

## Correspondance

9. Nicolle LE. Asymptomatic bacteriuria in institutionalized elderly people: evidence and practice [commentary]. *CMAJ* 2000;163(3):285-6.

## [The commentator responds:]

John Miller highlights an important diagnostic challenge. If fever and an acute confusional state are the only presenting signs, when is urinary infection the cause of clinical deterioration in elderly residents of nursing homes? In this situation, although a positive urine culture is necessary to diagnose a urinary infection, it is not sufficient. At any given time as many as 50% of residents without symptoms have a positive urine culture, usually with pyuria, and a positive culture has a low predictive value for symptomatic urinary infection.<sup>1</sup> Unfortunately, in the absence of localizing genitourinary findings such as costovertebral angle tenderness or hematuria, the relatively small proportion of these episodes that are due to urinary infection in the noncatheterized resident cannot be differentiated from episodes due to other causes.<sup>2</sup> In the face of this uncertainty, the practitioner must base the treatment decision for each episode on his or her clinical judgement. The management issue here is not the treatment of asymptomatic bacteriuria, but the diagnosis of symptomatic urinary infection and the lack of specificity of that diagnosis.

A major plea of my commentary is that physicians acknowledge this diagnostic uncertainty and consider a management approach of observation for residents who have only mild or moderate symptoms.<sup>3</sup> In patients who are seriously ill, empiric antimicrobial therapy is certainly appropriate, given the diagnostic limitations. However, further systematic evaluation of diagnostic and management strategies in this population is necessary to identify optimal approaches to care.

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## References

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3. Nicolle LE. Asymptomatic bacteriuria in institutionalized elderly people: evidence and practice [commentary]. *CMAJ* 2000;163(3):285-6.

## Patient-controlled analgesia

Patient-controlled analgesia (PCA) is a computer-based medical technology now used extensively in Canada to treat postoperative pain. A typical PCA machine contains an embedded microcomputer programmed to give, for instance, 1 mg of morphine intravenously every time the patient pushes a button on the end of a cable. To prevent excessive drug administration, the onboard computer ignores further patient demands until a lockout period (usually set for 5-10 minutes) has passed.

Recently, the Institute for Safe Medication Practices reported that a patient had received a lethal morphine overdose while connected to the Abbott Lifecare 4100 PCA Plus II machine.<sup>1</sup> This machine is easily misprogrammed by caregivers, who must manually enter the PCA parameters, and it needs a more sensible and forgiving user interface.<sup>2</sup> A number of patients have received opiate overdoses as a result of PCA errors: insertion of a 5 mg/mL morphine cartridge when the machine is expecting a 1 mg/mL concentration, or acceptance of the default (initial) drug concentration when the correct action is to scroll up to the correct value, among other errors.<sup>3,4</sup>

In 1997, ECRI documented 3 deaths that occurred while patients were connected to the Lifecare 4100.<sup>5</sup> In at least 2 of the cases, the alleged reasons for the deaths were the same. In the mode of operation in use, when nurses program the drug concentration the Lifecare 4100 display shows a particular concentration (e.g., 0.1 mg/mL). Nurses can either accept this initially displayed value or modify it using the arrow controls. The critical flaw in the design is that in this situation the Lifecare 4100

offers the minimal drug concentration as the initial choice. If nurses mistakenly accept the initially displayed minimal value (e.g., 0.1 mg/mL) instead of changing it to the correct (and higher) value (e.g., 2.0 mg/mL), the machine will "think" that the drug is less concentrated than it really is. As a result, it will pump more liquid, and thus more narcotic, into the patient than is desired.

The purpose of this letter is to warn clinicians of continuing fatal drug overdoses from the Abbott Lifecare 4100 PCA Plus II machine. If you use this machine, please contact your risk management officer and your biomedical engineering department for advice. Fortunately, Abbott is not the only supplier of PCA machines.

We have informed American and Canadian regulatory authorities; they are, of course, now studying the problem.

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## References

1. Design flaw predisposes Abbott Lifecare PCA Plus II pump to dangerous medication errors. *ISMP Medication Safety Alert* 2000;5:2. Huntingdon Valley (PA): Institute for Safe Medication Practices; 2000.  
2. Lin L, Isla R, Doniz K, Harkness H, Vicente KJ, Doyle DJ. Applying human factors to the design of medical equipment: patient-controlled analgesia. *J Clin Monit Comput* 1998;14:253-63.  
3. Notcutt W. Overdose of opioid from patient controlled analgesia pumps. *Br J Anaesth* 1992; 68:50.  
4. Grover ER, Heath ML. Patient-controlled analgesia. A serious incident. *Anaesthesia* 1992; 47:402-4.  
5. ECRI. Abbott PCA Plus II patient-controlled analgesia pumps prone to misprogramming resulting in narcotic overinfusions. *Health Devices* 1997;26:389-91.

## [A representative from Abbott Laboratories Inc. responds:]

Patient-controlled analgesia (PCA), introduced by Abbott 17 years ago, inaugurated a new standard for the safe management of pain by simplifying the

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.<sup>1</sup>

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 substan-

tial advance in reducing the risk of medication error.

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1. US Food and Drug Administration. *MedWatch*. Rockville (MD): The Administration; Jul 1997 – Jun 2000.

## 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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. Penwalt Inc. put emphasis on its slow-release form of PPA, which was supposedly devoid of this effect, and asked me for a retraction.<sup>4</sup> Thompson Medical Co. Ltd. tried to defend its marketing of another supposedly innocent PPA isomer.<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> The present FDA warning<sup>1</sup> and various drugstore announcements of the withdrawal of PPA<sup>8</sup> 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.

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#### References

1. FDA issues public health warning on phenylpropanolamine. FDA Talk Paper T00-58; 6 Nov 2000. Available: [www.fda.gov/bbs/topics/ANSWERS/ANS01051.html](http://www.fda.gov/bbs/topics/ANSWERS/ANS01051.html) (accessed 5 Feb 2001).
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7. Bravo LE. Phenylpropanolamine. In: Laragh JH, Brenner BM, editors. *Hypertension: pathophysiology, diagnosis and management*. New York: Raven Press Ltd.; 1990. p. 1911-6.
8. Pharmacie Jean Coutu : message au sujet des médicaments contenant de la phénylpropanolamine. *La Presse* 2000 8 Nov;Sect 1:20.

## Correction

The surname of the author of a letter published in the Jan. 9, 2001, issue<sup>1</sup> was misspelled: the correct spelling of the author's name is Paul Swyer.

#### Reference

1. Swyer P.R. Debate about our youngest doctor continues [letter]. *CMAJ* 2001;164(1):15.