**Summer Training at**
**Sree Chitra Tirunal Institute for Medical Science and Technology,**
**Trivandrum, Kerala**
**(April 1–May 31, 2014)**

# Safety of Cardiology and Neurology Implant Patients

**By**
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**Under the guidance of**
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**MBA- Hospital & Health Management (MBA-HM)**
**2013-2015**


**The IIHMR University, Jaipur**
**2014**

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# CERTIFICATE

This is to certify that **Dr.Seema Singh** has undergone her summer training in **Sree Chitra Tirunal Institute For Medical Sciences and Technology, Trivandrum,** from 1st April 2014 to 31st May 2014. The candidate herself carried out all the studies related to her summer training. Her approach to the study has been scientific and analytical. This summer training is in the partial fulfilment of the course requirement recommended for the award of Post Graduate Diploma in Hospital and Health Management with specialisation in Hospital Management.

I wish her success in all her future endeavours.

Col. (Dr.) Ashok Kaushik
Dean (Academic & Student Affairs)
IIHMR Jaipur

23/07/14
Dr. Susmit Jain
Assistant Professor
IIHMR Jaipur

# ACKNOWLEDGEMENT

A summer project is a golden opportunity for learning and self development. I consider myself lucky and honored to have so many wonderful people lead me through the completion of this project.

I consider myself fortunate for having been provided an opportunity to undergo summer training at Sree Chitra Tirunal Institute For Medical Sciences and Technology, Trivandrum, Kerala and wish to express my indebted gratitude to Dr.S.K.Jawahar (Administrative Medical Officer, SCTIMST) who has given his invaluable time for guiding me and completing the project successfully.

I also wish to extend a special thanks to Dr. Kalliyanakrishnan V. (BMT Wing), who in spite of being extraordinarily busy with his duties, took time out to hear, guide and keep me on the correct path and helped me to carry out my project work at their esteemed organization during the training.

I am obliged to staff members of SCTIMST, Trivandrum, Kerala for the valuable information provided by them in their respective fields. I am also grateful for their cooperation during the period of my assignment.

Lastly, I thank almighty, my family and friends for their constant encouragement without which this assignment would not have been possible.

# PREFACE

Summer internship is an integral part of PGDHM curriculum. As a part of course, student of first year required to under summer placement at any reputed organization to get in depth exposure of various departments in the organization and have better understanding in the health care delivery system and its functions.

The major objectives of summer training are as follows:

1. To understand and learn day to day operational management of hospital/health cares and its service centers.
2. To study identified issues and problems associated with some specific operational area/programs.
3. To acquire more knowledge and responsibilities of key players and stake holders in the hospital & to understand various functions in hospital by interactions with key stake holders, policy makers, acemaedians and researchers.
4. To work on the project/task assigned by the summer training organization.

During the training period I had an overview of various department of the hospital. I had also done study on the “SAFETY OF CARDIOLOGY AND NEUROLOGY IMPLANT PATIENTS”.

The aim of the study was to identify the various risk factors which cause the malfunctioning and post operated complication in cardiology and neurology implant patients and hampers or diminishes the safety of patients.

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## ABOUT THE ORGANIZATION

The origin of the Institute dates back to 1973 when the Royal Family of Travancore gifted a multistoried building for the people and Government of Kerala. Sri. P. N. Haskar, the then Deputy Chairman, Planning Commission, inaugurated the Sree Chitra Tirunal Medical Center in 1976, when patient services including inpatient treatment got underway. At the Satelmond Palace, Poojapura, nearly 11 km away from this Hospital Wing, the Biomedical Technology Wing followed soon, again a gift by the Royal Family.

The concept of amalgamating medical sciences and technology within a single institutional framework was regarded as sufficiently important by the Government of India to declare the center as an Institute of National Importance under the Department of Science and Technology by an Act of Parliament in 1980, and named it as Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

Dr. Manmohan Singh, the then Honorable Finance Minister of Government of India, laid the foundation stone of the third dimension of the Institute, Achutha Menon Center for Health Science Studies (AMCHSS) on June 15, 1992. Dr. Murali Manohar Joshi, the then Honorable Minister of Science and Technology and Human Resource Development, Government of India, dedicated the AMCHSS to the nation on January 30, 2000.

### MISSION

- Promote research and development in biomedical engineering and technology
- Deliver high quality patient care in selected specialties and subspecialties
- Develop innovative postgraduate training programs in advanced medical specialties, and biomedical engineering and technology
- Participate in public health reforms through research, training and interventions

### VISION

- Become a Global Leader in Medical Devices Development, High Quality Patient Care, and Health Sciences Studies by 2020

The hospital has 253 beds and serves as tertiary referral center for cardio-vascular, thoracic and neurologic diseases. With a number of highly qualified personnel including doctors, nurses and other para-medical staff, various departments of the hospital have updated state-of-the-art facilities for diagnosis and treatment with highly advance starting 1976.

VARIOUS DEPARTMENTS IN HOSPITAL

- Administrative Services
  - Administration
  - Director's Office
  - Finance and Accounts Division
  - Medical Superintendent's Office
  - Security
  - Stores & Purchase
- Anesthesiology Department
- Biochemistry
- Cardiology Department
- Cardiovascular and Thoracic Surgery Department
- Cellular and Molecular Cardiology
- Clinical Engineering
- Computer Division
- Deputy Registrar's Office
- Imaging Sciences and Intervention Radiology Department
- Medical Records
- Microbiology
- Neurology Department
  - Cognition & Behavioral Neurology
  - Comprehensive Care Centre for Movement Disorders
  - Comprehensive Center for Sleep Disorders
  - Comprehensive Stroke Care Center
  - R Madhavan Nayar Center for Comprehensive Epilepsy Care
- Neurosurgery Department
- Nursing Education
- Nursing Services
- Pathology
- Registrar's Office

## SPECIFIC PROJECT

This report addresses the following factors:

- To assess the basic safety measures followed by the operator for cardiology and neurology implants.
- To assess sources causing malfunctioning of implants.
- To assess the causes increasing the risk factor and diminish the quality of care and also increasing the cost effectiveness of implants.
- To identify training needs if any for the operating technician.

The areas covered for this project are as follows:

1. Cath lab
2. Cardiology ICU
3. Cardiology ward
4. Neurology OT
5. Neurology ICU
6. Neurology ward

## INTRODUCTION

Patient safety is a new health care discipline that emphasizes the reporting, analysis and prevention of medical error that often leads to adverse health care events. The frequency and magnitude of avoidable adverse patient events was not well known until the 1990s, when multiple countries reporting staggering number of patients harmed and killed by medical errors. Recognizing that health care impact 1 in every 10 patients around the world, the World Health Organization calls the patient safety an endemic concern. Indeed, patient safety has emerged as a distinct health care discipline supported by an immature yet developing scientific frame work. There is significant transdisciplinary body of theoretical and research literature that inform the signs of patient safety. The resulting patient safety knowledge continually informs improvement efforts such as applying lessons learn from business and industry, adopting innovative technologies, educating provider and consumers, enhancing error reporting systems, and developing new economic incentives.

### Causes of health care error:

1. Human Factors

- Variation in health care provider training and experience, fatigue, depression and burnout.
- Diverse patient, unfamiliar settings and time pressure.
- Failure to acknowledge the prevalence and seriousness of medical errors.

2. Medical Complexity

- Complicated technologies, powerful drugs.
- Intensive care, prolonged hospital stay.

3. System Failure

- Poor communication, unclear lines of authority of surgeons, nurse and other care providers.
- Complications increase as patient to nursing staff ratio increase.

- Disconnected reporting system within a hospital: fragmented system in which numerous hands-offs of patient"s results lack of coordination and errors.
- Drug names that look alike and sounds alike.
- The impression that action is being taken by other group within the institution.
- Reliance on automated systems to prevent errors.
- Inadequate system to share information about errors hampers analysis of contributory causes and improvement strategy.
- Cost-cutting measures by hospitals in response to reimbursement cut backs.
- Environment and design factors. In emergencies, patient care may be rendered in areas poorly suited for safe monitoring.
- Infrastructure Failure-According to WHO, 50% of the medical equipments in developing countries is only partly usable due to lack of skilled operators or parts.

## REVIEW OF LITERATURE

An implant is a medical device manufactured to replace a missing biological structure, support a damaged biological structure, or enhance an existing biological structure. Medical implants are man-made devices, in contrast to a transplant, which is a transplanted biomedical tissue. The surface of implants that contact the body might be made of a biomedical material such as titanium, silicone or apatite depending on what is the most functional. In some cases implants contain electronics e.g. artificial pacemaker and cochlear implants. Some implants are bioactive, such as subcutaneous drug delivery devices in the form of implantable pills or drug-eluting stents.

### Applications

Examples of implants are pins, rods, screws, and plates used to anchor fractured bones while they heal.

### Classification

### United States classification

Medical devices are classified by the US Food and Drug Administration (FDA) under three different classes depending on the risks the medical device may impose on the user. Class I devices are considered to pose the least amount of risk to the user and require the least

amount of control. Class I devices include simple devices such as arm slings and hand-held surgical instruments. Class II devices are considered to need more regulation than Class I devices and are required to undergo specific requirements before FDA approval. Class II devices include X-ray systems and physiological monitors. Class III devices require the most regulatory controls since the device supports or sustains human life or may not be well tested. Class III devices include replacement heart valves and implanted cerebellar stimulators. Many implants typically fall under Class II and Class III devices.

## Complications

Under ideal conditions, implants should initiate the desired host response. Ideally, the implant should not cause any undesired reaction from neighboring or distant tissues. However, the interaction between the implant and the tissue surrounding the implant can lead to complications. The process of implantation of medical devices is subjected to the same complications that other invasive medical procedures can have during or after surgery along with several different complications. Common complications include infection, inflammation, and pain. Other complications that can occur include risk of rejection from implant-induced coagulation and allergic. Depending on the type of implant, the complications may vary.

When the site of an implant becomes infected during or after surgery, the surrounding tissue becomes infected by microorganisms. Three main categories of infection can occur after operation. Superficial immediate infections are caused by organisms that commonly grow near or on skin. The infection usually occurs at the surgical opening. Deep immediate infection, the second type, occurs immediately after surgery at the site of the implant. Skin-dwelling and airborne bacteria cause deep immediate infection. These bacteria enter the body by attaching to the implant"s surface prior to implantation. Though not common, deep immediate infections can also occur from dormant bacteria from previous infections of the tissue at the implantation site that have been activated from being disturbed during the surgery. The last type, late infection, occurs months to years after the implantation of the implant. Late infections are caused by dormant blood-borne bacteria attached to the implant prior to implantation. The blood-borne bacteria colonize on the implant and eventually get released from it. Depending on the type of material used to make the implant, it may be infused with antibiotics to lower the risk

of infections during surgery. However, only certain types of materials can be infused with antibiotics, the use of antibiotic-infused implants runs the risk of rejection by the patient since the patient may develop sensitivity to the antibiotic, and the antibiotic may not work on the bacteria.

Inflammation, a common occurrence after any surgical procedure, is the body"s response to tissue damage as a result of trauma, infection, intrusion of foreign materials, or local cell death, or as a part of an immune response. Inflammation starts with the rapid dilation of local capillaries to supply the local tissue with blood. The inflow of blood causes the tissue to become swollen and may cause cell death. The excess blood, or edema, can activate pain receptors at the tissue. The site of the inflammation becomes warm from local disturbances of fluid flow and the increased cellular activity to repair the tissue or remove debris from the site.

Implant-induced coagulation is similar to the coagulation process done within the body to prevent blood loss from damaged blood vessels. However, the coagulation process is triggered from proteins that become attached to the implant surface and lose their shapes. When this occurs, the protein changes conformation and different activation sites become exposed, which may trigger an immune system response where the body attempts to attack the implant to remove the foreign material. The trigger of the immune system response can be accompanied by inflammation. The immune system response may lead to chronic inflammation where the implant is rejected and has to be removed from the body. The immune system may encapsulate the implant as an attempt to remove the foreign material from the site of the tissue by encapsulating the implant in fibrogen and platelets. The encapsulation of the implant can lead to further complications, since the thick layers of fibrous capsulation may prevent the implant from performing the desired functions. Bacteria may attack the fibrous encapsulation and become embedded into the fibers. Since the layers of fibers are thick, antibiotics may not be able to reach the bacteria and the bacteria may grow and infect the surrounding tissue. In order to remove the bacteria, the implant would have to be removed. Lastly, the immune system may accept the presence of the implant and repair and remodel the surrounding tissue. Similar responses occur when the body initiates an allergic foreign body response. In the case of an allergic foreign body response, the implant would have to be removed.

## Failures

The many examples of implant failures include rupture of silicone breast implants, hip replacement joints, and artificial heart valves, such as the Bjork–Shiley valve, all of which have caused FDA intervention. The consequences of implant failure depend on the nature of the implant and its position in the body. Thus, heart valve failure is likely to threaten the life of the individual, while breast implant or hip joint failure is less likely to be life-threatening.

Numerous organizations, government branches and private companies conduct research studies to investigate the over all health of patient safety in America and across the globe. Despite the shocking and widely publicized statistics on preventable death due to medical errors in America"s hospitals, the 2006 National Healthcare Quality Report assembled by the Agency for Healthcare Research and Quality (AHRQ) had the following sobering assessment:

1. Most measures of Quality are improving but the pace remains modest.
2. Quality improvement varies by setting and phase of care.
3. The rate of improvement accelerated for some measures while a few continued to show deterioration.
4. Variation in Health care quality remains high.

A qualitative study “why do intern make prescribing errors” MJA 2008;188(2);89-94 by Ian D Coombes, Danielle A Stowasser, Judith A Coombes and Charles Mitchell suggested SWISS CHESSE MODEL according to which factors affecting health care errors are:

1. Latent Factors :
    - Organizational Processes-Work load, Hand –written prescriptions.
    - Management Decisions- Staffing levels, Culture of lack of support for interns.

2. Error Producing Factors:
    - Environmental- Busy wards, interruptions.

- Team- Lack of supervision.
- Individual-Limited knowledge.
- Task-Repetitions, poor medications chart design.
- Patient-Complex, communication difficulties.

3. Active Failures:
   - Errors-Slip, lapse, violations.

4. Defence:
   - Missing-No pharmacist.

According to study of AORN, a US based professional Organization of preoperative registered nurses, proposed a initiative “NEAR- MISS REPORTING” to increase patient safety.

A near miss is an unplanned event that did not result in injury, illness or damage but had the potential to do so. Reporting of near misses by observers is an established error reduction technique.

According to study by RAND health, the U.S. healthcare system could reduce to adverse healthcare events, and improve the quality of care if health information technology (HIT) widely adopted. The most immediate barrier to widespread adoption of technology is cost despite the patient benefit from better health, and payer benefit from lower costs. However hospital pays both in higher costs for implementation and potential low revenues (depending on reimbursement scheme) due to reduced patient length of stay. The benefit provided by technological innovations also give rise to serious issues with the introduction of new and previously unseen error types.

Handwritten reports or notes, manual order entry, on standard abbreviations and poor legibility lead to substantial errors and injuries, according to IOM (2000) report. The follow-up IOM report crossing the Quality Chasm: A New Health System For the 21$^{st}$ Century, advised rapid adoption of electronic patient records, Electronic medication

ordering, with computer-and internet-based information systems to support clinical decision. This section contains only the patient safety related aspects of HIT:

- Electronic Health Records (EHR)-The Electronic Health Record (EHR), previously known as Electronic Medical Record (EMR), reduces several types of errors, including those related to prescription drugs, to emergent and preventive care, and to test and procedures. Important features of modern EHR include automated drug/drug-food interaction checks and allergy checks, standard drug dosages and patient education information. Also, these systems provide recurring alerts to remind clinicians of intervals for preventive care and to track referrals and test results.

- Computerized Provided Order Entry (CPOE): Prescribing errors are the largest identified source of preventable errors in hospitals (IOM, 2000; 2007).The IOM (2006) estimates that each hospitalized patients, on average, is exposed to one medication error each day. Computerized Provided Order Entry (CPOE), formerly called computer physician order entry can reduce medication errors by 80% overall but most importantly decreases harm to patient by 55%.

- Complete Safety Medication System-A standardized bar code system for dispensing drugs might prevent 25% medication error.

Evidence based medicine- integrates an individual doctor"s exam and diagnostic skills for specific patient, with the best available evidence from medical research. The doctor"s expertise includes both diagnostic skills and considerations of individual patient"s rights and preferences in making decisions about his or her care. The clinician uses pertinent clinical research on the accuracy of diagnostic tests and the efficacy and safety of therapy, rehabilitation and prevention to develop individual plan of care.

- Advantages:

1. Evidence based medicine may reduce adverse events, especially those involving incorrect diagnosis, outdated or risky test or procedures, or medication overuse.
2. Clinical guidelines provide a common framework for improving communication among clinicians, patient and non medical purchaser of health care.
3. Errors related to changing shifts and medical specialists are reduced by consistent plan of care.
4. Information on the clinical effectiveness of treatment and services can help providers, consumers and purchasers of health care make better use of limited resources.
5. As medical advances became available, doctors and nurses can keep up with new tests and treatments as guidelines are improved.

## GUIDELINES FOR FOLLOW UP OF IMPLANTABLE CARDIAC DEVICES FOR CARDIAC RHYTHM MANAGEMENT

### INTRODUCTION

Guidelines for pacemaker follow up were first published in Heart in November 19961 as the result of a British Pacing and Electrophysiology Group (BPEG) policy conference. These were agreed by consensus and have been the primary source of guidance for the management of implanted devices within the UK to date.

The continuing evolution of device technology has resulted in the production of a range of devices capable of treating bradycardias, complex cardiac tachyarrhythmias, and heart failure management. These devices have multiple modalities and programmable features. The challenge of these treatments lies not only in the implantation of the devices but also in comprehensive follow-up of the implanted devices as part of the lifelong management of the patient. As the number and variety of implanted devices increase so does the burden of follow-up and the knowledge required to optimize and troubleshoot their use. This is compounded by the increasing volume of data provided by devices, and the increasing sophistication of programming therapy and detection algorithms

As a result of this increasing complexity,inappropriate or incorrect use of these algorithms or other errors with aspects of device programming may result in serious harm to the patient.

Device follow-up clinics now encompass various types of devices ranging from single/dual chamber bradycardia devices, atrial tachycardia devices and implantable cardioverter defibrillators, to multi-chamber cardiac resynchronisation devices incorporating new modalities such as impedance monitors for assessing heart failure. Although the original guidelines stated that pacemaker clinics should be the responsibility of a lead physician, the practice of device management follow-up in the UK is now almost solely led and practiced by Cardiac Physiologists (CPs), and in some cases by specialist nurses. It is vital therefore that clinical governance mechanisms and lines of clinical responsibility are clearly established for all follow-up clinics.

1. Device follow-up remains the clinical responsibility of the Consultant Cardiologist (consultant physician with specialist interest) in charge of the device follow-up service – although it is a Cardiac Physiologist run service. Physicians providing such a service should have the required knowledge to do so. Ideally, such physicians would be current holders of (or working towards) a recognised pacing qualification such as certificate of accreditation with Heart Rhythm UK (HRUK, previously BPEG exam), European Heart Rhythm Association (EHRA) or International Boards of Heart Rhythm Examiners (IBHRE, formerly North American Society of Pacing and Electrophysiology (NASPE)).

The following guidelines for Cardiac Physiologist led clinics have been drawn up by HRUK and the Society for Cardio logical Science and Technology (SCST), both of which are affiliated groups of the British Cardiovascular Society.

These groups have been instrumental in guiding device follow up training since the previous policy conference conducted by the British Pacing and Electrophysiology Group (now HRUK). Section A Bradycardia Pacemaker Follow up Clinics.

There should be a clearly defined protocol documenting the lines of communication and support between the lead Cardiac Physiologist for the bradycardia pacemaker

Follow-up service and the Consultant Cardiologist (consultant physician with specialist interest) responsible for the onsite service to ensure that clinical governance requirements are met. The lead Cardiac Physiologist for bradycardia pacemaker follow-up services at non-implanting hospitals must also have strong links with the lead Cardiac Physiologist and Consultant Cardiologist at the implant centre.

The lines of clinical responsibility must be clearly defined in the local trust policy. Trusts delivering bradycardia pacemaker follow-up services have a responsibility to ensure appropriate arrangements are in place to cover clinic activity (elective or urgent).

## Bradycardia Pacemaker Follow-up Clinic Objectives:

1. To optimize the pacing system to the individual patient needs whilst maximizing generator life. Safety must be paramount whilst manufacturer guidance and HRUK recommendations should also be taken into account.

2. To identify any abnormalities in the pacemaker system and complications of the therapy in order to ensure prompt treatment.

3. To assess battery status to predict end-of-life (EOL) of the pulse generator in order to permit timely elective generator replacement.

4. To provide patient and family support and education.

5. To ensure that the patient"s experience is as safe, comfortable and reassuring as possible.

6. To ensure that safe and accurate measurements are made of device and lead function and that accurate records of each visit are kept. Staff leading the clinic must be able to recognize problems and complications and make the appropriate changes or recommendations.

7. To ensure that the patient"s experience is as safe, comfortable and reassuring as possible.

8. To ensure that safe and accurate measurements are made of device and lead function and that accurate records of each visit are kept. Staff leading the clinic must be able to recognize problems and complications and make the appropriate changes or recommendations.

9. To monitor the device implant site and manage any risk of infection.

10. To maximize clinical safety and efficiency in line with clinical governance requirements.

11. To regularly review patients in line with local, manufacturer and National guidelines.

10. To implement relevant advisories from device manufacturers and the Medicines and Healthcare products Regulatory Agency (MHRA) guidelines and advice.

11. To notify the MHRA and manufacturer of any problems arising with devices or leads.

12. To be aware of the need to identify clinical problems and refer patients for immediate or deferred medical care appropriately in line with local policy.

13. To provide accurate and complete communication about patient-device interaction and appropriate functionality to GPs and other relevant health professionals.

Suggested Procedure for Referrals to a Bradycardia Pacemaker Service Follow-Up Clinic at non-implant centers

On receipt of referral from implant physician/centre the patient is registered and scheduled for review. The referral information must include:

¾ Patient name and address and telephone number ¾ Patient GP details ¾ Hospital / H&C number ¾ Date of birth ¾ Referring consultant ¾ Pacemaker type and parameters ¾ Pacemaker lead models and serial numbers ¾ Most recent threshold, battery voltage and lead impedance evaluation results ¾ Patient mobility ¾ Cross infection issues ¾ Indications for implant ¾ Medication details.

## Suggested appointments schedule

- Yearly for pacemakers implanted for less than 7-10 years depending on the manufacturers recommendation and expected battery longevity.
- 6 monthly for implants exceeding 7-10 years until ERI is reached.
- 3-6 monthly for Devices that exceed the manufacturer‟s suggested longevity or show decline in battery life.
- At Cardiac Physiologists discretion for devices that require closer monitoring e.g. programming/lead issues.

## Reports

- A report is generated by Cardiac Physiologists in charge of the follow-up clinic and all parameters and clinical details are documented in department‟s database and/or the patient's pacemaker notes.
- A copy of the report or a letter is sent to the patient‟s general practitioner and the referring hospital where appropriate.

- The implant centre need only be contacted when seeking additional advice or when making a referral to the implanting physician.

## Staffing: Qualifications and Training

Ideally the clinic should be manned with two staff, one of who meets the lead role competencies. The Second staff member can be undergoing training.

## Lead Cardiac Physiologist

- A qualified Cardiac Physiologist (BSc Clinical Physiology or equivalent)
- Evidence of post-graduate training in cardiac rhythm management techniques, e.g. holds appropriate Certification of Accreditation HRUK or IBHRE
- Hold current ILS or ALS accreditation
- Evidence of Continual Professional Development (CPD) in cardiac rhythm management
- Perform minimum of 100 bradycardia pacemaker system follow-up review procedures per year
- Attend local implant centre regularly and not less than twice per annum to remain familiar with evolving technology (CP"s leading Follow-Up Clinic at non implant hospitals)
- Demonstrate high level of understanding and knowledge of the full range of diagnostic cardiac investigations

## Cardiac Physiologist

- A qualified Cardiac Physiologist (BSc Clinical Physiology or equivalent)
- Holds a current ILS accreditation
- Has a proven understanding of bradycardia pacemaker implant procedures
- Has a proven knowledge of bradycardia pacemaker technology
- Has current CPD by attending relevant recognized training study days

## Equipment and Other Essential Requirements

A wide range of equipment is essential within the clinic or immediate vicinity of the clinic with access to further cardiac investigations (which need not necessarily be on site). These are listed below.

Equipment essential in the Pacemaker clinic (or in the immediate vicinity):

- 12-Lead electrocardiograph (ECG) machine with real time recording
- An appropriate range of manufacturer programmers (with appropriate documentation for use of each specific model)

• Emergency „crash" trolley and defibrillator with integrated pacing function.
• Magnet
• Wound treatment pack
• Telephone and/or arrest call button
• Callipers, rate ruler etc
• Data management system/patient notes
• Sharps box
• Oxygen, suction and relevant adjuncts.

There should also be access to MHRA Pacemaker adverse incident reporting forms.

Investigations to which the cardiac physiologist should have referral access:

• X-Ray facilities
• Ambulatory ECG Recording
• Echocardiogram.

Cardiac investigations to which it may be desirable to have referral access:

• Exercise Stress Testing
• Head-up Tilt-Table Testing.

Access for rapid referral of any patient needing urgent admission should also be available. Section B ICD/CRT Device Follow up Clinics

There should be a clearly defined protocol documenting the lines of communication and support between the lead Cardiac Physiologist for the implantable cardio defibrillator (ICD) and cardiac resynchronisation therapy (CRT) follow-up service and the Consultant Cardiologist responsible for the onsite service to ensure that clinical governance requirements are met. ICD and CRT follow-up clinics should not be undertaken without a designated physician available onsite.

The lines of clinical responsibility must be clearly defined in the local trust policy. Trusts delivering ICD/CRT device follow-up services have a responsibility to ensure appropriate arrangements are in place to cover clinic activity (elective or urgent).

## ICD/CRT Device Clinic Follow Up Aims and Objectives

1. To optimize the system to provide delivery of optimal therapy for the individual patient needs whilst maximizing generator life. Safety must be paramount whilst manufacturer guidance and HRUK recommendations should also be taken into account.
2. To identify any abnormalities in the ICD/CRT system and any complications of the therapy in order to ensure prompt treatment.
3. To assess battery status to predict end-of-life (EOL) of the pulse generator in order to permit timely elective generator replacement.
4. To provide patient and family support and education together with any other healthcare professionals involved in the patient"s management.
5. To ensure that the patient"s experience is as safe, comfortable and reassuring as possible.
6. To ensure that safe and accurate measurements are made and that accurate records of each visit are kept. Staff leading the clinic must be able to identify problems and complications and make the appropriate changes or recommendations.
7. To monitor the device implant site and manage any risk of infection.
8. To maximize clinical safety and efficiency in line with clinical governance requirements.
9. To regularly review patients in line with local, manufacturer and National guidelines.
10. To implement relevant advisories from device manufacturers and the Medicines and Healthcare products Regulatory Agency (MHRA) guidelines and advice.
11. To notify the MHRA and manufacturer of any problems arising with devices or leads.
12. To be aware of the need to identify clinical problems and refer patients for immediate or deferred medical care appropriately in line with local policy.
13. To provide accurate and complete communication about patient-device interaction and appropriate functionality to GPs and other relevant health professionals.
14. To monitor any counters of intra-cardiac events or episodes to ensure that appropriate therapy is being delivered and to minimize patients symptoms where necessary.

Staffing: Qualifications and Training

Ideally the clinic should be manned with two staff, one of who meets the lead role competencies. The Second staff member can be undergoing training.

Lead Cardiac Physiologist

• A qualified Cardiac Physiologist (BSC Clinical Physiology or equivalent) • Evidence of post-graduate training in cardiac rhythm management techniques e.g. holds appropriate Certification of Accreditation HRUK or IBHRE • Hold current ILS or ALS accreditation • Evidence of Continual Professional Development (CPD) in cardiac rhythm management • Perform minimum of 100 ICD/CRT device follow-up review procedures per year • Demonstrate high level of understanding and knowledge of the full range of diagnostic cardiac investigations • Must attend an ICD/CRT device course, which has been accredited by HRUK or SCST at least once per year

In some cases it may be appropriate that with the relevant training and competencies that the lead Cardiac Physiologist may take responsibility for titrating drugs for heart failure optimization.

## Cardiac Physiologist

• A qualified Cardiac Physiologist (BSc Clinical Physiology or equivalent)
• Holds current ILS accreditation
• Proven understanding and experience in bradycardia pacemaker and ICD/CRT device implant procedures
• Has a proven knowledge of bradycardia pacemaker and ICD/CRT device technology
• Has a proven experience in bradycardia pacemaker follow up clinics
• Has current CPD by attending relevant recognized training study days

## Equipment and Other Essential Requirements

A wide range of equipment is essential within the clinic or immediate vicinity of the clinic with access to further cardiac investigations (which need not necessarily be on site). These are listed below.

Equipment essential in the Pacemaker clinic (or in the immediate vicinity):

- 12-Lead electrocardiograph (ECG) machine with real time recording
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- Data management system/patient notes
- Sharps box
- Oxygen, suction and relevant adjuncts.

There should also be access to MHRA Pacemaker adverse incident reporting forms. Investigations to which the cardiac physiologist should have referral access:

- X-Ray facilities
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Cardiac investigations to which it may be desirable to have referral access:

- Exercise Stress Testing
- Head-up Tilt-Table Testing.

Access for rapid referral of any patient needing urgent admission should also be available.

Section C Transmitted/Remote Device follow-up With a rapidly evolving technology, telephone transmission is likely to change the face of device follow up and management in the very near future. There are already several methods of telephonic transmission available and more are currently in development.

Each company may use different technology and this will add further complexity to device follow-up services. However it is anticipated that there will be added benefits in reduced patient journeys and unnecessary hospital admissions and therefore allowing more time available for complex device follow-up by experienced Cardiac Physiologists.

The Cardiac Physiologist supervising such a remote service will therefore require the same level of expertise and training of the Cardiac Physiologist leading a clinic attended directly by patients.

Guidance will be taken from manufacturers and the European taskforce group on regulations relating to Remote device follows up and Trust protocols, agreed by the responsible Consultant Cardiologist/Lead Cardiac Physiologist must be in place.

## Clinic Procedures

All device follow up clinics should work to a standard procedure/protocol. This may be locally developed but should incorporate the minimum requirements set out in these guidelines.

### A procedure for device follow-up should include the following where possible:

• Recording of an ECG rhythm strip to verify device function and monitoring this throughout the check

• Maintenance of device function throughout check

• Identification of the device and leads from the patient records

• Initial interrogation of the device and recording of any relevant information

• Assessment of device battery status and comparison with previous records

• Safe testing of device and lead status including thresholds for sensing and capture as well as impedance measurements .

• Assessment of diagnostics, events and appropriate counters/histograms for rate assessment and appropriate function.

• Appropriate troubleshooting for complications/problems using other investigations where necessary.

• Appropriate reprogramming of the device to ensure that optimal settings for clinical outcomes are provided for the patient.

• Recording all the above.

• Checking final settings and ensuring that any changes have been fully and appropriately documented and checked to ensure patient safety.

• Appropriate scheduling of the next appointment or referral.

• Ensuring that device registration has been undertaken and that all patients have their registration/ID cards and all appropriate information.

## METHOD AND DATA-

- Information regarding organization, location, history, area, planning, manpower, organizational hierarchy and other details collected from hospital"s manual concerned authorities and other source.
- Various departments were identified.
- Training in identified areas were done by collecting information and data from co-ordinators, personal observation and by assisting concerned personnel in daily operational management of that area.
- Data were collected by reviewing records and from co-ordinators. Data comprises of: -Input to the department.
  -Output generated.
  -Other data specific to the department.
- Information was collected regarding location, equipment used, policies, procedures and other managerial works.
- Additional information was collected wherever required.
- Observational finding and information were compiled and a report was prepared

## METHODOLOGY

- The study was carried out for duration of 2 months.
- There are total of 200 doctors, 350 nurses and 250 Non -medical staff.10% of all of the above are taken as sample which gives a total of 80 as sample size.
- Study Design-Cluster sampling was used consisting of 12 doctors, 8 paramedics, 30 nurses and 30 non-medical staff. Data was collected using a questionnaire based on 5 point like RT scale.

Note-Large no. of nurses were opted because they are once having major contact with patient and are most importantly responsible for patient safety.

- Data type used was quantitative.
- The survey was conducted at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala.
- Analysis was done Using SPSS.

## FINDINGS

| S.no. | Questions | Doctors | Paramedics | Nurses | Non-medical Staff |
|---|---|---|---|---|---|
| | **Overall percentage of safety** | | | | |
| **1.** | Patient safety is never sacrificed to get more work done | 75% agree | 50% strongly agree | 46.7% agree | 66.7% agree |
| **2.** | Our procedures and systems are good at preventive errors from happening. | 41.7% agree | 75% agree | 53.3% agree | 66.7% agree |
| | F**requency of events reported** | | | | |
| **1.** | When a mistake is made,but is caught and corrected,before affecting the patient,how often is this reported? | 58.3% sometimes | 50% most of the times | 46.7% most of the times | 30% Sometimes |
| **2.** | When a mistake is made, and no potential to harm the patient,how often is this reported? | 50% sometimes | 37.5% always | 30% most of the times | 30% Sometimes |
| **3.** | When a mistake is made, and could harm the patient,but does not,how often is this reported? | 58.3% sometimes | 50% sometimes | 36.7% most of the times | 33.3% most of the times |
| | **Supervisors/Managers expectations and actions promoting patient safety** | | | | |
| **1.** | My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedure. | 66.7 agree % | 62.5% agree | 66.7% agree | 73.3% agree |
| **2.** | My supervisor/manager seriously consider staff suggestion for improving patient safety. | 58.3% agree | 75% agree | 70% agree | 60% agree |
| **3.** | My supervisor/manager overlook patient safety problem that happen over and over. | 33.3% agree | 12.5% agree | 50% agree | 33.3% agree |
| **4.** | When pressure builds up my supervisor/manager wants us to work faster even if it means taking shortcuts. | 41.7% agree | 37.5% agree | 26.7% agree | 23.3% agree |

| | | | | | |
|---|---|---|---|---|---|
| | **Organizational learning: Continous improvement** | | | | |
| 1. | We are actively doing things to improve patient safety | 66.7% agree | 62.5% agree | 56.7% agree | 63.3% agree |
| 2. | After we make changes to improve patient safety,we evaluate their effectiveness. | 58.3% agree | 50% agree | 53.3% agree | 76.7% agree |
| 3. | Mistakes have lead to positive changes here. | 50% agree | 50% agree | 56.7% agree | 56.7% agree |
| | Teamwork within units | | | | |
| 1. | People support one another in this unit and work together as a team when needed. | 66.7% agree | 62.5% agree | 60% strongly agree | 56.7% agree |
| 2. | When one area in this unit gets really busy,other helps out. | 66.7% agree | 37.5% agree | 53.3% agree | 33.3% agree |
| | **Communication Openness** | | | | |
| 1. | Staff feel free in question the decision and actions of those with more authority. | 41.7% sometimes | 75% most of the time | 30% most of the time | 36.7% rarely |
| | **Feedback and communication about error** | | | | |
| 1. | We are given feedback on changes put into place based on event reports. | 50% sometimes | 62.5% most of the time | 53.3% most of the time | 56.7% most of the time |
| 2. | We are informed about error that happen in this unit. | 41.7% sometimes | 50% most of the time | 43.3% most of the time | 40% most of the time |
| 3. | In this unit,we discuss ways to prevent errors from happening again. | 41.7% most of the time | 50% always | 46.7% most of the time | 43.3% most of the time |
| | **Non primitive response to error** | | | | |
| 1. | When an event is reported,it feel like the person is being written up,not the problem. | 33.3% agree | 50% agree | 40% agree | 23.3% agree |
| 2. | Staff worry that their mistakes are held against them and kept in their personal file. | 58.3% agree | 37.5% agree | 26.7% agree | 36.7% agree |
| | Staffing | | | | |
| 1. | We have enough staff to handle the work load | 50% agree | 50% agree | 16.7% agree | 43.3% agree |
| 2. | Staff in this unit work longer hours then is best for patient care. | 58.3% agree | 62.5% agree | 56.7% agree | 53.3% agree |
| 3. | We work in “crisis mode” trying to do too much,too quickly. | 25% agree | 37. 5% agree | 26.7% agree | 36.7% agree |

| | **Hospital management supports for patient safety** | | | | |
|---|---|---|---|---|---|
| 1. | Management in this facility provides climate that promotes patient safety as top priority. | 50% agree | 75% agree | 56.7% agree | 80% agree |
| 2. | Management in this facility access interest in patient safety only after an adverse event happens. | 33.3% agree | 50% agree | 43.3% agree | 36.7% agree |
| | Teamwork across hospital units | | | | |
| 1. | There is good co-operation among unit that need to work together. | 66.7% agree | 87.5% agree | 53.3% agree | 76.7% agree |
| 2. | It is unpleasant to work with staff in this facility. | 8.3% agree | 25% agree | 53.3% agree | 16.7% agree |
| | Hospital handoffs and transitions | | | | |
| 1. | Important patient care information is lost during shift changes. | 33.3% agree | 25% agree | 40% agree | 20% agree |
| 2. | Problem often occur in the exchange of information across units. | 16.7% agree | 37.5% agree | 50% agree | 23.3% agree |
| 3. | Shift changes are problematic for patients. | 16.7% agree | 12.5% agree | 33.3% agree | 13.3% agree |

**Note**: Details of questionnaire attached in annexure 2.

## CONCLUSION AND DISCUSSION

### Strengths-

We identified as strength those positively worded items which about 75% of respondents endorse by answering “Agree/Strongly Agree”, or “Most of the time /Always”(or when about 75% of respondents disagreed with negatively worded items.)

A number of strength emerged from the results:

- The procedures and system at the hospital are good at preventing errors from happening.
- People support one another and work together on a team in various units of the hospital.
- Employees are appreciated by the supervisor/Manager when they perform the job according to the expectation.
- Things are actively done to improve the patient safety in the hospital.
- There is good co-operation among the various units of the hospital.
- Most respondents graded the overall patient safety very good.

### Areas for improvement-

Areas with potential for improvement were identified as items which about 50% of respondents answered negatively using “Disagree/Strongly agree” or “Never / Rarely”(or when 50% of respondents disagreed with positively worded items.)

A number of areas emerged from the results:

- Staff should be given feedback about changes put into a place based on event reports.
- Staff should be informed about errors that happen in their respective units.
- Staff should feel free to question the decisions and actions of those with more authority.
- Ways o prevent error from happening again should be frequently discussed among the staff.
- More staff should be there to handle the workload in each unit of the hospital.
- Management should always be interested in patient safety, not only after an adverse event happen.

## WORK PLAN:

| Weeks / Activity | FIRST | SECOND | THIRD | FOURTH | FIFTH |
|---|---|---|---|---|---|
| Initial discussions | | | | | |
| Review of literature | | | | | |
| Preparation of guidelines &tool | | | | | |
| Data collection | | | | | |
| Analysis | | | | | |
| Draft report | | | | | |
| Final report | | | | | |

REFERENCES:


1. 2006 National Healthcare Quality Report assembled by the Agency for Healthcare research and Quality(AHRQ)

2. Study on “why do interns make prescribing errors” MJA 2008;188(2);89-94 by Ian D Coombes, Danielle A Stowasser, Judith A Coombes and Charles Mitchell.

3. Study by Aorn, a US-based professional organizations of preoperative registered nurses.

4. Study by RAND Health, the U.S healthcare system.

5. The Joint Commission Journal on Quality and Patient Safety, 2012 John M. Eisenberg Patient Safety and Quality Awards, Innovation in Patient Safety and Quality at the National Level by Elizabeth W. Paxton, MA; Mary-Lou Kiley, MBA; Rebecca Love, MPH, RN; Thomas C. Barber, MD; Tadashi T. Funahashi, MD; Maria CS Inacio, MS

6. GUIDELINES FOR FOLLOW UP OF IMPLANTABLE CARDIAC DEVICES FOR CARDIAC RHYTHM MANAGEMENT – October 2008
   Sue Jones, Michael Gammage and Nick Linker for HRUK; Brian Campbell and Wilson McNair for SCST

7. Standard Operative Procedures SCTIMST, Trivandrum.

# ANNEXURES

**ANNEXURE 1**

**Survey on Patient Safety**

| **Instructions** |
|---|

This survey asks for your opinions about patient safety issue, medical error and event reporting in your facility and will take about 10 to 15 minutes to complete.

If you do not wish to answer a question or if a question does not apply to you, you may leave your answer blank

- An "event" is defined as any type of error, mistake, incident, accident or deviation regarding of whether or not it result in patient him
- "Patient Safety" is divided as the avoidance and prevention of patient injuries or advance events resulting from the processes of health on delivery

**SECTION A: Your Work Area/ Unit**

In this survey, think of your work area as unit, department or clinical area of your facility where you spend most of your work time or provide most of your clinical services.

What is your work area or unit in your facility? Select ONE answer.

☐ a. Many different units/ No specific Unit

☐ b. Medicine (Non- Surgical)
☐ c.Obstetrics
☐ d.Pediatrics
☐ e. Emergency department
☐ f. Intensive care unit (Any type)
☐ g.Psychiatry/mental health
☐ h. Pharmacy
☐ i. Laboratory
☐ j. Radiology
☐ k. Anesthology
☐ l. Nursing
☐ m. Attending/ Staff Physician
☐ n. Resident physical/ Physician In Training
☐ o. Dietician
☐ p. Unit Assistant/ Clerk/Secretary
☐ q. Respiratory therapist
☐ r. Administration/Management
☐ s. Others Please Specify:

Please indicate your agreement or disagreement with the following statements about your work area/unit

| **Think about your work area/unit** | Strongly Disagree | Disagree | Neither | Agree | Strongly Agree |
|---|---|---|---|---|---|
| 1. People support one another in this unit And work together as a team when needed | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. We have enough staff to handle the work load | ☐ | ☐ | ☐ | ☐ | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| 3. Staff in this unit works longer hours than is best for present care. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. We are actively doing things to improve patient safety | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Mistakes have led to patient changes here. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. When one area in this unit gets really busy, other help out. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. When an event is reported, it looks like the person Is being written up, not the problem. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 8. After we make changes to improve person safety, we evaluate their effectiveness. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. We work in „crisis mode" trying to do too much too quickly. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10. Patient safety is never sacrificed to get more work done. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 11. Staff worry that their mistakes are held against them and kept in their personnel file. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 12. Our procedure and systems are good at preventing errors from happening. | ☐ | ☐ | ☐ | ☐ | ☐ |

**SECTION B: Your Supervisor/ Manager**

**Please indicate your agreement or disagreement with the following statements about your immediate supervisor/manager or person to whom you directly report.**

| | Strongly Disagree ⇩ | Disagree ⇩ | Neither ⇩ | Agree ⇩ | Strongly Agree ⇩ |
|---|---|---|---|---|---|
| 1. My supervisor/ Manager says a good word when He/she sees a job done according to established patient safety procedure. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. My supervisor/ Manager seriously considers staff suggestions for improving patient safety. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Whenever pressure builds up, my supervisor/ Manager wants us to work together, even it taking short cut. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. My supervisor/ Manager overlooks patient safety problems that happen over and over. | ☐ | ☐ | ☐ | ☐ | ☐ |

**SECTION C: Communications**

**How often do the following things happen in your work area/unit?**

| **Think about your work area/unit** | **Never** | **Rarely** | **Some-times** | **Most of the times** | **Always** |
|---|---|---|---|---|---|
| 1. We are given feedback about changes put into place Based on event reports. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. We are informed about errors that happens in this unit | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Staff feels free to question the decision or action of theses with more authority. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. In this unit we discuss ways to protect errors from happening again. | ☐ | ☐ | ☐ | ☐ | ☐ |

**SECTION D: Frequency of Events Reported**

**In your work area/unit, when the following mistakes happen, how often they are reported?**

| | **Never** | **Rarely** | **Some-times** | **Most of the times** | **Always** |
|---|---|---|---|---|---|
| 1. When a mistake is made, but is *caught and corrected Before affecting the patient*, how often is this Reported? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2.When a mistake is made, but has *no potential to harm the patient,*, how often is this reported? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3.When a mistake is made that *could harm the patient,* But does not, how often is this reported? | ☐ | ☐ | ☐ | ☐ | ☐ |

**SECTION E: Patient Safety Grade**

**Please give your work areas/unit an overall grade on patient safety?**

| ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|
| **A** | **B** | **C** | **D** | **E** |
| Excellent | Very Good | Acceptable | Poor | Fairing |

**SECTION F: Your Facility**

Please indicate your agreement or disagreement with the following statements about your work area/unit

| **Think about your Facility….** | Strongly Disagree | Disagree | Neither | Agree | Strongly Agree |
|---|---|---|---|---|---|
| 1. Management in this facility provides work climate that promotes patient safety as a top priority. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. There is a good cooperation among the units that needs to work together. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Important patient care information is often kept | ☐ | ☐ | ☐ | ☐ | ☐ |

during shift change.

| | | | | | |
|---|---|---|---|---|---|
| 4. It is often unpleasant to work with staff from other units in this facility. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Problems often occur in the exchange of information across units in this facility. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Management in this facility seems interested in patient safety only after an adverse event happens. | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. Shift changes are problematic for patient in this facility. | ☐ | ☐ | ☐ | ☐ | ☐ |

**SECTION G: Numbers of Events Reported**

**In the past 12 months, how many events reports have you filled out and submitted?**

☐ a. No Events Reports
☐ b. 1 to 2 events reports
☐ c. 3 to 5 events reports
☐ d. 6 to 10 events reports
☐ d. 11 to 20 events reports
☐ d. 21 events reports or more

**SECTION H: Background Information**

**This information will help in the analysis of the survey results 1. How long have you been worked in this facility?**

☐ a. Less than 1 Year.
☐ b. 1 to 5 Years
☐ c. More than 5 Years

**2. How long have you worked in your current work area/unit?**

☐ a. Less than 1 Year.
☐ b. 1 to 5 Years
☐ c. More than 5 Years

**3. Typically, how many hours per week do you work in this facility?**

☐ a. Less than 20 hours per week
☐ b. 20 to 39 hours per week
☐ c. 40 to 59 hours per week
☐ d. 20 to 39 hours per week
☐ e. 80 to 90 hours per week
☐ f. 100 hours per week or more

**4. In your staff position, do you typically have direct interaction or contact with patient?**

☐ a. Yes, I typically have direct interaction or contact with patient.

☐ b. No, I typically do not have direct interaction or contact with patient

**5. How long have you worked in your current specialty or profession?**

☐ a. Less than 1 year

☐ b. 1 to 5 years

☐ c. 6 to 10 years

☐ d. 11 to 15 years

☐ e. 18 to 20 years

☐ f. 21 years or more

**SECTION I: Your comments**

**Please feel free to write any comments about patient safety, errors or event reporting in your facility.**

***THANK YOU FOR COMPLETING THE SURVEY***

**ANNEXURE-2**

| S No | Question | **Doctors** | **Paramedics** | **Nurses** | **Non medical Staff** |
|---|---|---|---|---|---|
| | **Overall perceptions of safety** | | | | |
| 1 | Patient safety is never compromised to get more work done | Neither-16.7%<br>Agree-75%<br>Strongly Agree-8.3% | Agree-50%<br>Strongly Agree- 50% | Strongly Disagree-10%<br>Disagree-10%<br>Neither23.3%<br>Agree-46.7%<br>Strongly agree-10% | Strongly Disagree-6.7%<br>Neither-13.3%<br>Agree-66.7%<br>Strongly agree-13.3% |
| 2 | Our procedures and systems are good at preventing errors from happening. | Neither-25%<br>Agree-41.7%<br>Strongly Agree-33.3% | Agree-75%<br>Strongly Agree- 25% | Disagree-10%<br>Neither-13.3%<br>Agree-53.3%<br>Strongly agree-23.3% | Disagree-6.7%<br>Neither-16.7%<br>Agree-66.7%<br>Strongly agree-10% |
| | **Frequency of events reported** | | | | |
| 1 | When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? | Never-8.3%<br>Rarely- 25%<br>Sometimes-58.3%<br>Most of the times-8.3% | Rarely-12.5%<br>Sometimes-12.5%<br>Most of the times-50%<br>Always-25% | Never-3.3%<br>Rarely-10%<br>Sometimes-10%<br>Most of the times-46.7%<br>Always-30% | Neither-6.7%<br>Rarely-16.7%<br>Sometimes-30%<br>Most of the times-26.7%<br>Always-20% |
| 2 | When a mistake is made, but has no potential to hurts the patient, how often is this reported? | Rarely- 33.3%<br>Sometimes-50%<br>Most of the times-16.7% | Rarely-12.5%<br>Sometimes-25%<br>Most of the times-25%<br>Always-37.5% | Rarely-23.3%<br>Sometimes-20%<br>Most of the times-30%<br>Always-26.7% | Neither-10%<br>Rarely-16.7%<br>Sometimes-30%<br>Most of the times-26.7%<br>Always-20% |
| 3 | When a mistake is made that could harm the patient, but does not, how often is this reported? | Never-16.7%<br>Sometimes-58.3%<br>Most of the times-16.7%<br>Always-8.3% | Sometimes-25%<br>Most of the times-25%<br>Always-50% | Rarely-10%<br>Sometimes-26.7%<br>Most of the times-36.7%<br>Always-26.7% | Neither-6.7%<br>Rarely-6.7%<br>Sometimes-23.3%<br>Most of the times-33.3%<br>Always-30% |
| | **Number of events reported** | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 1 | In the past 12 months, how many events reports have you filled out and submitted | No events reported-58.3%<br>1-2 Reported-16.7%<br>3-5 Reported-16.7%<br>11-20 Reported-8.3% | No events reported-25%<br>1-2 Reported-37.5%<br>3-5 Reported-37.5% | No events reported-30%<br>1-2 Reported-43.3%<br>3-5 Reported-16.7%<br>6-10 Reported-6.7%<br>11-20 Reported-3.3% | No events reported-40%<br>1-2 Reported-43.3%<br>3-5 Reported-6.7%<br>6-10 Reported-10% |

| | | | | | |
|---|---|---|---|---|---|
| | **Overall patient safety grade** | | | | |
| 1 | Please give your work area/unit an overall grade on patient safety | Excellent-8.3%<br>Very good-58.3%<br>Acceptable-16.7%<br>Poor-16.7% | Excellent-37.5%<br>Very good-62.5% | Excellent-50%<br>Very good-36.7%<br>Acceptable-10%<br>Failing-3.3% | Excellent-30%<br>Very good-46.7%<br>Acceptable-20%<br>Poor-3.3% |
| | **Supervisor/manager expectation and actions promoting patient safety** | | | | |
| 1 | My supervisor/ manager says a good word when he/she sees a good job done according to established patient safety procedure | Neither-25%<br>Agree-66.7%<br>Strongly Disagree-8.3% | Disagree-25%<br>Agree-62.5%<br>Strongly Disagree-12.5% | Strongly Disagree-3.3%<br>Disagree-3.3%<br>Neither-16.7%<br>Agree-66.7%<br>Strongly agree-10% | Strongly Disagree-3.3%<br>Disagree-3.3%<br>Neither-6.7%<br>Agree-73.3%<br>Strongly agree-13.3% |
| 2 | My supervisor/ manager seriously considers staff suggestion for improving patient safety | Disagree-8.3%<br>Neither-33.3%<br>Agree-58.3% | Neither-12.5%<br>Agree-75%<br>Strongly Disagree-12.5% | Strongly Disagree-6.7%<br>Disagree-6.7%<br>Neither-10%<br>Agree-70%<br>Strongly agree-6.7% | Strongly Disagree-3.3%<br>Disagree-3.3%<br>Neither-13.3%<br>Agree-60%<br>Strongly agree-20% |
| 3 | Whenever pressure builds up My supervisor/ manager wants us to work faster even it means taking shortcut | Disagree-25%<br>Neither-33.3%<br>Agree-41.7% | Strongly Disagree-10%<br>Disagree-13.3%<br>Neither-50%<br>Agree-26.7%<br>Strongly agree-6.7% | Strongly Disagree-20%<br>Disagree-46.7%<br>Neither-30%<br>Agree-26.7%<br>Strongly agree-6.7% | Strongly Disagree-20%<br>Disagree-46.7%<br>Neither-10%<br>Agree-23.3% |
| 4 | My supervisor/ manager overlooks patient safety problems that | Strongly Disagree-8.3%<br>Disagree-25%<br>Neither-33.3% | Strongly Disagree-12.5%<br>Disagree- | Strongly Disagree-16.7%<br>Disagree-13.3%<br>Neither-10% | Strongly Disagree-23.3%<br>Disagree-30%<br>Neither-13.3% |

| | | | | | |
|---|---|---|---|---|---|
| | happens over and over | Agree-33.3% | 13.3%<br>Agree-37.5%<br>Strongly agree-12.5% | Agree-50%<br>Strongly agree-10% | Agree-33.3% |
| | **Organizational learning continuous improvements** | | | | |
| 1 | We are actively doing things to improve patient safety | Neither-8.3%<br>Agree-66.7%<br>Strongly agree-25% | Agree-37.5%<br>Strongly agree-62.5% | Disagree-Neither-3.3%<br>Agree-56.7%<br>Strongly agree-36.7% | Disagree-3.3%<br>Agree-63.3%<br>Strongly agree-33.3% |
| 2 | Mistakes have led to positive changes here. | Disagree-8.3%<br>Neither-8.3%<br>Agree-66.7%<br>Strongly agree-8.3% | Neither-25%<br>Agree-50%<br>Strongly agree-25% | Strongly disagree-13.3%<br>Disagree-13.3%<br>Neither-6.7%<br>Agree-56.7%<br>Strongly agree-10% | Strongly Disagree-3.3%<br>Disagree-13.3%<br>Neither-6.7%<br>Agree-56.7%<br>Strongly agree-20% |
| 3 | After we make changes to improve patient safety, we evaluate their effectiveness | Neither-41.7%<br>Agree-58.3% | Neither-25%<br>Agree-50%<br>Strongly agree-25% | Disagree-3.3%<br>Neither-26.7%<br>Agree-53.3%<br>Strongly agree-16.7% | Strongly Disagree-6.7%<br>Neither-10%<br>Agree-76.7%<br>Strongly agree-6.7% |
| | **Teamwork within units** | | | | |
| 1 | People support one another in this unit and work together as team when needed | Strongly Disagree-33.3%<br>Agree-66.7% | Agree-37.5%<br>Strongly agree-62.5% | Disagree-6.7%<br>Agree-33.3%<br>Strongly agree-60% | Neither-3.3%<br>Agree-56.7%<br>Strongly agree-40% |
| 2 | When one team in this unit gets really busy, others help out | Disagree-16.7%<br>Neither-8.3%<br>Agree-66.7%<br>Strongly agree-8.3% | Disagree-<br>Agree-<br>Strongly agree- | Strongly Disagree-<br>Disagree-<br>Neither-<br>Agree-<br>Strongly agree- | Strongly Disagree-<br>Disagree-<br>Neither-<br>Agree-<br>Strongly agree- |
| | **Communication effectiveness** | | | | |
| 1 | Staff feel free to question the decisions and action of those with more authority | Never-8.3%<br>Rarely -8.3%<br>Sometimes-41.7%<br>Most of the times-8.3%<br>Always-% | Sometimes-25%<br>Most of the times-75% | Neither-16.7%<br>Rarely-23.3%<br>Sometimes-23.3%<br>Most of the times-30%<br>Always-6.7% | Never-3.3%<br>Rarely-36.7%<br>Sometimes-20%<br>Most of the times-30%<br>Always-10% |

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| | **Feedback and communication about error** | | | | |
| 1 | We are given feedback about changes put into place based on event reported | Rarely -8.3%<br>Sometimes-50%<br>Most of the times-41.7% | Sometimes-25%<br>Most of the times-62.5%<br>Always-12.5% | Neither-13.3%<br>Rarely-10%<br>Sometimes-20%<br>Most of the times-53.3% | Rarely-3.3%<br>Sometimes-30%<br>Most of the times-56.7%<br>Always-10% |
| 2 | We are informed about errors that happens in this unit | Neither-16.7%<br>Rarely-8.3%<br>Sometimes-41.7%<br>Most of the times-33.3% | Neither-12.5%<br>Sometimes-12.5%<br>Most of the times-50%<br>Always-25% | Neither-3.3%<br>Rarely-10%<br>Sometimes-20%<br>Most of the times-43.3%<br>Always-23.3% | Rarely-13.3%<br>Sometimes-30%<br>Most of the times-40%<br>Always-16.7% |
| 3 | In this unit we discuss ways to prevent errors from happening again | Neither-8.3%<br>Rarely -8.3%<br>Sometimes-33.3%<br>Most of the times- 41.7%<br>Always- 8.3% | Most of the times-50%<br>Always-50% | Neither-3.3%<br>Rarely -20%<br>Sometimes-10%<br>Most of the times-46.7%<br>Always- 20% | Rarely – 3.3%<br>Sometimes-20%<br>Most of the times- 43.3%<br>Always-23.3% |
| | **Non preventive response to error** | | | | |
| 1 | When an event is reported, it feels like the person is being written up, not the problem | Neither-50%<br>Agree-33.3%<br>Strongly Agree-16.7% | Disagree-12.5%<br>Neither-37.5 %<br>Agree-50 % | Strongly Disagree-3.3%<br>Disagree-16.7%<br>Neither-23.3%<br>Agree-40%<br>Strongly agree-16.7% | Strongly Disagree-6.7%<br>Disagree-36.7%<br>Neither-30%<br>Agree-23.3%<br>Strongly agree-3.3% |
| 2 | Staff worry that their mistakes are held against them and kept in their file | Disagree- %<br>Neither- %<br>Agree- % | Neither- %<br>Agree- % | Disagree- %<br>Neither- %<br>Agree- %<br>Strongly agree- % | Disagree- %<br>Neither- %<br>Agree- %<br>Strongly agree-% |
| | **Staffing** | | | | |
| 1 | We have enough staff to handle the work load | Strongly Disagree-8.3%<br>Disagree-16.7%<br>Neither-8.3%<br>Agree-50%<br>Strongly agree-16.7% | Strongly agree-12.5%<br>Disagree-12.5%<br>Neither-25%<br>Agree-50% | Strongly Disagree-30%<br>Disagree-26.7%<br>Neither-20%<br>Agree- 16.7%<br>Strongly agree-6.7% | Strongly Disagree-3.3 %<br>Disagree-23.3 %<br>Neither-16.7 %<br>Agree-43.3 %<br>Strongly agree-13.3% |

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| 2 | Staff in this unit work longer hours than is bear for patient care | Neither-41.7%<br>Agree- 58.3% | Neither-12.5%<br>Agree-62.5%<br>Strongly agree-25 % | Strongly Disagree-6.7%<br>Disagree-3.3%<br>Neither-13.3%<br>Agree-56.7%<br>Strongly agree-20% | Disagree-23.3%<br>Neither-16.7%<br>Agree-43.3%<br>Strongly agree-13.3% |
| 3 | We work in "Crisis mode" trying to do too much, too quickly | Disagree-25%<br>Neither-50%<br>Agree- 25% | Agree-100 % | Strongly Disagree-3.3%<br>Disagree- 13.3%<br>Neither- 16.7%<br>Agree- 50%<br>Strongly agree-16.7% | Strongly Disagree- 3.3%<br>Disagree-10%<br>Neither-26.7%<br>Agree-50%<br>Strongly agree-10% |

| | **Hospital management support for patient safety** | | | | |
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| 1 | Management in this facility provides a work climate that promotes patient safety a top priority | Disagree-8.3%<br>Neither-25%<br>Agree-50%<br>Strongly agree-16.7% | Agree-75%<br>Strongly agree-25% | Disagree-10%<br>Neither-13.3%<br>Agree-56.7%<br>Strongly agree-20% | Disagree-3.3%<br>Agree-80%<br>Strongly agree-16.7% |
| 2 | Management in this facility seems interested in patient safety only after an adverse event happens | Strongly Disagree-8.3%<br>Disagree-33.3%<br>Neither-25%<br>Agree-33.3% | Strongly Disagree-25%<br>Disagree-25%<br>Agree- 50% | Strongly Disagree-10%<br>Disagree- 20%<br>Neither-16.7 %<br>Agree-43.3%<br>Strongly agree-10% | Strongly Disagree-13.3%<br>Disagree-30 %<br>Neither-16.7 %<br>Agree-36.7 %<br>Strongly agree-3.3% |
| | **Team work across hospital units** | | | | |
| 1 | There is good cooperation among units that comes to work together | Neither-25%<br>Agree- 66.7%<br>Strongly agree-8.3% | Agree-87.5%<br>Strongly agree-12.5% | Disagree-10%<br>Neither-13.3 %<br>Agree- 53.3%<br>Strongly agree-23.3% | Disagree-3.3%<br>Neither- 3.3%<br>Agree-76.7 %<br>Strongly agree-16.7% |
| 2 | It is often unpleasant to work with staff from other units in this facility | Disagree-50%<br>Neither-41.7%<br>Agree-8.3 % | Strongly Disagree-25%<br>Disagree-37.5%<br>Neither-12.5 %<br>Agree-25 % | Strongly Disagree-10%<br>Disagree-10 %<br>Neither-23.3 %<br>Agree-53.3 %<br>Strongly agree-3.3% | Strongly Disagree-10%<br>Disagree-56.7 %<br>Neither-13.3 %<br>Agree-16.7 %<br>Strongly agree-3.3% |
| | **Hospital handoffs and transition** | | | | |

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| 1 | Important patient care information is often lost during shift changes | Strongly Disagree-8.3%<br>Disagree- 50%<br>Neither-8.3%<br>Agree-33.3% | Disagree-50%<br>Neither-25%<br>Agree- 25% | Strongly Disagree-26.7%<br>Disagree-10%<br>Neither-20%<br>Agree-40%<br>Strongly agree-3.3% | Strongly Disagree-13.3%<br>Disagree-30 %<br>Neither- 30%<br>Agree-20 %<br>Strongly agree-16.7% |
| 2 | Problem often occur in exchange of information across units | Strongly Disagree-16.7%<br>Disagree-33.3 %<br>Neither-33.3 %<br>Agree-16.7 % | Disagree-37.5%<br>Neither-25%<br>Agree- 37.5% | Strongly Disagree-16.7%<br>Disagree-10 %<br>Neither-16.7 %<br>Agree- 50%<br>Strongly agree-6.7% | Strongly Disagree-13.3%<br>Disagree-46.7 %<br>Neither-16.7 %<br>Agree-23.3 % |
| 3 | Shift changes are problematic for patient | Disagree-58.3%<br>Neither-25%<br>Agree- 16.7% | Strongly Disagree-12.5%<br>Disagree-37.5%<br>Neither-37.5%<br>Agree-12.5% | Strongly Disagree-13.3%<br>Disagree-26.7 %<br>Neither- 20%<br>Agree- 33.3%<br>Strongly agree-6.7% | Strongly Disagree-13.3%<br>Disagree- 36.7%<br>Neither- 26.7%<br>Agree-13.3 %<br>Strongly agree-10% |