Older people's experiences of changed medication appearance due to generic prescribing: a qualitative study

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SUMMARY REPORT

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Full report available from http://usir.salford.ac.uk/7203/

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Introduction

Research was undertaken in response to requests by older people in Rochdale Borough to investigate an issue of great concern to them namely prescription medications constantly changing appearance due to generic prescribing. When branded drugs are still in their 'patent' period, which is a number of years after they are introduced into the market, there is only one sole supplier. Expiration of this period allows other manufacturers to 'mimic' the branded product, at a fraction of the cost. It is an NHS directive for prescribers to use the generic drug name when a drug is prescribed unless there is a clinical justification for using the brand name.

When people receive their tablet medicines from their pharmacist, the brand and so the appearance (colour, size, shape) can be vastly different to those dispensed following their previous prescription despite having the same active ingredient. This is often due to a lack of standardisation practice required amongst manufacturers. Drugs are made to British and European Pharmacopoeia standards but these do not specify colour, size and shape. Medicines are required to be of 'essential similarity' but that does not include appearance. Many pharmacists believe that standardisation, should not only include size, shape, colour but also packaging. Packaging changes from the same company on consecutive orders presents considerable challenge to pharmacists as well as patients.

Older people from Rochdale User Carer Action Forum initially suggested the topic of changed appearance of medications as a focus for research. They provided anecdotal evidence of the problems experienced by some older people as a result of frequent changes in size, colour and shape of tablet medications in particular. They reported that these changes had caused some older people anxiety, confusion and distress. They also believed some drug errors were occurring with a risk of hospitalisation as a result. In response, an initial survey funded by the University of Salford was undertaken with 2000 older people across Greater Manchester which supported many of these claims (Williamson *et al* 2009) [available from http://usir.salford.ac.uk/2989/]. Funding was found from the Greater Manchester Primary Care Trust Alliance through the Older People's Network to support a qualitative study to gain deeper insights into the problems of changed medication appearance. Older people from the Rochdale User Carer Action Forum acted as study advisors.

The study

The aims of the study were:

1. To design a qualitative study in partnership with older people to elicit older people's experiences in relation to changed medication appearance
2. To identify any impact on older people's personal approach to medication management as a result of changed medication appearance

The study was a patient experience study as opposed to a study of pharmaceutical or prescribing practices.

Following recruitment undertaken at the same time as an earlier survey (Williamson *et al* 2009), 32 participants taking three or more prescribed tablet medications and aged between 62 and 88 years of age from across Greater Manchester, expressed an interest in being interviewed about their views of changed medication appearance. Interviews were face-to-face and digitally audio recorded with almost half being video recorded. Participants were an almost even mix of men and women.

Findings

After careful thematic analysis, three categories and one core category emerged from the data. These are ***the importance of routine***, ***confidence***, ***being old*** and a core category of ***retaining control***. The categories illustrate the concerns raised by participants surrounding the impact of changes in medication appearance on their medicines management. The categories highlight their need for maintaining routine and the impact of appearance changes on confidence at a personal level, in others (health care professionals) and with the medications themselves. Participant's held shared perceptions about 'being old' and how these influenced their management of the appearance changes. The core category of ***retaining control*** is reflected throughout all other categories and illustrates how participants seek to maintain stability with their medicines management through such measures as avoidance of changes in appearance or by adapting to change through information.

Findings revealed that these older people were challenged by the changes in their medications which impacted on their confidence and forced them to repeatedly double check their medicine regimes. The older people we interviewed felt they were only able to cope with the changes in medicine appearance due to their own diligence and because they had capacity to do so. Most were very concerned that as they became older and their capacity to self-manage medicines reduced, that they would be at risk of medication errors. They also believed there were many older people less capable than themselves who were already struggling to cope with medicine appearance changes.

One participant said "You wouldn't buy an orange cabbage would you?" to illustrate how disconcerting they found changes to their established medicines.

The importance of routine:

In nearly all cases participants had a regimented routine which they maintained despite any medication changes. Their routine was the bedrock of their medication management and provided a 'security blanket' which they used to help remain in control of their tablets. Any change to medication appearance threatened this position and prompted participants to reassess their medications and question or double check their routine. Thus the impact of the

appearance changes varied. From the outset, it became evident that although the participants generally felt that they had little or no actual problems as a result of the changes, they had impacted on their daily medication administration in a number of ways. Many had to double check their tablets and some felt the need to contact the pharmacist or GP about them whilst a number of participants questioned the rationale for the changes. Their main concerns related to colour change. Some felt that the size, accessibility of packaging and naming of the tablets was frustrating. Generally, the participants said that they managed the changes satisfactorily but were clearly tired of keeping up with the frequency of the changes they experienced.

In all cases, the participants demonstrated how they managed their tablets through complex administration systems, through to simple cardboard boxes and counting out morning, afternoon and evening tablets. The range of routines displayed throughout the project was extensive and many participants prided themselves on their control and organisation of their medication. As can be expected, those with more medications to take than others found appearance changes more challenging.

Changes in colour

Changes in medication colour were by far the most common changes noted by the participants. Although many did not refer to these as major problems they did confess that these changes cause some concern. Interestingly, colour was viewed as a particularly important factor in the management and control of self-administered medication. For many, colour was used to denote a particular tablet – for example, some participants referred to “I take the blue one first and then the pink”.

Changes in shape

With nearly all participants, a good routine was essential in order to maintain their medicines management. Shape was important in recognising tablets but not as much as colour.

Changes in packaging

Whilst the focus of this study is on appearance of medications themselves, some participants raised changes in appearance of packaging as an issue. Some packets changed to have similar colours and shape to others which again made it difficult for the participants to discern one medication from another

Managing access

In some cases, participants reported difficulty in physically accessing their tablets due to a change in the cover of the tablets. For those participants with arthritic thumbs access to some tablets was especially difficult. Others dropped tablets as they were considered ‘fiddly’.

Confidence:

Confidence became a significant category and was broken down into three sub categories.

Confidence in self

Over the duration of the study, it became apparent that the participants needed to be confident in a range of areas. The frequent changes in medication appearance hampered their confidence that they had previously formed through their medicines management routine, knowledge of medication and confidence in health professionals. For some, loss of confidence also extended to their beliefs about the quality and effectiveness of a drug. These different sources of reduced confidence compounded to reduce self-confidence generally.

Confidence in others

For the vast majority of participants, any medication changes could be readily checked with the pharmacist or the GP. Most of the participants felt confident in contacting their GP or pharmacists for advice. The helpfulness of pharmacists in relation to responding to queries was strongly evident across most of the interviews. Some participants did not check any changes with health care professionals because they had faith in their GP and were confident that the tablet content would be the same. Participants warned that not all older people physically went into a pharmacist nor were able or comfortable in using a telephone to gain advice from a pharmacist, and so may miss out on support.

Some participants stated that their medications had often changed as a result of attending a different pharmacy. In these cases, the tablets changed depending on what type the differing pharmacies dispensed. This caused some of the participants to go elsewhere for their medication although most were happy with the pharmacists and continued with the same pharmacy.

Only one participant stated that they had been contacted prior to a change in medication appearance although many did suggest that information provision and being alerted to any changes would have been useful and allayed some of their initial anxieties.

Confidence in medications

On the most part participants recognised a need for the NHS to reduce costs and manage its pharmacy services cost-effectively and this helped them to accept any medication appearance change. Some participants (*n*=8) however questioned the quality of the medication and felt that reduced cost meant that the tablets may not be as effective. Whilst this didn't deter these participants from taking the medications it did reduce their confidence in them and two participants stated that they had noticed a change in the effect of their tablets. Confidence with the tablets was implied in nearly all of the interviews and was seemingly underpinned by participant's familiarity with the tablets they were taking. Thus any changes to the tablet affected this confidence.

Being 'Old':

A further category that arose was that of 'being old'. Participants were keen to share their views about control and management of their medications, but wanted also to highlight their concerns for themselves and others. Whilst for many, the repeated medication appearance changes were manageable, many harboured significant concerns that as their age progressed, they would likely experience a loss of physical ability that would eventually compromise their ability to manage their tablets.

Any future changes in medication appearance were therefore recognised as potentially detrimental to participant's progress and health. This concern was reflected by most of the participants. Whilst keen to refute any negative effects of older age currently, these participants acknowledged some sense of inevitability of loss of physical ability at a later date. This raises questions about how at risk people will be recognised and helped to manage medication changes.

Retaining control:

Ultimately, the categories revealed a commonality amongst all of the participant's stories. The ways in which the changes in medication appearance had potentially disempowered them was quite striking. Almost all of the participants prided themselves on

their ability to manage and self-administer their medication and despite the appearance changes, they were able to do this because of a good routine and physical and mental capacity. To some extent, they all remarked on how this helped them remain in control of their tablets, rather than the tablets controlling them. In some respects, being in control of their medications went some way to busting the myth that they were ‘old’ or that they could be classified as such in an ageist way. For them, ‘old’ was a derogatory word which meant decline and dependence.

Participant’s methods for maintaining control echoed the ways they managed their tablets. All the regimens varied. Some kept their tablets in the original containers whilst others re-dispensed their medication into boxes, old margarine tub’s, Dosette boxes (a monitored dosage system) and small coloured containers. Some had an array of tablets spilling out from an undersized cup or box. It was obvious that all the approaches worked sufficiently well for the individuals using them – despite the outward appearance of some of them being in a jumble. This was made possible because of the person’s familiarity with the medication, confidence in the tablets, faith in the health professionals and subsequent control over the medications. Thus any changes were managed accordingly so that they did not disrupt the established routine.

Whilst few known medication errors were divulged by this group of participants, the risk for these is evident in the way that participants tailored their medicines management. These bespoke storage, labelling and administration solutions may not be what health professionals would advocate not least as they introduce room for error such as when participants decanted tablets into unmarked containers. However, for participants, disruption of an established routine such as when medication appearance changes, similarly introduces opportunity for mistakes of varying severity.

Discussion & Conclusions

Three categories and an overarching core category emerged from the data. Those interviewed generally did not find that medication appearance change caused them major difficulty because they were able to manage the changes competently. Participants were very clear that changes in appearance did cause them significant concern and in some cases anxiety for a number of reasons. More

importantly, those interviewed considered themselves not to be those most at risk from the changes as they had established their own informal medicines management approaches which generally worked for them. Participants were concerned for others who may be less competent and able than them. Participants did feel a number of their peers were at significantly more risk than them and that the experiences of these other older people require further investigation.

Participant's main concern was about the potential for them to lose capacity to manage their medicines in later life and how this would be identified as well as concern for those already with reduced capacity who may be being overlooked by health professionals who could address any risk.

Medication appearance changes compromised participant confidence at a personal level, with health professionals and in the medications themselves. Most felt they could overcome this reduced confidence by having routines that kept them in control of their regimes, by seeking advice and by reading routine or bespoke information about their medications. Participants agreed that high standards of practice by pharmacists should be encouraged to: avoid changes in appearance where possible; to notify people of changes where reasonable; and to avoid changes with those most at risk of being mal-affected by any changes. Further and better quality written information is also indicated as these participants found instruction leaflets to be unhelpful whilst information sheets that accompany Dosettes issued by a pharmacist were considered to be very useful. Some would have preferred both kinds of information. Further work to engage with older people and perhaps develop information materials that meet their needs is indicated.

The widespread use of Dosette boxes purchased by participants without prompt from a health professional is suggestive that older people are feeling in need of support with their medication taking and is perhaps an early indicator of them having such a need. Whilst Dosettes issued by a pharmacist follow an assessment of need, those bought by individuals from high street shops do not and a Dosette box may not be the best solution for that individual's needs. This and other strategies to self-manage medications at home need further exploration especially as some approaches

present more potential risk than others e.g. decanting medicines out of packaging into cups.

Colour changes were the most challenging changes in medication appearance for participants to manage as colour was often a key element to their informal medicines management routines. Shape was also an important factor which similarly helped participants identify medications especially when some were similarly coloured or there were many of them to take in a day. It may be helpful for pharmacists and other health professionals to be aware of *how* people specifically manage their medicines at home. Such knowledge would of course help identify those most at risk of errors from poor regimes but also help those who would benefit from consistency in medication appearance so that their existing regimes continue to work for them. Emphasis would be on maintaining those capable of self-care to do so for as long as possible.

This study has been valuable in that it complements our previous pan-Manchester survey of the same topic (Williamson *et al* 2009) which established evidence that many older people were experiencing anxiety, poor medicines management, upset, confusion, thus adding further to a very limited evidence base. Collectively we hope all these findings will prompt substantive further research into what we now believe is a widespread concern and problem of varying degrees amongst older people.

Of immediate concern to those who develop policy or provide healthcare services should be that these findings clearly show that some older people are being put at risk due to changed medication appearance. Whilst medicines management has especially been invested in during recent years by organisations such as Primary Care Trusts, we suggest a closer look is taken at the extent and nature of the key aspect of medicines management that these findings highlight, namely managing changes in appearance. Perhaps initiatives are needed that would accurately establish the number and nature of changes to individual's medication appearance (e.g. using pharmacy computer systems as opposed to patient recollection as with this study). This information could then be used towards identifying those patients who may be most vulnerable to medicines of altered appearance e.g. those experiencing frequent and / or multiple changes. This would be

complemented by having a greater appreciation of informal medicines management strategies used by older people at home.

The implications for the roles of those who prescribe or dispense medicines, or those who have caring responsibilities for older people such as district nurses and those from partner agencies such as Local Authorities need to be considered. For example, pharmacists could seek ways of flagging up more vulnerable adults to GPs or possibilities for expanding the role of pharmaceutical home-delivery drivers could be considered. The widely reported good practice of pharmacists who have helped many respondents by sticking to a certain medication brand if the patient requests it is to be praised and reinforced. This good practice may have cost implications for the pharmacist and perhaps ways should be found to reimburse them. Similarly the approachability and helpfulness of pharmacists and their good practice in allaying anxiety by providing support and advice regarding appearance changes is worth particular mention. Awareness raising and education for health care professionals could help them to support and educate older people to manage medicines that change appearance more effectively. We suggest that multi-disciplinary work is undertaken to explore: how older people can be better supported to maintain their informal medicines management strategies; how those at risk can be better identified; how individual needs can be better catered for; and how improved information can be developed and better provided.

Between January and March 2010 the Department of Health conducted a consultation on proposals to extend generic prescribing practices through the automated substitution of some branded drugs with generic ones. These study findings have been requested by the Department of Health and have been fed into the consultation.

Finally what this study has shown is that concerns and anxiety are being experienced by unacceptable numbers of older people and we suspect that there are others who experience far greater effects and whom need to be engaged with in future study so that we can better understand their situation as a means of better supporting them and minimising risk.

Recommendations

Study recommendations centre on future research and multiple agency work to:

- Improve written information and information processes
- Consider of the use of pictures on boxes of medications
- Require manufacturers to notify pharmacists and explain changes and provide standardised packaging in terms of quantity (28 or 30 day packs)
- Scope individual strategies - formal and informal - that people use to manage their medicines at home as a means of identifying risk
- Identify training / education needs amongst primary care workers e.g. district nurses, pharmacists and GPs and partners such as Local Authorities in supporting older people with their medicines and identifying those most at risk e.g. vulnerable adults
- Explore the frequency and nature of changes to individual's medication appearance
- Undertake economic analyses of generic prescribing practices including cost and quality of life implications
- Explore the impact of changed appearance of medication with the wider older population including those who are less able to participate e.g. seldom heard or marginalised groups, those who are socially isolated and especially those at higher risk of negative effects such as those with reduced capacity to self manage medications
- Devise a public information poster explaining 1) how large savings from generic prescribing are reinvested into patient services and 2) how when drugs come off patent, other manufacturers are free to produce them at lower cost, as long as they maintain efficacy 3) how pharmacists cannot order medicines from a specific manufacturer as it depends what wholesaler has in stock 4) the requirement to bulk some tablets up with excipients (e.g.sugars) 5) the need for patients to talk to their pharmacist