Evidence for a standardised approach to naming medicines on dispensed labelling

SHIPP Diana[1], ASLANI Parisa[2], TONG Vivien[2], RAYNOR DK[3], PARKINSON Brian[4], LALOR Daniel[5], SOBEY Andrew[5], GILBERT Alice[6], CROFTON Jackie[6], CARTER Sophie[2], POON Wing[7]

[1]Australian Commission on Safety & Quality in Health Care, Sydney; [2]The University of Sydney School of Pharmacy, Sydney; [3]School of Healthcare, University of Leeds, Leeds, UK; [4]Making Sense, Sheffield, UK; [5]The Canberra Hospital, Canberra; [6]The Royal Darwin Hospital, Darwin; [7]School of Pharmacy, The University of Nottingham, UK.

Background

- The ability to identify the active ingredient(s) of a medicine is paramount for medication safety.
- User testing facilitates the evaluation of written medicine information against benchmark performance standards.[1]
- Limited research has explored the impact of design and formatting on people's ability to discern between the active ingredient and brand name.

Objective

To evaluate people's ability to determine the active ingredient on dispensed prescription medicine labels and explore factors influencing their choice.

Methods

Label development

- 12 labels were developed for 4 fictitious medicines
- Each label stated active ingredient first, then brand name
- Active ingredient / brand name format was varied across the labels

Brand name	Active ingredient
Vipparoll	Myclofenac
Mixicillin	Pentoampicillin
Tapisoy	Ocylohydrosteroid
Lubidrops	Hypromethylmellose

Label user testing

- Demographically matched cohorts of 10 consumers evaluated 3 labels, for varying dosage forms, in a fixed order (A to C) (total n=40) (Figure 1)
- Participants were asked to determine the active ingredient for each label, with no interviewer prompting
- Participants discussed their choices in a semi-structured interview

Data analysis

- Responses were audio recorded, transcribed verbatim and the content was analysed
- Two research team members independently coded the responses

Figure 1. Example of formatting variation across 3 labels

Label A	**Myclofenac** 75mg Capsules Vipparoll
Label B	**PENTOAMPICILLIN** 500mg/5mL Suspension *mixicillin*
Label C	Hypromethylmellose 1% Eye Drops Lubidrops

Results

Self-reported factors contributing to active ingredient determination

- Co-location of active ingredient and medicine strength
- Stating brand name first then active ingredient (as is current practice)
- Brand name normally presented in bold
- Upper case and/or bolding together were indicative of brand name
- Italics signalled it was the active ingredient
- Scientific-sounding name
- Guesswork

Table 1: Summary of user testing findings relating to active ingredient

Dose form	Label	Active ingredient formatting; Brand name formatting	Number who found and understood active ingredient	Comment
Tablets/ Capsules (Label A)	1	Sentence Sentence	7	No bolding / upper case / italics used. Therefore, consider consistent formatting to help create meaning.
	3	Sentence **Bold** Sentence **Bold**	2	
	4	Sentence **Bold** Sentence	4	
	8	UPPER CASE **Bold** lower case **Bold**	3	Upper case bolding of active ingredient potentially signalled that it was the brand name instead.
Suspension (Label B)	6	UPPER CASE **Bold** Sentence	3	
	7	UPPER CASE **Bold** lower case *Italic*	3	
	9	Sentence **Bold** lower case **Bold**, *Italic*	7	
	10	Sentence **Bold** UPPER CASE **Bold**	5	
Cream (Label C)	2	Sentence Sentence *Italic*	3	
	5	Sentence **Bold** Sentence *Italic*	5	
Eye drops (Label C)	11	UPPER CASE **Bold** UPPER CASE **Bold**	9	Formatting for active ingredient and brand name was the same. Technical nature of the active ingredient name likely influenced decision.
	12	Sentence Sentence	8	

Conclusion

- Information formatting and positioning on dispensed prescription medicine labels influenced participants' ability to discern the active ingredient from the brand name of the medicine.
- Specifying which is the active ingredient and brand name on dispensed prescription medicine labels may mitigate patient ambiguity and reduce medication errors.

Subsequent evaluation and future directions

A second round of user testing revealed clear principles for presenting medicine names on dispensed medicine labels. Label prototypes stemming from this research will be evaluated quantitatively with labelled placebo products.

Consistent and standardised presentation of medicines information should help consumers of varying health literacy identify their medicine and understand how to use it[2,3]. The results from the user testing presented and subsequent evaluations will inform a national dispensed prescription medicine label standard.

References

[1]Raynor DK, Knapp P, Silcock J, Parkinson B, Feeney K. "User-testing" as a method for testing the fitness-for-purpose of written medicine information. Patient Educ Couns. 2011;83:404-410

[2]Roundtable Nov 2013 recommendations www.safetyandquality.gov.au/wp-content/uploads/2013/11/Pharmacy-Dispensing-Label-Workshop-25-Nov-2013-report-.pdf

[3]Health literacy. Taking action to improve safety and quality www.safetyandquality.gov.au/wp-content/uploads/2014/08/Health-Literacy-Taking-action-to-improve-safety-and-quality.pdf

Acknowledgements

The authors wish to extend their appreciation to all study participants for their time and contributions.
This study received funding from the Australian Commission on Safety and Quality in Health Care and was first presented at the 78th FIP World Congress of Pharmacy and Pharmaceutical Sciences. This research will contribute towards the development of an Australian national standard for dispensed prescription medicine labelling.
David K Raynor is co-founder and academic advisor to Luto Research (www.luto.co.uk) which develops, refines and tests health information materials.

For more detail on user testing of dispensed prescription medicine labels, please see poster: **Appropriate use of medicine: the role of dose information on dispensed prescription medicine labels**

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

www.safetyandquality.gov.au