Calm The Alarm
(A path forward for Safe Alarm Management of Biomedical Equipment)

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ABSTRACT

Biomedical equipment’s like infusion pumps, cardiac monitors, ventilators, syringe pumps and feeding pumps etc. are designed to generate alarm signals to indicate any unacceptable physiological patient conditions, unsatisfactory functional states of biomedical equipment or medical electrical systems, or to warn any operator threats. These are the alarms that are all too familiar to nurses & doctors, especially in the intensive care unit, and are all too acquainted with.

Alarm fatigue occurs when 72% to 99% of all alarms are false, according to a study. Alarm fatigue arises when the doctors/nurses are exposed to a large volume of medical device alerts, resulting in alarm desensitization and ignored or delayed alarms. Alarm fatigue is becoming more widely recognized as a serious patient safety issue as the number of alerts utilized in healthcare increases.

Having those advantages of alarm management also comes with its own challenges in implementation and sustainability(quality). This paper aims to solve those challenges where most of the challenges are identified followed with solutions which are implemented in 700+ bedded hospital and results are compared with earlier to show the effectiveness of the solution proposed by the author. The study aims to provide an overview of studies, interventions and initiatives that highlight attempts to manage and improve alarm systems for quality and patient safety in the hospital context through academic literature reviews, clinician interviews, and evaluations of alarm-related standards and various other steps taken to strengthen the alarm management on the biomedical equipment.

The goal of the entire project was to:- 1) About the Patient:- To improve patient care, safety and reduce risk of adverse events by developing culture of safe alarm management practices. 2) Standardize & Implement:- Across Hospital 3) Improve Process:- Establish a process for improvement of alarm policies and configurations. 4) Identification and Mitigation:- To identify default alarm limits as per patient’s clinical conditions and mitigate risks associated with false alarms. 5) Competency:- To train and orient the staff to operate and manage the alarm system in biomedical equipment. 6) ZERO in Everything:- Zero consultant/patient complaints, Zero patient harm due to alarm mismanagement, Zero false alarms, Zero alarm fatigue, Zero anxiety among caregivers, Zero sleep deprivation in patient due to alarm.

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INTRODUCTION
The purpose of alarming medical devices is to produce alarm signals "to indicate inadequate physiological patient states, inadequate functional states of medical electrical equipment or medical electrical system or to warn the operator of hazards to the patient or operator due to the medical electrical equipment or medical electrical system”. Ironically, it has been claimed that medical gadget alarms pose a risk to the security of patients. The biggest contributor to the alarm-related adverse effects is due to the large number of alarms ringing in the clinical environment. This leads to desensitization among the caregivers, especially in the critical alarm situations, wherein they don’t respond to the clinically critical alarms, thus invoking the patient safety.

Problem Statement is given below:
1) Too many alarms lead to alarm fatigue among users thus, leading to silencing of the alarms more often with no intervention. Hence, desensitization for alarm management and inability to differentiate between various biomedical equipment alarms simultaneously takes place.
2) Risk of a missed or mismanaged actionable, relevant clinical alarms due to too many alarms ringing or any other factor can lead to patient’s clinical deterioration and other adverse effect, thus jeopardizing the patient safety and lower productivity.
3) Lack of knowledge and competency of nurses on handling clinical/technical alarm, normal ranges of alarms and its management, wherever required.
4) Noise can lead to acute stress for patients and chronic stress for caregivers, with direct physiological and psychological consequences.
5) It disrupts the patient’s sleep, leading to sleep deprivation and a depressed immune system, thus affecting the recovery and length of stay.
6) High levels of non-actionable alarms absorb a significant amount of nurse time, thus compromising a pro-active patient care, with possible impact on quality and patient satisfaction.
7) Consultant complaints due to missed/unattended alarms.
8) Staff lack the competency of alarm management in biomedical equipment, thus leading to silencing of alarms more often with no response and intervention.

A multi-disciplinary team consisting of the Biomedical Department, Nursing and Quality was formed for brainstorming the solutions to these challenges and hence develop Alarm Management as a high risk improvement project. The methodology adopted was PDCA-Plan, Do, Check, Act, Literature Reviews, Brainstorming, Qualitative and Quantitative analysis.

III (a) Goal
1) About the Patient:- To improve patient care, safety and reduce risk of adverse events by developing culture of safe alarm management practices.
2) Standardize & Implement:- Across Hospital
3) Improve Process:- Establish a process for improvement of alarm policies and configurations.
4) Identification and Mitigation:- To identify default alarm limits as per patient’s clinical conditions and mitigate risks associated with false alarms.
5) Competency:- To train and orient the staff to operate and manage the alarm system in biomedical equipment.
6) ZERO in Everything:- Zero consultant/patient complaints, Zero patient harm due to alarm mismanagement, Zero false alarms, Zero alarm fatigue, Zero anxiety among caregivers, Zero sleep deprivation in patient due to alarm

III (b) Projected Business Benefits
Clinical alarms are a real and serious problem in all areas of the hospital. An effective alarm management program improves patient care, saves time and money, reduces alarm fatigue, and uses technology to improve the quality of life for the healthcare providers. Decreased alarm fatigue means nurses can more effectively
take care of their patients. After successful implementation of the program, the competency of nurses on clinical alarms will improve, resulting in enhanced patient safety.

Alarm management for biomedical equipment is challenging. However, this project has benefitted the quality of patient care by ensuring prompt interventions and correct actions by the healthcare providers.

Effective alarm management led to a reduced risk of a missed or mismanaged actionable, relevant clinical alarms due to too many alarms ringing or any other factor could lead to a patient’s clinical deterioration or other adverse effect, thus jeopardizing patient safety and lowering productivity. Unit study every month led to the identification of issues and opportunities that could possibly reduce the number of false alarms, etc.

Long term benefits include clinical as well as service excellence that would be enhanced and strengthened by this pragmatic approach wherein minimizing false, nuisance alarms is targeted, leading to more accurate, timely, prompt, and enhanced quality of patient care.

IV. MATERIALS AND METHODS

Action Plan: The Calm the Alarm project was initiated in four phases described below along with the sustainance plan.

PHASE-1
(Hospital wide survey & competency mapping)

- 1-hour study for 7 days (7 hours/week).

Unit: Two ICU’s taken to observe the following:

1) Unit survey for the consultant’s & patient’s feedback on clinical alarms (Annexes 9,10).

Note: Conscious oriented/ Spontaneous patient’s feedback to be considered only.

2) Total no. of alarms, equipment wise bifurcation of alarms and the number of alarms per bed (Annexure 1).

3) Total number of false/nuisance alarms, how frequent the nurses are silencing the alarm with no corrective action, if applicable, any (Annexure 1).

UNIT AUDIT CHECKLIST

<table>
<thead>
<tr>
<th>Date</th>
<th>Dept.</th>
<th>Custodian Name</th>
<th>Custodian Clock No</th>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>S.No</th>
<th>Date</th>
<th>Equipment Name (Ventilator, Infusion Pump, Patient Monitor etc...)</th>
<th>Alarm Color (Red/Yellow/Green/Blue)</th>
<th>Type of Alarm (False/Nuisance/True/Technical)</th>
<th>Alarm Description</th>
<th>Silenced Alarm (Yes/No)</th>
<th>Action taken to manage the alarm</th>
</tr>
</thead>
<tbody>
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### Sr No. Cumulative Summary (For both GLMICU & MICU) Result

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<th>07-Jul</th>
<th>08-Jul</th>
<th>09-Jul</th>
<th>10-Jul</th>
<th>11-Jul</th>
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<td>Total number of alarms in 1 ICU per day</td>
<td>56</td>
<td>48</td>
<td>51</td>
<td>43</td>
<td>33</td>
<td>33</td>
<td>8</td>
<td>12</td>
<td>284</td>
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<tr>
<td>2</td>
<td>Number of ventilator alarms per day (Average)</td>
<td>12</td>
<td>10</td>
<td>9</td>
<td>4</td>
<td>7</td>
<td>6</td>
<td>0</td>
<td>2</td>
<td>50</td>
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<tr>
<td>3</td>
<td>Number of hemodynamic alarms (Average)</td>
<td>19</td>
<td>30</td>
<td>23</td>
<td>26</td>
<td>15</td>
<td>14</td>
<td>7</td>
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<td>136</td>
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<td>4</td>
<td>Percentage of alarms that came from the violations in heart rate</td>
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<td>2</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td>40</td>
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<tr>
<td>5</td>
<td>Percentage of Alarms from SPO2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>17</td>
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<tr>
<td>6</td>
<td>Number of Nuisance Alarms</td>
<td>13</td>
<td>22</td>
<td>8</td>
<td>13</td>
<td>7</td>
<td>5</td>
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<td>68</td>
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<td>Number of False Alarms</td>
<td>9</td>
<td>9</td>
<td>23</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>5</td>
<td>2</td>
<td>87</td>
</tr>
</tbody>
</table>

#### Annexure 1: Unit Pre-Analysis on Alarm Management

- **Survey conducted** for nurses on alarm management along with their feedback/suggestions for improvement (Annexure 11).
- Preparation of Standard Operating Procedure (SOP) for Patient Clinical Alarms Safety.
- Preparation of Alarm matrix of biomedical equipment and circulated among all the users (Annexure 2).
### Annexure 2: Glimpse of Alarm Management Matrix

**PHASE-2 for 1 Month (Sensitization of staff)**

- **Master Training Class** conducted twice for all the nursing process owners/custodians across a Group of Hospitals by the Nursing Biomedical Engineer along with Post Test.

- **Train the Trainers** Pretest, trainings and post test conducted followed by their competency mapping. Retraining’s done till they are compliant.

- Sensitization of nurses on alarm management along with competency mapping (Annexure 3) post training.
### Annexure 3: Competency Mapping of Nurses on Alarm Management

<table>
<thead>
<tr>
<th>S.No</th>
<th>Proficiency Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Knowledgeable about colour coding of alarms as per the equipment?</td>
</tr>
<tr>
<td></td>
<td><strong>Reference table for assessment:</strong></td>
</tr>
<tr>
<td></td>
<td>Red alarm: High priority: Immediately alerted and take action accordingly.</td>
</tr>
<tr>
<td></td>
<td>Yellow alarm: Medium priority: Attend at the earliest and take action accordingly.</td>
</tr>
<tr>
<td></td>
<td>Green/alarm: Low priority: Acknowledge, do not ignore and take action accordingly.</td>
</tr>
<tr>
<td>2</td>
<td>Skilful in acknowledging &amp; setting off alarms as per the equipment?</td>
</tr>
<tr>
<td></td>
<td>Explanation: If there is any alarm coming in the equipment, acknowledge, do not ignore, and the necessary intervention should be done as per the alarm. The alarm limits can also be changed as per the clinical condition of the patient and doctor’s advice.</td>
</tr>
<tr>
<td>3</td>
<td>Skilful in setting alarm limits, wherever applicable as per the clinical condition of the patient as advised by the doctor?</td>
</tr>
<tr>
<td></td>
<td>Notes: Should know about the normal range (high and low limits) of parameters like SpO2, NIBP, RR, HR, Pressures, Rate, Minute Volume &amp; CC, like in Monitors and Ventilators respectively.</td>
</tr>
<tr>
<td>4</td>
<td>Aware about the activation of the alarm at all the times with an audible volume in all the equipment?</td>
</tr>
</tbody>
</table>

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| 5    | Aware about the escalation protocol as per the requirement to the concerned team? |
|      | Notes: |
|      | • For actionable clinical alarm: Notification to the doctor, charge nurse/team leader with necessary intervention. |
|      | • For technical alarm: Escalation to the biomedical department. |
| 6    | Skilful in writing clinical alarm details in hard copy/time out wherever applicable? |
|      | Notes: To ensure patient safety, information about important alarms that require extra vigilance along with the changed alarm limits shall be written and communicated during clinical handover/time out. |
| 7    | Aware about the escalation & reporting protocol as per the policy in case of any sentinel/near miss events arising due to patient monitoring/clinical equipment alarm failure? |
|      | Notes: In case of any above-mentioned situations, the same shall be reported to the charge nurse/team leader, Head of Nursing & biomedical department, Incidents to be reported in AIB (Apollo Incident Reporting System). |
| 8    | Aware about the unexplained nuisance/false alarms to be reported to biomedical department/medical team with the necessary intervention? |
|      | Example of False alarm: No indication of ECG rhythm due to the patient movement / ECG lead disconnection. |
| 9    | Knowledgeable about purpose & proper operation of alarm systems for which they are responsible? |
|      | Note: At no time should the biomedical equipment alarms be disabled and should have functional alarms. |
| 10   | Aware about the identification of high-risk alarms and their management? |
|      | Notes: Every nurse should be able to identify actionable alarms (clinical deterioration of the patient), high-risk alarms like "High Inspiratory Pressure", "Low Fio2", in ventilators etc.
External Trainings organized (by the Company Engineer & Doctor) on the biomedical equipment and their alarm management.

Awards and accolades given for best managers of clinical alarm management as per the audit check tool (Annexure 4).

Annexure 4: Audit tool to assess the best clinical alarm managers-Unit & Staff

PHASE-3
(Post Training Analysis & Reinforcement)

Same study conducted in the same ICU’s as selected in the Pre-analysis phase to study patient & consultant feedback (Annexes 9,10) post implementation and to study about the alarm management practices & protocols being followed in the unit (Annexure 5).

<table>
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<th>23-Aug Number</th>
<th>24-Aug Number</th>
<th>25-Aug Number</th>
<th>26-Aug Number</th>
<th>27-Aug Number</th>
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<td>Total number of alarms</td>
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<td>12</td>
<td>36</td>
<td>16</td>
<td>16</td>
<td>6</td>
<td>14</td>
<td>112</td>
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<tr>
<td>2</td>
<td>Number of ventilator alarms</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>24</td>
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<tr>
<td>3</td>
<td>Number of hemodynamic alarms</td>
<td>9</td>
<td>9</td>
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<td>2</td>
<td>11</td>
<td>82</td>
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<td>Percentage of alarms that came from the violations in heart rate</td>
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<td>3</td>
<td>9</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
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<td>Percentage of Alarms from SPO2</td>
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<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>6</td>
<td>Number of Nuisance Alarms</td>
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<td>3</td>
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<td>7</td>
<td>Number of False Alarms</td>
<td>6</td>
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<td>18</td>
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<td>8</td>
<td>2</td>
<td>10</td>
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<td>56</td>
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<td>Number of ventilator alarms</td>
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<td>2</td>
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<td>1</td>
<td>10</td>
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<td>Percentage of alarms that came from the violations in heart rate</td>
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<td>1</td>
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<td>2</td>
<td>2</td>
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<td>0</td>
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<td>Total number of alarms in 1 ICU per day</td>
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Annexure 5:- Unit Post-Analysis on Alarm Management

**ACTIVITIES**

(To Continue Reinforcement)

- Post analysis quiz (Annexure 6) via Google form for the nurses to assess the knowledge and competency on alarms due to biomedical equipment.

Annexure 6:- Post Analysis Quiz on Alarm Management
SSLC (Slow & Special Learning Classes) for the non-compliant staff. Retraining is done till they are compliant.

“Pick-a-Chit” - Unit based activity (hands on demonstration) conducted along with the gift distribution to the compliant staff.

**PHASE-4**
(Intervention for Sustainability of the project)

- In service training for sustaining Clinical Alarm Safety Program like Induction, Mandatory, Post error, Monthly practicum etc.
- External Trainings organized (by the Company Engineer & Doctor) on the biomedical equipment.
- Hospital-wide yearly survey to identify the loopholes, issues, suggestions etc. and competency assessment shall be carried out in order to take corrective actions for the same (September 2022 onwards).
- Random audit as per the tracker (Annexure 7) conducted by the custodian along with monthly reporting.

### Annexure 7:- Alarm Management Tracker

- Inventory list on alarm management troubleshooting shared among all nurses for reference.
- A ready reckoner on alarm management also shared for reference.
- Reinforcement of the escalation protocol for alarms on a regular basis.
- The Impact of the Clinical Alarm Safety Program (Annexure 8) shall be monitored regularly as per the checklist in one unit/month.
Annexure 8:- Impact of Clinical Alarm Safety Checklist

The Impact of the Clinical Alarm Safety Program shall be monitored with respect to the following aspects:

- Total number of alarms in one ICU per day - _________
  (can be studied any 7 days a month for 1-hour, i.e. 7 hours/month/ICU)
- Number of ventilator alarms per day (average) - _________
  (can be studied any 7 days a month for 1-hour, i.e. 7 hours/month/ICU)
- Hemodynamic alarms per day (average) - _______
  (can be studied any 7 days a month for 1-hour, i.e. 7 hours/month/ICU)
- % of the alarms from the violations in heart rate default settings - _________
  (can be studied any 7 days a month for 1-hour, i.e. 7 hours/month/ICU)
- % of alarms from SpO2 - _________
  (can be studied any 7 days a month for 1-hour, i.e. 7 hours/month/ICU)
- Number of Patient complaints due to noise caused by biomedical equipment - _______
- Total number of Consultant complaints due to noisy wards and ICUs - _______
- Total number of staffs trained on Clinical Alarm Management & Safety - _______
- Reduction in Nuisance alarms - _____________
- Reduction in False alarms - _____________
- Any other can be added up as per the unit requirement.

**Cost of Implementation** - Rs. 1800/- for the prize distribution, gifts & accolades.

**Challenges faced during implementation** -
There are still some challenges because of the high attrition rate, huge alarm inventory, different models of equipment, staff competency in True, False & Nuisance alarms differentiation, response time based on priority and action to be taken, thus, regular training on alarm management is very important. It has been made a monthly ongoing process so that all our new and existing staff are in compliance with the new JCI standards and protocol also do not jeopardize the quality of patient care or safety due to mismanagement of alarms. Regular meetings are also done with all the stakeholders to discuss any issues related to the mismanagement of alarms, implementation, compliance, enhanced coordination and to look for any scope of improvement, if any. Random audits along with the unit analysis to monitor the process continuously are done to ensure compliance, look for scope of improvement and thus strengthen the process.

**RESULTS**
- The number of False Alarms reduced from 87 to 69 and the number of Nuisance alarms reduced from 68 to 26 (cumulative total for 7 days).
- Reduction in the total number of alarms from 35.5 to 24 (cumulative for 7 days).
- Reduction in consultant complaints and improvement in their satisfaction rate (Annexure 9).
Improvement in Patient Satisfaction rate (Annexure 10) in terms to the staff managing the alarms of biomedical equipment.
Annexure 10: Patient Survey - Pre & Post Analysis

In the Pre-analysis phase, the following result was recorded (total no. of participants- 293) via Google form Survey (Annexure 11).
How often does the biomedical equipment alarm in your unit?

293 responses

- Never: 15.4%
- Rarely: 15.4%
- Sometimes: 24.9%
- Often: 42%
- Always: 15.4%

Which of the following equipment gives the maximum number of alarms?

293 responses

- Cardiac Monitor: 101 (61.8%)
- Ventilator
- Syringe/Infusion Pump
- Cardiac Monitor
- If Others, specify at the end in the feedback
- Bipap
- Cautery machine
- Infusion pumps
- Infusion pump Auto
- Nil

Do you take any action after silencing the alarms?

293 responses

- Yes: 90.9%
- No: 9.1%

Do you inform the treating team about the patient’s clinical deterioration as per the clinical alarm?

293 responses

- Yes: 90.9%
- No: 9.1%
Are you escalating any technical alarm issues to the biomedical team?
293 responses

Do you set the alarm limits as per the patient's clinical condition?
293 responses

How frequently have you attended the training on Alarm Management?
293 responses

How often have the doctors complained about the clinical alarm?
293 responses
In the Pre-test conducted for all the trainers, the average score achieved was 6.73 out of 10 points and in the Post-test it was 9.30 out of 10 points (total no. of participants- 49) (Annexure 12).

The knowledge check was done for the senior level staff across a group of hospitals on alarm management after the effective training and the average score was found to be 9.63 out of 12 points (Total no. of participants- 87).

During the audits as per the Alarm Management Tracker starting in September 2022, the percentage compliance was 83.08% in September, 88.64% in October (Annexure 13).
Other units can also adopt this project in a systematic and phased manner, thus leading to better management of clinical true actionable alarms, reduce false & nuisance alarms, enhance staff knowledge and awareness on alarm management, thus leading to improved quality of patient care.

**DISCUSSION**

Clinical alarms are a real and serious problem in all areas of the hospital. An effective alarm management program improves patient care, saves time and money, reduces alarm fatigue, and uses technology to improve the quality of life for the healthcare providers. Decreased alarm fatigue means nurses can more effectively take care of their patients. After successful implementation of the program, the competency of nurses on clinical alarms will improve, resulting in enhanced patient safety.

Alarm management for biomedical equipment is challenging. However, this project has benefitted the quality of patient care by ensuring prompt interventions and correct actions by the healthcare providers. Staff awareness of alarm management was enhanced, leading to better quality patient care.

Quality of patient care and alarm management of biomedical equipment led to sensitization for alarm management and an enhanced ability to differentiate between various biomedical equipment alarms that take place simultaneously.

Effective alarm management led to a reduced risk of a missed or mismanaged actionable, relevant clinical alarms due to too many alarms ringing or any other factor could lead to a patient’s clinical deterioration or other adverse effect, thus jeopardizing patient safety and lowering productivity. Unit study every month led to the identification of issues and opportunities that could possibly reduce the number of false alarms, etc.

Monthly practicum for the existing staff, regular induction training for new joiners, and other in-house and out-house trainings have been incorporated, leading to enhanced knowledge and competency of nurses on handling clinical/technical alarms, normal ranges of alarms and their management, wherever required.

Reduced number of alarms has led to reduced noise that could lead to acute stress for patients and chronic stress for caregivers, with direct physiological and psychological consequences, also disrupting the patient’s sleep, leading to sleep deprivation and a depressed immune system, thus effecting the recovery and length of stay. This has led to positive patient & consultant feedback on the alarms ringing in the units.

**Annexure 13: Percentage compliance on Alarm Management**

![Percentage Compliance on Alarm Management-Overall](image)

83.08% - Sep-22
88.64% - Oct-22

80.00% 82.00% 84.00% 86.00% 88.00% 90.00%
Non-actionable alarms (False & Nuisance) have reduced leading to a significant amount of nurse time spent in a proactive patient care, with a possible impact on quality and patient satisfaction. Consultant visits and complaints due to missed/unattended alarms have also decreased, leading to better quality of patient care. Patient’s feedback also turned positive after effective implementation of alarm management protocols. It has also become an ongoing process, leading to continuous monitoring of the loopholes, issues related to alarm mismanagement that can harm the patient. The Alarm Management has a oversight of many custodians - Quality, Nursing, Biomedical Department, Biomedical Engineer (Nursing) along with the Charge Nurses of the respective units, thus strengthening the process. Hence, Standard Operating Procedures, Alarm Matrix and continuous training were identified for all the nursing staff so as to enhance & strengthen their competency and knowledge on alarm management of biomedical equipment. Regular meetings by the concerned stakeholders have led to improved coordination between various departments, better problem solving capabilities and efficient alarm management of biomedical equipment. Unit level study conducted on monthly basis led to better monitoring, control and execution of alarm management protocols at the ground level, enhancing the quality of patient care. Long term benefits include clinical as well as service excellence that would be enhanced and strengthened by this pragmatic approach wherein minimizing false, nuisance alarms is targeted, leading to more accurate, 

CONCLUSION

Clinical alarms are a real and serious problem in all areas of the hospital. An effective alarm management program improves patient care, saves time and money, reduces alarm fatigue, and uses technology to improve the quality of life for the healthcare providers. Decreased alarm fatigue means nurses can more effectively take care of their patients. After successful implementation of the program, the competency of nurses on clinical alarms will be improved, resulting in the enhanced patient safety. 

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