A comparison of medication administration errors from original medication packaging and multi-compartment compliance aids in care homes: a prospective observational study

ABSTRACT

Background

No published study has been specifically designed to compare medication administration errors between original medication packaging and multi-compartment compliance aids in care homes, using direct observation.

Objectives

Compare the effect of original medication packaging and multi-compartment compliance aids on medication administration accuracy.

Design

Prospective observational.

Setting

Ten Greater London care homes.

Participants

Nurses and carers administering medications.

Methods

Between October 2014 and June 2015, a pharmacist researcher directly observed solid, orally administered medications in tablet or capsule form at ten purposively sampled care homes (five only used original medication packaging and five used both multi-compartment compliance aids and original medication packaging). The medication administration error rate was calculated as the

number of observed doses administered (or omitted) in error according to medication administration records, compared to the opportunities for error (total number of observed doses plus omitted doses).

Results

Over 108.4 hours, 42 staff (36 nurses, 6 carers) were observed to administer medications to 823 residents during 90 medication administration rounds. A total of 2,452 medication doses were observed (1,385 from original medication packaging, 1,067 from multi-compartment compliance aids). One hundred and seventy eight medication administration errors were identified from 2,493 opportunities for error (7.1% overall medication administration error rate). A greater medication administration error rate was seen for original medication packaging than multi-compartment compliance aids (9.3% and 3.1% respectively, risk ratio (RR)=3.9, 95% confidence interval (CI) 2.4 to 6.1, p<0.001). Similar differences existed when comparing medication administration error rates between original medication packaging (from original medication packaging-only care homes) and multi-compartment compliance aids (RR=2.3, 95%CI 1.1 to 4.9, p=0.03), and between original medication packaging and multi-compartment compliance aids within care homes that used a combination of both medication administration systems (RR=4.3, 95%CI 2.7 to 6.8, p<0.001). A significant difference in error rate was not observed between use of a single or combination medication administration system (p>0.05).

Conclusion

The significant difference in, and high overall, medication administration error rate between original medication packaging and multi-compartment compliance aids supports the use of the latter in care homes, as well as local investigation of tablet and capsule impact on medication administration errors and staff training to prevent errors occurring. As a significant difference in error rate was not observed between use of a single or combination medication administration system, common

practice of using both multi-compartment compliance aids (for most medications) and original packaging (for medications with stability issues) is supported.

Key words

Medication errors, medication safety, nurses, nursing homes

What is known about this subject

- Systems that endeavour to improve medication supply to older populations, such as multi-compartment compliance aids (MCAs), via increased efficiency, ease of use, reduced costs and errors, require regular evaluation.
- Though MCA systems are commonly used by care homes for medication administration, they have not been regularly or extensively evaluated.

What this study adds

- The significant difference in, and high overall, medication administration error rate between original medication packaging and multi-compartment compliance aids supports the use of the latter in care homes, as well as local investigation of tablet and capsule impact on medication administration errors and staff training to prevent errors occurring.
- As a significant difference in error rate was not observed between use of a single or combination medication administration system, common practice of using both multi-compartment compliance aids (most medications) and original packaging (for medications with stability issues) is supported.

INTRODUCTION

Care home (CH) medication administration systems should be regularly evaluated to ensure a high standard of care and to minimise errors associated with their use.[1] A key variable in assessing health care facility medication systems is whether patients receive medications as prescribed.[2] Despite the high reliability of observational methods to identify medication administration errors (MAEs),[3, 4] few studies employing this ethnographic research approach have been published in the CH setting.[5] In a 2013 systematic review of literature examining MAEs identified by observation, 89% (n=81) of the studies were conducted in the hospital setting while 11% (n=10) were conducted in long term care facilities (including nursing/care/assisted living homes).[5] Of the 10 studies, only one was conducted in the UK (USA n=6, Netherlands n=2, Belgium n=1), the majority (n=7) included 12 or less CHs in their sample, and the majority (n=6) either did not specify the duration of observation or observed medication administration for approximately 25 days or less.[5] No study was specifically designed to observe only tablet or capsule oral administration (all 10 studies observed all routes of administration) and two studies used disguised observation while the remaining eight did not specify the type of observation.[5] It is a limitation that only two studies used the medication expertise of pharmacist observers (although the majority used observers with a pharmacy background n= 5), while remaining studies used nurses (n=3) or observers from the Department of Health (n=1) or a Consulting Agency (n=1).[5] Nurses or nursing staff were observed in six studies and the remaining studies observed other staff at the CH.[5] It is a strength that a uniform method for calculating and reporting MAE rates was used in all studies, where the numerator related to the number of doses with one or more medication errors and the denominator corresponded to the total opportunities for error.[5]

It is difficult to apply findings arising from hospital-based research to CHs due to significant differences in support structures within the respective work environments, facilities available and the level of education and training of staff. When conducting research in CHs, unique complexities

arise from the interaction between the residential and medical aspects of the CH environment.[6] Care homes are a complex healthcare setting, where a home-like environment is created, while also incorporating processes and protocols to facilitate efficient and effective healthcare delivery by onsite staff and visiting healthcare professionals. Compared to a hospital environment, CH residents may be cared for by staff who have varying levels of education and skills related to healthcare provision, and varying access to prompt, specialist healthcare support and advice.

The Care Home Use of Medicines Study (CHUMS) established the prevalence, types and underlying causes of medication errors in CHs in England.[1, 7] Of the 256 residents from 55 CHs involved in CHUMS, 69.5% had at least one medication error.[1] The prevalence of MAEs by opportunity for error was 8.4% (involving all administered medication formulations including solid oral, liquid, topical medications) and 22.3% of residents were observed to be exposed to a MAE.[1] Alldred *et al* also identified in adjusted analyses of CHUMS data that there was a statistically significant doubling of the odds of a MAE for tablets and capsules administered from original packaging (OP) compared to multi-compartment compliance aid (MCA) medication administration systems (odds ratio=2.14, 95% confidence interval (CI)=1.02 to 4.51). [8] However, CHUMS was not specifically designed to compare the accuracy of medication administration between these two medication administration systems.[8] CHUMS recommended that research should be conducted into the effectiveness of MCAs.[7] This limitation has been addressed in the current study.

In UK CHs, MCAs are commonly prepared by pharmacy staff at pharmacies and delivered to CHs. They assist CH staff with managing large volumes of medications[9] by organising medications according to the day of the week and time of the day in which they must be administered. Different types of MCAs exist worldwide, however, UK CHs commonly use MCAs that may be referred to as unit-dose, bubble pocket blister packs. The 28 clear plastic bubble pockets on a single MCA each contain the same medication to be administered at a specific dosing interval (e.g. breakfast, lunch, dinner or bedtime) for every day of the week, for 28 days. The plastic bubble is pushed to force

medications through the paper backing of the MCA and into an administration device. A resident's entire medication regimen may be contained within multiple MCAs, which correspond to different medications, and which are to be given at different dosing intervals.

Limitations associated with the use of MCAs have been identified by pharmacists, including reduced staff alertness during medication administration, restricted ability to identify medications and medication wastage.[10] Pharmacists predict continued use of MCAs in the future due to their perceived benefits of improved safety and efficiency.[10] This is despite the Royal Pharmaceutical Societies of England and Scotland cautioning against the routine use of MCAs, calling for a need to review the value of their continued use,[11] taking into account the evidence-base for their effectiveness as one medication adherence intervention amongst many.[12] Published research has also explored pharmacist perceptions of stability issues associated with medications packed into MCAs[13] and pharmacy dispensing incidents associated with their preparation.[14]

The aim of this study was to use a prospective observational study design to compare the effect of OP and MCAs on the accuracy of medication administration in nursing and residential CHs located in Greater London.

METHODS

Sampling strategy

This study was powered to identify a difference in how accurately medications are administered from OP and MCAs. Accuracy was determined by identifying discrepancies (i.e. MAEs) between observed, solid, orally administered medications in tablet or capsule form and information contained on medication administration records (MARs). A required sample size was calculated to detect the difference in MAE rates as seen in previously published literature, where MAE rates of 6.9% (OP) and

4.2% (MCAs) have been reported.[1] The required sample size was 2,246 doses of observed solid, orally administered medications in tablet or capsule form (1,123 doses from each of OP and MCAs), calculated with a power of 80% and p=0.05. Assuming that the average number of medications prescribed per resident, and number of residents per CH, was 7 and 30 respectively,[1] 10 CHs were recruited. Of these 10 CHs, five CHs only used OP and five CHs used both MCAs and OP. Where MCAs are used to administer medications in CHs, OP must also be used for medications that cannot be repackaged into MCAs (e.g. due to stability concerns). It was estimated that 230 doses would be observed at each CH to achieve the required sample size of observed doses.

Residential CHs (provide daily care and support for activities of daily living such as washing and dressing) and nursing CHs (provide 24-hour care from a qualified nurse) that accommodated older people, and where medications were administered by staff, were sampled purposively from around Greater London.[15] Both residential CHs and nursing CHs were involved in this study. The researcher observed both nurses and carers administer medications, as a statistically significant difference in MAE rates between nurses and carers was not identified in CHUMS (although CHUMS was not designed to detect such a difference).[1]

CHs were identified via: the website of the Care Quality Commission, the independent regulator of health and adult social care in England (http://www.cqc.org.uk/); staff who worked at CHs participating in the study; and personal contacts of the research team, such as pharmacists who themselves worked with CHs or had colleagues who worked with CHs. As relatively few CHs in England administer medications from only OP, these CHs were purposively identified and recruited (e.g. by contacting CHs that were part of a franchise known to administer medications from only OP).

Recruitment

The research team contacted managers or deputy managers of each CH via telephone to ascertain initial interest in the study. Study information, including a letter of invitation, information sheet and reply slip was subsequently sent via email. Interested CHs were personally visited by the researcher to formalise recruitment and to introduce themselves to managers or deputy managers of the CH and staff involved in medication administration. Additionally, the researcher provided study information to staff involved in medication administration, including a letter of invitation, information sheet and consent form, answered questions about the study, obtained practical information to guide data collection e.g. visit dates and times, and familiarised themselves with the CH layout.

Data collection instrument

The data collection protocol and instruments were developed in conjunction with the research team, with reference to templates from previously conducted studies involving CH medication audits.[1, 14] The research team had expertise in relevant research methods and previous experience of undertaking research in CHs. Information collected included: the time of medication administration; resident age and gender; administered medication name and strength; if the medication was administered from an OP or MCA; whether the administered medication was a tablet or capsule and its quantity; if the medication was crushed; if the staff administering medications observed and signed for administration; and if the administered medication matched information contained on the MAR and details of any discrepancies identified. It was anticipated that collection of information regarding resident characteristics (other than gender, age and medication information) would have required individual resident study consent. As this was not feasible, ethical approval was not obtained to collect these data. With regards to the model of care involved at each CH, information collected included the type of care provided (nursing or residential), medication administration system in use (OP or MCA, single or combination system) and information about staff administering medications (nurse or carer, gender, years of experience, country of qualification). Observed barriers

and facilitators with regards to the overall process of medication administration were also recorded. Data collection instruments were assessed for face and content validity by the research team and were piloted in one CH. Following the pilot, recorded data were reviewed to ensure the study aim was being met, and to assess the appropriateness of data collection instruments and procedures. Minor formatting changes were made to data collection instruments for ease of recording.

Data collection procedure

On each day of data collection, the pharmacist researcher aimed to arrive at the CH just before the morning hand-over meeting. During this time, staff would congregate in preparation for the hand-over meeting and could be easily located in the CH. Additionally, the breakfast medication administration round, when the largest quantity of medications are usually administered, would not have commenced. The researcher gave staff administering medications written study information and time to consider study involvement.

When a signed consent form was obtained, staff were observed administering medications during the breakfast, lunch, dinner and/or any additional morning/afternoon medication administration rounds. To prevent changes in nurse or carer behaviour as a result of the research pharmacist being present, the researcher did not interfere with medication administration and only spoke with staff where appropriate, such as when clarifying the identity of an administered medication (if this could not be determined from medication labels). Additionally, the researcher: established rapport with the nurse or carer and asked them to administer medications as they normally would; maintained an appropriate distance between themselves and the nurse or carer while they were preparing medications for administration; and limited opportunities for staff to observe them taking notes. Information regarding observed solid, orally administered medications in tablet or capsule form was identified from labels affixed to OP and MCAs or by asking staff, and recorded at the time of administration. These labels included information about the medication name, strength, form and formulation. As a result of referring to medication labels or asking staff, as well as observing

medication preparation for all recorded observations, the research pharmacist always knew what medications were being administered from OP or MCAs. Additionally, medication labels, which were attached to all OP or MCAs, were referred to by nurses or carers, to ensure that the correct medication had been supplied. Observed medication doses could include both 'regular' and 'when required' medications. Due to issues of privacy (e.g. if the resident was not dressed) or under staff instruction (e.g. if staff did not feel it was appropriate for the pharmacist researcher to observe the resident, based on their knowledge of the resident's personality or preferences), medication consumption by the resident was not always observed. However, the pharmacist researcher clarified with staff if the resident actually consumed the medication.

Individual staff were observed once, during a single medication administration round (e.g. Monday breakfast), or they were observed more than once, during multiple medication administration rounds on the same day (e.g. Monday breakfast and lunch) or over different days (e.g. Monday breakfast and Tuesday breakfast). The number of different staff observed was dependent on the number of staff administering medications on a particular day and their willingness to be involved in the study. The number of days (up to four) and length of time spent each day, at each CH, was guided by the requirement to observe approximately 230 solid, orally administered medication doses in tablet or capsule form per CH. The length of the observation period at each CH varied (both between CHs and within individual CHs) and was influenced by factors such as: the number of residents in the CH who required medication administration and the number of medications each resident was prescribed, and the number of residents (and the number of medications per resident) an individual nurse or carer had to administer medications to at each medication administration round.

Where possible, entire medication administration rounds were observed, except where rounds had already commenced or the researcher had to leave the CH early. Observations concluded when the

staff administering medications said that the round had finished, even if some residents still required medication administration, such as after earlier refusal.

The process of administering medications usually began when the nurse or carer collected the medication administration trolley, and all residents' medications and MARs from a secure medication room. The trolley would then be transported to each resident who required medications to be administered at that time of day. Information contained within a resident's specific MAR was used to prepare their medications for administration. As the nurse or carer read each medication to be administered, they would locate the corresponding OP or MCA and transfer the required medication dose into an administration device (e.g. medication cup or spoon). This transfer process often involved either opening the lid of an OP and selecting the medication dose, or, popping the medications out of a bubble pocket (through the paper backing) of a blister pack MCA. Medications were then given to residents to consume. Either immediately prior, or following medication consumption, the nurse or carer signed the MAR to indicate that a medication had been administered.

Classifying medication administration errors

At the conclusion of the medication administration round, the researcher compared their recorded observations with information contained on the MAR to identify discrepancies. If, and when a serious discrepancy was identified, staff were notified. This is consistent with methodology used previously.[1] Discrepancies that occurred as a result of staff exercising their clinical judgement during medication administration, and which were documented on the MAR or communicated to the researcher verbally, were not recorded as MAEs. Observed MAEs were classified into the following types:[1] omission, allergy inaccuracy, extra dose, wrong dose, un-prescribed medication, medication incorrect, formulation incorrect, timing inaccuracy (for time-critical medications only), or 'other' error (e.g. crushing a modified release formulation) (Table 1).

Table 1. Medication administration error types.

MAE types	Explanation
Omission	A medication dose that was not observed to be administered during the MAR-specified medication administration round.
Allergy inaccuracy	Administration of a medication for which the resident has a known allergy (as recorded on the MAR).
Extra dose	Administration of an additional dose of a prescribed medication e.g. administration of a medication dose after it has been ceased.
Wrong dose	Administration of a medication in a quantity that was not prescribed e.g. administration of incorrect number of dose units or medication strength.
Un-prescribed medication	Administration of a medication that was not prescribed (classified as a 'medication incorrect' inaccuracy if medication X prescribed but medication Y administered instead).
Medication incorrect	Administration of a medication that is not the medication prescribed.
Formulation incorrect	Administration of a medication in a formulation that was not prescribed e.g. administration of a modified release when a non-modified release was prescribed.
Timing inaccuracy	Antibiotics or levodopa-containing medications administered >1 hour outside the time prescribed on the MAR.
'Other'	Any other inaccuracy that is not covered above e.g. administering a medication with food despite its requirement to be administered on an empty stomach, crushing or splitting an enteric coated or modified

	release formulation, and administering a bisphosphonate with other medications.
MAE - medication administration error; MAR - medication administration record.	

The MAE rate was calculated as the number of observed doses administered (or omitted) in error compared to the opportunities for error (total number of observed doses plus omitted doses).[8, 16] This definition is consistent with previously conducted studies.[5] The British National Formulary[17] was used as a reference, for example, to identify medications with food-specific administration requirements.

Data analysis

The Stata 14 statistical software package was used to analyse quantitative data. Quantitative data were summarized with descriptive statistics such as percentages, medians and ranges as appropriate. A four-level hierarchical Poisson regression model was fitted to the number of MAEs with the total opportunities for error as the rate denominator included as an offset term. The hierarchy observed was observations of a residents' medication administration, i.e. multiple medications per resident, with residents clustered by medication administrator and then within CHs. Type of medication administration system (OP/MCA) was included in the model as a three-category explanatory variable according to CH system as: OP use in OP-only CH; OP use in combination CH (where both OP and MCA are used); MCA use in a combination CH (where both OP and MCA are used). In secondary analyses using the same general model structure, type of CH was included as a binary explanatory variable (nursing CH versus residential CH). Other potentially confounding variables were examined subsequently in a similar fashion. In other secondary analyses, the models were restricted to nursing CHs only. The World Health Organization Anatomical Therapeutic Chemical Classification System (ATC) was used to classify observed administered medications.[18]

Ethical approval

Ethical approval was obtained from the University Research Ethics Committee. Consent was not required from residents in order to observe medication administration, or view their medications and MARs. Residents were provided with study information upon request, or if they enquired about the presence of the pharmacist researcher at the CH. If residents requested that their medication administration was not observed, their wishes were respected. Consent was required from staff who were observed as they administered medications.

RESULTS

Recruitment

Thirty-nine CHs were contacted to recruit 10 (25.6% recruitment rate). Of CHs that provided reasons for non-participation, some reasons included that the CH: already received pharmacy services; had recently changed medication administration system; did not have a patient participation platform to support research; had their own internal audits; and was in the middle of a refurbishment. Of the 10 recruited CHs, eight were classified as nursing and two were residential CHs. As per the purposive sampling strategy, five CHs administered medications only from OP (all nursing) and five CHs administered medications from both MCAs and OP (three nursing and two residential).

Observations

Observations were conducted over a total of 30 days, between October 2014 and June 2015. Medications were observed to be administered to 823 residents during 90 medication administration rounds, lasting a total of approximately 108.4 hours (6,503 minutes) (Table 2). Doses administered from OP were observed at all ten CHs (including CHs that only used OP and CHs that used both MCAs and OP). Doses administered from MCAs were only observed at the five CHs that used both MCAs and OP.

1 Table 2. Medication administration errors by care home.

CH code	1		2		3		4		5		6		7		8		9		10	
CH classification	Nursing		Nursing		Nursing		Nursing		Nursing		Nursing		Residential		Residential		Nursing		Nursing	
CH location in Greater London	Central		Central		South		Central		West		North		North		North		Central		North	
Total days of observation	3		3		3		3		2		4		3		3		3		3	
Total rounds observed	6		8		12		8		6		12		12		7		9		10	
Total time observed (minutes)	538		431		631		768		615		1,056		466		364		737		897	
Staff observed	Nurses		Nurses		Nurses		Nurses		Nurses		Nurses		Carers		Carers		Nurses		Nurses	
Total (different) staff observed	4		5		6		4		3		7		3		3		3		3	
Total residents observed	67		47		78		62		75		166		91		60		84		93	
Medication administration system	OP		OP		OP		OP		OP		OP/MCA		OP/MCA		OP/MCA		OP/MCA		OP/MCA	
Total observed doses	236		142		235		197		241		482		257		196		226		240	
Observed doses by system (OP/MCA)	236	0	142	0	235	0	197	0	241	0	152	330	60	197	35	161	40	186	47	193

Total omitted doses by system (OP/MCA/unsure*)	2	0	0	1	0	0	5	0	0	0	0	0	5	0	0	2	0	2	6	6	8	0	0	0	0	0	1	0	0	3
Total opportunities for error (OP/MCA/overall)	23	0	238	14	0	143	24	0	240	19	0	197	24	0	246	15	33	486	66	20	277	35	16	196	40	18	227	47	19	243
Total MAEs (OP/MCA/unsure)	5	0	0	5	0	0	21	0	0	16	0	0	39	0	0	18	6	2	13	15	8	6	1	0	4	5	1	4	6	3
Overall MAE rate per CH (%)	2.1			3.5			8.8			8.1			15.9			5.3			13.0			3.6			4.4			5.3		

CH - care home; OP - original packaging; MCA - multi-compartment compliance aid; MAE - medication administration error.

* cannot infer which medication administration system the medication would have been administered from (because both OP and MCAs were being used at the CH)

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Overall, each medication administration round lasted a median of approximately 65 minutes (range: 8-245 minutes). The median duration of the breakfast round was 118.5 minutes (range: 50-245), lunch 40 minutes (range: 13-90), dinner 63 minutes (range: 8-115), and the median duration of extra morning or afternoon rounds observed was 23 minutes (range: 15-23) (all approximates).

Of the 823 residents whose medication administration was observed, 338 residents were observed once and 485 residents were observed more than once. Six hundred and seventy two residents were living in nursing CHs while 151 were living in residential CHs. The average resident was female (61.8%) and 82 years old (range: 24-103 years). Of the 3,715 medication items prescribed on MARs for each unique resident observed, medications in tablet or capsule form comprised 66.9% (n=2,487) of all items.

Of the 41 different staff observed to be administering medications, 35 were female and 6 were male, 35 were nurses and 6 were carers (Table 2). Observed staff had worked in CHs for a median of 72 months (range: 3-336). Observed staff had obtained their original nursing or carer qualifications in the UK (n=17), Philippines (n=5), Romania (n=5), South Africa (n=3), Kenya (n=2), Pakistan (n=2), India (n=2), Spain (n=1), Nigeria (n=1), Greece (n=1) Poland (n=1), and unknown (n=1).

Of the 2,452 doses observed, 1,385 were administered from OP and 1,067 were administered from MCAs, and 1,999 were administered in nursing CHs and 453 in residential CHs (Table 2). According to medication administration round, 1,633 doses were observed during breakfast, 273 during lunch, 528 during dinner and 18 during extra morning or afternoon medication administration rounds.

Of the 2,665 medication types observed to be administered (where certain combination medications were counted as two separate medication types e.g. vitamin and mineral combinations), the top five medication classes observed were analgesics (12.3%, n=327), vitamins (10.5%, n=279), minerals (7.2%, n=193), antithrombotic agents (7.1%, n=190) and medications for acid related disorders

(6.6%, n=176). Psycholeptics, such as antipsychotics, anxiolytics, hypnotics and sedatives, comprised 3.3% (n=87) of observed administered medications.

Of the 2,452 doses observed, 8.0% (n=196) of tablet doses were crushed (whether appropriate or not), 28.4% (n=696) were not observed (by nurses or carers) to be consumed by the resident, 3.1% (n=75) were refused by the resident, and 4.3% (n=105) were not signed for after medication administration.

Medication administration errors

One hundred and seventy eight doses did not correlate with information contained on the MARs (i.e. were MAEs). A total of 2,493 opportunities for error were identified, leading to an overall MAE rate of 7.1% (178/2,493) (Table 3). MAE rates ranged from 2.1% to 15.9% by CH (Table 2).

1 Table 3. Medication administration errors by type of medication administration system.

	Total	**OP** (from both OP-only CHs and CHs that used both OP and MCAs)	**MCA**	**RR** **(95%CI, p value)**	**OP** (from OP-only CHs)
Number of observed doses	2,452	1,385	1,067		1,051
Number of omitted doses	41	21	6		13
Opportunities for error (observed + omitted doses)	2,493	1,406	1,073		1,064
Number of MAEs*	178	131	33		86
Rate of MAEs per number of opportunities for error (%)	7.1	9.3	3.1	3.9 (2.4 to 6.1, p<0.001)	8.1

OP - original packaging; MCA - multi-compartment compliance aid; MAE - medication administration error.

*cannot infer which medication administration system the medication would have been administered from (as a result of the CH using both MCAs and OP), therefore 14 MAEs of omission could not be assigned to either MCA or OP

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A statistically significant higher MAE rate of 9.3% was seen for solid, orally administered medications in tablet or capsule form administered from OP (from OP-only CHs and CHs that used both MCAs and OP) when compared with 3.1% for MCAs (RR=3.9, 95%CI 2.4 to 6.1, p<0.001; see Table 3 and Table 4). Similar differences were found when comparing the MAE rate between OP from OP-only CHs and MCAs, and when comparing MAE rates between OP and MCAs only considering CHs that used both MCAs and OP (Table 4).

A statistically significant difference did not exist in MAE rates between OP from OP-only CHs and OP from CHs that used a combination of MCAs and OP, nor between CHs that administered medications from a single medication administration system (OP-only CHs) and CHs that used a combination of systems (MCAs and OP) (Table 4).

The same conclusions were reached when the two (out of ten) residential CHs where carers administered medications instead of nurses (a potential confounding factor) were removed from analyses.

In CHs that used a combination of MCAs and OP, a statistically significant difference did not exist in MAE rates between medications administered by carers and nurses for either MCA (RR for carers v. nurses=1.5, 95%CI 0.4 to 5.1, p=0.51), OP (RR=1.8, 95%CI 0.9 to 3.4, p=0.08) or overall medication administration (OP and MCAs) (RR=1.8, 95%CI 0.9 to 3.3, p=0.08).

Residents' age and gender and the type of medication administration round were not statistically significantly related to the MAE rate (data not shown). Compared to administering one medication dose, administering two or more doses resulted in a lower MAE rate (RR=0.643, 95%CI 0.41 to 0.97, p=0.043). None of the medication administrator factors (the length of their experience or their gender) and the duration of the medication administration round, were statistically significantly related to the MAE rate (data not shown).

Of the 178 doses observed to be administered (or omitted) in error, the top three most common MAE types included timing inaccuracy (2.9% error rate, n=73), omission (1.6%, n=41) and wrong dose (1.2%, n=29) (Table 5).

Table 4. Medication administration errors by source of medication administration system; relative risks comparing error risks between OP and MCA in OP-only care homes and care homes that used both systems.

Source of OP RR (95%CI)		Source of MCA	P value
OP-only CHs	**CHs that used both OP and MCAs**	**CHs that used both OP and MCAs**	
3.9 (2.4 to 6.1)		Reference	<0.001
2.3 (1.1 to 4.9)		Reference	0.03
	4.3 (2.7 to 6.8)	Reference	<0.001
Reference	1.8 (0.9 to 3.8)		0.10
1.3 (0.6 to 2.7)	Reference		0.44

CH - care home; OP - original packaging; MCA - multi-compartment compliance aid; RR - relative risk.

33 Table 5. Medication administration error types.

	OP Total opportunities for error = 1,406		MCA Total opportunities for error = 1,073		Unsure*	Totals Total opportunities for error = 2,493 (OP+MCA+unsure)	
	n	MAE rate %	n	MAE rate %		n	MAE rate %
Omission	21	1.5	6	0.6	14	41	1.6
Allergy inaccuracy	0	0	4	0.4		4	0.2
Wrong dose	24	1.7	5	0.5		29	1.2
Un-prescribed medication	3	0.2	0	0		3	0.1
Medication incorrect	7	0.5	0	0		7	0.3
Formulation incorrect	7	0.5	0	0		7	0.3
Timing inaccuracy	57	4.1	16	1.5		73	2.9
'Other'	12	1.8	2	0.2		14	0.6

OP - original packaging; MCA - multi-compartment compliance aid; MAE - medication administration error.

*cannot infer which medication administration system the medication would have been administered from (as a result of the CH using both MCAs and OP), therefore 14 MAEs of omission could not be assigned to either MCA or OP

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The top three most common World Health Organization Anatomical Therapeutic Chemical Classification System (ATC) codes involved in MAEs were anti-bacterials for systemic use (23.0%, n=41), anti-parkinson medications (22.5%, n=40) and analgesics (18.0%, n=32).

A number of potential contributing factors (and the MAE types they contributed to) were observed, including: medications not supplied by the pharmacy or duplicate MAR medication entries (omission); administering a particular medication from both an MCA and an OP to the same individual (wrong dose); transcription errors between old and new MARs (un-prescribed medication); newly commenced medications not recorded on the MAR (un-prescribed medication); lengthy medication administration rounds (timing inaccuracy); delayed medication administration round start times (timing inaccuracy); administering medications with meals ('other' errors); and staff forgetting to administer bisphosphonate medications earlier in the day requiring later administration with other medications ('other').

Five main barriers and related facilitators were identified during medication administration observations, involving the resident, workplace, pharmacy, medication trolley and MAR. Firstly, it was observed that residents did not always cooperate with staff administering medications and experienced unpredictable mood fluctuations that impacted on their level of cooperation. To overcome this barrier, staff administering medications familiarised themselves with individual resident medication-taking preferences (e.g. consuming medications with certain food or drink) and used strategies to encourage medication consumption (e.g. calming music). Secondly, staff administering medications were often interrupted, distracted and delayed. Interruptions and distractions were especially evident when administration occurred in communal living spaces such as the CH dining room, where other residents, CH staff or visitors could easily interrupt or distract staff administering medications. Additionally, medication administration was often delayed by residents receiving personal care. To overcome this barrier, medication trolleys were parked away from communal meeting areas, and staff who were providing personal care were notified of medication

administration schedules in advance. Thirdly, medications were sometimes missing from pharmacy deliveries, which CH staff promptly followed-up via telephone. Fourthly, medication trolleys were sometimes disorganised and lacked equipment necessary for medication administration. This barrier was overcome by staff ensuring that medication trolleys were adequately organised and equipped prior to leaving the medication room and commencing medication administration, and using items such as trays or buckets to facilitate organisation. Lastly, MARs were sometimes disorganised, or had unclear or inaccurate medication information. This barrier was overcome by staff allocating time to tidy MARs and editing information contained within them where necessary (including asking the pharmacy to assist with amendments).

DISCUSSION

This is the first published study specifically designed to compare, and subsequently identify a statistically significant difference in, the MAE rate between solid, orally administered medications in tablet or capsule form administered from OP and MCAs.

The overall MAE rate identified in the current study (7.1%) is lower than that reported by others (8.4% - 21.7%).[2, 7] This may be due to differences in the dosage forms observed (all dosage forms-other studies, compared with only oral dosage forms-the present study), research professionals involved, definitions of MAE and research methods used. For example, Barker *et al* involved nurses and pharmacy technicians who directly observed MAEs in all administered medications;[2] Szczepura *et al* used a disguised observation technique and analysis of deviations between prescribed medications and dispensed items prior to administration;[19] Van den bemt *et al* also used a disguised observation technique and considered the lack of supervision of medication consumption as a MAE;[20] and Scott-Cawiezell *et al* did not include 'timing inaccuracy' as an error.[21] However, the top three types of MAE identified in the current study are similar to other studies.[7, 19, 20] No statistically significant differences were observed in MAE rates between nursing and residential CHs, which is comparable to CHUMs,[1] which used the same methodology as the current study. In contrast,

Szczepura *et al* found that the potential MAE rate was higher in nursing CHs compared to residential CHs.[19] However, the current study was not designed to detect such a difference and only two residential CHs were included in the sample.

The statistically significant difference in MAE rates between OP and MCAs remained, even when the potential confounding factor of using more than one medication administration system at the CH was considered in analyses, as well as the type of CH (nursing or residential). A significant difference in MAE rates was not identified when comparing medication administration between CHs that only used one medication administration system (OP) and CHs that used more than one system (OP and MCAs). This indicates that using both OP and MCAs (as occurs in the majority of CHs in the UK) does not lead to significantly higher MAE rates. Additionally, this indicates that there are unique factors associated with using OP that contribute to their higher MAE rate. Future research should explore what these unique factors are (and how they influence MAEs), alongside one obvious factor of nurse or carer freedom of choice associated with administering medications from OP compared to pre-prepared MCAs. Although this study was not designed to explore this, the study findings suggest a higher MAE rate (although not statistically significant) when carers administer medications compared to nurses (as is becoming increasingly common in UK CHs).

Implications for policy and practice and further research

This study provides direction to CH staff and pharmacy and nursing organisations that are involved in evaluation and quality improvement of CH medication administration systems. The overall MAE rate (7.1%) identified in administered tablets and capsules, which comprised the majority of prescribed medication forms contained on the MARs (66.9%), highlights that tablets and capsules are susceptible to MAEs, despite anecdotal perceptions that MAEs predominantly involve complex medication forms (e.g. injections, inhalers). Study findings support local CH policy and practice change that incorporates investigation of tablet and capsule impact on medication administration errors and staff training to prevent errors occurring. The significant difference in MAE rate between

OP and MCAs, highlights the importance of specifically targeting these medication administration systems in CH quality improvement activities. Study findings support the use of MCAs in CHs that may be experiencing high MAE rates. Additionally, CH medication management guidelines, such as the National Institute for Health and Care Excellence Managing Medicines in Care Homes guidelines (written in the context of health and social care in England)[22] and pharmacy guidelines[12, 23, 24] could also include greater direction regarding MAEs that could result from using these systems. For example, a comprehensive list could be provided of the types of MAEs that can occur during medication administration (e.g. MAE types included in Table 1) and barriers that may contribute towards MAEs. Additionally, the lack of a significant difference in MAE rates between CHs that administered medications from a single medication administration system (OP-only) and CHs that used a combination of systems (OP and MCA), or between nurse and carer-administered medications, indicates that CHs can continue practicing medication administration using a combination of systems and staff qualifications, as is commonly seen in UK CHs, without being concerned about a significant increase in MAEs (compared to only using OP or nurse-administered medications). The finding that administering two or more doses resulted in a lower MAE rate warrants further research before it discourages CHs from exploring opportunities and benefits of de-prescribing (reducing the number of medications a resident is prescribed).

A root cause analysis of identified MAEs was not conducted in this study. However, the five main barriers that were observed during medication administration provide important contextual information. While it is not certain whether these barriers influenced MAEs, it is clear that they did not facilitate the medication administration process. For example, if residents are uncooperative during medication administration and staff become flustered, they could fail to notice medication formulations as recorded in MARs and try to facilitate administration by crushing controlled-release medications ('other MAE'). If staff are interrupted or distracted, they could lose their train of thought and inadvertently give double the dose of a medication (wrong dose). If pharmacies fail to supply the entire medication delivery, or medication trolleys are inadequately equipped with all

medications and staff do not notice, they could inadvertently omit a medication (omission). If MARs do not include clear information about medication administration times, staff could inadvertently administer medications at the wrong time of day (timing inaccuracy).

Future research should involve a larger CH sample, across the UK, to determine whether observed barriers exist outside this study sample and the impact of these barriers on MAEs. A comprehensive list of strategies that can be used to overcome related barriers should be developed and shared among CHs. Additionally, when updating local medication administration CH policies and practices, it would be beneficial to explore what barriers exist and what local strategies can be implemented to overcome them. This proactive, facility-wide approach has the potential to more efficiently and effectively facilitate medication administration, as opposed to relying on individual CH staff to be aware of barriers and facilitative strategies and to put them into practice.

Future research could consider the potential for pharmacists to observe medication administration rounds to gain a greater understanding of associated problems,[25] and also explore potential risks associated with medication crushing and failing to observe medication consumption. Paradiso *et al* found that in 34% of medication administration observations in 10 Australian CHs, at least one medication was altered (e.g. crushed).[26] Of these altered medications, 17% had the potential to cause increased toxicity, decreased efficacy, unpalatability, safety or stability concerns.[26] It was recommended that regularly updated medication lists are developed, to highlight medications that should not be altered and alternative medication formulations that are available.[26]

Strengths and limitations

It is a strength that a large number of staff (n=42) were observed to administer medications to a large number of residents (n=823) over a large number of medication administration rounds (n=90). Additionally, this study involved a single research pharmacist directly observing medication

administration to identify MAEs compared to potentially less efficient and accurate methods of using nursing staff to review medication records and incident reports.[4]

A small sample of CHs (10) located around Greater London was involved in this study, limiting generalisability of findings. Confounding factors that were not explored in this study (e.g. complexity of CH residents, education and training of CH staff, type of MCA or medication ordering system in use and the model of care provided by the CH) may have contributed to the wide and overlapping ranges of MAE rates between CHs that only used OP (2.1% to 15.9%) and CHs that used both OP and MCAs (3.6% to 13.0%). There is also the potential for researcher presence to influence the MAE rate, although this may not be a substantial bias.[27] The clinical significance of MAEs was not determined in this study, however, there is currently no consensus on the relative importance of different types of MAE in CHs.[19] Previous research has classified dispensing errors associated with preparing MCAs, according to their potential risk of causing an adverse event in the CH resident.[28] Additionally, discrepancies were identified by comparing administered medications with the MAR (instead of the original medication prescription). Finally, this study did not observe medications other than for solid, orally administered tablets and capsules. Alldred *et al* identified that medication formulations other than tablets and capsules are particularly at risk of being administered incorrectly.[29] Therefore the findings of this study alone cannot be used to determine the most appropriate medication administration system for individual CHs, especially by those considering changing their current system.[30]

CONCLUSION

The significant difference in, and high overall, medication administration error rate between original medication packaging and multi-compartment compliance aids supports the use of the latter in care homes, as well as local investigation of tablet and capsule impact on medication administration errors and staff training to prevent errors occurring. As a significant difference in error rate was not observed between use of a single or combination medication administration system, common

practice of using both multi-compartment compliance aids (majority of medications) and original packaging (medications with stability issues) is supported. Findings can inform local care home practice, as well as professional body and Government policies.

ACKNOWLEDGEMENTS

(see Cover Letter)

DECLARATION OF INTEREST

Conflicts of interest: none

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