ROYAL PHARMACEUTICAL SOCIETY

Improving patient outcomes

The better use of multi-compartment compliance aids

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UKMi UK Medicines Information

United Kingdom Clinical Pharmacy Association

Faculty of Pharmaceutical Medicine 1989

Acknowledgements

This document has been prepared by the Royal Pharmaceutical Society (RPS). We understand that health and social care is constantly developing, so intend to periodically review this resource. Comments from healthcare professionals and stakeholders are welcome and can be sent to support@rpharms.com

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Faculty of Pharmaceutical Medicine
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National Clinical Trials Group
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Numark
Pharmacists Law and Ethics Association
Pharmaceutical Advisors Group
Pharmaceutical Committee
Pharmacy Voice
Primary and Community Care Pharmacy Network
Primary Care Group of the Scottish Directors of Pharmacy
Primary Care Pharmacists Association
RPS National Pharmacy Boards
RPS Pharmaceutical Science Expert Advisory Panel
Scottish Directors of Pharmacy Group
The Medicines and Healthcare products Regulatory Agency
The Pharmaceutical Services Negotiating Committee
United Kingdom Medicines Information Executive
UK Ophthalmic Pharmacy Group
W and W Medsystems

Foreword

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists and pharmacy. Our Royal Charter contains four objectives one of which is to promote and protect the health and well being of the public through the professional leadership and development of the pharmacy profession and another is to maintain and develop the science and practice of pharmacy in its contribution to the health and well being of the public. It is an imperative that we lead and promote the advancement of science, practice and education in pharmacy in order to shape and influence the future delivery of pharmacy driven services.

As the proportion of older people continues to grow in Scotland, England and Wales it is anticipated that social factors will continue to drive health and social care requirements. The need for medicines and the demand for quality pharmaceutical care supporting people to best use their medicines will continue to grow.

A review into general care for older people in Scotland[1] has identified that the existing approach must be improved so that care is patient-centred and outcome-focussed, designed to support patient capability, independence and re-ablement as opposed to care which is designed around dependence, incapacity or on the assumption that it will always be required. In England, the concept of medicines optimisation[2] has similar drivers and is underpinned by four key principles: i) understanding the patient experience; ii) evidence-based choice of medicines; iii) ensuring that medicines use is as safe as possible; and iv) making medicines optimisation part of routine practice.

Leadership together with appropriate incentives are required to promote change in the existing infrastructure, so that better and sustainable services can be designed around patients and delivered successfully to support healthy independent living and the safe and effective use of medicines. Services must ensure that polypharmacy is appropriate, fully involve patients in decisions about their health and social care needs, and aim to achieve both adherence to treatment and concordance between healthcare professionals and patients.

The RPS believes that supporting the best use of medicines will involve identifying problems with medicines-use, medication review and consideration of patient characteristics to find the best solution. A multi-compartment compliance aid is one tool amongst many to help with medicines use but other interventions also exist, which as part of a patient-centred and quality approach must also be considered. The overarching goal of this report is to improve patient outcomes in medicines use through a better understanding of patient needs and expectations and which is informed by the evidence-base currently available.

Mair Davies
Welsh Pharmacy Board Chair
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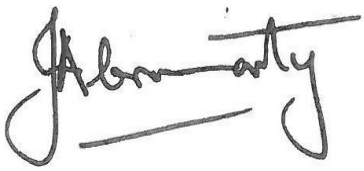

John Cromarty
Scottish Pharmacy Board Chair
Royal Pharmaceutical Society

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Executive Summary

The use of multi-compartment compliance aids (MCA)* has become regarded as a panacea for medicines use and is often integrated into practice and service policy without giving due consideration to the alternatives available.

This report aims to help continue the journey to improving patient outcomes with the better use of medicines, through the provision of knowledge and information to pharmacists, healthcare professionals and other stakeholders involved in health and social care. There needs to be a better understanding of the selection of an MCA as one adherence intervention amongst many, the evidence-base with the use of MCA, the practice considerations and the benefits and risks.

Although MCA may be of value to help some patients with problems managing their medicines and maintaining independent healthy living, they are not the best intervention for all patients and many alternative interventions are available. The evidence-base indicates that MCA should not automatically be the intervention of choice for all patients.

Not all medicines are suitable for inclusion in MCA. Furthermore, all stakeholders should recognise that the re-packaging of medication from the manufacturer's original packaging may often be unlicensed and involves risks and responsibility for the decisions made.

With the limited evidence base currently indicating a lack of patient benefit outcomes with the use of MCA, it is a recommendation of the RPS that the use of original packs of medicines, supported by appropriate pharmaceutical care, should be the preferred intervention for the supply of medicines in the absence of a specific need for an MCA in all settings. This is in line with the findings of the RPS working group looking at pharmaceutical care in care home settings in Scotland, in their report *Improving Pharmaceutical Care in Care Homes*.[3]

A patient-centred approach to identifying the best intervention must be through a sustainable and robust individual assessment of both the level of care required by the individual, the reasons for both intentional and non-intentional non-adherence and the most suitable solution.

The RPS recognises that patient-facing pharmacists cannot fully implement the recommendations within this document on their own and that an integrated approach between health and social care, between commissioners and service providers, and amongst pharmacy bodies is required on the continuing journey to improve patient outcomes.

*This document defines a multi-compartment compliance aid as a repackaging system for solid dosage form medicines, such as tablets and capsules, where the medicines are removed from manufacturer's original packaging and repackaged into the MCA. For the purposes of this document, this definition of an MCA would include repackaging systems such as monitored dosage systems (MDS) and daily dose reminders. Some new MCA systems are now marketed as being able to accommodate liquid dosage forms. MCA exist as both sealed or unsealed systems, and cassette (where several medicines can be in one compartment) or blister (where there is only one dose of a medication in each compartment) systems.

1 Our recommendations

There are many ways in which patients can be helped to take their medicines safely, or carers supported to administer medicines correctly, and a broad range of alternative interventions (of which MCA are one type) are discussed within this report.

The choice of an MCA must be considered within the range of alternative intervention options, and must not be regarded as the only solution. Health and social care professionals must collaborate to ensure that:

1. The use of original packs of medicines with appropriate support is the preferred option of supplying medicines to patients in the absence of a specific need requiring an MCA as an adherence intervention.
2. In support of independence and re-ablement, patients who can safely self-administer their medicines should be encouraged to do so and where they are unable to do so, there must be appropriate training for carers so that they are able to administer medicines from original packaging.
3. Every patient identified as having medicines adherence issues should have a robust individual assessment to identify the best intervention based on their needs and the evidence currently available. This assessment should incorporate a clinical medication review, any reasons for nonadherence, medicines suitability, a consideration of all possible options to support the patient and follow up. Supporting guidance for an individual patient assessment is available in appendix 1. Support for medicines stability assessment is available in appendix 2.
4. The development of an evaluated national, multi-disciplinary assessment tool designed to identify, assess and resolve medicines issues is needed. Nationally developed tools and documentation should be suitable for use in all health and social care sectors and integrated to the appropriate health and social planning process.
5. Where a patient assessment indicates an MCA is the intervention of choice, it is important that this is supported with the provision of information, appropriate counselling and follow up for the patient and that the health or social care professional is aware of the legal, professional and practice considerations. Practice considerations for the use of MCA are given in appendix 3.
6. Robust person-centred policies supporting practice are in place to ensure that people receive their medicines at the right time, irrespective of whether or not they are packaged in an MCA.
7. Existing and future pharmaceutical care services which support patient-centred healthcare and the best use of medicines should be maintained and developed (e.g. targeted medicines use reviews (MUR), new medication service (NMS), chronic medication service (CMS) and locally commissioned services).
8. Further evidence of the effect of the use of MCA on patient outcomes and safety is needed to determine the place of MCA as an intervention option to support self care, re-ablement and medicines administration when evaluated against alternative interventions.

2 Rationale supporting recommendations

2.1 Adherence and patient outcomes

In general there is insufficient evidence to support the benefits of MCA in improving medicines adherence in patients, or in improving patient outcomes and the available evidence does not support recommendations for the use of MCA as a panacea in health or social care policy. However, the evidence does indicate that MCA may be of value for some patients who have been assessed as having practical problems in managing their medicines. Each patient's needs must be assessed on an individual basis and any intervention must be tailored to the patient's specific requirements.

"They (MCA) are of great value for a limited period of time where a person is trying to maintain independent living and has no other support systems that assist them to take medicines and alternative systems have failed."

Hospital Chief Pharmacist

"Having her regular medication in an MDS enables her to take this reliably and remain independent".

Clinical Pharmacy Manager regarding an 83 year old woman who lives independently on multiple regular medication and is attending a hospital as a day patient for treatment of cancer

In England, a NICE Clinical Guideline[4] includes best practice advice on how to involve patients in decisions about prescribed medicines and how to support adherence. Interventions that have been investigated to determine whether they improve patient adherence include suggesting the patient records their medicine taking, encouraging patients to monitor their condition, simplifying the dosage regimen, using alternative packaging for the medicine and using an MCA system. However, because of the lack of evidence that these interventions increase adherence, NICE recommend that any interventions should only be used to overcome practical problems associated with non-adherence if a specific need is identified. NICE also note that no specific intervention could be recommended for all patients.

In a report on medicines adherence, Nunes et al[5] reported on the widespread use of re-usable MCA that are refilled regularly by pharmacists and patients. The authors noted that many individuals develop their own strategies to assist them with their medicine taking and that the evidence showing that MCA improve adherence was not strong enough to make recommendations for widespread use. However, MCA may be of value for patients who have been assessed as having specific issues in managing their medicines.

A Cochrane Review published in 2011,[6] assessed the effects of reminder packaging such as monitored dosage systems, calendar blisters, dose administration aids with sliding lids, or unit dose packaging, on patient adherence. The authors noted that there was a paucity of high quality trials in this subject area and that further trials were warranted. From the trials that met the Cochrane Review criteria, it was suggested that reminder packaging improved adherence when assessed using tablet counts (the percentage of tablets taken out of the total prescribed), although the effect on adherence was not large. No statistically significant difference was noted when adherence was measured as the proportion of people self-reporting adequate adherence. There was some evidence to suggest that reminder packaging may improve clinical outcomes such as

blood pressure in hypertensive patients and that appropriately designed reminder packaging may be preferred by individuals with low literacy levels. Until results from further trials become available, the use of reminder packaging may be justified in certain patients according to needs and preferences.

The Care Home Use of Medicines Study (CHUMS) report published in 2009[7]concluded that, with regard to monitored dosage systems (MDS), it is not yet proven that MDS can be considered safer than other forms of medicines administration. The report assessment suggested that MDS may be associated with a higher level of dispensing errors than medicines which cannot be packaged within an MDS; that they contributed to administration errors; that there could be labelling problems due to lack of space; that there were medicine identification problems compounded by differences in appearance between generic medicines; and that identification problems with white tablets were found to contribute to errors. The report also highlighted that within the care homes using MDS that were part of the study, 40% of doses for residents could not be handled using MDS and recommended that research should be carried out into the use of MDS in general and the ways in which medicines could be administered more safely and accurately in the care home setting. The situation is similar for people receiving support from formal or informal carers in their own home.

Alldred et al[8] found that in care providers where MDS are used, medication administration errors occurred more frequently with medicines that cannot be packaged in MDS such as, inhalers, liquid medicines and eye drops, than with tablets and capsules packed in MDS. Whilst this suggests that administering medicines in MDS is associated with fewer administration errors, the authors warn that the results should be interpreted cautiously as the study was not designed to assess the impact of MDS. In addition, the authors highlighted that there was a clear need for medication administration training for care home staff to administer medicines that cannot be packaged into MDS such as liquids and inhalers.

It is important to remember that the provision of an MCA in itself may not fully ensure adherence, whether the person is self-administering or receiving support from formal or informal carers.

In Scotland, the Scottish Commission for the Regulation of Care (now the Care Inspectorate) reported that MCA have been marketed as time saving repackaging systems that simplify the medicines administration process. However, they noted that MCA are a form of packaging for a limited group of medicines and safe practice is not guaranteed by the use of any MCA alone.[9]

Athwal et al[10] described five types of patient groups* with differing levels of physical and cognitive impairment and care support. It was found that of the five groups, defined only two had characteristics (patients with physical impairment but no formal or informal carers, or patients with cognitive impairment and formal or informal carers) that meant the supply of an MCA should be further considered.

Whilst there are anecdotal reports of MCA helping patients, an evidence base does not exist to support the choice of MCA as the only way to support medicines use or to improve patient outcomes.[1]

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*The five patients groups were: Group A – physically and cognitively able, Group B – physical impairment and has formal/informal carers, Group C – physical impairment but no formal/informal carers, Group D – cognitive impairment but has formal/informal carers, Group E - cognitive impairment but no formal/informal carers. Athwal et al[9] found that only groups C and D should be further considered for the supply of an MCA.

2.2 Stability of medicines stored outside of their original packaging

There are insufficient data in the published literature and no up-to-date authoritative resource that provides data on the stability of medicines when stored outside of the manufacturer's original packaging. Conversely there are illustrative examples of degradation of medicines when stored outside of their original packaging.

To obtain a marketing authorisation for a medicine, data must be submitted to the licensing authority that demonstrates the medicine in its packaging remains within its product specification throughout its entire shelf life. The removal of a medicine from the manufacturer's original packaging and its repackaging into an MCA will often be an unlicensed use of the product which will impact upon the stability of the medicine and increase the level of responsibility for decisions made, risks and liabilities.

In addition to the stability of the active drug substance, other formulation components or different manufacturing processes may also have an important role to play in the overall stability of the medicine. Thus, it cannot be assumed that products containing the same active ingredient but from different manufacturers will behave in the same way. To illustrate this point, generic omeprazole is reported to be hygroscopic and unsuitable for inclusion in a compliance aid, while Losec capsules, a proprietary form of omeprazole, are stable for 14 days at room temperature and up to 75% relative humidity.[11]

While there are few published studies that present stability data to support the inclusion of medicines in MCA, there are reports of how inappropriate storage of medicines can affect their properties.

In 1990, the FDA reported that carbamazepine tablets can lose one third of their effectiveness if exposed to moisture due to tablet hardening, poor dissolution and poor absorption in the body.[12] It was suggested that this tablet hardening may explain the variability in the ability of carbamazepine to prevent seizures in some patients.[13,14]

There has been some published information, generally gathered from medicines manufacturers, about the suitability of their products for repackaging in MCA and it is recognised that there are some products that must not be placed in MCA because of stability issues unless there are exceptional circumstances upon patient assessment requiring a professional judgment call. Since the 1990s there have been several papers published in the Pharmaceutical Journal that present information collated from some product manufacturers to indicate whether or not products are suitable for removal from their original packaging; the most recent article appeared in the Pharmaceutical Journal in 2006.[11]

Medicines Information at Pinderfields General Hospital gathered and for a time, regularly updated information from manufacturers on the stability and suitability of medicines in compliance aids and collated this into a reference resource entitled *Stability of Drugs in Compliance Aids*. Although a useful guide, this information was limited in content and the information was only applicable to medicines of a specific marketing authorisation. However, since 2006, Pinderfields has stopped updating their guidance document and now recommend that individual product manufacturers are contacted for advice on the stability and suitability of their medicines in compliance aids. It is recognised that this may not be practical within a working environment in a pharmacy. Additionally manufacturers of medicines are not required to test the stability of their products repackaged within MCA and they may not be able to supply the information required. The manufacturer of the MCA would be best placed to provide evidence that their product is safe and fit for purpose; this would include stability data for medicines intended for repackaging within their MCA.

Data for the stability of medicines outside of their original packaging

The UK Medicines Information (UKMi) executive is developing an open access, web accessible, searchable database to provide information and guidance about the stability of solid dosage forms of medicines stored outside of their original packaging. This database is expected to be ready in 2013 and will include medicines listed within the British National Formulary. See the UKMi website for details http://www.ukmi.nhs.uk/default.asp

2.3 Barrier properties

Unsealed MCA provide no significant barrier to water vapour or atmospheric gases such as oxygen. There is insufficient available evidence demonstrating the effectiveness of the barrier properties of sealed MCA.

Pharmaceutical companies invest substantial resources into the development of packaging technology, to protect against counterfeiting and to assure the quality and integrity of the finished medicinal product. In order to attain a marketing authorisation the company must ensure the packaging used for their medicines provides the correct level of protection to water vapour, atmospheric gases and light.

The level of protection that MCA provide against moisture, gases and light is not well documented and it cannot be assumed that they will provide a suitable level of protection for any medicine.

Systems based on a series of compartments with sliding lids (unsealed MCA) will provide no significant barrier to water vapour and atmospheric gases, with any light protection generally provided by an external cover.

For those MCA based on 'sealed' blister type packaging (sealed MCA), the barrier to water vapour and atmospheric gases is likely to be better than for unsealed MCA, but again, light protection generally requires some form of secondary cover. Data published by the MCA manufacturers that describe the barrier properties of their repackaging systems, or of published stability data for specific medicines when packaged or stored in their MCA, are not generally available.

A study published in 1994[15] investigated the moisture vapour permeability of several blister type MDS using a test method described in the United States Pharmacopeia (USP). Results showed that there was great variability in the moisture vapour permeability of the MDS packaging tested, with none of the packages tested meeting the most stringent moisture vapour permeability requirements defined by the USP. Indeed, only half of the MDS packaging tested passed the USP minimum requirements for this type of blister packaging for medicines.

2.4 Potential interactions between medicines repackaged within multi-compartment compliance aids

Where multiple medicines are repackaged within a single MCA compartment, this can lead to the medicines interacting (see appendix 2).

A recent study investigated the effects of adding atenolol tablets and aspirin tablets to the same compartment of an MCA. Although the chemical stability of atenolol in the atenolol tablets was not affected, the hardness, and disintegration time of the tablets could change depending on the brand of the atenolol tablet, the type of MCA used and the storage conditions. Changes in the hardness of the aspirin tablets were also reported. In addition, when the two drugs were stored at elevated temperature and humidity conditions, the appearance of non-coated aspirin tablets could change which may impact on the patient's perception of the quality of the medicine.[16]

The risk of medicines interacting within a single MCA compartment is an important factor that should be considered when making a professional decision on the choice of MCA type to use, together with all other factors (see appendix 2). However, there is currently no evidence to indicate the clinical significance of any such interactions.

2.5 Risks of concurrent use of multi compartment compliance aids and other systems of medicines administration

If other systems of medicines administration are required in addition to MCA (for example where the formulation or dosage of medicines are not suitable for inclusion within an MCA) this introduces complexity and potential confusion. Care providers and individual patients will have to deal with using several different medicines administration systems which may raise questions around the necessity of the MCA and increase the risks of the patient not receiving their medication correctly.

"The over reliance on MDS was causing difficulties within the home as it meant that more than one system was being used and this increased the risk of error. Nursing staff had also reported anxiety around signing for medications from MDS as they had been removed from the original pack and were not sure if they were the correct medication. Over a two month period we worked closely with the community pharmacy team and changed over to using original packs. It has been so successful we will be doing this in other homes".

Nursing Home Deputy Manager, Edinburgh

MCA are generally only used for oral solid dosage forms and are usually restricted to medicines taken at regular times during the day. This necessitates the supply of other types of dosage forms, such as suppositories, oral liquids, creams, ointments, eye drops, inhalers, and medicines considered to be unsuitable for inclusion in an MCA such as "when required" medication and effervescent medicines, being supplied in traditional dispensing containers or their original packaging. See also appendix 2.

Depending on the medication prescribed for a particular patient, this is likely to mean that care providers or patients will have at least two different medicines administration systems operating to ensure that all medicines are administered to the right patient at the right time at the right dose.

This results in a more complex medicines administration system, compared to the use of only one system (i.e. the use of original packs for all medicines supported by a Medicines Chart and/or Medicines Administration Record) and introduces potential confusion and patient safety and risk issues.

2.6 Risks where an MCA system cannot accommodate dosing instructions or cannot include all necessary information

The use of MCA systems is associated with disadvantages in the supply of relevant necessary information

MCA systems are often unable to accommodate dosing instructions, for example when medicines must be taken with, after or before food, medicines taken “when required”, or if doses are likely to vary according to response, or the patient’s condition is unstable. This raises the risk of medicines being administered incorrectly, increasing the likelihood of adverse effects or potentially being ineffective and impacting upon patient safety and health outcomes.

There are also problems with including all the necessary information about the medicines, which should accompany the MCA to support safe use, for example descriptors of the medicine and patient information leaflets.

2.7 Alternatives to multi-compartment compliance aids

There are many alternative interventions, which may be more appropriate to be used in preference to MCA in helping patients to take their medicines and to maintain their independence. Some interventions support the use of original packs of medicines. The use of original packs of medicines with appropriate support should be the preferred option of supplying medicines.

"Another interesting one we came across recently was an elderly woman who was on four medicines, all of which were in a Venalink (an MDS system). She lived alone at home and had been assessed by her community pharmacist as being someone who would benefit from an MDS. This was working well. After a recent hospital admission, three of the four drugs where stopped, leaving only lansoprazole. After discussion with the patient and community pharmacist, the MDS was stopped and the lansoprazole dispensed in the appropriate packaging from the manufacturer."

Clinical Pharmacy Manager

A 2012 report on improving the use of medicines and reducing medicines waste[17] noted that the increasing use of MDS in care homes was based on the belief that they may save staff time, standardise processes across a home, or on the unproven belief that such systems reduce the incidence of medication errors. The report noted that the supply of MDS can be driven by patient demand and care home managers. Health professionals were encouraged to discuss whether an MDS is the best option for an individual patient or whether some other mechanism to support adherence may better suit them.

Consideration of alternatives to MCA should be part of an integrated assessment and care plan for the patient. In areas where this has not yet been developed, the information below may be useful in practice.

There are many ways in which patients can be helped to take their medicines safely, or carers supported to administer medicines correctly. Interventions include, medication review to reduce inappropriate polypharmacy and simplifying regimen which is particularly important as the number of prescribed medicines has been shown to be a powerful predictor of non-adherence,[18] patient counselling to improve understanding of medicines-use, the use of reminder charts (as a memory aid), the use of medicines administration record (MAR) charts, labels with pictograms, large print labels, information sheets, reminder alarms, IT solutions and new technology such as phone apps and telemedicine. All of these interventions have a place in ensuring patients take or receive the correct medicines at the right time. The use of an MCA is just one additional intervention in a range of intervention options.

In addition, patients themselves may have developed reminder systems to help them take their medicines correctly and care workers, family and friends may be in a position to provide support to patients. Patients should be encouraged and supported to retain autonomy over their own medicines administration for as long as they feel capable of doing this.

RPS has produced a reminder resource for patients which may be helpful for some patients

(http://www.rpharms.com/toc-resources/my-current-medicines-form-final.doc).

2.8 Reduction in patient and carer understanding of medicines

There are risks that the use of MCA can lead to the loss of skills for carers and patients when using their medicines.

"Some staff members are losing the skills to give liquids or tablets/capsules which are not supplied in MDS packs. The use of MDS has made medicines administration a robotic task with little consideration about what the medicines are prescribed for. The current model is based around the concept of institutionalised drug round. In recent years there has been a move to more personalised care and the storing of medicines in the person's room."

Excerpt from Scottish Care Inspectorate Reports shared with RPS

The use of MCA systems by patients and carers can result in a gradual reduction in knowledge and understanding of the patient's medicines and how, why and when they should be administered. This leads to a potentially dangerous loss of skills and administration knowledge, as well as a loss in patient autonomy and choice around their medicines taking with the risk that medicines are administered or taken simply because they have been repackaged within the MCA.

This risk can only be avoided by not repackaging medicines within MCA or partly mitigated by ensuring that patients who have been assessed as requiring MCA have access to information and advice from a pharmacist or prescriber and is pro-actively educated on the use of their medicines.

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Royal Pharmaceutical Society Documents

Handling of Medicines in Social Care.

(http://www.rpharms.com/support/pdfs/handlingmedsocialcare.pdf)

Medicines Adherence Quick Reference Sheet for Pharmacists.

(http://www.rpharms.com/support-resources-a-z/medicines-adherence-quick-reference-guide.asp)

Principles of Safe and Appropriate Production of Medicines Administration Charts.

(http://www.rpharms.com/support-pdfs/marchartsguid.pdf)

Professional Judgement Quick Reference Guide.

(http://www.rpharms.com/support-tools/professional-judgement-quick-reference.asp)

General Pharmaceutical Council Documents

Inspectors' Checklist - Monitoring and Inspection Visits.

(http://www.pharmacyregulation.org/pdfs/other/inspectorchecklistversionfinalpdf.pdf)

Guidance on Equality Act 2010

Government Equalities Office - Equality Act 2010.

(http://homeoffice.gov.uk/equalities/)

Government Equalities Office - Equality Act 2010: What do I need to know?

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Commissioning resources

Oboh L. Supporting older people in community to optomise their medicines including the use of multicompartment compliance aids (MCA) Vs3. A resource to help health and social care organisations to work together to optimise patient care. East & South East England Specialist Pharmacy Services, June 2013.

(http://www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Meds-use-and-safety/Service-deliv-and-devel/Older-people-care-homes/MCA-Toolkit-Vs3-Jun13/)

Appendix 1: Patient assessment criteria

The following criteria should be considered as part of the individual patient assessment and in the creation of assessment frameworks in support of the agreed care packages.

1. Involve the patient or carer in the decision-making process, including sharing information of the advantages, uncertainties and risks of different intervention options.
2. Involve a pharmacist, or a multi-disciplinary team including a pharmacist, with experience of applying knowledge of the pharmaceutics, pharmacology, pharmacokinetics and stability of medicines, as well as the necessary clinical expertise, in the assessment of intervention options.
3. Consider all the available underpinning evidence and information including an assessment of:
   a. Patient characteristics including, relevant medical history, physical and cognitive ability of the patient and nature of the care support available. This will include dexterity, memory, visual impairment, hearing impairment, literacy problems, language problems, health literacy learning disability, beliefs and choices. Any assessment should incorporate a clinical medication review.

      The nature of the care support available is important because the needs of an individual patient self-administering are different to the needs of an institution providing care to an individual.
   b. Whether non-adherence (if present) is intentional or non-intentional and for how long the patient has not taken their medication as prescribed. Explore these areas and address where possible.
   c. Whether a history of consistent non-adherence could lead to adverse effects with interventions that suddenly ensure adherence e.g. high risk medicines and drugs with a narrow therapeutic index, or those that increase the risk of falls.
   d. All alternative intervention options which can assist the patient to take their medicines (e.g. simplification of regimen, medicines administration record (MAR) sheets patient reminder charts, pill press, pill punch, eye drop dispenser, prescription ordering, availability of professional and lay helpers to administer medicines from their original packaging, patient counselling services).
   e. Current available evidence of medicines stability (see also appendix 2 for medicines stability assessment tool).
   f. Overall benefits and risks to the patient of supplying, or not supplying, within an MCA based on their individuals needs.
4. Have an agreed plan for how the self-administration/prompting or administering of medicines not suitable for inclusion in an MCA (e.g. when inhalers eye or ear drops or “when required” are prescribed) will be managed and who will do this.
5. Involve effective communication pathways to support the transfer of care, between the prescriber, team supplying the MCA and patient receiving the MCA. Agreement from GP, pharmacy and social services to share appropriate information e.g. changes in medication and if the patient is in hospital.
6. Involve follow-up and regular review of the need of an MCA or other intervention on an individual basis. The circumstances leading to decision to supply medicines in an MCA may be temporary or resolve over time and an MCA may no longer remain the intervention of choice. Roles and responsibilities for this should be agreed as part of local arrangements.
7. Consider equality and disability discrimination legislation.
8. Involve appropriate record keeping and documentation to maintain an audit trail, to support decisions made.

Appendix 2: Medicines suitability guidance

The guidance is intended to be general and does not take into account the individual characteristics of different MCA systems, such as whether they are sealed or unsealed or storage periods, which may inform professional judgment and decisions.

The lack of sufficient stability data to support the repackaging of medicines within MCA is a contributory factor to why MCA may not be the best intervention for patients.

This section provides guidance on how to best assess the suitability of medicines for repackaging in an MCA, particularly in the absence of published stability data.

1. Whenever reliable published data are available these should always be used although it should be recognised that these data might be limited to specific marketing authorisations. (See section 2.2 for information about the UKMi stability database).
2. Where published data do not exist and it is impractical to conduct a medicine stability assessment the medicine should be considered to be at risk of not being stable within the MCA.
3. Where a medicines stability assessment can be carried out, a pharmacist's knowledge of pharmaceutical science, including pharmaceutics, pharmacology and pharmacokinetics, together with clinical expertise, should be considered along with the points outlined in the medicines stability assessment.
4. In situations where a medicines stability assessment is not carried out, or there are stability issues that make it undesirable to include the patients' medicines in their MCA, pharmacists must use their professional judgement as part of individual patient assessment in deciding if they should supply the medicines in the MCA based on the benefits and risks to the individual patient.

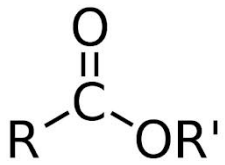
Medicines stability assessment

Some pharmaceutical products are particularly sensitive to the effects of water vapour, atmospheric gases and/or light and exposure to these conditions may result in the chemical or physical stability of the medicine being compromised.

Pharmacists should consider whether there are any factors, which may indicate a medicine to be sensitive to moisture or light, such as the following:

- Packaging of solid dosage forms in foil/foil strip i.e. the primary packaging is composed entirely of foil. As this is a relatively expensive form of packaging, it is an indication that the product is particularly sensitive to the effects of moisture.
- The presence of desiccants in packaging is an indicator that the product is sensitive to the effects of moisture.
- Packaging of medicines in glass containers may indicate a medicine requires additional protection. If a pharmacist cannot establish why a glass container is used, the medicine should not be removed from the glass container and repackaged.
- Darkly coloured blister packs (i.e. those which are not clear or white) are signs that the product requires protection from the effects of light.
- In general, sugar coated tablets will provide a better barrier to moisture and light than most film coated tablets. However, there are certain specialised film coatings that can provide good protection to light, moisture and gases.
- Effervescent, dispersible or hygroscopic products are most sensitive to the effects of moisture, with water ingress causing changes in chemical and/or physical stability.

- The most common form of drug degradation is hydrolysis, which requires the presence of water. Hydrolysis is most likely to occur in (carboxylic) ester containing drugs such as aspirin. A knowledge of the chemical structure of a drug and the presence of these functional groups may help identify drugs which may be susceptible to the effects of moisture.[1]



Ester: where R and R' are an alkyl or aryl (cyclic or acyclic) group. R and R' may be identical.

In addition, pharmacists should consider whether the medicine falls into one of the following categories that are generally considered to be unsuitable for inclusion in MCA:

- Mucosal dosage forms including buccal and sublingual preparations due to the risk of them being swallowed as oral preparations.
- Medicines whose active ingredient has cytotoxic potential.
- Medicines dispensed in glass containers such as glyceryltrinitrate or clomethiazole.
- Medicines that are given "as required"; this is due to the risk of administration of the medicine to a patient when it is not actually required and the potential contribution to medicines waste if not used.
- Medicines that should be stored at a specific temperature e.g. refrigerated or frozen products.
- Large tablets that will not fit into a compartment.
- Medicines whose dose varies according to a blood test (such as warfarin). The National Patient Safety Agency (NPSA) advises that the inclusion of anticoagulants in MCA should be minimised,[2] patient risk assessment is essential to decide whether the anticoagulant should be placed in the packaging.
- Medicines which require patients to take their medicines in a very specific way e.g. alendronate.

When assessing which types of medicine can be added to an MCA, the following points should be considered:

- Drug release from modified release tablets may be affected by the ingress of water into formulation excipients that swell or gel on contact with water.
- Both soft and hard gelatin capsule shells have high water content. Mixing capsules with tablets can result in the movement of water from capsule shells to tablets with the potential to increase the risk of hydrolysis of susceptible drugs, although the clinical impact of such hydrolysis in patients is not known. In particular, mixing capsules with modified release tablets should be avoided where possible due to the risk of changing the release characteristics of the tablets.
- The exchange of water between soft gelatin capsules and hard gelatin capsules can occur with the risk of capsule brittleness or capsule softening and distortion, although the extent to which this occurs in MCA has not been established. The inclusion of both hard and soft gelatin capsules in a single compartment should be avoided.

References for Appendix 2

1. Snape TJ, et al. Understanding the chemical basis of drug stability and degradation. *Pharmaceutical Journal* 2010; 285: 416-417.
2. National Patient Safety Agency – National Reporting and Learning Agency. Actions that can make anticoagulant therapy safer: Alert and other information, March 2008. (http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59814 accessed July 2013).

Appendix 3: Practice considerations for the use of MCA

The following practice considerations support the best use of MCA, following an individual patient assessment that an MCA is the intervention of choice.

Appropriate standard operating procedures should be in place to support all of the processes below.

Protecting Children Counsel patients and carers about the potential risks of MCA to children.	It is important to understand that MCA packaging is extremely unlikely to be child resistant and may not be tamper evident. This is a potential risk, particularly to children, so patients and carers should be informed of this risk and advised to take particular care with the storage of their medicines.
Packaging considerations Do not repackage MCA by inclusion of the original strip or blister packaging.	Medicines should not be repackaged within MCA in their original strip or blister packaging as there have been reports of patients swallowing the medicine and its packaging resulting in gastric perforation[1-3] or pelvic abscesses.[4] The MCA package should be sealed as soon as possible after filling.
Medication changes Counsel patients not to attempt to make changes to the contents of an MCA and to instead contact the pharmacy.	Patients and carers should be advised not to attempt to make any changes to the contents of an MCA as this could place the patient at risk due to the difficulties in identifying medicines. Instead they should be advised to contact the pharmacy where the MCA was dispensed. Due to the potential complexity of adding or removing medicines mid-cycle, the safest, most effective and efficient way to achieve this should be agreed through local discussion between the pharmacist, the patient, the care provider and the prescriber. In some instances it may be more practical to action changes at the end of a supply cycle depending on the urgency of the changes proposed.
Spillage Counsel patients on steps to take if the content of the MCA is spilled.	When MCA are supplied, pharmacists should advise patients or carers on the steps they should take in the event of medicines spillage. If the contents are spilled, the patient or carer should not try and put the medicines back into the MCA, but should be encouraged to return the packaging and the medicines to the pharmacy where they were dispensed for arrangements to be made for resupply. Depending upon the circumstances this may require a new prescription or an emergency supply.

Understanding accountability Be aware of potential accountability and liability for repackaging medicines outside of their original packaging.	Prescribers, pharmacists and other stakeholders must understand the potential liability issues when requesting or supplying a medicine in an MCA. Removing a medicine from the manufacturers packaging, which has been designed to provide the required protection and repackaging the medicine in an MCA is activity which would not to be covered within the marketing authorisation. The consequences of this are that such removal would result in responsibility for the stability of the repackaged medicines transferring from the manufacturer to the prescriber, pharmacist and other stakeholders, with the relative liability depending on the individual circumstances. When making a professional judgment it is important that pharmacists ensure that the best interests of the patient, the available evidence and an integrated assessment and care plan are at the heart of the decision-making process. The decision-making process relating to this should be documented with the appropriate signed agreement and consent.
Controlled drugs Be aware that controlled drug legislation applies to controlled drugs stored or supplied within MCA.	Medicines containing controlled drugs should be assessed in the same way as other medicines (see appendix 2) before deciding whether or not to repackage within an MCA. In situations where the controlled drug requires safe custody and has already been repackaged within the MCA with other medicines, the whole MCA must be stored in a controlled drug cabinet prior to collection. If an entry in the controlled drug register is necessary, this should be made at the time of supply. The addition of a controlled drug to an MCA is unlikely to be appropriate in situations where the dose and strength of the preparation may need to change rapidly to accommodate the patient's condition, e.g. palliative care.

Identifying medication within an MCA	It is commonplace for different proprietary (branded) medicines or generic medicines with the same active ingredient to be available for use within a pharmacy. This creates problems if these are repackaged into MCA as the physical appearance of proprietary and generic versions of medicines containing the same active ingredient can vary. Many people using MCA have multiple morbidities with many routinely taking between ten to fifteen medicines. When presented in the same compartment in an MCA, it can be difficult to distinguish or identify each medicine, even if descriptors are available. There are inherent difficulties in identifying medicines repackaged within an MCA. This can lead to loss of independence and cause confusion to patients and carers (formal and informal) when they are trying to identify medicines, e.g. if they are choosing not to take a medicine at a specific time for life style reasons (such as with a diuretic). This also provides a challenge for care providers who must be able to identify the medication when they are administering medicines. This problem can also lead to waste and delay when the person transfers from one care setting to another, where to reduce costs the patient's own medicines are being used wherever possible e.g. into hospital or care home. Staff may be unhappy to continue to use the MCA if they cannot guarantee that the accuracy of the medicines in the same way that they can with an original pack. An accurate description of the appearance of each medicine accompanying an MCA can be useful for patients, carers and healthcare professionals to identify the medicines prescribed, dispensed and administered. We are aware that with the use of some MCA systems, this may not always be possible in practice.

Expiry Date Be aware of stability issues and limitations to expiry of repackaged medicines.	There is a lack of published data to demonstrate the stability of medicines in MCA which could be used to determine appropriate expiry dates. In the absence of applicable data and in order to support practice, RPS recommends a maximum interim expiry date of eight weeks for products in sealed MCA. This pragmatic decision was taken to support pharmacists in their practice and was based on current practice rather than having any scientific basis. However, it should be recognised that there may well be circumstances where an expiry date of less than eight weeks is used for a product in a sealed MCA if this is recommended by the medicines manufacturer or indicated by published scientific studies. With regard to unsealed MCA, it has been common practice since 1987 to store medicines in daily dose reminders for up to seven days. This seven day expiry date for unsealed MCA is an arbitrary timescale which reflects what typically happens in practice as, in most cases, unsealed MCA have sufficient space for seven days medication. Arbitrary expiry dates suggested for MCA are generally kept as short as possible in recognition that there are often little or no data to support these periods. However, as with all arbitrary shelf lives, there will be medicines that have specific stability issues where the appropriate expiry date is shorter than the suggested arbitrary life.
Record Keeping Keep appropriate supporting documentation to maintain an audit trail and to support decisions.	The provision of an MCA should be viewed as a package of care, with the appropriate supporting documentation which should be recorded and retained where available e.g. patient assessment documentation, decisions and reasons for medicines inclusion/exclusion, follow up, note of changes to medicines and who requested change, note of when medicines are collected or delivered, carer details and appropriate clinical information. This supports both patient care and helps to justify decisions made.

Hygiene and contamination In all circumstances, the pharmacy must ensure that the MCA is filled ensuring that poor hygiene, microbial contamination or cross contamination do not present a risk to the patient. Medicines must only be supplied in an MCA that is suitable for use. Medicines must not be handled with bare hands.	The risks of microbial contamination and of cross contamination by medicines, especially from uncoated tablets must be minimised to prevent risk to patients at all stages of filling the MCA. If the MCA or any part of the packaging system is not disposable, then it must be thoroughly cleaned before reuse in accordance with advice of the manufacturer of the MCA. Depending upon the circumstances, the responsibility for ensuring MCA are maintained in an acceptable state of hygiene will, by agreement, rest with the patient, carer or pharmacy. However, in all circumstances the pharmacy must only supply medicines within an MCA that is suitable for use.
Delivery	Patients who live alone are particularly vulnerable. Consider and mitigate the risks of delivery of MCA to these patients as there is a reduced ability to review how well the patient is managing their medicines.
Frequency of supply	Agree the frequency of supply with the prescriber, patient and pharmacy ensuring that arrangements are in place to manage the risks if multiple packs are available at the same time. There must be appropriate communication between health and social care professionals so that supply requirements or restrictions are understood.
Labelling Be aware of the importance of labelling information and provide accurate descriptions.	Legislation requires that a dispensing label should be prepared for each item dispensed into an MCA and attached directly to the packaging each time the medicine is dispensed. With some MCA, there is insufficient space to accommodate all the medicine labels and as a pragmatic solution, the labels are often attached to a separate card which accompanies the MCA. In this case, systems should be in place to ensure the card with the up-to-date medicine labels is linked to the MCA tray containing the medicine and there is no risk of separation.

Patient information leaflets Be aware of the importance supplying information about medicines to patients and legal requirements in relation to patient information leaflets.	When medicines are dispensed into an MCA, it remains a legal requirement that a patient information leaflet (PIL) is supplied for every dispensed medicinal product included. The RPS believes that patients and carers should always have access to a PIL for every medicine and should always be able to identify the medicine to which the PIL relates. We recognise that in practice, with patient and carer consent, a safe outcome can be achieved by sensible and pragmatic alternatives to supplying a PIL on each and every occasion and this view has been included in the RPS responses to the Medicines Act consolidation and review consultation in 2012. However, it still remains a legal requirement to supply a PIL with all medicines and pharmacists should carefully consider the implications of not supplying one.

References for Appendix 3

1. Ishikura H, et al. Intestinal perforation due to ingestion of blister-wrapped tablet in press-through packaging. *American Journal of Gastroenterology* 2003; 98: 1665-1666.
2. Fulford S, Tooley AH. Intestinal perforation after ingestion of a blister-wrapped tablet. *Lancet* 1996;347: 128-129.
3. Norstein J, et al. Intestinal perforation after ingestion of a blister-wrapped tablet. *Lancet* 1995; 346:1308.
4. Gupta V, et al. Pelvic abscess after ingestion of blister-wrapped tablet. *American Journal of Gastroenterology* 2002; 97: 2142-2143.
5. Daily dose reminders. *Pharmaceutical Journal* 1987; 239: 598.