administration of potent pain medications. Since Abbott’s LifeCare PCA system was introduced in 1988, more than 22 million patients have used it safely. According to the US Food and Drug Administration’s (FDA) safety database, the incidence of serious injury or death reported with the Abbott PCA system remains low.1

Unfortunately, no technique for delivering medication is completely risk free. The LifeCare PCA system is safe and reliable when used as directed, but as with any device its operation is subject to human error. Abbott is concerned about and examines every patient complication involving its PCA system. Following the incident cited by John Doyle and Kim Vicente, Abbott immediately reported the event to the FDA. Independently, we convened a group of practising anesthesia and pain-management experts from academic and private-practice settings to objectively review the potential for human error in operation of the device and to solicit their advice for future improvements. Abbott has endeavoured to further reduce PCA-related errors by improving labelling and by making prefilled syringes available. The company has also developed continuing medical education programs in cooperation with the Institute for Safe Medication Practices.

To further reduce the possibility of error, Abbott developed the PCA III, a next-generation device that will be introduced this year. The new PCA pump will feature numerous safety improvements, including sophisticated, integral bar-code technology that will automatically load information about the drug and drug concentration into the device. This technology addresses the major concern raised by Doyle and Vicente related to inconsistencies between a loaded drug’s actual concentration and the concentration programmed by the clinician. By eliminating the need to program this information, this state-of-the-art technology offers a substantial advance in reducing the risk of medication error.

Charles H. McLeskey
Senior Director, Clinical Development
Abbott Laboratories — Hospital Products Division
Abbott Park, Ill.

Phenylpropanolamine, stroke and hypertension

The US Food and Drug Administration has issued a warning about the danger of phenylpropanolamine (PPA), a decongestant and appetite suppressant that occurs in various over-the-counter and prescription medications, after a report by researchers at Yale University revealed a link between exposure to PPA and strokes in women.1 For the last 20 years, one of the research interests of the Hypertension Group at the Montreal Research Institute has been patients with pseudopheochromocytoma, paroxysmal hypertension in the absence of pheochromocytoma.2 Among many patients referred for this condition were 2 who had experienced hypertensive episodes that were evidently induced by PPA. This spurred me to write an article warning health care professionals about adverse reactions to PPA.1 It would have been desirable for Health Canada to have reacted to this warning at least as quickly as the 2 drug companies who responded to my article. Pennwalt Inc. put emphasis on its slow-release form of PPA, which was supposedly devoid of this effect, and asked me for a retraction.1 Thompson Medical Co. Ltd. tried to defend its marketing of another supposedly innocent PPA isomer.1 I reluctantly wrote a retraction, and I had to admit that fewer hypertension-producing isomers of PPA may be used in North America than in Europe and Australia.4 At that time, I was not aware of further studies indicating that adverse reactions had also been associated with slow-release formulations and with isomers of PPA. The present FDA warning5 and various drugstore announcements of the withdrawal of PPA6 do not make a distinction between different PPA formulations either. It is conceivable that a more proactive response by Health Canada could have prevented the wide use of this potentially dangerous drug for the last 12 years.

Otto Kuchel
Emeritus Professor
Clinical Research Institute
Université de Montréal
Montreal, Que.

References

Correction

The surname of the author of a letter published in the Jan. 9, 2001, issue1 was misspelled: the correct spelling of the author’s name is Paul Swyer.

Reference