

Responding to the challenge of look-alike, sound-alike drug names

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Despite significant advances in medication safety, errors related to confusion between drug names are a cause of preventable adverse events and serious harm,¹ and remain a patient safety priority.^{2–3} Although drug name confusion is recognised as a factor contributing to error, its minimisation or elimination is a prevailing challenge.^{4–5} In this issue, Schroeder *et al*⁶ postulate that despite industry's efforts to follow regulators' guidance⁷ on how to review drug names, more objective evidence, in a standardised format, is needed to improve decision-making about the acceptability of a name. To address this concern, the authors assessed the association between error rates in laboratory-based tests of drug name memory and perception and rates of real-world errors related to drug name confusion.

We commend the authors for their contribution to this important area of study. Results from a study of a postmarket strategy for preventing drug name errors (ie, Tallman lettering) with look-alike, sound-alike (LASA) drug names did not demonstrate effectiveness in reducing medication errors.^{8–9} Reliable strategies for preventing drug name confusion errors, before they reach the market, are needed. The authors present a validated approach that provides an opportunity for identifying confusing drug names during the premarket phase with the goal of identifying safer names for products and preventing the associated costs when LASA drug names are identified postmarket. Here, we comment briefly on the article with the aim of provoking further reflection upon some of the fundamental issues surrounding assessment of LASA drug names and to protect patients from potentially harmful medication errors.

The findings of the thoughtfully executed study by Schroeder *et al* represent an important contribution to knowledge about the roles of misperceiving, misremembering and drug name confusion in healthcare.

The key strength of the paper lies in its focus on quantifying the association between laboratory results and real-world data. In what follows, we raise points that merit further consideration.

OPPORTUNITY FOR UNDERSTANDING RELATIVE ADDITIVE EFFECTIVENESS

The authors point out that the premarket strategies for identifying potentially confusing names that are set out in the Food and Drug Administration and Health Canada guidance documents are not supported by strong evidence of effectiveness. Schroeder *et al* provide much-needed evidence of the association between laboratory tests for identifying confusing drug names and real-world data and their method serves as a standard against which other LASA drug name assessment methods can be compared.

OPPORTUNITY TO ASSESS THE EFFICIENCY OF PROPOSED MEMORY AND PERCEPTION TESTS

Strategies for identifying drug name confusion must be efficient. Finding a new drug name has become increasingly complex. The naming process can start with a list of hundreds or even thousands of names, which then gets reduced to a handful of names before the drug is submitted for regulatory approval. Although the entire process can take from a few months to a few years, and the estimated cost ranges from US\$75 000 to US\$500 000 for a single brand name,¹⁰ the importance of the issue lies in patient safety and the prevention of harm from medication errors. The cost of mitigating safety risks with LASA drug names is exponentially higher when risks are identified *after* products are available on the market compared with during the pre-approval process.

Schroeder *et al* state that their study was motivated by rejection of a proposal



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to include the same memory and perception tests in Health Canada's guidance document for industry review of drug brand names.⁷ Specifically, Schroeder *et al*⁶ state, "Health Canada recommended that drug companies use a standard battery of memory and perception tests to assess the confusability of new drug names, but this proposal was dropped in the final guidance after stakeholders argued that the methods were burdensome and had not been shown to predict real-world error rates".

In their study, the authors address the concern related to real-world error prediction, but fall short in addressing the burden associated with the proposed tests. Given that these memory and perception tests require participants to perform standardised tests, there is opportunity to demonstrate efficiency with wide adoption. The authors conclude that regulators and drug companies should use these simple and inexpensive tests to identify confusing names. As such, evidence to show that they allow for efficient and scalable query of newly proposed drug names, for example, through manufacturer usability testing, will be helpful.

NEED TO ASSESS THE EFFECTIVENESS OF PROPOSED MEMORY AND PERCEPTION TESTS USING ONE OR MORE DRUG NAMES THAT ARE UNFAMILIAR TO CLINICIANS

In the study by Schroeder *et al*, participants (except for the lay participants) had strong familiarity with the drug names tested. Thus, the authors were assessing the association between laboratory results and real-world errors for drugs already familiar to clinician end-users, but the following question remains: How would the results have differed if clinicians had been unfamiliar with one or both of the drug names? Further studies are required to assess whether the memory and perception tests are effective at predicting name confusion errors for drug pairs that include unfamiliar drug names.

NEED TO CONSIDER POTENTIAL COGNITIVE BIASES

The authors focused on lapses in memory and perception during a study of drug name confusability; the study would have benefited from attention to the potential contribution of cognitive biases, such as confirmation bias and framing effect.

Future research on preventing medication errors, including potential LASA drug name errors, should consider how the negative effects of cognitive biases can be mitigated when a new drug enters the market.

Confirmation bias

Confirmation bias is the tendency to seek out or interpret information that confirms one's preconceptions.¹¹ As noted, the clinician participants in the study by Schroeder *et al* were familiar with the drug

names that were tested. Furthermore, the memory and perception tests required a 'forced choice' answer (ie, selection between two drug names). In reality, however, when clinicians are faced with an unfamiliar drug name and do not have a forced choice between two alternatives, confirmation bias may lead them to interpret and recall the drug name in a way that confirms their pre-existing beliefs or hypotheses (ie, the drug name they expect to see or hear). The potential for confirmation bias is an important factor to consider when assessing drug name confusion, especially when clinicians are unaware of the existence of a newly launched drug.

Framing effect

Framing effect is the tendency to draw conclusions that are based on how data are presented.¹² For example, a pharmacist may misinterpret a prescription (dispensing drug A instead of drug B) because the physician commonly prescribes drug A.

NEED TO CONSIDER OTHER FACTORS THAT LEAD TO LASA DRUG NAME ERRORS

The study by Schroeder *et al* correlated rates of drug name confusion errors observed in the real world with those observed in laboratory-based tests of memory and perception. However, drug name confusion can arise because of factors other than memory and perceptual lapses related to phonetic and orthographic similarity. For example, similar packaging or labelling, similar indications and dosing regimens are all examples of factors that can lead to drug confusability.

CURRENT FOCUS ON A PERSONS-BASED APPROACH AS OPPOSED TO A SYSTEMS-BASED APPROACH

The persistence of drug confusion errors may reflect the strategies that are currently being used to assess the problem. That is, strategies to reduce LASA drug name selection relies heavily on human behaviour and are dependent on human intervention. The hierarchy of effectiveness,¹³ a framework for intervention design, rates interventions that rely on human behaviour as inferior to technological interventions (eg, computerised systems), which are considered more reliable. For example, in the context of drug name confusion, machine-learning, which involves storing patterns and making predictions on the basis of orthographics, phonetics and dosages could be used to predict names that are likely to be confused. With good predictive capabilities, pattern recognition will more readily be able to detect similarities in drug names.

CONCLUSION

With more than 20 000 marketed health products in Canada alone (where we work), the problem of LASA

drug names is challenging for all stakeholders, including manufacturers, healthcare providers, regulators and patients. Drug name confusion errors can cause harm by depriving patients of the correct treatment and unintentionally subjecting them to risks associated with an incorrect treatment. Processes for assessing new drug names during the premarket phase have been developed in both the USA and Canada and likely in other countries as well. It will be important to continuously identify opportunities to improve the LASA drug name assessment process. The tool developed by Schroeder *et al*, which relies on human participants, has the potential to complement existing assessment processes. However, more research is needed to evaluate its efficiency and scalability. Ideally, more automated processes for identifying LASA drug names will be implemented to decrease potential for LASA medication errors. We hope that this research impels additional efforts to solve the challenge of LASA drug names.

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