North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 13th September 2011 at Northumbria House, Cobalt Business Park, North Tyneside

Present

David Campbell (DC) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sue Brent (SB)	Director	RDTC
Sarah Chandler (SC)	Formulary Pharmacist	NCHT
Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
Helen Coundon (HC)	GP Consortia representative, Engage Health	
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Rosie England (RE)	Associate Director of Medicines Management	NHS NoT
Matt Grove (MG)	Consultant Rheumatologist	NHCT
Janet Kelly (JK)	Nurse Clinical Manager	NHCT
Matthew Lowery (ML)	Formulary Pharmacist	NUTH
Tom McCullough (TM)	Community Pharmacist	LPC
Peter McEvedy (PM)	GP representative from the PBC community North of Tyne	NHS NoT
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH Medicines Management Committee.	NUTH

In Attendance

Prof D Burn (for item 2011/54a)	Consultant Neurologist, Freeman Hospital.	NUTH
Sister P McGee (for item 2011/54a)	Parkinson's Disease Nurse Specialist	NUTH

Apologies

Steve Williamson	Consultant Pharmacist in Cancer Services	NECN
Sue Gordon	Executive Director of Public Health	NHS NoT
Zahra Irannejad	Head of Prescribing	NNTCH
Susan Turner	Professional Secretary and Medicines Management Adviser	NHS NoT

NECN	North of England Cancer Network
NHCT	Northumbria Healthcare NHS Foundation Trust
NHS NoT	NHS North of Tyne
NNTCH	Newcastle, North Tyneside Community Health Services
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2011/52 Minutes of the meeting held on Tuesday 12th July 2011

These were accepted with a minor amendment as below as a true record.

Minor amendment to formulary subcommittee recommendations from meeting on 30th June 2011:
Some savings could be realised for PCTs by moving from modified release (mr) capsules to mr tablets however this would increase costs for secondary care. The formulary subcommittee was asked to work with NTW to develop guidance for prescribers to define the circumstances in which venlafaxine mr preparations may be considered clinically appropriate. This will be supported through the NTW medicines management committee.

2011/53 Matters arising

2011/37a Diamorphine to Morphine switches

NW reported guidelines on oral and parenteral opiate choice had been prepared which recommends morphine as the drug of choice. NW is working with the palliative care network and Alex Nicholson to produce a document to explain the background to the review and rationale behind the recommendation. This will be discussed with the Controlled Drug Accountable Officers. It was noted that NHCT would support a switch to morphine from diamorphine if that was what was agreed. There had been a suggestion made that NUTH were not clear on which opiates were being used in NUTH; NW asked for it to be noted that NUTH are very clear about which opiates are currently being used within the trust.
Recommendations will be brought to the next APC.

2011/46 Terms of reference

DC reported that revised terms of reference will:

- need to be discussed with clinical commissioning group chairs for their comments
- include interface with prisons
- include as a possibility the approval of drug related pathways and guidelines following the apparent demise of the NoT pathways and guidelines group.

HW reported on current discussions to investigate the rising coagucheck use in primary care which has raised governance, safety and commissioning issues. Further discussions are needed to agree a consistent approach.

It was noted that the TOR will need to include governance and commissioning as part of our core principles

2011/54 Appeals against previous decisions

a) Apomorphine pre-filled syringes (Apo-Go®) (refused by the APC on 12th July 2011

Prof David Burn, Professor in Movement Disorders Neurology and Honorary Consultant Neurologist, Newcastle upon Tyne Hospitals NHS Trust and Sister P McGee, Parkinson's Nurse Specialist attended for this item.
DB reported that since the original application the prices had changed and the pre-filled syringe is now the same price as the vials. He clarified that the anticipated use of pre-filled syringe are single figure patient numbers. The benefits are ease of use and safety for the patient / carer in administration. Market forces and the current monopoly on supply were discussed. DB said that if a suitable alternative cheaper syringe / device were launched patients could be retrained.

DECISION: Approved. If another product is brought to the market which is cheaper the product choices will be reviewed

2011/55 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Tuesday 23rd August 2011

The above minutes and recommendations were received by the committee.
The summary of decisions made by the committee on new product requests is listed in **Appendix 1**.

However the following specific points were highlighted:

- New product request Lidocaine 4% cream (LMX4®) – deferred. ML has contacted the specialists who have stated as they are a busy unit with changing theatre lists they do not wish to use Ametop because it needs to be removed within the hour and other products do not have this time constraint. SC has spoken to NHCT consultants who have the same view. LMX4 would not replace EMLA. EMLA is widely used in primary care.

DECISION: Approved hospital use only (RED). Lidocaine 4% cream (LMX4®) approved for topical anaesthesia before venous cannulation in adults and children over 1 month for hospital use only.

- New formulation Somatropin prefilled liquid cartridges (Saizen) requested to aid patient compliance and reduce poor mixing techniques. ML and NW are to meet with Professor Cant, Clinical Director of Paediatrics and Paediatric Endocrinologists to discuss the review and transition of existing patients to less expensive products. The committee view was that no new growth hormone preparations will be considered until the review is complete.

DECISION: Refused. Somatropin prefilled liquid cartridges

- Pregabalin – review of specialist use and wording in formulary. The committee agreed that GPs could prescribe pregabalin (after amitriptyline and gabapentin). Pregabalin is the second choice second-line treatment. NICE CG96 states that third-line treatment requires referral to the specialist pain service.

DECISION: GPs can prescribe pregabalin after amitriptyline and gabapentin have been tried as a second choice second-line treatment

- Dabigatran – for prevention of stroke in non-valvular atrial fibrillation. The committee noted the position of NETAG and the recently published differing negative NICE appraisal consultation document (ACD). It is anticipated that NETAG will review their position pending the publication of the NICE guidance. HW stated that there were a few exceptional patients who would continue to receive dabigatran

- Agomelatine – treatment of major depressive episodes. The committee were asked to remove agomelatine from the formulary following the termination of its appraisal by NICE. It was agreed that the decision is deferred until it is reviewed by NETAG and TD has spoken to specialists within NTW.

- Mexiletine – neuropathic pain has been approved as a blue drug and an information sheet is to be prepared. Guidance for mexiletine recommends that monitoring for cardiac arrhythmia occurs which will be carried out by the specialists. RE asked whether GPs would be comfortable to prescribe this drug. HW clarified that patients will have ECG monitoring on initiation and

stabilisation of therapy and will be transferred to GP prescribing once stable. The information sheet will come to the APC for approval. HC and PM stated that the status of any drugs which require on-going monitoring should be amber. This principle was agreed by the committee.

- ST reported that 3 representatives from County Durham and Darlington attended the formulary sub committee. They will take formulary sub committee recommendations back to their APC for approval. It was noted that their APC may then subsequently make a different recommendation to us. They will manage their own appeals.

- Wound care products. A meeting has been arranged to review the current APC wound care products and the Newcastle community services wound care formulary. Tissue Viability Nurses will be involved. DC noted that the revised APC terms of reference would include wound care as core business of the APC. JK asked that the review included a mechanism for monitoring compliance with the wound care formulary.

2011/56 Report from the Shared Care Group (SCG)

a) **No report received as meeting is tomorrow**
b) **High dose Venlafaxine information sheet** – subject to minor amendment this was approved.
c) **Traffic light list** – updated list circulated for information. A request has been made to class drugs for gender dysphoria as BLUE. It was noted that ML is to meet with the psychiatrists treating this area and this will be discussed at formulary subcommittee.

2011/57 Report from the Antimicrobial Chemotherapy Sub-Group

Review of Terms of Reference
It was noted that the group works across the primary/secondary care interface and therefore needs to have robust links with other groups responsible for infection control. DC requested that the terms of reference be reviewed to ensure they incorporate the comments made.

ACTION: ML to review the Terms of Reference.

2011/58 Report from the Medicines Management QIPP Sub-Group

No report received. Next meeting 21st September 2011.

2011/59 Documents previously circulated
These were noted as having been received.

NETAG decision summary – Rituximab (MabThera®) in rheumatoid arthritis: non-NICE approved indication email sent 22.7.2011. MG reported that he had submitted an appeal to the NETAG decision. DC stated that he had discussed with the secretary of NETAG the need for improved consultation with clinical networks in the NE – DC had also acknowledged the importance for APC officers to be proactive in this regard too.

2011/60 Chair's action

Nothing to report.

2011/61 Any other business

a) NICE clinical guideline Hypertension update August 2011
ST commented that the NICE guideline recommends products not currently on our formulary such as chlorthalidone and indapamide 2.5mg mr. It was noted that Jane Skinner is coordinating a review of the North of Tyne hypertension guideline.

b) Haemophilus B for bronchiectasis
SC raised a query from Dr Melville, consultant respiratory physician who runs the broncicctasis clinic at Wansbeck. As part of the BTS guidelines for patients with bronchiectasis it is routine for patients to have a Hib titre performed and anyone with a low titre is given a Hib vaccine and a retitre performed 6 weeks later. This performs part of a diagnostic test which may require the patient to come under the care of an immunologist. Normally the consultant would ask the GP to prescribe and administer the vaccine but recently a practice has said that this is not an appropriate request for primary care. Advice has been received from public health and the Health Protection Agency who have confirmed that this is not recommenced by the JCVI and not appropriate for primary care.
The committee felt that if this is part of a diagnostic test then it should be given in the outpatient clinic but noted that there may be cost implications for referral and inconvenience for the patient. SC agreed to find out what is done in Newcastle.

Date and time of next meeting
The date of the next meeting is Tuesday 8th November 2011.
Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: .....

Date: 8/11/11

(Chair of the APC)

Appendix 1:

North of Tyne
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 13th September 2011.**

Classification of products:

R = 'RED' drugs for hospital use only
A = 'AMBER' drugs suitable for use under Shared Care arrangements
B = 'BLUE' drugs initiated in secondary care where an information sheet for GPs is recommended
T = 'RED' drugs used in Tertiary Care only.

Product	Decision			Comments / notes
	Approved [1]	Refused	Deferred	
1) Requests deferred from previous meetings				
Sublingual Fentanyl Citrate (Abstral®)		√		Sublingual fentanyl citrate (Abstral®) has previously been refused by NETAG for its licensed indications but is now being requested for the rapid relief of sudden pain on movement for patients undergoing radiotherapy. Actiq, the product currently used for this indication, takes fifteen minutes to take effect whereas Abstral is effective within ten minutes. This application was originally deferred as specialists were asked to provide safety data. There were concerns about respiratory depression and patients being left alone while having radiotherapy. **Recommendation:** The Committee has been informed that the specialists have been contacted, but no further responses have been received. The application should be withdrawn.
2) New Requests				
Lidocaine 4% Cream (LMX4®)	√ R			LMX4 is a liposomal lidocaine 4% cream. It has a short onset of action and minimal vasoactive properties that reduce any potential interference with cannulation success. It has been proven to be bioequivalent to EMLA. The adverse effects reported for LMX4 are considerably milder than those reported with EMLA and Ametop. EMLA causes vasoconstriction, which can potentially obscure landmarks, making cannulation more difficult. Unlike EMLA, LMX4 is not associated with methaemoglobinemia, a systemic side effect of EMLA. It is slightly cheaper than EMLA but more expensive than Ametop; however, Ametop is only licensed to be left on the skin for one hour. **Recommendation**: **Approved** for hospital use only (RED). Lidocaine 4% cream (LMX4®) approved for topical anaesthesia before venous cannulation in adults and children over 1 month for hospital use only

[1] R = 'RED' drugs for hospital use only, A = 'AMBER' drugs suitable for use under Shared Care arrangements, T = drugs used in Tertiary Care only.

Retigabine (Trobalt®)	√ B			Retigabine is the first of a new class of antiepileptic drug that acts on potassium ion channels. Retigabine is administered three times daily; this compares to a once daily dosing administration regimen for eslicarbazepine and zonisamide and twice daily for lacosamide. A less frequent dosing regimen may be favoured by patients although it is acknowledged that patients are likely to be concurrently receiving other antiepileptic drugs which may require twice or three times daily administration. NICE has published guidance on the use of retigabine for the treatment of partial onset seizures in epilepsy and treatment will be in line with NICE guidance. **Recommendation**: Approved: Retigabine should be included in the North of Tyne Formulary, with blue traffic light status, for the treatment of partial onset seizures in epilepsy. Treatment will be in line with NICE guidance.
Spectinomycin – Treatment of gonorrhoea	√			Spectinomycin is an aminoglycoside that was previously licensed in the UK but was withdrawn due to a decrease in demand. It is now available as an unlicensed product, and is recommended in national guidelines for the diagnosis and treatment of gonorrhoea in adults. Increasing resistance in *Neisseria gonorrhoeae* to antibiotics has limited the options for patients with beta lactam allergy and those with multi resistant strains. **Recommendation:** Approved.
3) New formulations & extensions to use				
Mexiletine – Neuropathic pain	√ B			Mexiletine is an orally active anti-arrythmic agent which is structurally related to lidocaine. In 2008 it was withdrawn from the market due to a decrease in demand. Mexiletine has been requested for inclusion in the North of Tyne Formulary for use in neuropathic pain. When used on an individual patient basis, it has shown to be effective, and has increased patients' quality of life. It is recommended that patients who receive mexiletine require monitoring for cardiac arrhythmias. **Recommendation:** Approved. ECG monitoring is required to be carried out by pain clinic consultants as part of the initiation process of mexiletine. GPs can take over prescribing once the patient is stabalised.

Somatropin pre- filled liquid cartridges (Saizen®)		√		Saizen 8mg vials powder for reconstitution is currently included in the North of Tyne Formulary. Saizen is now available in a new, ready mixed formulation. No reconstitution is required and it is anticipated that this will reduce drug wastage and lead to better compliance. Studies have demonstrated that the prefilled cartridges are bioequivalent to the click easy powder for reconstitution. **Recommendation: Refused.** The APC has recently approved a recommendation to make Omnitrope the first line growth hormone with Saizen® to be used only in patients with poor compliance. A meeting has been arranged between pharmacy, the clinical director of paediatrics and paediatric endocrinologists to discuss how the transition of existing patients to less expensive products may be managed. The committee view is that no new growth hormone preparations will be considered until the review is complete.
Peginterferon alfa-2a pens (Pegasys®)	√			Peginterferon alfa 2a 135 & 180 microgram pre-filled syringes (Pegasys®) are included in the North of Tyne Formulary. Roche has now launched 135 & 180 microgram prefilled pens, and a request has been made for the Committee to consider replacing the current products with the pre-filled pens. They are price equivalent and will aid patient compliance. The prefilled pens have a shorter shelf life of 18 months compared to 3 years for the prefilled syringes. **Recommendation: Approved.** Pegasys® pre-filled pens should replace the pre-filled syringes.
Interferon beta-1a pens (Avonex®)	√			Interferon beta – 1a 30 microgram (6 million units) prefilled syringes (Avonex®) are included in the Formulary. A pre-filled pen has now been launched. The specialist MS nurses at NUTH have requested that the Committee considers whether the pre-filled pens can replace the pre-filled syringes. They will improve patient compliance and storage instructions are equivalent. The shelf life of both products is equivalent. **Recommendation: Approved.** Interferon beta 1a pens (Avonex®) should replace the pre-filled syringes in the Formulary.

4) Products considered by NECDAG				
Dexrazoxane (Savene TM)	√			Approved - to be added to NECN Extravasation Guidelines.
5) Products considered by NETAG				
Novel oromucosal (Abstral®, Effentora®) and nasal (Instanyl®) fentanyl for breakthrough pain associated with cancer: Updated appraisal including nasal fentanyl (PecFent®)		√		The North East Treatment Advisory Group does not recommend the novel fentanyl analgesics (Abstral®, Effentora®, Instanyl® and PecFent®) for breakthrough pain associated with cancer.
Bevacizumab (Avastin®) in the management of neovascular age-related macular degeneration: Updated appraisal	√			The North East Treatment Advisory Group recommends bevacizumab (Avastin®) 1.25 mg intravitreal injection as a cost effective treatment option for age-related macular degeneration.
Collagenase (Xiapex®) for Dupuytren's contracture		√		The North East Treatment Advisory Group considered the use of collagenase(Xiapex®) within its licensed indication for the treatment of Dupuytren's contracture and as a potential substitute for established surgical interventions. The North East Treatment Advisory Group does not recommend collagenase (Xiapex®) for Dupuytren's contracture.
Paliperidone depot injection (Xeplion®) for schizophrenia		√		The North East Treatment Advisory Group does not recommend paliperidone depot injection (Xeplion®) for schizophrenia.
Pegvisomant (Somavert®) for acromegaly		√		The North East Treatment Advisory Group does not recommend pegvisomant (Somavert®) for acromegaly. The group considers that pegvisomant is unlikely to meet conventional cost effectiveness criteria.
Rituximab (MabThera®) in rheumatoid arthritis: non-NICE approved indication	See notes			The North East Treatment Advisory Group recommends rituximab (MabThera®) in combination with methotrexate as first-line biological therapy for severe active rheumatoid arthritis in cases where there is an absolute contra-indication to tumour necrosis factor inhibitors. The group recognises that rituximab (MabThera®) monotherapy or in combination with other (non-methotrexate) disease-modifying anti-rheumatic drugs may be suitable in complicated individual cases of severe active rheumatoid arthritis. However the group does not generally recommend this use and such cases must be referred via local individual funding request mechanisms.

Tolvaptan (Samsca®) for the syndrome of inappropriate anti-diuretic hormone secretion (SIADH) An appeal was made of the NETAG recommendation (April 2011) regarding the long-term use of tolvaptan for the management of treatment-refractory and uncontrolled hyponatraemia due to SIADH			√	The North East Treatment Advisory Group has opted to defer their decision on an appeal of their recommendation for tolvaptan (Samsca®) for hyponatraemia due to SIADH pending resolution of issues relating to clinical audit, prescribing and drug costs.
6) Appeals against earlier decisions by the APC				
Apomorphine pre-filled syringes (Apo-Go®) (refused by the APC on 12th July 2011	√			since the original application the prices have changed and the pre-filled syringe is now the same price as the vials. It was clarified that the anticipated use of pre-filled syringe are single figure patient numbers. The benefits are ease of use and safety for the patient / carer in administration. Market forces and the current monopoly on supply were discussed. It was agreed that if a suitable alternative cheaper syringe / device were launched patients could be retrained. **DECISION: Approved**. If another product is brought to the market which is cheaper the product choices will be reviewed
7) Miscellaneous decisions by the APC				
Venlafaxine MR preparations - Review			√	The Formulary Subcommittee has been asked to review the MR venlafaxine preparations. **Recommendation:** Deferred until the evaluation has been discussed by NTW Medicines Management Committee
Review of COPD inhalers			√	The Formulary Subcommittee has been asked to review the COPD inhalers that are currently included in the Formulary. **Recommendation:** This will be discussed at the next Formulary Subcommittee meeting.
Cimetidine IV discontinued	See Notes			Cimetidine IV has been discontinued. **Recommendation:** This was noted and no amendments are required to the Formulary.
Estradiol implants 25mg, 50mg &100mg discontinued	See Notes			Estradiol implants have been discontinued and are included in the North of Tyne Formulary. **Recommendation:** The patches should be removed from the Formulary and no further action required.

Pregabalin – review of 'specialist' use	See Notes			The Formulary Subcommittee has been asked by GPs to review the current position of pregabalin in the Formulary. Contrary to NICE CG96, pregabalin was limited in NoT to 3rd treatment (after amitryptiline and gabapentin) and to specialist prescribing. Comments received suggest that it is impractical to refer this group of patients to pain clinics and hence pregabalin should be made available for GPs to prescribe. **Recommendation:** The committee agreed that GPs could prescribe pregabalin (after amitriptyline and gabapentin). Pregabalin is the second choice second-line treatment. NICE CG96 states that third-line treatment requires referral to the specialist pain service.
Agomelatine for the treatment of major depressive episodes	See notes		✓	The committee were asked to remove agomelatine from the formulary following the termination of its appraisal by NICE. It was agreed that the decision is deferred until it is reviewed by NETAG and discussed with specialists within NTW.
Bivalirudin for the treatment of ST-segment elevation MI	See notes			NICE TAG 230: - Bivalirudin in combination with asprin and clopidogrel is recommended for the treatment of adults with ST segment elevation MI undergoing percutaneous coronary intervention. Recommendation: The North of Tyne Formulary should be amended to reflect NICE guidance
Dabigatran – for prevention of stroke in non-valvular atrial fibrillation.	See notes			The committee noted the position of NETAG and the recently published differing negative NICE appraisal consultation document (ACD). It is anticipated that NETAG will review their position pending the publication of the NICE guidance.