

North East & North Cumbria Medicines Adherence Support Project

Report Date: 31st January 2019

Report by: If there are any questions about this report, please contact:
Andre Yeung – andre.yeung@nhs.net / 07476228778

Why read this report?

This report is a summary of a 2-year investigation into the use of Multicompartment Compliance Aids (MCAs) in England. Within the report you will learn that hundreds of thousands of patients are inappropriately supplied these devices by pharmacies and pharmacists each year. You will also learn why this situation has developed and importantly how we can improve the use of these devices.

What is a Multi-Compartment Compliance Aid?

“A multi-compartment compliance aid is 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. There are different types. MCA exist as both sealed and 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.”



Royal Pharmaceutical Society, 2013

Project Background and Objectives

In September 2016, a 2-year project was commissioned by the Academic Health Sciences Network for North East of England and North Cumbria to investigate the use of Multi-Compartment Compliance Aids and other forms of adherence support supplied by pharmacies in England. The project objectives were:

1. Investigate policies/practices that drive the use of MCAs
2. Gather information about current practice across health and social care in NENC
3. Raise awareness in NHS and social care providers re positive and negative aspects of MCAs and alternative means of adherence support.
4. Produce a simple to use assessment tool for all sectors to facilitate the selection of the correct medication support when required.
5. Monitor the impact of the introduction of the assessment tool across health and social care – numbers of MCAs & benefits



What people told us...

Over a period of two years the project embarked upon a large number of interviews, meetings and conversations with experts from across health and social care to develop of a more rounded understanding of the use of MCAs and opinions regarding their use. Some themes from those discussions are summarised below:

1. That once a patient is on an MCA they never come off.
2. That the root cause for many MCA patients is having too many medicines (problematic polypharmacy).
3. That MCAs increase risks for patients due to increased number and severity of dispensing errors.
4. That MCAs increase risks for patients due to problems when patients are admitted and discharged from hospitals.
5. That MCAs increase risks for patients due to the fact that they often do not address the root cause of the non-adherence e.g. intentional non-compliance.
6. That MCAs increase risks for patients due to problems with the stability of medicines that are repackaged from their original packs.
7. Through commissioning arrangements that do not specify medicines standards, local authorities are driving demand for MCAs
8. Acute Trusts have highly variable policies and practices but Chief Pharmacists consistently report concerns and express low opinions regarding the use of MCAs citing a lack of evidence for their use.
9. Many people, groups and areas have tried to improve MCA practice in the past but with limited success.
10. We were unable to locate a single example in England where a project has resulted in a demonstrable improvement in MCA practice over an area or system (we have found individual organisations only e.g. nursing homes).
11. Almost unanimously, there was a recognition by people across health and social care that current MCA practice is far from the standards described in national guidance.
12. Due to individual past experience, people do not believe that current MCA practice can be improved.
13. Patients and carers 'ask and get' MCAs without sufficient pharmaceutical input or intervention.
14. Many patients do benefit from the use of MCAs.
15. Formal and informal carers have fears and lack confidence when dealing with medicines due to a lack of training.
16. The more medicines training people have the more likely they are to refuse to administer from MCAs due to an increased awareness of risk (e.g. nurses).
17. Demand for MCAs has grown over the years despite medicines guidance for pharmacists and care homes etc.
18. That MCAs increase medicines waste.
19. That MCAs erode a patient's independence and awareness of their medicines.
20. Medicines inappropriate for inclusion within an MCA are often included e.g. medicines to be taken 'when required' e.g. codeine for pain.
21. Views from some that community pharmacists' profit from the use of MCAs.
22. Pharmacists report that there is no payment to cover the supply of an MCA so they incur additional costs vs supplying medicines in their original packaging.
23. There is no single consistent assessment tool that empowers decision making by pharmacists.

What industry best practice guidance tells us...

“...it is a recommendation of the RPS that the use of original packs should be the preferred intervention for the supply of medicines in the absence of a specific need for an MCA in all settings.” **Royal Pharmaceutical Society**

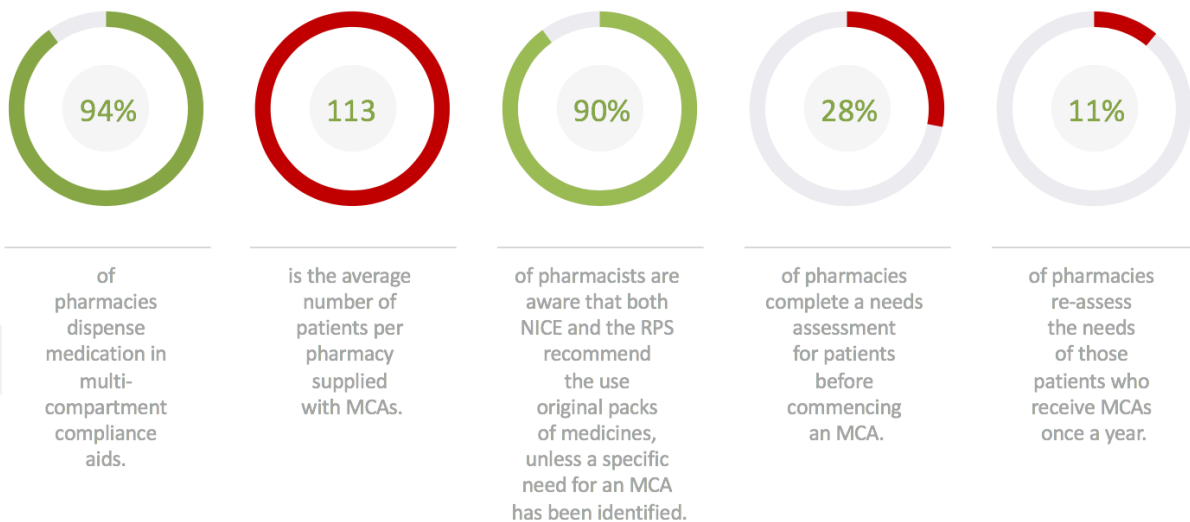
“Consider using a monitored dosage system only when an assessment by a health professional (for example, a pharmacist) has been carried out, in line with the Equality Act 2010, and a specific need has been identified to support medicines adherence.” **NICE**

What research told us...

We conducted some simple research into the use of MCAs by speaking to a random selection of 50 community pharmacists and asking them questions. The results of this telephone survey are shown below:

Adherence support survey results

We asked 50 X Community Pharmacists...



The results tell us that each year in England approximately **64 million MCAs** are given out by community pharmacies. Although pharmacists are for the most part aware of the recommendations of both NICE and The Royal Pharmaceutical Society, just under **3 out of every 4 people** supplied an MCA by a community pharmacy do not receive any prior assessment of need (contrary to all available guidance ref NICE, RPS, UKMI etc.) and only **1 out of 10 patients** ever get a re-assessment despite the progressive nature of some of the known causes of non-adherence.

Summary of current situation

MCA's are being used inappropriately for hundreds of thousands of patients each year in England...

What are the implications for patients?

In terms of risks, we know that unfortunately some patients have died as a result of repackaging medicines into MCAs e.g. a patient death caused by Epilim packaging perforating the intestine in 2016¹. However, putting aside the many individual examples we know about, it is likely that most damage (at a population level) caused by inappropriate MCA use results from the hundreds of thousands of patients who a) can't refuse a medicine (e.g. codeine/senna/PRN meds) because it's in a tray and go on to suffer adverse effects as a result, b) don't have the root cause of their non-adherence (e.g. intentional non-compliance) addressed as there was never an assessment carried out in the first place and c) have a progressive illness (e.g. arthritis or dementia) and don't get re-assessed once they are on a tray and it's ceased to become useful and may in fact be a risk.

We know that some other negative implications of repackaging medicines into an MCA are:

- patients are not supplying their informed consent,
- reduced medicine stability,
- increased medicines wastage,
- increased error frequency and severity,
- patients have reduced awareness of their medicines,
- medicines identification becomes more difficult,
- separate supplies of liquids, fridge lines and CDs cause confusion,
- the time taken to prepare MCAs is significant

Patients are not being adequately protected from known MCA issues by the professionals they trust. Pharmacists are often not aware that repackaging results in unlicensed supply of a medicine. The data shows that despite all the risks, pharmacists often don't know if people need an MCA before supplying one and once you're on an MCA, you're usually not coming off one.

¹ <https://www.pharmacyregulation.org/regulate/article/using-blister-packs-medicines-compliance-aids>

Why is this happening despite the above known issues with MCAs?

The behaviour of individual stakeholder groups is understandable and predictable however the combined effect is the creation of a system that does not operate in the best interests of patients and taxpayers. When this occurs in a market, it is termed: 'market failure'.

Why is this happening?

What forces are at work?

Drivers

Local Authorities, Care Homes, Home Care ALL lack full understanding of issues & have other priorities & are under financial pressure. **Patients and carers** just 'feel' that MCAs are the solution.

GPs and Trusts

They disapprove of the inappropriate use of MCAs but have limited ability to influence the situation.



Community Pharmacists

Competitive forces are overriding the ability of individuals to resist requests by patients and carers. Without collaborative cross-sector action by pharmacies, improvements will not be possible.

The Regulators

GPhC & CQC. The main regulator is the GPhC but they have been silent on this issue despite being made aware.

Below are a list of stakeholders and their behaviours:

- **Local authorities** are under significant financial pressure and will understandably pursue the cheapest arrangement to cater for the needs of people who need social care. As a result, contracts allow private contractors considerable freedom to provide services without detailed consideration to the quality of that provision.
- **Home Care & Care Home Organisations** provide the cheapest possible arrangement within the broad boundaries set by Local Authorities. They see MCAs as a tool to achieve efficient medicines service.
- **Patients and informal carers** who are not aware of other options available to them and the negative implications of using an MCA request them as a way to solve a multitude of medicines related issues.
- **Community Pharmacists and pharmacies** operate within a very competitive market where prescription volumes are critical to business success so Pharmacists are unable to unilaterally act as 'the gatekeeper' for inappropriate MCA use. Competitive forces mean that if 'Pharmacy A' wishes to introduce an appropriate needs assessment (and by doing so refuse more patients the supply of an MCA) then patients will move to 'Pharmacy B' where no such assessment exists. This negative incentive to improve practice is a critical factor.
- **General Practice** despite some stopping 7-day prescriptions have limited ability to influence the other stakeholders.
- **Hospital Trusts** are impacted adversely by MCAs in circulation but lack the power or proximity to influence the behaviours of other stakeholders.
- **The regulators GPhC & CQC** are, despite the above risks to patients, silent on this issue, perhaps even mistaking 'established practice' with 'best practice' themselves.

We know that markets often fail to deliver best outcomes for customers². This is especially true in markets where the behaviour of consumers is irrational or based on an incomplete understanding of all factors that should be considered before demanding a product or service. For example, in the energy market in the UK, it is known that people are overpaying by hundreds of millions of pounds each year simply because they won't switch supplier. So, we know that the behaviour of organisations and people within markets can have damaging outputs and this is undoubtedly true of the adherence support market in England where organisations and consumers are effectively 'incentivised' to behave in certain ways by the structure of the market and the product on offer (an MCA).

It is undoubtedly the role of a regulator to monitor the outputs of the market they regulate and to identify when and where people are being adversely affected by a 'market failure'. Unfortunately for us, the growth of the use of MCAs in England has been left unchecked for many years with, at various points, individual organisations promoting their use (mainly community pharmacy, care homes and home care) to patients without due consideration for the risks involved. Although the GPhC have the role to regulate pharmacists and pharmacies in England with the aim to assure and improve standards they have failed to act to protect patients.

What benefits would improvements in medicines adherence support deliver?

What potential benefits?

AHSN - System wide effects in England



Adherence

Increased adherence
By actually addressing
the problem!



Wastage

Reduced wastage
By using original packs



Safety

Improved safety
Better stability, use of medicine,
independence etc.



Time

Reduced resource
By saving on preparation
of trays

Improvements in adherence support decisions by pharmacists would undoubtedly generate benefits that would include; **a) increased adherence to medicines, b) reduced wastage of medicines, c) better safety and d) reduced time spent on unnecessary repackaging medicines.**

² <http://www.behaviouralinsights.co.uk/wp-content/uploads/2016/05/Applying-behavioural-insights-to-regulated-markets-final.pdf>



Conclusions and recommendations - how can things be improved?

Although many people have described previous initiatives designed to improve MCA practice we have found no one area that is able to demonstrate a sustainable reduction in the inappropriate use of MCAs. Therefore, we conclude that if we are to improve practice, we must adopt a different approach. Previous initiatives have shown that 'issuing more guidance', 'forming voluntary partnerships between stakeholder groups' or 'commissioning at placed based care level' have failed to make any sustainable impact on the inappropriate use of MCAs. Moreover, we know that when markets fail (as in this case), interventions must be designed to deliver a person centred & system wide outcome with due consideration to how the market behaves.

Therefore, our conclusion is that action must be taken to ensure that if any pharmacist wishes to re-package a patient's medicines into a compliance aid (and in doing so raise certain risks to patients) then they must have a good reason for doing so i.e. a recognised needs assessment must have been completed, be held on file in the pharmacy and should be reviewed annually. The critical decision to repackage a patient's medicines into an MCA sits squarely within the domain of the pharmacy profession. The decision to re-package medicines should not just be that of the patient/carer/prescriber/care home manager in isolation (with due respect to those groups they do not understand many of the factors that should be considered); the expert input of pharmacists is a crucial part of safely supporting adherence and ultimately, they should act as the gatekeeper in deciding when an appropriate threshold has been met.

Report recommendation:

To ensure the appropriate use of multicompartiment compliance aids (and other forms of adherence support) the intervention of the General Pharmaceutical Council is needed so that all patients, irrespective of their chosen pharmacy or care setting, receive an appropriate³ assessment of need before a decision is made to repackage medicines into an MCA AND so that an annual appropriate³ re-assessment is undertaken for all patients who receive an MCA. The GPhC can achieve this by changing the way that it inspects and regulates community pharmacies.

Existing pharmacy practice evidence and guidance is clearly sufficient to support regulatory intervention of this type and it is the conclusion of this report that it is ONLY with regulatory support (combined with national communications, refreshed guidance and an appropriate assessment tool) that we will see a shift in MCA culture in England.

Yes, it really is that simple!!!

Next steps - how can you help?

- a) **Promote the need for change:** We ask for the everyone's help to share the findings of this investigation with networks across health and social care.
- b) **Regulatory commitment:** We will work to secure commitment from the GPhC to properly regulate this area of practice. Please help us by making your views known.
- c) **Adopt an appropriate assessment tool:** We've produced a simple appropriate assessment tool and will work with the RPS to update guidance if this is required.

³ 'Appropriate' meaning that the assessment is of sufficient quality to ensure that patient needs are fully explored, appropriate forms of adherence support suggested, due consideration given to risk and that patients give their informed consent.