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Assessing the impact of label format on people's ability to interpret and apply prescription medicine information

Findings from a multi-site label evaluation study

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Executive summary

Introduction

Labels affixed to dispensed prescription medicines are an important source of written information aimed at ensuring appropriate use of medicines. However, labels do not always effectively communicate medicine information to the intended users. Previous research[1] has demonstrated that the way in which dosage information is expressed on a label can affect how the information is understood and applied. Moreover, people have not been able to correctly discern between a medicine's active ingredient and brand name depending on the formatting used,[1] which has implications for generic brand substitution and quality use of medicines.

Identifying specific labelling characteristics that support improved understanding of dispensed prescription medicine labels is a critical step towards effective communication on labels. In particular, it is important to examine whether certain labelling approaches may support those with lower health literacy to better understand and appropriately apply and act on dispensed prescription medicine label instructions. Standardisation of such labelling characteristics can help ensure appropriate and effective use of medicines.

Aims and Objectives

Building on our previous research, this study aimed to evaluate the performance of dispensed prescription medicine labels developed from user testing, patient-centred language and layout, and expert recommendations.

The study's objectives were to:

- Explore the impact of labelling characteristics on people's ability to apply dosage-related information, and
- Compare the performance of the study-developed dispensed prescription medicine labels with a currently implemented label format.

Methods

This study was part of a larger research project which developed and evaluated, through consumer user testing, a number of labels with varying labelling characteristics, and recommended labelling characteristics which can be implemented to ensure effective communication of medicine information. This study took place from April 2019 to October 2019 (inclusive), and evaluated 16 labels with patients due for discharge from four Australian hospitals in three states/territories.

Labels

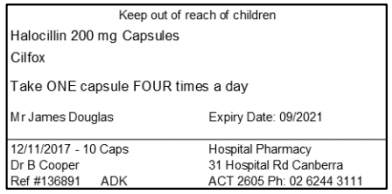
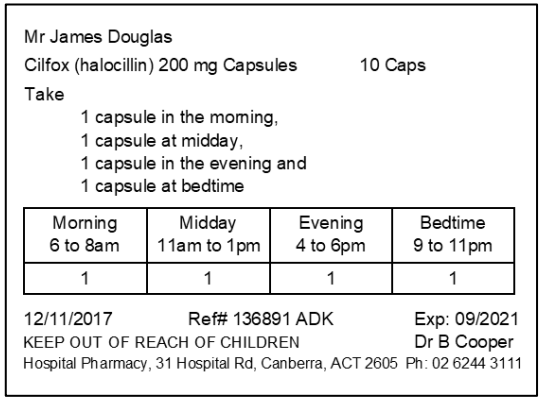
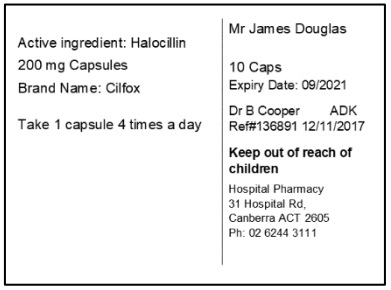
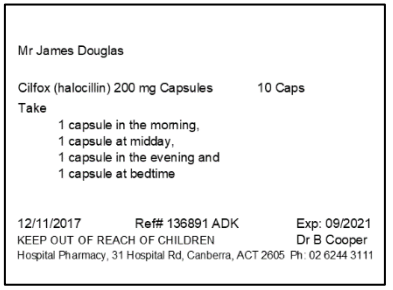
A total of 16 labels (four label formats x four fictitious medicines) were developed based on previous user testing[1] and other[2, 3] research. Each fictitious medicine had unique dosage instructions and capsule colour (Table ES1). The active ingredient, corresponding brand name, capsule colour, and dosage for the fictitious medicine were kept constant regardless of the label format.

Table ES1. Fictitious medicines and dose instructions

	Active ingredient	Brand name	Capsule colour	Dose
Medicine 1	myclofenac	Vipparoll	White	Two capsules twice a day
Medicine 2	halocillin	Cilfox	Green	One capsule four times a day
Medicine 3	cabergamol	Dariol	Blue	Two capsules three times a day
Medicine 4	abalazine	Butafor	Yellow	Two capsules four times a day

The key labelling characteristics that underpinned the four study label formats are outlined in Table ES2.
All evaluated labels can be seen in Appendix 1.

Table ES2. Summary of variables considered for label development

Variables	Label format 1	Label format 2	Label format 3	Label format 4
Label dimensions	80 mm x 38 mm	90 mm x 65 mm	90 mm x 65 mm	90 mm x 65 mm
Active ingredient and brand name order and positioning	Active ingredient presented first, above the brand name (on separate lines)	Active ingredient presented second (in brackets) after the brand name (on the same line)	Signposted active ingredient presented first, above the brand name (on separate lines)	Active ingredient presented second (in brackets) after the brand name (on the same line)
Format: 1 column versus 2 columns	Top half of label = 1 column Bottom half of label = 2 columns, separated by line	Top half of label = 1 column Bottom half of label = UMS[a] table	2 columns, separated by line	1 column
Indentation of dosing information	No	Yes	No	Yes
Expression of dosage (examples given from Kit A):	Take TWO capsules TWICE a day	Take 1 capsule in the morning, 1 capsule at midday, 1 capsule in the evening and 1 capsule at bedtime Morning 6 to 8am: 1 / Midday 11am to 1pm: 1 / Evening 4 to 6pm: 1 / Bedtime 9 to 11pm: 1	Take 2 capsules 3 times a day	Take 2 capsules in the morning, 2 capsules at midday, 2 capsules in the evening and 2 capsules at bedtime
Label format example (examples shown for halocillin)				

[a] UMS refers to Universal Medication Schedule.[3-5]

Each medicine had a label produced in all four label formats, and the labels were randomised into four kits for evaluation. Each kit that was evaluated by participants contained four labels, representing one of each label format and fictitious medicine in varying combinations. A Latin square matrix was used to randomise the label formats into four kits (Table ES3). Labels were printed in black and white, and affixed to blank cardboard boxes with one strip of ten blister-packed placebo capsules inside each box. The kits were then randomised into a listed order, and then packaged and numbered by the lead site. At each site, kits were used in the order in which they were numbered to maintain the randomisation schedule.

Table ES3. Latin square matrix randomisation of label formats into kits

Label format	Medicine 1 myclofenac	Medicine 2 halocillin	Medicine 3 cabergamol	Medicine 4 abalazine
1	Kit A	Kit D	Kit C	Kit B
2	Kit B	Kit A	Kit D	Kit C
3	Kit C	Kit B	Kit A	Kit D
4	Kit D	Kit C	Kit B	Kit A

Evaluation questionnaire

A questionnaire was developed comprising three sections:

1. Evaluation of medicine-related information on each label (in the medicine label order: halocillin, abalazine, cabergamol, and myclofenac);
2. A dosette packing task; and
3. Participant demographics and health literacy assessment (via the Newest Vital Sign UK (NVS-UK)[6]).

The medicine-related information evaluated included whether participants could identify:

- Who the medicine belonged to (patient name) – This question was asked only once per participant for the first label evaluated
- The dosage prescribed
- The active ingredient of the medicine
- How many capsules should be taken over the course of one day (total number of capsules per day)
- The medicine strength (amount of active ingredient)

The dosette packing task was modelled on a previous study.[7] A 24-well dosette, where each well equated to an hour of the day, was provided to the participants. They were asked to place the required number of capsules in the well that represented the time of day that they would take them based on the instructions provided on the labels (see Appendix 2 for images of the 24-well dosette and an example of a completed dosette).

Recruitment

Participants were recruited from Top End Health Service (Royal Darwin Hospital and Palmerston Regional Hospital), Canberra Health Services (Canberra Hospital), and Melbourne Health (Royal Melbourne Hospital). At each site, patients who were waiting for discharge in the hospital wards and in the discharge lounge were invited to participate in the study.

Study process

Figure ES1 illustrates the study process.

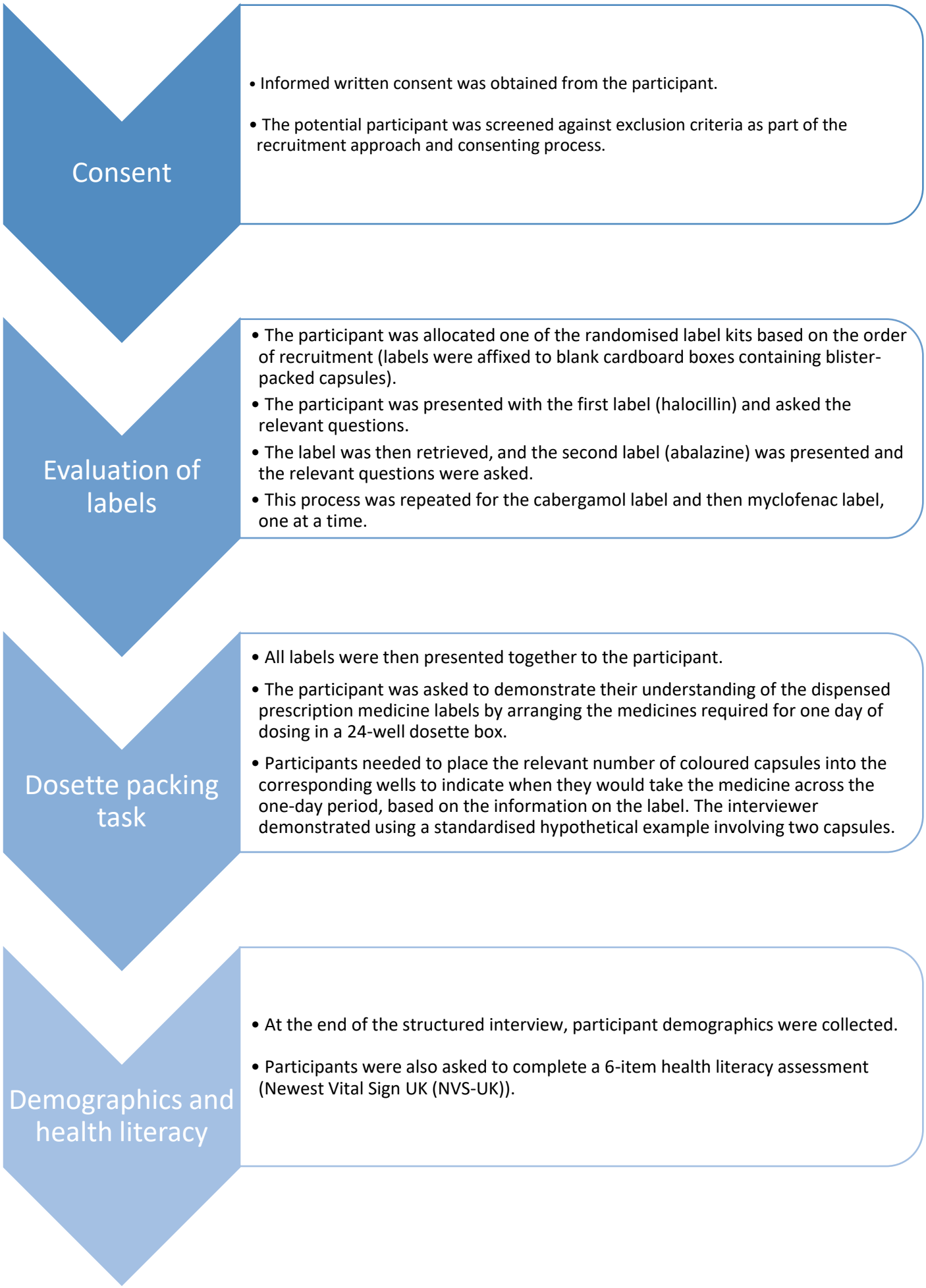


Figure ES1. Overview of study process

Data analysis

The key outcome measures were participants' ability to:

- Find and understand key information on the label relating to:
  - Patient name (for the first label only); and
  - Dosage, active ingredient, total number of capsules per day, and medicine strength, for all labels
- Correctly complete the dosette for:
  - Each medicine individually (each label format per kit); and
  - Overall (for all four medicines collectively)

The dosette packing task was analysed using two coding frameworks:

- UMS-based coding framework – this was based on the UMS[3-5] and how the dosing was communicated by the information on the label
- Tailored coding framework – this was based on the dosing information on the label and appropriate dosing intervals which were not restricted by the UMS time frames stated on the label

Using two coding frameworks afforded the opportunity to examine the impact of labelling on people's interpretation and planned application of the dosage information, with and without restriction of timing stated by the UMS.

The UMS-based coding framework designated specific windows of time where doses were expected to be placed in the dosette packs, and the number of capsules per dose. For each medicine, in order to be coded as correct, the number of capsules and the placement of capsules within the allowed time frame had to correspond to the model answer. Any deviations from the framework for any study medicine was deemed as inappropriate and coded as incorrect. Completion of the dosette for each one of the four medicines must have been deemed correct for the overall dosette to be coded as correct.

The tailored coding framework considered the total number of capsules to be taken correctly per day, number of correct doses per day (i.e. how many times the medicine should be taken per day), and the number of capsules to be taken correctly per dose, in the same way as the UMS-based coding framework. Additionally, it considered the minimum and maximum dosing intervals (per medicine), and the doses were required to be within the specified time frames as stated on the labels with the UMS table (where applicable).

Statistical analyses

All data were reported using descriptive statistics. Univariate and multivariate analyses were conducted to assess if any participant characteristics, including health literacy, and label format, were associated with correctly interpreting label information. This included participants' ability to correctly complete the dosette packing task, and correctly respond to the questions about the information on the labels.

Results

Participant characteristics

Of the 281 kits that were used in the study, data for 275 participants were analysed. Overall, participant characteristics were well balanced between the kits. Participants' age ranged from 19 to 93 years (mean=54.9, SD=17.5), and a higher proportion were male (n=178, 64.7%). The majority of participants spoke English as their main language at home (n=244, 88.7%), had completed either the Higher School Certificate or below (n=159, 57.8%), and had either no (n=69, 25.1%) or 1 to 2 medical conditions (n=119, 43.3%) for which they took medication. Of those who completed the NVS-UK, 43.6% of participants had adequate health literacy, and 56.4% had either intermediate or low health literacy.

Patient name identification

Nearly all participants (97.8%) correctly identified the name of the patient on the label. There was no association between the kit (and therefore label format) and participants correctly identifying who the medicine belonged to (P=0.32).

Dosage

Most of the participants (95.2% total correct responses across all four medicines) were able to correctly identify how much of each medicine should be taken and how often. Differences in label formatting and design did not have a large impact on whether participants could say how much of the medicine should be taken and how often (P=0.016).

Total number of capsules per day

Most of the participants (93.1% total correct responses across all four medicines) correctly identified the total number of capsules that should be taken in a day. The label format did not have a substantial impact on participants being able to determine how many capsules in total should be taken in a day (P=0.027).

Active ingredient

Label format 3 (Table ES2) was the most effective in communicating the active ingredient name to the participants (Table ES4). In this format, the active ingredient and brand name were signposted. Label format 1 supported correct active ingredient identification in 68.6% of participants (compared to 93.8% for label format 3).

Table ES4. Summary of correct responses per label format and medicine for question: *What is the active ingredient found in this medicine?*[a]

Medicine	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
Total correct	188 (68.6; n=274)	165 (60.0; n=275)	257 (93.8; n=274)	167 (60.9; n=274)	777 (70.8; n=1097)	**<0.001**

[a] Missing data have not been included (cabergamol missing n=1; myclofenac missing n=2).

For those who had low or intermediate health literacy, there was a difference in the proportion who could correctly identify the active ingredient depending on the label format (P<0.001). For the adequate health literacy group, active ingredient and brand name signposting on label format 3 enabled 100% of the participants to correctly identify the active ingredient (Figure ES2). Label format 3 was the superior label across all three health literacy levels, with the highest proportion of participants correctly identifying the active ingredient compared with the other label formats (Figure ES2).

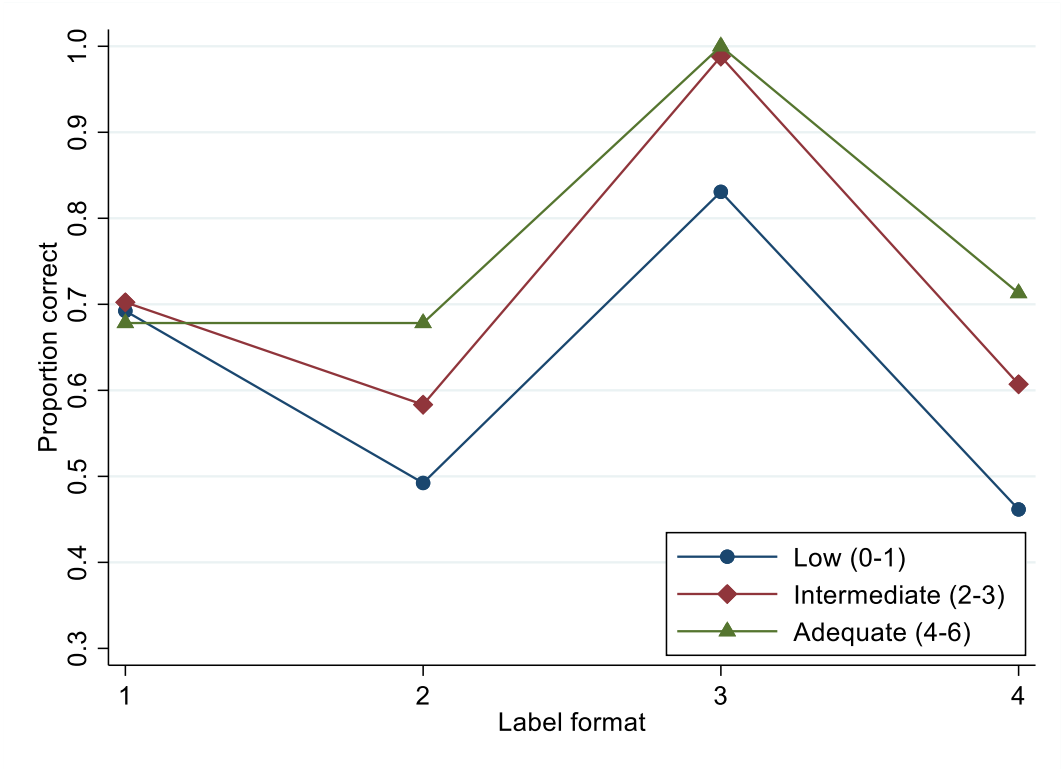


Figure ES2. Proportion of participants who correctly identified the active ingredient by label type, stratified by NVS-UK score

Medicine strength

Overall, most participants (91.3% total correct responses across all four medicines) were able to correctly identify the amount of active ingredient in each capsule of the four medicines. Differences in overall label formatting and design did not impact whether participants were able to identify how much of the active ingredient was in each capsule of the medicine.

Dosette packing task – ability to apply information on prescription labels

Of the 275 participants, 271 completed the dosette packing task. Participants grouped the doses of the four medicines from 3 to 13 times a day (mean=6.3, SD=2.0). For most participants (n=224; 82.7%), the first dose of the day indicated was between 6 am and 8 am. Almost all participants (n=252; 93.0%) nominated their last dose of the day to be between 9 pm and 11 pm.

Entire dosette completion

There was an increased number of entirely correct dosette completions (n=74; 27.3%) when the data were analysed using the tailored coding framework, compared to the UMS-based framework (n=62; 22.9%).

Dosette completion per medicine

Based on the data coded using either coding framework, a lower proportion of participants correctly completed the dosette using label formats 1 and 3 compared to the other two label formats. When comparing the proportions correct by label format for the tailored coding framework with the UMS-based coding framework (Table ES5; Figure ES3 and ES4), the proportion correct was higher for label formats 1 (from 44.6% to 63.1%) and 3 (from 36.9% to 62.4%), and slightly lower for label formats 2 (from 75.6% to 69.4%) and 4 (from 73.8% to 70.5%).

Table ES5. Summary of correct responses per label format and medicine for dosette packing task – both coding frameworks[a]

Medicine	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
Total correct – UMS-based framework	121 (44.6; n=271)	205 (75.6; n=271)	100 (36.9; n=271)	200 (73.8; n=271)	626 (57.7; n=1084)	**<0.001**
Total correct – tailored framework	171 (63.1; n=271)	188 (69.4; n=271)	169 (62.4; n=271)	191 (70.5; n=271)	719 (66.3; n=1084)	**0.047**

[a] Missing data have not been included (missing n=4 dosettes overall and therefore, n=4 missing for each medicine).

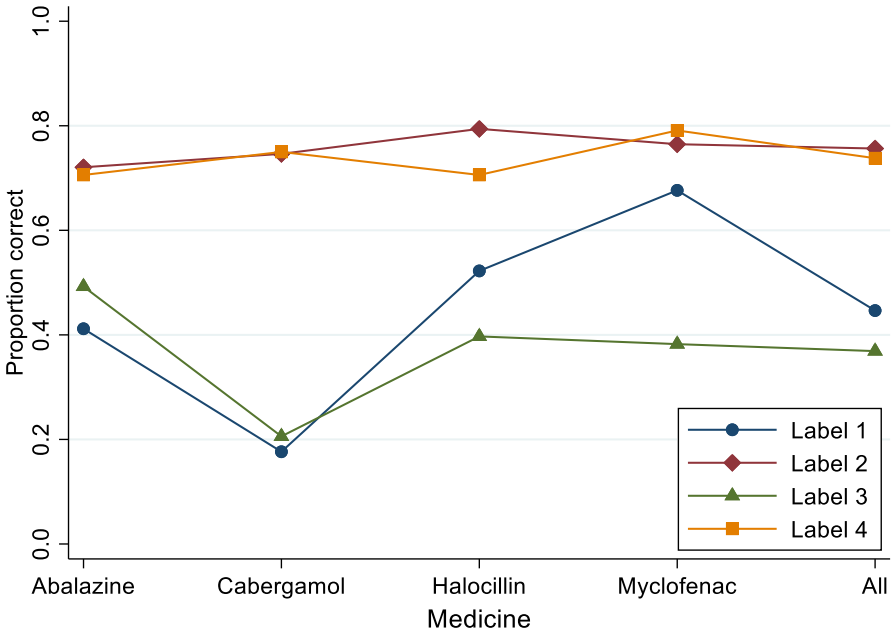


Figure ES3. Proportion of participants correctly completing the dosette packing task per medicine and label format – UMS-based framework

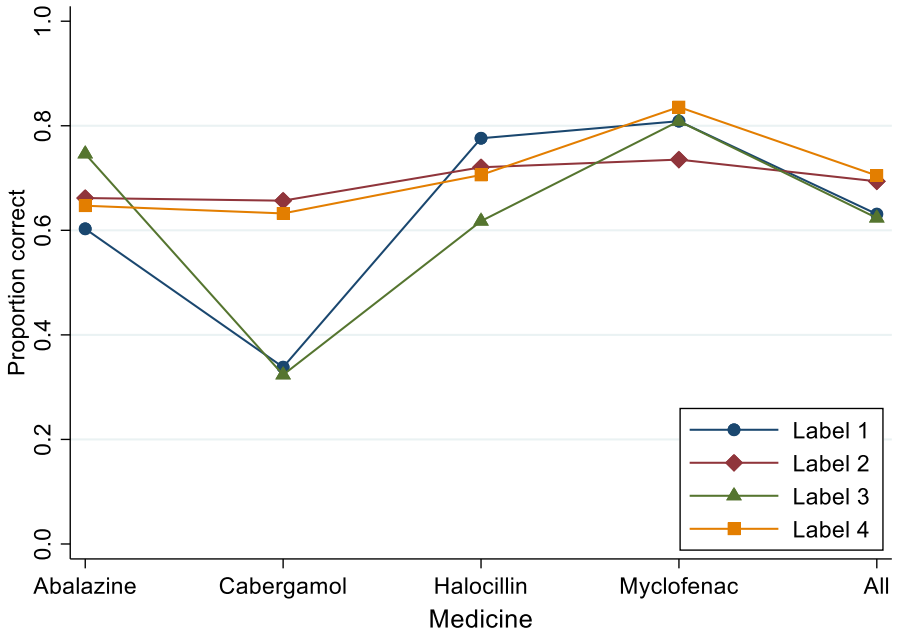


Figure ES4. Proportion of participants correctly completing the dosette packing task per medicine and label format – tailored coding framework

Differences in label format performance in the dosette packing task, stratified by NVS-UK scores

Label formats 2 and 4, modelled on UMS labelling characteristics, performed consistently better than label formats 1 and 3 across all health literacy levels (when the data were coded using the UMS-based framework). There were no statistically significant differences between label formats at any of the health literacy levels when the dosette data were coded using the tailored coding framework.

The group with adequate health literacy performed consistently better across all the label formats, regardless of the coding framework used, and vice versa for those with low health literacy (Figure ES5 and ES6).

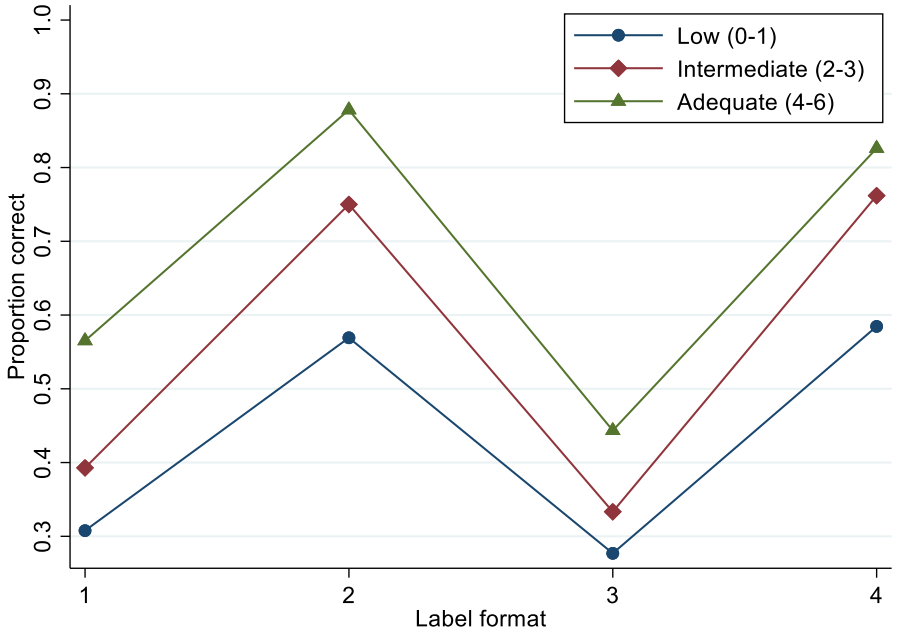


Figure ES5. Proportion who correctly completed the dosette packing task per label format according to stratified NVS-UK scores – UMS-based coding framework

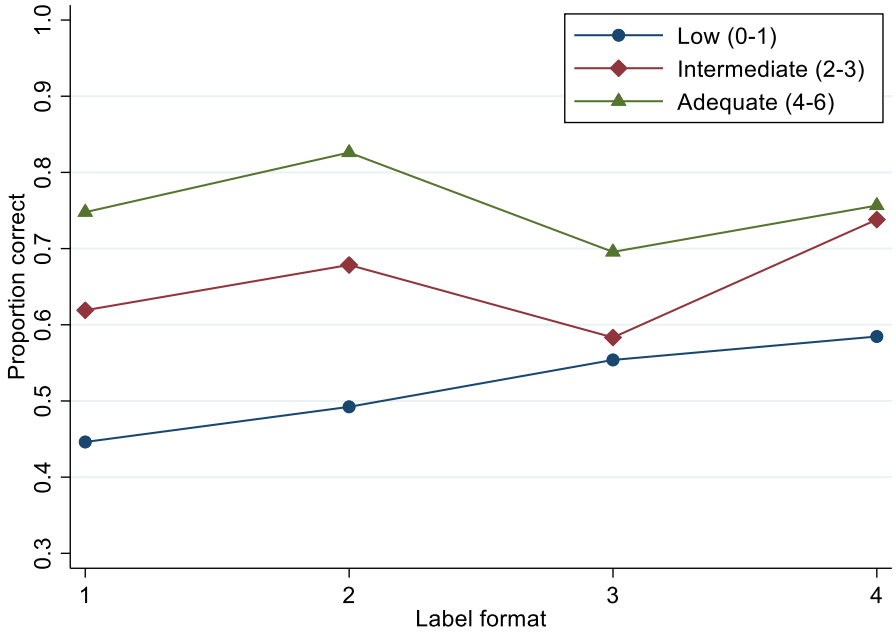


Figure ES6. Proportion who correctly completed the dosette packing task per label format according to stratified NVS-UK scores – tailored coding framework

Factors associated with participants' ability to correctly interpret medicine information

Active ingredient

Age, employment status, and highest level of education were found to be factors associated with participants' ability to correctly identify the active ingredient from the label. Participants who were older were less likely to correctly identify the active ingredient: the older the age group, the lower the probability of correctly identifying the active ingredient (P=0.009). Compared to participants employed full time, being retired was associated with an 88% higher chance of correctly identifying the active ingredient (adjusted OR 1.88; 95% CI 1.05-3.37 versus full time; P=0.004). Those who had completed tertiary education had a higher chance of correctly identifying the active ingredient (adjusted OR 2.74; 95% CI 1.28-5.87 versus those that had only completed primary school; P=0.004).

Dosette completion per medicine

Main language spoken at home and NVS-UK score were factors associated with participants' ability to correctly complete the dosette per medicine, regardless of whether the data were analysed using the UMS-based or tailored coding framework.

Those whose main language spoken at home was not English had significantly lower odds of correctly completing the dosette per medicine (UMS-based: adjusted OR 0.38, 95% CI 0.19-0.79, P=0.009; tailored: adjusted OR 0.29, 95% CI 0.14-0.58, P<0.001).

Those with either intermediate (adjusted OR 1.70; 95% CI 1.01-2.85) or adequate health literacy (adjusted OR 2.80; 95% CI 1.63-4.81) had a greater chance of correctly completing the dosette per medicine according to the UMS-based coding framework, compared to those with low health literacy (P<0.001). Similar results were observed for NVS-UK scores using the tailored coding framework.

Entire dosette completion (all four medicines)

Participants with a higher NVS-UK score performed better than those with a lower NVS-UK score. Participants with adequate health literacy were significantly more likely to correctly complete the entire dosette as determined using the UMS-based framework (adjusted OR 4.24; 95% CI 1.45-12.36) versus low health literacy (P=0.02). Although the result for NVS-UK scores were not statistically significant when using the tailored coding framework (P=0.06), the results are qualitatively similar, displaying the same trend.

Participants whose main language at home was not English performed poorly in completing the dosette correctly for all four medicines.

Conclusions

Clear labelling strategies provide benefits for all, regardless of health literacy levels. The study-designed label formats were effective in communicating information regarding the patient's name, dosage, total number of capsules to be taken per day, and the amount of active ingredient. Clear signposting of the active ingredient and brand name was by far the most effective approach for communicating a medicine's active ingredient, with nearly all participants able to identify the active ingredient.

Participants could correctly report the dosage-related information regardless of label format. However, the proportion who could apply this information and correctly complete the dosette per medicine was considerably lower. This indicates that people's ability to act on the information was impacted by other factors such as health literacy. Fewer participants with low health literacy were able to complete the dosette for all four medicines correctly. Those with adequate health literacy performed consistently better in completing the dosette across the different label formats. Differences in dosette completion data were noted between the data derived from the two coding frameworks. However, both sets of findings illustrated that explicit labelling directions, where approximate times of day are used to express doses, lead to a higher proportion of participants being able to demonstrate their understanding by correctly completing a dosette for the relevant medicine.

Labelling standards that reflect evidence-based strategies will inform development of user-friendly dispensed prescription medicine labels to support safe and effective medication use and adherence. Importantly, dosing and expression of dosing must be tailored for the person to ensure they are able to take all of their medicines appropriately. Labels should be supported by person-centred education and counselling, and integrating medication taking into people's daily routine to optimise medicines use.

Recommendations

<table>
<tr><th>DO</th><th>CONSIDER</th><th>DO NOT</th></tr>
<tr><td colspan="3">Active ingredient / brand name formatting</td></tr>
<tr><td>Signpost the active ingredient and brand name on the label</td><td rowspan="2"></td><td rowspan="2">Include the brand name and active ingredient on the same line together with the active ingredient name in brackets, without other formatting cues</td></tr>
<tr><td>Include the active ingredient and brand name on separate lines</td></tr>
<tr><td colspan="3">Communication of medicine-related information</td></tr>
<tr><td>Use explicit labelling directions, where approximate times of day are used to communicate dosage information
e.g. Take 1 capsule in the morning and 1 capsule in the evening</td><td>People's sleep-wake cycles and daily lifestyles when stating set time frames for medicine taking on the label</td><td></td></tr>
</table>

1. Background

Labels remain the mainstay of written medicine information accompanying dispensed prescription medicines in both hospital and community settings. In response to the recommendations from a national roundtable in 2013,[8] research was conducted to evaluate the most effective way of communicating medicine information on dispensed prescription medicine labels,[1] with the intention for these evidence-based recommendations to be integrated into national dispensed medicine labelling standards.

Based on the previous two rounds of user testing conducted,[1] findings indicated that dosage expression can influence people's ability to apply the information. Furthermore, in the absence of clear signposting of active ingredient and brand name, people had difficulty discerning between the two names.[1] Participant understanding was influenced by specific formatting and information positioning differences. For instance, when active ingredient was specified first and in bold font, with the brand name next to it in brackets, this caused misunderstanding because it was the opposite of what people intrinsically linked with current Australian labelling practices.

Consequently, specific labelling characteristics identified as supporting improved understanding of labels warranted further evaluation. In particular, it is important to examine whether certain labelling approaches may support those with lower health literacy to better understand and appropriately apply and act on dispensed prescription medicine instructions. Labels were subsequently proposed for quantitative evaluation to examine their performance, in comparison to a label format modelled on what is currently implemented in Australian hospital and community settings, to better understand the impact of labelling characteristics.

2. Study aim and objectives

This study aimed to evaluate the performance of dispensed prescription medicine labels that have been developed based on user testing findings, patient-centred language and layout, and expert recommendations.

The study objectives were to:

- Explore the impact of labelling characteristics on people's ability to apply dosage-related information, and
- Compare the performance of the study-developed dispensed prescription medicine labels with a currently implemented label format.

3. Methods

The broader study consisted of five stages:

1) Development of labels with varying labelling characteristics (e.g. dosage expression, information positioning/formatting/layout)
2) Round 1 user testing (12 labels for four fictitious medicines; n=40 participants)
3) Iterative label revisions and Round 2 user testing (7 labels for four fictitious medicines; n=20)
4) Consolidation of labelling recommendations and development of study labels; and
5) Label evaluation (four Australian hospitals; three states/territories) with patients due for discharge (four label designs for four fictitious medicines (16 labels in total)).

The study reported here was the final stage of this research, and informed by the four preceding stages.

3.1 Ethics approval and study conduct

Ethics approval for the study was granted from the ACT Health Human Research Ethics Committee (approval number ETH.1.18.014) for the Canberra and Melbourne sites, and the Top End Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (approval number 2018-3155) for the Darwin sites.

This study took place from April 2019 to October 2019 (inclusive), with site-specific start dates determined by when each site received ethics approval and/or site-specific authorisation.

At a site level, recruitment and data collection took place in:

- Canberra (the lead study site), from April 2019 to October 2019 (inclusive);
- Darwin, from May 2019 to October 2019 (inclusive); and
- Melbourne, from May 2019 to October 2019 (inclusive).

Data collection was formally concluded across all sites at the end of October 2019.

Participants provided written informed consent. Participants did not receive any financial reimbursement for their participation in the study.

3.2 Study material development and preparation

3.2.1 Study labels for quantitative evaluation

A total of 16 labels (four label formats x four fictitious medicines, randomised into four kits) were developed for quantitative evaluation. Findings from the user testing[1] (stage 2 and 3 of the broader project), relevant labelling literature,[2, 3] together with input from the research team members, informed the development of the four label formats.

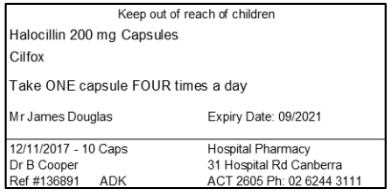
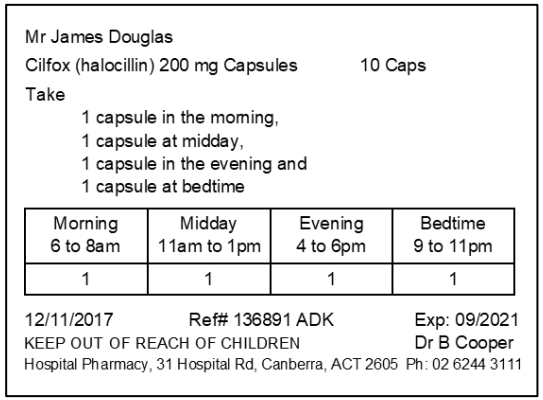
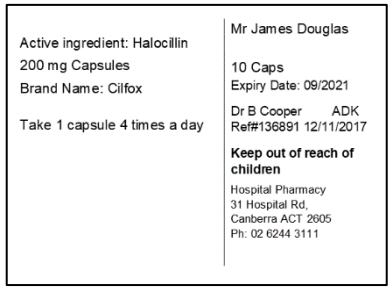
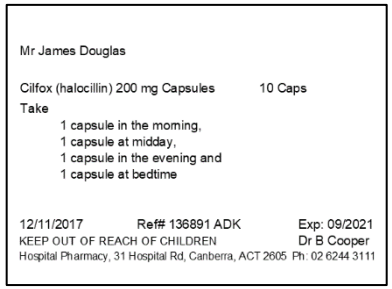
Fictitious medicines were intentionally used to avoid prior knowledge about a particular medicine (including the name and/or dosage) influencing participant responses. Each fictitious medicine had unique dosage instructions and capsule colour (Table 1). The active ingredient, corresponding brand name, capsule colour, and dosage for the fictitious medicine were kept constant regardless of label format (Table 1). All active ingredient names were presented in lower case when in brackets (for 2/4 label formats), with the remaining two label formats presenting the active ingredient using sentence case; brand names were presented in sentence case.

Key label variables underpinned the four developed label formats (Table 2). The study labels allowed for investigation of how well participants understood dosing information, comparing explicit dosing instruction (Take two capsules in the morning and two capsules at bedtime) with standard instructions (Take two capsules twice a day). Where label format 1 was modelled on labels used in current practice in Australia, label format 2 presented participants with the Universal Medication Schedule (UMS); the UMS is a way of expressing dosing instructions using consistent times of the day, which can also include a complementary table that aims to help simplify dosing regimens into four times of the day.[3] Label format 4 was similar to label format 2 but did not include the table.

Table 1. Fictitious medicines and dose instructions

	Active ingredient	Brand name	Capsule colour	Dose
Medicine 1	myclofenac	Vipparoll	White	2 bd (two capsules twice a day)
Medicine 2	halocillin	Cilfox	Green	1 qid (one capsule four times a day)
Medicine 3	cabergamol	Dariol	Blue	2 tds (two capsules three times a day)
Medicine 4	abalazine	Butafor	Yellow	2 qid (two capsules four times a day)

Table 2. Summary of variables considered for label development

Variables	Label format 1	Label format 2	Label format 3	Label format 4
Label dimensions	80 mm x 38 mm	90 mm x 65 mm	90 mm x 65 mm	90 mm x 65 mm
Active ingredient and brand name order and positioning	Active ingredient presented first, above the brand name (on separate lines)	Active ingredient presented second (in brackets) after the brand name (on the same line)	Signposted active ingredient presented first, above the brand name (on separate lines)	Active ingredient presented second (in brackets) after the brand name (on the same line)
Format: 1 column versus 2 columns	Top half of label = 1 column Bottom half of label = 2 columns, separated by line	Top half of label = 1 column Bottom half of label = UMS[a] table	2 columns, separated by line	1 column
Indentation of dosing information	No	Yes	No	Yes
Expression of dosage (examples given from Kit A)	Take TWO capsules TWICE a day	Take 1 capsule in the morning, 1 capsule at midday, 1 capsule in the evening and 1 capsule at bedtime Morning 6 to 8am: 1 / Midday 11am to 1pm: 1 / Evening 4 to 6pm: 1 / Bedtime 9 to 11pm: 1	Take 2 capsules 3 times a day	Take 2 capsules in the morning, 2 capsules at midday, 2 capsules in the evening and 2 capsules at bedtime
Label format example (label examples shown for halocillin)				

[a] UMS refers to Universal Medication Schedule.[3-5]

Each kit that was evaluated by participants contained four labels, representing one of each label design and fictitious medicine in varying combinations. A Latin square matrix was used to randomise the label formats into four kits (Table 3, Figures 1a-1d and Appendix 1). Labels were printed in black and white, and affixed to blank cardboard boxes with one strip of ten blister-packed placebo capsules inside each box. Capsules were colour-coded according to the fictitious medicine; this was standardised across all kits. The kits were then randomised into a listed order, and then packaged and numbered by the lead site, Canberra Hospital. The kits were then distributed for use at the other hospital sites. At each site, kits were used in the order in which they were numbered to maintain the randomisation schedule.

Table 3. Latin square matrix randomisation of label formats into kits

Label format	Medicine 1 myclofenac	Medicine 2 halocillin	Medicine 3 cabergamol	Medicine 4 abalazine
Label format 1	Kit A	Kit D	Kit C	Kit B
Label format 2	Kit B	Kit A	Kit D	Kit C
Label format 3	Kit C	Kit B	Kit A	Kit D
Label format 4	Kit D	Kit C	Kit B	Kit A

Halocillin label (90 mm x 65 mm) Label format 2

Mr James Douglas

Cilfox (halocillin) 200 mg Capsules 10 Caps

Take
1 capsule in the morning,
1 capsule at midday,
1 capsule in the evening and
1 capsule at bedtime

Morning 6 to 8am	Midday 11am to 1pm	Evening 4 to 6pm	Bedtime 9 to 11pm
1	1	1	1

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Abalazine label (90 mm x 65 mm) Label format 4

Mr James Douglas

Butafor (abalazine) 80 mg Capsules 10 Caps

Take
2 capsules in the morning,
2 capsules at midday,
2 capsules in the evening and
2 capsules at bedtime

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Cabergamol label (90 mm x 65 mm) Label format 3

Active ingredient: Cabergamol
10 mg Capsules
Brand Name: Dariol

Take 2 capsules 3 times a day

Mr James Douglas

10 Caps
Expiry Date: 09/2021

Dr B Cooper ADK
Ref#136891 12/11/2017

Keep out of reach of children

Hospital Pharmacy
31 Hospital Rd,
Canberra ACT 2605
Ph: 02 6244 3111

Myclofenac label (80 mm x 38 mm) Label format 1

Keep out of reach of children
Myclofenac 75 mg Capsules
Vipparoll

Take TWO capsules TWICE a day

Mr James Douglas Expiry Date: 09/2021

12/11/2017 - 10 Caps
Dr B Cooper
Ref #136891 ADK

Hospital Pharmacy
31 Hospital Rd Canberra
ACT 2605 Ph: 02 6244 3111

Figure 1a. Kit A labels

Halocillin label (90 mm x 65 mm) Label format 3

Active ingredient: Halocillin
200 mg Capsules
Brand Name: Cilfox

Take 1 capsule 4 times a day

Mr James Douglas

10 Caps
Expiry Date: 09/2021

Dr B Cooper ADK
Ref#136891 12/11/2017

Keep out of reach of children

Hospital Pharmacy
31 Hospital Rd,
Canberra ACT 2605
Ph: 02 6244 3111

Abalazine label (80 mm x 38 mm) Label format 1

Keep out of reach of children

Abalazine 80 mg Capsules
Butafor

Take TWO capsules FOUR times a day

Mr James Douglas Expiry Date: 09/2021

12/11/2017 - 10 Caps
Dr B Cooper
Ref #136891 ADK

Hospital Pharmacy
31 Hospital Rd Canberra
ACT 2605 Ph: 02 6244 3111

Cabergamol label (90 mm x 65 mm) Label format 4

Mr James Douglas

Dariol (cabergamol) 10 mg Capsules 10 Caps

Take
2 capsules in the morning,
2 capsules at midday and
2 capsules at bedtime

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Myclofenac label (90 mm x 65 mm) Label format 2

Mr James Douglas
Vipparoll (myclofenac) 75 mg Capsules 10 Caps

Take
2 capsules in the morning and
2 capsules at bedtime

Morning 6 to 8am	Midday 11am to 1pm	Evening 4 to 6pm	Bedtime 9 to 11pm
2			2

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Figure 1b. Kit B labels

Halocillin label (90 mm x 65 mm) Label format 4

Mr James Douglas

Cilfox (halocillin) 200 mg Capsules 10 Caps

Take
1 capsule in the morning,
1 capsule at midday,
1 capsule in the evening and
1 capsule at bedtime

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Abalazine label (90 mm x 65 mm) Label format 2

Mr James Douglas
Butafor (abalazine) 80 mg Capsules 10 Caps

Take
2 capsules in the morning,
2 capsules at midday,
2 capsules in the evening and
2 capsules at bedtime

Morning 6 to 8am	Midday 11am to 1pm	Evening 4 to 6pm	Bedtime 9 to 11pm
2	2	2	2

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Cabergamol label (80 mm x 38 mm) Label format 1

Keep out of reach of children
Cabergamol 10 mg Capsules
Dariol

Take TWO capsules THREE times a day

Mr James Douglas Expiry Date: 09/2021

12/11/2017 - 10 Caps Hospital Pharmacy
Dr B Cooper 31 Hospital Rd Canberra
Ref #136891 ADK ACT 2605 Ph: 02 6244 3111

Myclofenac label (90 mm x 65 mm) Label format 3

Active ingredient: Myclofenac
75 mg Capsules
Brand Name: Vipparoll

Take 2 capsules 2 times a day

Mr James Douglas

10 Caps
Expiry Date: 09/2021

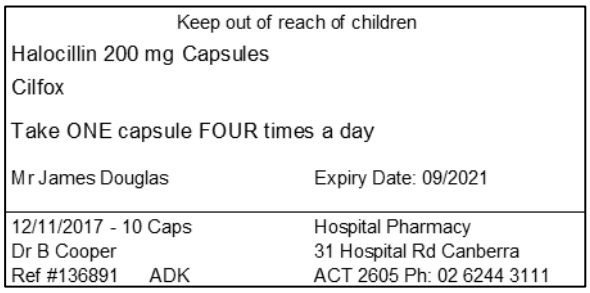
Dr B Cooper ADK
Ref#136891 12/11/2017

Keep out of reach of children

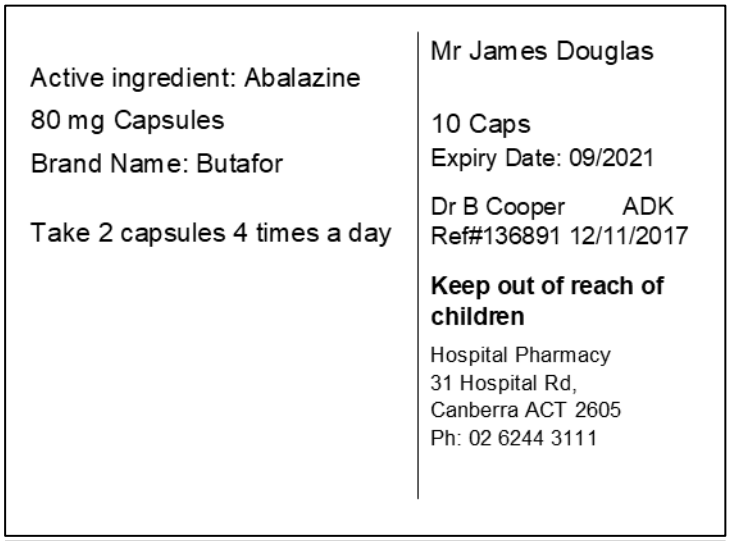
Hospital Pharmacy
31 Hospital Rd,
Canberra ACT 2605
Ph: 02 6244 3111

Figure 1c. Kit C labels

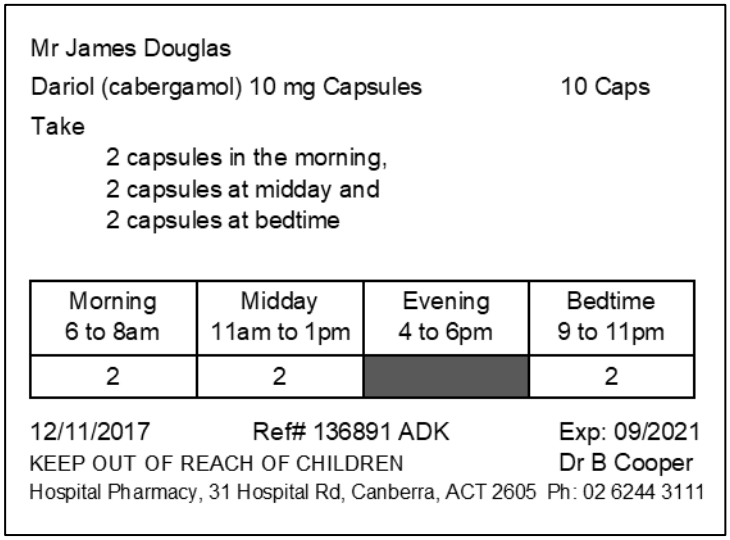
Halocillin label (80 mm x 38 mm) Label format 1



Abalazine label (90 mm x 65 mm) Label format 3



Cabergamol label (90 mm x 65 mm) Label format 2



Myclofenac label (90 mm x 65 mm) Label format 4

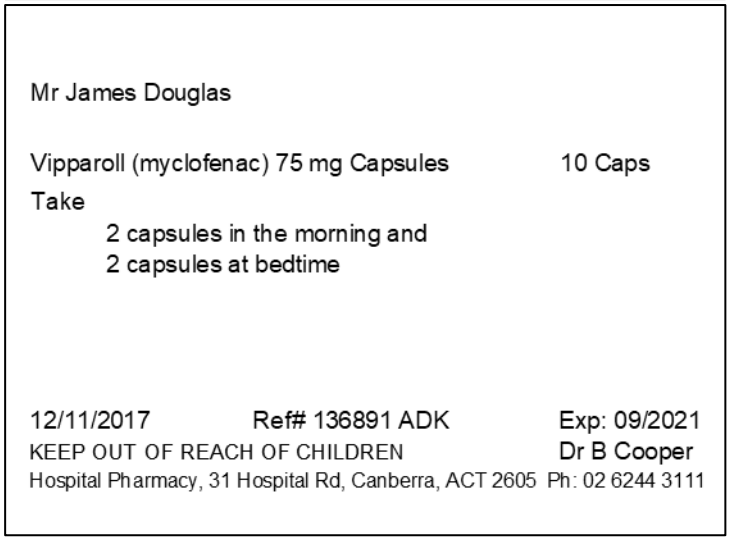


Figure 1d. Kit D labels

3.2.2 Questionnaire development

To help evaluate the labels, a questionnaire was developed by the lead site, with input from the research team and reference to the previous stages,[1] for data collection. The questionnaire comprised three key sections (Table 4):

1. Evaluation of medicine-related information on each label (in the medicine label order: halocillin, abalazine, cabergamol, and myclofenac);
2. A dosette packing task (see Appendix 2 for images of the 24-well dosette used and an example of a completed dosette for all medicines); and
3. Participant demographics and health literacy assessment (via the Newest Vital Sign UK (NVS-UK)[6]).

Table 4. Overview of study questionnaire and rationale for specific questions / tasks

Questionnaire section	Question (Question focus)	First label halocillin	Second label abalazine	Third label cabergamol	Fourth label myclofenac	Rationale
1. Evaluation of medicine-related information on each label	Who does this medicine belong to? (Patient name)	✓[a]				The question on patient name was only asked for the first medicine to examine whether the patient name could be located on each label format. If it could not be found, the answer was given to the participant as the following questions referred to the patient name.
	(Dosage)	Looking at the information on the label, how much should James[b] take and how often?	Imagine that James has just collected this medicine from the pharmacy. How much should he take and how often?	Looking at the information on this label, how much should James take and how often?	Imagine James has just been prescribed this medicine by his doctor. How much should he take and how often?	Dosage information on medicines is critical to support safe and appropriate medication use.
	What is the active ingredient found in this medicine? (Active ingredient)	✓	✓	What is the active ingredient in this medicine?	✓	Active ingredient identification is imperative to ensure that the correct medicine is being used, and will help minimise medication-related errors e.g. double dosing. This information should be easily accessible to label users, supported by appropriate formatting.
	How many capsules in total would James take in 1 day? (Total number of capsules per day)	✓	✓	How many capsules would James take in 1 day?	✓	Total daily dose understanding informs a person's ability to plan their medication taking per day.
	How much of the active ingredient is in each capsule? (Medicine strength)	✓	✓	✓	✓	Medicine strength together with active ingredient information should be able to be identified to ensure the appropriate medicine is being used.

Questionnaire section	Question (Question focus)	First label halocillin	Second label abalazine	Third label cabergamol	Fourth label myclofenac	Rationale
2. Dosette packing task	"This is a dosette box that represents the hours in 1 day. It has 24 places to put medicines where each place matches up to a different time during the day. 'Imagine that your doctor has prescribed you these medicines. I would like you to please show me when you would take these medicines over the course of 1 day.'[7(p.301)] Please do this by putting the required number of capsules in the well that represents the time of day that you would take them." [*Explicitly demonstrate the use of the medication box using two loose placebo capsules:* "I will demonstrate an example for you. If one of these capsules needs to be taken in the morning and another one capsule in the evening, I would place one in the morning at 7 am and one at 5 pm to reflect when I would take them."]					The 24-well dosette box was purpose-built for the study, based on the dosette design used in previous research.[7] The instructions provided for this task were also modelled on the previous study conducted by Wolf et al.[7]
3. Participant demographics and health literacy assessment (NVS-UK[6])	Participant demographics information requested: • Age (in years) • Gender • Country of birth • Main language spoken at home • Other language(s) spoken at home • Highest level of education • Employment status • Number of medications usually taken each day • Number of doses of medication usually taken each day • Number of medical conditions for which medicines are taken Health literacy assessment administered: • NVS-UK[6]					Similar demographics were collected as previous user testing research.[1] Questions regarding medicines and medical conditions were asked to ascertain the prevalence of polypharmacy within the participant sample. The NVS was administered in a previous labelling study[7] that informed the present study design; however, as the tool was being administered in the Australian context, the NVS-UK was chosen for use instead, considering the similarities between UK and Australian English.

[a] The question was asked only once per participant for the relevant label format of the fictitious medicine that was evaluated first.

[b] James Douglas was the fictitious patient name included on the labels.

3.3 Study location

Participants were recruited from Top End Health Service (Royal Darwin Hospital and Palmerston Regional Hospital), Canberra Health Services (Canberra Hospital), and Melbourne Health (Royal Melbourne Hospital).

At each site, patients who were waiting for discharge in the hospital wards and in the discharge lounge were invited to participate in the study (Table 5). Interviews were conducted in a secluded segment of the discharge lounge or ward to protect the confidentiality of participants.

Table 5. Recruitment locations within the four study hospitals

Main recruitment hospital / service	Recruitment location
Canberra Hospital	• Discharge lounge
Royal Darwin Hospital	• Transit lounge • Lorraine Brennan Centre • General wards (e.g. rapid assessment and planning unit, surgical, medical, and coronary care wards)
Palmerston Regional Hospital	• Rehabilitation ward
Royal Melbourne Hospital	• Discharge lounge • Cardiology and cardiothoracic surgery wards

3.4 Recruitment

3.4.1 Study participants

Inclusion and exclusion criteria for the study participants were based on stages 2 and 3 of the broader research[1] and previous research conducted by members of the research team.[9-11]

People were eligible to be recruited into the study if they were:

- 18 years or older, and
- Were sufficiently proficient in the English language to enable them to read and understand the participant information statement, consent form, and relevant study materials without the need for help from a translator, thereby allowing them to take part in the study.

People were ineligible to participate if they:

- Were a health care professional (HCP) regardless of their current practice status (practising or retired) or who were currently working in a role which largely involved the use of medicines information
- Had significant visual impairment
- Had significant cognitive impairment
- Had been a participant in a user testing study within the previous 6 months, or
- Were too unwell to participate.

3.4.2 Sample size calculation

We required a sample of 368 to be able to detect a 10% difference between two labels, with approximately 80% power, using a 5% significance level for a two-sided test, and conservatively assuming the proportion of discordant pairs to be 0.5 – if the proportion of discordant pairs is lower, then the power will be higher. We aimed for a sample size of 500 to take into account drop-out rates and to ensure that we had a sufficient number of participants who had poor health literacy skills. We estimated that approximately 60% of participants would have poor health literacy, that is, not have basic health literacy skills that are needed to understand health-related information, such as instructions for use typed on prescription medicine labels.[12]

The sample size for Royal Darwin Hospital (and subsequently, Palmerston Regional Hospital) was capped at 150 participants as the hospital has lower bed numbers.

3.5 Study process

3.5.1 Identification of potential participants

Research officers introduced the study, including the inclusion and exclusion criteria, to the nursing team leaders of the transit lounge and inpatient wards at the study hospitals. Nursing team leaders were asked to identify patients who were awaiting discharge from the area and who may be eligible to participate.

3.5.2 Recruitment protocol

Identified patients awaiting discharge were approached by a research officer. The research officer was not someone who was or had been directly involved in the patient's care at the hospital.

For the Darwin protocol, if they indicated interest in participating, screening of the potential participant for any exclusion criteria took place immediately after the introduction to the study. Participants were provided with the participant information statement (PIS) and consent form to read and consider. They were also given the opportunity to ask questions. Those interested in proceeding with the study provided written consent.

Based on the Canberra and Melbourne protocol, screening of the potential participant took place after general explanation of the study and reading of the PIS, and consent form completion.

All participants were informed about the study and what participation involved prior to obtaining written consent. They were also informed that they were not under any obligation to participate and that they could withdraw from the study at any time.

3.5.3 Study process and data collection

Data collection was completed by appropriate personnel from each site who had been trained by a research team member with extensive experience in user testing protocol (VT) (Figure 2); one additional team member in Darwin was trained later by a fellow site team member who had previously received training.

Figure 2. Overview of study process

3.6 Data analysis

3.6.1 Outcome measures

The key outcome measures for the study were participants' ability to:

- Find and understand key information on the label (treated as a single outcome measure) relating to:
  - Patient name (for the first label only); and
  - Dosage, active ingredient, total number of capsules per day, and medicine strength, for all labels
- Correctly complete the dosette for:
  - Each medicine individually (each label format per kit); and
  - Overall (for all four medicines collectively)
    (see Section 3.6.3 for further information on the coding frameworks used)

3.6.2 Data management and cleaning

3.6.2.1 Initial data review and recoding

Data were entered at each site from hardcopy data record sheets (for each participant) into a standardised Excel database developed by the lead site (Canberra Hospital). Final data were then sent to The University of Sydney and merged for analysis. Comments included by the site researchers for participants were reviewed by a research team member (VT), and discussed with a second researcher (PA), and a consensus was reached regarding any actions to be taken. Actions included data being recoded, participants being excluded from the final dataset, or further data analyses (see the Results section for further details regarding excluded data).

Participant demographics data were reviewed for any discrepancies. Participant data for number of medicines, number of doses per day and number of medical conditions were recoded, as appropriate:

- Number of medicines taken regularly: the category ">5" was replaced with "≥5";
- Number of medication doses usually taken each day: The questionnaire inadvertently had a response category missing. This was noticed prior to data collection and the data was collected separately. Re-categorisation was completed for the analysis, where the category "7-12" doses was introduced; this data was then merged with the ">12" category to have a "≥ 7" category for analysis and reporting;
- Number of medical conditions: ">5" was replaced with "≥5" (similar to number of medicines taken regularly);
- Employment status: casual employment was coded as "part time".

3.6.3 Data analysis plan – dosette packing task

The dosette packing task was analysed using two coding frameworks to compare findings for the key outcome measure of appropriate/inappropriate dosing (coded as correct or incorrect) for each medicine:

- UMS-based coding framework – this was based on the UMS[3-5] and how the dosing was communicated by the information on the label
- Tailored coding framework – this was based on the dosing information on the label and appropriate dosing intervals, which were not restricted by the UMS time frames

Using two coding frameworks afforded the opportunity to examine the impact of labelling on people's interpretation and planned application of the dosage information, with and without restriction of timing by the UMS.

3.6.3.1 UMS-based coding framework

A coding framework was developed *a priori* by the Canberra Hospital team in order to code the dosette packing task responses (Tables 6-9). All research team members involved in data collection were made aware of this coding framework, in particular, for data entry and preliminary coding within the Excel database at the site level.

The key outcome measure was appropriateness of dosette packing for all four study medicines and for each individual medicine. The UMS-based coding framework designated specific windows where doses were expected to be placed in the dosette box, and the number of capsules per dose – any deviations from the framework for any study medicine was deemed as inappropriate and coded as incorrect.

For each medicine, in order to be coded as correct, the number of capsules and the placement of capsules within the allowed time frame (highlighted in green in the model answer per kit) had to correspond to the model answer. Completion of the dosette for all four medicines must have been deemed correct for the overall dosette to be coded as correct.

Table 6. UMS-based coding framework model answers – Kit A

Time → Medication↓	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am	12pm	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm
halocillin (green) 1 QID							1	1	1			1	1	1			1	1	1			1	1	1
abalazine (yellow) 2 QID							2	2	2			2	2	2			2	2	2			2	2	2
cabergamol (blue) 2 TDS							2	2	2					2	2	2					2	2	2	2
myclofenac (white) 2 BD							2	2	2	2	2								2	2	2	2	2	

Table 7. UMS-based coding framework model answers – Kit B

Time → Medication↓	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am	12pm	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm
halocillin (green) 1 QID							1	1	1			1	1	1			1	1	1			1	1	1
abalazine (yellow) 2 QID							2	2	2			2	2	2			2	2	2			2	2	2
cabergamol (blue) 2 TDS							2	2	2				2	2	2	2					2	2	2	2
myclofenac (white) 2 BD							2	2	2													2	2	2

Table 8. UMS-based coding framework model answers – Kit C

Time → Medication↓	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am	12pm	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm
halocillin (green) 1 QID							**1**	**1**	**1**			**1**	**1**	**1**			**1**	**1**	**1**			**1**	**1**	**1**
abalazine (yellow) 2 QID							**2**	**2**	**2**			**2**	**2**	**2**			**2**	**2**	**2**			**2**	**2**	**2**
cabergamol (blue) 2 TDS							**2**	**2**	**2**					**2**	**2**	**2**					**2**	**2**	**2**	**2**
myclofenac (white) 2 BD							**2**	**2**	**2**	**2**											**2**	**2**	**2**	**2**

Table 9. UMS-based coding framework model answers – Kit D

Time → / Medication↓	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am	12pm	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm
halocillin (green) 1 QID							**1**	**1**	**1**			**1**	**1**	**1**			**1**	**1**	**1**			**1**	**1**	**1**
abalazine (yellow) 2 QID							**2**	**2**	**2**			**2**	**2**	**2**			**2**	**2**	**2**			**2**	**2**	**2**
cabergamol (blue) 2 TDS							**2**	**2**	**2**			**2**	**2**	**2**								**2**	**2**	**2**
myclofenac (white) 2 BD							**2**	**2**	**2**	**2**											**2**	**2**	**2**	**2**

3.6.3.2 Tailored coding framework

To complement the UMS-based coding framework, a second framework was developed by the research team members based at The University of Sydney as a comparator to reflect tailored coding for the dosette packing task responses. Each label and label kit were systematically reviewed to determine an appropriate/inappropriate daily schedule for the medicine based on the label to inform the coding framework.

The primary considerations were (Table 10):

- Total number of capsules to be taken correctly per day,
- Number of correct doses per day (i.e. how many times the medicine should be taken per day),
- Number of capsules to be taken correctly per dose,
- The minimum and maximum dosing intervals (per medicine), and
- For all labels with the UMS table, the doses were required to be within the specific time frames included in the table, i.e. 6-8 am, 11-1 pm, 4-6 pm and 9-11 pm, as appropriate for the medicine.

Where there were similarities between labels across kits, consistent coding was used where possible. Due to the emphasis on dosing intervals within this coding framework, dosing intervals were calculated for each participant-completed dosette to examine whether specific label formats support more appropriate dosing intervals over others.

In addition to the primary considerations above, all labels that included a UMS table were required to have all doses within the designated time frames on the label, as well as appropriate dosing intervals in order to be coded as correct. Any deviations from the coding framework were regarded as inappropriate and coded as incorrect.

Additional data reported with the tailored coding framework were:

- Time of first dose of the day (per participant, when taking into consideration all four medicines)
- Time of last dose of the day (per participant, when taking into consideration all four medicines)
- Number of grouped medication doses per day per participant (to examine how participants timed multiple doses for multiple medicines, similar to previous research[7, 13])
- What time equates to “midday” for participants (i.e. the second dose of the medication, determined by reviewing the dosette from left to right), and
- What time equates to “bedtime” for participants (i.e. the third or fourth dose of the medication, determined by reviewing the dosette from left to right, for the relevant labels for medications dosed three and four times a day, respectively).

A database was created to capture the data arising from the additional analyses. To ensure validity and reliability, one researcher analysed all data using the tailored coding framework and identified the above additional data. All relevant data were entered into the purpose-built database along with comments about any differences in coding when comparing the findings between the UMS-based and the tailored coding frameworks.

Table 10. Tailored coding framework, grouped by medicine and dosing regimen

Medicine and kit	Label directions	Appropriate response – total no. of capsules	Appropriate response – no. of doses per day	Appropriate response – no. of capsules per dose	**Appropriate response – Minimum dosing interval (in hours) between doses**	**Appropriate response – Maximum dosing interval (in hours) between doses**	Comment(s) / Other consideration(s)
myclofenac – Kit A	Take TWO capsules TWICE a day	4	2	2	**9**	**15**	• Doses 12 hours apart ideal • The earliest accepted morning dose is 4 am
myclofenac – Kit C	Take 2 capsules 2 times a day						
myclofenac – Kit B	Take 2 capsules in the morning and 2 capsules at bedtime **+ UMS table**						• As UMS table included on label, the doses **MUST** be within the designated time frames (6-8 am and 9-11 pm, respectively), **AND** observing appropriate dosing intervals
myclofenac – Kit D	Take 2 capsules in the morning and 2 capsules at bedtime						• **First dose must be taken before 12 noon = morning dose; the earliest accepted morning dose is 4 am** • Upper limit of 15 hours between doses adapted based on the Kit B myclofenac label (not an unreasonable dosing interval given the directions expressed in approx. times of day e.g. 7 am and 10 pm dose)

Medicine and kit	Label directions	Appropriate response – total no. of capsules	Appropriate response – no. of doses per day	Appropriate response – no. of capsules per dose	**Appropriate response – Minimum dosing interval (in hours) between doses**	**Appropriate response – Maximum dosing interval (in hours) between doses**	Comment(s) / Other consideration(s)
abalazine – Kit B	Take TWO capsules FOUR times a day	8	4	2	**4**	**7**	• Consistency with four times a day dosing intervals of 4-6 hours to be maintained • The earliest accepted morning dose is 4 am
abalazine – Kit D	Take 2 capsules 4 times a day						
abalazine – Kit A	Take 2 capsules in the morning, 2 capsules at midday, 2 capsules in the evening and 2 capsules at bedtime						• **First dose of the day must be before 12 noon = morning dose** • The earliest accepted morning dose is 4 am
abalazine – Kit C	Take 2 capsules in the morning, 2 capsules at midday, 2 capsules in the evening and 2 capsules at bedtime **+ UMS table**						• As UMS table included on label, the doses **MUST** be within the designated time frames (6-8 am, 11 am-1 pm, 4-6 pm, and 9-11 pm, respectively), **AND** observing appropriate dosing intervals
halocillin – Kit A	Take 1 capsule in the morning, 1 capsule at midday, 1 capsule in the evening and 1 capsule at bedtime **+ UMS table**	4	4	1			• As UMS table included on label, the doses **MUST** be within the designated time frames (6-8 am, 11 am-1 pm, 4-6 pm, and 9-11 pm, respectively), **AND** observing appropriate dosing intervals
halocillin – Kit C	Take 1 capsule in the morning, 1 capsule at midday, 1 capsule in the evening and 1 capsule at bedtime						• **First dose must be taken before 12 noon = morning dose; the earliest accepted morning dose is 4 am** • The coding for the first dose is strict, as noted above, and the coding for the remaining doses is based on the timing of the first dose and the dosing intervals followed. This coding is based on the instructions and the fact that there is no UMS table on this label
halocillin – Kit B	Take 1 capsule 4 times a day						• Consistency with four times a day dosing intervals of 4-6 hours to be maintained • The earliest accepted morning dose is 4 am
halocillin – Kit D	Take ONE capsule FOUR times a day						

Medicine and kit	Label directions	Appropriate response – total no. of capsules	Appropriate response – no. of doses per day	Appropriate response – no. of capsules per dose	**Appropriate response – Minimum dosing interval (in hours) between doses**	**Appropriate response – Maximum dosing interval (in hours) between doses**	Comment(s) / Other consideration(s)
cabergamol – Kit A	Take 2 capsules 3 times a day	6	3	2	**6**	**10**	• 6-8 hours is the typical three times a day dosing interval schedule • Therefore 6 hours is designated as the minimum dosing interval for three times a day regimen (no lower dosing interval used here as it would merge into a four times a day dosing interval) • 10 hours is the upper limit used, as a higher upper limit would merge into a twice a day dosing interval • The earliest accepted morning dose is 4 am
cabergamol – Kit C	Take TWO capsules THREE times a day						
cabergamol – Kit B	Take 2 capsules in the morning, 2 capsules at midday and 2 capsules at bedtime				**5 (between morning and midday dose)**	**9 (between morning and midday dose)**	• **First dose must be taken before 12 noon = morning dose**; the earliest accepted morning dose is 4 am
cabergamol – Kit D	Take 2 capsules in the morning, 2 capsules at midday and 2 capsules at bedtime **+ UMS table**				**8 (between midday and bedtime dose)**	**11 (between midday and bedtime dose)**	• As UMS table included on label, the doses **MUST** be within the designated time frames (6-8 am, 11 am-1 pm, and 9-11 pm, respectively), **AND** observing appropriate dosing intervals

3.6.4 Data coding accuracy check

3.6.4.1 UMS-based coding framework

To independently examine the accuracy of the coding of the dosette pack responses, a proportional check per site was conducted by a research team member who was not directly involved in data collection or data entry (VT).

Based on the preliminary participant totals per site, a 10% random check for each site was conducted (data for n=12, 11, 6 checked for Canberra, Darwin and Melbourne, respectively).

The data coding check consisted of:

- Referring to the data entered for each participant for the doses (number of capsules) planned to be taken for each medicine and the corresponding times that participants planned to take the medicines,
- Recoding the above data using the model answers (developed using the UMS-based coding framework), and then
- Comparing the recoded data to the coded data completed by each site.

As coding discrepancies were found during this 10% check, all data entered by the site teams were recoded and checked by one researcher at The University of Sydney (VT). Once all data were checked, all discrepancies discovered were flagged and double checked by a second researcher (PA), who recoded the data independently. Ten percent of the total data entered was also recoded by the second researcher, and compared to the coding completed by VT and the site.

Both researchers who checked the coding agreed upon the discrepancies identified across the entire dataset. Based on this, the relevant raw data were requested from each site to verify the dosette-related discrepancies. The data entered into the Excel databases were then checked against the raw data. Any data entry and data coding errors were addressed, and the final merged dataset was finalised.

3.6.4.2 Tailored framework

An independent 10% check of the coded data was conducted by a second researcher (PA). Data were independently recoded and compared with the entered data that was coded initially by another researcher (VT). Outcomes of the coding checks were compared between the two researchers. The minor discrepancies that were identified were discussed and addressed as appropriate; a further proportion of dosette data was checked until no errors were detected, at which point the dataset was finalised.

3.6.5 Statistical analyses

Participant demographics were summarised by each kit using counts and proportions for categorical variables, and means and standard deviations for continuous variables. Correct answers to questions and dosettes were summarised using counts and proportions for each label – both individually for each medicine and collectively for all four medicines. P-values were calculated to determine if the proportion of correct answers differed between label formats. To calculate P-values, logistic regression models were fitted with label format as a categorical explanatory variable. When collectively analysing all four medicines, the logistic regression models also included:

- medicine as a categorical variable, to adjust for any differences in level of difficulty per medicine; and
- a random effect for individual, to adjust for the person-effect across the four medicines.

A $P<0.05$ for label format indicated evidence that the proportion of correct answers depends on the label format.

A subgroup analysis was conducted to determine if the proportion of correct answers for a label format depended on individuals' health literacy, and in particular, whether the impact of health literacy differed between label formats. To assess the latter, an interaction term between label format and NVS-UK score was added to the logistic regression models. NVS-UK score was fitted as a categorical variable, with categories of "Low (0-1)", "Intermediate (2-3)" and "Adequate (4-6)" health literacy, reflective of the interpretation of NVS-UK scores outlined by Rowlands et al.[6] If the P-value for the interaction term was $P<0.05$, then we concluded that the impact of health literacy differed between label formats.

An analysis was conducted to assess if any participant characteristics are associated with correctly interpreting label information. For each question, the proportion of correct answers was summarised by each participant characteristic. To determine which factors, if any, were associated with correctly interpreting label information, logistic regression models were fitted to each question, with the proportion of correct answers as the outcome, and participant characteristics fitted as explanatory variables. Both unadjusted and adjusted P-values were obtained by fitting univariable and multivariable models, respectively. The univariable models included only one explanatory variable per model, while the multivariable models included all the participant characteristics as variables in the model. However, due to the correlation between number of medication doses per day, number of medicines taken regularly, and number of medical conditions (variance inflation factor >10), only one of these variables, number of medicines taken regularly, was included in the multivariable models. The multivariable model also included site. Models which were fitted to data where there were multiple responses per participant (i.e. four rows of data per person due to a response for each medicine), included a random effect for person. The adjusted odds ratio and 95% confidence intervals have been presented from the multivariable models.

4. Results

4.1 Sample and participant characteristics summary

4.1.1 Response rate and final number of participants

A total of 281 randomised kits were used in the study: 117 at the Canberra site, 54 at the Melbourne site, and 110 at the Darwin sites (Appendix 3). Of these 281 kits allocated to consenting individuals (n=281), data pertaining to 6 individuals were excluded due to the following reasons:

- Data associated with kits allocated to 3 people were excluded from the final dataset analyses for Darwin
    - n=1 withdrew consent
    - n=1 met exclusion criteria – no data was entered in the final dataset for this person
    - n=1 did not meet inclusion criteria, identified after commencement of the structured interview
- Data associated with kits allocated to 3 people were excluded from the final dataset analyses for Canberra
    - n=2 met exclusion criteria, identified after commencement of the structured interview
    - n=1 discontinued – no data was entered in the final dataset for this person

Therefore, the total number of participants included in the final dataset and analyses was 275.

4.1.2 Pooled participant characteristics

Overall, participant characteristics were reasonably well balanced between the kits (Table 11). The majority of participants spoke English as their main language at home, had completed either the Higher School Certificate or below, and had no more than two medical conditions for which they took medication.

Of those who completed the NVS-UK, 43.6% of participants had adequate health literacy, and 56.4% had either intermediate or low health literacy. The mean NVS-UK score was lower for those who were allocated Kit B in comparison to the others (Mean=2.5, SD=1.9).

Table 11. Summary of participant characteristics by label kit

Characteristic		Kit A n (%) or Mean (SD)	Kit B n (%) or Mean (SD)	Kit C n (%) or Mean (SD)	Kit D n (%) or Mean (SD)	Total n (%) or Mean (SD)
Site[a]	Canberra	29 (25.4)	30 (26.3)	28 (24.6)	27 (23.7)	114 (100.0)
	Darwin	27 (25.2)	25 (23.4)	27 (25.2)	28 (26.2)	107 (100.0)
	Melbourne	14 (25.9)	14 (25.9)	13 (24.1)	13 (24.1)	54 (100.0)
	Total	70 (25.5)	69 (25.1)	68 (24.7)	68 (24.7)	275 (100.0)
Age	Mean (SD)	54.3 (SD=17.6)	55.9 (SD=18.2)	54.8 (SD=16.9)	54.5 (SD=17.6)	54.9 (SD=17.5)
	Range	21-81	19-93	22-85	19-85	19-93
Sex	Male	39 (55.7)	50 (72.5)	47 (69.1)	42 (61.8)	178 (64.7)
	Female	30 (42.9)	19 (27.5)	21 (30.9)	26 (38.2)	96 (34.9)
	Missing	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)
Country of birth	Australia	51 (72.9)	48 (69.6)	52 (76.5)	47 (69.1)	198 (72.0)
	Overseas	18 (25.7)	21 (30.4)	15 (22.1)	20 (29.4)	74 (26.9)
	Missing	1 (1.4)	0 (0.0)	1 (1.5)	1 (1.5)	3 (1.1)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)
Main language spoken at home	English	63 (90.0)	60 (87.0)	62 (91.2)	59 (86.8)	244 (88.7)
	Other	6 (8.6)	9 (13.0)	5 (7.4)	8 (11.8)	28 (10.2)
	Missing	1 (1.4)	0 (0.0)	1 (1.5)	1 (1.5)	3 (1.1)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)
Highest level of education attained	Primary School	3 (4.3)	7 (10.1)	1 (1.5)	2 (2.9)	13 (4.7)
	School Certificate	19 (27.1)	18 (26.1)	17 (25.0)	20 (29.4)	74 (26.9)
	Higher School Certificate	18 (25.7)	19 (27.5)	15 (22.1)	20 (29.4)	72 (26.2)
	Tertiary	29 (41.4)	25 (36.2)	34 (50.0)	25 (36.8)	113 (41.1)
	Missing	1 (1.4)	0 (0.0)	1 (1.5)	1 (1.5)	3 (1.1)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)

Characteristic		Kit A n (%) or Mean (SD)	Kit B n (%) or Mean (SD)	Kit C n (%) or Mean (SD)	Kit D n (%) or Mean (SD)	Total n (%) or Mean (SD)
Employment status	Full time	24 (34.3)	22 (31.9)	31 (45.6)	23 (33.8)	100 (36.4)
	Not working	10 (14.3)	16 (23.2)	6 (8.8)	15 (22.1)	47 (17.1)
	Part time	9 (12.9)	12 (17.4)	4 (5.9)	5 (7.4)	30 (10.9)
	Retired	25 (35.7)	18 (26.1)	23 (33.8)	24 (35.3)	90 (32.7)
	Student	1 (1.4)	1 (1.4)	2 (2.9)	0 (0.0)	4 (1.5)
	Missing	1 (1.4)	0 (0.0)	2 (2.9)	1 (1.5)	4 (1.5)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)
Number of medications usually taken each day	0	18 (25.7)	14 (20.3)	14 (20.6)	20 (29.4)	66 (24.0)
	1-2	16 (22.9)	19 (27.5)	18 (26.5)	17 (25.0)	70 (25.5)
	3-4	15 (21.4)	7 (10.1)	14 (20.6)	13 (19.1)	49 (17.8)
	≥5	20 (28.6)	28 (40.6)	21 (30.9)	17 (25.0)	86 (31.3)
	Missing	1 (1.4)	1 (1.4)	1 (1.5)	1 (1.5)	4 (1.5)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)
Number of doses of medication usually taken each day	0	18 (25.7)	14 (20.3)	14 (20.6)	20 (29.4)	66 (24.0)
	1-3	29 (41.4)	21 (30.4)	29 (42.6)	26 (38.2)	105 (38.2)
	4-6	14 (20.0)	19 (27.5)	12 (17.6)	12 (17.6)	57 (20.7)
	≥7	8 (11.4)	15 (21.7)	12 (17.6)	9 (13.2)	44 (16.0)
	Missing	1 (1.4)	0 (0.0)	1 (1.5)	1 (1.5)	3 (1.1)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)
Number of medical conditions for which medication is taken	0	19 (27.1)	14 (20.3)	15 (22.1)	21 (30.9)	69 (25.1)
	1-2	30 (42.9)	31 (44.9)	32 (47.1)	26 (38.2)	119 (43.3)
	3-4	15 (21.4)	15 (21.7)	14 (20.6)	17 (25.0)	61 (22.2)
	≥5	5 (7.1)	8 (11.6)	6 (8.8)	3 (4.4)	22 (8.0)
	Missing	1 (1.4)	1 (1.4)	1 (1.5)	1 (1.5)	4 (1.5)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)

Characteristic		Kit A n (%) or Mean (SD)	Kit B n (%) or Mean (SD)	Kit C n (%) or Mean (SD)	Kit D n (%) or Mean (SD)	Total n (%) or Mean (SD)
Newest Vital Sign UK (NVS-UK) score[b]	0-1 (low)	13 (18.6)	20 (29.0)	16 (23.5)	16 (23.5)	65 (23.6)
	2-3 (intermediate)	18 (25.7)	25 (36.2)	20 (29.4)	21 (30.9)	84 (30.5)
	4-6 (adequate)	36 (51.4)	21 (30.4)	29 (42.6)	29 (42.6)	115 (41.8)
	Missing	3 (4.3)	3 (4.3)	3 (4.4)	2 (2.9)	11 (4.0)
	Total	70 (100.0)	69 (100.0)	68 (100.0)	68 (100.0)	275 (100.0)
	Mean (SD)	3.4 (SD=1.9)	2.5 (SD=1.9)	3.3 (SD=2.0)	3.1 (SD=1.9)	3.1 (SD=1.9)

[a] Row percentages included for number of participants per kit per site. Column percentages are reported for all other values in the table. Percentages and standard deviation values have been rounded to one decimal place.

[b] NVS-UK scores can be interpreted as: 4-6 = adequate health literacy; 2-3 = intermediate health literacy; 0-1 = low health literacy.[6]

4.2 Patient name identification and label format

For the first label evaluated in each kit (halocillin), all participants were asked who the medicine belonged to. Nearly all participants correctly identified the name of the patient. There was no association between the kit (and therefore label format) and participants correctly identifying who the medicine belonged to (P=0.32) (Table 12; Figure 3). This suggests that differences in label formatting and design do not significantly impact whether participants can identify the patient name from the label.

Table 12. Summary of correct responses per kit for question:
Who does this medicine belong to? [a]

Kit	Kit A (n=70)	Kit B (n=69)	Kit C (n=68)	Kit D (n=68)	Total n (% correct) (n=275)	P-value (difference between label formats)
Label format	**Label format 2 n (% correct)**	**Label format 3 n (% correct)**	**Label format 4 n (% correct)**	**Label format 1 n (% correct)**		
Total correct	70 (100.0)	67 (97.1)	65 (95.6)	67 (98.5)	269 (97.8)	0.32

[a] There were no missing values.

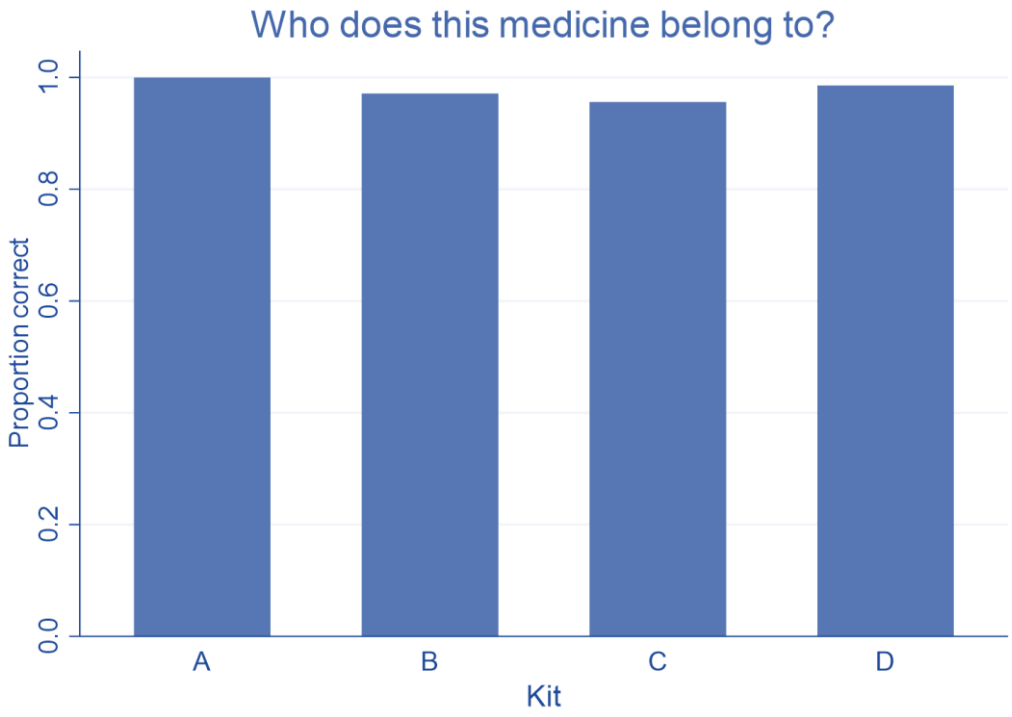


Figure 3. Proportion of participants who could correctly identify the patient name per kit

4.3 Dosage / directions for use and label format

4.3.1 Dosage

Most of the participants were able to correctly identify how much of each medicine should be taken and how often. Differences in label formatting and design did not have a large impact on whether participants could say how much of the medicine should be taken and how often. Despite the overall P-value being statistically significant (P=0.016), the differences in the proportion of correct responses between the label formats were minimal (Table 13; Figure 4).

Table 13. Summary of correct responses per label format and medicine for question: *How much should "James" take and how often?*[a]

Medicine	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
halocillin	67 (98.5; n=68)	62 (88.6; n=70)	68 (98.6; n=69)	65 (95.6; n=68)	262 (95.3; n=275)	**0.048**
abalazine	67 (97.1; n=69)	63 (92.6; n=68)	67 (98.5; n=68)	62 (88.6; n=70)	259 (94.2; n=275)	0.099
cabergamol	68 (100.0; n=68)	62 (91.2; n=68)	66 (95.7; n=69)	67 (97.1; n=69)	263 (96.0; n=274)	0.067
myclofenac	65 (94.2; n=69)	69 (100.0; n=69)	64 (94.1; n=68)	62 (92.5; n=67)	260 (95.2; n=273)	0.91
Total correct	267 (97.4; n=274)	256 (93.1; n=275)	265 (96.7; n=274)	256 (93.4; n=274)	1044 (95.2; n=1097)	**0.016**

[a] Missing data have not been included (cabergamol missing n=1; myclofenac missing n=2).

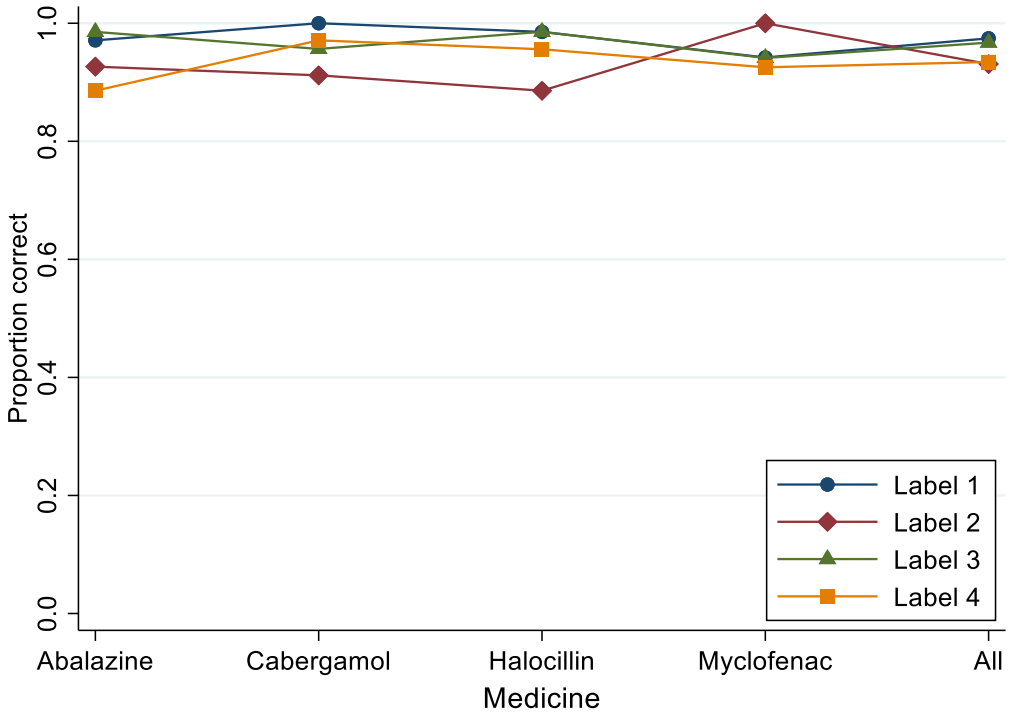


Figure 4. Proportion of participants who could correctly indicate the dosage for each medicine per label format

4.3.2 Total number of capsules per day

Most of the participants correctly identified the total number of capsules that should be taken in a day (93%). The label format did not have a substantial impact on participants being able to determine how many capsules in total should be taken in a day. Despite the P-value for the total correct being statistically significant (P=0.027), the differences in the proportion correct between label formats were small (Table 14; Figure 5).

Table 14. Summary of correct responses per label format and medicine for question: *How many capsules in total would "James" take in 1 day?*[a]

Medicine	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
halocillin	63 (92.6; n=68)	66 (94.3; n=70)	63 (91.3; n=69)	66 (97.1; n=68)	258 (93.8; n=275)	0.57
abalazine	59 (85.5; n=69)	65 (95.6; n=68)	59 (86.8; n=68)	64 (92.8; n=69)	247 (90.1; n=274)	0.18
cabergamol	62 (91.2; n=68)	64 (94.1; n=68)	65 (94.2; n=69)	64 (92.8; n=69)	255 (93.1; n=274)	0.89
myclofenac	64 (92.8; n=69)	66 (95.7; n=69)	65 (95.6; n=68)	64 (97.0; n=66)	259 (95.2; n=272)	0.71
Total correct	248 (90.5; n=274)	261 (94.9; n=275)	252 (92.0; n=274)	258 (94.9; n=272)	1019 (93.1; n=1095)	**0.027**

[a] Missing data have not been included (abalazine missing n=1; cabergamol missing n=1; myclofenac missing n=3).

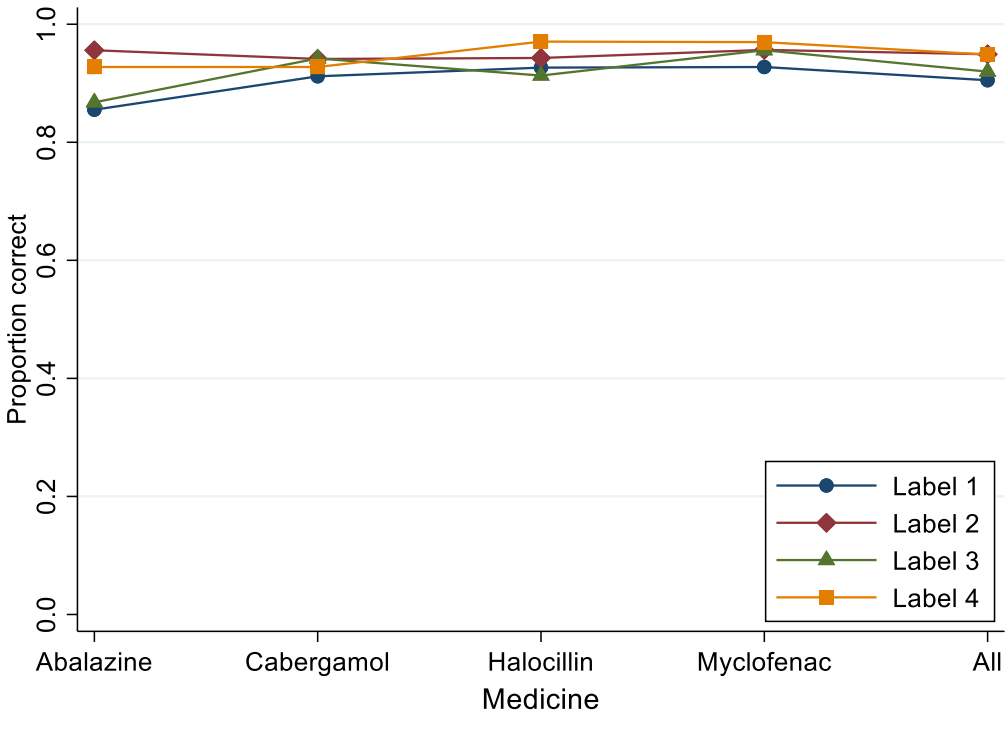


Figure 5. Proportion of participants correctly identifying the total number of capsules per day for each medicine per label format

4.4 Active ingredient and medicine strength identification by label format

4.4.1 Active ingredient

When participants were asked to identify the active ingredient in each medicine, label format 3 was the most effective. Label format 3 was the only format where the active ingredient and brand name were clearly signposted. Overall, 93.8% of answers correctly identified the active ingredient when it was signposted (Table 15; Figure 6).

Table 15. Summary of correct responses per label format and medicine for question: *What is the active ingredient found in this medicine?*[a]

Medicine	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
halocillin	47 (69.1; n=68)	47 (67.1; n=70)	65 (94.2; n=69)	52 (76.5; n=68)	211 (76.7; n=275)	**0.002**
abalazine	46 (66.7; n=69)	56 (82.4; n=68)	64 (94.1; n=68)	47 (67.1; n=70)	213 (77.5; n=275)	**<0.001**
cabergamol	49 (72.1; n=68)	33 (48.5; n=68)	66 (95.7; n=69)	37 (53.6; n=69)	185 (67.5; n=274)	**<0.001**
myclofenac	46 (66.7; n=69)	29 (42.0; n=69)	62 (91.2; n=68)	31 (46.3; n=67)	168 (61.5; n=273)	**<0.001**
Total correct	188 (68.6; n=274)	165 (60.0; n=275)	257 (93.8; n=274)	167 (60.9; n=274)	777 (70.8; n=1097)	**<0.001**

[a] Missing data have not been included (cabergamol missing n=1; myclofenac missing n=2).

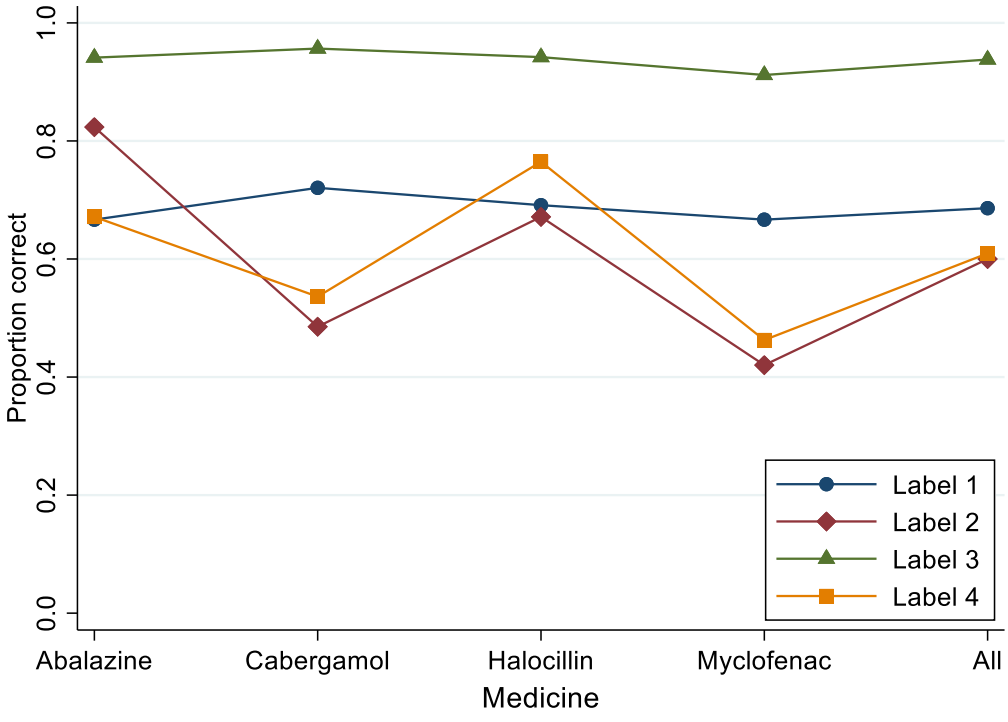


Figure 6. Proportion of participants who could correctly identify the active ingredient of the medicine per label format

4.4.2 Impact of order of brand name and active ingredient on the label for active ingredient identification

An additional analysis was conducted to determine whether the label format and the formatting and order of the active ingredient and brand name presented on the label led to a difference in the proportion that could correctly identify the active ingredient and brand name. The active ingredient and brand name formatting differences were:

- Label format 1 = Active ingredient presented first, above the brand name (on separate lines)
- Label format 3 = Signposted active ingredient presented first, above the brand name (on separate lines)
- Label formats 2 and 4 = Active ingredient presented second (in brackets) after the brand name (on the same line)

As mentioned above (Section 4.4.1), label format 3 was clearly the superior label format for expressing the active ingredient and brand name. Label format 1 supported a slightly higher proportion of participants to correctly identify the active ingredient (68.6%) compared with label formats 2 and 4 (60.5%). This difference was statistically significant (Table 16). This suggests that conveying the active ingredient first and then the brand name, with each on a separate line, is slightly clearer than having both on the same line with the brand name first and active ingredient in brackets.

Table 16. Summary of total correct responses per label format for question:
***What is the active ingredient found in this medicine?*[a]**

Label format	Label format 1 n (% correct) n=274	Label format 3 n (% correct) n=274	Label formats 2 and 4 n (% correct) n=549	Total n (% correct) n=1097	P-value (difference between label format 1 versus label formats 2 and 4)
Total correct	188 (68.6)	257 (93.8)	332 (60.5)	777 (70.8)	**0.009**

[a] Missing data have not been included (missing n=3).

4.4.3 Differences in participants' ability to correctly identify the active ingredient by label format, stratified by NVS-UK score

A statistically significant difference between the label formats was seen at both low and intermediate health literacy levels by stratified NVS-UK scores (P<0.001) (Table 17). A P-value could not be calculated when comparing within the adequate health literacy group, as clear active ingredient and brand name signposting on label format 3 enabled 100% of the participants with adequate health literacy to correctly identify the active ingredient.

Label format 3 was the superior label across all three health literacy levels, with the highest proportion of participants correctly identifying the active ingredient compared with the other label formats (Figure 7).

Table 17. Summary of correct responses per label format and stratified NVS-UK score for question: *What is the active ingredient found in this medicine?*[a]

NVS-UK score	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
0-1 (low)	45 (69.2; n=65)	32 (49.2; n=65)	54 (83.1; n=65)	30 (46.2; n=65)	161 (61.9; n=260)	**<0.001**
2-3 (intermediate)	59 (70.2; n=84)	49 (58.3; n=84)	83 (98.8; n=84)	51 (60.7; n=84)	242 (72.0; n=336)	**<0.001**
4-6 (adequate)	78 (67.8; n=115)	78 (67.8; n=115)	115 (100.0; n=115)	82 (71.3; n=115)	353 (76.7; n=460)	Could not be calculated

[a] Missing data has not been included (NVS-UK score missing for n=11 participants).
[b] There is evidence of an interaction between label format and NVS-UK (P=0.04).

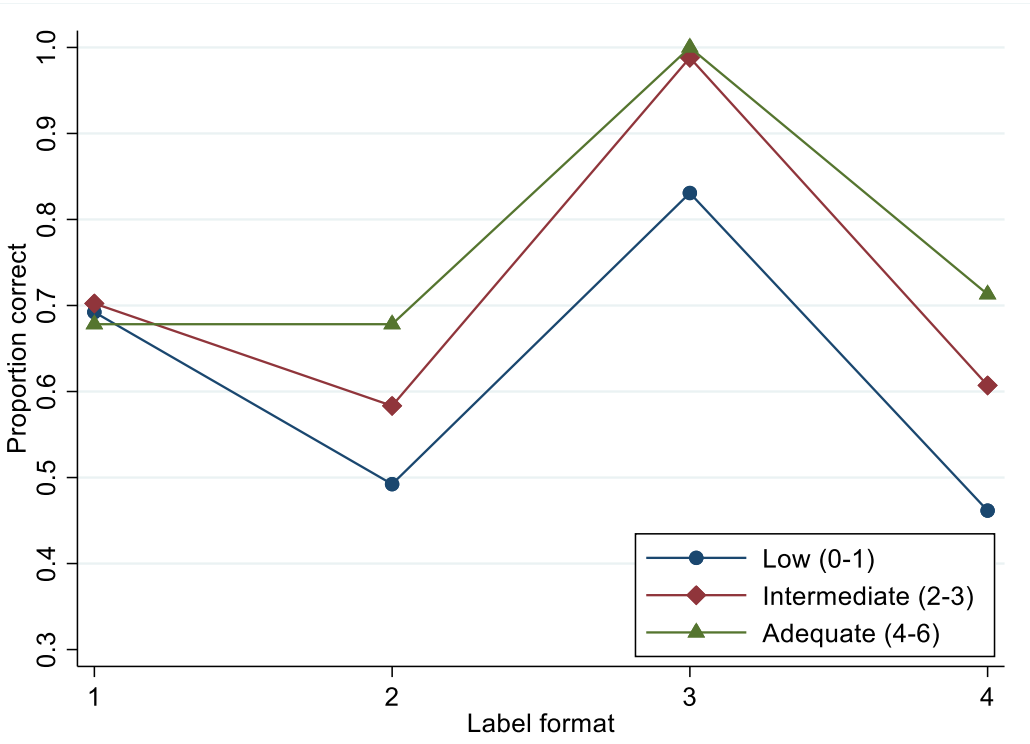


Figure 7. Proportion of participants who correctly identified the active ingredient by label format, stratified by NVS-UK score

4.4.4 Medicine strength

For the question on medicine strength (that is, the amount of active ingredient in each capsule), differences in overall label formatting and design did not impact whether participants were able to identify how much of the active ingredient was in each capsule of the medicine. There were no statistically significant differences observed between the label formats and subsequently, their ability to help people understand this information (Table 18; Figure 8). Overall, most participants were able to correctly identify the amount of active ingredient in each capsule of the four medicines.

Table 18. Summary of correct responses per label format and medicine for question: *How much of the active ingredient is in each capsule?*[a]

Medicine	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
halocillin	62 (91.2; n=68)	60 (85.7; n=70)	64 (92.8; n=69)	60 (88.2; n=68)	246 (89.5; n=275)	0.55
abalazine	61 (88.4; n=69)	62 (91.2; n=68)	65 (95.6; n=68)	62 (89.9; n=69)	250 (91.2; n=274)	0.51
cabergamol	65 (95.6; n=68)	64 (94.1; n=68)	61 (88.4; n=69)	63 (92.6; n=68)	253 (92.7; n=273)	0.42
myclofenac	61 (88.4; n=69)	64 (92.8; n=69)	63 (92.6; n=68)	63 (94.0; n=67)	251 (91.9; n=273)	0.65
Total correct	249 (90.9; n=274)	250 (90.9; n=275)	253 (92.3; n=274)	248 (91.2; n=272)	1000 (91.3; n=1095)	0.76

[a] Missing data have not been included (abalazine missing n=1; cabergamol missing n=2; myclofenac missing n=2).

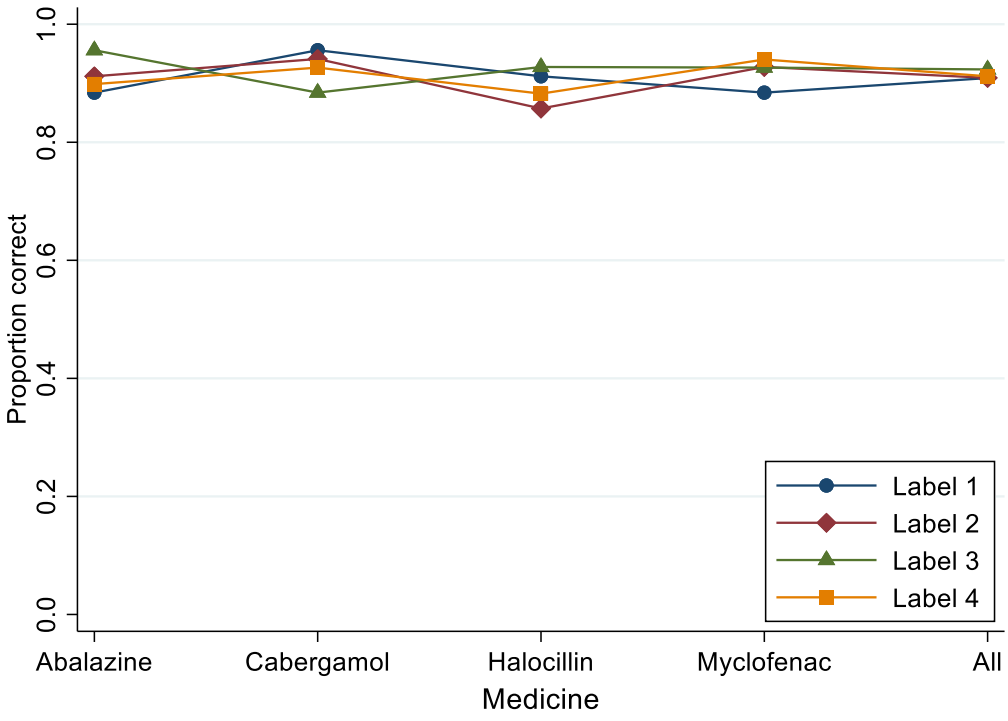


Figure 8. Proportion of participants correctly identifying the medicine strength for each medicine per label format

4.5 Dosette packing task – ability to apply information on dispensed prescription medicine labels

4.5.1 Dosette data overview

Of the 275 participants, 271 completed the dosette packing task. Most participants (n=224; 82.7%) nominated their first dose of the day to be at 6 am, 7 am, or 8 am; 7 am was the specified first dose time for 42.4% (n=115). Almost all participants (n=252; 93.0%) nominated their last dose of the day to be at 9 pm, 10 pm, or 11 pm. Of these times, 10 pm was the most frequent time of last dose (n=126; 46.5%).

For the labels where a "midday" dose was required (halocillin and abalazine labels for Kits A and C, and the cabergamol label for Kits B and D), most dose times were between 11 am and 1 pm:

- 12 pm equated to midday for 85.3% of participant responses (n=347/407 responses across the three medicines),
- 5.7% (n=23/407) indicated they would take the midday dose at 11 am, and
- 4.7% (n=19/407) at 1 pm.

For those who received Kits A or C, where there were two medicines to be taken at midday, 87.5% would have taken both medicines' "midday" doses at the same time (n=119/136).

For the labels where a "bedtime" dose was required (halocillin and abalazine labels for Kits A and C; cabergamol and myclofenac labels for Kits B and D), the majority of bedtime dose times were either 9 pm or 10 pm:

- 39.7% of responses (n=211/532 across all four medicines) indicated a "bedtime" dose time of 10 pm, and
- 33.3% of response (n=177/532 across all four medicines) at 9 pm.

Where two "bedtime" doses were required (because there were two labels per kit which explicitly stated that doses were to be taken at "bedtime"), 71.1% of participants would have taken their two "bedtime" doses at the same time (n=187/263). However, the time of the "bedtime" dose(s) did not always equate to the last dose of medicine taken for the day by the participant. Approximately 9% (n=24/266) had their last dose for the day (for one or both of the other medicines) after their "bedtime" dose(s).

The number of grouped doses per day ranged from 3 to 13 (Figure 9), with the mean number of grouped doses being 6.3 (SD=2.0). There was no significant difference in the mean number of grouped doses between Kits A and C (combined) and Kits A and D (combined) (P=0.58).

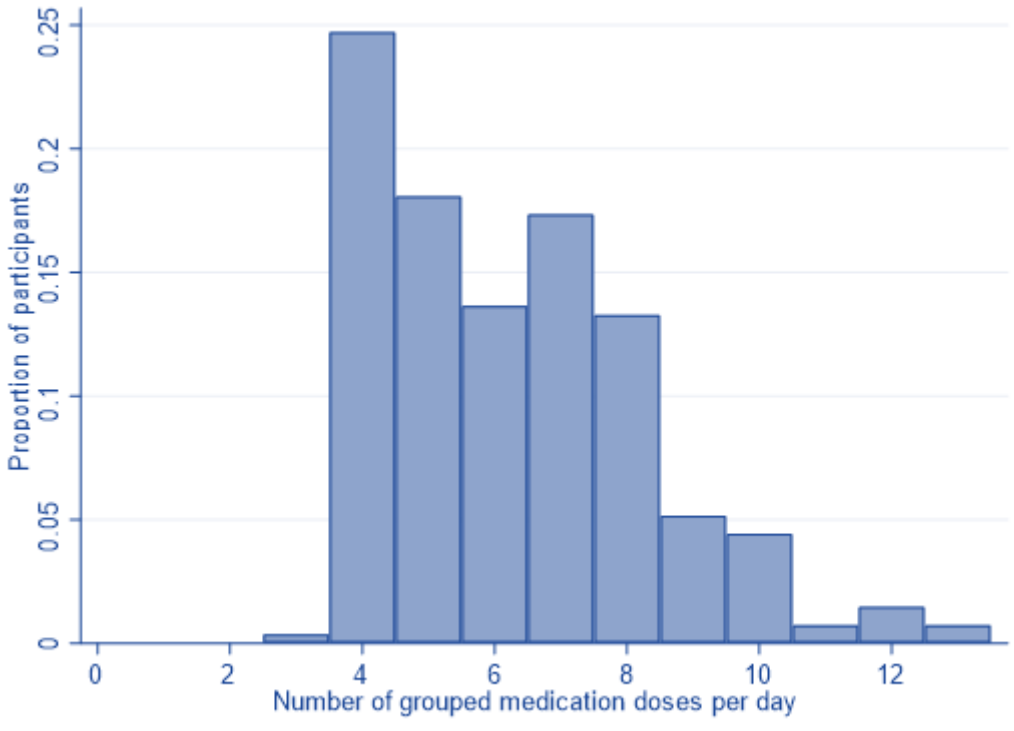


Figure 9. Proportion of participants by number of grouped medication doses per day

4.5.2 Findings – UMS-based coding framework application

When coding participant responses for the dosette coding task using the UMS-based coding framework, only 62 participants correctly completed the entire dosette (i.e. where all four medicines were dosed appropriately), equating to approximately 23% of the sample that completed the dosette (Table 19). A statistically significant difference between the kits for correct dosette completion was seen; a higher proportion of participants who correctly completed the entire dosette received either Kit B or D, in comparison to the proportion seen with Kit A and C (Table 19; Figure 10).

Table 19. Summary of correct entire dosette completion for all four medicines as determined using the UMS-based coding framework[a]

Dosette	Kit A n (% correct) (n=68)	Kit B n (% correct) (n=68)	Kit C n (% correct) (n=68)	Kit D n (% correct) (n=67)	Total n (% correct) (n=271)	P-value (difference between kits)
All correct	7 (10.3)	22 (32.4)	6 (8.8)	27 (40.3)	62 (22.9)	**<0.001**

[a] Missing data have not been included (missing n=4).

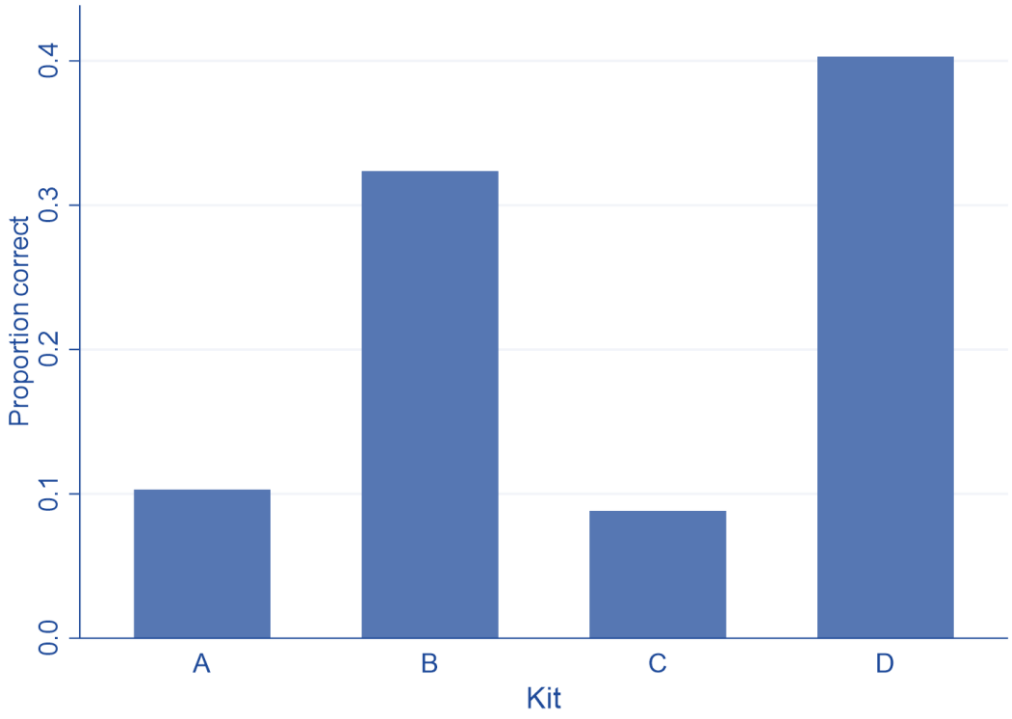


Figure 10. Proportion of participants who correctly completed the entire dosette for all four medicines by kit – UMS-based coding framework

For each of the four medicines, correct dosette completion (regardless of label format) was relatively similar between the medicines. Correct completion per medicine ranged from approximately 47% (for cabergamol) to 65% (for myclofenac) (Table 20).

When examining the findings according to label format, a difference can be seen in correct dosette completion between the label formats. Label format 2 (UMS table and explicit labelling directions using standardised approximate times of day) and label format 4 (explicit labelling directions using standardised approximate times of day) enabled a higher proportion of participants to correctly complete the dosette overall across the four medicines (Table 20), in comparison to label formats 1 and 3 (Figure 11).

Table 20. Summary of correct responses per label format and medicine for dosette packing task – UMS-based coding framework[a]

Medicine	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
halocillin	35 (52.2; n=67)	54 (79.4; n=68)	27 (39.7; n=68)	48 (70.6; n=68)	164 (60.5; n=271)	**<0.001**
abalazine	28 (41.2; n=68)	49 (72.1; n=68)	33 (49.3; n=67)	48 (70.6; n=68)	158 (58.3; n=271)	**<0.001**
cabergamol	12 (17.6; n=68)	50 (74.6; n=67)	14 (20.6; n=68)	51 (75.0; n=68)	127 (46.9; n=271)	**<0.001**
myclofenac	46 (67.6; n=68)	52 (76.5; n=68)	26 (38.2; n=68)	53 (79.1; n=67)	177 (65.3; n=271)	**<0.001**
Total correct	121 (44.6; n=271)	205 (75.6; n=271)	100 (36.9; n=271)	200 (73.8; n=271)	626 (57.7; n=1084)	**<0.001**

[a] Missing data have not been included (missing n=4 dosettes overall and therefore, n=4 missing for each medicine).

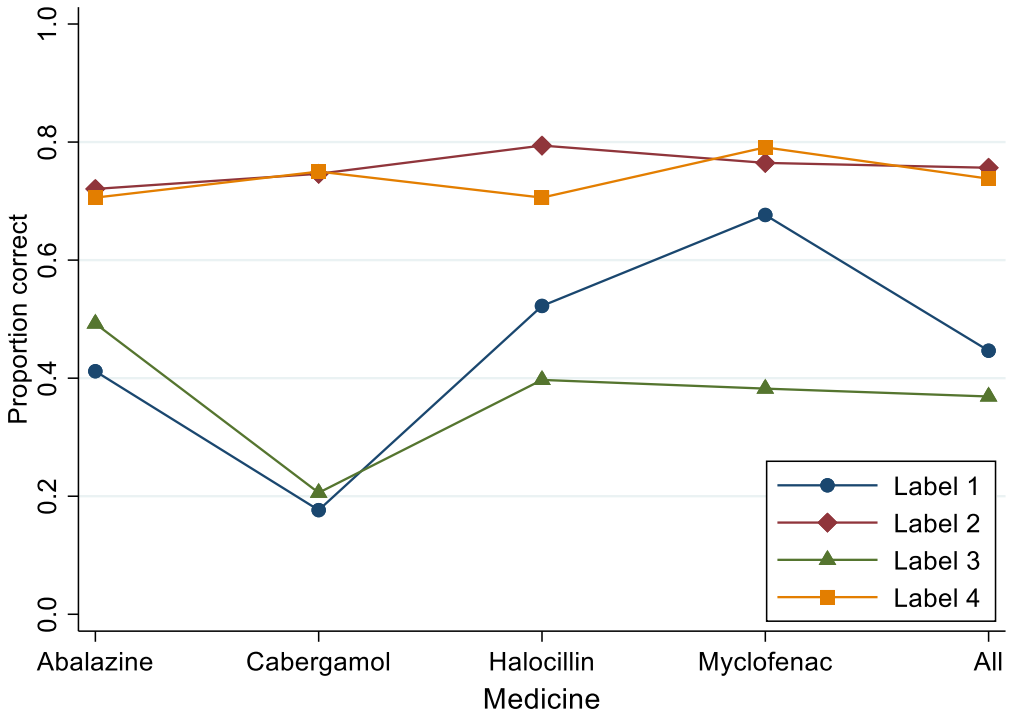


Figure 11. Proportion of participants correctly completing the dosette packing task per medicine and label format – UMS-based coding framework

4.5.3 Findings – Tailored coding framework application

There was an increased number of entirely correct dosette completions (n=74; 27.3%) when the data were analysed using the tailored coding framework, compared to the UMS-based coding framework (n=62; 22.9%) (Table 21).
A statistically significant difference in the proportion correct between the kits was also seen (Table 21; Figure 12).

Table 21. Summary of correct entire dosette completion for all four medicines as determined using the tailored coding framework[a]

Dosette	Kit A n (% correct) (n=68)	Kit B n (% correct) (n=68)	Kit C n (% correct) (n=68)	Kit D n (% correct) (n=67)	Total n (% correct) (n=271)	P-value (difference between kits)
All correct	11 (16.2)	21 (30.9)	12 (17.6)	30 (44.8)	74 (27.3)	**<0.001**

[a] Missing data have not been included (missing n=4).

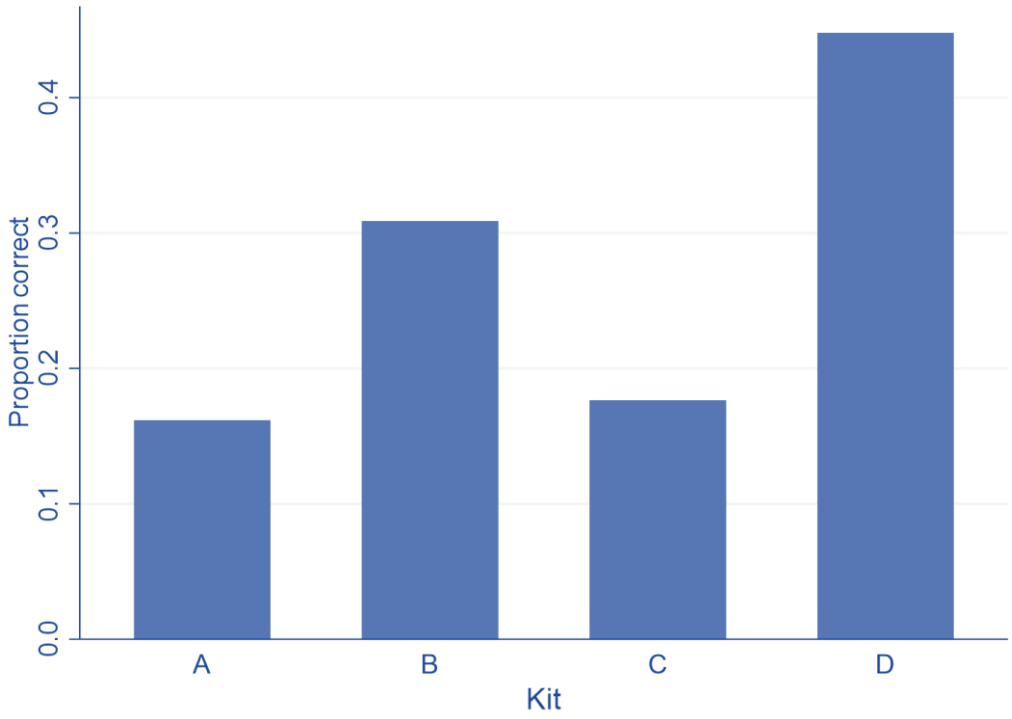


Figure 12. Proportion of participants who correctly completed the entire dosette for all four medicines by kit – tailored coding framework

Similar to the UMS-based framework findings, the proportion who correctly completed the dosette per medicine was lowest for cabergamol (approximately 49%), and highest for myclofenac with approximately 80% correctly completing the dosette (Table 22).

There is evidence of a difference between the label formats and participants correctly completing the dosette (P=0.047). However, for most medicines, the difference is small, with the exception of cabergamol, where a statistically significant difference was observed (P<0.001) (Figure 13). A slightly lower proportion of participants correctly completed the dosette using label formats 1 and 3 compared to the other two label formats (Table 22).

When comparing the proportions correct by label format for the tailored coding framework with the UMS-based coding framework, the proportion correct was higher for label formats 1 (from 44.6% to 63.1%) and 3 (from 36.9% to 62.4%), and slightly lower for label formats 2 (from 75.6% to 69.4%) and 4 (from 73.8% to 70.5%).

Table 22. Summary of correct responses per label format and medicine for dosette packing task – tailored coding framework[a]

Medicine	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between label formats)
halocillin	52 (77.6; n=67)	49 (72.1; n=68)	42 (61.8; n=68)	48 (70.6; n=68)	191 (70.5; n=271)	0.25
abalazine	41 (60.3; n=68)	45 (66.2; n=68)	50 (74.6; n=67)	44 (64.7; n=68)	180 (66.4; n=271)	0.36
cabergamol	23 (33.8; n=68)	44 (65.7; n=67)	22 (32.4; n=68)	43 (63.2; n=68)	132 (48.7; n=271)	**<0.001**
myclofenac	55 (80.9; n=68)	50 (73.5; n=68)	55 (80.9; n=68)	56 (83.6; n=67)	216 (79.7; n=271)	0.51
Total correct	171 (63.1; n=271)	188 (69.4; n=271)	169 (62.4; n=271)	191 (70.5; n=271)	719 (66.3; n=1084)	**0.047**

[a] Missing data have not been included (missing n=4).

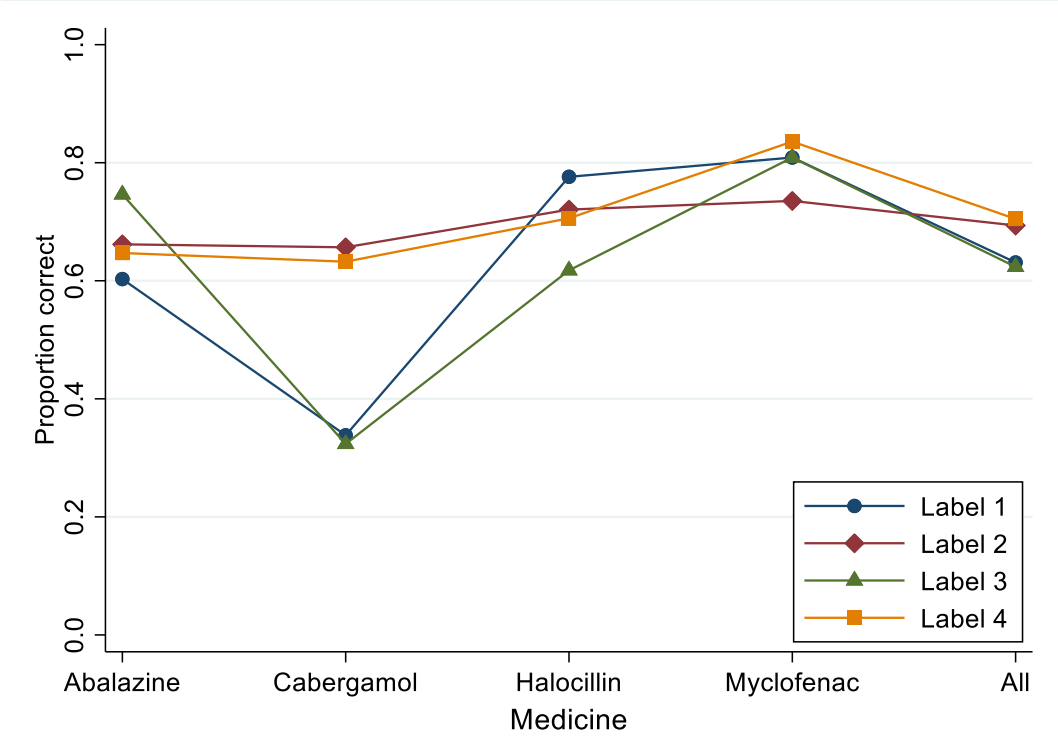


Figure 13. Proportion of participants correctly completing the dosette packing task per medicine and label format – tailored coding framework

4.5.4 Differences in label format performance in the dosette packing task, stratified by NVS-UK scores

When examining whether there were differences between correct dosette completion by label format and stratified NVS-UK scores (low, intermediate, and adequate health literacy levels), statistically significant differences were seen for the UMS-based coding framework findings for each NVS-UK score group. Label formats 2 and 4 performed consistently better than label formats 1 and 3 across all health literacy levels, when the data were coded using the UMS-based framework (Table 23). There were no statistically significant differences between label formats at any of the health literacy levels when the dosette data were coded using the tailored coding framework.

The group with adequate health literacy performed consistently better across all the label formats, regardless of the coding framework used, and vice versa for those with low health literacy (Figure 14 and 15).

Table 23. Summary of correct responses per label type and NVS-UK score stratification for the dosette packing task[a]

NVS-UK score	Coding framework[b,c]	Label format 1 n (% correct; total n)	Label format 2 n (% correct; total n)	Label format 3 n (% correct; total n)	Label format 4 n (% correct; total n)	Total n (% correct; total n)	P-value (difference between labels)
0-1 (low)	UMS-based	20 (30.8; n=65)	37 (56.9; n=65)	18 (27.7; n=65)	38 (58.5; n=65)	113 (43.5; n=260)	**<0.001**
	Tailored	29 (44.6; n=65)	32 (49.2; n=65)	36 (55.4; n=65)	38 (58.5; n=65)	135 (51.9; n=260)	0.21
2-3 (intermediate)	UMS-based	33 (39.3; n=84)	63 (75.0; n=84)	28 (33.3; n=84)	64 (76.2; n=84)	188 (56.0; n=336)	**<0.001**
	Tailored	52 (61.9; n=84)	57 (67.9; n=84)	49 (58.3; n=84)	62 (73.8; n=84)	220 (65.5; n=336)	0.052
4-6 (adequate)	UMS-based	65 (56.5; n=115)	101 (87.8; n=115)	51 (44.3; n=115)	95 (82.6; n=115)	312 (67.8; n=460)	**<0.001**
	Tailored	86 (74.8; n=115)	95 (82.6; n=115)	80 (69.6; n=115)	87 (75.7; n=115)	348 (75.7; n=460)	0.10

[a] Missing data have not been included in the table (missing data for n=7 participants).

[b] There is no evidence of an interaction between NVS-UK and correct dosette completion (P=0.44) as determined using the UMS-based coding framework.

[c] There is no evidence of an interaction between NVS-UK and correct dosette completion (P= 0.16) as determined using the tailored coding framework.

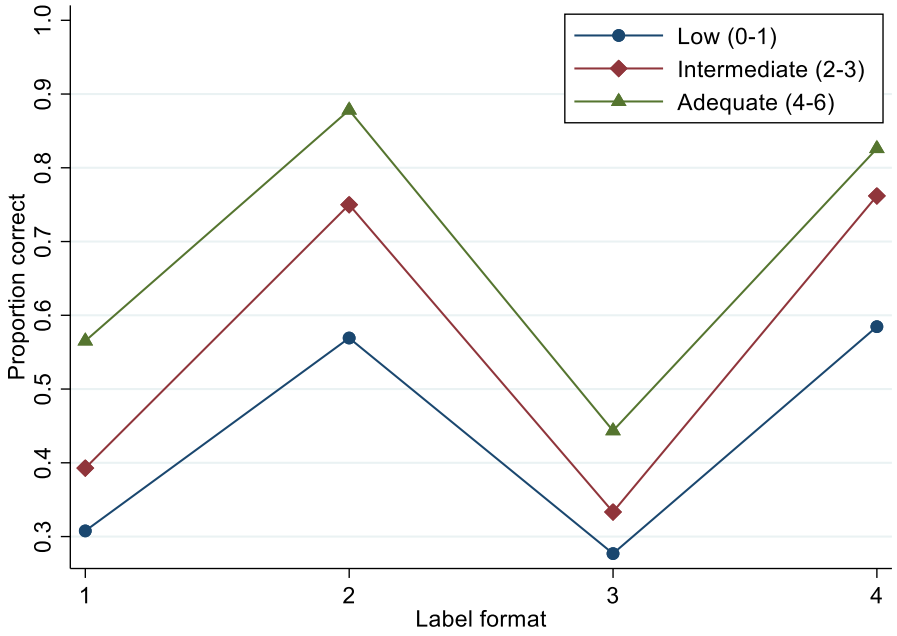


Figure 14. Proportion who correctly completed the dosette packing task per label format according to stratified NVS-UK scores – UMS-based coding framework

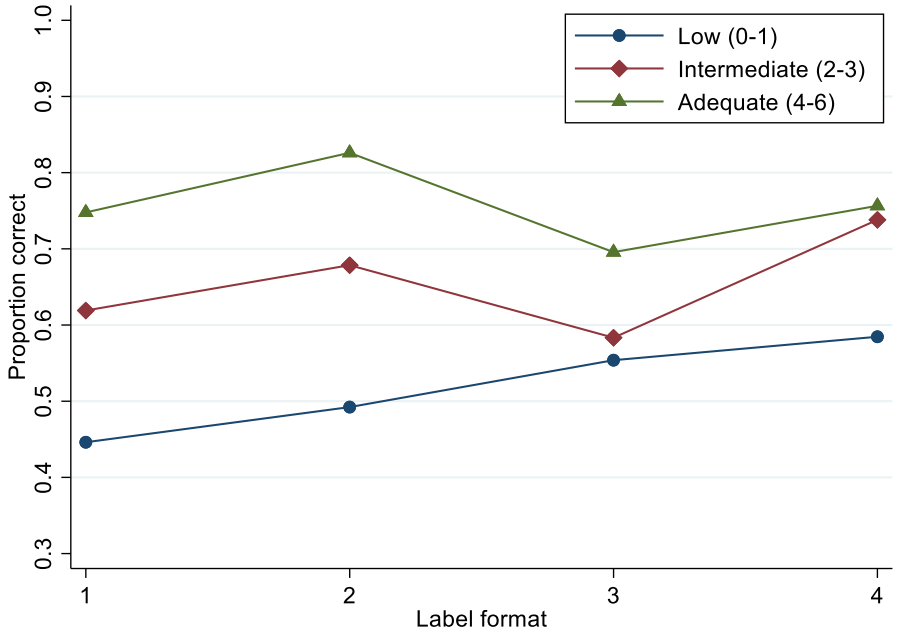


Figure 15. Proportion who correctly completed the dosette packing task per label format according to stratified NVS-UK scores – tailored coding framework

4.6 Factors associated with participants' ability to correctly interpret medicine information

4.6.1 Adjusted results

4.6.1.1 Dosage, total number of capsules per day, and medicine strength

There were no factors that were associated with participants' ability to correctly report the dosage based on the label format.

Country of birth, highest level of education, and NVS-UK score were associated with participants being able to correctly determine the total number of capsules per day (Table 24). Those born overseas had a lower chance of correctly determining the total number of capsules that needed to be taken per day for the medicine (adjusted odds ratio (OR) 0.28; 95% confidence interval (CI) 0.09-0.83 versus reference group Australia; P=0.02). Those who had completed tertiary education had a significantly higher chance of correctly determining the total number of capsules per day (adjusted OR 10.11; 95% CI 1.85-55.28 versus primary school; P=0.04). As NVS-UK score increased, the odds of correctly determining the total number of capsules per day substantially increased with the adjusted ORs for intermediate and adequate health literacy 10.57 (95% CI 3.52-31.75) and 47.14 (95% CI 8.28-268.38), respectively versus 0-1 low health literacy (P<0.001).

Age and main language spoken at home were associated with correctly identifying the medicine strength (Table 24). The older the person, the less likely they would obtain the correct answer (P=0.03) and those whose main language spoken at home was not English performed poorly (P=0.006).

Table 24. Summary of adjusted results – factors associated with participants' ability to correctly answer the label-related questions on dosage, total number of capsules per day, and medicine strength[a]

Characteristic		Dosage			Total number of capsules per day			Medicine strength		
		OR	95% CI	P-value	OR	95% CI	P-value	OR	95% CI	P-value
Sex	Female	1	(reference)	0.06	1	(reference)	0.42	1	(reference)	0.07
	Male	0.38	0.14-1.03		0.69	0.28-1.69		4.52	0.88-23.21	
Age	18-34	1	(reference)	0.52	1	(reference)	0.15	1	(reference)	**0.03**
	35-49	0.52	0.13-2.04		2.24	0.50-9.96		3.47	0.10-118.78	
	50-64	1.00	0.23-4.38		3.03	0.58-15.78		0.15	0.01-2.82	
	65-79	0.48	0.08-2.88		1.25	0.20-7.71		0.02	0.00-0.57	
	80-94	2.06	0.11-37.76		0.36	0.04-3.15		<0.01	0.00-0.13	
Country of birth	Australia	1	(reference)	0.95	1	(reference)	**0.02**	1	(reference)	0.37
	Overseas	1.03	0.38-2.83		0.28	0.09-0.83		2.29	0.38-13.90	
Main language spoken at home	English	1	(reference)	0.05	1	(reference)	0.56	1	(reference)	**0.006**
	Other	0.28	0.08-1.02		0.70	0.22-2.26		0.02	0.00-0.30	
Employment status	Full time	1	(reference)	0.62	1	(reference)	0.12	1	(reference)	0.15
	Not working	0.53	0.15-1.82		0.34	0.09-1.23		0.16	0.01-2.24	
	Part time	0.84	0.20-3.55		0.72	0.17-3.06		0.78	0.03-18.17	
	Retired	1.50	0.33-6.76		2.03	0.45-9.16		0.50	0.04-7.13	
	Student[b]	0.25	0.01-4.35		∞	-		<0.01	0.00-0.32	
Highest level of education attained	Primary School	1	(reference)	0.90	1	(reference)	**0.04**	1	(reference)	0.94
	School Certificate	0.49	0.06-3.83		2.05	0.45-9.36		1.27	0.04-38.97	
	Higher School Certificate	0.66	0.08-5.65		2.28	0.47-11.01		0.97	0.03-30.96	
	Tertiary	0.59	0.07-4.67		10.11	1.85-55.28		0.67	0.02-18.73	
Number of medications usually taken each day	0	1	(reference)	0.65	1	(reference)	0.17	1	(reference)	0.30
	1-2	2.12	0.60-7.50		0.75	0.18-3.09		10.94	0.76-157.43	
	3-4	1.75	0.43-7.17		1.39	0.25-7.69		2.86	0.20-40.26	
	≥5	1.28	0.35-4.67		2.68	0.56-12.95		7.10	0.60-83.40	
Newest Vital Sign UK (NVS-UK) score	0-1 (low)	1	(reference)	0.33	1	(reference)	**<0.001**	1	(reference)	0.66
	2-3 (intermediate)	2.26	0.73-7.03		10.57	3.52-31.75		1.37	0.22-8.58	
	4-6 (adequate)	2.05	0.63-6.64		47.14	8.28-268.38		2.71	0.31-23.80	

[a] Results were adjusted for site. Odds ratio = OR; CI = confidence interval.

[b] All students were able to correctly identity the total number of capsules per day (100% correct). Consequently, the univariable estimated OR is ∞, but the multivariable OR cannot be estimated.

4.6.1.2 Active ingredient

Age, employment status, and highest level of education were found to be factors associated with participants' ability to correctly identify the active ingredient from the label (Table 25). Participants who were older were less likely to correctly identify the active ingredient: the older the age group, the lower the probability of correctly identifying the active ingredient (P=0.009). Compared to participants employed full time, being retired was associated with an 88% higher chance of correctly identifying the active ingredient (adjusted OR 1.88; 95% CI 1.05-3.37 versus full time; P=0.004). For education, those who had completed tertiary education had a higher chance of correctly identifying the active ingredient (adjusted OR 2.74; 95% CI 1.28-5.87 versus those that had only completed primary school; P=0.004).

Table 25. Summary of adjusted results – factors associated with participants' ability to correctly answer the question on active ingredient[a]

Characteristic		Active ingredient		
		OR	95% CI	P-value
Sex	Female	1	(reference)	0.28
	Male	1.22	0.85-1.74	
Age	18-34	1	(reference)	**0.009**
	35-49	0.66	0.37-1.20	
	50-64	0.43	0.23-0.78	
	65-79	0.40	0.19-0.83	
	80-94	0.19	0.07-0.50	
Country of birth	Australia	1	(reference)	0.96
	Overseas	1.01	0.68-1.49	
Main language spoken at home	English	1	(reference)	0.77
	Other	0.91	0.48-1.71	
Employment status	Full time	1	(reference)	**0.004**
	Not working	0.62	0.37-1.04	
	Part time	1.54	0.83-2.86	
	Retired	1.88	1.05-3.37	
	Student	0.43	0.11-1.64	
Highest level of education attained	Primary School	1	(reference)	**0.004**
	School Certificate	1.50	0.70-3.20	
	Higher School Certificate	1.43	0.66-3.13	
	Tertiary	2.74	1.28-5.87	
Number of medications usually taken each day	0	1	(reference)	0.78
	1-2	1.08	0.65-1.78	
	3-4	1.28	0.72-2.29	
	≥5	1.27	0.74-2.16	
Newest Vital Sign UK (NVS-UK) score	0-1 (low)	1	(reference)	0.15
	2-3 (intermediate)	1.39	0.88-2.17	
	4-6 (adequate)	1.59	0.99-2.54	

[a] Results were adjusted for site. Odds ratio = OR; CI = confidence interval.

4.6.1.3 Dosette completion per medicine

Main language spoken at home and NVS-UK score were factors associated with participants' ability to correctly complete the dosette per medicine, regardless of whether the data were analysed using the UMS-based or tailored coding framework (Table 26).

Those whose main language spoken at home was not English had significantly lower odds of correctly completing the dosette per medicine (UMS-based: adjusted OR 0.38, 95% CI 0.19-0.79, P=0.009; tailored: adjusted OR 0.29, 95% CI 0.14-0.58, P<0.001).

Those with either intermediate (adjusted OR 1.70; 95% CI 1.01-2.85) or adequate health literacy (adjusted OR 2.80; 95% CI 1.63-4.81) had a greater chance of correctly completing the dosette per medicine according to the UMS-based coding framework, compared to those with low health literacy (P<0.001). Similar results were observed for NVS-UK scores using the tailored coding framework.

Table 26. Summary of adjusted results – factors associated with participants' ability to correctly complete the dosette per medicine according to the UMS-based and tailored coding frameworks[a]

Characteristic		Dosette completion per medicine – UMS-based coding framework			Dosette completion per medicine – tailored coding framework		
		OR	95% CI	P-value	OR	95% CI	P-value
Sex	Female	1	(reference)	0.17	1	(reference)	0.55
	Male	0.75	0.50-1.13		0.89	0.60-1.32	
Age	18-34	1	(reference)	0.17	1	(reference)	0.83
	35-49	1.38	0.72-2.63		1.40	0.74-2.66	
	50-64	0.94	0.48-1.81		1.14	0.59-2.20	
	65-79	1.75	0.77-4.01		1.23	0.55-2.77	
	80-94	0.99	0.33-2.94		0.97	0.34-2.80	
Country of birth	Australia	1	(reference)	0.72	1	(reference)	0.16
	Overseas	0.92	0.60-1.43		1.36	0.88-2.11	
Main language spoken at home	English	1	(reference)	**0.009**	1	(reference)	**<0.001**
	Other	0.38	0.19-0.79		0.29	0.14-0.58	
Employment status	Full time	1	(reference)	0.14	1	(reference)	0.63
	Not working	0.67	0.37-1.21		0.73	0.41-1.31	
	Part time	1.29	0.65-2.56		1.11	0.56-2.18	
	Retired	0.59	0.31-1.14		0.83	0.44-1.57	
	Student	0.39	0.09-1.73		2.18	0.35-13.67	
Highest level of education attained	Primary School	1	(reference)	0.31	1	(reference)	0.16
	School Certificate	0.72	0.29-1.80		0.77	0.32-1.85	
	Higher School Certificate	1.06	0.41-2.70		1.25	0.51-3.09	
	Tertiary	1.14	0.46-2.84		1.29	0.54-3.09	
Number of medications usually taken each day	0	1	(reference)	0.77	1	(reference)	0.82
	1-2	0.88	0.50-1.55		0.93	0.53-1.63	
	3-4	0.98	0.51-1.86		1.09	0.57-2.07	
	≥5	1.16	0.63-2.13		0.84	0.46-1.53	
Newest Vital Sign UK (NVS-UK) score	0-1 (low)	1	(reference)	**<0.001**	1	(reference)	**0.009**
	2-3 (intermediate)	1.70	1.01-2.85		1.61	0.98-2.65	
	4-6 (adequate)	2.80	1.63-4.81		2.27	1.35-3.84	

[a] Results were adjusted for site. Odds ratio = OR; CI = confidence interval.

4.6.1.4 Entire dosette completion (all four medicines)

There were two factors associated with participants' ability to correctly complete the entire dosette for all four medicines: NVS-UK score and main language spoken at home (Table 27). Participants with a higher NVS-UK score performed better than those with a lower NVS-UK score: adequate health literacy were significantly more likely to correctly complete the entire dosette as determined using the UMS-based framework (adjusted OR 4.24; 95% CI 1.45-12.36) versus low health literacy (P=0.02). Although the result for NVS-UK scores were not statistically significant when using the tailored coding framework (P=0.06), the results are qualitatively similar, displaying the same trend.

Participants whose main language at home was not English performed poorly in completing the dosette correctly for all four medicines. For the UMS-based coding framework, if English was not the main language spoken at home, then the person was unable to complete the dosette correctly for all four medicines (0% correct). Similarly, the odds ratio was close to zero for those who did not speak English at home as their main language, compared to those whose main language was English (adjusted OR 0.05; 95% CI 0.01-0.44; P=0.007) using the tailored coding framework.

Table 27. Summary of adjusted results – factors associated with participants' ability to correctly complete the dosette for all four medicines (the entire dosette) according to both UMS-based and tailored coding frameworks[a]

Characteristic		Entire dosette (all four medicines) – UMS-based coding framework			Entire dosette (all four medicines) – tailored coding framework		
		OR	95% CI	P-value	OR	95% CI	P-value
Sex	Female	1	(reference)	0.47	1	(reference)	0.58
	Male	0.77	0.39-1.55		0.83	0.43-1.61	
Age	18-34	1	(reference)	0.09	1	(reference)	0.24
	35-49	3.65	1.16-11.47		2.24	0.82-6.15	
	50-64	1.30	0.39-4.40		0.86	0.29-2.52	
	65-79	2.80	0.63-12.43		0.83	0.21-3.32	
	80-94	2.78	0.37-20.98		0.88	0.14-5.46	
Country of birth	Australia	1	(reference)	0.64	1	(reference)	0.14
	Overseas	1.19	0.57-2.47		1.67	0.84-3.33	
Main language spoken at home[1]	English	1	(reference)	-	1	(reference)	**0.007**
	Other[b]	*0.00*	n/a		0.05	0.01-0.44	
Employment status	Full time	1	(reference)	0.75	1	(reference)	0.22
	Not working	0.95	0.33-2.77		2.10	0.77-5.79	
	Part time	1.57	0.52-4.71		2.76	0.92-8.29	
	Retired	0.77	0.24-2.50		3.11	0.97-9.91	
	Student[c]	*0.00*	-		2.42	0.27-21.88	
Highest level of education attained	Primary School	1	(reference)	0.77	1	(reference)	0.27
	School Certificate	0.50	0.10-2.50		0.53	0.11-2.54	
	Higher School Certificate	0.75	0.15-3.80		1.15	0.24-5.54	
	Tertiary	0.68	0.14-3.26		1.20	0.26-5.47	
Number of medications usually taken each day	0	1	(reference)	0.32	1	(reference)	0.28
	1-2	0.56	0.21-1.48		0.48	0.19-1.17	
	3-4	0.43	0.14-1.31		0.52	0.18-1.47	
	≥5	0.89	0.32-2.49		0.39	0.14-1.06	
Newest Vital Sign UK (NVS-UK) score	0-1 (low)	1	(reference)	**0.02**	1	(reference)	0.06
	2-3 (intermediate)	2.00	0.69-5.81		1.51	0.58-3.98	
	4-6 (adequate)	4.24	1.45-12.36		2.98	1.11-8.04	

[a] Results were adjusted for site. Odds ratio = OR; CI = confidence interval.

[b] For the UMS-based coding framework, if English was not the main language spoken at home, then the person was unable to complete the dosette correctly for all four medicines (0% correct). Consequently, the univariable estimated OR is 0, but the multivariable OR cannot be estimated, nor can the P-value for main language spoken at home be calculated.

[c] For the UMS-based coding framework, no students were able to complete the dosette correctly for all four medicines (0% correct). Consequently, the univariable estimated OR is 0, but the multivariable OR cannot be estimated.

5. Discussion

5.1 Overview of key findings

Overall, there were no statistically significant differences between the label formats for enabling participants to correctly identify the patient name and medicine strength on the label. Small differences were observed between the label formats in their ability to support participants to correctly identify the dosage and total number of capsules to be taken per day. Clear signposting of the active ingredient (label format 3) was the most effective in enabling participants to correctly identify the active ingredient; it was also the superior label format across all three health literacy levels for correct active ingredient identification.

For the dosette packing task, label formats 2 and 4, modelled on UMS labelling characteristics, were clearly superior in supporting correct dosette completion per medicine as ascertained via the UMS-based coding framework. When data were analysed using the tailored coding framework however, the most noticeable difference between label formats was seen for cabergamol, where label formats 2 and 4 continued to be superior. Participants with adequate health literacy performed consistently better across all label formats regardless of how dosette data were coded, with the converse being true for those with low health literacy. Main language spoken at home and NVS-UK score were factors associated with participants' ability to correctly complete the dosette per medicine, regardless of the coding framework.

5.2 Label-related questions on patient name and dosage information

Similar to the previous phase of this broader project,[1] participants did not have difficulty in locating the patient name on the label regardless of format. This indicates that labelling format does not have a significant influence for this point of information and that labelling approaches should be targeted towards optimising other labelling aspects of priority, namely relating to critical medicine-related information.

Overall, most participants could state the dosage of the medicine correctly regardless of the label format. This ability did not appear to be influenced by whether numbers were expressed using words (label format 3) or numerals (label format 1) for the dosage-related information. This indicates that there is likely to be no difference in using numeric digits or words to express dosage information relating to oral solid dosage forms. This was similar to the earlier user testing findings.[1] Therefore, we continue to recommend the use of numerical digits to convey dosage information in line with findings of previous research and in recognition of study participants' general preference for numerical digits.[1]

5.3 Active ingredient understanding

Signposting of the active ingredient and brand name on the label (label format 3) was found to be the superior approach in communicating this information to the participants. These findings also support the results of the earlier user testing research.[1] Signposting the active ingredient and brand name was superior across all health literacy levels, suggesting that the broader population with diverse health literacy levels will largely benefit from widespread active ingredient signposting on dispensed prescription medicine labels. More than 80% of participants at each health literacy level were able to correctly identify the active ingredient when it was signposted. This means that user testing success criteria[14] for this information have been achieved, further emphasising the robustness of signposting as an approach to communicating active ingredient information.

Signposting will be useful to better support people in understanding their medicines especially in light of the introduction of active ingredient prescribing as legislated practice for Pharmaceutical Benefits Scheme prescriptions, via the National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019.[15] Signposting may be especially helpful in the case of generic medicines where the active ingredient has been included as part of the "brand name" itself. This labelling approach will also be useful in the Australian hospital setting where blank boxes are used to package specific quantities of dispensed medicines for patients being discharged.

Label format 1, which conveyed the active ingredient in sentence case first followed by the brand name in sentence case below on a separate line also performed relatively well and was the second best performing label (after signposting). This finding was similar to the findings in the user testing phase.[1] As previously discussed,[1] the close proximity of the medicine strength and active ingredient could have assisted participants in being able to identify the active ingredient. This way of formatting active ingredient and brand name information on the label could also be adapted for implementation, as a next-best approach to signposting.

The active ingredient in brackets with the brand name stated first did not perform as well as the other label formats. This active ingredient and brand name formatting combination reflects what people commonly associate with current practice.[1] The findings reinforce the unparalleled benefits of clear signposting in communicating active ingredient information to people.

Label formats 2 and 4 had the brand name and active ingredient on the same line, which is a point of difference with label formats 1 and 3 that performed better. It is possible that label formats 2 and 4 did not perform as well because the active ingredient and brand name were positioned together on the same line, brackets were used, and bolding was not used for emphasis and as a cue for the brand name.[1]

Recommendations

DO:

✓ Signpost the active ingredient and brand name on the label

✓ Include the active ingredient and brand name on separate lines

DO NOT:

✘ Include the brand name and active ingredient on the same line together with the active ingredient name in brackets, without other formatting cues

5.4 Label format and dosette packing task outcomes

The dosette packing task is reflective of the ability of people to apply and act on the combined information provided on all four labels, when planning a regimen for all four medicines in the one dosette. This activity is reflective of the real-world impact of polypharmacy and managing multiple medicines simultaneously. Whilst the majority of participants could correctly answer questions about how much to take and how often for each medicine, about a quarter of the participants could correctly complete the dosette for all four medicines. This difference is primarily due to the fact that the participants had to process dosage information for four medicines and then plan when they would take these medicines during their day. This plan requires an understanding of the doses for all four medicines, and then timetabling the dosing across their day, reflecting the behaviour of people taking several medicines in primary care.

This study builds on a previous study conducted by Wolf et al.,[7] on which the 24-hour dosette packing task has been based.[7] Bailey et al. also used a similar approach.[13] Overall, participants did not consolidate doses of the four medicines as effectively as they could have, with a mean number of grouped doses per day of 6.3, comparable to previous findings.[7] However, the present study provided each participant with at least one label format which included the UMS-worded dosage together with a UMS table. This was different to the study by Wolf et al.,[7] in which the UMS was not explicitly evaluated and the emphasis appeared to be on the wording of the dosage information.[7] For example, two labels had identical dosage expressions, others had varied ways of expressing a twice-a-day dosing regimen, and some labels had additional directions relating to timing doses with meals (expressed differently) or for how long the medicine should be taken.[7] Despite each kit in our study having a UMS-based label with a UMS table, the similar mean number of grouped doses between the two studies indicates that providing each participant with only a proportion of labels with a UMS-based label (with or without the table) does not necessarily impact how participants choose to dose several different medicines at the same time. In addition, the first box of medicine that the participant used to complete the dosette may have also influenced how they completed the dosette for the medicines thereafter. Had participants received all medicines with UMS-based labels, more effective consolidation may have been observed, as previously demonstrated by Bailey et al.[13]

Some participants appeared to be planning their medicine taking one medicine at a time, rather than perceiving all medicines as a collective regimen that they could effectively consolidate to reduce the number of times the medicines needed to be taken in a day. This may partly be due to being in a study and planning four fictitious medicines, and partly because the participants did not have the health literacy skills to understand the task being asked of them and/or apply the information. Another potential contributor may be that participants were not adequately motivated to carefully plan the best regimen as part of their responses. This may also be reflective of similar behaviour in a real-life setting, if also presented with a complex medication regimen for their own medicines. This presents challenges in the context of polypharmacy and how people plan their medicine taking. Importantly, any change in labelling strategy that aims for a consistent, standardised approach, must be paired with appropriate people-centred counselling and education in a real-world setting.

5.4.1 Entire dosette completion

At a kit level, those who received Kit D had the highest proportion of correct entire dosette completion, followed by Kit B (see Figure 1d and 1b, or Appendix 1d and 1b). Specifically, Kit D had the cabergamol label designated as the UMS-based label format with the table (label format 2), while Kit B had the dosage expressed using similar UMS standardised times of day (with no table included) (label format 4). When considering the four specific UMS time frames, the three-times-a-day dosing regimen may be considered as the "most difficult" timing when compared with twice a day and four times a day. Participants' difficulty with correctly dosing cabergamol three times a day was seen in cabergamol having the lowest proportion of correct responses for the dosette completion task in comparison to the other three medicines. Stark differences were seen in the proportion correct for cabergamol label formats 1 and 3, versus label formats 2 and 4.

If considering cabergamol as the "difficult" dosing regimen of the four medicines, cabergamol may have been the reason why participants were unable to complete the entire dosette correctly. In particular, label format 2 defined the exact time frames for morning (6 to 8 am), midday (11 am to 1 pm), and bedtime (9 to 11 pm) in the table. This may have helped make the "difficult" dosing regimen simpler for those who received Kit D, as cabergamol had label format 2 and the exact time frames in the table, which were a better guide for dosing than not having exact time frames. Therefore, this may explain why Kit D had the highest proportion of correct entire dosette completion.

From a practice perspective, it is important to recognise that the proportion of participants correctly completing the entire dosette was low, highlighting the challenges associated with polypharmacy that need to be addressed in the broader healthcare context. Effective and consistently clear labelling will help provide a better foundation for people to then appropriately action the information provided to them.

5.4.2 Dosette completion per medicine – effect of label format: UMS-based coding framework

When dosette completion data per medicine were coded using the UMS-based coding framework, label formats 2 and 4 were the best performing labels. However, it should be acknowledged that the UMS-based coding framework was based around the UMS times. Therefore, it was more likely that the UMS-based labels (label formats 2 and 4) would perform better when the data were coded using this framework. This was clearly evident in the study results.

It should be noted that label format 4, which did not have the dosing table, would still be considered a label that adopted explicit labelling directions (UMS language) through specification of the times of day.[16] In a retrospective study, people above the age of 65, who were not as highly educated and who took medicine(s) dosed more than once a day benefited more from UMS labels that used the standardised times of day.[16] In the present study, the UMS table included on label format 2 did not provide substantial added benefit compared to a UMS-based label without the table (label format 4) when looking at the ability to complete the dosette per medicine. This suggests that there may be two reasons for this:

- Either the participant picked up on the similarity in the standardised times of day used to express doses on these two label formats, and matched their dosette completion for the two relevant medicines based on the time frames stated in the table on label format 2; or
- The standardised times of day may be sufficient and possibly of more use than the UMS table to people planning their medicine taking for a day.

Complexity in timing of doses may also be further influenced by sleep-wake times, meal times, and other general routine considerations that are unique to the individual, which labels alone fail to take into consideration. This is particularly relevant for the UMS table due to its specificity in defining exact time frames mapped to morning, midday, evening, and bedtime. Within the literature, the specificity of the UMS time frame defined as "morning" also varies: 6-8 am has been presented[2] (and adopted in this study) and 7-9 am seen on an exemplar label in another study.[3] Therefore, in order to support more flexible dosing and tailoring, a table may not be necessary to express specific times of day according to prescribed time frames. Approximate times of day included on labels when conveying dosage information may be sufficient, whilst being more advantageous compared to just stating the number of times a day a medicine should be taken,[17] and may better support flexibility to tailor dosing regimens.

Interestingly, in the study recently published by Wolf et al.,[16] UMS-based labels with standardised times of day were only associated with a small, albeit significant, improvement in adherence. However, the benefit for these labels was more for people above the age of 65, who were not as highly educated and who took medicine(s) dosed more than once a day.[16] Our findings support previous evidence on the usefulness of the UMS,[3, 4, 16] as well as the findings of the earlier part of this research (initial user testing).[1] However, future studies are required to examine the impact of implementation of an Australian national dispensed labelling standard endorsing the UMS approach on patient-related outcomes.

Standardising the times of day used to express dosage information on dispensed prescription medicine labels and applying them to other written information will improve the consistency of information provided in written medicine information documents and leaflets received by people. However, only mandating the exact UMS standardised times of day on dispensed prescription medicine labels may lead to inconsistencies in medicine information presentation across other areas of practice. For example, dose administration aids may use different yet standardised approximate times of day that are based around mealtimes e.g. breakfast, lunch, dinner and bedtime such as used on a Webster-pak®.[18] Written discharge medication lists or summaries routinely provided by hospitals, may also use a similar way to express these times of day to assist people taking multiple medicines.[19] Inconsistencies in labelling of medicines dispensed by the hospitals compared to a discharge medication list issued by the same hospital pharmacy may exacerbate medication-related problems at transitions of care, where patients are already vulnerable.

Recommendations

DO:

✓ Use explicit labelling directions, where approximate times of day are used to communicate dosage information e.g. Take 1 capsule in the morning and 1 capsule in the evening

CONSIDER:

✓ People's sleep-wake cycles and daily lifestyles when stating set time frames for medicine taking on the label

5.5 Differences between tailored versus UMS-based coding framework findings

The tailored coding framework emphasised the importance of maintaining appropriate dosing intervals. When dosette packing task data were analysed with this framework, there was an overall increase in the proportion of correct dosette completion per medicine for label formats 1 and 3. The slight decrease in the proportion correct for the label formats with explicit labelling directions using standardised approximate times of day (label format 4) and the UMS table (label format 2) could be attributed to dosing intervals defined as inappropriate. For example, the overall increase in the proportion correctly dosing myclofenac was attributed to an appropriate interval being observed, despite the dose time(s) falling outside of the appropriate time frames for the UMS-based coding framework. This could also explain the increase in proportion correct for label formats 1 and 3, where directions were expressed on the label as twice a day or 2 times a day.

Although observations suggest the UMS table enables people to more easily follow directions for dosing, it can lead to shorter and/or longer dosing intervals which may have clinical implications depending on the medicine. This practical implication should be considered if advocating for the use of a UMS-like table as a standardised dispensed prescription medicine labelling approach. The emphasis is to ensure the label format adequately supports the person to understand the specific dosing regimen; supporting appropriate understanding and application of dosing information must remain the primary objective, rather than standardisation of labelling alone.

According to the tailored coding framework, cabergamol was the only medicine that had a statistically significant difference in the proportion that correctly completed the dosette for the medicine between the label formats. Label formats 2 and 4 had a higher proportion correct than label formats 1 and 3. Furthermore, when looking at the proportion correct for label formats 1 and 3 by medicine, cabergamol had the lowest proportion correct out of all the four medicines. This highlights that a three-times-a-day regimen is likely more challenging for people than a twice-a-day or four-times-a-day dosing regimen especially when taking multiple medicines (polypharmacy). The "difficulty" seen with this regimen may or may not be demonstrated if this was the only medicine being taken, compared with being hypothetically taken alongside three other medicines, as was the scenario in this study. Most participants have not been able to demonstrate that they understand the appropriate dosing interval for a medicine that needs to be taken three times a day, based on the tailored coding framework. Consequently, to support appropriate spacing of doses, especially if a person is taking multiple medicines concomitantly, it may be useful to consider dosing intervals expressed using a narrow range, as recommended from the previous user testing.[1]

Although most participants were able to correctly answer the label-based question on dosage, the proportion correctly demonstrating their understanding in the dosette packing task was substantially lower. A similar finding was noted by Davis et al.[20] where approximately 71% of participants with low health literacy could verbalise the relevant dosage, but only about 35% could demonstrate how many tablets needed to be taken. This suggests that people struggle to apply dosage information when it has only been provided on a label. Labels are not intended to be standalone and as seen from the dosette completion findings, they are insufficient as standalone sources of medicine information. Future health literacy initiatives should focus on enabling people to plan and manage complex dosage regimens for multiple medicines. Enhanced label formats may then result in enhanced ability to apply information regardless of people's health literacy levels and resonates with the universal precautions approach to health literacy.[21] The importance of this is highlighted in that the use of clear labelling is critical to help people apply the information for the most "difficult" dosing regimen (three times a day, in this study), despite minimal differences seen between the different labelling approaches for "easier" dosing regimens.

5.6 Factors influencing participants' ability to apply medicine information

Highest level of education and NVS-UK score were factors associated with participants being able to correctly determine the total number of capsules per day. This alludes to the importance of numeracy in health literacy,[2] as participants were required to calculate the number of capsules based on the dosage information provided.

Main language spoken at home and NVS-UK score were factors that influenced participant's ability to correctly complete the dosette per medicine, regardless of the coding framework used. This highlights the intrinsic, complementary importance of literacy and health literacy in understanding and actioning health and medicines-related information. People firstly need sufficient proficiency in understanding the language used to express directions, in this case literacy in English. They then need to have adequate health literacy competencies in order to apply the communicated information.

According to the UMS-based coding framework, label formats 2 and 4 were superior when it came to dosette completion per medicine. This indicates that everyone benefits from having a "well-designed" label, even those who have adequate health literacy. However, according to the tailored coding framework, although those with adequate health literacy had a higher proportion correctly completing the dosette per medicine, the impact of label format was less pronounced. This highlights the fundamental difference underpinning each framework, and is also a point of reflection regarding what we want people to be able to do with dispensed prescription medicine labels: take medicines within time frames that are deemed correct and appropriate, and consider planning a dosing regimen that adheres to appropriate dosing intervals tailored to them.

5.7 Study limitations

As participation in the study was voluntary, those with low health literacy may have declined to participate and may be under-represented in the study. Similarly, culturally and linguistically diverse communities may be under-represented, as they were not specifically targeted as part of the recruitment protocol. In particular, for the Darwin sites, the absence of an Aboriginal health practitioner or liaison officer to explain the study may have impacted recruitment of people from an Aboriginal background.

This study focused on solid oral dosage forms to be taken regularly (that is, not on an as-needed basis). Non-oral dosage forms were not evaluated as part of the fictitious medicines used in this study. Non-oral dosage forms may have different implications on labelling characteristics that have not been investigated as part of this study. In addition, directions on the study labels did not include extended directions such as whether the capsules were required to be taken on an empty stomach, with food or after food or meals. Such instructions could have further implications on how people choose to dose their medicines throughout the day; future work is required in integrating UMS times and instructions to time doses around food and mealtimes, as noted by other researchers.[16]

The choice of utilising a 24-hour dosette may have impacted participants' dosage planning, and may not be reflective of how these medicines will be used in a real life context. This would be dependent on the dosettes available in practice.

Data was not collected regarding the person's waking time and when they would take their first dose in relation to this, and similarly, when they would go to bed. This person-dependent variability in daily routines, such as that associated with shift workers, is an important consideration for future work to ascertain appropriate labelling to support people to tailor their daily dose appropriately. This information would help determine the individual "index" dose, and the waking time frame for determining appropriate interval determination.

6. Conclusions

Clear labelling strategies provide benefits for all, regardless of health literacy levels. The study-designed label formats were effective in communicating information regarding the patient's name, dosage, total number of capsules to be taken per day, and the amount of active ingredient. Clear signposting of the active ingredient and brand name was by far the most effective approach for communicating a medicine's active ingredient, with nearly all participants able to identify the active ingredient.

Participants could correctly report the dosage-related information regardless of label format. However, the proportion who could apply this information and correctly complete the dosette per medicine was considerably lower. This indicates that people's ability to act on the information was impacted by other factors such as health literacy. Fewer participants with low health literacy were able to complete the dosette for all four medicines correctly. Those with adequate health literacy performed consistently better in completing the dosette across the different label formats. Differences in dosette completion data were noted between the data derived from the two coding frameworks. However, both sets of findings illustrated that explicit labelling directions, where approximate times of day are used to express doses, lead to a higher proportion of participants being able to demonstrate their understanding by correctly completing a dosette for the relevant medicine.

Labelling standards that reflect evidence-based strategies will inform development of user-friendly dispensed prescription medicine labels to support safe and effective medication use and adherence. Importantly, dosing and expression of dosing must be tailored for the person to ensure they are able to take all of their medicines appropriately. Labels should be supported by person-centred education and counselling, and integrating medication taking into people's daily routine to optimise medicines use.

7. Recommendations

DO

Aspect(s)	Rationale / evidence
Active ingredient / brand name formatting	
Signpost the active ingredient and brand name on the label	• The earlier user testing conducted as part of the broader project found that signposting was the superior approach to communicating active ingredient and brand name information on the label.[1] • In this study, label format 3, which included signposting, was identified to be the superior label format for communicating active ingredient and brand name information.
Include the active ingredient and brand name on separate lines	• Label format 1, which had active ingredient presented first and then the brand name second on the line below was the next best labelling option after clear signposting.
Communication of medicine-related information	
Use explicit labelling directions, where approximate times of day are used to communicate dosage information e.g. Take 1 capsule in the morning and 1 capsule in the evening	• Label formats 2 and 4 supported a higher proportion of participants to correctly complete the dosette per medicine, compared to the other two label formats. • There did not appear to be a clear advantage in including the UMS table compared to only expressing dosing regimens using standardised UMS approximate times of day. Approximate times of day are preferable, permitting flexibility in dosing and the ability for people to individually tailor their dosing regimens.

CONSIDER

Aspect(s)	Rationale / evidence
Communication of medicine-related information	
People's sleep-wake cycles and daily lifestyles when stating set time frames for medicine taking on the label	• This study did not consider factors such as shift work, which can impact medicine-taking. For example, people may take medicines at 2 am. Medicine information included on a label must be tailored to the individual to ensure that it is most appropriate for their given circumstances.

DO NOT

Aspect(s)	Rationale / evidence
Active ingredient / brand name formatting	
Include the brand name and active ingredient on the same line together with the active ingredient name in brackets, without other formatting cues	• This formatting combination did not perform as well in comparison to clear signposting of the active ingredient and brand name, and the active ingredient first with the brand name second on a separate line. • It is possible that label formats 2 and 4 did not perform as well because the active ingredient and brand name were positioned together on the same line, brackets were used, and bolding was not used for emphasis and as a cue for the brand name.[1]

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Appendices

Appendix 1. Evaluated labels

Halocillin label (90 mm x 65 mm) Label format 2

Mr James Douglas

Cilfox (halocillin) 200 mg Capsules 10 Caps

Take
1 capsule in the morning,
1 capsule at midday,
1 capsule in the evening and
1 capsule at bedtime

Morning 6 to 8am	Midday 11am to 1pm	Evening 4 to 6pm	Bedtime 9 to 11pm
1	1	1	1

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Abalazine label (90 mm x 65 mm) Label format 4

Mr James Douglas

Butafor (abalazine) 80 mg Capsules 10 Caps

Take
2 capsules in the morning,
2 capsules at midday,
2 capsules in the evening and
2 capsules at bedtime

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Cabergamol label (90 mm x 65 mm) Label format 3

Active ingredient: Cabergamol
10 mg Capsules
Brand Name: Dariol

Take 2 capsules 3 times a day

Mr James Douglas

10 Caps
Expiry Date: 09/2021

Dr B Cooper ADK
Ref#136891 12/11/2017

Keep out of reach of children

Hospital Pharmacy
31 Hospital Rd,
Canberra ACT 2605
Ph: 02 6244 3111

Myclofenac label (80 mm x 38 mm) Label format 1

Keep out of reach of children
Myclofenac 75 mg Capsules
Vipparoll

Take TWO capsules TWICE a day

Mr James Douglas Expiry Date: 09/2021

12/11/2017 - 10 Caps
Dr B Cooper
Ref #136891 ADK

Hospital Pharmacy
31 Hospital Rd Canberra
ACT 2605 Ph: 02 6244 3111

Appendix 1a. Kit A labels

Halocillin label (90 mm x 65 mm) Label format 3

Active ingredient: Halocillin
200 mg Capsules
Brand Name: Cilfox

Take 1 capsule 4 times a day

Mr James Douglas

10 Caps
Expiry Date: 09/2021

Dr B Cooper ADK
Ref#136891 12/11/2017

Keep out of reach of children

Hospital Pharmacy
31 Hospital Rd,
Canberra ACT 2605
Ph: 02 6244 3111

Abalazine label (80 mm x 38 mm) Label format 1

Keep out of reach of children

Abalazine 80 mg Capsules
Butafor

Take TWO capsules FOUR times a day

Mr James Douglas Expiry Date: 09/2021

12/11/2017 - 10 Caps
Dr B Cooper
Ref #136891 ADK

Hospital Pharmacy
31 Hospital Rd Canberra
ACT 2605 Ph: 02 6244 3111

Cabergamol label (90 mm x 65 mm) Label format 4

Mr James Douglas

Dariol (cabergamol) 10 mg Capsules 10 Caps

Take
2 capsules in the morning,
2 capsules at midday and
2 capsules at bedtime

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Myclofenac label (90 mm x 65 mm) Label format 2

Mr James Douglas
Vipparoll (myclofenac) 75 mg Capsules 10 Caps

Take
2 capsules in the morning and
2 capsules at bedtime

Morning 6 to 8am	Midday 11am to 1pm	Evening 4 to 6pm	Bedtime 9 to 11pm
2			2

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Appendix 1b. Kit B labels

Halocillin label (90 mm x 65 mm) Label format 4

Mr James Douglas

Cilfox (halocillin) 200 mg Capsules 10 Caps

Take
1 capsule in the morning,
1 capsule at midday,
1 capsule in the evening and
1 capsule at bedtime

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Abalazine label (90 mm x 65 mm) Label format 2

Mr James Douglas
Butafor (abalazine) 80 mg Capsules 10 Caps

Take
2 capsules in the morning,
2 capsules at midday,
2 capsules in the evening and
2 capsules at bedtime

Morning 6 to 8am	Midday 11am to 1pm	Evening 4 to 6pm	Bedtime 9 to 11pm
2	2	2	2

12/11/2017 Ref# 136891 ADK Exp: 09/2021
KEEP OUT OF REACH OF CHILDREN Dr B Cooper
Hospital Pharmacy, 31 Hospital Rd, Canberra, ACT 2605 Ph: 02 6244 3111

Cabergamol label (80 mm x 38 mm) Label format 1

Keep out of reach of children
Cabergamol 10 mg Capsules
Dariol

Take TWO capsules THREE times a day

Mr James Douglas Expiry Date: 09/2021

12/11/2017 - 10 Caps Hospital Pharmacy
Dr B Cooper 31 Hospital Rd Canberra
Ref #136891 ADK ACT 2605 Ph: 02 6244 3111

Myclofenac label (90 mm x 65 mm) Label format 3

Active ingredient: Myclofenac
75 mg Capsules
Brand Name: Vipparoll

Take 2 capsules 2 times a day

Mr James Douglas

10 Caps
Expiry Date: 09/2021

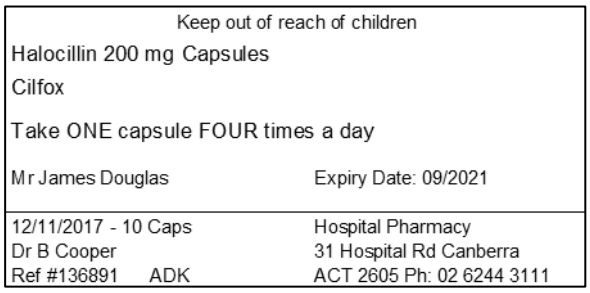
Dr B Cooper ADK
Ref#136891 12/11/2017

Keep out of reach of children

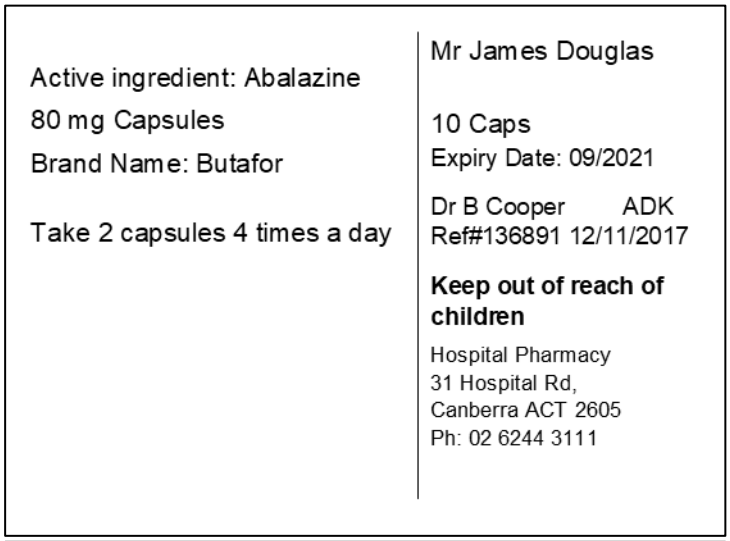
Hospital Pharmacy
31 Hospital Rd,
Canberra ACT 2605
Ph: 02 6244 3111

Appendix 1c. Kit C labels

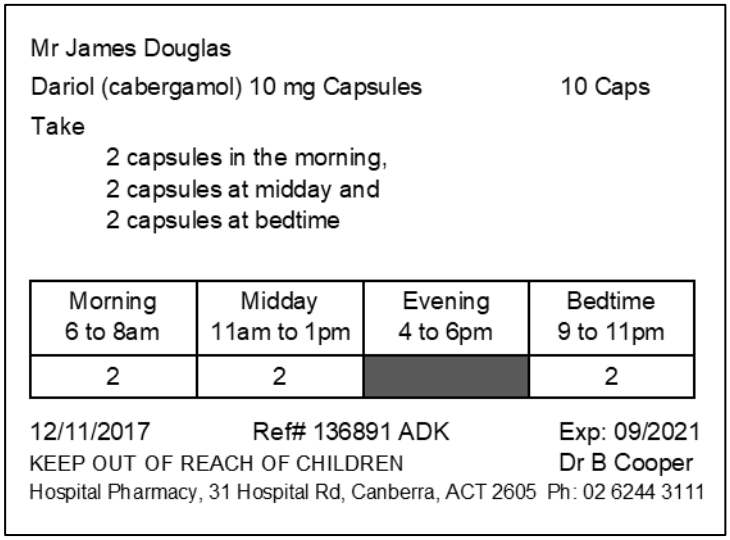
Halocillin label (80 mm x 38 mm) Label format 1



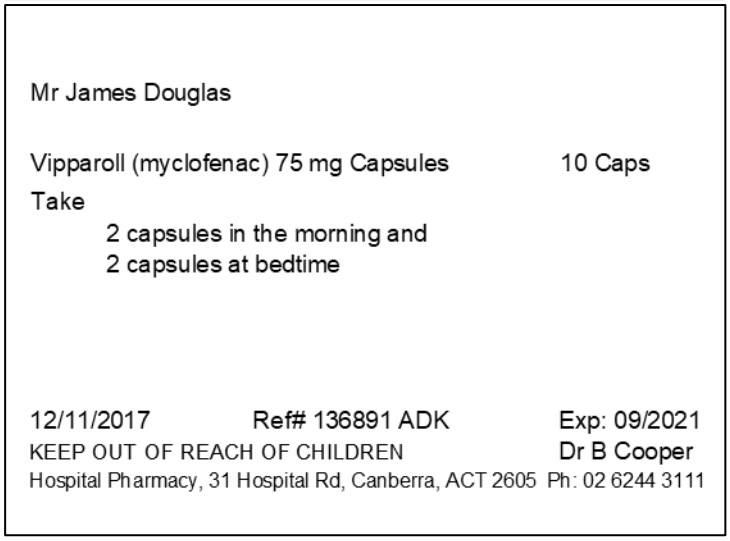
Abalazine label (90 mm x 65 mm) Label format 3



Cabergamol label (90 mm x 65 mm) Label format 2



Myclofenac label (90 mm x 65 mm) Label format 4

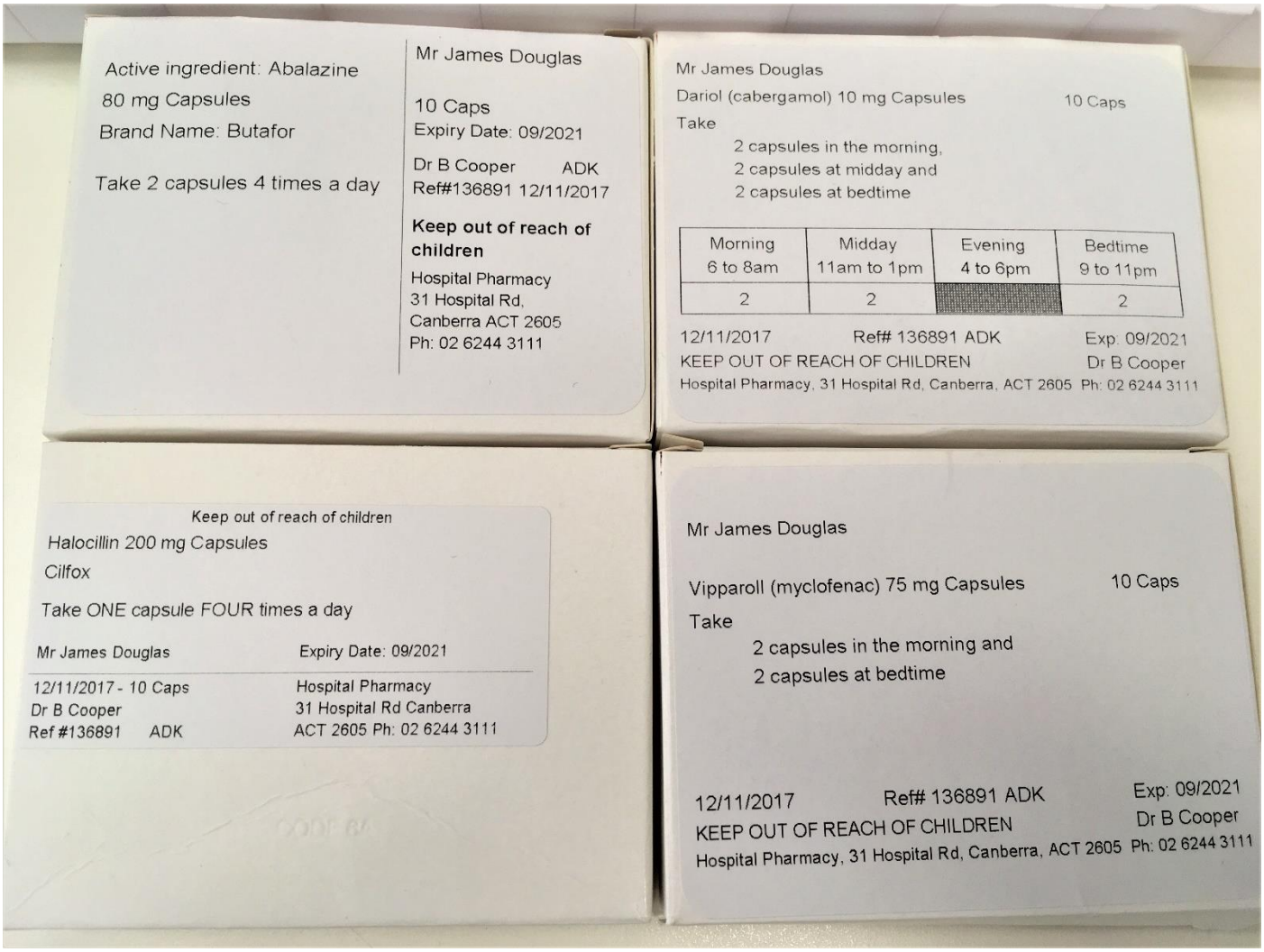


Appendix 1d. Kit D labels

Appendix 2. Dosette packing task – Images of the 24-well dosette and an example of a completed dosette

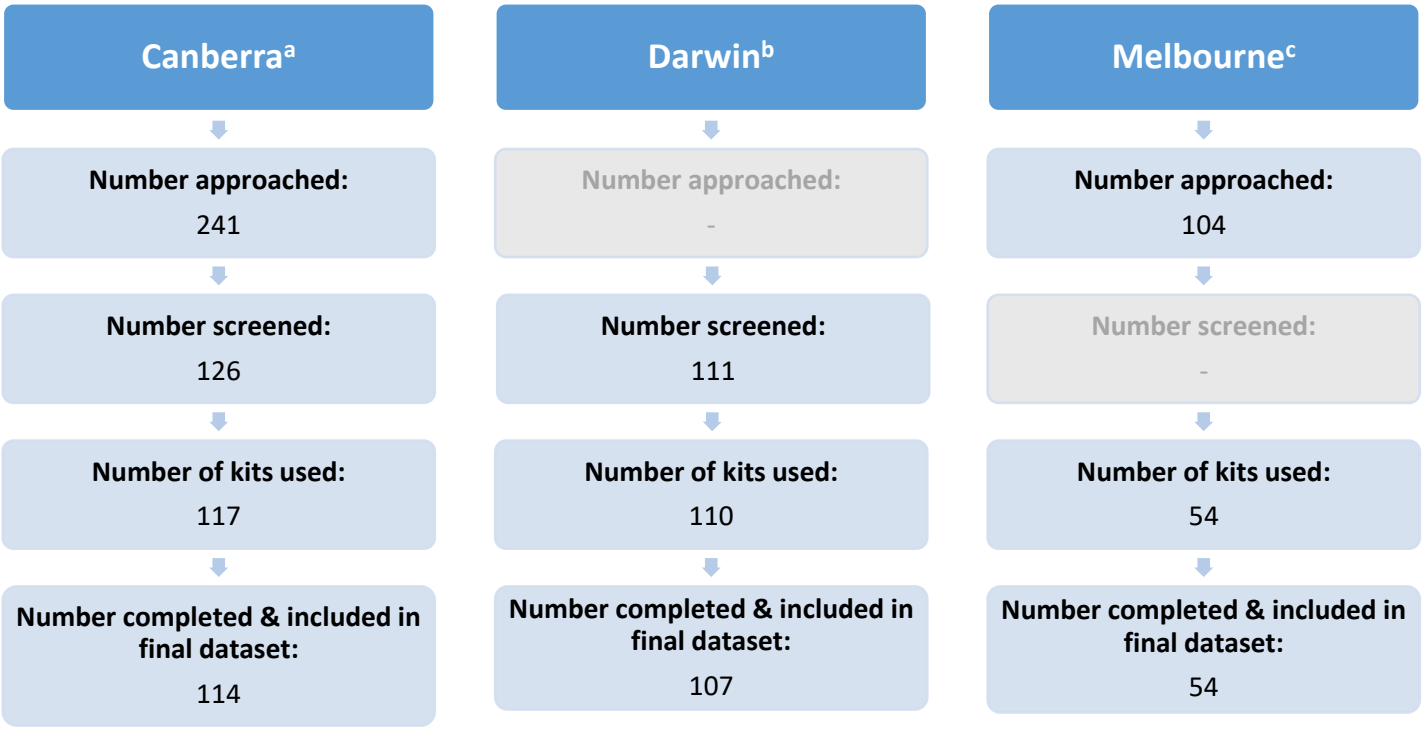
Appendix 2a. 24-well dosette used by participants for the dosette packing task

Appendix 2b. Example of a completed dosette for all four medicines



Appendix 2c. Close-up image of the kit of labels affixed to blank cardboard boxes

Appendix 3. Response rate data



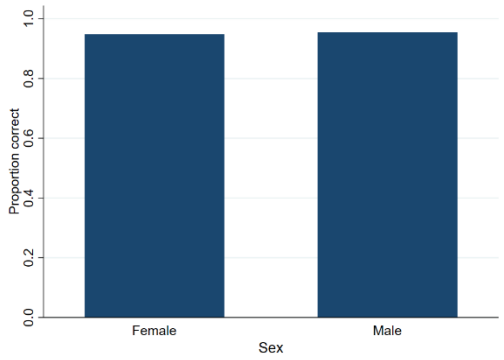
[a] Some values that have been included in these summed figures are reported estimates, as annotated by the site.
[b] Missing data and data that could not be reconciled have not been reported. Based on the records supplied by the site and numbers provided, minimum response rate-related data were calculated using available data. One person withdrew consent.
[c] Missing data and data that could not be reconciled have not been reported. Based on the records supplied by the site and numbers provided, minimum response rate-related data were calculated using available data. Two people withdrew consent before the kits were used.

Appendix 4. Unadjusted results – Factors associated with participants' ability to correctly interpret medicine information

Unadjusted results have been presented visually on the following pages (Appendix 4a-4h) together with the relevant P-values for the statistical tests conducted to determine if there were any differences between the categories for each participant characteristic.

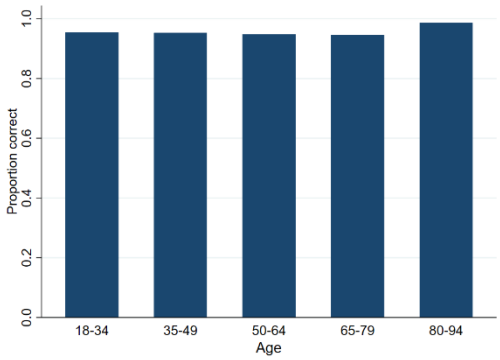
a. Sex

(P=0.95)



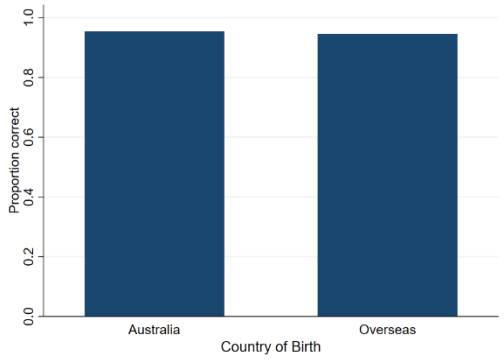
b. Age

(P=0.82)



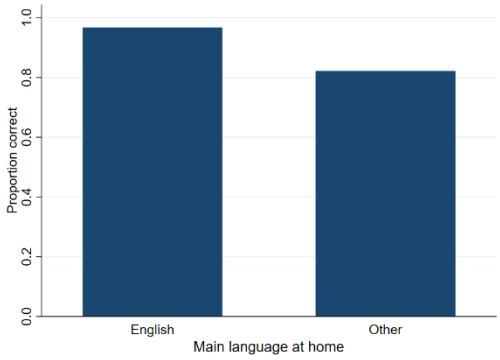
c. Country of birth

(P=0.77)



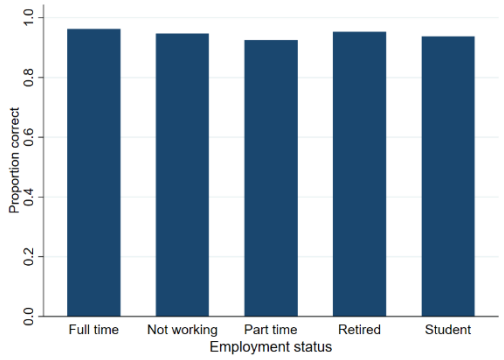
d. Main language spoken at home

(P<0.001)

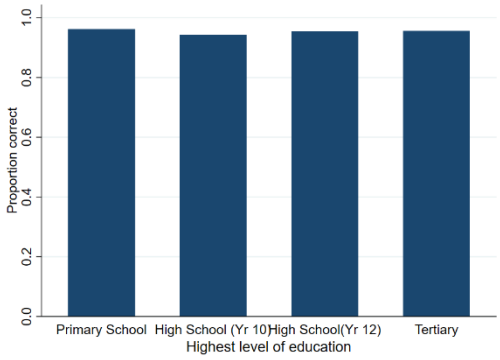


e. Employment status

(P=0.79)

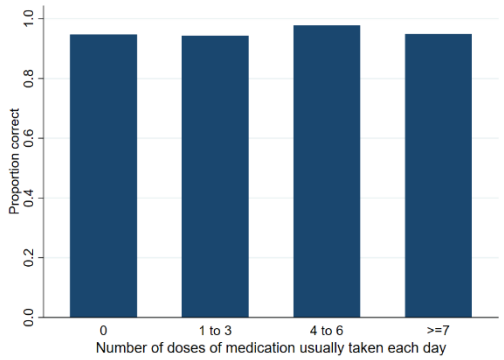


f. Highest level of education (P=0.87)



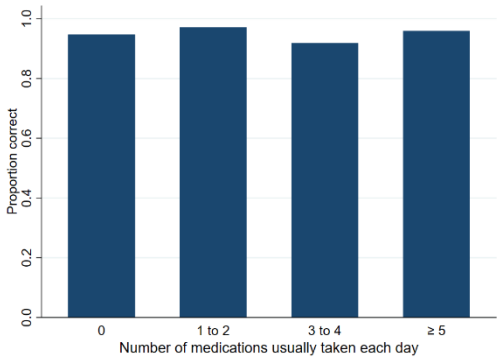
g. Number of medication doses per day

(P=0.49)



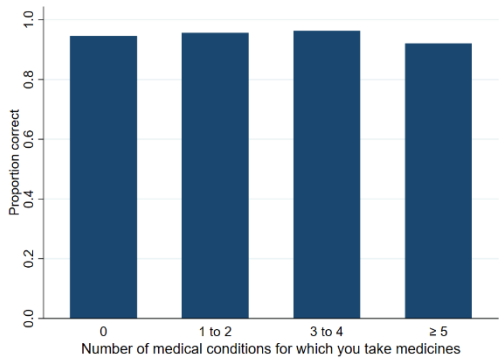
h. Number of medicines taken regularly

(P=0.32)



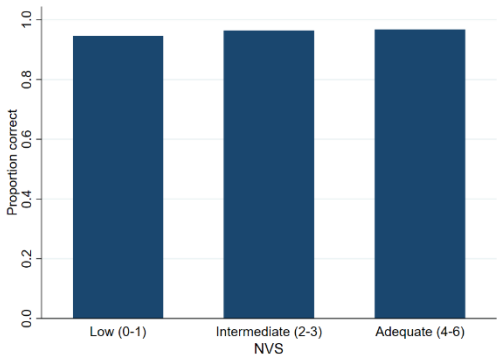
i. Number of medical conditions

(P=0.58)



j. NVS-UK score

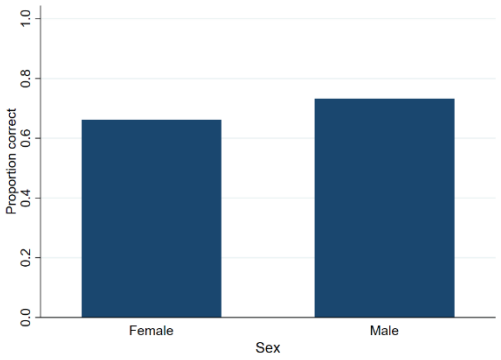
(P=0.43)



Appendix 4a. The proportion of correct answers by participant characteristics for Q2 How much should James take and how often? (The P-values indicate whether there was a statistically significant difference in the proportion correct between categories.)

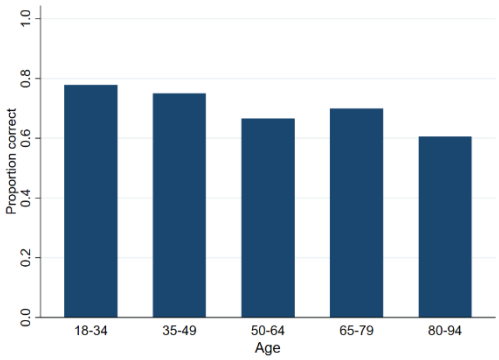
a. Sex

(P=0.04)



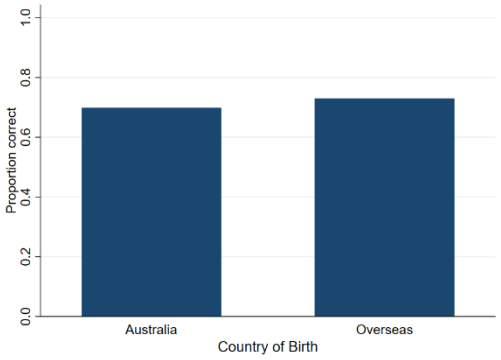
b. Age

(P=0.06)



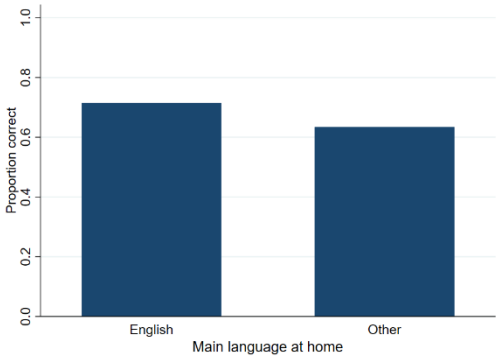
c. Country of birth

(P=0.41)



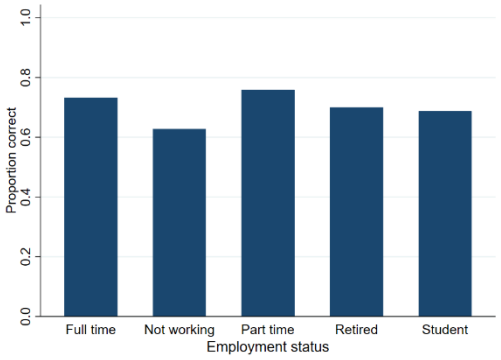
d. Main language spoken at home

(P=0.15)



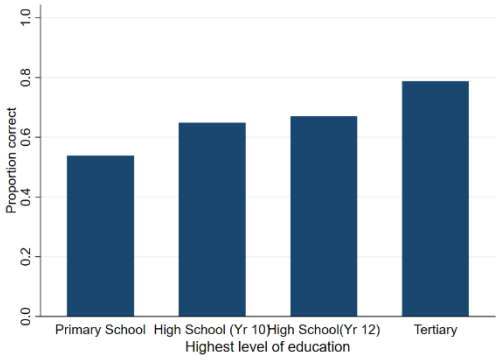
e. Employment status

(P=0.20)



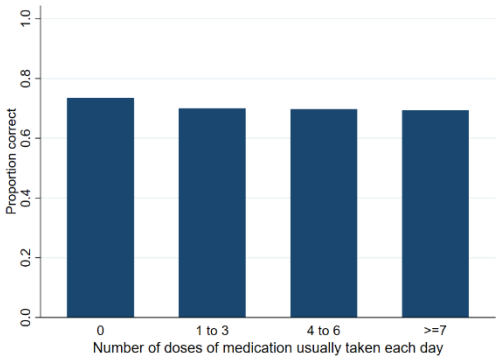
f. Highest level of education

(P<0.001)



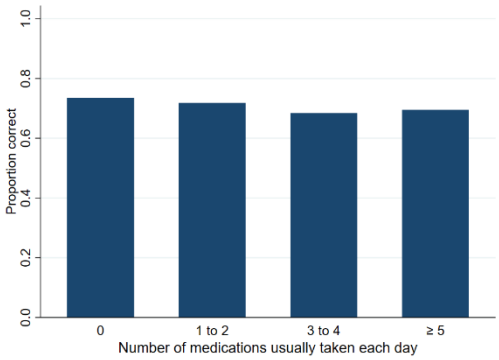
g. Number of medication doses per day

(P=0.83)



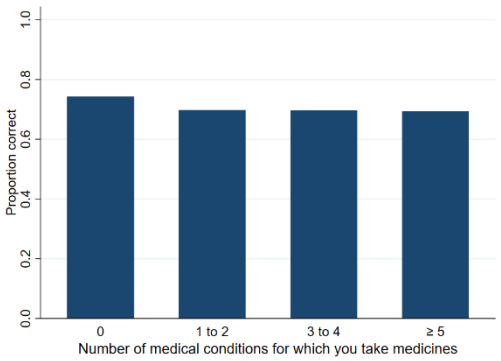
h. Number of medicines taken regularly

(P=0.75)



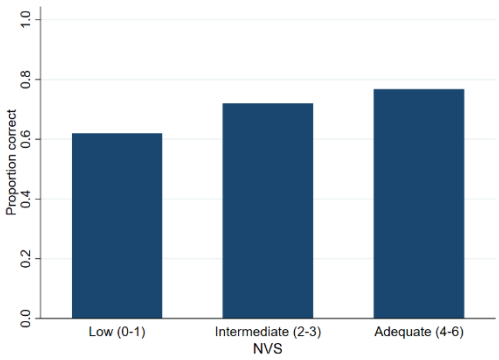
i. Number of medical conditions

(P=0.70)



j. NVS-UK score

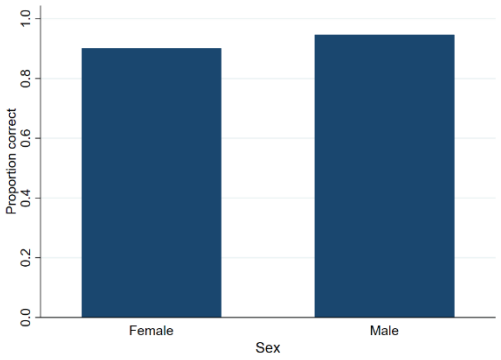
(P=0.002)



Appendix 4b. The proportion of correct answers by participant characteristics for Q3 What is the active ingredient found in this medicine? (The P-values indicate whether there was a statistically significant difference in the proportion correct between categories.)

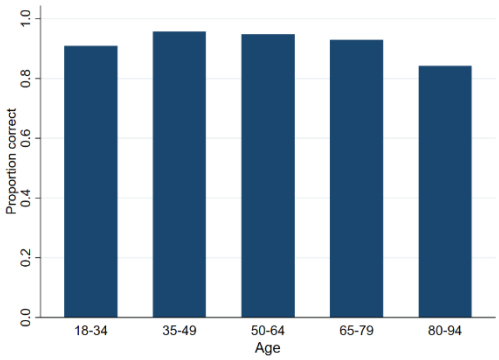
a. Sex

(P=0.15)



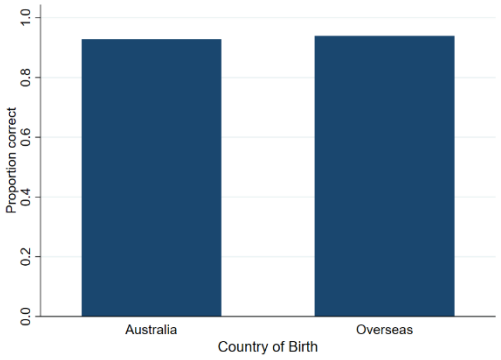
b. Age

(P=0.16)



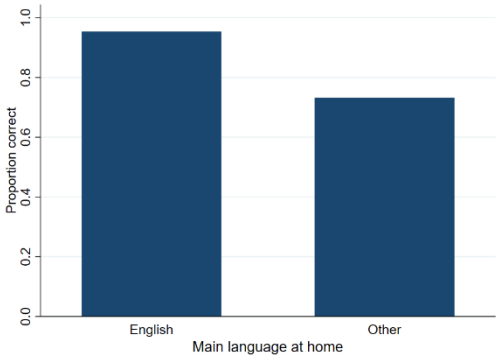
c. Country of birth

(P=0.98)



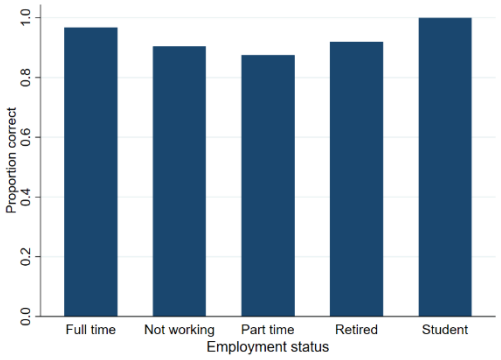
d. Main language spoken at home

(P<0.001)



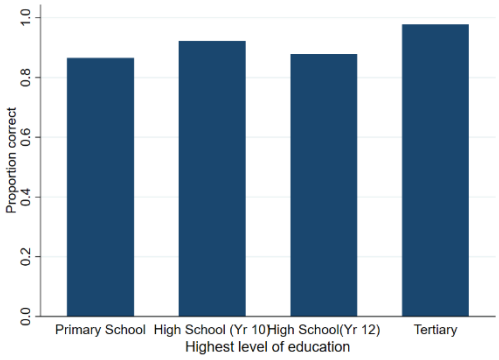
e. Employment status

(P=0.05)



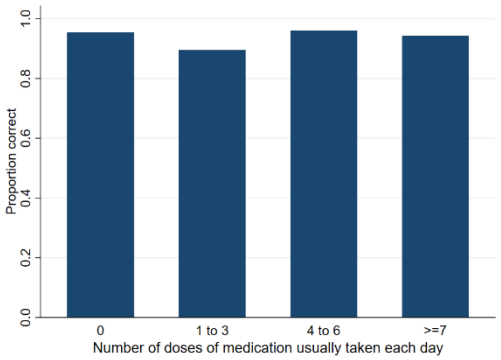
f. Highest level of education

(P=0.007)



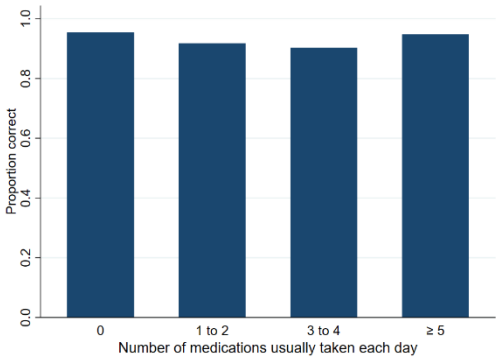
g. Number of medication doses per day

(P=0.19)



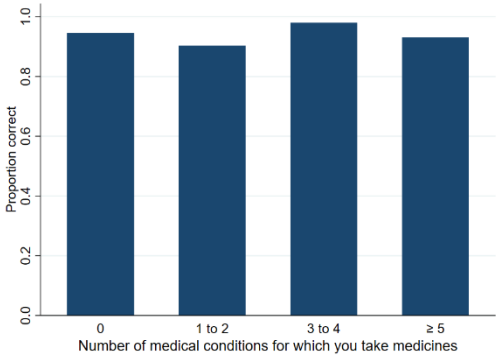
h. Number of medicines taken regularly

(P=0.46)



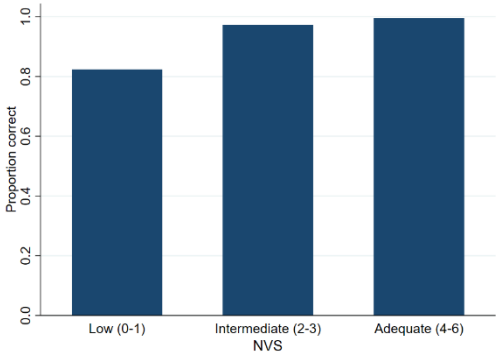
i. Number of medical conditions

(P=0.08)



j. NVS-UK score

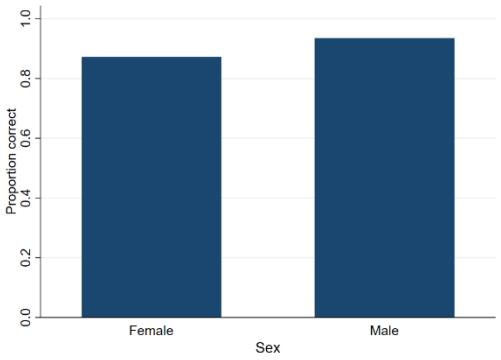
(P<0.001)



Appendix 4c. The proportion of correct answers by participant characteristics for Q4 How many capsules in total would James take in 1 day? (The P-values indicate whether there was a statistically significant difference in the proportion correct between categories.)

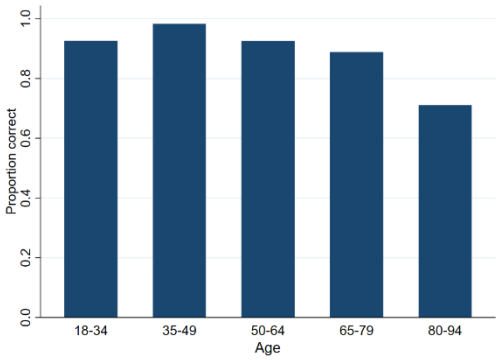
a. Sex

(P=0.02)



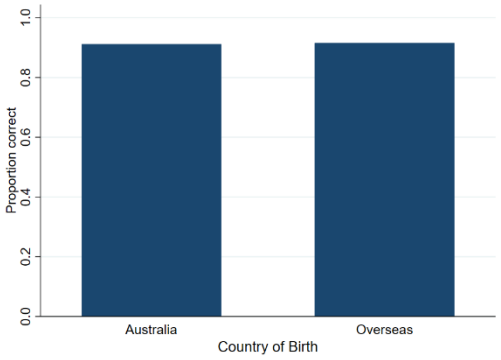
b. Age

(P=0.001)



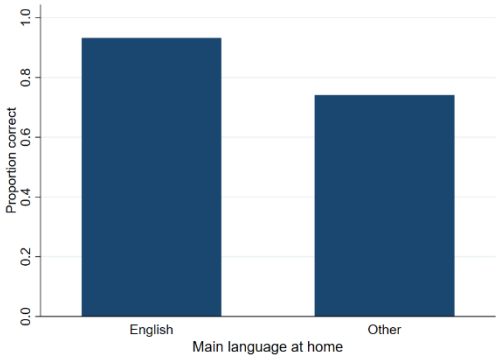
c. Country of birth

(P=0.86)



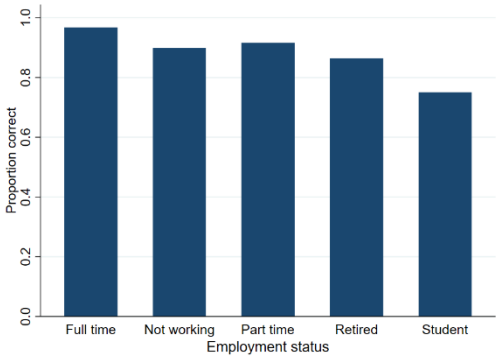
d. Main language spoken at home

(P<0.001)



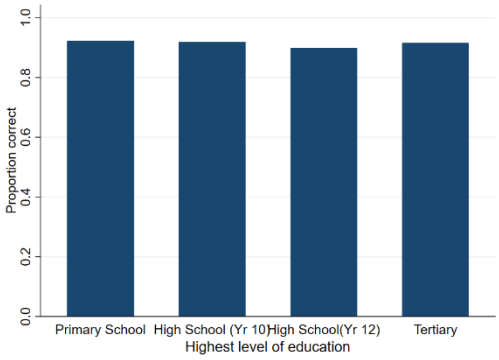
e. Employment status

(P=0.01)



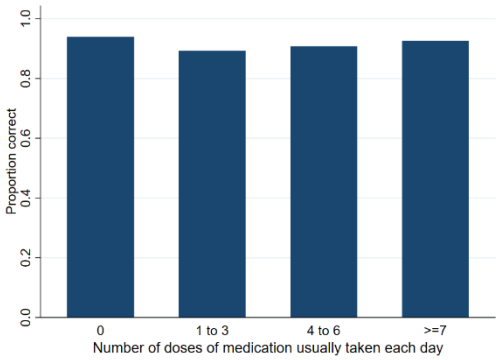
f. Highest level of education

(P=0.96)



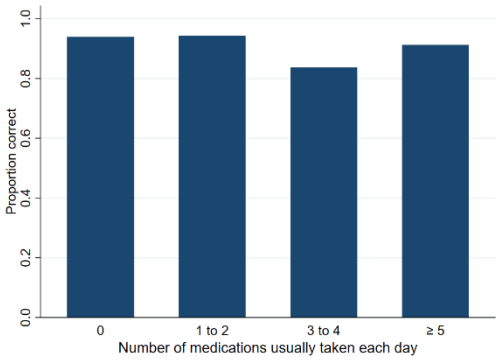
g. Number of medication doses per day

(P=0.46)



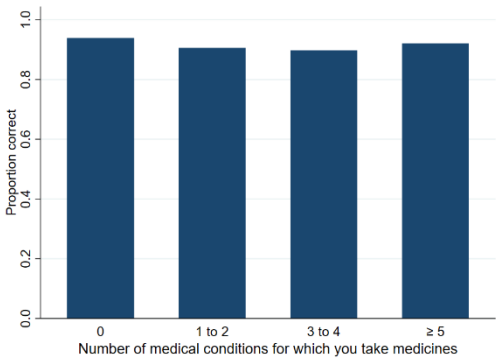
h. Number of medicines taken regularly

(P=0.05)



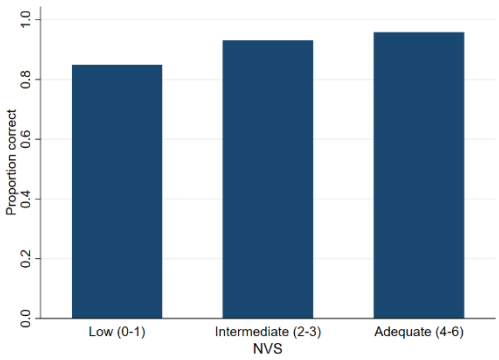
i. Number of medical conditions

(P=0.57)



j. NVS-UK score

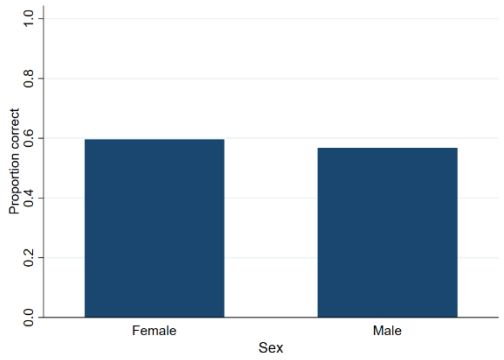
(P=0.002)



Appendix 4d. The proportion of correct answers by participant characteristics for Q5 How much of the active ingredient is in each capsule? (The P-values indicate whether there was a statistically significant difference in the proportion correct between categories.)

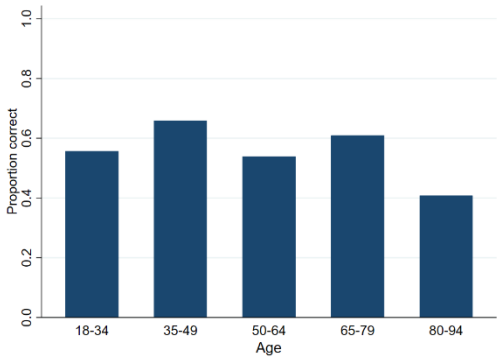
a. Sex

(P=0.49)



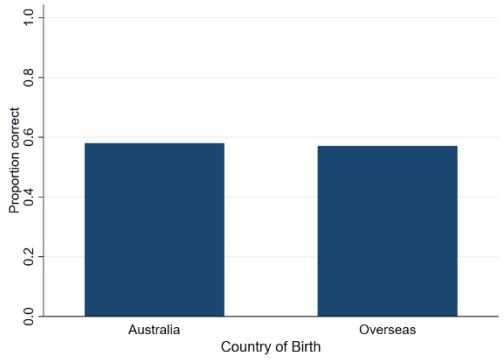
b. Age

(P=0.03)



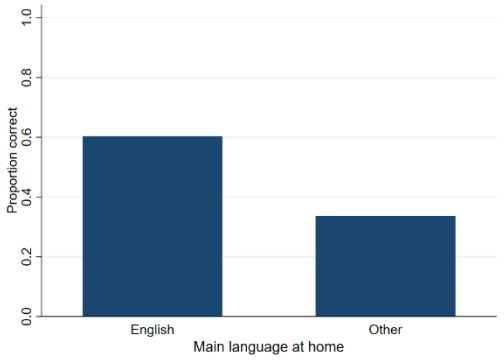
c. Country of birth

(P=0.84)



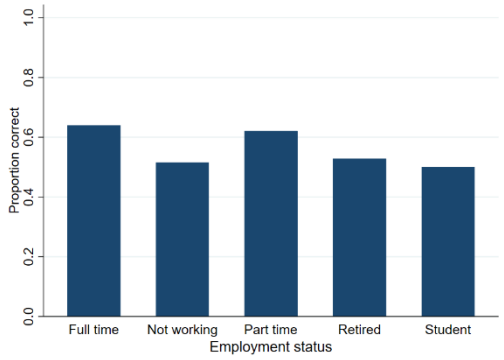
d. Main language spoken at home

(P<0.001)



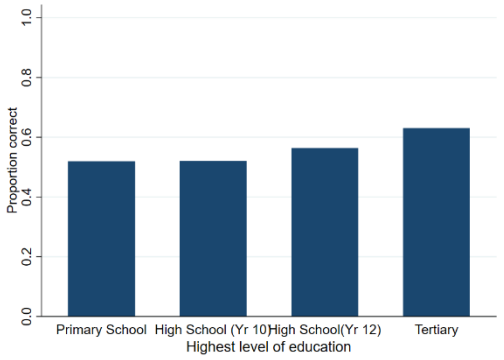
e. Employment status

(P=0.08)



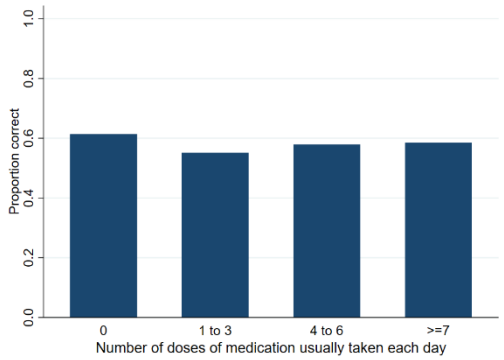
f. Highest level of education

(P=0.12)



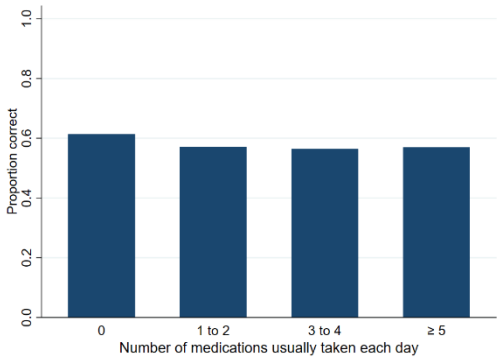
g. Number of medication doses per day

(P=0.64)



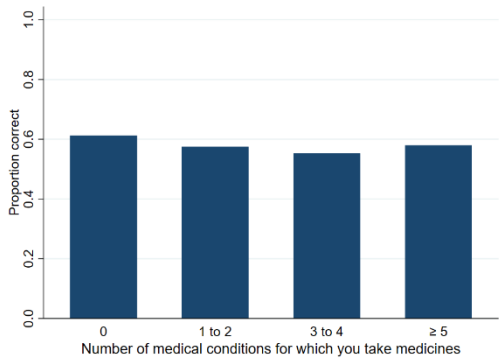
h. Number of medicines taken regularly

(P=0.79)



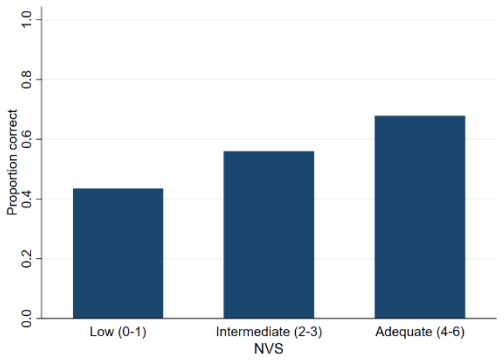
i. Number of medical conditions

(P=0.75)



j. NVS-UK score

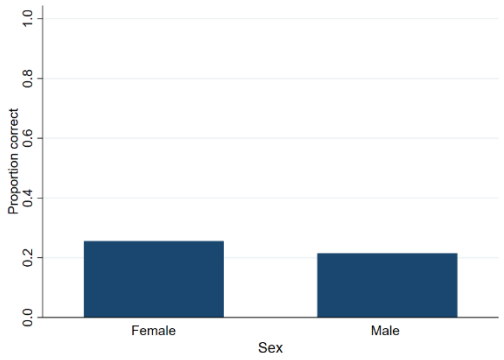
(P<0.001)



Appendix 4e. The proportion of correct answers by participant characteristics for getting the dosette correct per medicine using the UMS-based coding framework. (The P-values indicate whether there was a statistically significant difference in the proportion correct between categories.)

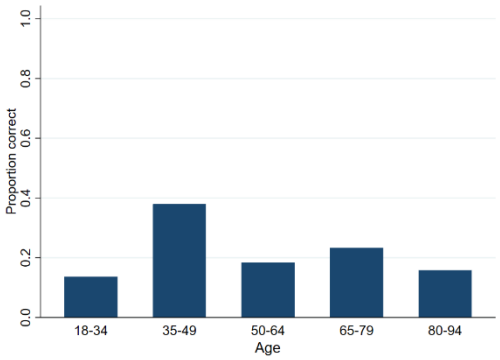
a. Sex

(P=0.45)



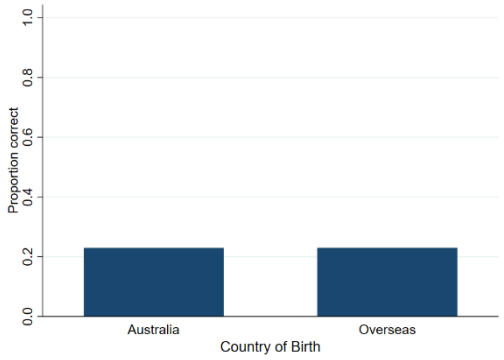
b. Age

(P=0.03)



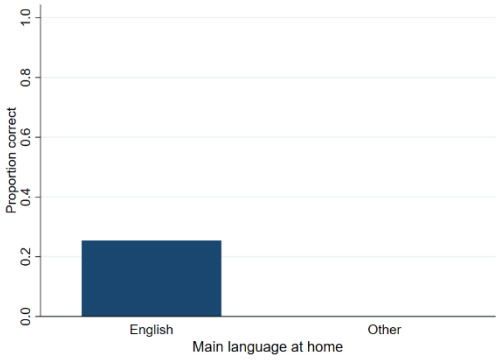
c. Country of birth

(P=1.00)



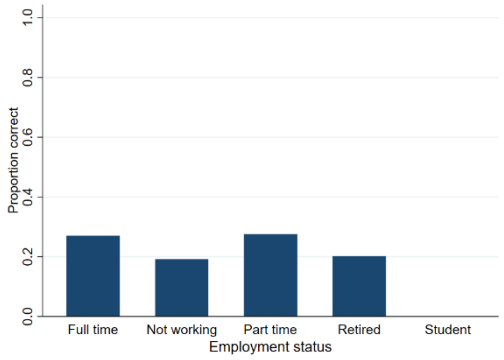
d. Main language spoken at home

(P value could not be calculated)



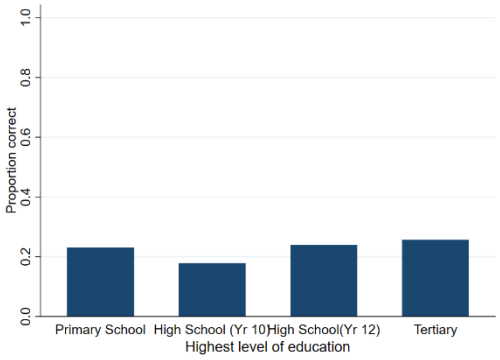
e. Employment status

(P=0.58)



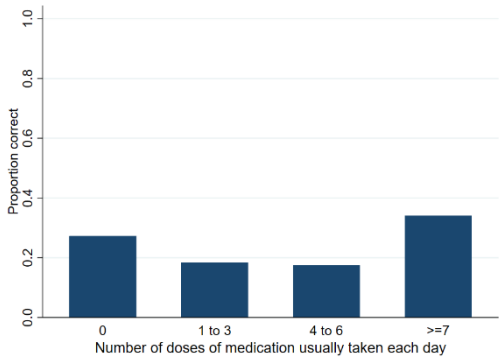
f. Highest level of education

(P=0.66)



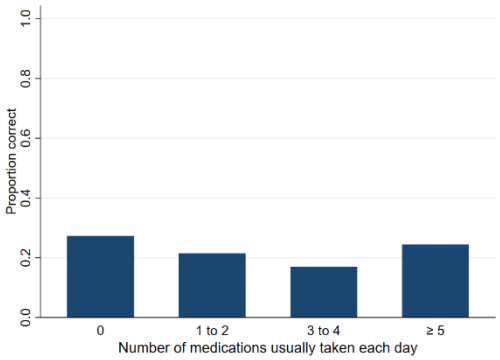
g. Number of medication doses per day

(P=0.12)



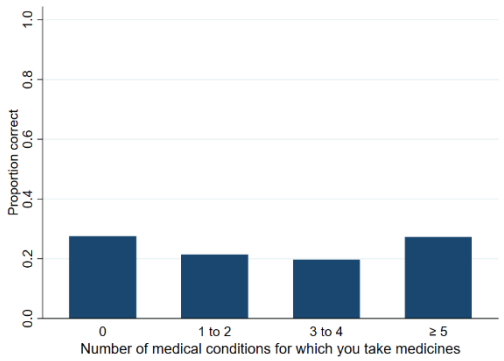
h. Number of medicines taken regularly

(P=0.61)



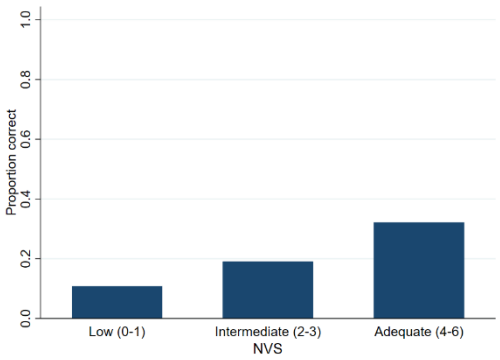
i. Number of medical conditions

(P=0.67)



j. NVS-UK score

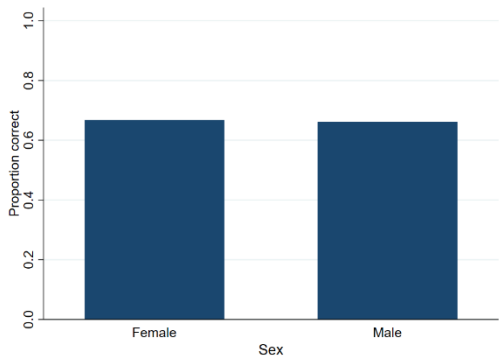
(P=0.004)



Appendix 4f. The proportion of correct answers by participant characteristics for getting the dosette correct for all four medicines using the UMS-based coding framework. (The P-values indicate whether there was a statistically significant difference in the proportion correct between categories.)

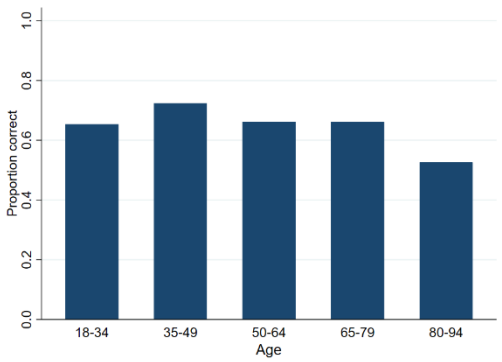
a. Sex

(P=0.84)



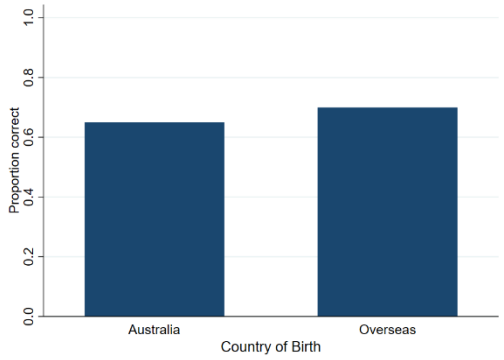
b. Age

(P=0.17)



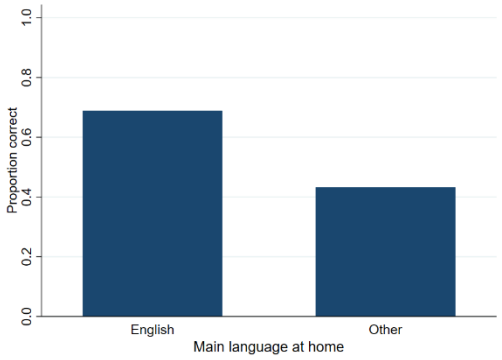
c. Country of birth

(P=0.22)



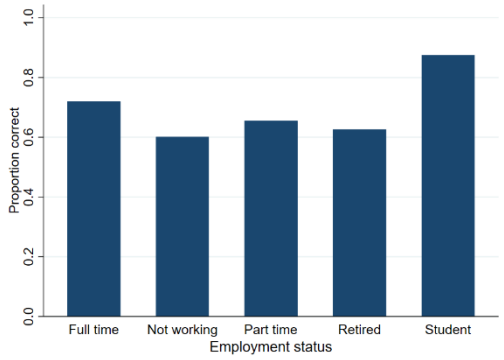
d. Main language spoken at home

(P<0.001)



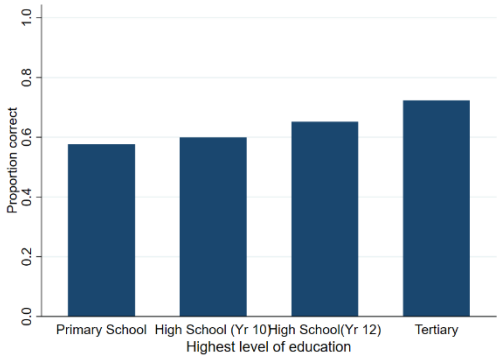
e. Employment status

(P=0.07)



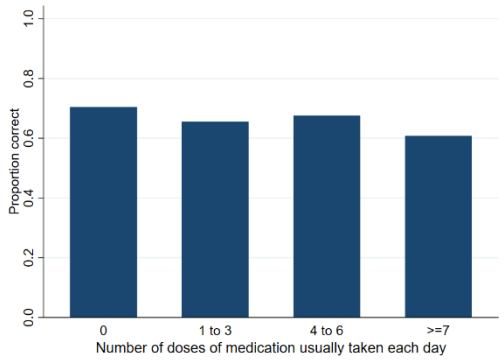
f. Highest level of education

(P=0.03)



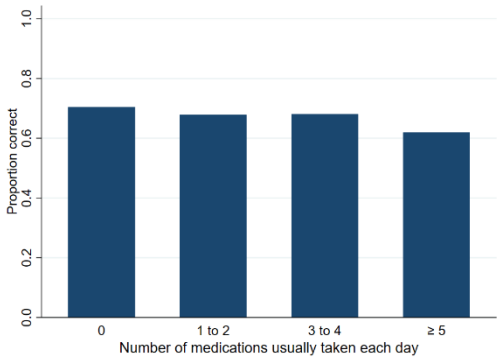
g. Number of medication doses per day

(P=0.42)



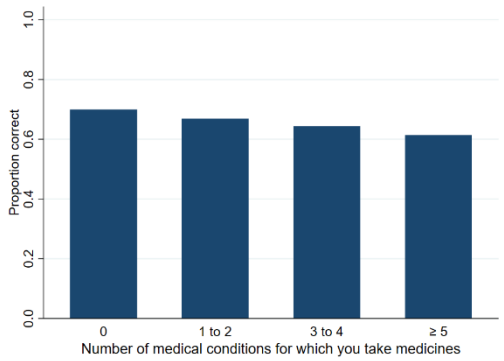
h. Number of medicines taken regularly

(P=0.32)



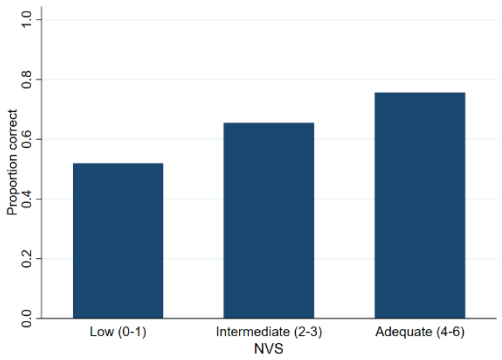
i. Number of medical conditions

(P=0.57)



j. NVS-UK score

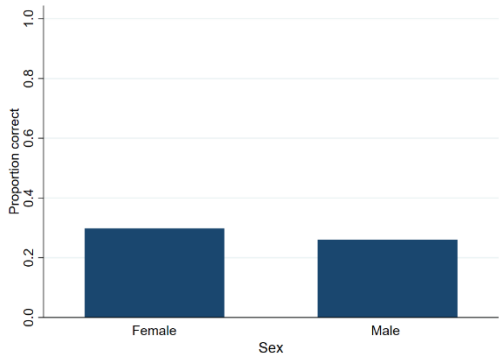
(P<0.001)



Appendix 4g. The proportion of correct answers by participant characteristics for getting the dosette correct per medicine using the tailored coding framework. (The P-values indicate whether there was a statistically significant difference in the proportion correct between categories.)

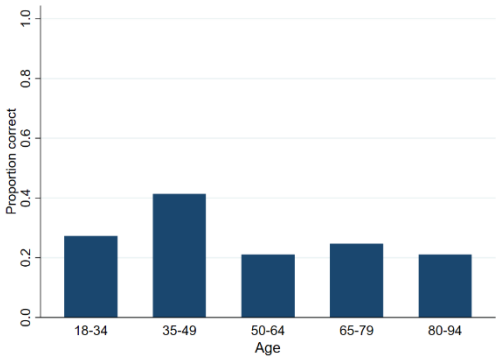
a. Sex

(P=0.50)



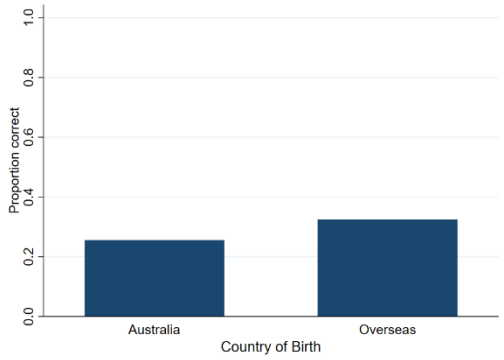
b. Age

(P=0.10)



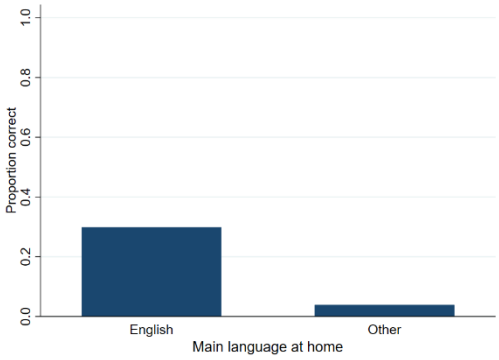
c. Country of birth

(P=0.26)



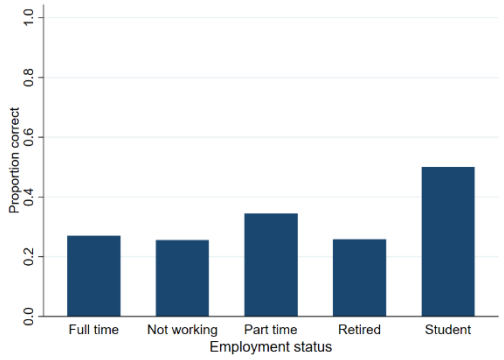
d. Main language spoken at home

(P=0.21)



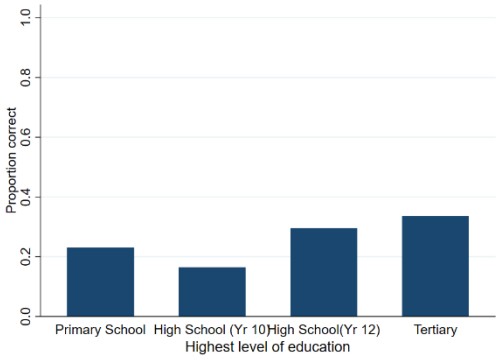
e. Employment status

(P=0.76)



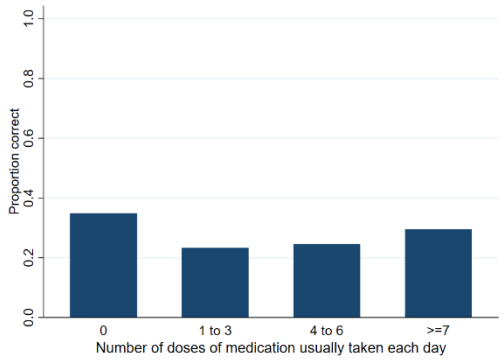
f. Highest level of education

(P=0.08)



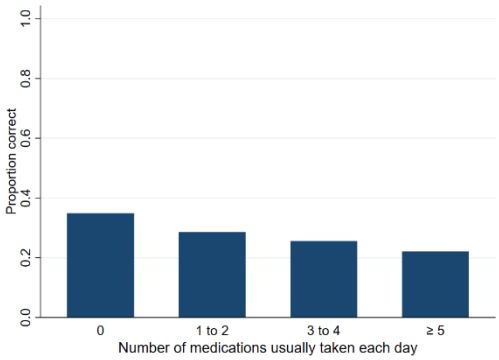
g. Number of medication doses per day

(P=0.39)



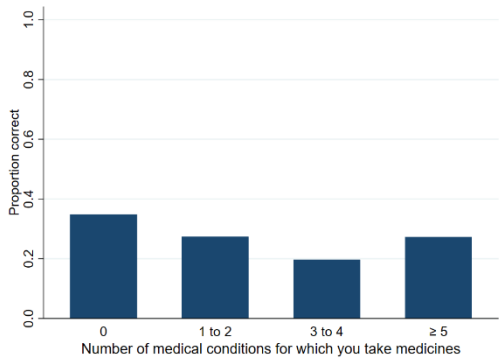
h. Number of medicines taken regularly

(P=0.37)



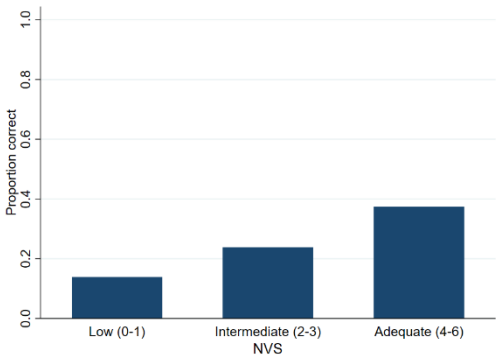
i. Number of medical conditions

(P=0.30)



j. NVS-UK score

(P=0.003)



Appendix 4h. The proportion of correct answers by participant characteristics for getting the dosette correct for all four medicines using the tailored coding framework. (The P-values indicate whether there was a statistically significant difference in the proportion correct between categories.)