PEADIATRIC INDEX OF MORTALITY 2 (PIM 2) SCORE AS PREDICTOR OF MORTALITY IN PICU

Dissertation submitted to

THE TAMIL NADU DR.M.G.R. MEDICAL UNIVERSITY

In partial fulfillment of the regulations
for the award of degree of

M.D DEGREE (PEDIATRICS) BRANCH VII

INSTITUTE OF CHILD HEALTH AND
HOSPITAL FOR CHILDREN
MADRAS MEDICAL COLLEGE

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CERTIFICATE

This is to certify that the dissertation titled **"PEDIATRIC INDEX OF MORTALITY – 2 (PIM-2) SCORE AS PREDICTOR OF MORTALITY IN PICU"** submitted by ***Dr.G.Jeyanthi*** to the Faculty of pediatrics, The Tamilnadu Dr. M.G.R. Medical university, Chennai in partial fulfillment of the requirement for the award of M.D. Degree (Paediatrics) is a bonafide research work carried out by her under our direct supervision and guidance.

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DECLARATION

I. **DR.G.JEYANTHI** solemnly declare that the dissertation titled **"PEDIATRIC INDEX OF MORTALITY – 2 (PIM-2) SCORE AS PREDICTOR OF MORTALITY IN PICU"** has been prepared by me. This is submitted to **The Tamilnadu Dr. M.G.R. Medical University**, Chennai in partial fulfillment of the rules and regulations for the M.D. Degree Examination in Paediatrics.

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CERTIFICATE OF APPROVAL

To

Dr. G. Jeyanthi
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Dear Dr. G. Jeyanthi

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the proposal entitled "Conducting a study on paediatric index of mortality – 2 (PIM-2) score as predictor of mortality at PICU" No. 28022011.

The following members of Ethics Committee were present in the meeting held on 17.02.2011 conducted at Madras Medical College, Chennai -3.

1. Prof. S.K. Rajan, MD	– Chairperson
2. Prof. A. Sundaram, MD Dean i/c , Madras Medical College, Chennai -3	– Member Secretary
3. Prof R. Sathianathan Director , Institute of Psychiatry, MMC,Ch-3	– Member
4. Prof R. Nandhini, MD Director, Institute of Pharmacology, MMC, Ch-3	– Member
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7. Prof. Geetha Subramanian, MD,DM Prof. & Head , Dept. of Cardiology, MMC, Ch-3	– Member
8. Thiru. A. Ulaganathan Administrative Officer, MMC, Chennai -3	– Layperson
9. Thiru. S. Govindasamy . BA.BL	– Lawyer
10. Tmt. Arnold Soulina	– Social Scientist

We approve the proposal to be conducted in its presented form.

Sd /. Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report

Member Secretary, Ethics Committee

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CONTENTS

INTRODUCTION

INTRODUCTION

Many illness severity scoring systems are being used for predicting the outcome of patients admitted to intensive care units (ICU) (1). Although it is difficult to predict individual outcome of ICU patients accurately, there have been attempts to codify and validate models which may prognosticate groups of patients having similar presentations of the illness (2). Scoring systems are primarily being used to predict the general prognosis of patients but are also used as performance indicators of ICUs (3).

Pediatric Index of Mortality (PIM) was introduced by Shann *et a*l in 1997 to predict outcome in children admitted to ICUs (4). This system was revised (PIM-2) and published in the year 2003 and is supposedly better than the earlier version in outcome- predictability(5)

Scoring systems and their need:

There is an increase in emphasis on the evaluation and monitoring of various aspects of health care services. Scoring systems aim at providing an objective and measurable value for any such service. The goal is to provide the highest quality of care with

available resources to achieve best outcome. All scoring systems are designed to quantify and reduce a number of discrete but interrelated patient characteristics to a single value. This value can be used to compare and analyze disease severity, therapies used or final outcome. The scoring system forms the backbone of any hospital audit.

Scoring systems in critical care:

Like in other areas of health care, intensive care also needs audit and evaluation of clinical effectiveness. Although various modalities of treatment are available, no strict guidelines exist for the likelihood of successful therapy. The clinical effectiveness of any therapy requires research to measure outcome. Outcome audit can be done by measurement of mortality, morbidity, disability, functional health status and quality of life. In general health care, death is infrequent and hence an insensitive measure of outcome. However, in intensive care areas, deaths do offer a sensitive and appropriate measure. Thus, mortality prediction by the scoring system, becomes a tool for evaluation of quality of care.

Scoring systems aim at an equation to estimate probability of outcome. Each system has a group of independent variables (case mix)

and the dependent variable (death) in the form of mathematical equation. The equation is applied to the current intensive care unit statistics and a death rate is derived. Then the predicted death rate by scoring system is compared with actual death rate.

Scoring systems : Historical aspects and Examples:

Perhaps first known scoring system developed was in the care of the newborn - the APGAR score(6), in 1953. The Glasgow coma scale (7) , which was introduced in 1974 by Teasdale and Jenette for evaluating severity of the neurological insult, is another important scoring system that was widely used. The Acute Physiology And Chronic Health Evaluation (APACHE) scoring system was designed in 1981 by Kaus et al, later revised as APACHE II(8) . PRISM score was developed and published in 1988 (9), later it was updated as PRISM III, in the year 1996 (10).Pediatric Index of Mortality (PIM) was introduced by Shann et al in 1997 (4), later updated as PIM2 score in 2003 (5) .

Types of Scoring system in PICU: (11)

Various scoring systems are currently used in the Pediatric Intensive Care Unit (PICU)

These include

1. Organ specific systems. Example: Glasgow coma scale
2. Mechanism of injury systems. Example: Pediatric trauma score, Injury severity score
3. Pediatric systems. Example: PIM score, PRISM score.

Applications of scoring systems:

Scoring systems provide a measurable, objective value for the outcome variable being studied. In the intensive care setting, most scores measure probability of mortality. This data is used for purposes of clinical research, performance assessment and resource allocation.

- Clinical research: The scores are used as an objective measure to demonstrate equivalence of study and control patients in various therapeutic trials. Data from scoring systems are used for inclusion criteria to enroll patients within a specified

severity or risk range. The data also enable risk stratification for outcome comparisons.

- Performance assessment: Data from the scoring systems allows the use of treatment resources within a given setup. Comparisons between hospitals with similar patient populations as well as outcome of a single intensive care unit over time, can be performed with the help of these data.
- Resource allocation: Data generated from various scoring systems can help in optimal allocation of resources based on the severity of illness and the therapeutic needs.

Use of scoring systems in the pediatric ICU:

Pediatric intensive care is a rapidly evolving area in pediatric medicine. A more complete understanding of the patho physiological processes in critically ill infants and children has led to statistical refinements in intensive care units. It is important to develop methods for evaluation of this area of care. As PICUs are multidisciplinary in nature, not confined to one area (example: trauma) but to critical care in general, scoring systems are important and necessary. These scoring

systems must be applicable to patients with a wide variety of disease states.

Pediatric Index of Mortality Score (4)

The PIM uses a logistic regression model to predict population mortality risk. Three prospective cohort studies, from 1988 to 1995, were used to determine the variables for the final model. A fourth cohort study, from 1994 to 1996, collected information from consecutive admissions to all seven dedicated pediatric intensive care units in Australia and one in Britain. PIM score was developed on data from four of the units and tested on data from the other four units. The model fitted the test data well (deciles of risk goodness-of-fit test p=0.40) and discriminated well between death and survival (area under the receiver operating characteristic plot 0.90). The final PIM model used the data from all 5695 children and also fitted well (p=0.37) and discriminated well. The variables of PIM score were given in Table 1.

Table 1 : PIM Score

Sl. No.	Variables	Value (1 if yes, 0 if no)	Beta
1	Elective admission.		
2	Underlying condition		
3	Response of pupils to bright light(>3 mm and both fixed)		
4	Mechanical ventilation (at any time during first hour in ICU)		
5	Systolic blood pressure (mmhg)		
6	Base excess (mmol/L) (arterial or capillary blood)		
7	FiO2(%)/ PaO2 (mmHg)		

Predicted death rate is calculated from PIM logit which is derived from the equation.

Logit = (-4.873) + (values * Beta) + (0.021 * (absolute (SBP-120))) + (0.071 * (absolute base excess)) + (0.415 * (FiO2/PaO2))

Predicted death rate = $e^{Logit}/ (1+e^{Logit})$

Development of PIM 2 score : (5,11)

Slater A, Shann F, Pearson G revised PIM score to adjust for improvement in the outcome of pediatric intensive care. It has been calibrated to a cohort of >20,000 children in 14 ICUs in Australia, New Zealand and Great Britain.

The final PIM2 model, derived from the entire sample of 19638 survivors and 1104 children who died, also fitted and discriminated well [chi-square 11.56, p=0.17; area 0.90 (0.89-0.91)]. PIM2 is calculated from the information collected at the time a child is admitted to ICU. Because PIM2 describes how ill the child was at the time of starting intensive care, the observations to be recorded are those made at or about the time of first face-to-face (not telephone) contact between the patient and a doctor from intensive care unit. Use the first value of each variable measured within the period from the time of first contact to 1 hour after arrival to ICU. The first contact may be in ICU, emergency department, or ward of a hospital. If information is missing (e.g. Base Excess is not measured), it is recorded as zero, except for systolic blood pressure, which should be recorded as 120. All the children admitted to ICU (consecutive admissions) are included. Its ease of use has made it a relatively

popular tool for assessment of ICU performance and research population comparisons.

New variables added to PIM2 score was, recovery post procedure, cardiac bypass and instead of underlying condition in PIM score, high risk and low risk diagnosis were added to PIM 2 score. The variables of PIM2 score were given in Table 2.

Table 2 : PIM 2 Score

Sl. No	Variables	Value (1 If Yes, 0 If No)	Beta
1	Elective admission.		
2	Recovery post procedure		
3	Cardiac bypass		
4	High risk diagnosis		
5	Low risk diagnosis		
6	No Response of pupils to bright light(>3 mm and both fixed)		
7	Mechanical ventilation (at any time during first hour in ICU)		
8	Systolic blood pressure (mm hg)		
9	Base excess (mmol/L) (arterial or capillary blood)		
10	FiO2 (%) / PaO2 (mmHg)		

Predicted death rate is calculated from PIM 2 logit which is derived from the equation

Logit = (-4.8841) + (values * Beta) + (0.01395 * (absolute (SBP-120))) + (0.1040 * (absolute base excess)) + (0.2888 * (100*FiO2/PaO2))

Predicted death rate = e^{Logit}/ (1+ e^{Logit}).

The following instructions were adopted while performing PIM 2 score:

1. Systolic blood pressure, mmHg (unknown=120)[1]
2. Pupillary reactions to bright light (>3 mm and both fixed=1, other or unknown=0)[2]
3. PaO2, mmHg (unknown=0), FIO2 at the time of PaO2 if oxygen via ETT or head box (unknown=0)
4. Base Excess in arterial or capillary blood, mmol/l (unknown=0)
5. Mechanical ventilation at any time during the first hour in ICU (no=0, yes=1)[3]
6. Elective admission to ICU (no=0, yes=1)[4]
7. Recovery from surgery or a procedure is the main reason for ICU admission (no=0,yes=1)[5]

8. Admitted following cardiac bypass (no=0, yes=1)[6]
9. **High risk diagnosis**. Record the number in brackets. If in doubt record 0.

   [0] None

   [1] Cardiac arrest preceding ICU admission [7]

   [2] Severe combined immune deficiency

   [3] Leukaemia or lymphoma after first induction

   [4] Spontaneous cerebral haemorrhage [8]

   [5] Cardiomyopathy or myocarditis

   [6] Hypoplastic left heart syndrome [9]

   [7] HIV infection

   [8] Liver failure is the main reason for ICU admission [10]

   [9] Neuro-degenerative disorder [11]

10. **Low risk diagnosis**. Record the number in brackets. If in doubt record 0.

    [0] None

    [1] Asthma is the main reason for ICU admission

    [2] Bronchiolitis is the main reason for ICU admission [12]

[3] Croup is the main reason for ICU admission

[4] Obstructive sleep apnoea is the main reason for ICU admission [13]

[5] Diabetic keto-acidosis is the main reason for ICU admission

Coding rules. These rules were followed carefully for PIM2 to perform reliably :

1. Record SBP as 0 if the patient is in cardiac arrest, record 30 if the patient is shocked and the blood pressure is so low that it cannot be measured.
2. Pupillary reactions to bright light are used as an index of brain function. Do not record an abnormal finding if this is due to drugs, toxins or local eye injury.
3. Mechanical ventilation includes mask or nasal CPAP or BiPAP or negative pressure ventilation.
4. Elective admission. Include admission after elective surgery or admission for an elective procedure (e.g. insertion of a central line), or elective monitoring. An ICU admission or an operation is considered elective if it could be post poned for more than 6 hours without adverse effect.

5. Recovery from surgery or procedure includes a radiology procedure or cardiac catheter. Do not include patients admitted from the operating theatre where recovery from surgery is not the main reason for ICU admission (e.g. a patient with a head injury who is admitted from theatre after insertion of an ICP monitor; in this patient the main reason for ICU admission is the head injury).
6. Cardiac bypass. These patients must also be coded as recovery from surgery.
7. Cardiac arrest preceding ICU admission includes both in-hospital and out-of-hospital arrests. Requires either documented absent pulse or the requirement for external cardiac compression. Do not include past history of cardiac arrest.
8. Cerebral hemorrhage must be spontaneous (e.g. from aneurysm or AV malformation). Do not include traumatic cerebral hemorrhage or intracranial hemorrhage that is not intra cerebral (e.g. subdural hemorrhage).
9. Hypo plastic left heart syndrome. Any age, but include only cases where a Norwood procedure or equivalent is or was required in the neonatal period to sustain life.

10. Liver failure acute or chronic must be the main reason for ICU admission. Include patients admitted for recovery following liver transplantation for acute or chronic liver failure.
11. Neuro-degenerative disorder. Requires a history of progressive loss of milestones or a diagnosis where this will inevitably occur.
12. Bronchiolitis. Include children who present either with respiratory distress or central apnoea where the clinical diagnosis is bronchiolitis.
13. Obstructive sleep apnoea. Include patients admitted following adenoidectomy and/or tonsillectomy in whom obstructive sleep apnoea is the main reason for ICU admission (and code as recovery from surgery).

For example, PIM 2 score was calculated as follows:

Elective admission (if no=value 0), Recovery post procedure (if no=value 0),Cardiac bypass (if no= value 0), High risk diagnosis (if no= value 0),Low risk diagnosis(if no= value 0), No response of pupils to bright light(if no= value 0), Mechanical ventilation (if yes=value 1), systolic Bp 120, Base excess=8.5, FiO2*100/ PaO2 (mmHg)=35.08. Above values were computed in logit formula as follows

Logit = (-4.8841) + (values * Beta) + (0.01395 * (absolute(SBP-120))) + (0.1040 * (absolute base excess)) + (0.2888 * (100*FiO2/PaO2))

Predicted death rate = $e^{Logit}/ (1+e^{Logit})$=99.9%

Limitations of scoring systems:

Every score has an average miscalculation rate of 10-15%. The following are the important limitations in the area of prognostic scoring systems.

Certain limitations have been identified in the use of scoring systems.

1. Limitation of application: Detailed instructions as to how to apply the system are not mentioned often. For instance, inclusion criteria, time period of data collection and different outcome variables are not provided.
2. Limitation of data collection in scoring: The original database for development varies in validity, reliability and completeness. The details of this are rarely reported. Generally, missing data are reported as normal. The confounding effect of this on scoring is not made clear.
3. Limitation of accuracy of scoring system: Due to insufficient adjustment of case mix in the original database, the scoring may not be valid in all racial and hospital settings.
4. Limitation in interpretation of results: Scoring systems like TISS (Therapeutic intervention scoring system) was based on the therapy used. The therapy employed may not be available in all PICUs. The treatment practices may vary from one ICU to another. Further, the appropriateness of

therapy chosen is not verified. The probability data from scoring systems have to be evaluated with the understanding of these shortcomings.

5. Though death is the most convenient variable, merely using mortality prediction scores ignores quality of life or morbidity issues. Also, it disregards group of physiologically stable patients who need intensive observation not possible without an ICU setting. Though these patients may have a low score based on the predictive models, their need for ICU care can not be disregarded.
6. None of the scoring systems can be used to predict individual patient outcome. Resource utilization is an important aim of scoring systems.
7. Patients, who are moribund with a very high probability of death, survive for only few hours in the ICU. These patients derive little benefit from ICU. However hospitals by protocol admit these patients at ICU. Their high mortality prediction score is little valuable.
8. Scores based on the therapeutic interventions have the fallacy of the physicians' perception of illness. There is no

way to ensure a uniform system of therapeutic intervention in all PICUs.

9. Current scoring systems do not account for the changes in the status of a patient in the ICU for prolonged duration. It is unlikely that a score computed at admission will predict the outcome of a long term patient.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

A number of studies have been done using PIM2 score. These primarily look at three aspects:

1. Validation of usefulness of PIM 2 score
2. Comparisons of PIM2 score with other scoring systems
3. New ways of using PIM2 score

1. Validation of usefulness of PIM2 score

PIM2 score was formulated in developed countries. It is essential to validate it in developing country. Hariharan *et al* evaluated performance of a PICU in a developing country by using PIM2 score and found performance of the pediatric ICU in Barbados is comparable to that of developed world by risk adjusted outcome evaluation.(12).

Daniel K Ng *et al*. compared probabilities of death predicted by PIM2 and PIM1 models against actual mortalities in 3 PICUs in Hong Kong and found both PIM1 and PIM2 had similar accuracy (13). Andrea Wolfler *et al* assessed the performance of the PIM2 score in Italian PICU and showed PIM2 provides a valid mortality index for

multicenter national studies and help improve child health care policies through out the country.(14).

Adriana M. Lopez *et al* used PIM2 score in assessing the variation in Pediatric intensive care therapies and outcome by Race, Gender, and Insurance status, by using PIM 2 score. (15)

PIM2 score has also been evaluated for specific disease states. Czaja et al assessed the performance of PIM2 score in pediatric cardiac surgery patients admitted at PICU and concluded that, PIM2 score had poor performance with fair discrimination in those patients, although larger studies are needed to confirm it.(16)

Kim JS *et al* evaluated validity of PIM2 score in Korea and stated PIM2 showed a good performance (17) Eulmesekian PG *et al* validated PIM 2 score in a single PICU at Argentina and concluded PIM2 score showed an adequate discrimination between death and survival.(18)

2. Comparison of PIM2 score with other scoring systems

PritoEspunes S *et al* assessed the validity of the PRISM, PIM, PIM2 in two spanish PICUs and concluded that both PIM and PIM2 showed better discrimination and calibration than PRISM.(19)

Roshani *et al* compared the performance of PIM and PRISM in a Indian PICU and concluded both PIM and PRISM scores discriminated well between survivors and moribund patients.(20)

Paediatric Risk of Mortality (PRISM) requires an observation period of 24 hours, and PRISM III measures severity at two time points (at 12 hours and 24 hours) after admission, which represents a limitation for clinical trials that require earlier inclusion. The Paediatric Index of Mortality (PIM) is calculated 1 hour after admission but does not take into account the stabilization period following admission. To avoid these limitations, Stephane Leteurtre et al chose to conduct assessments of PRISM , PRISM III, PIM at 4 hours after PICU admission. They validated these scores at the time points for which they were developed, and to compare their accuracy in predicting mortality at those times with their accuracy at 4 hours. They found the discrimination of the PIM, PRISM and PRISM III scores was good whereas calibration was poor for the time points for which the scores were developed. At 4 hours, only the PIM score had good discrimination and calibration.(21)

Thukral *et al* assessed the performance of PRISM , PRISM III, PIM2 in PICU of AIIMS and concluded all the 3 models underpredicted mortality. They explained differences in patient profile

and greater load of severity of illness being managed with lesser resources, to be the reason for underprediction.(22)

Slater A *et al* analysed PIM,PIM2,PRISM and PRISM III for monitoring quality of PICU and concluded PIM2 was the most accurate and had the best fit in different diagnostic and risk groups; therefore, it is the most suitable mortality prediction model to use for monitoring the quality of pediatric intensive care(23)

Ahmad Usaid Qureshi AU *et al* compared PRISM ,PELOD PIM 2 and concluded that PRISM as well as PIM 2 is validated for PICU setting in Pakistani circumstances. PELOD performed poorly. PIM 2 has advantages over PRISM for stratification of patients in clinical trials.(24)

Grinkeviciute DE *et al* compared PIM 2 score, Pediatric Trauma Score (PTS), and Glasgow Coma Scale (GCS) score for mortality in children after severe head injury and found PIM 2 score provided the best discrimination between survivors and nonsurvivors.(25)

F Shann *et al* original developers of PIM score suggested that the Scores which use the worst value of their predictor variables in the first 12–24 hours should not be used to compare different units patients mismanaged in a bad unit will have higher scores than similar

patients managed in a good unit, and the bad unit‘s high mortality rate will be incorrectly attributed to its having sicker patients. PIM is a simple model. It is accurate enough to be used to describe the risk of mortality in groups of children. (4)

The treatment given just before admission to intensive care is likely to affect admission score such as PIM2. For example, in a patient with shock, appropriate administration of fluid and sympathomimmetics in the emergency department may increase blood pressure and restore the base excess to normal,(Both blood pressure and base excess are variables of PIM 2 score), which will affect the PIM 2 score. However, if this treatment improves the patient‘s prognosis at the time of admission to intensive care, it is appropriate that it alters the PIM2 score. This is confirmed by Shann et al in their study stating that the time spent in hospital before admission to intensive care was not statistically significant when added to the PIM model(4)

The significant proportion of paediatric mortality occurs soon after ICU admission(26), thus a score such as PIM that allows early identification of high risk patients has greater usefulness.Indeed this

has been a criticism levelled at PRISM II, in that It may diagnose rather than predict death.(4)

Chunxiao Wang *et al* tested the applicability of PRISM,PIM, PIM2 scores to term Chinese neonates admitted at NICU and stated that although PRISM,PIM,PIM2 have displayed good discrimination and calibration in the present setting, PIM is considered as the most accurate and appropriate tool for predicting mortality in the studied NICU.(27)

3. **New ways of using PIM2 score:**

One of the limitations of the PIM 2 score is its dependency on arterial blood gas analysis, which is unavailable at peripheral centers. To overcome this, Leteurtre *et al*, assessed PIM2 score with Spo_2/Fio_2 ratios instead of Pao_2/Fio_2 and they suggested that the Spo_2/Fio_2 ratio could be used in place of $Pao_2/Fio_2$for calculating Pediatric Index of Mortality 2, however to be confirmed by larger studies.(28)

JUSTIFICATION FOR THE STUDY

JUSTIFICATION FOR THE STUDY

Following rapid advances in medical therapy and critical care technology in recent years, coupled with the spiraling cost of medical care, outcome analysis including mortality risk prediction is important for the physicians.

Institute of child health and hospital for children is a tertiary care center in the government sector which is the principal referral unit, providing treatment free of cost not only for the children from the state of Tamilnadu but also from the neighboring states like Andhra Pradesh. Being the most important referral center for South India and one of the largest pediatric hospitals in South Asia, this hospital becomes the end referral center. Significant number of patients were referred to this hospital from other tertiary care centers, in terminally ill , moribund condition and hence mortality of PICU was high. During 2010, there were about 37787 patients admitted to Institute of child health and hospital for children, with a total death of 1984 deaths (5.25%).The total number of patients admitted to Pediatric intensive care unit(PICU) were 984 with a mortality of 398 (40.4%) in the same year indicating that PICU has nearly 8 times more mortality than overall mortality of ICH. The admission and mortality

rate for the whole hospital and PICU for the last three consecutive years are given in Table 3. So mortality risk prediction will be a useful tool for the intensivists for counseling of parents as well as resource allocation.

Table 3 : Mortality pattern in Institute of Child Health

Year	Hospital		PICU	
	Total no. of patients admitted	**Mortality N (%)**	**Total no. of patients admitted**	**Mortality N (%)**
2008	37117	1968 (5.3)	963	386 (40.1)
2009	37152	1828 (4.9)	847	348 (41.1)
2010	37787	1984 (5.25)	984	398 (40.4)

AIM OF THE STUDY

AIM OF THE STUDY

PRIMARY:

To evaluate the usefulness of PIM 2 score in predicting mortality in PICU in a tertiary care pediatric hospital.

SECONDARY:

To assess the associated factors predicting mortality such as need for assisted ventilation, presence of shock and poor Glasgow coma scale.

SUBJECTS AND METHODS

SUBJECTS AND METHODS

STUDY DESIGN:

This is a prospective descriptive study to evaluate the usefulness of a diagnostic scoring system namely, PIM 2 score.

STUDY PLACE :

Department of Pediatric intensive care unit (PICU),Institute of Child Health and Hospital for children ,Madras Medical College, Chennai.

SAMPLE SIZE:

Annually,900 – 1000 children are admitted in PICU, Institute of Child Health with a mortality rate of 30-40%.For an expected sensitivity of 85% with allowable error of 5%, 119 patients were studied.

STUDY PERIOD:

Total duration of the study was one year including protocol formation, data collection, data analysis and manuscript preparation.

INCLUSION CRITERIA:

All consecutive patients admitted at PICU, Institute of Child Health aged 1 month upto 12 years.

EXCLUSION CRITERIA:

Neonates were excluded from the study.

Characteristics of the PICU, Institute of Child Health.

The Pediatric ICU of Institute of Child Health and Hospital for children is a 15 bedded unit. Patients aged 1 month to 12 years who require intensive care are admitted, with the exception of patients with burns. The admissions are primarily through Emergency department or from the pediatric general wards. One professor and four Assistant professors look after the unit. There are two fellowship residents in Intensive care posted round the clock at PICU in shift. Four Pediatric post graduate residents are dedicated exclusively to the Pediatric ICU and are posted in shifts round the clock. The PICU has 15 ventilators. Blood gas analysis is available at the bedside.

The following procedures are routinely done in the Pediatric ICU:

A. Mechanical Ventilation
B. Peritoneal dialysis
C. Intercostal drainage.

MANOEUVRE:

PIM2 scoring which involves both clinical and laboratory data was done once at the time of admission to PICU using a pretested proforma. The clinical condition at arrival to PICU was documented and not the condition at arrival to the emergency department. Demographic data, age, gender were recorded. The vital parameters – blood pressure, pupillary reaction to light, Glasgow coma scale were recorded by attending pediatric resident on arrival at PICU. Arterial blood gas analysis was done within one hour of PICU admission and base excess, PaO2 were recorded by pediatric resident. The patient's course of PICU stay, need for ventilation, presence of shock and duration of PICU stay, were recorded. The outcome was recorded as 'discharged' or 'death'.

PIM 2 score was assigned to each case as follows; Data to calculate PIM2 score was obtained within one hour of PICU

admission. Each of the ten variables, to be entered into a logit formula to form the PIM2 score and that score has been converted to a probability of mortality by means of standard methods based on logistic regression analysis. For convenience, PIM 2 score was derived by computing above 10 variables by using a software and further, PIM2 logit score (which was used in all statistical analysis) was calculated. This is freely available at www.sfar.org /scores2 /pim22.html. We report the probability of mortality from the PIM 2 log it score and use this probability in all analysis.

Clinical diagnosis was classified system wise. The group infection was defined as those with no definite focus of infection and who were not classified under any other system. If a child had both clinical and investigative evidence of a definite focus of infection, he/she was classified under that system. The child continued to be in that group irrespective of further complication in the PICU which may have been the immediate cause of death. (For example: A ventilator associated pneumonia in a child with viral encephalitis). For the purpose of analysis, those patients who were discharged against medical advice were included in deaths as has been done in previous studies.

STATISTICAL ANALYSIS

The results were tabulated. The simple percentage, proportions were calculated for age, gender, clinical diagnosis and length of PICU stay. The predicted mortality by PIM 2 (logit) score was compared with observed mortality. A receiver operating characteristic (ROC) was constructed by using statistical package "med calc". The area under curve provides a parameter for the discriminatory performance of model

The associated factors were analyzed by using SPSS version 17. The associated factors like presence of shock, need for ventilation and poor Glasgow coma scale were analyzed to find out the association with mortality. Univariate analysis was done. Odd's Ratio for predictive factors were calculated. The significant p- value was calculated with 95% confidence interval. To adjust for confounding effect of one factor(s) over the other, multivariate (binary logistic regression) analysis was done.

Receiver Operating Characteristic Curve:

During validation of a scoring system, the discrimination and calibration are measured. Discrimination tests the ability of a model to determine patients who live (when death is the outcome variable) from patients who die. The cut off points of probability are plotted to give a receiver operating characteristic (ROC) curve. The greater the true positive rate to the false positive rate, the greater is the area under the ROC curve. The area may range from 0.5 (purely due to chance) to 1.0 (perfect).

The ROC curve is a graphical representation of the discriminative power of a test. Any biological variable, for example hemoglobin has a range of normal values. If one cut off point is chosen to differentiate normal from abnormal, at the extremes of the range, there are bound to be false positives and false negatives. Based on where the cut off is assigned, the test will return either many false positives (specificity poor but sensitivity good) or many false negatives (sensitivity poor but specificity good). Thus we require that optimal cutoff point where the both sensitivity and specificity are optimal.

For any particular test (a laboratory value or scoring system), various cutoff points are plotted as sensitivity (true positives) against true negatives (1- specificity). The resulting curve is the ROC curve. The curve demonstrates the discriminative power (to separate for example recovery from death in a mortality score) at various score points. The test is said to have good performance if the area under the curve nears 1. A 0.5 result is interpreted as worthless as this could be by pure chance and the laboratory test or scoring system has not had a good discriminative power. The following ROC curve (Fig. 1) demonstrates the area under the curve and its interpretation.

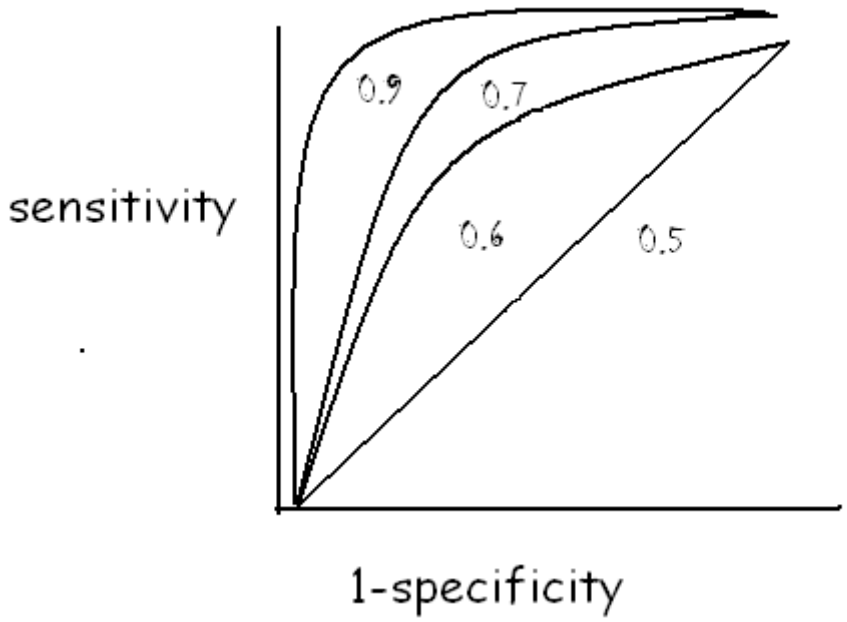

Fig 1 : Receiver Operating Curve And Its Distribution

A rough guide for classifying the accuracy of a diagnostic test is the traditional academic point system:

0.90-1	=	Excellent (A)
0.80- 0.90	=	Good (B)
0.70-0.80	=	Fair (C)
0.60-0.70	=	Poor (D)
0.50-0.60	=	Fail

OBSERVATIONS

OBSERVATIONS

Total number of children admitted at PICU from March2011 to June 2011 were 221. Among them, 119 consecutive children who met with the inclusion and exclusion criteria and whose parents consented for study were analyzed. The results were presented in the following order.

1. **PIM 2 Score**

   a. Distribution of PIM 2 Score
   b. Receiver operating characteristic curve (ROC)
   c. PIM 2 (log it) Score and mortality

2. **Clinical Variables**

   a. Age distribution
   b. Gender distribution
   c. Clinical diagnosis
   d. Duration of stay

3. **Associated Factors**

   a. Presence of shock
   b. Need for ventilator care
   c. Glasgow coma scale of less than 8

4. **Univariate Analysis**

5. **Multivariate Analysis**

1. **PIM 2 Score**

Total number of consecutive patients enrolled was	: 119
The Range of PIM 2 score in this study was	: 0.2 to 38.5
The Range of PIM2 (log it) score was (PIM2 (log it) score was used in all statistical analysis)	: 6.2 to 100
The Mean PIM2 (log it) score was	: 94.26
The Mode of PIM2 (log it)score was	: 100
The Median of PIM2 (log it) score was	: 99.9
The Mean PIM 2 (log it) score for those who were discharged was	: 94.25
The Mean PIM 2 (log it) score for those who died was	: 97.52
The observed death rate was	: 46.21% (N=55)
The predicted death rate was	: 68.00% (N=64)

a. Distribution of PIM 2 (log it) Score

The distribution of the PIM 2 (logit) score with the number of patients is shown in the Fig:2. There was clustering of cases in the region of PIM2 (logit) score 99.9 and100.

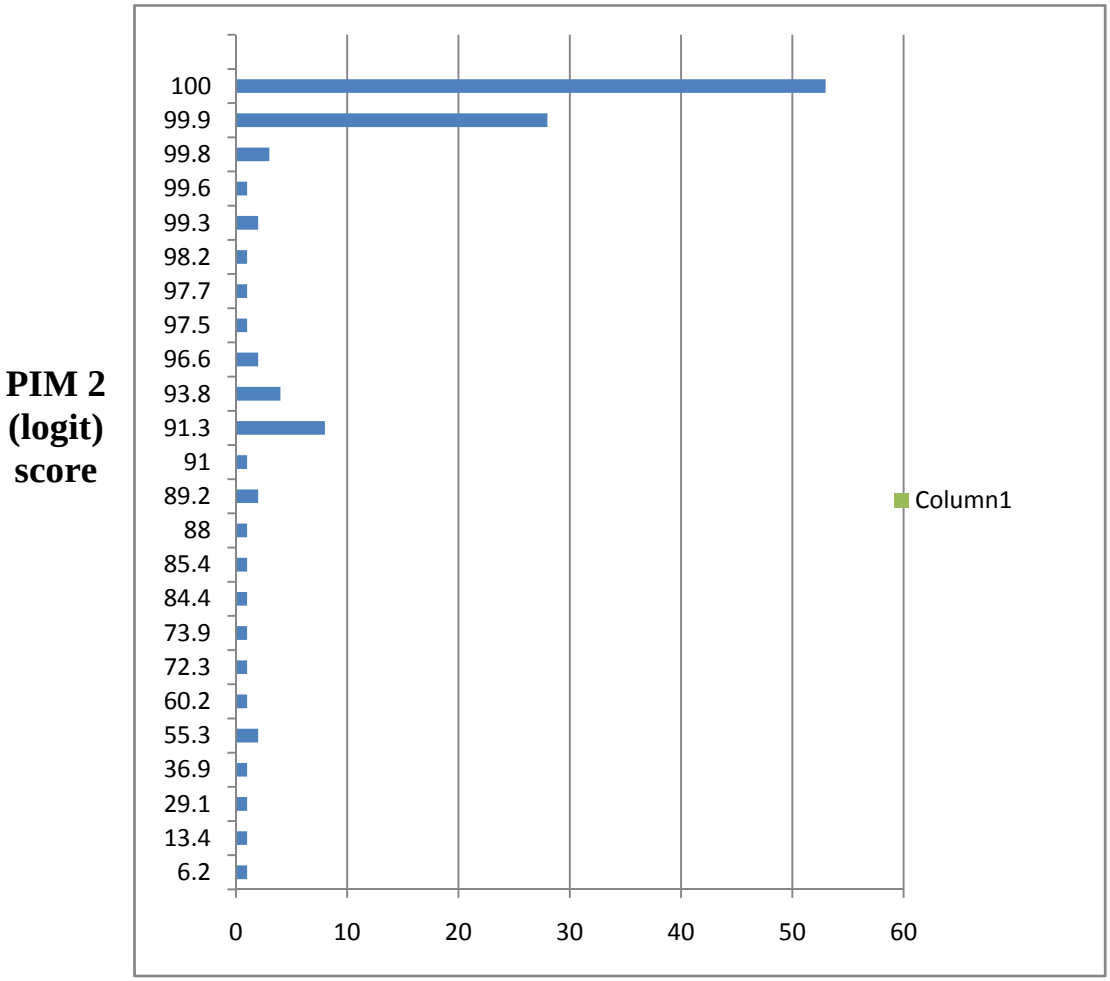

Fig : 2 The Distribution Of PIM 2 (Logit) Score

Mean : 94.26

Median : 99.9

Mode : 100

Mortality risk was found to be increasing with increase in the PIM 2 (logit) score. When the score was less than 90, mortality risk was 7.1% and While the score was between 90 and 99, the risk increased to 50%. When the score was above 99, mortality raised to 51.7%.This is given in Table 4.

Table 4: Ranges of PIM 2 (Logit) Score and Mortality

PIM 2 (logit) Score	Total patients (N)	Mortality N (%)
<90	14	1 (7.1)
90-99	18	9 (50)
>99	87	45 (51.7)

b. Receiver Operating Characteristic Curve

To find out the cut off of PIM 2 (logit) score which would predict the mortality optimally, receiver operating characteristic curve (ROC) was constructed. The best cutoff value at which sensitivity and specificity were optimal was 99.8.

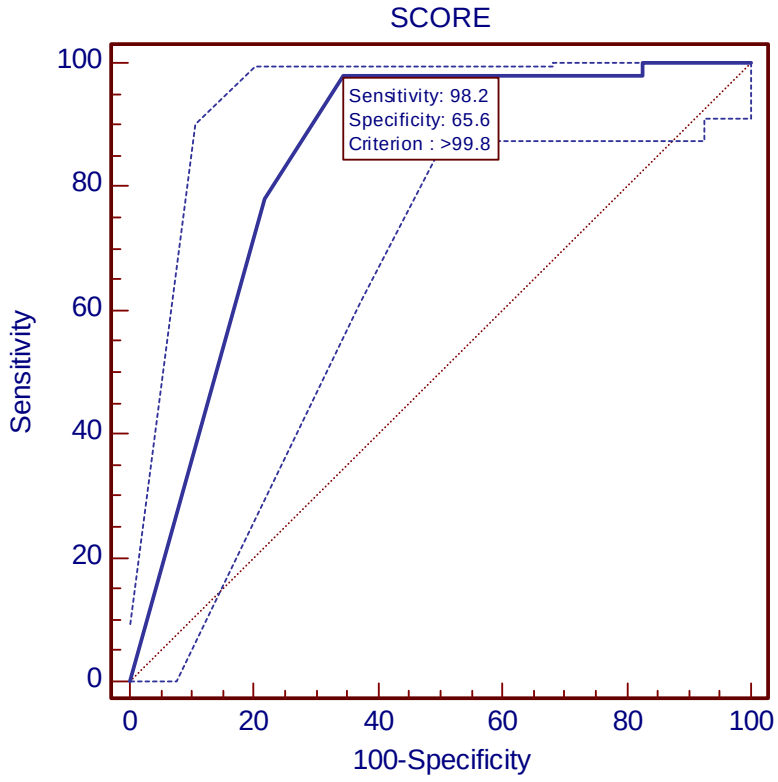

Fig 3 : Receiver operating characteristic curve

From Fig : 3, the area under the ROC curve was 0.843 with the 95% confidence interval being 0.765 to 0.903. The best cutoff of PIM 2 (log it) score was at 99.8 with a sensitivity of 98.2% and specificity of 65.6%

Area Under Curve : 0.843 (95% C.I: 0.765, 0.903)

Sensitivity at criterion 99.8 : 98.18

Specificity at criterion 99.8 : 65.62

Positive predictive value at criterion 99.8 : 71.1

Negative predictive value at criterion 99.8 : 97.7

c. PIM 2 (Logit) Score and Mortality

Based on observation, cut off for PIM 2 (log it) score which predicts mortality with highest possible sensitivity and specificity, from ROC curve was arrived as 99.8. The analysis was done for those who had score less than or equal to 99.8 and those who had more than 99.8. Those who had a score of less than or equal to 99.8, had a mortality risk of 26.3% and those who crossed it had a higher mortality (55.6%) rate. The difference was statistically significant.(p-value 0.003).(Table 5).

Table 5 : PIM 2 (logit) Score and mortality

PIM 2 (Logit) Score	Died N (%)	Discharged N (%)
>99.8	45 (55.6)	36 (44.4)
≤99.8	10 (26.3)	28 (73.7)

Chi-square value: 8.897

P value:0.003

CLINICAL VARIABLES

a. **Age distribution and mortality.**

Patients aged one month to 12 years were the study population. Age distribution and mortality pattern were given in the Fig 4.

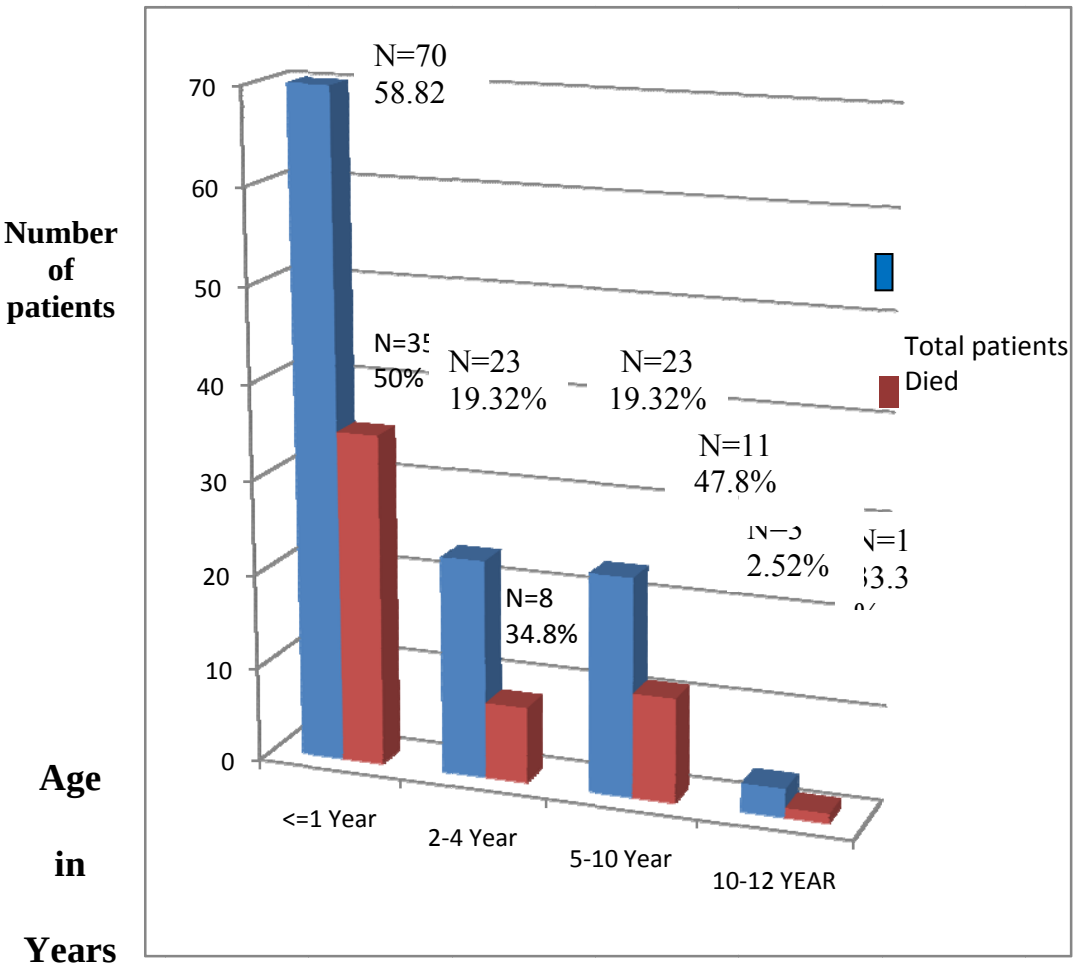

Fig 4 : Age distribution and mortality

From fig 4, we infer more than half of the patients (58.82%) were infants and mortality was also more (50%) among this group.

b. Gender and mortality

The ratio of male to female in this study was 1.1:1.Their mortality was given in Figure 5.

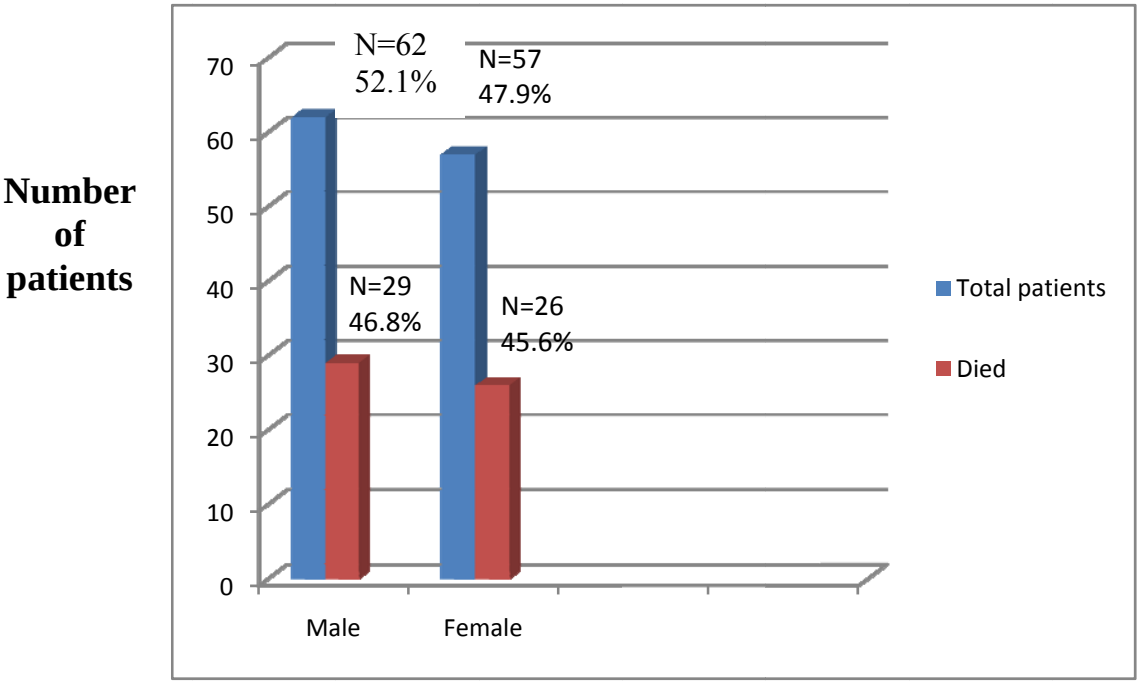

Fig 5 : Gender distribution and mortality

From fig 5, we infer, there was no significant difference in mortality between male and female patients.

Clinical diagnosis

The diagnosis of the children enrolled was classified based on the system involved and the distribution of the diseases, was shown in Fig 6. Neurological diseases were the major cause for admission to the PICU followed by respiratory diseases , infections, cardiovascular diseases, renal diseases, gastrointestinal diseases and postoperative cases.

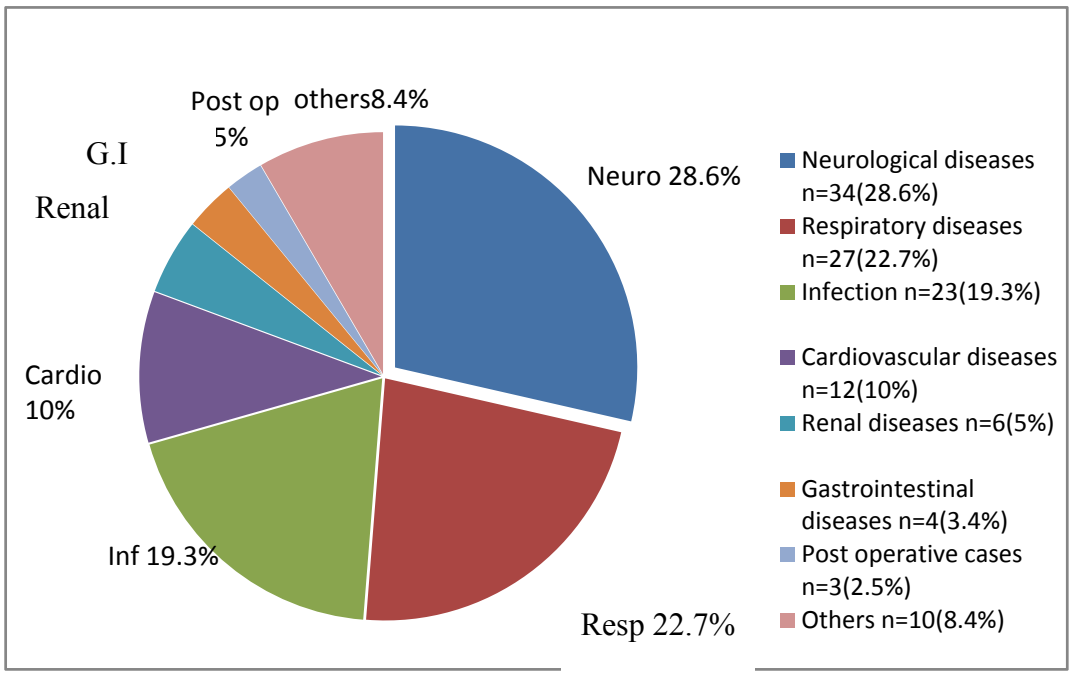

Fig 6 : Clinical Diagnosis

The diagnosis were classified into 8 broad categories and were given in Table 6.The tabular column was arranged as per total number of admissions in each system in descending order. Because of small sample size, children with DKA, Poisoning, scorpion sting, snake bite were included in others list.

Table 6 : Diagnosis and mortality analysis

Diseases	Total	Discharged N (%)	Died N (%)
Neurological diseases	34	14 (41.2)	20 (58.8)
Respiratory diseases	27	20 (74.1)	7 (25.9)
Infection	23	13 (56.5)	10 (43.5)
Cardiovascular diseases	12	3 (25)	9 (75)
Renal diseases	6	3 (50)	3 (50)
Gastrointestinal diseases	4	3 (75)	1 (25)
Post operative cases	3	2 (66.7)	1 (33.3)
Others*	10	6 (60)	4 (40)

*Includes Diabetic keto acidosis, Kerosene poisoning, Neem oil poisoning, snake bite, scorpion sting.

The Table 7 shows the distribution of Neurological diseases, which formed the major clinical diagnosis admitted in PICU.

Table 7 : Neurological diseases and mortality

Diagnosis	No. of Cases N(% of Total Neurological Cases)	Mortality N (% of Mortality In Neurological Diseases)
Neurological diseases	N = 34	N = 20
Seizure disorder/status epilepticus	11 (32.4)	8 (40)
Intracranial bleed	8 (23.5)	6 (30)
Pyogenic meningitis	6 (17.6)	1 (5)
Acute encephalitis	3 (8.8)	1 (5)
TB meningitis	2 (5.9)	1 (5)
Gullaine-Barre syndrome	2 (5.9)	1 (5)
Brain abscess	1 (2.9)	1(5)
Spinal muscular atrophy	1 (2.9)	1 (5)

Respiratory diseases and Infections were major disease categories that were admitted in our PICU. Distribution and mortality pattern is given in the following table 8,9.

Table 8 : Respiratory Diseases and Mortality

Diagnosis	Total No of Cases N (% of Total Respiratory Diseases)	Mortality N (% of Mortality In Respiratory Diseases)
Respiratory diseases	N = 27	N = 7
Bronchopneumonia	18 (66.7)	6 (85.7)
Bronchiolitis	3 (11.1)	
Empyema	3 (11.1)	
Fungal pneumonia	1 (3.7)	1 (14.3)
Pneumothorax	1 (3.7)	
Asthma	1 (3.7)	

Table 9: Infection and Mortality

Infections	Total No. of Cases N (% of Total Infections)	Mortality N (% of Mortality In Infections)
Septicemia	12 (52.2)	3 (30)
Septic shock	7 (30.4)	5 (50)
Viral hemorrhagic fever	2 (8.7)	1 (10)
Cellulitis	1 (4.3)	
Urosepsis	1 (4.3)	1 (10)

Table 10 : Minor Clinical Diagnosis and Mortality

Diagnosis	**No. of Cases. N (% of Total Cardiovascular Diseases)**	**Mortality N (% of Mortality in Cardiovascular Diseases)**
Cardiovascular diseases	12 (10)	9 (16.4)
Acyanotic congenital heart diseases	5 (41.7)	4 (44.4)
Cyanotic congenital heart diseases	4 (33.3)	3 (33.3)
Dilated cardiomyopathy	1 (8.3)	1 (11.1)
Cardiac tamponade	1 (8.3)	1 (11.1)
ALCAPA	1 (8.3)	-
Renal Diseases	**Total no. of cases N (% of total renal cases)**	**Mortality N (% of mortality in renal diseases)**
Chronic renal failure	3 (50)	
Acute renal failure	2 (33.3)	2 (66.7)
Uremic pericarditis	1 (16.7)	1 (33.3)
Gastrointestinal Diseases	**Total no. of cases N (% of total gastrointestinal diseases)**	**Mortality (% of mortality in gastrointestinal diseases)**
Inflammatory bowel disease	1 (25)	1 (100)
Viral hepatitis	1 (25)	
Cholecystitis	1 (25)	
Intussuception	1 (25)	

Table 10 : Minor Clinical Diagnosis and Mortality

Continued…

Post Operative Cases	**Total No. of Cases N (% of Total Post Operative Cases)**	**Mortality N (% of Mortality in Post Operative Cases)**
Appendicular abscess	1 (33.3)	
Cholecystectomy	1 (33.3)	
Thoracoscopy	1 (3.33)	1 (100)
Other Diseases	**Total No. of Cases N (% of Other Diseases)**	**Mortality N (% of Mortality in Other Diseases)**
Diabetic keto acidosis	5 (50)	2 (50)
Kerosene poisoning	2 (20)	2 (50)
Neem oil poisoning	1 (10)	
Snake bite	1 (10)	
Scorpion sting	1 (10)	

Rest of the disease categories like cardiovascular diseases, renal diseases, gastro intestinal diseases, post operative cases and others formed only 35 cases out of 119 (29.41%) which were given in Table10. Mortality is highest for neurological diseases, followed by infection and respiratory diseases.

Duration of stay :

The average duration of stay in the PICU was 3.5 days. The mean hospital stay for those who died was 2.98 and those who were discharged was 3.95 days. This was given in Table 11.

Table 11 : Duration of Stay and Mortality

Outcome	N	Mean	Standard Deviation	Standard Error Mean
Death	55	2.98	3.45	0.465
Discharged	64	3.95	1.56	0.195

P value : 0.045

ASSOCIATED FACTOR ANALYSIS

Common risk factors for poor outcome like age less than 1 year, patients with a Glasgow coma scale score of less than 8, those who presented with shock and those who required mechanical ventilation were analyzed to find out whether there was any statistically significant association with mortality. All variables except age less than 1 year were found to be statistically significant, as shown in the Table 12.

Table 12: Associated Factors- Univariate Analysis

Factors	Discharged N %	Death N %	Odds Ratio	95% C.I	P. Value
Age<1year	35 (49.3)	36 (50.7)	1.569	0.7, 3.5	0.233
>1year	29 (60.4)	19 (39.6)			
Shock present	25 (34.3)	48 (65.8)	10.697	4.2,27.3	0.000
Absent	39 (84.8)	7 (15.2)			
Mechanical ventilation Required	31 (38.3)	50 (61.7)	10.645	3.8,30.2	0.000
Not required	33 (86.8)	5 (13.2)			
Glasgow coma scale<=8	24 (34.8)	45 (65.2)	7.5	3.2,17.6	0.000
>8	40 (80.0)	10 (20.0)			

Presence of shock:

Presence of shock is a common indication for admission to our PICU. There were about 73 (61.3%), of total cases presented with shock. Among them 36 (49.3%) patients were admitted through emergency department and 25(34.2%) patients were admitted from general pediatric ward. Rest of the 12 (16.4%) patients developed shock after getting admitted to PICU. Shock was around 11 times more commonly observed among those who died when compared to those without shock . OR (95% C.I)= 10.697(4.2,27.3).65.8% of those who had shock died when compared to 15.2% who did not have it.

Need for ventilation

As requirement of assisted ventilation is a risk factor for poor outcome, it was analyzed statistically. (table 12).Those who had died were about 11 times most likely to be ventilated when compared to those who recovered. OR (95% C.I)=10.645 (3.8,30.2).Among 81 ventilated . Among 81 ventilated patients,54 patients from Emergency department, 7 patients from general pediatric ward and 3 post operative patients were intubated and started on bag and tube ventilation even before they were transferred to the PICU. Rest of the 17 patients were intubated and put on assisted ventilation in the PICU.

64 patients were on mechanical ventilation within one hour of PICU admission.

Presence of Glasgow coma scale<8 and mortality

Glasgow coma scale is one of the important tools in assessing general condition of the patients. In this study, 71 (59.7%) patients had Glasgow coma scale less than 8 and 65.2% of those who had GCS <8 died compared to 20% who did not have it. Glasgow coma scale less than 8 was around 8 times more commonly observed among those who died when compared to those without GCS<8.OR (95% C.I)=7.5 (3.2, 17.6).

MULTIVARIATE ANALYSIS

The risk factors that were deemed to significantly contribute to mortality like Glasgow coma scale less than 8, and need for assisted ventilation, shock were further analyzed using binary logistic regression model. Glasgow coma scale less than 8 failed to show significant association in multivariate analysis but the other two namely, need for assisted ventilation, shock were independently associated with mortality.(Table13).

Table 13: Multivariate analysis and mortality

Variables	Adjusted Odd's ratio	95% C.I	P value
Shock	7.020	2.6,18.95	0.000
Ventilation	6.429	2.1,19.59	0.001

DISCUSSION

DISCUSSION

The use of scoring systems and the audit of intensive care has not been widely reported in India. There have been few studies addressing the needs of pediatric critical care. Most scoring systems were designed in the west and need to be validated in our country**. In our study, the discrimination of PIM 2 score between death and survival was good at cutoff 99.8, reflected by area under Receiver operating characteristic curve(ROC) which was 0.843 (95% C.I: 0.765, 0.903)**.

Hariharan S, *et al* showed that PIM2 score had good discrimination, with area under ROC being 0.82 (95% C.I: 0.72-0.92) in a PICU of a developing country (12). Clearly PIM2 score performed well in our study and it is comparable to the original developer of PIM2 score, Slater A, who showed, PIM2 discriminated between death and survival well, with area under the receiver operating characteristic (ROC) plot 0.90 (0.89-0.92).(5)

Since the sensitivity of PIM 2 score, at significant PIM2 (log it) score criterion >99.8 was 98.18%, it can be used as a screening tool for assessing severity of illness of PICU admissions.

Since the PIM2 (logit) score has high negative predictive value (97.7%) at cut off of PIM2 (logit) score of 99.8, there were more chances for the child to survive, if he/she scores less than 99.8.This helps to identify children who have more chances of survival which helps in counseling parents and get their co-operation.

The low specificity (65.6%) of PIM2 (logit) score denotes not all patients with high score are going for mortality. This reflects effective interventions at PICU, reduces mortality of those who had high score at the time of admission and thereby indicating good performance of PICU.

In this study, infants (N=70; 58.8%) had more mortality rate compared to non infant group (N=49:41.2%), similar to previous studies (20). But the difference in mortality between infant and non infant group was not statistically significant. (p value 0.233)

In this study, neurological diseases contributed to more (36.4%) mortality, followed by infections (18.1%) and Respiratory diseases (12.7%).This is similar to previous study. (12)

The analysis of associated risk factors like presence of shock, need for mechanical ventilation, Glasgow coma scale less than 8, was

done to find out whether they have any statistically significant association with mortality.

They were analyzed by univariate analysis ,followed by multivariate analysis. By univariate analysis, all the three associated factors showed statistical significance (p value <0.05) in association with mortality. But multivariate analysis showed need for ventilation, presence of shock were independently associated with mortality.

This Institution being the apex premier institute in Tamilnadu, this is the end referral center. Many children were referred from other government tertiary care centers and non governmental tertiary institutions. The most common reason for referral being, need for mechanical ventilation, which the low and middle income strata can not afford at private paying institutions. Many children treated elsewhere for prolonged periods without assisted ventilation, were eventually referred to this institution in a moribund condition. This fact explains following results of this study namely,

1. Higher death rate (46.2%) in contrast to other study whose mortality rate was 5.5%.(12)

2. Lesser length of hospital stay was associated with high mortality, in contrast to previous study (29).

   (Mean hospital stay lesser (2.98 days) for mortality group compared to those who were discharged (3.95 days))

3. Increased rate of mechanical ventilation. (N=81;68.06%) in contrast to previous study whose mechanical ventilation rate was 23.5% (18)

In contrast to other scores used in PICU which are done at 12 and 24 hours of PICU admission, PIM 2 score is done within one hour of PICU admission, therefore early identification of severity of illness, thereby stratification of children can be done early. This will be useful in clinical trials. (24)

As the mean PIM 2 (log it) score is lower in those who were discharged (94.25) , than those who died (97.52), its estimation does throw light on severity of disease process. When the PIM 2 (logit) score was less than 90, mortality was 7.1%.Increase in score was associated with increase in mortality. As the score increased above 99, mortality risk also increased to 51.7%. Thus increase in score indirectly indicates increase in severity of disease and thus mortality.

PIM 2 scores were equally valid in the three main subgroups such as Neurological diseases, Infection and Respiratory diseases. These subgroups will form the majority of cases in most of the PICUs (12,13). This means the assessment of the PIM 2 score in the PICU will provide:

1. Prediction of survival (since high negative predictive value).
2. Objective measure of severity of disease. (As the PIM2 score increases, mortality also increases.)
3. To stratify sick children in clinical trial.

The data required for calculation of this score are easy to collect, non-proprietary, and because the data are collected at "point-of-care", risk stratification can be done and mortality risk can be calculated at an early stage after ICU admission.(30)

When comparing the performance of PIM2 score in different organ systems, the results were not very different. This has also been shown by Grinkeviciute DE et al(25) showed that PIM 2 score provided the best discrimination between survivors and non survivors in head injury patients compared to pediatric trauma score (PTS) and Glasgow coma scale score (GCS). Czaja et al(16) showed PIM 2 score had fair

discrimination of survivor and non survivor in cardiac surgery patients.

Limitation of the current study

1. Although clinical parameters of PIM2 score can be easily recorded, PIM 2 score also depends on arterial blood gas analysis, which is available only at PICU of tertiary care center and not at peripheral hospitals. Simpler scoring systems which do not need laboratory parameters will allow for such systems to be used in peripheral hospitals also.

2. The original PIM 2 score was developed with larger number of patients and at many centers. The current study has been done on relatively small number of subjects. Validity of a score like PIM 2 score will have to be observed in multicentric trial which will allow for large case mix and hence more representative of an average Indian PICU.

3. No individual patient decision can be taken based on PIM 2 scoring alone. This has been common limitation in all mortality scoring systems.

4. While the outcome variable of mortality may be acceptable in a PICU, the PIM 2 score has no measure of morbidity or ultimate outcome in terms of disability after transfer from the PICU. Newer scores which quantify disability and long term outcome are required to be developed.

5. One of the aims of any scoring system is the optimal use of resources. Though the PIM 2 score correlates well with chances of mortality, this information alone will not affect utilization of PICU resources. No child can be denied admission to the PICU based on a low PIM2 score alone if clinically he/she warrant close monitoring. The same also holds true for a moribund child admitted with a very high score. Based on the high score and very high probability of mortality, admission and therapy cannot be withheld. Thus use of PICU resources will continue as required by the individual hospitals' needs and no scoring system however accurately decide the pattern of admissions.

CONCLUSION

CONCLUSION

1. PIM 2 score discriminated well between survivors and death at PICU of this tertiary pediatric care hospital.

2. PIM 2 score provides an objective assessment of severity of illness.

3. PIM 2 score helps to assess the severity of illness earlier (within an hour). Based on this, early vigorous management can be done in clinically borderline severe cases, which would have been missed otherwise and patients can be saved.

4. Associated factors such as presence of shock, need for mechanical ventilation were significantly associated with mortality.

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ANNEXURE

DATA ENTRY FORM

PIM 2 SCORE PROFORMA

1. Patient Name
2. Age
3. Sex
4. IP Number
5. DOA in word
6. Number of days inward
7. Date of admission PICU
8. Diagnosis and reason for admission in PICU
9. Number of days in PICU
10. Date of death
11. Date of Discharge

PIM 2 SCORE

S.No	Variables	Yes / No	Values	Beta
1.	Elective admission			
2.	Recovery Post Procedure			
3.	Cardiac bypass			
4.	High Risk diagnosis			
5.	Low Risk diagnosis			
6.	No response to pupils to bright Light (>3mm & both fixed)			
7.	Mechanical Ventilation (at any time during first hr in ICU)			
8.	Systolic Bp (mm Hg)			
9.	Base excess mmol/L (arterial or capillary blood)			
10.	FiO_2			
	PaO_2			
	$\frac{FiO_2}{PaO_2}$ x 100 mm Hg			

Predicted death rate:

(PIM 2 (Logit) Score)

Associated factors	Yes / No
Assisted ventilation	
Shock	
GCS < 8	

Diagnosis diseases ---------- **(1/2/3/4/5/6/7/8)**

(1 Neurological diseases / 2 – Respiratory disease/ 3- Infections / 4- Cardiovascular diseases / 5 – Gastro Intestinal diseases / 6 – Postoperative cases / 7- Renal diseases / 8 – others)

Outcome:---------- **(0/1)**

(0-discharged, 1- died)

Total PIM 2 (Logit) Score:

Predicted death rate:

ABBREVIATIONS

PIM	-	Pediatric Index of Mortality
PICU	-	Pediatric Intensive Care Unit
ICH	-	Institute of Child Health
GCS	-	Glasgow Coma Scale
C.I	-	Confidence interval
CVS	-	Cardiovascular system

INFORMATION SHEET

Pediatric index of mortality – 2 (PIM2) score as predictor of mortality in PICU

Investigator Name : Dr. G. Jeyanthi ~~MD~~.,D.C.H.,

Dr. S.Shanthi, MD., D.C.H.,

Dr. V.Poovazhagi, MD., D.C.H.,

Dr. Luke Ravi Chellaiah, MD.,

Dr. P. Jeyachandran, MD.,D.C.H.,

Dr. D. Gunasingh, M.D.,D.C.H.,

(To be read to caretakers in the presence of witness)

Institute of child health & hospital for children, Egmore, being the most important referral centre in south India, outcome analysis including mortality risk prediction is important.

Total number of patients admitted at PICU in a year were 900 – 1000 with a mortality of 40% indicating that PICU has nearly 8 times more mortality than overall mortality of ICH. This study aims at

mortality risk prediction at PICU which will be a useful tool for intensivisits for counselling of parents and for resource allocation.

How is the Study being done?

PIM – 2 score has both clinical parameters (Blood pressure measurement, reaction of pupil to bright light) and blood gas analysis (which is one of the routine investigations done for all PICU admissions). This score is done once in all PICU patients within 1 hour of PICU admission. Predicted death rate computed by software at PICU will be compared with outcome (discharge or death) of patient.

Can I refuse to join the study?

You may refuse to participate or withdraw from the study at anytime. In both cases, your child will be treated in the usual manner is the hospital.

Is there benefit or harm to be in this study?

Within 6 hrs of PICU admission, PIM2 score will be done and so the patient's severity of illness will be known. So your will be counseled about your child's condition as early as possible.

There is no harm to the patient is this study.

CONFIDENTIALITY:

The data collected from the study will be used for the purpose of the study only. The results of the study are to be published. Personal information of the children participating in the study will be kept confidential. There will not be any disclosure about your child's information without your permission.

SUBJECT RIGHTS:

I understood that if I wish further information regarding my child's rights as a research subject, I may contact intensivists at PICU where the study is taking place.

Signature of investigator Signature of Parent / Guardian

Date

INFORMED CONSENT FORM

TITLE OF STUDY :

Paediatric index of mortality-2 (PIM2) score as predictor of mortality in PICU.

Name : Date :

Age : In patient No :

Sex : Research Roll No :

I have been fully informed about the study and the benefits to my child and possible harm that can happen.

This authorization is valid only for this study.

"I have understood and received copy of the consent form" I agree for my child's participation in this research study.

Signature of the investigator Signature / Thumb Print of Parent /Guardian

Witness Signature

Date :

Principle investigator:

Address :

Phone :

ஆராய்ச்சி தகவல் தாள்

பிம்-2 மதிப்பீடு, தீவிர சிகிச்சை பிரிவில் உள்ள குழந்தைகளின் இறப்பை கணிக்குமா? என்பதற்கான ஆய்வு.

ஆய்வாளர்கள் :

1. மரு.கா.ஜெயந்தி முதன்மை ஆய்வாளர்
2. மரு.சாந்தி M.D., D.C.H., மேற்பார்வையாளர்
3. மரு.வ.பூவழகி M.D., D.C.H., மேற்பார்வையாளர்
4. மரு.லூக்ரவி செல்லையா M.D., மேற்பார்வையாளர்
5. மரு. ஜெயசந்திரன் M.D.,D.C.H., மேற்பார்வையாளர்
6. மரு. குணசிங் M.D.,D.C.H., மேற்பார்வையாளர்

ஆய்வின் நோக்கம்:

தென் இந்தியாவின், நோயுற்ற குழந்தைகளை மேற்சிகிச்சைக்காக பரிந்துரைக்கப்படும் மருத்துவனைகளில் ஒன்று, எக்மோரில் உள்ள குழந்தைகள் நல மருத்துவமனை மற்றும் ஆராய்ச்சி நிலையம் அங்கு சிகிச்சையளிக்கப்படும் குழந்தைகளின் இறப்பை கணிப்பது உட்பட அம்மருத்துவமனையின் வெளிப்பாடுகளை கண்டறிவது முக்கியமாகும்

கடந்த சில வருடங்களில், அம்மருத்துவமனையின் தீவிர சிகிச்சைப் பிரிவில் வருடத்திற்கு 900 முதல் 1000 குழந்தைகள் வரை உள்நோயாளிகளாக சிகிச்சைப் பெற்றுள்ளனர். அக்குழந்தைகளில் 40 சதவீதம் இறந்துள்ளனர். இது அம்மருத்துவமனையின் மொத்த இறப்பு விகிதத்தைவிட 8 மடங்கு அதிகமாகும். தீவிர சிகிச்சைப் பிரிவில் உள்நோயாளியாக சேர்க்கப்படும் குழந்தைகளின் இறப்பை கணிப்பது இந்த ஆராய்ச்சியின் நோக்கமாகும். இதன் மூலம் அங்கு பணியாற்றும் மருத்துவர்கள் அங்கு அனுமதிக்கப்படும் குழந்தைகளின் நோயின் தீவிர தன்மை குறித்து பெற்றோரிடம் விளக்கமுடியும்.

ஆராய்ச்சி நடவடிக்கைகள்:

பிம்-2 மதிப்பீட்டில் குழந்தைகளின் உடல்நிலை மற்றும் இரத்த வாயு நிலை பரிசோதிக்கப்படுகிறது. தீவிர சிகிச்சைப் பிரிவில் உள்நோயாளியாக அனுமதிக்கப்படும் எல்லா குழந்தைகளுக்கும், உள்ளே அனுதிக்கப்பட்ட 1 மணி நேரத்திற்குள் பிம்-2 மதிப்பீடு போடப்படுகிறது. பின்னர் கணினி மூலமாக பிம்-2 மதிப்பீடு இறப்பு விகிதம் கணக்கிடப்படுகிறது. பிம்-2 மதிப்பீட்டின் இறப்பு விகிதம் குழந்தைகளின் வெளிப்பாடுகளுடன் (நலமாகி வீட்டிற்கு செல்லுதல் அல்லது இறப்பு) பொருந்துகிறதா என ஆராயப்படுகிறது.

அபாயம் மற்றும் நன்மைகள் :

இந்த ஆய்வினால் எந்த ஆபத்தோ அல்லது அசௌகரியமோ ஏற்படுவதில்லை.

தகவலளிக்கப்பட்ட ஒப்புதல் படிவம்:

இந்த ஆய்வு பற்றி கணக்கு விளக்கமாக எனது தாய்மொழியில் (தமிழ்) சொல்லப்பட்டது. இந்த ஆய்வில் பங்கெடுத்துக் கொள்வதால் எனது குழந்தைக்கு ஏற்படக்கூடிய அபாயங்கள் மற்றும் நன்மைகள் பற்றி எனக்கு விளக்கப் பட்டது. இந்த ஆய்வில் எனது குழந்தையை பங்கெடுத்துக் கொள்ள முழுமனதுடன் சம்மதிக்கிறேன். கேள்விகள் கேட்பதற்கு எனக்கு வாய்ப்பு அளிக்கப்பட்டது. இந்த ஆய்விலிருந்து கிடைக்கும் முடிவுகளை பயன்படுத்துபவரை கட்டுப்படுத்தாமல் இருக்க நான் சம்மதிக்கிறேன்.

ஆராய்ச்சியாளர் கையொப்பம் பெற்றோர்/காப்பாளர்

கையொப்பம்

தேதி

தகவல் அளிக்கப்பட்ட ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு :

பிம்-2 மதிப்பீடு, தீவிர சிகிச்சை பிரிவில் உள்ள குழந்தைகளின் இறப்பை கணிக்குமா? என்பதற்கான ஆய்வு.

பெயர் : தேதி :

வயது : உள்நோயாளி எண் :

பால் : ஆராய்ச்சி சேர்க்கை எண் :

இந்த ஆய்வு பற்றி எனக்கு விளக்காக எனது தாய்மொழியில் தெரிவிக்கப்பட்டது. இந்த ஆய்வில் பங்கெடுத்துக் கொள்வதால் எனது குழந்தைக்கு ஏற்படக்கூடிய அபாயங்கள் மற்றும் நன்மைகள் பற்றி எனக்கு விவரமாக தெரிவிக்கப்பட்டது. இந்த ஆய்வில் எனது குழந்தையை பங்கெடுத்துக் கொள்ள முழுமனதுடன் சம்மதிக்கிறேன். கேள்விகள் கேட்பதற்கு எனக்கு வாய்ப்பளிக்கப்பட்டது.

இந்த ஆய்விலிருந்து கிடைக்கும் முடிவுகளை பயன்படுத்துபவரை கட்டுப்படுத்தாமலிருக்க நான் சம்மதிக்கிறேன்.

குழந்தையின் பெயர் -

குழந்தையின் பெற்றோர் / -

கண்காணிப்பாளர் பெயர்

குழந்தையின் பெற்றோர் -

கண்காணிப்பாளர் பெயர்

கையெழுத்து

தேதி -

எழுதப்படிக்கத் தெரியாத -

பெற்றோர் / கண்காணிப்பாளர்

கைவிரல் ரேகை

சாட்சியின் பெயர் -

சாட்சியின் கையெழுத்து -

தேதி -

முதன்மை ஆய்வு -

மருத்துவா பெயர்

ஆய்வாளர் / ஆய்வு -

மருத்துவர் கையெழுத்து

தேதி -