

Medical Gas Safety Management: Evidence based Risk Intervention Study of HMA Gold Award Project at Vietnamese Hospital

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Abstract: Background: Safety of medical gas management is challenging issue in emerging countries like Vietnam, India, Bangladesh and Sri Lanka. No medical gas complies with the international system for colour coding gas cylinders. Cylinders are often the same colour regardless of the contents and the labelling is often a poor quality and inconsistent. Because of this, there is a risk of the wrong cylinder being delivered accidentally to healthcare facilities. Poorly trained staff are not aware of the importance of ensuring the correct tanks are connected to the right lines and there is not a universal system of compatibility of fittings for each type of medical gas. Hence, there is a high change of wrong gas induction to the patient and a high chance of sentinel event that leads to permanent injury or even death. Methods: In Vietnam, none of these safeguards are in place. As a result, Hanh Phuc International Hospital, as part of its risk management activities, identified issues with medical gases as a high risk area. The hospital used 'Failure Mode Effect Analysis (FMEA)' risk assessment tool to determine the risk score of medical gas safety practice in the hospital. Results: The first FMEA score reflected (648 to 749/1000) that the medical gas safety is a high risk practice in the hospital. After intervention with colour code system, the risk reduced (120-60/1000) at minimal level. Also, the rate of compliance with medical gas safety protocols improved from 40% in the first audit in Jan 2017 to 94% in Feb 2017 after improvement. This rate of compliance has been sustained from the start of the project up to the present with many months showing 100% compliance. Conclusions: The cost of the total project was less than dollars but return of impact is very significant. Although there has been no direct serious incidents reported due to medical gas injury, the FMEA indicated that there was a possibility of such an incident. The project won the 'Gold award' after competing with 451 award entries from 123 hospitals in 18 countries at the Hospital management Asia conference, 2018 Thailand. This project has great applicability to other hospitals in developing countries that do not have strict controls over medical gases.

Keywords: Medical Gas Safety, Four Rights, FMEA, Risk Assessment, International Colour Code

1. Background

Reliable medical gas and vacuum systems are at the pinnacle of patient care and provide critical sources of life-supporting gases that are required for proper treatment of patients in critical care areas of the hospital. The ongoing operation and maintenance of these systems for existing facilities is vital to ensuring that they remain safe and dependable for patients who rely on them for survival. However, safety of medical gas management is challenging issue in Emerging countries like Vietnam, Bangladesh, India, Sri Lanka and so on. No medical gas cylinders comply with the international system for colour coding. Cylinders are often the same colour regardless of the contents and the labelling is often a poor quality and inconsistent. Because of this, there is a risk of the wrong cylinder being delivered accidentally to healthcare facilities. Poorly trained staffs are not aware of the importance of ensuring the correct tanks are connected to the right lines and there is not a universal system of

compatibility of fittings for each type of medical gas. Hence, there is a high change of wrong gas induction to the patient and a high chance of sentinel event that leads to permanent injury or even mass death. In Vietnam, incidents related to medical gas issues have not been widely reported and there is little heard on medical gas injury in hospitals in Vietnam. In the world, these events are classified as "*never events*" but still are occasionally occurring.

A review of the literature identified a number of incidents in the US, where strict regulations are already in place relating to medical gas systems. Examples of incidents that occurred included:

In 1996: Nine children in New York were poisoned by CO₂ from employee who mistakenly installed the CO₂ cylinder instead of the oxygen cylinder.

In 1997, a technician overrode safety protocols and failsafe mechanisms and incorrectly a tank of argon gas to the hospital oxygen system and resulted in a patient death.

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In 2000, at a nursing home in Ohio, two people were found dead and 8 people were severely poisoned when a technician bypassed safety systems and hooked up a nitrogen tank to the oxygen system.

These events occurred in a health system with strict controls and layers of both mechanical and procedural safeguards. In Vietnam, none of these safeguards are in place. As a result, Hanh Phuc International Hospital, as part of its risk management activities, identified issues with medical gases as a high risk area. And the objective of this article is to disseminate the risk mitigation outcome to other emerging countries for a call to action.

2. Introduction

A medical gas used for treating or preventing disease and for life support of patient. The use of medical gases should be subject to prescription by a clinician. Due to the fact that all medical gases are considered drugs which are only available by prescription, the standards with which they are governed are strictly controlled by a national regulation and there should be an oversight agency [1-5].

The Four Tenets of Medical Gas System Safety Medical gas systems are an essential part of any hospital as they dispense essential gases and produce vacuum for medical treatments and medical equipment operation. The Four Tenets of Medical Gas System Safety: (1) *Continuity*: The gas supplies must always be available; (2) *Adequacy*: The correct flow and pressure must always be delivered; (3) *Identity*: The correct gas should always be administered; and (4) *Quality*: Gases must be safe and pure [6-9].

Most people think of the medical gas system as oxygen that is pumped to patients in surgery or in their hospital room [10]. In fact, there are several gases that make up the average medical gas system including the anaesthesia gases that are part of the cart in the operating room. That's why medical gas systems sustain life and are regulated as a drug. This means multiple layers of restrictions and instruction on the proper, safe and legal way to do things. Medical gas systems can be appreciated as life-support systems as a failure in the system could lead to the death of the patient [11]. Some medical gases used in patient care include the following: (1) *Oxygen*: Delivered directly to patients via cannula, blenders, ventilators, and others methods; (2) *Medical air*: High quality air for patient ventilation and equipment; (3) *Nitrous oxide*: Administered to patients via anaesthesia machines; (4) *Nitrogen*: A gas that powers medical equipment; and (5) *Vacuum*: This function provides the means for suctioning and for anaesthesia waste gas evacuation [7-9].

Usually, the physical and chemical composition of a medical gas, the maximum levels of its contaminants and the way in which it is administered and packaged are governed by the regulatory authority. "Gases used for human healthcare are strictly controlled by both legislation and industrial standards so as to not impair human physiology". Gases of this nature may be manufactured as pure gases or as compounds, but are always filtered to the highest quality possible. The application of each individual gas determines

its production and distribution. The equipment with which medical gases are applied to a patient, production process, or other task is strictly controlled. More than 225 standards relating to pharmaceutical and medical gases are available through the IHS (Information Handling Service) Global Standards Store [4]. All individuals who install or maintain medical gas systems must receive appropriate training and complete the Medical Gas Installer Exam. Those who administer or prescribe pharmaceutical-grade gases undergo extensive medical training and licensing programs. Until a certification has been granted, anyone marketing a medical gas for human or animal drug use without an approved application under section 505 or 512 of the FD&C Act is marketing an unapproved new drug. There are two main standards in use internationally that provide best practice guidance for medical gas systems and products:-NFPA 99(US) and HTM 02 01 (Health Technical Memorandum 02 Medical gases, UK) [2-7].

Having such strict regulation and monitoring, the USP (United States Pharmacopeia) Medication Errors Reporting (MER) Program received a report from a community hospital concerning medical gas tanks that were mislabelled. According to the report, the hospital received four yellow air tanks with air tank fittings (valves) from its supplier that were mislabelled as nitrogen. A respiratory therapist was alerted to the error by the distinctive air valve on the tank [13]. Although this error did not result in patient harm, the Food and Drug Administration (FDA) received four reports in the last four years in which medical gas mix-ups have resulted in a total of 7 deaths and 15 serious injuries [13]. The most recent incident occurred in December 2000 at a nursing home in Ohio. In all cases the patients were thought to be receiving medical grade oxygen, but instead were receiving industrial grade nitrogen, or industrial grade argon, or carbon dioxide, which had been incorrectly connected to the oxygen supply system [13].

The death of a new-born baby in an Australian hospital in July 2016, while another infant at the same hospital was left in critical condition, highlights how easily gas pipeline errors can remain undetected until significant injury or death occurs. The death of one infant, and brain injury to the other, was caused by anoxia (ie, starvation of oxygen) due to a mistake in connecting nitrous oxide to a pipeline that should have contained oxygen. Crossing gas pipes led to the 100% nitrous oxide being delivered through the "oxygen" outlet to resuscitation equipment. This incident was the result of a series of mistakes and breeches international standards, processes, and procedures. Standardisation has been mandated for indexing the wall gas outlets controlling the connection of gas supply to medical devices in the same manner that the connection of gas cylinders is indexed [14].

In Vietnam, incidents related to medical gas issues have not been widely reported and there is little heard on medical gas injury in hospitals in Vietnam. In literature review, there is no medical gas incident reported in Bangladesh and or India too. It's clear that most incidents are underreported and under the iceberg. In the world, these events are classified as "never events" but still are occasionally occurring. These events occurred in a health system with strict controls and layers of both mechanical and procedural safeguards. In

Vietnam, none of these safeguards are in place. As a result, Hanh Phuc International Hospital in Vietnam, as part of its risk management activities, identified issues with medical gases as a high risk area by using proactive risk assessment FMEA tool.

FMEA (Failure Mode effective Analysis) tool is widely used in proactive risk assessment process which is a prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome [2]. In other words the FMEA is a systematic approach to identify and prevent product and process problems before they occur. Hence, FMEA method/process tool is proactive risk reduction tool where the real incident or accident hasn't happened yet. The FMEA tools follow the six steps:

Step 1: Define the FMEA Topic: Define the topic of the FMEA along with a clear definition of the process to be studied.

Step 2: Assemble the Team: The team is to be multidisciplinary including the subject matter expert(s) and an advisor, if possible.

Step 3: Graphically Describe the Process:

- 1) Develop and verify the flow diagram.
- 2) Consecutively number each process step identified in the process flow diagram.
- 3) If the process is complex, identify the area of the process to focus on (take manageable bites).

Step 4: Conduct a Risk/Hazard Analysis:

- 1) List all possible/potential failure modes for the process steps identified in Step 3. Failure modes include anything that could go wrong that would prevent the process step from being carried out. Use various methods including triggering questions, brainstorming, cause and effect diagramming to identify potential failure modes.
- 2) Consecutively number these failure modes. Transfer the failure modes to the FMEA form.
- 3) List all possible/potential effects of the failure mode. Effects include anything that could happen if the failure actually occurs.
- 4) Determine the severity of each effect by using the Severity Rating table. Document the severity rating on the FMEA form.
- 5) Determine the potential cause(s) of each failure mode. Each failure mode may have multiple failure mode causes. For example: if logging onto a laptop computer is the process step, possible failure modes are not being able to log in and delayed login. Possible failure mode causes would include the computer not being available, no power, and no log in ID for the operator etc. Document the cause(s) on the FMEA form.
- 6) Determine the probability of occurrence for each of the potential causes by using the Probability Rating table and record these on the FMEA form.
- 7) Determine the Hazard Score by multiplying the Probability Score by the Severity Score.
- 8) Use the Hazard Decision Matrix to determine if the failure mode warrants further action. If the score is 8 or

higher, strong consideration should be given to developing an action plan.

- 9) Record if a corrective action will be developed, for each failure mode, on the FMEA form. If the hazard score is >8 and the decision is to not develop an action plan, document the reason on the FMEA form.

Step 5: Actions and Outcome Measures

- 1) Identify an Action Plan for each failure mode that will be corrected, using the FMEA Action Planning Worksheet. Place the corrective actions in the process at the earliest feasible point. Multiple actions can be placed in the process to control a single hazard. An action can be used more than one time in the process. Solicit input from the process owners if they are not represented on the team. Try to simulate any recommended process change to test them before facility-wide implementation.
- 2) Identify process and/or outcome measures that will be used to analyze and test the redesigned process.
- 3) Identify a single, responsible individual by title to complete the recommended action.
- 4) Indicate whether top management has concurred with the recommended action.
- 5) Record the recommended action, responsibility and target date on the FMEA form.

Step 6: Follow-up on Actions Taken

- 1) After the target date for the recommended action(s), follow-up to make sure the actions were implemented and on what date. Document your findings on the FMEA form.
- 2) Now that the recommended actions have been implemented, the hazard score should be lower. So, revisit the probability of that failure mode cause using the Probability Rating table and document the new rating on the FMEA form.
- 3) Obtain the new hazard score by multiplying the severity times the probability and document on the FMEA form. The new hazard score should now be <8 . If not, revisit the recommended actions.

The FMEA action follow chart will follow the following 6 steps:



Figure 1: Standards FMEA process follows 6 steps

3. Material and Methods

Medical Gas Management is one of the critical parts of their safety program of which Hanh Phuc hospital has maintained since 2016 after introducing FMEA tool. The medical gas system was identified as a potential high risk area and the hospital conducted a thorough audit of the system and found the following gaps:

- 1) Gas cylinder storage systems were not adequate and were not following standard policies, procedures or safety protocols
- 2) The gas cylinders used did NOT use standard colour codes and it was necessary to dependent on supplier verification. The supplier was also not following a standard colour coding system

- 3) No training was provided for clinical staff on cylinder safety and colour coding.
- 4) No medical gas safety training was provided to maintenance staff on gas handling
- 5) No audits were conducted on cylinder usage, colour coding or the overall medical gas systems
- 6) Poor signage was present at the central medical gas supply room for different gas cylinders. There were also no safety signage or written instructions on how to replenish medical gas at storage area.
- 7) Cylinders used in clinical units were not covered and stored.

The hospital adopted the international colour code to intervene the risk by using a Failure Mode Effect Analysis (FMEA) tool. The colour codes tool is:



Figure 2: International Medical Gas Cylinder Colour code, adapted in Hanh Phuc International Hospital

To identify the risk of medical gas system in the Hanh Phuc international hospital took the FMEA (Failure Mood effective Analysis) tool which follows the nine (09) steps:

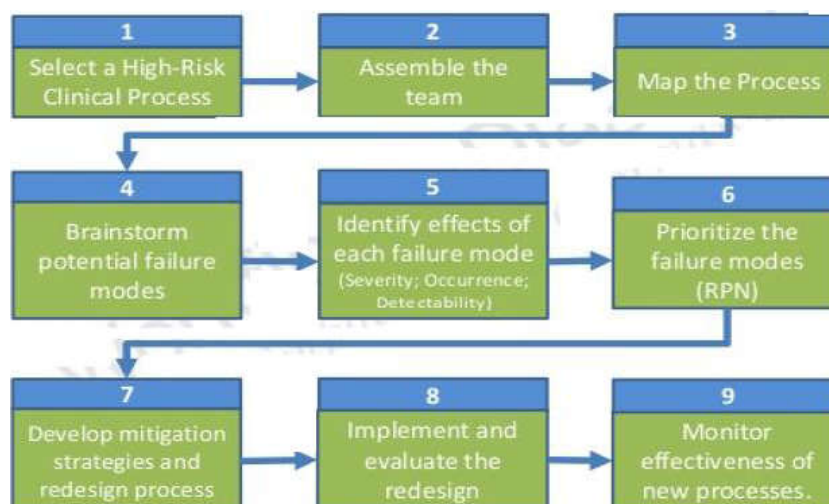


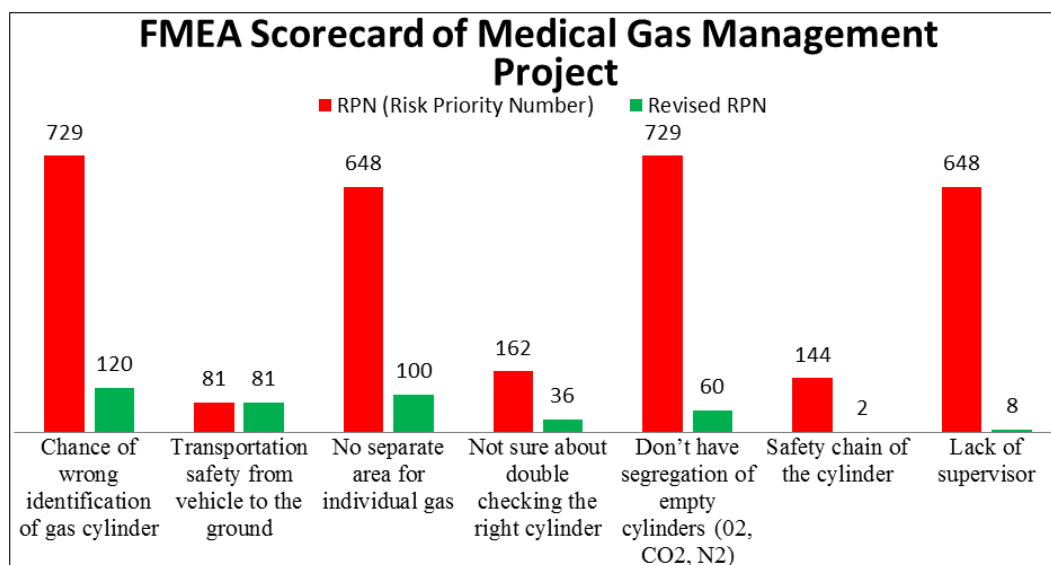
Figure 3: Hanh Phuc International Hospital adopted 9 process to conduct FMEA on Medical Gas Risk Assessment

4. Results

The result of FMEA risk assessment is reflecting the evidence of taking the safety intervention of medical gas management system in the hospital. The hospital identifies the following risk points to conduct the FMEA and those are: (1) Chance of wrong identification of gas cylinder, (2) Transportation safety from vehicle to the ground, (3) No separate area for individual gas, (4) Not sure about doubling checking the right cylinder, (5) Don't have segregation of empty cylinders, (6) Safety chain of the cylinder, and (7) Lack of supervision.

The initial RPN (Risk priority number score out of 1000) result was showing that 'Chance of wrong identification of gas cylinder' and 'Don't have segregation of empty cylinders' RPN scored highest risk (729/1000) area, followed by 'No separate area for individual gas' and 'Lack of supervision' scored next highest risk (648/1000) area. Besides, 'Not sure about doubling checking the right cylinder' scored 162/1000, 'Safety chain of the cylinder' scored 144/1000, and the 'Transportation safety from vehicle to the ground' scored lowest 81/1000.

After intervention with colour code and audit, training and checklist to improve the safety the following RPN score was significantly reduced to 84%, even up to 99%.



The rate of compliance with medical gas safety protocols as outlined in this document, improved from 40% in the first audit in Jan 2017 to 94% in Feb 2017 after improvement. This rate of compliance has been sustained from the start of

the project up to the present with many months showing 100% compliance.

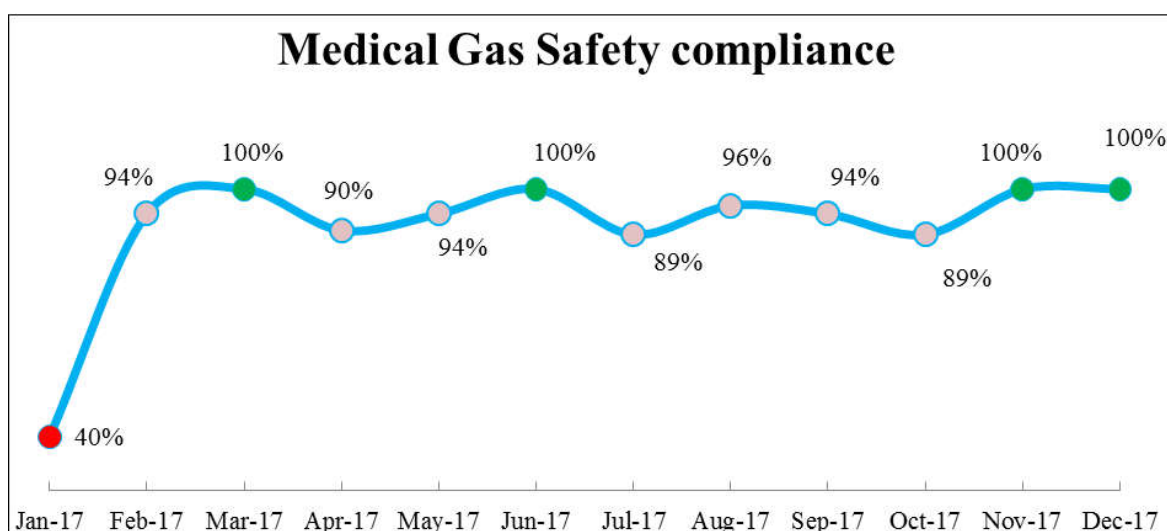


Figure 4: Line graph showing the distribution of medical gas safety colour code compliance

Besides, Hospital also conducted the medical gas cylinder expiry audit every month to check the cylinder compliance with the medical gas safety protocol. The initial month of Jan 2017, it was reported only 65% compliance, but after strict regular audit, it improved from 65% to 97% in Feb

2017. The rate of compliance has been sustained and improved from Feb 2017 to the present with many months showing 100% compliance.

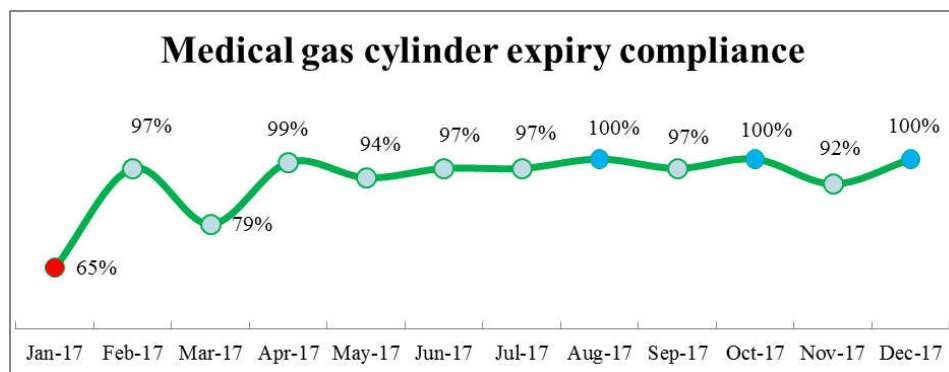


Figure 5: Line graph showing the distribution of medical gas cylinder expiry compliance

Besides, the outcome of FMEA result, the medical gas management project achieved a number of measureable outcomes:

- 1) Achieved zero (incidents / sentinel event related medical gases during 2017 and continuing to 2018
- 2) Increased awareness among staff to make sure the RIGHT Gas with the RIGHT Colour with the RIGHT Cover for the RIGHT Patient
- 3) Consistent monthly self-auditing and spot checking to prevent chance of mismatch medical gas.
- 4) Increased job satisfaction and staff morale and trust of patient.

5. Discussion

The medical gas safety management project improvement in quality and safety is achieved and sustained. This is a continuous on-going program as a part of our overall risk management program to identify and to proactively reduce unanticipated adverse events and other safety risks to patients and staff [15-22]. The cost of the total project was less than dollars but return of impact is very significant. Although there has been no direct serious incidents reported due to medical gas injury, the FMEA indicated that there was a possibility of such an incident. The impact of such an incident on the patient, their family our staff and the hospital would be high. This project also supports our progress for JCI Accreditation as it relates to The Joint Commission International (JCI) Standards FMS. 4, FMS.11, QPS.10 and QPS.11 [12].

Key changes following intervention is implemented included:

- 1) Safety chains were used to keep cylinder steady in the storage.
- 2) The signage of cylinder colour code was posted to the user area for identification of gas
- 3) Special medical cylinders must be locked and key kept by supervisor or security
- 4) All medical cylinders were separated by colour code
- 5) A cylinder tag was used to identify cylinder number, size, type of gas, full or in-service or empty cylinder
- 6) Development of specialized forms including medical gas cylinder ordering, handover between maintenance and end use, handover between maintenance and supplier
- 7) Handover log books were modified.
- 8) Strengthen security and safety signage at medical gas storage area.

Although the rate of compliance is close to 100%, the hospital will continue to monitor adherence to guidelines due to critical nature of having a safe medical gas system. This is an excellent example of a low cost project with high impact that has immediate and significant impact in our hospital. The project was submitted for HMA award competition and after successful scrutiny; project got the 'Gold award' after competing with 451 award entries from 123 hospitals in 18 countries [23]. This project has great applicability to other hospitals in developing countries that do not have strict controls over medical gases. During 2018, it is planned that this project will be expanded to all national hospitals in Vietnam. And this experience sharing will enable to process a national wide a call to action to prevent such medical gas incident in Vietnam, Bangladesh, India, Sri Lanka, and South African countries where medical gas supervision is minimum.

6. Conclusion

In this project, the outcome of intervention is significant and risk is reduced dramatically. The measurable tools are simple to use and continuous monitoring, training and auditing is required to maintain the result. Although the risk is propagated to the medical gas supplier and they need to follow the similar colour code within their practice. Besides, the MoH (Ministry of Health) and or DoH (Department of Health) should maintain strict surveillance to check the regulation compliance of the medical gas colour code for each cylinder supplied by vendor and used by hospital. The developing partners in emerging country where medical Gas safety supervision is least possible, should take appropriate measure to scale up this project at national level. This will ultimately ensure medical gas safety practice in emerging countries like Bangladesh, Vietnam, India, Sri Lanka and ensure staff and, patient safety by ensuring four (04) rights i.e RIGHT Gas with the RIGHT Colour with the RIGHT Cover for the RIGHT Patient for the improvement in the future.

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