

# Pediatric intensive and palliative care in pediatric/neonatal intensive care units around the world

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>09/07/2019   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>12/07/2019 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>18/08/2023       | <b>Condition category</b><br>Neonatal Diseases    | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

Pediatric palliative care (PPC) is a human right and, in many cases, a foundational component of the best available standard of care. Across the world, PPC is not adequately available in a variety of clinical environments, including in many pediatric and neonatal intensive care units (PICUs /NICUs). While PPC is most popularly integrated into such units through consultative models of care in which external teams are called to address PPC needs as they are identified, integrative models of care (IMOC) also exist in which ICU personnel identify and address PPC needs within the unit as they arise. The less common IMOC may be uniquely beneficial in its ability to facilitate the delivery of care to special needs patients, maximize available resources, build local PPC capacity, and make PC available in under-resourced environments. Building international PC capacity and integrating the IMOC into PICUs/NICUs depend upon a chain of interventions like The Initiative for Pediatric Palliative Care (IPPC) guidelines, which outline six domains of quality PPC. The objective of this multicenter study was to assess how different PICU/NICU centers around the world currently implement an IMOC of PPC and pediatric critical care in relation to the IPPC recommendations. In addition, this study sought to identify whether the physical environment, technological infrastructure, and human resources of each unit may shape the provision and outcomes of care in relation to IPPC guidelines.

### Who can participate?

PICUs/NICUs representing countries from the Americas, Europe, Asia, and Africa.

### What does the study involve?

Two questionnaires with multiple choice and open-ended questions were applied to all PICU /NICU centers to develop detailed descriptions of the participating units and the level of IMOC they apply.

### What are the possible benefits and risks of participating?

None

Where is the study run from?  
Colegio de Ciencias de la Salud (College of Health Sciences), Quito, Ecuador

When is the study starting and how long is it expected to run for?  
June 2016 to February 2019

Who is funding the study?  
Universidad San Francisco de Quito (Ecuador)

Who is the main contact?  
Dr Michelle Grunauer  
mgrunauer@usfq.edu.ec

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
2016-091IN

## Study information

**Scientific Title**  
PICU MIC: Integrated care in pediatric/neonatal intensive care units around the world

**Acronym**  
PICU MIC

**Study objectives**  
Participating pediatric intensive care units (PICUs)/neonatal intensive care units (NICUs) implement an integrated model of care combining pediatric intensive and palliative care according to the domains outlined in the Initiative for Pediatric Palliative Care (IPPC) guidelines

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 15/06/2016, Comité de Ética de Investigación en Seres Humanos de la Universidad San Francisco de Quito-Committee of Bioethics Research in Human Beings (IRB) (Campus Cumbáy - Diego de Robles y Via Interoceánica Oficina G206 Casilla Postal 17-1200-841 Quito, Ecuador; (+593) 2-297-1700, ext 1149; comitebioetica@usfq.edu.ec), ref: 2016-091IN.

## **Primary study design**

Observational

## **Study design**

Cross-sectional prospective observational study

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Pediatric palliative and intensive care, pediatric and neonatal diseases

## **Interventions**

This cross-sectional prospective study included a convenience sample of 34 (updated 02/09 /2019, previously: 33) participating PICUs/NICUs representing 18 countries from the Americas, Europe, Asia, and Africa.

Two questionnaires with multiple choice and open-ended questions were applied to all centers to develop detailed descriptions of the participating units.

Questionnaire 1 focused exclusively on unit infrastructure, technology availability, and personnel ratios. Questionnaire 2 gathered further data on personnel, policies, and limited clinical and demographic data on a small sample of currently admitted patients.

Based on the IPPC recommendations, Questionnaire 2 inquired about practices related to the IPPC (The Initiative for Pediatric Palliative Care (IPPC): Quality domains, goals and indicators for family-centered care of children living with life-threatening conditions) domains:

1. Holistic care
2. Family support
3. Child-family unit involvement in care
4. Control of pain and other symptoms
5. Continuity of care
6. Support for grief and bereavement

The sum of these data reflects important aspects of the models of care employed in participating PICUs

## **Intervention Type**

Other

## **Primary outcome(s)**

Adherence of PICUs/NICUs to the IPPC's recommendations assessed using questionnaire 2.

## **Key secondary outcome(s)**

PICUs/NICUs unit infrastructure, technology availability, and personnel ratios assessed by questionnaire 1.

**Completion date**

01/02/2019

## **Eligibility**

**Key inclusion criteria**

1. PICUs/NICUs
2. Local IRB approval to take part in the study

**Participant type(s)**

Other

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

Not Specified

**Key exclusion criteria**

ICUs that are not solely for pediatric/neonatal patients.

**Date of first enrolment**

01/06/2016

**Date of final enrolment**

01/07/2018

## **Locations**

**Countries of recruitment**

Argentina

Bolivia

Chile

China

Ecuador

Ethiopia

Ghana

India

Italy

Kazakhstan

Malaysia

Mexico

Philippines

Spain

Switzerland

Türkiye

Ukraine

United States of America

**Study participating centre**

**PICU- The CHILDS TRust Medical Research Foundation**

12-A Nageswara Road

Nungambakkam

Chennai

India

600034

**Study participating centre**

**PICU-Nirmal Hospital, Ltd.**

Ring Road

Surat

India

395002

**Study participating centre**

**Dayanand Medical College & Hospital**

Civil Lines

Ludhiana

India

141001

**Study participating centre**  
**University of Florida COM-PICU**  
841 Prudential Drive  
Jacksonville, Florida  
United States of America  
32207

**Study participating centre**  
**Geneva University Hospitals-Commission cantonale d'éthique de la recherche (CCER) Pharmacien cantonal Rue Adrien-Lachenal 8 1207 Genève N/réf. : OH/fr Dre Marie SAINT-FAUST Service des Soins Intensifs Pédiatriques Dpt des Enfants et Adolescents HUG-PICU**  
Rue Gabrielle Perret-Gentil 4 1211 Genève 14  
Geneva  
Switzerland  
1205

**Study participating centre**  
**Hospital General Universitario Gregorio Marañón-UCIP**  
Calle del Dr. Esquerdo, 46  
Madrid  
Spain  
28007

**Study participating centre**  
**Dicle University Medical Hospital-PICU**  
Dicle Üniversitesi Rektörlüğü  
Diyarbakır  
Türkiye  
21280

**Study participating centre**  
**Istanbul University Faculty of Medicine PICU**  
Beyazıt  
Fatih/Istanbul  
Türkiye  
31387

**Study participating centre**  
**Akdeniz University-Faculty of Medicine PICU**  
Pınarbaşı Mahallesi  
Akdeniz Üniv.

Antalya  
Türkiye  
07070

**Study participating centre**  
**Gaziosmanpaşa University School of Medicine Tokat- PICU**  
Tokat Gaziosmanpaşa Üniversitesi  
Taşlıçiftlik Yerleşkesi  
Tokat  
Türkiye  
60250

**Study participating centre**  
**Nazarbayev University- PICU at Astana**  
53 Kabanbay Batyr Ave  
Nur-Sultan  
Astana  
Kazakhstan  
010000

**Study participating centre**  
**Nazarbayev University- PICU at Karaganda**  
53 Kabanbay Batyr Ave  
Nur-Sultan  
Karaganda  
Kazakhstan  
010000

**Study participating centre**  
**Hospital del Niño Manuel Ascencio Villarroel, Cochabamba-PICU**  
HN MAV Av Aniceto Arce esq. G. Urquidi  
Cochabamba  
Bolivia  
4220232

**Study participating centre**  
**Çukurova University Medical Faculty**  
Balcalı, Çukurova Üniversitesi Rektörlüğü  
Adana  
Türkiye  
01330

**Study participating centre**

**Hospital de Niños Roberto del Río-UPC**

Prof. Zañartu 1085

Independencia

Región Metropolitana

Santiago

Chile

8380000

**Study participating centre**

**University Malaya Medical Center-PICU**

Lembah Pantai

Kuala Lumpur

Malaysia

59100

**Study participating centre**

**Vinnitsa National Medical University-PICU**

Pyrohova St 56

Vinnytsia

Vinnyts'ka oblast

Vinnitsa

Ukraine

21018

**Study participating centre**

**Pediatric hospital of Fudan University-PICU**

399 Wanyuan Rd

Minhang Qu

Shanghai Shi

Fudan

China

200032

**Study participating centre**

**Pediatric Critical Care Medicine**

20 York St

New Haven



New Haven, CT  
United States of America  
06510

**Study participating centre**

**Hospital de los Valles- UCIP/UCIN**

Avenida Interoceanica y avenida Florencia Torre 2 piso 1 consultorio 134 Edificio Especialidades  
Médicas Hospital de los Valles  
Cumbaya, Quito  
Ecuador  
170157

**Study participating centre**

**UCIP**

Hospital Regional De Alta Especialidad De Ixtapaluca  
Ixtapaluca  
Mexico  
56530

**Study participating centre**

**PICU Directorate of child Health Komfo Anokye Teaching Hospital**

Room 7 Block J  
School of Medical Sciences, KNUST  
Kumasi  
Ghana  
23321

**Study participating centre**

**Unidad Pediátrica de Quemados de los Servicios de Salud del Estado de Puebla, Mexico**

Calzada Zalvareta  
Hospital para El Niño Poblano  
Puebla  
Mexico  
72000

**Study participating centre**

**Hospital Sotero Del Rio-UCIP**

Av. Concha Y Toro 3459  
Puente Alto  
Región Metropolitana  
Gran Santiago

Chile  
8150215

**Study participating centre**  
**Ospedale Pediatrico Bambino Gesù-PICU**  
Viale Ferdinando Baldelli n.41-00146  
Roma  
Italy  
00146

**Study participating centre**  
**Division of Pediatric Critical Care Medicine at Stanford University Medical Center-PICU**  
300 Pasteur Dr. Stanford  
Stanford  
United States of America  
94305

**Study participating centre**  
**Koru Hospital-PICU**  
Kızılırmak, 1450. Sk. No:13  
Çankaya  
Ankara  
Türkiye  
06510

**Study participating centre**  
**Azienda Ospedaliera Universitaria Integrata Verona- PICU**  
Piazzale Aristide Stefani, 1  
Verona  
Italy  
37126

**Study participating centre**  
**Universidad Austral Argentina-PICU**  
Mariano Acosta 1611  
B1630FHB Pilar  
Buenos Aires  
Argentina  
B1629WWA

**Study participating centre****University Hospitals Cleveland Medical Center-PICU**

11100 Euclid Avenue  
Cleveland, Ohio  
United States of America  
44106

**Study participating centre****AMANG Rodriguez Memorial Medical Center-PICU**

Sumulong Highway Sto. Nino  
Marikina  
1800 Metro Manila  
Manila  
Philippines  
54025002

**Study participating centre****Addis Ababa University, College of Health Sciences-PICU**

TikurAnbessa Hospital School of medicine building 4th floor  
Lideta sub-city Addis Ababa  
Addis Ababa  
Ethiopia  
9086

**Study participating centre****The Johns Hopkins Children's Center PICU**

Johns Hopkins Children's Center  
1800 Orleans Street  
Baltimore, MD  
United States of America  
21287

**Study participating centre****PICU of National Research Center for Maternal and Child Health**

Turan ave. 32  
Astana  
Kazakhstan  
010000

**Sponsor information**

## Organisation

Universidad San Francisco de Quito

## ROR

<https://ror.org/01r2c3v86>

## Funder(s)

### Funder type

University/education

### Funder Name

Universidad San Francisco de Quito (Ecuador)

## Results and Publications

### Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

### IPD sharing plan summary

Available on request

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 28/10/2021   | 26/11/2021 | Yes            | No              |
| <a href="#">Results article</a> |         | 05/10/2021   | 26/11/2021 | Yes            | No              |
| <a href="#">Results article</a> |         | 15/11/2021   | 18/08/2023 | Yes            | No              |