SIAARTI-SARNePI Clinical-Organizational Standards for paediatric anaesthesia


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** SARNePI member

1. **Aim and field of application**

This document was drawn up by a Joint Committee of two Italian scientific societies: SIAARTI (Società Italiana di Anestesia, Rianimazione e Terapia Intensiva) and SARNePI (Società Italiana di Anestesia, Rianimazione Neonatale e Pediatrica). It sets out the clinical standards aimed at limiting the risk of major complications during general or regional anaesthesia, or deep sedation, in children. These standards are based on analysis of the literature and the expertise of the Committee members. The document will be regularly updated in the light of future scientific evidence and the recommended process of centralization of children’s care.

2. **To whom the document is addressed**

The document is intended for anaesthetists who have a regular commitment to paediatric anaesthesia or those with occasional paediatric practice. The standards proposed should also be helpful for hospital managers in scheduling paediatric surgery for the different specialities.

3. **Content**

3.1 **Background**

3.1.1 **Incidents in anaesthesia and risk factors**
The incidence of major critical events, with risk of death, cardiac arrest, or serious long lasting neurologic damage is significantly higher in children undergoing anaesthesia than in adults (1-3). The following risk factors for major critical events have been identified (4-6):

i. The child’s age, particularly under the age of one year, and even greater risk under one month;

ii. The co-morbidity and severity of the acute pathology (ASA ≥ III);

iii. The operator(s)’ experience;

iv. The level of emergency/urgency.

Premature babies requiring anaesthesia are the paediatric population at greatest risk, and their mortality is approximately double that of term infants (7-11).

3.1.2 Competencies in paediatric anaesthesia

The literature illustrates the correlation between the number of anaesthetics performed by each individual anaesthetist and the complications, in adults (12) and children (13). Auroy et al. reported that fewer than 200 anaesthetics/year doubled the rate of critical events in children (14), and Zgleszewsky et al. (6) found an inverse correlation between the number of days spent on paediatric anaesthesia and the risk of peri-operative cardiac arrest. These figures have served to propose a minimum number of anaesthetics administered per year by each anaesthetist in order to maintain his/her paediatric anaesthesiology skills (15). Some European countries recommend solutions such as having two anaesthetists in attendance at induction and awakening, for the smallest children. In France, children under the age of three years are treated only in centralized specialized hospitals (16). In the USA, the specific features of paediatric anaesthesiology have led to the recognition of a sub-speciality in this area, and some Northern European countries run ad hoc university and post-graduate training courses.

3.1.3 Paediatric surgical admissions in Italy

To enable us to draw up a picture of paediatric anaesthesia in Italy, the Ministry of Health was asked to provide a database of hospital discharges after in-patient or day-case surgery, for the population under the age of 18 years, in 2014. The data were then statistically analysed by the Istituto Superiore di Sanità
(National Institute of Health). The figures do not include sedation or anaesthesia for diagnostic or therapeutic procedures that did not lead to a surgical diagnosis-related group (DRG): endoscopy, radiological investigations, etc. Analysis of this data indicated that 68% of patients aged less than 18 years were inappropriately admitted to adult wards. The figure was lower (41%) for children aged three years or less, and 30% for those younger than one year, but these inappropriate admissions are still unacceptably high (Appendix 1). The Code for the Rights of Minors to Health and healthcare services, issued by the Italian Ministry of Health in 2012, specifies that children should always be cared for in paediatric departments (17). These figures also highlighted the extreme fragmentation of paediatric care in Italy, which is dealt with in no fewer than 875 centres, though with significant differences from one Region to another. This exposes children to the potential of additional risks resulting from the limited experience of the healthcare teams in hospitals with small paediatric caseload. In terms of risk management this splintered organization is considered a ‘latent or system error’ and can raise the likelihood of adverse events.

3.1.4 Regional paediatric network

As part of the overall design for the hospital network, Law no. 135 dated 7 August 2012 specifies the division into pathology networks, and makes reference to a specific paediatric network, to be organized by the Regions. Appendix 2 illustrates a proposal for the organization of a network of paediatric hospitals, on the basis of the *Hub&Spoke* model, in accordance with the details of the law (18), which specify concentrating the most complex cases in a limited number of “hubs” – hospitals which will work closely with the peripheral “spokes”.

3.2. Clinical-organizational standards for paediatric anaesthesia

Based on the above discussed points, the SIAARTI-SARNePI Committee proposes the following clinical standards for paediatric anaesthesia, which takes into account of the complexity of the situation in Italy and which will have to be updated in the future in the light of the most recent knowledge and the changes of the organizational patterns.
1. All children should always be assigned to paediatric departments where they will receive care in dedicated areas, in the pre-admission zone and in the surgical block. Paediatric operating lists must be separate from those for adults, and children must be managed by dedicated staff with specific paediatric experience.

2. Paediatric anaesthesia should be part of a paediatric care network organized in three levels of hospitals (Base Spoke, Levels I Spoke and Level II Spoke or Hub) (Appendix 2). The main points in the network are:
   a. **centralization** towards higher level of Paediatric Care: the decisive points are the patient’s age, ASA classification, the availability of specialized paediatric anaesthetists (discussed in section 3), and the complexity of the operation (see flow charts in Figs 1 and 2).
   b. An efficient **transport system** able to ensure prompt, safe transfer to the most appropriate centre.
   c. Adequate training for the **management of paediatric emergencies and urgencies**, especially in spoke hospitals where there is no specialist in paediatric anaesthesia or paediatric intensivist, following a dedicated protocol, agreed with the strategic management.

As required by a law dated 30 December 2004, a paediatric care network should be set up, on a regional or supra-regional basis, on the *Hub&Spoke* model, where there is not yet one active.
(*) Individual anesthetist’s minimum experience:
• 150 anesthetics/year for children < 10 years, of which:
  - 40 anesthetics/year for children < 3 years
  - 10 anesthetics/year for children < 6 months

Figure 1 – Organizational flow chart for paediatric anaesthesia for elective surgery.

Figure 2 – Organizational flow chart for centralising pediatric anesthesiology in emergency/urgency situations
3. The hospitals where paediatric surgery is performed should prepare an operating procedure, agreed by the head of the Anaesthesia and Intensive Care Department and the Hospital Management, mentioning the minimum number of anaesthetics administered that are considered necessary to maintain the skills of the paediatric care team. If these are not indicated, the Committee suggests the following numbers per individual anaesthetist, to minimize the risk of peri-operative critical events:

   **150 deep sedations/anaesthetics in children under the age of 10 years, of which**

   i. **40 deep sedations/anaesthetics in children under the age of 3 years.**

   ii. **10 deep sedations/anaesthetics in children under the age of 6 months.**

   The Committee recommends that nursing staff assisting the anaesthetist should have the same level of experience.

4. A nurse dedicated to anaesthesia, with all the necessary skills, should always be present when an anaesthetic is being used.

5. All children requiring anaesthesia should be assessed in advance by an anaesthetist.

6. A paediatric anaesthesia unit requires certain basic equipment and features, as follows (19-20):

   a. The premises used for paediatric care should always have room for parents, or caregivers, who should be separated from the children for as short a time as possible. The pre-operative and recovery areas in this surgical block should therefore be separate from zones for adults. All hospitals without paediatric intensive care facilities should maintain an area equipped for children in critical conditions.

   b. Hospitals where paediatric anaesthesia is employed should be fully equipped for the care of children, with all devices of the appropriate sizes for children of different ages. This will have to include:

   ✓ **Emergency trolley(s)** with all the necessary monitoring equipment, defibrillator with paediatric plates, vasoactive drugs and dantrolene (according to the hospital procedure). The trolley should have a check-list naming the drugs for use in an emergency, their concentrations and dosages.
A trolley equipped for dealing with difficult paediatric airways, including a laryngoscope and video-laryngoscope, with blades of different sizes, face and laryngeal masks, endotracheal tubes, styles, fibreoptic scope with adequate sizes for all ages, and instruments for rapid tracheal access, as recommended by SIAARTI for the management of difficult airways in children (21).

Anaesthesia equipment, with a ventilator adequate for paediatric use, EKG and heart rate monitor, pulse oximeter, capnometer, oxygen, and halogenated agents, and pressure monitor, as specified in the SIAARTI standards for minimal monitoring equipment (22).

**Temperature control equipment:** heat lamps, body and fluid warming systems, medical gas humidifiers, room temperature control systems, body temperature monitors.

Systems for infusion of fluids including volumetric pumps. Syringe-pump for drugs.

Peripheral and central venous catheters; intra-osseous needles and arterial catheters in all sizes.

Ultrasound with paediatric probes for central venous cannulation.

Trolley for moving all paediatric monitoring equipment and ventilator.

All hospitals should have internally approved protocols for treating emergencies: anaphylactic shock, airway obstruction, local anaesthetics toxicity, malignant hyperthermia.
4. Regulatory references and bibliography

18. Legge 7 agosto 2015 n. 135. Disponibile in: http://www.gazzettaufficiale.it/eli/id/2012/08/14/12A09068/sg
Appendix 1: Paediatric surgery admissions in Italy, 2014

Table 1 lists the figures for paediatric surgery admissions in Italy in 2014.

Table 2 divides the surgery according to specialty. Of the total of 228,000 admissions, 30% were for urology-digestive tract surgery, 24% for orthopedic operations, 23% for ENT cases (70% of them tonsillectomy), and 4% eye surgery. Only 4% were admitted for cardiac or neuro-surgery.

Analysis also focused on the distribution of paediatric surgery in the different categories of hospital, and brought to light the extreme fragmentation of surgery in Italy, where there are no fewer than 875 centres, though with appreciable differences between regions. Tuscany provides a good example of centralization: 61% of admissions for surgery in 2014 took place in only four centres. Liguria concentrated 71% of admissions in the Gaslini Paediatric Institute. In Lombardy, however, only 24% of admissions were to the four hospitals most specialized in paediatrics, while 131 others hospitals recorded some paediatric surgery.
Table 1. Hospital admissions for paediatric surgery

<table>
<thead>
<tr>
<th>Surgical admissions</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>1425000</td>
<td>100</td>
</tr>
<tr>
<td>Paediatric</td>
<td>228000</td>
<td>16</td>
</tr>
</tbody>
</table>

**Paediatric surgical admissions**

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective</td>
<td>186960</td>
<td>82</td>
</tr>
<tr>
<td>Urgent</td>
<td>41040</td>
<td>18</td>
</tr>
<tr>
<td>In-patient</td>
<td>141000</td>
<td>62</td>
</tr>
<tr>
<td>Day-case</td>
<td>87000</td>
<td>38</td>
</tr>
</tbody>
</table>

**Department at discharge**

<table>
<thead>
<tr>
<th>Age</th>
<th>Paediatric</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 1 year</td>
<td>70%</td>
<td>30%</td>
</tr>
<tr>
<td>1-3 years</td>
<td>59%</td>
<td>41%</td>
</tr>
<tr>
<td>more than 3 years</td>
<td>32%</td>
<td>68%</td>
</tr>
</tbody>
</table>

Table 2: Types of surgery

<table>
<thead>
<tr>
<th></th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urology/digestive tract</td>
<td>68400</td>
<td>30</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>54720</td>
<td>24</td>
</tr>
<tr>
<td>ENT (tonsillectomy)</td>
<td>52440</td>
<td>23 (70)</td>
</tr>
<tr>
<td>Oculistic</td>
<td>9120</td>
<td>4</td>
</tr>
<tr>
<td>Neuro- and cardiac surgery</td>
<td>9120</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix 2: Paediatric hospital network

Italian law no. 135 dated 7 August 2012 specifies that hospitals are to be classified on three levels (basic, levels I and II care) depending on their catchment area and the complexity of the care provided (18). Within the overall hospital system, pathology networks are to be set up, and reference is made to a specific paediatric network to be established by regional authorities, divided as follows:

- centres acting as Basic Paediatric Spoke. These hospitals have no paediatric departments, and consequently should not do elective paediatric cases;
- centres acting as Level I Paediatric Spoke. These hospitals have paediatric departments but no paediatric intensive care units, and provide minor elective interventions not requiring post-operative intensive care. They work according to a program shared with the hubs for managing children lower than 3 years, with ASA score > 2, undergoing highly complex surgery or in critical conditions;
- centres acting as Level II Paediatric Spoke or Hubs. These hospitals have multi-specialist paediatric competencies, including paediatric intensive care. They may be paediatric hospitals, regional paediatric care centres, and level II paediatric emergency admission facilities (Italian Paediatrics DEA) in hospitals with high level of paediatric specialization. They should coordinate the network’s activities, organizing training for spoke hospitals, and promote research.

The network’s function is therefore based on three main points:

a) Centralized admission in referral paediatric centres for the most complex paediatric cases by age, severity (concomitant acute and/or chronic pathology), type of surgery and level of urgency.

b) An efficient transport system for rapid transfer to the most appropriate hospital, with well-equipped vehicles and specialized staff, in order to minimize the risk of adverse events and improve survival (23-25). Some Italian regions have a neonatal transport system (STEN) which is a valid reference model.

c) Specific training for managing paediatric emergencies and urgencies in all the hospitals equipped to care for children.

An important point, particularly in today’s conditions, is that children from ‘developing countries’ must be assured full access to social and health care (including surgery) on an ad hoc basis; protocols should
be drawn up that take account of the institutions and associations working in this field, as set down in Article 21 of the Code for the Rights of Minors to Health.

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