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Recommendations for the minimal requirements necessary to deliver safe anesthetic procedures in neonatal and pediatric age

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SIAATIP COMMITTEE FOR GUIDELINES AND RECOMMENDATIONS IN NEONATAL AND PEDIATRIC ANESTHESIA

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Abstract

Introduction

Over the last years the field of pediatric and neonatal anesthesia has become a recognized subspecialty in many countries of the world and the need for appropriate training and availability of a specially equipped environment has now been commonly accepted.

In order to standardize and guarantee the same level of care for an infant or child definition of the minimal requirements for training, equipment and hospital organization are required.

For this purpose, the committee of the Italian Society of Pediatric Anesthesia, Analgesia and Intensive Care (SIAATIP – Società Italiana di Anestesia, Analgesia e Terapia Intensiva Pediatrica), formed of experts in the field of pediatric anesthesia and intensive care, has decided to release a statement for the minimal requirements to deliver safe pediatric anesthesia.

Methodology

For level of evidences and strength of recommendations the Society referred to the document produced by the National Program for Guidelines (PNLG) of the Italian Superior Health Institute, and to its methodological manual available on the official website www.snlg-iss.it. Since it is not a clinical-experimental work, the SIAATIP committee decided to use the Italian scheme adopted by the PNLG

Content and purpose

The SIAATIP Committee established that the skills in pediatric and neonatal anesthesia must follow the minimal standards of safety according to the indications of literature and of international scientific community, adapted them to Italian health organizational reality.

The purpose of this recommendations is to establish the minimum standards necessary for professional competence and organization of hospitals to ensure pediatric and neonatal anesthesia procedures with maximum safety, effectiveness and efficiency by reducing the risks and complications, pursuing the maximum strictness in their application.

Keywords: guidelines, recommendations, pediatric anesthesia, neonatal anesthesia, safe procedures.

Introduction

The recommendations were drawn up by a committee of experts and approved by the Board of the Italian Society of Paediatric Anesthesia, Analgesia and Intensive Care (SIAATIP – Società Italiana di Anestesia, Analgesia e Terapia Intensiva Pediatrica), taking into account the recent scientific literature as well as guidelines and international recommendations concerning the discipline. These recommendations have been also approved by the following societies: Società Italiana di Partoanalgesia, PAICSAT (Pediatric Anesthesia and Intensive Care Society and Applied Technologies), SUA (Society for Ultrasound in Anaesthesia), Scuola Italiana Emegenze, Health Management Institute, Florence, Italy.

In addition, SIAATIP has conducted a study on the Italian national territory examining the issues reported by intensivist and anesthesiologists working in hospitals of every levels, whose results were published in the British Journal of Anaesthesia.[1] From the analysis of the study the scientific society has drawn useful considerations about the real operative conditions and working criticalities highlighted, and processed the interventions and recommendations to adopt also through the suggestions of anesthesiologists interviewed, always merging the scientific knowledges with operational need.

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I	Evidences obtained from several randomized controlled trials and/or systematic reviews of randomized trials.
II	Evidences obtained from a single randomized trial of adequate design.
III	Evidences obtained from cohort studies with control groups or their meta-analysis.
IV	Evidences from retrospective case-control studies or their meta-analysis.
V	Evidences from case reports (*series of cases*) without a control group.
VI	Evidences based on the opinion of experts or expert committees as indicated in guidelines or consensus conferences or based on opinions of the members of the working group responsible for these guidelines.

Table 1. Levels of proof (LDP in the PNLG scheme)

A	Execution of that particular procedure or diagnostic test is strongly recommended. It shows a particular recommendation supported by good-quality scientific evidence, though not necessarily of type I or II.
B	There are doubts whether that particular procedure/intervention should always be recommended but it is believed that his execution should be carefully considered
C	Significant uncertainty exist in favor or against the recommendation to perform the procedure or surgery.
D	The execution of the procedure is not recommended.
E	It is strongly not recommended the execution of procedure.

Table 2. Strength of recommendations (FDR in the PNLG scheme)

In the guidelines, the recommendations are qualified with a degree of:

a) Levels of proof (LDP), expressed in Roman numerals (from I to VI);

b) Strength of recommendation (FDR), expressed in letters (from A to E).

LDP refers to the probability that a certain amount of knowledges is derived from studies planned and conducted in a way to produce valid information and with no systematic errors. FDR refers to the probability that the practical application of a recommendation leads to an improvement of the health status of the target population. Therefore, there may be recommendations of strength A or E even in absence of levels of evidence I. For example the recommendation that "in children under the age of twelve is contraindicated ASA (acetylsalicylic acid) has strenght E, but only a level of evidence III. For ease of consultation and to avoid difficulties of interpretation, we used arabic numerals instead of roman ones. For example the degree "B5" is much clearer than the degree "BV", where the "V" sign may be confused with the capital letter "V".

Risks in pediatric and neonatal anesthesia

The risks and complications for every anesthetic procedure or sedation, conducted in pediatric and neonatal age, are higher than in adult patients. All children under one year of age, especially premature ones, new-borns and infants are at much higher risks.

The up to date literature describes complications ten times more frequently than in adults and many of them occur in children under normal health conditions.[2]

Moreover, a recent study has demonstrated that the anesthesiologist's experience in pediatric field determines a lower incidence of complications, that are 1,48 times higher if those procedures are performed by anesthesiologists that only occasionally execute pediatric procedures and in ASA II, III and IV patients.[3]

One major problem observed in this kind of patients is represented by the proper management of airways during procedures under sedation, analgosedation and general anesthesia and/or locoregional anesthesia.

The lower volumes of respiratory reserve and reduced functional residual capacity of these patients, together with the different evoluting physiology and development of organs and apparatus, are able to determine a quick worsening of clinical conditions which can hesitate in cardiovascular failure in a short time, even in the postoperative period.[4,11]

It is demonstrated that many of these complications are directly related to inexperience of anesthesiologist, human factors, and in hospital settings with organizational criticalities and lack of paths and specific operational and dedicated protocols.[12]

This aspect makes it imperative and compulsory rapid intervention strategies that can be implemented by properly trained and competent personnel, in organized hospital settings.[7,13,14] (Grade A6).

In emergency and urgency conditions, in presence of comorbidities and in children in serious conditions, such criticalities increase considerably.

Diagnostic, therapeutic and assistance pathways (PDTA)

The Italian Ministerial Decree 70/2015 states that all health and hospitals organizations of every level must adopt *Diagnostic, Therapeutic and Assistance Pathways (PDTA).*

SIAATIP Committee considers PDTA essential to ensure safe and effective treatments through shared and interdisciplinary paths.

Even hospitals that treat pediatric patients only occasionally must study and adopt diagnostic, therapeutic and assistance pathways in pediatric and neonatal anesthesia defining flowcharts with a precise indication of paths, operating units, personnel and means to ensure safety and effectiveness in pediatric patients in need of care and procedures that require anesthesia, sedation, analgesia and in all emergency clinical conditions and urgency.[15] The path must identify the staff with well-documented experience and competence in pediatric anesthesia and the identification of operating theatre considered suitable and equipped for the execution of procedures for all age brackets.[3]

PDTA must be structured on the specific needs of each hospital and on the qualitative and quantitative typology of case history, and contain specific operational protocols (eg. removal of foreign bodies by the airways and digestive tract, procedures in analgosedation, sedation for imaging procedures etc).

Children should be cared in dedicated areas and spaces and separated from adults[16,19] (Grade B5) with dedicated and competent staff. [7,16-20] (Grade B5)

Skills acquisition

It is now recognized by the literature that the clinical case histories has a fundamental role to gain experience in each branch of medicine.[3]

There is medical liability (civil and penal) when the patient has not received the treatments and assistance he should have received, according to what are the specific guidelines and to the medical science, with the procurement of a damage.

To the overall case history must be added the continuity of activities until reaching degrees of operational complexity and higher competences. This concept has greater importance in children.

The minimum number of pediatric patients treated that give competence in the anesthesia field is different between European and non-European countries. The foreign countries have organizations and laws different from Italy and in many cases there are educational courses and certifications dedicated to pediatric anesthesia that are not present in our country and that the specialization schools do not provide. Similarly the pediatric anesthesia services in hospitals are very different between European and non-European countries. The specialization schools include in their programs a short training that are considered, by anesthesiologists interviewed through the SIAATIP survey, inadequate in real

clinical practice.[1,21] The only formative post-specialization option in Italy is represented by university masters or other courses of different typology. A similar application in Italy is therefore difficult to implement. SIAATIP Committee considers that, in the absence of recognized certifications and courses, and dedicated paths during university studies and specialization, the minimum number of patients treated in order to acquire clinical skills must be clearly established not only by age but also by typology of procedure performed. Moreover, it is necessary to distinguish the skills in two groups of intensivist/anesthetists:

a) those that carry out activities with continuity, in pediatric hospitals or whatever with significant pediatric anesthesia activity;

b) those who develop the activities with discontinuity or occasionally/rarely

In particular for intensivist/anesthesiologists referred to point b) it is necessary to establish the standard for the acquisition of competences. Standards must be agreed jointly among intensivist/anesthesiologists, hospital management and unit chiefs through the realization of PDTA on the basis of volumes and typologies of clinical activities of the hospital, also taking into account the needs linked to the transfer of children and new-borns that requires expertise and organization.[3,22] In shortage of directives, the Intensivist/anesthesiologists and the hospital managements must refer to the current recommendations.

SIAATIP Committee has considered the hypothesis to use two anesthetists for the procedures on younger children and new-borns in analogy as happens in some European countries, as it will be specified below. This hypothesis, though desirable and recommendable, is difficult to achieve in Italy and can evidence points of weakness for the following reasons:

a) the serious lack of anesthesiologists in the national territory;
b) the presence of two anesthesiologists, with possible lack of competences of both of them, not increase the safety nor reduces the complications.

Therefore, though it is recommendable the presence of two anesthesiologists, both of them must be expert in high complexity procedures or in small children as neonates, infants and premature babies.

SIAATIP national survey on the status of skills in pediatric anesthesia of italian anesthesiologists

In 2008 has been published, on Pediatric Anesthesia journal, an Italian national survey in order to evaluate the pediatric training developed by postgraduate students in Anesthesia and Intensive Care.[21] We evidenced that training period vary from 2 to 6 months, but only 29% of postgraduate schools requires a minimum number of procedures. It follows that the post graduate schools, in spite of the most recent updating of study programs don't form enough the future anesthetists in pediatric field. This is confirmed also by anesthetists questioned through the survey conducted by SIAATIP [1]: FEAPA (Federation of European Associations of Pediatric Anesthesia), today ESPA (European Society of Pediatric Anesthesia), published some recommendations that are not still completely satisfied: European guidelines for training in pediatric anesthesia and recommendations for pediatric anesthesia services in Europe. During 2015, as already pointed, SIAATIP carried out a national survey among Italian anesthesiologists to value the competences and the clinical organizational aspects in pediatric anesthesia both in routine and emergency situations in all Italian hospitals. The result of study underlined a remarkable shortage of competences and/or staff dedicated in all hospitals, with the exclusion of specialized pediatric hospitals. It is not recorded a remarkable shortage of pediatric devices (except for videolaryngoscopes and fibroscopes at disposal only of a third of responders) and at the same time anesthesiolo-

gists questioned declared that the hospital managements has not implemented protocols and/or dedicated PDTA (Fig. 1).

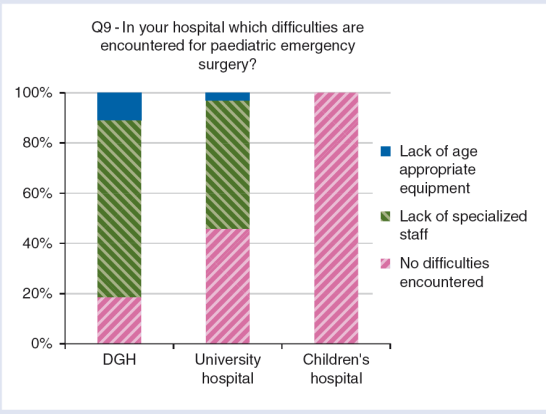

Fig 1 Percentage and type of difficulties encountered in relation to type of hospital.

Moreover, 46,1% of anesthesiologists interviewed declared to put a cut-off of weight and age for election surgeries with remarkable differences among regions and sometimes also inside a same region.

The majority of the transfers of pediatric patients at regional structures of reference were related to this cut-off.

Most anesthesiologists questioned consider fundamental a training and subsequent retraining that are seriously lacking in not specialized hospitals and considers not enough/not suitable the training period in pediatric field during postgraduate school.

The pediatric specialized hospitals are few (13 in Italy) sometimes very far by so-called "peripheral" hospitals. Peripheral hospitals represent a significant part of accesses for pediatric patients with large geographical distribution.

This means that the problem linked to emergency, to the pediatric anesthesia and to the staff competences is very important, of particular consideration in all the national territory. It is necessary to provide to the mentioned structures and staff precise indications for the safety not only of patients but also of the same workers.

The network of pediatric emergency and skills related to classification on hospitals *(document licensed in 2015 by technical board Agenas-Ministry of Health-Regions-Scientific Societies)*

At the end of 2015 has ended the work of a Technical Board composed by Agenas (National Agency for Regional Health System), members of Italian Ministry of Health and Regional governments, with the participation of SIAATIP and the production of a document of recommendations to improve and monitor the organization of the pediatric assistance system within the network of pediatric emergency-urgency in order to avoid discrepancies and to rationalize the use of the available resources. From the document we report what has been undersigned by the Technical Board related to the classification of structures dedicated to the pediatric hospital emergency, functionally integrated into Department of Emergency and that has to be considered valid even for pediatric anesthetic procedures in urgency regimen, ensuring interdisciplinarity as well as trained and competent staff.

Basic Hospitals

Basic hospitals (80.000-150.000 inhabitants) within the network of pediatric emergency-urgency must be able to ensure the initial care, the stabilization and the eventual transfer of the child, if necessary, to the Department of Emergency-Urgency (DEA) of reference for specific pathology. The physician and nursing staff that works in such structures must have specific competences within management of pediatric emergencies-urgencies, included psychiatric emergencies, acquired through specific training and have to work within specific protocols and procedures. A narrow teamwork, also by telematics means, must therefore be established with the Pediatric Operative Unit (U.O.) of reference, for the evaluation and the discussion of most significant clinical cases and for continuous updating. Whenever the clinical conditions should be critical, it has to be provide the active

involvement of Anesthesia and Intensive Care Unit of the same hospital, which components must possess the formative skills previously described. It's important to implement, within the network, pediatric specialistic consultations since the first phases of assistance, also through transmission of data and images. Moreover, it must be always guaranteed in every health structure the standard equipment suitable for the different age brackets; the staff must be trained on their proper use.

First Level DEA

In hospitals with first level DEA (150.000-300.000 inhabitants), physicians of Pediatric Units, on a 24/24 rota, should take in charge all subjects in pediatric age presenting at Emergency Department (in italian system Pronto Soccorso, P.S,) , creating a functional service of P.S. with inter-disciplinary integration of all services and operative units inside the hospital.

As an alternative to dedicated spaces at P.S., a protected path towards the pediatric unit must be provided. At P.S., the skills for a pediatric triage, in order to establish the degree of priority of care, has to be provided. In case a clinical condition that cannot be managed in the hospital is identified, the patient must be transferred in the most suitable pediatric structure after stabilization.

Therefore, considering that in first level DEA is provided the immediate clinical and therapeutical stabilization, has to be available also suitable staff with structural and instrumental equipment. For particularly critical patients it is necessary to start a functional link with second level DEA of reference, sharing diagnostic and assistance protocols also with regard to the probable transfer.

A pediatric Short Intensive Observation Unit (OBI - up to 24-36 hours) must be realized that, allowing a diagnostic timeline and the application of first aid therapy, can permit to send the patient at home, safely after the first treatment, as well as stabilize the critical patient until the transfer to Competent Services and Unit. Moreover, a protected discharge from the hospital should be activated in collaboration with general pediatricians, possibly with the computerization of the system.

The nursing staff of P.S. must attend specific courses on pediatric triage, on use of medications and drugs in pediatrics and must have suitable training in psychiatric emergencies and in pediatric basic life support. Peditricians must have suitable training in the pediatric advanced life support. Intensivist/anesthesiologists must have specific skills in pediatric field too.

Second Level DEA

Regions define their organizational arrangement for the pediatric emergency-urgency, identifying the function of pediatric hub and defining the pediatric skills in other DEA of the area.

Hospitals with second level DEA (600.000-1.200.000 inhabitants), in function of the planned specialties from the regional planning, must ensure a more qualified and complete health system. Inside DEA the pediatric P.S. should have its functional and operative autonomy. The pediatrician in 24/24 rota, must always intervene for the first evaluation of patient, guarantee and manage the multi disciplinarities and the coordination of the case with shared protocols; moreover, there must be pediatric nurses, or nurses with documented training on pediatric urgency-emergency.

From the structural point of view, it is appropriate to identify a pediatric sector of P.S. with pediatric triage, with different paths from adult ones, outpatients area and short intensive observation area specifically dedicated; all materials and devices suitable for all emergencies must be available.

In case second level DEA is also a Trauma Center (CTS), it is necessary that the trauma team for adult acquire pediatric skills. If in the hospital there is not a pediatric intensive care unit, it should be guaranteed to the child in critical conditions the transfer in a hospital with pediatric second level DEA, even extra-regional if not

available in the same region, following specific shared protocols. In case of absolute inability to the transfer, it must be guaranteed in any case, only for the minimum time necessary to organize a transfer, the admission to a a neonatal intensive care unit (NICU) and/or in general intensive care unit, with a clinical integrated management shared with the specialists of the pediatric intensive care unit of reference.

Pediatric Second level DEA

The pediatric hospitals must have a poly-specialistic characterization for children and youth and the presence of pediatric DEA with the functions already described for second level DEA, in addition to high specialities and sub-specialities of pediatric field (neonatal and pediatric intensive care, pediatric emergency, pediatric surgery, neonatal surgery, cardiology, heart surgery, neurosurgery, orthopedics, infectious diseases, oncology, hematology, broncopneumology, nephrology and dialysis, metabolic diseases, pain therapy, endocrinology, ENT, ophthalmology, neurology, psychology and pediatric psychiatry, etc). In such hospitals must be centralized the cases of great medical emergency-urgency, surgery and traumatology that exceed the skills of the others DEA (for Trauma Centers refer to specific chapter).

Pediatric second level DEA must cover a regional or interregional area and, in every case, serve a population not lower than maximum value for second level DEA (Decree 2/4/2015 n.70). Regions with such hospitals define their organizational arrangement for pediatric emergency-urgency developing the function of hub and defining the pediatric skills in the others DEA of the area in a functional way in order to use the available resources at its best.

In the function of hub is included the coordination of the organization of neonatal transport if in the structure there is also a birth point and a NICU (second level birth point), and of the assisted pediatric transport, with operative protocols agreed with the territorial system 118 and with the other regional hospitals.

Pediatric Trauma Center

Trauma represents the main cause of death and of serious sequel in pediatric population after the first year of life. In particular, 44% of deaths between 1-4 years is due to a trauma. The prognosis of a politraumatized child, except for most devastating trauma, can be favorable and it's influenced by a suitable and rapid treatment starting in the first minutes from the event. The availability of an efficient system of territorial emergency that is able to stabilize the victim on the place of event, when possible, and to carry it quickly and "in safety" to a highly specialized center can result therefore decisive to improve the final prognosis of patient. Beyond necessary prevention's projects, the consequences of trauma are reducible through the setting up of integrated care models between territory and hospital (Integrated System for the Assistance to Trauma or SIAT), oriented to guarantee the arrival of patient in the quickest possible time to the hospital able to supply the final treatment. Moreover, also for pediatric patient has to be guaranteed the timely charge of serious traumatized patients from rehabilitation's structures (agreement State-Regions 4 april 2002 and 29 april 2004).

The areas of belonging for highly specialized trauma center (CTS) with pediatric commitment are defined based on aggregation of area identified for the network of serious trauma of adult.

Trauma Team of CTS with Pediatric Commitment should have pediatric staff of specialties of reference; therefore it is strongly recommendable that the reference for serious pediatric trauma is at pediatric second level DEA, if necessary integrated to CTS for adults.

The coexistence of an heliport/helipad with traumatology skills (anesthetist, general surgeon, thoracic, vascular, orthopedic, neurosurgeon, interventional radiologist), with those pediatric (pediatric surgeon), allows the

treatment of greater traumatology in children, according the model of Pediatric Trauma Center, already widely experienced in Europe and North America.

Pediatric Intensive Care Unit (PICU)

They represent a fundamental knot in emergency network and should be allocated in pediatric hub of II level or in a basin not less to 2 millions of inhabitants. PICUs must develop also a formative function towards P.S., with or without pediatric advice, and DEA aimed mainly to the definition and sharing of care protocols in urgency/emergency, to identification of predictive conditions of special and intensive treatments and supports the recurrent discussion on the real operativeness of pediatric emergency network. In the system of pediatric transport, PICU develops a support function to its functioning. Hub centers with PICU are required to accept all primary transports coming from territory of competence independently from the availability of beds in ordinary, sub-intensive or intensive units. Hub centers are the first reference also for secondary transports from territory of competence; in the absence of beds in the hub center the research of beds in other PICUs and the secondary transport are managed by 118 previous contact of PICU that will take in charge the child. In a logic of network, back-transport toward transferring hospital or proximity hospital, needs to be encouraged at the end of the critical phase.

Pediatric Sub-intensive Care Unit

In order to improve the appropriateness of admissions in PICUs it is hoped the realization of sub-intensive pediatric units to allocate inside of pediatrics wards of hospitals with second level DEA or pediatric second level DEA.

Short Intensive Observation Unit (OBI)

The pediatric OBI, usually contained within the first 24 hours and in some cases (on the base of specific regional set of rules) within the first 36 hours must be organized in all the pediatric hospital structures, with a careful evaluation of resources employed and of obtainable results in terms of rate reduction of admission to hospital, of rationalization of care paths and of control of expenditure. Above all, in hospitals of little sizes, with a pediatrics unit characterized from low complexity case histories and/or from low rate of beds occupancy, some beds could be allocated to short intensive observation, using at best the available human and organizational resources. Many pediatric patients suffering from not critical pathologies, referable as an example to infections of the first airways, to gastroenteritis, to abdominal colic and other common pediatric acute pathologies, after a short period of observation and the probable execution of some simple instrumental or laboratory exams, can indeed be discharged. Territory pediatricians that have organized their work within continuity care, provided by pediatricians in partnership or by U.T.A.P. (territorial units of primary care) can evaluate the provisional observation comparing to guidelines and clinical and organizational paths agreed with pediatric units of reference.

Neonatal emergencies

Neonatal emergencies were treated by the commission that worked out the guidelines for the promotion and the improvement of quality, safety and appropriateness of care interventions in the path birth and for the reduction of caesarian section, approved from the Conference State-Regions on 16.12.2010, attached 1B. It has to be bear in mind that the number of NICUs in our country is elevated and that the quality of neonatal assistance is linked to number of neonates of weight lower to 1500 g/y for every center, for which it seems considerable to remind the chance to apply the approved indications reducing those NICUs that care less of 50 neonates/y with weight at birth < 1500 g. For new-born (up to 28 days) with important issues of emergency-urgency should be provided, where possible, a direct access in NICU, avoiding the access to P.S. In alternative it must be, an-

yway, provided a protected route. For a proper regionalization of perinatal assistance services (so as provided from the national health plan for years 2006-2008), in every region must be brought to regimen the service of neonatal transport in emergency (STEN), providing also the so-called "transport in uterus" (STAM) that, also with the support of new technologies (telemedicine), should be always more implemented as well as the concentration of pregnancies at risk at reference centers for the assistance to childbirths and to neonates at high risk. The protocols of management in situations of saturation of beds in NICU of reference, that must provide the guarantee of appropriate management of emergency situation, are included in the organization of such system of transports.

Training

It develops a strategic role for the correct working, the integration, efficiency and effectiveness of pediatric network for emergency urgency.

The themes of training must be correctly determined on the basis of determination of specific formative needs, both clinical care and organizational. Primary training objective is to acquire and maintain in all the pediatric and non pediatric staff, involved to varied title in the network, 118 and territorial pediatrician included, the necessary skills to face up in an appropriate way the pediatric urgencies-emergencies.

A correct formative planning is particularly considerable in order to maintain a homogeneous and suitable level of quality and safety of network's response to pediatric urgencies and emergencies and in a particular way for all the components of network where is not always available a pediatrician, or where pediatric patients are not particularly numerous or in case of low frequency of pathologies or pediatric procedures. The fields where it is strategically relevant this formative need are the staff of 118, intensivist and anesthetists, physicians dedicated to some particular pediatric pathologies and territorial pediatricians; particular attention should be paid to P.S., above all in the structures where pediatricians are not available 24/24, in terms of stabilization of patients as well as the aspects related to pediatric triage. An important formative need is the one related to the management and treatment of psychiatric urgencies and emergencies in pediatric age, particularly in those health structures where it is not immediately available a child neuro-psychiatrist. The training of all staff involved in the pediatric emergency-urgency must moreover contain also a considerable part to spreading, sharing and updating of protocols, organizational and clinical procedures in use at regional and hospital level, pain therapy in pediatric emergency-urgency, the use of devices and pediatric drugs, the correct communication with children and parents.

The training must be planned in formative regional and local plans, in consistency with formative objectives of regional and national level and achieved, based on specific peculiarities and needs, mainly by regional and local institutions, by university, by hub centers. It's Important, for these purposes, an economic budget for training at hospital level, the involvement of scientific societies in some formative fields, the use of advanced techniques of pediatric simulation, a shared planning of courses ECM. University postgraduate schools have already planned a pediatric emergency training, with the new organization of speciality schools, taking into account a careful planning of the number of pediatricians necessary in order to guarantee sub-specialistic skill, taking into account also the physiologic turnover. It is moreover important to dedicate a specific space in formative programs concerning the treatment of urgencies and emergencies of rare diseases with particular reference to procedures, drugs and management of airways. Considerable are the formative and communicative actions concerning the health education and the information to parents and teachers in order to improve

the knowledge on conditions that require the access in P.S.

NORA (Non Operating Room Anesthesia)

It has to be recalled the joined document of scientific societies SIAARTI, SIARED, AAROI and SIAATIP undersigned on 23 June 2015 and sent to Ministry of Health and to President of Conference of Regions and of self-governing Provinces (available by request getting in touch with the above-named scientific societies), about operational procedures at low complexity and/or with low invasive character developed in NORA. In particular it has to be under attention those procedures under sedation, designated by scale (Ramsay Scale, introduced in 1974 or UMSS of Michigan Sedation Scale proposed by American Academy of Pediatrics since 1992) that merely consider clinical effects and not those predictable with the administration, even combined, of medications active not only on sedation but also with major analgesic effect, if not absolutely anesthetic. The level of sedation can therefore bring to general anesthesia. This aspect is much more evident and risky in pediatric patients (and neonatal), where the border between sedation, analog-sedation and general anesthesia is very weak.[9,11,23-25] (grade B6)

Moreover, the combination of sedation with techniques of loco-regional anesthesia (frequent in pediatric age) increases further the risks. For above-named reasons all the procedures in sedation or achieved in NORA must be developed observing the same recommendations of professional skills, clinical-instrumental organization and logistics of surgeries performed in operating theatre.[23-25] As matter of fact such procedures can quickly evolve in a clinical condition of general anesthesia or urgency-emergency. (Grade B6)

The anesthetists must mark out to the director of structure and to hospital direction any instrumental shortage, organizational and of professional skills and are not liable, expect for emergency and urgency situations, to achieve such procedures if above-named requirements are not secured. If necessary the patient can be transferred to regional reference center or the closest one. In patients in pediatric and neonatal age the procedures of sedation, analog-sedation and NORA must be performed only by qualified anesthetist qualified and with certified experience and suitable training.

Such procedures cannot be entrusted without direct supervision, to doctors in training or non medical staff.

Anesthetist that perform such procedures cannot be assigned at the same time to other functions or to two or more patients.

It should be avoided the use of denomination “sedation” in all cases in which medications have “major hypnotics” effects, as they cannot have only a ”sedative” effect, but they are to be reserved to general anesthesia, i.e. hypno-inductor effect in order to induce a general anesthesia (es. Propofol) or major analgesic effect (es. Remifentanil).

Day Surgery interventions

The interventions in day surgery, even if under loco-regional anesthesia, must be performed in patients in good conditions of health or suffering from not serious and under control pathologies and/or comorbidities, for minor surgery and in patients stable from a haemodynamic and respiratory point of view.

All the safety measures and standard expected for admissions to hospital and ordinary surgeries must be adopted.[26-29] (Grade A5)

The minimum limit of age for the execution of such procedures depends on experience of staff and by the conditions of health of the child. In every case preterm babies cannot be submitted to anesthesia procedures in day surgery unless they have not reached a post-conceptional age of 55-60 weeks.

The related risks are discussed individually and the suitability to intervention is at exclusive judgment of the anesthesiologist. Criteria of hospital discharge must be

clearly established and implemented through protocols shared with the operative surgical unit.

Anesthetic management for rare diseases

Children suffering by rare diseases can show serious complications during anesthetic procedures. The poor knowledge of these pathologies can represent a point of weakness with increase of clinical risk.

It is recommended to anesthesiologists to enter in contact with regional or national reference centers in order to gather information before starting anesthesia procedures[30,31] (Grade B6), carefully evaluating the eventual necessity of transfer to the closest and equipped specialist centers. Anesthesiologists can make contact directly with SIAATIP (www.siaatip.it) or consult the database of the German Society of Anesthesiology and Intensive care medicine that realized a website dedicated to anesthesia procedures in case of rare diseases: www.orphananesthesia.eu

Moreover, it is possible to consult the ORPHANET portal www.orpha.net of rare diseases and medication to get detailed information on rare diseases and reference centers.

SIAATIP recommend and encourage the use of digital and modern means for the access and the exchange of information in real time with frequent updating.

Requirements and minimal clinical casistic necessary to acquire pediatric anesthesia skills

The acquisition of skills in pediatric anesthesia must be formalized by hospital directions implementing paths in pediatric and neonatal anesthesia, specific for volumes and qualitative typology of activities. In literature there are very few publications about the minimal numerical standard in order to acquire skill in pediatric anesthesia, though standards are different among European and extra-European countries.

A first indication was proposed by FEAPA, Federation of European Associations of Pediatric Anesthesia (FEAPA quit in 2009 originating ESPA, European Society for Pediatric Anaesthesiology). FEAPA created two documents: “European guidelines for training in pediatric anesthesia” and “Recommendations for pediatric anesthesia services in Europe” where were indicated the minimal casistic for age brackets and clinical-organizational aspects. Afterwards the Safetots team (Safe Anesthesia for Every TOT) analysed the minimal clinical casistic and the clinical-organizational aspects finding and confirming a remarkable discrepancy among European countries.[32] In Denmark, Holland and Switzerland two expert anesthesiologists are required in pediatric anesthesia procedures.

This standard is hardly practicable in many other European countries, among which Italy, because of shortage of specialistic staff. Moreover, the Safetots Team provide indications on “who, where, what, when and how” anesthesia should be provided in children, defining these requirements “The 5 Ws - The Who, Where, What, When And How Anesthesia Should Be Provided In Children”. The Safetots Team, after evaluating the indexed literature, suggest a minimum of 200-300 children until 10 years of age and an infant per month as minimal personal casistic for anesthetist in order to reduce complications, underlines the importance of reference center and specialized for complex pathologies, for newborns and preterms babies besides staff with adequate skills. The optimal timing for elective surgeries, in order to avoid delays that can hesitate in emergent risky conditions, it’s another point considered by Safetot Team.[33-41] (Grade A5)

In 2017 Lancet published a multi-centric observational study (APRICOT, Anaesthesia PRactice In Children Observational Trial, 261 hospitals) about adverse events in paediatrics, highlighting that the age bracket of maximum incidence is under 6 years, and suggesting to provide anesthetic procedures in kids under 3-3,5 years in third level hospitals or with anesthesiologist with specific paediatric training.[3]

The SIAATIP Committee established that the skills in pediatric and neonatal anesthesia must follow the minimal standards of safety according to the indications of literature and of international scientific community, adapted them to Italian health organizational reality. Therefore, we determine that for the acquisition of skills in pediatric anesthesia the single anesthetist must possess the following minimal annual clinical casistic, qualitative and quantitative:

- *Anesthesiologists continuosly dedicated in pediatric anesthesia procedures*[3-32] (Grade B6)

  250 anesthesia – deep sedations/year in children of age below 10 years, of which:
  50 anesthesia – deep sedations/year below 3 years of life,
  20 anesthesia – deep sedations/year below 6 months of life.

- *Anesthesiologists discontinuosly dedicated in pediatric anesthesia procedures*[3-32] (Grade B6)

  150 anesthesia – deep sedations/year in children of age below 10 years, of which:
  40 anesthesia – deep sedations/year below 3 years of life,
  12 anesthesia – deep sedations/year year below 1 year of life.

- *Anesthesiologists occasionally dedicated in pediatric anesthesia procedures*[3,17,18,32] (Grade B6)

  Except for emergencies and urgencies, in absence of skills acquired and documented with annual training and retraining in hospitals of reference, anesthesiologists with occasional casistic can provide procedures only in children over three years of age.

In case the anesthetist could not gain the minimal personal casistic required inside his hospital, he/she can complete it through a compulsory training in another hospital of reference, that should provide a certification of the clinical casistic. This training must be repeated annually.

The SIAATIP Committee assume that, in order to maintain the necessary safety standards, those volumes of activity are required even for nurses involved in the activity of support to the intensivist/anesthetist physicians.

Qualitative typology of anesthetic performances

Considering the minimal casistic above established, anesthesiologists must acquire and maintain knowledges and skills for all age brackets in[3,18,19] (Grade A6)

a) preoperative evaluation
b) Techniques of basic and advanced life support
c) Stabilization and transport of critical child
d) Management of airways in all age brackets and with all devices (tracheal tubes, supra-glottic devices, use of traditional laryngoscopy and video-laryngoscopy, difficult intubation, rigid and flexible bronchoscopy)
e) Management of general and locoregional - peripheral and neuraxial (preferably ultrasound guided) – anesthesia.
f) Basic and advanced monitoring (hemodynamic, respiratory, neuromuscular, depth of anesthesia)
g) Vascular peripheral and central access (preferably ultrasound guided)
h) Perioperative pain therapy
i) Management and stabilization in recovery room
j) Communicative skills with parents and relatives
k) Knowledge of the main rare diseases that involve difficulty of intubation and proscription of anesthetic drugs and diversified anesthetic choices
l) For anesthesiologists working in hospitals HUB, second level DEA and centers with specialistic activity of pediatric surgery, knowledge of physiology

and development of neonate, also pre-term/premature baby, and skills for the execution of anesthesia procedures for complex and/or highly specialistic surgeries.

Those skills should be acquired on the field and through specific courses as indicated afterwards.

Institutional obligations in absence of skills in pediatric and neonatal anesthesia

A big debate exist on the precise definition of minimum age *(cut-off ages)* under which the child should be followed by an anesthetist experienced in pediatric procedures. A point in common among all European countries (together with USA, and in part with Australia and New Zealand) is that the training period must be at least of one year.

In Italy, where the majority of hospitals is not specialized in pediatrics, this point is particularly admitted and still regulated only by local directives. Below we list some European references:

United Kingdom: every anesthetist must be able to manage common surgeries in age >3 years (and to stabilize, in emergency, a patient for the transfer in a hospital of superior level). Until few years ago this limit was fixed to 5 years.

France: the pediatric surgery pathology needs recognized anesthesia and surgery skills for children under the age of 3 years.

Switzerland: cut-off age 2 years, every hospital must define a responsible anesthetist for pediatric patients, in case of patients in pre-school age the pediatric anesthetist must on call inside the hospital; for infants must be directly present.

Austria: infants or kids with co-morbidities or in complex surgeries must be treated in a pediatric centre. Kids from 1 to 3 years of age can be treated even in non specialistic hospitals if: a) presence of two anesthesist with more than 30 anesthetic procedures /year in infant; b) those anesthesist with documented experience must follow apdating paths in a specialistic centre every two years

Germany: no cut-off ages exists, nor dedicated paths or training.

In other European countries postgraduate student must be tutored directly by an expert in presence of a child of age <3 years and in not specialized hospitals, patients of age <3 or < 2 years must be transferred.

That being stated, until an agreement with other countries regarding the period of training in pediatric anesthesia, the SIAATIP Committee recommend that the cut-off age is established to 3 years. This applies above all for peripheral hospitals and for anesthesiologists with only occasional and/or irregular pediatric activity.

Therefore, outside clinical emergency and urgency situations, where intensivist/anesthesiologist must promptly operate, according to its professional experience and means provided by hospital, it is strictly forbidden the execution of elective anesthetic procedures in pediatric patients below 3 years of age[17] (Grade B6) to intensivist/anesthesiologists that cannot present in their curriculum a pediatric clinical competence comparable with the standards required in other European countries and based on the present recommendations, and/or have not dedicated devices available, and/or are not adequately trained by their hospitals, and/or in absence of paths, protocols or hospital operative instructions.[3] The SIAATIP Committee, in fact, considers they should prevail the interest for the health of the child who should entrust to staff of proved clinical experience and in suitable and equipped hospital structures.

We recommend to intensivist/anesthesiologist to formally ask to their hospitals and to directors to follow periods of training in pediatric field in order to acquire the right professional skills.

Anesthesiologists are required, moreover, to inform the Risk Management Unit about all clinical and organiza-

tional lack. The regional organization in network of hospitals Hub & Spoke must be considered as a reference for the transfer to centers with proved experience in the treatment of pediatric patients, that cannot be otherwise treated.

The transfer of a child to other centers must develop in safety using suitable means and staff, through an active interdisciplinary collaboration as showed in chapter 7 and using for new-born the STEN service of neonatal transport.[22] (Grade B6)

Training

Aside the skills acquired through the minimal clinical casistic, anesthetist must follow special programs of training and recurrent certified retraining. In absence of training and/or skills the hospital directions and the directors of complex structure cannot oblige the anesthetist to perform procedures except for clinical conditions of emergency-urgency. The programs can be followed at the structure of belonging, if the minimal casistic is ensured, or at other structures with greater casistic or clinical complexity or at specialized structures if ultra-specialistic skills are needed. It is fundamental that anesthetist continue to maintain appropriate clinical skills.

The skills and the programs of training must be certified and documented as well as it happens in other European/extra-European countries. Certifications can be issued by hospital structures, scientific societies and university.

For the purposes of training the anesthetist must attend courses also with use of simulators in order to improve knowledge in basic and advanced anesthesia techniques in pediatric and neonatal field.[44-46] (Grade B6)

It is desirable to identify regional reference centers for training as well as national ones.

Moreover, clinical audit and discussion of clinical cases and sentinel events/near miss events are useful in a training purpose.[12,36] (Grade B6)

The training can also include research and study activity regarding anesthesia procedures in pediatric field, respecting rules established by ethical committees.

Skills of nursing staff, instrumental equipment and devices availability

Nurses and technical staff involved in the treatment of neonates and children must have training and experience in routine and emergency-urgency pediatric perioperative treatment[47-51] (Grade A6).

Important considerations regarding training of such human resources are:

a) The ability to prepare drugs and infusions of appropriate doses, concentrations and volumes for pediatric patients;
b) experience in respiratory assistance for neonates and children;
c) recurrent formative training and retraining at its structure;
d) pediatric training in regional reference centers for whoever is not routinely involved, but only occasionally is involved in pediatric field.

All centers that occasionally are involved in pediatric anaesthesia must be adequately equipped as follows[19,52,53]: (Grade A6).

a) Equipment of a cart, dedicated for emergencies and urgencies, that must be equipped with all devices for age brackets and with a check list for recurrent check and of drugs' expirations. Attached to the cart a transportable bag must be available, based on Broselow band model.
b) Equipment of a cart for management of airways and difficult airways, including laryngoscopes, Miller and Macintosh laryngoscope blades, video-laryngoscopes, fibrobronchoscopes, laryngeal masks, tracheal tubes, oral airways, stylets, tubes, tracheostomy/cricothyrotomy sets, also percutaneous, of all measures, both pediatric and neonatal.

c) Equipment for cardiorespiratory monitoring system for all age brackets
d) Equipment for monitoring of neuromuscular blockade
e) Equipment for monitoring of anesthesia depth (BIS; Entropy)
f) Equipment for manual and mechanical ventilation systems to all age brackets.
g) Equipment for maintenance and monitoring of body temperature, thermal blanket, forced air heaters, heaters of fluids. The ambient temperature of operating theatre should be able to be quickly regulated until a range of 26-28°C in case of surgeries on neonates and premature babies.
h) Sets for central and peripheral vascular cannulation suitable for all age brackets, also neonatal, systems for intra-osseous administration of drugs and liquids, infusion pumps.
i) Availability of ultrasound with pediatric linear probes for vascular ultrasound guided central venous cannulation, as well as arterial cannulation and for execution of loco-regional anesthesia.
j) Equipment of defibrillator with pediatric and neonatal plates. The defibrillator must be tested daily and the efficiency of the internal batteries checked. Verification tests must be reported on apposite register with indication of the person that performed the check.
k) Equipment of systems for continuous infusion of analgesics drugs for postoperative pain.
l) A recovery room with all equipment for cardiorespiratory monitoring and airways management must be available and separated by adult patients.
m) A list of drugs with indication of dosages and pediatric and neonatal formulations must be exposed and well visible.

Recovery room

In many European countries post-anesthesia recovery rooms are mandatory and widespread. Recovery rooms with dedicated staff reduce considerably the incidence of adverse events in the phase of complete recovery of consciousness. This aspect is particularly critical in patients in pediatric age. In Italy still exists still serious lacks and applicative delays that cannot be postponed anymore. All hospitals where pediatric anesthesia procedures are performed must therefore create at least a recovery room.[54-56] (Grade B6).

National register of critical events in pediatric and neonatal anesthesia

SIAATIP established the National Register Of Critical Events In Pediatric And Neonatal Anesthesia in order to gather information on critical events and anesthetic incidents involving pediatric patients on all national territory. The reports are collected through a record card marked with the SIAATIP logo, available exclusively upon specific request contacting SIAATIP (siaatip@siaatip.it).

Anesthesiologists are encouraged to report to the Scientific Society the critical events occurred during pediatric anesthesia procedures. The information reported on the report card are anonymous, with a guarantee of confidentiality of personal data of the anesthesiologist, patient and staff involved. The card is provided exclusively by email to those having the necessity to communicate a critical event (it will not be provided for any other reasons and/or means) and it should be sent always by email within the term of 7 days, filled in every part. Different and not allowed uses or misuses will be reported to the hospital directions of the reference hospitals and to the SIAATIP Board for the appropriate measures. The confidential nature, custody, collection and check of accuracy of data is guaranteed and ensured by direct responsibility of SIAATIP Board with the supervision of the Presidency Office. SIAATIP reserves periodically

to analyse, communicate and publish statistical data of synthesis derived by exam of all cards received to ensure a correct analysis of strength and weakness points of the organizational aspects and anesthesia procedures in pediatric and neonatal field on national territory. Such analysis will be used to bring corrective elements, to emit recommendations and guidelines, to study the best strategies in order to guarantee greater safety and efficacy in pediatric and neonatal anesthesia.

Transfer and hospitalization in pediatric postoperative intensive care and surgical emergencies

In case of complications or necessities related to clinical conditions of child that can occur in postoperative period, a protocols of transfer in pediatric intensive care, intra o extra-hospital, must be established. It is necessary the intervention of a multidisciplinary team that involve surgeons, anesthesiologists, nurses, pediatric intensivists, pediatricians, neonatologists. This applies also for the common pediatric surgical emergencies-urgencies, for which the anesthesiologist must possess suitable skills and proceed through activations of dedicated paths and operative protocols.

It is essential that these routes are implemented through PDTA, in a clear and definite way in order to ensure rapid interventions, in respect of procedures of safety and efficacy, in respect of regional regulations, of services of STEN and STAM and of recommendations/guidelines.[20,22,57,58] (Grade B6)

Report for parents and psychological support

It is recommendable to put at disposal of parents and children some informative brochures with complete and extensive explanations about anesthesia procedures, about hospitalization and recovery and about organization of services in hospital.

Brochure directed to children must be adapted at their specific age inserting amusing illustrations and of easy comprehension, realized also through consultation of psychologists, pediatricians and children's neuropsychiatrist.

It is showed, through STAIC-S (State-Trait Anxiety Inventory for Children- State subscale), that this kind of information reduces preoperative anxiety in children.[59]

All brochures must highlight contacts numbers of the structure of anesthesia and intensive care for eventual request of information also after discharge.[55](Grade B6).

The psychological support for children and for parents, with the help of specialists, is recommendable in all cases and above all in clinical conditions of particular seriousness, terminally-ill children and during the cares of end life.

Limits and conclusions

SIAATIP Committee is fully aware that recommendations in this document have often been described in terms of "strength of recommendations" type B and "levels of evidence" 5 or 6 (Table 3).

This arises from the fact that the literature about this topic is practically limited to panels of experts, reviews or by foreign guidelines that show only few points in common, in consideration of the different typologies of training and postgraduate schools and the different national health systems in the world.

Moreover, RCT works or meta-analysis with universal, applicable EBM evidences are missing.

Revision of document

Recommendations must be submitted to recurrent revisions in order to update to possible new standard of treatments, ministerial provisions, evolution of scientific knowledges. The current recommendations will be revised every three-year. SIAATIP Committee established that the next revision of document is expected in 2020 except for urgent need of updating.

GRADE A	GRADE B
Day-hospital: measures of safety expected for ordinary recoveries A5	Dedicated areas and spaces dedicated B5
Staff adequately trained in organized hospital contexts A6	Minimal personal casistic, continuity of fulfillment B6
Anesthetists must acquire and maintain knowledges and skills for all age brackets A6	During School of Speciality in Anesthesia and Intensive Care a minimum period of 3 months in pediatrics B6
Nurses and technical staff trained and with routine and emergency perioperative experience A6	Post graduate courses, master, programs of (re)training, simulators B6
	Not only quantitative differentiation of skill B6
	Anesthetists continuously and occasionally engaged in pediatric activityB6
	Network 118, transport: trained staff B6
	NORA and sedation: same criteria of operating theatre B6
	Rare diseases: enter in contact with centers of reference B6
	Recovery room if children B6
	Explicative brochures B6
	Transfer in pediatric postoperative intensive therapy (TIPO) B6

Table 3. Strength of recommendations

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