

## ‘Not the full Monty’: a qualitative study of seniors’ perceptions of generic medicines in Western Australia

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**Abstract.** The study explored consumers’ perspectives on generic medicine use in Australia. A qualitative methodology was used to explore the topic, including community participation in the form of forums, focus groups and a panel of seniors. Three consumer forums were held from which a seniors’ panel was formed and a series of focus groups were conducted. Participants demonstrated considerable mistrust of generic medicines. Participants highlighted their uncertainty about the extent of pharmaceutical companies’ influence on health professionals, the mistrust of foreign generic manufacturers and scepticism in their equivalence. In addition, the substitution of generic medicines and variability in packaging added to the overall concern and reported poor compliance. Altering consumers’ beliefs and attitudes about generic medicines might require a more concerted effort to reduce consumer mistrust. Consumers’ beliefs about generic medicines will strongly affect attempts to increase generic prescribing in Australia. Many seniors require multiple medications for a range of chronic conditions. Currently however, the lack of uniformity in information and packaging implies that closer monitoring, greater clarity of information and improved packaging of generic medicines is required. Otherwise, the widespread problems and lower uptake of generic medicines amongst seniors will remain.

**Additional keywords:** compliance, medications safety.

### Introduction

While several international studies have explored consumers’ attitudes towards generic medicines and some Australian prescribers’ opinions (Hassali *et al.* 2006), there has been limited examination of consumers’ perspectives on generic medicine use in Australia (Hassali *et al.* 2005). Consumers’ beliefs about generic medicines will strongly affect attempts to increase generic prescribing in Australia and thereby reduce growing Pharmaceutical Benefits Scheme (PBS) costs.

We report the findings of a qualitative study conducted in Western Australia, of seniors’ views about generic medicines, set in the context of a broader project on the safe use of medicines among older people.

### Background

Research has shown mistrust of generic medicines among the general population both in Australia and overseas (Valles *et al.* 2003; Ringuier *et al.* 2008). More specifically, studies overseas have identified this as particularly problematic

among older people, people with low socioeconomic status and those with low levels of health literacy (Blasco Oliete *et al.* 2003; Sagardui-Villamor *et al.* 2005; Iosifescu *et al.* 2008). In Australia, the majority of available medicines are subsidised by the government through the PBS to make them more affordable to consumers. Approximately 15% of the total PBS budget is accounted for by generic medicines (Beecroft 2007). In addition, many of the top 100 PBS drugs (by volume) are due to or have recently come off patent, which has led to a range of policies to increase generic medicine use in Australia and thereby potentially reduce costs to both government and consumers. These policies include changes to legislation (Searles *et al.* 2007) and education programs aimed at consumers and health professionals such as the campaign ‘Generic medicines are an equal choice’ run by the National Prescribing Service (NPS 2007). This study lends weight to similar research overseas indicating that the use and substitution of generics is still poorly understood by seniors in particular.

This project received ethical approval from the Human Research Ethics Committee of the University of Western

Australia. Written consent to participate was obtained from each participant of the forums and focus groups.

## Methods

Initial information was collected during three consumer forums for seniors held between 2006 and 2007 in conjunction with the Health Consumers Council of Western Australia (HCCWA).

### Forum structure

Seniors (65 years and above) were invited to attend the consumer forums through advertisements in local community newspapers and a range of consumer groups with an interest in various chronic diseases. The conditions were identified by the HCCWA as diabetes, chronic heart disease and chronic obstructive pulmonary disease. Older people with chronic conditions such as asthma and rheumatoid arthritis were also encouraged to attend. The consumer forums were attended by a total of 104 seniors aged over 65 years.

The initial forum discussion resulted in a series of core issues being identified around medication safety noted as pertinent to attendees. Consumers at the forums then reflected on the identified core issues about medication safety during facilitated smaller round table discussions as follows:

- The key concerns when taking prescribed medicines
- Effective ways of discussing potential side effects with their doctor
- Use of complementary medicines
- Priorities for research on medication safety

These discussions were recorded by audio tape and analysed to identify key themes for further exploration in a series of subsequent focus groups. Once the forum had concluded, attendees were invited to engage further in the research by joining a consumer panel or attending a focus group at a later date to be confirmed. A follow-up form detailing the topics for discussion was sent out to those wishing to participate in a focus group. Participants then sent back their preferred topics, dates and times to the researcher by reply paid envelope.

### Consumer panel

Following the forums, the consumer panel was convened. The panel comprised 10 people who had a range of chronic conditions of varying severity. The panel discussed findings and informed further exploration of the existing data and advised on whether additional data were required. Initially, in a first meeting, the panel was presented with summaries of the findings from the three consumer forums to agree on the main areas for more detailed exploration in subsequent focus groups.

### Focus group composition

Six focus groups, each comprising between 9 and 12 seniors, were conducted in total with an overall 58 seniors participating. The following areas were identified by the panel

and researcher and explored in depth during each of the focus groups:

- The role of the doctor and the pharmacist in ensuring safe use of medicines
- Side effects and interactions in medications
- Generic medicines and access to information about medicines in general
- Over-the-counter and complementary medicines
- Chronic conditions and medication safety
- The role of carers in managing medicines

The researchers acted as facilitator and scribe for each focus group. The topic of generic medicines was discussed in the first focus group in the context of the role of health professionals to inform seniors about medication safety. The topic was explored in subsequent groups within the context of the other areas noted above.

## Analysis

Discussions from the focus groups were recorded and transcribed. The data were then analysed using data management tool QSR NVivo Version 7.0 (Bazeley 2007). The content of the transcripts was analysed and coded using a constant comparative technique (Glaser and Strauss 1967) as the focus groups progressed and the topic of generic medicine was explored further. Key themes were identified and refined into categories around seniors' perspectives on medication safety. In addition, transcripts were also read through by the School of Population Health consumer advocate, who had attended the initial focus group. The purpose of this was to establish validity in regard to identifying key themes that had emerged from the transcript analysis. These findings were presented and discussed further with the seniors' consumer panel throughout the course of the project.

The results reported here focus on a recurring theme from the forums and all six focus groups, that is, generic medicines and drug packaging in relation to medication safety among seniors.

## Results

### Perceptions of generic medicines

Participants from all focus groups expressed considerable mistrust and confusion about generic medicines.

Participants recounted news stories and other media from which they had formed an opinion about the quality of generic medicines.

*Ah well, at the time there was a lot of scandal about dodgy drug companies selling drugs to third world countries so they would be getting drugs that didn't cure fully. So the penicillin was low strength and so on. (Male: multiple medications for heart disease and high blood pressure)*

Although some participants were well informed about generic medicines and actually advocated their use, many other participants were wary of them, whether due to personal experience, that of a family member or friend, or a general

belief that generic medicines are not equivalent in quality to branded medicines. There was also confusion about terminology and the distinction between brand names, generic names and the active pharmacological ingredient in a medicine. One participant noted that she would usually ask her pharmacist to make note of the active ingredient on the generics' packaging to avoid confusion. It was noted that future packaging should make the active ingredient the central focus of the packaging rather than the brand name. Some hospitals in Western Australia have tried to address the problem of adverse events related to patients taking multiple medicines.

*The hospital gave me a booklet with a list of medications as well as some generic names and a number to call for further information.* (Female: medications for heart disease and arthritis)

Reluctance to use a generic rather than the branded medicine was due partly to a lack of knowledge about generic medicines, compounded by several common misconceptions. Participants' mistrust was based partly upon a perceived lack of transparency in the relationship that pharmaceutical companies had with doctors and pharmacists. In particular, participants expressed concerns about pharmaceutical representatives promoting specific branded medicines through the use of starter packs and excessive lobbying of health care professionals. The fear that doctors or pharmacists might therefore not make impartial prescribing or dispensing decisions in regard to possible substitution added to negative beliefs about the decision to prescribe branded or generic medicines.

There was a perception that some generic medicine manufacturers could not be trusted to reliably produce safe, equivalent drugs. One participant spoke of a recent news report of internationally produced generic medicines that were 'not the full Monty'. As a result of this he said:

*I just wasn't convinced that these generic ones are made by reputable drug companies. I just can't understand where they come from.* (Male: multiple medications for heart disease and high blood pressure)

There was limited understanding about the potential financial implications of taking generic rather than branded medicines. In some participants, mistrust of generic medicines completely outweighed any perceived financial benefit of using them. The implications of generic prescribing and potential for saving taxpayers' money at a national level had not been considered by most consumers who participated in the focus groups.

One bad experience or side effect, whether or not correctly identified as a result of use of a generic medicine, could significantly influence willingness to use any generic drug subsequently. There was concern that although the generic forms of a drug were purported to be the same as the original brand, there were differences in flavouring or additional ingredients used to prepare the formulation. One participant gave the following example:

*I tried the generic one but it disagreed with me because it has a different flavour. It was a lemon flavour.* (Female: blood pressure and also caring for husband with dementia)

There was considerable discussion over access to trustworthy information about generic medicines and who is best placed to discuss the use of generics. One participant said that she had no background knowledge of generics and asked the group where and how one could obtain such information:

*One thing that I worry about is when you take in your script that the pharmacist asks if you want the generic and I wonder if that is ok. I mean I don't know anything about the generics in that sense, can you get a lot of information about the generics to see that they are really the same thing?* (Female: husband with heart condition)

Some participants had attended community information sessions about generic medicines facilitated by non-government organisations or local councils, but these did not fully dispel fears. One explained how she felt at the end of a community information session:

*Well there were hundreds of us there and they sort of gave us questions first such as 'what do you know'? Then the experts gave us the scientific stuff. Then we filled in the form and I thought, 'well, I am still a bit nervous about this'. I think three-quarters of the people there would have said, 'No way'. We just weren't convinced about it.* (Female: arthritis and blood pressure problems)

#### *Generic substitution issues and relationship with pharmacist*

Participants raised the issue of 'generic substitution', which was perceived as being rarely discussed by the prescribing doctor, even though the doctor must indicate disagreement with this option on the prescription. This created an impact on the decision to agree to generic substitution and this was evident in the following participant's query to the group:

*Yes – because we're talking dollars now. Sometimes you don't get generics mentioned by the GP and until you get to the pharmacist.* (Female: blood pressure problems)

Participants agreed that doctors should discuss generic medicines more frequently, as usually it was not until the pharmacist was about to dispense the drug that the possibility of generic substitution was mentioned. However, some had a longer-term relationship with a pharmacist whom they felt they could trust in relation to seeking information and advice regarding medicines. Participants felt that the pharmacist had greater in-depth knowledge of medicine. Furthermore, that there was more time to ask questions and seek information at the pharmacy than within a brief doctor consult. One said:

*When you think about it, the pharmacist, he or she is the specialist in drugs and drug reactions. They are only concentrating on drugs and medications, whereas the*

*doctors get to deal with all sorts of other things, so I think the pharmacist is the ideal person.* (Female: high blood pressure and heart condition)

Another group participant said that she had the same chemist for 15 years and that she knew him very well:

*I talked about this to him and he said that a good chemist is always willing to give information. He knows more about the drugs than the doctor does. He has the facilities behind for you to pick up the phone if you don't understand the doctor. Or if the doctor hasn't had time to tell you or even if the doctor hasn't understood it. And you're invited to pick up the phone and to go straight to the person who can give you the information because if he doesn't know it already then he knows who does.* (Female: multiple medications)

Nonetheless, the prescribing doctor was also acknowledged as someone who could reduce mistrust, fear and uncertainty of generic medicines by exploring patients' concerns around the use of generics during the consult before having the script filled at the pharmacy.

#### *Generic medicines and drug packaging*

Study results showed that part of the confusion about terminology and the broader concerns about the use of generic medicines relate to the way that medicines are packaged and labelled. Packaging used for medicines was identified as one of the major issues and areas of concern for consumers and was felt by them to have a major role in poor compliance and drug safety.

*I think that one of the main things is changing packages of tablets. Sometimes you get them in a different colour. I think people get confused.* (Male: asthmatic)

Frequent generic substitution was believed to add to the overall uncertainty of drug packaging and labelling. In addition, packaging often changed without warning at each dispensing of a medicine and each generic had different packaging without the active ingredient being clearly printed on that packet:

*Sometimes they say, 'Oh, take this. . .it's the same tablet but the package is different and it is cheaper. One day you get it out of the cupboard and you know and the next time it is in a different packet. It's always different.* (Female: carer)

#### **Discussion**

This was a qualitative study involving 107 seniors with personal experience of chronic disease who were therefore very familiar with issues relating to taking multiple medicines. Our initial consumer forums and first focus group identified generic medicines as an important issue, which was explored further among other topics during each additional focus group. Furthermore, members of the consumer panel for this study brought specific examples of problems they had encountered,

particularly when receiving medicines from different pharmacies.

A study by Salzman (1995) highlighted that non-adherence among seniors was attributable to several reasons such as forgetting and alteration of schedules and doses. This study would add that the increase in generic medicines substitution alongside variations in packaging and labelling adds to the burden of ensuring safer use of medications among seniors in Australia. Thus, while our initial broad research question related to medication safety, generic substitution was identified by the consumers in this age group as a major issue underlying problems of medication compliance and potential for incorrect use of medicines for the reasons presented in the results section. Inconsistent generic substitution and variable packaging added to the overall concern that poorly controlled use of generics could contribute to poor compliance and problems with medication safety.

Compounding this problem is that study participants demonstrated mistrust of generic medicines despite recent media advertising campaigns to address misconceptions specifically among this age group. Participants expressed negative beliefs about the influence of pharmaceutical companies on health professionals; mistrust of foreign generic medicines manufacturers; and disbelief in the equivalence of generic alternatives.

Interestingly, findings of a US study by Keshishian *et al.* (2008), stating that participants had a better quality of relationship with their doctor than their pharmacist were not borne out in this study. In contrast, seniors in this study noted that they had a better relationship with their pharmacist than with their doctor; generally, the pharmacist was more approachable, had more time to answer questions and was more knowledgeable about medicines and their interactions and side effects. While limited knowledge about generics has been seen as a major barrier to their wider uptake (Hassali *et al.* 2006; NPS 2007) this is not necessarily the most important factor that could affect peoples' decisions about the use of generic medicines. Our study confirmed that patients were confused about the language and terminology surrounding drug brands and generic medicines. A study by Hughes (2004) states that the role of the pharmacist should be to communicate well with the patient and that good patient-pharmacist communication would facilitate medicines adherence. The study results indicate that building upon a good relationship with the pharmacist could potentially be one strategy used to target awareness and ensure better medication safety among seniors.

However, consumers' overall mistrust about the equivalence of generic medicines is of greater concern. This seemed to be fuelled at least in part by a previously mentioned widespread concern about the influence of the pharmaceutical industry on doctors and pharmacists (Breen 2004) and the safety and reliability of international generic medicine manufacturers (Ryan 2009). In general, although pharmaceutical representatives may be focussed on promoting the prescribing of specific drug brands rather than

generic versions of a drug, awareness of this distinction was not made by consumers in this study. Altering consumers' beliefs and attitudes about generic medicines might therefore require a more sustained and targeted effort to reduce consumer mistrust of the pharmaceutical industry more widely.

Health professionals at the point of prescribing and dispensing were seen as having an important role in discussing the safety and use of generic medicines. Large surveys of American consumers have found that consumer beliefs and communication with providers are the two strongest predictors of uptake of generic medicines (Shrank *et al.* 2009). However, even though there is strong evidence of bioequivalence for several classes of generic medicines (Dong *et al.* 1997; Kesselheim *et al.* 2008) many health professionals share concerns with their patients about clinical equivalence. Until professional beliefs are altered and prescribing by generic name (i.e. active ingredient) rather than brand name becomes more common, it is unlikely that large increases in generic dispensing will be achieved. Further, while short general practice consultations remain more financially viable than longer ones, education about generic substitution will be too difficult to incorporate into a GP visit and may still only occur at the point of dispensing.

Given the significant increase in hospital admission rates due to adverse drug events in the last two decades, particularly in people over 80 years old (Burgess *et al.* 2005), all issues that affect medication safety should be considered. Poor medication compliance is also associated with complexity of treatment regimens (Hughes 2004; Osterberg and Blaschke 2005). Confusion caused by changes in drug labelling, packaging, appearance, brand name and, in specific cases, drug strength, could contribute to adverse drug effects or treatment failure through under- or overconsumption of the same drug. Despite clear guidelines from the Therapeutic Goods Administration on the labelling of prescription medicines (Department of Health and Aging 2005), there is still considerable room for improvement by the manufacturers of medicines, particularly in relation to generic drugs, that could affect medication safety in Australia (Shrank *et al.* 2007).

### Limitations

Those participating in the research were self-selecting for participation in the focus groups and as such there may have been a bias towards those who were better informed and more opinionated about the use of generic medicines. However, within a qualitative methodology, purposive sampling seeks to explore the experience of those best informed to speak about the topic.

Given that focus group participants had originally attended the consumer forum, this may have raised greater awareness of this and other issues for both themselves and in hearing others give their opinions. Further studies would seek to conduct interviews and focus groups with the wider community among this age group such as nursing home residents and those attending day centres.

### Conclusion

The consumers in this study identified the important link between generic substitution and threat to drug compliance and medication safety. The example of confusing labelling and packaging we report is just one of several examples provided by our consumer panel from their personal experiences and suggests the potential importance of continuity of pharmacist to reduce multiple generic substitutions.

### Practical implications

In order to address the widespread issues of trust among seniors in regard to generic medicines, a more consolidated effort is required across a wide range of resources and relevant educational strategies. In particular, given that many seniors required multiple medications, the lack of uniformity in packaging implies that until a policy for ensuring closer monitoring and clarity of information are in place, the widespread problems with generic medicines uptake among seniors in Australia will remain.

### Conflicts of interest

No conflicts of interest exist.

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