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

Williamson, T, Greene, L, Prashar, A and Schafheitle, E

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

FINAL REPORT

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April 2009
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Staff from the 6 GP practices in Greater Manchester who distributed the questionnaire are thanked greatly.
PART 1

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.
PART 2

Literature Overview

The following literature overview provides a helpful policy, practice and research context within which these survey findings can be situated. Relevant literature was located concerning four distinct subject areas and each of these will be considered in turn.

- Medication management and safety in older people
- Polypharmacy
- Medication compliance and concordance
- Tablets: packaging, preferences and price

Medication management and safety in older people

As people get older, their use of medicines tends to increase so they need to be sure they have the right medicine, at the right dose and in the right form (Department of Health - DH 2001). Medication mismanagement is an issue that is common amongst some older people and it can initiate adverse drug reactions. As people age, their central nervous system develops increased sensitivity so they are more susceptible to the actions of drugs. The median age of patients admitted to hospital with adverse drug reactions is 76 years old (Pirmohamed et al 2004).

According to Teeling and Feely (2005), adverse drug reactions are responsible for approximately 6% of hospital admissions with two particular risk factors being extremes of age and polypharmacy (use of 4 or more drugs). To limit the excessive use of prescription medicines, the DH Medicines and Older People Policy (2001) recommends that ‘all people over 75 years should normally have their medicines reviewed at least annually’.

Another factor that contributes to medication mismanagement is low health literacy. Health literacy can be defined as ‘the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions’ (Healthy People 2010, cited in Riley et al 2006). Previous studies have found that adverse drug
reactions are related to how medicines are used and low health literacy increases drug use error (Metlay et al 2005). Low health literacy means that people may not be able to understand complicated medication instructions. Particular challenges may pertain to understanding of verbal instructions, calculation of medication dosages and understanding of complex delivery systems (Riley et al 2006).

Other recognised contributing factors to potential medicines mismanagement include removing medicines from their original containers, poor eyesight, which could limit the ability to read instruction labels, and polypharmacy. During medication reviews it is essential that GPs and pharmacists ask appropriate questions to ascertain whether there is a medicine mismanagement problem and take steps to address these (DH 2001).

**Polypharmacy**

Polypharmacy is defined by the Department of Health as being ‘where a patient is prescribed four or more drugs’ (DH 2001). In their systematic review of the causes and effects of polypharmacy amongst older people, Reid and Crome (2005) define polypharmacy as ‘prescription of more drugs than is clinically justified’. Polypharmacy is not necessarily bad; sometimes it is necessary. However, as previously discussed, polypharmacy can lead to potential harm from medication mismanagement.

Older people form 18% of the population of the UK and polypharmacy is common in this age group as they consume 45% of all drug prescriptions and the average number of prescribed drugs increases with age:

‘51% of patients over 65 who receive repeat prescriptions get four or more concurrent repeats.’

(Reid & Crome 2005)

Reid and Crome (2005) mention two main reasons for inappropriate polypharmacy. Firstly, is the failure to discontinue drugs that are no longer necessary, and secondly, is the ‘prescribing cascade’. This is where a drug is prescribed that
causes a side effect, another drug is then prescribed to counteract the side effect and further side effects follow.

Kippen et al (2005) discovered that older people were particularly concerned about taking medication simply to manage side effects from other medication. Reid and Crome (2005) recommend that one way to avoid polypharmacy is to use a single drug to treat more than one clinical problem, for example in the treatment of hypertension and angina. Some older people have also commented that it would be a good idea to combine medicines ‘so that tablets that were commonly taken together under the same conditions could be merged and become one ‘super-drug’ (Kippen et al 2005). Also, Rudd et al (1992) recommended prescribing longer-acting medicines, which would reduce the daily amount of medication required. All of these ideas need to be taken into consideration, to reduce medication mismanagement in older people.

Repeat prescription systems also need to be improved to reduce polypharmacy. This would help by ‘synchronising quantities’, ‘ensuring regular review of the need for each medicine’ and ‘monitoring that the medicine is being taken and the patient is benefiting from it’ (DH 2001). Reid and Crome (2005) suggest that ‘in the next few years prescribing systems will be integrated with electronic patient records to avoid over prescribing and polypharmacy’.

There is a strong correlation between non-concordance and polypharmacy. Muir et al (2001) found that ‘when the complexity of the medication was reduced, concordance with medication improved’.

**Medication compliance and concordance**

Often the words compliance and concordance are used interchangeably in relation to medicines. To clarify, the DH (2001) defines medication compliance as ‘the extent to which a patient takes or uses a medicine as intended by the prescriber’. Concordance means ‘a partnership between patient and health professional in which an agreement is reached about whether and how medicines are taken/used’ (DH 2001).
Hill and Ball (1992) reported that 25-59% of older individuals do not adhere to medication regimens. Kippen et al (2005) used focus groups with five groups of participants aged over 60 years to provide valuable insight into reasons why older people do not comply with their medication regimes. These reasons included impact on lifestyle, lack of reliable information about their medicines, debilitating side-effects and issues relating to packaging (Kippen et al 2005). These authors also found that many of the older people questioned referred to a ‘loss of control’ of their lives as they were required to take medicines on a long-term basis. The results showed that there is a need for GPs and pharmacists to give older people clearer information regarding medicines. It was also discovered that the size, shape and packaging of medication can make it difficult to access and as a consequence, accidental non-compliance was commonly reported (Kippen et al 2005).

Steinmetz et al (2005) discovered that another reason for non-compliance with medication regimes in older people was the lack of specific prescribing information, for example, dosing and safety information, on drug labels. They found that often the package insert contains no information on drug dosing for older people and that the information inserts were difficult to locate (Steinmetz et al 2005).

A comprehensive review conducted by Banning (2004) discovered theories behind non-concordant behaviour, including that patients have a tendency to adjust their medicines in relation to how well they feel and other socio-cultural, behavioural and financial reasons. Older people are given limited information and education on their medicines so they often forget to take them, or take too many. It is now recognised at a policy level, that GPs and pharmacists must ensure that older people are provided with written instructions (in large print if needed) and a full explanation of how to take their medicines so that ‘no older person is in receipt of medicines labelled “as directed”’ (DH 2001). Social and personal factors affect medicine compliance and concordance, including poor vision, dexterity and confusion. To discover if this is the case, questions must be asked during medication review to ascertain if the patient is taking their medicines and support offered.
**Tablets: packaging, preferences and price**

Packaging, the type of tablet and the cost to the government also create boundaries that affect medication management in older people. In primary care it is common for patients to have their medication changed to improve the cost-effectiveness of prescribing (Thompson *et al* 2006). However, there is a lack of information within the literature on how well patients accept these changes. Thompson *et al*’s (2006) study employed a postal survey to evaluate patients’ experiences of switching medication, acceptability of the change, communication and packaging. They discovered that 91% of patients reported experiencing no problems following the change in medication. However, they did not focus on tablet medicines within a specific population or investigate the nature of the changes (Thompson *et al* 2006).

It is concerning that almost two thirds of patients questioned in the Thompson *et al* (2006) study did not feel that they had the opportunity to discuss their medication changes and some of the respondents felt that their views would not affect the outcome, as the change was ‘inevitable’. These authors also discovered that older people found it challenging to cope with changing appearance especially when these concerned colour, shape and packaging (Thompson *et al* 2006). Kippen *et al* (2005) discovered that packaging was often not ‘user friendly’ and prescribing was ‘sometimes done in a way that could create waste and confusion’.

Overgaard *et al* (2001) carried out a study in which patients were asked to swallow different sized tablets with different surfaces and visually assess the shape and colour of tablets. The results showed that gelatine capsules were easier to swallow than tablets, coated tablets were easier to swallow than uncoated normal tablets, the preferred colour was white for both capsules and tablets, the most disliked colours were purple and brown, the preferred shape was arched circular for small tablets, oval for medium sized and big tablets and the difficulty to swallow tablets increased with increasing size.

De Craen *et al* (1996) performed a systematic review to investigate the perceived effect of colour of drugs. They discovered that colours have universal meanings. In a wide variety of cultures, red is considered strong and active whereas blue and green are associated with good (Adams & Osgood 1973). The colour of drug
formulations might cause different expectations in patients, and could therefore produce different therapeutic effects. The results showed that red, orange and yellow tablets are best for stimulant drugs and blue and green tablets are best for sedative drugs. It was also found that red, yellow and orange are related to stimulant effect whilst blue and green are associated with tranquillising effect.

Colorcon Inc. is a company that produces ‘patient-friendly tablets that are easy to identify and swallow’. Colorcon Inc. sponsored a survey to discover whether distinctive tablet appearance reduces dispensing and patient medication errors (Primezone 2006). This survey found that medication errors were reduced by tablets with distinctive colours and shape (Primezone 2006). They found that differentiating between tablets was difficult, especially when tablets and capsules are removed from their original packaging.

Generic drug companies must perform tests and show that their drugs are equivalent in terms of therapeutic effect to the brand-name drug. These companies must show that the ingredients of the generic drug enter into the bloodstream in the same way and in the same length of time as the brand-name drug.

Meadows (2005) explains that:

‘Patent protection gives brand-name manufacturers the right to be the sole source of a drug for a certain time period so they can recoup the money they invested in trying to develop the product.’

However, as soon as this patent protection expires, the generic version of a drug can be sold. They also state economic reasons why pharmacists request generic drugs in preference to brand-name drugs:

‘Generic drugs have exactly the same active ingredients and effects as brand-name drugs, but they can cost 30 percent to 80 percent less.’

(Meadows 2005)
It is perhaps important to use generic medication suppliers to reduce prescription costs for the NHS. However, generic suppliers’ packaging changes frequently and tablet packaging affects medicine compliance. Drugs need to be ‘patient-friendly’ to improve medication management in older people. Consideration must be made for older patients, who may struggle to comply with medicine regimes due to difficulties swallowing large tablets and accessing ‘child-resistant’ packaging. Furthermore, many older people have difficulty accepting changes in tablet colour, shape and packaging.

Conclusion

Whilst much is written about compliance, concordance and medicines management, there is a great lack of evidence concerning changed appearance of medicines and effects of this on older people. This study seeks to address this gap by contributing modest research evidence on this issue.
PART 3

Study Design

Study Aim

In conjunction with study advisors, the aim of the study was agreed as being:

To develop a questionnaire in partnership with older people to survey older people’s views of fluctuating 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 participants 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. As one advisor is Chair of Age Concern Metro Rochdale this enabled the research team to link closely with this organisation. 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.

Sampling

Eligibility

The population for inclusion was all older people aged 50 years or over residing in Greater Manchester and currently prescribed three or more medicines in tablet/capsule form.
Size

Statistical advice indicated a sample of 2000 participants would be appropriate.

Survey Tool

An eight-item questionnaire was devised in partnership with older people from the study advisory group (see Appendix 1). This is a self-completion, mostly tick-box design with room for comments.

Data Collection

All Primary Care Trusts (PCT) in Greater Manchester were invited to take part. Of the six that consented, all GP practices within them were sent a written invitation 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 was visited to deliver 200 pre-packed survey envelopes comprising a detailed study cover letter and questionnaire. Practice staff followed manual randomisation procedures as instructed by the research team in determining which patients should form the sample. Practice staff also made judgements to exclude patients who they felt it was inappropriate to contact e.g. recently bereaved or critically ill people. At no time did the research team have access to patient identifiable information and first contact was made by their GP who included a cover letter of their own in each survey envelope.

Surveys were distributed in January 2008. Participants were asked to return anonymous, completed questionnaires in pre-paid reply envelopes to Age Concern Metro Rochdale, ideally within 6 weeks. Returns ceased by the end of March 2008.

Data Analysis

Survey data was analysed using the Statistical Package for Social Scientists (SPSS). Descriptive statistics (percentages) and Chi Square tests for independence were employed where appropriate
and thematic qualitative analysis of free-text responses was undertaken.

**Ethical Approvals**

The study received approval from Ashton, Wigan and Leigh Local Research Ethics Committee and The University of Salford’s Research Governance and Ethics Committee whilst research governance approval was gained from ReGrouP based at Salford PCT. Study design was informed by the Patient Information Advisory Group (Department of Health) such that approval was not required from it.

**Limitations:**

It has not been possible within this study to drill down to ascertain causes of changed appearance of medicines. It can be reasonably expected to be due to parallel imports and generic prescribing practices but it is acknowledged that reported changes in appearance may have been due to other causes such as dose changes. The study relies on participants’ recollections of changes in their medication appearance. An alternative approach may be to examine what medicines are dispensed and the actual reasons for any changes in their appearance.

The questionnaire tool developed has not been formally validated. The study design purposefully traded validity with a participatory approach whereby older people informed the tool design and questions were worded in ways they felt were meaningful and most likely to be interpreted as intended.

The study was insufficiently funded to send reminder letters as is good practice to maximise response rate. It was felt other measures such as the return address being an Age Concern office, went some way to address this issue.

As with all postal surveys, the views of non-respondents are of interest but steps to identifying these views were beyond the scope of this study.
PART 4

Results

Introduction

Results are presented as simple percentages or have been statistically tested using Chi-square tests where appropriate (see Appendix 2 for the relevant calculations). 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

Of the 2000 copies of the questionnaire that were distributed, 581 responses were received, which is a 29% return rate.

B. Demographic 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+

See Graph 1 below:
Age of respondents to ‘Taking tablets questionnaire’

- Between 50-64 (17.6%)
- Between 65-74 (44.1%)
- Between 75-84 (32.2%)
- 85+ (6.2%)

**Graph 1**

**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

See Graph 2 below:
C. Changes in tablet appearance

Questions 1 and 2 were screening questions to see if respondents were taking any tablet medicines and if so, whether these were prescribed.

The questionnaire then asked whether participants had experienced changes in appearance of their tablet medicines (other than due to changes in dose or drug) (Question 3).

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.

A number of assumptions were tested out to see if experiences of changes to medication appearance varied amongst respondents of different gender, age and ethnicity.
Gender:

From a response rate of 562, the number of males who experienced changes to appearance of prescribed tablet medicines was 162 (63.8%) and the number of females who experienced changes to prescribed tablet medicines was 195 (63.3%). The differences in the proportion of men and women who experienced change were not statistically significant.

Age:

Based on the 569 respondents, the proportions of people who noticed appearance changes to prescribed tablet medicines are similarly distributed across all age categories.

Ethnicity:

All ethnic groups other than ‘White’ have been summed to form a separate group called ‘Other’, due to their small number.

The number of white people who experienced changes to the appearance of their tablet medicines was 341 (64.7%) and 19 (47.5%) from the ‘Other’ group experienced changes.

Based on the 567 respondents, the proportions of people who noticed appearance changes to prescribed tablet medicines are not similar across the different ethnic groups. There were significant differences between the different ethnic groups. White people tended to notice changes occurring to their prescribed tablet medicines more than people in other ethnic groups.

D. Nature of changes

Further analyses were undertaken to explore the proportions of respondents who experienced specific changes to their tablet medicines. Participants were asked to report all of the changes that they had experienced.

The results are presented in Graph 3 below:
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.

Further analysis was used to discover whether the changes were specifically related to the tablets themselves, the written information that accompanies tablet medicines or the packaging. The number of people who observed the changes was summed to form more general categories. Colour, shape and size of tablets were combined to form a new category; ‘Tablets’. Labelling, language and information leaflet were combined to form a ‘Written Information’ category. ‘Packaging’ remained as a third category.

Changes to ‘Tablets’ were selected 553 times, ‘Written Information’ 131 times and ‘Packaging’ 258 times. Most changes are therefore occurring to tablets themselves as opposed to the written information.
E. Advice seeking

The survey sought to identify whether changes in the appearance of tablet medicines affected older people in terms of advice seeking:

When asked if the changes to their prescribed tablet medicines had led them to seek advice (Question 4), 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.

Further assumptions were tested to explore advice seeking practices amongst respondents of differing genders, age and ethnicity.

Gender:

The number of males who sought advice was 32 (20.9%) and the number of females who sought advice was 53 (28.5%). Whereas, the number of males who did not seek advice was 121 (79.1%) and the number of females who did not seek advice was 133 (71.5%). The differences in the proportion of men and women who sought advice were not statistically significant.

Age:

Based on the 343 people who responded, the proportions of people who sought advice regarding the appearance changes to their prescribed tablet medicines are similarly distributed across all age categories.

Ethnicity:

Based on the 342 people who responded, the proportions of people who sought advice regarding the appearance changes to their prescribed tablet medicines are similarly distributed across all ethnic groups.
F. Medication borrowing practices

Question 7 was included as it was a particular concern of the study advisors. It asked whether respondents had borrowed prescribed medicines in the preceding 2 years.

Of the people who responded to this question (n=411), 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.
PART 5

Analysis of Free Text Responses

Introduction

Space was given in the questionnaire for respondents to write comments or give further details. This was in part an acknowledgement that participants in such research often want to 'have a say' but also a means of gaining insights that could then be explored at interview as part of the qualitative study running consecutively to this one. A summary of these comments is given here to illustrate the issues as experienced by respondents.

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.

Most frequently named drugs with changed appearance included Atenolol, Pravastatin, Doxazosin, Lisinopril, Omeprazole, Atorvastatin and Simvastatin. Others were Lansapriazole, Meloxican, Aspirin e.c., Sotalol, Propanolol Hydrochloride, Levothyroxine, Lipitor, Cialis, Glucosamine, Amlodipine, Diclofenac, Metformin, Zolpidem, Gliclazide, Ramipril, Gabapentin, Co-codamol, Alendronic Acid, Nicardipine, and Amitriptylline.

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.

Other changes of note included presence of the preparation’s dual name or name change e.g. Atorvastatin to Simvastatin and manufacturers changing from Generics UK to Almus or Teva UK to Bristol Labs Ltd. Smaller wording size for the warning paragraph had been a change for one respondent. A few respondents mentioned the main language in the information leaflet being Spanish (especially with Losartan) or sometimes French or German. For one a name change was noted e.g. Bendrofluazide to Bendroflumethiazide but noted that the tablet itself had been unchanged.

B. Effects of changes in appearance of tablet medicines

Questions 5 and 6 sought to identify the nature of any personal effects that changes in prescribed tablet medicine appearance had on respondents and any subsequent changes in the day-to-day ways in which they took those medicines.
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.
PART 6

Critical Commentary

To further contextualise the survey findings against current pharmacy policy and research, the services of a pharmacy researcher were commissioned to provide the following critical commentary.

Commentary by Dr Ellen Schafheutle
MRPharmS
MSc – Clinical Pharmacy & Pharmacy Practice – 1994
PhD – Pharmacy Practice – 1999
MRes – Health & Community (policy pathway) – 2005
http://www.pharmacy.manchester.ac.uk/staff/19444

I am writing this critical commentary in my capacity as Research Fellow at The University of Manchester's School of Pharmacy and Pharmaceutical Sciences. I have nearly 15 years research experience, where I have employed both qualitative and quantitative methods. The majority of my research has been in the broad areas of pharmacy / pharmacists and medicines (patients’ access and use, including adherence). I am also a GB registered pharmacist, originally qualified in Germany, and, until 2005, practised regularly as a locum in community pharmacy throughout my research studies and employment.

Available literature

Very little published research evidence is available directly related to the issue of tablet appearance (size, colour, shape etc). Two UK publications were located, where the issue of changes in medicines appearance due to generic prescribing / manufacturing, and the impact this may have on patients is acknowledged (Winfield & Bond 2004; Jackson 2005). The chapter by Winfield and Bond raises the issue in connection with pharmacists involved in the dispensing of such medicines, and how they have a role to play in educating patients and thus supporting medicines adherence (Winfield & Bond 2004).
Literature specifically about tablet and capsule appearance

Even though not directly related to the research aim, there are some studies that have looked at the impact of tablet appearance on effectiveness. They found that blue and green, for example, are better for achieving a calming effect in anxiety, or for inducing sleep (Lucchelli et al 1978; Schapira et al 1970; de Craen et al 1996).

Other studies have explored patients’ preferences for different shapes and sizes, and established, for example, that gelatine capsules were found easier to swallow than tablets, and coated tablets were easier than uncoated tablets. White was a popular colour, and purple and brown were least popular. Oval shapes for medium to bigger size tablets were preferred to round ones (Overgaard et al 2001).

Literature on information leaflets, packaging, labelling and language

Besides changes in appearance of tablets and capsules, this survey is also concerned with changes in information leaflets, packaging, labelling and language. One research group in particular, that of Theo Raynor based at the School of Health Care in Leeds, have many years experience with researching different aspects on how medicines information is conveyed to patients, and specifically patient information leaflets. I would suggest having a look through their publications, but want to give a recent example here (Carrigan et al. 2008).

There are a number of studies that have looked at the impact of the provision of written patient information on patients’ management decisions or adherence, and a wider literature review would be useful to identify these. One Canadian study, for example, explored the effect of three different types of patient information leaflets on elderly patients’ treatment intentions (Whatley et al 2002). Another study from Denmark found that patient information leaflets vary considerably for different brands of generically identical products (Bjerrum & Foged 2003).
Medicines adherence

As the issues under investigation in this study are likely to impact on patients’ (either intentional or unintentional) medicines adherence, the (relatively large) body of literature related to this will be useful to contextualise this study.

Comments on survey findings

From Graph 5 it can be seen that the most commonly reported changes in appearance of tablets and capsules are colour, shape and size (in this order). Changes in packaging were the most commonly reported change overall. These are likely to be changes due to generic prescribing and the dispensing of the same generic item, but produced by different licensed manufacturers. Manufacturers commonly have packaging design specific to them, in a way a form of branding their (generic) products. If the manufacturer is different, the most likely change in appearance would be a difference in package design.

Individualised labels are issued in community pharmacies when dispensing prescribed medicines. The information contained on these labels follow strict rules, so the content itself is unlikely to differ between different community pharmacies. However, different dispensing and labelling software means that the way this information is printed may differ (i.e. design issues). The design of the labels themselves, bearing the community pharmacy / chain (e.g. Boots, Lloyds etc.) address and logo, also usually differ.

If people go to the same pharmacy to get their regular prescriptions dispensed, all above mentioned differences are less likely to occur, than if they go to different pharmacies (and this would be an important question to ask in any further work). Individualised pharmacy labels will look the same (see above), and companies are often more likely to have consistent suppliers / manufacturers for their generic products. However, pharmacists do not always have control over which generic products are supplied to them (hence the topic of this study). Nevertheless, they can have information on manufacturers preferred by certain patients stored on their Patient Medication Records (PMRs), provided the issue has been raised with them (Winfield & Bond 2004).
Surprisingly language was only mentioned by less than 5% of respondents (see Graph 5) as, due to parallel imports (see below), packaging and especially calendar blister packs can come from countries using languages other than English. Qualitative work may be able to shed light on whether this is not in fact an issue, or whether the question was not phrased clearly and unambiguously enough.

Why changes in appearance may occur (reasonably)

As rightly stated in the project proposal, community pharmacies in England can supply a licensed generic product from any licensed manufacturer. Due to the lack of standardisation other than with regards to the active ingredient, the shape, colour, size, taste, as well as packaging and information leaflet can differ.

However, there are examples where agreement has been reached on colour, for example, with the aim of increasing patient safety. One such example is warfarin which is used to prevent and treat the formation of harmful blood clots by thinning the blood. In the UK, it comes in four different strengths, and agreement has been reached among manufacturers with regards to colour coding of different strength warfarin tablets. They are: 0.5mg – white, 1mg – brown, 3mg – blue, 5mg – pink) (National Patient Safety Agency & British Society for Haematology 2007). Tablet colour has been recognised as important, due to the importance of the patient’s involvement in monitoring and adjusting warfarin doses, as well as the seriousness of side-effects. It ensures that there should be no mix-up for pharmacists dispensing different strength warfarin tablets, as well as for patients taking them. Nevertheless, size and shape can still differ from different manufacturers.

Difference in tablet / capsule colour (and size) by one manufacturer

Differences in tablet or capsule colour, in particular, but also size, for example, are commonly used by the same manufacturer to differentiate different strengths of the same drug. This aids easier identification and checking by dispensing pharmacists (historically mostly when dispensing from bulk) as well as patients. From the survey results it may be difficult to establish whether a change in appearance occurred due to a change in strength (i.e. increased or reduced dose), for example, or a change that is solely
due to a change of the same generic ingredient from a different manufacturer. A change in tablet or capsule strength would not be unusual in this population of older people on multiple medicines. Qualitative interviews will be useful to explore further whether respondents did indeed understand the terms ‘dose’ and ‘drug’, as these are words we tend to avoid in medicines related research with patients.

**Difference in language**

Due to parallel imports of generic products, which are commonly available cheaper in other European countries, dispensed products often bear the originators’ country's language on the package and blister pack (e.g. names of days on calendar packs). However, a label stating the necessary information in English is always present on the box, and patient information leaflets need to be inserted in English. The issue of language on calendar packs is not usually rectified and may lead to confusion.

**Conclusion**

We know that older patients’ adherence to prescribed regular medication is a problem, and one that is complicated for people on multiple medicines, as in this study. To ensure that patients get the best out of the treatments available to them, it is crucial to identify and understand all factors that impact on adherence, and there are many. The factors explored in this study, of changes in tablet / capsule and packaging appearance are therefore important and need to be seen in the overall context of medicines adherence. They may contribute to unintentional, but possibly also intentional non-adherence. Other than anecdotally, they have not, to my knowledge, been the subject of a research study. This study therefore provides very useful information that adds to the evidence we have on factors impacting on adherence. Further qualitative work (such as one-to-one interviews) will be very useful to explore and explain some of the findings in this study. Usefully funding has been gained by the research team to undertake interviews in coming months. They will also be useful for the design of any future questionnaire instrument that could be used to establish more clearly the extent to which changes in appearance cause problems for older patients on multiple medicines. Involvement of other stakeholder groups, such as community pharmacies and manufacturers of generic products, may also be
very useful, as this may help identify solutions or at least improvements.

This is a worthwhile study which provides support for the premise that changes in appearance due in part to generic prescribing cause problems for some older patients on multiple medicines. Further qualitative and quantitative work would be required to explore reasons for the observations made in this survey, and thus refine and validate a questionnaire instrument which could establish the scale of, and causes for, the problems changes in appearance may cause for patients.
**PART 7**

**Conclusions**

This survey has achieved a modest yet respectable response rate for a postal questionnaire survey. It is acknowledged that the views of those who did not respond may differ from those that did. What is of concern is whether there was a higher prevalence 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. Only future enquiry may address this concern. 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
Taking tablets questionnaire

The questions are about your use of medicines that come in TABLET FORM ONLY e.g. tablets, capsules. Please DO NOT tell us about other medicines e.g. inhalers, creams, drops.

Please tick the relevant box to indicate your view or write in the space provided

1. Are you on any tablet medicines?
   Yes ☐ No ☐

2. Are all of your tablet medicines prescribed to you (e.g. by a doctor)?
   Yes ☐ No ☐

3. In the last 2 years, has the appearance of your prescribed tablet medicines ever changed (other than due to changes in dose or drug)?
   Yes ☐ No ☐

   *If yes*, please specify in what ways it has changed appearance:

<table>
<thead>
<tr>
<th></th>
<th>Please tick any that apply</th>
<th>Give examples where you can</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Changed COLOUR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. Changed SHAPE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. Changed SIZE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D. Changed INFORMATION LEAFLET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. Changed PACKAGING</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F. Changed LABELLING</td>
<td></td>
<td></td>
</tr>
<tr>
<td>G. Changed LANGUAGE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H. OTHER</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
If you answered NO to Question 3 this is the end of the questionnaire—thank you - Please go to Page 4

4. In the last 2 years, have any of these changes (listed A-G in Question 3) led you to seek advice?

Yes ☐  No ☐

*If yes, where did you seek advice from? (E.g. a friend, pharmacist, family member, doctor) Please give details:

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5. If you have experienced changes in the appearance of your tablets/capsules (e.g. colour, size or shape) what effect have these changes had on:

a) you personally?
Comments…………………………………………………………………………………………
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........................................................................................................................................

b) the way you take your medicines?
Comments…………………………………………………………………………………………
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........................................................................................................................................
6. If you have experienced changes in packaging, labelling, information leaflet or language of your tablet medicines - what effect have these changes had on:

a) you personally?

Comments……………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………

b) the way you take your medicines?

Comments ……………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………

7. In the last 2 years, have you used any prescribed tablet medicines from any other source?

Yes                            No

If yes, was the source a:

☐ Neighbour                   ☐ Family member
☐ Friend                     ☐ Supermarket
☐ Other

If yes, please specify:

i) WHAT medicine/s it was………………………………………………………………………………
…………………………………………………………………………………………………………
…………………………………………………………………………………………………………
…………………………………………………………………………………………………………

ii) WHY did you borrow the medicine?………………………………………………………………
…………………………………………………………………………………………………………
…………………………………………………………………………………………………………
…………………………………………………………………………………………………………

WE DO NOT RECOMMEND THE USE OF OTHER PEOPLE’S MEDICATIONS. ALWAYS CHECK FIRST WITH YOUR PHARMACIST OR DOCTOR.
8. Are there any other comments or suggestions you wish to make?

…………………………………………………………………………
…………………………………………………………………………
…………………………………………………………………………
…………………………………………………………………………
…………………………………………………………………………
…………………………………………………………………………
…………………………………………………………………………

Additional information:

a) Gender
I am: Male ☐ Female ☐

b) Age
Aged between 50 and 64 years ☐
Aged between 65 and 74 years ☐
Aged between 75 and 84 years ☐
85 years and over ☐

c) Ethnicity
White ☐ White, Irish ☐ White, other ☐ Mixed ☐
Indian ☐ Pakistani ☐ Asian, other ☐
Black African ☐ Black Caribbean ☐
Black, other ☐ Chinese ☐
Other Ethnic Group (please specify) ……………………………..

d) If you are completing this questionnaire on behalf of someone, please state your relationship to them (e.g. spouse, carer).…………………………
…………………………………………………………………………

Thank you for taking time to complete this questionnaire.
Please return in the pre-paid envelope provided to:
Age Concern, 12 South Parade, Rochdale, OL16 1LR.

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Appendix 2

Results Calculations

The calculations provided in this appendix are for those readers who are particularly interested in the statistical tests used and are not intended for a general audience.

Sometimes the differences we observe in a study are simply due to the fact that we had to rely on a small sample of the target population. In a significance test we calculate how likely it is that the sample would contain such differences if there was no real difference in the population from which the sample was selected. If the likelihood is small (as evidenced by a p value of less than 0.05), we can assume that the sample differences reflect the wider, target population.

Chi-square test calculations

**Gender and age:**

<table>
<thead>
<tr>
<th>Age</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 – 64</td>
<td>46 (18.2%)</td>
<td>53 (17.2%)</td>
</tr>
<tr>
<td>65 – 74</td>
<td>119 (47.0%)</td>
<td>132 (42.9%)</td>
</tr>
<tr>
<td>75 – 84</td>
<td>80 (31.6%)</td>
<td>98 (31.8%)</td>
</tr>
<tr>
<td>85+</td>
<td>8 (3.2%)</td>
<td>25 (8.1%)</td>
</tr>
</tbody>
</table>

There were significant differences in age between men and women in the study; Chi-square = 8.758, df = 1, p = 0.003. Women tended to be older than men.

**Gender and ethnicity:**

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>231 (92%)</td>
<td>289 (93.8%)</td>
</tr>
<tr>
<td>White Irish</td>
<td>5 (2.0%)</td>
<td>8 (2.6%)</td>
</tr>
<tr>
<td>White other</td>
<td>-</td>
<td>2 (0.6%)</td>
</tr>
<tr>
<td>Indian</td>
<td>1 (0.4%)</td>
<td>-</td>
</tr>
<tr>
<td>Pakistani</td>
<td>4 (1.6%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Asian other</td>
<td>7 (2.8%)</td>
<td>6 (1.9%)</td>
</tr>
<tr>
<td>Black Caribbean</td>
<td>2 (0.8%)</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.4%)</td>
<td>2 (0.6%)</td>
</tr>
</tbody>
</table>
Hypotheses

A number of hypotheses (assumptions) were tested out to see if experiences of changes to medication appearance varied amongst respondents of differing genders, ages and ethnicity:

Hypothesis (1):
Is the proportion of males who have noticed appearance changes to prescribed tablet medicines the same as the proportion of females?

$n = 562$

The number of males who experienced changes to prescribed tablet medicines was 162 (63.8%) and the number of females who experienced changes to prescribed tablet medicines was 195 (63.3%). Whereas the number of males who did not experience changes to prescribed tablet medicines was 92 (36.2%) and the number of females who did not experience changes to prescribed tablet medicines was 113 (36.7%).

Chi-square test for independence:
Chi-square value = 0.001, df = 1, p = 0.979
(continuity correction value used to compensate for the overestimation of chi-square value due to 2x2 table).

Therefore, the significance value (p) is greater than 0.05, so the result is not statistically significant. This means that, although there were differences in the proportion of men and women who experienced change, the difference is not statistically significant.

Hypothesis (2):
Is the proportion of people who have noticed appearance changes to prescribed tablet medicines the same across all age categories?

$n = 569$

<table>
<thead>
<tr>
<th>Age</th>
<th>Appearance changed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>50-64</td>
<td>66 (66%)</td>
</tr>
<tr>
<td>65-74</td>
<td>164 (65.3%)</td>
</tr>
<tr>
<td>75-84</td>
<td>114 (62.3%)</td>
</tr>
<tr>
<td>85+</td>
<td>17 (48.6%)</td>
</tr>
</tbody>
</table>
Chi-square test for independence:
Chi-square value = 4.112, df = 3, p = 0.250

Therefore, the significance value (p) is greater than 0.05, so the result is not statistically significant. Whilst the percentage of respondents who noticed appearance changes in the 85+ group appears noticeably lower than the other age categories, the difference is not statistically significant.

Hypothesis (3):
Is the proportion of people who have noticed appearance changes to prescribed tablet medicines the same across all ethnic groups?
All ethnic groups other than ‘White’ have been summed to form a separate group called ‘Other’
n = 567

The number of white people who experienced changes to the appearance of their tablet medicines was 341 (64.7%) and 19 (47.5%) from the ‘Other’ group experienced changes. On the other hand, 186 (35.3%) ‘White’ people did not experience changes to their tablet medicines whilst 21 (52.5%) ‘Other’ people did not experience any changes.

Chi-square test for independence:
Chi-square value = 4.035, df = 1, p = 0.045

Therefore, the significance value (p) is less than 0.05, so the result is statistically significant. This means that the proportions of people who have noticed appearance changes to prescribed tablet medicines are not similarly distributed across the different ethnic groups. More white people tended to notice changes occurring to their prescribed tablet medicines.

Further hypotheses (assumptions) were tested out to explore the proportions of respondents who experienced the different changes to their tablet medicines:

Hypothesis (4):
Is the proportion of males that sought advice the same as the proportion of females?
n = 339
The number of males who sought advice was 32 (20.9%) and the number of females who sought advice was 53 (28.5%). Whereas, the number of males who did not seek advice was 121 (79.1%) and the number of females who did not seek advice was 133 (71.5%).

Chi-square test for independence:
Chi-square value = 2.180, df = 1, p = 0.140  
(continuity correction value used to compensate for the overestimation of chi-square value due to 2x2 table).

Therefore, the significance value (p) is greater than 0.05, so the result is not statistically significant. This means that, although there were differences between the proportion of men and women who sought advice regarding the appearance changes to their prescribed tablet medicines, the difference is not statistically significant.

Hypothesis (5):
Is the proportion of people seeking advice the same across all age categories?

The age ranges of people who sought advice are as follows:

<table>
<thead>
<tr>
<th>Age</th>
<th>Advice sought</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>50-64</td>
<td>12 (18.8%)</td>
</tr>
<tr>
<td>65-74</td>
<td>43 (26.9%)</td>
</tr>
<tr>
<td>75-84</td>
<td>24 (23.3%)</td>
</tr>
<tr>
<td>85+</td>
<td>8 (50%)</td>
</tr>
</tbody>
</table>

Chi-square test for independence:
Chi-square value = 7.033, df = 3, p = 0.071

Therefore, the significance value (p) is greater than 0.05, so the result is not statistically significant. Whilst there are noticeable differences between the proportion of people seeking advice in the different age categories, these differences are not statistically significant.
Hypothesis (6):
Is the proportion of people seeking advice the same across all ethnic groups?
Again, all ethnic groups other than ‘White’ have been summed to form a separate group called ‘Other’.

\[ n = 342 \]

79 (24.4%) ‘White’ people sought advice
8 (44.4%) ‘Other’ people sought advice
245 (75.6%) ‘White’ people did not seek advice
10 (55.6%) ‘Other’ people did not seek advice

**Chi-square test for independence:**
Chi-square value = 2.638, df = 1, \( p = 0.104 \)

Therefore, the significance value \( (p) \) is greater than 0.05, so the result is not statistically significant. This means that, although there were differences in the proportion of people who sought advice across ethnic groups, this difference is not statistically significant.
References


De Craen, AJM; Roos, PJ; De Vries, AL; and Kleijnen, J (1996) Effect of colour of drugs: Systematic review of perceived effect of drugs and of their effectiveness. *British Medical Journal* 313, 1624-1626

Department of Health (2001) *Medicines and Older People: Implementing medicines-related aspects of the NSF for Older People*.

Hill, P and Ball, D (1992) Self-medication for elderly care. *Care of the Elderly*, 4, 405-7


Lucchelli, PE; Cattaneo, AD; and Zattoni, J (1978) Effect of capsule colour and order of administration of hypnotic treatments. *European Journal of Clinical Pharmacology*, 13, 153-155


Metlay, J; Cohen, A; Polsky, D; Kimmel, SE; Koppel, R; and Hennessy, S (2005) Medication Safety in Older Adults: Home-Based Practice Patterns. *Journal of the American Geriatrics Society*, 53, 976–982
Muir, A; Snaders, LL; Williams, MS; Wilkinson, E; and Schamader, K (2001) Reducing medication regimen complexity. A controlled trial. *Journal of General Internal Medicine*, 16, 77-82


Overgaard, ABA; Møller-Sonnergaard, J; Christrup, LL; Højsted, J; and Hansen, R (2001) Patients' evaluation of shape, size and colour of solid dosage forms. *Pharmacy World and Science*, 23, 185-188.

Pirmohamed, M; James, S; Meakin, S; Green, C; Scott, AK; Walley, TJ; Farrar, K; Park, BK; and Breckenridge, AM (2004) Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *British Medical Journal*, 329, 15-19.


Schapira, K; McClelland, HA; Griffiths, NR; and Newell, DJ (1970) Study on the effects of tablet colour in the treatment of anxiety states. *British Medical Journal*, 1, 446-449


Thompson, A; Green, S; Dubois, S; Ansell, A; Harewood, E; and Ayre, J (2006) Evaluation of patient satisfaction with switching medication. *Prescriber*, 17, 27-35

Whatley, S; Mamdani, M; and Upshur, REG (2002) A randomised comparison of the effect of three patient information leaflet models on older patients' treatment intentions. *British Journal of General Practice*, 52, 483-484