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**Salford Centre for Nursing,
Midwifery & Collaborative
Research**

Older people's experiences of changed appearance of medications: a survey

SUMMARY REPORT

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Introduction

In England, government policy causes pharmacists to be financially rewarded for issuing the least costly version of a medication. For example, Panadol (brand name) may be issued as a generic medication (paracetamol) at a fraction of the price. When people receive their tablet / capsule 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 Pharmacopoeia standards but these do not specify colour, size and shape. The Directive 2001/83/EC of the European Parliament stated that medicines had to be of 'essential similarity' but that does not include appearance.

This 'generic prescribing' does enable the pharmacist to supply any licensed generic product. This ensures market forces operate and a medicine of the required quality, purchased at the least cost can be supplied. However, there are some community pharmacies that purchase generic products on a 'spot market' basis and ask wholesalers to send them the 'cheapest' product whenever they order, even when the cheapest product is cheaper by one or two pence from the previous supply.

Furthermore, some changes in appearance of tablets and capsules are due to 'parallel imports'. These are medications that are supplied by parallel importers from Europe which can be re-sold to pharmacies in the UK so long as labelling in English is attached.

Whatever the cause of the changes in appearance of tablets and capsules, substantive anecdotal evidence that the changes presented challenges to many older people was presented to the research team by older people in Rochdale Borough. Members of the Rochdale User Carer Action Forum raised concerns that the changes in appearance of medicines had contributed to people they knew ending up being admitted to hospital due to poor medicine control. They provided examples of older people becoming confused or upset by unexpected changes in the appearance of their prescription medicines. Older people were known to have omitted their medicines for several days until clarity

was gained, or for example where a tablet had become smaller, doses were doubled 'just in case'.

Email conversations took place between the project lead and the European Commission and National Patient Safety Agency. It was concluded that whilst these agencies had themselves heard anecdotal evidence of a problem concerning appearance of medicines, there would need to be a substantial body of evidence of significant risk in order to influence the EU and National Governments to change EU directives concerning medicines.

The research team was approached to see if it could acquire funding to investigate the problem further on behalf of Rochdale User Carer Action Forum members. Funding for the survey described here was gained and six older people volunteered to be study advisors to inform the design and conduct of the study.

Study Approach

Aim

The aim of the study was to develop a questionnaire in partnership with older people to survey older people's views of fluctuating tablet medication appearance and the impact on their medication-taking practices.

Older People's Involvement

Older people have prompted this study and have been involved as advisors since its outset. Rochdale User Carer Action Forum members have informed the study design also. The advisors have had an impact on the questions to be asked and wording of these as well as specifying the target population as being respondents aged 50 years and above. Advisors were clear that response rate would be optimised by return of questionnaires to an Age Concern office rather than a University of Salford address as first proposed. Advisors provided access to the Rochdale User Carer Action Forum to gain first hand anecdotal accounts of older people to inform study design. Individual advisors' own networks e.g. Pensioners' Association, Over 50s Group, permitted a wider reach to gain the views of older people to inform the study focus as well as providing direct access to audiences to disseminate findings to.

Advisors helped design the pilot survey and then administered it to their contacts.

Sample

The survey was sent to 2000 older people aged 50 years or over residing in Greater Manchester and currently prescribed three or more medicines in tablet/capsule form.

Questionnaire

An eight-question questionnaire was devised in partnership with older people from the study advisory group. This is a self-completion, mostly tick-box design with room for comments.

Data Collection

Of all of the Primary Care Trusts in Greater Manchester who were invited to take part, six agreed to work with us. All GP practices within them were asked to assist in forwarding a questionnaire to patients who met the study criteria. From those six PCTs, a total of ten GP practices agreed to assist. The PCTs were Heywood, Middleton & Rochdale PCT; Stockport PCT; Ashton, Leigh & Wigan PCT; Oldham PCT; Salford PCT; and Tameside & Glossop PCT.

Each GP practice forwarded 200 questionnaires to eligible respondents and returns of completed questionnaires ceased by the end of March 2008.

Ethical Approvals

Usual university, NHS research ethics and research governance approvals were gained.

Results

As not all questions were answered by all people returning the questionnaire, the number of respondents for each question is made clear by putting the number ('*n*') in brackets e.g. (*n*=540).

A. Response Rate

Out of 2000 questionnaires sent, 581 responses were received, which is a 29% return rate.

B. Personal data

Gender ($n = 562$)

254 (45.2%) were male

308 (54.8%) were female

Age ($n = 569$)

100 people (17.6%) were aged 50-64

251 people (44.1%) were aged 65-74

183 people (32.2%) were aged 75-84

35 people (6.2%) were aged 85+

Ethnicity ($n = 567$)

Ethnicity was described by respondents as:

527 (92.9%) White

14 (2.5%) White, Irish

2 (0.4%) White, other

1 (0.2%) Indian

5 (0.9%) Pakistani

13 (2.3%) Asian, other

2 (0.4%) Black Caribbean

3 (0.5%) Other

C. Changes in tablet appearance

The questionnaire asked whether respondents had experienced changes in appearance of their tablet medicines (other than due to changes in dose or drug).

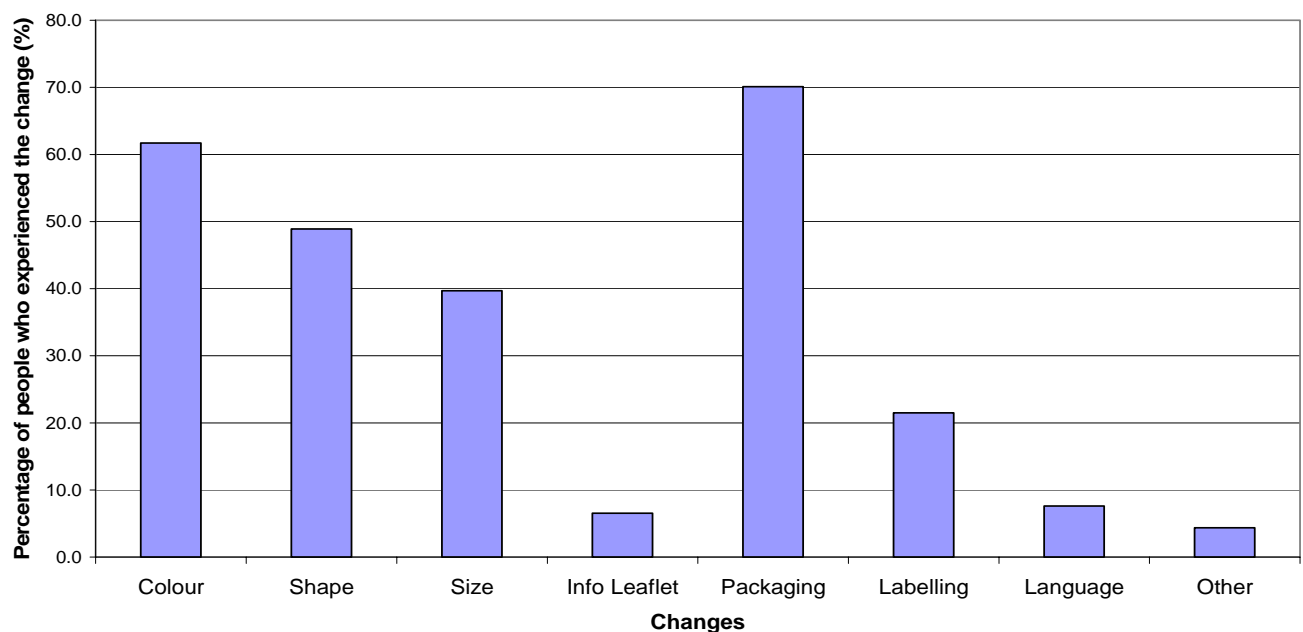
Of the respondents answering this question, 368 people (63.3%) had experienced a change in the appearance of their tablet medicines. In contrast, 213 people (36.7%) had not experienced a change in the appearance of their tablet medicine.

Of those who had noticed a change, there was no significant difference amongst men and women's responses. Neither were there any significant differences in responses from across age categories. However, respondents who identified themselves as 'White' tended to notice changes occurring to their prescribed tablet medicines significantly more than people in other ethnic groups.

D. Nature of changes

Experiences of specific changes to the appearance of tablet medicines were then sought. Respondents were asked to report all of the changes that they had experienced.

Specific ways the appearance of prescribed tablet medicines changed



These findings suggest that the most common change to the appearance of prescribed tablet medicines is found in the packaging, followed by the colour of the tablets, then the shape and size of tablets.

E. Advice seeking

When asked if the changes to their prescribed tablet medicines had led them to seek advice, of the 347 people who replied, 257 (74.1%) indicated that they had not sought advice and 90 (25.9%) indicated that they had sought advice. The advice seeking group did so from their pharmacist, doctor or a family member.

Of those who had sought advice, the number of men was 32 (20.9%) and the number of women was 53 (28.5%). There were no significant differences across age groups or ethnic groups as to who sought advice.

F. Medication borrowing practices

Of the 411 people who replied to the question about borrowing prescribed medicines, 15 people (3.6%) stated that they had used prescribed tablet medicines from other sources than their GP, including neighbours, friends and family members, whereas 396 (96.4%) stated that they had not borrowed prescribed tablet medicines from sources other than their GP.

Analysis of Comments

There was space in the questionnaire for respondents to write comments or give further details and a summary is given here.

A. Changes in appearance of tablet medicines

The results of the survey indicated large numbers of respondents who had experienced changes in the colour ($n=227$), shape ($n=180$) and size ($n=146$) of their tablet medicines.

Respondents were invited to give examples of these changes which are summarised here.

Colour changes tended to be complete changes e.g. from white to orange although some were more subtle changes such as brown to pale brown. Others were dual-coloured whereby one colour changed e.g. from purple and white to pink and white. Some changed from a single colour to dual colours e.g. from white to

orange and white and *vice versa*. Others changed several shades e.g. white to pale orange to dark orange. Sometimes colours changed back and forth between original colour and new colour. Respondents noted that changes sometimes depended on which Dispensing Pharmacy they attended and that it was not always possible to go to the same place.

Size changes related mostly to tablets becoming smaller or larger but retaining the same colour. For a few, other changes were in both size and colour simultaneously. Sometimes size changed back and forth between original size and new size.

Shape changes were mostly from round to oval shape and *vice versa*. Some changes were from round to rectangular shape. One was from diamond to round shape and for another the change was from triangle to oval shape. A further change was from a blue triangle to a white round shape.

Packaging changes generally concerned moves from coloured boxes (manufacturer's own) to plain dispensing boxes. Boxes also changed in size. Several reported changes concerned the move from calendar packaging to non-calendar packaging and those with days of the week marked on to those without such markings. Further changes included bottle to blister pack, foil packaging becoming very thick and from foil wrapper to bottle. Occasional mention was made of tablets being transferred into dosette boxes which generally helped although there was a single mention that information leaflets concerning the medicines were absent. Another isolated comment was that larger blister packs had days indicated on them but no days were indicated on small packs of the same drug.

B. Effects of changes in appearance of tablet medicines

Respondents were asked how they had been affected by changes in prescribed tablet medicine appearance.

a) Personal effects

- Having to check medicine name and strength
- That they change colour, size and shape all the time and I find this extremely confusing
- Have given much cause for concern

- I wonder if much smaller tablets are as good. Do they contain as much medication?
- Sometimes not taken until found out if OK to do so, so as not to take wrong ones. I do wonder if these contain other ingredients
- As I get older I can see difficulties with this
- I find changes in the size and colour of tablets very confusing
- I have to double check they are the same prescription
- I also have to be careful as my husband takes a tablet that can look similar for a different condition
- Foreign language days of the week are confusing
- Being partially sighted I find it confusing
- I think the survey is very good as the change of tablet (shape and colour) can cause confusion
- As I have been given wrong tablets by the pharmacist on two separate occasions, changing the colours of the tablets/capsules only add to the anxiety
- Very confusing for people taking 13 a day after stroke
- Confused. Loss of confidence in being able to take medication on my own
- Gives rise to doubts as to correct medicine until verified
- Uncertainty and unease about taking the tablets before seeking the advice of the pharmacist
- Annoyance and concern for the tablet takers who suffer poor eyesight
- Concern that it was not as good as my previous one which I found to be satisfactory
- I dispense weekly to daily containers ... I regularly have to tell her of colour or shape change. My wife gets confused and accuses me of giving her wrong medicines
- Frustration!!!
- Did not feel I could take the tablets with as much confidence
- Colour change made me feel that the medication was not as effective in helping the relief of my pain
- The colour change upset me when the chemist changed supply
- Anxiety - wondering if the tablets are incorrect and given by mistake
- I rely a lot on others and changes like this make me feel even more reliant
- When changes are made in size, colour and shape for no apparent reason it really annoys me

Large numbers of respondents expressed no problem with changes in medication appearance or said that they were fine once they had sought advice. Many others said they had experienced confusion.

b) Way take medicines

- Sometimes I have to cut them in half
- Some medicines don't have days of the week on them and this can lead to confusion whether you have taken them
- I like to take tablets in order and usually go by colour, size and shape and then I do not forget to take any
- I find a packet better because it enables me to write on it to remind me what the medication is for and I can colour it as a code for myself as to when to take it e.g. morning or night
- I have to check the boxes because they change so much. It's so easy until you get used to the new packaging to get mixed up. You get used to them and then they change them again
- I put my tablets in a 7 day pill box. Changes in shape and colour make it difficult to check at a glance
- Wife has to issue them
- Need help in taking medication when packaging changes but once adjusted I am able to cope
- I re-think the medicine only to have to change back the following month
- I do think about the changes but I haven't been to seek advice
- I usually remove all tablets from their foil containers on receipt and transfer them to empty, clearly labelled bottles
- Taken the wrong tablets - my husband's - instead of mine because the colours are the same. Also taken my night-time in the morning because they look the same

c) General comments

- It would be less confusing if the same brands were prescribed each month when I collect tablets from the chemist
- Just wish they would stop changing the tablets and leave as they are
- Is it possible for 2/3 different medicines to be combined in one tablet to ease arthritic fingers fumbling with small blister packs?
- I find it confusing when I have to get my prescription from a different pharmacy than usual as the tablets can then

change. Sometimes I get a different brand from the same pharmacy

- Just didn't want to take them without assurance that they were the same tablets
- All tablets from different manufacturers should be standardised
- The writing on all medicines could be bigger
- I would feel more comfortable with the same brands all the time
- I am not confident that anyone is protecting us from standards existing in say Romania. I would like reassurance that we are not getting cheap substitutes
- I guess why the drugs change so much, they say the right name, but it's just cheaper to sell another brand and it's wrong. That's why people get mixed up - sometimes I know I do
- No change as my doctor had written and advised me it was the same formula under a new name, but colour changes are confusing
- If licenses are granted to several pharmaceutical companies could conformity of appearance be put into the contract?
- Sometimes my blood pressure tablets are not written in English on the calendar pack. It helps at my age to know that I have missed any
- Sometimes the foil covering the tablets is very thick which makes it difficult to press out and the tablets break
- It would be much better if the respective tablets and packaging could be standardised irrespective of who manufactures them - otherwise if care is not taken, the wrong tablets could be taken at the wrong time
- Pharmacist, 2 different size tablets in one bottle, sought advice was told a different supplier but there was no label attached or any verbal information before I sought advice
- To change things just to save a few pence is not always a good thing to do. People's lives come first
- Medication labels in patient's ethnic language would be very helpful. I appreciate this would be costly but it would enable me to regain confidence and independence while also being sure that I am taking the right dose at the right time when no-one is available to help me
- Pharmaceutical purchasing officers should be made aware of the difficulties caused for the patient when packaging specifications vary

- I would definitely prefer my medicines to be all the same brand
- Perhaps explanation of any changes might be given by the pharmacist to alleviate or allay any worry someone might feel if unable to read or understand why the appearance of medication had changed
- Tablets and packaging for older people should be kept the same
- Labelling should be in bigger writing and clearer e.g. faint ink from printer
- The name of the manufacturer was important to me - I felt that the quality and effectiveness of the drug was superior to the one made by the little known drug companies
- Gets very confusing. Would be better if there were standards across all drug companies to keep each named drug same colour, size and shape and recognisable packaging
- I wish we could have an MOT (like a car) once a year to check how our tablets are working for us
- Whilst I am totally in control of my faculties I can imagine that these changes may be traumatic to some people
- We should have a choice between bottles or foils
- Very small print on packages and leaflets can be barely readable even with a magnifying glass. Also inadequate colour contrast on leaflets etc i.e. dark blue print on pale blue background; yellow on green etc
- A warning sticker may be the answer just confirming the 'look' of the tablet may have changed but the content is the same

Large numbers of respondents suggested standardisation of tablet appearance. Many others indicated problems with foil packaging.

Conclusions

This is a modest yet valuable survey. It is noted that the views of those who did not respond may differ from those that did. What is of concern is whether there exists a higher level of negative experiences amongst those non-responders, some of whom may have been less able to participate and may also be less able to manage any medication appearance changes. We also accept that we have relied on the recollections of respondents, some of whom may not have recalled their experiences with accuracy. Some of

the changes in appearance noted may have been due to other reasons than generic prescribing or parallel import practices such as changes in dose.

What is of more importance to those older people who have prompted the study is that a voice has been given to at least some of their peers to articulate the problems as they see them with regards to changed tablet medication appearance. Evidence that a problem exists for many - anxiety, poor medicines management, upset, confusion - has been uncovered which will add to a very limited existing evidence base. This will go some way to inform future research such as our own study starting in 2009 which will employ video-taped interviews of older people sharing their experiences of changed medication appearance. Collectively we hope all these findings will prompt substantive research into what we now believe is a widespread problem.

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 pharmacy monitoring systems need to be revised (or developed where they do not exist) to establish the number and nature of changes to individuals' medication appearance and to use this information to make decisions about which patients are best able to cope with medicines of altered appearance. 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, need to 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 and for allaying anxiety by providing support and advice regarding appearance changes, is to be praised and reinforced. Awareness raising and education for health care professionals could help them to help and educate older people to manage medicines that change appearance more effectively.

Others would need to establish the cost implications of adjusting the current approaches of generic prescribing and parallel imports

to avoid their use with those patients at most risk of making mistakes. This study is clearly too small and of too limited a focus to recommend adjustments to these practices. What we have shown is that risk and harm *is* being experienced by unacceptable numbers of older people, which may be the tip of the iceberg and that the remainder of the iceberg should be explored substantively. Meanwhile the existing *known* risk needs addressing.

Recommendations:

- Ways need to be sought to manage the known risk and harm being experienced by some older people when faced with changed medication appearance
- Means of educating healthcare professionals to support older people at most risk to better manage their medicines with regards to changed appearance need to be developed

Future audit or research is needed to:

- Explore the extent of the problems identified here amongst the wider older population including those who are less able to participate e.g. seldom heard or marginalised groups, those who are socially isolated etc
- Monitor medicines with changed appearance that are dispensed to establish the nature, frequency and extent of changes for individuals as well as the profiles of those they are dispensed to
- Establish the cost and quality of life implications of supplying generic medicines or parallel imports amongst vulnerable older adults