NATIONAL CLINICAL ASSESSMENT SERVICE

INVESTIGATING CONCERNS ABOUT THE PRESCRIPTION OF CONTROLLED DRUGS IN GENERAL PRACTICE

1. INTRODUCTION

1.1. In the year Aug 2008 to Aug 2009, 6,098,816 prescriptions for Schedule 2 controlled drugs were issued. Schedule 2 of the Misuse of Drugs Regulations 2001 includes drugs such as diamorphine, subject to the full controlled drug requirements relating to prescriptions, safe custody (except for secobarbital) and the need to keep registers.

1.2 The majority of prescriptions issued are entirely appropriate and, in general, most examples of unusual patterns of prescribing are explained by exceptional patient need rather than by poor clinical performance, fraud or criminal behaviour. However, this explanation should be accepted only after the less common causes have been excluded.

1.3 This paper outlines the processes for investigation of apparently idiosyncratic prescribing of controlled drugs in general practice and suggests ways in which the less common causes of poor professional performance, fraud and criminal behaviour may be identified.

1.4 There are clear advantages to following standard processes in investigating concerns: they can be published in advance so that those subject to them can comment on them and be aware of the process that will be followed and of the possible need for secrecy in the early stages of an investigation. They will help to ensure that the PCT's procedures are robust and able to withstand legal challenge and are linked to local clinical governance and risk management processes.

2. BACKGROUND

2.1 All NHS organisations are required to have an Accountable Officer for Controlled Drugs (AO). AOs are charged with regularly monitoring the prescribing of CDs within their organisation, investigating incidents and liaising with other bodies and agencies in sharing intelligence.

2.2 In many organisations much of this role is undertaken by prescribing advisers (PA) on behalf of the AO. In acute trusts the Chief Pharmacist often takes the role equivalent to the PA. The regulations state that the AO should not be involved in the prescribing or dispensing of CDs. PCTs are required to take the lead in their area and have a statutory duty to run a Local Intelligence Network (LIN) to whom all trusts report incidents.

2.3 Memoranda of agreement around information sharing should exist between all organisations involved and there should be clear links with local police and with the Care Quality Commission.

3. IDENTIFYING THE PROBLEM

3.1 The PA should have the knowledge, skills and resources to initiate investigations about CD prescribing within the PCT. The PA should be the recipient of concerns about CD prescribing including:

- **Cost of CD prescribing** on an individual prescription or set against a comparator group;
- **Quantity of CDs prescribed** apparently excessive amounts on an individual prescription;
- **Volume of CDs prescribed** set against a comparator group of practitioners, practices or PCTs;

3.2 This information may be received from a variety of sources including:

- **The pharmacist dispensing the prescription** e.g. concern raised by an individual prescription or by a pattern of prescribing originating from an individual general practitioner or practice;
- **The doctor's partners or nursing colleagues** e.g. concerns about a practitioner prescribing outside of local guidelines or reporting concerns about the practitioner himself;
- **Local drugs misuse services** e.g. concerns about a practitioner prescribing outside of local guidelines or not cooperating with shared care guidelines;
- **Another general practice** concerns about the prescribing at a patient's previous practice;
- **The Prescription Pricing Division of NHS Business Services (PPD)** e.g. if the cost and volume of prescribing triggers preset alarm systems;
- **Local audits and monitoring** e.g. preset ePact audits of CDs; the template audit tool on the NPC web-site or locally developed systems;
- **The patient or someone acting on their behalf;**
- **Excessive stock ordering by a practice or practitioner;**
- **Local police information** e.g. an increase in street availability;
- **Other sources from within the PCT prescribing team** e.g. practice pharmacists or locums

4. INFORMING OTHERS

4.1 PAs should not act alone or in isolation, but on behalf of the AO, the PCT and its local group charged with handling concerns about performance of general practitioners. The detailed nature of the structures and membership of groups for handling concerns about general practitioner performance will have been determined locally. However, all systems for handling concerns about general practitioners should

- Protect the safety and well being of patients and the public;
- Provide a fair and effective process for doctors.

4.2 The local performance Decision Making Group (DMG) will collate information about the general practitioner and the concerns raised from a variety of sources:

- Reactive – complaints, incident reporting, whistle blowing, clinical governance;
- Proactive – prescribing and other indicators, routine data, reports.

4.3 At an early stage the DMG will need to consider if there are any immediate concerns for patient safety that may require the PCT to act quickly to stop the general practitioner continuing to prescribe CDs. If this is a possibility then the PCT is advised to contact the National Clinical Assessment Service (NCAS) as this could mean suspension from the performers list, or a contract action to limit the treatment of drug users.

4.4 If fraud is being considered the PCT will need to seek advice from the local counter fraud management service (CFMS) about the possible need to secure information and protect evidence. Occasionally the national fraud team from the PPD is involved.

4.5 Information about concerns will also have to be shared within the LIN. The police are part of LINs and will therefore, be involved in making a decision as to whether or not a criminal act is likely and will need investigating according to their procedures, in order to preserve evidence.

4.6 Once a concern has been raised then it is usual for the DMG to ask the PA to undertake further investigation looking either at individual prescriptions and/or prescribing patterns compared to national, local or regional norms.

5. INVESTIGATING CONCERNS - Reviewing the appropriateness of individual prescriptions (this guidance applies to both NHS and private scripts)

5.1 If the dispensing pharmacy is known it may be possible to retrieve the prescriptions that gave rise to the cause for concern. In continuing their investigation PAs may need to review:

- **The prescription –** consider the complete pathway from the preparation and signature of the prescription through to the dispenser and the recipient of the drugs;

- **The prescriber –** does the local performance decision making group have any other concerns about the individual doctor or practice?

- **The quantity-** prescriptions for CDs are now only valid for 28 days and all prescribers are strongly advised to restrict prescriptions to amounts no more than is sufficient to meet the patient's clinical need for up to 30 days.

  At present clinicians can prescribe any amount of CD on a single prescription though the National Drug Misuse Clinical Guidelines recommend that no more than two weeks be issued on a single prescription. Prescribing large amounts on a single prescription may place the patient at risk of over using the medication and of the medication being diverted. However, there may be a number of valid reasons why large amounts may be prescribed such as:

  - The patient needs high dose treatment e.g. via a syringe driver;
  - The patient going on holiday and requiring unusually large amounts;
  - The patient has a very high tolerance to opiates and hence requires large doses;
  - If the patient is travelling home to die.

- **The drug -** Often it is the choice of drug which will draw attention to the clinician. There are a number of controlled drugs that when used in primary care may be an indication that the clinician is moving away from established clinical practice and that his/her prescribing needs further investigation. The following is not a comprehensive list and the PA and AO should be alert to any unusual CD or formulation. The following is a summary of CDs prescribed in primary care categorised into good and potentially poor practice.

Summary of use/ potential misuse of controlled drugs	***Examples of drugs***
Drugs that are used by primary care practitioners as part of generalist work	Morphine Diamorphine 30mg or less used for the treatment of acute or severe pain. Oxycodone Pethidine
Drugs that are used by generalist practitioners under shared care arrangements	Methadone Mixture 1mg/ml Buprenorphine- in the form of high dose Subutex (*this is not the same as temgesic) shared care only*
Drugs that should only be used after initiation or consultation with a specialist practitioner and in the context of on-going shared care	Methadone tablets 5mg Methylphenidate Diamorphine 30mg, 100mg, 500mg
Drugs that should rarely be prescribed in primary care	Dipipanone Diamorphine reefers

Summary of use/ potential misuse of controlled drugs	*Examples of drugs*
	Dexedrine for purpose of addiction Dextromoramide for the treatment of addiction Methamphetamine Any Barbiturate for the treatment of addiction Methadone Concentrate (10mg, 20mg, 50mg/ml) for the purpose of addiction Methadone ampoules
Drugs that have a limited place in primary care	All barbiturates

- **The patient and his/her condition -** It may be necessary to reconcile the indications for the prescription with the patient and their medical record. This will require the PCT to gain access to the patient's medical record and the patient should be asked for consent to do this. If consent is refused or there are reasons why it cannot be given then the PCT may choose to gain access but only after careful consideration and with the advice and guidance of the information governance lead. It may be that public interest justifies disclosure without consent. Where consent has not been obtained patients should be informed that disclosure has taken place.

6. INVESTIGATING CONCERNS – Reviewing comparative prescribing patterns

6.1 Concerns may be raised by apparently excessive cost or volume prescribing, compared with a comparator group of practices or individual doctors, obtained from PACT data. PAs will be aware that variation in prescribing rates is seen in all therapeutic areas. It is always necessary to understand the local causes of variation before drawing inferences about a clinician's practice compared to national or PCT norms.

6.2 While a detailed description of the use of comparative PACT data is beyond the scope of this paper, comparisons between practices or individual doctors highlight variations that are the consequence of differences between:

- **Practice populations-** Is the practice or doctor prescribing for a population that is broadly similar to the comparison population? Have ethnographic issues been considered e.g. large numbers of single homeless or sickle cell patients?

- **Doctors' behaviour, skills and knowledge-** e.g. is the general practitioner a GPSWI in drug misuse, palliative care, child and adolescent mental health? A GP for a hospice, homeless hostel or care home or a lead for an addiction service?

7. REVIEWING THE SITUATION

7.1 Following further investigation the PA will report to the AO, who will decide if the results of the investigation merit referral to the DMG. Except in the case of

suspected fraud or criminality the practitioner should be informed that concerns have been raised and investigated.

8. ACTING ON THE OUTCOME OF THE INVESTIGATION

Possible outcomes are:

- **Concerns are not substantiated** and the practitioner's prescribing of CDs is appropriate. This is the outcome in the majority of investigations. An explanation of why there has been an investigation and the reasons why the practitioner's prescribing was initially a cause for concern should be made to the practitioner. If there are exceptional circumstances identified then the PCT may wish to give help and support to the practitioner.

- **Practitioner's prescribing is irresponsible and inappropriate.** Physical and mental ill health should be considered routinely as a possible cause of poor performance. The local performance management or decision making group may wish to consult NCAS or may, if circumstances are sufficiently serious call into question the practitioner's registration with the GMC.

- **There is evidence of fraud or other criminal activity.** The local counter fraud office or the police service should be informed. The need for further investigation of either of these may lead the PCT to consider suspension.

Following every investigation and particularly where there is an unfavourable outcome the PCT will need to consider how the situation arose and what can be done to prevent a recurrence.

10. REFERENCES

Statutory Instrument 2006 N0 3148 The Controlled Drugs (Supervision of management and use) Regulations 2006

Safer management of Controlled Drugs private CD prescriptions and other changes to the prescribing and dispensing of controlled drugs. Guidance for Implementation Gateway Ref 6820

Changes to the requirements for requisitions for the supply of Schedule 1,2 and 3 Controlled Drugs. Guidance (E) Gateway Ref 8713

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