PINEAPPLE

(Paedlatric caNcellation ratEs And Peri-oPerative clinicaL Evaluation)

Project leads: Catherine Riley / Hannah Lewis / Tom Bennett

Application for the Paediatric Anaesthesia Research Fund of the APA statutes
Paediatric Anaesthesia Trainee Research Network (PATRN) 2021
Updated Jan 2023

BACKGROUND

Paediatric peri-operative medicine (P-POM) is an emerging field with the potential to improve outcomes for the patient and the organisation:

- improve peri-operative outcomes by optimising co-morbidities
- improve patient experience by reducing patient and parental anxiety
- maximise theatre efficiency by preventing late starts and on-the-day cancellations
- introduce health promotion

The Royal College of Paediatrics and Child Health have published guidance for the recovery of elective surgery in children, citing the increasing surgical workload caused by cessation of elective surgery during March to May 2020, when over 50,000 children had their operations postponed[1]. Pre-operative assessment is recommended as a way of improving theatre list efficiency and maximising operating capacity.

The Royal College of Anaesthetists recognises perioperative medicine as “the pathway to better surgical care”[2] and though this vision targets adult patients, the concept can be extrapolated to the paediatric population. There a number of conditions in children which can be assessed and optimised, including asthma, diabetes, anaemia and anxiety. Careful pre-operative planning is required for children with complex medical needs such as congenital cardiac disease, metabolic disease, the complications of prematurity, haemoglobinopathy, and neuromuscular or genetic syndromes.

P-POM offers the possibility of opportunistic health screening and intervention, such as child or parental smoking or obesity. Exposure to environmental tobacco smoke doubles the risk of a perioperative respiratory adverse event[3] and children with obesity have

increased risk at all stages of the perioperative journey[4]. Preassessment offers a "teachable moment" when patients and families are motivated to make a behavioural change; this is encouraged in the NHS Long Term and the campaign Making Every Contact Count[5], which aims to embed public health education into every consultant between a patient and health care professionals. Delivering health improvement has the potential to improve perioperative outcomes if delivered at pre-assessment rather than on the day of surgery; furthermore, there is the possibility to improve the child's general health beyond the planned procedure.

Guidelines for the Provision of Anaesthetic Services[6] strongly recommend that centres offering paediatric anaesthesia "should be offered a preassessment service prior to the day of their procedure" but specific details on the form that preassessment may take and suggested preoperative investigations and interventions are not available.

A pilot study across 8 sites in the South West of England was performed in 2019 to assess the current provision of pre-operative assessment services for children and young people[7]. It showed considerable variation in pre-operative assessment practice, as reported by the paediatric anaesthesia lead in each centre: three centres have no face-to-face pre-assessment services, and two have no telephone service. Only 1 hospital had dedicated anaesthetic PA time for paediatric pre-operative assessment. No hospital had a strategy for managing children with anxiety once they have been identified. 46.6% pre-operative assessments were performed in nurse-led clinics, 34.4% by telephone and 19% by joint surgeon and anaesthetic nurses clinic.

The study documented the necessity of a P-POM service: only 60% assessments were routine; a specific intervention was required in 40%. 11.6% cases required discussion with an anaesthetist. An anxiety issue was identified in 21.3% of face-to-face assessments, compared to only 6.9% of telephone assessments: telephone assessments were well received by parents but seem less likely to identify children with anxiety.

Both telephone and face-to-face assessments were valued by parents and reduced anxiety levels in parents and children. Overall, 88.8% of children had a pre-operative assessment and their families were surveyed. 98% of parents rated their pre-operative assessment (either phonecall or clinic visit) as good or excellent. 82.5% parents and 66.3% children reported reduced anxiety as a result of their assessment.

Anaesthetists identified issues affecting the smooth running of the lists in 39% of lists. Thorough pre-operative assessment could have identified these issues in 37.5% of cases. Hospitals with no pre-operative assessment services had more than 50% lists affected. Pre-operative assessment is effective at identifying and addressing issues and leads to fewer cancellations and improved list efficiency.

There is thus wide variation in the provision of paediatric pre-assessment services, which in turn have the potential to improve children's perioperative experience and outcomes, deliver health promotion and maximise theatre efficiency.

References

1. https://www.rcpch.ac.uk/resources/national-guidance-recovery-elective-surgery-children#recommendations---pre-admission Accessed 09/05/2021
2. cpoc.org.uk Accessed 09/05/2021
3. Riley and Ladak. Reducing paediatric exposure to environmental tobacco smoke: the effects of paediatric exposure to environmental tobacco smoke and the role of paediatric perioperative care. Paediatric Anaesthesia (2020) 30; 1199-1203
4. Prevalence of perioperative childhood obesity in children undergoing general anaesthesia in the UK: A prospective, multicentre, observational cohort study. Burton, Lewis, Bennett et al. BJA (2021); 127: 953-61
5. https://www.makingeverycontactcount.co.uk/ Accessed 09/05/2021
6. Chapter 10 Guidelines for the Provision of Paediatric Anaesthesia Services, The Royal College of Anaesthetists
7. Fergusson and Courtman (own data)

Aims

1. To establish the proportion of children ≤16 years old seen in paediatric pre-assessment prior to elective surgery
2. To establish the on-the-day cancellation rate for children ≤16 years old presenting for elective surgery and the reason for cancellation.
3. To establish the incidence and impact of anxiety in children identified at pre-assessment and on the day of surgery

Primary outcome

The proportion of children ≤16 years old seen in paediatric pre-assessment and the format of that pre-assessment

Secondary outcomes

- The proportion of children ≤16 years old cancelled on the day of elective surgery and the reason for cancellation
- The proportion of children ≤16 years old with anxiety identified at pre-assessment and on the day of elective surgery
- The timing of paediatric pre-assessment in advance of elective surgery

STUDY OUTLINE

Study Design

A prospective observational cohort study.

Pilot study (surveys / background)

Extracting data from PATRN's recent PAediatric unPlanned dAYcase Admissions (PAPAYA) and PErioperative CHildhood ObesitY (PEACHY) study, it can be estimated that between 90-105 UK paediatric centres will participate in PINEAPPLE. The mean number of day cases on a weekly basis was 83.5 across all centres that submitted data (range 3 – 230). Since day cases can be considered to account for up to 90-95% of cases, we may expect a further 5-10% per week in addition. Across 90 centres this would mean we may expect to collect data from the region of 7590 patients over a 10 day weekday period.

Overview

The expected timescale of the key components of the study is shown in Table 1.

Date 2022/2023	Time allocated	Task
30th September 2022	1 month	Submission of PINEAPPLE proposal to PATRN Committee and APAGBI Scientific Committee.
30th October 2022	1 month	Decision regarding successful project made by APAGBI Scientific Committee. Formulation of draft study proposal for review by PATRN Chairs.
30th November 2022	1 month	Initial discussion with statistical analysis and data management teams. Completion of study proposal including data management and statistical plan.
1st December 2022	1 month	Apply for study funding from the Association of Anaesthetists of Great Britain and Ireland (to cover statistical analysis and data management, study logo).
2nd January 2023	4 weeks	Registration form sent out by email to all PATRN representative trainees and Lead Consultant in each hospital on the database (approximately 120 centres).
6th February		Study launch date.
6th February	4 weeks	Initial Survey Registered centres to complete short survey regarding current hospital size and paediatric pre-assessment service offered
6tht February	8 weeks	Centres to register involvement in study with individual local audit departments and send confirmation of local approval to PATRN in order to complete registration as participants. REDCap Usernames to be created
3rd April	8 weeks	Data collection period (14 day period chosen by participating hospital within 8 week window).
29th May		End data collection period.
3rd July	4 weeks	Data to be uploaded to REDCap system by individual centres. Deadline 30th June 2022.
September 2023	2 months	Certificates for participants to be distributed.
Winter 2023	10 months	Write up and present study results.

Table 1. Timescale of the key components of the study

In January, all representatives on the PATRN database will receive an invitation to participate in the study (Appendix 1) which will be accompanied by a study summary information sheet (Appendix 2). We will also advertise via the Research and Audit Federation of Trainees (RAFT) and APAGBI linkmen coordinator to recruit new centres.

PINEAPPLE will be launched in February and centres will have a four week window in which to return their registration forms. This will incorporate information regarding the hospital and whether there is a paediatric pre-assessment service and how it is run. A total eight-week period from the launch date will be given for centres to return confirmation of local approval to participate in the study. This will complete the registration process.

Data collection period

The data collection period for this study is two weeks. This will be confined to a 8 week window from 25th April - 13th June 2023. An8 week window has been chosen to allow a suitable 14-day window to be chosen by individual hospitals. It is perceived that an intensive data collection period will be more likely to capture good quality data compared to a more extended period.

Inclusion criteria

- All children aged ≤16 years and presenting for an elective procedure involving general anaesthesia during the defined study period.
- Elective cases, day cases will be included.
- MRI, radiology, and dental cases will be included provided the patient receives a general anaesthetic.

All UK hospitals performing general anaesthesia for children aged ≤16 years will be invited to take part in this study. Currently there are approximately 120 hospitals undertaking paediatric anaesthesia in the UK which have a named representative in the PATRN database. During the last National study "PEACHY", data was collected from 102 of these centres and the aim would be to improve on this figure in PINEAPPLE

Exclusion criteria

- Procedures performed under sedation or local anaesthesia.
- Emergency procedures as these children will not be seen in pre-assessment prior to emergency surgery.
- Anaesthetic involvement in critically ill children e.g. airway management in ED, PICU
- Oncology patients for non-theatre procedures or repeated general anaesthetics e.g. Lumbar puncture, intrathecal therapy, radiotherapy. These are generally urgent procedures where children will not necessarily pass through the usual preassessment process or have had multiple anaesthetics before.

Ethics and consent

This study will be classified according to the HRA as a nationally coordinated locally conducted audit in which each participating centre will maintain ownership of their individual data. As such no ethical approval will be required. Copies of the HRA decision tool (Appendix 4) regarding research will be included in the study information available to each participating centre. No patient and/or parental consent will be required for this study.

METHODOLOGY

Data collection

Data will be collected for all children ≤16 years old undergoing elective surgery during the 2-week long data collection period. Data will be collected using a single data sheet per patient. This will be initiated by the anaesthetist in the operating theatre. The data collection sheet is attached (Appendix 5). The following clinical and anthropometric information will be collected on all patients: age (in years and months, included corrected gestational age for ex-premature infants), sex, American Society of Anesthesiology (ASA) physical status, co-morbidity and surgical specialty.

Patient identifiable data will be collected on paper forms for traceability in terms of missing data. Individual centres will be responsible for uploading anonymised data directly to the REDCap data collection system. Date of birth will be converted to age to the nearest year and month during the data upload process by REDCap. No identifiable data will be stored.

Sample size

Assuming we obtain data from 100 hospitals and a total of approximately 7590 children attend for surgery.

Statistical analysis plan

All data will be entered onto an excel database and initial range and logic checks performed. Data will then be transferred into IBM SPSS Statistics version 24 and SAS for statistical analysis. For each variable, appropriate descriptive statistics will be calculated (percentage and n for categorical variables and mean, standard deviation or median interquartile range, plus minimum and maximum for continuous variables).

Data storage

Data from local centres will be uploaded to the REDCap data portal. Each PATRN representative will be issued with personal login details to upload their own data to this system. They will not be able to access any data from any other participating centres. All data will be visible to REDCap administrators. Administrators will be members of the PATRN committee PINEAPPLE co-ordinators and our consultant advisors. The data will also be accessible to the statistical team via personal login details.

Required funding

Following quotes, costs of data management to facilitate REDCap data entry are £700 and statistical analysis costs will be £7000. The total therefore is £7700.

Study management

The project team will be led be the chief investigators CR, TB and HL. Communication will be regular by email and telephone amongst the PATRN committee, data collectors and consultant supervisors NW and PB.

Dissemination and transparency policy

We intend to publish the results of this study in a scientific journal and at a national/international conference by poster or oral presentation. CR,HL and TB will be joint first authors on any publications. PATRN will be listed as an author. All data collectors will be listed as collaborators and RAFT and any regional networks will also be acknowledged. We will make anonymised data available to all participating hospitals, and they will be able to identify themselves amongst the dataset.

Study collaborators

Chief investigators	Catherine Riley Hannah Lewis Tom Bennett (PATRN)	
PATRN	Paediatric Anaesthesia Trainee Research Network committee	
APA Scientific Committee	Natasha Woodman (Kings College London) Peter Brooks (Chelsea & Westminster)	
Statistician	*Support from University of Aberdeen*	
Data management		
Statistical support		
Research and Audit Federation of Trainees (RAFT)	RAFT support our network and advertise	
Regional networks	PLAN	London
	OXCCARE	Oxford
	SWARM	South West
	SHARC	South Yorkshire
	SPARC	Wessex
	West Scotland	
	MAGIQ	Merseyside
	MERCAT	East Midlands
	INCARNNET	North East
	SEQuoIA	East Scotland
	SQUARES	Scotland
	AARMY	East and West Yorkshire

APPENDICES

1. Invitation to participate
2. Study summary
3. Registration form
4. HRA decision tool
5. Data collection sheet