Conference Report

Symposium on ergonomics in drug delivery

Beverley Orser MD PhD FRCPC,
D. John Doyle MD PhD FRCPC,
Larry Futers, Project Manager

THE *Canadian Standards Association* (CSA) Symposium on Ergonomics in Drug Delivery was held on January 21, 1997, at The Michener Institute for Applied Health Sciences in Toronto, Canada. Ergonomics is the engineering discipline that reconciles the design of products and systems with human capabilities and limitations. Inattention to human factors can lead to a misfit between the task, the physical environment, and the people. The impact of human factors is only beginning to be appreciated in the design of medical systems. Therefore, it is not surprising that human error is a major contributing factor to many mishaps in medicine. Human factors contribute to errors during anaesthesia, particularly those associated with the administration of drugs. Drug error is increasingly being recognized as a major cause of morbidity and mortality in patients undergoing anaesthesia and misidentification of ampoules or syringes is often a contributing factor.

In the last year, the CSA has received numerous requests from concerned individuals to address several pressing issues in drug delivery. Most importantly, it was suggested that the CSA develop national standards for the labeling of drug ampoules and vials. In addition, the need for a national standard for Metered Dose Inhaler Spacer Devices was identified. In order to develop an effective standard, it is important that all affected groups be given an opportunity to provide their perspective. Therefore, the purpose of the symposium was not only to educate those who attended, but to determine if new standards are required.

The symposium was attended by individuals representing academia, consumer groups, pharmaceutical and device manufacturers, health care practitioners, and hospital and retail pharmacists. In addition, representatives from both the provincial and federal regulatory authorities attended. The sessions were moderated by Dr. Wayne Taylor, an Associate Professor of Business, Public and Health Policy at McMaster University. The morning discussion was

devoted to ergonomic issues in drug delivery, drug safety in critical care environments, and the design of a "blueprint" for error-proofing pharmaceutical trademarks and labels. Perspectives were provided by the Canadian Anaesthetists' Society, the Canadian Drug Manufacturers Association, the Canadian Nurses Association, Health Canada Drugs Directorate, and other interested organizations. The discussion generated four specific recommendations.

1. Develop a national standard for the labeling of drug ampoules and vials.

It was recommended that the CSA develop a consensus-based national standard for the labeling of drug ampoules and vials. The CSA will start its standards-development work in the Spring of 1997, using the Canadian Society of Hospital Pharmacists Guidelines as the seed document. Working closely with stakeholders, the CSA will work to facilitate the development of a nationally-acceptable, voluntary standard.

2. Establish a national medication error reporting programme.

According to Mr. Michael Cohen, Director of the American Institute for Safe Medication Practices (ISMP), as many as one in every five drugs administered is given in the wrong *dose*, by the wrong *route*, at the wrong *time*, or to the wrong *patient*. Alternatively, the wrong drug is administered. Since the United States Pharmacopoeia (USP) began a voluntary drug error reporting program (known as the USP-Practitioner Reporting Network) in 1991, more than 2,000 reports of actual and potential medication errors have been received. Recurring errors have been identified and efforts made to reduce the likelihood of a recurrence. No similar drug reporting programme exists in Canada. The CSA will determine how a programme, similar to the USP-Practitioner Reporting Network, could be implemented in Canada. They will assess who should be involved in its administration, and what avenues are available for funding.

3. Convey concern regarding the use of line-extensions by pharmaceutical manufacturers to the Drugs Directorate of Health Canada and the appropriate authorities.

"Line-extension" refers to the use of successful brand names in the marketing of other products. A hypothetical example of line-extension is the addition of pseudophedrine to an antihistamine such as diphenhydramine. In the absence of pseudophedrine, the product is labeled "Benadryl" whereas, the product containing pseudophedrine is called "Benadryl-No-Doze Formulation." Such use of similar brand names has lead to confusion among consumers.

4. Develop a safety standard for Metered Dose Inhaler Spacer Devices.

Such a standard would establish minimum design requirements which take into consideration the efficacy of drug delivery.

The Canadian Anaesthetists' Society has a long and credible record for providing national standards. Its recommendations have been used as seed documents for international standards developed by the International Organization for Standardization (ISO). The theory behind consensus standards is simple: the most effective standards are developed by those who will use and benefit from them. This helps to ensure that the final products are accepted and developed in a cost-effective manner.

Individuals interested in providing suggestions or participating on technical committees which will address these recommendations can contact Mr. Larry Futers at the address provided below.

Beverley Orser MD PhD FRCPC
Department of Anaesthesia, Sunnybrook Health
Science Centre, Toronto, Ontario
Email: beverley.orser@utoronto.ca

D. John Doyle MD PhD FRCPC
Department of Anaesthesia, Toronto Hospital,
Toronto, Ontario
Email: djdoyle@compuserve.com

Larry Futers,
Project Manager, Health Care Program,
CSA Standards Development
178 Rexdale Blvd., Etobicoke, Ontario, Canada,
M9W 1R3
Phone: (416) 747-2272; Fax: (416) 747-2473;
E-mail: futersl@csa.ca