

BELGIAN STANDARDS FOR PATIENT SAFETY IN ANESTHESIA AN UPDATE

Belgian Professional Association of Specialists
in Anesthesia and Resuscitation

Belgian Society of Anesthesia and Resuscitation

INTRODUCTION

The present standards and recommendations have been defined by the Belgian anesthesiologists, during their meeting of February 27, 1999. They were prepared by the Belgian Society for Anesthesia and Resuscitation and by the Belgian Professional Association of Specialists in Anesthesia and Resuscitation.

This updated version replaces the standards published in the *Acta Anaesthesiologica Belgica* n° 40 in December 1989, a text also referred to under the name "Safety First".

Standards and recommendations can not replace sound clinical judgement. In circumstances where the application of the standards is not possible, the reason therefore should be reported on the anesthesia record.

Whenever an anesthesia department has trouble obtaining the necessary means for a safe practice, or undergoes undue pressure to proceed without adequate coverage of anesthetized patients by anesthesiologists, we recommend the chief anesthesiologist to call for an independent audit performed by qualified professionals from outside the hospital. Such audit can be organized by the Belgian Society for Anesthesia and Resuscitation and/or by the Belgian Professional Association of Specialists in Anesthesia and Resuscitation. If the hospital management makes it impossible to put these standards into practice, despite a formal written request, we strongly recommend the chief anesthesiologist to call for an external audit to document the problem and the efforts made by the department to comply with the standards.

PART ONE : MINIMAL STANDARDS

Section I : General principles

1.01 The function "Anesthesiology", which is included in the K.B.-A.R. 30.01.1989, automatically implies the existence of an organized department of anesthesiology.

1.02 The accreditation of a hospital depends on the application of minimal standards in anesthesia. These standards are to be met every time a patient undergoes general anesthesia, major regional anesthesia or sedation given by an anesthesiologist for diagnostic or surgical procedures.

1.03 The hospital manager is responsible for the provision of nursing staff, equipment for anesthesia and monitoring, according to the advice of the department of anesthesiology. The hospital manager is also responsible for the effective maintenance of this equipment.

Section II : Departmental organization

1.04 Each department of anesthesiology has a chief-anesthesiologist who is responsible for the organization and coordination of all activities of the department. He must be a physician and fully certified anesthesiologist.

1.05 Staff members in each department of anesthesiology define and apply together a common policy in the interests of the patient.

1.06 The department of anesthesiology must have suitable space for its professional and educational activities and sufficient secretarial support.

Section III : Assistance for the Anesthesiologist: Minimal standards

1.07 The anesthesiologist is always assisted by properly trained nursing staff during induction and emergence periods. During maintenance of anesthesia, assistance is available on demand. This assistance has priority and is given in such a way as to allow the anesthesiologist close contact with the patient, at all times. This also applies to anesthesia care outside the main operating theatre area.

1.08 The department of anesthesiology must request the nursing management to transfer a nurse for reasons of incompetence or unreliability. If this transfer is not made, the anesthesiologist can not be held responsible for the consequences. He will ask the management to notify in writing and justify the decision of a possible refusal.

1.09 A registered technician responsible for the maintenance of ventilators and monitorings and for any other equipment necessary for the practice of anesthesia can be called at any time and must be available at any time.

Section IV : General equipment Minimal standards

1.10 All equipment is in accordance with ISO standards and meets applicable European Union regulations.

1.11 The basic equipment comprises for each anesthesia workstation :

1. A standard anesthesia trolley in the sole form selected by the department of anesthesiology and an anesthesia machine.
2. A suction appliance.
3. Equipment for ventilation with pure oxygen by mask, including a self-filling ventilation balloon, and instrumentation for tracheal intubation, with at least two laryngoscopes.
4. Specific equipment for the adequate lighting of the patient, the anesthesia machine, the anesthesia trolley and the monitoring equipment.
5. Means of communication including :
 - a. a telephone, reserved for the anesthesiologist, placed if possible so that the user may continue to observe the patient and the monitors ;
 - b. an intercom ;
 - c. a "cardiac arrest" call button or any equivalent system to call for help in case of emergency.
6. Electric power points, connected to an emergency supply source of electricity, in sufficient number so as to allow the functioning of all the necessary appliances and monitors.
7. Outlets for medical gases from a central supply. The tubings which connect wall plugs to the anesthesia machine are manufactured and supplied as single pieces, without any detachable components.

1.12 In addition to this basic equipment :

- a. a standard resuscitation cart in the sole form selected by the department of anesthesiology must be available within two minutes. It contains, amongst other things, a defibrillator and an emergency airway access set.
- b. a spare tank of oxygen, cool infusion solutions, ice and a minimum of 240 mg of dantrolene must be quickly available, at all times.

Section V : Monitoring equipment : Minimal standards

1.13 Minimal standard monitoring equipment includes for each anesthesia workstation :

1. An oxygen analyser, incorporating an audible signal to warn of low oxygen concentration, correctly fitted into the breathing system ;
2. When an automatic ventilator is in use :
 - a. a manometer to display the pressure in the breathing system ;
 - b. a pressure alarm system including :
 - a high pressure alarm sounding each time the maximum selected pressure is reached ;
 - a disconnection alarm, indicating that the minimum selected pressure has not been reached in the last twenty seconds. This delay of twenty seconds may be prolonged tem-

porarily but not permanently. The starting and stopping of the alarm system should be independent to the functions of the respirator ;

- c. a device to measure the respiratory frequency continuously ⁽¹⁾ ;
- d. a device to measure the expired gas volume continuously ;
3. A device to measure systolic and diastolic arterial pressure with appropriate sizes of inflatable cuffs ;
4. Equipment to display the electrocardiogram continuously ;
5. Equipment to read the cardiac frequency continuously ;
6. Equipment to measure the body temperature continuously ;
7. A pulse-oximeter with a minimum value alarm setting ;
8. A device to measure the CO₂-concentration of inspiratory and expiratory gases and displaying the tidal curves on a screen, continuously ;
9. A device to continuously measure the concentration of all inhalation anesthetics used in the respiratory system ;
10. A monitor of neuromuscular function ;
11. An anesthesia record, fulfilling the specific requirements of the department of anesthesiology ;
12. Computerized automatic filing of data captured by the patient monitors is recommended.

1.14 In addition to this basic equipment, there must be around the clock facilities in the operating theatres or in the hospital for relevant biochemical and hematological monitoring, including : pH, blood gases, hemoglobin concentration, hematocrit, serum electrolytes, glucose, blood group, blood compatibility, and blood coagulation tests.

Section VI : Transport of the patient

1.15 A battery powered pulse-oximeter and an oxygen delivery system are available.

Section VII : Post-Anesthesia Care Unit (PACU) : Minimal standards

1.16 The minimal standards for the post anesthesia care unit (PACU) are as follows :

1. 1.5 beds per operating room ;
2. One nurse, properly trained and exclusively assigned to the PACU, for each unit of three or less patients in normal conditions of anesthesia recovery ;

⁽¹⁾ In this text the words "continuous" and "continuously" mean without interruption, whereas the words "continual" and "continually" refer to actions which are performed on a regular basis throughout the procedure.

3. A device for ventilation with pure oxygen, including a self-inflatable ventilation balloon and the appropriate equipment for tracheal intubation ;
4. For each patient, the following equipment is available :
 - a. an oxygen delivery system ;
 - b. a suction appliance ;
 - c. a displayed electrocardiogram ;
 - d. a blood pressure measurement device ;
 - e. a device to continuously measure the temperature ;
 - f. a continuous pulse-oximeter (SpO₂), with a lower limit alarm ;
 - g. a respiratory monitor which operates either :
 - by recording expiratory CO₂ concentration (ETCO₂), if the patient is intubated, or,
 - by impedance measurement between ECG electrodes, or,
 - by any other reliable system ;
 - h. Outlets for medical gases from a central supply. All tubings which connect wall plugs to breathing systems are manufactured and supplied as single pieces, without any detachable components ;
 - i. Electric power points, connected to an emergency supply source of electricity, in sufficient number so as to allow the functioning of all the necessary appliances and monitors ;
5. A standard resuscitation cart in the sole form selected by the department of anesthesiology, available within two minutes. It contains, amongst other things, a defibrillator and an emergency airway access set ;
6. The following means of communication :
 - a. a telephone placed so that the user may continue to observe the patients.
 - b. at each bed : an intercom, a "cardiac arrest" call button, or any equivalent system to call for help in case of emergency.

Section VIII : Maintenance of equipment in Anesthesia and PACU

1.17 Systematic control and maintenance is carried out bi-annually for anesthesia machines and respirators and annually for monitoring equipment.

1.18 These duties are undertaken either by commercial firms or by the biotechnical department of the hospital. In both situations, a detailed written maintenance contract is agreed upon. Whenever maintenance is carried out a printed report is provided to the chief-anesthesiologist.

1.19 A label is attached to each appliance, showing the dates of controls, maintenance and repairs, and the date of the next control due. A technical journal of every appliance is kept by the department of anesthesiology.

1.20 The technical department and the hospital pharmacist ensure that the chief of the department of

anesthesiology or his acting deputy is informed of any work carried out on the medical gas distribution system.

1.21 The technical department ensures that the chief of the department of anesthesiology or his acting deputy is informed of any work carried out on the electricity power supply.

PART TWO : SAFETY RECOMMENDATIONS FOR THE PRACTICE OF ANESTHESIA.

Section I : General organization

2.01 The anesthesiologist takes an active role in the setting up of the operating list. The interest of the patient is paramount in the compilation of the list.

2.02 The anesthesiologist ensures that the surgical activity is homogeneously spread over the working hours, in order to make the best possible use of anesthesiologists, nurses and operating theatre facilities.

2.03 The anesthesiologist devotes the necessary time to the induction of and the emergence from anesthesia.

Section II : Preoperative visit

2.04 A preoperative examination of the patient in conjunction with the consultation of the patient's file is essential. Thereafter the anesthesia can be planned in accordance with the patient's particular problems and needs.

2.05 Consequently, the anesthesiologist must be informed of the surgery schedule. This information must be given in good time and at the very latest, the day before the operation.

Section III : Basic controls

2.06 Basic controls comprise :

1. Identity of the patient : before starting, the anesthesiologist ascertains the patient's identity, the scheduled operation and, if relevant, the site of the operation. This control made by the anesthesiologist does not discharge the surgeon from his responsibility for the same control.
2. Drugs : the anesthesiologist verifies the label of all drugs before loading the syringe. If the anesthesiologist is wearing sterile garments, the drug is shown to him in such a way as to allow him to read the label.
3. Syringes : each syringe is labelled with the name of the drug and, if possible, the concentration.
4. Perfusions : each container to which a drug has been added, is clearly labelled with the required information.
5. Transfusions : for all preparations supplied by the blood bank for which the compatibility with the patient needs to be tested, the anesthesiologist ascertains whether this test has been done. Before con-

necting the blood bank product to the patient's perfusion set, the anesthesiologist notes on the anesthesia record the references of the patient's blood group and those of the blood bank container.

6. Before starting the first case of the day, the anesthesiologist checks the equipment and completes a printed checklist made for that purpose.
Before starting each anesthesia or sedation, the anesthesiologist checks :
 - the oxygen supply,
 - the artificial ventilation systems, means of intubation and suction equipment,
 - the presence of emergency drugs on the anesthesia trolley.
7. Prior to general anesthesia, all patients are preoxygenated, except when this is contraindicated ; verification is made that the effects of the inhaled gas are those of oxygen and not of nitrous oxide.

Section IV : Intra-operative patient control

2.07 From the beginning of the anesthesia to the transfer to the post-anesthesia care unit or to the intensive care unit, an anesthesiologist attends the patient in close vicinity. This attendance is continuous. The anesthesiologist continually monitors the patient's condition and tailors the anesthesia to the patients' particular needs.

2.08 When several anesthesiologists take care of one patient at the same time, one of them is specifically designated to conduct the anesthesia and to be formally responsible for the patient's safety.

2.09 Except in cases of vital emergencies, simultaneous anesthesia are forbidden. (Simultaneous anesthesia means the simultaneous administration of narcotics to more than one patient).

The anesthesiologist in charge of the patient remains continuously with him. If by exception to the above-mentioned rule the anesthesiologist must leave his patient for a short time, he will designate a skilled person who will ensure this surveillance to the exclusion of any other activity during his absence. This surveillance remains the sole responsibility of the anesthesiologist in charge of the patient.

2.10 When primary responsibility for the anesthesia is handed over to another anesthesiologist, that anesthesiologist is made aware of all relevant information concerning the patient, the conduct of the anesthesia and the apparatus used. The patient's condition and the proper functioning of the apparatus is checked before and after the hand over, and this is noted on the anesthesia record.

2.11 If the doctor in charge is a trainee the degree of supervision by a qualified specialist which he requires is in accordance with his level of competence and the complexity of the case.

2.12 Clinical observation by the anesthesiologist is of the utmost importance. For this, access to some part of the patient's body is required. If, in particular circum-

stances, this access does not exist, the reasons are noted on the anesthesia record. Other causes making clinical observation impossible are also noted.

2.13 As far as indicated and technically possible, the continual clinical monitoring of the patient throughout the anesthesia comprises the observation of :

1. Ventilation. Auscultation of breathing sounds is performed when necessary.
2. Circulation. This includes peripheral pulse and heart sounds when necessary.
3. Mucosae, and/or feeling of the skin, including at the extremities.
4. Urinary flow.
5. Surgical field.

2.14 Whenever the patient's position is changed, the anesthesiologist proceeds to a complete verification of equipment and clinical observation, before allowing surgery to be started or resumed.

Section V : Transport of the patient

2.15 After general anesthesia, sedation or major regional blocks, transfer of the patient to the post-anesthesia care unit or the intensive care unit is done with oxygen administration and with pulse oximetry (SpO_2), in accordance to the patient's needs and the duration of the journey.

Section VI : Post-Anesthesia Care Unit (PACU)

2.16 Supervision of the patient in the PACU is delegated to nurses, properly trained and exclusively assigned to the PACU. However an anesthesiologist is available at all times.

The responsibility of the Post-Anesthesia Care Unit belongs to an anesthesiologist, member of the anesthesia department.

Section VII : Anesthesia records

2.17 The anesthesiologist records the preoperative examination, the anesthesia and the post anesthesia phases by completing the appropriate printed forms. These anesthesia records are added to the patient's file.

2.18 All the documents are clear, complete, accurate and readable.

2.19 All automated printed records from monitoring equipment are considered as part of the anesthesia records and are safely retained.

2.20 Circumstances may arise which prevent the anesthesiologist from completing the records on the spot. Short notes of events and times will then help the anesthesiologist to fully report the case at a later and quieter moment.

2.21 If severe complications arise, the unfolding of events is described with the greatest precision, without stating any responsibility there may be.

Section VIII : Quality control

2.22 For all cases in which unexpected clinical events have arisen, which could have been or have been harmful to the patient, a complementary report is prepared.

2.23 Such reports, which may be filed anonymously, are discussed during staff-meetings.

2.24 The patient is seen postoperatively by an anesthesiologist in order to ascertain his degree of satisfaction or otherwise with the anesthesia and any side effects he may have experienced.

Section IX : Continuing medical education

2.25 The anesthesiologist takes part in a continuing educational programme, for which certification is given.

Accreditation according to the national system is strongly recommended.

This programme involves attendance at national and international meetings, seminars and courses. It may also include periods of practice in an established teaching department.

2.26 Appropriate study leave is provided for this purpose, and the hospital administration understands that it is the hospital and ultimately the patients who will be the beneficiaries of this continuing educational programme.

2.27 The scientific society sets up a yearly scientific program allowing to satisfy the annual requirements for national accreditation.

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