SANS 444:2014: A new standard for small-ampoule labelling and a chance to reduce drug administration errors in South Africa

To the Editor: Drug administration errors remain a hazard in operating theatres and other clinical areas in healthcare facilities worldwide. A prospective study published in 2009 involving over 30 000 anaesthetics at three South African (SA) academic institutions confirmed that drug administration errors by anaesthetists are common. In the study, the incidence of either a drug administration error or a near miss was 1:274 anaesthetics. The most common cause of error (36.9%) was drug ampoule misidentification, and of these errors the majority were due to similar-looking ampoules. Although there were no deaths due to drug errors in the study, a previous survey into drug administration errors by SA anaesthetists revealed that more than 94% of respondents had made a drug error and that in a minority of cases the error caused death or non-fatal cardiac arrest.

These figures are similar to those published in the international literature.

A significant step towards improving drug administration safety is the 2014 publication of a new South African Bureau of Standards (SABS) standard for ampoule labelling. The key feature of the new standard is that labels will be much more legible in the clinical arena. The standard focuses on font size, text legibility and orientation, text contrasts, ordering of label content, and language. It mandates the use of the generic name of the drug on the label and states that, if used, the trade name may not exceed the size of the generic name. To create space for clearer labelling on small ampoules, English is now the only mandatory language. The standard also recommends that where applicable, manufacturers should on part of the label utilise the colours specified for identifying specific drug classes on syringe labels, as per the SABS standard (South African National Standards) SANS 26825.

This new SANS standard should decrease the risk of drug substitution errors if adopted by the pharmaceutical industry, and by national professional bodies, hospital groups and the national and provincial departments of health as a key standard to their drug ordering strategies.

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