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TITLE PAGE

A case study investigation into the use of multi-compartment compliance aids in older people resident in very sheltered housing

RUNNING TITLE

Use of multi-compartment compliance aids in older residents of very sheltered housing

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ABSTRACT

Background

Multi-compartment compliance aids (MCAs) are repackaging systems for solid dosage form medicines, heralded by some as a solution to non-adherence but with little evidence of benefit.

Objective

To use a theoretical approach to describe the behavioural determinants impacting the use of MCAs in older people from the perspectives of the individual and health and social care providers.

Design

A case study investigation.

Setting

Three very sheltered housing sites in North-East Scotland.

Subjects

Twenty residents (≥ 65 years) using an MCA for at least six months and 34 members of their care team (17 formal carers, 8 general practitioners (GPs), 8 pharmacists, one family member).

Methods

Semi-structured, face to face interviews with items based on the Theoretical Domains Framework. Interviews were audio-recorded, transcribed and analysed thematically.

Results

Several behavioural determinants impacted the use of MCAs from the perspectives of the stakeholders involved. Goals of use related to promoting adherence and safety, with less emphasis on independence. Beliefs of consequences related to these goals and were considered of value, with additional consequences of concern around reduced awareness of medicines and complexities of changing medicines. There was a lack of clearly defined roles of professionals for all processes of MCA use, with evidence of blurring and gaps in roles. There were additional issues relating to capabilities of older people in using MCAs and capacity issues for pharmacy supplied MCAs.

Conclusions

Several behavioural determinants impacted the use of MCAs and while MCAs were valued, there is a need to more clearly define, develop, implement and evaluate a model of care encompassing resident and medicines assessment, supply and ongoing review of MCAs.

Key points

1. Several behavioural determinants impacted the use of MCAs in older people within very sheltered housing
2. While valued, there were concerns of reduced awareness of medicines and complexities of changing medicines
3. There was a lack of clearly defined roles in all MCA processes, issues of capabilities of older people and pharmacy capacity.

Keywords

Multi-compartment compliance aids; older people; sheltered housing; case study; behaviours

1. INTRODUCTION

In 2009, the Scottish Government developed a strategy for improving the quality and outcomes of current models of care for older people to ensure that they are valued as an 'asset', that their voices are heard and that they are supported to enjoy full and positive lives in their own home or homely setting [1]. Giving voice to the individual is congruent with community care legislation which has at its core the 'ability of individuals to articulate their own needs' [2]. This emphasis on inclusion is integral to the personalisation agenda [3] where 'people become more involved in how services are designed and receive the support that is most suited to them' [4]. More recently the focus for the support of older people has been based on themes of enablement to assist them to 'either learn or re-learn those skills needed for a successful and fulfilling life' [5].

Enablement, appropriate support and articulation of need are of direct relevance to the management of medicines. Given the prevalence of multimorbidity [6,7] and the emphasis on evidence based therapeutics, older people are likely to be prescribed multiple medicines. Recent United Kingdom data highlighted that 20.8% of those with two clinical conditions were prescribed four to nine medicines, and 1.1% of patients ten or more medicines [8]. Promoting appropriate polypharmacy (defined as appropriate prescribing of many medicines) [9] through concordant models of care should be a key goal in older people.

Overprescribing has serious consequences of increasing the likelihood of adverse drug reactions and hospitalisation [10,11]. Medicines adherence, defined as 'the process by which patients take their medicines as prescribed, composed of initiation, implementation and discontinuation' [12], may also be impacted. Medicines adherence is a 'complex multidimensional behaviour' [13], with non-adherence estimated to be prevalent in 47% to 100% of older people [14]. Key factors related to unintentional non-adherence are complex medicines regimens, poor memory and cognition [15].

Multi-compartment compliance aids (MCAs) are repackaging systems for solid dosage form medication, which are removed from manufacturer's original packaging and repackaged into the MCA [16]. While these are heralded by some as a solution to non-adherence, the Royal Pharmaceutical Society of Great Britain has stated that pharmacy supplied MCAs have 'become regarded as a panacea for

medicines use and often integrated into practice and service policy without giving due consideration to the alternatives' [16].

Despite their use, there is scant evidence that MCAs improve medicines adherence or lead to greater involvement in decision making [17-19]. Nunney *et al.* reported a qualitative study of older people living independently in the community and an unrelated sample of health professionals involved in the supply of MCAs [20]. Key findings were that maintaining independence and control over medicines was important but that MCAs were often initiated without any systematic assessment. To date, no published studies have employed a case study approach to study MCA use in a targeted population of older people. Furthermore, there is notable absence of any theoretically based studies hence insufficient understanding of the behavioural determinants of MCA use.

The aim of this research was to use a theoretical approach to describe the behavioural determinants impacting the use of MCAs in older people resident in very sheltered housing from the perspectives of older people, their families and health and social care providers.

2. METHOD

2.1 Design

This was a case study investigation, described as a 'wrapper for different methods' [21] or a means with which 'to explain present circumstances...[through]...in-depth description of social phenomenon' [22]. The case study approach seeks to understand a phenomenon (MCA use) in-depth through empirically gathered data.

2.2 Inclusion and exclusion criteria

Multiple case studies were conducted in North-East Scotland focusing on residents of very sheltered housing (VSH) aged 65 years or over who had been using an MCA for at least six months. Sheltered housing is a United Kingdom term covering a wide range of rented housing for older and/or disabled or other vulnerable people. VSH generally has all the features of sheltered housing, but has a greater level of care and support offered through the service of extra wardens, full-time carers, assistance with everyday living and the provision of meals [23]. Potential participants were identified by the VSH senior carer who also screened and excluded residents with significant cognitive or welfare issues.

2.3 Recruitment

The primary care lead pharmacist (who was known to the VSH senior carer) invited verbally each of the screened residents to take part in a face-to-face, audio-recorded, semi-structured interview of approximately 15 minutes duration. The content of the study information leaflet was discussed and their questions answered before informed, signed consent was taken and the interview arranged for a time convenient to the participant.

2.4 Data generation

Interviews, which were conducted by a senior researcher with extensive experience in qualitative interviewing and iterative techniques, took place either within the resident's home or a quiet space within the VSH. Residents participating were asked to name people in their care team involved in any aspect of MCA use who could also be interviewed for this research. They were prompted by the researcher with suggestions of formal carers within the VSH, their general practitioner (GP), pharmacist, family and friends or others. The researcher contacted all of the identified individuals, with no exclusions, provided information and invited their informed consent prior to arranging a time convenient to them for a face-to-face or telephone interview of approximately 15 minutes duration.

2.5 Interview schedule

The questions in the semi-structured interview schedules were developed from the Theoretical Domains Framework (TDF) which includes constructs from 33 behaviour change theories, and proposes that determinants of behaviour are clustered into 14 domains of: goals; beliefs about consequences; intentions; professional role and identity; knowledge; beliefs about capabilities; environmental context and resources; skills; optimism; reinforcement; memory, attention and deficit processes; social influences; emotions; and behavioural regulation [24,25]. Use of this framework ensured that a wide range of theoretical explanations for behaviour were considered. Two interview schedules were collectively developed by the research team: one for residents; one for the others. Each interview schedule was reviewed independently for credibility by an expert panel four individuals with expertise in health services research and use of the TDF.

The schedule for the resident focused on: when and why an MCA was first introduced; who was involved in making that decision; how the MCA was used and any difficulties encountered; perceptions of benefit; and any monitoring or

review undertaken. The schedule for the care team was similar, with additional coverage of: any resident or medicines assessment undertaken prior to introducing the MCA; perceptions of the roles of other members of the care team in MCA use; and general comments on the use of MCAs in older people.

2.6 Data handling

Audio-recordings were transcribed verbatim and checked for transcribing accuracy by a member of the research team. Members of the research team met to agree consistency of the initial coding framework. Transcripts were analysed independently by three researchers using the Framework Approach following the five steps of: data familiarisation; identifying constructs; indexing; charting; mapping; and interpreting [26].

2.7 Ethical approval

This study had formal approval from the NHS North of Scotland Research Ethical Review Service (14/NW/1168) and NHS Grampian Research & Development Committee (2014RG002).

3. RESULTS

Twenty interviews were conducted with residents at three sites (A,B,C). All of the residents were aged 65 and over, and 15 were female. Further interviews were conducted with people in the residents' care team which included: formal carers (17), GPs (8), pharmacists (8) and one family member.

Key themes are described in relation to TDF domains.

3.1. Goals of MCA use

While carers, GPs and pharmacists described a number of the goals they hoped to achieve by using MCAs, residents were generally less aware of the goals.

3.1a. Adherence

One goal cited by many was to promote medicines adherence, particularly given the number of medicines residents were likely to be prescribed and their potential physical and cognitive issues.

“To help bring some rationality and repetitive drug taking that is the chaos of most people's multiple pharmacy.” (GP 1 at C)

"Just to make it easier for people to handle their medicines, be it if they've got memory problems or too many medicines for them to cope with...hand issues...sight problems also." (Pharmacist 1 at C)

"It's a weekly dosage system, an aide memoire to the person to tell them what time of the day their medications due, what pill they're supposed to take at that time." (Carer 2 at C)

3.1b. Safety

Promoting safe use of medicines was also a goal, cited largely by carers. Residents were described as being at potential harm due to the number and types of medicines, and that these were reduced through MCA use,

"The safety of the resident as well, I think, if they've got loads of medications then it's easier just to have it in the one little thing instead of spread out..." (Carer 1 at B)

3.1c. Independence

Fewer interviewees described goals related to promoting resident independence, described in the context of both medicines adherence and promoting resident safety,

"...it keeps people independent for longer I think. Sometimes if you're just able to work it out and make it a bit simpler for them they're able to stay at home and not do themselves any harm." (GP 1 at A)

3.2. Beliefs of consequences of MCA use

Several of the beliefs of consequences of using MCAs were also closely related to the goals of adherence and safety.

3.2a. Adherence

Many interviewees, including several residents, noted the enhanced adherence,

"Well they make certain that people who might not have full comprehension don't take their tablets at the wrong time and in the wrong sequence." (Resident 3 at B)

3.2b. Safety

Carers, GPs and pharmacists described MCA use resulting in reduced potential for harm, particularly in vulnerable residents,

“It's somebody else's life you're dealing with and some people are on an antipsychotic medication, so you've got to be very careful what you're doing, so it's definitely a good idea.” (Carer 4 at A)

“Quicker and easier for them...and various issues around patient safety...” (Pharmacist 2 at B)

“I think it can take away the stress...it can be a safer way of doing it.” (GP2 at A)

3.2c. Independence

While few had mentioned independence as a goal of using MCAs, several viewed that enhanced resident independence was a consequence,

“It's about the tenants taking ownership of the medication as well and realising that... it's giving them ownership as well and responsibility.” (Carer 2 at A)

Several additional themes emerged, which had not been described in relation to the purpose or goals of using MCAs.

3.2d. Patient centred care

Several carers believed as a result of the MCA, time was released for them to devote to person centred care. They described that prior to the MCA, they spent much more time assisting the residents with their medicines rather than focusing on the residents themselves,

“ I think it's giving us more time with them and that is I think the benefit of having a blister pack [MCA] is that you're nae [not] having to, 'faff about' with loads of other bottles...and give them your time” (Carer 1 at C)

3.2e. Reduced awareness

One negative consequence was the reduced awareness of the medicines being taken and their indications, described by residents, carers and GPs,

"I don't know what tablets look like to be honest, because I don't see them...I try to describe them when the patient has them..." (GP 1 at B)

"Sometimes we're not 100% aware what the tablets are for..." (Carer 1 at C)

"...I think one is especially at night for sleeping. The other ones is just, I think, vitamins." (Resident 5 at A)

3.2f. Changes to medicines

One consequence which was a major concern was the complexities and associated workload around managing changes in residents' medicines, particularly when this occurred part way through the MCA cycle. This issue was described at length by carers, GPs, pharmacists and some residents,

"Yeah, so you can't identify them. I've seen us getting a phone call to say that a certain tablet has been stopped. Can you remove it from the blister pack [MCA] ? It's a little white tablet, well she's got 3 or 4 of those..." (Carer 1 at B)

"If we go and say 'let's stop this one', and even, if you change it on the computer but don't actually manage to tell the pharmacist, it can lead to problems because they're not aware..." (GP 2 at A)

"At one point, it was like 4, 5 changes a week, so you're talking about 20 boxes are getting redone." (Pharmacist 2 at C)

3.3. Intention to use MCAs

Several GPs were of the opinion that there was a need to increase the use of MCAs in older people,

"...most people over 75 should probably, would probably benefit from a lot of their medicines being in a Dosette [MCA]. It almost should be maybe an opt out rather than an opt in." (GP 1 at C)

3.4. Social and professional roles relating to MCA use

Residents, carers, GPs and pharmacists all described a range of views and experiences regarding their role in the commencement, supply and use of MCAs. It was clear that there were great variations in practice and very little standardisation.

3.4a. Assessment process

In terms of assessing whether or not a resident would be suitable for an MCA, a very mixed picture emerged as to whose role it was,

“Well, the patient, the family and myself probably.” (GP 1 at C)

“And that was discussed with the GP and when they [my parents] came here it was decided...” (Relative of Resident 5 at B)

“Generally, they mostly come from the doctor... and nurses, they've had quite a bit of input recently as well, a few of the district nurses.”
(Pharmacist 1 at C)

One pharmacist described situations where MCAs had been commenced on the instruction of GPs without any systematic assessment resulting in the residents being provided with MCAs that they were unable to use,

“we've started 3 that we didn't assess on the doc [doctor's instructions], because we were told...you know, they don't need assessed and then they haven't been able to use it.” (Pharmacist 3 at A)

One pharmacist expressed concern over the lack of resident involvement in making the decision to commence an MCA,

“But I think we need to be having a bit of two way dialogue and discussing things, getting the patient involved in the decision as well so it's not completely taking that decision away from them.” (Pharmacist 1 at A)

While there was no systematic approach, one pharmacist described how it could operate in practice, focusing on the multidisciplinary team and the resident,

"I think it should be multidisciplinary, it should really be initial assessment to see how they're managing...I think generally should be an approach from a family member and then maybe on to the GP, possibly a health care visitor or a nurse maybe go out and assess it, depending on what level of needs they have." (Pharmacist 2 at C)

3.4b. Reviewing medicines

The review of medicines, as part of the assessment process was uncertain; where it was performed, it was rather opportunistic,

"What medications they're on, yeah. So I think in terms of the blister pack [MCA] review, that's usually pharmacists, relatives, carers, that sort of thing or a GP opportunistically." (GP 2 at A)

"So the patient prescription would get ordered by the pharmacy, doctor would just see the request and they'd just sign it." (Pharmacist 2 at C)

3.4c. Preparation of the MCA

While there was general agreement that preparing the MCA was the remit of pharmacy, it was less clear who should negotiate this with the pharmacy,

"Well the way I usually play it is to say to the patient or the relative it's up to them to negotiate with the pharmacy if they'll agree to do it because obviously, obviously, it's a time element for the pharmacist." (GP 3 at B)

3.4d. Monitoring

Very little emphasis was placed on the role of monitoring the benefits, or otherwise, or the need to continue the MCA,

"...so I guess opportunistically, when you go in to do a house call you can often tell. Sometimes when the pharmacies go in to deliver, it if they find there's maybe three unopened ones in someone's house or relatives see that people are not opening their blister packs [MCAs], we get feedback that way." (GP 2 at A)

3.5. Knowledge impacting MCA use

While there was little discussion of knowledge, several GPs noted that they had no awareness of any alternatives to assist residents with managing their medicines,

“It's hard to know when you don't know what the alternatives are, never worked with alternatives, it's hard to think what they are.” (GP 1 at B)

3.6. Beliefs of capabilities in using MCAs

3.6a. Dexterity

Many residents, carers, GPs and pharmacists described that using an MCA was not always easy for residents or carers and that a high level of manual dexterity was required,

“I would say sometimes, I've, you've got a really little one [tablet] and it sticks in the corner...You've to watch that you get that one, you know.” (Resident 1 at C)

“I've lost a few little eins [ones], dropped on the floor, ken [know] like that thyroid tablets, their teeny [tiny]...They're awful little, if you drop one it's always picked up, know what I mean, they're dirty.” (Resident 4 at A)

“it's sometimes quite difficult, they may all come out at once and may end up on the floor.” (GP 4 at A)

3.6b. Confusion

One carer also described situations where residents had taken the wrong medicine at the wrong time,

“... some have inadvertently popped morning when it should have been night and vice versa.” (Carer 2 at C)

3.7. Environmental context and resources impacting MCA use

Several themes emerged in relation to environment and resources which influenced MCA use.

3.7a. Capacity

Capacity within pharmacies to cope with the demands for MCAs and the resultant workload was a major concern for pharmacists,

“I mean it's something I deal with every day of my life, every minute of the day really. There's always a phone call about Dositte boxes [MCAs]...”
(Pharmacist 3 at A)

While some GPs were aware of the issue they did not understand fully the implications,

“As far as I'm aware most pharmacies just have a capacity issue with the number they can do. What those issues are around that I don't really know but, I guess it's probably quite time consuming to put together...”
(GP 3 at A)

3.7b. Remuneration

Pharmacists did not feel that the current remuneration system was appropriate in terms of rewarding the time and risk involved and did not encourage them to adopt a more clinical role,

“To my mind it doesn't satisfactorily reimburse for the amount of time that goes into the process and it doesn't, it doesn't let us, kind of, let us do what we should be doing which is kind of reviewing patients before they start on the system to make sure the right people are on...” (Pharmacist 1 at A)

4. DISCUSSION

This research employed a theoretical approach to extend the evidence base around MCA use in older people. Key findings are that several behavioural determinants impact the use of MCAs from the perspectives of the stakeholders involved. Goals of use related to the perceived value of MCAs in promoting adherence and safety, with less emphasis on independence. While these were linked to the beliefs of the consequences of use, there were additional consequences which are of concern; reduced awareness of medicines and complexities of changing medicines. There was a lack of clearly defined professional and social roles in all processes of MCA use, issues relating to

capabilities of older people to use MCAs and capacity issues for pharmacy supplied MCAs.

Steps were taken to promote research trustworthiness (e.g. expert review of the interview schedules, triangulation of the perspectives of the residents and members of the care team and iterative questioning) which enhanced the credibility and dependability of the findings [27]. There are, however, some limitations hence the findings should be interpreted with caution. The research was undertaken in North-East Scotland in VSH residents without significant cognitive or welfare issues thus the findings may not be transferable to other populations or health systems. Despite this limitation, some of the findings (e.g. MCAs often initiated without systematic assessment) are similar to that of Nunney *et al.* [20] in a study conducted in England in older community dwelling people.

Our case study based research generated data from multiple sources and perspectives. Older people being valued as assets, articulating their own needs, being involved in service design, staying in homely settings and enablement are core to the Scottish Government '2020 Vision' and associated agendas [1-5]. While MCAs are valued and may support medicines management in older people, through the articulated goals of adherence, safety and independence, the findings indicate that there are key issues from the perspective of residents, carers, GPs and pharmacists which require to be addressed.

The use of the theoretical framework (TDF) has allowed greater understanding of the determinants of MCA use and the different perspectives of those involved. Issues of medicines management generally and non-adherence specifically are likely to be prevalent in older people in VSH settings and MCAs are often seen as solutions [3]. This was evident from this research in that promoting adherence and patient safety were cited as goals which impacted the decision to commence MCAs. However, there was little clarity over who was or should be involved in that decision or the factors considered. The processes of patient assessment for suitability, review of medicines, communication within the health and social care team and with the resident, supply of the MCA and review of any benefit in relation to the goals seemed uncertain, blurred and often absent. However, all interviewees expressed views in relation to their beliefs of the consequences of MCAs, indicating that these were considered to be valuable in resident care. These positive consequences centred on adherence, safety and independence

with negative consequences around managing changes in medicines, reduced awareness of medicines and perhaps reduced resident independence. However, it was evident that there was a lack of alternatives so starting an MCA was perceived to be the only option.

While MCAs were valued, there is a need to more clearly define, develop, implement and evaluate a model of care relating to MCAs. This is warranted given the demographic change of the population hence the likely increasing demand for pharmacy supplied MCAs, as described by several interviewees. One benefit of the theoretical focus of this research is that specific behavioural determinants can be linked to change strategies and indeed evidence suggests that TDF-based interviews may encourage respondents to identify barriers that they would not otherwise disclose [28]. Cane *et al.* have aligned behaviour change techniques mapped to TDF behavioural determinants as an aid to characterising and designing behaviour change interventions [29]. For example, while information provision via education and training may be relevant to change knowledge and skills, altering beliefs of consequences may require persuasive communication and monitoring the consequences of one's own behaviour. Changing aspects of the professional role and identity and the environmental context and resources will be much more complex involving remodeling of health and social care structures and processes. Another theoretical framework worthy of consideration in remodeling is

Further research should now focus on a larger scale study to confirm the key determinants before developing, implementing and evaluating a model of care to meet defined and agreed goals. The model of care should encompass: the identification of individuals who may benefit from an MCA; review of the medicines; assessment of capability to use an MCA; issues relating to supply; and review of benefit. Given the lack of published evidence in this area, the first stage of development should involve all the key stakeholders (particularly older people and their carers) using a consensus based approach.

In conclusion, this study has identified that several behavioural determinants impact the use of MCAs in older people within VSH and that while these are valued, there is a need to more clearly define, develop, implement and evaluate the model of care.

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Conflicts of interest

DS, KM, JM, KFM, VP, SC, AS and RL confirm that they have no conflicts of interest to declare.

Compliance with Ethical Standards

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