North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES
Minutes from the meeting held on 21st July 2022

Present:	Prof A Hingorani	NCL JFC Chair	(Chair)
	Dr B Subel	NCL JFC Vice Chair	(Vice Chair)
	Dr A Worth	GOSH, DTC Chair	
	Mr A Sell	RNOH, DTC Chair	
	Dr A Scourfield	UCLH, DTC Chair	
	Mr S Semple	NCL ICS, Interim Chief Pharmacist; GOSH, Interim Chief Pharmacist	
	Mr A Shah	RNOH, Chief Pharmacist	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr S Richardson	WH, Chief Pharmacist	
	Ms R Clarke	NCL CCG, Head of Medicines Management (Camden)	
	Mr P Gouldstone	NCL CCG, Head of Medicines Management (Enfield)	
	Ms E Mortty	NCL CCG, Deputy Head of Medicines Management (Haringey)	
	Mr A Dutt	NCL CCG, Head of Medicines Management (Islington)	
	Dr M George	UCLH, Consultant Clinical Pharmacologist	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Dr D Roberts	Islington Borough, Clinical Director	
	Dr L Waters	CNWL, Consultant Physician in HIV	
	Mr A Stein	NMUH, Deputy Chief Pharmacist (on behalf of Sarah Stern)	
	Ms J Bloom	MEH, Associate Chief Pharmacist (on behalf of Naheed Phul)	
In attendance:	Ms S Sanghvi	North London Partners, JFC Principal Pharmacist	
	Mr G Grewal	North London Partners, JFC Support Pharmacist	
	Mr R Rajan	North London Partners, JFC Support Pharmacist	
	Ms S Amin	IPMO Programme Team, Lead Pharmacist	
	Ms M Kassam	MEH, Senior Pharmacist	
	Ms A Dhanoa	NMUH, Formulary Pharmacist	
	Ms H Thoong	GOSH, Formulary Pharmacist	
	Ms M Thacker	RFL, Clinical Lead Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Mr H Shahbakhti	RFL, Formulary Pharmacist	
	Mr A Barron	UCLH, Formulary Pharmacist	
	Mr S O'Callaghan	UCLH, Formulary Pharmacist	
	Ms S Maru	UCLH, Formulary Pharmacist	
	Ms H Weaver	NHSE, Specialised Commissioning Pharmacist	
	Ms A Fakoya	NHS London Shared Service, Contract & Commissioning Support Pharmacist	
	Ms A Sharma	Senior Interface Pharmacist, East Suffolk and North Essex NHS Foundation Trust	
	Ms H Williams	NHSEI National Specialty Adviser for CVD Prevention	
	Dr C Mitchell	NMUH, Consultant Haematologist	
	Ms C Gates	UCLH, Haematology Pharmacist	
	Mr R Shulman	UCLH, Critical Care Pharmacist	
Apologies:	Prof A Tufail	MEH, DTC Chair	
	Dr D Burrage	WH, Consultant Clinical Pharmacologist	
	Ms L Reeves	C&I, Chief Pharmacist	
	Ms N Phul	MEH, Chief Pharmacist	

Ms S Stern	NMUH, Chief Pharmacist
Dr K Tasopoulos	NMUH, DTC Chair
Mr J Harchowal	UCLH, Chief Pharmacist
Dr M Kelsey	WH, DTC Chair
Ms K Delargy	BEH, Chief Pharmacist
Ms M Singh	NCL CCG, Head of Medicines Management (Barnet)
Dr R Urquhart	UCLH, Divisional Clinical Director

2. Meeting observers

Prof Hingorani welcomed observers to the meeting.

3. Members' declaration of interests

Declarations of interests register included for information. No interests relevant to the agenda were declared.

4. Minutes of the last meeting

The minutes and abbreviated minutes will be circulated to the Committee for approval outside the meeting.

5. Matters arising

Nil.

6. Review of action tracker

Action tracker included for information.

7. JFC Outstanding Items & Work Plan

These items were included for information only. Any questions should be directed to Ms Sanghvi.

8. Local DTC recommendations / minutes

DTC site	Month	Drug	Indication	JFC outcome
RFL	May 2022	FOC scheme: Pembrolizumab†	EAP for Triple Negative High Risk Early Breast Cancer	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** N/A – Free of charge **Funding:** N/A – Free of charge **Fact sheet or shared care required:** No
UCLH	Sept 2012	Testosterone Testogel® and Tostran® pump and sachets	Male hypogonadism	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Primary and secondary care **Tariff status:** In tariff **Funding:** Trust and CCG **Fact sheet or shared care required:** No
UCLH	Jul 2022	Duloxetine	For patients with migraine syndromes and depression as a comorbidity	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care initiation; primary care continuation **Tariff status:** In tariff **Funding:** Trust and CCG **Fact sheet or shared care required:** No
UCLH	Jun 2022	Intravenous dihydroergotamine	A transitional therapy for patients with migraine syndromes and cluster headaches	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** In tariff **Funding:** Trust **Fact sheet or shared care required:** No

UCLH	Jun 2022	Flunarazine	Migraine syndromes where established therapies (including b-blockers, tricyclic antidepressants, angiotensin-II receptor antagonists and antiepileptics) are ineffective, not tolerated or cautioned	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** In tariff **Funding:** Trust **Fact sheet or shared care required:** No
UCLH	Jun 2022	FOC scheme: Pembrolizumab and lenvatinib†	Treatment of metastatic/recurrent pMMR endometrial cancer (including carcinosarcoma) following progression on carboplatin/paclitaxel or carboplatin	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** N/A – Free of charge **Funding:** N/A – Free of charge **Fact sheet or shared care required:** No
UCLH	Jun 2022	Indocyanine green	Delineation of the intersegmental plane during pulmonary sementectomy and pulmonary nodule localisation (off-label)	**Decision:** Added to the NCL Joint Formulary **Prescribing:** TBD (see below) **Tariff status:** In tariff **Funding:** Trust and CCG **Fact sheet or shared care required:** No
UCLH	Jun 2022	MHRA EAMS: Efgartigimod alfa†	Myasthenia gravis	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** N/A – Free of charge **Funding:** N/A – Free of charge **Fact sheet or shared care required:** No
UCLH	Jul 2022	MHRA EAMS: Risankizumab†*	Moderately to severely active Crohn's disease	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** N/A – Free of charge **Funding:** N/A – Free of charge **Fact sheet or shared care required:** No **Additional information:** Approved clinically; deferred to NCL JFC for funding consideration (see item 10)

† The relevant commissioner should be notified in line with NCL Free of Charge scheme guidance. Approval is conditional on the provision of a free of charge scheme agreement and funding statement. * Subject to funding consideration.

9. New Medicine Reviews

Nil to review.

10. Risankizumab post-EAMS commissioning arrangements

The Committee considered the commissioning arrangements of risankizumab, an interleukin 23 inhibitor, which had recently become available via an MHRA EAMS in adults and adolescents with moderate-to-severe active Crohn's disease. The EAMS was approved clinically by UCLH DTC, who agreed there was evidence of benefit in terms of clinical remission following induction and maintenance treatment. The Committee considered the possible commissioning arrangements following a positive NICE TA (expected in March 2023) for patients initiated on therapy during the EAMS programme.

For adolescents, NHSE is the commissioner and would routinely commission 30 days post-NICE TA.

For adults, NCL ICB would be the commissioner and currently commission 4 lines of therapy, which reflects JFC advice that pathways should include '1 drug per mechanism of action and a second biosimilar anti-TNF'. It was acknowledged that risankizumab represents a new mechanism of action and, as per the MHRA EAMS, would be positioned 5th line in adults. Prior to NICE TA publication, the ICB will therefore need to consider the position of this drug within the NCL IBD pathway, and position on number of lines of therapy within the pathway.

The Committee supported the UCLH decision that risankizumab was likely to be clinically effective for patients eligible for the EAMS. In terms of post-EAMS access, in the event of a positive NICE TA, NHSE would commission for adolescents. For adults, the product positioning fell outside existing routine commissioning arrangements with NCL ICB. It was not within JFC's remit to provide funding certainty, therefore Trusts wishing to use the EAMS would have to do so at financial risk. The Committee agreed that prior to NICE TA publication date, the existing pathway should be updated and presented to the ICB for funding consideration.

11. NCL Lipid Pathway & Prescribing Status Recommendations

Ms Sanghvi presented an updated NCL lipid management pathway incorporating therapies recently approved by NICE. This has been developed by a working group supported by NCL JFC and UCLP teams, with input from clinicians in primary and secondary care. The working group also proposed a green prescribing status (suitable for initiation in primary or secondary care) for ezetimibe (NICE TA 385), bempedoic acid + ezetimibe (NICE TA 694) and inclisiran (NICE TA 733), Work is ongoing to consider service developments in primary care (e.g. PCN specialist lipid hubs) to support prescribing and delivery of the lipid pathway.

Both the pathway and the prescribing status recommendations were circulated for NCL-wide consultation to NCL formulary pharmacists, commissioners, specialists, PCN clinical leads and pharmacists, and via the NCL Cardiovascular Disease Network and LMC.

The Committee approved the pathway and prescribing status recommendations.

12. Mental Health Formulary Alignment

The Committee was informed that one of the most common reasons for mental health medicine omissions at NCL acute Trusts was non-formulary status, which meant that the medication is not available on electronic prescribing systems and pharmacy stock management systems. The same supply principles should be applied to both mental and physical health medicines.

JFC Support reviewed the formularies of the two mental health trusts in NCL (Camden and Islington NHS Foundation Trust; Barnet, Enfield and Haringey Mental Health NHS Trust) and worked with mental health pharmacy teams to align formulary decisions and create a harmonised NCL mental health formulary. A small number of medicine decisions requiring further discussion to align practice will be considered by the mental health trust DTCs before returning to JFC for ratification.

Once ratified, a spreadsheet will be disseminated to NCL formulary pharmacists to identify and action on electronic prescribing systems and local pharmacy stock management systems. NCL formulary pharmacists will also be asked to review and update NetFormulary entries of monographs at respective Trusts. Concurrently, JFC Support will update monographs of medicines that require specialist initiation with: *This medicine should only be initiated or discontinued by a mental health specialist, or under the supervision of a mental health specialist*.

The Committee approved the mental health formulary decisions and proposed actions.

13. NHSE Updates on Innovative Medicines Fund and Commercial Framework for Medicines

The Committee noted NHSE developments in relation to the Innovative Medicines Fund, NHS Commercial Framework for New Medicines and pilot subscription payment model for two new antibiotics (cefiderocol and ceftazidime-avibactam). The Committee agreed that local DTCs should update NICE TA processes and policies with information on the Innovative Medicines Fund and support implementation of Blueteq forms for the new antibiotics.

14. DOACs Phase 2 Edoxaban Review

In May 2022 Phase 2 of the edoxaban workstream was approved 'in principle' by the Committee, pending review of:

i) The criteria to exclude high-risk patients with non-valcular atrial fibrillation already receiving a DOAC in primary care for the prevention of stroke from a switch to edoxaban; and

ii) Oversight on the implementation plan to ensure safe switching for patients.

The Committee were presented with these updates.

High-risk exclusion criteria: The Committee heard that the criteria had been updated from the draft presented to JFC in May 2022 following consultation with relevant stakeholders, including haematology, cardiology, care of the elderly and stroke specialists and GPs. The eligibility criteria for switching to edoxaban were narrowed

to only include current low-risk patients with non-valcular atrial fibrillation receiving rivaroxaban for the prevention of stroke in primary care. Patients currently receiving apixaban, dabigatran or warfarin were excluded as they will most likely be high-risk patients that have been initiated on the particular oral anticoagulant for specific clinical reasons.

It was highlighted by the Committee that the definition of 'frail' and 'frail elderly' may require further clarification in order to avoid ambiguity. Consultation feedback indicated that a frailty score would not be appropriate to assess the use of a DOAC in this setting and that body weight would be a more accurate indicator alongside clinician judgement. The Committee highlighted that the electronic EMIS systems utilised within general practice flags patients with frailty, and this should be used as an aid. The risk versus benefit of anticoagulation with DOACs in patients who have experienced recent falls was also highlighted, and it was noted that clinical judgement should be exercised when considering whether to continue with current rivaroxaban therapy. The Committee welcomed Helen Williams (Consultant Pharmacist and National Specialty Adviser for CVD Prevention) who advised that the NCL criteria is in keeping with national guidance and highlighted that the criteria developed ensures only low-risk patients will be targeted for a switch. In summary, the Committee were supportive of the criteria presented and approved phase 2 switching proposals pending revisions to the wording related to frailty and falls.

Implementation plan: An overview of the implementation plan to support safe switching of low-risk patients receiving rivaroxaban in primary care (for the prevention of stroke) to edoxaban was presented to the Committee. The Committee heard an overview of the areas of risk which have been identified by the NCL Edoxaban Working Group in relation to the switching programme, and the measures which are being taken to mitigate these risks. Primary care members highlighted the increased work required in general practice to implement the switching programme, however the Committee agreed that incentivisation via the Investment and Impact Fund (IIF) indicator and work to produce NCL-wide documents to support implementation of the switch were appropriate mitigations. The Committee also recommended that the working group consider engagement with patient and public forums as part of the implementation plan. In summary, the Committee were supportive of the implementation plan and approved Phase 2 (switching patients to edoxaban).

15. Intranasal dexmedetomidine sedation for paediatrics undergoing scans or painless procedures

The Committee considered the use of dexmedetomidine, an alpha-2 adrenoceptor agonist, administered intranasally for the off-label indication of sedation in paediatrics prior to painless procedures or scans. NICE guidance currently recommends the use of chloral hydrate or midazolam as first-line agents but does not provide a recommendation for or against the use of intranasal dexmedetomidine (IND). However, the NICE guidance was last updated in 2010 with no review date proposed. IND is already in use at GOSH and NMUH, and was brought to JFC following a request to implement practice at WH. The proposal for use at WH is in line with NMUH guidelines as follows:

- Patients ≥3 months but <1 year and <10kg: CH 50mg/kg initially; IND 1microgram/kg thereafter as rescue medication
- Patients ≥1 year and 10-15kg: CH 50mg/kg initially; IND 2microgram/kg thereafter as rescue medication
- Patients ≥15kg or failed previous chloral sedation: IND 4micrograms/kg
- Patients ≥15kg and failed dexmedetomidine alone previously: CH 50mg/kg (max 1g) and IND rescue dose as for a 10-15kg child

Several meta-analyses were considered. The first by Wang et al (2022) was a systematic review and meta-analysis to determine the efficacy and safety of IND vs CH. The authors included randomised controlled trials involving paediatric patients which compared IND to CH and were published in either English or Chinese. 14 studies were included in the analyses (n=3,749). The rate of sedation was significantly better with IND compared to CH (13 studies; relative risk = 1.139 [95% CI 1.051 to 1.235]). IND also demonstrated significant improvements compared with CH for the duration of sedation, latency of sedation, time to recovery from sedation and total sedation time. Key limitations of the study were that not all sources of bias were discussed in details and the ambiguity of the units used for efficacy endpoints. The second publication by Fong et al (2021) was a systematic review and meta-analysis to assess the efficacy and safety of CH as a sedative for non-invasive neurodiagnostic procedures. The authors included randomised controlled trials which assessed CH against other sedative agents, non-drug agents or placebo; whilst the meta-analysis focused on CH, one analysis compared CH versus IND (1 study; n=196). The time to achieve adequate sedation was significantly better with IND compared to CH (mean difference = 2.8 minutes; relative risk = 1.139 [95% CI 1.051 to 1.235]). A key

limitation was that this study focused on neurodiagnostic procedures and therefore excluded other painless procedures. A final meta-analysis by Jun et al (2017) was considered in brief as it focused on invasive procedures, though demonstrated that there was no significant difference between IND and intranasal midazolam at either mask induction or parent separation; there was also no significant difference between IND and oral midazolam at mask induction, though IND was significantly better at achieving satisfactory sedation at parent separation compared with oral midazolam (RR = 1.56 [95% CI 1.15 to 2.11]).

The Committee also considered the results of an audit undertaken at NMUH from February 2019 to May 2021, in which three different sedation regimens were used and compared against each other. The initial phase was a retrospective audit where the sedation protocol used NICE recommended sedating agents; the protocol for the second phase used CH in all patients; the third phase used an IND-containing protocol as per the NMUH guideline. The success rate of sedation was significantly better with the IND protocol compared to the protocol using NICE recommended sedating agents (81.2% vs 51.5% [p=0.017]).

In terms of safety, Wang et al found that IND significantly reduced the incidence of all adverse events (RR = 0.282 [95% CI 0.086 to 0.928]), though this was mainly driven by a significant reduction in vomiting. Compared with CH, IND was associated with an increased incidence of hypotension (RR = 1.500 [95% CI 0.939 to 2.397]), and significantly increased the risk of bradycardia (RR = 4.212 [95% CI 2.173 to 8.164]). Similar outcomes were seen by Fong et al, as CH was found to have a lower incidence of bradycardia events compared with IND (3 events vs 14 events; RR = 0.17 [95% CI 0.05 to 0.59]). Jun et al also found that IND significantly lowered systolic blood pressure (weighted mean difference = 6.7mmHg [95% CI -10.5 to -2.9]), and significantly lowered heart rate (weighted mean difference -6.8 beats/min [95% CI -11.3 to -2.6]). The NMUH audit also found that 72% of patients who used IND had a heart rate lower than the age adjusted APLS range, though only 11% had a heart rate >20% lower than the APLS range. In all studies, it was stated that no patients required treatment for hypotension or bradycardia.

In terms of budget impact, IND is expected to cost approximately £1,300 more than CH per 85 patients treated. However, an economic analysis was not available, and it was suggested that there may be an overall cost saving from the use of IND if it led to more successful sedation attempts and a reduction in cancelled procedures.

The Committee noted that there have been many studies which investigated the utility of IND, demonstrating improved efficacy for onset of sedation, time to recovery and successful sedation compared with CH, albeit with small absolute differences. However, IND comes with an increased risk of hypotension and bradycardia, though interventions appear to be rare. It was acknowledged that IND is established practice at both NMUH and GOSH, although use at GOSH may be sufficiently different from other NCL Acute Trusts due to the wider range of specialist procedures. The Committee supported the use of IND at interested organisations within NCL to reach an equitable position, although requested that WH and NMUH work together to produce treatment guidelines which include risk reduction strategies (e.g., the role of nurses and doctors in its administration; appropriate follow-up monitoring; warning signs for hypotension and bradycardia; thresholds for when and which interventions are required in the event of ADRs). These can then be adopted for use by other Trusts across NCL.

Decision: Approved for criteria outlined above, pending submission of guidelines with risk mitigation details.
Prescribing: Secondary Care Only
Tariff status: In tariff
Funding: Trusts
Fact sheet or shared care required: No
Additional information: WH and NMUH clinicians to work together to create a set of core principles to include in their respective Trust policies; WH to bring their guideline back to the JFC for final sign-off

Post-meeting note: JFC received a request to ratify the use of IND as a pre-medication prior to general anaesthesia for invasive procedures; this will be considered at a future JFC meeting

16. Safety considerations for intravenous dexmedetomidine

In 2019, NCL JFC approved intravenous dexmedetomidine for light sedation in mechanically ventilated patients with CAM ICU positive agitated delirium which precludes weaning and extubation. The Committee were informed of a safety alert highlighting an increased risk of mortality with intravenous dexmedetomidine in patients aged ≤65 years in the ICU. The risk was stated to be most prominent in patients admitted for reasons other than postoperative care or those with increasing APACHE II scores.

The Committee considered the evidence which underpinned the alert, which came from a post-hoc analysis of the SPICE-III study. The original study was by Shehabi et al (2019) and was an international, multi-centre, open-label, randomised trial to assess the role of dexmedetomidine as the sole or primary sedative agent in patients within 12 hours of undergoing mechanical ventilation in the ICU, with a target RASS of -2 to +1 (n=4,000). Patients were randomised to intravenous dexmedetomidine up to a maximum of 1.5microgram/kg/hour or usual care (which could include propofol, midazolam or other sedatives); propofol and benzodiazepines were allowed in the dexmedetomidine group. There was no significant difference in the primary endpoint of the rate of 90-day mortality from any cause between the intravenous dexmedetomidine group versus the usual care group. In a pre-specified analysis, the rate of 90-day mortality in patients at or below the median age (63.7 years) was higher with dexmedetomidine compared to usual care (22.4% vs 18.1% [95% CI 0.8 to 7.9]); conversely, the rate of 90-day mortality in patients above the median age was significantly lower with dexmedetomidine compared to usual care (35.7% vs 40.1% [95% CI -8.7 to -0.1]). Key limitations of the study were the inclusion of patients who required deep sedation, the lack of an assessment of other ICU factors (e.g., vasopressor use) and the use of other sedating agents in both arms.

The post-hoc analysis by Shehabi et al (2021) was a Bayesian analysis of the SPICE III study. Dexmedetomidine was associated with a lower 90-day mortality compared to usual care (OR = 0.83 [95% CrI 0.68 to 1.00]), with 97.7% probability of reduced mortality across broad categories of illness severity. Conversely, dexmedetomidine was associated with higher 90-day mortality in patients aged ≤65 years compared with usual care (OR = 1.26 [95% CrI 1.02 to 1.56]). Two clusters of patients were identified; cluster 1 were mostly operative patients (n=976) and cluster 2 were mostly non-operative patients (n=2,346) – the latter having higher baseline APACHE-II scores. There was a greater probability of benefit in cluster 1 compared to cluster 2. Key limitations include that the study was a post-hoc analysis, and therefore considered hypothesis generating rather than hypothesis testing.

The Committee heard from Mr Shulman that ICU teams would like to continue using dexmedetomidine, including in the at-risk population after exhausting 1st and 2nd line sedating agents as this cohort has limited alternative options. UCLH have access to the A2B study, which is designed to assess the efficacy and safety of intravenous dexmedetomidine compared to intravenous clonidine or intravenous propofol and will continue to enrol into this (although other NCL Trusts may not have access to this).

The Committee discussed the available evidence and agreed that as the alert is based off a post-hoc sub-group analysis, it is difficult to determine whether there is a true signal for increased risk of mortality, and that further evidence is warranted. The Committee advised that the primary outcome of the A2B study is time to first successful extubation and it is unlikely to provide meaningful data on mortality risk. The Committee agreed that ICU clinicians across NCL Providers Trusts should be made aware of the alert and asked to consider how they use intravenous dexmedetomidine in the at-risk group, with restricted use where possible. The Committee also agreed that any further evidence or national advice (e.g., MHRA safety alerts) should be brought back to NCL JFC for discussion.

17. Review of use of potassium permanganate

The Committee considered a National Patient Safety Alert (NatPSA/2022/003/NHSPS) about inadvertent oral administration of potassium permanganate issued by NHSE. A review of the National Reporting and Learning System between Jan 2019 and Dec 2021 showed that 35 incidents occurred relating to ingestion of potassium permanganate; 15 of which were due to healthcare staff administering orally to patients and 9 were self-administered. Area prescribing committees were asked to review the use of potassium permanganate to consider if the benefit outweighs the risk for inclusion on local formularies.

Potassium permanganate is an oxidising agent strictly for topical use in wound management. Indications for use are not described uniformly in available guidance, however the BNF indicates it can be used for cleansing and deodorising suppurating eczematous reactions and wounds. The Committee considered the available evidence on efficacy and safety.

Wahab et al. (n=21) was a phase III, open-label, active control study to assess the efficacy of potassium permanganate compared to super-oxidised hydrogel in adult patients with clinical diagnosis of limb cellulitis with presence of clinical signs of erythema, warmth and oedema. The primary outcome, reduction of erythema (measured as a percentage of reduction of total surface area erythema; evaluated as a sign of improvement of local inflammation), was significantly higher with hydrogel dressing than potassium permanganate-soaked dressing (57% vs 37%, p=0.007). The Committee noted study limitations of a small cohort and open-label design.

Delgado-Enciso et al. (n=24) was a phase III, single-blind, randomised active control study to assess the efficacy of potassium permanganate compared to standard of care measures (such as reduce pressure on ulcerated areas, daily cleansing of the ulcer with potable water and antiseptic wash solution and application of disinfectant solution). Adult patients with type 2 diabetes with superficial or deep ulcers with a history progression were randomised to receive treatment for 21 days. The primary outcome, ulcer area measurement at the end of treatment compared to baseline, was significantly decreased in the potassium permanganate group than the control group (73% vs 38%, $p<0.009$).

In terms of safety, potassium permanganate can cause skin irritation, redness, pain, burns and skin hardening on contact with the dry crystals or concentrated solutions. Staining of skin care can be experienced even with dilute solutions. The Committee noted that potassium permanganate, a chemical substance, is subject to the Control of Substances Hazardous to Health (COSHH) Regulations and the NPSA alert identified a death due to accidental ingestion of potassium permanganate tablets.

Community tissue viability nurses informed JFC Support that there was no interest in using potassium permanganate due to the risk of accidental ingestion of tablets. Other alternatives such as paste bandages, steroid creams or Dermol 500 emollients would be used for cleaning. UCLH dermatology teams estimate use in up to 5 patients if reserved for use in acute suppurating, bullous and acantholytic skin diseases, where alternative treatments have been ineffective. The Committee were informed that a working group at RFL, which hosts the largest dermatology service in NCL, are currently reviewing implications of the NPSA alert.

In summary, the Committee agreed a preference to remove potassium permanganate from formulary due to limited evidence of efficacy and known significant risk of harm. However, the Committee requested feedback from the RFL dermatology working group on whether assigning a non-formulary status would be acceptable and what alternatives could be used. If feedback indicated that restricted use was required, the Committee suggested restricting use to secondary care and requested feedback from RFL dermatology team on specific criteria for use and risk mitigations in line with the NPSA alert and British Association of Dermatologists recommendations.

18. Next meeting

Thursday 18th August 2022

19. Any other business

Dr Burrage and Mr Rajan will be leaving NCL to take up new roles and will therefore step down as member and secretariat of NCL JFC respectively. The Committee thanked Dr Burrage and Mr Rajan for their contributions to the Committee and wished them both well in their new roles.

Mr Semple noted that discussions regarding ICB governance for medicines optimisation are underway and will clarify upward reporting and scope of JFC. Meetings should continue in the meantime and Prof Hingorani will be invited to participate in ICB discussions on behalf of JFC.