SUMMARY OF REPLEIES TO MLX 303 - PROPOSALS TO EXPAND THE RANGE OF CONDITIONS TREATABLE BY EXTENDED FORMULARY NURSE PRESCRIBERS AND THE RANGE OF PRESCRIPTION ONLY MEDICINES IN THE NURSE PRESCRIBERS EXTENDED FORMULARY

The replies are summaries in the attached Annexes as follows:

Annex A – replies from England and from UK-wide organisations

Annex B – replies from Wales

Annex C – replies from Scotland

Annex D – replies from Northern Ireland
ANNEX A

Consultation on the Proposals to expand the range of Prescription Only Medicines in the Nurse Prescribers Extended Formulary (MLX 303)

Summary of comments received from respondents in England/UK-wide organisations

Number of respondents

number of replies received by closing date 181

Analysis of respondents

Medical Colleges, Societies and interests 11
Pharmaceutical Colleges, Societies and interests 5
Nursing Colleges, Societies and interests 6
Other organisations 13
From the NHS 75
Replies from individuals 71

Summary

3 respondents accepted proposals with no further comment.

Comments on specific proposals in the MLX:

1. Proposed additions to the conditions currently treatable under the NPEF

REPLEIS FROM MEDICAL COLLEGES/BODIES/INTERESTS

Royal College of Paediatrics and Child Health felt very strongly that, in order to improve patient care, nurse prescribers should be able to prescribe any medicines within the range of their professional competence rather than be limited by a restricted list of conditions and medicines. The College considered that some of the proposals were inconsistent with the purpose of nurses supporting extension of walk-in centres; providing Primary Care out of hours and helping to reduce unnecessary burdens on ambulance services and A&E departments and that some recommendations were inconsistent with others within the same document. The College made the following specific comments on the proposals:

- **Nausea and vomiting:** the 5HT3 antagonists list for post operative nausea and vomiting should be added to the list of medicines available.
- **Acute exacerbation of chronic bronchitis:** Oxytetracycline is inappropriate for use in children. They noted that Oxytetracycline has not been carried forward to the list in paragraph 14 for the treatment of the same condition.
- **Acute severe pain after trauma:** disappointed that the use of morphine during intubation of neonates is not specifically mentioned as this would allow neonatal nurse practitioners to carry out this procedure in total.
Generalised tonic clonic seizures: the use of buccal Midazolam would be unlicensed or off label.

Fluid replacement: did not agree that 10% glucose solutions would be used in this situation. The College feel strongly that the use of hypo-tonic sodium chloride solutions such as sodium chloride 0.018% with glucose 4% are inappropriate for children and that a combination of 0.45% sodium chloride with 5% glucose would be much more appropriate.

Potassium replacement: inclusion of a solution for children of 0.45% sodium chloride with 5% glucose and 20mmol per litre of potassium should be considered.

Prophylaxis and treatment of nausea and vomiting in the post operative period: the College did not understand why, if this indication is to be included in the nurse prescribing formulary, why post operative analgesia cannot be included.

Plasma substitutes: 0.9% sodium chloride should be included.

Molluscum contagiosum: the College questioned why nurse prescribers would be treating this.

Flushing cannulae: sodium chloride 0.9% with heparin should be included.

Dental infections: supported the inclusion of Metronidazole for this indication.

Cellulitis: Fusidic acid is preferred in this indication.

Post operative pain relief: proposal is over restrictive. Nurse prescribers should be able to prescribe in this area.

Lower urinary tract infection in children and lower respiratory tract infection in children: strongly agreed that Trimethoprim should not be available for this indication.

The Royal College of Physicians supported the proposals with some important provisos: the proposals are potentially valuable where the need to start treatment is urgent or semi-urgent but there is an issue as to continuation of treatment. This needs to be co-ordinated with a doctor, and provision for such ought to be included. Training needs to be both in diagnosis and treatment; it needs to be validated, and there will need to be a robust system for revalidation. The areas of expertise will need to be defined. Also, there is a danger of confusing overall responsibility for the patient. Does it lie with the doctor or the nurse? The College recommended a built in medical review of the initiating action taken by the nurse. The College made the following comments in relation to specific treatment areas.

Nausea and vomiting: would not have any problem with the proposed drugs being prescribed by nurses. Would like to add Domperidone because it has certain advantages over Metaclopramide with less central action.

Anaphylaxis: were happy for the drugs listed under anaphylaxis to be included in the EFNP with one very important proviso. The current designated use of adrenaline as parenteral is potentially dangerous, as it might be given intravenously. It would be important therefore to indicate that it is for intramuscular usage.

Generalised tonic-clonic seizures: the College was strongly in favour of the proposal.

Acute alcohol withdrawal. The drugs proposed here are clearly appropriate to be used in this context. Chlordiazepoxide is the mainline treatment for moderate and severe withdrawal. They should only be prescribed strictly according to local guidelines that have been agreed by Trusts. Managing
patients with acute alcohol withdrawal is a complex procedure carrying significant risks for patients and needs to be part of a team event. It is only in such circumstances that these drugs should be prescribed by nurses.

- **Prophylaxis of acid aspiration during surgery:** there is very little evidence to suggest that acid suppression significantly influences the outcome of inhalation during surgery but if one is going to recommend an acid suppressant then it needs to be the best and therefore a PPI would be more appropriate than an H2 receptor antagonist. Because of the long action of PPIs we cannot see any reason why they could not be given orally in advance of the surgery rather than being given parenterally. Obviously, in an emergency situation, they would need to be given parenterally.

- **Acute dystonias:** are particularly more common in HIV infection. They are particularly unpleasant symptoms, and it was perfectly reasonable for a nurse to treat if trained to recognize the syndrome.

- **Vaccine to prevent travellers against meningococcal infection:** this extends a nurse's ability to prescribe and administer the tetravalent meningococcal vaccine for travelling and the College saw no problems with this.

- **Cellulitis:** The College considered that the proposal to allow nurses to give parenteral Benzylpenicillin for cellulitis depends on how easy it is to diagnose this condition. In practice, Flucloxacinill is a better choice. Enabling the prescribing of benzylpenicillin in the community without appropriate review may be inappropriate and, as the condition is rarely life-threatening, medical review and prescribing would be more acceptable.

- **Emergency treatment of meningitis:** rapid treatment is really much more important for meningococcal septicaemia than for meningitis per se. It was reasonable for nurses to treat in the community if they suspect meningococcal septicaemia or meningitis, but unreasonable in a casualty department where medical assessment is available. Differential diagnosis of meningitis is quite wide. A nurse's administration of antibiotics may confuse microbiological results and may also stop people thinking about other differential diagnoses.

- The College was in agreement with the proposals to include **acute myocardial infarction, acute pulmonary oedema associated with cardiac failure/ventricular fibrillation or pulseless ventricular tachycardia, thromboprophylaxis, acute reversible airways obstruction, acute exacerbation of chronic bronchitis and tetanus treatment,**

- The College agreed the proposals **not to include adrenaline, atropine and clopidogrel.**

The Royal College of Radiologists was generally in favour of extending the role of nurses (and radiographers). They said, however, that safeguards were needed, including appropriate training, clear guidance on delegation, agreed protocols and practice within a team which includes the opportunity for medical consultation. The British Medical Association were fully supportive of the proposals, as were the British Association for Accident and Emergency Medicine and the Joint Royal Colleges Ambulance Liaison Committee. The Royal College of General Practitioners supported the proposals with a number of reservations. They commented that as the proposals are primarily aimed at Accident and Emergency Departments and Walk-In Centres, the range of drugs should be reviewed by a panel of primary care nurses before it is finalised as there may be omissions or inconsistencies. Regarding the proposed additions to conditions currently treatable under the NPEF the College remarked that emergencies might present at a treatment room when there is no doctor on the premises such as anaphylaxis, epileptic fits,
acute pulmonary oedema, severe asthma. The main role for treatment room nurses would be recognition of the emergency, summoning assistance, providing first aid and supportive treatment. In isolated situations or where medical or paramedical help would be delayed, there is a case for appropriately trained nurse prescribers to administer first line drugs autonomously. However these situations differ from A&E or ICU in the rarity of such occurrences and consequently the lack of experience and familiarity of individual prescribers, so that the balance of advantage may swing towards waiting for medical or paramedical assistance, rather than nurse prescribing. The College considered that there does not seem to be a need in primary care for the proposed extension of “off label” prescribing and with regard to controlled drugs in palliative care good practice includes the system whereby anti-emetics and increased doses of opiates are signed up in advance by the prescribing doctor on a “when necessary” basis for implementation by the community or palliative care nurse. Good communication and clearly defined roles are the essence of good palliative care, and increasing the number of prescribers may adversely affect the treatment plan and confuse lines of responsibility. On the proposed extensions regarding Antimicrobials and other drugs the College supported the limitation of antimicrobial prescribing on grounds of minimising antibiotic resistance, conforming to the evidence base regarding its lack of benefit in common respiratory and ENT conditions and curbing public expectation of antibiotic prescription. The College also considered that there is benefit in maintaining a clear distinction between medical (diagnosis and decision to prescribe) and nursing roles (triage and provision of nursing care), which not only conforms to the expectation of patients, but also provides a clear boundary which would otherwise lead to contention about what are the acceptable norms for each profession. The College raised a number of specific points, including:

- **Skin conditions:** while there is no reason why nurses should not diagnose molluscum contagiosum, the inclusion of psoriasis seems anomalous since prescribing for it is not an urgent matter and the diagnosis, which may not be straightforward, is a function of the GP. Also, Molloscum contagiosum is usually not treated actively. The use of salicylic acid has no substantial evidence base to support it and its prescribing would be off-licence.
- **The document defines cellulitis as ascending cellulitis of the leg. This appears overly limiting. Can it define cellulitis more widely to include the rest of the body?**
- **“poisoning” is not defined - are these general symptomatic treatments or specific antidotes?**
- **In prophylaxis of acid aspiration during surgery Proton Pump Inhibitors and motility reducing drugs are not mentioned even though there is considerable evidence they may have advantages over H2 Blockers**
- **Acute dystonias are frequently drug related, particularly with older anti-psychotic drugs. Why are specific drugs to prophylactically avoid or limit the dystonic and other side effects of such drugs not included?**
- **Under the treatment of cellulitis and other skin infections are any drugs included that would be suitable for treating anaerobes and the mixed growth of very dirty wounds?**
- **Acute reversible airways obstruction: ipratropium bromide by inhalation has no evidence base to support inclusion, with the possible exception as second line therapy in acute severe asthma in children, which is not responding to salbutamol or terbutaline, Consequently we suggest the ipratropium is not added.**
The Association of Medical Microbiologists supported the concept of prescribing by nurses who have been appropriately trained, and whose competence is maintained through a programme of continuing professional development. The Association was pleased that the particular potential impact of excessive or inappropriate antimicrobial prescribing on antimicrobial resistance has been recognised. The Association made the following specific comments:

- Tetanus immunoglobulin for treatment of tetanus, the Association commented that tetanus is a rare condition, and if the condition is suspected, the patient should be assessed by an intensivist or other senior physician to make the clinical diagnosis, ensure that appropriate diagnostic specimens are collected and to initiate treatment that should include antimicrobials in addition to immunoglobulin. Furthermore, tetanus can be confused with other differential diagnoses. The Association did not see any advantage to inclusion of this drug, but considered that there might be a place for the inclusion of tetanus immunoglobulin in the management of tetanus-prone injuries.

- The Association supported the inclusion of Meningococcal polysaccharide vaccine A, C, W135, Y for the protection of travellers against meningococcal infection. They also supported the inclusion of Amoxicillin trihydrate, Erythromycin, Erythromycin stearate, Erythromycin ethyl succinate (oral) for treatment of dental infections.

- On the proposals to include Amoxicillin trihydrate, Erythromycin, Erythromycin stearate, Erythromycin ethyl succinate, Oxytetracycline dihydrate (oral) for treatment of acute exacerbations of chronic bronchitis, the Association commented that such exacerbations are frequently of viral aetiology and as they do not necessarily require antibiotic treatment they had serious reservations about the inclusion of this condition.

- The Association supported the use of amoxicillin trihydrate and oxytetracycline dihydrate for the treatment of uncomplicated exacerbations of chronic bronchitis. However, they considered that none of the preparations of Erythromycin are suitable as mono-therapy for this indication due to the agent’s poor activity against *Haemophilus influenzae*. They therefore advised against inclusion of this product for this indication.

- The Association recognized that cellulitis can vary from a minor localized infection to a rapidly progressing life-threatening condition. They supported the availability of parenteral benzylpenicillin and flucloxacillin to treat appropriate cases rapidly, particularly if there would otherwise be a danger of delay in commencing treatment. They considered it essential that all such patients are evaluated urgently by an experienced doctor as accurate assessment of the potential severity of an individual case is sometimes not easy and antimicrobial treatment alone may be insufficient to successfully treat more serious infections. In their view, an argument could be made for treating relatively minor cases of cellulitis in primary care with oral antibiotics. However, it was essential that all clinical staff who see such patients are fully aware of the rapidity with which apparently minor cellulitis can progress to a far more serious condition. Until such time that comprehensive and in-depth training programmes are set up, and more importantly quality-assured, the Association were of the view that cases of cellulitis should not be treated with oral antibiotics unless the patient is evaluated by an experienced doctor.

- The Association suggested that consideration be given to the inclusion of topical products including Mupirocin for the eradication of MRSA.
The Royal College of Ophthalmologists supported the addition of Fluorescein, Tropicamide, Oxybuprocaine hydrochloride and Proxymetacine hydrochloride to the NPEF, but commented that nurse prescribers should have access to a slit lamp biomicroscope and be able to use it to examine the patient’s eyes prior to prescribing. Tear deficiency is a complex disorder which may indicate serious underlying systemic illness. Simple dry eye is already self treated by many patients with ‘over the counter’ lubricants. True ‘tear deficiency’ requires more detailed assessment and investigation and should be managed by a doctor. Inflammation following ophthalmic surgery - the vast majority of such surgery is intraocular. Post operative inflammation is unusual and may indicate serious intraocular infection which could lead to blindness. It should be managed by ophthalmologists. Corneal trauma may involve penetration of the patient’s globe - for example, injuries involving hammer and chisel. Nurse management should be restricted to minor corneal trauma such as mechanical abrasions or corneal foreign bodies. The College did not support the addition of Tetracaine hydrochloride (toxic to the corneal epithelium), Acetylcysteine (should not be used indiscriminately as it can be toxic to the cornea), or Diclofenac sodium (there are reports of corneal melt and perforation). The General Medical Council agreed with the proposed additions, as long as there was adequate training in how to reach correct diagnoses and in the pharmacology of the proposed drugs. They did not understand why cefotaxime should not be given by nurses in cases of suspected meningitis where the patient is known to be penicillin sensitive. The Medical Protection Society welcomed the proposals saying that proper training, assessment and monitoring of adverse incidents were crucial as in their experience a number of claims arise from prescribing errors or from failure to adequately monitor a patient’s progress. The National Poisons Information Service (NPIS) advised that it had been advising the NHS for about 40 years on the management of poisoning and its advice is carried on the national internet database – TOXBASE. The Directors of NPIS considered nurse prescribing for “poisoning” would provide an opportunity to increase the availability of some antidotes for the benefit of patients. In particular, NPIS would suggest N-acetylcysteine in the hospital setting and perhaps activated charcoal outside hospital. They also felt there would be a role for naloxone.

REPLIES FROM PHARMACY COLLEGES/BODIES/INTERESTS
The National Pharmaceutical Association supported the proposals, in particular welcoming the move to allow nurse prescribers to prescribe 'black triangle' drugs. They believed that the proposed additions to the conditions currently treatable under the NPEF would lead to better patient care, particularly in emergency care situations. They also supported the proposed extension in restricted circumstances of "off label" prescribing. However, they believed that it was imperative that EFNP's are made fully aware of the legal liability and personal indemnity issues involved in such prescribing. The Association agreed that EFNP's should be able to prescribe from a restricted range of controlled drugs, and suggested that morphine for palliative care should also be included in a further extension to the NPEF. The Faculty of Pharmaceutical Medicine of the Royal College of Physicians was supportive of the proposals. They did, however, emphasise the need for follow up with suitable medical care, for example after emergency treatment by nurse prescribers for meningitis. They were reassured that not all nurse prescribers are likely to use all of the proposed drugs. While broadly supportive of the proposed extensions to the range of treatable conditions, the Faculty was concerned that the wording concerning gastrointestinal conditions should be amended to indicate prophylactics against acid aspiration prior
to surgery. Similarly, they believed that there needed to be a clarification of the types of "poisoning" and the sorts of treatment to be used. They believed that most cases of poisoning required hospital management and that nurse prescribing should be limited to drugs required for circulatory and respiratory support. The Faculty was supportive of the proposals concerning off-label prescribing and the prescribing of controlled drugs. They assumed that the proposals concerning thrombolytic therapy referred to a "one-off" bolus prior to hospital management, and suggested that a statement be added to the section dealing with thromboprophylaxis to indicate the need for careful monitoring of anticoagulant effects. They were concerned as to how serum potassium levels would be ascertained to assess the need for the use of potassium supplemented infusion fluids, and how subsequent biochemical values would be monitored. The College of Pharmacy - Faculty of Prescribing & Medicines Management supported the proposed additions to the list of conditions currently treatable under the NPEF. The College supported the inclusion of the proposed controlled drugs providing that all the safeguards around the prescribing and administration of such drugs apply and that there were adequate systems in place for clear accountability and audit trails. They supported the proposed drug additions to the NPEF and agreed broadly with the Prescribing Working Group’s comments. However, they believed that the use of intravenous infusions to which potassium has to be added has been a major hazard and continues to be a potential hazard ready-made products are not used. Therefore, the inclusion of potassium-containing infusions should only be available in the NPEF as ready-made products. The College said that they were not aware of robust evidence for using salicyclic acid for molluscum contagiosum and, as the condition is self-limiting, wonder how effective and safe the treatment is in children. The British Pharmacological Society (BPS) generally welcomed the proposals, but considered that some of the conditions were complex and questioned whether nurse training as presently conducted was adequate to allow safe prescribing. They were particularly concerned with the treatment of poisoning. They had concerns about permitting more prescribers to use controlled drugs, and suggested that maximum amounts which could be prescribed by a nurse should be included in the NPEF. The Guild of Healthcare Pharmacists supported the proposed extension to the NPEF and, as all nurses are now able to report adverse drug reactions, saw no reason why EFNPs should not prescribe 'black triangle' drugs.

**REPLIES FROM NURSING COLLEGES/BODIES/INTERESTS**

The Royal College of Nursing welcomed the proposals. They said, however, that the fragmented way in which the formulary had been opened up to nurses has caused confusion to practitioners. They re-emphasised that they continue to propose that nurses have full prescribing rights from the entire BNF, limited only by the Nursing & Midwifery Council's Code of Professional Conduct. The College made the following specific points:

- Off label indications which might be of significant use to primary care nurses should be considered, for example the use of the oral contraceptive pill for menorrhagia and dysmenorrhoea.
- The omission of cefalexin for the treatment of lower female urinary tract infections is unfortunate, as this is the recommended first line treatment in some areas.
- Penicillin for tonsillitis was rejected on the grounds that it is rarely indicated. This would seem to be short sighted. There is no evidence that nurses support the inappropriate use of antibiotics for tonsillitis. This proposal will not reduce the number of patients receiving antibiotics, it will merely encourage nurses to
continue with the current practice of obtaining them through producing a prescription for a GP to sign or via a Patient Group Direction. The same comment also applies to the omission of antibiotic treatment for conditions such as otitis media and sinusitis.

- The rejection of inhaled beclometasone for complete care in asthma management fails to take account of the fact that many patients presenting with exacerbation of asthma do so because they have stopped using their inhaled steroid, and such a prescription is frequently indicated in the acute context. The division of acute and chronic asthma is artificial and unworkable in practice.

- The proposals will limit all nurses working in acute pain settings. Nurses are unable to work within the recommendations of the NHS Plan which means many patients are not getting fast access to treatment.

- The MLX proposes that acute severe pain after trauma be added to the conditions and that the EFNP be able to prescribe morphine for this condition. The RCN say that it could therefore be argued that a nurse could prescribe morphine in an emergency care setting. However, under paragraph 15, nurses are unable to do so as the Working Group considers that "post operative pain is the direct responsibility of the anaesthetist." The anaesthetist will not necessarily have contact with the patient in the post operative period - the Acute Pain Service will be the point of contact and most of these are nurse-orientated.

- If parenteral morphine is added to the NPEF, then naloxone should also be an addition. It is unsafe practice to give intravenous opioids without naloxone being made ready and available for administration.

- Why is post operative pain management considered inappropriate to add to the formulary whereas post operative nausea and vomiting is considered acceptable? Could it not be argued that both are integral parts of post operative care? The exclusion of post operative pain means that nurses working in this area of practice are unable to fully utilise the EFNP qualification.

- Additions to the formulary are needed for the alleviation of symptoms associated with drug withdrawal in a first contact situation, where supplementary prescribing is not an option.

- Nurses can already prescribe for hayfever, and black triangle drugs are no longer excluded so the newer antihistamines (levocetirizine and desloratidine) should be included.

- Routes of administration should be reviewed: for example, paracetamol can be administered orally, but not per rectum. This would be valuable for practitioners in a paediatric setting as many patients are unable to take oral medication.

- Finally, the College considered that human soluble insulin should be included for hyperglycaemia as, if this were included, first contact nurses working with diabetic patients may be able to prevent hospital admission.

**The British Dermatological Nursing Group** regarded nurse prescribing as a significant development within their specialty. The NPEF has been extremely important to the successful development of nurse-led skin disease clinics in both primary and secondary care and they were particularly pleased to see the proposed inclusion of psoriasis as another condition which ENP can diagnose and treat. The Group were pleased with the inclusion of topical calcipotriol, calcitriol and tacalcitol but felt this was an extremely limited formulary to treat psoriasis and would severely impair the ability of nurses to treat people with psoriasis holistically. Without a more extensive formulary nurses with a case load of patients with psoriasis will have to resort to either waiting around for a doctor to sign the script, make a second
appointment for the patient to see the doctor or resort to supplementary prescribing which is more complicated and unnecessary in this instance. They urged inclusion of:

- Topical mild to moderate corticosteroids for facial, ear and flexural psoriasis, potent topical corticosteroids for the management of scalp psoriasis and some plaque psoriasis; very potent topical corticosteroids for palmar/plantar psoriasis. Psoriasis in skin folds is prone to secondary infection and access to combination corticosteroids with antibiotic/anti yeast would be useful.

- higher strengths topical tar preparations and proprietary Dithranol

and, while the Association accepted that the diagnosis for Rosacea may be difficult especially for those not working within the specialist field of dermatology, they hoped this will be reconsidered in the future. The British Association for Nursing in Cardiac Care supported the proposals in principle but did not feel that they were wide enough to fully address the needs of the patient requiring the administration of therapy associated with acute myocardial infarction. The administration of Alteplase, Reteplase and Tenecteplase must be associated with concomitant administration of Heparin. The Association therefore proposed that the inclusion of heparin. The Association For Nurse Prescribing (ANP) welcomed increased opportunities for nurse prescribers to use their skills to maximum effect. They were appreciative of the regular review of drugs that could be included within the NPEF, but frustrated by the fact that this exercise will need to be continually repeated. Allowing nurse prescribers free access to the entire BNF would solve this lengthy and time consuming process as well as ensuring that all patients seen by nurse prescribers would have equal access to prompt treatment. These patients would also be safe in the knowledge that nurses are limited by their scope of practice and would not, therefore prescribe outside their area of competence or expertise. They support the proposal for some treatments to be prescribed by nurses “off label” as it recognises that this allows highly individualised care that may be more “unusual” but is in the best interests of the patient. The ANP would like to see more commonly used “off label” prescribing become acceptable for nurses, e.g. the use of the combined oral contraceptive pill to regulate the menstrual cycle, and to reduce dysmenorrhoea. They welcomed the opportunity to introduce controlled drugs within their prescribing range. However, limiting the use of these to certain conditions e.g. the proposal that morphine can only be prescribed for “acute severe pain after trauma” is unfortunate. This means, for example, that an advanced nurse practitioner admitting a patient suffering from a myocardial infarction would be unable to relieve the pain effectively because she would be prescribing under the wrong “category of condition”. The Nursing and Midwifery Council supported the proposals but made no comments on specific proposals. The Community Practitioners and Health Visitors' Association welcomed the proposals but believed that the fundamental principle behind nurse prescribing should be that suitably qualified and competent nurses are able to prescribe whatever they require to deliver nursing care to their patients. They also commented that the present nurse prescribing system was too complex, and not understood by many nurses, doctors and pharmacists.

OTHER PROFESSIONS/INTERESTS
The College of Optometrists gave a general welcome to the proposals. They said that the additions to the ophthalmic conditions were reasonable, endorsed the proposals to include fluorescin, tropicamide, oxybuprocaine hydrochloride and proxymetacaine hydrochloride and shared the Working Groups reservations on the use of tetracaine. They wondered what diagnostic use tetracaine would be for and felt that in cases where oxybuprocaine hydrochloride and proxymetacaine hydrochloride
were insufficient a patient would be better seen by a doctor. The **British Association of Dermatologists** broadly supported the proposals. They strongly supported the addition of psoriasis to the list of conditions covered by the proposals and the addition of Vitamin D analogues for use in this indication. They suggested that it would be appropriate for mild to moderate steroid preparations which are already included in the formulary to be available for use in this indication as well as for the various forms of eczema. The Association had anxieties about an extension of prescribing for off label use of medications but saw that there might be benefits if the circumstances can be properly restricted. Clarity in the drafting of the restrictions is crucial.

**OTHER ORGANISATIONS**

The **Meningitis Research Foundation** supported the proposals for meningitis, but said that the terminology is confusing and could be dangerous. They wrote that it would not be helpful to restrict nurses to prescribing benzylpenicillin (bp) for 'meningitis', because it is meningococcal septicaemia in particular in which early treatment with antibiotics is crucial. The great majority of fatal cases of meningococcal disease have a primarily septicaemic presentation and seldom show classic meningitis symptoms such as stiff neck, headache or photophobia. All of the Chief Medical Officer professional letters refer to use of bp for meningococcal meningitis and septicaemia, or meningococcal infection/ meningococcal disease, not just meningitis. The BNF states that bp should be used for initial blind therapy of meningitis, but emphasises its use in suspected meningococcal infection. They consulted a number of health professionals with a particular interest in meningococcal disease and this point was picked up very strongly, for example - "It is vital that antibiotics are given early in septicaemia, as we all know. I suspect that this is simply a matter of them meaning septicaemia but saying meningitis... If they could be persuaded to allow nurse prescribing of benzylpenicillin for septicaemia and/or meningitis that would be fine." The Foundation was concerned that if the terminology remains unchanged, local protocols might require that the patient has, for example, neck stiffness (which is not often seen in septicaemia and is unusual in young children even with pure meningitis), and septicaemic presentations will be left out. Prescribing should also be extended to include 3rd generation cephalosporins ceftriaxone/cefotaxime. **Diabetes UK** disagreed with the proposal not to include human insulin. They said that an appropriately trained diabetes specialist nurse or EFNP who is permitted to prescribe short acting insulin may well be able to prevent hospital admission in people with diabetes with intercurrent illness. In addition people who are sent urgently to their diabetes clinic and found to have hyperglycaemia and ketones in their urine would also be able to access insulin quickly. It may not always be possible to access medical staff during nurse-led clinics. Benefits could also occur where a diabetic needs insulin when he/she does not have it readily available. Having the ability to obtain insulin quickly would prevent a patient becoming ketotic or unwell (especially in children where this can occur quite quickly) and could also help avoid a hospital admission. The **Pain Society** were pleased to see the recognition of particular painful episodes such as dressings and trauma. However, they felt the division of nausea and vomiting into three categories (palliative care, 'normal' and postoperative) may be confusing. For example postoperative nausea and vomiting may be managed by the three 5HT3 agonists listed. However other anti-emetics are commonly used. It would appear that nurses would be able to prescribe the (more expensive) 5HT3 medicines but not the cheaper (and effective) other anti-emetics in the postoperative period. The Society
supported the proposed extension of the prescribing of controlled drugs, plus they strongly recommended the inclusion of Naloxone. The Society was very disappointed to see that the WG did not support the use of morphine sulphate for postoperative pain relief. The impact of the European Working Directive will mean that for some hospitals there will be no on-site anaesthetic cover from 9pm. There will, however, be patients who have had major surgery that day. It would seem likely that there will be a growing number of situations where analgesia would be more appropriately prescribed by non-anaesthetic staff. The Skin Care Campaign welcomed the proposals, but were concerned that topical corticosteroids were not included in relation to psoriasis. Mild to moderate topical corticosteroids are the first line treatment for psoriasis, and the absence of such treatments from the NPEF severely restricts the ability of nurse prescribers to provide care for psoriatic patients. The same views were made by the Psoriasis Association who regarded the current list as not only limiting the EFNPs range of options but also the patients’ choice of preferred treatment. The Association for Continence Advice requested that anticholinergic medication for the treatment of overactive bladder be included under NPEF. The University of Huddersfield (Department of Health & Community Studies) welcomed the proposed additions to treatable conditions, and suggested that cellulitis in drug misuse should be added. Whilst also welcoming the proposed additions to the NPEF they suggested that sodium chloride 0.45, sodium chloride 0.45 with glucose, potassium replacement (all for use with children), and heparin for the flushing of cannulae should also be added. They also commented that human soluble insulin is often administered as a bolus injection, and would therefore wish to see its use included in the NPEF. Whilst agreeing that post operative pain is the responsibility of the anaesthetist, post operative patients in pain do not have immediate access to an anaesthetist. Specialist nurses in pain management should be able to prescribe a full range of analgesia for such patients. The British Heart Foundation supported the proposals and the British Cardiac Patients Association and the Health Professions Council made no comment.

NHS BODIES/INTERESTS & INDIVIDUALS
There were 146 responses from those working within the NHS. All supported the NPEF and the development of nurse prescribing in principle although views differed on specific proposals in the MLX. Many of the responses made the point that, by the very nature of extending the formulary in stages, the formulary itself would remain restrictive and inflexible. Many respondents asked that the whole BNF should be available to suitably qualified and competent independent nurse prescribers. A representative sample of points made is summarised as follows. Several respondents requested that post-operative pain relief be included. A typical comment was that "post operative analgesia is not exclusively managed by anaesthetists, but rather by a team based approach involving specialist nurses. Delay in providing pain relief in this situation is not acceptable. Actual patient needs are not always predictable and anaesthetists are not ward based." Another condition that several respondents suggested should be included in the NPEF was "mental health/depression". Some nurses also asked that parenteral ceftriaxone and parenteral clindamycin be added to the NPEF for the treatment of Cellulitis. There were several responses asking that "more consideration be given to the addition of human insulin - particularly Human Actrapid - for the treatment of hyperglycaemia, as this is a common presentation of diabetic patients in secondary care." Several respondents suggested that warfarin should be added to the formulary for use in deep vein thrombosis and for stroke prevention. It was also widely felt that more antibiotics, in particular
penicillin for tonsillitis, should be included in the NPEF on the basis that nurses would prescribe antibiotics as carefully as doctors. Several comments were made to the effect that there were currently no effective evidence based treatments for molluscum contagiosum.
ANNEX B

Consultation on the Proposals to expand the range of Prescription Only Medicines in the Nurse Prescribers Extended Formulary (MLX 303)

Summary of comments received from respondents in Wales

Number of respondents

number of replies received by closing date 15

Analysis of respondents

Local Health Boards 2
NHS Trusts 6
NHS Regional Offices 2
National Public Health Service 1
Health Professional Groups 2
Other Organisations 2

Summary

respondents accepting proposals with no further comment 6

Comments on specific proposals in the MLX:

1. Proposed additions to the conditions currently treatable under the NPEF

Central Nervous System
- Emergency treatment of meningitis - by only using benzylpenicillin, you are excluding patients who:
  - are penicillin allergic
  - have infections with penicillin resistant organisms. There are national working group guidelines to cover this scenario, also need to consider adding cefotaxime / ceftriaxone
- Acute severe pain after trauma - Morphine and any other CD … should be excluded
- Generalised tonic-clonic seizures - … and any other CD including the benzodiazepines should be excluded

Circulatory
- Noted that intravenous hypertonic fluids are included for fluid replacement, their safe use must be considered
- Fluid, potassium replacement and plasma substitutes should be managed in close conjunction with clinical colleagues except in a dire emergency
**Eye**
- Inflammation following ophthalmic surgery - Prescribing should only be given following discussion with an ophthalmic surgeon.

**Gastro-intestinal Conditions**
- Prophylaxis of acid aspiration during surgery - should be prescribed with analgesia on admission

**Infections**
- Cellulitis - care needs to be taken to identify necrotising fasciitis if present
- Tetanus treatment – description should be changed to tetanus prophylaxis

**Poisoning**
- Term needs to be expanded as there are a wide range of medicines used to treat specific conditions of poisoning
- Term not qualified, and should be

**Additional comments on additions to the conditions currently treatable under the NPEF**
- General support for proposals – one suggestion is that the list is reviewed by a panel of primary care nurses before it is finalised to identify omissions, inconsistencies
- Human bites - concerned that this has already been accepted and recommends that it should be removed. A human bite mark on the skin is one of the hallmarks of abuse. Practitioners have the appropriate training in diagnosis, management and referral of abuse cases which lies outside the usual training for nurse prescribers

2. **Proposed extension, in restricted circumstances, of 'off-label' or 'off-licence' prescribing**
- The proposed extension of 'off-label' prescribing was not supported by the National Public Health Service (NPHS) for Wales, who considered such prescribing should be managed through the supplementary prescribing route as specified in the Clinical Management Plan rather than through the independent nurse prescribing route.
- Consideration needs to be given to the problems that may arise when people other than carers are expected to administer in 'off-licence' situations e.g. Midazolam buccal; as there is no licensed preparation, the parenteral preparation is sometimes prescribed which has caused problems when a child is at school.
- Other replies that specifically commented on this proposal were in favour.

3. **Proposed extension of the prescribing of controlled drugs**
- NPHS acknowledges the advantages of allowing suitably qualified nurses to prescribe and administer controlled drugs in the emergency setting such as parenteral morphine in acute severe pain after trauma
- NPHS consider the prescribing oral formulations of morphine in acute severe pain after trauma should be restricted to supplementary prescribing. Also recommends waiting for the outcome of the Shipman Inquiry before amending the legislation
Morphine - inclusion of CDs is welcomed but will require strict protocols and reporting arrangements would be required to protect the patient and the professional accountability of the nurse.

- Morphine and any other CD including the benzodiazepines should be excluded
- One reply supported the proposal without further comment

4. **Proposed additional POMs for NPEF**

**Acute myocardial infarction**
- Tenecteplase etc., NPHS comment that the addition of drugs such as tenecteplase for the management of acute myocardial infarction on the justification that nurses can advise paramedics raises interesting points. This would presumably put the nurse in the same legal position as a medical practitioner if something goes wrong.

**Anaphylaxis**
- Adrenaline - appears in the 'recommended' group for anaphylaxis and also in the 'non-recommended' group for cardio-pulmonary resuscitation. Support its inclusion. Strength should be stated
- Adrenaline - it should be clearly stated that adrenaline needs only to be prescribed when needed to be held by someone for the prevention of subsequent anaphylactic attacks

**Ventricular fibrillation or pulseless ventricular tachycardia**
- Parenteral amiodarone – should be excluded except for specially trained nurses in CCU

**Thromboprophylaxis**
- Certoparin Sodium - No longer available so should be removed from the list

**Acute severe pain after trauma**
- NPHS acknowledges the advantages of allowing suitably qualified nurses to prescribe and administer controlled drugs in the emergency setting such as parenteral morphine in acute severe pain after trauma
- NPHS consider oral formulations of morphine in acute severe pain after trauma should be restricted to supplementary prescribing. Also recommends waiting for the outcome of the Shipman Inquiry before amending the legislation
- Morphine - inclusion of CDs is welcomed but will require strict protocols and reporting arrangements would be required to protect the patient and the professional accountability of the nurse
- Morphine and any other CD including the benzodiazepines should be excluded

**Generalised tonic - clonic seizures**
- Controlled Drugs - NPHS consider prescribing oral formulations should be restricted to supplementary prescribing.
- Morphine and any other CD including the benzodiazepines should be excluded

**Acute alcohol withdrawal**
- Diazepam and chlordiazepoxide – addition supported for Acute alcohol withdrawal
Fluid replacement
- Noted that intravenous hypertonic fluids are included; their safe use must be considered
- Should be managed in close conjunction with clinical colleagues except in a dire emergency

Potassium replacement
- Should be managed in close conjunction with clinical colleagues except in a dire emergency

Diagnostics in Ophthalmology
- Tetracaine, Oxybuprocaine and Proxymetacaine - These local anaesthetic preparations are used in minor procedures, not as diagnostic aids.
- Eye: no objection to the proposals for listed diagnostic agents

Tear deficiency
- Acetylcisteine - used as a tear substitute is often very irritative, locally it is restricted to a form of dry eye known as filamentary keratitis.

Inflammation following ophthalmic surgery
- Prescribing should only be given following discussion with an ophthalmic surgeon.

Tetanus treatment
Descriptions should be changed to tetanus prophylaxis

Prophylaxis & Treatment of PONV
- 5HT₃ antagonists - these are not first line within the [named] Trust, are they necessary for nurse prescribing?

Plasma substitutes
- Should be managed in close conjunction with clinical colleagues except in a dire emergency

Molluscum contagiosum
- Treatment of molluscum contagiosum – no preparation/s or strength/s mentioned in the proposals

Vaccines for travellers
- prophylactic travel vaccines are not available at NHS expense

Additional comments on proposed additional POMs for NPEF
- General support for proposals – one suggestion is that the list is reviewed by a panel of primary care nurses before it is finalised to identify omissions, inconsistencies. NPHS comment that minor ailments, health promotion and potentially life-threatening situations are scenarios where appropriately trained nurses can reduce the need for medical input, enabling more effective use of human resources and improved patient access
5. **Further proposed amendments concerning antimicrobials**
   - NPHS fully supports the principle of minimising the potential for widespread antibacterial prescribing. Provided antibiotic prescribing is appropriate, controlled and strictly managed the NPHS supports prescribing for dental infections, acute exacerbations of chronic bronchitis, cellulitis and the emergency treatment of meningitis.
   - Antibiotics for dental infections should be referred to dentist in case of other complications.
   - In supporting proposals, comment made that a nurse may prescribe fewer antibiotics than a doctor.

6. **Comments on proposals not recommended for inclusion in the NPEF**
   - The four replies that commented on these proposals agreed that the medicines not recommended for the NPEF should not be added.

7. **General: additional comments made by respondents in Wales**

   **Training**
   - Training standards / competence should be nationally determined; provision of appropriate training must be in place; there needs to be some guarantee that those trained will have a real impact on the outcomes for patients.

   **Related to Supplementary prescribing and PGDs**
   - In non-acute situations where the management of the patient involves diagnosis by medical staff and close multi-disciplinary team working, such as chronic conditions and in palliative care, prescribing is considered best managed through the supplementary prescribing route as part of an overall Clinical Management Plan. These form the main principles and context in which the NHPS views the expansion of independent nurse prescribing.
   - Prescribing medicines outside their licensed indications should be managed through the supplementary prescribing route as specified in the Clinical Management Plan rather than through the independent nurse prescribing route.
   - Controlled Drugs: prescribing oral formulations should be restricted to supplementary prescribing. Also recommends waiting for the outcome of the Shipman Inquiry before amending the legislation.
   - Patient Group Directions would be the optimum way of allowing nurses to administer medication.

   **Other comments**
   - Strong support for extended independent nurse prescribing in the management of minor ailments, health promotion and in potentially life-threatening situations.
   - Must maintain a clear distinction between medical (diagnosis and decision to prescribe) and nursing roles (triage and provision of nursing care). This should over-ride any potential benefit of proposals listed in Sections 14 and 15 of the consultation document.
   - Suggests that only specialty areas should be targeted for extended formulary nurse prescribing. Areas suggested include homeless outreach and asylum seekers.
   - Concludes that extended nurse prescribing would be good for patients and good for nurses professionally, but it needs to be in specialist areas only.
ANNEX C

Consultation on the Proposals to expand the range of Prescription Only Medicines in the Nurse Prescribers Extended Formulary (MLX 303)

Summary of comments received from respondents in Scotland (NB: 6 replies were received directly by the MHRA – these are shown below)

Number of respondents
number of replies received by closing date 41 (35 + 6)

Analysis of respondents
Medical Colleges, Societies and interests 6 (5+1)
Pharmaceutical Colleges, Societies and interests 2
Nursing Colleges, Societies and interests 4 (3+1)
NHS Scotland 20 (19+1)
Organisations outside the NHS 2
Replies from individuals 7 (4+3)

Summary
respondents accepting proposals with no further comment 3

Comments on specific proposals in the MLX:

1. Proposed additions to the conditions currently treatable under the NPEF
The proposals were generally welcomed. It was felt that they will particularly benefit Extended Formulary Nurse Prescribers in the hospital setting and also lead to increased numbers of EFNPs. However, the Royal College of Physicians of Edinburgh commented that they had some reservations about whether EFNPs can diagnose some of the conditions detailed. The Department of General Practice at the University of Aberdeen commented that some of the conditions mentioned were not straightforward to diagnose and diagnosis would need to be supported by further tests. They also felt that some of the chronic conditions were more appropriate for supplementary prescribing and could not support the inclusion of all of the conditions.

Other comments were:

- Some of the conditions are vague e.g. poisoning. Would this include drug overdose?
- More professions prescribing antimicrobials would damage efforts to restrict antimicrobial prescribing. Its inclusion will exacerbate increasing dangers of antimicrobial resistance. (this view is also expressed in relation to paragraph 14)
- It is not only the education provision required that needs consideration but the rate of implementation.
- Some conditions are suitable only for specialist nurses who must have appropriate training to ensure patient safety.
2. Proposed extension, in restricted circumstances, of “off label” or “off licence” prescribing

Most respondents were in favour of an extension. However, a number qualified their support by saying that nurses must make themselves aware of their liability in prescribing off licence and their professional responsibility. There also needs to be a clear distinction between the use of licensed products outwith their licensed indications and the use of unlicensed preparations. A number of those who supported the proposal commented that it was particularly appropriate in palliative care settings and also in relation to prescribing for children. One respondent was totally opposed to the proposal and commented that it is inappropriate for even nurses with degrees in palliative care to prescribe “off label” as nurses are not diagnosticians. Their training does not include potential drug interactions that may occur or the problems that may occur with co-morbidity existing in the patient. The Scottish Committee of the Royal College of Paediatrics and Child Health [reply rec’d by MHRA] commented that the situation with regards to “off label” prescribing for children will be improved when the proposed Children’s BNF, presently being discussed as a successor to the RCPCH's Medicines for Children, is published.

Other comments were that:

- appropriate training and competencies should be defined
- such prescribing must be in line with clinical governance and local prescribing guidelines
- should only be allowed where evidence is available to demonstrate the effectiveness of the medication

3. Proposed extension of the prescribing of controlled drugs

Again, these proposals were broadly welcomed and were thought to be appropriate in the situations set out in the text of the MLX. A number of respondents felt that it may be prudent to await the outcome of the Shipman Inquiry before adding more CDs to the NPEF, and that any changes must be in line with the Inquiry’s recommendations.

Other comments were that:

- diamorphine should be added as an alternative to morphine in paragraph 13 for acute severe pain after trauma
- the proposal would be of particular benefit for Emergency Nurse Practitioners with ENPF qualifications in remote A & E units where they could ensure swift intervention for patients in severe pain
- consideration should be given to the inclusion of certain controlled drugs only and also dose range and dose increments
### 4. Proposed additional POMs for NPEF

<table>
<thead>
<tr>
<th>Treatment Area</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea and vomiting</td>
<td>Can indicate sinister or severe (even life-threatening) conditions. Need to be more specific. Nurse prescribers should be made aware of potential for oculogyric reaction to prochlorperazine and/or metoclopramine. Need to consider suitable medication for children and young people receiving chemotherapy. Oral cyclizine not standard treatment and is inappropriate. Cyclizine and prochlolperazine contraindicated in the elderly – no need for extension. Anti-emetics should only be prescribed when the cause of vomiting is known.</td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>Concerns expressed about diagnostic criteria to be applied and significant clarification required. Heparin should be included. Concerns expressed about possible second use – access to records will be essential.</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>Diagnosis must be correct. Appropriate strengths of preparations should be included.</td>
</tr>
<tr>
<td>Acute pulmonary oedema associated with cardiac failure</td>
<td>Concerns about diagnosis. Only appropriate for specialist nurses in coronary units and appropriately skilled EFNPs. Parenteral administration can upset electrolyte balance.</td>
</tr>
<tr>
<td>Ventricular fibrillation or pulseless ventricular tachycardia</td>
<td>Diagnosis is not straightforward. Should only be undertaken by EFNPs trained encompassing the competencies necessary within paramedic training. Administration would need to be closely linked to local protocols from cardiology departments.</td>
</tr>
<tr>
<td>“Thromboprophylaxis” – as defined in the MLX</td>
<td>More appropriate for prescription to be provided by clinician. All prescribing should conform to local protocols and drug formularies. Should not be used outside licensed indications. Unfractionated heparin should be included.</td>
</tr>
<tr>
<td>Acute reversible airways obstruction (acute severe asthma or acute exacerbation of chronic obstructive pulmonary disease.)</td>
<td>EFNPs must be made aware of the danger of rapid administration of hydrocortisone sodium succinate and the potential for significant reactions. Salbutamol should be included. Combivent should be considered. For hydrocortisone the strength of preparation should be specified as 100mg.</td>
</tr>
<tr>
<td>Acute exacerbation of chronic bronchitis</td>
<td>Oxytetracycline dihydrate should only be authorised where local formularies expressly recommend this antibiotic. Non-specific use of a broad spectrum antibiotic such as this should not be encouraged. Inappropriate for use in children. More appropriate in supplementary prescribing. Not first line antibiotic – infection often viral and lab culture required.</td>
</tr>
<tr>
<td>Acute severe pain after trauma</td>
<td>Neonatal nurse practitioners disappointed that the use of morphine during intubation of neonates is not mentioned as it would allow them to carry out the procedure in total. May be prudent to wait until after Shipman Inquiry recommendations. Initial dose of morphine and dose range should be specified.</td>
</tr>
<tr>
<td>Topic</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Pain and inflammation/soft tissue injury</td>
<td>Support for WG comments and suggestion that the NPEF should differentiate between adults, adolescents and children and that EFNPs should have their prescribing activities restricted to area of expertise controlled by defined protocols. Perhaps open this field a little wider and include naproxen.</td>
</tr>
<tr>
<td>Generalised tonic/clonic seizures</td>
<td>Use of buccal midazolam would be “off label”. Useful but must take account of Shipman inquiry recommendations. Scottish Intercollegiate Guidelines Network Guideline 70 does not list midazolam and notes that buccal midazolam is used mainly in children and needs further assessment therefore it is not clear why it is recommended for inclusion.</td>
</tr>
<tr>
<td>Croup</td>
<td>SMASAC concerned about the inclusion of dexamethasone in a condition normally affecting young people and assumes that paediatric colleagues were fully consulted. Concerns about “off label” use and alternative licensed drugs preferred. Oral prednisolone most frequently used.</td>
</tr>
<tr>
<td>Local analgesia (other than for ophthalmic conditions) when procedure requires it</td>
<td>Concerns about general drug pharmacology and training. Only considered appropriate for specialised nursing staff.</td>
</tr>
<tr>
<td>Acute alcohol withdrawal</td>
<td>SMASAC would only recommend the administration of these drugs in this situation as part of a clearly defined protocol. More appropriate for supplementary prescribing for nurses working in the field of alcohol abuse. Only chlordiazepoxide should be included as recommended in SIGN Guideline 74 for 7 days only. Await recommendations from Shipman Inquiry.</td>
</tr>
<tr>
<td>Fluid replacement (hypovolaemia and dehydration)</td>
<td>There should be a clear statement about the approved rate of administration before authorisation for intravenous fluids is allowed. Do not agree with use of 10% glucose solutions. Sodium chloride 0.018% with glucose 4% is inappropriate for children. Combination of 0.45% sodium chloride with glucose 5% more appropriate.</td>
</tr>
<tr>
<td>Potassium replacement (hypokalaemia)</td>
<td>Vital that rate of infusion is strictly governed since potentially lethal if given too fast. Inclusion of a solution of 0.45% sodium chloride with 5% glucose and 10mmol or 20 mmol per litre should be considered. Laboratory support required to establish a patient’s serum potassium level before any supplement prescribed – could not support proposal without this requirement. Only ready-made potassium-containing infusions should be prescribed.</td>
</tr>
<tr>
<td>Diagnostic use in ophthalmology</td>
<td>Support for WG concerns about use of tetracaine for local analgesia in ophthalmic conditions. Recommend only for use by specialist EFNPs within ophthalmology units. Recommend that tetracaine is not added at this time.</td>
</tr>
<tr>
<td>Tear deficiency</td>
<td>Should not be added as non-POMs are available.</td>
</tr>
<tr>
<td>Inflammation following ophthalmic surgery and corneal trauma</td>
<td>Should only be prescribed by specialist nurses within ophthalmic units. May be more appropriate for supplementary prescribing.</td>
</tr>
<tr>
<td>Tetanus treatment</td>
<td>Welcome addition.</td>
</tr>
</tbody>
</table>
Prophylaxis of acid aspiration during surgery

Assume this relates to endoscopic surgery and/or investigation in which case more appropriate for prescription to be provided by clinician. More appropriate for supplementary prescribing to ensure appropriate patient care. Query about the need for both parenteral cimetidine and ranitidine. Ranitidine injection given over at least 2 minutes is easier to administer.

Prophylaxis and treatment of nausea and vomiting in the post-operative period

Consideration should be given to adding the 5HT3 antagonists list. More appropriate for supplementary prescribing to ensure appropriate patient care. Conflicting evidence as to the effectiveness of these in comparison to metoclopramine and further consideration of the evidence should be undertaken.

Plasma substitutes for patients with a low blood volume (e.g. in cases of shock arising from burns or septicaemia)

SMASAC would seek clarification on the diagnosis of low blood volume/shock and the number of “bags” that would be authorised for use before a careful clinical review was required. 0.9% sodium chloride should be included. More appropriate for supplementary prescribing to ensure appropriate patient care. Not supported for patients in shock.

Acute dystonias

More appropriate for supplementary prescribing to ensure appropriate patient care.

Psoriasis

Require accurate diagnosis and careful chronic management. More appropriate for supplementary prescribing to ensure appropriate patient care. The British Dermatological Nursing Group felt that the treatments included were unnecessarily restrictive and should be expanded.

Molluscum contagiosum

Needs reference to the evidence base for using salicylic acid – the general teaching is not to treat. Query why EFNPs would be treating this. Not appropriate and should not be added. In elderly could be a sign that patient is immunocompromised.

Vaccine to protect travellers against meningococcal infection

Appropriate addition.

Flushing cannulae

Support inclusion and would wish it to be extended to include central venous access devices. Important to specify that 10mls phials of sodium chloride is expected rather than larger volumes.

Reconstitution of injections

No comments

5. Comments on proposals concerning antimicrobials

A number of respondents were concerned that increasing the number of prescribers could lead to an increase in antimicrobial prescribing and drug resistance. However, the situations cited are appropriate and would benefit patient care. Four respondents thought that it would be prudent to wait for the results of the evaluation of Extended Formulary Nurse prescribing being undertaken by the University of Southampton prior to setting out proposals.
Further comments were that any prescribing of antibiotics should take into account the local antimicrobial resistance patterns and treatment protocols.

| Dental infections | Should be a clear differentiation and distinction between the different erythromycin preparations offered. It would be best to decide on one and perhaps relate an alternative under specified circumstances. Concerns that metronidazole is not available to be prescribed as the majority of acute dental infections are caused by anaerobic pathogens which will not respond to penicillin alone. |
| Acute exacerbation of chronic bronchitis | More appropriate to be within a patient care plan and prescribed through supplementary prescribing. Query about the use of beta lactam antibiotics. A detailed history is required to identify a suitable antibacterial for patients presenting with this. Studies have shown that greater than 90% of acute exacerbations of chronic bronchitis are caused by viral agents, which will not respond to antibiotic treatment and, that the commonest bacterial pathogens have increasing resistance to beta lactam antibiotics. |
| Cellulitis | SMASAC commented that it is concerned about authorising the use of benzilpenicillin and flucloxacillin for the treatment of cellulitis. The management of skin and soft tissue infections is a specialised and complicated process starting with the difficulty of diagnosis. They would be most concerned to hear of a patient requiring parenteral antibiotics for a potentially life-threatening condition (the differential diagnosis of cellulitis must include rare but nevertheless life-threatening conditions such as necrotizing fasciitis) without adequate medical review. Fusidic acid is preferred in this indication. No provision made for patients allergic to penicillin. The Royal College of Physicians of Edinburgh felt that flucloxacillin rather than erythromycin might be worth considering for cellulitis. |
| Emergency treatment of meningitis | This addition would improve access of patient care. However, SMASAC were of the view that it is entirely inappropriate to expect nursing staff to take responsibility for the management of meningitis – a life-threatening condition. Any potential case of meningitis merits immediate medical attention. No provision made for patients allergic to penicillin – should include cefotaxime for penicillin allergic patients or chloramphenicol for dual penicillin/cephalosporin allergic patients. Ceftriaxone should also be included. |

6. **Comments on proposals not recommended for inclusion in the NPEF**
These proposals were broadly supported. It was felt that these areas should be the remit of medical staff, perhaps supported by supplementary prescribers. It was also suggested that PGDs would be ideal in some of these areas. However, one respondent felt that the management of post-operative pain relief was unduly restrictive and that it should be included.

7. **General: additional comments made by respondents in Scotland**
The Dept of Liaison Psychiatry NHS Stirling were disappointed that role of the mental health nurses in acute care was not examined in more depth. Great advantage
to be able to prescribe for acute dystonic reactions. However lorazepam is not included for emergency sedation/acute agitation and this would have been useful for mental health nurses working in acute mental health. Depression as a condition is an area that is often picked up by nurses working in liaison psychiatry who then ask an SHO or GP to prescribe an antidepressant medication. If the patient is being seen at an outreach clinic then often have to wait a week for an appointment with GP. If liaison nurse could consult with GP and prescribe this would be smoother for the patient.
ANNEX D

Consultation on the Proposals to expand the range of Prescription Only Medicines in the Nurse Prescribers Extended Formulary (MLX 303)

Summary of comments received from respondents from Northern Ireland

Number of respondents
number of replies received by closing date 13

Analysis of respondents
Medical Colleges, Societies and interests
Pharmaceutical Colleges, Societies and interests
Nursing Colleges, Societies and interests 1
From the NHS 10
Organisations outside the NHS
Replies from individuals

Summary
respondents accepting proposals without detailed comment 3

Comments on specific proposals in the MLX:

1. Proposed additions to the conditions currently treatable under the NPEF

The Northern Ireland Practice & Education Council for Nursing and Midwifery (NIPEC) were pleased with the further developments of the NPEF, and particularly into first contact care. NIPEC endorse all the proposals in the MLX for additional conditions treatable by EFNPs as do the Western Area Strategic Nursing Group which consider the proposals timely given the new roles nurses are taking on in chronic conditions management, minor injuries, emergency treatment and first contact care. The North Down Health and Social Care Group welcomed the proposals, particularly to aid improvements in palliative care. The Area Pharmaceutical Advisory Committee (the APAC), Western Health & Social Services Board commented that the service requirements identified in the MLX include Walk-in Centres. Such centres do not exist in Northern Ireland, although developments in that vein have been mooted. Other service areas translate more readily and therefore the proposals in general will help deliver better services locally. APAC supported the full range of conditions as identified. The Pharmaceutical Services, Southern Health and Social Services Board agree the proposed additions saying that protocols should be in placed back with appropriate training which should be equivalent to medical training and result in practice to equivalent standards. The Nursing Service of the Northern Health and Social Services Board welcomes and supports the additions to the NPEF. Belfast City Hospital (Pharmacy interests) suggest that additions of, eg, nausea and vomiting, anaphylaxis, airways obstruction, prophylaxis of acid aspiration during surgery, post-op nausea and vomiting, psoriasis, molluscum contagiosum, travel vaccination and flushing cannulae seem reasonable and would enhance patient care. However, conditions such as Acute MI, oedema with heart failure, Ventricular Fibrillation, thrombi- prophylaxis, seizures,
fluid replacements and potassium replacements do not seem ideal because of the ongoing monitoring that is required alongside these conditions. The **Chief Executive (CE) of the Eastern Health and Social Board** welcomes the proposals but is disappointed that a number of important drugs are missing for the treatment of, eg, diabetic care, antibiotic therapy for minor infections, inhaled steroids and antihistamines. The CE also feels the proposals fail to enhance care for patients beyond the acute sector in other specialities or settings. The CE comments that the current approach of prescribing within a list of conditions can lead to anomalies and, as it does not allow for a nurse’s professional judgement, suggests that nurses should be able to prescribe subject to competence, scope of practice and code of professional conduct. **Causeway Hospital (pharmacy)** considered that, in addition to the conditions appropriate for EFNP in general or recommended for restriction to specialist areas, the following should not be included in the NPEF:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningitis</td>
<td>Condition can be very difficult to diagnose</td>
</tr>
<tr>
<td>Fluid/potassium replacement</td>
<td>Specialist knowledge required. This is high risk area as adult and paediatric deaths have occurred</td>
</tr>
<tr>
<td>Fluid replacement</td>
<td></td>
</tr>
<tr>
<td>Fluid replacement</td>
<td></td>
</tr>
<tr>
<td>Cellulitis</td>
<td>Specialist knowledge required to prevent mis-diagnosis and to ensure appropriate treatment</td>
</tr>
<tr>
<td>Poisoning</td>
<td>Specialist knowledge required particularly where multiple agents have been taken and patient suffers from chronic conditions</td>
</tr>
</tbody>
</table>

The nurse prescribing adviser, Northern Health and Social Services Board commented, that while the expansion of the NPEF was welcomed, nurses should not be restricted to prescribing for a limited range of conditions and medicines.

2. **Proposed extension, in restricted circumstances, of 'off-label' or 'off-licence' prescribing**

NIPEC endorsed the proposals for off label prescribing as did the Western Area Strategic Nursing Group. APAC viewed the limited proposals to be acceptable to help support better patient care, APAC cautioned that it will be necessary to ensure in implementation that prescribers are aware of their responsibilities in prescribing off-label or off-licence. The Pharmaceutical Services, Southern Health and Social Services Board agree the proposed additions with regard to palliative care if restricted to nurses experienced in that care. They commented that there was little support for the EFNP off licence prescribing of the listed drugs for children and that this should remain with a doctor. The Nursing Service of the Northern Health and Social Services Board welcomes the proposed extension of “off label” prescribing. Belfast City Hospital are concerned about proposal as Off Label/off licence is difficult to monitor and it may difficult to keep control of unlicensed prescribers. Therefore better to limit unlicensed prescribing to doctors. The Chief Executive (CE) of the Eastern Health and Social Board welcomes the proposals but suggests that further enhancement – eg the use of oral contraception to treat dysmenorrhoea – would be beneficial. Similar views were held by the prescribing adviser, Northern Health and Social Services Board who also favoured a specific “off label” list for those working in neonatology and paediatrics.

3. **Proposed extension of the prescribing of controlled drugs**

NIPEC welcomed the proposals for additional CDs as did the Western Area Strategic Nursing Group which considered these would allow for an improved response and
quality of care for patients in palliative care. The North Down Health and Social Care Group considered that the proposals on CDs were particularly appropriate to reduce stress and reduce delays especially with regard to palliative care in the community.

APAC considered the proposals reasonable saying that further amendments will be needed in the future to allow the prescribing of diamorphine, which is essential in pain control of patients following myocardial infarction. While agreeing that EFNPs should be able to prescribe CDs where appropriate, the Pharmaceutical Services, Southern Health and Social Services Board considered that it would be difficult for pharmacists to be able to confirm which nurses were properly prescribing CDs to meet the record-keeping requirements for such drugs. They also commented that there might be a need to include some specific CDs for dressing changes. The Nursing Service of the Northern Health and Social Services Board welcomes the proposal to extend independent prescribing of controlled drugs to nurses as this will enable nurses to offer more a comprehensive and seamless services to patients, particularly those patients with palliative care needs. Belfast City Hospital caution that careful consideration need to be given to allow CDs on formulary particularly with respect to Shipman. The more people allowed to prescribe CDs, the tighter the controls need to be. The Chief Executive (CE) of the Eastern Health and Social Board welcomes the proposals as an advance for patients needing pain management or palliative care. The prescribing adviser, Northern Health and Social Services Board welcomed the addition of further CDs.

4. **Proposed additional POMs for NPEF**

APAC view the proposals as reasonable. In giving broad agreement to the proposals, the Pharmaceutical Services, Southern Health and Social Services Board considered that diagnosis and management of many of the conditions is complex and should be undertaken only by those suitably trained and experienced to a high standard. Essential for an emphasis on a team-based approach, supported by protocols. The Chief Executive (CE) of the Eastern Health and Social Board welcomes the proposals. The Pharmaceutical Services, Southern Health and Social Services Board commented specifically on:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation/Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea and vomiting</td>
<td>Agreed that drugs should be added to the NPEF but that prescribing should follow established “step-up” anti-emetic policies. Nurse prescribers must be made aware of restrictions on prescribing of metoclopramine to those under 20 years.</td>
</tr>
<tr>
<td>Generalised tonic/clonic seizures</td>
<td>midazolam not licensed for this condition</td>
</tr>
<tr>
<td>LMWH</td>
<td>Need to consider renal impairment when drawing up dosing guidelines</td>
</tr>
<tr>
<td>Meningitis</td>
<td>Early treatment saves lives so the first health professional to see a child and suspect meningitis should be able to give [administer] benzylpenicillin. However this must not delay attention by a doctor as meningitis can be difficult to diagnose.</td>
</tr>
</tbody>
</table>

The prescribing adviser, Northern Health and Social Services Board regrets the continuing omission of cefalexin for lower urinary tract infection.
Causeway Hospital (pharmacy) considered the following drugs *should not* be included in the NPEF:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Drug</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>nausea and vomiting</td>
<td>Prochlorperazine mesilate Prochlorperazine maleate</td>
<td>Not first line. Extra pyramidal side effects, especially in children, elderly and debilitated</td>
</tr>
<tr>
<td>acute myocardial infarction</td>
<td>Tenecteplase</td>
<td>BT</td>
</tr>
<tr>
<td>Thromboprophylaxis</td>
<td>Certoparin sodium Reviparin sodium</td>
<td>Licensed for prophylaxis only Discontinued</td>
</tr>
<tr>
<td>[also that EFNPs should not prescribe aspirin for DVT]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute exacerbation of chronic bronchitis</td>
<td>Oxytetracycline dihydrate</td>
<td>Not first line.</td>
</tr>
<tr>
<td>acute severe pain after trauma</td>
<td>Morphine</td>
<td>Avoid post-Shipman?</td>
</tr>
<tr>
<td>pain and inflammation/soft tissue injury</td>
<td>Diclofenac sodium</td>
<td>Irritant to GI tract – use ibuprofen instead</td>
</tr>
<tr>
<td>Croup</td>
<td>Dexamethasone sodium phosphate</td>
<td>Not first line.</td>
</tr>
<tr>
<td>acute alcohol withdrawal</td>
<td>Diazepam</td>
<td>High addiction potential</td>
</tr>
<tr>
<td>tear deficiency</td>
<td>Acetylcysteine</td>
<td>Not first line</td>
</tr>
<tr>
<td>prophylaxis of acid aspiration during surgery</td>
<td>Cimetidine</td>
<td>Not first line</td>
</tr>
<tr>
<td>prophylaxis and treatment of nausea and vomiting in the postoperative period.</td>
<td>Tropisetron hydrochloride</td>
<td>Cardiac cautions</td>
</tr>
<tr>
<td>psoriasis</td>
<td>Calcipotriol</td>
<td>More irritant than the other proposals</td>
</tr>
</tbody>
</table>

The same respondent recommended that oral rantitidine should be included for prophylaxis of acid aspiration during surgery and that specialist EFNPS should be able to prescribe meningitis prophylaxis (as per the recommendations of the BNF) to the contacts of patients that have been diagnosed as suffering from bacterial meningitis.

5.  *Further proposed amendments concerning antimicrobials*
NIPEC agreed the proposals re: antimicrobials given the risks associated with antimicrobial resistance. The Western Area Strategic Nursing Group welcomed the additions saying that they hoped the evaluation of the NPEF would show that increasing the number of prescribing did not lead to an increase in antimicrobial prescribing. APAC view the proposals as reasonable. The Pharmaceutical Services, Southern Health and Social Services Board commented that any prescribing of antimicrobials must be in accordance with local policies and advice from the area/etc
microbiologist. Important that extension of prescribing results in appropriate antimicrobial prescribing and the Southampton evaluation eagerly awaited. Belfast City Hospital consider that antimicrobial drugs available on the NPEF should not be expanded due to risk of over-prescribing. The Chief Executive (CE) of the Eastern Health and Social Board welcomes the proposals. Causeway Hospital (pharmacy) suggested that antimicrobial prescribing could be time limited to, as an example, a maximum of 5 days per six months.

6. **Comments on proposals not recommended for inclusion in the NPEF**

APAC view the proposals as reasonable. The Pharmaceutical Services, Southern Health and Social Services Board considers that the management of meningitis in those allergic to penicillins or cephalosporins should be addressed in agreed local protocols. Belfast City Hospital consider that, for bacterial tonsillitis, several papers show that the use of cephalosporins to be more effective than the penicillins. Causeway Hospital (pharmacy) agreed the proposals. The Chief Executive (CE) of the Eastern Health and Social Board hopes these exclusions will be reconsidered, quoting as an example that beclometasone is often required when the condition is exacerbated and the Supplementary Prescriber may not be available. A similar comment was made by held by the prescribing adviser, Northern Health and Social Services Board.

7. **General: additional comments made by respondents**

- Each further development of the NPEF has implications for EFNPs accountability and competencies. It is therefore vital that support networks and regular clinical updating are in place.

- Clear policies and guidelines to underpin prescribing practice should be an essential requisite and it would be preferable for EFNPs to be practising as recognised specialists in their area or at practitioner level

- While acknowledging that a significant number of drugs have been added to the formulary, a number are still missing. This includes, drugs for the treatment of diabetes some minor infections and inhaled steroids for the treatment of respiratory conditions. The proposals still restrict nurses to prescribing particular drugs for particular medical conditions and therefore limit the nurse from being able to prescribe possible alternatives. This approach restricts the nurse from using their professional judgement as an autonomous practitioner.

- The proposed changes to the NPEF has potential to enhance quick access for patients but requires nurses to undertake major academic and clinical updating alongside opportunities to practice in a volume of work that enables them to hone their skills and knowledge. There is a lack of parity between doctors and nurses in terms of the infrastructure to support nurses’ efforts. Unless steps are taken to reduce this inequity, there will never be the momentum expected in EFNP.

- The APAC also commented that the service requirements identified in the MLX include Walk-in Centres. Such centres do not exist in Northern Ireland, although developments in that vein have been mooted. In Northern Ireland, there is one community pharmacy per 3,000 population and these 509 community pharmacies have been providing an informal walk-in centre service for several years. Such services will be further developed in line with the new Community Pharmacy
Strategy for Northern Ireland, “Making it Better”. With regard to other emergency care areas, a network of Accident and Emergency Department pharmacists have been recruited to provide pharmaceutical support to this pressurised service area. In supporting the proposals in general, APAC would therefore commend the need to develop proposals for independent pharmacist prescribing to allow the development of additional service models.