Clinical Research Application Form

Created: 09/21/2015
Last updated: 09/23/2015

Page 1

Section A: General Project Information

Geographical information

In which country does your project take place?	Thailand
In which ISN region does your project take place?	Oceania and South East Asia

What is the title of your project?

Please choose a short but descriptive title: e.g.: "CKD screening in Abuja, Nigeria"

AKI epidemiology in South East Asia

Name and address of the coordinating Institution

Legal name:	King Chulalongkorn Memorial Hospital
Address:	King Chulalongkorn Memorial Hospital, Pathumwan, Bangkok. Thailand
Head of the Institute:	Professor Kearkiat Praditpornsilpa

Name of the local coordinator of the project

Full Name:	Nattachai Srisawat
Position:	Assistant Professor
Email:	drnattachai@yahoo.com
Phone no:	(No response)
Fax no:	(No response)

Duration of the project (in months- max 36)

12

Co-Investigators / Collaborators

Name	Sadudee Peerapornratana
Role in project	Design the study protocol and recruitment patients

Name of the Regional Coordinator who was consulted about the project

Page 2

Section B: Concept summary (maximum 300 words)

What (intervention/exposure, outcome) will this project study, why (rationale), in whom (population), how (what design will be used), over how long (duration) and what impact will it have (significance)?

This is the first prospective multicenter observational study of AKI epidemiology in Southeast Asia. We will collect the data by registration in electronic web-based format (see Appendix). The data will be serially collected on the first 28 days of ICU admission. Standard KDIGO criteria is used to define AKI incidence. We use mortality at hospital discharge time as the clinical outcome. We also explore the impact of age, gender, co-morbidity disease, APACHE II score, primary diagnosis, fluid balance, and timing of ICU admission to the AKI incidence and outcome. We expect this study may raise the public concern that AKI is a common and has great impact on ICU patients' survival in Thailand and Laos.

Section C: Project description (maximum 6 pages, single spaced)

Please prepare and upload a document with the following information:

1. **Specific aims of the program (approximately 0.5 pages):** What are the objectives of your project? Please provie 1-4 objectives: fewer is better. Each objective should be specific, measurable and linked to a hypothesis. See Appendix for examples.
2. **Background and rationale (approximately 1 page):** What is the previoous work that has led you to contemplate this study? Why is this project important? Why is it important for the investigator's country/region? Why is this work novel or how will it extend what has already been done? How will the results be used?
3. **Methods (approximately 2-3 pages):** Provide a detailed description of how the work will be done. Try to address the following as appropriate:
   • **Primary and secondary outcomes**: What outcomes will you study? How will these outcomes be defined? Who will assess them and how?
   • **Inclusion criteria/exclusion criteria:** who will be eligible and ineligble to participate, and why?
   • **Confounders/covariates:** how will you account for the possibility of confounding and bias? If there are potential confounders, how will these be defined/measured and how will you account for them in analysis?
   • **Recruitment/sampling method; sample size calculation:** how will you identify participants? How many participants do you need to make the study worthwhile and is this feasible?
   • **Statistical methods:** how will you analyze the data? Do you have the skills to do the analysis yourself, or will you involve a statistician colleague?
   • **Ethical considerations:** have you obtained/will you obtain ethics approval for this study? Are there any other ethical considerations to be addressed?
   • **Knowledge translation:** who needs to know about the results of your study, and how will you ensure that they are aware of the findings once the study is finished?
4. **Research team (approximately 0.5 pages):** who are the members of your team, why are their qualifications/experience relevant for this study? What will each member of the team do? Does the team have the necessary skills and experience to do the work?
5. **Institutional environment (approximately 0.5 pages):** provide a few details about your institution, and why it is a suitable environment do this work. Does it have the necessary facilities/patient population to do the work?
6. **Significance (approximately 0.25 pages):** what do you expect to find, and how will this make a difference? What impact will it have scientifically, or to healthcare in your country/region? What are the next steps once this study is finished?

http://cr.theisn.org/media/assets/survey-uploads/29711/4245870-8dtRBRtpNz/ISN_proposal_section_C.doc

Section D: timelines (Gantt chart)

Upload a planning or gantt chart with a timeline, milestones and deliverables.

http://cr.theisn.org/media/assets/survey-uploads/29711/4245870-XCnZzGq4pV/ISN_research_proposal_section_D.doc

Section E: Relevant references

1. Srisawat N, Kellum JA. Acute kidney injury: definition, epidemiology, and outcome. Curr Opin Crit Care. 2011;17(6):548-55.
2. Coca SG, Yusuf B, Shlipak MG, Garg AX, Parikh CR. Long-term risk of mortality and other adverse outcomes after acute kidney injury: a systematic review and meta-analysis. Am J Kidney Dis. 2009;53(6):961-73.
3. Lindsay J, Apple S, Pinnow EE, Gevorkian N, Gruberg L, Satler LF, et al. Percutaneous coronary intervention-associated nephropathy foreshadows increased risk of late adverse events in patients with normal baseline serum creatinine. Catheter Cardiovasc Interv. 2003;59(3):338-43.
4. Report for Selected Country Groups and Subjects (PPP valuation of country GDP)". IMF. Retrieved April 8, 2015.
5. Susantitaphong P, Cruz DN, Cerda J, Abulfaraj M, Alqahtani F, Koulouridis I, et al; Acute Kidney Injury Advisory Group of the American Society of Nephrology. World incidence of AKI: a meta-analysis. Clin J Am Soc Nephrol. 2013;8(9):1482-93.
6. Domrongkitchaiporn S, Sritara P, Kitiyakara C, Stitchantrakul W, Krittaphol V, Lolekha P, et al. Risk factors for development of decreased kidney function in a southeast Asian population: a 12-year cohort study. J Am Soc Nephrol. 2005;16(3):791-9.
7. Perkovic V, Cass A, Patel AA et al. High prevalence of chronic kidney disease in Thailand. Kidney Int 2008; 73: 473–479
8. Chittinandana A, Chailimpamontree W, Chaloeiphap P. Prevalence of chronic kidney disease in Thai adult population. J Med Assoc Thai 2006; 89: S112–S120
9. Ingsathit A, Thakkinstian A, Chaiprasert A, Sangthawan P, Gojaseni P, Kiattisunthorn K, et al, Thai-SEEK Group. Prevalence and risk factors of chronic kidney disease in the Thai adult population: Thai SEEK study. Nephrol Dial Transplant. 2010;25(5):1567-75.
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11. Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group:
KDIGO clinical practice guideline for acute kidney injury. Kidney Int 2012; 2: 1–138.
12. Srisawat N, Sileanu FE, Murugan R, Bellomod R, Calzavacca P, Cartin-Ceba R,
et al; Acute Kidney Injury-6 Study Group. Variation in risk and mortality of acute kidney injury in critically ill patients: a multicenter study. Am J Nephrol. 2015;41(1):81-8.
13. Siew ED, Matheny ME, Ikizler TA, Lewis JB, Miller RA, Waitman LR, et a. Commonly used surrogates for baseline renal function affect the classification and prognosis of acute kidney injury. Kidney Int. 2010;77(6):536-42.
14. Carr BG, Addyson DK, Kahn JM. Variation in Critical Care Beds Per Capita in the United States: Implications for Pandemic and Disaster Planning. JAMA. 2010;303(14):1371-72.
15. Uchino S, Kellum JA, Bellomo R, Doig GS, Morimatsu H, Morgera S, et al; Beginning and Ending Supportive Therapy for the Kidney (BEST Kidney) Investigators. Acute renal failure in critically ill patients: a multinational, multicenter study. JAMA. 2005;294(7):813-8.
16. Chawla LS, Amdur RL, Amodeo S, Kimmel PL, Palant CE. The severity of acute kidney injury predicts progression to chronic kidney disease. Kidney Int. 2011;79(12):1361-9.
17. Bagshaw SM, George C, Bellomo R; ANZICS Database Management Committee. A comparison of the RIFLE and AKIN criteria for acute kidney injury in critically ill patients. Nephrol Dial Transplant. 2008; 23:1569-74.
18. Uchino S, Bellomo R, Goldsmith D, Bates S, Ronco C. An assessment of the RIFLE criteria for acute renal failure in hospitalized patients. Crit Care Med. 2006; 34: 1913-17.
19. Závada J, Hoste E, Cartin-Ceba R, Calzavacca P, Gajic O, Clermont G, Bellomo
R, Kellum JA; AKI6 investigators. A comparison of three methods to estimate baseline creatinine for RIFLE classification. Nephrol Dial Transplant. 2010; 25: 3911-18.

Section F: Detailed budget in local currency and USD

What funds do you need and why? is the budget sufficient to complete the project? If not, where will additional funds come from? How did you estimate the costs?

Description of funds	(No response)
Budget requested to ISN in USD	20000

Upload a detailed budget

http://cr.theisn.org/media/assets/survey-uploads/29711/4245870-piNWJbrTRE/ISN_research_proposal_Section_F.doc

Section G: Patient Information Sheet and Informed Consent Form

Please upload the form: a standard form can be found in the Guidelines for Applicants

http://cr.theisn.org/media/assets/survey-uploads/29711/4245870-HtvwS6527K/ISN_research_proposal_waived_inform_consent.doc

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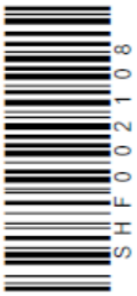


22 Sept, 2015

Prof Marcello Tonelli
Clinical Research Program
ISN.

Dear Cello

I write to provide my regional endorsement for the project submitted by Dr Nattachai Srisawat, from the Chulalongkorn Univesity and Hospital, Bangkok, Thailand.

The project around assessing the incidence and demographics of AKI in urban and rural Thailand as well as Laos is very well planned and structured. As well Dr Srisawat is very well credentialed to conduct such a study. The study, of course, fits very well with the 0 by 25 project of the ISN.

I look forward to the outcome of the forthcoming round of grants,

Yours sincerely,

Prof Peter G Kerr
Chair, OSEA Regional Board

ISN Clinical Research Proposal

Project title: The Epidemiology and Prognostic Factors for Mortality in Intensive Care Unit Patients with Acute Kidney Injury in South East Asia

Section C: Project description

1. Specific aims of the program:

- To determine the incidence of AKI among ICU patients in Thailand and Laos
- To determine mortality rate of AKI patients in Thailand and Laos and compare the mortality between patients with and without AKI
- To determine the incidence of renal replacement therapy among ICU patients in Thailand and Laos
- To compare the length of ICU and hospital stay, total ventilator and inotropic drug days between patients with and without AKI

2. Background and Rationale:

Acute kidney injury (AKI) is one of the most common and important problems in intensive care unit (ICU) patients. The incidence of AKI in ICU varies from 20% to as much as 50%. AKI plays an important role in patients' morbidity and mortality. AKI associated hospital mortality rate in ICU patients ranged

from 20% to 50% and may reach 60% if the patients required renal replacement therapy (RRT). Not only hospital mortality, AKI patients also have greater relative risk of death and cardiovascular events in long term follow up. The differences in incidence and outcome of AKI may be attributed to the criteria for AKI diagnosis, the population, and the centers studied.

Although the standard criteria for diagnosis of AKI have been established for more than 10 years. The incidence and outcome of AKI in the large clinical scale in Southeast Asia (SEA) region, a subregion of ASIA, which comprises of more than 600 milliion people, have never been reported. The same thing happen in Thailand, one of the top three biggest country in this region and ranks number 22nd by gross development product by International Monetary Fund (IMF). Moreover, recent meta-analysis reported the world incidence of AKI without the data from SEA region. In Thailand, we have at least five large cohort of chronic kidney disease (CKD) studies but having only small single center study for AKI. Studying the AKI epidemiology in multicenter level will help to complete the missing piece of kidney disease epidemiology of Thailand and SEA region.

Recent data showed that CKD is another consequence of AKI. Coca et al reported the incidence rate of CKD after AKI episode to be as much as 7.8 per 100 patient years. The data

of AKI epidemiology will be the first step in linking the process of AKI progression to CKD in Thailand.

The present prospective observational study is conducted to determine the incidence and outcome of AKI among ICU patients in Thailand, and to analyze the factors that might impact the AKI incidence and outcome.

3. Methods:

This study is a prospective multicenter observational study which will be conducted in 14 hospitals from Northern, Northeastern, Western, Central, and Southern regions across Thailand. Four hospitals from Laos, 2 centers from Northern, 1 center form the Central, and 1 center from Southern of Laos will participate. All the hospitals in this cohort can be divided into 3 groups depending on level of care, university hospital, regional hospital and provincial hospital. We enroll all the patients who were older than 18 years old and admitted to the participating ICU during 1 year. Patients with end stage renal disease (ESRD) on chronic dialysis were excluded. If the patient has multiple admissions, we collected the data in only the first admission. The study protocol is reviewed by the ethics committee, or the institutional review board at each participating site and the need for informed consent is waived.

Data collection

We collected the data by registration in electronic web-based format. Demographic, clinical and laboratorial data were recorded. Demographic data included age, gender, timing of hospital and ICU admission, co-morbidity disease and primary diagnosis at ICU admission. Clinical data included Acute Physiology and Chronic Health Evaluation (APACHE) II score at ICU admission, Sequential Organ Failure Assessment (SOFA) scores for the first three days, fluid balance status, the use of mechanical ventilator, vasopressor and RRT. Laboratory data included blood urea nitrogen and serum creatinine if available. The data were serially collected everyday for the first 7 days and then weekly collected on day 14, 21 and 28. The outcomes were AKI incidence, ICU and hospital mortality, length of stay, total mechanical ventilator days, and RRT days in ICU.

Sample size

6000 ICU patients

Definition

Definition of AKI

The diagnosis of AKI was determined by KDIGO criteria. For the baseline serum creatinine, we used the most recent available serum creatinine before hospital admission within one year. If the patients had no baseline serum creatinine, we estimated baseline serum creatinine by using the lower value between the serum creatinine at the time of hospital admission

(admission serum creatinine) or the back calculation of serum creatinine from the Modification on Diet in Renal Disease (MDRD) equation using a GFR of 75 ml/min/1.73 m^2 (MDRD serum creatinine).

For urine output criteria, we modified the urine output criteria to use the cumulative 24 hours urine output. We defined the patients who had urine output > 0.5 ml/kg/h as no AKI, 0.3-0.5 ml/kg/h as KDIGO stage 2 and < 0.3 ml/kg/h as KDIGO stage 3.[12] For the body weight, we used the value before hospital admission to calculate the rate of urine flow. If no known body weight available, we used ideal body weight which was calculated from height (cm)-100 in male or height (cm)-110 in female.

Statistical analysis

The data is analysed using SPSS version 17. Categorical data were presented as number and percentage. Continuous data is presented as mean and standard deviation (SD) if normally distributed or median and interquartile range (IQR) if non normal distributed. The Chi-square test is used for the comparison of proportion (risk factors of AKI and hospital mortality in AKI and non AKI patients). The Student's t test and Mann Whitney U test are used for the comparison of mean and median, respectively. Multiple logistic regression are used for assess the adjusted risk for AKI incidence and AKI associated

mortality. A P value of less than 0.05is considered to be significant.

Web-based case record form

1. Baseline patient characteristic

Patient Number * :

รหัสประจำตัวคนไข้ / HN

Personal Information

Birth date :

Gender * :

Weight :

Height :

Date of hospital admission : 22/4/2014

Date of ICU admission : 22/4/2014

Reimbursement (สิทธิการรักษา) :

Diagnosis (At ICU admission) :

Underlying disease

HT : Yes No

DM : Yes No

CAD : Yes No

Cerebrovascular disease : Yes No

Malignancy : Yes No

CKD : Yes No

ESRD : Yes No

Baseline serum Cr * :

Date of baseline serum Cr : 22/4/2014

ICU : Medical Surgical CCU CVT Neurosurgery Mixed

APACHE II Score

Physiologic Variable (A)

Temperature(c°) :

Mean arterial pressure -mm hg :

Heart Rate :

Respiratory rate :

Oxygenation a. FIO ≥ 0.5 and b FiO2 < 0.5 :

Arterial pH :

Serum sodium (mMol/L) :

Serum potassium (mMol/L) :

Serum creatinine (mg/dl) :

Hematocrit(%) :

White blood count (total/mm3) :

Age Points (B)

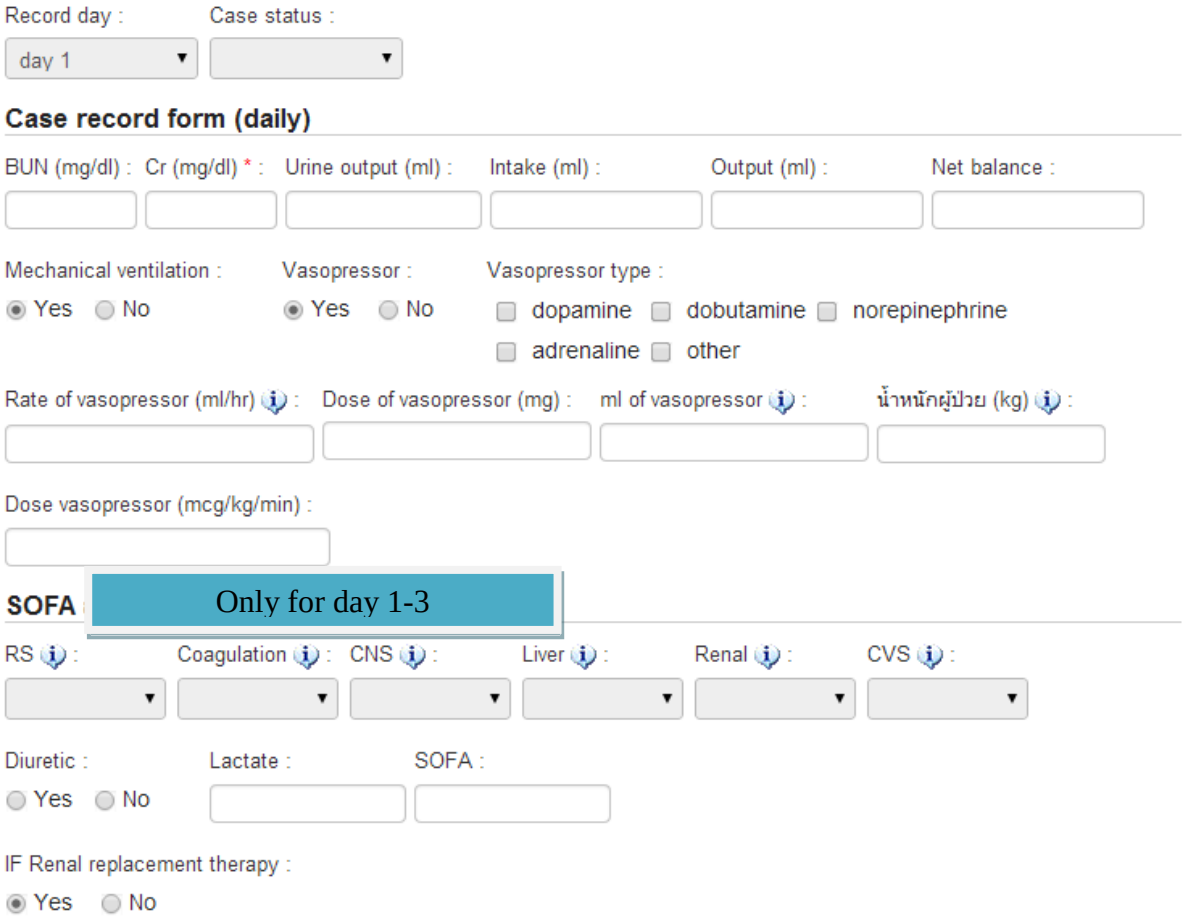
Age :

Chronic Health Points (C)

Chronic health points :

APACHE II (A+B+C) :

2. Daily information



3. Renal replacement therapy (RRT) form (if patient required RRT)

RRT

Indication (เลือกได้หลายข้อ) :

- ☐ 1. Refractory acidosis (pH < 7.2 or HCO3<15)
- ☐ 2. Refractory volume overload (severe peripheral edema or pulmonary edema or increase CVP and unresponsive to diuretic)
- ☐ 3. Refractory hyperkalemia (K>6.2 or EKG change)
- ☐ 4. Anuria or oliguria (urine output < 0.5 ml/kg/h for 6-12 h)
- ☐ 5. Uremic symptom & sign (mental status change, pericardial friction rub, intractable nausea vomitting, myoclonus or seizure not attributable to another etiology)
- ☐ 6. High BUN > 60

Mode of RRT :

○ IHD ○ CRRT ○ PD ○ SLED

IHD

Type of vascular access :
- ☐ Temporary catheter
- ☐ Permanent catheter
- ☐ AVF or AVG

Site of vascular access :
- ☐ Internal jugular vein
- ☐ Femoral vein
- ☐ Subclavian vein

Left or right : ☐ Left ☐ Right

BFR (ml/min) : DFR (ml/min) :

Dialyzer : Anticoagulant :

Complication :
- ☐ Bleeding
- ☐ major arrhythmia
- ☐ Air emboli
- ☐ catheter malfunction
- ☐ catheter infection
- ☐ no complication

SLED

Type of vascular access :
- ☐ Temporary catheter
- ☐ Permanent catheter
- ☐ AVF or AVG

Site of vascular access :
- ☐ Internal jugular vein
- ☐ Femoral vein
- ☐ Subclavian vein

Left or right : ☐ Left ☐ Right

Duration (hours) : BFR (ml/min) : DFR (ml/min) :

Dialyzer : Anticoagulant :

Complication :
- ☐ Bleeding
- ☐ major arrhythmia
- ☐ Air emboli
- ☐ catheter malfunction
- ☐ catheter infection
- ☐ no complication

CRRT

Type of vascular access :
- ☐ Temporary catheter
- ☐ Permanent catheter
- ☐ AVF or AVG

Site of vascular access crrt :
- ☐ Internal jugular vein
- ☐ Femoral vein
- ☐ Subclavian vein

Left or Right : ☐ Left ☐ Right

BFR (ml/min) : UFR (ml/h) : RFR (ml/h) :

Machine type :
- ☐ manual
- ☐ integrated

Mode : Anticoagulant :

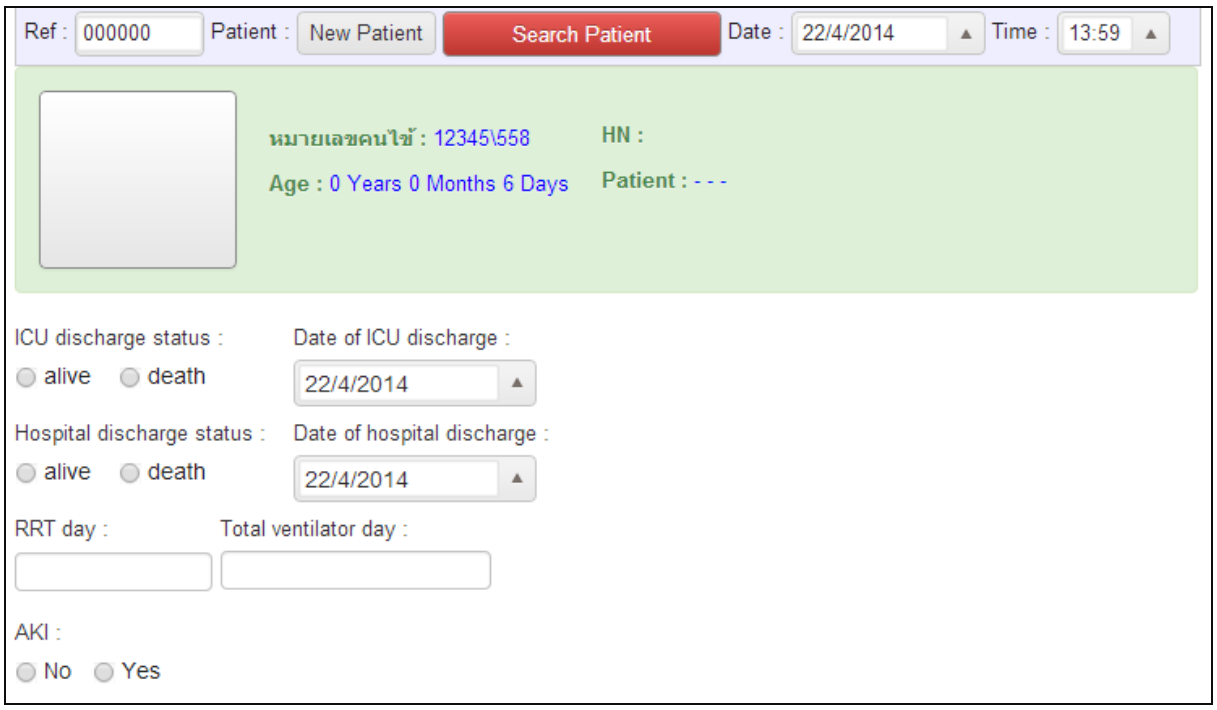
Complication :
- ☐ Bleeding
- ☐ major arrhythmia
- ☐ Air emboli
- ☐ catheter malfunction
- ☐ catheter infection
- ☐ no complication

PD

type of catheter : Type solution : ☐ 1.5% PDF ☐ 2.5%PDF ☐ 4.25%PDF ☐ icodextrin

Cycle : Fill volume (ml) : Dwell time :

Complication :
- ☐ Bowel injury
- ☐ Peritonitis
- ☐ Catheter malfunction
- ☐ Leakage of peritoneal fluid
- ☐ No complication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New Patient
Search Patient
Date : 22/4/2014
Time : 13:59
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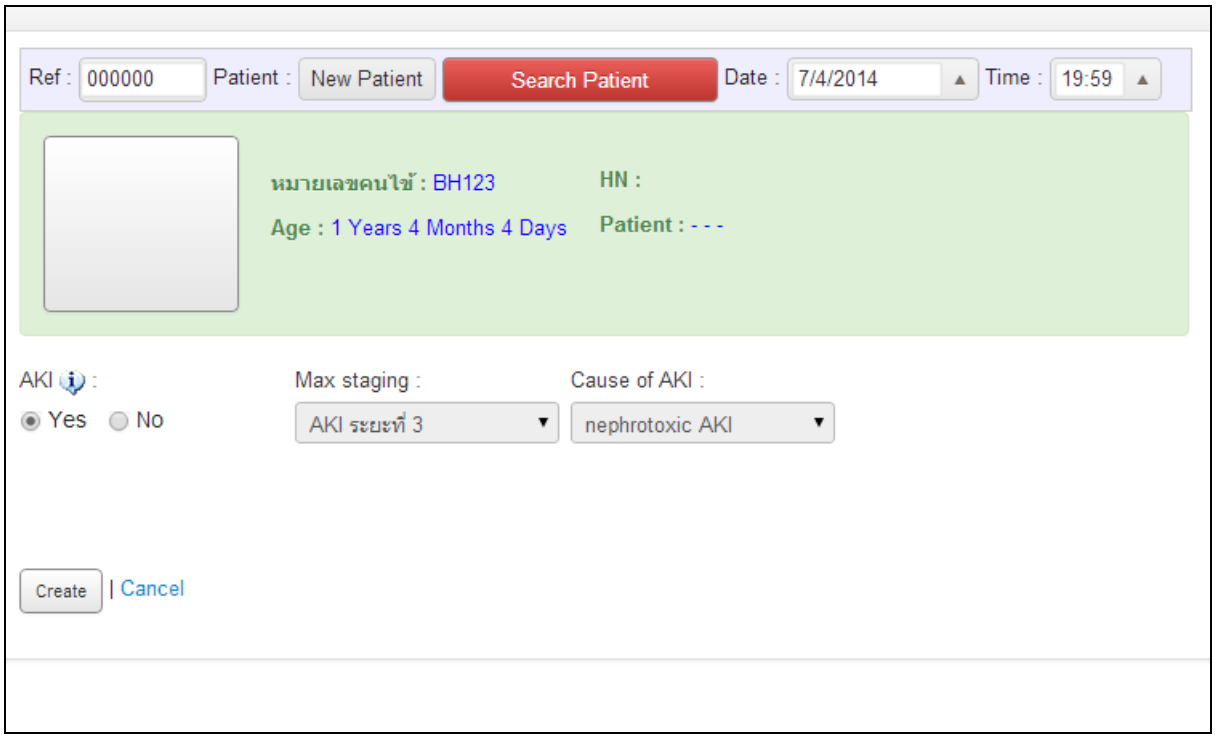
HN :
Age : 0 Years 0 Months 6 Days
Patient : - - -
ICU discharge status :
alive
death
Date of ICU discharge :
22/4/2014
Hospital discharge status :
alive
death
Date of hospital discharge :
22/4/2014
RRT day :
Total ventilator day :
AKI :
No
Yes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Patient :
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Search Patient
Date : 7/4/2014
Time : 19:59
หมายเลขคนไข้ : BH123
HN :
Age : 1 Years 4 Months 4 Days
Patient : - - -
AKI :
Yes
No
Max staging :
AKI ระยะที่ 3
Cause of AKI :
nephrotoxic AKI
Create
| Cancel

4. Research team

SEA-AKI study team member:

- Nattachai Srisawat, M.D., Noppathorn Mahamitra, M.D., Kearkiat Praditpornsilpa, M.D., Sadudee Peerapornrattana, M.D., Passisd Loahaveeravat, M.D., Asada Leelahavanichkul,

M.D.,Khajohn Tiranathanagul, M.D. Kriang Tungsanga, M.D., Somchai Eiam-Ong, M.D.,Visith Sitprija, M.D. from Division of Nephrology, Department of Medicine, Faculty of Medicine, Chulalongkorn University, and King Chulalongkorn Memorial Hospital, Thailand.\

- Noot Sengthavisouk, M.D., Mittrapab hospital, Vientaine, Laos PDR

- Anan Chuasuwan, M.D. from Department of Medicine, Bhumibol Adulyadej Hospital, Royal Thai Air Force, Bangkok, Thailand.

- Konlawij Trongtrakul, M.D. from [4]Department of Mediicne, Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand.

- Adis Tasnarong, M.D., Pattharawin Pattharanitima, M.D. from Department of Medicine, Faculty of Medicine, Thammasat University, Bangkok, Thailand.

- Ratapum Champunot, M.D. from Buddhachinaraj Hospital, Phitsanulok, Thailand

- Rangsun Bhurayanontachai, M.D. from Division of Critical Care Medicine, Department of Medicine, Faculty of Medicine, Prince Songkla University, Songkla, Thailand

- Manusanan Kongwibulwut, M.D., Pornlert Chatkaew, M.D. from Department of Anesthesiology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand.

- Petchdee Oranrigsupak, M.D. from Nan hospital, Nan, Thailand
- Theerapon Sukmark, M.D. from Tungsong Hospital, Nakhon Si Thammarat, Thailand
- Natthapon Laohacharoenyot, M.D. from Sriphat Medical Center, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand
- Karjbundid Surasit, M.D. from Nakornping Hospital, Chiang Mai, Thailand.
- Thathsalang Keobounma, M.D. fro Thabo Crown Prince Hospital, Nong Khai, Thailand.
- Kamol Khositrangsikun, M.D. from Maharaj Nakhon Si Thammarat hospital, Nakhon Si Thammarat, Thailand,
- Ummarit Suwattanasilpa, M.D. from Mahasarakarm hospital, Mahasarakarm, Thailand.
- Poramin Santithisadeekorn, M.D. from Taksinmaharaj Hospital, Tak, Thailand.
- Janmaly Keomany, M.D. from Mitrapab Hospital, Vientiane, Laos.
- Noot Sengthavisouk, M.D. from Mitrapab Hospital, Vientiane, Laos.

5. Institutional environment

This study will mainly conduct by Excellence Center for Critical Care Nephrology (ECCCN), which is the academic center under the support of Thai Red Cross. The main focus of this center is conducting the research in the field of AKI, biomarkers, and acute renal replacement therapy. The director of the ECCCN is Assistant Professor Dr. Nattachai Srisawat who previously CRISMA research fellow under the mentor by Professor John A Kellum, Department of Critical Care Medicine, University of Pittsburgh School of Medicine, Pennsylvania, USA. The ECCCN comprised of the 4 full-time experienced researchers who currently work in various AKI project. This team will help to conduct the AKI epidemiology research in term of recruiting the cases, cleaning the data set, creation the electronic web based program. The ECCCN has one project manager who will closely coordinate with the hospital in and outside Bangkok. Each participating hospitals will have the coordinator nurses who will response and fill the patients data for their centers. Before starting the project, the coordinator nurses will be trained until they feel comfortable to fill the data record form.

6. Significance

To our knowledge, this study will be the first and the largest prospective AKI epidemiologic study in Southeast Asia. We include the centers from all of the regions in Thailand and Laos in order to represent Thai and Laos population. The population which is covered by the participating hospital is about nine million people for Thailand (about 14% of total Thailand population). While about 1.5 million people will be covered for Laos.

The significance of the study can be in many ways. First, we expect this study may raise the public concern in our community that AKI is common and has great impact on patient outcome. Second, most of the study of AKI epidemiology come from high income country which may have the characteristic and outcome difference from the low middle income country. Therefore, any finding from previous reports may not apply to SEA. Third, the finding will provide the estimation budget for cost of AKI treatment.

ISN Clinical Research Proposal

Project title: The Epidemiology and Prognostic Factors for Mortality in Intensive Care Unit Patients with Acute Kidney Injury in South East Asia

Activity	2015			2016								
	10	11	12	1	2	3	4	5	6	7	8	9

Section D: Timeline

1.Preparation - Electronic medical record system, training coordinator nurse,	x	x									
2.Data collection - Cleaning data			x	x							
3. Data analysis					x	x	x	x	x	x	
4. Manuscript preparation										x	x

ISN Clinical Research Proposal

Project title: The Epidemiology and Prognostic Factors for Mortality in Intensive Care Unit Patients with Acute Kidney Injury in Southeast Asia

Methods:

This study is a prospective multicenter observational study which will be conducted in 14 hospitals from Northern, Northeastern, Western, Central, and Southern regions across Thailand. Four hospitals from Laos, 2 centers from Northern, 1 center form the Central, and 1 center from Southern of Laos will participate. All the hospitals in this cohort can be divided into 3 groups depending on level of care, university hospital, regional hospital and provincial hospital. We enroll all the patients who were older than 18 years old and admitted to the participating ICU during 1 year. Patients with end stage renal disease (ESRD) on chronic dialysis were excluded. If the patient has multiple admissions, we collected the data in only the first admission. The study protocol is reviewed by the ethics committee, or the institutional review board at each participating site. Because we use the code number instead of the participant name. Therefore, the need for informed consent is waived.