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Singapore's Health outcomes After Critical illness in Kids: SHACK study protocol exploring health outcomes of families six-months after critical illness.

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Authors contribution

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE: <http://www.icmje.org/recommendations/>):

1. Made substantial contribution and design, or acquisition of data, or analysis and interpretation of data;
2. Involved in drafting the manuscript or revising it critically for important intellectual content;
3. Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content;
4. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Dr Joseph Manning is currently funded through NIHR HEE ICA Clinical Lectureship and therefore the views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care, UK.

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Ethical Approval

SingHealth Centralised Institutional Review Board (CIRB) (Ref: 2020/2997, November 2020) and the Faculty Research Ethics and Integrity Committee of the University of Plymouth (Ref: 2020-2506-1464, December 2020)

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Abstract

Aim: To explore and understand the impact of paediatric intensive unit (PICU) admission on longitudinal health outcomes, experiences and support needs of children and their parents in the first six months after PICU discharge, and to examine the role of ethnicity.

Design: This study uses a prospective, longitudinal design.

Methods: The sample will include children (n=110) and at least one parent (n=110) admitted to the (PICU) (KKH-AM start-up fund, October 2020).

Quantitative study: Participants will be recruited at PICU admission. Data will be collected at five time-points: during PICU admission (T0); at PICU discharge (T1); 1 month (T2); 3 months (T3); and 6 months (T4) after PICU discharge. Questionnaires will assess physical and cognitive outcomes of the child survivor. Emotional and social health outcomes will be assessed for both the child and parents.

Qualitative study: At least 12 parents will take part in a semi-structured interview conducted at both 1 and 6 months after PICU to explore their experiences and support needs after PICU discharge. All interviews will be audio-recorded with verbatim transcription. We will use framework analysis for qualitative data analysis.

Discussion: Understanding of health outcomes of children and families after critical illness is limited. There is an urgent need to comprehensively understand the health trajectory and consequences of the PICU child survivor and their families. This research will be the first to explore the health outcomes, needs and experiences after paediatric critical illness in Asia.

Impact: This study will provide an understanding of the health outcomes and trajectory of children and parents in the first 6 months after PICU discharge and examine the association between race and outcomes after PICU discharge. Identification of modifiable pre-disposing risk factors during the PICU admission will inform future interventions to improve long-term outcomes of children and parents following paediatric critical illness.

Keywords: Critical illness, children, family, health outcomes, nursing, post-intensive care syndrome, intensive care.

1 INTRODUCTION

Advances in medical technologies have improved the survival rates of critically ill paediatric patients (Pollack et al., 2014). Every year in the United Kingdom (UK) and United States (USA), approximately 20 000 and 230 000 children, respectively, require admission to the paediatric intensive care unit (PICU) (Garber, Watson, & Linde-Zwirble, 2003; PICANet, 2017). Most children (95%) will be discharged alive (PICANet, 2017), but with this reduced mortality more children are discharged with increased morbidity (Pollack et al., 2014; Senna et al., 2020). Emotional distress and de-conditioned physical and mental impairment have become increasingly evident in paediatric critical care survivors (Shudy et al., 2006). In addition, the emotional and social impact of the PICU experience may extend to parents who experience the PICU first-hand by being present (Abela, Wardell, Rozmus, & LoBiondo-Wood, 2020). As a result, the post-intensive care syndrome in paediatrics (PICS-p) framework was conceptualised in recognition of the unique experiences of children and their families after critical illness (Manning, Pinto, Rennick, Colville, & Curley, 2018). The PICS-p framework incorporates the physical, cognitive, social and emotional health of PICU child survivor and their families. However, most studies are conducted in the USA and the UK, and less is known about the health outcomes of PICU survivors and their families in Asia. Singapore is a multiracial island state in Southeast Asia with a population of five million (Singapore Department of Statistics, 2019) comprising mainly Chinese, Malay, Indian, and Others (CMIO) and is therefore a suitable location for the study of these health outcomes. There are two quaternary PICUs providing medical care to critically ill children in Singapore.

1.1 BACKGROUND

Children

Growing evidence shows that children are being discharged from the PICU with physical and cognitive impairment (Hordijk et al., 2020; Killien, Farris, Watson, Dervan, & Zimmerman, 2019) and 30% of PICU child survivors show sustained emotional impact of their critical illness. These patients reported deterioration of their emotional well-being up to one year after discharge (Abela et al., 2020; Shudy et al., 2006), and PICU child survivors continues to exhibit negative behaviour and psychological responses in the first year after PICU discharge (Melnik et al., 2004). The duration of impairment varies, with some reporting lasting impact (Pollack et al., 2021).

A qualitative systematic review examining the psychosocial impact of a PICU admission revealed that children experienced confusion, relied on their parents' narration, and were focused on their former selves and meaning of normality (Manning, Hemingway, & Redsell, 2014). These psychological and social impacts were confirmed by two systematic review examining quantitative data (Abela et al., 2020;

Procter, Morrow, Pienaar, Shelton, & Argent, 2021). The sustained negative emotional and social effects on well-being may potentially disrupt childhood as a dynamic state of continuous growth and development after the critical illness.

Parents

A systematic review by Abela (2019), showed that parents were affected emotionally and socially to a large extent after their child's critical illness. More than half of the parents reported anxiety (60%), up to 50% were depressed and 30% presented with subclinical and clinical symptoms of post-traumatic stress disorder (PTSD). Similarly, qualitative studies which examined the experiences of families of PICU survivors, found that these families had distressing memories, increased anxiety and were over-protective of the children (Foster, Young, Mitchell, Van, & Curtis, 2017). Parenting roles evolved, to cope with the behavioural changes of the PICU survivors. Caring for a PICU survivor, places considerable financial and time commitment stressors on families (Terp & Sjostrom-Strand, 2017). Alteration in parental role and parenting style after paediatric critical illness were reported as coping responses towards the care of a PICU survivor (Dahav & Sjostrom-Strand, 2018). There is currently limited knowledge about the bidirectional interaction between PICU survivors and their parents' health after a critical illness.

Ethnicity

Ethnicity is considered a key determinant of health outcomes, because of their association with social and economic opportunities and resources. This relationship was well documented in the infant and adult population but is less known in the paediatric population (Mehta, Lee, & Ylitalo, 2013). A study examined 12,000 critically ill oncology paediatric patients found that after controlling for severity and cancer type, ethnicity influence PICU mortality (Leimanis Laurens et al., 2020). Literature on the impact of ethnicity on health outcomes in paediatric critical care is lacking. Most studies did not examine the difference in health outcomes according to ethnicity. The few available studies which examined outcomes by ethnicity were mainly conducted in the USA (Balluffi et al., 2004; Melnyk et al., 2004) and UK (Colville et al., 2009; Colville & Pierce, 2012), with most studies comparing study participants between White and Black or others. Minority groups reported worse outcomes for stress, anxiety, depression and posttraumatic stress after PICU discharge (Balluffi et al., 2004; Bronner et al., 2010). Minority groups also reported higher social and healthcare utilisation. In Singapore, differences in parental satisfaction were noted in the PICU population, with Malay families reporting less satisfied (Sng, Kirk, Buang, & Lee, 2017). Another study showed that Malay families of children with complex health condition reported higher levels of stress (Chan, Lim, Bautista, Malhotra, & Ostbye, 2019).

Currently, there is still a gap in the comprehensive understanding of the long-term health outcomes of the PICU survivors and their families following PICU discharge. The association between ethnicity and health outcomes after paediatric critical illness is limited. This proposed study, exploring the trajectory of health outcomes in children and families after PICU discharge in Singapore will contribute to the understanding of the Post-intensive care syndrome-paediatrics (PICS-p) in a multiracial context.

2. The Study

2.1 Research Question

What are the longitudinal health outcomes, experiences, and support needs of children and their parents up to six months after PICU discharge?

2.2 Aim

The aim of this study is to explore and understand the impact of PICU admission on longitudinal health outcomes, experiences, and support needs of children and their parents in the first six months after PICU discharge, and to examine the role of ethnicity.

Objectives:

1. To describe the physical, cognitive, emotional, and social health outcomes of children and the trajectory in the first six months after PICU discharge.
2. To describe parental emotional and social health outcomes in the first six months after PICU discharge.
3. To explore the experiences and support needs of parents after PICU discharge.
4. To understand the role of ethnicity in children and parents health outcomes after PICU discharge

2.3 Methodology

A longitudinal, single centre study design will be adopted. This study will have two work streams: 1) a quantitative study exploring prospectively the longitudinal health outcomes of 110 children and 110 parents and 2) an embedded qualitative study exploring the experiences and support needs via semi-structured interview with at least 12 parents at 1 month and 6 months after PICU discharge.

2.3.1 Theoretical framework

Post-Intensive Care Syndrome - paediatrics

The Post-Intensive Care Syndrome-paediatrics (PICS-p) framework (Figure 1) conceptually organises health outcomes of children, parents, and siblings of a child survivor after PICU discharge (Manning et

al., 2018). The framework views childhood as a dynamic state where the critical illness occurs at a time of tremendous growth and development. The framework also accounts for the potential impact of baseline developmental disabilities on quality-of-life after PICU recovery. The PICS-p framework includes physical, cognition, emotional and social health outcomes of children with various recovery trajectory after PICU discharge. Unlike the Post-Intensive Care Syndrome framework used in adults (Needham et al., 2012), the PICS-p includes the family as an interdependent unit. In this framework, parental and siblings emotional and social health outcomes are integrated within the pathway of the PICU survivor. This integration aids the recognition of potential bidirectional influence of health outcomes, where the PICU survivors are heavily dependent on their family.

2.4 Setting, participants, and recruitment

2.4.1 Setting

We will recruit participants from one PICU in a tertiary paediatric hospital, KK Women's and Children's Hospital in Singapore to capture variation in case mix and patient demographic. The study site is an 800-bed hospital specialising in women's and child's health, with 400 beds dedicated to paediatric services including a 16 bedded multidisciplinary (medical, surgical and cardiac) quaternary PICU facility. The PICU admits up to 600 patients a year. Following hospital discharge, patients will receive medical follow-up from the respective subspecialist depending on their admission diagnosis to the PICU. Families who required social assistance will continue to receive support from the medical social workers. The suitability of this hospital for the purpose of this study lies in its ability to access a large number of families of children who require critical care, with different socio-demographics and different types of diagnosis. Therefore, this hospital is considered a suitable study site for a representative sample of families of children requiring paediatric intensive care in Singapore.

2.4.2 Eligibility Criteria

Participants for this study include: (1) PICU child survivors and (2) parents/legal guardian.

1. PICU child survivors: (a) Aged 1 month to 18 years at the point of PICU admission; (b) at least 48 hours of PICU length of stay; (c) received PICU therapies for at least one organ dysfunction; (d) at least one parent/ legal guardian living with the potential study child participant.

2. Parent: (a) Parent or legal guardian; (b) cohabits with the PICU child survivor.

2.4.3 Participants

Quantitative study: We anticipate enrolling 110 children and their parents over an 18-month period. Based on the 20% attrition rate reported in previous PICU studies, we conservatively estimate a 40% attrition over 6 months (Balluffi et al., 2004; Keenan, Runyan, & Nocera, 2006; Rodriguez-Rey, Alonso-Tapia, & Colville, 2018). Thus, we expect having complete follow-up (i.e. 6-months outcomes) for 66 participants.

A sample size of 64 will be required for this study and was calculated based on the following parameters: mean difference of the Paediatric Quality of Life Inventory (Varni, 2001) of 3.0 with estimated standard deviation of paired differences of 9.5 between PICU admission and 6 months post PICU discharge, 80% power and a two-sided alpha of 5%. Paired sample T-test was used to compute sample size. After accounting for 40% attrition rate over six months, finally we will need to recruit 110 patients.

Qualitative study: A stratified purposive sample of at least 12 parents (at least 24 participants if both mother and father agree to participate) will be enrolled into the qualitative interviews (Polit & Beck, 2020). This sample size will capture diverse perspective around experiences from PICU admission up to six months after discharge, support needs, caregiving roles and responsibilities (Morse, 2000).

Recruitment will be stratified according to race (Chinese, Malay, Indian and Others). We will interview at least 12 parents at both 1 and 6 months after PICU discharge.

2.4.4 Recruitment

We will recruit children and parents during the PICU admission. The study team will screen the medical records of patients admitted to PICU daily to identify eligible patients. We will review clinical information of each patient's record to facilitate identification of eligible participants. We will share information about the study in the participant information sheet. The CONSORT flow diagram will illustrate the recruitment of this study (Moher et al., 2010).

At 1 month post PICU discharge (T2), with parental permission, the study team will invite children (aged 5 years and above) who are competent and able to complete the assessments to take part in the study. The parents will decide if they would ask their child for participation. If the child chooses not to participate, the study team will cease contact with the child. However, parents will still be able to continue their own participation irrespective of their child's involvement. Participants will receive SGD\$50 in staggered amount across the five time-points of data collection (T3: SGD\$10, T4:SGD\$10 and T5:SGD\$30).

2.5 Data Collection

2.5.1 Quantitative study

Data collection will include baseline and clinical characteristics such as demographics (age, gender, education level, ethnicity and religion) and socioeconomic data, pre-PICU health status and current illness data (PICU admission and discharge diagnoses, co-morbidities, surgical and invasive procedures performed; duration of mechanical ventilation, continuous renal replacement therapy, extracorporeal membrane oxygenation, inotropic support, sedative medications, PICU and hospital length of stay). We will extract data from the electronic medical records by research staff who will enter the data directly into a secure web application (JISC Online Survey) hosted by the University of Plymouth. Each child (or proxy) and their parent will provide data on health outcomes prospectively over the first six months after PICU discharge.

The focus and selection of study measures were informed by the PICS-p framework (Manning et al., 2018). We will collect outcomes at five time-points; baseline status (at consent); at PICU discharge; 1,3 and 6 months after PICU discharge (Figure 2). The outcome measures and time points are presented in Table 1, detailed explanation of the individual measurement instrument is presented in the electronic supplement material 1.

2.5.2 Qualitative study

Qualitative data will be collected virtually with parents of the PICU child survivors. Individual or paired parents semi-structured interviews lasting approximately 30 to 60 minutes will be conducted with parents/legal guardian at one (T1) and six (T4) months after PICU discharge. An interview guide will be used to explore the experiences and support needs of parents. The interview guide is developed based on semi-structured qualitative research methods (Dicicco-Bloom & Crabtree, 2006), recommendations by research team members and paediatric critical care literatures. Reflective field notes captured during the interviews will be used to highlight gestures and reactions by unveiling important elements such as emotions experienced by participants (Saldana, 2016). Interviews will be conducted in English, audio-recorded and transcribed verbatim.

2.6 Data analysis

Descriptive statistics will be presented for demographic and clinical characteristics. All PICU child survivors and parents related outcome measures will be calculated, including means, standard deviation, median and inter-quartile range for continuous variables. Frequency counts and percentage will be reported for categorical variables. Normality, outliers and systemic missing data will be assessed. Data transformation will be performed as necessary (Polit & Beck, 2020).

2.6.1 Quantitative data analysis

Analysis related to specific objectives includes:

Objective 1: To describe physical, cognitive, emotional, and social health outcomes of children in the in the first six months after PICU discharge. **Objective 2:** To describe parental emotional, social health outcomes and coping in the first six months after their child's' PICU discharge.

Descriptive statistics such as mean, standard deviation (SD), median and interquartile range (IQR) will be used to describe participant reported outcomes in the first six months after PICU discharge.

Mixed model ANOVA for repeated measurements will be used to examine the trajectory in children and their parents across baseline to six months after PICU discharge. Difference in the level of quality-of-life (QOL), functional status and cognition across five time-points will be examined in children.

Depression, anxiety, post-traumatic stress disorder (PTSD), family impact and coping strategies will be analysed for parental participants. The assumption for the mixed model will be addressed by analysing the sample for normality, homogeneity of variance, independence, and sphericity. A post-hoc test will be used to examine the differences in variables of significant difference with p-value <0.05.

Objective 4: To understand the role of ethnicity in children and parents' health outcomes after PICU discharge.

Mixed-model ANOVA for repeated measures will be used to examine the differences in different outcomes and race.

2.6.2 Qualitative data analysis

Audiotape recordings for each interview session will be transcribed verbatim and double checked for accurate transcription. Transcripts will be imported into the qualitative software package using the QSR International's NVivo 12 software for sorting, coding and categorizing of the data.

The adapted five-stage framework analysis process will be used for qualitative data analysis to achieve **Objective 3:** To explore the experiences and support needs and coping of parents after their children PICU discharge. The five stages are: (1) familiarization of the full transcript through immersion (2) development of a theoretical framework by identifying recurrent and important themes; (3) indexing and pilot charting; (4) summarizing data in an analytical framework; and (5) synthesizing data by mapping and interpreting (Ward, Furber, Tierney, & Swallow, 2013). Stage 5 will allow for the data to be compared across time points (1-3 months and 3-6 months).

2.7 Ethical considerations

The purpose of the study will be explained to prospective eligible participants and the level of involvement required of them for the research. Participants will be informed that the study team will only

be able to destroy information that were yet anonymised. We will assign a unique identification number in lieu of names on the questionnaire to maintain confidentiality. All participants will be asked to sign a written consent, with the signed consent form photocopied for parents' record. Parents will provide consent for children unable to provide consent/assent at time of enrolment. The patient information sheet and consent, questionnaires and reimbursement schedule were reviewed by three parents of PICU survivors. An incentive of SGD\$50 will be given to parents after completing questionnaires across 5 time-points.

Ethical review

The study protocol was reviewed by the SingHealth Centralised Institutional Review Board (CIRB Ref: 2020/2997 and the Faculty Research Ethics and Integrity Committee of the University of Plymouth (Ref: 2020-2506-1464). This study has been internally peer reviewed and awarded funding through the Academic Medicine start-up fund (KKH-AM/2020/04 (KRDUK20AR100)). The study has been registered at ClinicalTrials.gov (Identifier: NCT04637113)

2.8 Validity and reliability / Rigour

The study design creates the opportunity to triangulate and integrate quantitative and qualitative data (Onwuegbuzie & Johnson, 2006). To promote rigour in the project, we will respect the application of principles specific to each quantitative and qualitative work project. For the quantitative component, we adopted the principles of validity, reliability and generalizability (Polit & Beck, 2020). Principles of credibility, dependability, confirmability and transferability will be observed for the qualitative component (Lincoln & Guba, 1985).

2.8.1 Quantitative validity

Outcome measures used in this study were selected for their validity, reliability, ease of use, availability in electronic versions and previous use with PICU child survivors and their families. The selection was further informed by the PICS-p framework and current literature (Manning et al., 2018).

2.8.2 Qualitative validity

Credibility will be ensured by following the steps in framework analysis and coding the experiences of parents of PICU survivors (Saldana, 2016). Findings will be shared with researchers experienced in qualitative methods with PICU families to refine the final results. Dependability will be enhanced by having two researchers to code all interview transcripts, this is to ensure consistency in coding data across diverse participant groups (Graneheim & Lundman, 2004). An audit trail will be maintained to facilitate evaluation of the consistency of the research process and demonstrate the process of conceptualization

(Polit & Beck, 2020). The audit trail will include interview transcripts, coding records, and field notes. Confirmability will be enhanced through consensus during thematic analysis, participants' narratives will be used to report of the study findings. Participant demographic, description of context, and the audit trail of data source will strengthen the transferability of the study findings (Polit & Beck, 2020).

3 DISCUSSION

Research in long-term health outcomes is limited for children surviving a critical illness. Previous studies focused on specific patient groups (e.g., traumatic brain injuries, congenital heart disease or acute respiratory distress syndrome) using cross-sectional research design, measuring various outcomes (functional health, psychological wellbeing, health related quality-of-life) and often do not account for the child's pre-PICU health status. Understanding of the trajectory and longitudinal health outcomes of children and families after PICU discharge is severely limited. To improve outcomes for children and their families, multinational stakeholders from across 6 continents through consensus determined a set of PICU core outcomes (Fink et al., 2020). The use of longitudinal design and choice of outcome measures in the current study are aligned with the OCEANIC study (Manning et al., 2020). Thereby, our study attempts to create a community of research practice among colleagues in the PICU worldwide and align outcomes measures that enable us to compare robust data. In addition, this study will enhance understanding of the relationship between ethnicity and health outcomes. Collectively, these results can be used to inform practices of health care and other professionals, future research and policy development targeting specific groups.

Dissemination of findings will include presentations at international critical care conferences, the research team will actively engage in dissemination of findings to targeted practitioners, academics, decision-makers and the general public. Through the Paediatric Acute & Critical Care Medicine Asian Network (PACCMAN), we will have opportunities to disseminate the findings and replicate/scale up this project across Asia countries, reaching an audience much broader than the academic and local community. This will ensure that information about successful and unsuccessful features of our project is shared.

3.1 Limitations

First, the possibility exists that, because of the child's critical illness, parents are less likely to consent for the study. Therefore, a member from the care team will assess the parents' well-being before inviting them to participate in this study. They will be given time to consider and be reassured that participation is voluntary and that the care of the child will not be affected by their decision to participation.

Second, fathers may be under-represented as shown in previous PICU related research. This will affect the understanding of the impact of paediatric critical illness in fathers. To improve father's participation rate, the study team members will conduct invitation in the presence of both parents, keeping fathers involved throughout the conversation.

Third, due to the nature of the care burden after critical illness, participants are likely to drop out from a longitudinal study. Participants will be briefed and given an information sheet about their involvement in this study. They will be given on a monthly update on the recruitment rates and a pictorial road map to reflect their journey in the study. Based on reported attrition rates of 20% in longitudinal PICU studies, we conservatively estimate a 40% attrition rate.

4 CONCLUSION

Our research outcomes will help improve the delivery of current health-care services, short-term policy, and healthcare innovations for PICU survivors and their families. The results from this study will continue to build a sound foundation for ongoing research and policy development to support the complex needs of the PICU child survivor and their families. Lastly, results and template of our project are transferable and scalable to other countries across Asia and beyond the goal of understanding the health outcomes, experiences and needs to improve the lives of PICU child survivor and their families.

References

- Abela, K. M., Wardell, D., Rozmus, C., & LoBiondo-Wood, G. (2020). Impact of Paediatric Critical Illness and Injury on Families: An Updated Systematic Review. *Journal of Pediatric Nursing, 51*, 21-31. doi:10.1016/j.pedn.2019.10.013
- Baldacchino, D. R., & Buhagiar, A. (2003). Psychometric evaluation of the Spiritual Coping Strategies scale in English, Maltese, back-translation and bilingual versions. *Journal of Advanced Nursing, 42*(6), 558-570. doi:10.1046/j.1365-2648.2003.02659.x
- Balluffi, A., Kassam-Adams, N., Kazak, A., Tucker, M., Dominguez, T., & Helfaer, M. (2004). Traumatic stress in parents of children admitted to the paediatric intensive care unit. *Paediatric Critical Care Medicine: A Journal Of The Society Of Critical Care Medicine And The World Federation Of Paediatric Intensive And Critical Care Societies, 5*(6), 547-553.
- Bronner, M. B., Peek, N., Knoester, H., Bos, A. P., Last, B. F., & Grootenhuys, M. A. (2010). Course and predictors of posttraumatic stress disorder in parents after paediatric intensive care treatment of their child. *Journal Pediatric Psychology, 35*(9), 966-974. doi:10.1093/jpepsy/jsq004
- Chan, Y. H., Lim, C. Z., Bautista, D., Malhotra, R., & Ostbye, T. (2019). The Health and Well-Being of Caregivers of Technologically Dependent Children. *Global Pediatric Health, 6*, 2333794X18823000. doi:10.1177/2333794X18823000
- Colville, G., Darkins, J., Hesketh, J., Bennett, V., Alcock, J., & Noyes, J. (2009). The impact on parents of a child's admission to intensive care: integration of qualitative findings from a cross-sectional study. *Intensive & Critical Care Nursing, 25*(2), 72-79.
- Colville, G., & Pierce, C. (2012). Patterns of post-traumatic stress symptoms in families after paediatric intensive care. *Intensive Care Medicine, 38*(9), 1523-1531. doi:10.1007/s00134-012-2612-2
- Dahav, P., & Sjostrom-Strand, A. (2018). Parents' experiences of their child being admitted to a paediatric intensive care unit: a qualitative study-like being in another world. *Scandinavian Journal of Caring Sciences, 32*(1), 363-370. doi:10.1111/scs.12470
- Dicicco-Bloom, B., & Crabtree, B. F. (2006). The qualitative research interview. *Medical Education, 40*(4), 314-321. doi:10.1111/j.1365-2929.2006.02418.x
- Fink, E. L., Maddux, A. B., Pinto, N., Sorenson, S., Notterman, D., Dean, J. M., . . . Human Development Collaborative Paediatric Critical Care Research, N. (2020). A Core Outcome Set for Paediatric Critical Care. *Critical Care Medicine, 48*(12), 1819-1828. doi:10.1097/CCM.0000000000004660
- Foster, K., Young, A., Mitchell, R., Van, C., & Curtis, K. (2017). Experiences and needs of parents of critically injured children during the acute hospital phase: A qualitative investigation. *Injury, 48*(1), 114-120. doi:10.1016/j.injury.2016.09.034
- Garber, N., Watson, R., & Linde-Zwirble, W. (2003). The size and scope of intensive care for children in the US. *Critical Care Medicine, 31*((S)(A78)).
- Graneheim, U. H., & Lundman, B. (2004). Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Education Today, 24*(2), 105-112. doi:10.1016/j.nedt.2003.10.001
- Hordijk, J., Verbruggen, S., Vanhorebeek, I., Van den Berghe, G., Utens, E., Joosten, K., & Dulfer, K. (2020). Health-related quality of life of children and their parents 6 months after children's critical illness. *Quality Life Research, 29*(1), 179-189. doi:10.1007/s11136-019-02347-x
- Keenan, H. T., Runyan, D. K., & Nocera, M. (2006). Longitudinal follow-up of families and young children with traumatic brain injury. *Paediatrics, 117*(4), 1291-1297.
- Killien, E. Y., Farris, R. W. D., Watson, R. S., Dervan, L. A., & Zimmerman, J. J. (2019). Health-Related Quality of Life Among Survivors of Paediatric Sepsis. *Pediatric Critical Care Medicine, 20*(6), 501-509. doi:10.1097/PCC.0000000000001886
- Kroenke, K., Spitzer, R. L., Williams, J. B., & Lowe, B. (2009). An ultra-brief screening scale for anxiety and depression: the PHQ-4. *Psychosomatics, 50*(6), 613-621. doi:10.1176/appi.psy.50.6.613
- Leimanis Laurens, M., Snyder, K., Davis, A. T., Fitzgerald, R. K., Hackbarth, R., & Rajasekaran, S. (2020). Racial/Ethnic Minority Children With Cancer Experience Higher Mortality on Admission

- to the ICU in the United States. *Pediatr Critic Care Medicine*, 21(10), 859-868.
doi:10.1097/PCC.0000000000002375
- Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*: Sage.
- Manning, J. C., Hemingway, P., & Redsell, S. A. (2014). Long-term psychosocial impact reported by childhood critical illness survivors: a systematic review. *Nurse Critical Care*, 19(3), 145-156.
doi:10.1111/nicc.12049
- Manning, J. C., Latour, J. M., Curley, M. A. Q., Draper, E. S., Jilani, T., Quinlan, P. R., . . . Investigators, O. S. (2020). Study protocol for a multicentre longitudinal mixed methods study to explore the Outcomes of ChildrEn and fAmilies in the first year after paediatric Intensive Care: the OCEANIC study. *BMJ Open*, 10(5), e038974. doi:10.1136/bmjopen-2020-038974
- Manning, J. C., Pinto, N. P., Rennick, J. E., Colville, G., & Curley, M. A. Q. (2018). Conceptualizing Post Intensive Care Syndrome in Children-The PICS-p Framework. *Pediatric Critical Care Medine*, 19(4), 298-300. doi:10.1097/PCC.0000000000001476
- Mehta, N. K., Lee, H., & Ylitalo, K. R. (2013). Child health in the United States: recent trends in racial/ethnic disparities. *Social Science and Medicine*, 95, 6-15.
doi:10.1016/j.socscimed.2012.09.011
- Melnyk, B. M., Alpert-Gillis, L., Feinstein, N. F., Crean, H. F., Johnson, J., Fairbanks, E., . . . Corbo-Richert, B. (2004). Creating opportunities for parent empowerment: program effects on the mental health/coping outcomes of critically ill young children and their mothers. *Paediatrics*, 113(6), e597-607. doi:10.1542/peds.113.6.e597
- Moher, D., Hopewell, S., Schulz, K. F., Montori, V., Gotzsche, P. C., Devereaux, P. J., . . . Consolidated Standards of Reporting Trials, G. (2010). CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomised trials. *Journal of Clinical Epidemiology*, 63(8), e1-37. doi:10.1016/j.jclinepi.2010.03.004
- Morse, J. M. (2000). Determining sample size. *Qualitative Health Research*, 10, 3.
- Munro, B. H. (2005). *Statistical methods for health care research (5th ed.)*. Philadelphia: Lippincott Williams & Wilkins.
- Needham, D. M., Davidson, J., Cohen, H., Hopkins, R. O., Weinert, C., Wunsch, H., . . . Harvey, M. A. (2012). Improving long-term outcomes after discharge from intensive care unit: report from a stakeholders' conference. *Crit Care Med*, 40(2), 502-509. doi:10.1097/CCM.0b013e318232da75
- Onwuegbuzie, A. J., & Johnson, R. B. (2006). The validity issue in mixed research. *Research in the Schools*, 13(1), 15.
- PICANet. (2017). *Annual report: summary report*. Retrieved from Leeds:
- Polit, D., & Beck, C. (2020). *Nursing research: generating and assessing evidence for nursing practice (11th ed.)*. Philadelphia: Wolters Kluwer Health/lippincott Williams & Wilkins.
- Pollack, M. M., Banks, R., Holubkov, R., Meert, K. L., and the Eunice Kennedy Shriver National Institute of Child, H., & Human Development Collaborative Paediatric Critical Care Research, N. (2021). Long-Term Outcome of PICU Patients Discharged With New, Functional Status Morbidity. *Pediatric Critical Care Medicine*, 22(1), 27-39. doi:10.1097/PCC.0000000000002590
- Pollack, M. M., Holubkov, R., Funai, T., Clark, A., Berger, J. T., Meert, K., . . . Human Development Collaborative Paediatric Critical Care Research, N. (2014). Paediatric intensive care outcomes: development of new morbidities during paediatric critical care. *Pediatric Critical Care Medicine*, 15(9), 821-827. doi:10.1097/PCC.0000000000000250
- Pollack, M. M., Holubkov, R., Glass, P., Dean, J. M., Meert, K. L., Zimmerman, J., . . . Human Development Collaborative Paediatric Critical Care Research, N. (2009). Functional Status Scale: new paediatric outcome measure. *Paediatrics*, 124(1), e18-28. doi:10.1542/peds.2008-1987
- Procter, C., Morrow, B., Pienaar, G., Shelton, M., & Argent, A. (2021). Outcomes following admission to paediatric intensive care: A systematic review. *Journal of Paediatric and Child Health*.
doi:10.1111/jpc.15381

- Rodriguez-Rey, R., Alonso-Tapia, J., & Colville, G. (2018). Prediction of parental posttraumatic stress, anxiety and depression after a child's critical hospitalization. *Journal of Critical Care, 45*, 149-155.
- Saldana, J. (2016). *The Coding Manual for Qualitative Researchers*. London: SAGE Publications.
- Scheeringa, M. S. (2012). Young Child PTSD Screen. *Measurement Instrument Database for the Social Science*. Retrieved from www.midss.ie
- Scheeringa, M. S. (2019). Development of a Brief Screen for Symptoms of Posttraumatic Stress Disorder in Young Children: The Young Child PTSD Screen. *Journal of Developmental and Behavioural Pediatrics, 40*(2), 105-111. doi:10.1097/DBP.0000000000000639
- Senna, S., Ong, C., Wong, J. J., Allen, J. C., Jr., Sultana, R., & Lee, J. H. (2020). Prediction of Acquired Morbidity Using Illness Severity Indices in Paediatric Intensive Care Patients. *Pediatric Critical Care Medicine, 21*(11), e972-e980. doi:10.1097/PCC.0000000000002417
- Shudy, M., de Almeida, M. L., Ly, S., Landon, C., Groft, S., Jenkins, T. L., & Nicholson, C. E. (2006). Impact of paediatric critical illness and injury on families: a systematic literature review. *Paediatrics, 118 Suppl 3*, S203-218. doi:10.1542/peds.2006-0951B
- Singapore Department of Statistics. (2019). Singapore in Figures. Retrieved from <https://www.singstat.gov.sg/-/media/files/publications/reference/sif2019.pdf>
- Sng, Q. W., Kirk, A. H., Buang, S. N., & Lee, J. H. (2017). The Impact of Ethnic and Cultural Differences on Parental Satisfaction in the PICU. *Pediatric Critical Care Medicine, 18*(4), e167-e175. doi:10.1097/PCC.0000000000001095
- Sveen, J., Bondjers, K., & Willebrand, M. (2016). Psychometric properties of the PTSD Checklist for DSM-5: a pilot study. *European Journal of Psychotraumatology, 7*, 30165. doi:10.3402/ejpt.v7.30165
- Terp, K., & Sjostrom-Strand, A. (2017). Parents' experiences and the effect on the family two years after their child was admitted to a PICU-An interview study. *Intensive Critical Care Nursing, 43*, 143-148. doi:10.1016/j.iccn.2017.06.003
- Varni, J. W., Limbers, C. A., Sorensen, L. G., Neighbors, K., Martz, K., Bucuvalas, J. C., . . . Studies of Paediatric Liver Transplantation Functional Outcomes, G. (2011). PedsQL Cognitive Functioning Scale in paediatric liver transplant recipients: feasibility, reliability, and validity. *Quality of Life Research, 20*(6), 913-921. doi:10.1007/s11136-010-9823-1
- Varni, J. W., Seid, M., & Kurtin, P. S. (2001). PedsQL 4.0: reliability and validity of the Paediatric Quality of Life Inventory version 4.0 generic core scales in healthy and patient populations. *Medical Care, 39*(8), 800-812. doi:10.1097/00005650-200108000-00006
- Varni, J. W., Sherman, S. A., Burwinkle, T. M., Dickinson, P. E., & Dixon, P. (2004). The PedsQL Family Impact Module: preliminary reliability and validity. *Health Quality of Life Outcomes, 2*, 55. doi:10.1186/1477-7525-2-55
- Ward, D. J., Furber, C., Tierney, S., & Swallow, V. (2013). Using Framework Analysis in nursing research: a worked example. *Journal of Advanced Nursing, 69*(11), 2423-2431. doi:10.1111/jan.12127
- Watson, R. S., Choong, K., Colville, G., Crow, S., Dervan, L. A., Hopkins, R. O., . . . Curley, M. A. Q. (2018). Life after Critical Illness in Children-Toward an Understanding of Paediatric Post-intensive Care Syndrome. *Journal of Pediatrics, 198*, 16-24. doi:10.1016/j.jpeds.2017.12.084

Conceptual Framework for Pediatric PICS (PICS-p)

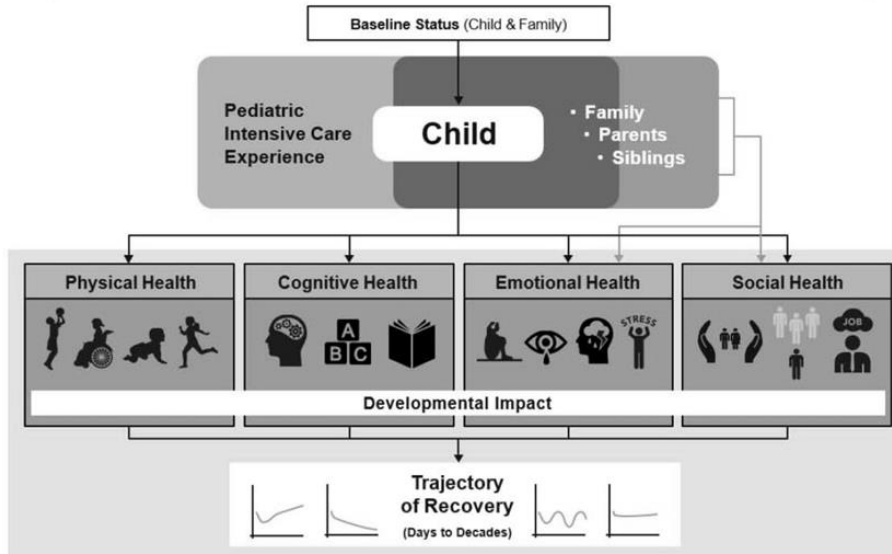


Figure 1. Post-intensive care syndrome in paediatrics (PICS-p) framework (Manning et al., 2018)

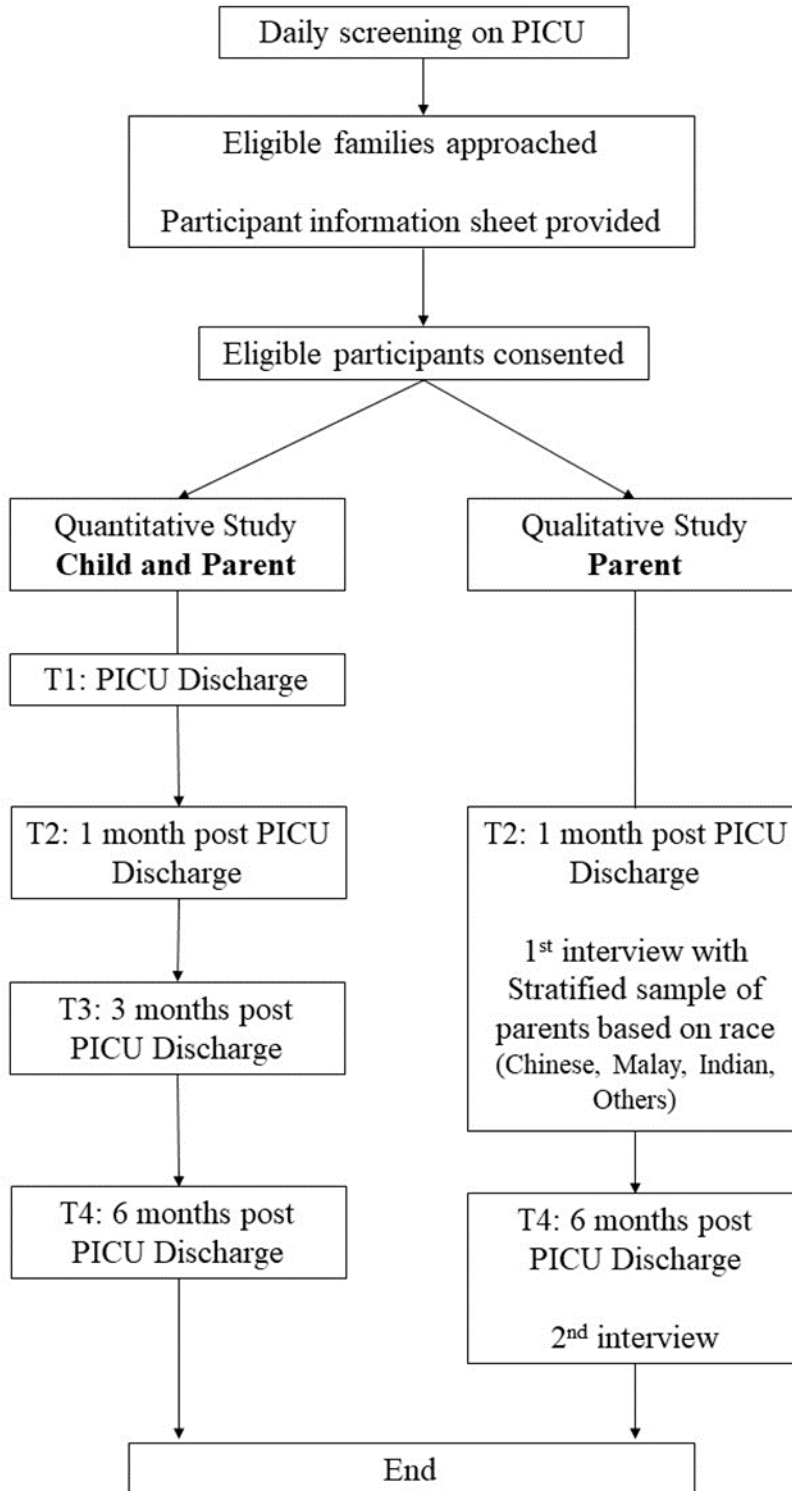


Figure 2. Overview of SHACK workflow in the first six months after paediatric intensive care discharge

Table 1 Data collection measures and time-points for child PICU survivor and parents

Measure	Items/ time required	Age Group	T0: Baseline	T1: PICU Discharge	Post- PICU Discharge		
					T2: 1 month	T3: 3 months	T4: 6 months
Child							
Paediatric Quality of Life Inventory Version 4 (PedsQL™) (Varni, Seid, & Kurtin, 2001)	23 items/7min	1 mo - 18 yrs.	*		*	*	*
Functional Status Scale (FSS) (Pollack et al., 2009)	6 items/5min	1 mo – 18 yrs.	*	*	*	*	*
PedsQL™ Cognitive Functioning Scale (Varni et al., 2011)	6 items/2min	5 yrs. – 19 yrs.	*	*			*
Young child PTSD Screen (YCPS) (Scheeringa, 2019)	6 items/2min	3 yrs. – 6 yrs.				*	*
Child and Adolescent PTSD Screen (CAPS) (Scheeringa, 2012)	6 items/2min	≥6 yrs. – 18 yrs.				*	*
		Total no. of measures	3	2	2	3	4
Parent							
Demographic Factors	14 items/ 5 mins		*				
PedsQL™ Family Impact Module V2 (Varni, Sherman, Burwinkle, Dickinson, & Dixon, 2004)	36 items/ 5 mins			*	*	*	*
Patient Health Questionnaire-4 (PHQ-4) (Kroenke, Spitzer, Williams, & Lowe, 2009)	4 items/ 2 mins			*	*	*	*
PTSD Checklist for DSM-5 (PCL-5) (Sveen, Bondjers, & Willebrand, 2016)	20 items/ 2-4 mins					*	*
Spiritual Coping Scale (SCS) (Baldacchino & Buhagiar, 2003)	20 items/ 5 mins			*			
		Total no. of measures	1	3	2	3	3

Electronic supplement material 1

Data collection and measures

Child-related measures

Paediatric Quality of Life Inventory Version 4.0 (PedsQL™), original English version will be used to measure Quality of Life (HRQOL) in children. The PedsQL instrument consist of 23 items which evaluates 4 domains: physical, emotional, social and school functioning with summary scores available for physical and psychological health. It is scored using a 5-point Likert scale from 0 (never) to 4 (A lot) with possible score of 0 to 100. This tool reports high reliability of $\alpha = 0.88$ (Varni, Seid, & Kurtin, 2001). The parent-proxy version will be used in children who are less than 5 years of age.

PedsQL™ Cognitive Functioning Scale is a validated and reliable tool to measure cognitive functioning in children. The PedsQL™ Cognitive Functional Scale consist of 6 questions scored on a 5-point Likert scale from 0 (never) to 4 (A lot). The total score ranges from 0 to 100, higher scores indicate lower problems. The reliability is high at $\alpha = 0.94$ (Varni et al., 2011).

Functional Status Scale (FSS), is a valid and reliable tool ($\alpha = 0.94$) tool to measure functional status (Pollack et al., 2009). The FSS consist of 6 items which evaluates 6 domains: mental status, sensory, communication, motor function, feeding, and respiratory. The tool uses a 5-point Likert scale from 1 (normally) to 5 (very severe dysfunction) with possible score ranges from 6 to 30, higher score indicates more severe dysfunction. The FSS provides an objective assessment and has been used in other outcomes studies among paediatrics critically ill patients.

Young Child PRSD Screen (YCPS) a reliable tool ($\alpha = 0.73$) will be used to screen for post-traumatic stress symptoms in children aged between 3 and 6 years (Scheeringa, 2019). The YCPS parents consist of 6 items, scored on a 3-point Likert Scale from 0 (No) to 2 (A lot), two symptoms endorsed (either 1 or 2) is considered a positive screen.

Child and Adolescent PTSD Screen (CAPS-P) assess PTSD symptoms that children can have after life-threatening events between children aged between 8 and 17 years. The CAPS-P consists of 6 items scored on a 3-point Likert Scale from 0 (No) to 2 (A lot) two symptoms (either 1 or 2) endorsed is considered a positive screen (Scheeringa, 2012).

Parent-related measures

PedsQL™ Family Impact Module, is a reliable ($\alpha = 0.9$) tool used to measure the impact of paediatric chronic health conditions on their family functioning (Varni, Sherman, Burwinkle, Dickinson, & Dixon, 2004). This instrument is composed of 36 items comprising 8 dimensions measuring the physical, emotional, social and cognitive functioning; communication; worry; daily activities and family relationships. This scale uses a 5-point Likert scale from 0 (never) to 4 (A lot), possible score ranges from 0 to 100 with high scores indicate better functioning.

PTSD Checklist for DSM-5 (PCL-5) assesses the 20 Diagnostic and Statistical Manual of Mental Disorder, Fifth Edition (DSM-5) symptoms of post-traumatic stress disorder with acceptable reliability ($\alpha = 0.56-0.77$) (Sveen, Bondjers, & Willebrand, 2016). The 20 item self-report measure is scored on a rating a 5-point Likert scale from 0 (Not at all) to 4 (Extremely). Symptoms severity score ranges from 0-80. A cut-off score between 31-33 is indicative of probable PTSD.

Patient Health Questionnaire – 4 (PHQ-4). The 4-item patient health questionnaire assess for anxiety and depression. Possible score ranges from 0 – 12, scored on a 4-point Likert scale from 0 (Not at all) to 3 (nearly everyday). A total score of ≥ 3 for the first or last 2 questions suggests anxiety or depression respectively. The reliability is acceptable at 0.75 (Kroenke, Spitzer, Williams, & Lowe, 2009).

Spiritual Coping Strategies (SCS) scale. The 20-item instrument contains two subscales: Religious coping strategies and Spiritual coping strategies. Respondents rates each item on a 4-points Likert scale ranging from 0 (never used) to 3 (often used), possible scores ranges from 0 to 60, with higher score indicating greater use of spiritual and religious coping strategies. The reported reliability is acceptable for religious coping ($\alpha = 0.82$) and the spiritual coping ($\alpha = 0.74$) (Baldacchino & Buhagiar, 2003).