LASOS-Peds

Latin American Surgical Outcomes Study in Pediatrics

LASOS-Peds

Latin American Surgical Outcomes Study in Pediatrics

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Background

- World Federation of Societies of Anesthesiologists (WFSA)
  - Need to train an additional 136,000 physician anesthesia providers
  - 5 per 100,000 population
- 19% of the total global surgical workforce live and work in LMICs
- 80% of global noncommunicable disease mortality occurring in LMICs
- For every child that faces a delay in basic and necessary surgical care, 8.4 years of disability is added to their life

Jonathan Niconchuk and Mark Newton, *Curr Opin Anaesthesiol,* 2022

Estimates of number of children and adolescents without access to surgical care

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Objective To estimate how many children and adolescent worldwide do not have access to surgical care.

Methods We estimated the number of children and adolescents younger than 19 years worldwide without access to safe, affordable and timely surgical care, by using population data for 2017 from the United Nations and international data on surgical access in 2015. We categorized countries by World Bank country income group and obtained the proportion of the population with no access to surgical care from a study by the *Lancet* Commission on Global Surgery.

Findings An estimated 1.7 billion (95% credible interval: 1.6–1.8) children and adolescents worldwide did not have access to surgical care in 2017. Lack of access occurred overwhelmingly in low- and middle-income countries where children and adolescents make up a disproportionately large fraction of the population. Moreover, 453 million children younger than 5 years did not have access to basic life-saving surgical care. According to *Lancet* Commission on Global Surgery criteria, less than 3% of the paediatric population in low-income countries and less than 8% in lower-middle-income countries had access to surgical care.

Conclusion There were substantial gaps in the availability of surgical services for children worldwide, particularly in low- and middle-income countries. Future research should focus on developing specific measures for assessing paediatric surgical access, delivery and outcomes and on clarifying how limited surgical access in the poorest parts of the world affects child health, especially mortality in children younger than 5 years.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article.

Introduction

The Millennium Development Goal period (i.e. 2000 to 2015) was characterized by an unprecedented decrease in child mortality.[1] Even in the poorest areas of the world, mortality in children younger than 5 years fell dramatically, which led to predictions that a grand global convergence in mortality in this age group would be possible by 2035.[2] However, further progress will depend on continued improvements across the full spectrum of child health services.

Surgical care for children is one area of child health that is often overlooked, yet can play an important role in preventing death and disability.[3] Surgery is vital for the repair of correctable congenital anomalies (e.g. congenital heart disease, cleft lip and palate and club foot), the treatment of life-threatening injuries and burns, and the diagnosis and treatment of childhood cancers. Surgery can minimize the acute and long-term suffering of children, protect families from substantial financial loss and increase economic productivity. In addition, surgical care can play a role in achieving health-related sustainable development goals and targets, in particular: (i) ending preventable deaths in newborn babies and children younger than 5 years; (ii) reducing death and disability due to road traffic injuries and noncommunicable diseases; (iii) ensuring universal health coverage; and (iv) increasing the health workforce.[4]

In 2015, the *Lancet* Commission on Global Surgery reported that at least 4.8 billion people worldwide lacked access to surgical care.[5,6] The Commission assessed the availability of surgical services using a chance tree, probability model, in which access was evaluated over four dimensions: (i) timeliness, which was assessed from the proportion of people with serious injuries who were transported by ambulance; (ii) surgical capacity, which was defined as the proportion of surgical procedures needed to meet demand that were actually undertaken; (iii) safety, which was assessed from the proportion of operating theatres with pulse oximetry; and (iv) affordability, which was defined as the proportion of patients undergoing surgery who were protected from catastrophic expenditure due to out-of-pocket payments.[6] Access to surgical care varied widely across geographical regions, with more than 95% of the population in South Asia and central, eastern and western sub-Saharan Africa having no access. It was not clear, however, how lack of access affects the paediatric population. Consequently, in our analysis, we sought to answer the specific question: "How many children and adolescents worldwide lack access to safe, affordable and timely surgical care?"

Methods

To estimate the number of children and adolescents without access to surgical care we used population data for 2017 from the United Nations and previously reported data on access to surgery from the *Lancet* Commission on Global Surgery.[5–7] The proportion of the population without access to surgical

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World Bank country income classification	Total population, in millions[a]	No. of children and adolescents, in millions (% of total population)[a]					Proportion of total population with no access to surgical care(95% CrI)[b]	No. of children and adolescent with no access to surgical care, in millions (95% CrI)				
		0–4 years	5–9 years	10–14 years	15–19 years	< 19 years		0–4 years	5–9 years	10–14 years	15–19 years	< 19 years
High	1180.1	65.1 (5.5)	66.8 (5.7)	65.6 (5.7)	68.6 (5.8)	266.1 (22.6)	14.9 (12.2–17.5)	9.7 (7.9–11.4)	10.0 (8.1–11.7)	9.8 (7.9–11.5)	10.2 (8.3–12.0)	39.6 (32.2–46.6)
Upper-middle	2588.4	185.2 (7.2)	177.1 (6.8)	171.0 (6.8)	174.0 (6.7)	707.3 (27.3)	58.7 (49.1–66.5)	108.7 (90.9–123.1)	104.0 (87.0–117.8)	100.4 (83.9–113.7)	102.2 (85.5–115.7)	415.2 (347.3–470.3)
Lower-middle	2969.9	319.8 (10.8)	308.8 (10.4)	295.1 (9.9)	281.4 (9.5)	1205.0 (40.6)	92.3 (89.3–94.5)	295.1 (285.5–302.2)	285.0 (275.7–291.8)	272.4 (263.5–278.9)	259.7 (251.3–265.9)	1112.2 (1076.1–1138.7)
Low	641.9	103.4 (16.1)	91.5 (14.3)	80.5 (12.5)	69.5 (10.8)	344.8 (53.7)	97.7 (95.6–99.5)	101.0 (98.8–102.9)	89.4 (87.5–91.0)	78.6 (76.9–80.1)	67.9 (66.4–69.1)	336.9 (329.6–343.1)
Total	**7380.2**	**673.4 (9.1)**	**644.2 (8.7)**	**612.2 (8.3)**	**593.4 (8.0)**	**2523.2 (34.2)**	**67.3 (64.1–70.4)**	**453.2 (431.7–474.1)**	**433.6 (413.0–453.5)**	**412.0 (392.4–431.0)**	**399.4 (380.4–417.8)**	**1698.1 (1617.4–1776.3)**

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SURGICAL SYMPOSIUM CONTRIBUTION

Global Initiative for Children's Surgery: A Model of Global Collaboration to Advance the Surgical Care of Children

Global Initiative for Children's Surgery[1]

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Abstract

Background Recommendations by the Lancet Commission on Global Surgery regarding surgical care in low- and middle-income countries (LMICs) require development to address the needs of children. The Global Initiative for Children's Surgery (GICS) was founded in 2016 to identify solutions to problems in children's surgery by utilizing the expertise of practitioners from around the world. This report details this unique process and underlying principles.

Methods Three global meetings convened providers of surgical services for children. Through working group meetings, participants reviewed the status of global children's surgery to develop priorities and identify necessary resources for implementation. Working groups were formed under LMIC leadership to address specific priorities. By creating networking opportunities, GICS has promoted the development of LMIC-LMIC and HIC-LMIC partnerships.

Results GICS members identified priorities for children's surgical care within four pillars: infrastructure, service delivery, training and research. Guidelines for provision of care at every healthcare level based on these pillars were created. Seventeen subspecialty, LMIC chaired working groups developed the Optimal Resources for Children's Surgery (OReCS) document. The guidelines are stratified by subspecialty and level of health care: primary health center, first-, second- and third-level hospitals, and the national children's hospital. The OReCS document delineates the personnel, equipment, facilities, procedures, training, research and quality improvement components at all levels of care.

Conclusion Worldwide collaboration with leadership by providers from LMICs holds the promise of improving children's surgical care. GICS will continue to evolve in order to achieve the vision of safe, affordable, timely surgical care for all children.

Defining the need

Surgical burden of disease

Since the conclusion of the United Nations' Millennium Development Goals (MDGs) and through the ongoing work toward Sustainable Development Goals (SDGs), tremendous progress has been made toward reducing childhood mortality [1, 2]. However, the care of children with surgical diseases remains an underappreciated and underfunded area in health care, despite congenital

Collaborating members are listed in the Acknowledgments.

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Incidence of severe critical events in paediatric anaesthesia (APRICOT): a prospective multicentre observational study in 261 hospitals in Europe

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This online publication has been corrected. The corrected version first appeared at thelancet.com/respiratory on April 6, 2017, and further corrections were added on April 28, 2017.

See Comment page 365

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Summary

Background Little is known about the incidence of severe critical events in children undergoing general anaesthesia in Europe. We aimed to identify the incidence, nature, and outcome of severe critical events in children undergoing anaesthesia, and the associated potential risk factors.

Methods The APRICOT study was a prospective observational multicentre cohort study of children from birth to 15 years of age undergoing elective or urgent anaesthesia for diagnostic or surgical procedures. Children were eligible for inclusion during a 2-week period determined prospectively by each centre. There were 261 participating centres across 33 European countries. The primary endpoint was the occurence of perioperative severe critical events requiring immediate intervention. A severe critical event was defined as the occurrence of respiratory, cardiac, allergic, or neurological complications requiring immediate intervention and that led (or could have led) to major disability or death. This study is registered with ClinicalTrials.gov, number NCT01878760.

Findings Between April 1, 2014, and Jan 31, 2015, 31 127 anaesthetic procedures in 30 874 children with a mean age of 6·35 years (SD 4·50) were included. The incidence of perioperative severe critical events was 5·2% (95% CI 5·0–5·5) with an incidence of respiratory critical events of 3·1% (2·9–3·3). Cardiovascular instability occurred in 1·9% (1·7–2·1), with an immediate poor outcome in 5·4% (3·7–7·5) of these cases. The all-cause 30-day in-hospital mortality rate was 10 in 10 000. This was independent of type of anaesthesia. Age (relative risk 0·88, 95% CI 0·86–0·90; p<0·0001), medical history, and physical condition (1·60, 1·40–1·82; p<0·0001) were the major risk factors for a serious critical event. Multivariate analysis revealed evidence for the beneficial effect of years of experience of the most senior anaesthesia team member (0·99, 0·981–0·997; p<0·0048 for respiratory critical events, and 0·98, 0·97–0·99; p=0·0039 for cardiovascular critical events), rather than the type of health institution or providers.

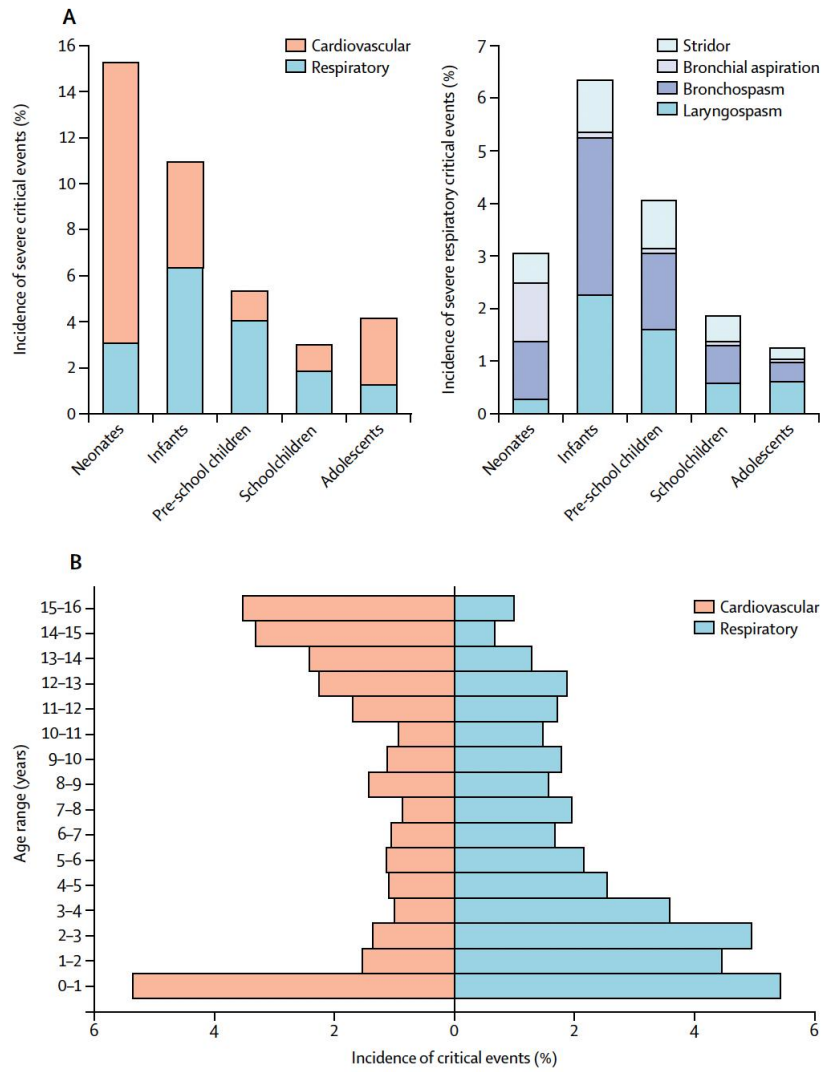
Interpretation This study highlights a relatively high rate of severe critical events during the anaesthesia management of children for surgical or diagnostic procedures in Europe, and a large variability in the practice of paediatric anaesthesia. These findings are substantial enough to warrant attention from national, regional, and specialist societies to target education of anaesthesiologists and their teams and implement strategies for quality improvement in paediatric anaesthesia.

Funding European Society of Anaesthesiology.

Introduction

Guidelines for paediatric anaesthesia management and structured programmes for specific training have been developed in Europe during the past decade to standardise practice and improve patient safety. The incidence, nature, and outcome of severe critical events in children during and immediately after anaesthesia in Europe, and the effects of variability in practice are unknown. Most of the literature on paediatric anaesthesia morbidity and mortality comprises clinical audits focusing on a single institution or country,[1–3] which were not sufficiently powered to study rare, severe complications or mortality.[4] Moreover, differences in study design and in the definitions of severe complications make comparisons between the studies problematic.

In 2014, a large North American register was initiated as part of a safety and quality improvement programme that revealed an incidence of severe critical events in paediatric anaesthesia of 0·14%.[5] This finding is in line with previous reports from single centres or countries, the findings of which show that the rate of major perioperative complications causing severe morbidity, mortality, or both, after general[3,6] or regional anaesthesia,[7–10] is low. Most studies have highlighted respiratory complications as the primary cause of severe adverse outcome following sedation or general anaesthesia in children.[11–13] Other publications have pointed out a significant increase in haemodynamic-related severe critical events as a consequence of bleeding or inadequate fluid management.[5,14] Although most of these studies attempted to identify major risk factors (such as age <1 year, the presence of comorbidities, and specific surgical procedures), identification of predictable and preventable risks is of paramount importance as the basis



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Paediatric Anaesthesia

PAEDIATRIC ANAESTHESIA

Morbidity and mortality after anaesthesia in early life: results of the European prospective multicentre observational study, neonate and children audit of anaesthesia practice in Europe (NECTARINE)

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Abstract

Background: Neonates and infants requiring anaesthesia are at risk of physiological instability and complications, but triggers for peri-anaesthetic interventions and associations with subsequent outcome are unknown.
Methods: This prospective, observational study recruited patients up to 60 weeks' postmenstrual age undergoing anaesthesia for surgical or diagnostic procedures from 165 centres in 31 European countries between March 2016 and January 2017. The primary aim was to identify thresholds of pre-determined physiological variables that triggered a medical intervention. The secondary aims were to evaluate morbidities, mortality at 30 and 90 days, or both, and associations with critical events.
Results: Infants (n=5609) born at mean (standard deviation [SD]) 36.2 (4.4) weeks postmenstrual age (35.7% preterm) underwent 6542 procedures within 63 (48) days of birth. Critical event(s) requiring intervention occurred in 35.2% of cases, mainly hypotension (>30% decrease in blood pressure) or reduced oxygenation (SpO_2 <85%). Postmenstrual age influenced the incidence and thresholds for intervention. Risk of critical events was increased by prior neonatal medical conditions, congenital anomalies, or both (relative risk [RR]=1.16; 95% confidence interval [CI], 1.04–1.28) and in those

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Editor's key points

- Neonates and infants have limited physiological reserve, and are at greater risk of complications with general anaesthesia.
- Premature neonates are at highest risk.
- This study quantifies the important physiological aberrations and their risk factors.
- A high degree of training and skill are required for safe delivery of anaesthesia for neonates and infants.

- One or more complications →16.3%
  - Respiratory
  - Surgical
  - Cardiovascular
- Overall mortality → 3.2%

ANESTHESIOLOGY

Pediatric Perioperative Mortality in Kenya

A Prospective Cohort Study from 24 Hospitals

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ABSTRACT

Background: The global surgery access imbalance will have a dramatic impact on the growing population of the world's children. In regions of the world with pediatric surgery and anesthesia manpower deficits and pediatric surgery–specific infrastructure and supply chain gaps, this expanding population will present new challenges. Perioperative mortality rate is an established indicator of the quality and safety of surgical care. To establish a baseline pediatric perioperative mortality rate and factors associated with mortality in Kenya, the authors designed a prospective cohort study and measured 24-h, 48-h, and 7-day perioperative mortality.

Methods: The authors trained anesthesia providers to electronically collect 132 data elements for pediatric surgical cases in 24 government and nongovernment facilities at primary, secondary, and tertiary hospitals from January 2014 to December 2016. Data assistants tracked all patients to 7 days postoperative, even if they had been discharged. Adjusted analyses were performed to compare mortality among different hospital levels after adjusting for prespecified risk factors.

Results: Of 6,005 cases analyzed, there were 46 (0.8%) 24-h, 62 (1.1%) 48-h, and 77 (1.7%) 7-day cumulative mortalities reported. In the adjusted analysis, factors associated with a statistically significant increase in 7-day mortality were American Society of Anesthesiologists Physical Status III or more, night or weekend surgery, and not having the Safe Surgery Checklist performed. The 7-day perioperative mortality rate is less in the secondary (1.4%) and tertiary (2.4%) hospitals when compared with the primary (3.7%) hospitals.

Conclusions: The authors have established a baseline pediatric perioperative mortality rate that is greater than 100 times higher than in high-income countries. The authors have identified factors associated with an increased mortality, such as not using the Safe Surgery Checklist. This analysis may be helpful in establishing pediatric surgical care systems in low–middle income countries and develop research pathways addressing interventions that will assist in decreasing mortality rate.

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EDITOR'S PERSPECTIVE

What We Already Know about This Topic

- The pediatric surgical load in low- and middle-income countries is growing; more than 50% of the population are children and up to 85% may require surgery.
- Data on perioperative mortality rates are sparse and inconsistently collected, but some studies indicate high rates in Africa.

What This Article Tells Us That Is New

- In a series of 24 Kenyan hospitals, an innovative, robust data tool for collecting more accurate mortality rates found cumulative rates of 0.8% at 24 h, 1.1% at 48 h, and 1.7% at 7 days postoperatively.
- In this sample, the 7-day mortality was more than 100 times higher than in high-resource settings and associated with American Society of Anesthesiologists Physical Status III or more, surgery at night or over the weekend, and not using the Safe Surgical Checklist. Mortality was also higher in primary hospitals compared to secondary or tertiary hospitals.

Children comprise more than 50% of the overall population in many low- and middle-income countries. Perhaps 85% of these children will require a surgical operation before their fifteenth birthday.[1] Surgical admissions account for 6 to 12% of all pediatric hospitalizations in Sub-Saharan Africa, although this may be even higher in urban settings or areas of conflict.[2,3] Surgical capacity in Sub-Saharan Africa is well below current goals. As such, pediatric surgical patients likely experience preventable morbidity and mortality. The lack of basic surgery infrastructure, shortages of pediatric surgeons and anesthesia providers, and absent or inadequate physiologic monitoring capability each degrade the safety of the pediatric surgery ecosystem while making access extremely difficult, or not affordable, for this large low- and middle-income country population.[4–9]

Against this backdrop, there has been a concerted effort by global health advocates to increase surgical capacity in low- and middle-income countries.[6] To measure the effectiveness of these capacity-building efforts, it is important to establish a baseline of performance for agreed-upon clinical

This article is featured in "This Month in Anesthesiology," page 1A. This article is accompanied by an editorial on p. 413. This article has a visual abstract available in the online version.

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Paediatric Anaesthesia

South African Paediatric Surgical Outcomes Study: a 14-day prospective, observational cohort study of paediatric surgical patients

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Abstract

Background: Children comprise a large proportion of the population in sub-Saharan Africa. The burden of paediatric surgical disease exceeds available resources in Africa, potentially increasing morbidity and mortality. There are few prospective paediatric perioperative outcomes studies, especially in low- and middle-income countries (LMICs).
Methods: We conducted a 14-day multicentre, prospective, observational cohort study of paediatric patients (aged <16 yrs) undergoing surgery in 43 government-funded hospitals in South Africa. The primary outcome was the incidence of in-hospital postoperative complications.
Results: We recruited 2024 patients at 43 hospitals. The overall incidence of postoperative complications was 9.7% [95% confidence interval (CI): 8.4–11.0]. The most common postoperative complications were infective (7.3%; 95% CI: 6.2–8.4%). In-hospital mortality rate was 1.1% (95% CI: 0.6–1.5), of which nine of the deaths (41%) were in ASA physical status 1 and 2 patients. The preoperative risk factors independently associated with postoperative complications were ASA physcial status, urgency of surgery, severity of surgery, and an infective indication for surgery.
Conclusions: The risk factors, frequency, and type of complications after paediatric surgery differ between LMICs and high-income countries. The in-hospital mortality is 10 times greater than in high-income countries. These findings

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Primary objective

- To determine the incidence of in-hospital postoperative complications up to 30 days after surgery in Latin American pediatric surgical patients (under 18-years-old)

Secondary objectives

- Determine the perioperative in-hospital mortality rate up to 30 days after surgery
- Determine the incidence of severe intraoperative adverse events
- Determine the association between preoperative, intraoperative, and infrastructural factors and postoperative complications and death

Study design

- 14-day Latin American international multicenter prospective cohort study of pediatric patients

Eligibility

- Inclusion criteria
  - Patients under 18-years-old who were admitted to participating hospitals
  - Elective and nonelective surgeries
  - Outpatient surgeries and surgical procedures outside of operating rooms requiring local or general anesthesia
- Exclusion criteria
  - Radiological exams without procedures (i.e. MRI)
  - Obstetrics

Ethics

- Research ethics and regulatory approvals before the initiation of the study in each location
- National leaders will ensure that the necessary ethical and regulatory approvals are obtained

Recruitment and data collection

- We expect that all consecutive pediatric patients under 18 years undergoing elective and nonelective surgeries will be included in the study
- Each hospital will individually collect and record data on paper case recording form (CRF) for each recruited patient
  - Eletronic CRF → REDCap
- Data will be pseudoanonymized by generating a unique numeric code and transcribed by local investigators into a secure electronic CRF on the REDCap platform

Outcomes

- Primary outcome
  - Postoperative complications in the hospital up to 30 days after surgery
- Secondary outcomes
  - Mortality on the day of surgery
  - Hospital mortality up to 30 days after surgery
  - Risk factors associated with in-hospital complications
  - Severe intraoperative adverse events
  - Level of qualification of anesthesia and surgery providers
  - Admission to intensive care

National coordinators

- Identify local coordinators at participating hospitals
- Ensure the distribution of research manuals and other research materials
- Ensure necessary regulatory and ethical approvals are in place before recruitment
- Ensure good communication with participating sites in your country

Local coordinators

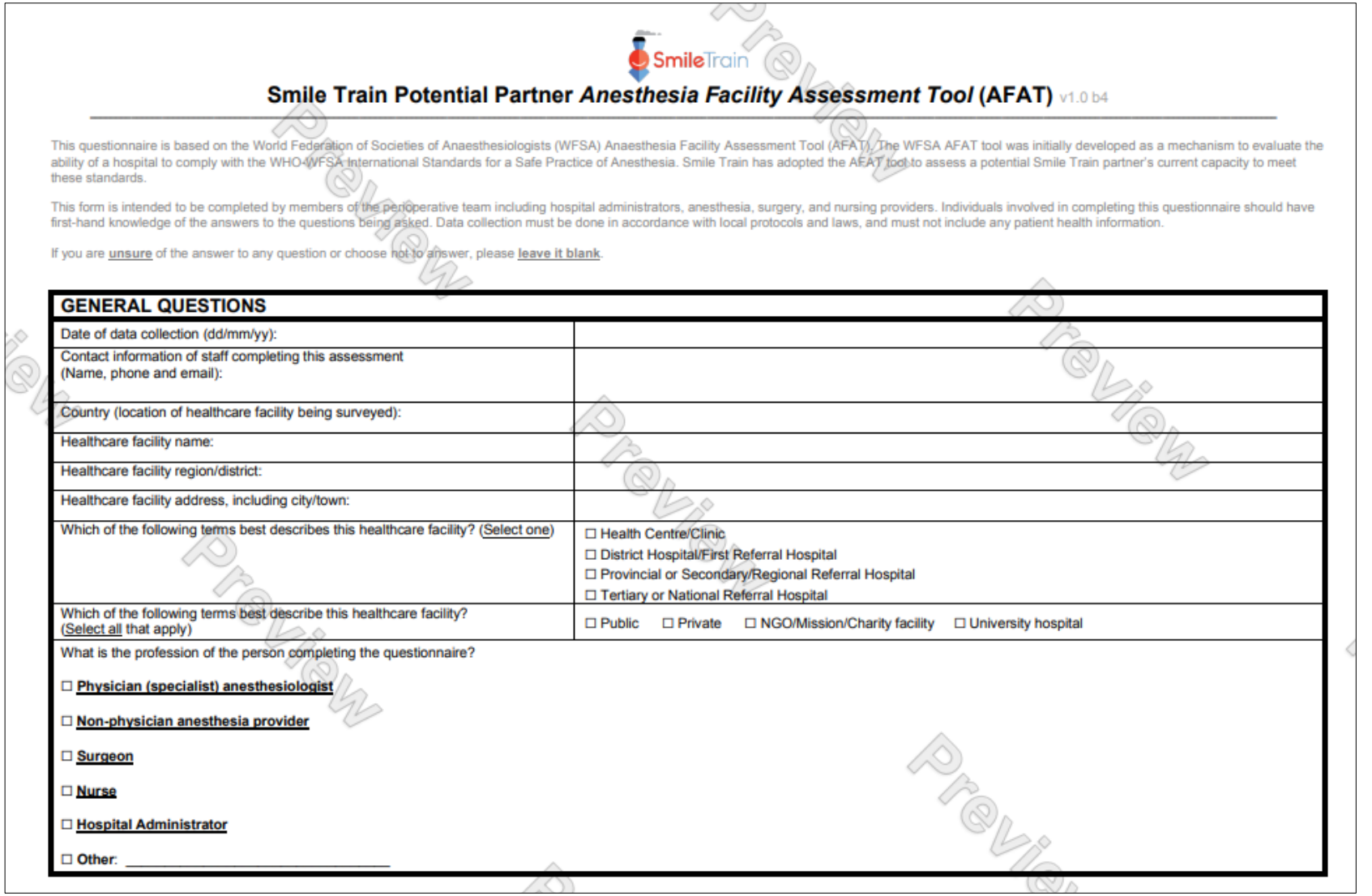
- Provide leadership for study at your institution
- Ensure that all relevant regulatory and ethical approvals are in place for your institution
- Ensure proper training of all relevant personnel before data collection
- Oversee daily data collection and site recruitment, as well as follow-up on management
- Act as a guarantor of the integrity and quality of the collected data
- Ensure the timely completion of electronic CRFs

Publication plan

- The group will be known as “The LASOS-Peds Investigators”
- It is anticipated that several secondary analyses will be performed
- LASOS-Peds investigators will be given priority to conduct secondary analyses
- Participation and authorship opportunities will be based on contributions to the primary study

AFAT – Anesthesia Facility Assessment Tool

LASOS-Peds
Latin American
Surgical Outcomes
Study in Pediatrics



SmileTrain

Smile Train Potential Partner *Anesthesia Facility Assessment Tool* (AFAT) v1.0 b4

This questionnaire is based on the World Federation of Societies of Anaesthesiologists (WFSA) Anaesthesia Facility Assessment Tool (AFAT). The WFSA AFAT tool was initially developed as a mechanism to evaluate the ability of a hospital to comply with the WHO-WFSA International Standards for a Safe Practice of Anesthesia. Smile Train has adopted the AFAT tool to assess a potential Smile Train partner's current capacity to meet these standards.

This form is intended to be completed by members of the perioperative team including hospital administrators, anesthesia, surgery, and nursing providers. Individuals involved in completing this questionnaire should have first-hand knowledge of the answers to the questions being asked. Data collection must be done in accordance with local protocols and laws, and must not include any patient health information.

If you are unsure of the answer to any question or choose not to answer, please leave it blank.

GENERAL QUESTIONS	
Date of data collection (dd/mm/yy):	
Contact information of staff completing this assessment (Name, phone and email):	
Country (location of healthcare facility being surveyed):	
Healthcare facility name:	
Healthcare facility region/district:	
Healthcare facility address, including city/town:	
Which of the following terms best describes this healthcare facility? (Select one)	☐ Health Centre/Clinic ☐ District Hospital/First Referral Hospital ☐ Provincial or Secondary/Regional Referral Hospital ☐ Tertiary or National Referral Hospital
Which of the following terms best describe this healthcare facility? (Select all that apply)	☐ Public ☐ Private ☐ NGO/Mission/Charity facility ☐ University hospital
What is the profession of the person completing the questionnaire? ☐ **Physician (specialist) anesthesiologist** ☐ **Non-physician anesthesia provider** ☐ **Surgeon** ☐ **Nurse** ☐ **Hospital Administrator** ☐ **Other**: _____	

Formulário para coleta dos dados

Protocolo LASOS Peds

Registro Intraoperatório

Registro hospitalar do paciente:_____

Data de Nascimento (DD/MM/YYYY): _____ **Sexo:** ☐ Masculino ☐ Feminino

Idade:_____ (campo auto calculável)
Peso: _____**kg**
Altura:_____**cm**
IMC: _____ (campo auto calculável)

Data de admissão neste hospital: ____/_____/____
Data da cirurgia: ____/_____/____
Classificação ASA ☐ I ☐ II ☐ III ☐ IV ☐ V
Hemoglobina:_____g/L (não mais de 28 dias antes da cirurgia)
Paciente apresenta alguma comorbidade: ☐ Sim ☐ Não
Caso sim, por favor assinale:
☐ Doença cardíaca ☐ Doença Respiratória Crônica ☐ Doença neurológica ☐ Doença infecciosa ☐ Câncer ☐ Infecção vigente do trato respiratório ☐ Alteração congênita/ Não Cardíaca
Urgência da cirurgia: ☐ Eletiva ☐ Urgência ☐ Emergência
Porte da cirurgia: ☐ Pequeno porte ☐ Médio porte ☐ Grande porte
Indicação primária para cirurgia:
☐ Doença não transmissível ☐ Lesão traumática ☐ Infecciosa ☐ Congênita
Tipo de cirurgia:
☐ Neurológica ☐ Cirurgia cardíaca (exceto transplante) ☐ Cirurgia ginecológica
☐ Cirurgia torácica ☐ Olhos – Nariz - Garganta ☐ Fissura Labial ☐ Fissura palatina
☐ Cirurgia hepatobiliar ☐ Cirurgia ortopédica ☐ Cirurgia Maxilofacial ou Craniofacial ☐ Cirurgia Gastrointestinal ☐ Cirurgia Dental ☐ Rins/ Urológica ☐ Oftalmológica
☐ Plástica/Cutânea ☐ Queimadura ☐ Transplante hepático ☐ Transplante renal
☐ Transplante cardíaco ☐ Procedimentos fora do Centro Cirúrgico ☐ Implante de cateter vascular
☐ Outra
Se outra cirurgia, descreva: _____

Horário de indução da anestesia: ____:_____
Horário do final da cirurgia:_____:_____
Duração da cirurgia: _____**min** (campo auto calculável)
Fora do horário padrão? ☐ Sim ☐ Não

Checklist de cirurgia foi utilizado (ex. WHO checklist)? ☐ Sim ☐ Não

Equipe – o professional mais experiente presente na sala de cirurgia
Anestesista: ☐ Especialista ☐ Médico não especialista ☐ Enfermeiro ☐ Não-médico
Cirurgião: ☐ Especialista ☐ Médico não especialista ☐ Enfermeiro ☐ Não-médico

Eventos adversos graves intra-operatórios:
☐ Laringoespasmo ☐ Broncoespasmo ☐ Dificuldade com a ventilação com mascara facial
☐ Falha na intubação ☐ Temperatura < 36°C ☐ Bradicardia ☐ Instabilidade cardiovascular
☐ Aspiração ☐ Hipoxemia ☐ Dificuldade na intubação ☐ Anafilaxia ☐ Erro de medicação
☐ Hipoglicemia ☐ Parada cardíaca

Registro Pós-operatório

Nível de cuidados no pós-operatório imediato:
☐Enfermaria ☐ Unidade Semi Intensiva ☐ Unidade de Terapia Intensiva

Complicações pós-operatórias:
Infecção
Infecção superficial do sítio cirúrgico ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Infecção profunda do sítio cirúrgico ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Infecção de cavidade abdominal ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Infecção sanguínea ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Pneumonia ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Outra infecção ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum

Complicação Cardiovascular
Arritmia ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Parada cardíaca ☐

Outras complicações
Sangramento ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Lesão renal aguda ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Outras ☐ Leve ☐ Moderada ☐ Grave ☐ Nenhum
Reoperação ☐
Data da alta hospitalar: ____/_____/____
Horas de internação após a cirurgia:_____ (campo auto calculável)
Duração da internação:_____ (campo auto calculável)
Status na alta hospitalar ou 30° dia de internação após a cirurgia ☐ Vivo ☐ Óbito

Iniciando o REDCap para inclusão dos dados

Preenchimento de 2 formulários para cada paciente: dados intraoperatórios e pós-operatórios

LASOS-Peds
Latin American
Surgical Outcomes
Study in Pediatrics

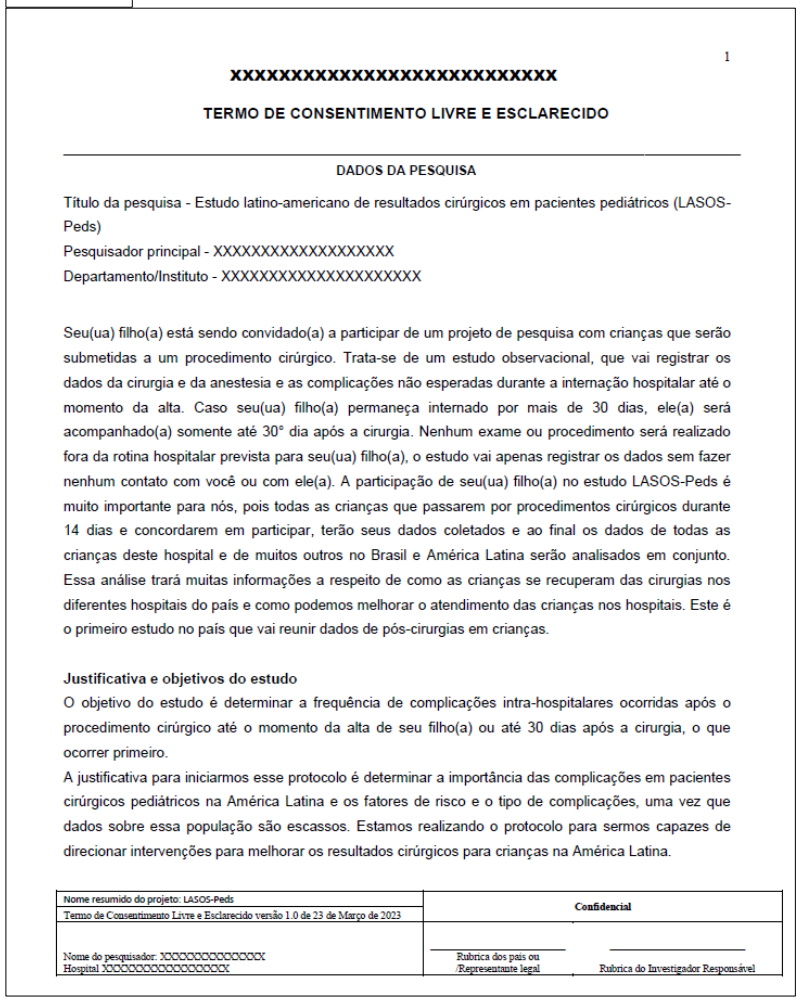
2 formulários

Definição de Eventos Adversos e Complicações

TCLE e TALEs – rubrica em todas as páginas e assinatura na última

LASOS-Peds
Latin American
Surgical Outcomes
Study in Pediatrics

PAIS



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XXXXXXXXXXXXXXXXXXXXXXXXXXXX

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

DADOS DA PESQUISA

Título da pesquisa - Estudo latino-americano de resultados cirúrgicos em pacientes pediátricos (LASOS-Peds)
Pesquisador principal - XXXXXXXXXXXXXXXXXX
Departamento/Instituto - XXXXXXXXXXXXXXXXXXXX

Seu(ua) filho(a) está sendo convidado(a) a participar de um projeto de pesquisa com crianças que serão submetidas a um procedimento cirúrgico. Trata-se de um estudo observacional, que vai registrar os dados da cirurgia e da anestesia e as complicações não esperadas durante a internação hospitalar até o momento da alta. Caso seu(ua) filho(a) permaneça internado por mais de 30 dias, ele(a) será acompanhado(a) somente até 30° dia após a cirurgia. Nenhum exame ou procedimento será realizado fora da rotina hospitalar prevista para seu(ua) filho(a), o estudo vai apenas registrar os dados sem fazer nenhum contato com você ou com ele(a). A participação de seu(ua) filho(a) no estudo LASOS-Peds é muito importante para nós, pois todas as crianças que passarem por procedimentos cirúrgicos durante 14 dias e concordarem em participar, terão seus dados coletados e ao final os dados de todas as crianças deste hospital e de muitos outros no Brasil e América Latina serão analisados em conjunto. Essa análise trará muitas informações a respeito de como as crianças se recuperam das cirurgias nos diferentes hospitais do país e como podemos melhorar o atendimento das crianças nos hospitais. Este é o primeiro estudo no país que vai reunir dados de pós-cirurgias em crianças.

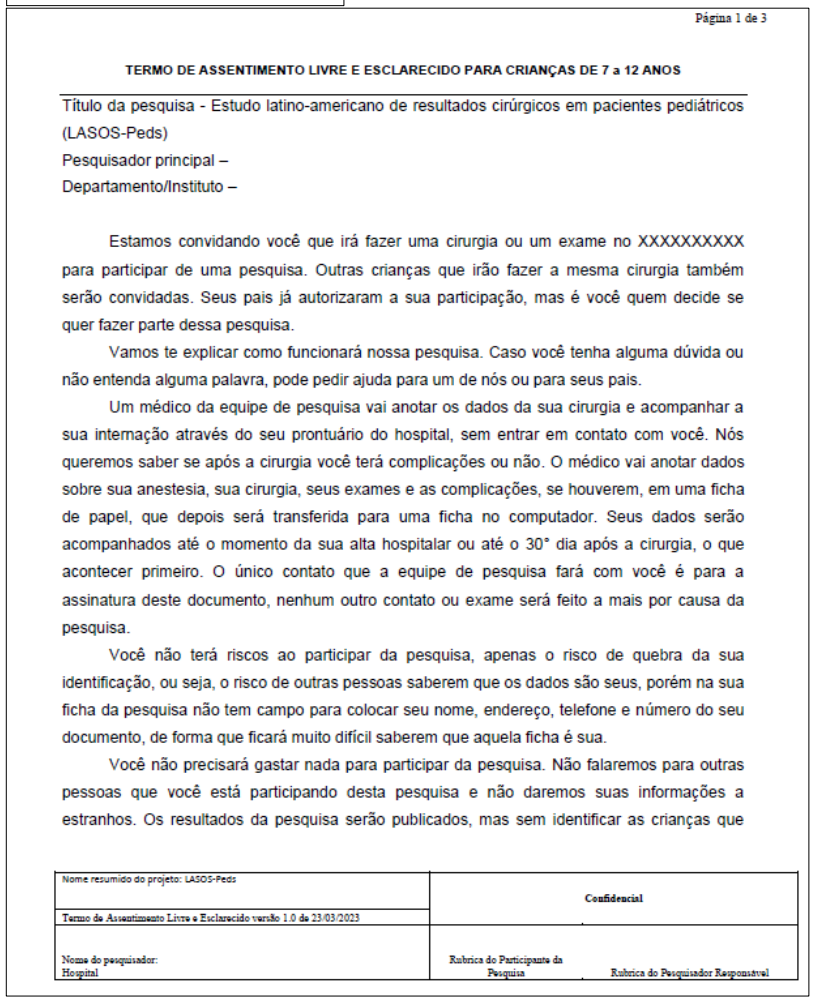
Justificativa e objetivos do estudo

O objetivo do estudo é determinar a frequência de complicações intra-hospitalares ocorridas após o procedimento cirúrgico até o momento da alta de seu filho(a) ou até 30 dias após a cirurgia, o que ocorrer primeiro.

A justificativa para iniciarmos esse protocolo é determinar a importância das complicações em pacientes cirúrgicos pediátricos na América Latina e os fatores de risco e o tipo de complicações, uma vez que dados sobre essa população são escassos. Estamos realizando o protocolo para sermos capazes de direcionar intervenções para melhorar os resultados cirúrgicos para crianças na América Latina.

Nome resumido do projeto: LASOS-Peds	Confidencial	
Termo de Consentimento Livre e Esclarecido versão 1.0 de 23 de Março de 2023		
Nome do pesquisador: XXXXXXXXXXXXXX Hospital XXXXXXXXXXXXXXXXX	Rubrica dos pais ou /Representante legal	Rubrica do Investigador Responsável

Crianças 7 a 12



Página 1 de 3

TERMO DE ASSENTIMENTO LIVRE E ESCLARECIDO PARA CRIANÇAS DE 7 a 12 ANOS

Título da pesquisa - Estudo latino-americano de resultados cirúrgicos em pacientes pediátricos (LASOS-Peds)
Pesquisador principal –
Departamento/Instituto –

Estamos convidando você que irá fazer uma cirurgia ou um exame no XXXXXXXXXX para participar de uma pesquisa. Outras crianças que irão fazer a mesma cirurgia também serão convidadas. Seus pais já autorizaram a sua participação, mas é você quem decide se quer fazer parte dessa pesquisa.

Vamos te explicar como funcionará nossa pesquisa. Caso você tenha alguma dúvida ou não entenda alguma palavra, pode pedir ajuda para um de nós ou para seus pais.

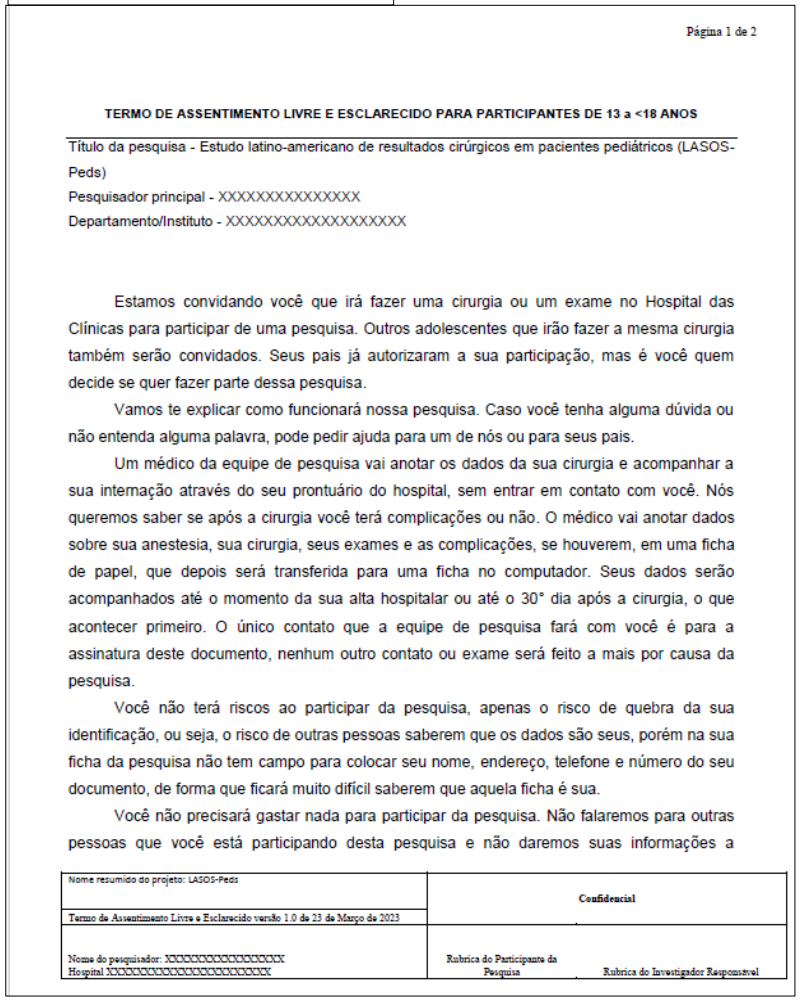
Um médico da equipe de pesquisa vai anotar os dados da sua cirurgia e acompanhar a sua internação através do seu prontuário do hospital, sem entrar em contato com você. Nós queremos saber se após a cirurgia você terá complicações ou não. O médico vai anotar dados sobre sua anestesia, sua cirurgia, seus exames e as complicações, se houverem, em uma ficha de papel, que depois será transferida para uma ficha no computador. Seus dados serão acompanhados até o momento da sua alta hospitalar ou até o 30° dia após a cirurgia, o que acontecer primeiro. O único contato que a equipe de pesquisa fará com você é para a assinatura deste documento, nenhum outro contato ou exame será feito a mais por causa da pesquisa.

Você não terá riscos ao participar da pesquisa, apenas o risco de quebra da sua identificação, ou seja, o risco de outras pessoas saberem que os dados são seus, porém na sua ficha da pesquisa não tem campo para colocar seu nome, endereço, telefone e número do seu documento, de forma que ficará muito difícil saberem que aquela ficha é sua.

Você não precisará gastar nada para participar da pesquisa. Não falaremos para outras pessoas que você está participando desta pesquisa e não daremos suas informações a estranhos. Os resultados da pesquisa serão publicados, mas sem identificar as crianças que

Nome resumido do projeto: LASOS-Peds	Confidencial	
Termo de Assentimento Livre e Esclarecido versão 1.0 de 23/03/2023		
Nome do pesquisador: Hospital	Rubrica do Participante da Pesquisa	Rubrica do Pesquisador Responsável

Crianças 13 a <18



Página 1 de 2

TERMO DE ASSENTIMENTO LIVRE E ESCLARECIDO PARA PARTICIPANTES DE 13 a <18 ANOS

Título da pesquisa - Estudo latino-americano de resultados cirúrgicos em pacientes pediátricos (LASOS-Peds)
Pesquisador principal - XXXXXXXXXXXXXXX
Departamento/Instituto - XXXXXXXXXXXXXXXXXXX

Estamos convidando você que irá fazer uma cirurgia ou um exame no Hospital das Clínicas para participar de uma pesquisa. Outros adolescentes que irão fazer a mesma cirurgia também serão convidados. Seus pais já autorizaram a sua participação, mas é você quem decide se quer fazer parte dessa pesquisa.

Vamos te explicar como funcionará nossa pesquisa. Caso você tenha alguma dúvida ou não entenda alguma palavra, pode pedir ajuda para um de nós ou para seus pais.

Um médico da equipe de pesquisa vai anotar os dados da sua cirurgia e acompanhar a sua internação através do seu prontuário do hospital, sem entrar em contato com você. Nós queremos saber se após a cirurgia você terá complicações ou não. O médico vai anotar dados sobre sua anestesia, sua cirurgia, seus exames e as complicações, se houverem, em uma ficha de papel, que depois será transferida para uma ficha no computador. Seus dados serão acompanhados até o momento da sua alta hospitalar ou até o 30° dia após a cirurgia, o que acontecer primeiro. O único contato que a equipe de pesquisa fará com você é para a assinatura deste documento, nenhum outro contato ou exame será feito a mais por causa da pesquisa.

Você não terá riscos ao participar da pesquisa, apenas o risco de quebra da sua identificação, ou seja, o risco de outras pessoas saberem que os dados são seus, porém na sua ficha da pesquisa não tem campo para colocar seu nome, endereço, telefone e número do seu documento, de forma que ficará muito difícil saberem que aquela ficha é sua.

Você não precisará gastar nada para participar da pesquisa. Não falaremos para outras pessoas que você está participando desta pesquisa e não daremos suas informações a

Nome resumido do projeto: LASOS-Peds	Confidencial	
Termo de Assentimento Livre e Esclarecido versão 1.0 de 23 de Março de 2023		
Nome do pesquisador: XXXXXXXXXXXXXXX Hospital XXXXXXXXXXXXXXXXXXXXX	Rubrica do Participante da Pesquisa	Rubrica do Investigador Responsável

Centros Aprovados Eticamente

HOSPITAIS APROVADOS PARA INÍCIO DO ESTUDO	
Hospital da Criança Santo Antônio - Roraima	Dr André Said Queiroz Lopes Rezek
Hospital Infantil Dr Jeser Amarante Faria	Dr Antonio Bedin
Hospital UNIMED Joinville	Dr Antonio Bedin
Círculo Operário Caxiense - Centro de Assistência à Saúde do Círculo	Dr Carlos André Tarrio Gandara
Hospital Estadual da Criança - Feira de Santana - BA	Dr Diego Venício Santos Argolo
Hospital Angelina Caron	Dr Emerson Alexandre Penteado de Carvalho
Casa de Saúde Santa Marcelina	Dr Emílio Carlos Del Massa
Hospital Municipal Menino Jesus	Dr Gabriel Soares de Sousa
Hospital São Camilo Santana	Dr Guinther Giroldo Badessa
Hospital Luz Vila Mariana	Dr João de Paula Beolchi
Hospital Infantil Varela Santiago	Dr Kleber Alberto de Souza Seabra
Santa Casa de Misericórdia de Ribeirão Preto	Dr Leandro Criscuolo Miksche
Hospital São Luiz Jabaquara	Dr Leopoldo Muniz da Silva
AACD	Dr Maurício Luiz Malito
Hospital Luz Sto Amaro	Dr Odair Antonio Abdala
Hospital Municipal de Barueri	Dr Paulo Fernando Tierno
Santa Casa de Misericórdia da Bahia	Dr Pedro Augusto Costa Rebouças de Castro
Hospital e Maternidade São Domingos	Dr Plinio da Cunha Leal
Hospital Metropolitano Dom José Maria Pires - PB	Dr Romulo Leal Almeida
Santa Casa de Misericórdia de Marília	Dr Teofilo Augusto Araújo Tiradentes
Santa Casa de São José dos Campos	Dr Tiago Caneu Rossi
Hospital Dr. Eulalino Ignácio de Andrade	Dra Alexandra Souza Neuba
Hospital Vila da Serra BH	Dra Amanda Jiran
Hospital das Clínicas da UNICAMP	Dra Ana Paula Damiano
Hospital de Messejana	Dra Andrea Consuelo de Oliveira Teles
Hospital da Criança e Maternidade - HBSJRP	Dra Eneida Maria Vieira
Hospital de Reabilitação de Anomalias Cranofaciais da USP	Dra Fernanda Leite
Maternidade Santa Isabel	Dra Fernanda Leite
Hospital de Clínicas de Porto Alegre	Dra Isabela Spido Sirtoli
Real Hospital Português	Dra Juliana Rodrigues Neves
Hospital Federal de Bonsucesso - HGB	Dra Juliana Soares Ribeiro
Hospital da Criança de Brasília	Dra Liliana Mesquita Andrade
Hospital João XXIII	Dra Luciana de Souza Cota Carvalho Laurentys
Hospital AC Camargo	Dra Maria Lucia de Pinho Apezzato
Hospital de Amor Infanto-Juvenil	Dra Marina Assunção Valadares Milani
Hospital das Clínicas da UFMG	Dra Marina Ayres Delgado
Hospital Estadual da Criança e do Adolescente - HECAD - GO	Dra Marise Helena Cardoso Tofoli
Hospital Augusto de Oliveira Camargo	Dra Mírnia Marília Duarte Marinho Paiva
Hospital das Clínicas da FM de Botucatu - UNESP	Dra Norma Sueli Pinheiro Módolo
Hospital Universitário Pedro Ernesto - UERJ	Dra Paula Florence Sampaio
Hospital Ferreira Machado	Dra Renata Restay
Hospital Regional Abelardo Santos	Dra Salime Saraty Malveira
Hospital Paranaense de Otorrinolaringologia	Dra Sarita França Coffani Duda
Instituto Dante Pazzanese	Dra Simone Rolim Fernandes Fontes Pedra
Hospital Santo Antonio - Obras Sociais Irmã Dulce	Dra Vera Lúcia Fernandes de Azevedo
Hospital Universitário da Universidade Federal de Sergipe	Dra Vera Maria Silveira
Hospital Municipal Antonio Giglio	Dra Vera Ruth Mendes Queiroz

Centros em Análise Ética

CENTROS EM ANÁLISE ÉTICA	
Associação de Proteção a Maternidade e a Infância de Cuiabá	Dr Alexandre Meirelles Borba
Hospital Nossa Sra da Conceição	Dr André Prato Schmidt
Instituto de Cardiologia e Transplantes do Distrito Federal	Dr Fernando Atik
Santa Casa de Misericórdia de Porto Alegre	Dr Florentino Fernandes Mendes
Hospital Universitário da UFMA	Dr João Batista Santos Garcia
Hospital Santa Catarina	Dr Maurício Giusti Calderon
Hospital e Maternidade Santa Joana	Dr Ricardo Vieira Carlos
Instituto de Medicina Integral Prof Fernando Figueira	Dr Rodrigo Melo Gallindo
Hospital das Clínicas da UFPR	Dra Camila Girardi Fachin
Hospital Felicio Rocho	Dra Claudia Helena Ribeiro da Silva
Hospital Sírio Libanês	Dra Claudia Simões
Hospital Pequeno Príncipe	Dra Daniela Bianchi Garcia
Hospital das Clínicas da FMRP-USP	Dra Maria de Fátima Galli Sorita Tazima
Hospital São Paulo - UNIFESP	Dra Mariana Fontes Lima Neville
Hospital Martagão Gesteira - BA	Dra Samantha Pereira Rosa Vilas Boas
Hospital Universitário Lauro Wanderley da UFPB	Dra Sheila Lucia Serpa Leal
Hospital Infantil Joana de Gusmão	Dra Valéria Viviana Blanco
Instituto de Puericultura e Pediatria Martagão Gesteira da UFRJ	Dra Danielle Nunes Forty
Hospital do Rim	Dra Suelen Bianca Stopa Martins

Centros com Solicitação Ética Pendente

CENTROS COM SOLICITAÇÃO PENDENTE	
Hospital São Vicente de Paulo	Dr Alexandre Pereira Tognon
Hospital de Clínicas da Universidade Federal de Uberlândia	Dr Célio Gomes de Amorim
Hospital Nossa Sra das Graças	Dr Clovis Arns da Cunha
Hospital Israelita Albert Einstein	Dr Daniel Sousa Cesar
Hospital Moinhos de Vento	Dr Eduardo Correa Costa
Hospital das Clínicas da UFPE	Dr Jayme Marques dos Santos Neto
Centro Infantil de Investigações Hematológicas Dr. Domingos A. Boldrini	Dr Luiz Henrique Pereira
Hospital São Francisco na Providência de Deus	Dr Pedro Izzo
Santa Casa de Misericórdia do Pará	Dr Thiago Said Daibes Pereira
Hospital Universitário de Jundiaí	Dr Tiago Silva e Silva
Hospital Universitário Julio Miller - UFMT	Dra Aline Maria Lima de Assis
Hospital Mater Dei - BH	Dra Eliane Cristina Souza Soares
Santa Casa de Belo Horizonte	Dra Magda Lourenço Fernandes
Hospital Estadual de Sumaré	Dra Maria Giovana Oliveira Farias
Hospital Santa Joana - Recife	Dra Marianne Weber Arnold
Hospital Universitário Ana Bezerra - UFRN	Dra Patrícia Hellering
Hospital Universitário da Universidade Estadual de Londrina	Dra Alexandra Souza Neuba

Meu centro está aprovado, e agora?

ARO-InCor vai enviar o parecer de aprovação e

TCLE e TALE – para centros que foram aprovados com essa obrigatoriedade

Pesquisador vai escolher 14 dias para a coleta de dados: Dez2023 a Dez2024

Escolher o período de maior contingente de cirurgias

Pesquisador vai enviar nome completo, e-mail e Instituição para ter acesso ao REDCap

Preencher o AFAT

Iniciar a coleta dos dados – pode ser feito prospectivamente ou retrospectivamente

Contacts

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  - Research associate
  - Phone: +55 11 2661-5795 or +55 11 99960-0922
  - aro@incor.usp.br

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- Gabriel Soares
  - Phone: +55 21 98742-9183

Visite: www.lasospeds-study.org