival in patients with a PD-L1 ≥ 50% was not reached regardless of prior treatment, whereas it was 8.8 months for the other PD-L1 subgroups. A sub group analysis by Hellman et al also showed favourable response in patients with PD-L1 expression >50%.

The Committee further considered the Keynote 010 phase 2/3 study; a randomised, controlled trial comparing efficacy and safety of pembrolizumab to docetaxel in 1034 patients with NSCLC that had failed to respond to platinum based chemotherapy +/- tyrosine kinase inhibitor where appropriate. The Committee noted that docetaxel monotherapy was previously standard of care however it is now used primarily with nintedanib in line with the published NICE TA.

The results showed favourable responses for pembrolizumab compared to docetaxel for overall survival in all patients (HR=0.67; 95% CI 0.56-0.80). For PFS pembrolizumab was favoured where PD-L1 expression was >50% and there was no significant difference in overall survival between the two treatments where PD-L1 expression was < 50%. The median overall survival was 10.4 months for the pembrolizumab 2mg/kg arm compared to 12.7 months for the 10mg/kg pembrolizumab arm, and 8.5 months for the docetaxel arm. EGFR mutations favoured using docetaxel in terms of PFS, however this was not statistically significantly different.

The most common adverse events for pembrolizumab across both studies were decreased appetite, fatigue and nausea. In the KEYNOTE 010 trial grade 3 to 5 adverse events attributed to study treatment occurred in 13% of the pembrolizumab 2mg/kg arm, 16% of the pembrolizumab 10mg/kg arm, and 35% of the docetaxel arm. The proportion of patients that discontinued study treatment due to adverse events was 4%, 5%, and 10%, respectively. Overall pembrolizumab showed a favourable tolerability profile compared to docetaxel. Adverse events of note with pembrolizumab include thyroid dysfunction, pneumonitis and pneumonia, and these would require careful monitoring. However the rates of neutropenia are significantly lower at <1% compared to 12% grade 3-5 neutropenia for docetaxel. Long term safety data is lacking for NSCLC patients, however pembrolizumab is also licensed and effective in melanomas.

Pembrolizumab is being offered at no cost under the compassionate use scheme. Written approval from the manufacturer is required to confirm that free supply would continue for patients until pembrolizumab is licensed and has a suitable commissioning route in place via NHS England/NICE.

Overall the Committee agreed that the evidence is limited at this stage, particularly compared to existing chemotherapy options. However pembrolizumab provides a targeted approach against PD-1 and has a favourable tolerability profile compared to docetaxel. The Committee noted that there are several ongoing trials assessing pembrolizumab, and agreed that all patients should be considered for enrolment on to a trial where eligible before considering compassionate use supply, particularly for first line use. The Committee approved pembrolizumab under the early access scheme restricted to patients who are not eligible for an ongoing trial and who express PDL1>50%.

Decision: Approved
Prescribing: Secondary care prescribing only
Tariff status: Free of charge
Funding: NA
Fact sheet or shared care required: NA
Audit required: No

8. Guidelines

8.1 Overactive bladder (OAB) guideline

The Committee reviewed an updated guideline for the management of OAB syndrome. This update follows on from a previous Committee review which generated comments on the specific recommendations. Mr Bodalia informed the Committee that the revised guideline incorporates the comments from the previous discussion, with choice of treatment reflective of cost [primary care] and absolute differences in treatment effect. The pathway was still made on the recommendations from NICE CG 171, NICE TA 290 and the in-house network meta-analysis. Key changes include:

- The emphasis of pharmacological treatment to be undertaken in primary care
- Clear guidance on red flag symptoms requiring referral to secondary care
- Clear guidance on review of treatment in the initial and maintenance period as well as a drug holiday
- The use of oxybutynin immediate-release (from modified-release) as the first-line anticholinergic
- The addition of tolterodine immediate-release for frail or elderly patients as the first-line anticholinergic
- Transfer into the NCL JFC template

The Committee questioned the inclusion of solifenacin over darifenacin as the second-line agent on the basis that darifenacin patent is due to expire in August 2016 whilst solifenacin will be in place until November 2018. The rationale behind this choice was the results of the network meta-analysis where darifenacin failed to demonstrate a statistically significant placebo-corrected mean difference for the efficacy endpoints (mean change from baseline versus placebo in micturition frequency per 24 hours and number of UUI episodes per 24 hours) whilst solifenacin demonstrated the most clinically significant treatment effect. The Committee acknowledged that use of solifenacin would delay access to mirabegron which is considerably more expensive and has the longest patient protection (until 2023).

The Committee approved the guideline pending minor correction to the diagram in Appendix 1. It was agreed that in situations where solifenacin had been prescribed in advance of oxybutynin or tolterodine, GPs are advised to review treatment, consider a drug holiday and re-prescribe treatment (if required) in accordance with the guideline. In existing patients in whom darifenacin is providing a clinically beneficial effect, there is no need to switch to solifenacin.

8.2 NOAC Prescribing Support Documents

Dr Anja Drebes (Consultant Haematologist, RFH) presented five documents to support anticoagulation prescribing which she has produced in collaboration with Ms Carolyn Gates (Pharmacist, UCLH) following consultation with an NCL NOAC steering group. It was agreed that NOAC should be used to replace DOAC throughout these documents.

CCG representatives were still concerned that the patient flow was not clear. The Committee noted that there are different commissioning arrangements in place for anticoagulation in NCL; it was agreed that it was more important for these documents to be viable for use across NCL than for individual patient pathways to be incorporated. It was agreed that VTE treatment pathways will be picked up separately

from this project. Dr McGuinness (Patient Partner) highlighted that patients will want to be fully informed about the benefits and risk of treatment with NOACs, particularly if moving between them and warfarin; the Committee agree that a link to the NICE Patient Decision Aid should therefore be included in the Prescribing Support Document.

The Committee discussed whether a rank order of NOACs should be used in NCL. Dr Sofat explained that a network meta-analysis conducted by the University of Bristol and UCL justifies implementing a rank order of drugs. The findings of this NMA will be presented to the JFC when they are published.

Anticoagulation Referral Form: A number of typographical corrections were recommended by the Committee and will be amended. It was agreed that email addresses for anticoagulation clinics would be more useful than fax numbers; the NCL NOAC stakeholder group will be approached to provide details of email addresses. Camden CCG has worked on an EMIS template for referral to anticoagulation services, which they will share with the other CCGs. This document should be provided in Word format to allow incorporation into clinical systems.

DOAC Drug Interactions: Typographical and formatting corrections were recommended by the Committee. It was noted by the Committee that there are a number of factual statements that have been updated since this version was sent out; a corrected version will be circulated when all amendments have been made to these documents.

DOAC Prescribing Support for NCL: The Committee discussed the principles of creatinine clearance (CrCl) versus eGFR for measuring renal function. It was recognised that CrCl is the correct measure of renal function as this was used in most of the licensing studies and it quoted in the Summary of Product Characteristics. As it is much more likely that GPs will be working with eGFR, a statement taken from the BNF will be added to explain the risks associated with using eGFR rather than CrCl to allow GPs to make an informed decision. A link to an online CrCl calculator will be provided.

In summary, pending the amendments recommended above, it was agreed that the documents presented will be useful to support GPs to prescribe NOACs in NCL. It was agreed that there may be a need to provide additional support (e.g. through training) to GPs, but it was acknowledged that this was outside the scope of the JFC meeting and that there would be difficulty finding budgets to support this. It was decided that the NOAC steering group should be reconvened to discuss implementation.

Actions: Dr Drebes and Ms Gates to make amendments suggested and seek Chair's action. VTE dosing tool, support for moving between drugs and bridging advice for simple procedures were recommended as separate documents. Mr Minshull to reconvene the NOAC steering group.

9. Regional Medicines Optimisation Committees (RMOC) - Update

The notes from the RMOC workshop meeting held on 20th April 2016 (as published by NHSE) were circulated for information. Key points noted were:

- RMOCs will focus on the review of new medicines which are not subject to a NICE technology appraisal or NHSE clinical commissioning policy assessment but are likely to be evaluated many times across the NHS
- RMOCs must engage hospital, and CCG stakeholders and not undermine the financial and clinical governance duties that rest with individual hospitals and CCGs
- RMOCs should 'recommend' and not 'mandate' the use of medicines that have been reviewed
- Interpretation and implementation of RMOC output should be conducted via Area Prescribing Committees

10. NCL prescribing policy

This item had been approved by NCL Medicines Optimisation Network and was included for information only.

11. JFC Work-plan

This item was included for information only. Any questions should be directed to Mr Barron.

12. Next meeting

Thursday 30th June 2016, Room 6LM1, Stephenson House, 75 Hampstead Rd.

13. Any Other Business

Dr Sofat informed the Committee that an intravenous immunoglobulin (IVIg) steering group was being set up across NCL. The group would report to JFC and was tasked with providing outcome data to NHS-England to enable continued funding. The group would support IVIg decision making and efficacy tracking

across all Provider Trusts in NCL. This committee would oversee the work of the individual IVIg panels within each Trust, membership being drawn from these.

Mr Minshull informed the Committee that a typo in the March 2016 JFC minutes had been corrected; the penultimate paragraph of item 4.1 now reads “Although avoiding *amenorrhoea* was raised as a potential reason for choosing Jaydess® over Mirena®, Dr Power again did not think this would form the main cohort of patients as there are other contraceptive methods available (e.g. combined oral contraceptive, patches, ring, barrier method and IUD).”