IMPLEMENTATION OF CANADIAN STANDARDS ASSOCIATION Z168.3-M 1980 ANAESTHETIC GAS MACHINE STANDARD: THE MANITOBA EXPERIENCE

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ABSTRACT

The Province of Manitoba Anaesthetic Machine Program, completed in June 1980, accommodated Canadian Standards Association Standard Z168.3-M1980, "Continuous Flow Inhalation Anesthetic Apparatus (Anesthetic Machines) for Medical Use". The goal of the program was to have all anaesthetic machines in hospitals in the province with the same basic design and safety features: "oxygen right"; characteristic oxygen knob profile; oxygen supply pressure failure device and alarm; standardized "oxygen flush" mechanism; pipeline inlets and pressure gauges; uniform color coding; standardized common gas outlet; pin indexed cylinder yokes; descriptive labels concerning safety devices; check valves within machine piping. Open group-purchase tenders were invited for both machine upgrading and replacement. Of 212 machines surveyed, 127 were upgraded (cost $100,000), 65 were replaced (cost $175,000), three were already satisfactory, and 17 were no longer required and were removed permanently from service. The Manitoba Program provided a satisfactory solution to a most important problem.

IN 1978, Canada became the first country to have a published comprehensive standard for anaesthetic gas machines. Canadian Standards Association (CSA) Standard Z-168.3 "Continuous Flow Inhalation Anaesthetic Apparatus (Anaesthetic Machines) for Medical Use" was published as a preliminary standard in 1978,[1] as a definitive standard in 1980.[2] The standard begins at the point of attachment of the anaesthetic machine to compressed gas sources and ends at the common gas outlet, the point of attachment of anaesthetic circuits.

The rationale for publication of a preliminary standard, as stated in the preface, was twofold. First was a perceived urgency to implement some portions of the standard, particularly the requirement that the oxygen flowmeter be located to the right of the bank of flowmeters. In Canada there was a mixture of anaesthetic machines of British design, with oxygen on the left of the bank of flowmeters, and machines of American design, with oxygen on the right. Second was the need to develop descriptions of a number of test methods and requirements, which were to be included in the definitive version of the standard.

Preceding the preliminary standard by one year was the June 1977 "Advance Standards Information" bulletin titled "Proposed New CSA Standard Z168.3. Anaesthetic Machines"[3] sent to the Canadian Hospital Association by the CSA, and subsequently received by all hospitals in the Province of Manitoba. This bulletin suggested that by July 1978 all anaesthetic machines in Canada should be converted to accommmodate a number of recommendations listed in the bulletin, or should be replaced by new machines. The principal recommendation was that the oxygen flowmeter should be located on the right side of the flowmeter bank on all machines.

Receipt of these recommendations created confusion and concern in those smaller hospitals which had not previously been aware of development of the CSA Standard. A number of hospitals, uncertain about the information they had received, sought the advice of the authors.

This request for assistance led, through a series of steps to be described, to a province-wide program under which by June 1980 all anaesthetic machines in Manitoba hospitals had either been upgraded to meet specified components of CSA Standard Z168.3, or replaced, if upgrading was not feasible. We feel that the Manitoba program offers a logical and manageable solution to a difficult but very important problem, and suggest that this solution may be a useful model for others to consider.

Scope of the upgrading program

It was our view from the outset that an upgrading program which was limited to the recommendations contained in the June 1977 bulletin[3] would be shortsighted. Absent, for example, would have been attention to such important machine components as oxygen supply pressure

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failure protection devices and alarms, oxygen and nitrous oxide pipeline inlets, and the oxygen flush valve. We advised the Manitoba Health Services Commission (MHSC), the agency responsible for the funding of health care programs in the province, that a more appropriate objective would be to undertake a program which assured that every anaesthetic machine in the province would meet certain essential requirements of the CSA Standard. Since the life of anaesthetic machines can be very long, often in excess of 20 years, only a comprehensive program involving all machines at one time would, within this century, be guaranteed to achieve the goal of uniformity of design and safety features for all machines in the province.

The following is a list of the components of the Manitoba anaesthetic machine upgrading program, with the relevant numbered clauses of the CSA Z168.3-M 1980 Standard indicated for information. Where an anaesthetic machine was found to be unsuitable for upgrading, for either mechanical or economic reasons, it was recommended that a replacement machine, meeting the CSA Standard, be acquired.

1. *Oxygen right*

The flowmeter for oxygen must be located at the right extremity of the bank of flowmeters (7.2.4). Only one flow control valve can be provided for each gas supplied to the patient (10.1.1), except that a separate flow control may be used to adjust the flow of oxygen or compressed air to a vaporizer. (Some models formerly had two separate flow controls for oxygen.)

2. *Oxygen downstream*

Where oxygen and other gases are delivered by their respective flowmeters into a common manifold, oxygen must be delivered downstream of all other gases (7.2.3). (This means that oxygen must be the last gas to enter the gas pathway. For machines with the usual left-sided position of the flowmeter block, this clause would be accommodated by item (1) above. If the flowmeter block were located on the right side of the machine, modification would be required to have both the oxygen flowmeter to the right, and oxygen as the last gas to enter the gas pathway.)

3. *Touch coding of oxygen knob*

The oxygen flow control knob must have a specified and unique profile, must not be recessed, and may project beyond the knobs controlling other gases in a bank of flowmeters (10.2.12).

4. *Oxygen supply pressure failure protection device and alarm*

The anaesthetic machine must be fitted with an oxygen supply failure device which, in the presence of a fall to 50 per cent of the normal oxygen supply pressure, will shut off the supply of all other gases, or open the breathing system to atmosphere (14.1.2). The device must sound an alarm when it is activated (14.1.1). The alarm must be a distinctive sound of at least seven seconds' duration (14.2.1). The energy required to operate this alarm must be derived solely from the normal oxygen supply pressure in the line between the cylinder or pipeline inlet on the anaesthetic machine and the oxygen flowmeter controls (14.2.2). There must be a label attached to the anaesthetic machine, stating that it is fitted with an oxygen supply pressure failure protection device and alarm, along with a description of their action and methods of testing them (14.1.4, 14.2.6).

5. *Oxygen Flush Valves*

The anaesthetic machine must be equipped with a manually operated single purpose flush-valve which delivers a limited but unmetered flow of oxygen directly to the common gas outlet (11.1). The valve must not lock in the open position (11.2.1) and must be designed to minimize inadvertent operation by equipment or personnel accidentally pressing against it (11.2.2). The oxygen flush valve control must be clearly marked with the name "oxygen-flush" or the symbol "O_2 flush" or "O_2+" (11.2.5).

6. *Common gas outlet*

A single common gas outlet is to be provided, and must be of specified size and design (13.1). (Some older model units have two common gas outlets.)

7. *Oxygen and nitrous oxide pipeline inlets*

The oxygen and nitrous oxide gas systems must each include pipeline inlets for connection of the anaesthetic machine to hospital pipelines (4.1). These connections must not be interchangeable and must be the appropriate DISS (Diameter Indexed Safety System) nut/nipple (4.2). The pipeline inlets must have pressure gauges, which indicate pressure in pipeline connecting hoses (6.3).

8. *Check valves in anaesthetic machine piping system*

Check valves must be provided which prevent reverse flow of gases from the anaesthetic machine to the hospital pipeline, or to atmosphere from gas cylinder connections (4.4).

9. *Pin indexed cylinder yokes*

Only pin-indexed gas cylinder yokes meeting the requirements of CSA standard B-96-1977 "Compressed Gas Cylinder Gas Valve Outlet and Inlet Connections",[4] are to be employed (5.2).

10. *Colour coding*

When employed, colour coding must conform with Canadian Government Specifications Board GP-12c-1977, "Colour Identification and Selection, Part 1".[5] 10 (oxygen white, nitrous oxide blue).

Program development and implementation

The Manitoba program was designed and implemented through a series of steps involving three principal parties. The authors, as members of the Department of Anaesthesia, Health Sciences Centre, and University of Manitoba, served in an advisory capacity. The Manitoba Health Services Commission (MHSC) sponsored the program. The Manitoba Health Organizations (MHO), a voluntary organization of health institutions in the Province, provided the mechanisms for program implementation. The Manitoba Anaesthetic Machine Program and its development can be described under two general headings (1) Program Development and Government Approval, (2) Program Implementation.

Program development and government approval

In June, 1977, the authors advised the MHSC of the need to consider a provincial program which would accommodate the impending CSA Anaesthetic Machine Standard. Following a series of preliminary meetings between the authors and MHSC staff, a mail survey of all 85 acute care health institutions in the Province of Manitoba was conducted in the summer of 1977. The results of this survey are summarized in the Table. Consultation with the manufacturers and suppliers of the anaesthetic machines then in place in the province allowed a separation of units into those which could be upgraded and those which could not, and would require replacement. Replies for 200 machines were received. It was accepted that a small number of machines had not been accounted for in this preliminary survey. Eighty-nine machines were viewed as suitable for upgrading, 98 were thought to require replacement, six were already satisfactory and seven required further review. The estimated cost of making these changes was $415,000.

With this information, and with the knowledge that the Z168.3 Preliminary Standard would be published in 1978, the MHSC included the anaesthetic machine program in their 1979 budget. This item received government approval and the program was announced by the Minister of Health.

The program approved, while sponsored by MHSC, was voluntary in that individual hospitals had the option to participate, or to act independently. All hospitals elected to take part. Broadly stated the MHSC program had the following components:

(1) The provision of specific recommendations, to individual hospitals, whether each existing anaesthetic machine could be upgraded or whether a replacement machine would be required.

(2) A group purchase arrangement for both the upgrading of machines and purchase of replacements, for those hospitals wishing to participate in such an arrangement. The rationale for the group purchase arrangement was an anticipated saving in comparison to individual purchase arrangements by the various hospitals.

(3) Provision of special funding through MHSC to those hospitals which were unable to fund replacement units from their own budgets. The funding for upgrading of machines was separate, and came from hospital equipment maintenance budgets.

Implementation

A second survey of anaesthetic machines was undertaken in the summer of 1979. This required the direct on-site inspection and testing of every anaesthetic machine in the province. The survey was conducted by one of the authors (JL) who visited each institution, inspected and tested the anaesthetic machines, and took Polaroid photographs of the front and back of each unit.

Following this second survey, there were detailed reviews of each anaesthetic machine by the authors, and subsequently by the authors in meetings with the various manufacturers and suppliers. The result was a new and more reliable separation of the anaesthetic machines into the various categories listed in Table I. An additional

TABLE I

	August 1977		March 1980	
	Number of machines	Estimated cost	Number of machines	Cost
Replace	98	$343,000	65	$175,000
Upgrade*	89	$ 72,000	127	$100,000
Review further	7	?	—	—
Already satisfactory	6	—	3	—
Not required	0	—	17	—
Totals	200	$415,000+	212	$275,000

*Upgrade as required to accommodate items listed in text.

12 machines were surveyed, with a new total of 212. One hundred and twenty-seven were found to be suitable for up-grading, 65 required replacement and three were already satisfactory. Seventeen machines fell into a new and important category of machines not required for further use. These units were disabled and permanently removed from service.

Separate tender documents for upgrading of existing machines and replacement of machines (including the transfer of equipment from existing to new units) were prepared by the MHO, following their standard group purchase and tendering arrangements. Both tenders were submitted to all known interested manufacturers and suppliers. Tenders for upgrading work were returned by the manufacturers or suppliers only for their own units. Five tenders for replacement machines were submitted.

The criteria used in considering the replacement machine tenders were: (a) cost, (b) compatability with existing equipment, (c) declared user preference, (d) local service availability, (e) future availability of replacement parts. The final cost of the replacement machines averaged $2,700 per unit, substantially less than the $3,500 per unit which had been estimated almost three years earlier. The cost of upgrading the 127 units was approximately $100,000.

Following review of the two tenders, orders were placed in January and February 1980. Delivery of new anaesthetic machines and upgrading of existing units began in April of 1980 and were completed in June. At that time every anaesthetic machine in the Province of Manitoba had similar basic design and safety features. In addition, the inventory of anaesthetic machines had been reduced from 212 to 195.

Discussion

We view the Manitoba Anaesthetic Machine Program as an unqualified success. The goal of uniform minimum design and safety features for every anaesthetic machine in the hospitals of the province has been achieved. Each machine now has the same oxygen safety features, with the right-sided location of the oxygen flowmeter, the characteristic profile of the oxygen knob, the presence of an oxygen supply pressure failure device and audible alarm, and the uniform oxygen flush mechanism. Each machine has pipeline inlets and pressure gauges for oxygen and nitrous oxide, thus eliminating the unsatisfactory and hazardous use of the cylinder yokes for connecting to pipelines. Pipeline inlet pressure gauges now indicate pipeline (hose) pressure and only this pressure. In some models machine circuit pressure was indicated on these gauges during use of cylinders, without connection to pipeline.[6] Colour coding is uniform on all machines for oxygen and nitrous-oxide and descriptive labels have been affixed to each machine, as is required by the CSA Standard. The standardized common gas outlet, the presence of check valves within the machine piping and confirmation of cylinder yoke pin indexing are also important contributions to patient safety.

It must be appreciated that an upgraded machine, although having the same features as a new machine, as noted above, is not fully equivalent to new machines which meet the CSA Z168.3 standard. To achieve full equivalency would have required complete stripping of all machine circuitry, leaving only the metal frame, and total rebuilding of the unit with new components. The result would have been an upgrading

cost which approximated or even exceeded the replacement cost. Many of the upgraded machines are relatively new, and basically sound. To have discarded such machines in favour of new units was, in our view, unwarranted. We feel that the Manitoba Program offers an acceptable accommodation of all of the most important requirements of the CSA Standard.

The fact that anaesthetic vaporizers, although included in the CSA Standard, were not part of the Manitoba program requires commentary. Although we recognize that the requirements for vaporizers contained in the standard are important, we feel there is an order-of-magnitude difference in the clinical importance of the basic anaesthetic machine requirements and the requirements relating to vaporizers. In addition, there have been recent changes in the volatile anaesthetic agents in clinical use, and further changes are imminent. Therefore we recommended that the MHSC not include vaporizers in the basic anaesthetic machine program, but rather leave this item for individual hospitals to deal with in the future, as the need arises.

Clause 3.3.1 (Hypoxic Mixture Alarm) of CSA Standard Z168.3-M1980[2] states: "if an anaesthetic machine is equipped with a device to warn the user that an hypoxic gas mixture is being delivered to the patient, that device shall monitor the oxygen content of the gas mixture delivered to the patient and sound an alarm ... if the mixture contains less than 21.0 per cent oxygen." A footnote states the opinion that no anaesthetic machine should be used without such an alarm. It also indicates that a CSA Standard for these devices is in preparation. The Manitoba Program did not include hypoxic mixture alarms. We noted that clause 3.3.1 was not in the form of a mandatory requirement ("shall' or "must"), and also that a CSA Standard is to be published. These facts, plus our detailed knowledge of the Manitoba situation, caused us to advise the M.H.S.C. not to include these devices in the basic Anaesthetic Machine Program. We did, however, point out the need to consider them in the future.

Some commentary about the process by which the program was implemented is in order. To our knowledge, this program is unique. The effective co-operation between the various agencies involved is noteworthy. We think it is remarkable that not one hospital declined to participate in what was clearly presented as a voluntary program. We found consistently that the hospitals were most anxious for recommendations as to how they should react to the CSA Standard, and that they were willing to accept the advice, and to use the available mechanisms to implement the recommendations.

Of all the steps in the program implementation process, there is no question that the single most important step was the on-site visit, with the inspection, testing and photographing of each anaesthetic machine. There were such variations in the anaesthetic machine configuration, even within the same manufacturer's model, that it would have been impossible to predict all that we found. Some units were well in excess of 25 years old, so that manufacturers' records were of no help. The cost of conducting this survey, including ground and air transportation, was approximately $5,000.

We present the two components of the Manitoba Anaesthetic Program as potential models for others to consider. This description of the program content and the process of implementation will, we hope, stimulate others to consider how they will solve the same problems which we faced in Manitoba.

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RÉSUMÉ

Au Manitoba, un programme de modernisation des appareils d'anesthésie pour conformer l'équipement à la norme Z168.3-M1980 de Standard Canada a été complété en juin 1980. L'objectif du programme consistait à modifier tous les appareils d'anesthésie de la province pour obtenir la même disposition de base et les mêmes éléments de sécurité: l'oxygène du côté droit; la forme caractéristique du bouton de contrôle de l'oxygène; un dispositif de prévention en cas de panne dans la canalisation d'alimentation d'oxygène avec une alarme; une soupape de vidange standard pour l'oxygène; des conduites d'alimentation incorporant un manomètre; un code de couleurs uniforme; une sortie de gaz standardisée; un système d'index clés pour les cylindres; des étiquettes descriptives affichant ces dispositifs de sécurité; des soupapes à même les canalisations internes de l'appareil. Des appels d'offre pour achat de groupe ont été suscitées autant pour les améliorations que pour les replacements. Des 212 appareils vérifiés, 127 ont été améliorés (au coût de $100,000), 65 ont été remplacés (au coût de $175,000), trois étaient déjà satisfaisants et 17 n'étaient plus requis et furent retirés du service de façon permanente. Le programme du Manitoba donne une réponse satisfaisante à une question très importante.