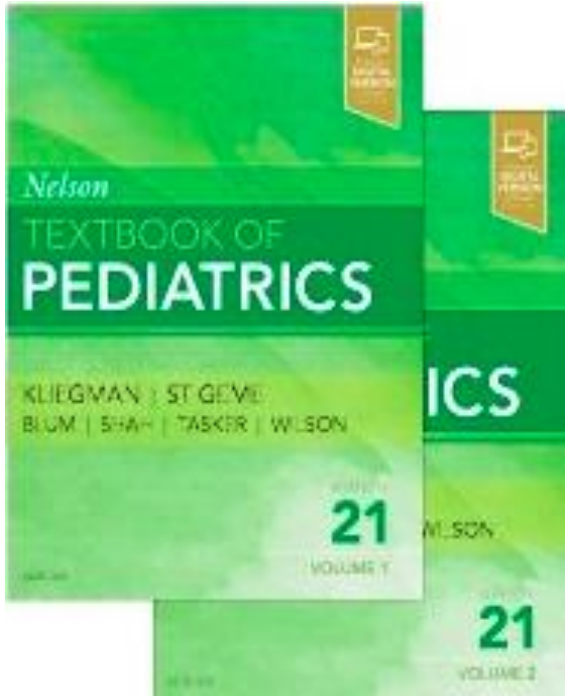
Boston Children's Hospital

Professor of Anesthesia
2011 Founding Chair in Neurocritical Care



Editor
Nelson's Textbook
21e, 22e, 23e (ongoing)

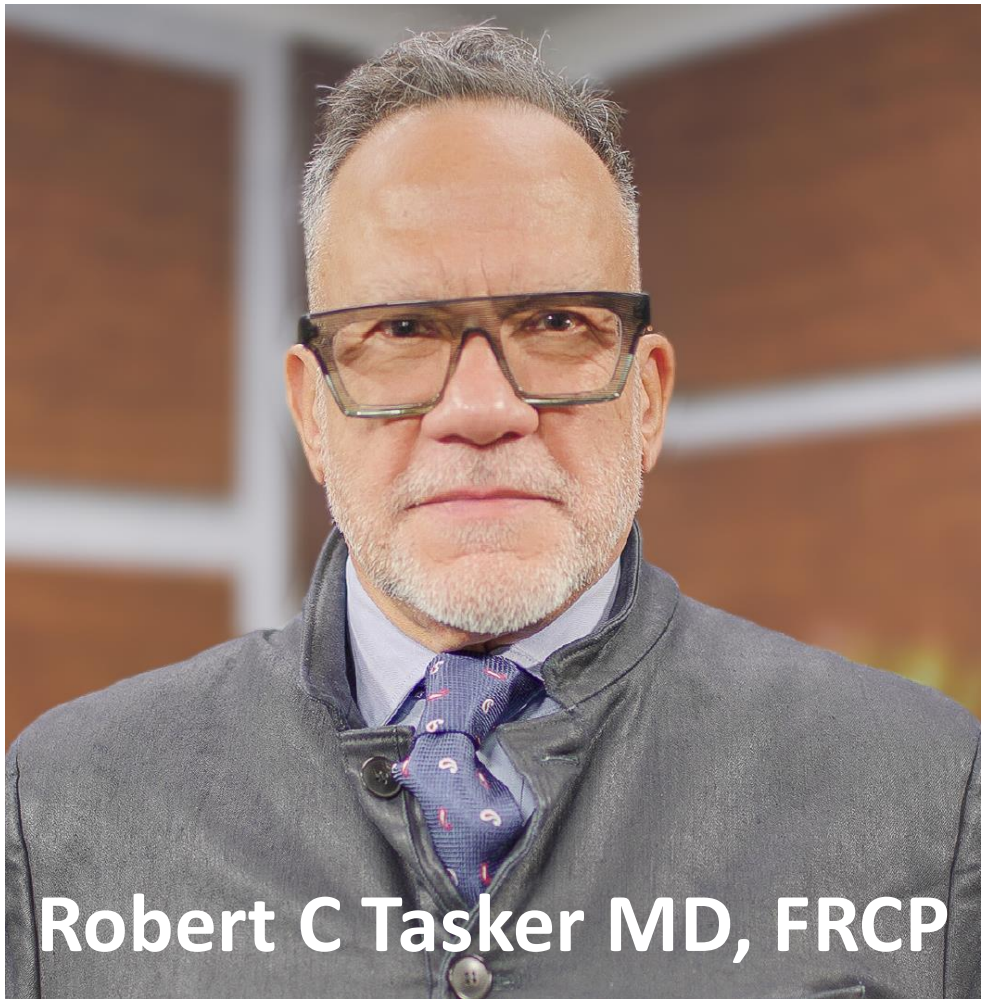
Editor-in-Chief
Pediatr Crit Care Med
Appointed 2020-

Selwyn College
Cambridge

Postgraduates' Tutor
College Lectureship
Fellow (2002-11, 2020-)

Harvard Medical School: robert.tasker@childrens.Harvard.edu

Selwyn, Cambridge: rct31@cam.ac.uk



Registry Science

1. Historical *weakness & limit*
2. *Strength & future*
3. The “why?” and “how?” of *journal selection/publication*

ST. LOUIS Children's HOSPITAL BJC HealthCare

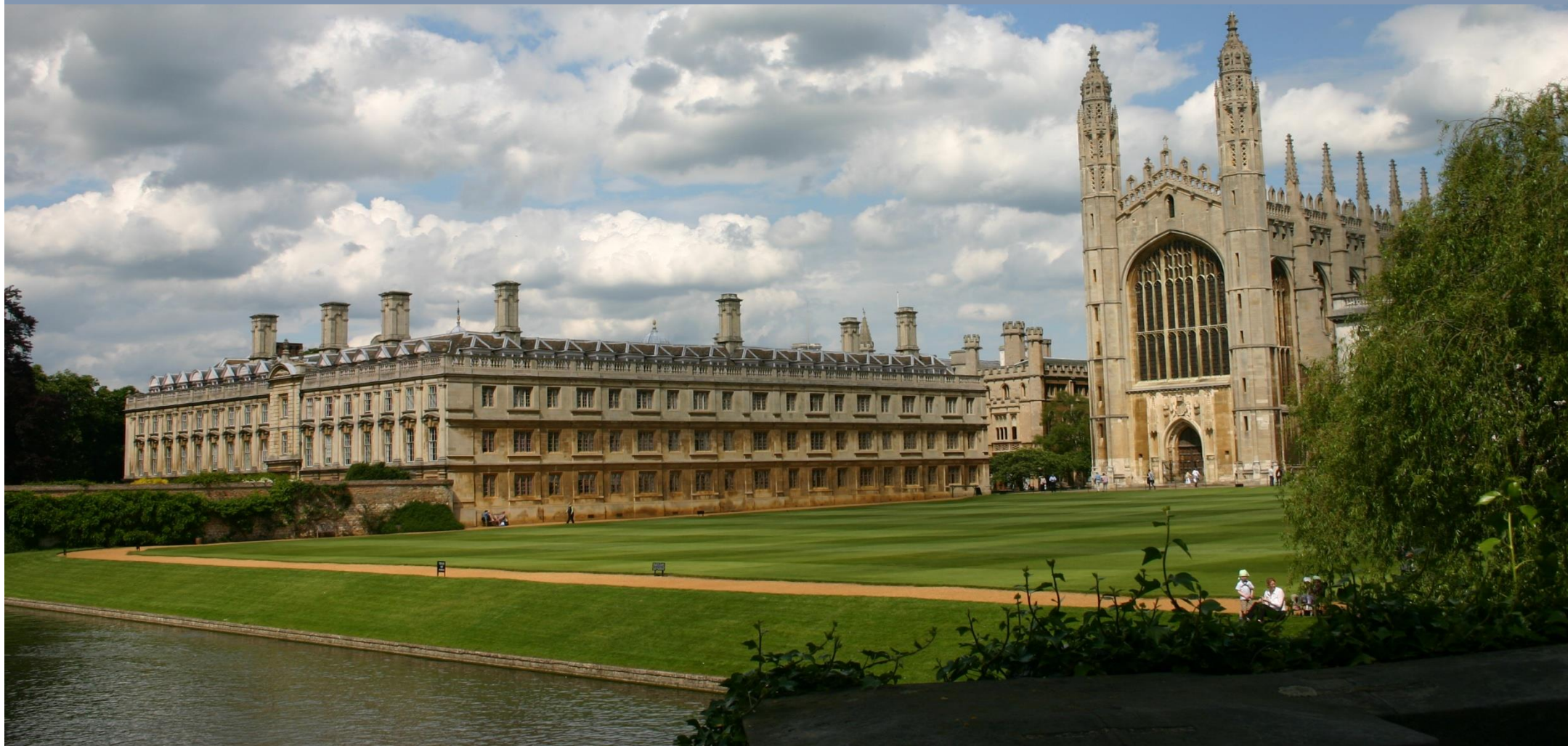
PC4 PAC3

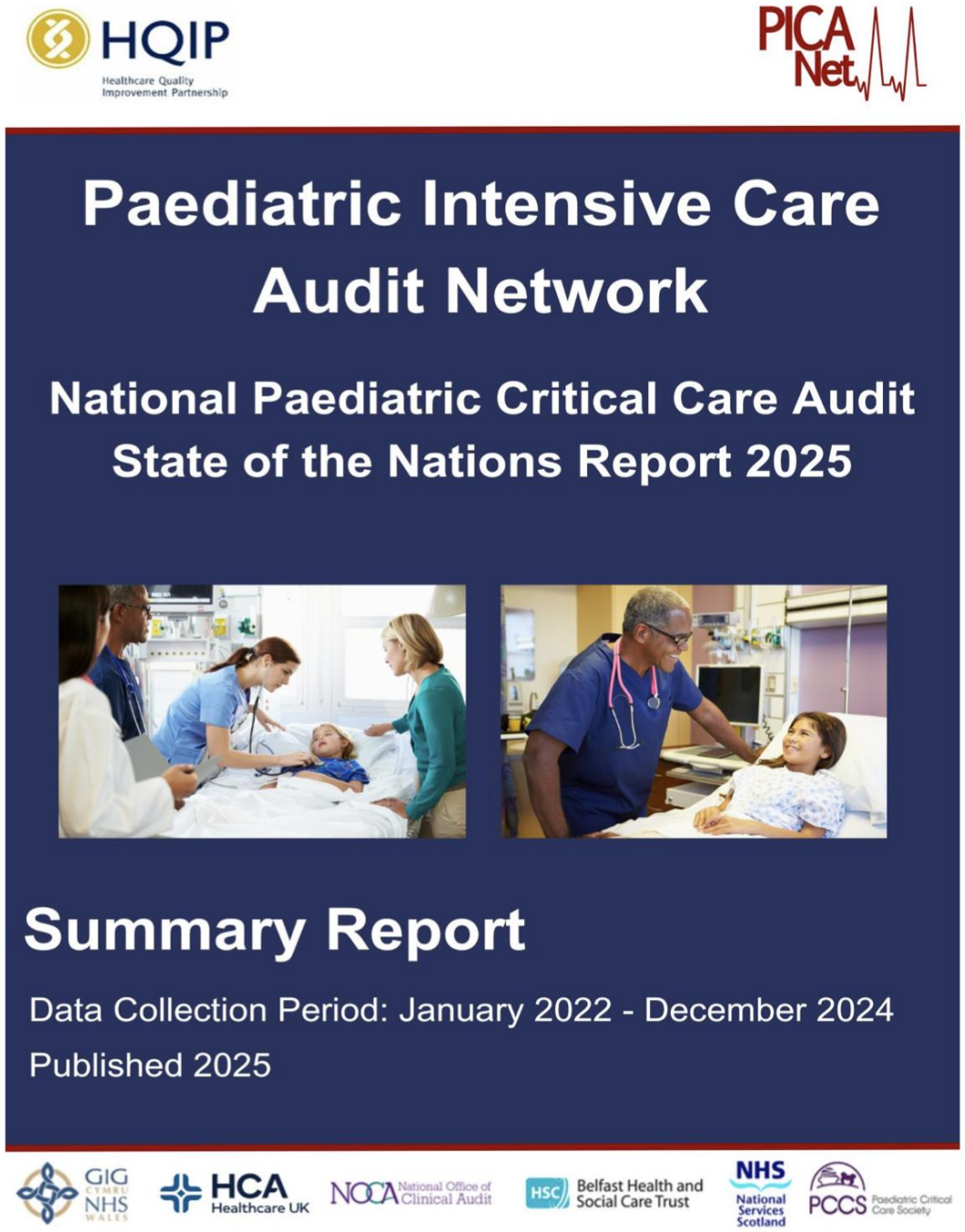
WashU Medicine

UK Paediatric Intensive Care Society Study Group

UK Paediatric Critical Care Society Study Group

Cambridge 2005 → 2026





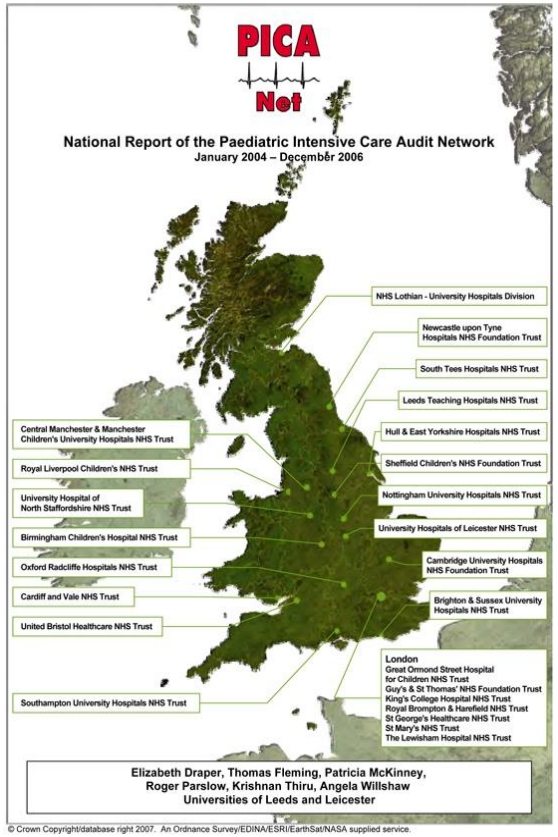
Era of Epidemiology → Clinical RCT → Curated datasets

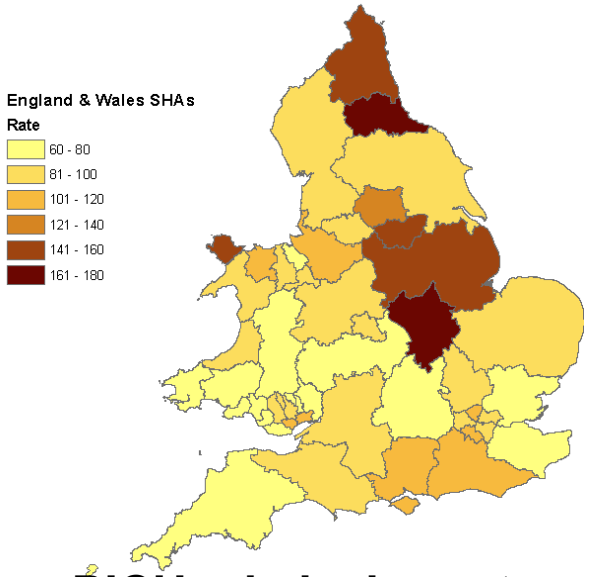
CHIP

Control of **H**yperglycemia **I**n **P**ediatric Intensive Care

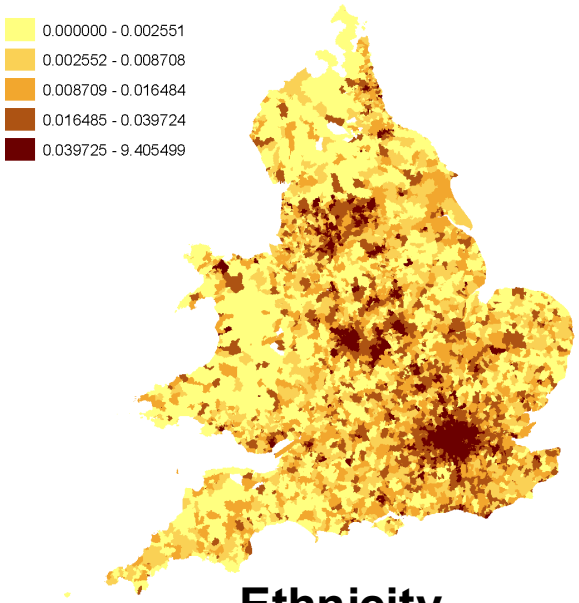
SLEEPS

Safety profi**L**e, **E**fficacy and **E**quivalence in **P**aediatric intensive care **S**edation

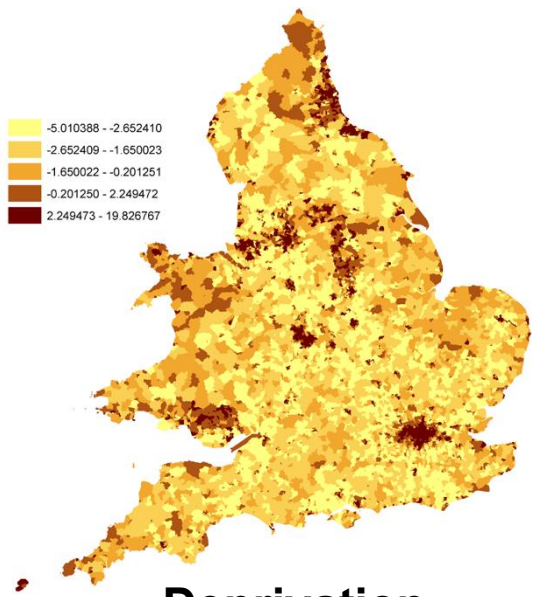




PICU admission rates
Standardized (census)



Ethnicity
Asian (census)



Deprivation
Townsend index (census)

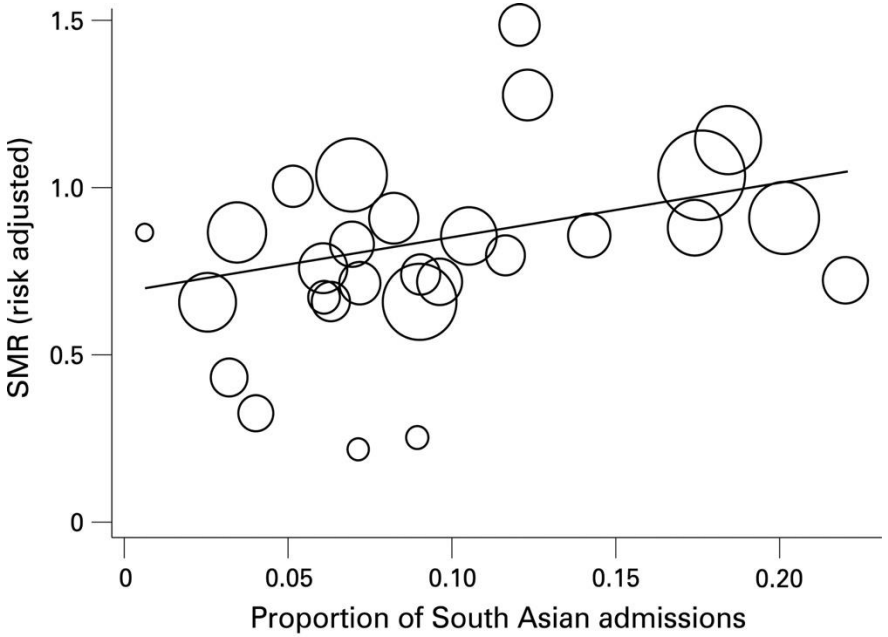
SDOH & PICU admission

PICU risk-adjusted mortality

- 100 / 100,000 children / yr
- No effect of deprivation
- Effect in south Asian children with

  OR 1.36 (95%CI 1.18 to 1.57)

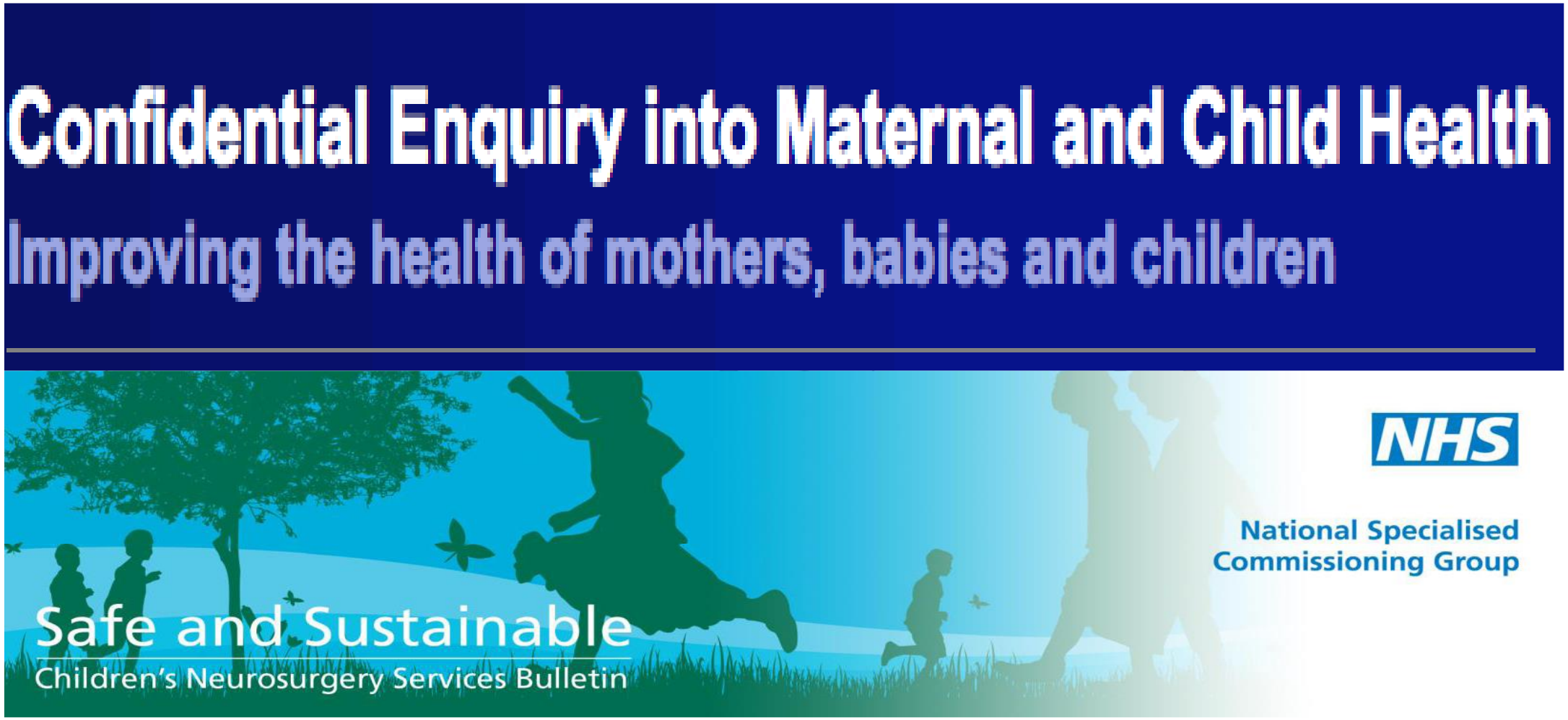
Parslow et al (2009) Arch Dis Child



ORIGINAL ARTICLE

Br J Neurosurg 2011;25:68-77

Severe head injury in children: intensive care unit activity and mortality in England and Wales



HQIP
Healthcare Quality Improvement Partnership

PICA Net

Paediatric Intensive Care Audit Network

National Paediatric Critical Care Audit
State of the Nations Report 2025

Summary Report

Data Collection Period: January 2022 - December 2024

Published 2025

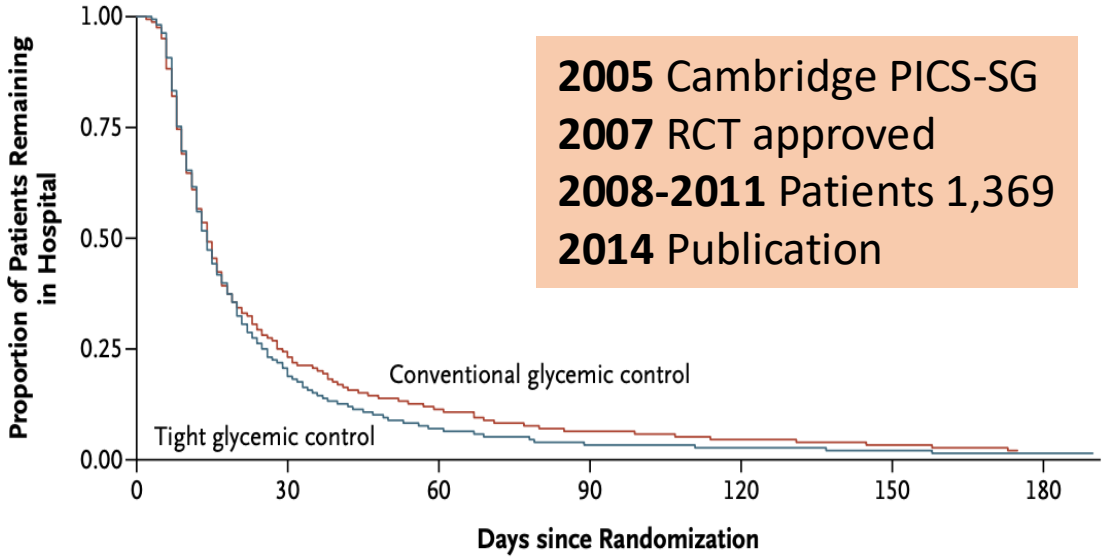
GIG CYMRU NHS WALES
HCA Healthcare UK
NCAA National Office of Clinical Audit
HSC Belfast Health and Social Care Trust
NHS National Services Scotland
PCCS Paediatric Critical Care Society

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 9, 2014 VOL. 370 NO. 2

A Randomized Trial of Hyperglycemic Control in Pediatric Intensive Care

Duncan Macrae, F.R.C.A., Richard Grieve, Ph.D., Elizabeth Allen, Ph.D., Zia Sadique, Ph.D., Kevin Morris, M.D., John Pappachan, F.R.C.A., Roger Parslow, Ph.D., Robert C. Tasker, M.D., and Diana Elbourne, Ph.D., for the CHiP Investigators*



2005 Cambridge PICS-SG
2007 RCT approved
2008-2011 Patients 1,369
2014 Publication

No. at Risk

Conventional glycemic control	675	162	76	40	29	21	12
Tight glycemic control	694	139	46	22	17	12	8

PCCM 2022

The United Kingdom Paediatric Critical Care Society Study Group: The 20-Year Journey Toward Pragmatic, Randomized Clinical Trials

Mark J. Peters, MBChB, PhD, MRCP, FRCPCH[1,2]

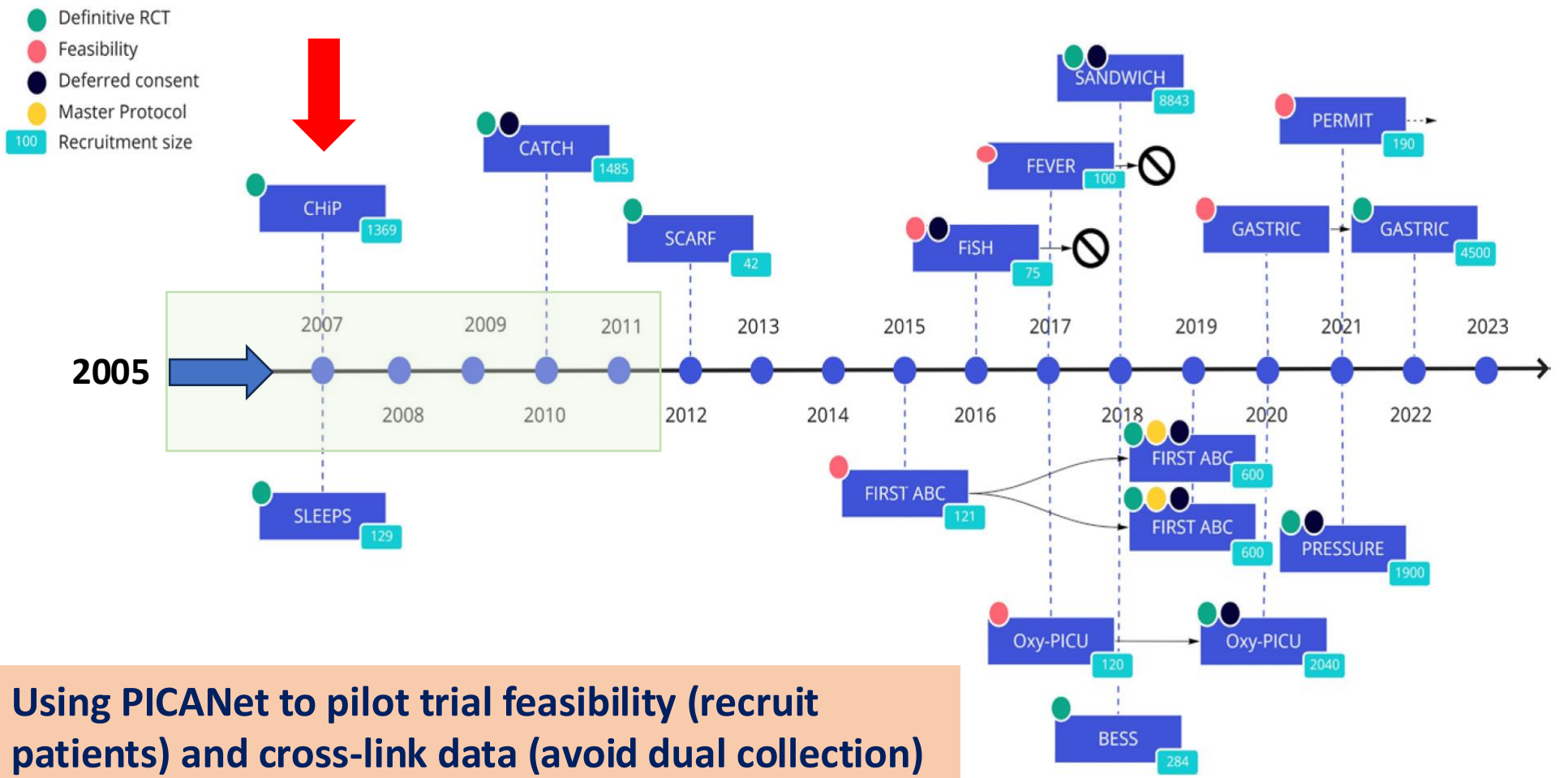
Padmanabhan Ramnarayan, MBBS, MD, FRCPCH, FFICM[3,4]

Barnaby R. Scholefield, MBBS, MRCPCH, PhD[5,6]

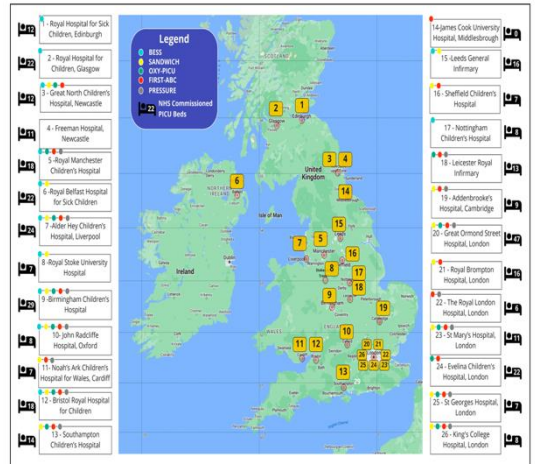
Lyvonne N. Tume , RN, PhD[7]

Robert C. Tasker, MBBS, MD, FRCP[8,9]

for the United Kingdom Paediatric Critical Care Society Study Group (PCCS-SG)



Using PICANet to pilot trial feasibility (recruit patients) and cross-link data (avoid dual collection)



Oxy-PICU, Lancet 2024
2020-2022
(n=2040)

Ethnicity and Observed Oxygen Saturations, Fraction of Inspired Oxygen, and Clinical Outcomes: A Post-Hoc Analysis of the Oxy-PICU Trial of Conservative Oxygenation*

2024

Gareth A.L. Jones, MD[1]
Martin Wiegand, PhD[2,3]
Samiran Ray[1,3,4]
Doug W. Gould, PhD[5]
Rachel Agbeko, PhD[6,7]
Elisa Giallongo, MSc[5]
Walton N. Charles, MBBS[5]
Marzena Orzol, MSc[5]
Lauran O'Neill, BSc[1]
Lamprini Lampro, MSc[5]
Jon Lillie, MD[8,9]
John Pappachan, MD[10]
Padmanabhan Ramnarayan, MD[11,12]
David A. Harrison, PhD[5]
Paul R. Mouncey, MSc[5]
Mark J. Peters, PhD[1,3,4,11]
for the Oxy-PICU Investigators of the Pediatric Critical Care Society Study Group

#1/4

***Post hoc* Subgroup Analyses**

CLINICAL INVESTIGATION ARTICLE

Severity of Impaired Oxygenation and Conservative Oxygenation Targets in Mechanically Ventilated Children: A Post Hoc Subgroup Analysis of the Oxy-PICU Trial of Conservative Oxygenation

2025

Samiran Ray, PhD[1,2,3]
Martin Wiegand, PhD[2,4]
Doug W. Gould, PhD[5]
David A. Harrison, PhD[5]
Paul R. Mouncey, MSc[5]
Mark J. Peters, PhD[1,2,3]
on behalf of the Oxy-PICU Investigators of the United Kingdom Paediatric Critical Care Society Study Group

OBJECTIVES: A conservative oxygenation strategy is recommended in adult and pediatric guidelines for the management of acute respiratory distress syndrome to reduce iatrogenic lung damage. In the recently reported Oxy-PICU trial, targeting peripheral oxygen saturations (Spo_2) between 88% and 92% was associated with a shorter duration of organ support and greater survival, compared with Spo_2 greater than 94%, in mechanically ventilated children following unplanned admission to PICU. We investigated whether this benefit was greater in those who had severely impaired oxygenation at randomization.

DESIGN: Post hoc analysis of a pragmatic, open-label, multicenter randomized controlled trial.

#2/4

PRESSURE protocol
2024 (n=1,900)
2021-2026

PCCM TRIAL

OPEN

Protocol for a Randomized Controlled Trial to Evaluate a Permissive Blood Pressure Target Versus Usual Care in Critically Ill Children with Hypotension (PRESSURE)

Robert Darnell, MA[1]
Alanna Brown, MSc[1]
Emma Laing, BSc[1]
Julia Edwards, PhD[1]
David A. Harrison, PhD[1]
Joseph C. Manning, PhD[2]
Mark J. Peters, PhD[3]
Padmanabhan Ramnarayan, MD[4]
Samiran Ray, PhD[3]
Zia Sadique, PhD[5]
Barnaby R. Scholefield, PhD[6]
Dermot Shortt, BE[7]
Lamprini Lampro, MSc[1]
Carly Au, BSc[1]
Kathy M. Rowan, PhD[1]
Paul Mouncey, MSc[1]
David P. Inwald, PhD[8]
Protocolised Evaluation of Permissive Blood Pressure Targets Versus Usual Care (PRESSURE) Trial Investigators on behalf of the U.K. Paediatric Critical Care Society Study Group (PCCS-SG)

Pediatric Critical Care Medicine
XXX 2026 • Volume 27 • Number 00 • Pages XX–XX

GASTRIC protocol
May 2026 (n=4,700)
2023-2025

PCCM TRIAL

OPEN

Protocol for a Randomized Clinical Trial to Evaluate Not Routinely Measuring Gastric Residual Volume to Guide Enteral Feeding Versus Routine Measurement in Mechanically Ventilated Critically Ill Children (GASTRIC-PICU)

Marzena Orzol, MA, MSc[1]
Irene Chang, MSc[1]
Emma Laing, BSc[1]
Mark J. Peters, MBChB, PhD[2,3]
Julia E. Edwards, PhD[1]
Paloma Ferrando-Vivas, BA[1]
Julie Camsooksai, RN, BSc[1]
Jahara Khatun, BSc[1]
Lamprini Lampro, MSc[1]
Millie Parke, BSc (Hons)[1]
Hannah Sedgwick, MSc[1]
Carly Au, BSc[1]
David Harrison, PhD[1]
Lynne Latten, RD, BSc (Hons)[4]

OBJECTIVE: Providing adequate nutrition is a key aspect of pediatric intensive care, with enteral administration preferred. The regular measurement of gastric residual volume (GRV) to guide feeding is common, but it results in frequent feed interruptions due to a perceived high GRV. The GASTRIC-PICU (GRV to guide enteral feeding vs. routine measurement in mechanically ventilated critically ill children) randomized controlled trial aims to evaluate the clinical and cost-effectiveness of not routinely measuring GRV to guide enteral feeding compared with the usual practice of routine measurement.

DESIGN: Multicenter, randomized, non-inferiority, open-label clinical trial with embedded health economic evaluation.

SETTING: Twenty-three PICUs across United Kingdom, Scotland, Northern Ireland, and Switzerland.

PATIENTS: Infants and children 37 weeks old or older corrected gestational age to 16 years admitted to participating PICUs, on mechanical ventilation and being enterally fed.

After the 1º reports:
Curated datasets → 2º analyses

#3/4

SANDWICH, JAMA 2021
2018-2019
(n=8,843)

PCCM 2025

2^{o} analysis of SANDWICH

Reader engagement in 2025 = 4,400 (#1)

FEATURED ORIGINAL RESEARCH ARTICLE

OPEN

Sedation and Ventilator Weaning Bundle and Time to Extubation in Infants With Bronchiolitis: Secondary Analysis of the Sedation AND Weaning in Children (SANDWICH) Trial

Rebecca B. Mitting, MRCPCH[1,2]
Cliona McDowell, CStat[3]
Bronagh Blackwood, PhD[3]
Samiran Ray, PhD[4,5]

OBJECTIVE: The Sedation and Weaning in Children (SANDWICH) trial of a sedation weaning and ventilator liberation bundle had a primary outcome of time to successful extubation, and showed significant but small difference. We explored the impact of the intervention on infants with bronchiolitis.

EDITORIAL

Digesting a Slice of the SANDWICH Trial and Its Effect on a Bronchiolitis Subpopulation

KEYWORDS: airway extubation; bronchiolitis; mechanical ventilation; patient-centered care; pediatrics; workload

Jeremy M. Loberger, MD[1]
Kristina A. Betters, MD[2]

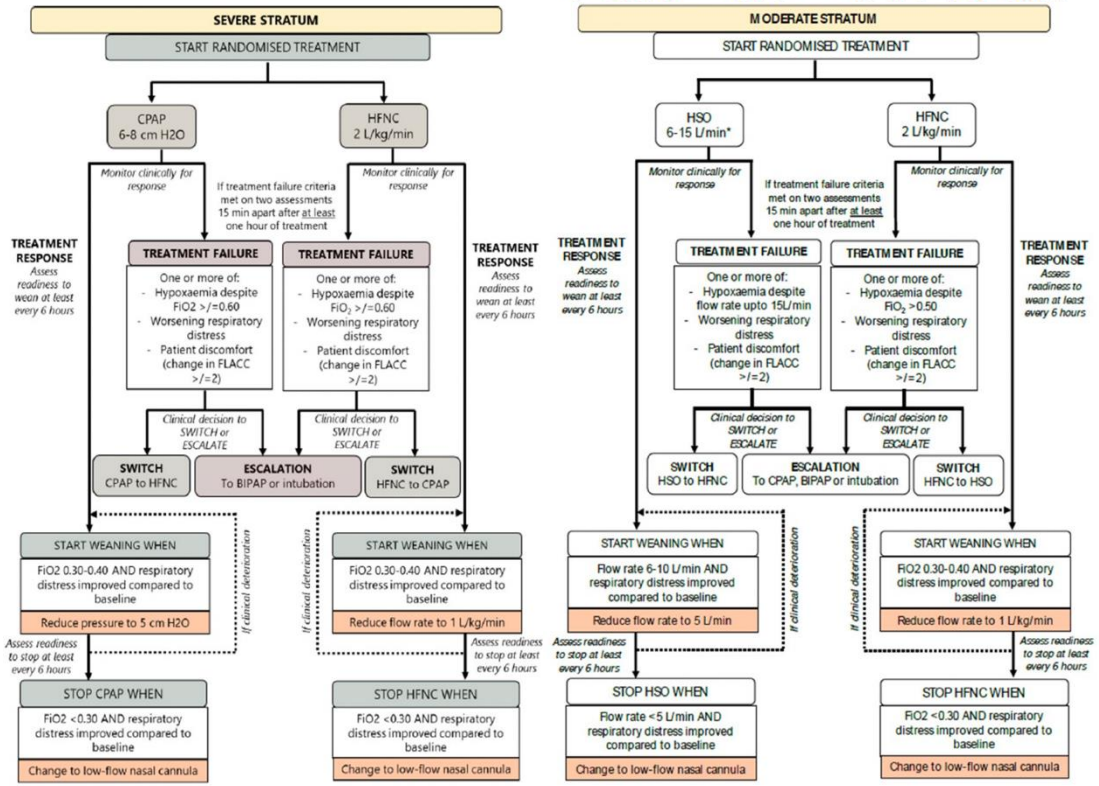
#4/4

BACHb protocol, 2025 (n=1,508) 2023-2026

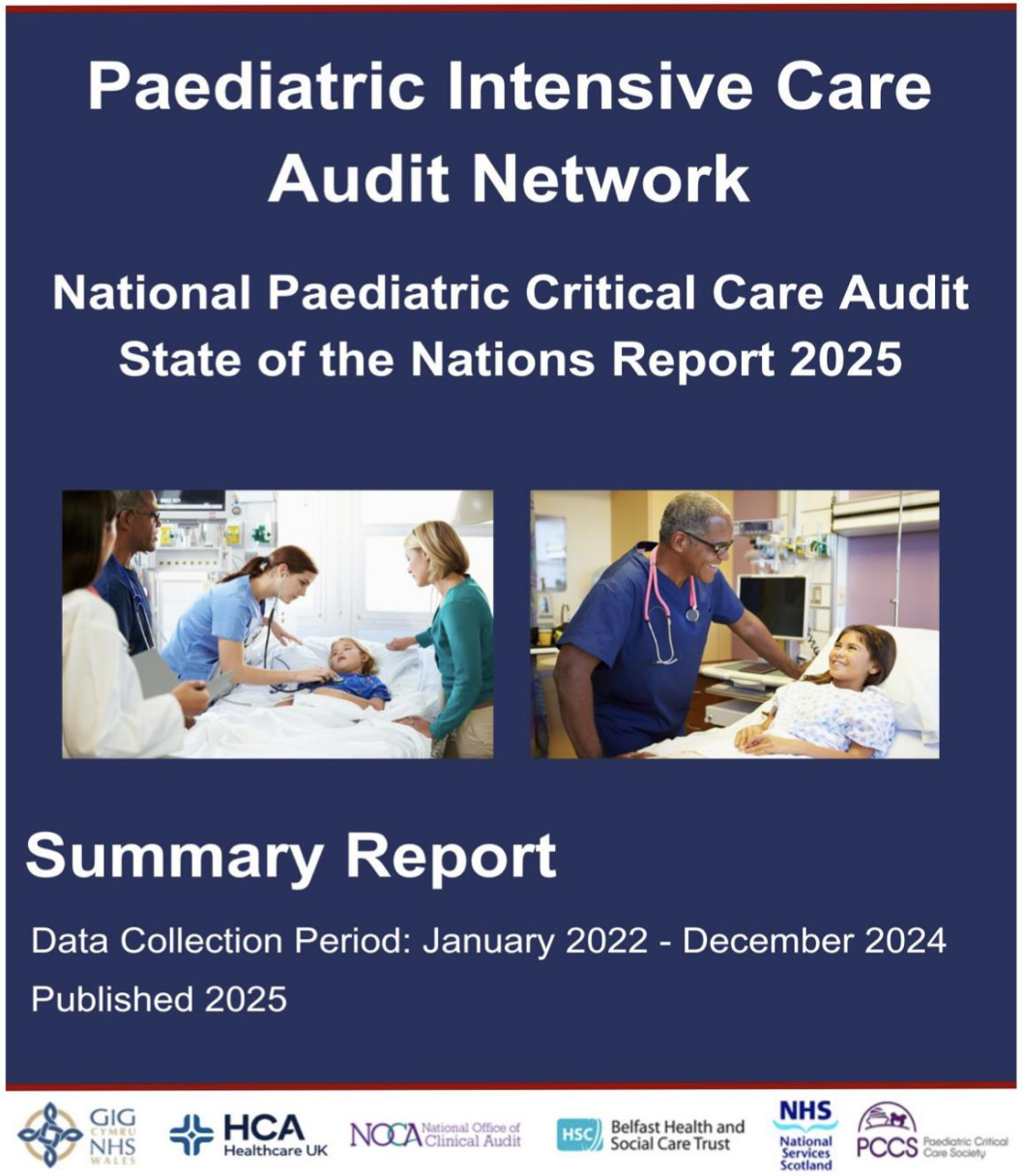
PCCM TRIAL

OPEN

Protocol for a Group-Sequential Two-Stratum Multicenter Open-Label Randomized Clinical Trial of Respiratory Support in Infants With Acute Bronchiolitis: Breathing Assistance in Children With Bronchiolitis (BACHb)



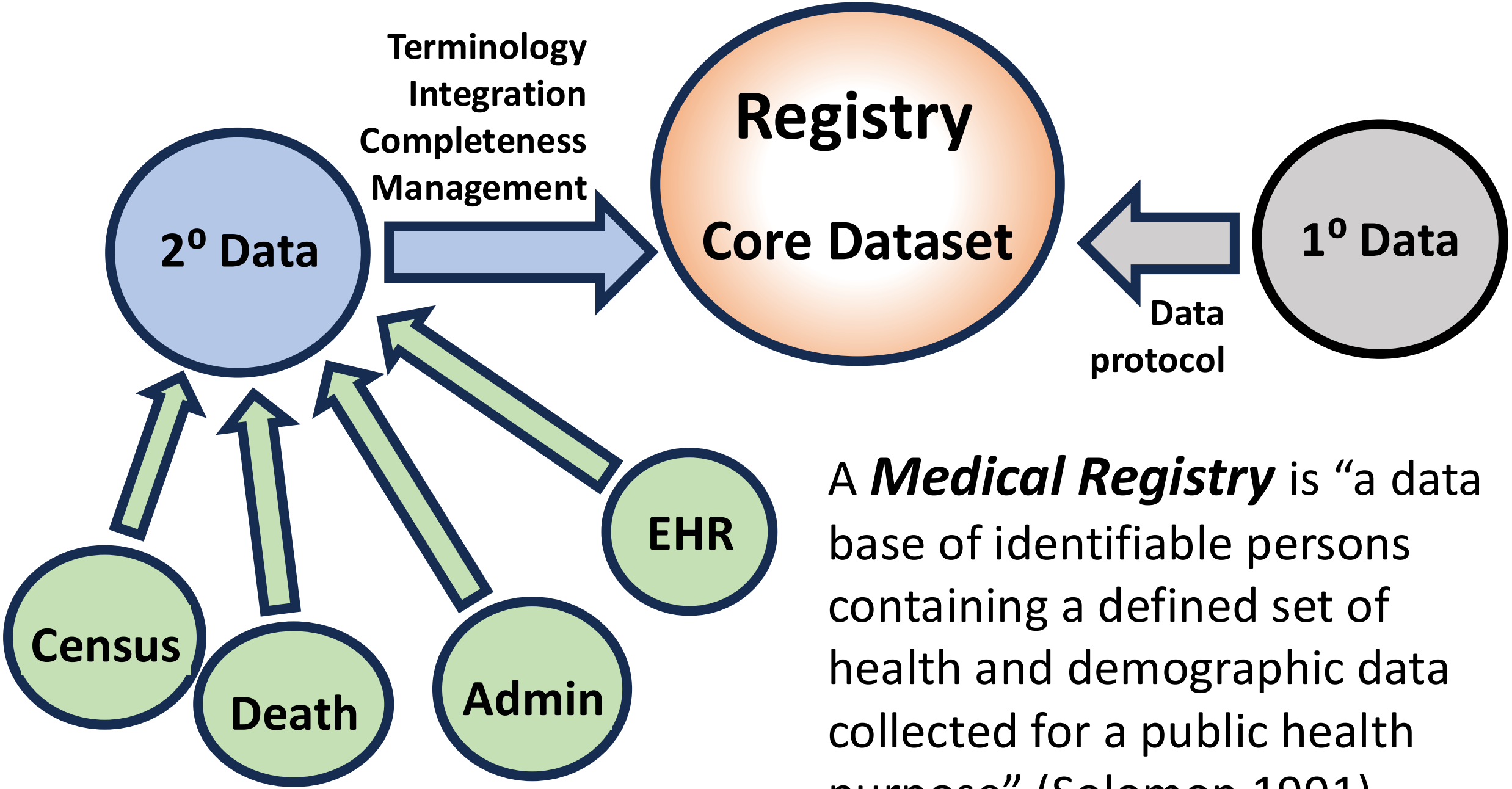
Isabel Johnson, RN, MPH[1]
Katy Bridges, RN[1]
Richard Cleaver, MSc[2]
Rayka Malek, PhD[3]
Mary Cross, BA[3]
Steve Cunningham, PhD[4]
Katrina Cathie, MD[5]
Mark D. Lyttle, PhD[6,7]
Rebecca Mitting, MRCPCH[8]
Paul Mouncey, MSc[9]
Damian Roland, PhD[10,11]
Stephen Turner, FRCPCH[12]
Olu Onyimadu, PhD[13]
Stavros Petrou, PhD[13]
Debra Quantrill[14]
Kate Chadwick[14]
Leila Janani, PhD[3]
Padmanabhan Ramnarayan, MD[2,8,15]



Era of Epidemiology → Clinical RCT → Curated datasets

RCT	Timeline	Sample	Publication
SANDWICH	2018-2019	8,843	**JAMA** 2021 **PCCM** 2025
Oxy-PICU	2020-2022	2,040	**Lancet** 2024 **PCCM** 2024, 2025
GASTRIC	2023-2025	4,700	**PCCM** 2026
PRESSURE	2021-2026	1,900	**PCCM** 2024, 2026
BACHb	2023-2026	1,508	**PCCM** 2025
	2018-2026	**~19,000**	

Where and what next?



A ***Medical Registry*** is "a data base of identifiable persons containing a defined set of health and demographic data collected for a public health purpose" (Solomon 1991)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Finding a Clinical Trial
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For Parents and Children
For Health Care Providers
For Researchers and Trial Sites
Educational Resources
List of Registries
Disclaimer
The following listing is not intended to be co
does not imply endorsement by the Nationa
intent is to provide information about regist
groups that can offer valuable assistance to
See frequently asked questions at the botto
Alzheimer's Prevention Registry
B2B
Bench to Bassinet
ABOUT
FOR FAMILIES
CENTERS
For Researchers
CHD GENES Study
Protocol
Electronic Case Report Forms (eCRFs)
Informed Consent Templates
Cohort Demographics
Submission of Ancillary Study Proposals
CHD Brain and Genes Study
Basic Science Data & Resource Sharing
B2B Data Sharing Plan
Requests for Limited Data
Challenge Prizes
PCGC and CDDRC Fellows Program
CHD GENES Study
PCGC Centers are recruiting individuals of all a
phenotypic and clinical data, and will follow the
genetic techniques to interrogate the genome f
conduct high
data, will cor
disorders. Th
pathology, a
children, and
Authorized a
approval is r
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EP Device Implant Registry
IMPACT Registry
LAAO Registry
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STS/ACC TVT Registry
IMPACT REGISTRY™
Improve CHD Patient Outcomes with Data-Driven Insights
Coming Soon: The newest version introduces a logic-based design across three procedural pathways, Interventional Cardiology, EP (with or without ablation) and CIED procedures, activating only the fields relevant to each procedure. Expanded procedural modules, refined data elements, simplified
Interested In Joining A Registry?
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Click Here
SV-ONE envisions a future where all affected by single ventricle heart disease can thrive and live long, fulfilling lives.
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Mission
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Improve Quality, Safety and Efficiency in Your PICU
Saving Children's Lives Through Actionable Data
ADMINISTRATOR
INTENSIVIST
NURSE MANAGER
RESEARCHER
QUALITY IMPROVEMENT
VPS has expanded its QI efforts in
COMPARATIVE REPORTING
High-fidelity reports comparing
RESEARCH
VPS has the largest research association in pediatric critical
PC4
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REPORTING PLATFORM
MEMBERS AREA
CONTACT US
Improving outcomes & quality through collaboration
The Pediatric Cardiac Critical Care Consortium (PC⁴) aims to improve the quality of care to patients with critical pediatric and congenital cardiovascular disease.
Reporting Platform
Members Area
Registry Science – how best to improve clinical care?

AIM 1: To understand the historical weaknesses and limit of Registry Science

Circulation: Cardiovascular Quality and Outcomes

2021

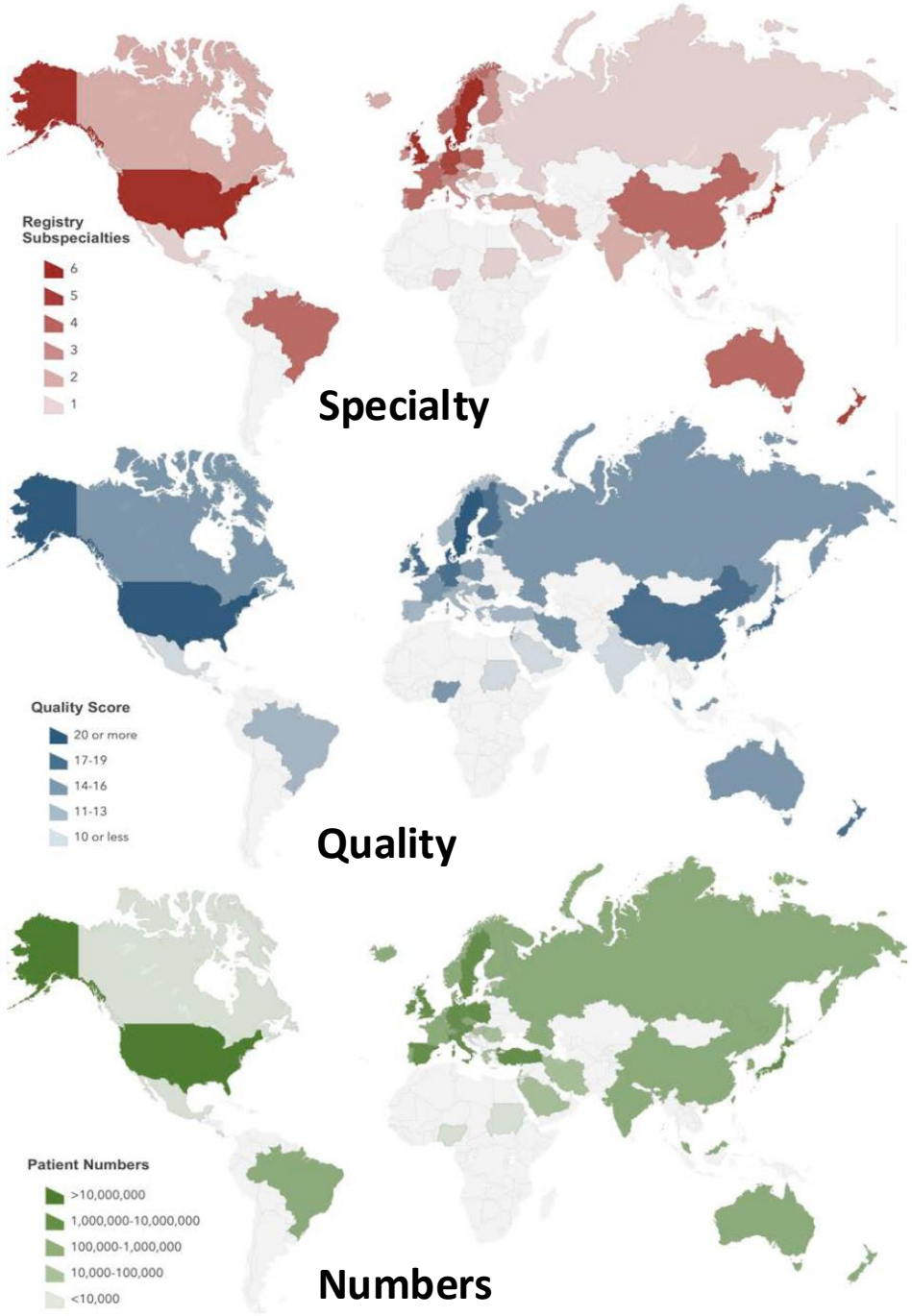
Circ Cardiovasc Qual Outcome 2021; 14:e007963

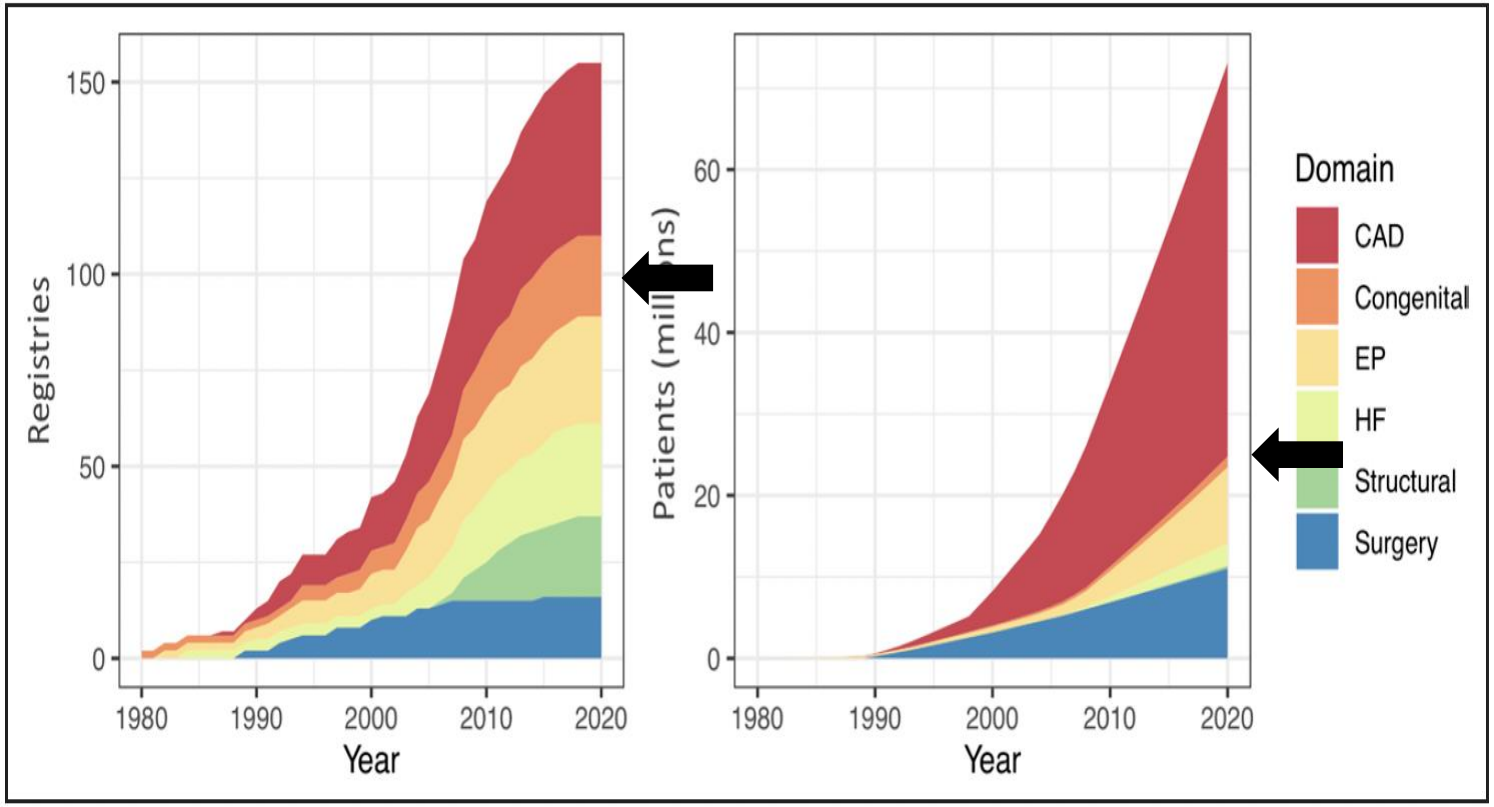
URL: https://www.crd.york.ac.uk/prospero; Unique identifier: CRD42020204224

ORIGINAL ARTICLE

Characteristics and Quality of National Cardiac Registries: A Systematic Review

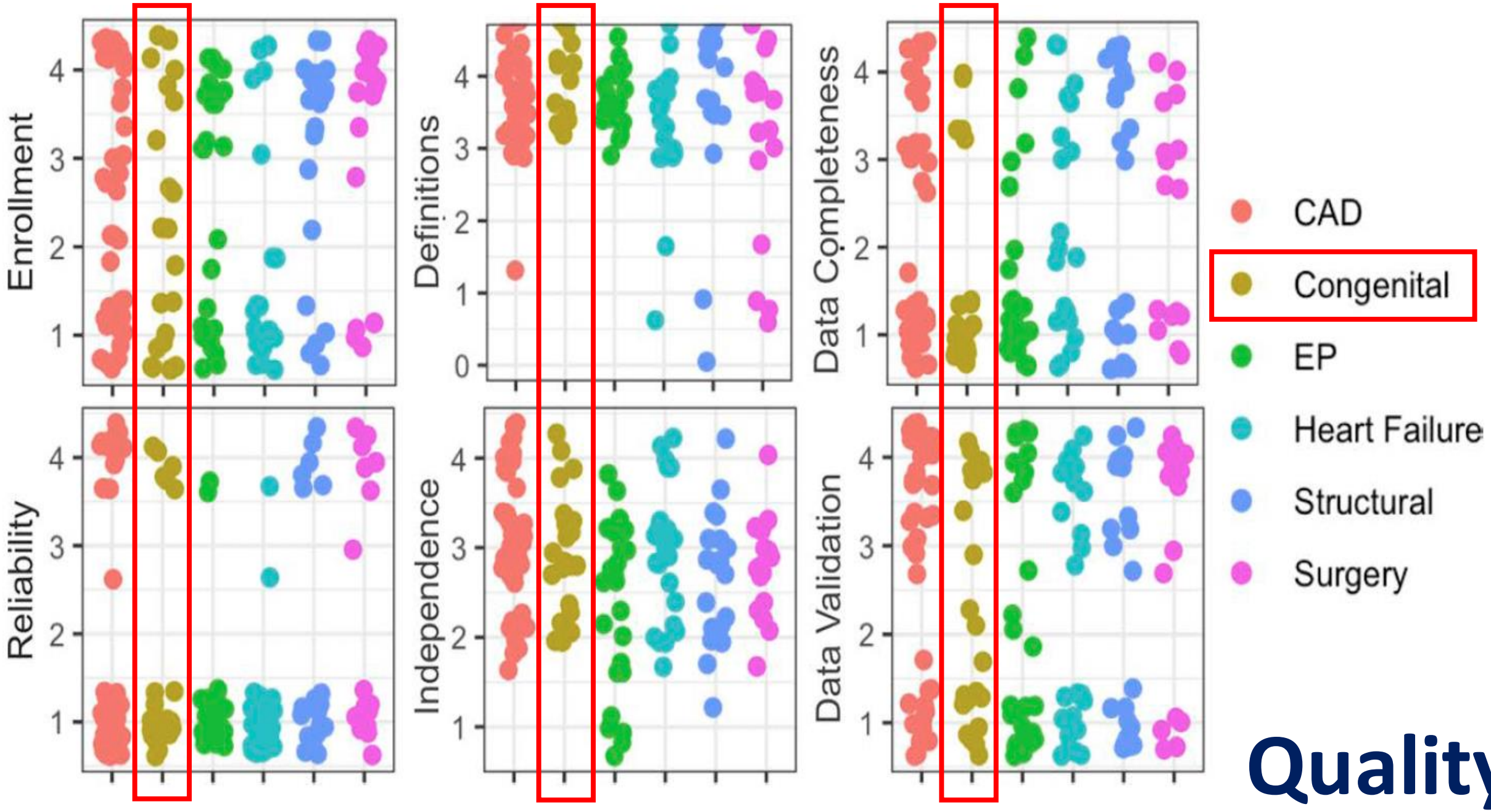
Luke P. Dawson, MBBS, MPH; Sinjini Biswas, MBBS, PhD; Jeffrey Lefkovits, MBBS; Dion Stub, MBBS, PhD; Luke Burchill, MBBS, PhD; Sue M. Evans, PhD; Christopher Reid, BA DipEd, PhD; David Eccleston, MBBS, MMedSci





National Cardiac Registries 1980 – 2020

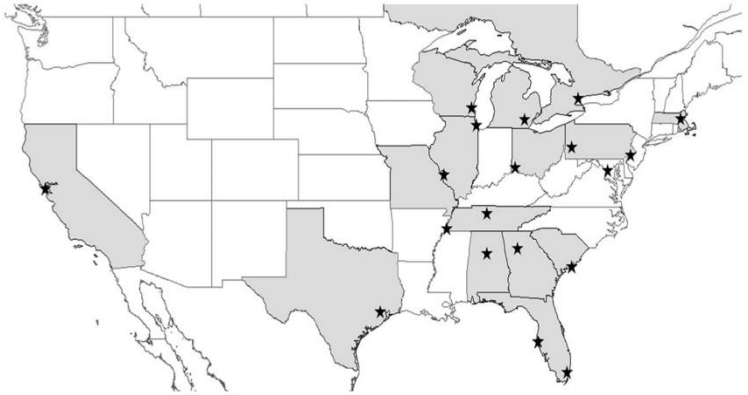
- 155 Registries in 49 countries
- 73.1 million patients
- 21 registries related to CHD


Enrollment
Definitions
Data Completeness
Reliability
Independence
Data Validation
CAD
Congenital
EP
Heart Failure
Structural
Surgery

Quality

Cardiology in the Young (2015), **25**, 951–957
doi:10.1017/S1047951114001450

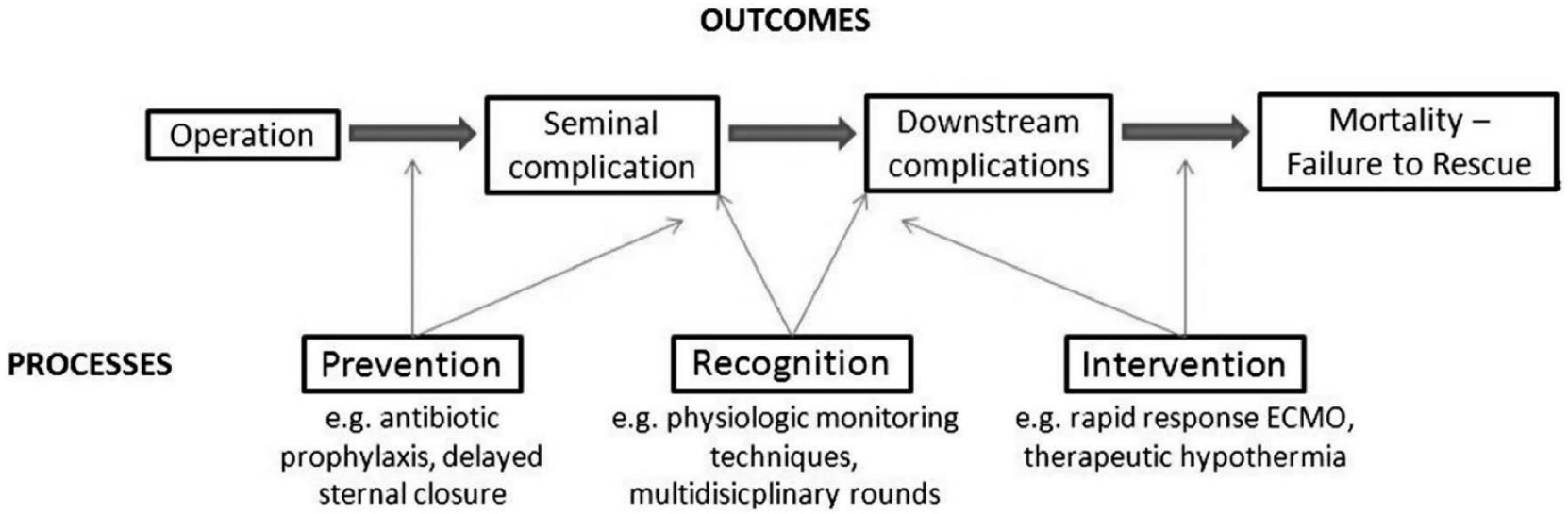
2014



Original Article

Collaborative quality improvement in the cardiac intensive care unit: development of the Paediatric Cardiac Critical Care Consortium (PC[4])

Michael Gaies,[1] David S. Cooper,[2] Sarah Tabbutt,[3] Steven M. Schwartz,[4] Nancy Ghanayem,[5] Nikhil K. Chanani,[6] John M. Costello,[7] Ravi R. Thiagarajan,[8] Peter C. Laussen,[9] Lara S. Shekerdemian,[10] Janet E. Donohue,[11] Gina M. Willis,[11] J. William Gaynor,[12] Jeffrey P. Jacobs,[13] Richard G. Ohye,[14] John R. Charpie,[1] Sara K. Pasquali,[1] Mark A. Scheurer[15]



MISSION STATEMENT

PC4 is a multi-institutional collaboration… across geographic, subspecialty boundaries:

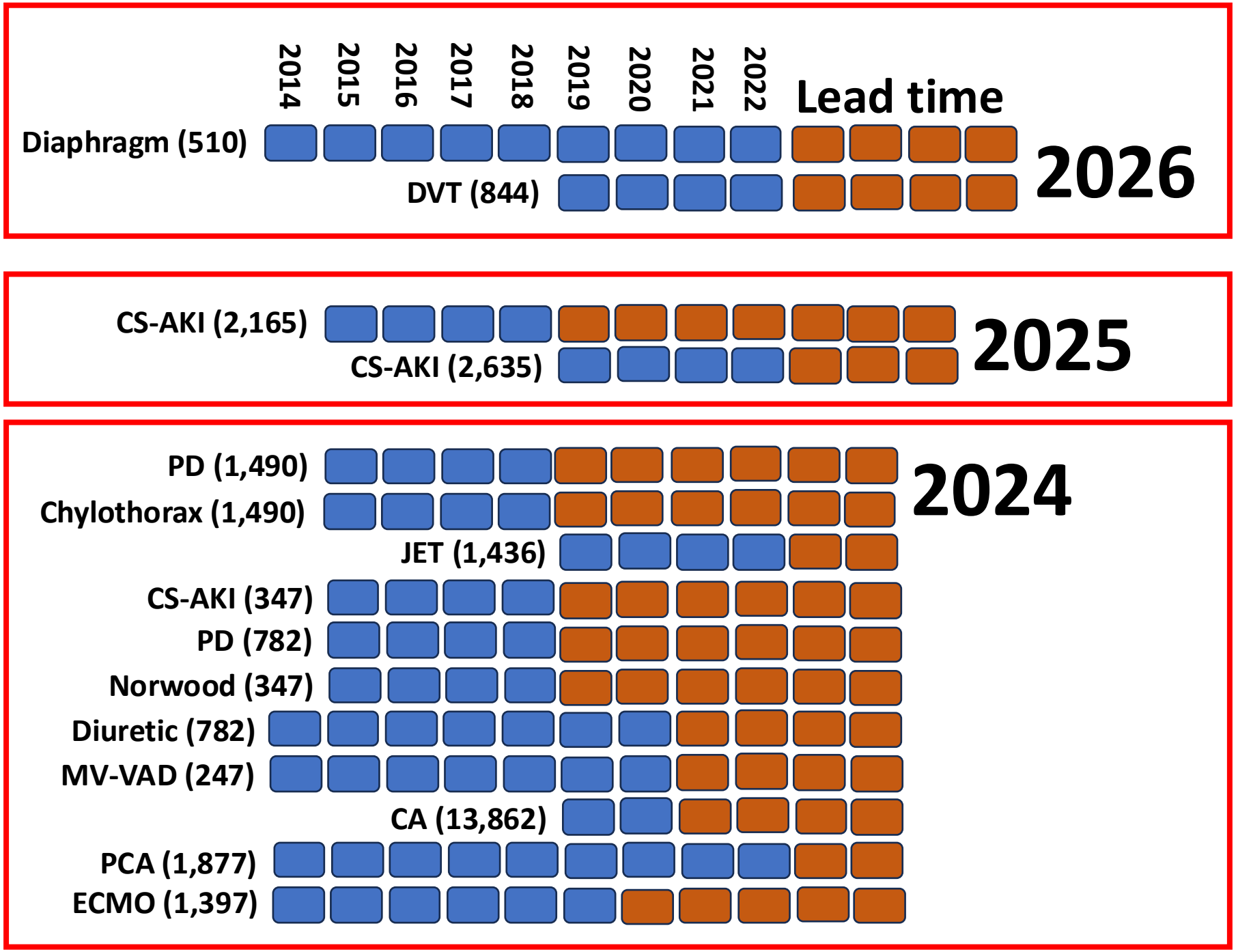
- To integrate databases
- To harmonise efforts
- To advance PCICM
- To evaluate data
- To identify EBM practice
- To disseminate findings

PC4 Data

n=77,383

- Real-World data
- Large sample
- Longitudinal
- Diverse
- Descriptive
- Exploratory

Lead time:
What was *vs.*
What is



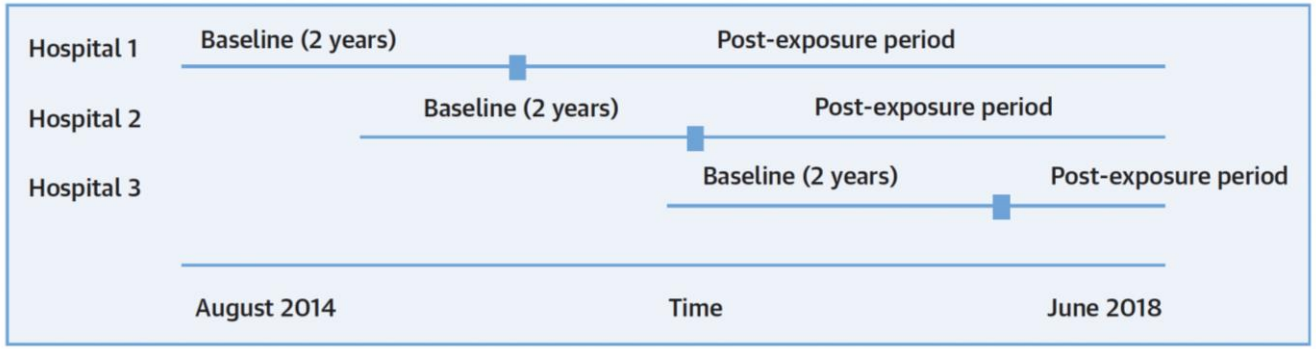
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. 74, NO. 22, 2019

PUBLISHED BY ELSEVIER

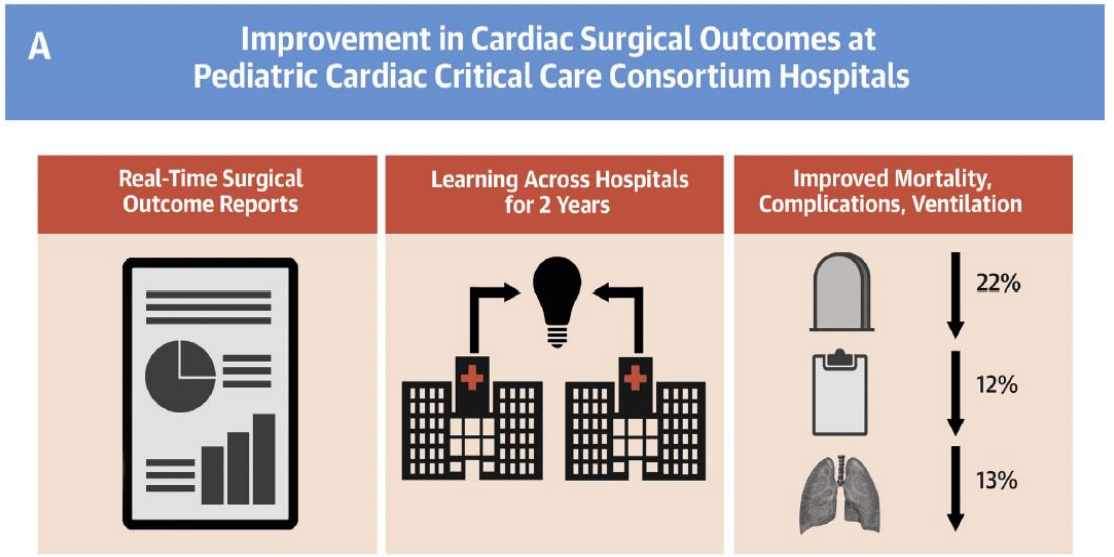
Improvement in Pediatric Cardiac Surgical Outcomes Through Interhospital Collaboration

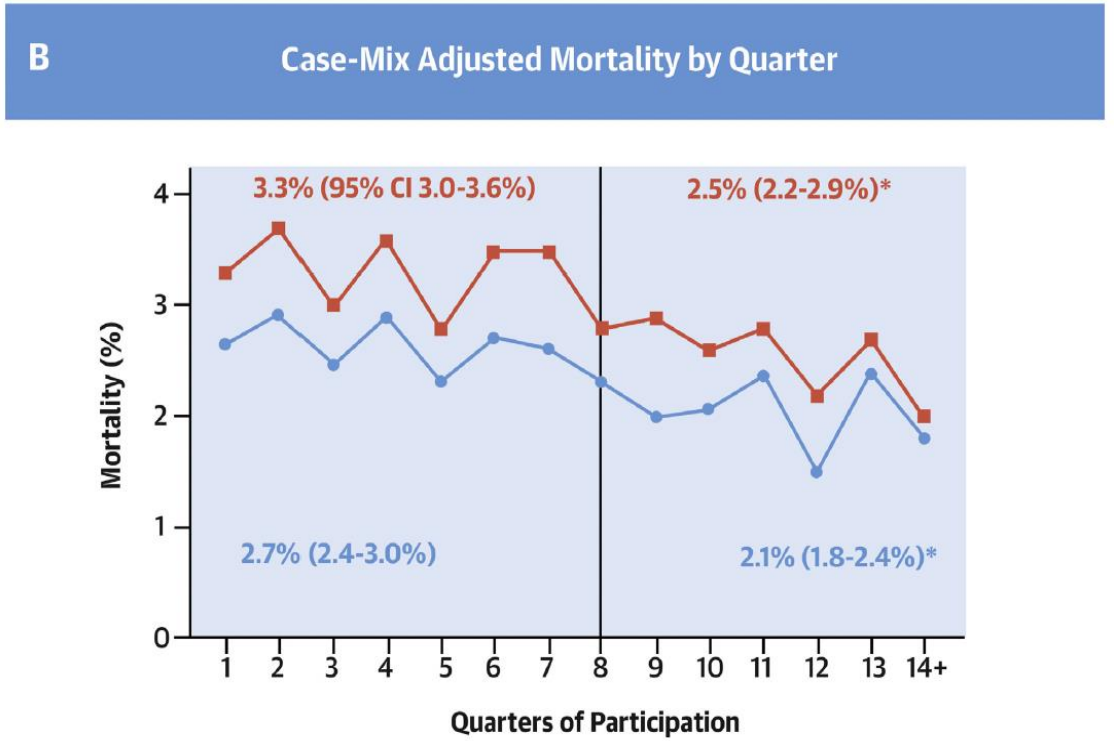
2019

Michael Gaies, MD, MPH, MS,[a] Sara K. Pasquali, MD, MHS,[a] Mousumi Banerjee, PhD,[b] Justin B. Dimick, MD, MPH,[c] John D. Birkmeyer, MD,[d] Wenying Zhang, MS,[e] Jeffrey A. Alten, MD,[f] Nikhil Chanani, MD,[g] David S. Cooper, MD,[f] John M. Costello, MD, MPH,[h] J. William Gaynor, MD, PhD,[i] Nancy Ghanayem, MD,[j] Jeffrey P. Jacobs, MD,[k] John E. Mayer, MD,[l] Richard G. Ohye, MD,[m] Mark A. Scheurer, MD,[h] Steven M. Schwartz, MD,[n] Sarah Tabbutt, MD, PhD,[o] John R. Charpie, MD, PhD[a]



19,600 admissions in 18 hospitals 2014-2018





ESC European Society of Cardiology
European Journal of Cardiovascular Nursing (2023) **22**, 220–225
https://doi.org/10.1093/eurjcn/zvad008

Methods Corner

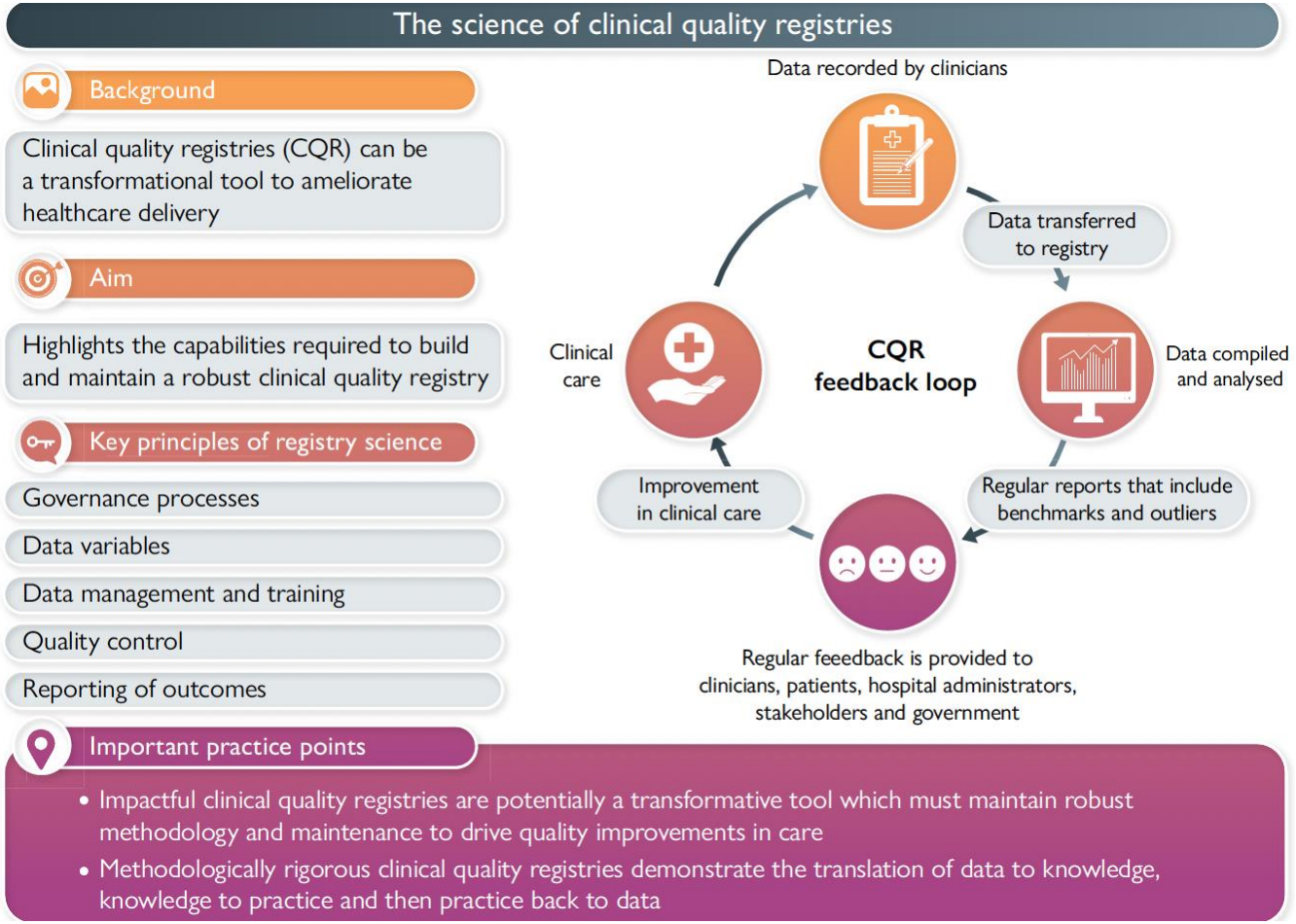
2023

The science of clinical quality registries

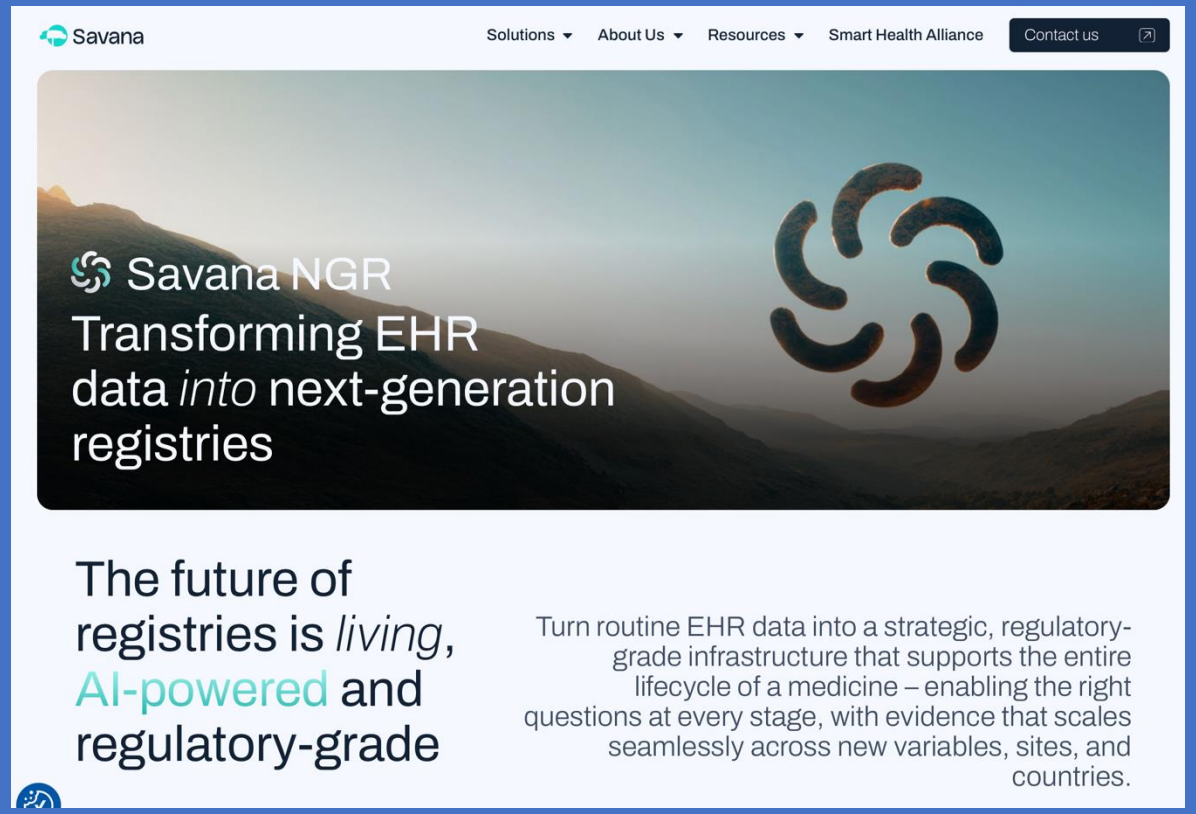
Kirsten J. Parker[1]*, Louise D. Hickman[1], and Caleb Ferguson[1,2]

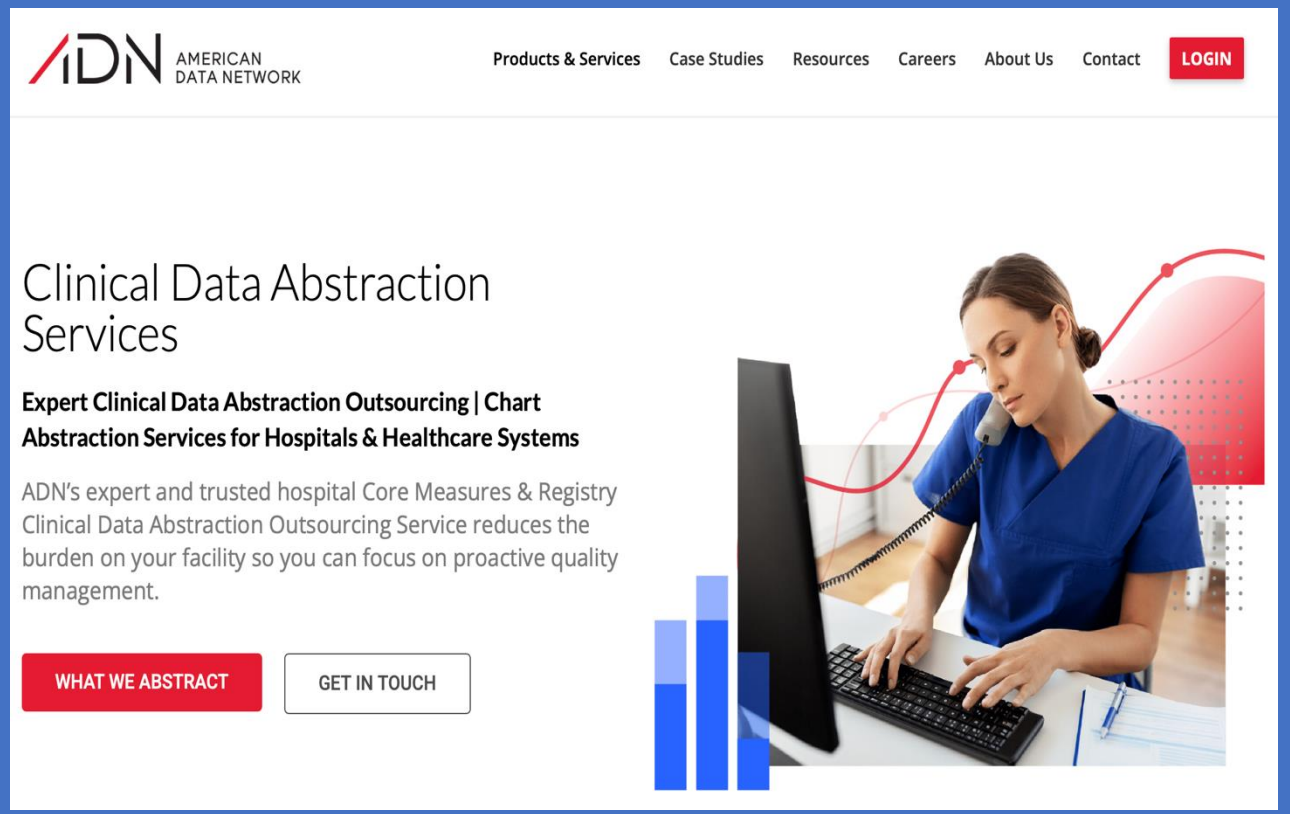
Potential Criticisms

- Limited feedback cycle
- Limits in generalizability
- Institutional inertia
- Cost and time
- Regulatory affairs
- Consent
- The “mass” of data



AIM 2: To understand the strength and future of Registry Science





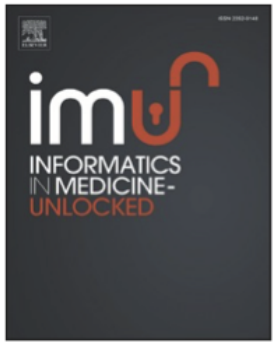
Informatics in Medicine Unlocked 41 (2023) 101309

2023

Contents lists available at ScienceDirect

Informatics in Medicine Unlocked

journal homepage: www.elsevier.com/locate/imu

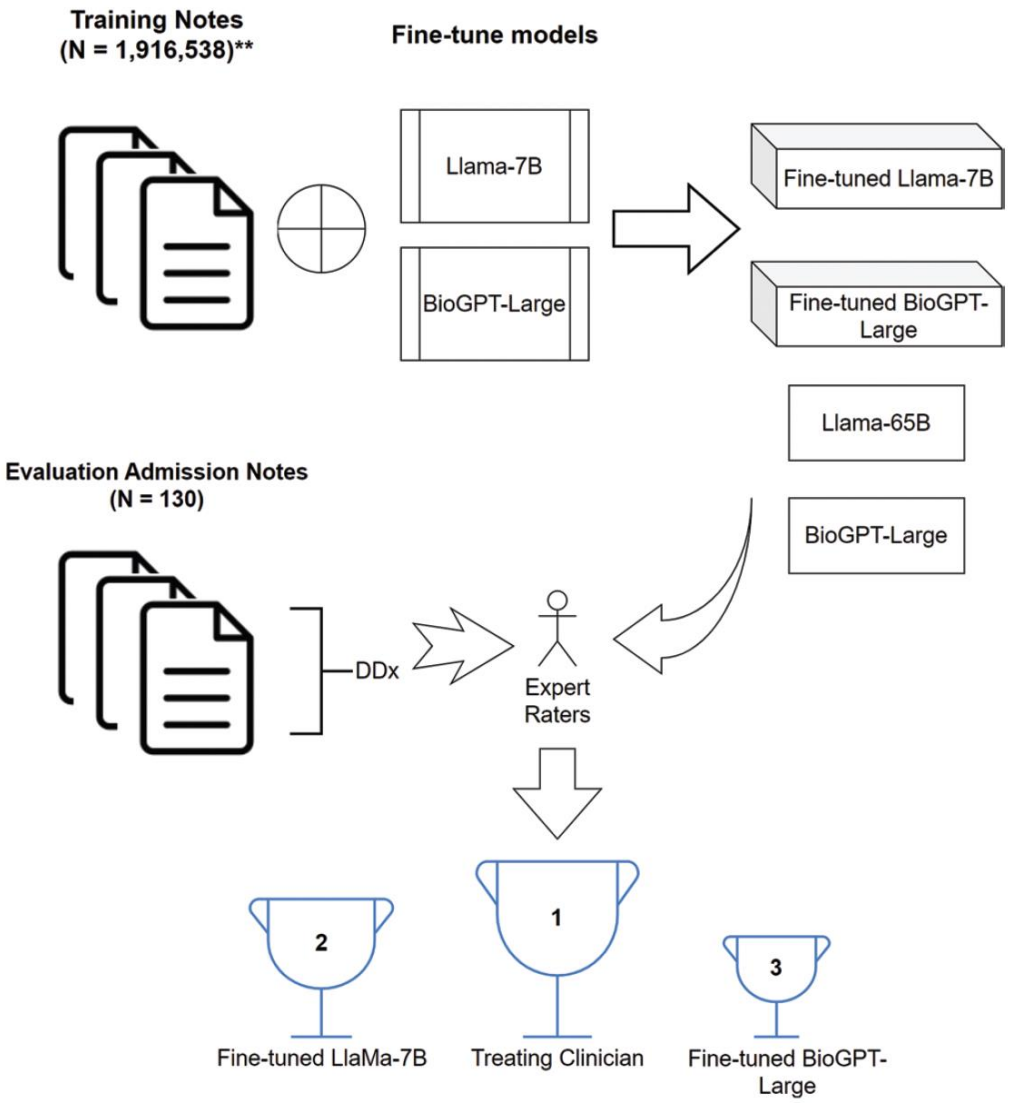


Novel use of natural language processing for registry development in peritoneal surface malignancies

Nicholas Brian Shannon [a,b,1], Louis Choon Kit Wong [a,b,1], Mariko Nakayama [c], Nguyen Tuan Anh Tran [d], Lionel Tim-Ee Cheng [d,f], Choon Hua Thng [g], Hairil Rizal Bin Abdullah [e,h], Wen Kai Darryl Juan [a,b], Ming Jie Demi Lum [a,b], Chin-Ann Johnny Ong [a,b,i,j,k,l], Chin Jin Seo [a,b], Claramae Shulyn Chia [a,b,i,j], Jolene Si Min Wong [a,b,i,j,*]

What about reading and cataloguing:

- **ECHO reports?**
- **Operation notes?**



PCCM 2024

ONLINE CLINICAL INVESTIGATIONS

Comparing the Quality of Domain-Specific Versus General Language Models for Artificial Intelligence-Generated Differential Diagnoses in PICU Patients*

OBJECTIVES: Generative language models (LMs) are being evaluated in a variety of tasks in healthcare, but pediatric critical care studies are scant. Our objective was to evaluate the utility of generative LMs in the pediatric critical care setting and to determine whether domain-adapted LMs can outperform much larger general-domain LMs in generating a differential diagnosis from the admission notes of PICU patients.

Alireza Akhondi-Asl, PhD[1–3]
Youyang Yang, MD, MHQS[1–3]
Matthew Luchette, MD[1–3]
Jeffrey P. Burns, MD, MPH[1–3]
Nilesh M. Mehta, MD, FASPEN[1,2]
Alon Geva, MD, MPH[1–4]

Navigating Complexity: Enhancing Pediatric Diagnostics With Large Language Models*

KEYWORDS: artificial intelligence; clinical decision-making; critical care; natural language processing; pediatrics

James Mitchell, PhD, MSc[1]
Tellen D. Bennett, MD, MS[1,2]

Artificial intelligence (AI) is the field of computer science involving the creation of systems that can perform tasks usually requiring human intelligence (1). Machine learning (ML) is a branch of AI that specifically involves machines learning from data with minimal human input. Clinical examples of ML include models to predict serious bacterial infection (2) and mortality (3) in PICU patients. Natural language processing (NLP), another

*See also p. e273.

DOI: 10.1097/PCC.0000000000003483

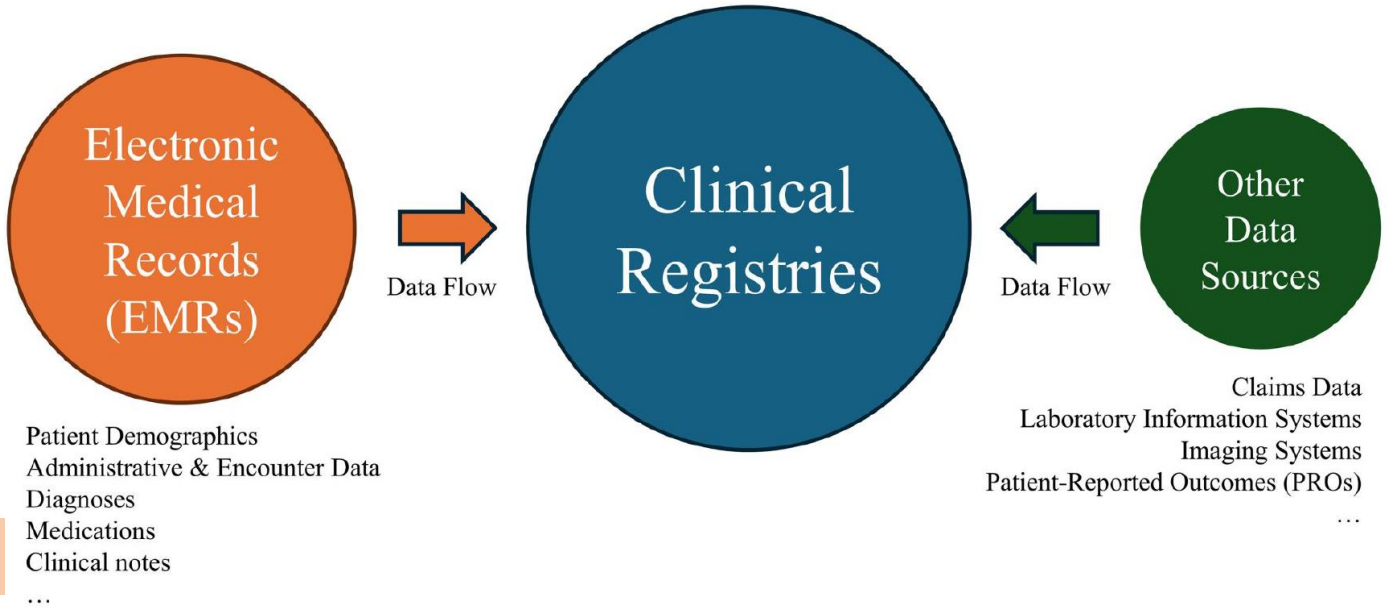
Journal of the American Medical Informatics Association, 2026, **33(2)**, 484–499
https://doi.org/10.1093/jamia/ocaf176
Advance access publication 15 October 2025
Review

Review

Using natural language processing to extract information from clinical text in electronic medical records for populating clinical registries: a systematic review

Leibo Liu, PhD*[,1], Victoria Blake, MSc[1], Matthew Barman, BASC[1], Blanca Gallego, PhD[1], Timothy Churches, MPhil[2], Georgina Kennedy, PhD[2,3], Sze-Yuan Ooi, MD[4,5], Geoffrey P. Delaney, MD, PhD[2,3], Louisa Jorm, PhD[1]

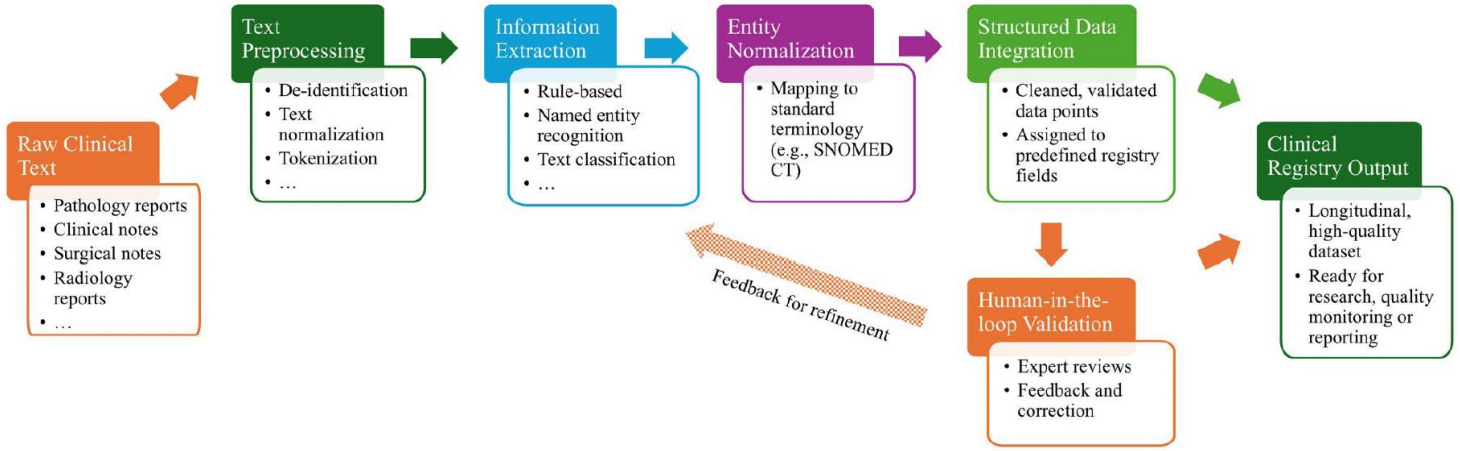
2025



Clinical notes

Imaging systems

Figure 1. Relationship between electronic medical records (EMRs) and clinical registries.



What about accessing decision-making?

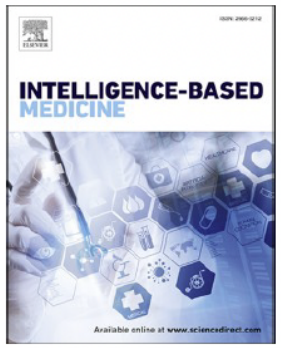
Intelligence-Based Medicine 7 (2023) 100098

2023

Contents lists available at ScienceDirect

Intelligence-Based Medicine

journal homepage: www.sciencedirect.com/journal/intelligence-based-medicine



Check for updates

Using machine learning and clinical registry data to uncover variation in clinical decision making

Charlotte James [a,*], Michael Allen [a,b], Martin James [a,c], Richard Everson [d]

National registry of stroke patients (2016-2018) managed in 132/180 acute care hospitals

- Decision-making around the time of thrombolysis – features related to the outcome
- Dataset limited to centers that care for at least 100 patients
- 88,928 patients, of which 26,257 received thrombolysis

Can a Registry lead & be used in a Clinical Trial?

#1/8

Open access Communication

BMJ Open

Registry randomised trials: a methodological perspective

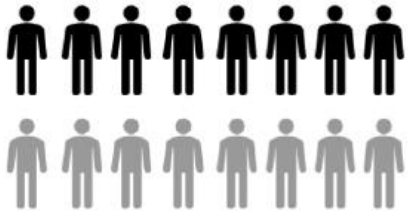
Dorota A Doherty,[1,2] Steven Y C Tong,[3,4] Jennifer Reilly ,[5,6] Jane Shrapnel,[7] Stephen McDonald,[8,9] Susannah Ahern,[10] Ian Harris,[11] Charmaine S Tam,[12] Angela L Brennan,[10] Carol Hodgson,[10] Leonie Wilcox,[13] Anitha Balagurunathan,[14] Belinda E Butcher ,[15,16] Christopher M Reid[10,17]

2023

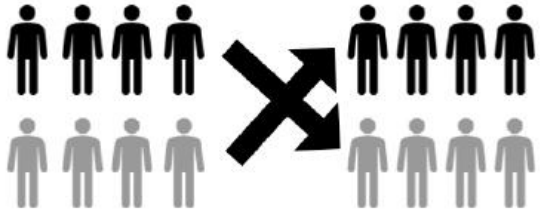
Individual patient randomised designs

Randomisation happens at the individual patient level

Parallel arm



Crossover



Intervention

Control

Cluster randomised designs

Randomisation happens at the level of the ICU, hospital, practice, school, rather than at inidividual patient level

Parallel cluster RCT

Cluster crossover

Stepped wedge

Intervention

Control

SPECIAL ARTICLE

HEROIC Trials to Answer Pragmatic Questions for Hospitalized Children

Eric R. Coon, MD, MS,[a] Christopher Bonafide, MD, MSCE,[b,c] Eyal Cohen, MD, MSc,[d,e,f] Anna Heath, MMath, PhD,[f,g,h] Corrie E. McDaniel, DO,[i] Alan R. Schroeder, MD,[j] Sunitha V. Kaiser, MD, MSc[k]

#3/8

2022

High-Efficiency RCTs

AAP (Hospital Pediatrics)

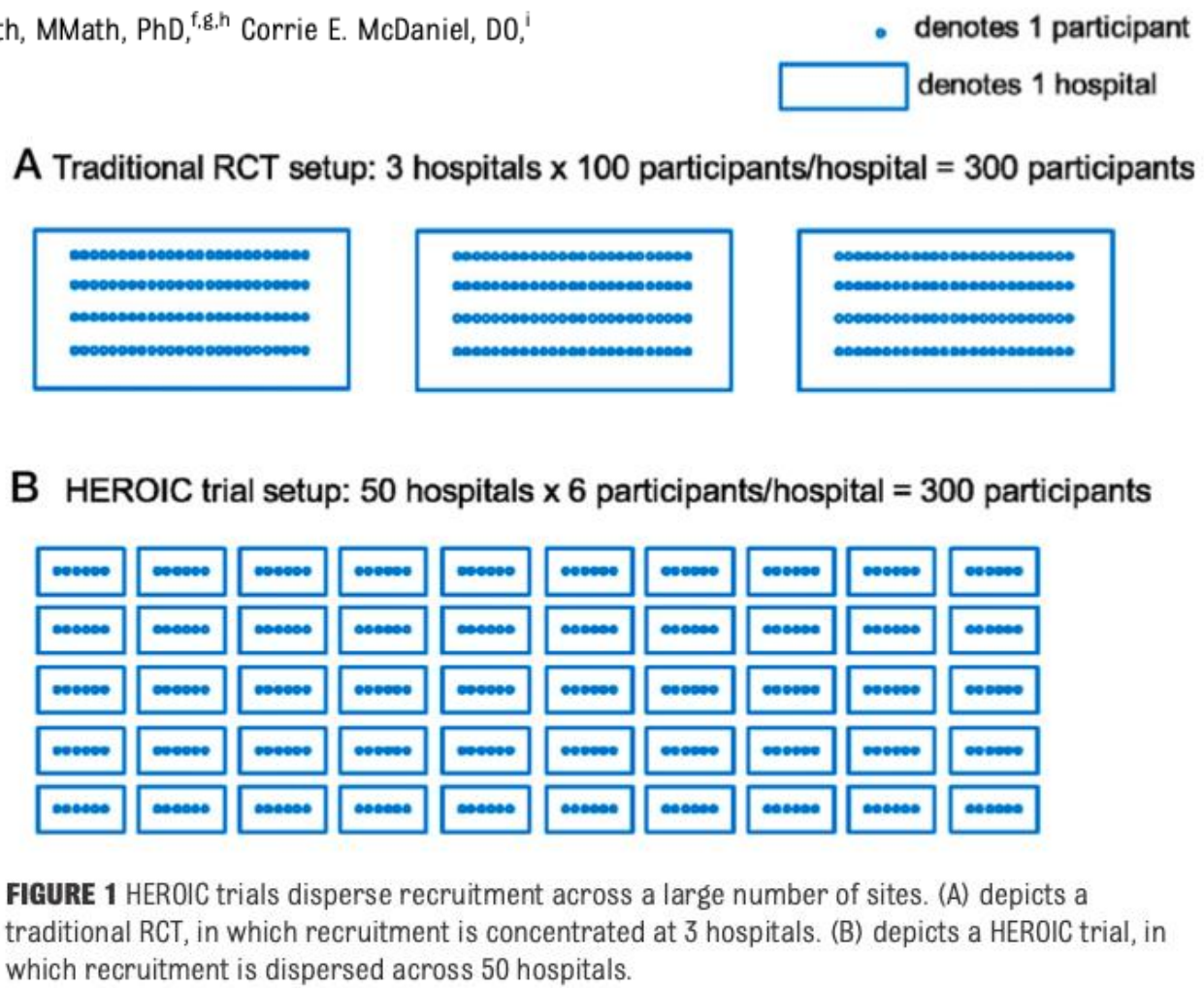


FIGURE 1 HEROIC trials disperse recruitment across a large number of sites. (A) depicts a traditional RCT, in which recruitment is concentrated at 3 hospitals. (B) depicts a HEROIC trial, in which recruitment is dispersed across 50 hospitals.

VIEWPOINT

INTEGRATING CLINICAL TRIALS AND PRACTICE

JAMA 2024

#4/8

Making Pragmatic Clinical Trials More Pragmatic

Richard Platt, MD, MSc
Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School, Boston, Massachusetts.

Hayden B. Bosworth, PhD
Department of Population Health Sciences, Duke University School of Medicine, Durham, North Carolina.

Gregory E. Simon, MD
Kaiser Permanente Washington Health Research Institute, Seattle.

Pragmatic clinical trials are having a moment—actually, a decade. More than 80% of National Library of Medicine citations identified by searching "pragmatic clinical trials" were published in the past 10 years. The Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) has been cited almost 700 times since its publication in 2015.[1] For this discussion, we define pragmatic clinical trials as ones "designed for the primary purpose of informing decision-makers regarding the comparative balance of benefits, burdens and risks of a biomedical or behavioral health intervention at the individual or population level."[2] Interest in pragmatic trials is due, in part, to a growing acknowledgment that clinicians often lack high-quality evidence to support medical decisions.[3] More than 15 years ago, the National Academy of Medicine called for a "Learning Health System"—in which clinical trials would be integrated with health care delivery in a continuous loop of knowledge generation—because the pace of medical research was inadequate.[3] The National Institutes of Health (NIH) created the Pragmatic Trials Collaboratory, health care system. Although it was expected that widespread dissemination and implementation might require both replication and time, in a surprising number of instances, the collaborating health care systems in which the trials were conducted did not make decisions strictly consistent with the trial findings for the protocol-defined primary outcomes, although they had been partners in trial design and implementation.[6] In some instances, such as the pain intervention, the original host systems did not adopt practices that met the trials' primary objective; in others, such as the decolonization study, they implemented practices that did not meet the trials' prespecified criteria for success.

A workshop held in 2023 explored the challenges of adopting the findings of these studies. In some instances, health care system leaders did not adopt a practice that had been shown to be effective by the trial's criteria, citing changed clinical circumstances, prohibitive costs, or the complexity of the intervention.[6] Occasionally, interventions were adopted as standard practice de-

TRIAL QUESTION	TRIAL TYPE	Patient	Intervention and/or Clinician
Can it work?	Explanatory	Selected; Carefully diagnosed; High risk of outcome; Most likely to respond	Likely to follow intervention or protocol; Comparison to placebo; Specialist clinical care support staff
Does it work in practice?	Management	Depends on efficacy; Diagnostic accuracy	Provider compliance; Real world clinical decision-making Coverage by the health service
Is it worth it?	Cost benefit		

NEJM Evidence

Published November 11, 2023
NEJM Evid 2024;3(2)
DOI: 10.1056/EVIDoa2300286

ORIGINAL ARTICLE

Dapagliflozin in Myocardial Infarction without Diabetes or Heart Failure

Stefan James, M.D., Ph.D.,[1,2] David Erlinge, M.D., Ph.D.,[3] Robert F. Storey, M.D., D.M.,[4,5] Darren K. McGuire, M.D.,[6,7] Mark de Belder, B.A. Cantab, M.B.B.S., M.A., M.D., F.R.C.P.,[8] Niclas Eriksson, Ph.D.,[1] Kasper Andersen, M.D., Ph.D.,[2,9] David Austin, M.D., F.R.C.P.,[10,11] Gabriel Arefalk, M.D., Ph.D.,[9,12] David Carrick, M.B.Ch.B., Ph.D., F.R.C.P.,[13,14] Robin Hofmann, M.D., Ph.D.,[15] Stephen P. Hoole, M.D., D.M.,[16] Daniel A. Jones, M.D., Ph.D.,[17,18] Kelvin Lee, M.R.C.P., Ph.D.,[19,20] Hans Tygesen, M.D., Ph.D.,[21,22] Peter A. Johansson, M.Sc.,[23] Anna Maria Langkilde, M.D., Ph.D.,[23] Wilhelm Ridderstråle, M.D., Ph.D.,[23] Ehsan Parvaresh Rizi, M.D., Ph.D.,[23] John Deanfield, C.B.E. F.Med.Sci. B.A. Hons. (Cantab), M.B., B.Chir., F.R.C.P., F.E.S.C., F.A.C.C.,[24] and Jonas Oldgren, M.D., Ph.D.,[1,2] for the DAPA-MI investigators*

NEJM Evidence

Published January 23, 2024
NEJM Evid 2024;3(2)
DOI: 10.1056/EVIDe2300310

EDITORIAL

The Registry-Based Randomized Trial — A Pragmatic Study Design

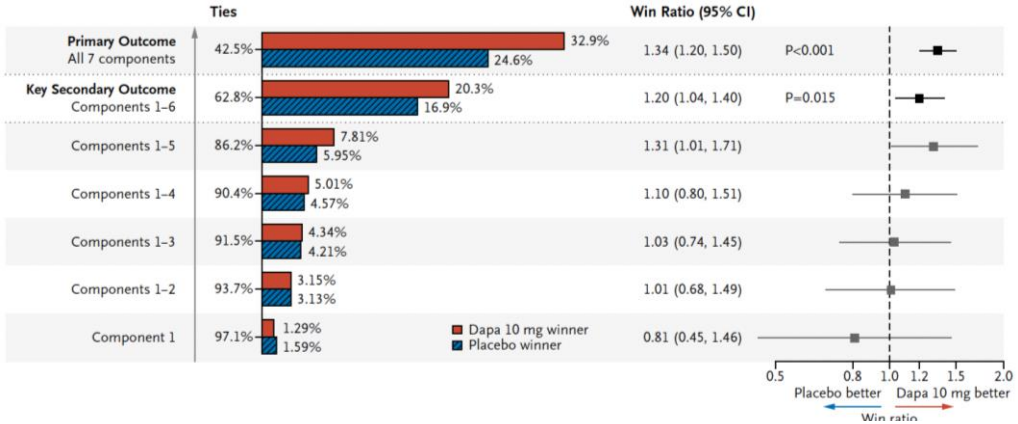
Andrea B. Troxel, Sc.D.,[1] and Erinn M. Hade, Ph.D.[1]

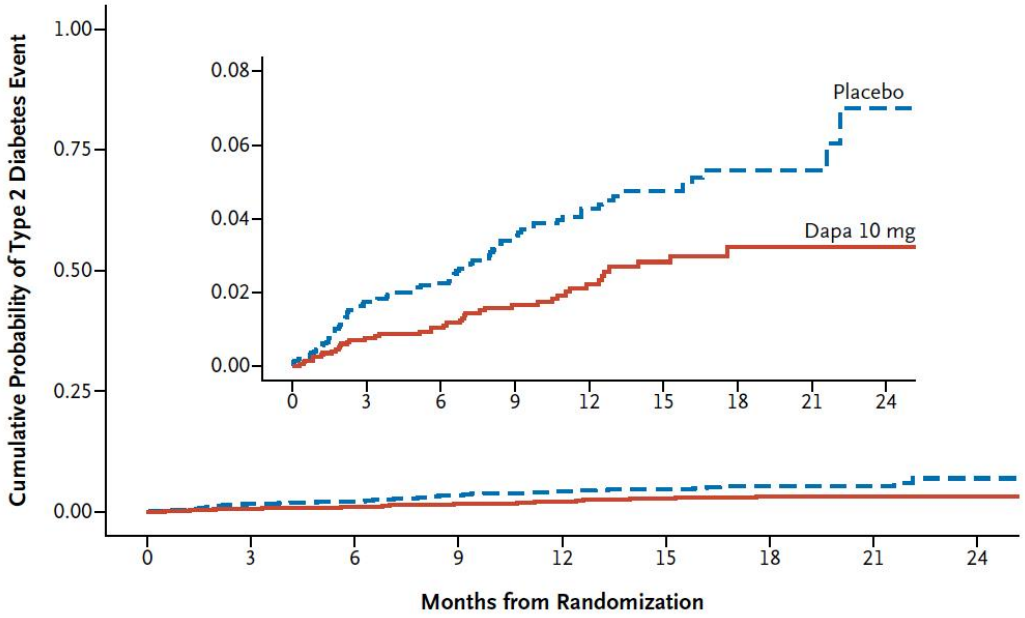
2024

2020-2023:

103 sites Sweden & UK
National Registries (SGLT-2)
4,017 patients randomized

#6/8





2024

#7/8

Shiely *et al. Trials* (2024) 25:375
https://doi.org/10.1186/s13063-024-08209-3

Trials

27 RCTs published up to 2020

REVIEW **Open Access**

Registry-based randomised controlled trials: conduct, advantages and challenges—a systematic review

Frances Shiely[1,2*], Niamh O Shea[1,3], Ellen Murphy[1,3] and Joseph Eustace[4]

"New registries should be designed and existing registries reviewed to enable the conduct of Registry-based RCTs"

Key pillars when considering a Registry-based RCT

Quality data collection	Established QA processes	Established Registry governance	Established informed consent; data protection & sharing governance policy	Good stakeholder contact & feedback	Good collaboration between clinicians, registry, trialists & statistician	Trial endpoint validation

When does a RCT become a Registry?

PIVOTAL protocol June 2026

New Era of PCCS-SG

Pediatric Critical Care Medicine
XXX 2026 • Volume 27 • Number 00 • Pages XX–XX

PCCM TRIAL

OPEN

The Paediatric Intensive Care Adaptive Platform Trial (PIVOTAL): Turning Pediatric Critical Care Practice Into Clinical Research

Mark J. Peters, MBChB, PhD[1,2,3]
Paul Mouncey, MSc[4]
Alexina Mason, PhD[4]
Tasnin Shahid, BSc[4]
Padmanabhan Ramnarayan, MBBS, MD[3,5]
Samiran Ray, MD, PhD[1,2]
Katherine Brown, MBBS, MD[6]
Irene Chang, MSc[4]
Doug W. Gould, PhD[4]
David Harrison, PhD[4]
and the Paediatric Intensive Care Adaptive Platform Trial (PIVOTAL) investigators for Paediatric Critical Care Society Study Group (PCCS-SG)

OBJECTIVES: To describe the rationale, design, and implementation of the Paediatric Intensive Care Adaptive Platform Trial (PIVOTAL), a novel approach to embed adaptive clinical research within routine pediatric critical care practice.

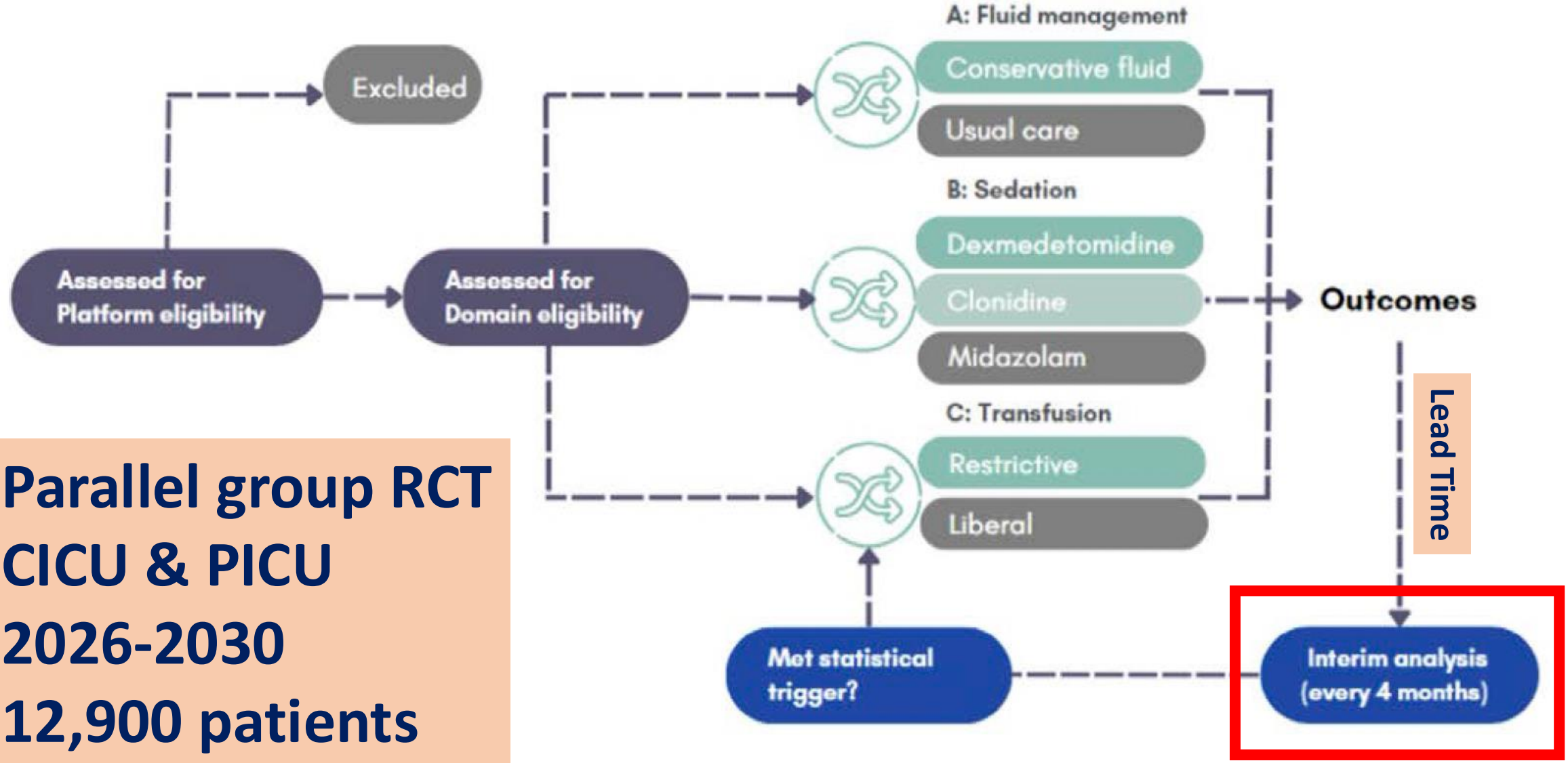
DESIGN: Prospective, multicenter, Bayesian adaptive platform trial developed by the U.K. Paediatric Critical Care Society Study Group (PCCS-SG) and funded by the U.K. National Institute for Health and Care Research Health Technology Assessment program.

SETTING: A minimum of 20 of the 33 PICUs across the United Kingdom that participating in the PCCS-SG research network.

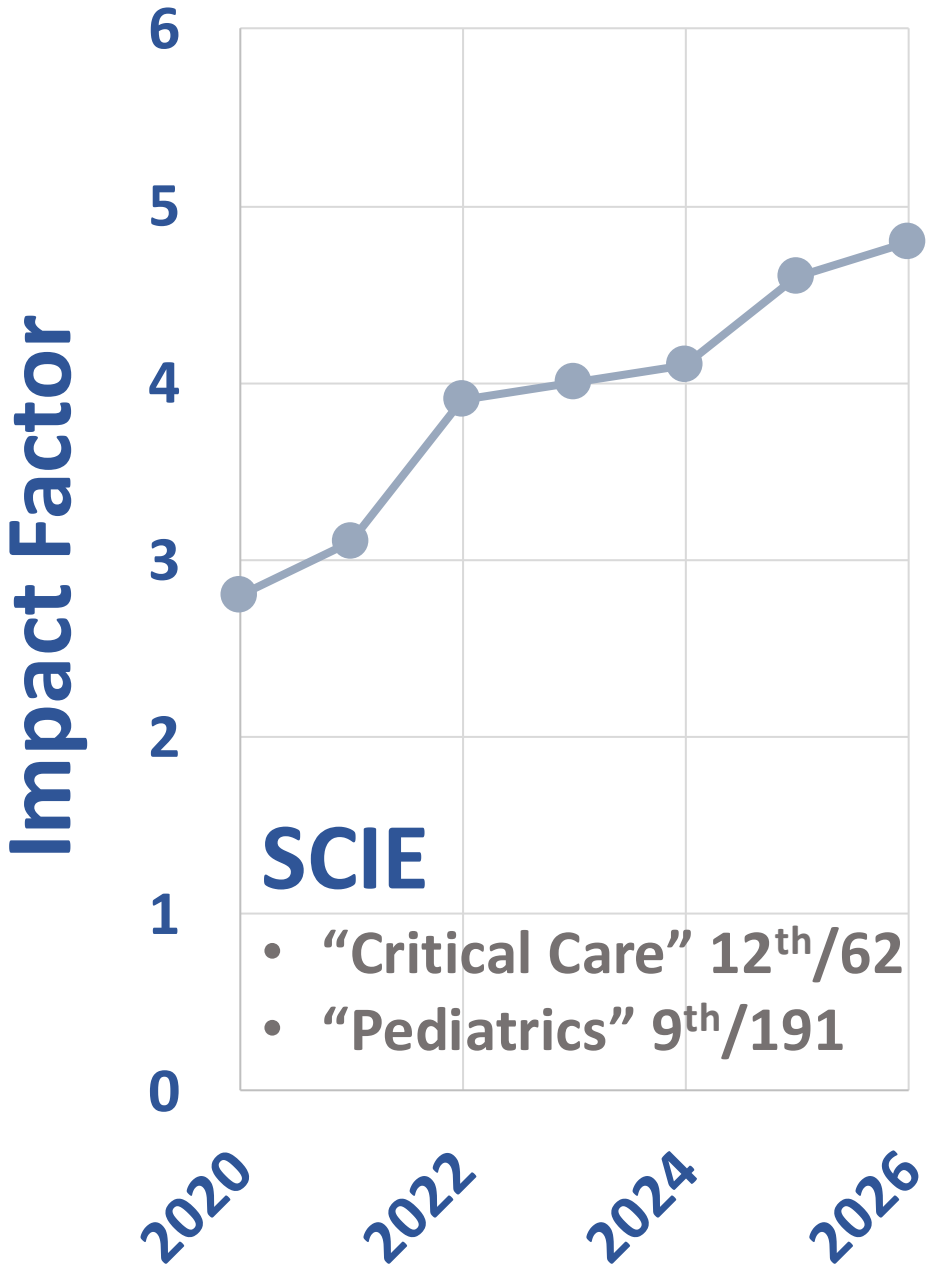
PATIENTS: Critically ill children admitted to a PICU requiring support for one or more organ systems.

INTERVENTIONS: Eligible patients will be randomized across multiple concurrent intervention domains. Each domain will test clinically relevant therapies where practice variation and evidence gaps exist. The adaptive Bayesian design allows dynamic modification of randomization ratios, dropping of inferior interventions, and addition of new domains over time.

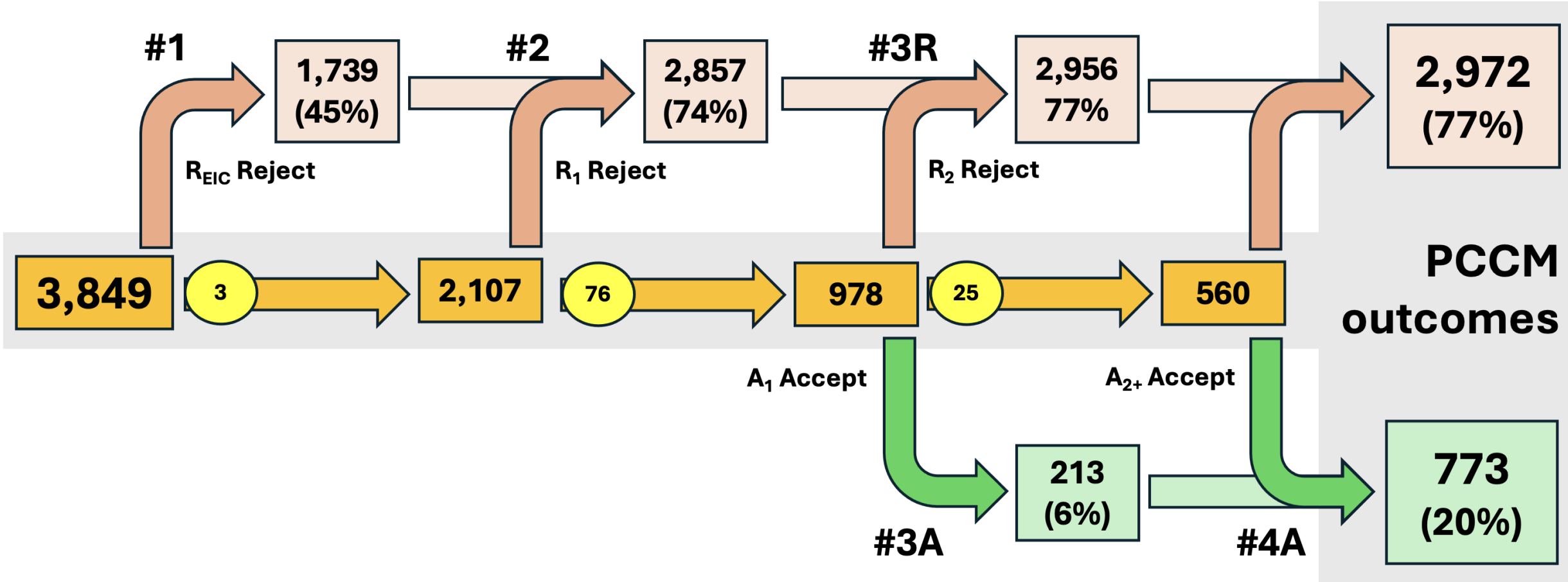
Think REMAP-CAP (Randomized, Embedded. Mulifactorial, Adaptive Platform trial of Community Aquired Pneumonia)



Parallel group RCT
CICU & PICU
2026-2030
12,900 patients



AIM 3: To understand the “why?” and “how?” of journal selection for Registry Science



Pediatric Critical Care Medicine

2021 to 2025 (5 years)

Science

SILICON VALLEY · YOUTUBE · GOOGLE · LATEST NEWS

WOMEN AND SCIENCE >

Scientific journals place less trust in women researchers

An analysis of more than 36 million articles written by women shows that the gender gap in research is also reflected in specialized journals

SELVA VARGAS REÁTEGUI

Madrid - FEB 11, 2026 - 17:07CET

A laboratory technician collects samples.
ALBERT GARCIA

Society of Critical Care Medicine
The Intensive Care Professionals

SCCM JOURNALS

PLOS Biology

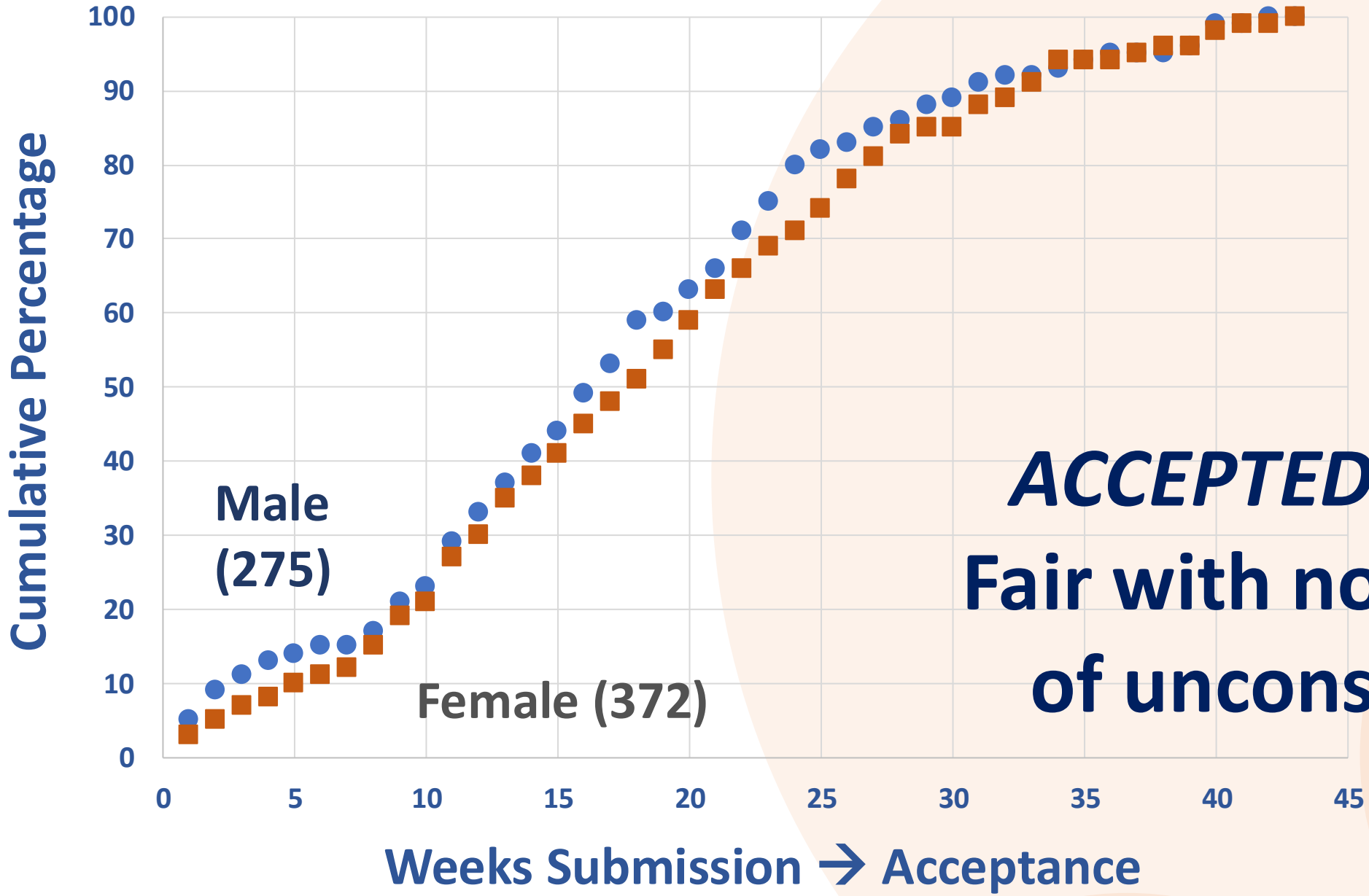
META-RESEARCH ARTICLE

Biomedical and life science articles by female researchers spend longer under review

David Alvarez-Ponce*, Gabrial Batz, Luis Ramirez Torres

Biology Department, University of Nevada, Reno, Nevada, United States of America

2026



ACCEPTED ARTICLES
Fair with no evidence of unconscious bias

Society of Critical Care Medicine
The Intensive Care Professionals

SCCM JOURNALS

PCCM EDITORIAL NOTES, METHODS, AND STATISTICS

December 2024

Writing for *Pediatric Critical Care Medicine*: A Checklist When Using Administrative and Clinical Databases for Research

Nine Questions to Consider
1. What is the new pediatric critical care research question and hypothesis?
2. Have the local or national institutional review board requirements been met?
3. Has an in-depth literature review of prior publications using the database/registry been completed?
4. What are the patient inclusions and exclusions, and what are the primary and secondary PICU outcomes?
5. Have the best variables for the pediatric critical care research question been considered?
6. Are you sure that the definitions of these variables in the database/registry have not changed over time?
7. Are there any known associations that arise from your literature review (Question No. 3) that mean these variables should also be included in any new outcome model?
8. What is the analytical strategy for missing data?
9. Can you provide an "at the bedside" or "what this study means" conclusion to your work?

Robert C. Tasker, MBBS, MD, FRCP[1,2]

ELSO (ECMO)
VPS (PICUs)
PC4 (CICU)
PHIS (Hospital)

Pediatric Critical Care Medicine
January 2026 • Volume 27 • Number 1 • Pages 120–123

PCCM NOTES, METHODS, AND STATISTICS

Writing for *Pediatric Critical Care Medicine*: What to Expect In the Final Pre-Acceptance Requests From the Editor

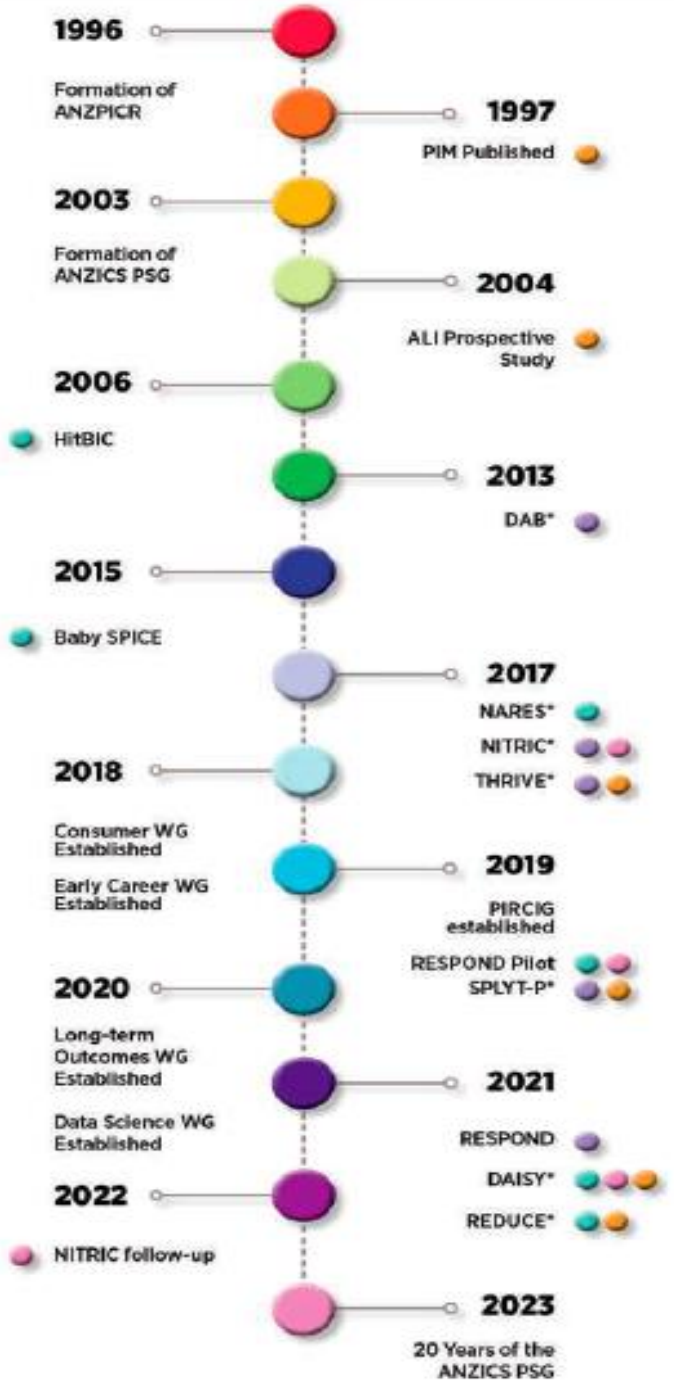
Robert C. Tasker, MBBS, MD, FRCP[1,2]

In the 2021-2025 cycle:

- Retractions 0/759 publications (UL 95%CI 0.4%)

Section or Part of Manuscript	Requirements
Title	Topic or field of study, followed by a colon, and then the methodology and years of study.
Abstract	When was the study done, how many patients, and is there is a ClinicalTrials.gov (NCT) number that should be included?
Information Boxes	Include a "Research in context" and a "What this study means," or "At the bedside" box; each has three bullet points, which are brief.
Introduction	Two paragraphs to save text for the Discussion. There is no need to provide a topic review, just the why and what was done, and the idea.
Methods	The research ethics committee approval comes first, with exact date. This date is checked against the dates of references in the Introduction.
Results	All Figures and Tables are checked along with the accompanying text. Make sure that precision and accuracy is appropriate, and the same.
Supplemental Digital Content	This content must be "camera ready" because it is not copyedited but posted online as submitted.
Discussion	Make sure that the observations are presented in the context of the most up-to-date literature, meaning the last couple of years.
References	All references are fact-checked for accuracy and relevance of content being quoted. Redundant references need to be removed.

Society of Critical Care Medicine
The Intensive Care Professionals
SCCM JOURNALS



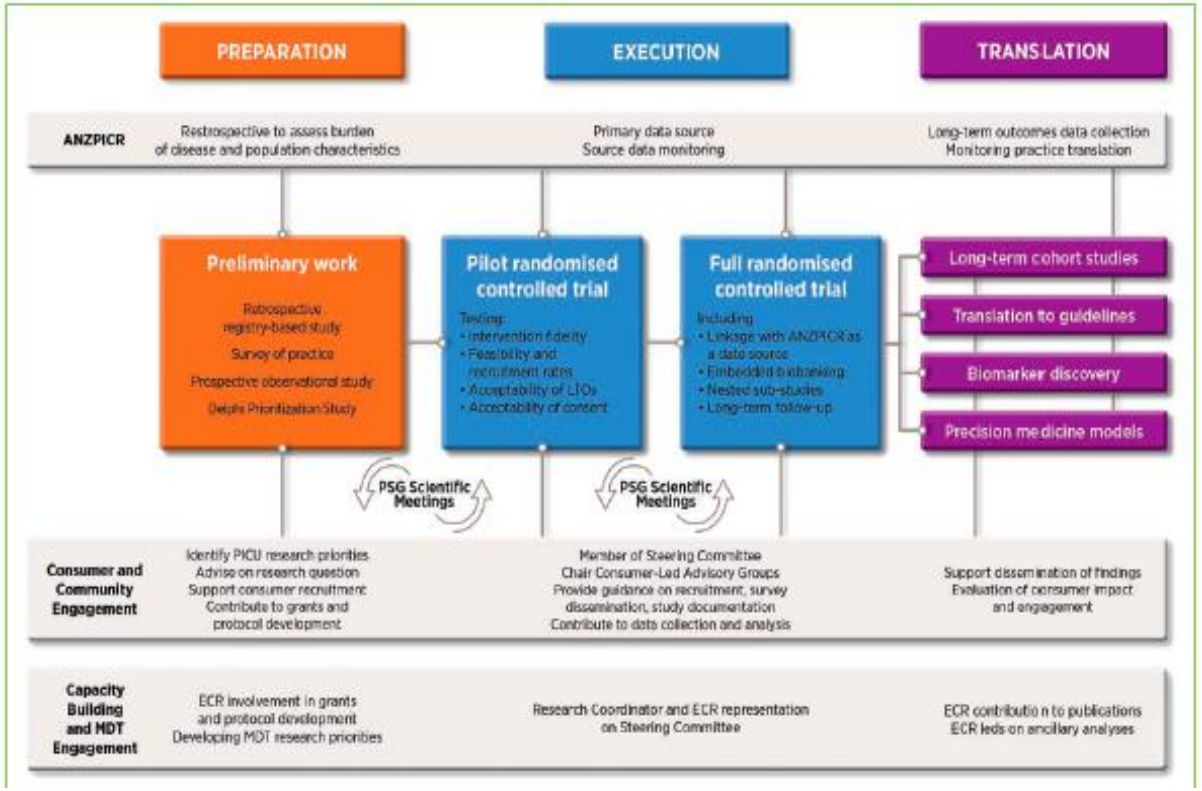
PCCM CONFERENCE REPORT & EXPERT PANEL

OPEN

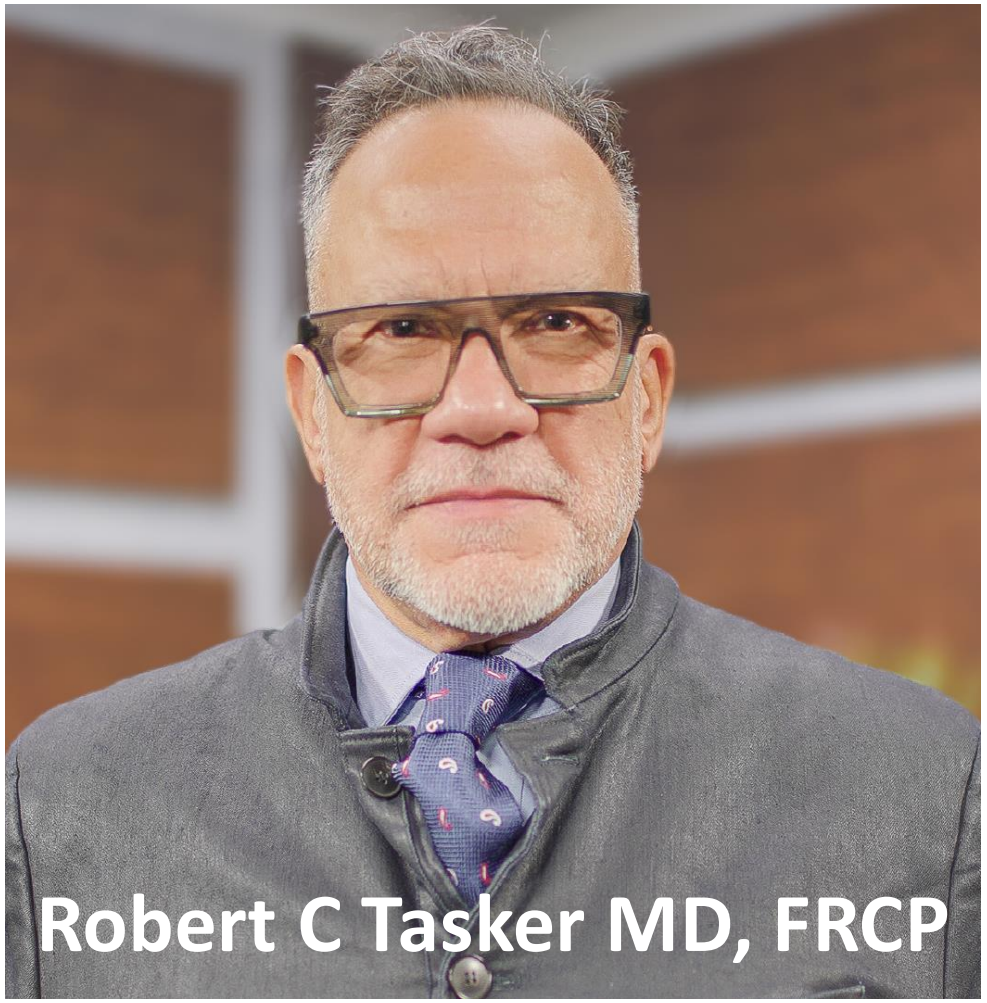
January 2025

The Australian and New Zealand Intensive Care Society Paediatric Study Group (ANZICS PSG): 20 Years of Collaborative Research

KEYWORDS: community participation; critical care; intensive care units, pediatric; randomized controlled trials; research networks



Kristen S. Gibbons, PhD[1]
John Beca, MBChB, FCICM[2]
Carmel Delzoppo, BAppSc[3,4]
Simon Erickson, MBBS, FCICM[5]
Marino Festa, MD (Res), FCICM[6]
Ben Gelbart, MBBS, PhD, FRACP, FCICM[3,4]
Debbie Long, PhD[7,8]
Kate Masterson, RN, MSc[3,4]
Johnny Millar, MBChB, PhD, MRCP, FRACP, FJFICM[3,4]
Sainath Raman, MRCPCH, PhD, FCICM[1,8]
Luregn J. Schlapbach, MD, PhD, FCICM[1,9]
Warwick Butt, MBBS, FRACP, FCICM, FELSO[3,4]
on behalf of the Australian and New Zealand Intensive Care Society Paediatric Study Group (ANZICS PSG)



Registry Science

1. Historical *weakness & limit*
2. *Strength & future*
3. The “why?” and “how?” of *journal selection/publication*

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