

The '360° Anzen-first model'
blends concepts of '**Patient for patient safety**' with Japanese '**Kiken-Yochi**' for
proactive risk mitigation from
life-threatening fire and pressure hazards
in Hyperbaric Oxygen Therapy (HBOT);
Indo-Japanese wisdom!

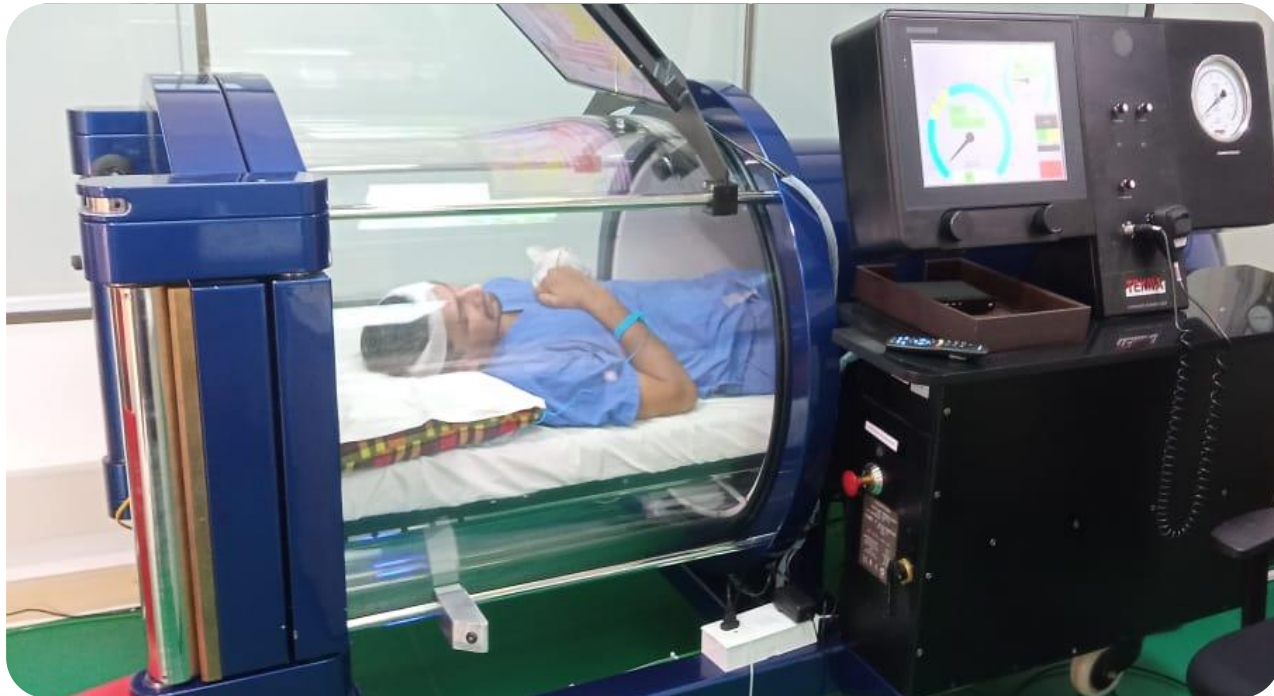


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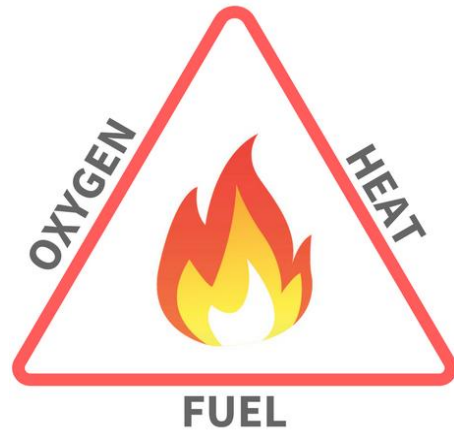
1. Background

Hyperbaric Oxygen Therapy (HBOT)

- Treatment in a closed chamber, providing 100% oxygen under 3times higher atmospheric pressures for 90minutes.
- In a highly pressurized chamber, HBOT poses serious fire and blast hazards.
- Historically, 80% of hyperbaric chamber fires resulted from entry of prohibited items.
- It is impossible to quickly open the door, hence rapid evacuation is not always possible.
- Treating comatose patients makes it most vulnerable



What is the danger?



Fire Triangle



High Pressure



Did it happen anywhere?



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Explosion in Lehi, Utah



Geisinger Medical Center, **Pennsylvania**, April 1989



March 2016, **Jakarta** Naval Hospital HBOT fire



Patient killed after hospital blown up as he smoked a cigarette HBOT chamber. Reported by Jennifer newton, 31 July 2014, Nanxiong People's Hospital in Nanxiong city in south-eastern China's Guangdong province



KESMARC HBOT in Florida

Hyperbaric Chamber explosion aftermath, (source: WFTV Ch 9)



Oxygen Chamber Explodes, Starts Fire In Russian Hospital, 31st October, 2020



City Hospital No 2 in Chelyabinsk
The blaze spread over an area of 1,400 sq ft, engulfing two floors. More than 20 residents in a nearby high-rise had to be evacuated after the blast shattered windows.

Two charged in deadly hyperbaric chamber fire that killed 4yrs boy and his grandmother

By [REBECCA SEALES](#) PUBLISHED: 10:24 GMT, 26 April 2012



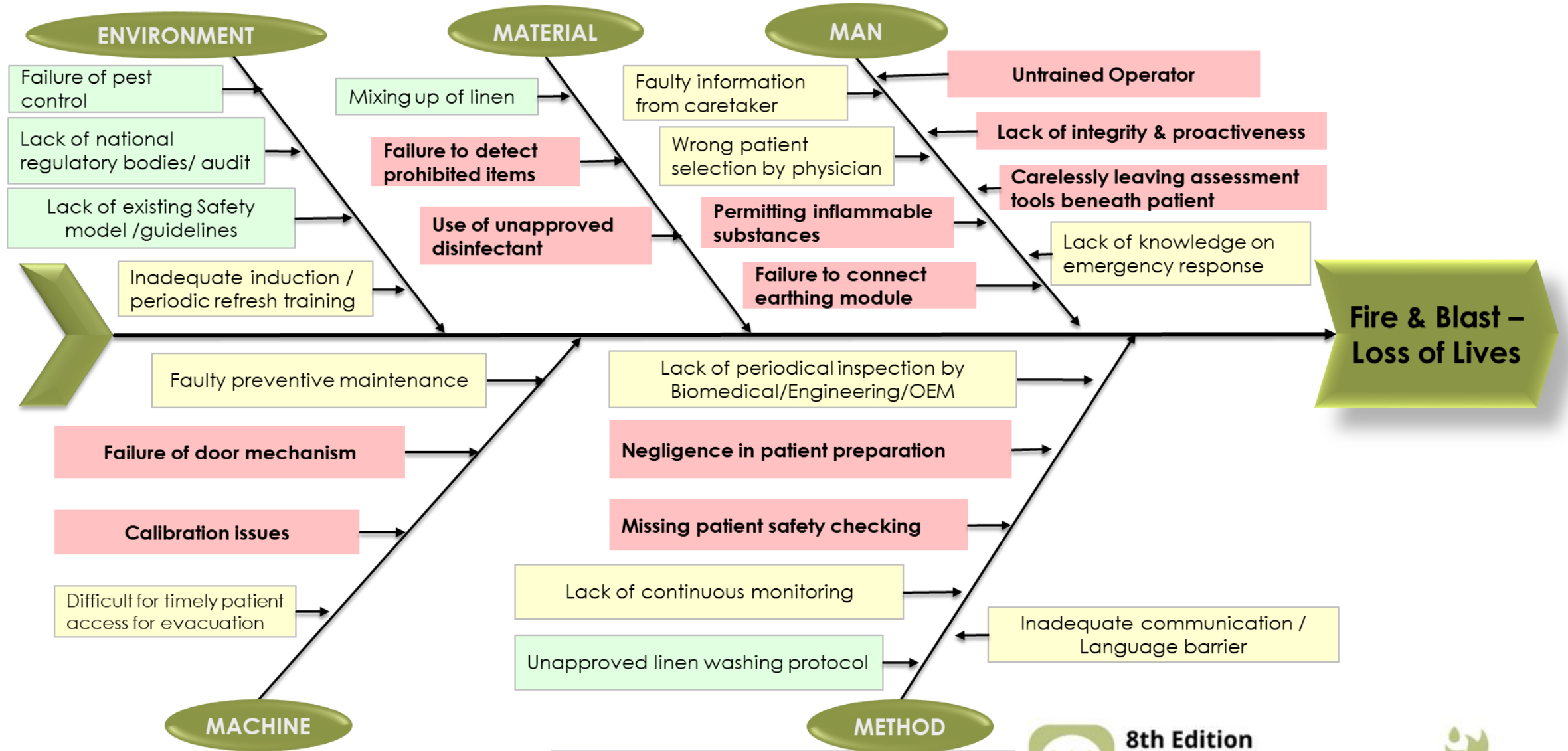
Globally reported HBOT Fire Blast incidents

- From 1923 to 1996, 77 human fatalities occurred in 35 hyperbaric chamber fires, reported in Asia, Europe, and USA
- In Wisconsin (1971) a chamber door failed, causing an explosive decompression
- In Belgium (1993) and United Kingdom (1996) smoking by occupants resulted in two fatalities
- In Japan (1996) a chemical hand warmer caused a fire that killed the occupant
- In Italy (1997) a hand warmer filled with benzene caused 11 fatalities.
- In Cuba (1997) a child's friction toy caused a fatal fire
- In July 1998, At Istanbul University Medical Center, Turkey, fire broke out killed 2
- In 2001 Chinese multiplace chamber fire caused by short in air conditioner; one fatality.
- In 2002 Chinese monoplace chamber fire caused by cell phone; one fatality
- In South Africa (2004) an HBOT fire explosion caused severe property damage
- In 2006, Peruvian monoplace chamber fire caused by intercom; one fatality
- In 31st October, 2020, Oxygen Chamber Explodes, starts fire in Russian Hospital



What are the probable causes of such fire blasts?

2. HBOT Fire Hazard – Root Cause Analysis through Ishikawa Diagram



Legend :

HIGH IMPACT	MEDIUM IMPACT	LOW IMPACT
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So..what's the real problem?

3. Problem Scenario: HBOT installations are exponentially increasing in India and there are no National regulatory guidelines as yet.

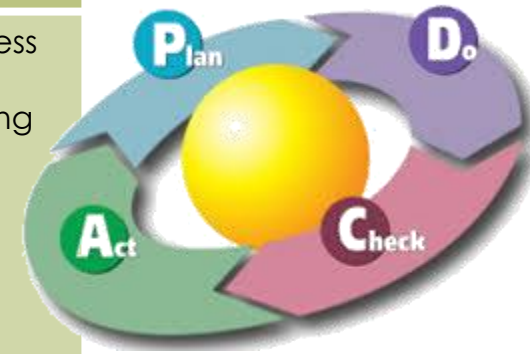
4. Objective: To formulate and implement “360° Safety-first model” for HBOT for proactive risk mitigation by integrating concepts of Patient Centred Care(PCC), ‘Patient for patient safety and Kiken-Yochi

5. Methodology: Type of study : Retrospective observational study

- Study setting: Sakra World Hospital, Bangalore
- Study period: **20 months** (July 2022 till Feb 2024)
- Sample size: **2700 HBOT dive sessions**
- Quality tools used: Ishikawa Diagram, Pareto Chart, Flow Chart, Checklist, HIRA, PDCA

6. Developing Countermeasures

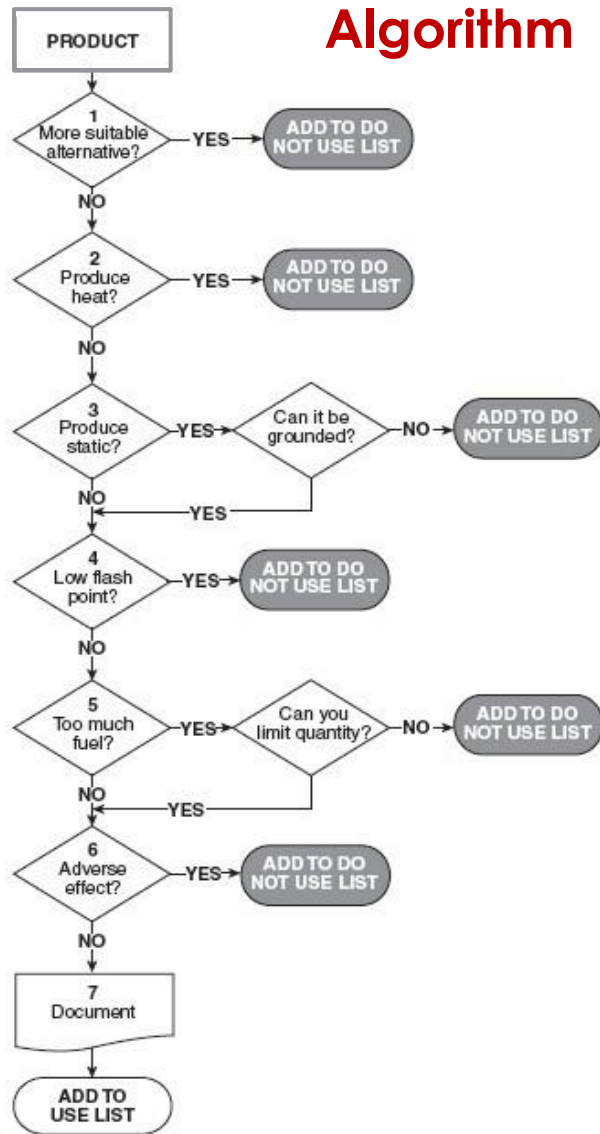
PLAN	DO	CHECK	ACT/ADJUST
<ul style="list-style-type: none"> • Quality Circle formation • Site plan & preparation • SOP creation • Capacity building • Clinician licensing • Patient Brochure • Consent Form • Assessment Forms • Safety Checklist • Risk Assessment FMEA 	<ul style="list-style-type: none"> • Procedure Implementation • Do'd and Don't Poster Display • Patient Education 	<ul style="list-style-type: none"> • FMEA analysis • HIRA analysis • Control measure review • Process KPI • Incident Analysis 	<ul style="list-style-type: none"> • Emergency Preparedness • Fire Mock Drill • KY checking and Training • Caregiver Involvement • Safety Director Genba Audit and debriefing • NO-Go Item Listing • PREM • 360Anzen first Model



What's the countermeasure?

7a. Developing Countermeasures - Identification of NO-Go Items (Prohibited Items)

NFPA Risk Assessment Algorithm



Burman Risk Scoring System

(Magnitude Of The Risk)

Risk Score	Risk Level	Risk Description
≥ 100	5	Extremely dangerous: do not operate facility
50 - 99	4	Very high: stop use of specific equipment, process or procedure
20 - 49	3	High: Requires urgent attention; proceed with great care
May-19	2	Medium: Attention needed but operation may continue
0-4	1	Low: Acceptable risk but noted



Kiken-Yochi



Kiken-Yochi



Metal detection



The sign out



The final Callout

What's the key principle?



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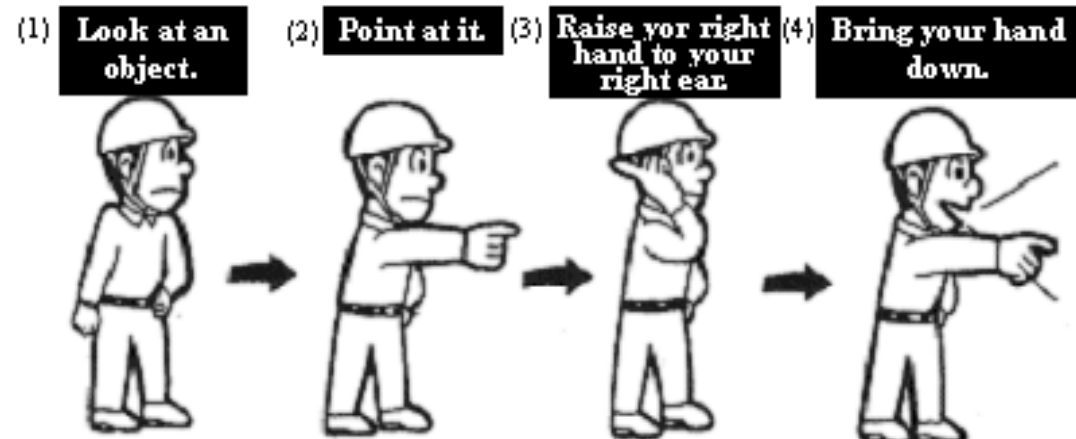
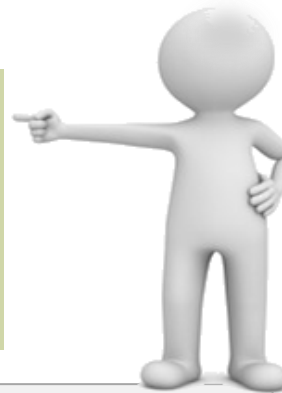
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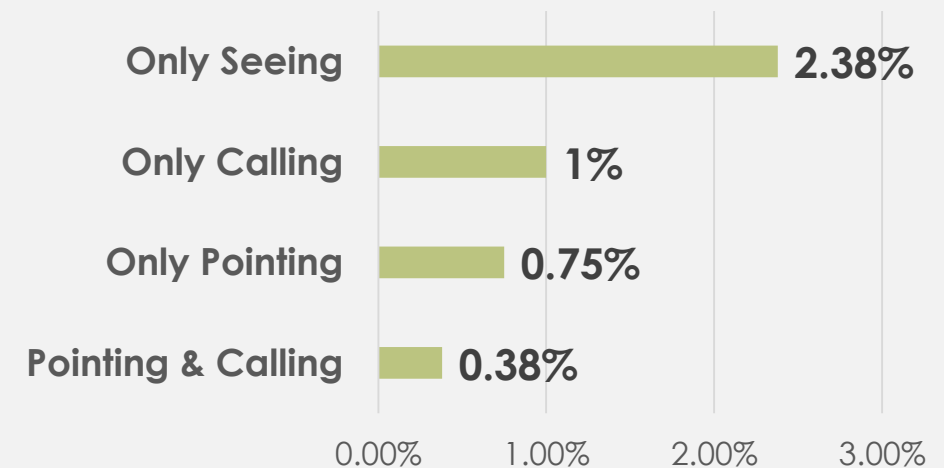
7b. Developing Countermeasures

'What-If', Kiken-Yochi Exercise: Pointing & Calling at target objects, by stretching arm and stating out loud & LISTEN OWN SOUND.

Multi sensory involvement! Eg. "The cable is badly cut, OO... OK"



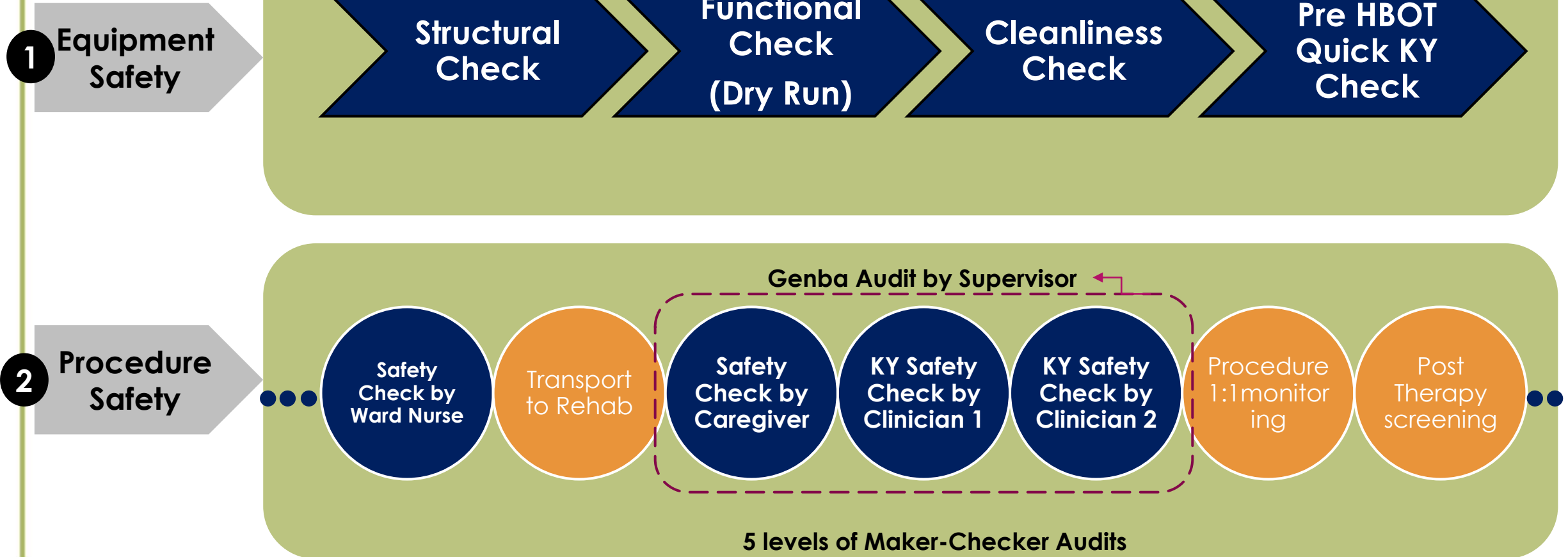
% chances of making mistakes



*Resource: Railway Technical Research Institute, 1994

8a. Implementing Countermeasures

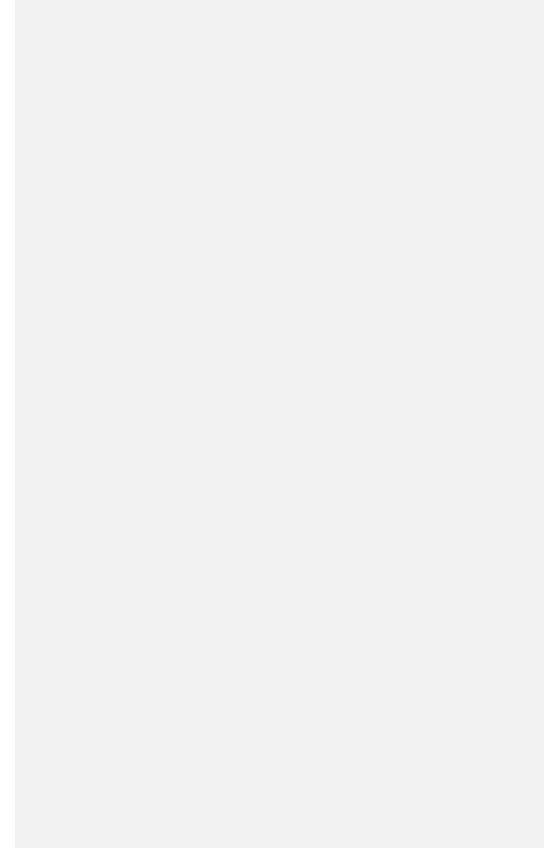
HBOT Multi-Level KY Safety Design



The glaring aspect?

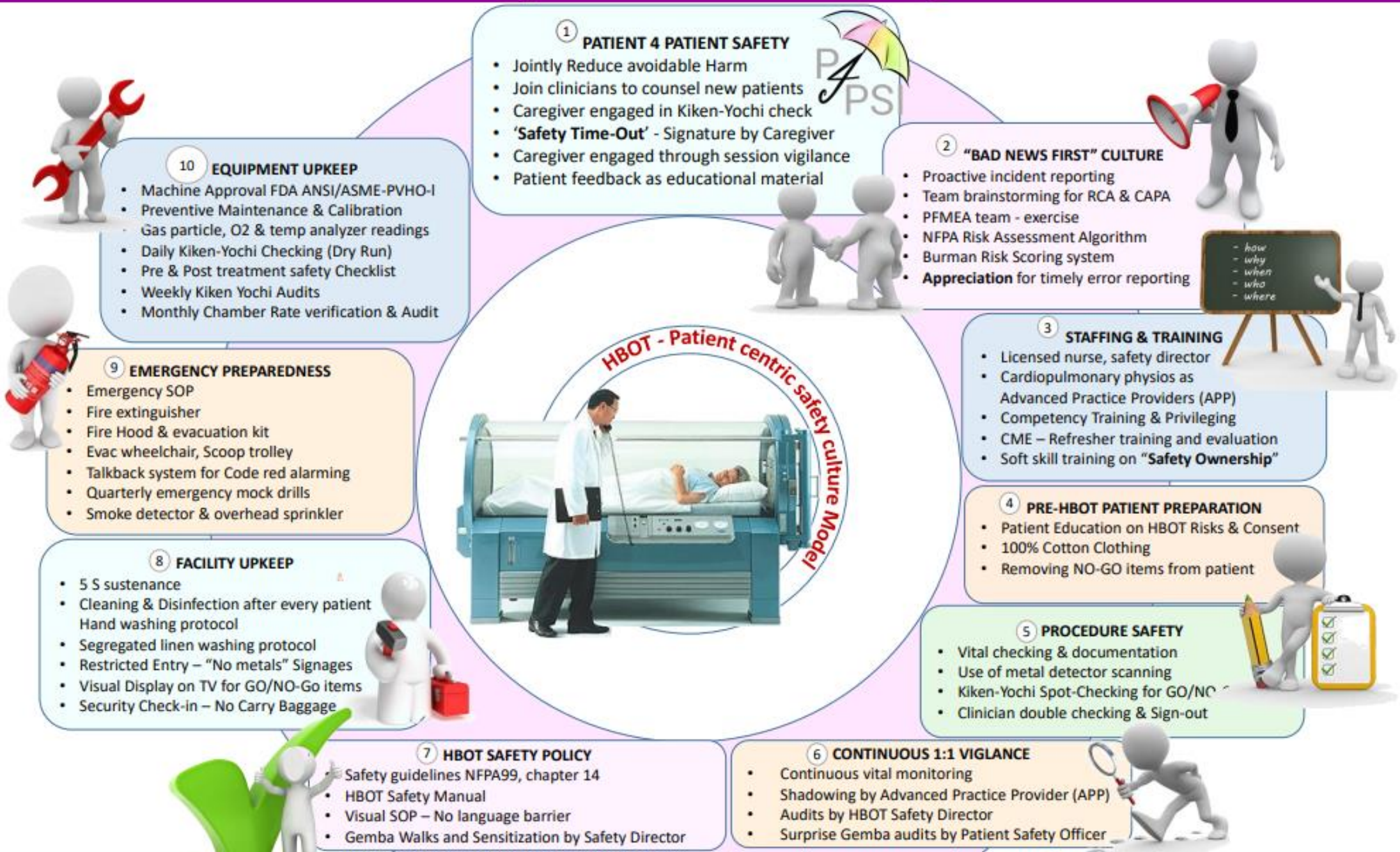
8b. Implementing Countermeasures

Integrating Patient 4 Patient Safety Concept



Active involvement of patient/caregiver in their own safety checking and declaration of NO-GO items

The concept to action



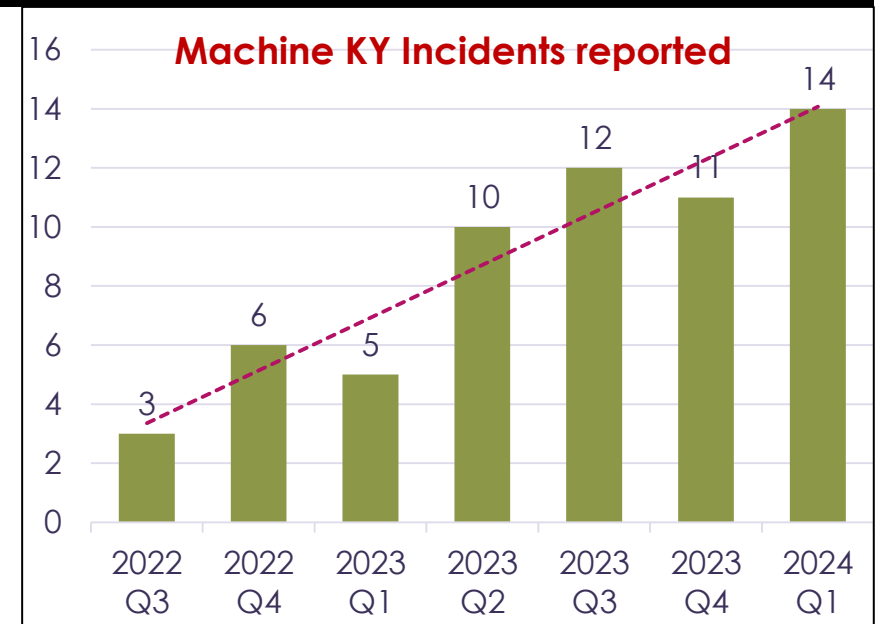
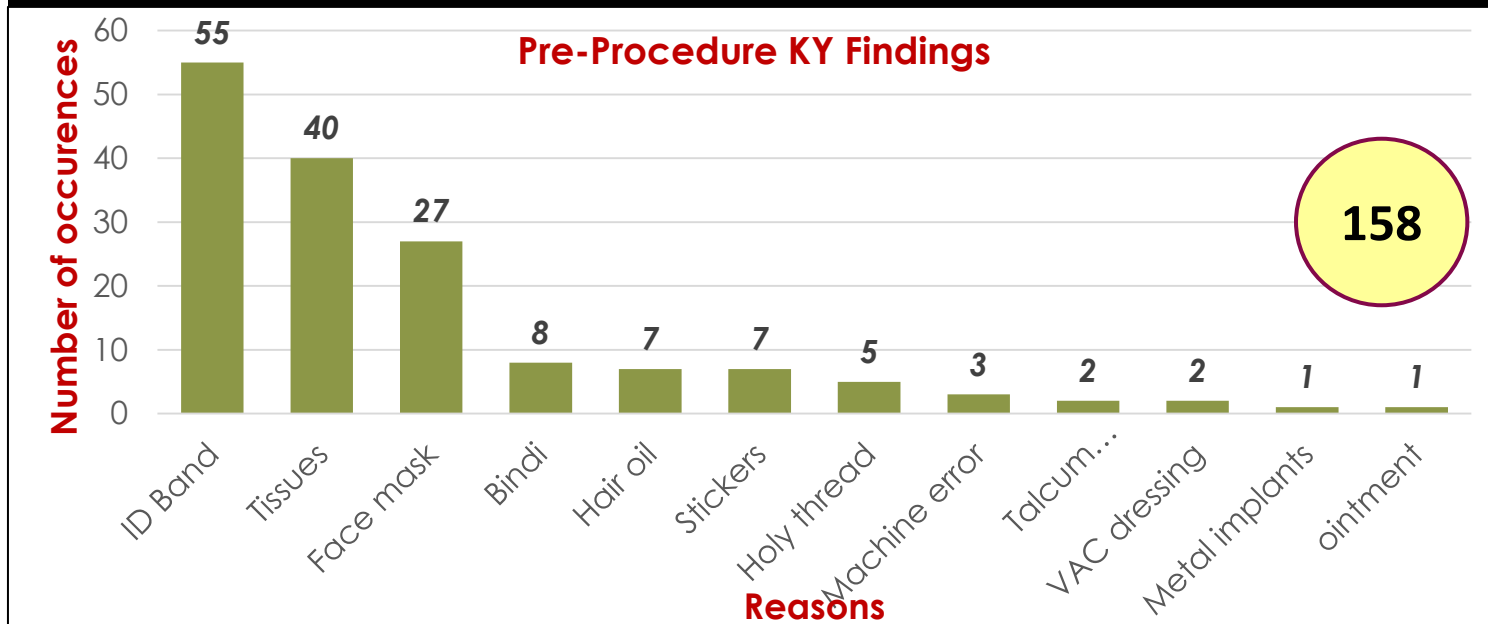
9a. Results: Hazard Identification and Risk Assessment (HIRA)

Hazard	Risk	Existing Control Measures	Residual Risk Rating				Risk Matrix Rating	Additional Control Required	Residual Risk Rating				
			Probability	Severity Impact					Probability	Severity Impact			Risk Matrix Rating
				H	P	B				H	P	B	
<p>Human exposure to 100% Oxygen and 2.0 ATA pressure inside HBOT chamber.</p> <p>Inclusion of vulnerable comatosed patients</p> <p>Undetected synthetic garments, metal objects that could spark, alcohol based agents inside HBOT chamber</p> <p>Inadequate patient education and verification by Nurse/Therapist</p> <p>Inadequate safety and facility checking</p>	<p>Accidental Fire or chamber burst causing injuries/death to patient, Nurse, Therapist and caregiver. Property damage.</p>	<p>Human Controls</p> <ol style="list-style-type: none"> 1. Thorough patient and family education to be done by HBOT Nurse/Therapist. Informed Consent 2. 1:1 continuous monitoring 3. Skill training of dedicated staff, Certification, Privileging <p>Engineering Controls</p> <ol style="list-style-type: none"> 1. Decompression mode activation for emergency 2. Provision of dedicated Fire extinguishers next to HBOT 3. Checking static electricity and neutralizing kit 4. Provision of dedicated vent 5. Connected to UPS power supply <p>Process related Controls</p> <ol style="list-style-type: none"> 1. Use of non alcoholic disinfectant and non abrasive napkin 2. Preventive Maintenance and periodical calibration 3. Restricted people entry, placing barricade to avoid accidental maneuvering of machine door to avoid accidental opening 4. Provision of extra patient scrubs and pure cotton bed sheets, cotton pillows. Separate linen management - not mixing with other hospital linen 	4	5	5	5	60	<p>Human Controls</p> <ol style="list-style-type: none"> 1. Supervisory double checking of Consent, Patient education and genba on-spot verification 2. Weekly sensitization meeting on genba 3. Patient/Caregiver safety checking & signature <p>Engineering Controls</p> <ol style="list-style-type: none"> 1. Availability of Fire hood for operator 2. Landphone next to HBOT 3. Provision of evacuation wheelchair, fire safety kit, sliders in the nearest fire exit 4. Provision of Metal detector to check presence of metal parts 5. Provision of external Oxygen monitoring device <p>Process Controls</p> <ol style="list-style-type: none"> 1. Display posters on "materials NOT permitted" 2. Visual SOP poster display for "education without communication barriers" 3. Floor PVC sticker -"Strictly no metal objects or alcohol agents allowed" 4. Emergency evacuation and Fire mock drills 5. Daily Kiken-Yochi genba checking and documentation 6. Creation of Safety checklist for documenting parameters as per SOP before / during procedure. 7. Double checking and countersignature by authorized personnel 	2	5	5	5	30

9b. KPI for Safety Assurance

	Process Compliance to safety measures	Frequency	Compliance
1	Proactive facility checking	Daily	95%
2	Evidence of Machine dry run	Daily	93%
3	Patient & Family education, Informed consent	Initial	100%
4	Double checking by clinicians	Session-wise	100%
5	Caregiver verification and declaration	Daily	88%
6	Kiken-Yochi checking for presence of prohibited items	Session-wise	100%

9c. Results: Occurrence of proactive hazard identification and risk mitigation



158 times vigilant staff has timely detected and aborted major disasters!

473

Operational Days

2700

HBOT Dives

0

Harm

99.16% Patient Satisfaction for HBOT Safety Measures



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10. Sustenance strategies



Clinician
Gemba
Audit



Error
Reporting
& Follow up



Incident
RCA &
CAPA



Appreciation
for
Integrity,
Ideas

Enhanced **Patient Centred Care (PCC)**

Evolved through **Japanese concept of Kiken-Yochi**

Integrated **“Patient 4 Patient Safety”** concept



- **Successfully established a robust safety culture**
- **Globally adaptable**
- **“Primum non nocere” : first, do no harm!**

Why?

Every Effort Counts, Every Patient Counts, Safety First!



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