

Guidance on the use of Monitored Dosage Systems (MDS)

1. Introduction

MDS is a medication storage device designed to simplify the administration of solid oral dose medication. MDS can potentially address the issues of difficulty accessing medication and following the regimen due to sight impairment and/or confusion / forgetfulness. However, the evidence to support these benefits is limited¹. There is no evidence based research to suggest that MDS improve patient concordance.

Not all medication formulations can be dispensed into MDS. These include hygroscopic or deliquescent products such as dispersible or soluble tablets, drugs which cause skin reactions such as chlorpromazine, drugs with cytotoxic potential, drugs which require refrigeration and many individual drugs which have found to be unstable such as sodium valproate, enteric coated tablets and certain formulations of omeprazole or clopidogrel. Many drug manufacturers will not advise on the stability or otherwise of their product in MDS and point out that this is an **unlicensed use**. Also, obviously oral liquids, eye-, ear- and nasal-drops, external formulations, suppositories and powders cannot be put into MDS. "PRN" medication is, by definition, not taken regularly and is therefore unsuitable for inclusion in MDS as that would lead to waste. Consequently, the MDS does not provide a complete solution for a patient's medication problem.

MDSs differ physically and offer differing stability conditions for their contents. They may be heat-sealed or cold-sealed or closed only by a piece of sliding plastic. Patients can be confused by the arrangement of the medicine compartments into times of the day and days of the week. It has been known for a patient to consume four "morning" doses in one day as s/he misread days of the week for the times of day.

MDS units can be physically difficult to manipulate. Puncturing the thin plastic seal over the medicine compartments can present a challenge. The MDS can often be rendered unusable by the efforts of the patient to gain access to their medication, or the contents are spilled.

Labelling the container in a manner that is clear, accurate and legal may require more time than for standard medicines containers, particularly when an up-to-date description of the medicine is required.

Urgent changes to medication which is already dispensed in the MDS necessitate re-dispensing of the MDS, which is time-consuming, costly and potentially confusing.

There are some reports that MDS are the best solution for around 50% of people referred for such a service. It is therefore very important to fully assess the need for an MDS which in turn provides an ideal opportunity to review treatment, reduce the number of medicines and the frequency of doses prescribed.

This guidance aims to clarify the roles and responsibilities of health and social care providers regarding the provision of MDS.

2. Over-arching principles

When considering the potential need for MDS, the following principles should be taken into account –

- MDS may improve compliance with medication but the evidence for this is limited
- Alternative options to improve compliance should also be considered – see below under “Community Pharmacists”
- The only national funding for MDS is provided within the community pharmacy contract for patients that comply under a Disability Discrimination Act (DDA) assessment undertaken by the pharmacist. All other patients and/or carers will need to pay for the service
- MDS, if appropriate and supplied under the Disability Discrimination Act (DDA), is intended for the benefit of the patient, not the carer. It is therefore not reasonable for carers, either formal or informal, to expect MDS to be provided outside of DDA guidelines unless they wish to pay for the service
- 7-day prescriptions should not be used for the purpose of supporting MDS supply if issuing scripts in this way is purely to generate extra fees and is without clinical need
- Seven day prescriptions should be reserved for those who require flexibility in dosing schedule and medication is likely to change frequently or where there is a risk to the patient or others if too much medication is stored at home

3. Responsibilities of health and social care professionals

The Royal Pharmaceutical Society has published the first national guidance for pharmacists, health and social care professionals on the best use of MCAS in July 2013.

3.1. General practitioners

The CCGs are receiving a growing number of queries regarding the supply of seven day prescriptions for patients in whom a MDS is being used. Pharmacists should not be requesting 7 day prescriptions for this purpose and GPs are under no obligation to supply them.

Much of this pressure to provide MDS (and hence 7 day prescriptions) has come from social care providers who request MDS for their clients who require supervision/ prompting of medication. Discussions with these care providers have revealed that it is a need for clear information about medicines, particularly at discharge from hospital, which often drives the requests for MDS. What is actually needed in many cases (rather than an MDS) is better information, including the provision of Medicines Administration Record (MAR) sheets. The care providers are often working in difficult circumstances and this information about medicines is paramount. The acute trusts have undertaken to improve the information flow for these care workers.

Community pharmacists have been put in a difficult position; trying to manage this increased demand for MDS, when there is no funding for the provision of MDS. When an MDS is requested for a patient not qualifying under the DDA to support care providers to administer medication, the patient or social care provider should usually pay for this provision. However, each case should be viewed according to its

individual circumstances and the social care provider should seek to liaise with the patient/patient representatives and health colleagues in order to reach the best solution in each case.

The CCGs do not encourage the provision of -day prescriptions solely for the purpose of supporting MDS supply;

- If issuing scripts in this way is purely to generate extra fees
- Without clinical need

It is entirely the pharmacist's decision to supply (or not) a MDS under the DDA legislation, which will then be free of charge to the patient. There is no need for the supply of 7-day prescriptions to "support" this service. A 28 day prescription should be issued for all patients with stable medication and four trays of seven days of medication will be supplied.

Seven day prescriptions should be reserved for;

- Patients who require flexibility in dosing schedule and medication is likely to change frequently
- When there is a risk to the patient or others if too much medication is stored at home

If a prescription is issued for 28 days in a MDS and the treatment is subsequently changed, then a new prescription is needed.

Seven day prescriptions should not be supplied to support the use of MDS in nursing or residential homes. Administration of medicines in these settings remains the responsibility of the care home.

3.2. Community Pharmacists

As acknowledged above, community pharmacists have been in a difficult position; trying to support patients or their carers with MDS provisions outside of the DDA, yet being understandably reluctant to request payment in many cases.

However, it is not appropriate to request 7 day prescriptions to fund this service. The prescription item fee is funded from the Global Sum which has been devolved to PCTs from April 2010. The level of 7-day scripts now being issued is putting pressure on this budget which is not sustainable and needs to be addressed before it becomes unmanageable. The Global Sum was never intended to fund MDS.

The New Pharmacy Contract initially included a proposed Essential Service (Essential Service 7) titled 'Support for People with Disabilities'. This Service was not transposed into the New Contract Regulations, however, pharmacy contractors have an existing and ongoing responsibility under the Disability Discrimination Act 1995 to make reasonable adjustments to their services and provide auxiliary aids where appropriate for people with disabilities.

The funding which was negotiated as part of the new contract monies for Essential Service 7 is distributed through an addition to the Practice Payment.

Community pharmacists thus have a contractual obligation to make an assessment of a patient's needs under the DDA and to provide reasonable adjustments to the service provided to those who, in the professional opinion of the pharmacist, require

such an adjustment. The adjustment provided does not necessarily need to be a MDS; it may be a compliance chart, non child proof lids, larger print labels.

Community pharmacists are not obliged to provide a compliance aid or make adjustments to their service for patients who do not qualify for an adjustment within the DDA. For those patients in whom the patient or carer (formal or informal) would prefer a compliance aid, they would be expected to pay for the service.

For existing patients who are currently receiving 7 day prescriptions to cover the costs of an MDS outside of the DDA legislation, a formal review of their requirements is recommended.

3.3. The Acute Trust Pharmacy Departments

It is recognised that the acute trusts need to discharge patients with their medicines supplied in a form in which they can use them. However, they are also under pressure due to the number of patients with an MDS which is for the benefit of the carer rather than the patient i.e. provided outside of the DDA requirements. In addition, due to the number of different types of MDS available, it is not reasonable or practical to expect the acute trusts to make all of these available. Supplying a patient with an MDS with which they are not familiar is likely to cause more problems than it would solve.

The following arrangements have therefore been agreed within the Service Level Agreement between Northampton and Kettering General Hospitals and the PCT for 2010-11.

- **Patients admitted using a MDS;** if this is required on discharge, NGH / KGH will liaise with the GP and usual community pharmacist in time for supplies to be ready for the patient's discharge. If there is a risk of the patient's discharge being delayed due to these arrangements not being in place, then NGH / KGH will supply the patient with medicines in conventional containers and provide a Medicines Administration Record (MAR) sheet(s) and a copy of the discharge prescription.
- **Patients identified, by NGH / KGH, as requiring any form of MDS by virtue of the DDA legislation:** NGH / KGH will inform the GP and usual community pharmacist of this assessment in time for arrangements to be ready for the patient's discharge. If there is a risk of the patient's discharge being delayed due to these arrangements not being in place, then NGH / KGH will supply the patient with medicines in conventional containers and provide a Medicines Administration Record (MAR) sheet(s) and a copy of the discharge prescription. It would be appropriate for the community pharmacist to undertake a DDA assessment at some point post-discharge to ascertain whether the MDS is still required, as patients circumstances may change.
- **Exceptions:** If a patient is:
 - > being discharged home, and
 - > they are using, or require a MDS, and
 - > there is no domiciliary care in place, and
 - > there is a risk of their discharge being delayed because arrangements have not been made for the GP/community pharmacist to provide the MDS in time for their discharge, then NGH / KGH will supply the patient with two

weeks supply of medicines in a disposable MDS and provide a Medicines Reminder Chart and a copy of the discharge prescription.

3.4. Social Care Providers

Social care clients represent a very vulnerable section of our community. Their vulnerability is heightened at times of disruption such as being admitted to or discharged from hospitals. There is a need for health organisations to improve information flow and to share information where medicines are involved. The primary focus should be on how hospital services link with other forms of support and care.

Care workers are trained in the administration of medicines but they must be given accurate and timely information in order to operate in compliance with CQC guidelines and legislation.

Care workers must not expect MDS to be provided for a client unless s/he has been specifically assessed as requiring MDS by a pharmacist to assist self-administration under the DDA.

If an MDS is requested for the benefit of the social care provider then the patient or social care provider should expect to pay for this service.

However, the following practical measures must be taken by medical professionals involved in the discharge from hospital of vulnerable adults in receipt of social care services:

- MDS systems must be deployed where possible at the point of discharge where the patient agrees to this, is going to self administer their medicines and qualifies under the DDA. This will usually be via the patient's community pharmacy as per the acute trust agreements above.
- MDS systems must be deployed where possible at the point of discharge where in use prior to hospital admission unless this runs against the interests and wishes of the patient. This will be via the patient's community pharmacy as per the acute trust agreements above. However, the need for this (if not under the DDA) and associated funding may need to be reviewed.
- Medicines Administration Record (MAR) sheet(s) must accompany the patient from the hospital setting whether or not an MDS system is being deployed. This will allow the social care worker to understand which medicines have been prescribed and those medicines already administered on the day of discharge. A sample MAR sheet can be found at appendix 1.
- There must be clear and unambiguous labelling of medicines.

Compliance with these measures will fulfil professional safeguarding obligations for these patients as they return to the community from hospital settings.

Administration by staff – guidance for the service provider

- Medicines that are prescribed for patients should be administered by using either i) MDS or ii) ordinary medicine containers. Medicines prescribed for one person must **not** be used for any other person.

- Whichever system is used, staff involved in the administration of medicines must be familiar with the system.
- Under no circumstances must social care staff fill compliance aids for self-administering patients.

Times of Administration of Doses - guidance for the service provider

- Reference should be made to the dosage instructions on the label of a medicine and possibly to the patient information leaflet when deciding the time(s) of doses. If there is any doubt, the social care provider must contact the pharmacist for advice. Particular attention must be given to a dose stated as ONCE daily, to ensure that it is given at the optimum time.
- Doses should indicate clearly how the medicine should be given. A dose such as 'take three daily' is unacceptable as it could mean 'take three at once' or 'take one three times daily', such a dose must be clarified with the pharmacist before any medicine is given. Where an MDS system is deployed the pharmacist will have placed the medicines into the appropriate dose times. If the medicine should be given before or after food then this will have been specifically stated on the label.
- Where medicine is directed to be taken 'when required', clarification **must** be sought from the GP or pharmacist **before** it is needed. Ideally the details should be printed on the medicine label but where space does not allow this, precise details should be entered on the patient's care plan and a reference to this be made on the MAR at the appropriate place.

4. Conclusions

It is clear that the current trend to use the fees from 7 day prescriptions to fund MDS is inappropriate and unsustainable. By following both the over-arching principles and the guidance for each health and social care area, as above, it is hoped that more appropriate arrangements will be put in place for those patients who may benefit from the use of MDS.

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Sue Smith
Head of Prescribing and Medicines Management, NHS Nene and Corby CCGs

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ⁱ Bhattacharya D : Indications for Multi compartment compliance aids (MCA) – also known as Monitored Dosage Systems (MDS) – provision January 2005