



The Paediatric Intensive Care Audit Network (PICANet) Project protocol

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Document History

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1.1	Draper/McKinney/Parry	09/08/2005	First submitted protocol
2.0	Draper/McKinney/Parslow	September 2006	Second Protocol
3.0	Draper/Parslow	23/01/2013	Third Protocol
4.0	Draper/Feltbower/Hiley	08/08/2018	Categorisation of aims and objectives and other minor updates
5.0	Draper/Feltbower/Lever /Preston	08/09/2022	Includes the expansion of PICANet to collect Level 2 care data, exemption and application National Data Opt-Out (England) and updated approval references.
6.0	Lever	11/07/2023	Minor updates and clarifications throughout to the status of the Level 2 data collection, application of the National Data Opt-Out, data collection training and data request review process.
7.0	Lever	12/05/2025	Co-Principal Investigator update. Addition of quality improvement to aims. PICU ECMO data collection included. Clarifications and updates throughout, including to data controllership and opt out information.

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Background and aims

The Paediatric Intensive Care Audit Network (PICANet) is an international clinical audit of paediatric intensive care (PIC) activity in the UK and Republic of Ireland. It was established in 2001 with the aim of providing a secure and confidential, high quality clinical database of paediatric intensive care activity. PICANet is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP), delivering the National Paediatric Critical Care Audit, and is recognised as the definitive source for paediatric critical care (PCC) data in the UK and Republic of Ireland.

PICANet collects data from NHS and private designated Paediatric Intensive Care Units (PICUs) providing paediatric Level 3 Critical Care¹ and Specialist Paediatric Critical Care Transport Services (see <https://www.picanet.org.uk/about/participating-organisations/> for a list of participating organisations).

In 2021 PICANet was commissioned by NHS England to undertake a development project to expand PICANet data collection and reporting to include discrete Level 2 PCC data and Extra Corporeal Membrane Oxygenation (ECMO) Admission and Referral data.

Upon successful completion of the pilot study in October 2022, the PICANet Level 2 expansion is taking place on a progressive course from February 2023 to involve collecting data for children and young people admitted to designated NHS Level 2 units in England.

In October 2023, PICANet launched the Extra Corporeal Membrane Oxygenation (ECMO) data collection. This is collected by the PICUs with paediatric ECMO Centre teams. Teams were encouraged to retrospectively collect data from April 2023.

The aims of PICANet are to support clinical audit, service evaluation, quality improvement and research. Audit and service evaluation are detailed below in relation to the Level 3 PCC data collection. The Level 2 PCC and ECMO data collections are for the purposes of non-research activity at this stage and will not form part of the PICANet research database.

¹ As defined in Time to Move On (RCPCH, 2014)

Audit

To improve the quality of care provided to patients as part of PIC services by measuring the quality of care and outcomes against pre-determined standards, benchmarking against other care teams and taking specific actions to improve quality of care.

Current measures include ²:

- Outcome data:
 - o Mortality in PICU
 - o Emergency re-admissions within 48 hours
 - o Unplanned extubation
- Monitoring of Paediatric Critical Care Society (PCCS) Quality Standards & other quality standards including:
 - o Timeliness of data submission to PICANet
 - o Retrieval mobilisation times
 - o Transport to bedside time
 - o Clinical team leader grade for transports
 - o Parent present for transports
- Customised data collections are occasionally undertaken which collect additional clinical data items (beyond the PICANet core dataset) specific to an area of care for the purposes of audit. These collections can be in response to local, national or international policy and clinical requirements.

Service evaluation

Generating data to define the supply, demand and outcomes for current PIC services and the patient population using the service. This supports healthcare planning, quantifies resource requirements and provides contextual information to facilitate the review of the audit data at both national and individual PICU level. It also highlights areas for local audits, future research and generates baseline data for clinical trials.

Current measures include²:

- Numbers and types of admissions to PICU
- Prevalence of admissions to PICU
- Number of children receiving care in adult ICUs³

² This list is not exhaustive and is subject to change as appropriate (in line with the purpose stated)

³ Data provided by ICNARC

- Numbers and types of referrals for admission and/or transport and their outcomes (accepted or not)
- Numbers of patients requiring transport to a PICU that may be outside of their geographical area/postcode to receive specialised care
- Transport outcomes and journey duration
- Interventions received (in PICU and during transport)
- Critical incidents in transport and any interventions carried out by the transport team
- Level of care provided (by Health Resource Group⁴)
- Ventilator free days
- Bed activity and length of stay
- Wider health service resource use for patients using PIC services ⁵

Quality improvement

Our Healthcare Quality Improvement Plan outlines methods of quality improvement and includes a number of healthcare quality improvement goals. Local organisations and the PICANet team, often in collaboration with paediatric critical care colleagues and researchers, utilise the clinical audit data to work towards achieving local and wider goals. The plan, along with our resources to promote and enable quality improvement is available on our Quality Improvement Resources webpage: <https://www.picanet.org.uk/quality-improvement-resources/>.

Research

To support high quality research in the areas of:

- paediatric intensive care
- specific conditions affecting children and young people accessing paediatric intensive care services (e.g. cardiac, neurological, infection, trauma)
- epidemiology of critical illness
- length of stay (e.g. variation in length of stay and understanding long stay)
- public health
- service evaluation, clinical audit or research methodology
- to extend the available knowledge with a view to ultimately providing benefits to patients.

⁴ As defined by National Casemix Office (commissioned by NHS England)

⁵ Including linkage to Hospital Episode Statistics (HES) data

The project has had Research Ethics Committee (REC) approval as a Research Database since July 2005 (current reference 23/EM/0189). Under this approval, research can be carried out either by the PICANet Database Research Team or by sharing de-identified data with other researchers. Data may also be shared for the purposes of research if the recipient has their own project specific-research ethics approval in place and appropriate legal basis for data sharing.

Any use of data for research purposes is subject to approval as described in the Data Request and Publication Procedures section.

Funding

The National Paediatric Critical Care Audit for the NHS Level 3 PICU and transport teams in England is commissioned by the Healthcare Quality Improvement Partnership (HQIP), as part of the National Clinical Audit & Patient Outcomes Programme (NCAPOP). Funders for the participation of the devolved nations and Republic of Ireland are the NHS Wales Joint Commissioning Committee, NHS Lothian and NHS Greater Glasgow and Clyde Health Boards, the Royal Belfast Hospital for Sick Children, and The National Office of Clinical Audit (NOCA), Republic of Ireland and HCA Healthcare.

NHS England commission and fund the Level 2 unit and ECMO data collections.

Management and governance

The PICANet Management Team consists of the Principal Investigators (PIs) and staff from the Universities of Leeds (PI: Professor Richard Feltbower) and Leicester (PI: Associate Professor Sarah Seaton). This team meets monthly to review progress against the timelines and contract deliverables, to consider any actual or potential barriers to satisfactory progress and to agree the work programme in the long and short term.

The entire project is overseen and guided by the PICANet Steering Group. The Steering Group oversees the wider governance of the project, providing advice and guidance on policy and operation to ensure that PICANet provides a sound evidence-base for audit, service evaluation and research in paediatric critical care. The Steering Group has representatives from a broad range of organisations across the UK and Republic of Ireland with an interest in PCC which includes parent/carers representation and the Paediatric Critical

Care Society. A full membership list is available on the PICANet website (<https://www.picanet.org.uk/people/steering-group/>).

In addition, PICANet is overseen by a clinical Advisory Group (CAG), whose members represent the paediatric critical care teams that submit data to PICANet. The CAG has the following functions: to provide practical clinical advice to the PICANet team; to act as a forum in which PCC staff can raise practical operational issues about data entry and transmission and validation; to contribute to discussions about the long-term strategic development of PICANet; to identify important audit and research questions that the PICANet database could address; and to review the results and interpretation of analyses from a clinical perspective. It also acts as the natural forum for the co-ordination of multi-centre clinical research studies and reviews requests for access to PICANet data to ensure feasibility, prevent duplication of service evaluation, audit or research activity and to encourage collaboration. The CAG has a representative on the Steering Group to give feedback from a clinical perspective. A full membership list is available on the PICANet website (<https://www.picanet.org.uk/people/clinical-advisory-group/>).

During the development and pilot stages of the expansion to collect Level 2 data, the Level 2 Expansion Advisory Working Group (AWG) provided support and advice. Membership of the L2E-AWG was determined by the need for clinical representation from all contributing profiles inclusive of clinical, nursing, data management and commissioning staff, geographical regions, and unit/service type. The remit of the L2E-AWG was to ensure clinical engagement and appropriate clinical input and expertise to guarantee that the Level 2 Expansion of PICANet remained “fit for purpose”. The involvement of representatives from devolved nations was to facilitate expansion beyond England at a later stage. AWG meetings took place on a regular, monthly basis to discuss and agree on key metrics/ data collection, the pilot units and outcome measures.

The PICANet Principal Investigators have regular contract review meetings with funders who monitor contract deliverables, finance and also provide advice on current national quality improvement policy objectives.

Data Controllers

NHS England is joint Data Controller with HQIP for the data collected from English NHS PICUs and transport teams.

The University of Leeds and the University of Leicester are joint Data Controllers for data collected from paediatric intensive care teams in Wales and Northern Ireland.

The joint Data Controllers and Data Processors for data collected from paediatric intensive care teams in Scotland are the University of Leeds and the University of Leicester and Lothian Health Board and Greater Glasgow and Clyde Health Board.

The joint Data Controllers and Data Processors for data collected from paediatric intensive care teams in Republic of Ireland are the University of Leeds and the University of Leicester and the Royal College of Surgeons in Ireland through the National Office of Clinical Audit.

The University of Leeds and HCA International Limited are Data controllers for the PICU data collected from the private hospital.

NHS England are the Data Controller for the English NHS level 2 PCC unit and ECMO data collection.

Consent and confidentiality

PICANet processes directly identifiable patient information including names, addresses, and healthcare system number (e.g. NHS number, CHI number, local case note number) from participating units and specialist transport and retrieval services in England, Wales and Scotland. With this information, PICANet can identify multiple admissions, referrals and transports for the same individual, making the dataset person and episode-based. In addition, national census and other geographical data can be linked with individual children using validated postcodes, enabling PICANet to assess the association between geo-demographic and environmental information and PCC admissions as well as assess patient flows across the country.

Processing of personally identifiable data without consent for the purposes of audit, service evaluation and research is supported by the Health Research Authority Confidentiality Advisory Group (formerly the Patient Information Advisory Group). This support is under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support' of the NHS Act 2006) for data collected in England and Wales. Support has been in place since 2002 and this has been renewed annually since this date. The references are: 21/CAG/0090 (non-research) and 21/CAG/0098 (research). The expansion of PICANet to collect Level 2 care data is included in the approved non-research CAG application (21/CAG/0090).

For the participating organisations in Scotland, local and Caldicott approvals are in place and PICANet have approval from the NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (NHS HSC-PBPP). The reference is 1819-0107 Feltbower.

Data from Northern Ireland and the Republic of Ireland is submitted in a pseudonymised format with only indirect identifiers being collected. Data within the organisations in Northern Ireland and the Republic of Ireland can be linked but episodes of care for the same patient treated elsewhere cannot be linked.

Ethical approval was originally granted by the Trent Medical Research Ethics Committee, ref. 05/MRE04/17. The current ethical approval was granted by East Midlands Derby REC, ref. 23/EM/0189. A list of patient identifiable data items collected and stored by PICANet is given in Appendix A along with justification for their use.

Opt out mechanisms

The [PICANet clinical audit and research database opt out policy for children, young people and parents](#) is available on the PICANet website. This policy details the opt out mechanisms available in relation to PICANet data collection and how they can be implemented.

Children and young people or their parent or carer can request that their/their child's personally identifiable information are removed from the PICANet database, with their anonymised information remaining in the PICANet database for audit (non-research) and approved research purposes.

PICANet have received permission from the Heath Research Authority Confidentiality Advisory Group for England and Wales not to apply the National Data Opt-Out which relates to information about an individual's health care provided in England. This application was made as an amendment to our existing non-research approval 21/CAG/0090. Permission was granted because the absence of even one child's data can lead to inaccurate conclusions.

However, there are two further opt out mechanisms if children and young people or their parent or carer do not want to have any of their/their child's data included in the research dataset.

1. PICANet applies the National Data Opt-Out (England) to the processing and/or release of data received from English hospitals in line with national guidance where the purpose is for secondary uses, such as approved research projects. Therefore, PICANet do not need to be contacted if a National Data Opt-Out has been set.
2. If a National Data Opt-Out has not been set, and/ or there is a wish to opt out of all data being included in approved research projects then there is guidance provided for how to contact PICANet to discuss and request that their/their child's data is not included in the research dataset.

Dataset development

Original PICANet Level 3 dataset

The original PICANet data set was established in consultation with members of the PICANet Clinical Advisory Group (CAG) and the Department of Health. The overriding criteria for inclusion of specific variables were that they provided key information on activity, case mix, demographics and outcome at a national and local level, that they were feasible to collect

and that the wider PIC community supported their inclusion in the national database. Subsequent additions to the dataset have been made to include data items that comprise the Paediatric Critical Care Minimum Data Set (PCCMDS)⁶, issued in February 2007 and the PICANet transport and referrals dataset. The Extra Corporeal Membrane Oxygenation (ECMO) Admission and Referral datasets were incorporated in 2023.

Data definitions are available in the PICANet Dataset Manuals available at: <https://www.picanet.org.uk/clinical-audit/>. Also available is the PICANet Dataset Changes Over Time document which contains details on data availability and limitations which should be considered when submitting a data or information access request for PICANet data.

In addition to the core datasets, customised data collection can be carried out in a number of specific areas to address the needs of specific audit and service evaluation activity.

Level 2 Admission data set

The level 2 Admission dataset is largely based on the existing level 3 dataset but is tailored for the level of care commonly received in these units. The level 2 dataset was formulated in consultation with the Level 2 AWG. Examples of the tailored clinical data collection for level 2 items include the Paediatric Early Warning Score (PEWS), blood gas measurements and respiratory or airway interventions that aren't typically used or recorded for Level 3 care. The patient identifiable data collected is the same as the level 3 dataset.

Data collection methods are the same as the level 3 PICU audit (manual data entry or the importing of data from local clinical management systems). The pilot study conducted in 2022 trialled the use of a combined Level 2 and Level 3 data capture form and the outcome was to provide separate forms.

Data entry and storage

Data entry is via a secure web-based application called PICANet Web, either directly or via an upload facility for PCC teams that have their own in-house database systems. The system has in built automated validations and allows units to download and report on their own data. All data collected, including identifiable patient data, is stored in the Leeds Analytic Secure Environment for Research (LASER) system. All data at rest in the LASER system is encrypted to AES-256 Bit encryption.

⁶https://www.datadictionary.nhs.uk/data_sets/supporting_data_sets/paediatric_critical_care_minimum_data_set.html

Training for those new to data entry is carried out within the individual organisations. To support this process, PICANet have made available a number of interactive guidance documents available on how to complete data entry, troubleshooting and FAQ's. PICANet staff are always available to answer any clinical and non clinical queries, and the virtual validation visits provide a platform to address any issues with education and training of staff.

Validation of data

Data validation is carried out at the point of data entry on the web system and centrally on the database. Validation checks for logical inconsistencies, out of range values and incorrect data are reported back to the individual participating organisations on demand via the web interface. In addition, validation reports are provided to participating organisations every 6 weeks. There are 6-monthly data cleaning intervals to distribute local resource required to carry out quality assurance checks within organisations throughout the year.

Virtual validation visits are conducted by PICANet staff, aiming to have one visit every 12 – 18 months per participating organisation. These validation visits are vitally important to maintain contact with PCC staff, to pick up on systematic errors that may appear in the data and assist in managing user access and identifying team changes not already reported to PICANet.

Case ascertainment is measured via units comparing the admission count in their admission book/electronic system over eight out of 12 months of the year and comparing these numbers to the number of admissions on PICANet Web database.

Reporting

PICANet produces an annual report on all level 3 data for the previous three calendar years. All the reports that have been published are available on the PICANet website at <https://www.picanet.org.uk/annual-reporting-and-publications/>. Local reports are available to participating organisations with the option of downloading aggregated data from all PIC teams for comparison from the PICANet Web database.

Data request and publication procedures

The first steps for applicants to take should they wish to request data is to contact PICANet to propose the idea and discuss the viability of the request. Where viable, the applicant completes the PICANet Feasibility Data Request Form. The form is reviewed by the multidisciplinary PICANet team (including statisticians, data managers and clinicians), and any queries raised with the applicant. The review assesses legal/ethical bases for processing data where relevant, level and detail of data requested and that there are sufficiently robust data security measures in place.

Applicants are asked to confirm what they will use the data for at the time of Data Request (e.g. for publication, internal audit etc.) and provision of the data is conditional on acceptance of the PICANet Data and information requests: policy on use of data, publication and authorship. The PICANet team determine if the National Data Opt-Out (England) should be applied to a data request.

All requests for processing of data by third parties (outside the Research Database Team) or for purposes outside the established audit and service evaluation are reviewed from a clinical perspective by the PICANet Clinical Advisory Group (CAG). The CAG review the merits of a data request to ensure scientific and clinical validity, that requests are in the public interest and to prevent duplication of effort in the clinical community, ensuring that there is good collaboration. The chair of the Paediatric Critical Care Society Study Group is a member of the PICANet CAG and is particularly well placed to advise on the latter two aspects. All reviewers are able give advice to applicants on their proposals and suggest collaborations.

Requests involving data from English providers, will be subject to approval by the HQIP Data Access Review Group (DARG) (<https://www.hqip.org.uk/national-programmes/accessing-ncapop-data/#.Wz4sWtVKhhE>). Prior to any data access/processing Data Sharing Agreement(s) will be put in place for all approved identifiable or de-identified data requests between the data controller(s) and the processor.

Data requests relating to data from Scotland, Wales, Northern Ireland, Ireland and private hospitals are processed, assessed and approved via the process described above; minus the requirement for approval by the HQIP DARG as HQIP are not a Data Controller for data originating from participating organisations in these countries and private providers. As the University of Leeds and University of Leicester (PICANet) are joint Data Controllers for data provided by all other providers, PICANet checks and approves these requests internally via

the Co-PIs, with feedback from the PICANet CAG; either approving the request or advising the data request is not possible.

The data requests process is outlined in the in the Data Request Process Flow Diagram, available here: <https://www.picanet.org.uk/data-collection/data-requests/>.

Details of data access requests fulfilled each year are included in the annual State of the Nation Report Appendices.

Anyone who receives data or information from PICANet must provide a written response on how the data has been used and acknowledge PICANet in all presentations and reports. In the case of publication, it is expected that a member of the PICANet team will be included as an author and therefore will have reviewed the manuscript and contributed to the analysis and interpretation.

Appendix A: Patient identifiable data items collected by PICANet

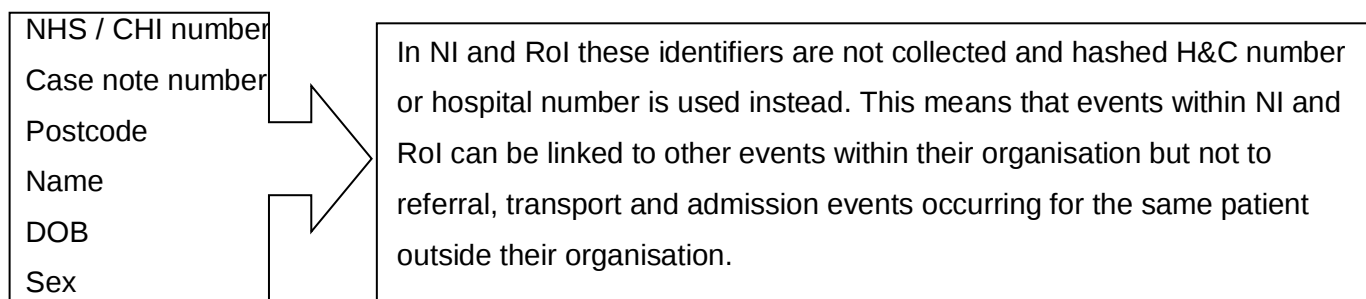
Data Categories	Is this field used?					Justifications
	England	Wales	Scotland	Northern Ireland (NI)	Republic of Ireland (RoI)	
Personal Data						
Name	Y	Y	Y	N	N	Required for assigning admission, referral and transport events to an individual patient identifier within the database using a probabilistic matching algorithm (see below) *. Used for data ascertainment purposes as part of routine data validation for the study Required for planned linkage to other routine data sets (e.g. ONS via NHS Digital) ** To assign and verify ethnic group based on name recognition software (e.g. OnoMap) Children were historically given their mother's NHS number at the time of birth. In such cases other identifiers have been required to distinguish between twins and to link any early admissions for such patients to subsequent admissions using their own NHS number once issued.
NHS number / CHI number / H&C number	Y	Y	Y	Submitted in hashed format	N	Required for assigning admission, referral and transport events to an individual patient identifier within the database using a probabilistic matching algorithm (see below) *. Used for data ascertainment purposes as part of routine data validation for the study

Data Categories	Is this field used?					Justifications
	England	Wales	Scotland	Northern Ireland (NI)	Republic of Ireland (RoI)	
						Required for planned linkage to other routine data sets (e.g. HES & ONS via NHS Digital) **
Address	Y	Y	Y	N	N	Required for planned linkage to other routine data sets (e.g. HES & ONS via NHS Digital) ** Address is used to validate postcode using appropriate software (or manually if not available in software).
Postcode	Y	Y	Y	N	N	Required for assigning admission, referral and transport events to an individual patient identifier within the database using a probabilistic matching algorithm (see below) * Required for planned linkage to other routine data sets (e.g. HES & ONS via NHS Digital) ** Postcode used to validate address using appropriate software (or manually if not available in software). Postcode is used to identify patients resident within a health authority area to provide information to commissioners. Address and postcode are also used for the devolved nations' reports, in which we report on children resident in the different countries. Also used to calculate distance between home and the unit of admission and assign deprivation score as part of health inequality analyses.

Data Categories	Is this field used?					Justifications
	England	Wales	Scotland	Northern Ireland (NI)	Republic of Ireland (RoI)	
Date of birth	Y	Y	Y	Y	Y	Required for assigning admission, referral and transport events to an individual patient identifier within the database using a probabilistic matching algorithm (see below) * Required for planned linkage to other routine data sets (e.g. HES & ONS via NHS Digital) **
Date of death	Y	Y	Y	Y	Y	To allow survival and mortality analyses to be performed. Used to check if the child was admitted after their death, an admission like this is excluded from the SMR analysis. Also used to clean the dataset before the production of the Annual Report, as we check for inconsistencies between discharge date and date of death. Also planned comparison with date of death in other routine datasets (e.g. ONS from NHS Digital) to ensure accurate data received
Sex	Y	Y	Y	Y	Y	Required for assigning admission, referral and transport events to an individual patient identifier within the database using a probabilistic matching algorithm (see below) * Required for planned linkage to other routine data sets (e.g. HES & ONS via NHS Digital) **

Data Categories	Is this field used?					Justifications
	England	Wales	Scotland	Northern Ireland (NI)	Republic of Ireland (RoI)	
						Used in various statistical models for analysis of the data as sex is a known confounder in clinical research.
General Identifier e.g. Hospital No	Y	Y	Y	Submitted in hashed format in absence of H&C number	Submitted in hashed format	Required for assigning admission, referral and transport events to an individual patient identifier within the database using a probabilistic matching algorithm (see below) * Local identifiers such as case note number are used for local cross referencing and validation.
Sensitive Personal Data						
Physical / Mental Health or Condition	Y	Y	Y	Y	Y	These data are collected to provide the data to fulfil the aims and objectives of the project
Racial / Ethnic Origin	Y	Y	Y	Y	Y	To allow assessment of outcomes according to ethnic origin – this has identified differences in outcomes which are being investigated

* A probabilistic matching algorithm is used for the following elements to assign admission, referral and transport events to an individual patient identifier within the database:



Use of these identifiers maximises distinction between siblings and multiple births and minimises non-matches and mis-matches.

Events need to be assigned to an individual patient in order to:

- identify emergency readmissions (an outcome measure)
- identify long term / repeated use of NHS services by individuals
- assess the number of referral / transport refusals for individual patients

The use of a pseudo-identifier to enable event assignment to an individual patient is not feasible or practical in the paediatric intensive care setting as the care pathway is highly complex with patients transferred between district general hospitals, specialist transport and retrieval teams and PICUs across the country (and across national borders) often in circumstances of emergency or urgent care need. As such the consistent and accurate communication of a PICANet identifier between all these different care teams would be unworkable and would not provide robust linkage.

** These are the key identifiers for undertaking electronic data linkage with routine datasets to examine longer term outcomes including survival, subsequent health service usage and morbidity. Without these identifiers there will be missed linkages and erroneous linkages [Hagger-Johnson G, Harron K, Fleming T, et al Data linkage errors in hospital administrative data when applying a pseudonymisation algorithm to paediatric intensive care records BMJ Open 2015;5:e008118. doi: 10.1136/bmjopen-2015-008118]