North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on Monday 19 February 2018
G12 Council Room, South Wing, UCL, Gower Street, London WC1E 6BT

Present:	Dr R MacAllister	NCL JFC Chair	**(Chair)**
	Dr R Sofat	UCLH, DTC Chair	
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Ms K Delargy	BEH, Deputy Chief Pharmacist	
	Dr A Mian	NMUH, Clinical Director for Specialty Medicine	
	Mr P Gouldstone	Enfield CCG, Head of Medicines Management	
	Dr M Kelsey	WH, Chair DTC	
	Ms A Fakoya	NEL CSU, Senior Prescribing Advisor	
	Ms P Taylor	Haringey CCG, Head of Medicines Management	
	Dr M Dhavale	Enfield CCG, GP Clinical Lead Medicines Management	
	Mr S Richardson	WH, Chief Pharmacist	
	Ms R Clark	Camden CCG, Head of Medicines Management	
	Dr A Stuart	Camden CCG, GP Clinical Lead Medicines Management	
In attendance:	Mr A Barron	NCL JFC, Support Pharmacist	
	Mr J Minshull	NCL JFC, Support Pharmacist	
	Mr P Bodalia	UCLH, Principal Pharmacist	
	Ms M Bhogal	NMUH, Formulary Pharmacist	
	Ms M Kassam	MEH, Formulary Pharmacist	
	Ms S Sanghvi	UCLH, Formulary Pharmacist	
	Dr H Amin	UCLH, SpR Clinical Pharmacology	
	Dr R Sweis	UCLH, Consultant Gastroenterologist	
	Dr K Anthony	WH, Consultant Diabetologist	
	Ms V Chaplin	NHS LPP, Pharmacist	
	Ms S McCarthy	RFL, Deputy Lead Nurse for Diabetes	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	
Apologies:	Mr G Kotey	NMUH, Chief Pharmacist	
	Mr A Dutt	Islington CCG, Head of Medicines Management	
	Prof L Smeeth	NCL JFC Vice-Chair	
	Mr T Dean	Patient Partner	
	Prof A Tufail	MEH, DTC Chair	
	Mr A Shah	RNOH, Chief Pharmacist	
	Dr A Sell	RNOH, DTC Chair	
	Dr R Kapoor	UCLH, Consultant Neurologist	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr B Sandhu	NEL CSU, Assistant Director Acute Services	
	Dr A Bansal	Barnet CCG, GP Clinical Lead Medicines Management	
	Ms L Reeves	C&I, Chief Pharmacist	
	Ms E Nassuna	Enfield Community Nurse, Bone Health	
	Dr R Woolfson	RFL, DTC Chair	
	Dr D Hughes	RFL, Consultant Haematologist	
	Dr S Ishaq	WH, Consultant Anaesthetist	

2. Meeting observers

There were no meeting observers.

3. Minutes of the last meeting

The minutes and abbreviated minutes were accepted as accurate reflections of the January meeting.

4. Matters arising

4.1 Applicant declaration of conflict of interest

Public confidence in a transparent relationship between the pharmaceutical industry and healthcare professionals and healthcare organisations is important. In 2016, the Disclosure UK online database was launched, publishing detail on payments and benefits in kind made by the pharmaceutical industry to individuals and organisations.

Pharmaceutical companies are responsible for submitting the data, which is published on the website on a named basis with the healthcare professional's consent. When consent has not been given, the data is published as an aggregate figure.

Currently 65% of healthcare professionals give consent for their data to be published on an individual basis, but the goal is 100%. If a significant increase in consent-giving is not seen in 2017, NHS England has confirmed it will introduce further measures to ensure full disclosure.

The Committee agreed that whilst consenting to full disclosure remains optional for healthcare professionals; when it is next reviewed, the application form should be changed so that applicants should describe in detail their payments from the pharmaceutical industry. The ToR will be updated to clarify that it is the applicant's responsibility to declare all relevant conflicts of interest on both the application form and at the meeting.

Committee members were asked to update their conflicts of interest form, and this would be requested of them every 12 months in line with the ToR.

5. Declarations of relevant conflicts of interest

Committee members declared no conflicts of interest. Dr Sweis declare an 'advisory board' payment from Dr Falk Pharma (the manufacturer of Jorveza®) relevant to discussion 8.1 and 8.2.

6. Local DTC recommendations / minutes

6.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
WH	Aug-11	Hyperbaric Prilocaine 2%	Short duration spinal anaesthesia restricted to use in day surgery setting only	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care only Tariff status: Included Funding: Trust Fact sheet or shared care required: No
RFL	Jun-13	Mitotane (off-label)	Adrenocortical carcinoma; adjuvant therapy after primary resection	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care only Tariff status: Included Funding: Trust Fact sheet or shared care required: No
RFL	Jun-13	Mitotane (off-label)	Adrenocortical carcinoma; metastatic	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care only Tariff status: Included Funding: Trust Fact sheet or shared care required: No

UCLH	Nov-15	LAT (lidocaine, adrenaline and tetracaine) gel (unlicensed)	Second line option (after lidocaine infiltration) for management of pain in children requiring suturing or debridement	Decision: Added to the NCL Joint Formulary* Prescribing: Secondary care only Tariff status: Included Funding: Trust Fact sheet or shared care required: No
RFL	Dec-17	Quinidine	Brugada Syndrome	Decision: RFL only Prescribing: Secondary care only Tariff status: Included Funding: Trust Fact sheet or shared care required: No
RFL	Dec-17	Sirolimus	Arteriovenous Malformation - low flow	Deferred[†]
UCLH	Dec-17	Indometacin oral tablets	Tocolytic therapy during pre-natal repair of myelomeningocele, a serious form of spina bifida	Decision: UCLH only Prescribing: Secondary care only Tariff status: Included Funding: Trust Fact sheet or shared care required: No
UCLH	Dec-17	Intra-amniotic clindamycin	Fetal spina bifida surgery	Decision: UCLH only Prescribing: Secondary care only Tariff status: Included Funding: Trust Fact sheet or shared care required: No

* LAT gel is an unlicensed medicine with a high risk of prescribing creep (displacing licensed alternatives). UCLH used successfully implemented procedures to restrict inappropriate use. Other Trusts are encouraged to implement the same procedures as UCLH.

[†] UCLH recently approved an application for 'Bleomycin sclerotherapy for low flow vascular malformations of the head and neck'. The Committee questioned whether the UCLH and RFL application were for the same indication.

Action: RFL to liaise with Dr A Rennie (UCLH) and Dr J Brookes (RFL) to resolve this query.

6.2 Catheter Directed Thrombolysis for DVT and PE

The Committee heard UCLH UMC had reviewed the evidence supporting Catheter Directed Thrombolysis (CDT) for DVT and PE and were in the process of collecting audit data from across the region; CDT services are already established at UCLH and RFL. The Committee heard it was unhelpful to bundle 'DVT and PE' into a single indication and agreed to differentiate three indications: (i) DVT, (ii) high risk PE, (ii) intermediate risk PE.

DVT

The Committee discussed the ATTRACT study (Vedantham et al; publication pending; n=692), a multi-centre, RCT comparing CDT plus standard therapy (anticoagulation and compression) to standard therapy alone in patients with iliofemoral or femoropopliteal DVT. The study failed to show a difference in the primary outcome of PTS rate between the CDT and standard therapy arms (46.7% vs 48.2%; p=0.56). There was a slight trend toward more recurrent VTE in the CDT arm (12.5% vs 8.5%; p=0.09) and little difference in QOL measures. Within the first 10 days, there was a statistically significant higher rate of major bleeding (1.7% vs 0.3%; p=0.49) and any bleeding (4.5% vs 1.7%; p=0.034) in the CDT arm.

The Committee acknowledged the efficacy of CDT may partially be dependent on the medical device however remained concerned that the available evidence supports a claim that CDT does harm and has no benefit. The Committee requested the Interventional Radiologists at UCLH and RFL review the ATTRACT study submit comments to UMC representatives who would work across NCL to agree the appropriate response. Members from NMUH and WH were asked to establish whether CDT is offered at their Trust.

High risk PE

Established evidence indicates systemic thrombolysis for high risk PE (Chatterjee et al. metaanalysis, Cochrane review, PEITHO trial) and it is recommended in European Society of Cardiology 2014 guidelines. The Committee heard there was no strong evidence for CDT for this indication. JFC asked UMC representatives to work across NCL to confirm whether CDT was recommended for this indication.

Intermediate risk PE

There is no strong evidence for systemic thrombolysis (not recommended by ESC, NICE) and some evidence exists for CDT (SEATTLE II, ULTIMA, PERFECT trials) although this is not recommended by ESC or NICE. JFC asked UMC representatives to work across NCL to confirm that CDT for this indication was a cost-effective use of NHS resources.

Action: Ms Bhogal and Mr Flor to confirm whether NMUH and WH respectively perform CDT for DVT or PE.

Action: Dr Sofat and Ms Sanghvi to invite investigational radiologists across NCL to comment on the ATTRACT study via the Formulary Pharmacy teams. UCLH UMC to assess the risk-benefit of CDT (for the three indications) on behalf of JFC.

Post meeting note: NMUH and WH do not offer CDT however will refer patients with symptomatic iliofemoral DVT to the RFL (patients should who have all of (i) symptoms of less than 14 days' duration, (ii) good functional status, (iii) a life expectancy of 1 year or more and (iv) a low risk of bleeding).

7. Approved under evaluations

The Committee reviewed an analysis of applications which were 'approved under evaluations' in NCL since September 2012; a total of 33 evaluations were identified. Whilst the number of evaluations appeared high the majority were for applications with a small financial risk to the health-economy (either small patient cohorts or low treatment costs per individual).

Some applications were 'approved under evaluation' with the intention on keeping controls on prescribing whilst the literature base matured; for example using anti-cancer therapies approved before the overall survival benefits are known. The Committee agreed such applications were not suitable for an evaluation and rather the Committee should mark the intervention for re-review by DTC/JFC after an agreed period of time.

Applications which claim to reduce the consequence of an adverse outcome (e.g. avoiding surgery) but lack the evidence to support the claim were identified as most useful for an evaluation. The Committee agreed the onus should be on the applicant to put forward a sufficiently robust proposal to collect high quality 'before and after' data. The drug should not be used until the protocol is agreed. Furthermore, JFC/DTCs should make it clear to applicants at the start of the evaluation process that if results are not provided after the agreed period, the drug would automatically be removed from the formulary.

The Committee requested Formulary Pharmacists and JFC Support seek to close all outstanding evaluations by May 2018.

Action: Formulary Pharmacists to chase evaluations underway at their respective Trusts and report back to JFC Support. JFC Support to summarise the evaluations and present to the Committee in May 2018.

8. New Medicine Reviews

8.1 Fluticasone inhaler for eosinophilic oesophagitis (Applicant: Dr R Sweis, UCLH)

This item was considered in conjunction with '8.2 Budesonide nasules for eosinophilic oesophagitis'.

8.2 Budesonide nasules for eosinophilic oesophagitis (Applicant: Dr R Sweis, UCLH)

The Committee considered an application to use fluticasone dry powder inhaler (first-line) and budesonide nasules dispersed in a sucralose-based artificial sweetener (Splenda®) (second-line) for eosinophilic oesophagitis (EoE).

The Committee reviewed a meta-analysis (MA) of topical corticosteroids for EoE. The MA included placebo-controlled randomised-controlled trials in adults and children, using inhaled, aerosolised or swallowed fluticasone or budesonide provided data on histological efficacy and/or clinical improvement were reported. In total 5 studies were identified; 1 budesonide aerosol, 1 budesonide oral viscous liquid and 3 using fluticasone aerosol. All studies were small (<25 patients in each arm) and duration of therapy was short (15 days to 3 months). Results found topical steroids were effective in inducing complete histological remission (odds ratio [OR]=20.81 [95% CI: 7.03 to 31.63], NNT = 3) and partial histological remission (OR=32.20 [95% CI: 6.82 to 152.04], NNT=2). However steroids were not associated with a statistically significant improvement in clinical symptoms (OR=2.72 [95%CI: 0.90 to 8.23]). A subgroup analysis shows budesonide was more effective than fluticasone for improvement in clinical symptoms. Of note, the OR for clinical symptoms is for any improvement and it is unknown whether all improvements are clinically significant.

Two more recent randomised-controlled trials were considered, including the licensing study for Jorveza® (budesonide orodispersible). These trials supported findings from the MA in terms of a positive histological response but inconstant improvements in QoL and clinical symptoms. The EPAR for Jorveza states "results with regard to the QoL endpoints are rather heterogeneous and do not unanimously allow a conclusion of a clear influence on QoL in these patients. However, according to the CHMP's understanding of HRQoL, the proposed treatment duration falls short of the necessary observation time for any claim on HRQoL. However, some beneficial effects have been detected, especially for the SHS scale indicating an improvement of the well-being of the patients".

The Committee heard from Dr Sweis that despite the EMA assigning Jorveza an 'orphan drug', EoE is a newly recognised but relatively common condition. The prevalence at UCLH is 8.6% of patients who undergo endoscopy for swallowing difficulties. The practice of using topical corticosteroids is in line with international guidelines. UCLH does not offer dietary modification therapy as it can take 48 weeks and involves 8 endoscopies which is an unattractive option for many patients. Fluticasone dry powder inhaler is already in use at UCLH (for adults) and budesonide is used at GOSH and RFL (for paediatrics). Both drugs are used long-term.

In summary, the Committee agreed the available evidence was limited to very small studies, which would be acceptable for rare disease however was disappointing given the apparently large cohort requiring treatment. However, the published evidence and Jorveza EPAR identified histological improvements and some QoL benefits therefore the Committee agreed to add fluticasone dry powder inhaler (first-line) and budesonide nasules dispersed in Splenda (second-line) to the NCL Joint Formulary for eosinophilic oesophagitis in both adults and children. This approval would not automatically be extended to Jorveza.

Primary care colleagues stated the unlicensed route of administration could create confusion in GP practices and Community Pharmacies therefore requested prescribing be retained in secondary care. The Committee agreed with the request in view of the fact EoE was a relatively unknown condition.

Splenda cannot be prescribed on the NHS therefore patients should be asked to purchase this from a supermarket (approximately £3 for 125g).

Decision: Approved
Prescribing: Secondary care only; patients to purchase their own Splenda to create 'budesonide slurry'
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: No

9. Azathioprine for autoimmune hepatitis

The Committee considered a request for azathioprine the management of autoimmune hepatitis (AIH) to be prescribed under shared care between hepatologists and GPs. Shared care will be sought once the patient has been on azathioprine for 2 months. Azathioprine is well established on the formulary at RFL for this indication, with approximately 50 to 60 patients treated. It is used in both the initial treatment of AIH and in the maintenance of remission.

As this has been established practice for several decades in this relatively uncommon condition, the Committee considered a review of this weak evidence in absence from a formal application. Use of azathioprine in AIH is supported by clinical guidelines published by the relevant bodies in Britain, Europe and America. Much of the clinical trial evidence dates from the 1970s and 1980s.

A systematic review of eleven RCTs (Lammers *et al* 2010) evaluated the use of azathioprine in both induction therapy (seven RCTs) and maintenance therapy (four RCTs). The RCTs included were of low

quality, but were included in the review because of the lack of suitable alternatives. Of the maintenance therapy RCTs, only two considered the efficacy of azathioprine. The finding from these two studies was that prednisolone plus azathioprine maintained remission more than prednisolone alone (96% vs. 68%, RR=1.40 [95% CI 1.13 to 1.73]), though this combination was no more effective at maintaining remission than azathioprine alone (RR=1.06 [95% CI 0.94 to 1.20]). Azathioprine alone was also more effective at maintaining remission than prednisolone alone (RR=1.35 [95% CI 1.07 to 1.70]). This was suggestive that azathioprine used with or without prednisolone would be effective at maintaining remission in AIH. Five studies that evaluated azathioprine in induction of remission from AIH in drug-naïve patients included 363 patients in 6 treatment arms. The studies had low Jadad scores, and were a mixture of head-to-head studies and an uncontrolled evaluation. Prednisolone therapy resulted in remission in 42% of the 95 patients treated, with a mortality rate of 15%. In comparison, azathioprine achieved remission in 14% of patients with 30% mortality (27/89 patients). Azathioprine and prednisolone combination had a remission rate of 43% of 44 patients, and 7% mortality. There was no statistically significant difference between prednisolone vs. prednisolone plus azathioprine at achieving remission (RR=0.98 [95% CI 0.65 to 1.47]).

The Committee acknowledged that azathioprine is already prescribed in primary care under shared care between dermatologists/gastroenterologists/rheumatologists and general practitioners using the established NCL Quick Reference Guide for Primary Care Prescribing Monitoring DMARDs. It was agreed that it would be beneficial for patient safety if monitoring requirements in autoimmune hepatitis were consistent with azathioprine monitoring in other indications. Clear guidance is needed to establish what GPs need to do if a patient has an abnormal blood result. It was questioned who would be conducting DEXA scans and screening for glaucoma, though the Committee acknowledged that this review was to consider the azathioprine element of therapy and not the steroid.

In summary, the Committee were supportive that azathioprine was suitable for prescribing in primary care under shared care for this indication. The Committee requested that the NCL Shared Care and Fact Sheet Group make the necessary amendments to the NCL Quick Reference Guide for Primary Care Prescribing Monitoring DMARDs.

Decision: Approved
Prescribing: Specialist initiation, continuation in general practice with appropriate shared care
Tariff status: In tariff
Funding: Trust and GP budgets
Fact sheet or shared care required: Yes – amendment to NCL DMARD Quick Reference Guide

10. **Freestyle Libre® – London implementation of RMOC guidance for Type 1 diabetes (Applicant: Dr K Anthony [WH], in attendance Ms V Chaplin [NHS LPP], Ms S McCarthy [RFL])**

The Committee reviewed the London implementation plan for Freestyle Libre® in Type 1 diabetes (published 6th February 2018) which was co-authored by NHS LPP and NHSE London Diabetes Clinical Network (LDCN) in response to the RMOC position statement (published 1st November 2017).

Medical devices are not included within the Committee's ToR however the JFC is the principal evidence-based decision making body for NCL. The JFC agreed to consider the implementation plan for Freestyle Libre given the substantial implications for CCG prescribing budgets.

The Committee considered the pivotal multi-centre, multi-national randomised controlled trial for Freestyle Libre (n=241). Self-managing stable and well-controlled adults with insulin dependent type 1 diabetes were included. Patients known to be allergic to medical grade adhesives were excluded. Subjects were randomised 1:1 to Freestyle Libre or finger-prick SMBG (with blinded Freestyle Libre). After 6 months, Freestyle Libre was associated with less time in hypoglycaemia (-1.24 hrs/day from baseline of 3.4hrs) and less time in hyperglycaemia (-0.37 hrs/day from a baseline 1.9hrs/day). There was no between group difference in HbA1c which might be expected given the low baseline (HbA1c = 6.7%). There were no between group differences in Hypoglycaemia Fear Survey and Diabetes Distress Scale although patients were more satisfied with their treatment.

The RMOC position statement recommends Freestyle Libre for the following patients:

- Patients who undertake intensive monitoring >8 times daily.
- Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycemia as described in NICE TA151) where a successful trial of FreeStyle Libre may avoid the need for pump therapy.

- Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre does not currently have that function.
- Frequent admissions (>2 per year) with DKA or hypoglycaemia.
- Those who require third parties to carry out monitoring and where conventional blood testing is not possible.

Minutes relating to the RMOC recommendations were not available however similarities between the RMOC position statement and the formulary case from Association of British Clinical Diabetologists (ABCD) were acknowledged. The Committee noted ABCD receive funding from the manufacturer of Freestyle Libre.

NHS LPP and LDCN have displayed the RMOC recommendations as three distinct groups/treatment areas:

1. Recommended implementation of FreeStyle Libre prescribing for patients with type 1 diabetes on MDI or insulin pump therapy who test frequently
    - Continuation criteria: reduce test strips by at least 8 strips a day (7 in children aged 0-19 years)
2. Recommended implementation of FreeStyle Libre prescribing for patients with type 1 diabetes with HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy as per TA151 (plus additional notes on those who can be considered for continuous glucose monitoring as per NG17 and NG18)
    - Continuation criteria: reduce HbA1c by 0.6% (6.6mmol/mol) and/or reduce severe hypoglycaemic episodes by 75%
3. Recommended implementation of FreeStyle Libre prescribing for patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing.
    - Continuation criteria: monitoring of glucose levels is possible for the patient

The best available budget impact assessment for North Central London CCGs for recommendation 1, 2 & 3 is £0-20K, £340K and £361K respectively. The values are thought to be a worst-case scenario but assume the stopping rules are followed.

There were concerns that Freestyle Libre would be difficult to stop if the required outcomes for each recommendation were not met; historically poor compliance to ceasing GLP-1RAs in patients with Type 2 diabetes who do not achieve an adequate reduction in HbA1c was noted. The Committee heard from Ms Chaplin that 'patient contracts' were being developed so patients consent to treatment withdrawal in the event of achieving inadequate outcomes. Ms McCarthy explained diabetes specialists routinely stop insulin pumps in those who fail to meet NICE continuation criteria. The Committee considered the only way to prevent inappropriate continuation was for prescribers to be responsible for costs; such as the case of insulin pumps not being reimbursed by CCGs if continuation criteria are not met.

Non-device costs associated with the introduction of Freestyle Libre were considered. Dr Anthony advised the Committee that patients with Type 1 diabetes regularly attend specialist clinics and patient training requirements would be absorbed within current activity, potentially with group sessions. Ms Chaplin advised that LPP/LDCN are developing short videos to support GP training given the logistical difficulties in offering face-to-face training. Specialist services already have the capabilities to monitoring clinical outcomes through specialist databases (e.g. DIAMOND).

There were implementation challenges that needed to be overcome in the event Freestyle Libre was commissioned in NCL. The current LPP/LDCN proposal is for specialists to initiate Freestyle Libre then transfer prescribing back to GPs; this process would be supported by 'transfer of care' letters. 'Recommendation 1' requires an assessment of strip use before and 2-6 months after Freestyle Libre initiation; specialists advised they did not know how many strips were used per day by each patient and the onus was on primary care to supply this data. Primary care colleagues noted that GP systems can output 'the number of strips prescribed in the last X months' however this was not synonymous to 'the number of strips used daily', it was unclear therefore whether any healthcare professionals could reliably monitor daily strip usage as an outcome.

The Committee commended the LPP/LDCN for their implementation plan and in achieving a broad clinical consensus in difficult circumstances.

In camera, the Committee found 'Recommendation 1' was supported by the available evidence base and was cost-effective given the reduction in time in hypoglycaemia and minimal budget impact. 'Recommendation 2' was not evidence-based and furthermore, a clinical trial to investigate the benefits

of Freestyle Libre in this cohort was feasible (following similar methodology to HypoDE study). 'Recommendation 3' was not evidence-based however a trial in this cohort would be more difficult to conduct. The Committee noted the uncertainty as to whether Freestyle Libre would be beneficial for patients included within 'Recommendation 2' and 'Recommendation 3'; in situations of uncertainty, decision making should be delayed until further research is available which confirms or disproves the hypothesis. The expectation is for the manufacturer to fund such research, such as the case of Dexcom Inc. for the Dexcom G4 CGM system in the HypoDE study. If the NHS adopts the technology the manufacturer will have no incentive to fund a study, and the opportunity for good decision making will be lost exposing the NHS to certain costs and uncertain benefits in the long term. Insulin degludec was cited as a good example of the NHS broadly rejecting the drug until the manufacturer funded a double-blind active-comparator study with a relevant primary outcome. The RMOC proposal for the NHS to fund the intervention and collect audit data in an attempt to plug the literature gap was unacceptable to the Committee and is inconsistent with NICE's 'only in research' guidance recommendations.

In summary, the Committee agreed 'Recommendation 1' was likely to be cost-effective and supported the proposal, subject to specialists and primary care colleagues confirming the continuation criteria can be accurately monitored. 'Recommendation 2' was not evidence-based, was suitable for a clinical trial, has a large opportunity-cost, and risked displacing evidence-based interventions therefore the Committee was unable to support this proposal. 'Recommendation 3' had a large opportunity-cost however could (despite no published evidence to support this claim) provide a benefit in terms of equality to patients with physical and mental health problems who cannot test using SMBG. The Committee acknowledged the pressure from within the NHS to approve the LPP/LDCN plan in full, therefore if other regions in London choose to implement fully, the Committee would support the plan on the grounds of equity (rather than cost-effectiveness). If commissioned, Freestyle Libre would be initiated in secondary care and an NCL implementation plan would be required.

These findings will be passed to NCL STP for funding consideration.

11. **MHRA alert: Ulipristal acetate for uterine fibroids**

An action plan had been agreed with NCL gynaecologists and the NCL Shared Care Guideline working group (a working group of NCL MOC) which had been disseminated to CCG Heads of Medicines Management and Trust Chief Pharmacists.

The Committee agreed to remove the NCL shared care guideline from the NCL MOC website and upload the MHRA alert in its place. Ulipristal should be removed from Trust formularies for new patients and patients starting their next treatment course (it can remain for women who are adequately counselled about the risks and benefits who want to continue their treatment course).

12. **Guidance: Guideline for blood glucose & ketone monitoring for adults with diabetes [update for approval]**

The guideline had undergone a minor revision to bring in line with the latest DVLA requirements. The Committee approved the guideline.

13. **NHSE Commissioning: RNOH to treat hypophosphatasia with asfotase alfa (adult expert centres)**

RNOH are commissioned by NHSE to provide asfotase alfa to adults to meet the NICE HST criteria for hypophosphatasia. The Committee agreed asfotase alfa should be added to the RNOH formulary in line with NICE HST6.

14. **Protocol variation: Prasugrel for elective placement of intracranial stents [update for information]**

The Committee noted an amendment to the UCLH protocol for elective placement of intracranial stents; instead of 30mg prasugrel and 300mg aspirin given on the each of the two days before the procedure, UCLH will give 5mg prasugrel and 75mg aspirin on each of the 6 days prior to the procedure. This change would have no impact on primary care as the initial prescription should come from hospital. Post procedure they will continue the same dose of both prasugrel and aspirin for 6 months and then continue on aspirin 75mg until further notice.

15. **JFC Work plan**

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

16. **Next meeting**

Monday 19 March 2018, G12 Council Room, South Wing, UCL, Gower St. WC1E 6BT

17. **Any other business**

Nil