Hampshire PCT South East
Portsmouth City PCT
Portsmouth Hospitals NHS Trust
Hampshire Partnership NHS Trust

AREA PRESCRIBING COMMITTEE

ANNUAL REPORT 2007-8

Dr P Edmondson-Jones
Director of Public Health & Well-being
Chairman

Jeff Watling
Clinical Director Medicines Management and Pharmacy
Secretary

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Chairman's Foreword

As chairman of the Area Prescribing Committee (APC), I am delighted to introduce this Annual Report for the committee for 2007/ 2008.

The whole health economy should celebrate the success of the APC which remains the guardian of the District Formulary, which together with other control measures, has contributed to the effective management of a combined drug budget of in excess of £100 million. This health economy includes Portsmouth Hospitals Trust, Portsmouth City PCT, the South East of Hampshire PCT and also a part of Hampshire Partnership Trust. Placing the health economy at the heart of the work undertaken by the APC has meant that the committee has been able to continue to work and develop despite recent NHS reorganisation.

However, it is important that the committee does continue to review its effectiveness in order to rise to the challenges presented by the World Class Commissioning agenda and other developments within the NHS which affect prescribing and medicines management. I would refer you to the review of the functioning of the committee which was undertaken and which is described within this document.

This next year will be one of further development to meet these recommendations and strengthening the committee role particularly around audit.

Dr P Edmondson-Jones
Chairman, Area Prescribing Committee
May 2008

Activity and Achievements

The Area Prescribing Committee (the APC) meets every two months in rotation with the Portsmouth Hospitals Formulary and Medicines Group (F&MG). The weight of business cases for new medicines ensures that agenda are substantial to the extent that attempts to include audit reports following introduction of new medicines have largely been thwarted. The Committee is the guardian of the Portsmouth and SE Hants District Prescribing Formulary and has responsibility for the clinical approval of all new medicines or new uses of medicines within the local health economy. The APC is responsible for approval of both drug therapy guidelines, where these have an impact on primary care and shared care guidelines. The APC is also responsible for receiving audits concerning compliance with business cases for new medicines, particularly those introduced as part of NICE Technology Appraisals.

District Prescribing Formulary

The District Prescribing Formulary is well established, acceptance is high and it is well policed within secondary care by the hospital clinical pharmacy services. Within primary care monitoring is undertaken by PCT Pharmaceutical Advisors. The master District Prescribing Formulary is available in electronic format, on the "Extranet" site for GPs and Primary Care Professionals to access and on the Portsmouth Hospitals Intranet.

Within Portsmouth Hospitals there is a system for approving non-formulary requests on a case-by-case basis. There have been have been 21 non-formulary requests in 2007/8. These are mostly from clinicians wishing to try a new medicine for a patient with a very specific indication or to pre-empt a business case. The rule that only two non-formulary requests are allowed before a business case is required is well accepted. In practice, most clinicians go straight to the business case route if a new medicine is required to be added to the District Formulary.

Introduction of New Medicines

Within secondary care a three stage approval/funding process, is well established, namely:
- clinical approval by Formulary and Medicines Group,
- district formulary approval by Area Prescribing Committee
- financial approval by Trust Planning Committee

Within primary care a similar approval / funding process is in place
- clinical approval by Formulary and Medicines Group* (as the medicines will potentially be used within secondary care as well as primary care) or PCT* internal medicines management committee if only for use within primary care or PCT provided service
- district formulary approval by Area Prescribing Committee
- financial approval by PCT Executive committees or similar committee with delegated authority.

*for mental health drugs Hampshire Partnership Trust may lead on clinical approval in collaboration with Portsmouth City's mental health services.

The combination of NICE Technology Appraisal costing templates and the need for explicit costing for TPC has improved the quality of costings attached to business cases. The majority of business cases now contain accurate estimates of costs and, in some cases, have successfully challenged the predictions in NICE costing templates because local incidence of disease is different from the average or that predicted in the model.

The system for categorizing medicines in terms of first, second or third line treatments and how they will be initiated, usually known as the "traffic light" system, is well established and accepted. Shared care guidelines are prepared routinely for "amber" drugs as part of the business case and most are approved by the Area Prescribing Committee because of the primary care interest in their content.

It is accepted that audit criteria are to be defined as part of the business case but the weakness in the system is now follow up to ensure feedback to the relevant committee. Only one audit has been fed back to a join session of the F&MG and APC in the last year.

Business Cases for New Medicines

The APC has received 44 business cases/requests for new medicines (See Appendix 2) for approval, of which 40 were approved for inclusion in the District Prescribing Formulary, in one case approval was granted following appeal and in three cases approval was delayed pending publication of a NICE Technology Appraisal.

Drug Therapy guidelines

Drug therapy guidelines are more usually the domain to the F&MG, however the APC is asked to approve them if they are applicable to primary care. The APC approved the following Drug Therapy Guidelines

Medicines for obesity
Treatment of gout
Treatment of community acquired pneumonia
Breast feeding and treatment of candidiasis

Shared Care Guidelines

The Area Prescribing Committee approved the following shared care guidelines:
Treatment of psoriasis
Prescribing of leflunomide
Prescribing of sevelamer
Treatment of Alzheimer's Disease
Treatment of hypoactive sexual desire disorder

There is still a problem with business cases for secondary care initiated, primary care continued, medicines being submitted without shared care guidelines. The F&MG will be asked not to approve such business cases without shared care guidelines.

Review of the role of Area Prescribing Committee

A review of the functions of the APC was carried out during 2007/8 following publication of National Prescribing Centre guidance entitled "Managing Medicines Across a Health Community." As a result, an action plan was prepared and discussed at the APC in April 2008. The review raised a number of issues under the headings of: governance, membership, functions [of the Committee], communication, decision making, audit and longer term goals. A series of actions were proposed to make the committee more accountable, proactive and transparent/consistent in its decision making. Central to the development of the committee is the appointment of a formulary pharmacist to lead the administrative processes on the committee. For details of the issues raised and proposed actions see appendix 4. The committee is developing a work programme based on these priority actions for the next year.

Appendix 1

Area Prescribing Committee

Membership - Mar 2008

Member	Post title	Represents	Total Meetings Attended (max 6)
Coln L Abdul-Aziz (part year)	Consultant Physician	Royal Hospital Haslar	1
Code A	Pharmaceutical Advisor	Hampshire PCT	6
Code A	Clinical Pharmacy Manager	Portsmouth Hospitals NHS Trust F&MG	4
Dr M Dennison	General Practitioner	Hampshire PCT	2
Dr A Dinapala (part year)	General Practitioner	Portsmouth City PCT	1
Code A	Chief Pharmacist	Royal Hospital Haslar	4
Dr P Edmondson-Jones (Chair)	Director of Public Health and Well-being	Portsmouth City PCT	4
Dr E Fellows	General Practitioner	Portsmouth City PCT	6
Dr N Ghaffer (part year)	Observer	Portsmouth City PCT	1
Code A	Pharmaceutical Advisor	Hampshire PCT	1
Code A	Head of Medicines Management	Portsmouth City PCT	5
Code A	Pharmacist	Hampsheir Partnership NHS Trust	1
Code A	Divisional General Manager	Portsmouth Hospitals NHS Trust	4
Code A	Pharmaceutical Advisor	Hampshire PCT	1
Code A	Chief Pharmacist	Hampshire Partnership NHS Trust	4
Code A	Pharmacist	Portsmouth City PCT	1
Dr David Pogson	Consultant Anaesthetist (Critical Care)	Portsmouth Hospitals NHS Trust F&MG	6
Dr Matthew Puliyel	Consultant Elderly Medicine	Portsmouth Hospitals NHS Trust F&MG	4
Dr G Venkat-Raman	Consultant Nephrologist Portsmouth Hospitals	Portsmouth Hospitals NHS Trust F&MG	4
Jeff Watling	Secretary and Clinical Director Medicines Management and Pharmacy	Portsmouth Hospitals NHS Trust F&MG	6
*Mr G Zaki	Medical Director	Portsmouth Hospitals NHS Trust	0

* Mr Zaki has been unable to attend in person due to consistent clashes with key meetings but he has kept in touch through the chairman and secretary at all stages.

Appendix 2

New Drug Additions to the District Prescribing Formulary

The following medicines or new treatments with medicines have been discussed by the Formulary and Medicines and Area Prescribing Committees.

Drug	External approval	Annual Cost	Comment
Meropenem	No	Cost Saving	Febrile neutropenia (replacement for imipenem)
Tigecycline	No	£3,800-£10,000	Multi-resistant infections
Sanatogen Gold	No	Cost Saving	Vitamin and mineral supplement (replacement for Forceval)
Ivadrabine	No	£10,000	Angina (secondary care initiation cardiology)
Balsalazide	No	13,500	Distal ulcerative colitis
Olopatadine eyedrops	No	<£1,000	Failed cromoglycate in 1° care 2° care initiation
Nedocronil eyedrops	No	<£1,000	Allergic conjunctivitis
Remeloxone eyedrops	No	<£1,000	Low potency corticosteroid
Fluromethalone eyedrops	No	<£1,000	Low potency corticosteroid
Travanoprost eyedrops	No	Cost saving	Glaucoma (cheaper that latanoprost)
Brinzolamide eyedrops	No	Cost neutral	Glaucoma
Ganfort	No	Cost neutral	Third line alternative treatment for glaucoma
Darinivir	No	£13,686	Third line HIV
Rectogesic	No	Cost neutral	Anal fissures
Capecitebine	No	£7,000	Pancreatic cancer
Botulinum A Toxin	No	£5,840	Intractable detrusor overactivity
Omalizumab	No	£7,440	Severe asthma
Sildenafil	No	Cost neutral	Pulmonary arterial hypertension in paediatrics
Zoledronic Acid	No	£93,350	Osteoporosis associated with prostate cancer
Adalimumab	No	£4,000	Crohn's disease alternative to infliximab previously NICEd
Exenatide	No	£9,900	Diabetes
Pemetrexed	NICE TA 135	£2-300K	Mesothelioma
Rituximab	NICE TA 126	£316,210	Rheumatoid arthritis
Adalimumab	NICE TA 125	£553,000	Psoriatic arthritis
Temozolamide	NICE TA 121	£120,820	Glioma
Sabotoxone	No	£360,000	Substance misuse service
Naltexone	No	<£500	Substance misuse service
Tesosterone patches	No	£1,680	Contraception and sexual health
Lumnity	No	£2,450	Cardiology/diagnostic imaging
Sonovue	No	£4,000	Cardiology/diagnostic imaging
Combivent	No	Cost neutral	Respiratory
Tiotropium	No	Cost neutral	Respiratory
Fometerol	No	Cost neutral	Respiratory
Daptomycin	No	£378	Microbiology
Alteplase	NICE TA 122	£27,000	Ischaemic stroke
Bortezomib	NICE TA 129	£199,594	Multiple myeloma

Erlotinib	No	£172,585	Lung cancer but only following positive gene identification.
Dinoprostone	No	Cost Neutral	Alterative delivery of drug
Zoledronic Acid	No	£33,300	Third line osteoporosis

The following medicines or new treatments with medicines have been discussed and rejected by the Area Prescribing Committee.

Drug	External approval	Comment
Grazax for allergic rhinitis	No	Poor evidence of cost benefit and potential for large patient numbers in primary care
Rimonobant for obesity	No	Approval delayed pending NICE TA Guidance
Sitagliptin for type 2 diabetes	No	Lack of meaningful costing/prevalence data
Olmesartan for essential hypertension	No	"Me too" drug with no cost benefit over first choice AIIRA

Appendix 3 Constitution and Terms of Reference of Area Prescribing Committee

Membership

PCT Consultant in Public Health Medicine (Chair)
Medical Director of PHT
PCT Pharmaceutical Advisor – Ports City PCT
PCT Pharmaceutical Advisor – Hants PCT
General Practitioner appointed by Ports City PCT
General Practitioner appointed by Hants PCT
General Practitioner appointed by LMC
Three Clinical Representatives from Portsmouth Hosp. NHS Trust appointed by Medical Director
Clinical Pharmacy Manager appointed by Chief Pharmacist PHT
Formulary pharmacist
Chief Pharmacist Hants Partnership Trust
Chief Pharmacist PHT Trust
One management representative from Portsmouth Hospitals NHS Trust appointed by the Medical Director

Accountability

The Committee shall report to all stakeholder organisations by way of annual report to Professional Executive Committee, PHT Governance Committee, Hampshire Partnership Medicines Management Committee, Hampshire PCT Medicines Management Committee. Individual members shall be accountable to their appointing body for the full timely and reasoned discharge of its functions to be clarified.

Purpose

Provide a forum for informed discussion between primary and secondary care; structured to ensure that the implications of any significant changes in practice related to medicines are defined and understood.

Functions

- Plan for and manage the introduction of new medicines and new indications for existing medicines into the local health economy
- Maintenance of District Prescribing Formulary
- Plan and facilitate local implementation of national policy e.g. NICE guidance and other national guidance
- Approve shared care protocols, treatment and/or prescribing guidelines and care pathways between primary and secondary care; help to decide who prescribes and where prescribing occurs
- Provide guidance on medicines management issues that have an effect on clinical practice and the overall delivery of healthcare in the local health economy
- Approval of class reviews of products for treatment of common diseases
- Make recommendation to commissioners about medicines linked to new interventions
- Highlight to commissioners potential impact (cost saving or cost generation) of approved medicines.
- Approving audit requirements of business cases for new medicines and receiving audits of prescribing to ensure that he terms of business cases are being adhered to
- To link with other existing groups with regard to medicine management issues i.e. Portsmouth and South East Hants Purchasing Strategy Group, Ports and South East Hants Medicines and Safety Committee, PHT Patient Group Direction Group, Joint Wound Formulary Group.
- Develop relationships with new and emerging organisation/groups who will have an impact on medicine management in the health community.

General

- Meeting to be chaired by Appointed Chairperson or deputy Chairperson
- Formulary pharmacist to act as secretary, to compose agenda at least two weeks before APC meeting in consultation with the Chairperson.
- Agenda and associated papers to be circulated to all APC members in paper and electronically.
- Formulary pharmacist to ensure applicants are invited to APC meeting at least two weeks in advance and given a designated time slot which they are to adhere to.
- Terms of reference will be reviewed annually.

Frequency of meetings

The 2nd Friday of every other month

Approved: April 2008
Date of next review: April 2009

Appendix 4 Issues raised and proposed actions following APC Review April 2008

Priority Actions

Governance

Issue	Action
APC needs to report to all stakeholder organisations	▪ Annual report to be produced by secretary and sent to Professional Executive Committee, PHT Governance Committee, Hampshire Partnership Medicines Management Committee, Hampshire PCT Medicines Management Committee.
No documented declaration of interests	▪ Declaration of interests to be completed by applicants of business cases ▪ Declaration of interests to be completed by members of APC and any additional to be documented at each meeting – agreed as a standard agenda item.
No stakeholder map	▪ Flow diagram has been drawn
Terms of Reference out of date	▪ Terms of reference updated (appendix 3 attached)

Membership

Membership list for APC out of date	▪ Review list of membership and ensure all members appropriate (appendix 3 attached) ▪ APC to decide which nursing representation is necessary and then to approach for membership (nurse prescriber to be nominated) ▪ Contact Jan Baker Secretary of Isle of Wight, Portsmouth and SE Hants LMC to ask for representation.

Functions

Duplication of functions by different groups	▪ Chairmen of relevant groups to decide in consultation with their members their terms of reference ▪ Chairmen then to meet and decide which groups are going to perform which functions and in what capacity i.e. developmental or decision making.
No horizon scanning	▪ Formulary pharmacist (when appointed) to use recognised resources to horizon scan for new drugs and hence design agenda accordingly
Agenda not adhered to because of presenting applicants	▪ Ensure applicants are informed of meeting with enough time to ensure attendance so to ensure enough time for decision making ▪ Structured agenda decided two weeks prior to meeting ▪ Agenda to be sent to all members and attendees in electronic form at least two weeks prior to meeting and no further items to be added after this time.

Communication

No direct communication of decision to applicant	▪ Standard letter to be produced stating decision, when effective from and anything else which is required – agreed but on appointment of formulary pharmacist, otherwise notes of meetings to go on Extranet and PHT intranet websites.
Greater communication needed regarding APC decisions to wider health community	▪ Website and electronic bulletin to be produced – on appointment of a formulary pharmacist
Lack of communication from Trust Planning to APC regarding decision and hence applicant	▪ Secretary of APC to meet with Secretary of Trust Planning to plan better communication links
Papers not received by secretary in timely fashion and so sent to APC members late.	▪ Need to decide hours of administrative support needed, write job description and secure funding – agreed but appointment of administrative support will not prevent late submission of papers.

Decision making

Lack of full independent critical appraisal of drugs	▪ Discuss with Simon Wills re: possibility of using existing resources at Southampton Regional MI to produce central appraisals ▪ Need to assess funding i.e. whether it is included in additional services payment or if extra funding is needed ▪ Formulary pharmacist to use existing appraisals where available
Need proactive review of classes when new drug applied for	▪ New business case proforma to ask if any drugs can be replaced ▪ Formulary pharmacist to review class as new drug applied for using any existing information available
Business cases often are presented to APC without necessary information and necessary consultation	▪ Job description for formulary pharmacist to be written ▪ Funding for formulary pharmacist to be secured
Business case time consuming to complete and doesn't support robust decision making	▪ Redesign of business case
No set Shared Care Proforma	▪ Redesigned Shared Care Proforma in place
No set process for decision making so decisions can be inconsistent	▪ A formal process of decision making to be designed but requirements to be built into business case proforma ▪ Decision making process to be documented in standard way within minutes

Audit

Audit data not completed and presented back to APC	▪ Formulary pharmacist if appointed to lead on implementation and monitoring ▪ Business cases only to be accepted by APC if valid audit criteria are submitted also ▪ Audits to be completed using existing resources within individual trusts ▪ Audits to be presented on centrally accessible database with option to review at APC if audit criteria not being met

Longer Term Goals

Issue	Action
Duplication of functions by different groups	▪ Chairmen of relevant groups to decide in consultation with their members their terms of reference ▪ Chairmen then to meet and decide which groups are going to perform which functions and in what capacity i.e. developmental or decision making.
No links with other local APCs	▪ Formulary pharmacists to link to reduce duplication of work ▪ Representatives (suggest chairs) to meet to discuss possibility of standard business cases, decision making tools.
Cancer Network Drug Evaluation Committee suspended at present	▪ Clarify terms of references with committee when meeting ▪ Clarify status of decisions and how/if APCs are to adopt decision
Hampshire Partnership Trust having to present business cases to all local APCs	▪ Chairmen of APCs to meet and discuss feasibility of HPT presenting to just one APC and the others adopting decision