

NORTH NOTTINGHAMSHIRE PRESCRIBING STRATEGY GROUP

Guidelines for Clinical and Prescribing Responsibility

Introduction

This document was originally developed by the North Nottinghamshire Drugs and Therapeutics Committee and has subsequently been revised and accepted by the North Nottinghamshire Prescribing Strategy Group (NNPSG). It is intended to define the process, which will apply within North Nottinghamshire for clarifying the clinical and prescribing responsibilities for individual drugs. In particular, attention will be paid to the introduction of new drugs, new uses of existing drugs and drugs whose use is under review in terms of shifting from predominantly being a drug normally prescribed within secondary care to a drug normally prescribed within primary care. Prescribing costs should not form part of discussions on clinical responsibilities between clinicians.

These guidelines address the circumstances where shared care prescribing arrangements might be appropriate, and explain how the management of shared care prescribing will proceed in the future in North Nottinghamshire. They provide a mechanism to determine the most appropriate clinician responsible for prescribing a particular drug. The development of shared care prescribing guidelines for particular drugs/conditions is outlined, for use when shared clinical care of the patient is *agreed* between the consultant and general practitioner.

This document should be the first point of reference for both general practitioners and consultants in the Trusts when considering the introduction of a new drug, a new use for an existing drug, the appropriateness of shared care prescribing arrangements for a particular condition, or the transfer of prescribing of an individual drug from one setting to another.

Division of clinical responsibility and therefore prescribing responsibility is considered and general principles are put forward to meet the needs and concerns of all those involved. Legal responsibility for prescribing lies with the doctor who signs the prescription, and this includes the correct completion of the prescription and full or shared clinical responsibility for the treatment of the patient.

Responsibilities to Patients

- Patients should not be involved in discussions or disputes between clinicians on clinical or prescribing responsibilities. Patients may need to be kept informed about specific problems involving "shared care prescribing arrangements", but must not be used as intermediaries between consultants and GPs.
- The best interests and convenience of patients must be considered at all times.

- A "safety net" is needed for patients so that their treatment does not suffer while decisions on clinical and prescribing responsibilities are made. Whilst a decision is awaited as to which category a drug belongs, or where shared care guidelines are being drawn up, the clinical responsibility and supply of the drug under issue to the patient will be retained by the physician who initiated the treatment. The NNPSG will consider the drug in question at their next meeting and determine the category to which it should be allocated. If a drug is deemed to be amber and a shared care guideline needs to be produced the drugs will be classified as red until such time as a shared care guideline is produced and approved by the relevant Trust Drugs and Therapeutics Committee(s) and the NNPSG.

The North Nottinghamshire Prescribing Strategy Group ["Traffic Lights" Pathway](#)

This should be followed with reference to the NNPSG "Traffic Lights" Pathway.

A drug is referred to the NNPSG. This may be via:

- a Trust Drugs and Therapeutics Committee (D&TC)
- a Primary Care Group Prescribing Subgroup
- the LMC
- an individual consultant or GP
- North Nottinghamshire Health Authority

The NNPSG will then follow the steps outlined below to categorise the drug.

Step 1 - Consideration of Evidence of Clinical and Cost-Effectiveness

The NNPSG will firstly need to determine whether the use of a drug is supported by evidence of clinical- and cost-effectiveness.

If evidence is not available, or the evidence available indicates that the drug in question is clinically ineffective or is not cost effective, the drug will be designated **BLUE**.

If evidence, published in a peer reviewed journal, is available but has not been appropriately evaluated the drug will remain in the BLUE list until such time as an evaluation of the evidence has taken place. The evaluation may be undertaken locally or nationally e.g. NICE, National Prescribing Centre.

BLUE

BLUE drugs will be reviewed, along with the other traffic light categories at each meeting of the NNPSG. Conditions may be attached to drugs within this category, e.g. prescribing of this drug to be funded through R&D for North Nottinghamshire residents.

If evidence is available to support the drug as clinically and/or cost effective the NNPSG will proceed to Step 2.

Step 2 - Determination of Drugs Appropriate for Prescribing in Secondary Care Only.

Is the GP normally clinically competent to undertake this specialised care with the provision of appropriate guidelines?

Primary Care Group Prescribing Subgroup representatives and the LMC representative on the NNPSG will normally make this decision after discussion with members of the organisations they represent. This decision should reflect the competency of the "average" GP to undertake this specialised care. Factors to be taken into consideration include: -

- ◆ Is the GP truly taking full clinical responsibility for that patient's treatment? (e.g. if monitoring is performed within secondary care and not by the GP it would normally be considered inappropriate for the GP to prescribe).
- ◆ If the drug is a new chemical entity, and still marked with a black triangle, i.e. there is limited experience of the use of the product and the CSM requests that all suspected adverse reactions be reported, prescribing should remain within secondary care until the NNPSG has had time to comment on its position in relation to the traffic lights pathway. It may be suitable for "me-too" products marked with a black triangle, where there is experience in the use of the group of drugs to which it belongs, to be prescribed in primary care.
- ◆ New, specialised drugs should only move into primary care once GPs have been provided with sufficient information in the form of a shared care guideline approved by the NPSG and / or been given the opportunity for training.

If the answer is **No**, the drug will be added to the **RED** category.

RED

For all RED drugs prescribing responsibility remains with the consultant at the hospital

This may particularly be the case for:

- certain new drugs and new indications for older drugs where there is at present no experience of use in general practice.
- clinical trial drugs which are being used in the hospital.
- medicines which require preparation by the hospital pharmacy, unless an acceptable procedure for supply through a community pharmacist can be arranged.
- drugs being used outside licensed indications.
- drugs, dressings or appliances not available or prescribable in general practice.
- patients attending the hospital frequently for complicated treatments and specialist

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investigations, and the consultant needs to monitor progress.

- the convenience of the patient and in the patient's best interest.
- circumstances where the GP justifiably refuses to take clinical responsibility.
- where a drug has been classified as amber but a shared care guideline, approved by all relevant Trust D&TC(s) and the NNPSG, is not yet available.

RED drugs will be reviewed, along with the other traffic light categories, at each meeting of the NNPSG.

Where there are major financial implications of the use of certain drugs, the costs should form part of the negotiation process for the Trust contract with the relevant Primary Care Group/Trust or the Health Authority.

If the answer is **Yes**, the drug will enter Step 3.

Step 3 - Determination of the Appropriateness of Shared Care Prescribing Arrangements.

Is the drug normally prescribed by the majority of GPs?

If the answer is **No**, the drug will be allocated to the **AMBER** category, appropriate for shared care prescribing arrangements between secondary and primary care.

The AMBER category can be split into two sections which can be defined as follows:

- AMBER (1) -Drugs that should normally be initiated by a specialist and prescribed by GPs under a shared care guideline agreed by the NNPSG.
- AMBER (2) -Drugs that can only be prescribed in general practice after specialist referral. A shared care guideline is not required.

AMBER

For all drugs allocated to AMBER, a shared care prescribing arrangement is appropriate. In these circumstances:

- hospital consultants and general practitioners may come to an agreement that they will share the clinical responsibility for a patient who is being seen by both of them - a "shared care" situation.
- prescribing in these circumstances is determined by the shared care prescribing arrangement negotiated for each individual drug.
- the GP must have a role in the care of the patient which is justifiable in terms of improvement in patient care and proper use of a GPs expertise. For drugs, which they

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have prescribed, GPs should have sufficient expertise to start, stop, or alter the dosage of the drug in appropriate circumstances. The degree of control, which they have over this prescribing, will form part of the shared care guidelines.

- agreements for shared care should not be used for cost shifting purposes only, so that prescribing can be transferred to the GP.
- GPs, as independent contractors, have the right to decline to take clinical and prescribing responsibilities for a patient on their medical list who is being treated elsewhere, but the reason for this action must be documented. In the view of the NNPSG, it would be inappropriate for a GP to refuse to take clinical and prescribing responsibilities for an individual drug, where shared care guidelines for that drug have become common practice and where shared care guidelines include adequate support, education, and information as approved by the NNPSG.
- where a dispute arises in this area, advice will be sought from the NNPSG. The GP(s) involved will then be written to by the Chair of the NNPSG advising them as to the most appropriate way forward.
- adequate support, education and information must be available to GPs who "share care" of patients with a consultant.
- the NNPSG will establish a mechanism to develop a guideline for each drug allocated to this Category:
 - for drugs already categorised as amber for which no shared care agreements are available the NNPSG will form task groups to produce guidelines for each drug, or group of drugs.
 - where consultants apply to their Trust D&TC, or equivalent, for a new drug to be entered on to the Trust Formulary, or for an existing drug to be used in a new indication, advice will be sought from the NNPSG as to which category that drug should fall. If the drug is categorised as amber the consultant as part of the process required by their Trust D&TC, or equivalent, must produce a shared care guideline.

The guideline developed should reflect all of the preceding principles. The aim of the guideline is to define the role and responsibilities of the GP and the Consultants who are agreeing to share clinical and prescribing responsibility for a particular patient with a particular disease or condition. A standard format for these guidelines is given at Appendix 1.

- The relevant Trust D&TC(s) and the NNPSG must approve all shared care guidelines produced before they can be distributed for use between primary and secondary care.
- where a drug is categorised as AMBER and a shared care guideline needs to be produced the drug will be categorised RED until such time as a shared care guideline is produced and approved by the relevant Trust D&TC(s) and the NNPSG.
- when legal responsibility for overall clinical care of the patient is shared, then the

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manner in which it is shared will be indicated by the shared care guideline.

- where appropriate, the NNPSG will review, or return guidelines to their author for review, on a regular basis as determined for each individual drug, all shared care prescribing arrangements. The NNPSG will consider whether AMBER drugs require recategorisation, at each of its meeting, along with the other traffic light categories and in light of any further evidence of experience.

If the answer is **Yes**, the drug will be allocated to the **GREEN** category.

GREEN

For all GREEN drugs prescribing responsibility remains with the general practitioner.

In particular this is the case in circumstances where GPs accept FULL clinical responsibility for the treatment of their patients in primary care and they also accept responsibility for prescribing all necessary drugs, dressings and appliances.

GPs, as independent contractors, have the right to decline to take clinical and prescribing responsibilities for a patient on their medical list who is being treated elsewhere, but the reason for this action must be documented. In the view of the NNPSG, it would be inappropriate for a GP to refuse to take clinical and prescribing responsibilities for an individual drug, where the prescribing of that drug within primary care has become common practice.

By default any drug not listed under RED, AMBER or BLUE may be considered GREEN. Drugs may be listed under GREEN where advice has been sought from the NNPSG on the categorisation of the drug within the “traffic lights” pathway and a recommendation has been made.

SHARED CARE PRESCRIBING GUIDELINE - REQUIRED FORMAT

APPENDIX 1

BACKGROUND INFORMATION ON CONDITION TO BE TREATED

Including information on the disease, diagnostic criteria and investigations, general treatment and management and patient selection for drug treatment.

DRUG TREATMENT, LICENSED INDICATIONS AND MANAGEMENT PLAN

Including indications and exclusion, pharmacology, products available, dosages, reconstituting, storage, administration, adverse effects, drug interactions, costs, patient information, and availability of other information.

PROCEDURES FOR INITIATING SHARED CARE PRESCRIBING

Including mechanism for reaching agreement, contractual and funding implications for Trusts, PCGs and the practices involved.

ROLE AND RESPONSIBILITIES OF TRUST

Including the role of the consultant, degree of control over prescribing, monitoring procedures, frequency of Trust attendance, emergency treatment arrangements, and exchange of information including change of treatment, special clinical and drug problems to be watched for.

ROLE AND RESPONSIBILITIES OF GP

Including the role of the GP, monitoring procedures, frequency of attendance at GP surgery, emergency treatment arrangements, exchange of information, degree of control over prescribing, notifications of change of treatment, special clinical and drug problems to be watched for.

PROFORMA

Details of the specific patient, Consultant and GP for which guideline is being used. Proforma for consultant to sign will list rules and responsibilities of Trust. Proforma for GP to sign will list roles and responsibilities of GP. Each party will retain a copy of the others signed proforma. [Example proformas are available from the HA Prescribing Advisor]

SUPPORT, EDUCATION AND INFORMATION

Support available from Trust, meetings and other education or instructional courses which may be available, information available such as literature, video and audio tapes, films and other organisations and individuals who can provide information and support.

ADVICE HELPLINE

Arrangement for immediate advice and help from trust consultants and other appropriate staff.

SAFETY NET

Procedure to be followed in case of problems initiating shared care.

NAME OF THE AUTHOR, REVIEW DATE

DATE SUBMITTED TO AND APPROVED BY THE TRUST DRUGS AND THERAPEUTICS COMMITTEE(S)

DATE SUBMITTED TO AND APPROVED BY THE NORTH NOTTINGHAMSHIRE PRESCRIBING STRATEGY GROUP