

**KHDC**  
**RESEARCH PROPOSAL**

**Section A: *General Project Information***

1. Country/region where the project takes place  
Asia / Africa / South America

2. Project title

**Risk Assessment Tool Kit for Community Acquired Acute Kidney Injury**

3. Name and address of the coordinating Institution (Applicant)

University of California – San Diego (UCSD)

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4. Name of the local coordinator of the project

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5. Duration of the project (in months)

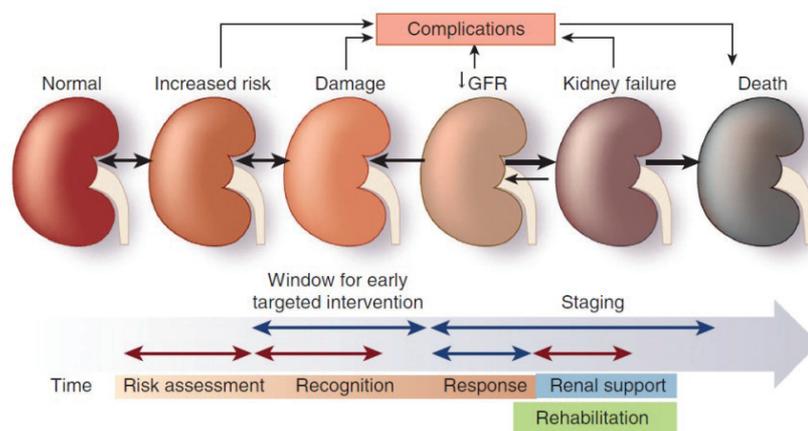
16 months

## Section B: *Project description*

### a. **Rationale of the project in the context of the need of the Applicant's country**

Over the last few years, information and guidelines on diagnosis and management of Acute Kidney Injury (AKI) have emerged and have been largely implemented in hospital settings in the developed world. There has been limited progress in incorporating this knowledge in the developing world, particularly in recognizing patients at high risk for developing AKI in different settings. Since AKI is not associated with any specific symptoms and the diagnosis is largely based on assessment of lab parameters, AKI is often not recognized, particularly in a community setting. Caregivers may not be equipped with the tools for early recognition, timely intervention, and effective follow up. Thus, key opportunities to prevent and treat AKI are lost and result in disability and a significant loss of life [1]. Given the increasing recognition of AKI as a marker of future CKD and the high incidence of AKI, there is a need to improve prediction of those at risk (Figure 1).

Figure 1 - Conceptual framework and targeted approach for raising awareness of AKI.



From: Lewington, Cerda and Mehta: The 5R approach; Raising Awareness AKI Kidney International 2013 [2].

Early identification of patients at increased risk for AKI is the first step for implementing preventive strategies. Most of the known risk factors associated with AKI have been identified in hospitalized patients in developed countries. In these settings,

efforts towards potentially modifiable factors are the main approach to prevention [3-5]. However, several different exposures contributing to AKI in different settings are unknown or difficult to access, challenging the development of a unified tool for risk assessment (Table 1) [6-13].

Table 1 - Main risk factors for developing acute kidney injury in low and low middle-income countries (LMIC). *Modified from [1].*

Patient		Exposures	
Non-modifiable	Modifiable	LMIC and less developed areas	Environmental and Infrastructure
<b>Comorbid medical conditions</b>	Dehydration	Diarrhea	Inadequate sanitation
Chronic kidney disease	Intravascular volume depletion	Obstetric complications (including septic absorption)	Limited clean water availability
Diabetes mellitus	Hypotension	Infectious diseases (malaria, leptospirosis, dengue, cholera, yellow fever, tetanus, Hantavirus)	Inadequate control of parasites
Chronic heart disease	Anemia		Inadequate control of infection-carrying vectors
Chronic lung disease	Hypoxia	Animal venoms (snakes, bees and wasps, Loxosceles spiders, Lonomia caterpillars)	Poor transportation
Chronic gastrointestinal disease	Use of nephrotoxic agents (antibiotics, iodinated contrast, nonsteroidal antiinflammatory drugs, anticancer drugs, antiretrovirals, calcineurin blockers)	Natural medicines	Inadequate health budget
<b>Demographic factors</b>			Insufficient health care human resources
Gender		Prolonged physically overwhelming work in an unhealthy environment	Insufficient health services and hospitals
Older age		Natural dyes	

The lack of infrastructure or inaccessibility to diagnostic tools, often due to financial constraints, coupled with limited access to health care and physician referral, contribute to the high morbidity and mortality of AKI in low and medium income countries (LMIC).

Development of risk scores to estimate the probability of AKI development is still an underutilized tool. Several risk scores for AKI have already been proposed [14, 15]. However, most of the available scores are specific for a risk setting, e.g. ICU, post-operative setting, and were developed based on data from hospitalized patients in

developed countries. In addition to patient risk factors, environmental and infrastructure particularities, such as inadequate sanitation, limited clean water availability, inadequate control of parasites and infection-carrying vectors and poor transportation can increase the risk of AKI (Table 1)[1].

There is thus a great need for a pragmatic, easy to use tool to enable physicians to identify and follow high-risk patients based on clinical parameters particularly in low resource settings. Without clear protocols to maintain surveillance, delay in recognition is an important factor contributing to adverse outcomes in AKI. The development of a simple clinical based tool to predict AKI in community patients would potentially help health care providers to determine level of care, interventions and need for follow up [16, 17]. This approach would be possible for the majority of low and for high-income countries.

**b. Objectives of the program**

**Primary**

1. Develop a simple clinical tool to predict the likelihood of developing AKI in the LMIC world.

**Secondary**

1. Assess the predictive performance of the tool to assess the course of kidney function in patients at risk for AKI in LMIC.
2. Assess the feasibility of implementing a risk assessment tool for AKI in different regions in the world.
3. Assess the feasibility of using the tool to determine the need for further point of care test and triaging for additional care.

**c. Plan of the project and methodology**

**Project plan**

We propose to divide the study into 4 sequential phases:

Phase 1 – Preparation phase – 4 months

- Identify the most important risk factors for AKI development based on data acquired from ISN GSN community acquired cases in Africa, Asia and South America.

- Modify the KEEP database to capture enhanced data from high-risk patients at pre-defined centers in Africa, Asia and South America.
- Identify and contact centers involved in GSN Centers that provided cases on community acquired AKI in outpatient settings in Africa, Asia and South America.
- Prepare documents and work with selected centers to get IRB consent to participate in the second phase of the study.

#### Phase 2 – Prospective Observation phase – 8 months

- Collect prospective data on screened patients from pre-defined centers in designated regions (see Figure for study design)
- Assure data quality and completeness and confidentiality

#### Phase 3 – Analytical phase – 4 months

- Analysis of prospective data and development of the risk scores for predicting community acquired AKI
- Develop application for use in web based scoring system and mobile applications

#### Phase 4 – Validation phase (not included in the project budget)

- Validation of AKI risk assessment tool in different centers from LMIC.
- Evaluate the feasibility and ease of use across selected centers worldwide leveraging AKIN network and O'Brien AKI registry database and ISN links.
- Assess the predictive ability of the tool to assess the course of kidney function in patients at risk for AKI in resource poor settings of LMIC.
- Assess the feasibility of using the tool to determine the need for further point of care interventions.

### **Description of study phases**

#### ***Phase 1 - Preparation phase*** - May to August 2014

The development of the AKI risk assessment tool will leverage existing data and expertise within the ISN 0by25 project that recently completed the Global Snapshot (GSN) of AKI. The GSN utilized a mobile enabled web based open source database (KEEP, Distributed Health Labs, San Diego) to capture data from patients during a physician's typical clinical day, over a 10-week enrollment period from September through December 2014. Patients who met KDIGO criteria for AKI were enrolled in the study and data was recorded in the database. The GSN project compiled information from

over 4000 patients recruited from 72 countries evaluating the risk factors for AKI as well as how it was identified, managed and treated in different settings around the globe. Patients were stratified into community versus hospital acquired AKI based on the timing and course of AKI. Included in the dataset are 1859 AKI cases that developed in the community setting within 39 countries from Asia, India, Africa and South America (Table 2).

Table 2 – Number of patients with Community Acquired AKI in the 0by25 Global Snapshot.

REGION	Number of patients
AFRICA	428
LATIN AMERICA & THE CARIBBEAN	305
NORTH & EAST ASIA	410
OCEANIA & SOUTH EAST ASIA	113
SOUTH ASIA	603
<b>Total</b>	<b>1859</b>

The dataset included detailed information on modifiable and non-modifiable risk factors for AKI and the exposures contributing to development of AKI. The frequency of the most common risk factor in community acquired AKI in the setting of the developing countries are described in Table 3.

Table 3 – Causes of AKI in the community acquired setting.

	REGION					
	AFRICA	LATIN AMERICA & THE CARIBBEAN	NORTH & EAST ASIA	OCEANIA & SOUTH EAST ASIA	SOUTH ASIA	
Dehydration	25.9%	18.7%	10.2%	18.6%	14.4%	17.1%
Hypotension and shock	19.9%	35.7%	17.8%	31.0%	21.7%	23.3%
Cardiac Comorbidities	6.5%	9.5%	17.6%	8.8%	4.8%	9.0%
Liver Disease	5.1%	2.6%	3.7%		4.0%	3.7%
Acute kidney diseases	10.5%	5.9%	8.8%	8.0%	15.6%	10.9%
Urinary obstruction	7.5%	9.8%	4.6%	8.0%	5.3%	6.6%
Infections	8.6%	6.9%	16.6%	11.5%	17.1%	13.0%
Pregnancy related	1.9%	.3%		.9%	1.2%	.9%
Systemic diseases	3.0%	3.9%	7.3%	1.8%	2.0%	3.7%
Nephrotoxic agents	7.2%	5.6%	7.6%	5.3%	9.6%	7.7%
Poisoning	.7%	.3%	2.0%	3.5%	1.2%	1.2%
Envenomation			2.7%	.9%	2.2%	1.3%
POST-SURGERY	1.6%	.3%	1.0%	1.8%	.5%	.9%

*Data from ISN 0 by 25 GSN.*

In the first phase of the study we will analyze the most frequent risk factors associated with community acquired AKI in patients from health centers and outpatient. We will categorize the risk as inherent and acquired factors. In inherent risk factors category, we will include patient characteristics and comorbidities. The acquired factors will include diseases and processes of care associated with development of AKI. Patients will be classified as high, medium, and low risk according to the presence of both inherent and acquired factors, just one, or none (see Figure 2). According to this first analysis we will modify the KEEP database to capture enhance data according to the most relevant inherent and acquired risk factors.

The centers that provided more cases from health clinics and community centers will be identified and contact. We have 158 different centers from Africa, Asia, South America and India that provided cases from community acquired AKI in the GSN. We plan to choose 2 to 3 centers in each region and propose the participation in the study. The proposal will include capturing clinical data on non-hospitalized patients in risk of acquiring AKI using the KEEP database and following them through the next clinic visit or hospital admission.

We will work with the physicians and health care providers to prepare and submit IRB documents for each participating center. After getting approval for the study, we will work with health care providers to training to use the KEEP database in different settings.

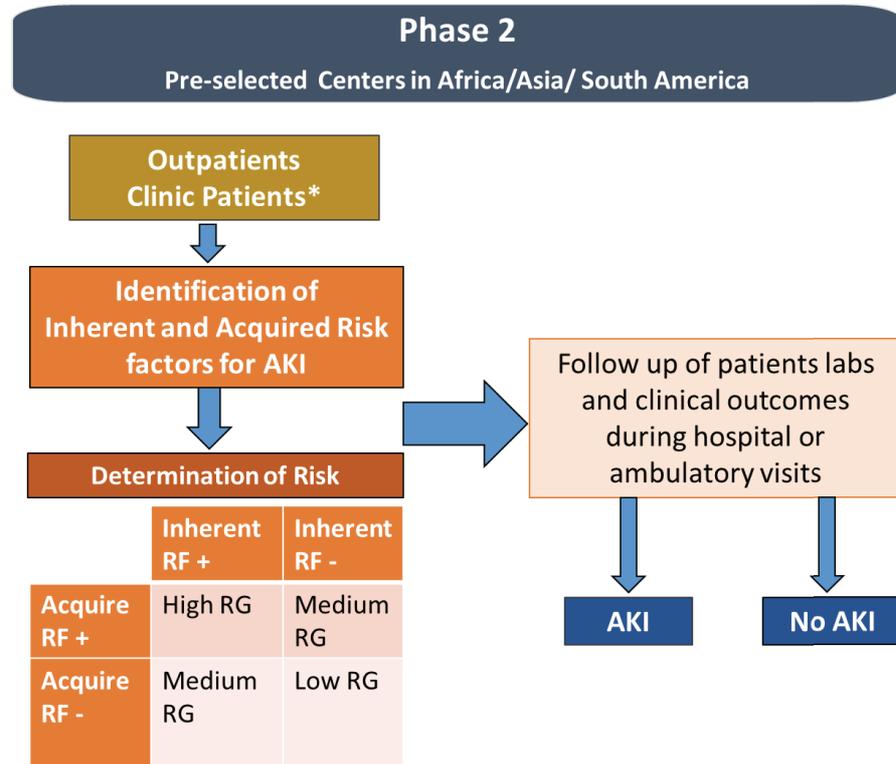
### **Phase 2 – Observation phase** – September 2015 to April 2016

During this phase, we will work with health care providers to guaranty the success in data acquisition, quality, and completeness.

In each participating center, we will determine according to the coordinator a period in which patients will be screened as they present to the clinic or hospital. During this period, inherent and acquired risk factors will be identified and patients will be classified as high, medium, and low risk for developing AKI. Medium and high-risk patients will be flagged and followed during hospital or ambulatory visits (Figure 2). Patients who meet the AKI, or AKD (definitions below) during the follow up will have more detailed data captured. Data will include information on the process of care during

the AKI period, details of renal replacement therapy (indications, modality, operations, dose) and in the post-AKI events, including management, progression, and outcomes.

Figure 2 – Phase 2 study flowchart.



\*Record total # of patients under care of physician on each day

Patient population

Inclusion criteria:

Patients seen by health care providers not receiving chronic dialysis (hemo or peritoneal dialysis), renal transplant recipients and prisoners.

Determination of risk factors:

Inherent risk factor for the development of AKI

- Age > 65
- Chronic kidney disease
- Diabetes mellitus
- Hypertension
- Heart failure/ liver failure

Acquired risk factors:

- Acute illness with:
  - Hypotension or shock

- Gastrointestinal infections
- Genitourinary infections
- Dehydration
- Diarrhea
- Acute use of nephrotoxic drugs (including: aminoglycosides, vancomycin, iodine contrast...)- complete list in the Appendix
- Poisoning
- Envenomation

#### Phase 2-study duration

In this phase, we plan to include 500 patients with high or medium risk for developing AKI. We hope to have complete information, including renal recovery data, on at least 200 patients that developed AKI. We estimate that we will need approximately 8 months to collect this data from the participating centers. During this period, we will keep contact with health care providers in the participating centers to track patient's visits in regional clinics and hospitals.

#### Data collection

All the data will be collected on online Case Report Forms (CRF) accessible on a website and stored on KEEP. Each subject entered will be assigned a random 10 digit number to identify his data so that no personal health information is required and prevents traceability. Providers will only have access to their entered subjects' records. The data coordinating center and the study's principal investigator will have access to all the subjects CRF data.

Completeness of data will be monitored and assessed continuously to detect early problems with the collected data. Data will be assessed for accuracy and corrected if necessary in two distinct methods. All access to protected health information (PHI) as defined by current and future federal standards will be carefully managed.

For each patient, we will have a maximum of 4 CRF to be filled, each including between 5 and 12 questions on a web-based.

CRF 1: Inherent Risk Assessment

CRF 2: Acquired Risk Assessment

CRF 3: Diagnostic and Treatment Information

CRF 4: Outcome information

- Follow up evaluation after AKI
- Dialysis requirement
- Renal recovery / Mortality

Definitions***Reference creatinine***

Most recent serum creatinine available in the last 12 months before presenting event. If the patient does not have a serum creatinine in last 12 months, we will use the initial creatinine as reference and compare to a subsequent creatinine to establish the diagnosis of AKI.

***Suspected AKI***

Oliguria (<200 mL/6 hours) and any AKI-related clinical signs or symptoms listed below or urinalysis/dipstick abnormality. All suspected AKI cases must be confirmed.

AKI-related clinical signs or symptoms: dehydration, diarrhea, vomiting, increased thirst, excessive sweating, fever, any infection, hypotension, weakness, shortness of breath, loss of weight, jaundice, pallor, allergic reaction, swelling, trauma, poisoning, animal/insect bite, pregnancy or delivery related symptoms, poisoning, animal/insect bite, pregnancy or delivery related symptoms.

***Confirmed AKI***

- Increase in SCr by more or equal to 0.3 mg/dl within 48 h or increase to more than 1.5 times baseline, known or presumed to have occurred within the prior 7 d.
- Oliguria – less than 0.5 m/kg/h for 6 hours or less than 30ml/kg in 6 hours

***Acute kidney disease (AKD)***

- GFR less than 60 ml/min per 1.73 m<sup>2</sup> for more than 3 months
- Decrease in GFR by more than 35% or increase in SCr by more than 50% for less than 3 months

Human subjects/Ethics

- Waiver of informed consent from participating institutions or central IRB according to local regulation.
- De-identified data with unique patient ID
- HIPAA compliant database
- A template of IRB application will be available as needed (See appendix).

**Phase 3 – Analytical phase** –May to August 2016

In the analytical phase of the study, we plan to develop the risk score based on the information of patients enrolled in phase 2. After the development of the risk score, we will incorporate it in the web-based platforms and in mobile phones (android and iphones). We estimate that will need 4 months to analyze the data and incorporate the score in applications.

**Phase 4 – Validation phase** (not included in the project proposal budget)

During this phase of the study, we plan to have more centers participating. The CRFs will be adjusted in accordance to the experience during phase 2 in order to facilitate the inclusion of patients' data. We expect to validate the risk score tool in multiple scenarios.

The risk score tool will be make available in a website and mobile applications. Analysis of the gathered data will determine the predictive ability of the tool to assess the course of kidney function in patients at risk for AKI in resource poor settings of LMIC.

In selected centers, we plan to assess the feasibility of using the tool to determine the need for further point of care interventions.

**d. Expected outcomes**

After completion of phase 1 of the study, we expect to determine the most relevant inherent and acquired risk factors for developing community acquired AKI in LMIC. We will hope to be able to categorize patients in high, medium, and low risk for AKI based on these predetermined risk factors. We anticipate that the during this preparation phase unexpected risk factors will be find to be associated with AKI in different regions. We expect to be able to incorporate these risk factors according to the patient region and setting.

During phase 2 we expect to be collect complete information on 500 new patients with high and medium risk for AKI development. We anticipate that some patients will not have point of care laboratory data to evaluate kidney function as a role, but we will follow patients and centers for an undetermined period to try to get renal function information.

During phase 3 we expect to develop a risk score tool that could early identify patients in the community setting in risk of developing AKI. We anticipate that our risk score will be based predominantly on patients' characteristics, comorbidities, and acute as well as chronic exposures. We will develop a score that could predict AKI independently of the assessment of point of care laboratory information. We anticipate that laboratory information will enhance the prediction ability of the risk score, but will not be fundamental to determine risk.

After the development of the risk score, we will be able to provide this tool in web base and mobile platforms. Having the tool available in multiple settings will offer the opportunity to evaluate the predictive ability of the tool to assess the course of kidney function in patients at risk for AKI in resource poor settings of LMIC.

We anticipate that the information provided by this prediction tool will improve health care personnel decision and could be used to help established which patients need point of care labs, or further consultation. This information could be used to create protocols that ultimately would improve patient care and AKI morbid mortality rate.

**e. Description of the Applicant's Institution.**

The UCSD School of Medicine (SOM) has an active clinical program encompassing primary and tertiary patient care for San Diego County. The infrastructure of UCSD research clinical laboratory

Dr. Mehta is a founding member of the AKI network and has access to the membership of this network through his relationships with the PICARD and ADQI network and as the Chair of the ISN committee on AKI. He will also facilitate the interaction among investigators through an established collaborative network that has leveraged the multidisciplinary AKIN group that was established in 2006 to facilitate

Etienne Macedo will work along with the database manager and statistician to facilitate the analysis of GSN database and modify the KEEP ISN 0 by 25 platform. Her clinical expertise in AKI follow up will help the contact with health care providers in the regional centers and their training in the database platform.

**Section C: Relevant references to the project**

1. Mehta RL, Cerdá J, Burdmann EA, Tonelli M, García-García G, Jha V, Susantitaphong P, Rocco M, Vanholder R, Sever MS *et al*: **International Society of Nephrology's Oby25 initiative for acute kidney injury (zero preventable deaths by 2025): a human rights case for nephrology.** *Lancet* 2015.
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**Section E: *Short summary of the project***

In the developing world, there is a need to simply predict who will develop AKI in community settings. Early identification or awareness of the possibility of AKI would permit the implementation of preventive strategies, and implementation of simple and early interventions. A practical simple tool that can predict the likelihood of developing AKI, could be used by all clinicians, in a variety of settings, in the developed and developing world. This tool would also enable strategies for identification of individuals at high risk for AKI and adverse outcomes that would benefit from surveillance and primary prevention and allow selection of high-risk patients most likely to benefit from an intervention.

The project will involve centers from centers of Africa, Asia and South America that captured data on community acquired AKI. We plan to analyze data from AKI patients in the community setting of the developing countries and determine the most important inherent and acquired risk factors associated with AKI in these setting. Our objective is to develop a simple clinical tool to predict the likelihood of developing AKI in community scenarios in the developing world. Our second objective is to assess the predictive performance of the tool to assess the course of kidney function in patients at risk for AKI in resource poor settings of LMIC.

We will contact centers that captured data on health centers and outpatient centers to propose the participation in the development and validation of the risk score. The proposal is to capture clinical data on non-hospitalized patients in risk of acquiring AKI using a web based system database provided by KEEP. We plan to include 500 risk patients for developing AKI. We hope to have complete information, including renal recovery data, on at least 200 AKI patients. We estimate that we will need approximately 8 months to collect this data. After analysis of the database, we plan to develop a clinical risk score to predict the development of AKI in community-acquired patients. After the development of the risk score, we will incorporate it in the web-based platforms and in mobiles phones (android and iPhone). In the last phase of the study, risk score validation, will have more centers include, and the CRFs will be adjusted accordantly to facilitate the inclusion of patients.

*Section F: Informed consent document***Risk Assessment Tool Kit for Community Acquired Acute Kidney Injury**

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I understood the purpose of the study as well as the potential benefits and risks of participating to the study. I had the opportunity to ask questions and my questions have been answered.

I hereby give my Informed Consent to participate to this study. I have been given a copy of this Informed Consent Form.

I understand that, by signing this Informed Consent, I authorize access to my medical records to the monitor(s) and the auditors(s), and possibly to members of the Ethical Committees or Health Authorities, for verification of clinical study procedures and/or data.

I also realize that the information obtained from this study, including the results of all tests upon myself, will be held in both computerized and paper filing systems, although these will not identify me by name.

I understand that I am free to withdraw from the study:

- at any time
- without having to give a reason for withdrawing
- and without affecting my future medical care

Subject/Patient's signature: \_\_\_\_\_

Patient's name: \_\_\_\_\_

**Appendix**

Table 1 - Study Timeline

TASK	2015								2016								
	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	
<b>Phase 1</b>																	
Analysis of GSN centers with community acquired AKI	x	x															
Create web based system to capture the data			x	x													
Contact Centers involved in GSN		x	x	x													
IRB Consent in involved centers			x	x													
Training Centers in the web base					x	x											
<b>Phase 2</b>																	
Data collection from pre-defined centers					x	x	x	x	x	x	x	x					
Assure data quality, completeness and confidentiality					x	x	x	x	x	x	x	x					
<b>Phase 3</b>																	
Develop risk scores for community patients														x	x	x	x
Web based scoring system														x	x	x	x
Mobile applications														x	x	x	x

Table 2 – List of Nephrotoxic Drugs

Acyclovir	Enalaprilat	Mesalamine
Ambisome	Foscarnet	Methotrexate
Amikacin	Gadopentetate dimeglumine	Nafcillin
Amphotericin B	Gadoxetate disodium	Piperacillin/tazobactam
Captopril	Ganciclovir	Piperacillin
Carboplatin	Gentamicin	Sirolimus
Cefotaxime	Ibuprofen	Sulfasalazine
Ceftazidime	Ifosfamide	Tacrolimus
Cefuroxime	Iodixanol	Ticarcillin/clavulanic acid
Cidofovir	Iohexol	Tobramycin
Cisplatin	Iopamidol	Topiramate
Colistimethate	Ioversol	Valacyclovir
Cyclosporine	Ketorolac	Valganciclovir
Dapsone	Lisinopril	Vancomycin
Enalapril	Lithium	Zonisamide

Table 3 – Study Personal

Name	Role
Ravindra L. Mehta	Principal Investigator
Etienne Macedo	Project Leader
Sam Kuo	Database Manager
Jing Zhang	Statistician
Alissar Nabali	Administrative Assistant