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An Evaluation of Proposed Graphical Symbols for Medical Devices

To the Editor:—Graphical symbols often are used on road signs and in public places to rapidly and unambiguously convey information. In places where people may not share a common language (such as the European Community), graphical symbols may be more widely understood than language-specific textual messages. For similar reasons, it has become increasingly common to use graphical symbols on medical devices (both equipment and disposable supplies). The standardization of such symbols would enhance the international use of medical devices by eliminating the need for multiple language versions. The European Committee for Standardization (CEN) recently proposed 11 symbols as European standards for labeling medical equipment and supplies used by anesthesiologists and other medical care providers [CEN TC 257; prEN 980:1992E]. Acceptance of these standard symbols by the European Community likely would result in their *de facto* use on medical devices marketed in the United States.

Therefore, we sought to investigate whether these proposed international symbols effectively conveyed their intended meanings. Two questionnaires were given to experienced anesthesia providers at the University of California San Diego Medical Center. The first questionnaire presented six of the proposed symbols (fig. 1). After giving informed consent, subjects were instructed to write in the space provided beneath each symbol what they thought that symbol meant (*i.e.*, "fill-in" question design). The second questionnaire was similar to the first except that a "matching" question design was used whereby an adjacent list of possible definitions was provided from which the subject was instructed to select the best corresponding meaning for each symbol. The "correct" (*e.g.*, intended) meanings of the six symbols are provided in Table 1 on the next page.

Fourteen experienced anesthesia care providers completed the first questionnaire. Fourteen other care providers who had not seen the first questionnaire completed the second questionnaire. The overall results from the two questionnaires are provided in Table 1.

None of the symbols from the first questionnaire conveyed CEN's intended meaning to more than one-quarter of the subjects. Only three of the symbols (B, C, and D) were matched correctly with CEN's intended meanings by more than three-quarters of those who completed the second questionnaire. These results suggest that the meanings associated with these three symbols, while not obvious at first glance, may be recognized and remembered once an individual has been provided with their meaning. The results also suggest that the meanings of symbols A, E, and F are neither intuitive nor easily recognizable to American anesthesia care providers.

Respondents to both questionnaires more commonly interpreted symbol A to mean "Not 2" or "Do not use #2" rather than "Do not

reuse," its intended meaning. The failure of an anesthesia provider to understand the meaning of this or other graphical symbols could result in adverse consequences for both the provider and the patient.

The full intended meaning of symbol E is "Attention, consult accompanying documents." Unfortunately, this symbol almost universally was interpreted to mean "Warning" or "Attention." This is consistent with its meaning on European road signs. None of the subjects who filled out the first questionnaire wrote anything about consulting accompanying documentation. Furthermore, 13 of the anesthesia providers who completed the matching questionnaire confidently assigned this symbol the meaning "Warning." The single clinician who gave the "correct" response said that he *remembered* that the symbol meant "look in the manual" but that he did not think it was a good symbol to convey this meaning. Interestingly, all of the subjects in this study are exposed on a daily basis in our operating rooms to Nellcor pulse oximeter (Hayward, CA), which has on its control panel this specific symbol with its associated meaning ("Refer to the manual") written below it.

On the other hand, there appears to be some ambiguity in the current use of this symbol on American anesthesia equipment. In our operating room, this symbol, occasionally with an associated

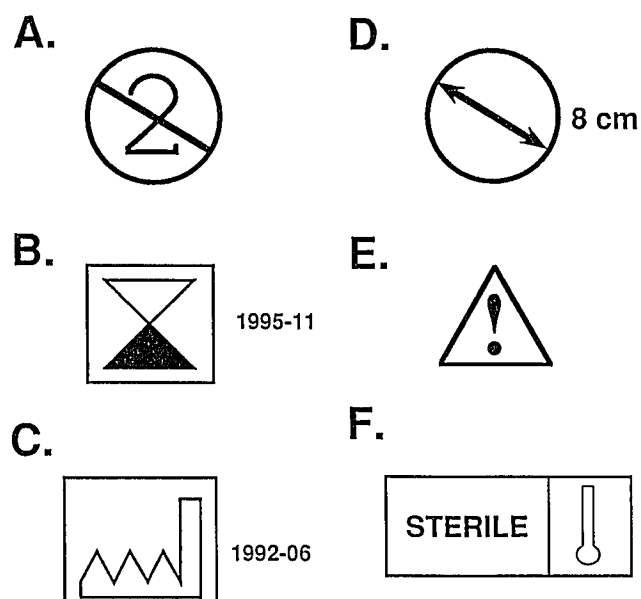


Fig. 1. Proposed European standard graphical symbols for labelling medical devices. Can you identify the intended meaning?

* Weitzner S: Personal communication. 1993.

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Table 1. Results of Symbol Questionnaires

Symbol (Refer to figure 1)	Intended Meaning	Questionnaire 1 ("Fill in") Number (%) Correct	Questionnaire 2 ("Matching") Number (%) Correct
A	Do not reuse	3 (21)	0 (0)
B	Do not use after November 1995	2 (14)	11 (79)
C	Manufactured in June 1992	3 (21)	13 (93)
D	Internal diameter 8 cm	2 (14)	11 (79)
E	See instruction leaflet(s)	0 (0)	1 (7)
F	Must be autoclaved	0 (0)	1 (7)

text warning, was found in multiple locations on a number of pieces of equipment (including Ohmeda Modulus II anesthesia machines and SpaceLabs and Hewlett Packard physiologic monitors). Yet, in only one of these locations was there an instruction to consult accompanying written documentation. Some anesthesia providers normally may respond to a warning symbol by consulting accompanying documents; however, it is unreasonable to expect that all or even most anesthesia providers would do so. We suggest that this symbol only conveys "Warning" or "Attention" and that an additional symbol should be developed to mean "Refer to instruction manual." A symbol containing an arrow pointing to an open book, for example, would more effectively convey this latter message (fig. 2).

Although our subjects recognized the word "Sterile," they misinterpreted the overall intended meaning of the symbol containing it. Only 1 of 28 subjects recognized that the symbol indicated that the device required heat sterilization. The remaining 27 thought that the symbol meant the device already had been sterilized. This kind of confusion could have dire consequences. Two dissimilar symbols for these significantly different meanings are indicated. Ideally, international symbols should not require familiarity with a specific word to convey their meaning.

Based on the results of this brief survey, we conclude that some of CEN's proposed graphical symbols do not effectively convey their intended meaning to American anesthesia care providers. The reasons for this may include cultural differences or perhaps simply lack of

prior exposure. The use of standardized international graphical symbols on medical devices is an excellent idea that, in the long term, will benefit both industry and users. However, the acceptance of CEN's proposed symbols as a European standard at this time may not be in the best interest of the international medical community.

With the assistance of the anesthesia providers who participated in this study, Dr. Roderick Calverley, and M. Ewan Sanko (a local artist with no medical background), we have developed some new symbols that might better convey the meanings intended with the original CEN symbols (fig. 2). These new symbols, like the ones proposed by CEN or other standards bodies, must undergo proper *field testing* before their acceptance.

Developing the best possible medical standards is important because our daily activities will be affected by the equipment and devices that will conform to these standards. The medical standards-making process is a laborious consensus-seeking iterative process that relies on frequent input from manufacturers, users, and regulators. Comments, suggestions, and questions regarding the proposed graphical symbols or other medical standards-making issues can be directed to Steven Cornish of the American National Standards Institute at 212-642-4969 (FAX 212-398-0023). Other medical standards organizations in the United States are the Association for the Advancement of Medical Instrumentation (703-525-4890) and the American Society for Testing and Materials (215-299-5400). Your involvement can make a difference.

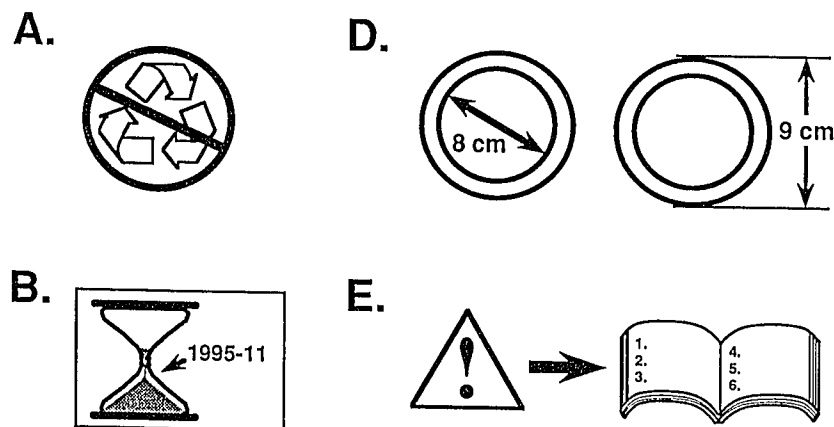


Fig. 2. Possible alternative graphical symbols for labelling medical devices. Letters correspond to symbols in figure 1.

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Ketamine Contains Benzethonium

To the Editor:—For a recent study Malinovsky *et al.* asked, “Is ketamine or its preservative responsible for neurotoxicity in the rabbit?”¹ They concluded, “The appearance of spinal cord lesions after intrathecal chlorobutanol strongly suggests that this preservative is responsible for apparent toxicity of ketamine and therefore should not be used in any solution intrathecally injected into humans.” However, chlorobutanol, which they studied, is not the preservative used in commercial preparations of ketamine available in the United States. Parke-Davis (Morris Plains, NJ) uses benzethonium chloride, up to 0.1 mg/ml, in preparations sold in the United States.* Malinovsky *et al.* studied ketamine solutions formulated in France, which, although also made by Parke-Davis (Courbevoie, France), are prepared differently than those made in the United States.†

Different preservatives probably explain the different findings of neurotoxicity reported in the world-wide literature referenced by Malinovsky *et al.* in their earlier study of ketamine toxicity.² Application, across national boundaries, of results from drug studies always must be interpreted carefully because the same drug, from the same

company, may be prepared and preserved differently in different countries.

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* Ketalar (ketamine hydrochloride) package insert, Revised 1990. Morris Plains, Parke-Davis.

† Rhodes D: Personal communication. 1993.

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In Reply:—The commercial preparation available in France is formulated with chlorobutanol. However, since lesions have been observed in earlier studies using the preparation containing benzethonium chloride, studies also are needed to determine the spinal cord toxicity of ketamine with and without the latter preservative.

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