

TRUST POLICY FOR PRODUCTION OF DRUG THERAPY GUIDELINES

CONTENTS LIST:

1. Item
2. Policy Statement
3. Definitions
4. Evidence Based Guideline
5. Forum For discussion
6. Audit Standards/Audit Tool
7. Education and Training
8. Risk Management
9. Associated documentation

APPENDICES:

| | |
|-------------------------------|---|
| Originator: | Jeff Watling Pharmacy Services Manager |
| Approval Route: | Formulary and Medicines Group Area Prescribing Committee Executive Membership of Clinical Governance Committee Sub-Group of Clinical Governance Committee Hospital Management Team |
| Issue No: | 2 |
| Date of issue: | May 2003 |
| Pilot Completion Date: | September 2003 |
| Review Date: | September 2004 |
| Audit Date: | September 2003 |

TRUST POLICY FOR PRODUCTION OF DRUG THERAPY GUIDELINES**CONTENTS LIST:**

1. Item
2. Policy Statement
3. Definitions
4. Evidence Based Guideline
5. Forum For discussion
6. Audit Standards/Audit Tool
7. Education and Training
8. Risk Management
9. Associated documentation

APPENDICES:

| | |
|-------------------------------|---|
| Originator: | Jeff Watling Pharmacy Services Manager |
| Approval Route: | Formulary and Medicines Group Area Prescribing Committee Executive Membership of Clinical Governance Committee Sub-Group of Clinical Governance Committee Hospital Management Team |
| Issue No: | 2 |
| Date of issue: | May 2003 |
| Pilot Completion Date: | September 2003 |
| Review Date: | September 2004 |
| Audit Date: | September 2003 |

1. ITEM

Policy for the Preparation, Approval, Publishing, Audit and Review of Drug Therapy Guidelines

2. POLICY STATEMENT

This document outlines the policy to ensure the consistent preparation, approval, publishing, audit and review of Drug Therapy Guidelines for use within Portsmouth Hospitals NHS Trust and throughout secondary care services within the Portsmouth and South East Hampshire health economy.

3. DEFINITION

Drug Therapy Guidelines

Guidance documents prepared to assist clinicians, nurses and pharmacists in the safe control and administration of medicines for specific clinical conditions.

RESPONSIBILITIES

Guideline Project Manager

A member of pharmacy staff designated, by the Pharmacy Services Manager to project manage the process for development of a Drug Therapy guideline.

Guideline Development Group

A group established by a Guideline Project Manager to prepare a Drug Therapy Guideline.

4. EVIDENCE BASED GUIDELINES/PROTOCOLS/PROCEDURE FOR PRACTICE

| ACTION | RATIONALE | EVIDENCE (Please rank the evidence as recommended) |
|--|---|--|
| Staff preparing Drug Therapy Guidelines will comply with PHPSWI07 001U (Appendix 1) Preparation and approval of Drug Therapy guidelines | Following the Work Instruction ensure a consistent format for Drug Therapy Guidelines. | See attached PHPSWI07 001U |
| Drug Therapy Guidelines will be submitted for approval to Committees specified in PHPSWI07 001U (Appendix 1) | This will ensure that all Drug Therapy Guidelines are submitted to multidisciplinary committees for approval prior to publication | See attached PHPSWI07 001U |
| Drug Therapy Guidelines will be published on the Portsmouth Hospitals Intranet Website and Portsmouth and SE Hants Extranet Website as read or print only documents, protected from amendment by password control. | This will ensure that all Drug Therapy Guidelines are widely available to the Portsmouth and S E Hants health economy. The latest version will be maintained on the web-server, obviating the need for an alternative document control system | The Portsmouth Hospitals Pharmacy Service will maintain a web-server specifically for the purpose of making available controlled documents associated with the Clinical Support Division Quality Systems, Drug Therapy Guidelines and Clinical Governance. |
| Drug Therapy Guidelines will be subject to an audit programme as determined by the ***** Group. Such that compliance with recommendations is audited at an appropriate period after publication | This will ensure that recommendations are implemented and feedback obtained from interested parties, which may be useful to the review process | See attached PHPSWI07 001U |
| Drug Therapy Guidelines will be subject to review at a frequency agreed by the Guideline Development Group but in addition new Drug Therapy | This will ensure that Drug Therapy Guidelines are reviewed within one year of first publication and at intervals, thereafter, agreed with the group responsible for their development | See attached PHPSWI07 001U |

**PORTSMOUTH HOSPITALS
POLICY AND PROCEDURES MANUAL**

Policy No. 15.11

| | | |
|---|--|--|
| Guidelines will be reviewed within one year after publication | | |
|---|--|--|

5. FORUM FOR DISCUSSION (FORUM OR WORKING PARTY)

Formulary and Medicines Group
Area Prescribing Committee

6. AUDIT STANDARDS / AUDIT TOOL

| ASPECT OF CARE/OUTCOMES | EXPECTED STANDARD/TARGET | SOURCE OF DATA COLLECTION |
|--|---|---|
| Preparation of Drug Therapy Guidelines will be in accordance with PHPSWI07 001U | 100% | Documentation of preparation process on PHPS Form 07 001U |
| Approval of Drug Therapy Guidelines will be by Committees specified in PHPSWI07 001U | 100% | Documentation of preparation process on PHPS Form 07 001U |
| Publication of Drug Therapy Guidelines will be as defined in this policy | 100% | Review of Portsmouth Hospitals Intranet Website and Portsmouth and SE Hants Extranet Website. |
| As a minimum, compliance with Drug Therapy Guidelines will be audited at an interval determined by the *****group | 100% audits undertaken at the agreed intervals | Documentation of audit process on PHPS Form 07 001U and appendices |
| As a minimum, content of Drug Therapy Guidelines will be reviewed at intervals defined by the Formulary and Medicines Group. | 100% reviews undertaken at the agreed intervals | Documentation of review process on revised PHPS Form 07 001U |

7. EDUCATION & TRAINING

The Director of Medical Education, the Director of Nursing and the Pharmacy Services Manager will ensure that availability of Drug Therapy Guidelines is highlighted in patient safety induction training for all staff involved in the medication process. It should also feature in specific training for junior medical staff, including schemes for locum staff.

8. RISK MANAGEMENT

Approval of audits of compliance with Drug Therapy Guidelines and their programme for updating will be included in the principal functions of the Area Prescribing Committee. Responsibility for reviewing the above will be the responsibility of the Guidelines and Medicines Management Sub Committee.

9. ASSOCIATED DOCUMENTATION

Appendix 1 PHPSWI07 001U Preparation, Approval, Publishing, Audit and Review of Drug Therapy Guidelines (see overleaf)

Appendix 2 PHPS Form 07 001U Documentation of Preparation, Approval, Publishing, Audit and Review of Drug Therapy Guidelines

Preparation, Approval, Publishing, Audit and Review of Drug Therapy Guidelines

This work instruction is issued and controlled by Portsmouth Hospitals Pharmacy Services. Changes may only be authorised by the Pharmacy Services Manager/Head of Purchasing. Authorised originals of this work instruction are controlled documents maintained on the Portsmouth Hospitals Intranet Website.

AUTHORISED ORIGINALS ON THE INTRANET WEBSITE MAY BE USED AS WORKING DOCUMENTS. PRINTED PAPER VERSIONS OF THIS WORK INSTRUCTION MAY BE USED AS WORKING DOCUMENTS BUT ARE CONTROLLED DOCUMENTS ONLY ON THE DAY THEY ARE PRINTED.

Originator: **Code A** Date: 19 May 2003
Authorised: Jeff Watling Date: 19 May 2003
Head of Purchasing/Pharmacy Services Manager

Date Printed: 19 May 2003

Date of Last Amendment: 24th March 2003

1. Purpose and scope

Portsmouth Hospitals NHS Trust has a policy to ensure the consistent preparation, approval, publishing, audit and review of Drug Therapy Guidelines. This Work Instruction describes how this will be achieved and documented.

2. Responsibility

- 2.1 The Head of Purchasing/Pharmacy Services Manager will be responsible for ensuring that this Work Instruction supports the Trust Policy for the Preparation, Approval, Publishing and Review of Drug Therapy Guidelines.
- 2.2 All staff within Portsmouth Hospitals Pharmacy Service will be responsible for ensuring that this work instruction is followed and that requirements for review and amendment are notified to the Departmental Manager.

3. References

- 3.1 ISO 9001:2000 para 4.2.3 Control of Documents
- 3.2 Trust Policy and Protocol for preparation, approval, publishing, audit and review of Drug Therapy guidelines

4. Definitions:

- 4.1 **PHPS** – Portsmouth Hospitals Pharmacy Service

-
- 4.2 **Drug Therapy Guidelines** - Guidance documents prepared to assist clinicians, nurses and pharmacists in the safe control and administration of medicines for specific clinical conditions.
- 4.3 **Guideline Project Manager** A member of pharmacy staff designated, by the Pharmacy Services Manager to project manage the process for development of a Drug Therapy Guideline.
- 4.4 **Guideline Development Group** A group established by a Guideline Project Manager to prepare a Drug Therapy Guideline.
- 5. Format of Drug Therapy Guidelines**
- 5.1 All Drug Therapy Guidelines prepared by Portsmouth Hospitals Pharmacy Service will follow the format specified in this Work Instruction.
- 5.2 All text will be in Arial font type (or equivalent) and 12 point font size throughout unless otherwise indicated
- 5.3 Format of Text
- 5.3.1 The front page will carry the following information:
- Standard header (see attached example) Including a guideline reference number, approval date by Guidelines and Medicines Management Sub-Committee and review date (see attached example)
 - Title in the form a bordered text box or single column single row table with white on black text font size 16pt (see attached example).
 - Introduction defining the reasons for the Drug Therapy Guideline, its objectives and the patients to whom it will apply.
 - Main text in the format of attached example
 - Reference to appendices, associated forms etc.
- 6. Process for preparation of Drug Therapy Guidelines**
- 6.1 The Pharmacy Services Manager will ensure that a system is in place to ensure that a member of pharmacy staff will be designated to project manage the process for development of Drug Therapy guidelines.
- 6.2 Drug Therapy Guidelines will be prepared independently, by NHS staff working within the Portsmouth and South East Hampshire Health Economy. Preparation of Drug Therapy Guidelines will be independent of funding or editorial influence from the pharmaceutical industry.
- 6.3 The Guideline Project Manager will establish a Guideline Development Group with representation from professional interests e.g. clinicians from appropriate specialities, nurses, pharmacists and other healthcare professionals
- 6.4 The Guideline Project Manager will ensure that, where appropriate, there is representation from other interest groups – including patients, during the guideline preparation process.
- 6.5 The Guideline Project Manager will document membership on PHPS Form 07 001U.

-
- 6.6 The Guideline Project Manager will document the sources of information used to select the evidence, on which the guidelines are based. Key references will be listed in the Drug Therapy Guideline but all references used will be documented on PHPS Form 07 001U.
- 6.7 The Guideline Project Manager will document, where possible, the methods used to interpret and assess the strength of evidence, on which key recommendations are made. In particular there should be an explicit link between major recommendations and the level of supporting evidence.
- 6.8 The Guideline Project Manager will document the methods used to formulate the recommendations. In particular a record will be made of how the views of interested parties not on the Guideline Development Group were taken into account.
- 6.9 If the Drug Therapy Guideline is to be piloted prior to implementation the Guideline Project Manager will manage the pilot study, document changes to the Drug Therapy Guideline as a result of the pilot study on PHPS Form 07 001U. Documentation of audits associated with the pilot study will be appended to PHPS Form 07 001U.
- 6.10 The text of the Drug Therapy Guideline should include as a minimum:
- the reasons for developing the Drug Therapy Guideline
 - the objectives of the Drug Therapy Guideline
 - a description of the patients to which the Drug Therapy Guideline should apply
 - definitions
 - a description of the condition to be detected, treated or prevented
 - a definition of alternative options for management of the condition, e.g. first/second line treatment, medical or surgical management
 - a presentation of the recommendations
 - a statement of how the Drug Therapy Guideline is to be disseminated
 - a description of the health benefits likely to be gained from following the recommendations
 - a description of the potential harm or risks that may result from the recommended management
 - reference(s) to key national guidelines
 - a comment concerning evidence base
- 6.11 In addition, the text of the Drug Therapy Guideline may include:
- estimated costs of expenditures likely to occur from the recommended management
 - an explicit statement of how patient preferences should be taken into account in applying the guidelines
 - If appropriate, the identification of standards or targets or measurable outcomes, that can be monitored

7 Approval

- 7.1 The Guideline Project Manager will ensure that Drug Therapy Guidelines are independently approved before publication. As a minimum this will be through the following:
- Formulary and Medicines Group
 - Sub Group of Clinical Governance Committee.

In addition, any guidelines likely to affect elderly patients or other patients within the care of Primary Care Trusts will be through the following:

-
- Guidelines and Medicines Management Committee
 - Area Prescribing Committee
 - PCT Clinical Governance and Risk Management Committee

7.2 The Guideline Project Manager will document approval dates on PHPS Form 07 001U

8 Publishing

8.1 On completion of the approval process the Guideline Project Manager make any necessary amendments and prepare a final version ready for publishing. This will then be passed to the appropriate document controller for publishing on the Trust Intranet Web-site and Portsmouth and ES Hants Extranet, if appropriate.

8.2 The Guideline Project Manager will document final version and publishing dates on PHPS Form 07 001U

9 Audit and Review

9.1 The Guideline Project Manager will liaise with the Guideline Development Group to agree a review date for the Drug Therapy Guideline and organise a method for review approximately three months prior to the review date. This process will be documented on PHPS Form 07 001U. The review process will be documented using a new PHPS Form 07 001U.

9.2 The Guideline Project Manager will liaise with the Guideline Development Group to agree an audit process for the Drug Therapy Guideline and organise an audit, preferably in conjunction with the Clinical Audit Manager for the Trust(s) concerned. Documentation of audits associated with the pilot study will be appended to PHPS Form 07 001U. Any reviews of the Drug Therapy Guideline as a result of the audit process will be documented using a new PHPS Form 07 001U.

Portsmouth Hospitals NHS Trust
Pharmacy Service

PHPS Form 07 001U
Revision level 2
Page 1 of 5

Record of Preparation, Publishing, Audit and Review of Drug Therapy Guidelines

Preparation

| | | |
|--|-------------|-------------|
| Title of Drug Therapy Guideline | | |
| | | |
| Name of Guideline Project Manager | | |
| Membership of Guideline Development Group | Name | Date |
| | | |
| References used in preparing Drug Therapy Guideline | | |
| | | |
| Methods used to interpret strength of evidence | | |
| | | |

Portsmouth Hospitals NHS Trust
Pharmacy Service

PHPS Form 07 001U
Revision level 2
Page 2 of 5

Methods used to formulate recommendations

| |
|--|
| |
|--|

Documentation of Review Process

| Group | Date |
|---|------|
| Initial proposal to Guideline Development Group | |
| | |
| | |
| | |
| Finalisation by Guideline Development Group | |

Documentation of Pilot Process

| Pilot Process | Duration |
|-------------------------------|----------|
| | |
| Audit of Pilot Process | |
| | |

Portsmouth Hospitals NHS Trust
Pharmacy Service

PHPS Form 07 001U
Revision level 2
Page 3 of 5

| Documentation of Minimum Requirements not included | | |
|--|------------|-----------------------------|
| Requirement | Inc | Reason for exclusion |
| Reasons for developing drug therapy guideline | | |
| Objectives of drug therapy guideline | | |
| A description of patients to whom the guideline should apply | | |
| A clear description of condition to be detected, treated or prevented | | |
| Clear description of health benefits likely to be gained from following the guidelines | | |
| Clear definition of alternative options for management of the condition | | |
| Statement of how the guideline to be disseminated | | |
| Clear presentation of the recommendations | | |
| An adequate description of harms and risks associated with recommended management | | |
| Reference to key national guidelines | | |
| Comment concerning evidence base | | |

| Documentation of Additional Requirements not included | | |
|---|------------|-----------------------------|
| Requirement | Inc | Reason for exclusion |
| Estimated costs of expenditures likely to occur from the recommended management | | |
| Explicit statement of how patient preferences should be taken into account in applying the guidelines | | |
| Clear definition of standards or targets or measurable outcomes, that can be monitored | | |

Approval

| Documentation of Approval Process | |
|--|-------------|
| Group | Date |
| Approval by Formulary and Medicines Group | |
| Approval by Guidelines and Medicines Management Committee | |
| Approval by sub-committee of Clinical Governance Committee | |
| | |

Publishing

| Final version prepared by Guideline Project Manager | Date |
|--|-------------|
| Name Guideline Project Manager | |

Portsmouth Hospitals NHS Trust
Pharmacy Service

PHPS Form 07 001U
Revision level 2
Page 4 of 5

| Final version place on intranet website | Date |
|--|-------------|
| Name Document Controller | |

Review and Audit

| Review date agreed with Guideline Development Group | Date |
|--|-------------|
| Proposed review date | |

Proposed review methodology

| Review completed | Date |
|-----------------------------------|-------------|
| Name Guideline Project Manager | |

| Revised version prepared by Guideline Project Manager | Date |
|--|-------------|
| Name Guideline Project Manager | |

| Revised version place on intranet website | Date |
|--|-------------|
| Name Document Controller | |

Detailed documentation of review of each drug therapy guideline will be undertaken using a new PHPS Form 07 001U in accordance with the requirement of PHPSWIYY

| Audit date agreed with Guideline Development Group | Date |
|---|-------------|
| Proposed audit date | |

Proposed audit methodology

| Audit completed | Date |
|-----------------------------------|-------------|
| Name Guideline Project Manager | |

| Revised version prepared by Guideline Project Manager | Date |
|--|-------------|
| Name Guideline Project Manager | |

| Revised version place on intranet website | Date |
|--|-------------|
| Name Document Controller | |

Portsmouth Hospitals NHS Trust
Pharmacy Service

PHPS Form 07 001U
Revision level 2
Page 5 of 5

Detailed documentation of audits of each drug therapy guideline will be undertaken using a new PHPS Form 07 001U in accordance with the requirement of PHPSWI07 001U