

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

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| Submission date 09/07/2019 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 12/07/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 18/08/2023 | Condition category 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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 Vía Interoceánica Oficina G206 Casilla Postal 17-1200-841 Quito, Ecuador; (+593) 2-297-1700, ext 1149; comitebioetica@usfq.edu.ec), ref: 2016-091IN.

Study design

Cross-sectional prospective observational study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

19/10/2015

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

Age group

Other

Sex

Not Specified

Target number of participants

34 centers

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
Dicel University Medical Hospital-PICU
Dicile 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
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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

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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

Sponsor details
Diego de Robles y Vía Interoceánica
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Sponsor type
University/education

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

Funder(s)

Funder type
University/education

Funder Name

Universidad San Francisco de Quito (Ecuador)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

15/08/2019

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 28/10/2021 | 26/11/2021 | Yes | No |
| Results article | | 05/10/2021 | 26/11/2021 | Yes | No |
| Results article | | 15/11/2021 | 18/08/2023 | Yes | No |