Improving the safety and quality of pharmacy dispensing labels

National round table report

25 November 2013

Contents

> **It is estimated that 60% of Australians aged 15 to 74 do not have the basic health literacy skills needed to understand information such as the instructions on a dispensing label.** [1]

Introduction

The Australian Commission on Safety and Quality in Health Care and the NSW Clinical Excellence Commission co-hosted a national round table discussion on improving the safety and quality of pharmacy dispensing labels on Monday 25 November 2013 in Sydney.

The purpose of the round table was to engage pharmacy organisations, consumers, educators, software vendors, pharmaceutical industry and patient safety agencies in a discussion about actions to improve the safety and quality of information provided in pharmacy dispensing labels. The aims of the round table were to:

- formulate a set of priorities for improving pharmacy dispensing labels
- identify the appropriate agencies to lead the work required.

Participants were invited from consumer and pharmacy professional organisations, regulatory agencies, universities, medical software industry, pharmacy indemnity insurers, pharmaceutical industry and quality use of medicines experts. See Appendix 1 for a list of round table participants and Appendix 2 for the round table program.

The Australian Commission on Safety and Quality in Health Care leads and coordinates national improvements in safety and quality in health care across Australia.

The NSW Clinical Excellence Commission promotes and supports improved clinical care, safety and quality across NSW.

Background

Prior to the meeting, participants were sent a discussion paper that outlined the subject background, evidence supporting the need for change, factors controlling pharmacy dispensing label content and work undertaken in other countries to improve the quality of pharmacy dispensing labels. A copy of the discussion paper forms Appendix 3 to this paper. Three speakers provided background and perspectives to round table participants.

Professor Michael Wolf

Prof Wolf of NorthWestern University, Chicago is a prominent academic working in the fields of health literacy and medication safety. Prof Wolf noted that in the United States, the annual cost of poor adherence to medicines resulting from poor health literacy is estimated to be $200billion.

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[1] Australian Bureau of Statistics (2006). Adult Literacy and Life Skills Survey, Summary Results. Canberra, Australian Bureau of Statistics: Australian Government Publishing Service. Cat No. 4228.0

He provided an overview of issues related to the design and content of pharmacy dispensing labels and presented interventions shown to improve both consumer comprehension of label content and adherence. These interventions included use of:

- explicit language
- sentence case rather than all capitals
- numeric figures (e.g. 2) rather than alphabetical figures (e.g. two) for numbers.

Prof Wolf also introduced the concept of the Universal Medicines Schedule which standardises medicines timing as follows:

- morning (7-9am)
- noon (11-1pm)
- evening (4-6pm)
- bedtime (9-11pm).

The schedule has been incorporated into the Prescription Container Labelling standard in the United States Pharmacopoeia.[2]

Generally the pharmacy dispensing label is the only tailored information that the consumer receives about their medicines. The challenge posed by Professor Wolf to participants was to find ways to simplify pharmacy dispensing labels and to confuse consumers less.

Mr Carlo Malaca

Mr Malaca, representing Consumers Health Forum, provided a consumer perspective on the:

- importance of medicines labelling
- problems of current labelling (including font size too small to read the directions, unclear instructions and poor visibility of active ingredient name)
- challenges associated with poor health literacy.

Mr Graham Sweet

Mr Sweet, a pharmacist with experience working in hospital and community practice, summarised work he had conducted in the Dandenong Division of General Practice.

The work assessed consumers' ability to read labels produced in standard and "large" format. The study found that font size contributed significantly to a consumer's ability to read a dispensing label and that through redesigning the dispensing label, cautionary and advisory statements could be appropriately incorporated. It was noted that including cautionary and advisory statements would require a larger label than that currently used.

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[2] United States Pharmacopeia. 2012. USP-NF General Chapter 17 – Prescription Container Labelling < http://www.usp.org/usp-nf/key-issues/usp-nf-general-chapter-prescription-container-labeling>

Discussion

Round table participants discussed the importance of improving health literacy and giving consumers the best possible chance of using their medicines correctly. The themes of improving communication of critical medicines information and confusing consumers less resonated strongly throughout the discussion.

It was recognised that there is not a strong awareness among pharmacists that the quality of label content and label format was problematic for consumers or that better comprehension can improve adherence. The first step in improving outcomes is communicating to health professionals that consumers do not always understand pharmacy dispensing label information, and ensuring that they do should be a priority.

While some of the solutions canvassed can be supported in medical and pharmacy software, shifting cultures to a greater consumer focus is required, and the first step toward achieving culture change is to create a sense of urgency. Improving consumer adherence is one area in which pharmacists can add significant value to the health system, and improving labels will contribute to efforts to improve consumer adherence.

There may be a need for a larger sized label which would require a revision of the dimensions of the designated pharmacy dispensing label space on manufacturer packaging. If this is recommended, it will require consultation with the Therapeutic Goods Administration and the pharmaceutical industry and possibly changes to the TGA labelling order. It was acknowledged that this work may have considerable resource implications for the pharmaceutical industry and would require significant lead time.

It was agreed that work should progress on improving pharmacy dispensing label design and content. Consultation on changes required to manufacturer packaging should occur in parallel.

Other key points from the general discussion included the:

- need to address the quality and consistency of all medicines information produced for consumers, not just the dispensing labels

- need to provide pharmacists with the correct tools to produce high quality dispensing labels

- large variation in practice and the need to eliminate this variability and inconsistency

- importance of consistency in presentation of medicine name e.g. the medicine name on the pharmacy dispensing label must be the same as the name on the manufacturer's pack and the name on the computer screen

- requirement for a set of standards to guide regulators to make changes to legislation

- imperative to act, and act now, based on current evidence that 50% of consumers in Australia cannot understand their pharmacy dispensing labels.

Recommendations

A series of recommendations were used to guide further discussion and obtain agreement on the content for an Australian standard (see Appendix 3). The recommendations were derived from health literacy studies, work undertaken by the United Kingdom's former National Patient Safety Authority, the United States Pharmacopeia prescription container labelling standards and an American College of Physicians Foundation white paper

The recommendations, along with round table endorsement status, key discussion points, the rationale and supporting evidence are listed below in Table 1. Recommendations are considered endorsed if supported by the majority of participants.

Table 1: Recommendations for an Australian Standard on pharmacy dispensing labelling

Recommendation 1
1.1: A standard should be developed that describes the content, format, design and application of pharmacy dispensing labels. **1.2**: A standard template should be developed to present information to consumers in a consistent format on pharmacy dispensing medicines labels.
Status: Endorsed
Rationale Research in the USA has demonstrated variability in pharmacy dispensing label content.[1] Anecdotally the variability exists in Australia. For example, label samples obtained from different software providers show considerable variation. Research has explored the effects of different label formats in both prescription and over the counter medicines.[2-4] Principles from the field of graphic design have been applied to improve the readability of labels and guidance developed by the former National Patient Safety Agency in the Guide to the design of dispensed medicines [5]. Using this information to develop a set of recommendations and templates will result in improved pharmacy dispensing labels.

Recommendation 2
2.1: Consumer-centred content should be of primary importance. **2.2**: Medicine name and specific dosage/usage instructions should be placed in greatest prominence.
Status: Endorsed
Rationale The main purpose of the label is to provide the consumer with information about how to take their medicine. In the majority of cases, it is the only source of written information for the consumer on how to take their medicine including information about dose and frequency.

Recommendation 3
3.1: Information should be organised in a way that best reflects how most consumers seek out and understand medication instructions.   **3.2**: Pharmacy dispensing labels should feature only the most important consumer information needed for safe and effective understanding and use.
Status: Endorsed
Rationale   People seek information in specific ways and it is best to present the most important information first. Information is also best understood if grouped according to themes.[6]

Recommendation 4
4.1: Information crucial to safe and effective medicines use should be prominently displayed.   **4.2**: A standard pharmacy dispensing label format should be developed to guide the display of crucial information. Each element (e.g. medicine name, consumer name etc.) should appear in the same place every time.
Status: Endorsed
Rationale   Following consumer workshops on labelling and packaging, Consumers' Health Forum recommended that "critical information, such as 'directions for use,' should appear in as large a font as possible to maximise legibility, on at least one face of the presentation. It should not be broken up or separated by non-critical information." [7]

Recommendation 5
5.1: Required pharmacy dispensing label information that is not directly related to use instructions (e.g. pharmacy name, phone number, prescriber name, prescription number) should be placed away from dosing instructions to reduce confusion.   **5.2**: Required information that is not directly related to providing instructions on use should be positioned toward the bottom of the pharmacy dispensing label.
Status: Endorsed
Discussion   Maximum space allowed for information related to the pharmacy dispensing the medicines should be established.
Rationale   Medicines labels are required by law to contain information that is unrelated to safe, day-to-day use of the medicine by the consumer. Such information includes a unique dispensing number and the name, address and phone number of the pharmacy. While this information is important, its inclusion reduces the available space for information such as the medicine name, or dose instructions. Approximately a third of the available space is allocated to this information on most standard Australian pharmacy dispensing labels.

Recommendation 6
6.1: Dosing instructions should be explicit and standardised. **6.2**: Dose should be clearly separated from the interval, and the frequency of the medicine explicit. For example, instructions such as "take 2 tablets in the morning and 2 tablets at night" should be universally used by pharmacists.
Status: Endorsed
Discussion A standard set of dosing instructions will need to be developed.
Rationale Studies conducted in the USA[4 8-10] and in Ireland[11] have shown that using explicit instructions for dosing results in improved consumer comprehension. Additionally, there is considerable variation in the way different pharmacists interpret the same prescription.[12] By creating a set of standard, explicit instructions, consumers can be provided with consistent, understandable instructions about dose and interval. Issues associated with lack of explicit instructions have also been cited by consumers during consultation undertaken by the Consumers Health Forum.[7]

Recommendation 7
A standard minimum font size should be established for each element required on a pharmacy dispensing label.
Status: Endorsed
Discussion Consideration needs to be given to medicines names that are long and may need to be abbreviated, or otherwise modified, to fit on the pharmacy dispensing label. Caution was urged in terms of abbreviating names, and the need for a standard for presenting medicines names was agreed. Recommendations 7 and 8 will need to be considered together as font size will vary with font type.
Rationale Research has shown that font size is related to the readability of a medicines label[2] as well as the acquisition of information.[3] Increased font size leads to improved acquisition of information on a simulated over the counter medicines label.[3] A study conducted in the Dandenong Division of General Practice examined the acceptability and readability of medicines labels produced in large font compared to standard font labels.[13] The study supported the use of increased font size. Consumers have also recommended larger font sizes when consulted.[14]

Recommendation 8
A standard, sans serif font should be used for all pharmacy dispensing labels.
Status: Endorsed
Discussion Recommendations 7 and 8 will need to be considered together as font size will vary with font type.
Rationale Font choice affects the readability of medicine labels. [2][5][6] A standard font should be used for all labels and should not be compressed or elaborate. Standardising the font used also makes it possible to standardise minimum font sizes, as size will vary with font type.

Recommendation 9
Sentence case should be used including capitalising the first letter of the first word in the sentence.
Status: Endorsed
Rationale The use of all capitals makes reading more difficult. The shape of words assists in reading them. Lower case letters are constructed from a greater number of unique shapes, creating greater variation in their appearance and less confusion when they are read.[6][15] For example, the word TRY in upper case has little of the shape it has in lower case (try). Text written in all capitals is read more slowly, and less accurately, than text in lower case.[6]

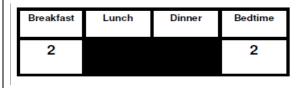| Recommendation 10 |
|---|
| Bolding and highlighting should only be used for pharmacy dispensing label information that provides instructions to the consumer (e.g. medicine name and dose). |
| **Status: Endorsed** |
| **Discussion**
Information that can be bolded and highlighted should be included in the standard pharmacy dispensing label template. |
| **Rationale**
Typographic techniques are often used to create emphasis on particular words or phrases. These techniques are effective and include such things as bolding and highlighting.[5][6] These techniques should be used sparingly, and only to draw attention to the information that consumers need in order to use their medicines appropriately. |

Recommendation 11

A graphic dose matrix, such as that on dose administration aids, should be included in the pharmacy dispensing label.

Breakfast	Lunch	Dinner	Bedtime
2			2

Status: Endorsed in principle. Considered as a future enhancement rather than an immediate change.

Discussion

Evidence only supports the use of a graphic dose matrix in medicines that are administered more than once per day, and the greatest benefit is seen for consumers who are on multiple medicines.
Label space may be an issue.
An ancillary label with a graphic dose matrix could be produced as an interim measure.

Inclusion of a graphic dose matrix on all medicines information, including pharmacy dispensing labels, could be a future goal.

Rationale

There is benefit in adding a visual dosing guide to the dispensing label for consumers with complex medicine regimens including medicines that are dosed multiple times per day, and for those with low health literacy.[4][11]

Recommendation 12

The indication for use should be included on the pharmacy dispensing label whenever possible and appropriate.

Status: Endorsed in principle. Considered as a future enhancement rather than an immediate change.

Discussion

Information that consumers want most (as reported to Consumers Health Forum) is information about indication. The information will need to be presented to consumers in a way that they can understand. For example, use of medical terms such as hypertension should be avoided.
This will require support amongst prescribers as the indication will need to be communicated as part of the prescription. This work should be considered for medium term implementation.
Privacy concerns may make this recommendation difficult to achieve.

Rationale

Consumers express a desire to have indication included on the pharmacy dispensing label whenever possible.[16] The indication for use is amongst items felt to be most important to consumers.[14]

Recommendation 13
Numbers should be presented numerically (2) rather than alphabetically (two).
Status: Endorsed
Discussion
Pharmacists have traditionally been taught to present numbers alphabetically so the recommendation will require significant education.   Software will need to be modified in order to change the way numbers are expressed.   Presentation of liquid volumes needs to be considered e.g. how best to express half a millilitre.
Rationale
Numbers are more easily understood if presented numerically rather than alphabetically.[6][16]

Recommendation 14
Auxiliary warning statements should be included on the pharmacy dispensing label in a standardised way.
Status: No decision
Discussion
The Australian Pharmaceutical Formulary (APF) has a process for considering advisory and cautionary label content. Any change will require a coordinated approach with the APF.
Rationale
Auxiliary warning labels are frequently overlooked by consumers.[17] This is likely related to both the placement and design of these labels. In addition, the small size font and complicated language used often means that they are not easily read and are poorly understood by consumers.[13][18]

Next steps

Standard for pharmacy dispensing labels

There was agreement that a national standard for pharmacy dispensing labels was required. It should include:

- label application
- standard for design, content and format.

Development of the standard could be achieved by:

- establishing a representative working group to progress the recommendations
- determining short and long term objectives
- prioritising the endorsed recommendations and determining specific actions to implement the recommendations
- developing a standard in consultation with relevant organisations, including medical and pharmacy software providers and health professional organisations
- consulting broadly on the proposed standard including with consumers, and regulators
- seeking endorsement of the standard by the Commission's Medication Reference Group and Board of the Australian Commission on Safety and Quality in Health Care.

Implementation of the standard

Implementation of the standard will require a range of different strategies including regulation, education, changes to medical and pharmacy software, practice change implementation and innovation.

Regulation

The Therapeutic Goods Administration and state and territory governments may be required to make regulatory changes to accommodate the standard. They should be consulted on processes for formalising and implementing the standard early in the project.

Education

Health professionals and consumers will require education on the new pharmacy labels.

Health professionals will require educating on:

- extent of the problem of poor health literacy particularly as it relates to understanding the instructions on pharmacy dispensing labels
- evidence that standardising the content of pharmacy dispensing labels and producing them in a consumer-centred format can reduce errors and improve consumer outcomes
- producing consumer-centred labels consistent with the standards.

Having a standardised format for pharmacy dispensing labels will make it easier for organisations such as NPS MedicineWise and Consumers Health Forum to improve consumer health literacy in relation to medicines labels generally.

Medical and pharmacy software

Engagement with medical and pharmacy software providers is essential and needs to occur from the outset. Electronic medication management software will need to be modified to generate new consumer-centred labels. With the advent of electronic transfer of prescription, there is an opportunity for prescribing software to be modified to support the use of consumer-centred instructions that can be transferred through to pharmacy systems and used to populate dispensed medicines pharmacy labels.

Innovation

Innovation often precedes legislation and regulatory change in effecting culture and practice changes. It should be encouraged as a strategy to implement the standard in all pharmacy settings.

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Appendix 1: List of participants

Name	Organisation
Claire Antrobus	Pharmaceutical Society of Australia
Parisa Aslani	Faculty of Pharmacy, Sydney University
Graham Bedford	Australian Commission on Safety and Quality in Health Care
Michael Dooley	Society of Hospital Pharmacists Australia
Margaret Duguid	Australian Commission on Safety and Quality in Health Care
Greg Duncan	Faculty of Medicine Nursing and Health Sciences, Monash University
Alice George	Medicines Australia
John Green	Medical Software Industry Association
Karen Kaye	NPS MedicineWise
Daniel Lalor	NSW Clinical Excellence Commission
Karen Luxford	NSW Clinical Excellence Commission
Judith Mackson	Pharmaceutical Services, NSW Ministry of Health
Carlo Malaca	Consumers Health Forum
Steve Marty	Pharmacy Board of Australia
Andrew Matthews	Pharmacy Guild of Australia
Andrew McLachlan	Faculty of Pharmacy, Sydney University
Judy Mullan	Graduate School of Medicine, University of Wollongong
Debora Picone	Australian Commission on Safety and Quality in Healthcare
Naomi Poole	Australian Commission on Safety and Quality in Health Care
Margaret Prichard	Medical Software Industry Association
Albert Regoli	Pharmaceutical Defence Limited
Ron Sinani	Shire Australia
Graham Sweet	Community Pharmacist
Glen Swinburne	Faculty of Medicine Nursing and Health Sciences, Monash University
Sally Wilson	Society of Hospital Pharmacists Australia
Michael Wolf	Northwestern University, Chicago

Appendix 2: Program

Round table program	
1.00 – 1.10	**Welcome** **Prof Debora Picone AM** *Australian Commission on Safety and Quality in Health Care*
1.10 – 2.00	**Health literacy, pharmacy labels, problems and solutions** **Prof Michael Wolf** *Professor, Medicine and Learning Sciences* *Northwestern University, Chicago*
2.00 – 2.15	**What consumers want from medicine labeling and packaging** **Mr Carlo Malaca** *Policy Advisor, Consumers' Health Forum*
2.15 – 2.30	**3D Labels Project** **Mr Graham Sweet** *Community pharmacist*
2.30 – 3.20	**Open Discussion** **Mr Daniel Lalor** *Medication Program Manager, NSW Clinical Excellence Commission* **Ms Margaret Duguid** *Pharmaceutical Advisor, Australian Commission on Safety and Quality in Health Care*
3.20 – 3.35	**Afternoon Tea**
3.35 – 4.20	**Discussion continued**
4.20 – 4.30	**Wrap up** **Dr Karen Luxford** *Director Patient Based Care, NSW Clinical Excellence Commission*

Improving the safety and quality of pharmacy dispensing labels

Round table discussion paper

Monday 25 November 2013

1.00 pm to 4.30 pm AEST

Australian Commission on Safety and Quality in Health Care

Level 7, 1 Oxford Street, Darlinghurst, NSW 2010

Contents

Background

Pharmacy applied medicines labels (dispensing labels) are a crucial component of the communication between healthcare professionals and consumers regarding prescription medicines. Often, they are the primary channel used to communicate information about the dose, frequency and indication for prescribed treatment. Maximising the quality of this information is thought to be important to health outcomes.

There has been sufficient evidence produced internationally, and sufficient concern voiced by consumers and health professionals in Australia, to indicate that there is work needed to improve the quality of information contained on dispensing labels.

During development of the 2008 National Medication Safety and Quality Scoping Study by the Australian Commission on Safety and Quality in Health Care[1], labels applied to medicines products were identified as a cause of medication error that required attention. A recommendation was made that the Commission:

> ***Work with pharmacy organisations to develop standards for improving labelling on dispensed products.***

The need for this work was supported by findings from the 2011 Consumer Health Forum work shop which considered how to achieve best practice in the packing and labelling of medicines[2]. During the workshop, consumers raised a number of concerns about the quality of pharmacy labels. Examples of specific issues raised include:

- provision of unclear or inadequate directions (such as "*take as directed*")
- use of ambiguous instructions
- font size of information provided.

There has been a considerable amount of work done to determine best practice principles for the content and design of medicines labels. The challenge is to apply this knowledge consistently across the Australian health care system in order to improve consumers' understanding of the content of dispensing labels.

A number of factors affect the design and content of dispensing labels including legislative requirements, software capability and configuration, professional standards and individual pharmacist preference and communication styles together with their understanding and awareness of issues related to health literacy.

Round table purpose

The round table has been convened in order to engage pharmacy organisations, consumers, educators, software vendors and patient safety agencies in a discussion about actions which can be taken to improve the quality and safety of information provided in dispensing labels. The aims are to formulate a set of priorities for improving dispensing labels and to identify the appropriate agencies to lead the work required.

Round table program		
1.00 – 1.10	**Welcome**	
	Prof Debora Picone AM	
	Australian Commission on Safety and Quality in Health Care	
1.10 – 2.00	**Health literacy, pharmacy labels, problems and solutions**	
	Prof Michael Wolf	
	Professor, Medicine and Learning Sciences	
	Northwestern University, Chicago	
2.00 – 2.15	**What consumers want from medicine labeling and packaging**	
	Mr Carlo Malaca	
	Policy Advisor, Consumers' Health Forum	
2.15 – 2.30	**3D Labels Project**	
	Mr Graham Sweet	
	Community pharmacist	
2.30 – 3.20	**Open Discussion**	
	Mr Daniel Lalor	
	Medication Program Manager, NSW Clinical Excellence Commission	
	Ms Margaret Duguid	
	Pharmaceutical Advisor, Australian Commission on Safety and Quality in Health Care	
3.20 – 3.35	**Afternoon Tea**	
3.35 – 4.20	**Discussion continued**	
4.20 – 4.30	**Wrap up**	
	Dr Karen Luxford	
	Director Patient Based Care, NSW Clinical Excellence Commission	

Evidence supporting the need to change

Low levels of health literacy among Australian adults and variability in the content and quality of pharmacy dispensing labels create a situation where change is needed to support the quality use of medicines.

Health literacy levels in Australia

The ability to access and understand health related information is not a universal skill amongst Australian adults. The 2006 Australian Adult Literacy and Life Skills survey provides evidence of the health literacy gaps amongst Australian adults. The study estimated that 60% of Australians aged 15 to 74 do not have the basic health literacy skills needed to understand information such as the instructions on a dispensing label[3].

Patient comprehension

A considerable body of work related to the quality and content of pharmacy applied labels now exists. In 2007, Shrank and colleagues[4] published a systematic review looking at the content and format of medicines labels and the effect that this had on their readability, patient understanding and on medicines use. The review looked at published studies related to all types of prescription medicine labelling including 19 studies that specifically looked at the content of dispensing labels. Many of these studies found significant gaps in patients' understanding of their medicines use.

These findings are well illustrated in a study be Davis and colleagues[5] who showed 5 medicines to 395 consumers waiting for medical appointments. The researchers assessed the participants' understanding of the instructions provided on the dispensing label. Understanding was first measured by asking the patient how they would take the medicine. 18.9% of responses were incorrect, with one of the medicine labels correctly interpreted only 67.1% of the time. For one medicine, participants were asked to show the number of tablets they would take in one day. The instructions on the label were to "Take two tablets by mouth twice daily". Correct responses were given by 80.2% of participants with adequate literacy, 62.8% of participants with marginal literacy and only 34.7% of participants with low literacy.

In a related study, Davis and colleagues[6] were able to create better patient understanding of dispensing labels through the use of explicit language. For example, the instructions "Take 2 pills in the morning and 2 pills in the evening" were more likely to be understood (89% of responses correct) than "Take two tablets by mouth twice daily" (61% correct).

Variability in label content

When Wolf and colleagues[7] had standardised prescriptions dispensed in 24 pharmacies across 4 US cities, they found considerable variability in the format and content of the labels produced. For example, a prescription was presented as:
    Bactrim DS tabs
    Take 1 tab BID
    Dispense 6
    Indication: UTI
    No refills

Instructions included on pharmacy produced labels included:
    "Take 1 tablet by mouth twice daily for UTI."
    "Take 1 tablet by mouth twice daily for urinary tract infection."

"Take 1 tablet by mouth 2 times a day."
"Take 1 tablet twice daily for 3 days."

Additional analysis was done on the format of the labels produced by the pharmacies in this study[8] and found that there was also considerable variability in the way information was presented, the font type and size used, and the use of warning labels.

Factors controlling dispensing label content

The content and format of dispensing labels is constrained by a number of factors. These include legislative requirements, professional standards, limitations of pharmacy software, and clinician recognition of issues related to health literacy. In order to provide consistent and standardised information to health care consumers, these factors must be considered.

Legislative factors

The content of pharmacy dispensing labels must adhere to legislative requirements as outlined in the relevant state regulations (generally the poisons and therapeutic goods regulations). In general, this legislation mandates that the following information must appear on a dispensing label:

- The brand and generic names of the medicine, the strength, the dose form and the quantity supplied;
- Specific directions for use, including frequency and dose;
- The patient's name;
- The date of dispensing or supply;
- The dispenser's (and if different, the checking pharmacist's) initials;
- A unique identifying code;
- The name, address and telephone number of the pharmacy or pharmacy department at which the prescription was dispensed;
- The words 'Keep out of reach of children'.

The content of pharmacy dispensing labels may also be affected by the need for certain medicines to carry warning statements as outlined in the Standard for the Uniform Scheduling of Medicines and Poisons No.4.

Professional standards

Standards have been released by organisations such as the Pharmacy Board of Australia[9], the Pharmaceutical Society of Australia[10] and in the Australian Pharmaceutical Formulary[11] (APF). These standards largely reflect the legislative requirements for label content but also contain general recommendations. For example, the APF has a section dedicated to the process of dispensing and labelling medicines. It lists a number of central steps to the dispensing and labelling process including: "using labels that provide clear dosing instruction and text that is legible and unambiguous"[10]. What constitutes clear, legible and unambiguous instruction is not explicitly outlined. This is the case also with the Guidelines for dispensing of medicines issued by the Pharmacy Board of Australia[9].

Software

Dispensing software is instrumental to the safe use of medicines and to the efficient functioning of pharmacy dispensaries. Due to the commercial nature of the medical software industry, there is variability in the systems that are available for use. However, the industry has successfully standardised various elements of different software systems in the interest of patient safety. Dispensing software has the ability to use SIG codes to produce instructions for labels. These SIG codes can be user defined, allowing variability in information provided by different pharmacists. Standard SIG codes are pre-populated in some software systems and may not produce the clearest, most unambiguous instructions possible.

Dispensing software and associated hardware also dictate the space available for instructions on a dispensing label. This, in turn, affects the ability of the pharmacist to produce labels with increased font size for visually impaired patients.

Clinician recognition of health literacy as an issue

Health literacy has become an increasing area of focus and interest in Australia. Evidence of this is provided by the Health Literacy Stocktake undertaken by the Australian Commission on Safety and Quality in Health Care in 2011/12[12]. The stocktake identified a range of initiatives underway to address health literacy, including a project to educate pharmacists about health literacy that is being funded under the 5th Community Pharmacy Agreement.

Kairuz and colleagues at the University of Queensland studied issues of health literacy in Brisbane pharmacies[13]. The research highlighted that pharmacists and pharmacy assistants acknowledged difficulties related to communicating medicines information. Barriers included patient understanding of dosing instructions and cautionary and advisory labels. Despite identifying the barriers, pharmacy staff seemed ill equipped to deal with them.

This view was supported by research undertaken in New Zealand earlier this year by the Health Quality and Safety Commission New Zealand[14]. This research was based on a pilot study to introduce a health literacy training program to community pharmacy in order to improve medication safety. In this study, pharmacists self-reported that they "*didn't know what they didn't know*". The pharmacists did not recognise the extent of the problems with health literacy and the limited understanding of their patients and reported that they engaged in behaviour, such as use of jargon, that they knew would limit patient comprehension.

Work undertaken in other jurisdictions

A number of pieces of work have been undertaken in other jurisdictions to support the safe and quality use of medicines by improving the quality of pharmacy dispensing labels. This work includes the development of a guide to the design of dispensed medicines by the National Patient Safety Agency in the United Kingdom[15] and the introduction of standards for the format and content of medicines container labels (dispensing labels) released by the United States Pharmacopoeia[16].

A white paper commissioned for the American College of Physicians (ACP) Foundation[17] provided an extensive review of the issues related to medicines container labels in the United States. The following recommendations have been taken directly from the paper.

Proposed Standard	Description
1. *Use explicit text to describe dosage/interval in instructions.*	Dosage/usage instructions must clearly separate dose from interval, and provide the explicit frequency of the drug (i.e. "take 4 tablets each day. Take 2 tablets in the morning, and 2 tablets in the evening" vs. "take two tablets by mouth twice daily"). These explicit dose/use instructions will be standardized by the pharmacy to avoid physician variability for the same dose frequency.
2. *Use a recognizable visual aid to convey dosage/use instructions.*	A visual aid 'matrix' can help patients identify and support the explicit text dosage/usage instructions, following a familiar format to cue patients (pill sorter box; morning (7am-9am); noon (11am-1pm); evening (4pm-6pm); night (8pm-10pm)). A tablet icon will be used to identify the appropriate dose.
3. *Organize label in a patient-centered manner.*	Patient-directed information must be organized in a way that best reflects how most patients seek out and understand medicine instructions. Patient-directed content will be at the top of the label, while provider-directed content will be placed at the bottom of the label. Drug name and specific dosage/usage instructions will be placed in greatest prominence.
4. *Include distinguishable front and back sides to the label.*	The Rx container label should have two distinct sides – a front (primary) and back (auxiliary) side on the bottle. The primary label will contain patient information (drug name, dose, dosage/usage instructions, patient name, doctor name, quantity, refill information) and provider content (pharmacy name/logo, phone number, national drug code #). The back should contain all appropriate warning and instruction messages and icons, supplanting the use of stickers.
5. When possible, include indication for use.	While Rx approval status and confidentiality may limit inclusion of indications for use, prior studies suggest this is very helpful to patients.

Proposed Standard	Description
6. Simplify language, avoiding unfamiliar words/medical jargon.	Language on the label, will avoid the use of unclarified medical jargon, and common terms and sentences will be used only. While readability formulas and software are not recommended for short excerpts of text such as what is included on Rx labels, the principles established by the Suitability Assessment of Materials by Doak, Doak, and Root for maintaining simple language can guide the simplification process. Feedback should also be sought from consumers.
7. *Improve typography, use larger, sans serif font.*	A standard for minimum font size (12 pt) will be set for patient name, drug name, and specific dosage-usage instructions (both in text and in matrix). Health literacy and adult education researchers recommend the use of Sans-Serif font (i.e. Arial) to more clearly present print text information to new adult learners. Patient information on front and back labels will be 12 pt font. Use of all capital letters should be avoided; the first letter of words in text will be capitalized only.
8. *When applicable, use numeric vs. alphabet characters.*	Our recent research efforts (see Section C), and a prior study, provide evidence that presenting numbers instead of the text equivalent (i.e. 2 vs. two) was more helpful to patients for understanding and more rapidly processing dosage/usage instructions.
9. *Use typographic cues* (*bolding and highlighting*) *for patient content only.*	Bolding and highlighting will be used for patient-centered information only. Drug name and dose will be highlighted, dosage/usage instructions bolded.
10. *Use horizontal text only.*	Several national pharmacy chains place text for warning and instruction messages vertical to the Rx label; requiring the patient to turn the bottle to read. This may create further difficulty among older adults. Only include horizontal text on the label.
11. *Use a standard icon system for signaling and organizing auxiliary warnings and instructions.*	Work towards a standard set of icons, or consider a single icon to flag patients that a warning exists for the prescribed medicine. Warnings will use 12 point font.

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