

# Organisational, technological and structural standards for office based ambulatory surgery and day surgery

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Received 1 September 1998; accepted 1 January 1999

## Abstract

In April 1996, the National Agency for Regional Health Care Services elaborated guidelines for the diffusion of day surgery, which have been the reference for many regions. One of the major problems to deal with has been the definitions of office based ambulatory surgery and day surgery, that have been introduced to distinguish the activities that could be performed in the offices of surgeons (within/outside hospitals) and the activities performed in the hospital setting. Once this separation was proposed, the organizational, technological and structural standards of both models were determined, to guide the development or to regulate these activities in the country. © 1999 Elsevier Science B.V. All rights reserved.

*Keywords:* Office based ambulatory surgery; Day surgery; Standards

## 1. Introduction

In the last 5 years, there has been an enormous increase in interest in day surgery in Italy, due to an aging population, new patterns of diseases and advances in diagnostic and therapeutic techniques, which have determined the growth of hospital beds dedicated to rehabilitation and long-term care, the growth of home care and day care services and the decrease of acute beds. At the same time, an in-depth reorganization of the hospital network has begun. This is to be completed by 31 December 1999. It will take into account the type and quality of activities and services necessary in individual areas thus allowing:

1. the identification of the hospital services for acute and post-acute patients and community residential and long-term care for patients with chronic disease;
2. the continuity of treatment by closer cooperation between hospitals and community services.

As regards the hospital sector, the goal will be to create a hospital network in which the principle of concentrating the more complex, but less frequent services, in fewer hospitals is associated with the principle

of decentralization, to ensure that the population need not travel too far to obtain essential services. This process is ongoing in many countries, with the consequent closing or conversion of some small hospitals, in which certain services, including day surgery, can be concentrated. The move to day surgery implies a great change in the surgical area, with the number of hospital beds kept lower than traditionally but occupied, in part, by more serious and complex cases and in part, by patients that can be treated during the day. This can only be brought about by a radical reorganization of the surgical services from a structural, technological and organizational point of view.

## 2. Definition

These definitions are based on the patients' conditions and the elective procedures to be performed, the dividing line being the necessity for admission to the hospital

*Office based ambulatory surgery* is the clinical, organisational and administrative ability to perform surgery or diagnostic procedures, both invasive and semi-invasive, in an office setting, under local anaesthesia, analgesia or sedation.

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*Day surgery* is the clinical, organisational and administrative ability to perform surgery, diagnostic or therapeutic procedures, both invasive and semi-invasive, with hospitalisation limited to one working day, or with overnight stay, under local, loco-regional or general anaesthesia.

The activities covered by office based ambulatory surgery and day surgery refer to selected surgical, diagnostic and therapeutic procedures.

### 3. Office based ambulatory surgery

#### 3.1. Locations

The services of office based ambulatory surgery can be offered, depending on their complexity, in the following locations:

1. offices;
2. protected offices.

The standards which follow refer to both structures, the latter operating within public or private hospitals.

#### 3.2. Minimum organisational standards

To record the operations and procedures performed, an ambulatory register is used to note:

- patient identification;
- diagnosis;
- names and qualification of the personnel;
- surgery undertaken;
- anaesthesia, analgesia, sedation used;
- time of initiation and end of the procedure;
- pain relief techniques administered;
- any immediate complications.

##### 3.2.1. The clinical record

A specific clinical record for each patient includes:

- diagnosis;
- type of surgery performed;
- course of the surgery;
- type of therapies given and prescribed;
- sedation and pain relief techniques;
- complications.

##### 3.2.2. Protocols for admission, treatment and discharge of the patient

Specific protocols for admission, treatment and discharge of the patient must be prepared. The assessment of the patient must be based on clinical evaluation, general condition, age, social and family background.

A discharge report for the general practitioner must be completed, containing all the information related to the surgery and procedures performed, in addition to the prescribed therapies.

##### 3.2.3. Personnel

An adequate number of medical and nursing personnel, in keeping with the number of patients and types of surgery offered, is needed.

The physician responsible for the procedures undertaken must possess relevant proven experience, with a case documentation of surgery performed in public or private offices.

Surgeons who do not possess such qualifications can be used as assistant surgeons if directly assisted by a colleague with the above mentioned qualifications.

##### 3.2.4. Quality control

Efficient control (by the competent authorities who issued the authorisation) of the activities undertaken is necessary to assess the quality of care and give directives that facilitate both medical and organisational decisions. To this aim several parameters should be monitored according to the following principals.

##### 3.2.5. Monitoring activity

Daily registration and recording of the opening times of the ambulatory unit and the number and type of the procedures performed is essential. Clinical records, with the protocols of admission, treatment and discharge of the patients, must be filed and readily available.

##### 3.2.6. Monitoring complications

The number and type of complications that caused hospitalisation of the patient following surgery must be recorded in a specific register, together with the number and the cause of those requiring urgent care.

An annual report summarising the monitored data must be prepared by the head of the office and made available to the authorities.

##### 3.2.7. Follow-up

Specific protocols for the follow-up of patients must be applied.

### 3.3. Technological standards

#### 3.3.1. Standards of equipment

Every office must be furnished with the following equipment:

- adequate operating table, scialytic lamp, dressings, instruments
- steriliser (where an external service is not available);
- manual ventilator, face masks and Guedel tubes;
- minimum equipment for surgical/medical emergencies;
- semi-automatic defibrillator.

The operating team must have all the materials necessary for the treatment and observation of the patients and must have immediate pre-, per- and post-operative access.

The materials must be of a suitable quality, in compliance with the number and type of operations.

The materials, drugs and equipment necessary for the treatment of possible complications must be readily available.

In larger offices with many specialties, the amount of equipment and drugs must be related to the volume of services offered.

### 3.4. Radiology

Basic instruments:

1. A basic radiodiagnostic unit, including:

- Three-phase AT generator;
- Folding table, preferably with remote control;
- Brightness intensifier with chain TV;
- Radiogenic tube with double fire and rotating anode with the possibility of stratification where remote control is not present;
- Potter Buchy;
- Teleradiograph;
- Dark room with an automatic developer, with an adequate number of radiological cassettes with reinforced screens.

2. Ultrasound scanner with:

- Colour Doppler;
- Probe for internal use;
- Superficial probe;
- Endo-cavitary probe (vaginal-rectal);
- Biopsy set.

3. Semi-automatic defibrillator.

4. Optional equipment:

- Mammography unit;
- Scanner;
- Equipment for vascular and cardiovascular diagnosis.

#### 3.4.1. Climatisation and illumination

The climatisation and illumination standards prescribed by national law, must be respected, in particular those referring to specific areas, such as the operating theatre and adjoining rooms.

### 3.5. Structural standards

#### 3.5.1. Accessibility

The offices in which surgery, diagnostic procedures and therapies, both invasive and semi-invasive, are performed must be located in areas easily accessible from outside.

Private offices, that are not part of a hospital or clinic, must occupy buildings or parts of buildings separate from any other use, residential or other.

#### 3.5.2. Minimum facilities

The following areas are requested:

- Waiting room;
- Toilets for personnel and patients;
- Registration/secretarial area;
- Examination room and ambulatory procedure room;
- Post-operative care (recovery area) compatible with the type of operation or therapy performed;
- Clean and dirty storage area.

#### 3.5.3. Theatre

The theatre must have an area of  $\geq 16 \text{ m}^2$  to allow both diagnostic and therapeutic activities, in particular:

- support to the patient;
- identification and illumination of the anatomical areas;
- continuous surveillance of the physiological parameters and the equipment, to assure their retrieval and upkeep;
- to undertake the operations;
- application and control of local anaesthetic;
- resuscitation.

The areas of the office used for surgery cannot be used for other purposes.

If ionising radiation is used, the uniformity of the prescription must be guaranteed, as foreseen in DL 230/95.

## 4. Day surgery

### 4.1. Location and organisational patterns

The activities of day surgery can follow three organisational models:

(A) An independent (free-standing) unit for day surgery composed of reception, beds, operating theatre, administrative offices and other services. These units have their own premises, equipment and personnel and are, therefore, independent from a structural, administrative and operational point of view.

(B) A multidisciplinary or monospecialist unit within a hospital, dedicated exclusively to day surgery, where the main operating theatres are used during particular hours or shifts *or* day surgery has exclusive use of operating theatres that must be near the wards.

(C) Hospital beds within an ordinary ward of general or surgical hospitals. This model permits day surgery even in hospitals with a smaller patient flow. The main operating theatres are used on specific days or in shifts.

### 4.2. Organisational standards

#### 4.2.1. Internal regulations

Every independent unit is governed by a set of regulations.

The regulations must be approved by the hospital in cases where the unit operates within a larger public structure.

Independent units, which are run privately, must submit their regulations to the competent authorities for approval.

#### 4.2.2. *Independent units (free-standing units)*

The independent units must:

- Submit to the authorities a list of the services they intend to offer, with an estimation of the number of monthly and annual procedures;
- Have the back-up and equipment necessary to immediately and effectively assist patients with complications;
- Formalise a written transfer agreement with a nearby hospital or clinic to guarantee the inpatient care of patients with complications when required;
- Guarantee use of a blood-bank in keeping with the type of surgery performed (as indicated in the decree 1/9/95 which regulates the relationship between public institutions which offer transfusion services and those, both public and private, accredited or not, who possess refrigerated blood banks);
- Guarantee a doctor on call 24 h;

The agreement with the hospital must include:

- A list of the procedures most frequently performed in the independent units;
- The definition of the organisational procedures for admission of patients in need of emergency care;
- The duty to provide all clinical information relative to patients admitted for complications or emergency care;
- The type of agreement between the two structures relative to the possible use of specialist or diagnostic services (laboratory analysis, radiology, cardiology, etc.)

All these points must have written documentation and be readily available.

Any overnight care must be provided exclusively in public or private hospitals.

#### 4.2.3. *Regulations for admission, treatment and discharge*

Specific protocols for admission, treatment and discharge of patients must be available.

Admission procedures for patients must be defined based on clinical evaluation, general health, age, family and social background.

The operations performed must be recorded in a specific register together with:

- identification of the patient;
- diagnosis;
- names and qualification of the personnel;
- procedures performed;

- the time of the beginning and end of the procedure;
- sedation techniques used;
- type of anaesthetic;
- any untoward event;
- immediate complications;
- details of any pathology specimens.

Every patient must have a clinical file, which includes the surgeon's and anaesthetist's reports and the post-operative records.

The discharge report for the general practitioner must contain all the elements relative to the treatment and procedures performed together with any therapeutic recommendations and proposed follow up.

#### 4.2.4. *Physician on call*

There must be a physician on call 24 h a day.

The way in which the physicians on call are organised must be made known to the patients and provided in writing at discharge.

In case of need, the physician on call must assure the hospitalisation of patients in structures associated with the day surgery unit.

#### 4.2.5. *Personnel*

The number and qualification of the personnel must be in keeping with the type and number of procedures performed.

#### 4.2.6. *Minimum levels*

A physician and a nurse must always be present during the working hours of the day surgery unit.

A responsible physician, an anaesthetist/resuscitator and a ward nurse (or nurse with at least 3 years experience in the operating theatre) must be present during the surgical activity of the unit. A scrub nurse and an assistant nurse are needed for each operating theatre.

#### 4.2.7. *Staff and their qualifications*

4.2.7.1. *Medical personnel.* The medical personnel must have the following professional qualifications.

The physicians of each speciality included in the day surgery program must have proven experience in the area in which they will be working, with a documented case history of the procedures performed as primary surgeon, in either public or private institutions.

Physicians who do not have these qualifications may operate as second surgeon, or as primary surgeon if directly assisted by a colleague with the above mentioned qualifications.

The anaesthetists/resuscitators must be specialist trained and have a documented record of at least 3 years experience in a public or private institution.

Specific experience is recommended for performing general anaesthesia on children.

*4.2.7.2. Nursing staff.* The nursing staff must possess a professional nursing diploma and the operating theatre staff must have documented experience and be trained in this field.

A senior ward nurse, responsible for the services, is foreseen in all the organisational models.

The ward nurse must be able to hold a management position.

*4.2.7.3. Technicians.* If radiology or other specialist services are foreseen, the personnel must be in possession of the relevant diplomas required by law.

#### *4.2.8. Responsible figures and their relative duties*

For each independent (free-standing) day surgery unit, there must be:

1. a person responsible for management and administration;
2. a ward nurse (or professional nurse, with at least 3 years experience in the operating theatre) responsible for the activities of the operating theatre, hospitalisation of the patients and admission/discharge procedures.

Co-operation between the different persons with different responsibilities for the unit is essential:

- to define the regulations;
- to define the organisational pattern of the unit;
- to establish guidelines for the treatment of patients;
- to propose plans for continuing education and re-qualification of the personnel;
- to prepare the annual report of the day surgery unit activity;
- to adopt methods for the periodic evaluation of the quality of the services offered;
- to assess the appropriate utilisation of the human and technological resources.

The person responsible for the administration and management of the independent unit and that of the mono- or multi-speciality unit:

- manages the available economic resources;
- programs the resource needs during the year;
- participates in the definition of the operational protocols;
- participates in the formulation of the regulations.

The ward nurse (or professional nurse) is responsible for the activities of the operating theatre and in particular:

- is responsible for the admission/discharge procedures;
- is responsible for planning and co-ordinating the care given to patients;

- co-ordinates the services offered;
- controls the risk of infection;
- gathers data on the activity of the services;
- participates in formulating the operational protocols;
- collaborates in the formulation of the methods of evaluation of the quality of the services given;
- manages the waiting list;
- participates in the formulation of the regulations, etc.

#### *4.2.9. Quality control*

The realisation of a safe and efficient day surgery programme depends on the collaboration of all the personnel, who must be aware of the aims and organisation of the unit in which the programme operates.

Efficient control of the activities undertaken is necessary to assess the quality of the services and direct decisions, both medical and organisational. For this reason, several parameters should be monitored according to the following principles.

#### *4.2.10. Waiting list*

1. A register, available to the public, shows possible waiting times.
2. A person is made responsible for the list.
3. The criteria by which the list operates must be made known.
4. The patient must be informed of his/her position on the list and possible waiting times.
5. Cancellations or patients who fail to present for the operation must be recorded.

#### *4.2.11. Monitoring activity*

A person is placed in charge of the register of operations. The clinical records are checked and updated daily. The working hours of the operating theatres are recorded, along with the number and type of procedures performed.

#### *4.2.12. Monitoring complications and follow-up*

Patients that are not discharged, those in need of re-admission following treatment and the number and nature of urgent calls, must be recorded in a specific register.

An annual report is compiled on the activities undertaken and the results obtained by the day surgery unit.

A written programme for the follow-up of the patients is mandatory.

#### *4.2.13. Management, quality evaluation and improvement*

Medical clinical audit is important for an evaluation of the quality of the service. In particular, protocols and guidelines referring to the more important technical procedures must be available along with service documents, updated for the principal support systems.

#### 4.2.14. Information systems

An information system is necessary to gather data from the clinical records and operating registers, for the control and evaluation, both internal and external, of the activities and services offered.

### 4.3. Technological standards

#### 4.3.1. Instrumentation

As standard, the following instrumentation is required.

#### 4.3.2. Operating theatre

- operating table;
- anaesthetic machine with spirometer alarm for disconnection of the patient from the automatic respirator; monitor for oxygen concentration; gas evacuation system; spirometer; cardiac, blood pressure and pulse monitor;
- system of extraction of anaesthetic gases linked directly to the anaesthetic machine;
- diathermy equipment;
- separate surgical and bronchial aspirators;
- scalytic lamp;
- wall diaphanoscope;
- trolleys;
- pulse oximeter;
- heart monitor with defibrillator;
- refrigerators for the storage of drugs and blood derivatives (can be located in adjacent rooms);
- autoclave for rapid sterilisation, linked directly with the operating theatre (where a centralised service is not available);
- appropriate instruments and materials for the types of operation.

#### 4.3.3. Recovery room

- oxygen supply;
- monitor systems including: multifunctional electrocardiograph (temperature and respiration), non-invasive instruments to measure blood pressure, oxygen saturation meter;
- aspirator for bronchoaspiration.

#### 4.3.4. Endoscopic room

- esophagogastroduodenoscope
- colonoscope
- lamp
- aspirator
- diathermy equipment
- stomach pump
- forceps for biopsy
- needles

- handles for polypectomies
- mechanical dilators
- trolley for cardio-respiratory emergencies and defibrillator (if not present in adjoining rooms);
- digital pulse oximeter.

#### 4.3.5. Radiology

In addition to the equipment already listed for the ambulatory unit, in case of specific vascular procedures, the following equipment must be present:

Vascular radiological and surgical equipment including:

- digital angiograph;
- arteriophlebograph;
- folding table with digital serigraph;
- automatic injector.

## 5. General and specific technological standards

The technological standards are the same as those required for hospital wards and operating theatres.

### 5.1. Structural standards

#### 5.1.1. Accessibility

The distribution of the various areas in the unit must be functional, allowing rational movement of patients, personnel and equipment. In particular:

- for a unit located within a hospital, particular attention must be made to differentiate the flows of in-patients from those of day surgery patients;
- for independent units, parking area must be adequate;
- drop-off and pick-up point for patients by entrance to day unit.

### 5.2. Minimum requirements for location

#### 5.2.1. Independent (free-standing) units

In independent (free-standing) units, the number of rooms and areas must be adequate for the volume of services offered.

Separate areas are foreseen for admission/prehospitalization, surgery, recovery and support of the patient in order to ensure:

- reception of the patient and accompanying persons;
- preparation of the patient for surgery;
- observation of the patient in the immediate post-operative phase;
- the privacy and comfort of the patient;
- the preparation of the operating theatre personnel.

#### 5.2.2. Standard areas

- waiting area;
- information, admission and secretarial desk;

- changing rooms for personnel;
- toilets for personnel;
- preparation area for the patient;
- changing area for the surgeons;
- operating theatre for every ten beds (this may vary according to case mix);
- endoscopic area with endoscopic room and separate area for washing and disinfecting of the instruments;
- recovery room;
- dirty and clean utility rooms for each theatre;
- sterile storage;
- equipment storage;
- visiting room;
- wards with services;
- toilets for patients (include one toilet for disabled patients);
- clean storage area;
- dirty storage area;
- medical records room;
- area for administration and recording data;
- staff room.

#### 5.2.3. Other areas (not compulsory)

- radiology (diagnostic and surgical);
- medical day case area;
- equipment storage.

#### 5.2.4. The operating theatre complex

In the complex, the following functions must be assured:

1. preparation of the patient for surgery;
2. surgery itself (undertaken in the protected zone);

3. immediate post-operative observance area;
4. recovery from the anaesthesia and resumption of vital functions;
5. preparation of the personnel according to the rules of hygiene and asepsis;
6. immediate availability of instruments, materials and drugs necessary to resume vital functions.

#### 5.2.5. The protected zone

Inside the operating theatre complex, the protected zone in which the operations and procedures are performed, must be clearly visible and well defined.

The operating theatre must have an area that allows a team of 2–4 persons to operate and must not be smaller than 20 m<sup>2</sup>.

#### 5.2.6. Endoscopic area

The endoscopic room must have sufficient space for the endoscopic examinations (bronchoscope, digestive endoscopy, etc.) and must not be smaller than 20 m<sup>2</sup>.

There must be a separate area for the washing and sterilisation of instruments.

One endoscopic room must be available for every 1000 examinations performed in a year.

#### 5.2.7. Radiology

The radiology area must have sufficient space for both diagnostic and surgical procedures and have separate areas for the treatment of radioactive materials, storage of radioactive material, a storage area for contrast liquids and a changing area for the patients.