

Establishment of Elements and Principles of High Reliability Organizations in Neonatal Intensive Care Unit of de Soyza Maternity Hospital, Colombo, Sri Lanka.



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ABSTRACT

Introduction: “High Reliability Organizations (HRO)” is an innovative safety management concept.

An effort to transform a health care setting in Sri Lanka to a HRO – management structure is worthwhile to experience the outcomes of this model in Sri Lankan hospital context.

Objective: To establish a HRO - management structure in the Neonatal Intensive Care Unit of De Soyza Maternity Hospital Colombo.

Design: Pre / post interventional study design was used. Functional status of HRO structure in the NICU was assessed; using 5 HRO principles (ie. Pre occupation with failure, Resistance to simplify, Sensitivity to operations, Commitment to resilience and Deference to expertise) and 5 HRO elements (ie. Process auditing, Rewarding, Avoidance of quality degradation, Risk perception, and Command and control), at pre and post interventional levels.

Methods:

Practice of HRO principles was assessed using a Self - Administered Questionnaire with a rating scale, with the participation of all the NICU staff. Practice of HRO elements was assessed by a facility survey using a check list.

Intervention consisted of a managerial plan with activities to establish the HRO concept.

Results: Results showed a statistically significant increase of “response scores” of participants towards HRO structure and the facility survey showed the establishment of planned activities.

Conclusion: It was concluded that implementation of this plan, is gradually establishing the HRO management structure in NICU of DMH.

KEYWORDS: High Reliability Organizations, Neonatal Intensive Care Units.

INTRODUCTION

High Reliability Organizations (HRO) operate under hazardous environments, while sustaining optimum safety. They are accepted globally as, organizations with comparatively error-free operations.⁽¹⁾ Quick identification of unsafe situations, careful analysis, identification of weaknesses, and prevention of adverse events are the main strategies executed by HROs. These organizations are known to maintain safety far better than health care.⁽²⁾ Therefore, Health care worldwide has been adopting the principles of HROs as an innovative safety management practice.⁽³⁾

HRO concept is operationalized through five “HRO Principles” namely; 1. Pre occupation with failure; 2. Resistance to simplify; 3. Sensitivity to operations; 4. Commitment to Resilience and 5. Deference to expertise.⁽²⁾ Development of these basic principles improves the “Collective Mindfulness” among employees in daily operations,⁽⁴⁾ which leads to improved reliability.

Five “HRO Elements” have also been described namely; 1. Process Auditing; 2. Implementing rewarding systems; 3. Avoiding quality degradation; 4. Risk Perception and 5. Command and Control. They are incorporated into assessments of hospitals practicing the HRO concept.⁽¹⁾

In Sri Lanka, static Neonatal Mortality Rates and essential & emergency new born care⁽⁵⁾ are compelling further improvement of Neonatal Intensive Care Units. Teaching Hospitals providing tertiary level maternity services; such as De Soyza Maternity Hospital

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(DMH), Colombo also did not show much improvement of perinatal deaths during the last decade⁽⁶⁾. Further, international experience shows that applying HRO principles is operationally and physically feasible and highly effective in enhancing reliability of clinical services⁽⁷⁾

OBJECTIVE

To establish a High Reliability Organization (HRO) - management structure in Neonatal Intensive Care Unit of De Soyza Maternity Hospital.

DESIGN

Pre / post interventional study design was used in this research project which was conducted in the Neonatal Intensive Care Unit, De Soyza Maternity Hospital, Colombo. Total study period was one year from June 2018 to June 2019 and implementation of the interventional plan was carried out over a period of three months.

Study was conducted in 4 stages; Pre Intervention Assessment, Development of HRO – Transformation Plan, Implementation of HRO Transformation Plan and Post Intervention Assessment. Functional status of HRO structure which was described under five HRO principles⁽²⁾ and five HRO elements⁽¹⁾ was assessed at pre and post interventional levels.

METHODOLOGY

1. Pre Intervention Assessment

Descriptive cross sectional study was carried out, involving the total staff of NICU as the sample. They were; Consultant neonatologists (N=2), Medical Officers (N=7), Nursing Officers (N=29) and minor staff (N=2). Sample size was 40.

A Self - Administered Questionnaire (SAQ) was used to assess the practice of “HRO Principles”. Facility Survey was carried out in the NICU using a Check List to assess the availability and practice of “HRO elements”. Descriptive quantitative data analysis was carried out.

2. Development of HRO – Transformation Plan

Literature review was carried out to prepare the Conceptual Framework. Interventions were developed targeting the first stage of the conceptual framework. (Annexure: 1 Figure -1)

Establishment of “HRO elements” is expected to achieve other levels on step wise manner. Therefore, Interventions were developed to establish “HRO elements”.

Two Focus Group Discussions (FGD) were conducted to develop the package of interventions. First one was held to brainstorm and list out activities which are relevant to different “HRO elements” and could be implemented in an NICU setting. Recommendations for NICU settings in the national Quality guidelines - 2010 were also included.

Focus group consisted of 10 participants. They were; the deputy director of the hospital, the medical officer – quality management, a matron, a nursing officer - infection control, two consultant neonatologists in NICU, two medical officers in NICU and two in - charge ward sisters in two sides of NICU. Second FGD was held with the same participants to finalize the plan. The package of interventions developed is summarized in figure 2.

Figure 2: HRO Interventions

<u>HRO Interventions - NICU</u>	
1.	<u>Process Auditing:</u> HRO meeting once a month. Review on Reporting of Adverse events/ Medical errors/Near Misses, Deaths; Infection control; Handing over /Taking over, Drug supply, Equipment testing, Infrastructure testing, Work Improvement, Rules and procedures.
2.	<u>Rewarding:</u> in the HRO meeting. Recognition and Documentation of Rewarding for Participation in review meetings & training, Adverse Events reporting, Risk identifications, Risk mitigations.
3.	<u>Avoidance of Quality Degradation:</u> A. Provision of ICU equipment: ECG monitor, Ventilators, Defibrillator, Nebulizing machine, Pulse Oxymeter, Sucker machine, Ambu – bag, Laryngoscopes , Blood gas analyzer, ICU beds, Medical Gases B. Emergency tray with essential supplies, solutions and drugs, available for every bed. C. Making a checklist for the emergency tray items available and maintained once a day. D. List of contact numbers of all relevant health personnel and services in emergency situations. E. 24 hour consultant coverage. F. Medical Officers and Nursing Officers duty roster. G. Maintenance of handing over/ Taking Over register
4.	<u>Risk perception</u> Training to improve behavior of risk perception (to have high estimates of risk probability and impact given the same information).
5.	<u>Command and control system</u> Migrating decision making: Authorization of the front line staff on early detection of subtle changes of unsafe conditions. Redundancy of people and hardware: Selected tasks are always performed by two members. Selected hardware always requiring back – up systems. Developing situational awareness: Recognition of the elements in the environment, Comprehension of their meaning and relationships, and Prediction of their status in the near future. Formal rules and procedures: Admission and discharge policy. Hand Off policy Infection control policy Training: HRO theory, Quality & safety, Communication, Handoffs, Team work, Mindfulness.

3. Implementation of HRO Transformation Plan

Activities in the plan were implemented for a period of three months. Preparation of supportive material (eg: posters, registers, charts, check lists and inventories), conducting training programmes, preparing work schedules, providing guidance and logistic management were done to facilitate the process. Training was focused on HRO concept and mindfulness. Establishment of a focal point, scheduling monthly HRO meetings and presentation of HRO statistics in the hospital perinatal meeting were designed for project sustainability.

4. Post Intervention Assessment

After three months of implementation, the descriptive cross sectional study was carried out with the participation of the same sample, using the same SAQ; to assess the practice of “HRO principles”. Responses were compared with the pre intervention responses. Post intervention facility survey was carried out at the NICU, using the same check list, to assess the availability and practice of “HRO elements”. Descriptive quantitative data analysis was carried out and results were compared with the results of first assessment.

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Development, Validation and Pretesting of Study Instruments

SAQ, Check list and FGD guide were prepared by the principle investigator (PI) with the consensus of the expert panel. Expert panel consisted of the supervisor, two consultant administrators and two consultant community physicians.

Statements in rating scales found in literature were incorporated into the SAQ, to assess the practice of “HRO principles” among participants. Check list was newly developed using the “HRO elements” which need to be demonstrated in HROs, to identify their availability and practice in the study setting.

Study instruments were validated in the FGD with the same sample of focus group members, for face validity and content validity.

Face validity was assured using a validation tool with a rating scale (not agreed; moderately agreed; agreed; highly agreed). Variables namely; concept, relevancy, formatting, clarity of language and depth of assessment, of each statement, with regard to each statement in the SAQ and each item in the check list were assessed.

Content validity was assured using a validation tool with a rating scale (“relevant & representative”; Not “relevant & representative”) with regard to the statements in the SAQ and the items in the check list.

SAQ was developed in English and translated into Sinhala and Tamil languages, using forward and backward translations. Pre testing was done with a similar group of participants in the NICU of Castle Street’s Hospital for Women, Colombo for face validity and reliability.

ETHICAL APPROVAL

Ethical approval was obtained from the Faculty of Medicine, University of Colombo.

DATA COLLECTION

Data was collected, for pre and post assessments, with the assistance of a trained data collector.

SAQ was grouped into 4 groups and named as; consultants, medical officers, nursing officers and health assistants. They were handed over to all the staff members in 4 groups in NICU; with the information sheet, consent form and an envelope; verbal instructions were provided by the PI; to complete the SAQ individually, put it in the envelope, seal and hand it over to data collectors. Consent forms were collected from consented participants. Same procedure was carried out for both pre - test and post - tests.

Facility Survey was carried out with the check list, by a team which consisted of the PI, Consultant neonatologists, Matron, Sister in charge of NICU and MO - Quality Improvement. Information confidentiality and security were maintained.

DATA ANALYSIS

Data were quantitatively analyzed using the Statistical Package for Social Sciences (SPSS) version 21. Same sample of participants were used for both pre and the post tests.

1. Mean Response score (in the 10 point scale) of each category of staff for each HRO principle, was calculated (Table 2).
2. Results were compared using paired sample t – test to test the significance (Table 2).
3. Three categories were described (in the 10 in the scale) as;
 - I. lowest category (if mean response score is between 0 – 3)
 - II. middle category (if mean response score is between 4 – 7)
 - III. highest category (if mean response score is between 8 – 10)
4. Frequency distribution of the staff, among these three response score categories on 5 “HRO principles” in pre & post tests were also calculated to identify any shifting of participants among different categories. (Graph 1).

RESULTS

In this interventional pre / post research project; 1. Demographic characteristics of the staff of NICU, 2. Distribution of “means of response scores” of consultants, medical officers and nursing officers on five HRO principles in pre and post - tests, 3. Frequency distribution of staff, in different “response - score categories”, on five HRO principles in pre and post - tests, and 4. Practice of HRO elements in pre & post - tests, were analyzed and results were compared to see any significance.

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Study had a response rate of 92.5%. In the study group, seventy one percent were Nursing Officers (NO); 18.4% were Medical Officers (MO); 5.3 % were Consultants and 2.6% were Health Assistants (HA). Majority were less than 30 years and 95% were females. (Table 1)

Table 1: Distribution of demographic characteristics of the staff of NICU.

Characteristic N= 38	Frequency	Percentage
Age (years)		
< 30	23	60.5
31 - 40	9	23.7
41 – 50	5	13.2
51 -60	1	2.6
Total	38	100
Gender		
Male	2	5.3
Female	36	94.7
Total	38	100
Staff category		
Consultants	2	5.3
Medical Officers	7	18.4
Nursing In charge	1	2.6
Nursing officers	27	71.1
Health Assistants	1	2.6
Total	38	100

Means of the response scores, in the rating scale (0 - 10) in both pre and post tests were above average (> 5.5) for all categories of staff in both pre and post - tests.

There is a statistically significant increase in the practice of all five “HRO principles among Medical Officers and Nursing Officers after the intervention. However, there was no statistically significant improvement of practice of HRO principles among consultants. (Table 2)

Table 2: Distribution of Means of response scores (0 -10) of consultants, medical officers and nursing officers on five HRO principles in pre and post tests.

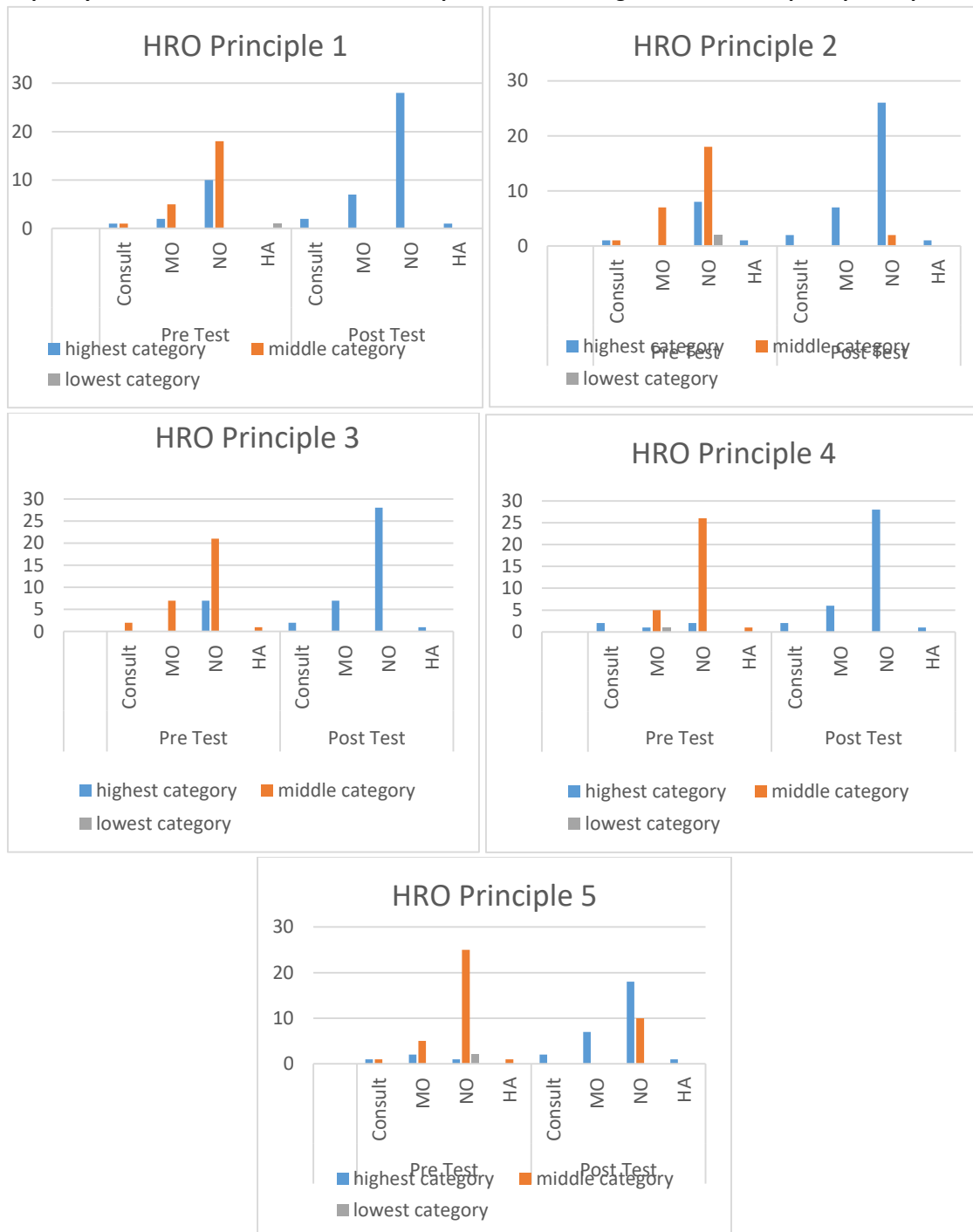
Staff Category	HRO principle	Pre test N =27		Post test		Significance		
		Mean	Std. Deviation	Mean	Std. Deviation	t	df	Sig (2 tailed)
Consultants	I	7.17	1.18	8.83	0.26	1.667	1	.344
	II	6.00	3.30	8.00	0.47	1.000	1	.500
	III	5.89	00	7.89	0.16	18.000	1	.035
	IV	7.25	00	9.13	0.19	15.000	1	.042
	V	7.5	0.35	8.25	0.35	1.500	1	.374
Medical Officers	I	6.14	2.15	8.48	1.15	6.173	6	.001
	II	5.18	1.67	7.48	0.98	6.124	6	.001
	III	5.38	3.60	7.67	0.42	22.961	6	.000
	IV	6.82	6.343	8.68	2.29	4.639	6	.002
	V	7.29	1.77	8.36	1.81	5.738	6	.001

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Nursing Officers	I	6.46	1.09	8.70	0.69	10.651	26	.000
	II	5.94	1.59	7.58	0.54	5.946	26	.000
	III	6.20	1.01	7.81	0.34	9.775	26	.000
	IV	6.39	1.07	8.85	0.32	12.259	26	.000
	V	6.03	1.18	7.89	0.60	9.357	26	.000

Majority has improved their practice in HRO principles from lower response – score categories to higher response – score categories. (Graph 1)

Graph 1: Frequency distribution of staff, in different response - score categories, on 5 -HRO principles in pre and post tests



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Results of the facility survey (Figure 3) showed that almost all the “HRO elements” which were not available in the initial survey were functional in the subsequent survey.

There is a mechanism established for; process auditing, rewarding, formulating policies; and continuous training on risk perception, situational awareness, HRO concept, and quality improvement.

Figure 3: Practice of HRO elements in pre & post - t

HRO Element	Activity	Pre assessment	Post assessment
Process auditing	HRO meeting <ul style="list-style-type: none"> • death review • Infection control review • adverse events review • drug review • Work Improvement plans • equipment testing • Infrastructure testing 	Not available	Functional
Rewarding	In HRO meeting	Not Available	Functional
Risk perception	Training on risk perception	Not Available	Functional
Situational awareness	Training on Situational Awareness	Not available	Conducted
Formal Rules	Written policies	Not available	Infection Control policy Handoff policy
Training	Training on HROs	Not available	Conducted

DISCUSSION

Health care worldwide has been adopting the model of High Reliability Organizations, as an innovative safety management practice.

Considering the above fact, this research project was conducted to experience the applicability of this concept in a Sri Lankan acute care setting.

Pre and post assessments were carried out using two data collecting techniques to increase the validity of information. Weick and Sutcliffe in 2005⁽⁸⁾ have also used “rating scales” and “check lists” to identify hospitals performing as a HRO. Using a rating scale and a check list in this study is comparable to their study. However, literature shows different rating scales developed and validated by researchers individually for such assessments.^(8,13) The current study has obtained inputs from many such validated rating scales when developing its SAQ to improve validity.

Robert et al in 2003 identified five “HRO elements”. These elements have been incorporated into the assessments of hospitals practicing HRO concept.^(1,3) Same five basic elements were incorporated into the check list of this study to improve content validity. Further, the items in the check list of this study have directly covered all the HRO elements. In contrast, check lists found in other studies⁽¹⁰⁾ have focused more on the establishment of different hospital processes which would improve their reliability and safety. Yet, improving reliability is not directly comparable to establishment of the concept of HRO. Accordingly, check list developed for this study is straight forward, concise and directly measures the functionality of HRO elements.

Assessing basic principles, with or without basic elements of HRO is one method to decide the level of establishment of HRO structure.⁽¹⁾ Output and outcome analysis by benchmarking the performance is an alternative method.⁽⁹⁾ However, HRO transformation is a long process and HRO concept is a new model to Sri Lanka. Therefore, this study focused more on establishment of the process in the way of improving the physical setting and modifying the cognitive and affective aspects of employees. Outcome and impact indicators would be incorporated gradually.

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Establishment of HRO elements was recognized as the first stage in the conceptual framework. Therefore, Interventions were developed based on the HRO elements. Here, several feasible evidence based activities were incorporated⁽¹⁰⁾ which included new concepts such as collective mindfulness⁽¹¹⁾ to improve long term outcomes.

If “collective mindfulness” is suddenly implemented it would increase recognition and reporting all the unsafe conditions, exceeding the capacity of addressing them.⁽¹²⁾ Hence this project was planned to introduce the concept gradually. Emphasis was made to ensure project sustainability and continuous improvement.

When measuring the effectiveness, mean responses on every HRO principle in both pre and post tests were above average as in a similar study done in an A&E unit in 2018 in Sri Lanka. In that study, Malawige⁽¹³⁾ has taken a mixture of staff and found; means of 4.29; 4.37; 4.69; 4.47 and 4.21 for 1 - V principles respectively. Malawige⁽¹³⁾ has also received the mean responses on every HRO principle in the positive half of the rating scale (>3 of 6 point scale) which is similar to the current study. It could be due to the fact that critical care settings such as NICUs and A & E units take all the possible measures to improve safety and reliability, even though they are exactly not aligned with the HRO principles.

Malawige⁽¹³⁾ has received the highest mean value for “Sensitivity to operations” while in the current study, Nursing officers has said that it was the second highest principle practiced. However, Consultants and Medical Officers have said that it was the least practiced. One reason for the discrepancy could be that she has calculated the mean for the total study population which had a mixture of all categories. Malawige⁽¹³⁾ has got the least value for “Difference to expertise”. In contrast, in the current study, both consultants and Medical Officers have said “Difference to expertise’ was the highest practiced which is completely the opposite. However, Nursing Officers have said that it was, the one before the last. One cause for this difference could be the same reason of neutralizing the opinion of one category with the opposite opinion of other categories.

Chassin & Loeb⁽³⁾; have assessed the hospital performance against “HRO principles” and found that; Hospitals accept failure as “unavoidable” as opposed to “preoccupation with failure”; Hospitals have “simplified observations” due to; the rarity of adverse events and higher confidence on safety systems; Hospitals “fail to be sensitive” because employees are not well sensitized; Hospitals do not show “resilience” efficiently; “Reporting errors” are not seen as valuable; employees are reluctant to expose mistakes; “alarm signals” of devices are poorly designed; Rigid “hierarchical structure” and “seniority model” prevent the most expert individual to implement remedies. Likewise, these researches say that HRO principals are not usually noticeable in hospital settings. Similar indicators used in the SAQ in this study have shown that there is a gap between what is existing and what needs to be achieved.

Chassin & Loeb⁽³⁾ have developed a frame work with three major incremental strategies to progress towards high reliability; 1. “Leaders commitment to zero harm”; 2. “Culture of safety and staff training” and 3. “Process improvement tools” such as lean management, six sigma and total quality improvement. Chassin & Loeb⁽³⁾ have used indicators such as; adverse events, hospital acquired infections, medical errors, errors during handoffs, wrong side surgeries, fire breaks, patient falls etc. to assess HRO concept which are actually of output and outcome indicators requiring a considerable time duration to show a significant result.

According to Hines et al⁽⁷⁾, changing the culture and processes to decrease system failures needs a stepwise process. The basic steps described by Hines et al.⁽⁷⁾ are; 1. Change internal and external environments; 2. Respond to them; 3. Plan improvement initiatives; 4. Adjust the work pattern of employees; and 5. Implement initiatives in selected settings and spread continuously. This process again needs a fair amount of time and leadership commitment to achieve objectives.

Panagos et al⁽¹⁰⁾, say that; creating a safety culture; involvement of all management levels; improvement of communication; monitoring adverse events; strengthening information technology; incident reporting and analysis; non-punitive approaches; staff engagement; use of quality improvement methodologies; and shared mental model tools; are required in the transformation. Indeed, current study also has incorporated several such feasible evidence based activities into this plan.

Weick et al,⁽¹¹⁾ have described a “Process of collective mindfulness in organizing for high reliability”. Weick et al,⁽¹¹⁾ say that HROs focus on failure; reliability; attention to design and procedures, redundancy, decentralizing decision-making, continuous training and strong culture of collective mindfulness for risk identification. This study plan too has absorbed some new concepts from such studies to improve long term outcomes.

However, as HRO transformation is a long term process, in this study of short duration, it was focused more on establishment of the process to have a cultural change. Outcome and impact indicators would be incorporated gradually in this continuous quality improvement effort.

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Hales &Chakravorty⁽¹²⁾say that “Soft systems method” using “mindfulness technique” is an effective method to create HRO structure. Anyway, Hines et al ⁽⁷⁾say; if “collective mindfulness” is suddenly implemented it will increase recognition of all the risks and go beyond the capacity of solving. Therefore, transformation of culture should be implemented gradually. Therefore, this project planned to introduce the concept gradually.

Chassin& Loeb⁽²⁾in their model with 3 domains have explained⁽²⁾ 4 stages of maturity (ie: Beginning, Developing, Advancing and Approaching) describing a series of actions during implementation. This study too needs to be monitored over a sufficient time as it passes through all these stages.

All categories of staff accepts that all 5 HRO principles are being established at an almost similar degree in the NICU.However, a statistical significance is seen with the responses of medical officers and nursing officers and not with the responses of consultants. The very low number of consultants (N=2) might have resulted in this unexpected observation.

Further, this study too needs to be monitored over a sufficient period of time as it passes through different stages of evolution. As HRO transformation needs a considerable period of time and effort, it is needed to facilitate and monitor the process in a sustainable manner.

CONCLUSION

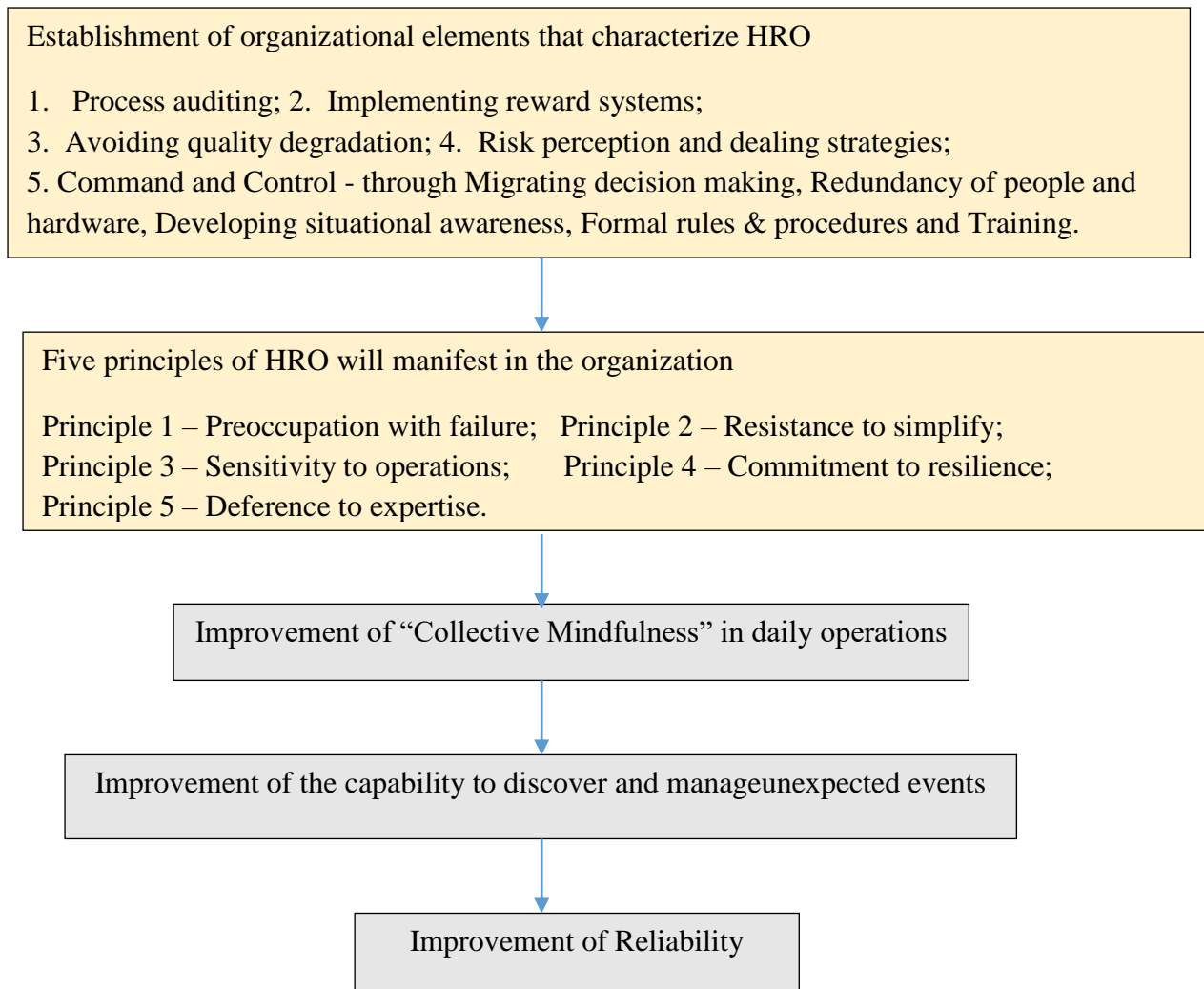
This interventional research project identified a gap in the current functional state of NICU, DMH against the concept of High Reliability Organization. The managerial plan developed and implemented in this setting showed a significant level of transformation of the study setting to a HRO management structure. The interventions used in this project can be recommended for any other health care setting as an introductory initiative of the HRO concept.

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ANNEXURE 1

Figure 1: Conceptual framework.



ANNEXURE 2

Validation Tool

1. Face Validity

“The degree to which an assessment/test subjectively appears to measure the variable/construct that it supposed to measure”

Agreement that each statement in the SAQ appears to measure the relevant principle of HRO and each item in the Check List appears to measure the relevant element of HRO.

Criteria	Not agreed	Moderately agreed	Agreed	Highly agreed
Concepts				
Relevancy				
Formatting				
Clarity of language				
Depth of assessment				

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2. Content Validity

“How well each statement in the SAQ and each item in the Check List measure the construct”; done by subject matter experts; To measure the degree of relevancy & representativeness of each statement/item.

Each expert rater in the judging panel responds to the following question for each item.

Is the particular HRO principle – measured by this statement in the SAQ?

Is the particular HRO element – measured by this item in the Check List?

Participants: 6 experts in the subject matter.

Principle	Statement in SAQ	Relevant & Representative	Not Relevant & Representative
1.	1. 2. 3. 4.		
Element	Item in the check List	Relevant & Representative	Not Relevant & Representative
1.	1. 2. 3. 4.		