

**SURVEILLANCE OF DEVICE ASSOCIATED HOSPITAL ACQUIRED
INFECTIONS IN PATIENTS ADMITTED IN MEDICAL INTENSIVE
CARE UNIT AND MEDICAL HIGH DEPENDENCY UNIT IN A
TERTIARY CARE HOSPITAL IN SOUTH INDIA**



A Dissertation submitted in partial fulfillment of

M.D (General Medicine) branch I Examination of the Tamil Nadu

DR. M.G.R. UNIVERSITY, CHENNAI to be held in 2016.

DECLARATION

I, Dr. Ebenezer Rajadurai . S hereby declare that the dissertation entitled “SURVEILLANCE OF DEVICE ASSOCIATED HOSPITAL ACQUIRED INFECTIONS IN PATIENTS ADMITTED IN MEDICAL INTENSIVE CARE UNIT AND MEDICAL HIGH DEPENDENCY UNIT IN A TERTIARY CARE HOSPITAL IN SOUTH INDIA” is a bonafide original work done by me, towards the M.D. Branch-I (General Medicine) Degree Examination of the Tamil Nadu

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With best wishes,

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Dear Dr. Ebenezer Rajadurai,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Surveillance of Device Associated Hospital Acquired Infections in Patients admitted in Medical Intensive Care Unit (MICU) and Medical High Dependency Unit (MHDU) in CMC Vellore during a 1 year period." on June 9th 2014.

The Committee reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae of Dr. Ebenezer Rajadurai, Dr. Ramya. I, Dr. Nathaniel Samson Devakiruba, Dr. Samuel George Hansdak, Dr. Peter John Victor.
3. Data Collection Sheet
4. Consent form (English, Tamil, Hindi & Telugu)
5. Information Sheet (English, Tamil, Hindi & Telugu)
6. No of documents 1-5

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on June 9th 2014 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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We approve the project to be conducted as presented.

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Fluid Grant Allocation:

A sum of 2,000/- INR (Rupees Two Thousand only) will be granted for 1 year.

Yours sincerely

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AIM

AIM

Surveillance of the incidence of Device associated hospital acquired infection among medical patients admitted in the Medical Intensive Care Unit and Medical High Dependency Unit in a tertiary care hospital from 1st January 2015 to 30th April 2015 using Centre for Disease Control National Health Safety Network (CDC NHSN) Surveillance Program Protocol.

OBJECTIVE

OBJECTIVE

PRIMARY OUTCOME

To study the incidence of Device Associated Hospital Acquired Infection among those patients admitted in the Medical Intensive Care Unit and Medical High Dependency Unit from 1st January 2015 to 30th April 2015 on ventilator, central line and urinary catheter using Centre for Disease Control National Health Safety Network (CDC NHSN) Surveillance Program Protocol.

SECONDARY OUTCOME

Microbiological Outcome – To study the profile of organisms causing device associated hospital acquired infection.

Clinical Outcome – Mortality associated with device associated hospital acquired infection.

REVIEW OF LITERATURE

INTRODUCTION

Modern medicine has seen an increase in patient admission into hospitals due to both communicable and non-communicable diseases. The improvements in medical facilities have facilitated good outcomes of many diseases at the cost of prolonged hospital stay. The critical care units have seen an arithmetic increase in the inpatient beds. This has also seen an increase in the number of hospital acquired infections in the country.

The incidence of hospital acquired infection from the data published by Malhotra et al is 8.78%ⁱ. The criteria used in this study are based on the CDC criteria published in 2008. The incidence of Ventilator associated Pneumonia in the country is 37%ⁱⁱ among patients in intensive care. The incidence of Central line associated blood stream infection was 6.3 per 1000 device days. The incidence of Catheter associated urinary tract infection was 9.08 per 1000 device days.

The studies done in developed countries have shown an incidence of Ventilator associated pneumonia of USA by CDC NHSN criteria was 4.4 per 1000 device days. The incidence of CLABSI by the same criteria was 1.1 per 1000 central line days. The incidence of CAUTI for the year 2014 was 0.7 per 1000 device days.ⁱⁱⁱ This shows that there is a great variability in incidence rates of device associated

countries among various countries especially the developed and developing countries.

The common organisms causing Ventilator associated Pneumonia in USA is Pseudomonas (24%) followed by Staph aureus (20.4%) and then streptococcal species followed by Enterobacteriaceae (14.4%).^{iv} In India the common organism is Acinetobacter species (41.03%) followed by other gram negative bacilli^v. The common organism associated with Central line associated blood stream infection in US is Staphylococcus aureus whereas in India it is most commonly Enterobacteriaceae. These data show that the common organisms causing Ventilator associated pneumonia and also the other hospital acquired infection vary greatly between nations and also between centers. A standardized surveillance criteria in each critical care unit is required to monitor device associated infections and also the causative organisms to initiate appropriate preventive strategies.

The previous CDC guidelines for monitoring hospital acquired infections were revised in 2013. The CDC had noted that even in hospitals within its National Health Survey Network had difficulty in reporting Ventilator associated pneumonia as it had required interpretation of Chest radiograph which is not accurate and was biased by the interpreter. The previous CDC guidelines also had clinical criteria which were subjective and so made it difficult for uniform

reporting. All this resulted in varied reporting and also incidence rates within the network.^{vi} It is for this reason that CDC has revised its criteria to make it objective. The new CDC criteria published in 2013 incorporate all these changes. In this dissertation I have used the new CDC criteria which report Ventilator associated events.

The dissertation attains significance as it has initiated a new surveillance in place in the hospital and it has used the new CDC NHSN criteria published in 2013 which have standardized monitoring of device associated hospital acquired infections using objective criteria. The dissertation and the results of the same will be helpful in initiation of intervention strategies and monitoring the outcome by means of incidence of device associated infection and also the causative organism profile.

HEALTHCARE ASSOCIATED INFECTION

Healthcare associated infection in any infection is defined as an infection that a person contracts after the person is admitted to the hospital. The infection is not present at the time of admission of the person into the hospital. The infection is acquired by the patient after the patient is admitted into the medical facility. The term is not used for medical personnel who contract the infection during the course of their work when it will be known as an occupational disease.^{vii}

Healthcare associated infection is usually taken after a period of stay within the hospital. The time period of 48 hours is usually taken as a standard guide to classify a person as having hospital acquired infection.^{viii}

The burden of hospital acquired infections have forced various international organizations like World Health Organization to study and release guidelines towards prevention of them.^{ix}

The burden of hospital acquired infections is so high in the population that the incidence of 8.7% was found among all the hospitalized patients in multinational multicentre study that was coordinated by the World Health Organization. The

study had shown that on an average about 1.4 million people on a global level have hospital acquired infections.^x

The incidence of hospital acquired infections was studied in various studies which were conducted individually in various parts of the world. The study among the eastern Mediterranean population had shown that the incidence of hospital acquired infection in the population was around 11.8%. The studies done among the southeastern Asian countries which are mostly developing countries on an economic basis have shown that the incidence of device associated hospital acquired infections was 10%. This incidence was much higher when compared to the value of 7.7 % in European countries.^{xi}

The costs involved in the management of the device associated infections are prohibitive. They cause a huge economic burden on the countries that suffer from the device associated hospital acquired infections. The cost of hospital acquired infection in the United States alone was 35-45 billion US dollars after adjusting for the consumer price index. The economic burden can be reduced up to a maximum of 80% by following surveillance and implementing newer infection control techniques^{xii}. The Economic burden in United Kingdom is 1.06 billion pounds.^{xiii}

Surveillance remains the cornerstone of management of hospital acquired infections. The various features of an ideal surveillance program are illustrated in the figures below. The surveillance program involves Doctors and Nurses. The program involves training staff for surveillance and educating the on floor staff including doctors, nurses and housekeeping staff about sterile techniques in prevention of hospital acquired infection.

It is important to keep people as the centre of attention. It is illustrated in the following box 1.

Box 1

People are at the centre of the phenomenon:

- as main reservoir and source of microorganisms
- as main transmitter, notably during treatment
- as receptor for microorganisms, thus becoming a new reservoir.

Desired Characteristics of Hospital acquired infection surveillance program: Box

2

Box 2 ^{xiv}

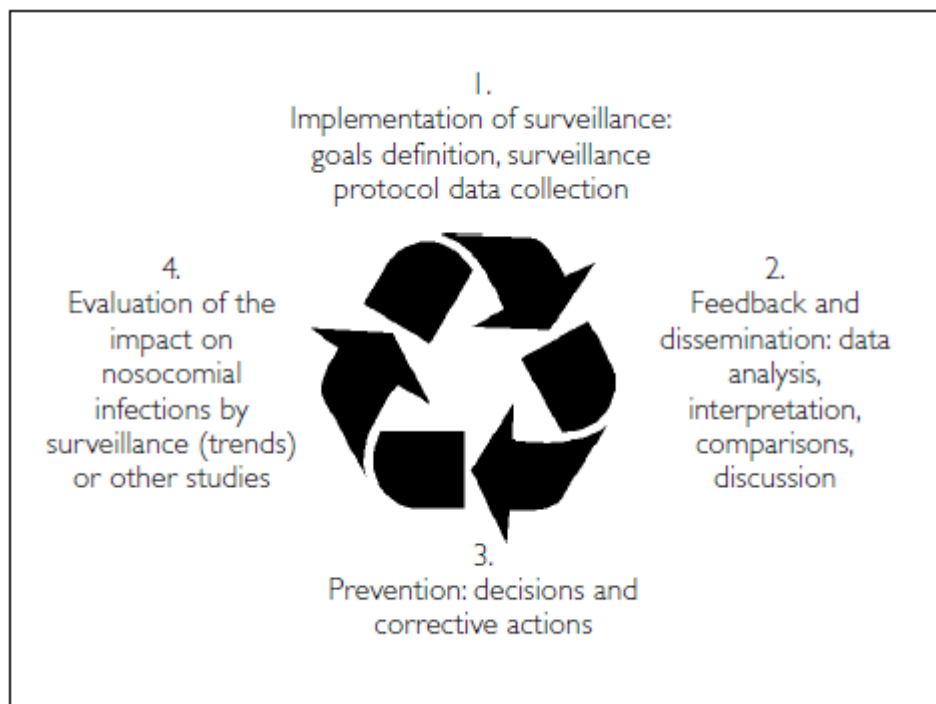
Characteristics of the system:

- timeliness, simplicity, flexibility
- acceptability, reasonable cost
- representativeness (or exhaustiveness)

Quality of the data provided:

- sensitivity, specificity
 - predictive value (positive and negative)
 - usefulness, in relation to the goals of the surveillance (quality indicators)
-

Box 3: Surveillance is a continuous circular process that continues even after intervention to monitor the impact of the preventive measures.



The key features of a good Surveillance study is illustrated in the following box

4.

Box 4: Features of good surveillance study

-
- Active surveillance (prevalence and incidence studies)
 - Targeted surveillance (site-, unit-, priority-oriented)
 - Appropriately trained investigators
 - Standardized methodology
 - Risk-adjusted rates for comparisons
-

VENTILATOR ASSOCIATED PNEUMONIA

Ventilator associated pneumonia is described as the occurrence of hospital acquired infection in patients who have been intubated and connected to a ventilator and have developed infection secondary to the device.

The important points to note is that the patient should not have had the infection at the time of admission into the setup and also the patient should have been on the ventilator for sufficient amount of time before he had developed the infection. The duration after which the patient is said to have developed the ventilator associated pneumonia is taken as 48 hours in most criteria.^{xv}

The epidemiology of device associated infections varies greatly between countries and also between various centers within the country. The incidence of ventilator associated pneumonia in the United States of America as estimated by the Centre for disease control criteria was 4.4 per 1000 ventilator days.^{xvi} The incidence of ventilator associated pneumonia in India as reported in a study in south India which was found to be 30.6 per 1000 ventilator days.^{xvii} The incidence of ventilator associated pneumonia in a hospital in north India was found to be 31.7 per 1000 device days as per previous guidelines.^{xviii}

The incidence in other centers around the country also varied. Most centre report in the form of number of device days whereas others report in the form of percentages.^{xix} The incidence rates also vary among developed countries. The incidence in the United Kingdom was found to be 9.2 per 1000 device days.^{xx} The incidence in France was found to be 20.6 per 1000 device days.^{xxi}

This varied incidence of device associated infections between centres's can be secondary to difference in the criteria they use like the CDC criteria or the ECDC criteria. It can also be due to difference in presentation and prevalence of organisms. The difference between temperate and tropical climates the difference can also be due to the economical condition of the countries and the specialized sterile techniques they might be following.

The evaluation of Ventilator associated pneumonia varies because even within India there have different scales used in different study. The clinical pulmonary infection severity scale (CPIS) is one such scale. The other method for surveillance is the modified Centre for disease control National Health Survey Network guidelines.

Clinical Pulmonary Infection Score (CPIS) is one of the most widely used methods for diagnosis. It was initially put forward in 1991 and it uses a combination of weighted clinical and microbiological criteria for the diagnosis of VAP. Box 5 illustrates the same.

Box 5: CLINICAL PULMONARY INFECTION SCORE

Clinical Parameter	Points
Temperature (°C)	
≥ 36.5 and ≤ 38.4	0
≥ 38.5 and ≤ 38.9	1
≥ 39.0 or ≤ 36.0	2
Blood leukocytes (x 10 ³ /mm ³)	
≥ 4 and ≤ 11	0
< 4 or > 11	1
Band forms ≥ 50%	Add 1
Tracheal secretions	
Absent	0
Nonpurulent	1
Purulent	2
Oxygenation: PaO ₂ :FiO ₂ (mm Hg)	
> 240 or ARDS	0
≤ 240 and no evidence of ARDS	2
Infiltrate on pulmonary radiography	
None	0
Diffuse or patchy	1
Localized	2
Pathogenic bacteria on tracheal-aspirate culture	
Rare, light quantity, or no growth	0
Moderate or heavy quantity	1
Also seen on Gram's stain	Add 1

PaO₂ = arterial partial pressure of oxygen; FiO₂ = fraction of inspired oxygen; ARDS = acute respiratory distress syndrome.

A study done to assess the accuracy of the CPIS score showed a sensitivity of 45.8% and specificity of 60.4%, when used at a cut off value of 6, and using autopsy findings as the gold standard. Earlier studies showed variability in sensitivity and specificity ranging from 72% to 77% and 85% to 42% respectively. In addition, this score was found to be subjective, with high inter observer variability (kappa-0.16). The drawbacks of poor sensitivity and subjectivity of the scoring system has prompted a re-look at how we diagnose ventilator associated pneumonias.^{xxiixxiii}

The Centre for disease control national health survey network criteria also known as the NHSN criteria is a new tool for the surveillance of device associated hospital acquired infections. The criteria are different from the previous CDC criteria as it does not include the X ray findings in the diagnosis of Ventilator associated pneumonia.^{xxiv}

The new CDC NHSN criteria for the diagnosis of Ventilator associated pneumonia is illustrated in the following figures.

BOX 6. VENTILATOR ASSOCIATED CONDITION

Patient has a baseline period of stability or improvement on the ventilator, defined by ≥ 2 calendar days of stable or decreasing daily minimum* FiO_2 or PEEP values. The baseline period is defined as the 2 calendar days immediately preceding the first day of increased daily minimum PEEP or FiO_2 .

*Daily minimum defined by lowest value of FiO_2 or PEEP during a calendar day that is maintained for at least 1 hour.

AND

After a period of stability or improvement on the ventilator, the patient has at least one of the following indicators of worsening oxygenation:

- 1) Increase in daily minimum* FiO_2 of ≥ 0.20 (20 points) over the daily minimum FiO_2 in the baseline period, sustained for ≥ 2 calendar days.
- 2) Increase in daily minimum* PEEP values of ≥ 3 cmH_2O over the daily minimum PEEP in the baseline period[†], sustained for ≥ 2 calendar days.

*Daily minimum defined by lowest value of FiO_2 or PEEP during a calendar day that is maintained for at least 1 hour.

[†]Daily minimum PEEP values of 0-5 cmH_2O are considered equivalent for the purposes of VAE surveillance.

BOX 7. INFECTION RELATED VENTILATOR ASSOCIATED
COMPLICATION

Patient meets criteria for VAC

AND

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, the patient meets both of the following criteria:

1) Temperature $> 38^{\circ}\text{C}$ or $< 36^{\circ}\text{C}$, **OR** white blood cell count $\geq 12,000$ cells/ mm^3 or $\leq 4,000$ cells/ mm^3 .

AND

2) A new antimicrobial agent(s)* is started, and is continued for ≥ 4 calendar days.

*See [Appendix](#) for eligible agents.

BOX 8. POSSIBLE VENTILATOR ASSOCIATED PNEUMONIA

Patient meets criteria for VAC and IVAC

AND

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, ONE of the following criteria is met:

- 1) Purulent respiratory secretions (from one or more specimen collections)
 - Defined as secretions from the lungs, bronchi, or trachea that contain ≥ 25 neutrophils and ≤ 10 squamous epithelial cells per low power field [lpf, x100].
 - If the laboratory reports semi-quantitative results, those results must be equivalent to the above quantitative thresholds.
 - See additional instructions for using the purulent respiratory secretions criterion in the VAE Protocol.

OR

- 2) Positive culture (qualitative, semi-quantitative or quantitative) of sputum^{*}, endotracheal aspirate^{*}, bronchoalveolar lavage^{*}, lung tissue, or protected specimen brushing^{*}

^{*}Excludes the following:

- Normal respiratory/oral flora, mixed respiratory/oral flora or equivalent
- *Candida* species or yeast not otherwise specified
- Coagulase-negative *Staphylococcus* species
- *Enterococcus* species

BOX 9: PROBABLE VENTILATOR ASSOCIATED PNEUMONIA

Patient meets criteria for VAC and IVAC

AND

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, ONE of the following criteria is met:

1) Purulent respiratory secretions (from one or more specimen collections—and defined as for possible VAP)

AND one of the following (see Table 2):

- Positive culture of endotracheal aspirate*, $\geq 10^5$ CFU/ml or equivalent semi-quantitative result
- Positive culture of bronchoalveolar lavage*, $\geq 10^4$ CFU/ml or equivalent semi-quantitative result
- Positive culture of lung tissue, $\geq 10^4$ CFU/g or equivalent semi-quantitative result
- Positive culture of protected specimen brush*, $\geq 10^3$ CFU/ml or equivalent semi-quantitative result

*Same organism exclusions as noted for Possible VAP.

OR

2) One of the following (without requirement for purulent respiratory secretions):

- Positive pleural fluid culture (where specimen was obtained during thoracentesis or initial placement of chest tube and NOT from an indwelling chest tube)
- Positive lung histopathology
- Positive diagnostic test for *Legionella* spp.
- Positive diagnostic test on respiratory secretions for influenza virus, respiratory syncytial virus, adenovirus, parainfluenza virus, rhinovirus, human metapneumovirus, coronavirus

The CDC guidelines have defined Ventilator associated condition as the event that occurs after 48 hours of admission and it usually results in increase in the ventilator parameters as mentioned in the Box 6.

Infection related Ventilator associated complication is a condition that has a worsening of the ventilator parameters and there also presence of clinical and laboratory evidence of infection. The presence of hyperthermia or hypothermia or the presence of leukocytosis or leucopenia along with a new antibiotic being started is the diagnostic criteria for this condition. Box 7 illustrates the same.

Possible Ventilator associated pneumonia as illustrated by the box 9 is the presence of purulent secretions or positive culture. Probable Ventilator associated pneumonia is the presence of purulent secretions and positive cultures with clinically relevant colony counts. The study also includes diagnosis by histopathology and also other detection techniques for viruses.

PATHOPHYSIOLOGY OF VENTILATOR ASSOCIATED PNEUMONIA

The pathophysiology of ventilator associated pneumonia involves the endotracheal tube serving as a bypass to the mucociliary defense mechanism. The endotracheal tube bypasses the mucociliary defense mechanism which involves clearing of particles by the cilia and also the humidification of inspired air by the nostrils. This provides a direct entry of organisms into the bronchus and the lungs.^{xxv}

The trachea also becomes a source of biofilm which consists of mucous and also the microorganisms colonizing the surface of the endotracheal tube. These organisms can subsequently enter the bronchus and lungs and cause ventilator associated pneumonia.

The use of humidifiers from external sources can also serve as a way of entry of the microorganisms if they are not sterilized in a prescribed manner.^{xxvi}

PREVENTION OF VENTILATOR ASSOCIATED PNEUMONIA

Ventilator associated pneumonia can be prevented by various preventive strategies.

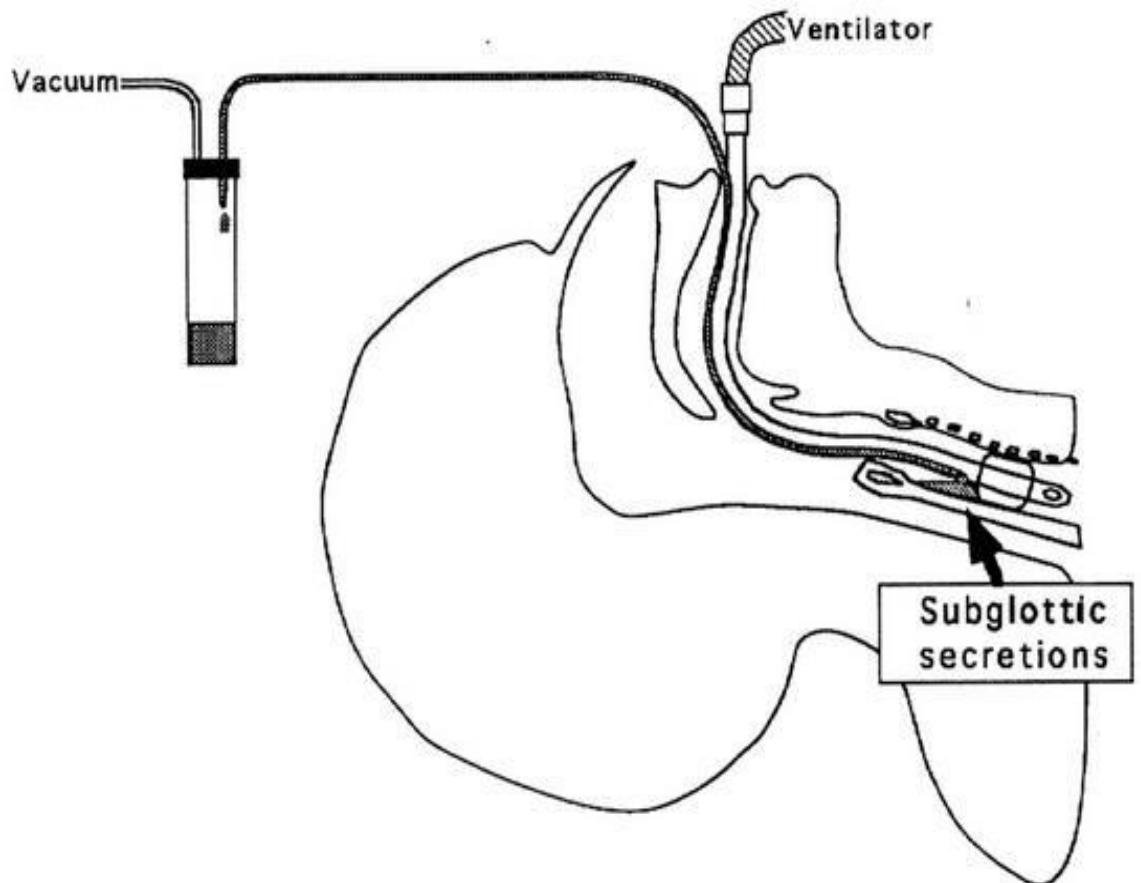
The use of closed suctioning of the endotracheal tube has shown to reduce the contact of the care giver and the endotracheal tube and so to reduce the incidence of ventilator associated pneumonia.^{xxvii}

The positioning of patient to adequately clear bronchial secretions and good chest physiotherapy will prevent orthostatic pneumonia and ventilator associated pneumonia.^{xxviii}

The use of subglottic suction is also shown to prevent pooling of secretions and colonization of the external tracheal surface. It also prevents development of ventilator associated pneumonia.^{xxix}

Strict isolation of patients with multidrug resistant organisms is also prescribed but studies are yet to demonstrate better outcomes with the same. The universally accepted method is to use strict patient to patient barrier with hand washing.

FIGURE 1: SUBGLOTTIC SUCTION



A FIGURE DEMONSTRATING SUBGLOTTIC SUCTION AS A TECHNIQUE OF REDUCING VENTILATOR ASSOCIATED EVENTS BY REMOVING SUBGLOTTIC SECRETIONS.

CENTRAL LINE ASSOCIATED BLOOD STREAM INFECTION

Epidemiology

Central venous catheters (CVC) are being used with increasing frequency in hospitals both in an ICU setting as well as outside ICU's. The infection of these CVC's is becoming an increasingly large problem worldwide. The incidence of central line infections in the USA is estimated to be 1.65 per 1000 central line days amounting to 23,000 infection events.^{xxx} This number is higher in the developing countries, with a large surveillance study conducted among ICU's in Latin America, Asia, Africa and Europe reporting a pooled rate of 6.8 per 1000 central line days.^{xxx}. Studies done in India have also reported infection rates ranging from 8.75-9.6 per 1000 central line days.^{xxxii}

One possible reason for the increased incidence in the developing countries is the lack of strict adherence to aseptic precautions during insertion of the lines, as well as the lack of clearly defined central line care bundles.

Clinical features

The importance of CRBSI is evident from the increased mortality that it causes, with one recent systematic review estimating almost two fold increased risk of mortality among those with CRBSI, even after matching for severity of illness. Another study 39 estimated an increase in ICU stay by 13 days in those with CRBSI and a crude mortality rate of 28%.^{xxxiii}

Risk factors

The risk factors for CRBSI can be classified a patient, personnel and device related factors.

The patient related factors include the degree of severity of the underlying illness, immunosuppression especially granulocytopenia, malnutrition, loss of integrity of skin especially in burns.^{xxxiv}

Operator related factors include degree of adherence to aseptic technique during placement of the line, as well as catheter site care.

Catheter related factors are the site of placement of the line, the duration of the line and characteristics of the line such as the material, number of lumens etc.^{xxxv}

Definitions:

The NHSN monitors the CRBSI, and publishes data on the yearly incidence of CRBSI.

The surveillance definition used by the NHSN is:

“Isolation of a recognized pathogen from blood culture(s), the presence of clinical signs of sepsis and/or shock (e.g., fever, chills, or hypotension), a determination that the infection is not from other sources, and confirmation that the organism is not a contaminant”^{xxxvi}

Diagnostic criteria and methods

Although the above definition serves as a useful guide, the clinical diagnosis of a catheter related infection still remains difficult because the clinical signs of inflammation at the catheter site are specific but not sensitive, and hence may not always be present. Secondly the clinical signs of systemic inflammation are very nonspecific and can be caused due to a host of other reasons, especially in a critically ill patient.

For a patient with a suspected CRBSI, paired blood samples drawn from both the central line and a peripheral vein must be labeled and sent to the laboratory. One study demonstrated that if samples were not drawn from all the lumens of a multi-lumen catheter, then the infection could be missed in almost 30% of the

patients. If a sample cannot be obtained from the central line, then two or more samples need to be taken from the catheter lumen and sent for culture. However, the need for cultures from all the lumens is not well defined in this setting.

Numerous methods for the diagnosis of CRBSI are available, with some necessitating catheter removal for facilitation of diagnosis, and other newer methods where the catheter can remain in place.^{xxxvii}

CATHETER ASSOCIATED URINARY TRACT INFECTION

Catheter associated urinary tract infection is defined by CDC NHSN criteria as urinary infection associated with clinical symptoms of fever and associated loin or suprapubic pain along with pyuria . The urine culture from the patient should grow significant colonies of the pathogen.^{xxxviii}

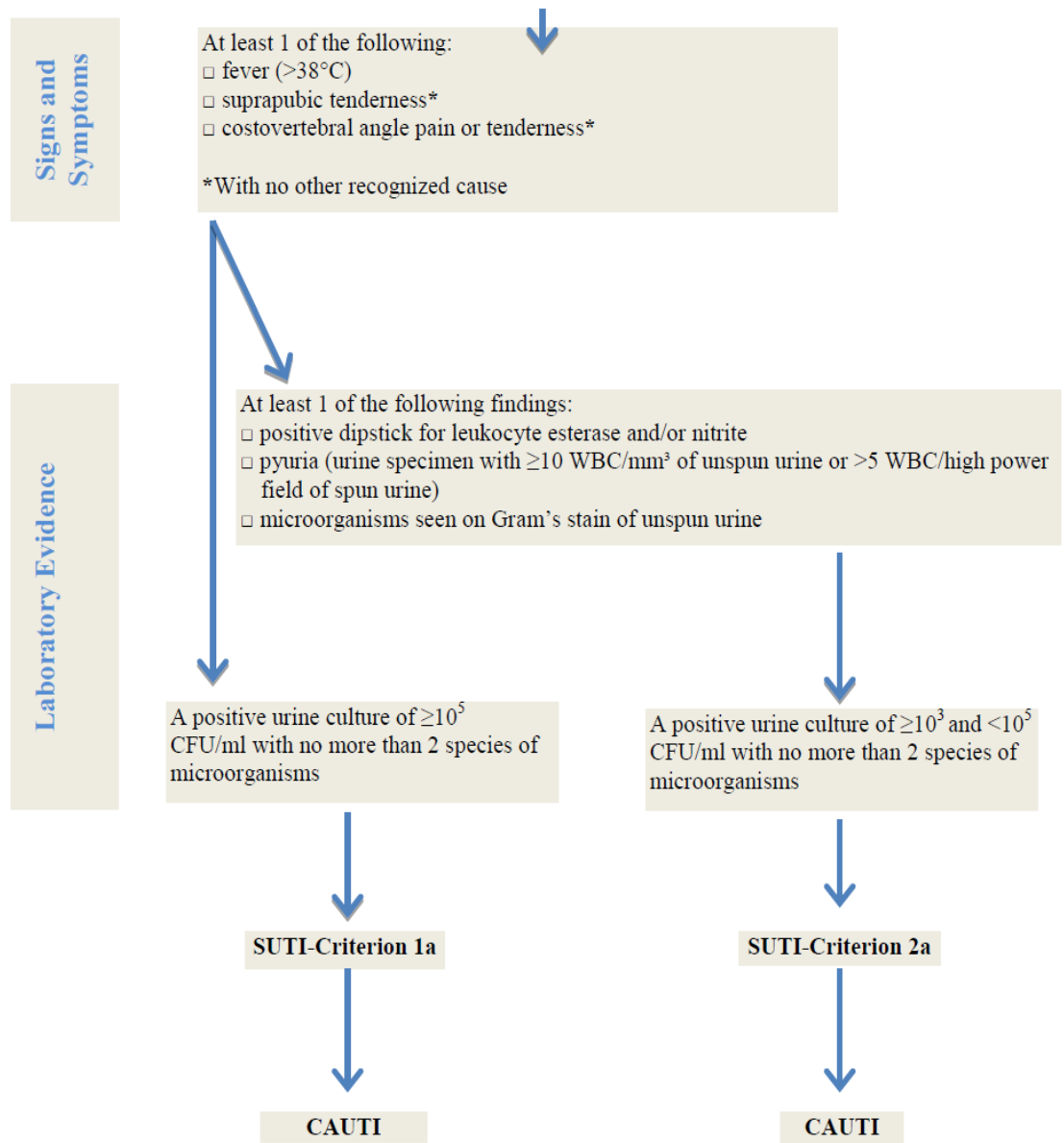
Urine infection secondary to urinary catheter in ICU is encountered either due to colonization or due to an infection. There can be formation of biofilm on the catheter which can penetrate the uroepithelium during micro abrasions during the ICU stay. There can also be poor handling of the catheters causing urinary infections.^{xxxix}

The incidence of Catheter associated urinary tract infection according to CDC NHSN criteria was found to be 0.7 per 1000 urinary catheter days.^{xl} Indian data has shown the incidence of Catheter associated urinary tract infection to be 9.8 per 1000 device days.^{xli}

The incidence of the catheter associated urinary tract infection involves various definitions leading to non standardization of the data. This study used the CDC NHSN criteria 2013.

BOX 10: CAUTI CDC CRITERIA

Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place on the date of event. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.



MATERIALS AND METHODS

This study is a prospective cohort study

All patients above 14 years of age admitted in Intensive Care Units (Medical Intensive care unit and Medical High Dependency unit) who develop a hospital acquired infection.

The Patients were studied for Ventilator associated Events, Central line associated blood stream infections and Catheter associated urinary tract infection.

SETTING

The setting of the study is a tertiary care centre. The patients admitted in the Medical Intensive Care Unit and Medical High Dependency Unit are critically ill patients who have shifted into the Intensive care unit from the emergency services or from medical wards. The patients are usually intubated for invasive ventilation. The setting has both open and closed suction systems to clear secretions from the endotracheal tube. The patients are also on urinary catheter after they are intubated in the intensive care unit. Since most of the patients are sick and require ionotropes they require central lines. The type of central lines used are triple lumens which are placed either as subclavian , jugular or femoral catheters.

The patients studied are critically ill patients requiring support through devices and are at high risk for hospital acquired infections and are ideal for a surveillance program.

PARTICIPANTS

The participants in the study were medical patients who were admitted from wards and from emergency into the Medical Intensive care unit and Medical High Dependency unit from January 1, 2015 to April 30, 2015 .

INCLUSION CRITERIA

All medical patients admitted from Emergency services or medical wards into Medical Intensive care or high dependency unit above the age of 14 years.

EXCLUSION CRITERIA

Patients below the age of 14 years

Patients not admitted under the medical units

Patients or relatives not willing to give consent for the study

METHODOLOGY

The study was presented as a proposal before the Institutional review board and the elite panel had personally interviewed the principal investigator and the dissertation guide before approving the study methodology and approving patient recruitment.

CASE ASCERTAINMENT

All patients who were admitted in the Medical Intensive care unit or the medical high dependency unit were included. The Patients usually arrive from the Emergency services or the Medical ward if they are clinically and by laboratory parameters found to be critically ill requiring Intensive care. The patients and relatives were discussed regarding the study on hospital acquired infections and their consent was obtained.

The study was carried out daily at 11pm by the principal investigator in the intensive care unit as this was the time when patient census is usually taken in the Intensive care unit and the variation in the numbers are minimum. The principal investigator carried out the consent procedure. The principal investigator also collected the demographic details, the associated co morbidities and the data according to the Centre for disease control National Health Survey Network

criteria. The patients were then observed everyday at around 1 pm for clinical symptoms and signs that they developed during the day and note was made. The patients were followed up to 2 days after discharge from Intensive care unit. The culture reports of all the patients were also followed up by the principal investigator.

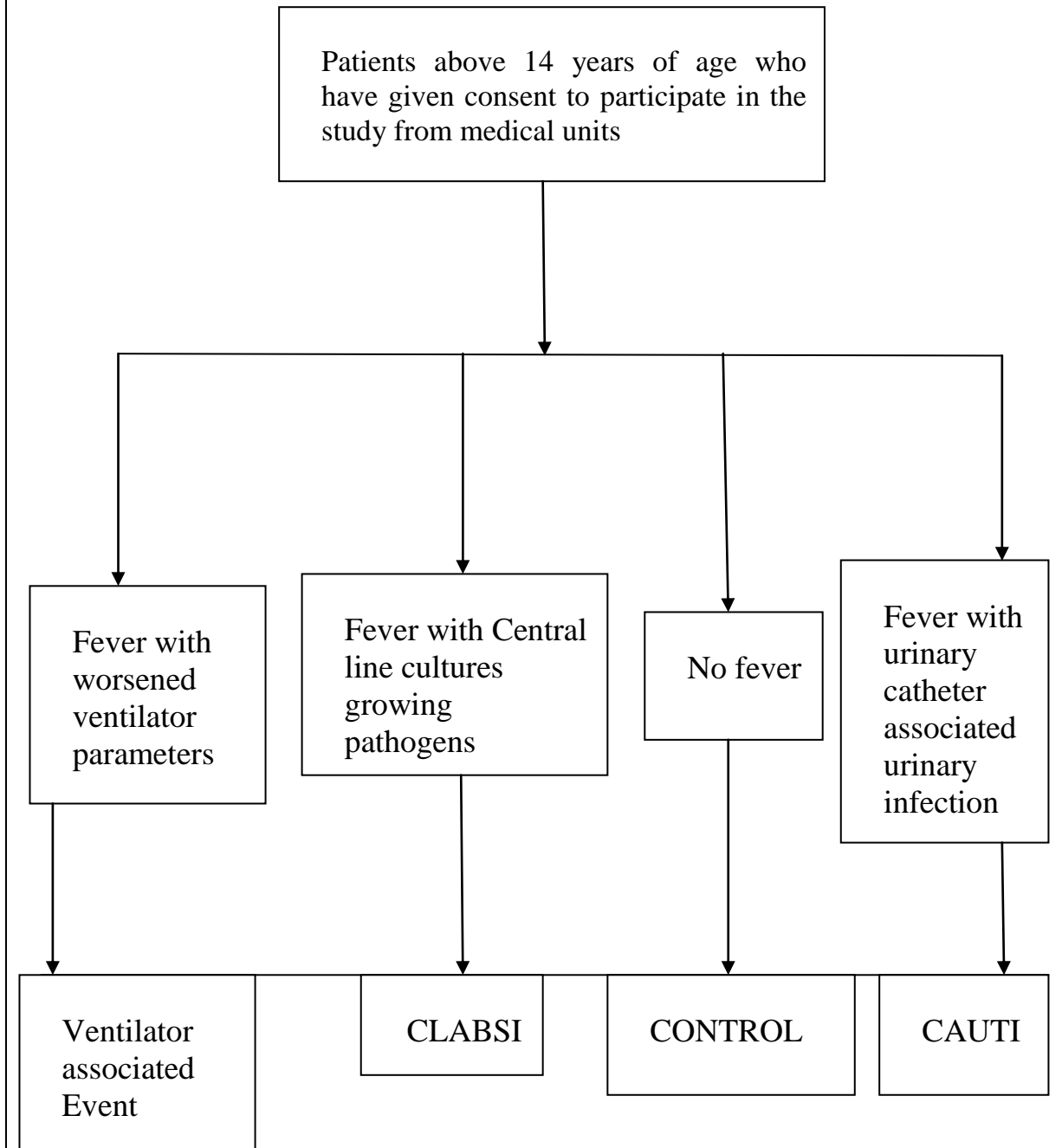
The demographic details of all patients were collected. All patients had a detailed history and examination done. The associated co morbidities of the patients were studied. They were also noted. The patients were monitored daily at a specific time. The records were studied for any fever or urinary symptoms. A note of the total and differential white blood cell counts of the patients was made. The patient was subsequently monitored according to the new centre for disease control criteria.

If the patient had fever after two days of admission and also had purulent sputum and had an increase in the ventilator setting in the form of increase in Peak end expiratory pressure of 3 cm of water or the fractional oxygen of 20 percentage along with an increase in the white blood cell count then they were considered to have a infected ventilator associated event. The patient had an endotracheal aspirate done and that was followed up for purulent sputum as indicated by the

leukocytes and less epithelial cells and also for the sputum culture. In case the patient was culture positive then ventilator associated pneumonia was diagnosed.

In case the patient has fever and also has an infected central line then the diagnosis of central line associated blood stream infection is made.

In case of the patient having urinary complaints with associated loin pain and the urine is showing pyuria along with the urine culture being positive for pathogens then the person is diagnosed to have catheter associated urinary tract infection.

FIGURE 2: ALGORITHM FOR STUDY METHODOLOGY

VENTILATOR ASSOCIATED EVENT

A Medical patient who has given consent to participate in the study is monitored daily for any fever. The fever is considered to be hospital acquired only if the fever develops after the second day of admission. Any fever that develops before the second day of admission is due to the pre existing illness or due to infection from a ward or hospital that the patient had been admitted into before his arrival into the Medical Intensive care unit or high dependency unit. After the second day any fever that the patient develops is recorded. The associated symptoms and signs are noted.

In case there is an increase in the ventilator setting with an increase in peak end expiratory pressure above 3 cm of water or the increase in fraction of inspired oxygen increases by 20% then the patient is considered to have developed a Ventilator associated condition.

If the patient has developed ventilator associated condition and there is presence of hyperthermia as noted by a temperature above 38 C or hypothermia as noted by a temperature of 36 C or if there is leukocytosis with an increase in WBC count of above or equal to 12000 cells per mm³ or leucopenia with a WBC counts of less than 4000 cells per mm³ and an antibiotic was started and

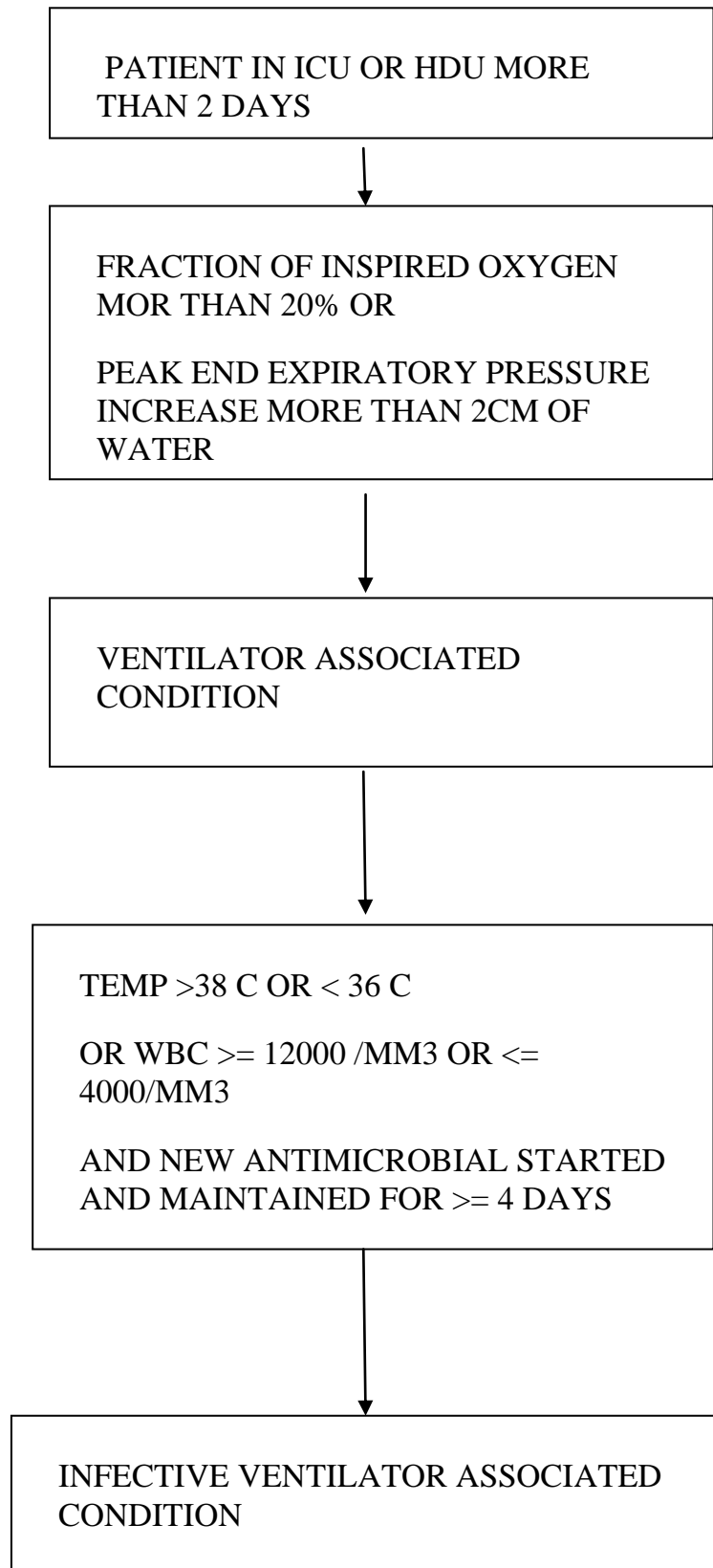
continued for more than four days then it is considered as a Infective ventilator associated condition.

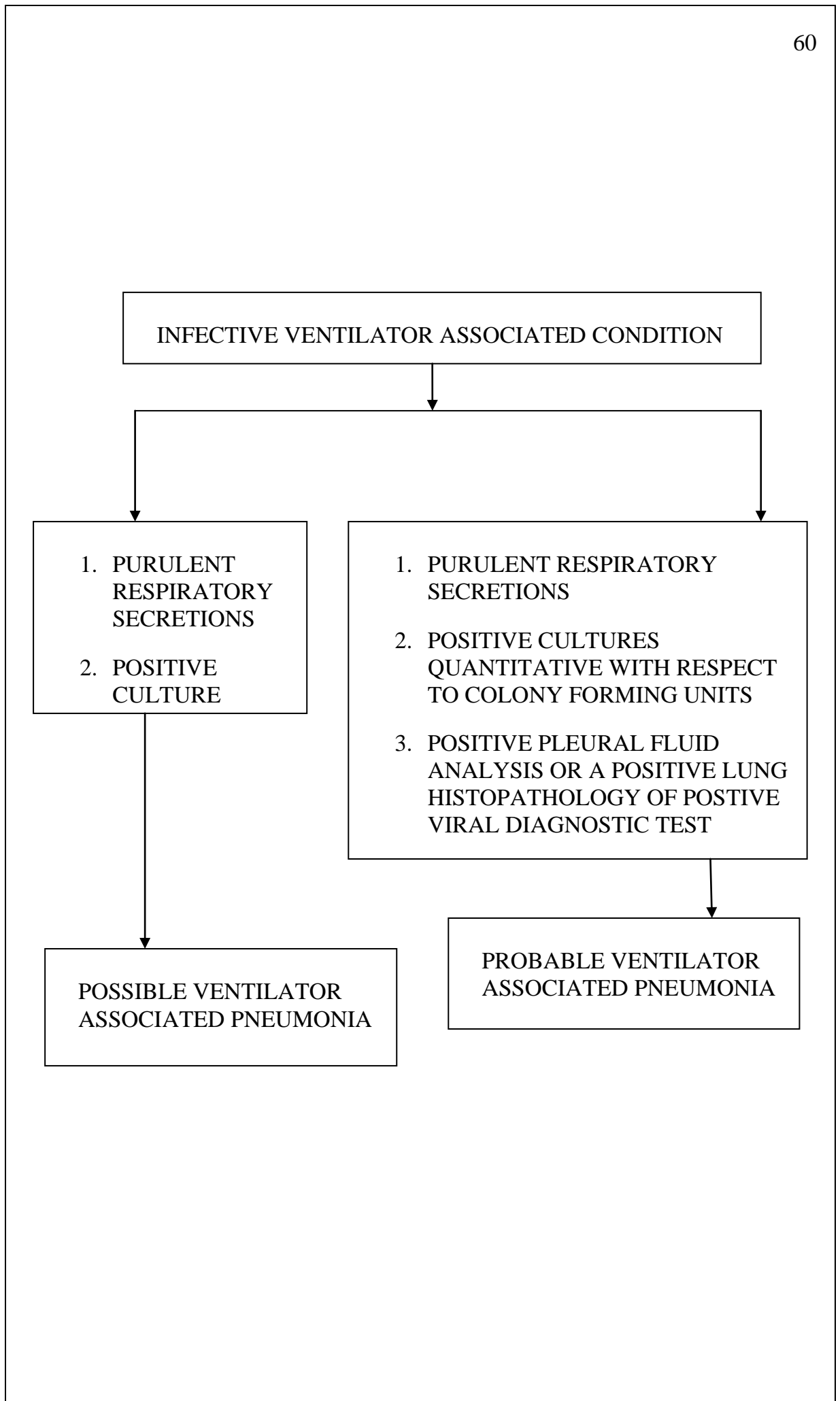
The patient with infective ventilator associated condition is monitored for any purulent sputum. This is monitored by sputum examination which shows more than or equal to 25 neutrophils and less than 10 epithelial cells. There is also a positive qualitative culture. If this criterion is fulfilled then it is known as Possible Ventilator Associated Pneumonia.

The patient with infective ventilator associated condition who has purulent respiratory secretions which shows more than or equal to 25 neutrophils and less than 10 epithelial cells and also a quantitative culture which shows more than 10^5 colony forming units in the endotracheal aspirate or more than 10^4 colonies in the bronchioalveolar lavage or biopsy of lung tissue or more than 10^3 colony forming units in the brush specimen of the specimen is taken as Probable ventilator associated pneumonia.

Probable ventilator associated pneumonia is also considered is there is a positive pleural fluid culture when the culture is obtained by procedure such as thoracocentesis. A positive lung histopathology is also considered as probable ventilator associated pneumonia. When tests are positive for diagnosis of legionella also it is considered as Probable ventilator associated pneumonia. A

positive serological testing for RSV is also considered as Probable ventilator associated pneumonia.

FIGURE 3: ALGORITHM OF VENTILATOR ASSOCIATED EVENT



INFECTIVE VENTILATOR ASSOCIATED CONDITION

1. PURULENT RESPIRATORY SECRETIONS
2. POSITIVE CULTURE

POSSIBLE VENTILATOR ASSOCIATED PNEUMONIA

1. PURULENT RESPIRATORY SECRETIONS
2. POSITIVE CULTURES QUANTITATIVE WITH RESPECT TO COLONY FORMING UNITS
3. POSITIVE PLEURAL FLUID ANALYSIS OR A POSITIVE LUNG HISTOPATHOLOGY OF POSTIVE VIRAL DIAGNOSTIC TEST

PROBABLE VENTILATOR ASSOCIATED PNEUMONIA

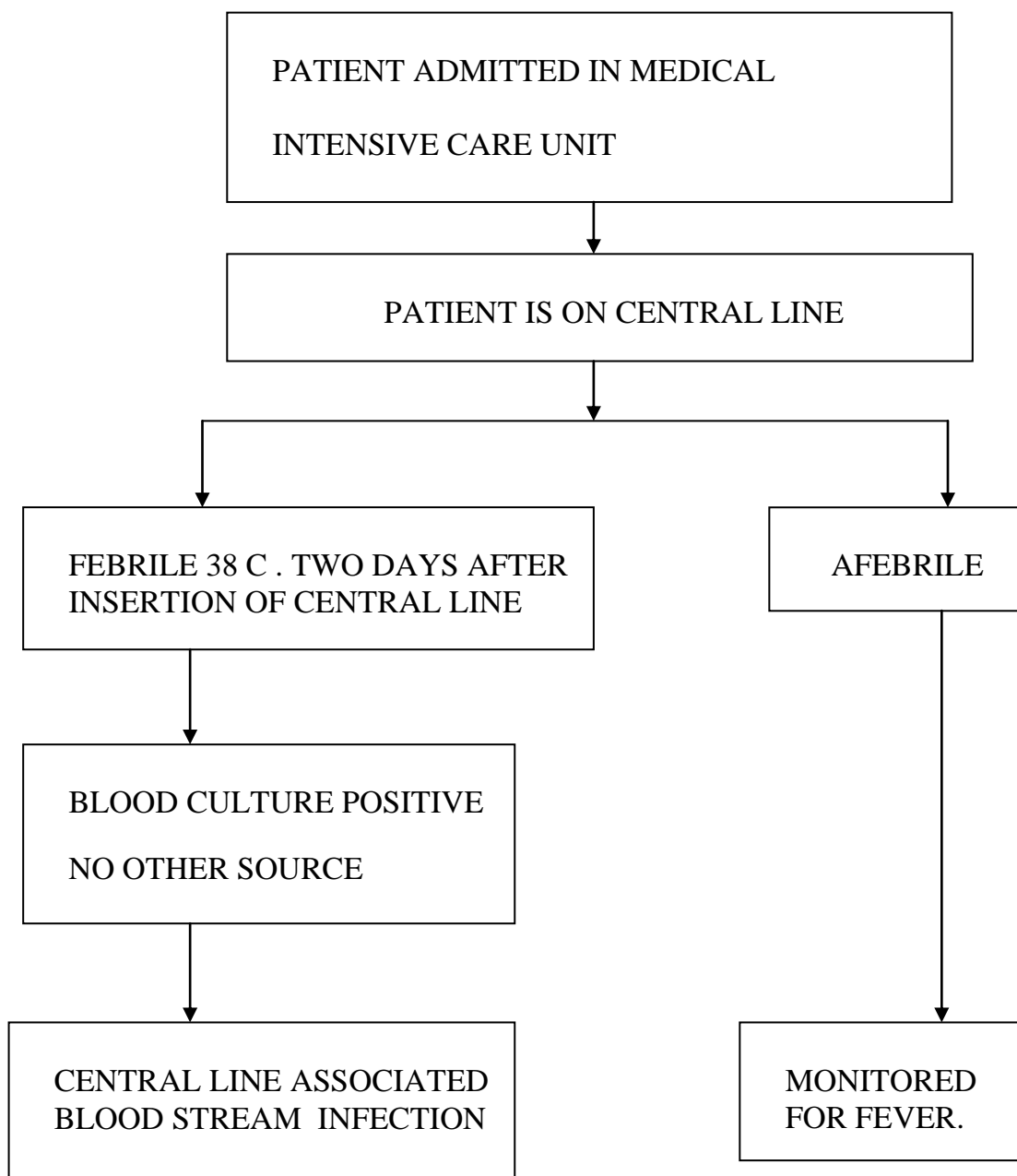
CENTRAL LINE ASSOCIATED BLOOD STREAM INFECTION

The patient is said to have Central line associated blood stream infection if they have fever after admission. The fever should have developed two days after admission and should not be related to infection at any other site. The fever can be associated with chills or hypotension. The blood culture should grow a pathogen or at least two blood cultures should grow a commensal. The organism in the blood culture should not be related to a ventilator associated infection or a urinary catheter associated infection.

The definition of blood stream infection associated with central line includes the central line and also dialysis catheter. The definition does not include peripheral lines. Arterial lines are not included in the study. The site of insertion of the central line is noted as that can affect the outcome. The date of insertion of the central line and the date of change of the same is also noted.

The patient with the infection is then monitored. The organism that grows in the blood culture is made a note of and the sensitivity is also noted. The outcome of the patient is also noted. The analysis consists of the presence of central line associated infection and the causative organism.

FIGURE 4: ALGORITHM FOR CENTRAL LINE ASSOCIATED BLOOD STREAM INFECTION

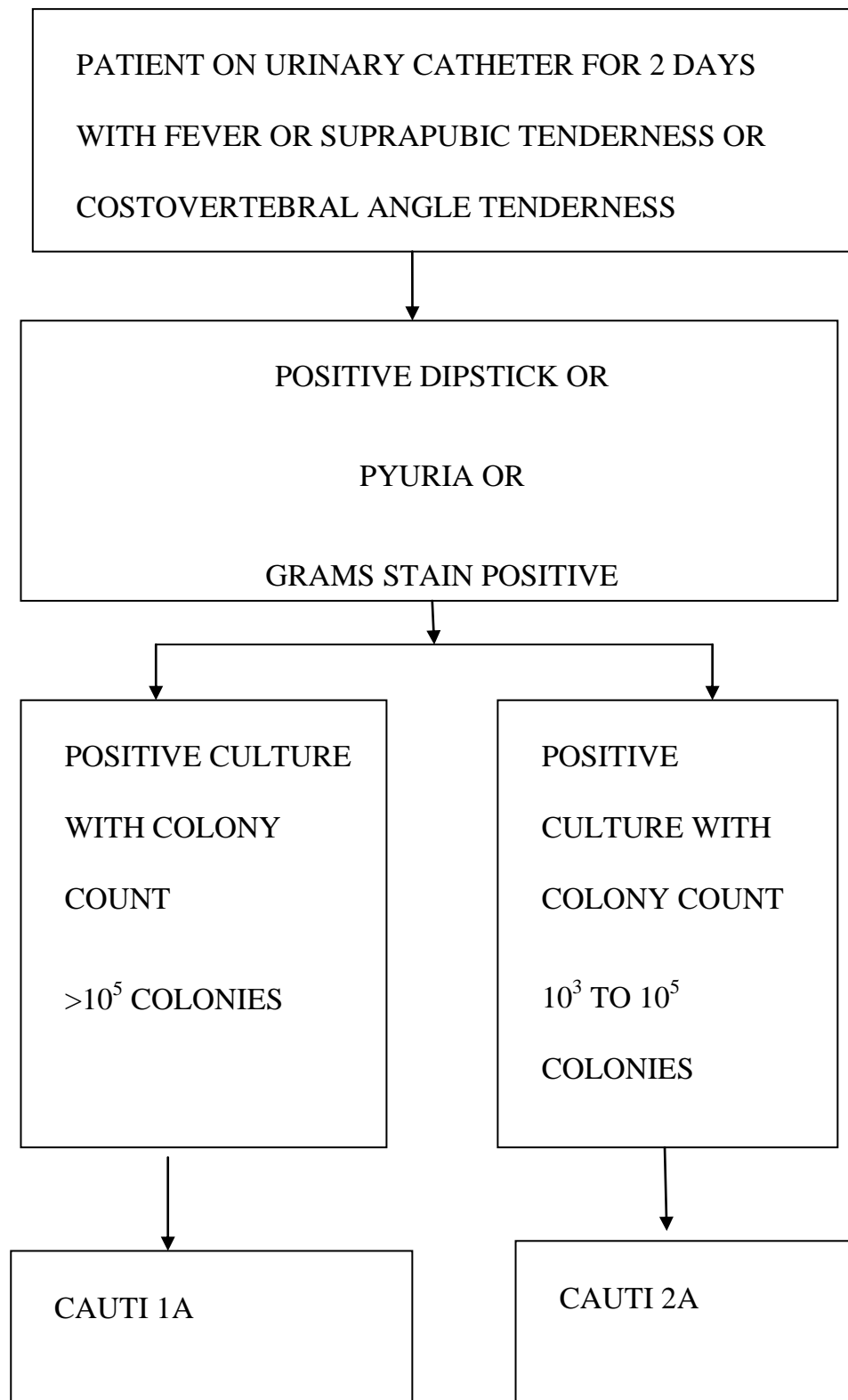


CATHETER ASSOCIATED URINARY TRACT INFECTION

Catheter associated urinary tract infection is when there are urinary symptoms of suprapubic tenderness or there is costovertebral angle pain or tenderness along with or exclusive of a hyperthermia of 38 C. The patient should also demonstrate a positive urine dipstick test for the leukocyte esterase which is very sensitive for pyuria or nitrite which is specific for bacteriuria. There can also be a pyuria as demonstrated in microscopy of the urine showing more than ten white blood cells. The patient can also have presence of microorganisms in urine analysis which is done with Gram stain.

The patient is screened for urinary catheter associated infection if the patient was already on urinary catheter for 2 days preceding the fever and the fever was after 2 days of admission. The urine cultures are then followed up and if it grows pathogens it is taken as positive. The colony count is also noted as the catheter associated urinary infection is classified as 1a and 2a based on a colony count more than 10^5 colonies or a colony count of 10^3 to 10^5 colonies. They are also classified as asymptomatic bacteriuria if they did not have any urinary symptoms and their urine had grown pathogens in significant colonies.

FIGURE 5: ALGORITHM FOR CATHETER ASSOCIATED URINARY TRACT INFECTION



OUTCOME ASSESMENT

Primary Outcome

The Primary outcome of the study was to analyze the incidence of device associated hospital acquired infections in the form of ventilator associated event, Central line associated blood stream infection and Catheter associated urinary tract infection.

The patients who were admitted under the study were followed up during the course of their stay in Intensive care unit or high dependency unit and also for two days after their discharge into the ward for any device associated infection.

Secondary Outcome

Microbiological outcome

The microbiological outcome that was studied in the patients was the causative organism in the case of device associated hospital acquired infection.

Clinical Outcome

The clinical outcome that was studied is the patient mortality.

SAMPLE SIZE CALCULATION

The incidence of device associated infection was taken as 46 per 1000 device days for ventilator associated infections

The Precision was taken as 10%

The confidence interval was taken as 95% confidence interval

The sample size was calculated as

$$\text{Sample size } n = 4 \cdot 46 \cdot 54 / 10^2$$

The sample size was 100

If 20% dropout was to be accounted for then the sample size was to be kept at 120

Since it is an observational study the samples to be included were all the patients for a period of 4 months.

STATISTICAL METHODS

The study is an observational study.

The patients were recruited prospectively.

The data was collected in data forms in Epidata software.

The analysis was done using STATA software.

The analysis method that was used to study the mortality statistics in the patient group was Pearson's chi test.

The Pearson's chi square test is used to test the categorical data to evaluate if the relationship between them arose by chance. It is for the use in unpaired data from large samples. The value is significant based on the p value within the significant range of less than or equal to 0.05.

RESULTS

INTENSIVE CARE UNIT STATISTICAL DATA

The study was done between 1st January 2014 to 30th April 2014 in Medical Intensive care unit and Medical high dependency unit.

The total number of patients included in the study was 283. This was more than the calculated sample size as this was an observational study over the span of 4 months and so all patients during this time period were included.

The average number of patients per year in the medical intensive care unit and high dependency unit is 1240.

The total number of patient days studied was 1444.

The total number of Ventilator days studied in the patients was 1216 ventilator days.

The total number of Central line days studied in these patients was 1361 central line days.

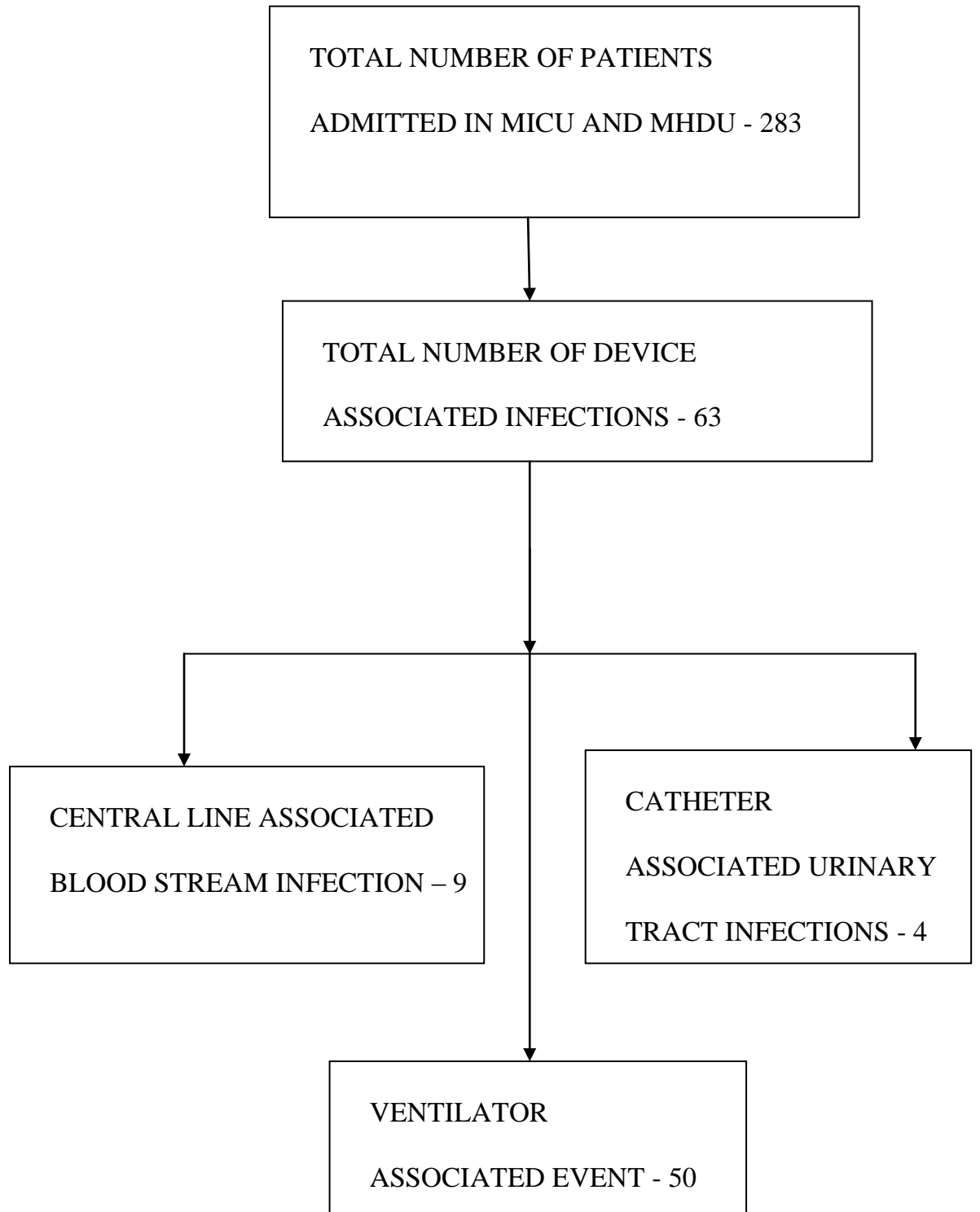
The total number of Urinary Catheter days studied in these patients was 1392 urinary catheter days.

The total number of patient days was 1444 days. The patient days are more as patients had their devices removed at times before they were shifted to ward. The central lines and urinary catheters are usually removed at the earliest to

prevent device associated infections as the chance of infection increases with duration.^{xlii}

BOX 11: INTENSIVE CARE UNIT STATISTICAL DATA

DEVICE	DAYS
VENTILATOR DAYS	1216
CENTRAL LINE DAYS	1361
URINARY CATHETER DAYS	1392

FIGURE 6: DEVICE ASSOCIATED INFECTIONS FLOW CHART

BASELINE CHARECTERISTICS

The patient group that was studied was 283 medical patients between 1st January 2015 to 30th April 2015. The patients were heterogeneous among the various age groups.

There were 146 men making up 51.5 % of the study population. The women were 137 in number.

The age groups of the patients were 123 patients between the ages of 15 to 40 who made up the majority of the patients accounting for 43.4% of the study population. There were 86 patients in the age group of 41 and 60 accounting for 30.3% of the study population. There were 74 patients above the age group of 60 accounting for 26.1% of the patients.

The baseline comorbidities showed that there are 87 diabetics accounting for 30.74 % of the study group and 71 hypertensives who account for 25.08% of the study group. There were 53 patients with ischemic heart disease who account for 18.7 % of patients of the study population. There were also 4.5% patients with COPD and 4.2% patients with chronic ethanol abuse.

The baseline diagnosis of the patients had shown that 15.1% of the patients had presented with Organophosphorus poisoning, 13.7% of the patients had presented with Community acquired pneumonia, 9.1% of the patients had presented with some form of tuberculosis, 8.1% of the patients had swine flu , 4.5% of patients had presented with alleged history of snake bite and 3.8% had presented with Dengue.

BASELINE CHARECTERISTICS**BOX 12: AGE AT PRESENTATION**

AGE	NUMBER	PERCENTAGE
15-40	123	43.4%
41-60	86	30.3%
MORE THAN 60	74	26.1%

BOX 13: SEX OF THE POPULATION

SEX	NUMBER	PERCENTAGE
MALE	146	51.5%
FEMALE	137	48.5%

BASELINE COMORBIDITIES**BOX 14: BASELINE COMORBIDITIES**

COMORBIDITY	NUMBER	PERCENT- AGE
DIABETES MELLITUS	87	30.74%
SYSTEMIC HYPERTENSION	71	25.08%
COPD	13	4.5%
ISCHAEMIC HEART DISEASE	53	18.7%
CHRONIC ETHANOL USE	12	4.2%

BOX 15: BASELINE DIAGNOSIS

DIAGNOSIS	NUMBER	PERCENTAGE
ORGANOPHOSPHORUS POISONING	43	15.1%
COMMUNITY ACQUIRED PNEUMONIA	39	13.7%
TUBERCULOSIS	26	9.1%
SWINE FLU	23	8.1%
SNAKE BITE	13	4.5%
DENGUE	11	3.8%

INCIDENCE OF VENTILATOR ASSOCIATED EVENT**BOX 16: VENTILATOR ASSOCIATED EVENT**

TYPE	NUMBER
VENTILATOR ASSOCIATED CONDITION	12
INFECTIVE VENTILATOR ASSOCIATED COMPLICATION	2
POSSIBLE VENTILATOR ASSOCIATED PNEUMONIA	3
PROBABLE VENTILATOR ASSOCIATED PNEUMONIA	33

BOX 17: MORTALITY IN VENTILATOR ASSOCIATED EVENT

TYPE	DEATH	DISCHARGE	TOTAL
NO VAE	45 (19.3%)	188	233
VAC	10 (83%)	2	12
I VAC	1 (50%)	1	2
POSSIBLE VAP	2 (66.6%)	1	3
PROBABLE VAP	19 (57.5%)	14	33
TOTAL	77	206	283

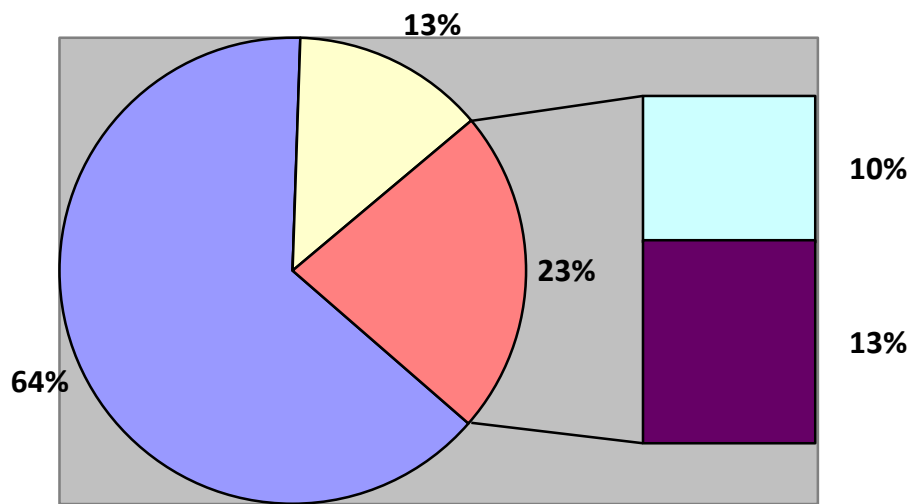
Pearson $\chi^2(4) = 44.6671$ Pr = 0.000

BOX 18: ORGANISMS CAUSING VENTILATOR ASSOCIATED EVENT

ORGANISM	FREQUENCY	PERCENTAGE
Acinetobacter	24	47%
NFGNB	13	25.5%
Klebsiella	5	9.8%
Pseudomonas	4	7%
Enterobacter	2	3.9%
Proteus	1	1.9%
Enterococcus	1	1.9%
Staphylococcus aureus	1	1.9%

FIGURE 7:

VENTILATOR ASSOCIATED EVENT



- ACINETOBACTER
- NON FERMENTING GRAM NEGATIVE BACILLI
- KLEBSIELLA
- PSEUDOMONAS
- OTHERS

INCIDENCE OF VENTILATOR ASSOCIATED EVENT

The incidence of Ventilator associated event is calculated as the sum of the incidence of Ventilator associated condition along with Infective ventilator associated complication and Ventilator associated pneumonia.

The Incidence of ventilator associated event is calculated by the dividing ventilator associated events by the total ventilator days and multiplying by 1000.

The total number of Ventilator days = 1216 device days

The total number of patients with ventilator associated pneumonia = 50 patients

Incidence of VAE = Total VAE * 1000 / Total ventilator days

$$= (50/1216) * 1000$$

The incidence of ventilator associated event was calculated to be 41 per 1000 ventilator days.

The mortality in Ventilator associated event group was 64 % when compared to the mortality in the group with Ventilator associated event which was 19.3%.

The mortality was highest in the Ventilator associated condition group with 83 % mortality.

The mortality in Ventilator associated event was significant with the Pearson $\chi^2 = 44.6671$ Pr = 0.000 which was statistically significant.

***INCIDENCE OF CENTRAL LINE ASSOCIATED BLOOD STREAM
INFECTION***

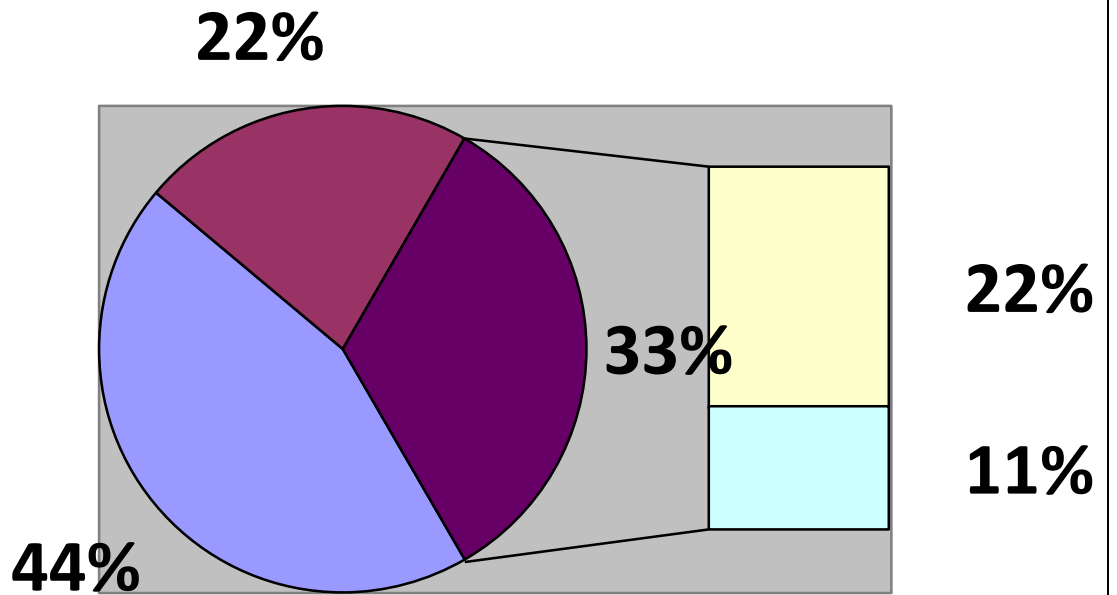
**BOX: 19 ORGANISMS CAUSING CENTRAL LINE ASSOCIATED BLOOD
STREAM INFECTION**

Organism	Frequency	Percentage
NFGNB	4	44%
Klebsiella	2	22%
Enterococcus faecium	1	11%
Enterococcus	1	11%
Acinetobacter	1	11%

NFGNB – Non Fermenting Gram Negative Bacteria

FIGURE 8:

CENTRAL LINE ASSOCIATED BLOOD STREAM INFECTION



- NON FERMENTING GRAM NEGATIVE BACILLI
- KLEBSIELLA
- ENTEROCOCCUS
- ACINETOBACTER

BOX 20: MORTALITY IN CENTRAL LINE ASSOCIATED BLOOD
STREAM INFECTION

	Death	Discharge	Total
No CLABSI	74(27%)	200	274
CLABSI	3(33.3%)	6	9

Pearson $\chi^2(2) = 0.8072$ Pr = 0.668

The incidence of central line associated blood stream infection is calculated by dividing the total number of central line associated blood stream infection by the total number of device days and multiplying it by 1000.

The central line associated blood stream infection (CLABSI) is calculated as a sum of both types of blood stream infection. The Centre for disease control National health survey network criteria is taken for the calculation.

The total number of Central line days = 1361 days

The total number of CLABSI = 9 patients

Incidence of CLABSI = number of CLABSI/total number of central line days
*1000

$$= (9/1361)*1000$$

$$= 6.6 \text{ per } 1000 \text{ device days}$$

The incidence of Central line associated blood stream infection was 6.6 per 1000 device days. The mortality associated with patients with Central line associated blood stream infection is 33% against a mortality of 27% in patients without Central line associated blood stream infection. The difference was not statistically significant with

$$\text{Pearson } \chi^2 = 0.8072 \quad \text{Pr} = 0.668 .$$

***INCIDENCE OF CATHETER ASSOCIATED URINARY TRACT
INFECTION***

**BOX 21: ORGANISMS CAUSING CATHETER ASSOCIATED URINARY
TRACT INFECTIONS**

Organism	Frequency	Percentage
Enterococcus	3	75%
Acinetobacter	1	25%

BOX 22: MORTALITY ASSOCIATED WITH CATHETER ASSOCIATED
URINARY TRACT INFECTION

	Death	Discharge	Total
No CAUTI	76 (27.2%)	203	279
CAUTI	1 (25%)	3	4

Pearson $\chi^2(3) = 3.7968$ Pr = 0.284

The incidence of device associated hospital acquired infection is calculated by dividing the total number of catheter associated urinary tract infection (CAUTI) by the total number of urinary catheter days and multiplying by 1000.

The total number of urinary catheter days = 1392 device days

The total number of CAUTI = 4 patients

Incidence of CAUTI = (CAUTI/number of catheter days)*1000

$$= (4/1392) * 1000$$

$$= 2.87 \text{ per } 1000 \text{ device days}$$

The incidence of Catheter associated urinary tract infection was found to be 2.87 per 1000 device days. The mortality associated with patients who had developed catheter associated urinary tract infection was 25% when compared to those who have not developed an infection. The Pearson chi² = 3.7968 with a Pr = 0.284 which was not statistically significant.

DISCUSSION

The study has shown in this centre the incidence of device associated hospital acquired infections is akin to the national available statistics. The incidence of ventilator associated events was found to be 41 per 1000 device days. The study in United states using the previous Centre for disease control National health survey criteria have shown an incidence of 4.1 per 1000 device days . The study has shown the vast differences in the incidence of organisms between two different countries with one being a developed nation and the other a developing country. The common organisms reported in the study in United States was Pseudomonas which accounted for 24% of the cases followed by Staphylococcus and Streptococcus both of which had accounted for 31% of the cases.^{xliii} This study had shown a different profile of organisms. The most common organisms were Acinetobacter which accounted for 47% of the organisms followed by Non fermenting gram negative bacilli which had accounted for 25% of the organisms.

The study was done using the modified Centre for disease control National health survey network criteria and had shown an incidence of ventilator associated event when compared to previous data reporting ventilator associated pneumonia which was based on different subjective criteria. The incidence of Ventilator associated event was 41 per 1000 device days when compared to study done in another centre in India which had an incidence of 30.6 per 1000 device days. This might demonstrate a higher pick up rate of ventilator associated events by using the

revised criteria. Further studies comparing both the criteria to validate this observation are required.

This study has shown a difference in the common organisms and incidence of ventilator associated pneumonia among the intensive care units in different countries. The intervention in developed countries that are being actively studied in various trials that have brought down the incidence of Ventilator associated pneumonia have been use of closed suction^{xliv} , following precautions like hand washing and also alcohol rubs between patients, strict isolation of patients with multidrug resistant organisms . These techniques need validation in our setup on a trial basis along with continuous surveillance to study the efficacy and the feasibility to follow them in the setup.

The incidence of Central line associated blood stream infection was found to be 6.6 per 1000 device days in this study The incidence in the US by the CDC NHSN criteria was found to be 1.1 per 1000 device days.^{xlv} The incidence in another centre within the country was found to be 6.8 per 1000 device days.^{xlvi} The common organism was Non fermenting gram negative bacillus which accounted for 44% of the cases followed by Klebsiella which had accounted for 22% of organisms This is different from setup in Western countries where the commonest organism is Staphylococcus aureus.

There is difference in the incidence of central line associated blood stream infection between the different intensive care units. The various intervention techniques that have been used are use of antibiotic coated central lines, daily central line dressing by trained staff, sterile manner of usage of central line akin to blood culture procedure and central line lumen caps which need less handling. These measures need further validation in our setup.

The incidence of Catheter associated urinary tract infection in this study was found to be 2.87 per 1000 device days. The incidence in the United States was found to be 0.7 per 1000 device days. The patients in the intensive care unit had their urinary catheter removed at the earliest which has brought down the incidence of Catheter associated urinary tract infection. The mortality associated with Catheter associated urinary tract infection was also less in view of the low incidence.

This study emphasizes the need for continuous surveillance of device associated hospital acquired infections and the need for concerted techniques to tackle the same.

LIMITATIONS

The study was powered as a surveillance tool for device associated infections so it might just be a snapshot of the four months of the study and to understand device associated hospital acquired infections and then to institute interventions and also to monitor the effectiveness of the same a system of continuous surveillance is to be done.

The study was not powered to look at the mortality associated with device associated hospital acquired infections so conclusions based on the mortality data could not be made.

The study was also limited to medical intensive care and medical high dependency unit so the conclusions made will be limited to the same.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSION

The conclusions of the study were

1. The incidence of Ventilator associated event was 41 per 1000 device days
2. The most common organism causing Ventilator associated pneumonia was *Acinetobacter* which made up 47% of the organisms.
3. The incidence of Central line associated blood stream infection was 6.6 per 1000 device days
4. The most common organism causing Central line associated blood stream infection was Non fermenting gram negative bacilli which accounted for 44% of the organisms
5. The incidence of Catheter associated urinary tract infections was 2.87 per 1000 device days
6. The most common organism causing Catheter associated urinary tract infection was *Enterococcus*
7. The mortality associated with ventilator associated event was 64% which was statistically significant

RECOMMENDATION

The study had shown significant increase in mortality in the group with ventilator associated event. As mentioned in Page 29 in Box 3 this study is the first step in a 4 step process. The study has been an initiation of surveillance. The next steps would involve discussion of the result with the treating team and formulating prevention techniques and then analyzing its results. On the basis of the results of my study I would recommend initiation of interventions to be made to see if decreased handling of the devices and handling in even more sterile manner would alter the incidence rates like usage of closed suction in endotracheal tubes, sterile handling of central lines, earlier removal of central lines and also staff education regarding the same. The need for continuous surveillance along the interventions would tell us the efficacy and feasibility of the above mentioned interventional techniques and the shortfalls of the same.

ANNEXURE

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INFORMATION SHEET

Surveillance of Device Associated Hospital Acquired Infections in Patients admitted in Medical Intensive Care Unit (MICU) and Medical High Dependency Unit (MHDU) in a Tertiary Care centre

What is Device Associated Hospital Acquired Infection?

Device associated Hospital acquired infections can develop in Intensive care unit due to the invasive devices like urinary catheter, central line or Ventilators. These devices can bypass the natural immunity of the body and at times predispose the body to associated lung, urine or blood infections.

This study looks at the chance of development of new infections and also the most common organisms and what medicines they respond well to. This will guide in future planning of treatment of patients and also to plan new ways to prevent these infections.

If you take part in the study what will you have to do?

If you take part in the study you will agree to allow the researcher to look at your records to assess if you have developed any infection and also to allow him to

follow up the type of infection and what medicines it responds well to. The information collected will be used for later analysis. You will not receive any financial compensation as part of the study. The study will not affect your treatment in any way.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

CONSENT FORM

Study Title: Surveillance of Infections that patients acquire from devices used on them hospital in Medical Intensive Care Unit and High Dependency in a tertiary care centre during a period of 1 year.

Study Number:

Participant's name:

Date of Birth / Age (in years):

I _____

_____, son/daughter of _____

(Please tick boxes)

Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. []

I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights []

I also understand that I do not need to pay for the study []

I understand that I will not receive any free treatment and other financial compensation during the course of the study []

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access []

I understand that my identity will not be revealed in any information released to third parties or published []

I voluntarily agree to take part in this study []

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date:

Name of Doctor:

Signature

CLINICAL RESEARCH FORM

Study Number

Name

Age

Sex

Hospital Number

Date of ICU Admission

Date of Discharge from ICU

Diagnosis at Admission

Co morbid Illness

1. Diabetes Mellitus 2. Hypertension 3. Dyslipidemia 4. COPD 5. Bronchial Asthma 6. Renal Failure 7. Chronic Liver Disease 8. Rheumatic Heart Disease 9. Hypothyroidism 10. Autonomic Dysfunction 11. Illicit Drug Use 12. Ischemic Heart disease 13. Hyperthyroidism 14. HIV infection 15. Anticholinergic drug use 16. Obesity 17. Other Chronic Lung disease 18. Chronic heart failure 19. Anemia 20. Pheochromocytoma 21. Alcohol 22. Others

Date of Intubation

Date of Urinary Catheter Insertion

Date Central line insertion

Type of Central line – Jugular / Femoral/ Subclavian

Central line site Infection –

Ventilator Associated Pneumonia

Increase in FiO₂ > 0.2 over 2 days

Increase in PEEP > 3 cm of water over 2 days

Temperature > 38 °C or < 36°C, OR white blood cell count \geq 12,000 cells/mm³
or \leq 4,000 cells/mm³

New antimicrobial agents is started, and is continued for \geq 4 calendar days

Purulent respiratory secretions

Positive culture

Type

Ventilator Associated Condition

Infective Ventilator Associated Complication

Possible Ventilator Associated Pneumonia

Probable Ventilator Associated Pneumonia

Organism 1 –

Sensitivity –

Organism 2 –

Sensitivity –

Central Line associated Blood Stream infection

Blood culture growth of recognized pathogen not related to any other site

Clinical signs

1.Fever

2.Chills

3.Hypotension

Blood Culture growth of commensal in two separate cultures on separate occasion

Type of CLABSI – LCBI 1 / LCBI 2

Organism 1 –

Sensitivity –

Organism 2 –

Sensitivity –

Catheter Associated Urinary Tract Infection

Criteria 1 – Any one

1. Fever ($>38^{\circ}\text{C}$)
2. Suprapubic tenderness
3. Costovertebral angle pain or tenderness

Criteria 2 – At least 1 of the following

1. Positive dipstick for leukocyte esterase and/or nitrite
2. pyuria (urine specimen with ≥ 10 white blood cells [WBC]/ mm^3 of unspun urine or >5 WBC/high power field of spun urine)
3. Microorganisms seen on Gram's stain of unspun urine

Urine culture –

1.Colony count $> 10^5$

2.Colony count 10^3 to 10^5

Organism 1 –

Sensitivity –

Organism 2 –

Type of CAUTI – Asymptomatic/ Symptomatic Criteria 1a / Symptomatic

Criteria 2a

CONDENSED DATA SHEET

The image shows a screenshot of a Microsoft Excel spreadsheet titled "data.xls [Compatibility Mode]". The spreadsheet contains a large table with approximately 25 columns and 35 rows of data. The columns are labeled with letters A through Z, and the rows are numbered 1 through 35. The data appears to be organized into several sections, with some rows highlighted in yellow. The spreadsheet is displayed in a window with standard Windows interface elements.

CONDENSED DATA SHEET

The image shows a screenshot of a Microsoft Excel spreadsheet titled "data.xlsx". The spreadsheet contains a table with 365 rows and 26 columns labeled A through AA. Each row represents a day of the year, with the first column (A) containing a date in MM/DD/YYYY format. The subsequent columns (B-AA) contain numerical data points, likely representing daily observations or measurements. The data is organized in a grid format, with each cell containing a specific value. The spreadsheet is displayed in a standard Excel interface, showing the grid lines and the column/row headers.



