INTEROPERABLE FRAMEWORK SOLUTION TO ICU HEALTH CARE MONITORING

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Abstract

An interoperable telehealth system provides an independent healthcare solution for better management of health and wellness. It allows people to manage their heart disease and diabetes etc. by sending their health parameters like blood pressure, heart rate, glucose levels, temperature, weight, respiration from remote place to health professional, and get real-time feedback on their condition. Here different medical devices are connected to the patient for monitoring. Each kind of device is manufactured by different vendors. And each device information and communication requires different installation and network design. It causes design complexities and network overheads when moving patients for diagnosis examinations. This problem will be solved by interoperability among devices. The ISO/IEEE 11073 is an international standard which produces interoperable hospital information system solution to medical devices. One such type of integrated environment that requires the integration of medical devices is ICU (Intensive Care Unit). This paper presents the issues for ICU monitoring system and framework solution for it.

Keywords:

Intensive Care Unit (ICU), Interoperable, Device Validation, Personal Area Network (PAN) and Local Area Network (LAN)

1. INTRODUCTION

Pervasive health care computing is the one providing health care solutions to different regions of people at any time and any place with the use of mobile and wireless technologies. This system supports healthcare solutions by removing the time and location constraints with increase in coverage and quality of health care. It is proactive health care system that will reduce the incidents of one or multiple conditions of chronic diseases. This vision includes prevention, healthcare maintenance and checkups; short-term monitoring (home healthcare monitoring), long-term monitoring (nursing home), personalized healthcare monitoring; emergency intervention, transportation and treatment. The pervasive healthcare applications include pervasive health monitoring, intelligent emergency management system, pervasive healthcare data access, and ubiquitous mobile telemedicine etc. Main reasons for pervasive healthcare computing: [10]

- Lack of focus on preventive care
- Widespread of multiple patients suffering with chronic problems
- Shortage of healthcare professionals
- Inefficiency in healthcare delivery
- Overpriced medications and poor adherence
- Large number of medical mistakes and quality of care challenges
- Lack of technologies and access to information
- Increasing in costs and complexity of payments

2. PATIENT MONITORING SYSTEM (PMS)

Patient health care monitoring is one of the main components in Pervasive healthcare computing. According to this, different vital parameters of the patients are sent to the care giver through various communication technologies. The care giver uses them for making clinical decisions to cure the disease levels of patients. These pervasive health care applications will improve the communication among patients, physicians and other health care workers [1]. The process of monitoring vital parameters, physical conditions of patients, used for curing the chronicle diseases and deciding therapeutic preventions and assessing those preventions to patients is termed as "Patient monitoring system".

Main components of patient monitoring system [2]

- Medical devices
- Connectivity for PMS
- Aggregators
- Service

2.1 MEDICAL DEVICES

The medical devices are nothing but biosensor device which senses the bio element (say enzyme) from the patients and converts it into electrical signal. This element is particular and specific to the analyzer used for measurement. Few examples of devices are like Home sensing & control, Bed/Chair sensors implant monitors, baby monitors and spirometers etc [2] are the different types of medical device sensors for health care. Based on the usage of the devices the medical devices are categorized as two types:

- PAN Devices
- LAN Devices

The PAN devices are the one which are connected in PAN network or home network system. And the LAN devices are those connected to the LAN e.g., in Hospital LANS.

2.2 CONNECTIVITY

It is the communication technology used for devices to talk with the data collectors. Based on the availability of the network the devices can be connected through wired or wireless. Wired: USB Serial port/RS232 physical connection, Wireless: Zigbee/Bluetooth & Wi-Fi etc.

2.3 AGGREGATORS

These are used for collecting the data from the medical devices and compute the data and produce the records/data for

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storage purpose. Possible parameters for the system are vital parameters, images, charts & records etc. All the components of PMS are shown in the Fig.1.
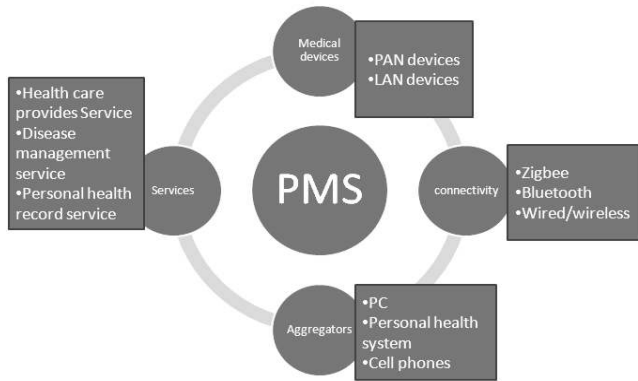

Fig.1. Patient Monitoring System

2.4 SERVICES

The collected data will be processed by the aggregators and generates reports. Then the reports will be stored into the health care data bases. These reports can be used for different services like disease management, preventing and curing their diseases, monitoring health conditions of patients and to social networks for record purposes.

3. BIG PICTURE OF PMS

As shown in the Fig.2 the vital parameters from patients are measured or sensed either directly or indirectly from the medical devices. The data is integrated, analyzed and processed for generating the reports. These reports are kept in patient data storage. These reports will be used by the viewers (Physicians/nurses/data analyzer). These reports are electronic generated data (EHR), consist of vital parameters, images or charts etc.
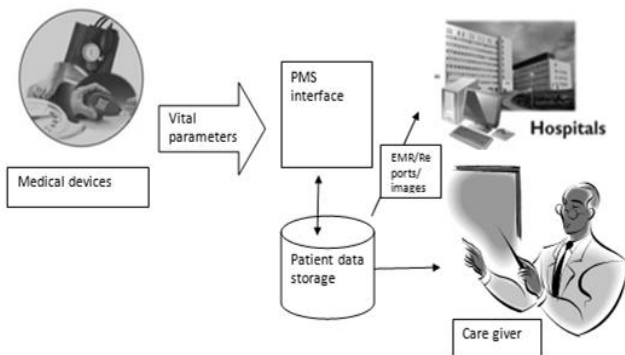

Fig.2. Big Picture of PMS

3.1 REMOTE MONITORING SYSTEM

It enables the monitoring patient's vital parameters outside of a conventional [11] clinical settings (e.g. from home, remote areas where there is no access to hospitals). It allows maintaining independent life, reduces the complications & minimizes the hospital costs to patients. It even provides the feel of comfort to patients and their family members when they were monitored

with problems. It helps in daily basis monitor of diabetic reports of patients, a case study review of the literature on home monitoring for heart failure [11] etc.

3.2 ICU MONITORING SYSTEM

The simultaneous monitoring of one or more parameters over time on a multimodal integrated monitor system in critical care units and the anesthetic machines in operation theaters [12] is considered as Intensive care unit monitoring. Here the patient is monitored continuously. The nurses and physicians will be informed about the changes of patients. Some vital signs even warn about the abnormal conditions of patients like artificial fibrillation or premature ventricular contraction [PVC] for fatal cardiac conditions.

3.3 AAL (AMBIENT ASSISTANT LIVING)

AAL supports new ICT technologies that will contribute services to older people to live independently in home for longer time. The services are provided through social communication networks. It improves the autonomy, employability and participation of older people or ill persons for managing their diseases or health parameters. It full fills the individual needs. This system mainly prolong the [9] life time of people in their home by increasing their autonomy and self-confidence.

In AAL the patients will wore one or more light weight medical devices to measure the vital signs wherever they were. These signs are carried over the social communication networks to care givers. The care givers send their feedback about their signs in case of abnormal situations and emergency conditions. The examples of AAL include home/personal care monitoring, health and fitness management and age independent solutions. The advantages of AAL include:

- People can live their preferable environment for treatment through mobility and autonomy.
- Healthy support to individually living people especially for older ones.
- To promote a better and healthier lifestyle
- To support family members and hospital organizations etc,.
- Reduces the hospital related costs.

4. CHALLENGES IN PMS

4.1 INTEROPERABILITY

In patient monitoring system many devices are sending vital parameters for patient's report generation. It includes exchange of health, wellness and fitness information, involves different technologies, devices and services. Different devices will communicate to the ecosystem or framework differently. The incompatibility across medical devices are the vital parameters, communication and technology. This may causes different programming errors. Different medical sensors in the system involve different calibrations and communication technologies. So it is difficult to provide communication activation for each device. To avoid this it is necessary that all medical device vendors should follow some integration standards to make use of

them in multi domain network environment systems like EHR and EMR generation for patient's medical data.

And the process of integrating and mixing of different medical devices used by patients/consumers at home, for remote monitoring, hospitals is termed as interoperability. This interconnect system is developed by adopting common standards. For example IEEE 11073 is used for medical device integration, HL7 for generating EHR/EMR reports and DICOM for processing medical image data.

4.2 PRIVACY & SECURITY

Due to the process of monitoring user actions, behavior, habits, actions, location and movements there is a chance of misuse of the monitoring computing environment. And the data to monitoring system will reach from patient's home, hospitals, ambulances [4] & care takers. It may leads to spam, black mail or other fraudulent access & security issues. So each location should be implemented with a different level of security to avoid abnormalities.

4.3 ADAPTION

Due to the dynamic behavior of mobile user the network in PMS in not fixed. And it involves different kind of mobile users who will carry the devices to different places. At different locations these is a dramatic change in the computing and networking environment. Based on the resources available in the environment the devices should adopt to those technologies. It involves searching and utilizing the available computing resources and making software and application changes in the new environment for adaption. So it is assumed that the computing resources are available and co-operative so that the mobile user is able to access them from his new location. The software and application changes are much more complex and involve moving the execution to another device or finding co-operative device/server to assist in the processing.[10]

4.4 ALARM MANAGEMENT

It is the process of alerting clinicians or care takers when vital parameters or medical devices are deviating from a predetermined "default" status [6]. In critical environments the alarms will be generated for vital parameters abnormalities and devices failures in the system. Many of patient's death occur when the alarms are ignored, avoided and silenced. If the frequency of the alarms is more, then the nurses may not sense or may even ignore the emergency alarm. Proper software modifications need to be provided for care taker to set the limit levels of alarms.

4.5 TIME ACCESS

For life threaten scenarios the data need to be send reliable and without delay.

4.6 ACCURACY

The data measurements should be as much accurate as possible.

4.7 SCALABILITY

The vital parameters monitoring from the patients will be more. So the monitoring frame work would be scalable enough to store all types of data.

4.8 CONTEXT- AWARENESS OF USER

As this pervasive health care computing the data of the patient is context or diseases dependent. So while informing about patient health parameters the frame work needs to consider the patient's circumstances, situations & disease conditions

4.9 ENERGY MANAGEMENT

To properly use the devices, use dynamic power management algorithms in devices in such a way that the devices should close and shut when ever particular app or device is not in use.

The existing system of interoperable frameworks is provided with respect to the integration of medical devices. This paper presents the integration of medical devices to ICU monitoring system.

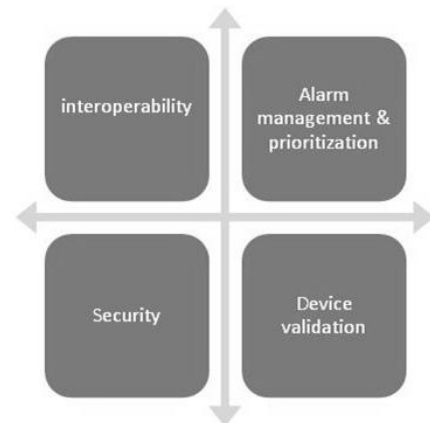## 5. ISSUES FOR ICU MONITORING SYSTEM

Fig.3. Challenges in ICU

The challenges considered for ICU framework are shown in Fig.3.

Interoperability: As in ICU environment the patient is connected with different devices like ventilometer, logical analyzer, ECG meters, etc., all these should be properly integrated with the device collector for taking the parameters. So it needs some standard interface to send their data.

Different organizations working for interoperability standards: [3]

- The Continua Alliance which is working for personal health device integration using IEEE11073 medical device standard.

- Integrating the Health Environment-Patient Care Devices Domain (IHE-PCD) working for alarm management

- American Society for Testing and Materials-Integrating the Clinical Environment (ASTM-ICE) for ICE integration.

- The Health Information Technology Standards Panel (HITSP) specification to meet the electronic medical records

Device Validation: when multiple devices are getting integrated in one environment for monitoring, the device manager should confirm that all the devices have to be connected properly before processing. It involves diagnosing each device to

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the framework before used by the people or environment. This device validation can be done by using ISO 14971 Risk management medical device standard [8].

Alarm management & prioritization of devices: For critical care units there was unstable situation, abnormal functionalities and malfunctions of devices which lead to serious problems even deaths some times. These situations should be intimated to care taker or nurses through alarms and alerts. To do the alarm the devices should be prioritized. When multiple devices are connected to the framework to which device the alarm should be given first is done through prioritizing of devices.

Security: High level security and privacy is considered to the patient's data when it is communicated to external network through Gateways.

6. THE HIGH LEVEL DESIGN OF THE ICU FRAMEWORK

High level design of a framework for ICU patient monitoring system is given in Fig.4. In ICU environment the caretaker should monitor different parameters of patient at a time. When all these devices attached to the patient, the care taker needs to look into each device parameter separately. This involves activating and inactivating the devices, wastage of resources of the system, involves more time for taking decisions on patients. In ICU or in an urgency environment a single minute waste of time is accountable. So to efficiently use the system resources and to avoid wastages of time a special framework is considered for ICU.

This framework should integrate all devices in to the system, able to measure and store the data and need to generate the reports for clinical decisions. The required frame work given is derived based on ASTM-ICE standard [3]. As shown in Fig.4 the environment needs.
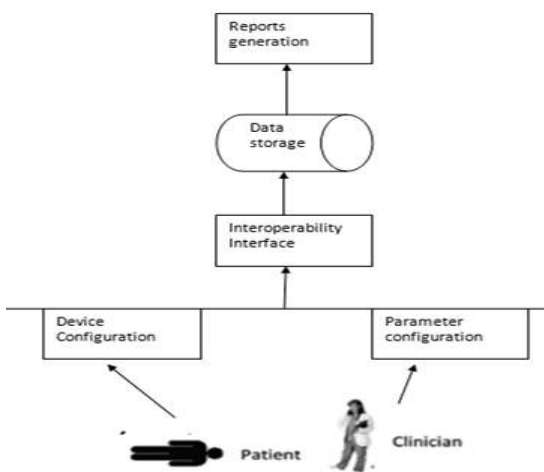

Fig.4. High level Design in ICU

- The interoperability interface for smart integration of different devices (interoperability interface)
- Storing the vital parameters of medical data to data base
- The stored data is used for generating the e-based reports like EHR, EMR etc

The configuration of medical devices is set by clinician based on the patient's health stability or disease category. Since for abnormal or disease situations what are the devices or parameters to be done should be decided by the physician.

7. ICU INTERFACE & NETWORK CONTROLLER

According to the ASTM [3] the definition of Intensive Care Environment (ICE) system is the one which needs safe data acquisition, integrating and controlling of heterogeneous combination of medical devices and other equipment in a high-acuity patient environment. It is mainly designed for creating patient safety, treatment efficiency and work flow efficiency. This is done with ICE interface. The tasks given to this controller involves:

- Integrating medical device sensors and other electrical equipment with ICU environment.
- Providing the interfacing with the devices (ICE interface) and network controller.
- Making the communication and association between devices.
- A supervising (Device manager) task is to properly assign the integrating paths between devices and operator.
- It checks the functional capabilities and delivers the reports to Device manager.
- Any technical alarm issues generated, for example the insufficient resource availability indication when new device connected.
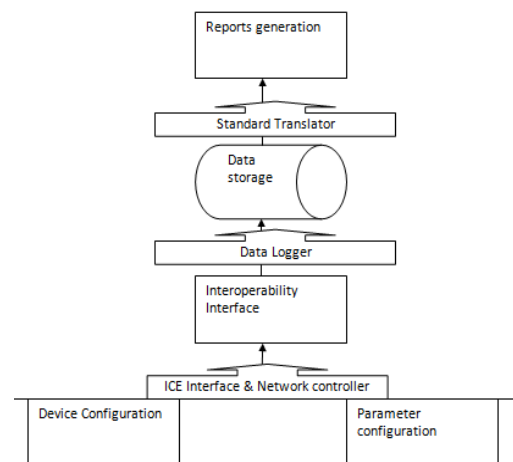

Fig.5. Interfaces in ICU

The ICE can include the External interface to connect the framework to communicate with outside world like health care network and connection to the internet. It is enabled with Risk management factor. This risk management is the one that includes the qualification test which performs basic safety and essential performance of the ICE interface. This is required prior to placing the device to the ICE equipment (Device validation). The definitions of different components of framework are discussed in the following sections.

7.1 INTEROPERABILITY INTERFACE

A standard or an integrating interface is considered for all medical device connectivity.

7.2 DATA LOGGER & DATA STORAGE

This is for logging and storing the data status of clinical environment on timely basis. The data logging is intended for the following tasks; [7]

- Technical parameters (functional & non functional) & alarm conditions
- Patient's physiological parameters & alarm variables
- Network controller status
- Important errors & significant events

7.3 STANDARD TRANSLATOR & REPORT GENERATION

This involves generating the report to the measured vital parameters. The data should be converted to electronically generated health record. It has the information of the entire patient's health report (EHR). This includes an intelligent medical driven system for generating the meaningful format (EHR/EMR) to clinicians. The generated report will be used by the clinicians to take clinical decisions to treat their patients. The EHR report includes patient's vital parameters, charts, images or other reports etc.

8. TECHNICAL DESIGN OF FRAMEWORK

The detailed design of the framework that includes all the components in each level is shown in Fig.6. The framework is divided with 5 levels.

1) Level I➔Device configuration & ICE interface
2) Level II➔Interoperability
3) Level III➔Data aggregation & Collection
4) Level IV➔Patient data management
5) Level V➔Services

8.1 LEVEL I (DEVICE CONFIGURATION & ICE INTERFACE)

This needs to connecting and setting the devices to ICU environment. Device settings, parameters configuration to alarm generation and prioritizing the devices based on the disease type or treatment the devices to alert will vary.

So the choice of setting the prioritizing of different devices should be done by the clinician or care taker. To communicate each device with ICE environment equipment, the device needs to understand its communication pattern to send its data. The understanding between the device and equipment interface (Level II) is done through ICE interface.

The primary goal of this framework is to improve the safety of the patient allowing the hospital staff to alert to the abnormal conditions and safety of the environment equipment. On this the alarm configuration is included as one of the component to the framework. The configuration to the alarm setting is decided

based on the patient disease level and is set by clinicians or doctors.
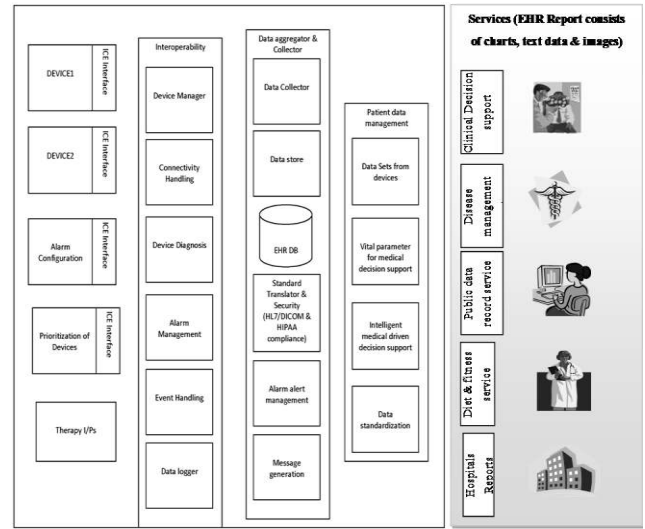

Fig.6. Technical design of framework

In ICU environment multiple devices are connected with a patient, then multiple devices may generate alerts at a time. At once time the system can trigger the alarm for one device so to which device's alarm should be considered. For example a cardiac attack patient who admitted into the ICU connected with devices like BP meters, pulse-oximetry meters, ventilator etc. When all these devices alerted the system considers the ventilator device for processing. The process of selecting the one for alarm generation would be done through prioritization process.

8.2 LEVEL II (INTEROPERABILITY)

In critical care monitoring the diagnosis, treatment or monitoring is performed on a single patient and he/she is connected with multiple medical sensors and other equipment [8]. And all these are interconnected with interoperability to reduce costs and to improve patient's safety. The interconnection task involves the following tasks:

8.2.1 Device Manager (ICE Supervisor):

This task is given for supervising all the devices communication or association, active and inactive condition. And it will check the functional capabilities of devices with interfaces like ICE network controller and interface. To know all these the device manager need to include the device's inputs, outputs, operational modes and mathematical models [8] of ICE equipment interface.

8.2.2 Connectivity Handling (ICE Network Controller):

The connectivity handling is the communication process between two different medical devices. Usually this is implemented either by TCP/IP or OSI reference model.

In a group of medical devices in ICU each device's data representation, units of measurements will differ from others. When different types of data presentation are involved it is necessary to include common standard data representations method to communicate the data in the ICU network interface.

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There are dozens of standards are available to standardize the various aspects of medical data e.g. HL7, DICOM etc, [7].

The flow of communication involved with each device in the system is given as follows:

From the Fig.7 the first three tasks considered for application level of data. This data of one device would be communicated with other device with association protocol. The association protocol performs the following functionalities;
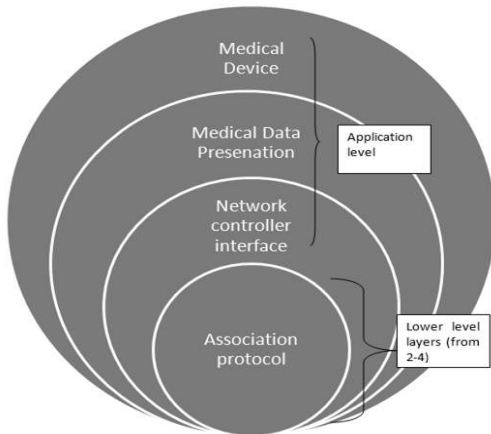

Fig.7. Communication layers between devices

• The logical communication of data between devices (transport layer)
• Identifying the destination device in the network (network layer)
• Sending the data through physical communication (wired communication channels, Physical and Data Link Layer)

And this association protocol can be implemented by using TCP/IP protocol stack.

8.2.3 Device Diagnosis:

This involves checking different conditions of devices to save the patient from harms or injuries. And it is a primary step to a medical device about its usage and working status confirmations. Examples of problems in medical devices usages:

• A medical device is not fitted into the fuses in right quantity while assembling
• Fitting the eye contact lenses in wrong way such that placing the inside part of lens to out
• A software hazard, for patient monitoring patient the system may experiences an unknown error in critical situations and does not go off
• The device power card insulation has been cracked and internal wires are exposed

The following are the definitions of medical device problems which are taken from ISO 14971 standards [8] for analysis of device problems:

Harm:

It is a physical injury or damage to the health of people, or damage to property or the environment. The above examples may cause cold, viruses, bacteria, low pressure to patients and vibrations or shocks to the property.

Hazard:

Potential source of harm.

Hazardous situation:

Circumstance in which people, property, or the environment are exposed to one or more hazard(s)

By considering these the risk of the medical device would be considered with the following two components [8]

• What is the probability of occurrence of harm?
• What are all the consequences of the harm, how much severe it might be.

The hazards stake holders involved are:

• Medical practitioners
• Patients
• Members in the health care
• Organization in the hospitals

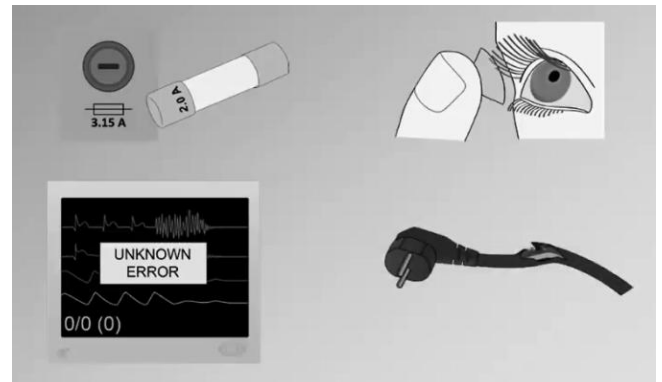The risk management analysis and control of medical device is done by ISO 14971 standards.

Fig.8. Taken from Gantus 2012 [13]

ISO 14971:

It instructs for medical device manufactures to manage their medical devices risks when is used for services, in a framework. Basically it comes into the part of quality management system. It deals the process of managing risks for patients, operators other persons, equipment and the environment.

The main intension of this standard is to make the stake holders need to understand the use of medical device with allowable level of risk. The level of risk may vary from person to person and environment to environment based on the usage of device. So it makes the user of the device to understand the possibility of risk when it is not used properly.

As a manufacturer of the medical device or when is used in a framework the risk management will be done as follows or the process of ISO 14971:

• Need to identify the hazards associated with a medical device
• Estimate the risks associated
• Evaluate the risks with the hazards
• Control the risks
• Monitor this control

This standard is not used for [8] Clinical decision support & specifying the levels risks.

Event Handling (Communication Management):

This task is for handling different events occurred to the ICU equipment like performing safety related events, performance conditions events and fault conditions events. According to ASTM-ICE standard the following principles are considered for event handling;

The integrated network controller environment & ICU interface should not fail due the message communication.

The errors handled by this event handler are:

- Failures of connections, problems with electrical and logical and interfacing equipments
- Failures with respect to the commands
- Failures for sending and receiving the messages
- Risk management factors for patient's safety

Data Logger

As discussed it basically for logging all input, error, network controller status etc.

Alarm Management

Two types of alarms are needed in this monitoring system:

- Patient status alarms
- System status alarms

System alarms are generated when there are device problems like mechanical, electrical problems e.g. failure of device, less charge in the device and breakage of connection with in the components etc.

Patient status alarms are triggered when there are different kinds of abnormalities with the patients. These will be divided into different levels to indicate the severity of the condition of it may be like critical, warning and advisory types[10] etc.

8.3 LEVEL III (DATA AGGREGATION & COLLECTION)

It includes collecting all the patient data, errors and alert messages etc., from the interoperable interface. And the collected need be stored in Health Information data storage. The stored data is given to patient management component to convert into patient data records. It can be done by using standard translators like HL7 and DICOM.

8.4 LEVEL IV (PATIENT DATA MANAGEMENT)

8.4.1 Data Sets from Devices:

The ICU environment includes data of vital results, alerts, treatment summaries, images. Here all this data will be available in different formats, units and sets. All these data sets would be aggregated stored and inter locked in a repository called as Health Information Technology (HIT) systems. To properly communicate this data set to care takers, clinicians the data must be in viewable or readable and understandable. i.e., the data need to be generated in a legible format. The conversion would be done by Health Information Exchange [HIE] approaches and tools. These tools will convert HIT information in desirable EHR formats.

These tools need the following process for generating the required formats.

8.4.2 Vital Parameters for Medical Decision Support:

It includes the following steps:

- Generating the meaningful format to clinical data
- Avoiding duplicate and electronic noises for the records
- Generate the clinical record system
- Organize the data based on the semantics, structures involved for the data.
- The understandable format of data will be done

8.4.3 Intelligent Medical Driven Support:

From the generated clinical report, required data is extracted. It includes the context of patients.

8.5 LEVEL V (SERVICES)

The important applications of patient monitoring includes personal health care monitoring, risk assessment of patient's health, storage of health data of patients, to take the decisions of patient's based on their health status, continuous surveillance of chronicle diseases, rescue procedures in emergency situations for remotely located patients etc.,

- It also provides the 24 × 7 availability and support to patients, aged people, for care takers and other purposes.
- It even provides maintenance support for generating Electronic health records, Electronic Medical records and patient health records etc.
- Supports the quality management, security & privacy for patient's health data.
- It increases the access to care and decreases the health care expenditure costs.
- These applications are particularly important for people who need complex self-care processes such as home hemodialysis, critical care monitoring like ICU's etc.

All these usage includes some of the following services:

- *Clinical decision support*: through the reports of vital parameters like charts helps to the care taker to take decision for his patients.
- *Disease Management*: By the continuous monitoring of patient's data chronic diseases like diabetes, chronic kidney and heart diseases are managed and controlled.
- *Public data record service*: to record patient data for global wise report diseases like TB, AIDS etc.
- *Diet & Fitness services*: to maintain and control one's life styles through continuous monitoring and feedback by the physicians. There the suggested precautions can be taken to maintain their diet and fitness.
- *Hospital records*: to maintain the records for hospitals like EMR, EHR & PHR etc.

9. CLINICAL SCENARIOS APPLICABLE FOR DESIGNING THE MODEL

Example 1:

A 49 year-old woman underwent abdominal hysterectomy and bilateral salpingo-oopherectomy [7]. Post operation she died

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because of over dosage of infusion of morphine via a patient controlled analgesia (PCA) pump. The PCA infusion is monitored based on the respiration rate monitor and a pulse oximeter. Due to the lack of proper optimization sensitivity between the two devices causes false alarm condition to the PCA pump injection. This cause over dosage into the patient leads to unable breath conditions finally to death.

Example 2:

A 32-year old woman who was admitted in the hospital for laparoscopic cholecystectomy [gall bladder removal][7] expired due to the lack of automatic synchronization between ventilator & portable x-ray connected to the integrated environment work station. This accident happened while performing anesthesia to the patient. Before operation at the surgeon's request while taking the x-ray during a cholangiogram the anesthesiologist stopped the ventilator for the film. After the film was attempted when they were trying to remove it from the table, they found it was jammed. When anesthesiologist attempted to help her (x-ray technician) and finally they removed the x-tray from the workstation. After some time the anesthesiologist glanced at the EKG of the patient and noticed severe bradycardia. They realized that, "they did not restart the ventilator". In the time gap the patient was expired. If the proper synchronization or providing interoperation communication between two devices between the ventilator and the portable x-ray is like when x-ray is under operation condition the ventilator should be paused and once the operation with x-ray is over automatically the ventilator should be resumed back.

Based on the above two examples to improve the patient safety to the integrated environment like ICU, needs to provide interoperation between device, false alarm free, secure and risk management to the devices.

Benefits of the proposed system:

- Early indication of sensitive & specific detection of discontinuation & medication of infusion pumps.

- Add error free integrated environment by eliminating the dependence of the operator (like anesthesia technician in second example).

- Security & confidentiality to the patient data & health monitoring system.

10. CONCLUSION

This type of interoperable, device validation and secure framework is well suitable for monitoring of different health care parameters. This even reduces the design complexity. This produces device diagnosis like it checks working condition of device before use. It provides high secured network to the medical devices, patient data and to monitoring system. It produces confidentiality to patient. This framework not only suggests solution to medical industry, but also expected can use it in other critical care industries.

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