Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

Response to TGA Medicine Labeling and Packaging Review Consultation Paper

The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) is strongly supportive of the TGA initiative to improve labeling on medicine packs and containers. We consider that any proposed changes should apply in all respects to ALL categories of medicines including prescription medicines, non- prescription medicines and complementary medicines.

Our specific comments on the issues that we consider of greatest concern (numbered as per the consultation document) are below.

1.1 The active ingredient(s) must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name.

We strongly recommend that the active ingredient (preferably the INN) is the primary identifier of the medicine and that the brand name follows or is below the drug name. We support this recommendation and would add to it that the ingredient(s) should be in bold and stand out more than the trade name, as in Fig 3.

We also suggest that consideration should be given to avoiding colours that are inappropriate such as red-green for the relatively large percentage of males with this problem.

There is an issue with spelling out the full salt name - eg hydrochloride; a) it could be a lower font size or b) use the chemical name HCL. This unclutters the long active ingredient names(s). Abbreviation to chemical name could problematic for salts such as maleate however.

1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name

We strongly support all the suggestions in this section and consider them all absolutely essential. We have always taught our students that they must prescribe using generic names and consider that medicines should be known to all who prescribe, dispense and use them by generic names whenever possible. That this does not happen is a major patient safety problem. Some of the

Website: www.ascept.org
Secretariat: Suite 25, Level 1, 213 Greenhill Road, Eastwood 5063
Telephone: 61 08 8274 3741
ABN:78 008 461 354
Facsimile: 61 08 8271 2884

medication safety issues with naming and labelling have been highlighted in a recent publication, citing relevant research, by some ASCEPT members (publication attached as Appendix One). [1]

Ideally we would prefer the active ingredient to be LARGER than the Trade Name ie the reverse of the present situation. 'Equal Prominence' is the minimum we would consider acceptable.

1.3 Where there are more than 3 active ingredients etc

We also strongly support these suggestions, in a difficult area, which represent a considerable improvement on the present situation and are clearly illustrated in Fig 4 which we recommend should be implemented.

1.4 Products containing day and night preparations etc.

Another difficult topic and again we strongly support the suggested solution as demonstrated in Fig 4.

1.5 The active ingredient must be included with, and with equal prominence as, the brand name on at least 3 opposing faces of a carton

We strongly support a change which would make it easier for consumers and health professionals to identify the active ingredient without searching all sides of the package with a magnifying glass which is currently sometimes the case.

1.6 Package information for non-prescription medicines containing paracetamol

Agree with and support proposal

1.7 Package information for non-prescription medicines containing ibuprofen

Agree and support

General Questions on the proposed changes

- **What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?**

1. This very important. Members of our Society have consistently held the position to increase the prominence of the active ingredient on medicine labels for many years. Patients, consumers and prescribers and other health professionals will all benefit from knowing what the active ingredient is.

2. This will help consumers and prescribers use and understand one name per medicine, rather than the potentially confusing plethora that currently exist (a generic name and several trade names from different companies).

3. It will support use of the generic name when health professionals discuss medicines with consumers, and enable use of consistent unbiased information in reference to that one medicine for which a common name will now be prominent.

4. It will improve safety by reducing duplication where patients inadvertently are prescribed and/or take two formulations with different trade names but that actually are the same

medicine.

5. It will reduce medication safety issues for medications with trade names that sound and/or look alike eg. Cardizem/Cardiprin; Prozac/Losec. [2,3,4]
6. It will improve prescribing by supporting identification of classes of medicine e.g. less likely to prescribe two of the same class of medicine e.g. two ACE inhibitors (…pril) or two statins (…statin) etc.[3] This is becoming increasingly important as more and more combination tablets for common diseases are coming on the market. There are major content overlaps for numerous antihypertensive and diabetes medications and analgesics [5].

- **What do you think about the proposed warnings for paracetamol and ibuprofen containing products?**

1. These are absolutely essential and we strongly support them. There are numerous over the counter preparations containing these analgesics and without a warning consumers are at high risk of unwittingly taking the same ingredient in a multiple doses.
2. As an example; several pharmaceutical companies market paracetamol products as Brand Name for headache, Brand name for backache, Brand name for joint pain etc. This could readily result in a consumer taking all three at the same time and suffering a paracetamol overdose .

- **Are there any other concerns you have with the size or position of brand names and active ingredient?**

1. For decades the size and position of the brand name has been the first word(s) to catch the eye. It takes effort, very good eyesight and some persistence to find the active ingredient. Few consumers know that they should do this and most only know the brand names. Teaching prescribers to prescribe generically has largely been nullified by marketing and labeling.

2. We consider it absolutely vital that the generic name is in print no smaller than, and has greater prominence than, the brand name. As mentioned earlier our preference would be for the active ingredient(s) to be in the present size of the brand name and vice versa.

- **If the active ingredient is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name?**

1. We find the suggestion that the generic name might be smaller than that of the brand name totally unacceptable.

2. If smaller than the brand name it will be less noticeable, less legible and less likely to be read by consumers.

- **What is the smallest size font you consider reasonable?**

This is not our area of expertise. However the major users of medications are elderly people many whom have poor eyesight. The acceptable font size for drug labels should be appropriate to the population not to "normal" vision.

We suggest that expert ophthalmological opinion is essential with regard to those receiving medications.

In this context we note that a number of companies eg J&J, GSK, Sanofi etc have improved pack instructions by increasing font size and consulting communication experts. The result is not perfect but is a big improvement on its predecessors. By no means all companies have done this and we suggest that a similar approach should be mandatory for ALL products-- including complementary medicines.

Look-alike sound-alike names and look-alike packaging

3.1 to 3.3

1. The primary mechanism for addressing sound alike trade names should be use of the generic drug name.
2. We consider these topics of importance and support the principles proposed but accept that considerable negotiation will be necessary with industry to achieve these changes. There could also be a need for international cooperation.
3. If achieved they would undoubtedly improve safety by reducing the existing confusion caused by the problems such as those listed in the document.
4. The Australian Council for Safety & Quality in Healthcare, Queensland Health and many others have compiled a list of similar medicine names which contribute to medication errors (ACSQH list is included as Appendix Two).[6,7]

Look-alike medicine branding

3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom.
For example: Products cannot be marketed as "BRAND headache", "BRAND backache", "BRAND joint pain" if they include the same active ingredients in the same quantity.

1. This issue is one that causes us many concerns because of the confusion it causes to consumers who may think 'I have a head and back ache so I'll take two of each! ', without realising they are the same drug.
2. We consider the proposal to be an excellent idea which reduces waste, reduces confusion and reduces rick of overdose.

3.6 The same brand name cannot be applied to products which have different active ingredients or combinations of active ingredients etc

1. We strongly agree with and support this suggestion. We consider it particularly confusing to have the same brand name refer to products containing different active ingredients (common examples include cold 'flu and sinusitis and pain products) We would favour having the active ingredients listed for the individual product.
2. The proposals would go a long way towards reducing confusion for consumers and improving the accuracy of communications between consumers and health professionals.

General Questions

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?

1. Considerable benefits will ensue to consumers, giving them the opportunity to understand that, unlike the current situation, the same brand name should always imply that it contains the same ingredients.
2. It will encourage consumers to find and read ingredients thus increasing safety
3. The change would hugely improve the accuracy of communications between consumers and health professionals. At present, unless the bottle is in front of them, a brand name for such products gives a prescriber no idea what their patient is taking and formulary or internet searches for recalled names are highly susceptible to error.

Do you understand the proposed changes?

The changes proposed would help to decrease confusion, and would lead to improved medication safety for Australians. We understand and support the proposed changes, and would like to see further prominence to the active ingredients of all medicines (prescription, non-prescription, complementary).

If you can read the labels and warnings clearly, will these changes reduce the potential for harm?

Yes. Further, if the primary identifier of the drug is the active ingredient name this will have substantial benefit. There have been many studies on medication safety now which demonstrate the importance of clarity of labeling and naming of medications in reducing harm to consumers.

Medicine Information Box

We support the introduction of a clear, standardised Medicine Information Box, as proposed. This would be a clear way to include unbiased information about the active ingredient(s). It should, however, also point to the Consumer Medicines Information that is available in full (either printed from their health professional or from a website). This would provide a good way for consumers to access information about their medicine, and would point the way to more complete information sources. The suggestion for 3 or more active ingredients is a compromise, and companies should be required to make strong arguments before being permitted to pursue this compromise.

Dispensing Label

The mandatory space proposed for the dispensing label is strongly supported. Currently it is often very difficult to attach a label without covering some essential material. Various ways of folding sticky labels to try and display the required information are often resorted to. This often leads then to tearing or other loss of information when the consumer accesses the doses over the ensuing month or so. The mandatory space would go a long way towards helping to ensure all vital information can be seen by the consumer and their health professionals, and would lead to improved storage and use of medicines.[8]

Blister Strip Packaging

The proposed changes for blister strip labeling are supported. Ideally every dose should be labeled with this information (rather than just every segment). The 'race track' packaging suggestions do

make sense, as the strips are not perforated – however they can (and are) often cut up into individual doses and therefore at least the active ingredient name would ideally be printed for each dose.

Small Containers

The compromises suggested for small containers are supported. However, the issue of the dispensing label attachment will still be problematic. Attaching like a flag can lead to damage with use.

Pack Insert

The package insert should definitely not include advertising material, and should not be printed on the inside of the box. The package insert should be the Consumer Medicines Information if one is available for that product, and should be based on the active ingredient(s), not on a branded product.

Labels and Packaging Advisory Committee

The proposed committee is an excellent idea, and should have strong consumer representation. The committee should have sufficient resources to be able to benchmark internationally, as more global integration of solutions and evaluation of improved labeling and packaging is essential. Such a committee would be a very good resource for the TGA. ASCEPT looks forward to making a contribution to the initiative and the Advisory Committee.

References

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Appendix One

IJPP INTERNATIONAL JOURNAL OF Pharmacy Practice

IJPP International Journal of Pharmacy Practice

Review Article

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Quality Use of Medicines – medication safety issues in naming; look-alike, sound-alike medicine names

Remo Ostini[a], Elizabeth E. Roughead[b], Carl M.J. Kirkpatrick[a,c], Greg R. Monteith[a] and Susan E. Tett[a]

[a]School of Pharmacy, The University of Queensland, Brisbane, Queensland, [b]School of Pharmacy and Medical Science, University of South Australia, Adelaide, [c]Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Melbourne, Victoria, Australia

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Correspondence
Professor Susan E. Tett, School of Pharmacy, The University of Queensland, Brisbane, Queensland 4072, Australia.
E-mail: s.tett@uq.edu.au

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Abstract

Objective To review current literature with the objective of developing strategies and recommendations to enhance patient safety and minimise clinical issues with look-alike, sound-alike medication names.

Methods A comprehensive search of the PubMed database and an Australian online repository of Quality Use of Medicines projects was conducted to identify publications addressing look-alike, sound-alike medication problems. Author networks, grey literature and the reference lists of published articles were also used to identify additional material.

Key findings Thirty-two publications describing the extent of the specific problem and recommending solutions were identified. The majority of these publications provided a qualitative assessment of the issues, with few quantitative estimates of the severity of the problem and very little intervention research. As a result, most recommendations for addressing the problem are the result of expert deliberations and not experimental research. This will affect the capacity of the recommendations to ameliorate and resolve problems caused by look-alike, sound-alike medication names. Themes identified from articles included the nature and causes of look-alike, sound-alike problems, potential solutions and recommendations.

Conclusions There are many existing medications which can potentially cause clinical issues due to mix-ups because of similar sounding or looking medication names. This confusion can be lethal for some medication errors. A multifaceted, integrated approach involving all aspects of the medication use process, from initial naming of INN through to consumer education, is suggested to minimise this issue for medication safety.

Introduction

Medication safety is recognised as a high priority in many healthcare systems because many avoidable problems are caused by medications. Medication errors are considered among the most common medical errors[1,2] and have been noted to be of particular concern in paediatric medicine,[3] obstetrics and gynaecology,[4] anaesthesiology[5] and psychiatry.[2] For example, approximately half of the iatrogenic complications that occur in neonatal intensive-care settings are related to medication errors.[6]

Broadly speaking, medication errors can be characterised as errors in the prescribing (including dose calculations), supply (dispensing) or administration of medicines, which include the elements of drug ordering, transcribing, communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administering, monitoring, education and use.[1,3] Interpreting the literature is complicated by variations in terminology. Twenty-six different definitions of medication error were identified in a review of 45 medication error studies.[7] The prevalence of errors in these studies ranged from 2–75%, but no associations were found between prevalence and definitions of error.[7]

In studies looking at all types of medication errors, prescribing errors accounted for the highest percentage,[7]

although the administration stage has been identified as the point at which the most harm to patients occurs.[4] The most common dispensing errors found in community and hospital pharmacies are dispensing the wrong drug, strength, form or quantity, and labelling medication with incorrect directions.[8] All but the last of these errors can occur as a result of medications having similar looking or similar sounding names. Rates of dispensing errors vary widely depending on context (community or hospital pharmacy), whether prevented or unprevented errors are measured, how errors are defined and how rates are calculated.[8] Estimates range from less than 0.5% up to 24% of medications dispensed.[8] While the effects of medications errors vary widely, they have the potential to cause adverse drug events, some of which can have serious consequences for patients.[9]

Medicines being incorrectly chosen and administered inadvertently because of similar sounding or looking names has great potential to cause harm.[10] Tamoxifen/tenoxicam is an example of generic name potential confusion. Up to 25% of medication errors in the USA are reported to involve drug name confusion[11,12] and up to 33% are attributed to packaging and/or labelling confusion.[12] Both orthographic (i.e., spelling) and phonological (i.e., sound) similarity increase the probability of name recognition errors among both experts and novices.[11]

Australia has a National Medicines Policy, comprising four arms,[13] one of which is Quality Use of Medicines (QUM). A number of programmes and activities have been pioneered in Australia to improve how medicines are used safely and effectively. These have been collated and documented on the QUMmap (http://www.qummap.net.au). The Australian National Medicines Policy Committee commissioned the study reported here, which evaluates the issue of medicine names that may cause confusion by their similarities, either by sounding similar or by looking similar when written. This issue has international implications for clinical practice.

Aim of the review

This review was designed to collate and describe current research about look-alike, sound-alike medicine names, especially any research focussing on solving issues rather than just describing problems, to arrive at recommendations suitable for national implementation on possible ways to address this issue.

Methods

The published literature and the QUMmap (http://www.qummap.net.au) were searched. Material was included if it was published after 1995 and in English. Original research on interventions (rather than describing the issue) was sought, and opinion pieces were excluded.

The PubMed database was searched (November 2010) using the terms look-alike drugs, sound-alike drugs, slip errors medication, lapse errors medication and brand extension to discover any publications on the issue of look-alike, sound-alike medicines. The QUMmap was also searched in November 2010, using the terms look-alike, sound-alike, packaging, labelling, slip error, lapse error and brand extension.

The personal contacts and networks of the authors were used to discern any other information or resources, published or otherwise. The grey literature was searched, mainly by tapping into known resources and following the leads generated by the authors from their expertise and experience and any leads given by their network of contacts.

The reference lists of the literature identified in these ways were also scanned for further relevant articles. This was not intended to be a general review on medication safety issues, however, and hence the material was restricted to focus specifically upon the topic of look-alike, sound-alike medication names, and particularly on original research testing interventions. The information sourced was then assessed for relevance and summarised, drawing together themes and ideas. Due to the heterogeneity of the relevant material that was identified, no formal quality assessment or data extraction tools were used. Rather, the primary contributions of each piece of work to the problem of look-alike, sound-alike medicine use were identified and collated across all relevant material. Finally, a series of recommendations were formulated.

Results

Thirty-two publications that investigated the issues around look-alike, sound-alike medication naming were identified.[8,11,12,14–42] These articles, together with descriptive characteristics and conclusions are reported in Table 1. Twenty-four articles were journal articles but only 14 reported original research and none were of interventions to prevent medication errors from look-alike, sound-alike medications. There were insufficient data from well-designed studies to perform any sort of systematic review or meta-analysis. Most of the studies qualitatively identified issues of look-alike, sound-alike medication names. Quantitative estimates of the problem were lacking and very little robust research about interventions was found. There were several publications which were very general, and were mainly concerned with a range of medication safety issues rather than specifically with look-alike, sound-alike medication names. Findings were collated into topics including: published lists of confusable names, the contribution of look-alike, sound-alike names to medication errors, the types of look-alike, sound-alike medication name confusion that occur and the solutions that have been proposed.

Table 1 Articles included in review

Reference	Source description	Conclusions
Lambert *et al.* (2001)[11]	Type: journal article Design: laboratory experiment	Drug name similarity increases false recognition memory errors
Berman (2004)[12]	Type: journal article Design: overview	Systems and recommendations are reported, which can reduce the occurrence of LASA medication errors
JCAHO (2005)[14]	Type: journal article Design: list and recommendations	Developed to assist healthcare organisations develop and maintain programmes to minimise risks from LASA drug names
Leape *et al.* (1995)[15]	Type: journal article Design: systems analysis of data from prospective cohort study	Systems analysis is a better method for addressing medication errors in hospitals than is focussing on individuals
Bates *et al.* (1995)[16]	Type: journal article Design: prospective cohort study	Adverse drug events are common and most result from errors at the ordering stage
Ferner *et al.* (2006)[17]	Type: journal article Design: classification study	Classification of medication errors helps address the different probabilities and remedies for different classes of errors
Schulmeister (2006)[18]	Type: journal article Design: overview	Describes examples of LASA medication errors, describes some of their causes and suggests a range of risk reduction strategies
Cohen (2002)[19]	Type: letter to the editor Design: error correction	Clarifies a number of perceived errors in an earlier article describing solutions to LASA medication problems
Lee (2007)[20]	Type: grey literature Design: survey study	The problem of LASA medication packaging and labelling has grown and requires a policy response
Phillips and Williams (2006)[21]	Type: journal article Design: professional organisation statement	Medical errors involving LASA neuromuscular blocking medications continue to result in patient morbidity and mortality
James *et al.* (2009)[8]	Type: journal article Design: review	Development of medication error reduction strategies is hampered by differences in definitions for dispensing errors, error rate and classification of error types
Ashcroft *et al.* (2005)[22]	Type: journal article Design: prospective study	A wide range of medication errors occur in community pharmacies
Peterson *et al.* (1999)[23]	Type: journal article Design: survey study	Dispensing errors occur in greater numbers than those reported to regulatory authorities and appear to be caused by high prescription volumes, fatigue and overwork
Hong *et al.* (2005)[24]	Type: journal article Design: retrospective follow-up study	Product line extensions help price rigidity in original brands
AHA (2005)[25]	Type: grey literature Design: medication safety brief	Provides case studies and an action agenda for reducing errors from LASA drugs
Aronson (2004)[26]	Type: journal article Design: editorial	Regulatory authorities and manufacturers should be vigilant when naming new drugs and formulations, in order to avoid drug name confusion
Lambert *et al.* (2010)[27]	Type: journal article Design: laboratory experiment	Clinician and lay person ability to identify spoken drug names is affected by signal-to-noise ratio, subjective familiarity, prescribing frequency and the similarity of drug names
Kenagy and Stein (2001)[28]	Type: journal article Design: overview	Drug names, labels and packaging are not chosen and designed in accordance with human factors principles and this contributes to medication errors that cause patient injuries and deaths
Santell and Cousins (2005)[29]	Type: journal article Design: overview	Efforts by regulatory authorities, drug manufacturers, pharmacists, other health care professionals and patients can reduce medication errors
Schwab *et al.* (2002)[30]	Type: journal article Design: clinical observation	Using trade names and omitting INNs can result in serious adverse drug events by overdose
McCoy (2005)[31]	Type: journal article Design: case study	Evaluation of potential LASA medication errors should occur proactively
ACSQHC (2002)[32]	Type: grey literature Design: report	Report seeks to increase general understanding of things that can go wrong with medicines, the size and nature of the problem in Australia, strategies that can make a difference and national directions being taken to improve medication safety
USP CAPS (2004)[33]	Type: grey literature Design: report	Provides a list of drug names that have caused confusion and reasons for that confusion
US Pharmacopeia (2010)[34]	Type: website Design: database	Provides a free tool for accessing drug names that have been associated with medication errors, as well as evidence on how communicating drug orders can lead to medication errors
Friedman (2005)[35]	Type: journal article Design: overview	Healthcare organisations should integrate JCAHO safety goals into their policies, procedures and clinician education, in order to avoid dangerous and costly medication errors
Kovacic and Chambers (2010)[36]	Type: journal article Design: orthographic analysis of drug names	Specialty areas of medical practice may require a proactive system for reviewing LASA drug name pairs
Lambert (1997)[37]	Type: journal article Design: observational retrospective	Automated measures of medication name similarities can be accurate, sensitive and specific
Kondrak and Dorr (2006)[38]	Type: journal article Design: laboratory experiment	A new orthographic measure outperforms other commonly used measures of similarity for LASA drug names
Filik *et al.* (2006)[39]	Type: journal article Design: laboratory experiment	Provides some support for the use of tall-man lettering to reduce look-alike medication errors
Filik *et al.* (2004)[40]	Type: journal article Design: laboratory experiment	Drug names using tall-man lettering were less likely to be incorrectly identified
Emmerton and Rizk (2010)[41]	Type: conference paper Design: review	Proposes an interactive model for cautions about LASA medicines in community and hospital pharmacy
Emery *et al.* (2010)[42]	Type: conference paper Design: review	Contribution of increased use of generic medicines to labelling problems

ACSQHC, Australian Council for Safety and Quality in Health Care; AHA, American Hospital Association; INN, international non-proprietary name; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; LASA, look-alike, sound-alike; USP CAPS, United States Pharmacopeia Center for the Advancement of Patient Safety.

Discussion

Published lists of confusable drug names

Various lists of look-alike, sound-alike names have been published, and many general medication safety publications describe the problem. For example, the US Joint Commission on Accreditation of Healthcare Organizations (JCAHO) published a 'safety goal' in 2005 highlighting the problem of look-alike, sound-alike medications.[14] They described confusing drug names as a common system failure and suggested that organisations (such as hospitals or pharmacies) conduct annual reviews of the look-alike, sound-alike drugs that they use. In Australia, such lists have been compiled (for example, by the Pharmacy Board of Victoria). However, the lists have not been widely adopted and there is no specific regulation in Australia to cease proliferation of look-alike, sound-alike names for new medicines.

A compiled list of look-alike, sound-alike medicines by the United States Pharmacopeia (USP) was provided in 2004.[33] Following this publication, USP developed a useful online search facility containing 1470 unique medications implicated in look-alike, sound-alike errors, contributing to more than 3170 confusing medicine name pairs.[34,43] The USP 2008 report provides information about the extent of the problem in the USA and the contribution of look-alike, sound-alike names to medication safety issues.[43] The US Institute for Safe Medication Practices (ISMP; http://www.ismp.org) publishes electronic subscription newsletters that report recently identified look-alike, sound-alike medication errors. This is a good source for timely information in the USA.

A list of 277 medication pairs was recently compiled as potentially causing confusion among medicines prescribed in Australia.[41] Of these medicine pairs, 267 were for unrelated medications, while 10 were for variations of the same drug.

Contribution to errors

Original, published and peer-reviewed research on the extent of the problem is limited. In two US tertiary care hospitals, 7% of adverse drug events (ADEs) over a 6-month period were the result of faulty medication identity checking, and most of those errors were identified as being due to confusion over medicines with similar names or similar packaging.[15] Most errors occurred at the ordering and administration stage. Other research suggests that name and labelling confusion is implicated in as many as half of all medication errors in the USA.[18] However, while it is likely that medication errors occur because of look-alike or sound-alike names, unclear labelling or poorly designed packaging, specific error rates and injuries associated with look-alike, sound-alike medicine names are unknown and difficult to estimate.[19,21]

A review of literature on dispensing errors identified look-alike, sound-alike medicine names as a subjectively reported factor contributing to dispensing errors.[8] A retrospective analysis of actual dispensing errors identified similar drug names as the second most common causes of such errors (the most common cause being workload issues).[8]

A small research project gave a subjective estimate of error rates, including near misses, from a group of pharmacists in South Australia as approximately 1% of all dispensings.[20] Pharmacists registered in Tasmania, Australia, identified similar or confusing drug names as important factors that contribute to dispensing errors in community pharmacies.[23] Pharmacists who had been professionally registered for a longer period of time found such confusion to be significantly less important than pharmacists registered for a shorter time period. Similarly, while improving labels and providing distinctive drug names were considered important factors in reducing dispensing errors a longer period of professional registration was again associated with less importance being placed on this.[23] These findings may be related to prescribing frequency being found important in drug name recall.[44] The associations between length of registration and both the importance of the problem, and the importance of improving labels, though significant, were weak.[23]

A study of community pharmacies in the UK identified a dispensing error rate of almost 4 per 10 000 items dispensed.[22] Similar drug names were found to be responsible for 16.8% of the errors recorded.

Consumers have also identified medication packaging and labelling, more generally, as major factors contributing to poor compliance and medication safety, particularly in the context of generic substitution.[42]

Types of problems

Aronsen has suggested that sources of confusion over medication names can arise from: different medications having similar names; formulations containing different medications sharing the same brand name; the same medicines marketed in different formulations having different brand names; and the use of abbreviated medication names.[26]

Brand extension, which is another problem causing confusion, refers to a new product that is a variation (e.g. new formulation or modified molecule) of an existing product.[24] Brand extensions are an effective way to support price rigidity in products that are going off-patent and can result in products with names similar to existing products. Brand extension leads to problems arising with drug names, particularly where products with different dosage forms are only indicated by the use of suffixes (e.g. XR, SR and XL in brand names for extended-release products, such as tramadol, tramadol XR, tramadol SR).[29] This has been identified as important for both prescription medicines and over-the-counter (OTC) medicines,[20] though it has been perceived to cause more confusion for prescription than for OTC medications.

The rate at which new drugs are introduced onto the market adds to the problem of look-alike, sound-alike medication names.[25] Kenagy and Stein suggest that the concept of 'trade dress' drives commercial considerations for naming, packaging and labelling.[28] Trade dress demands that a product projects an image of quality and, ultimately, that if something works (results in sales), that it should not be changed.[28] Unfortunately, adherence to this strategy for naming medications, including for brand-extension purposes, may not always serve the best interests of the consumer in terms of ensuring that they receive and take the intended medication.

Underlying this problem is the argument that existing pharmaceutical systems (prescribing, dispensing, administration) are flawed because they rely on human perfection.[28] That is, they often ignore important human factor concepts such as simplicity, standardisation, differentiation, lack of duplication and unambiguous communication in the process of drug naming, labelling and packaging. The result is drug names that look and sound alike. This can lead health professionals to unintended interchanges of medications with potentially serious clinical consequences for patients.[28] Lack of differentiation of medicine names may lead to slip/lapse errors as a class of medication error that results from the performance of an action that was not the intended action.[17] This type of error is facilitated when drugs have similar names, for example, a name like the intended medicine's name is written on a prescription; or when a product name that looks like the intended medicine name is selected in a dispensary.

Spoken medication orders can also be a source of slip/lapse errors and ambiguous communication errors for both clinicians and laypersons.[27] Accuracy in identifying spoken medicine names increases as the background noise levels decrease; when people are more familiar with a drug name; and when the national prescribing frequency of the drug is higher.[27] Other research has identified visual and auditory distractions, workflow and time pressures to be risks for the confusion of medicine names.[41]

Suggested solutions in the current literature

Research evidence for methods to reduce drug name confusion is rare. Nevertheless, a number of generally untested solutions to the problem of look-alike, sound-alike medication names have been promulgated.

Medication name remedies

In the context of spoken medication orders, the amount of background noise and familiarity effects are seen to be important targets for intervention to reduce errors.[27]

A strategy for managing look-alike, sound-alike drug name confusion used with oncology medicines[18,36] applied Levenshtein distance and Bigram similarity algorithms, same first and last letters and an online alert system to identify look-alike, sound-alike generic medicine names. Levenshtein distance is a measure of similarity in the ordering of a string of letters. It counts the total number of letter insertions, deletions or substitutions needed to change one name into the other. For example, applying the algorithm to Xanax and Zantac gives them a similarity score of three.[37] Bigram similarity looks at the number of adjacent letter pairs common to pairs of words. This approach has identified more potential medication name problems than were found in the published literature, possibly because most published lists are the result of voluntarily reported medication incidents. A proactive review of potential problems might contribute to averting errors with previously unidentified problem drugs.[36]

A model has been developed, also based on Levenshtein distance, which automates an orthographic approach to name comparisons, using similarities in the spelling of drug names to predict name confusion.[37] A distance value of five was found to provide a cut-off with high sensitivity and specificity. The method can provide agencies responsible for approving trademarks and drug names with a valid and reliable method for assessing the likelihood of look-alike, sound-alike medication name errors.[37] This method lacks features that manual evaluation of names by experts can provide – e.g. consideration of dosage, indication and physical appearance of the drug. However, as a computerised method, it allows the automated comparison of new drug names with the thousands of drug names already in existence.[37]

An alternative approach is to take advantage of the phonetic characteristics of individual sounds to estimate the similarity of names.[38] This does require phonetic transcription before analysis – but allows the identification of confusable words that orthographic methods do not pick up.[38] The highest accuracy in identifying confusable names is obtained by using a combination of orthographic and phonetic approaches.[38]

The likelihood of a medication name being confused is reduced, the more distinctive the name. This has led to the suggestion that the full names of drugs be used wherever possible (e.g. prednisolone sodium phosphate rather than prednisolone to reduce the risk of confusion with prednisone).[36] While it has been suggested that only generic names, or international non-proprietary names (INNs), be used in an effort to reduce look-alike, sound-alike errors involving proprietary (trade) names, it has also been suggested that only trade names be used to avoid confusion among similar sounding generic names.[12] The solution may be to use both generic as well as trade names (if one is available) for drugs with a known potential to cause confusion.[12] Including the

indication on the prescription (and possibly the medication label) would also assist correct recognition of the appropriate medication name.[43]

Some research looks at the use of 'tall-man' letters; that is, uppercase letters, to differentiate sections of drug names that may sound or look alike.[39,45] An example from the Australian national tall-man lettering list aims to differentiate cefUROXime, cefOTAXime, and cefTAZIDime.[46] Research suggests that tall-man letters do not make names less confusable in memory but do make similar names easier to distinguish – if participants are aware that this is the purpose of the uppercase letters.[39] Other research suggests that tall-man letters can reduce the number of errors made in selecting a target medicine when faced with an array of medication packs.[40] Tall-man lettering has been reported to reduce medication name confusion in a number of different groups of people, of different ages and professions, in laboratory-based tasks.[45] However, an evaluation conducted for the UK National Health Service cautions a pragmatic approach to the widespread implementation of tall-man lettering and suggests that the prevalence of other more likely errors indicate the need for broad research rather than just this limited potential solution to one aspect of the problem.[47]

Dispensing and administration contexts

Some suggested solutions focus on the characteristics of the locations where people obtain and take medicines. Strategies for use at the health centre level include: adding special warning labels to identify medications with the potential to be confused; adding a verification step (by a second staff member) to the process of medication selection; publishing information bulletins warning of potential look-alike, sound-alike drug names; and proactively identifying potential look-alike products through the involvement of inventory control technicians.[31] No evaluation to determine whether this intensive programme reduces errors was reported.

Another strategy for managing look-alike, sound-alike drugs suggests using the JCAHO list of problematic drug names to: identify drugs that are used by a home-care or hospice organisation; review patient medication profiles; and conduct home medication management reviews.[35]

Other suggested risk reduction strategies have included: healthcare workers being kept aware of medications that look or sound alike; the installation of pop-up alerts and bar coding on computer systems; putting distinctive labels and warning stickers on storage bins; and storing confusable medications in non-adjacent locations.[18]

Bar coding of medicines is sometimes considered a promising approach to reducing the level of dispensing errors.[22] However, this is dependent on the correct medicine being ordered and so does not eliminate problems of confusion in actual prescription. It also relies on pharmaceutical companies following a consistent bar-coding convention.

Educating patients on the risks of look-alike, sound-alike medications has also been suggested as an important line of defence against this type of medication error.[17,35]

Comprehensive approaches

A systems approach to risk reduction suggests that solutions should be implemented at all levels; medication production, dispensing, preparation and administration stages. This includes manufacturers and regulatory authorities being vigilant when new medications are named.[7] Such an approach must be complemented with a consumer focus, including consumer education, access to pharmacist counselling, and ensuring that consumers know and feel empowered to ask questions.

Aronson has proposed a comprehensive list of actions that could be taken by regulatory agencies, pharmaceutical manufacturers, prescriber, pharmacists, and patients to reduce the risk of errors resulting from drug name confusion.[26] These form the foundation for Table 2. Similar actions have been proposed by groups including the World Health Organization.[10]

Lambert and colleagues argue that, since name similarity is easily and cheaply measured, steps should be taken to monitor and reduce similarity as a way to reduce the likelihood of drug name confusions to improve medication safety. This is sound advice, but difficult to implement on a national or international scale.[11]

A number of organisations have produced broad strategies aimed at preventing drug confusion (JCAHO, ISMP and the US National Coordination Council for Medication Error Reporting).[12,14] There is considerable overlap with previously described strategies. Additional recommendations include the unambiguous labelling of injectable and IV drug containers, and proposing that all prescriptions clearly specify medication strength, dosage, route of administration and frequency, even where there is only one accepted option. Finally, there is a strong endorsement for collaboration among all stakeholders to facilitate the design of packaging and labelling that minimises error.

In addition to the actions proposed in Table 2, further processes recommended to reduce problems for pharmacists to use with error-associated medications[29] include keeping patient medication profiles current, with sufficient information for pharmacists to evaluate the appropriateness of medication orders, reading product labels at least three times (e.g., when a product is selected, packaged and returned to the shelf) and counselling patients in order to provide an opportunity to ensure that an order has been dispensed correctly and that the patient understands the proper use of the medication.[29]

Table 2 Minimising potential patient harm from look-alike, sound-alike medication names (modified from actions proposed by Aronson[26])

Group	Recommended actions
Prescribers	– Inspect actual medicines a consumer is taking, especially when adverse events occur, and be vigilant for possible confusion due to similar names – Report errors to the relevant government agency/ regulatory authority – Use INNs, if possible, or the national generic name when prescribing – Issue computer-printed prescriptions if possible; any handwritten prescriptions should be clearly written, using uppercase letters, and never abbreviated medicine names – Check unfamiliar names of medicines that patients report they are taking
Consumers	– Assume more responsibility for educating themselves about medicines they are taking, and asking questions of their health professionals – Take actual medicines along to consultations with prescriber or pharmacist – Tell each new prescriber about all medicines being taken – Report any suspected medication adverse events to their pharmacist and prescriber
Pharmacists	– Check that consumers recognise all the medicines they are taking – Discuss all medications with consumers, including likelihood for any confusion due to similarly named medicines – Clearly differentiate storage areas for medications with LASA names – Include alerts on shelves for medications known to be at risk for mix-ups due to similar names – Ask consumers for old containers when filling a new prescription – Report errors to the relevant government agency/regulatory authority – Liaise with prescribers, advising on potential for medication mix-ups due to LASA medication names – Instigate systems for always double checking prescriptions
Pharmaceutical companies	– Conduct market research on potential names with consumers, prescribers and pharmacists – Use available software (using orthographic and phonetic approaches) to test for LASA names and choose alternatives least likely to be confused with medicines already available – Cooperate in international process of choosing new names and be prepared to change brand names, worldwide, if necessary to avoid medication safety issues – Use the same INN (generic) name when naming new formulations – Emphasise INN above the brand name in all labelling, packaging and consumer or prescriber information
Regulatory authorities	– Government agencies should use more regulatory muscle to enforce naming that does not risk patient safety – Enforce use of INNs, rather than requiring different names in different jurisdictions – Harmonise international use of proposed new proprietary names – Use databases to compare existing names with proposed names (using software to test orthographic and phonetic LASA proposed names), so possible name confusion can be predicted and avoided by not becoming registered medications.

INN, international non-proprietary name; LASA, look-alike, sound-alike.

Finally, a medication safety issue brief for hospitals and health networks[25] suggests that actions to reduce errors from look-alike, sound-alike drugs should include organisations evaluating their formularies to identify medications that are prone to name confusion and that errors involving look-alike, sound-alike drugs are tracked, with the results used to educate staff. They also suggest providing drug name spelling with verbal orders, providing the intended use of the drug with the order, and conducting a 'failure mode and effects analysis' for all drugs being considered for inclusion on a formulary.

Barriers

Obstacles to changing names, labels or packages include: the nature of the problem; that standards for names, labels and packages do not incorporate human factors principles; and that most of the information on labelling and packaging problems is not systematic and comprehensive. There is also a barrier in the regulatory structure governing pharmaceuticals. Regulatory agencies do not yet 'own' the problem – they do not see it falling into their jurisdiction. A further issue is the mission of pharmaceutical companies.[28] Pharmaceutical companies do not consider design for safety to be their responsibility. They only feel bound to meet the regulatory demands for information on the package – placing responsibility for getting medicines mixed up squarely on the medication prescribers and users.[28]

Political will is required to overcome these barriers and to implement many of the solutions that have been proposed.

Study limitations

This review may not include all relevant research. Research that was not captured by the PubMed or QUMmap databases and that was also not identified in our follow-up procedures has not been reviewed. Furthermore, the variability of the included material, in terms of quality and type of

information presented, precludes a simple summation of the content or the strength of the findings. Finally, excluding non-English language material may have resulted in relevant material, such as the approach taken by the French drug regulatory agency,[48] being omitted from this review.

Conclusions

A multifactorial approach is essential to overcome the threats to patient safety from look-alike, sound-alike medication names. Each aspect of the medication use process, from original choice of INN through to dispensing, administration and consumer education require integrated attention. Unfortunately there is still very little intervention research which can guide development and implementation of systems to improve this aspect of medication safety. Various naming guidance documents have been developed (for example in the EU and by USP) and there are now ways of checking for similarities in 'sound' and 'look' of names, some of which could be implemented in an automated fashion by companies and regulatory agencies. Differentiation through use of techniques such as tall-man lettering or through use of bar codes require more international validation before widespread adoption is possible. Organisational aspects, paying attention to human factors, in methods of storage design, workload and occupational design (such as minimising distractions) are possible, but again these require rigorous research before universal adoption of specific systems can be recommended. The benefits of empowering and encouraging consumers to ask questions about their medications should not be underestimated and is part of any comprehensive solution.

Many of the recommendations in the literature could be adopted in many countries, supported by a national programme of implementation. Given that some of the major obstacles to improvement are structural, political commitment from governments will be required, supported by appropriate safety structures in health facilities. Interestingly, there appears to be a dearth of research in this area internationally. The problems caused by look-alike and sound-alike drug names are well described; priority should be given to funding innovative solutions. A step has been taken in this direction with a recent evaluation of the new national tall-man lettering list in Australia.[49,50]

Declarations

Conflict of interest

The Authors declare that they have no conflicts of interest to disclose.

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Appendix Two

III List of similar medication names that contribute to medication error

Similar names contribute to problems with medicines when they are confused due to poor handwriting, or they look-alike or sound similar when verbal instructions are given. Listed below are some examples where this may occur.

The following information has been collated from reports and complaints received by the Pharmacy Board of Victoria, Pharmacy Board of Tasmania and the Pharmaceutical Council of Western Australia together with the RGH, Daw Park, South Australia, Pharmacy E-Bulletin.

An increase in errors due to the product next to the intended item being selected has been noted this year (eg Lanoxin instead of Lanoxin PG, Luvox instead of Lovan, Avapro instead of Avapro HCT, Prozac instead of Provera). The use of scanners to cross check the selected container against the computer entry can minimise selection errors. Use of a pharmacy dispensing checklist is strongly recommended.

Generic names are shown in *italics*.

Achromycin	Aureomycin
Aclin	Zactin
Aclin	Alprim
Adalat	Aldomet
Advantan	Ativan
Aldactone	Aldomet
Aldactone	Aldazine
Aldazine	Amizide
Aldazine	Aldactone
Aldomet	Adalat
Aldomet	Aldactone
Alphamox	Amfamox
Alprim	Aclin
Amantadine	*Cimetidine*
Amfamox	Alphamox
Amiloride	*Amlodipine*
Aminophylline	*Amitriptyline*
Amitriptyline	*Aminophylline*
Amlodipine	*Amiloride*
Amizide	Aldazine
Amorolfine	*Aminophylline*
Amoxycillin	*Ampicillin*
Anafranil	Largactil
Anaprox	Aprinox
Anaprox	Avapro
Apomine	Avomine
Aprinox	Anaprox
Aratac	Aropax
Aropax	Aratac
Aropax	Aurorix
Arthrexin	*Cephalexin*
Atarax	Ativan
Ativan	Atarax
Ativan	Advantan
Atromid	Clomid
Aurorix	Aropax
Avandia	Avanza
Avanza	Avandia
Avapro	Anaprox
Avapro	Avapro HCT
Beclomethasone	*Betamethasone*
Beconase	Becotide
Becotide	Beconase
Becotide	Berotec
Becotide	Betaloc
Berotec	Becotide

Betaloc	Becotide
Betamethasone	*Beclomethasone*
Budesonide	*Bumetanide*
Bumetanide	*Budesonide*
Caltrate	Carafate
Capoten	Gopten
Carafate	Caltrate
Carbamazepine	*Carbimazole*
Carbimazole	*Carbamazepine*
Carboplatin	*Cisplatin*
Cardizem	Cardiprin
Cardiprin	Cardizem
Ceflin	Keflin
Cephalexin	Arthrexin
Chlorpromazine	*Clomipramine*
Cipramil	Ciproxin
Ciproxin	Cipramil
Cisplatin	*Carboplatin*
Clomid	Atromid
Clomiphene	*Clomipramine*
Clomipramine	*Clomiphene*
Clomipramine	*Chlorpramazine*
Clomipramine	*Imipramine*
Cordarone	Cortisone
Cortisone	Cordarone
Daonil	Deseril
Deseril	Desferal
Deseril	Daonil
Desferal	Deseril
Didrocal	Didronel
Didronel	Didrocal
Differin	Difflam
Difflam	Differin
Dothiepin	*Doxepin*
Doxepin	*Dothiepin*
Endep	Endone
Endone	Endep
Enoxacin	*Enoxaparin*
Enoxaparin	*Enoxacin*
Ergotamine	*Ergometrine*
Feldene	Teldane
Fluoxetine	*Paroxetine*
Glicazide	*Glipizide*
Glipizide	*Glicazide*
Gopten	Capoten
Hydralazine	*Hydroxyzine*
Hydrea	Hydrene
Hydrene	Hydrea
Hydroxyzine	*Hydralazine*
Imdur	Imuran
Imipramine	*Clomipramine*
Imipramine	*Trimipramine*
Imuran	Imdur
Keflin	Ceflin
Ketoprofen	*Ketotifen*
Ketotifen	*Ketoprofen*
Lamictal	Lamisil
Lamictal	Lomotil
Lamisil	Lamictal
Lanoxin	Lanoxin PG
Lansoprazole	*Omeprazole*
Largactil	Anafranil
Lasix	Losec
Lasix	Lescol
Lescol	Lasix
Lomotil	Lamictal
Losec	Lasix
Losec	Prozac
Lovan	Luvox
Luvox	Lovan

Maxolon	Moxacin
Midoride	Modizide
Modizide	Midoride
Moxacin	Maxolon
Neurontin	Noroxin
Noroxin	Neurontin
Olanzapine	*Omeprazole*
Omeprazole	*Olanzapine*
Omeprazole	*Lansoprazole*
Optimol	Optrol
Optrol	Optimol
Panafcort	Panafcortelone
Pethidine	Prothiaden
Pramin	Premarin
Prednisolone	*Prednisone*
Prednisolone	Risperidone
Prednisone	*Prednisolone*
Premarin	Pramin
Progout	Prograf
Prograf	Progout
Prothiaden	*Pethidine*
Prozac	Losec
Quinidine	*Quinine*
Quinine	*Quinidine*
Risperidone	Prednisolone
Rosig	Zomig
Sandimmum	Sandomigran
Sandomigran	Sandimmum
Tamoxifen	*Tenoxicam*
Teldane	Feldene
Tenoxicam	*Tamoxifen*
Terbinafine	*Terfenadine*
Terfenadine	*Terbinafine*
Thioriazine	*Thyroxine*
Thyroxine	*Thioridazine*
Tramal	Trandate
Trandate	Tramal
Trimeprazine	*Trimipramine*
Trimipramine	*Trimeprazine*
Trimipramine	*Imipramine*
Xenical	Xeloda
Xeloda	Xenical
Zactin	Aclin
Zantac	Zyrtec
Zestril	Zyrtec
Zinnat	Zinvit
Zinvit	Zinnat
Zocor	Zoton
Zocor	Zoloft
Zoloft	Zocor
Zomig	Rosig
Zoton	Zocor
Zyrtec	Zestril
Zyrtec	Zantac