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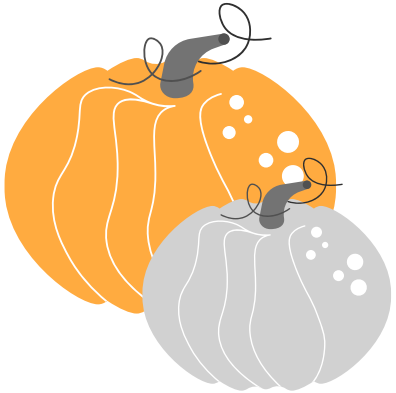
Healthcare Incident Management & Investigation



Master the Process

BY : Barbara Malanga, BSEE
ECRI

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ECRI

Independent organization
for
unbiased,
evidence-based
information
on healthcare technology

ECRI


Tens of
Thousands of
MEMBERS
MISSION
Advancing effective, evidence-based healthcare globally
A Trusted
INDEPENDENT
Voice

ECRI

Technology Decision Support

- Capital, Supplies & Purchased Services Decision Support
- Device Evaluation
- Value Analysis Workflow
- Cybersecurity
- Medical Equipment Planning

Patient Safety

- Patient Safety Organization
- Infection Prevention
- Healthcare Risk Assessments & Management
- Safe Medication Practices
- Healthcare Incident Investigation & Technology Consulting
- Hazard Reports & Alerts

Evidence-based Medicine

- Clinical Evidence Assessments
- Evidence-based Practice Center
- Emerging Technologies Profiles & Forecasts
- Horizon Scanning
- ECRI Guidelines Trust™

Non-Profit Advancing Effective, Evidence-based Healthcare Globally

Learning Objectives

- Understand the importance of effective incident investigation
- Master the 7 points of ECRI's Incident Management and Investigation (IMI) process
- Apply the process to a healthcare incident using an example of an investigation ECRI has done

Incident Management & Investigation

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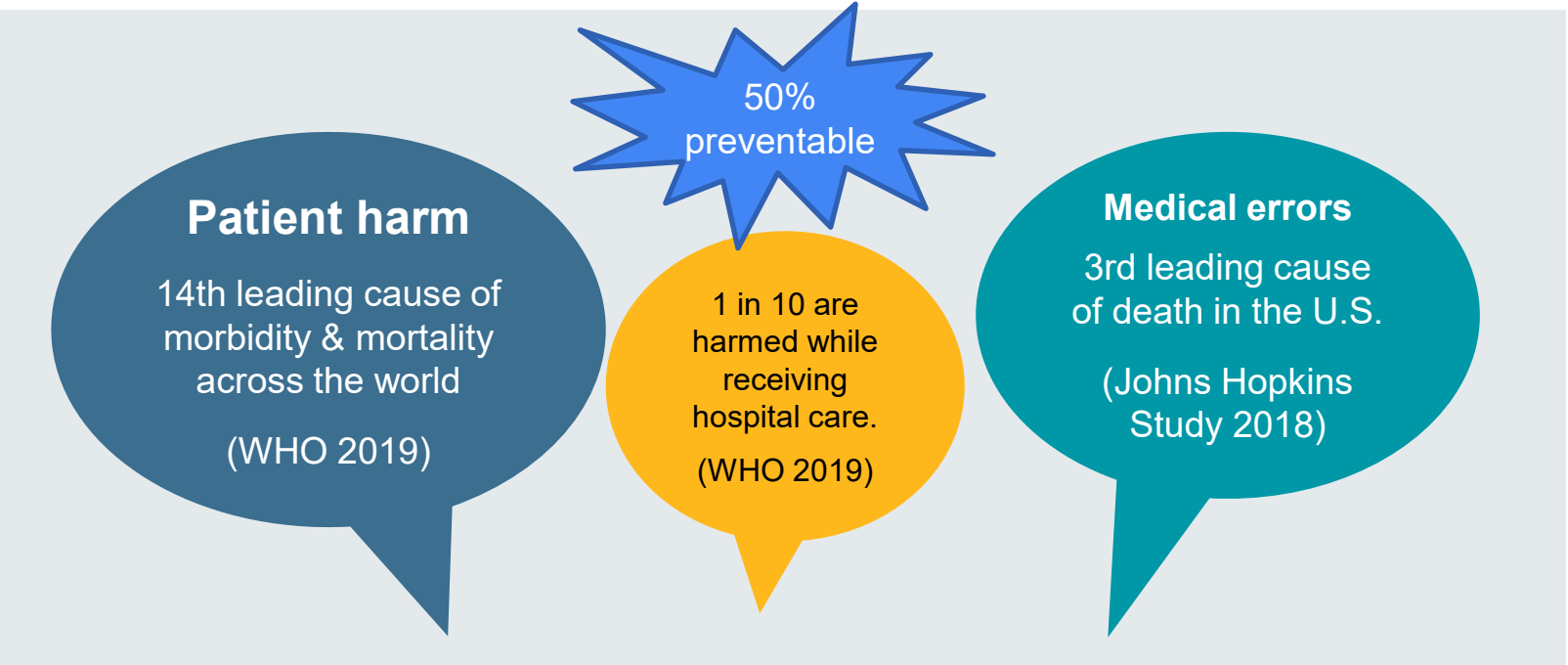

Crucial to properly manage Incidents

INCIDENTS

Accident

One or more unplanned, undesired incidents which result in harm

Near-Miss/Close Call

One or more unplanned, undesired incidents which nearly result harm

We should strive to investigate and prevent both

Incident Management & Investigation

1. Determine what happened
2. Prevent recurrence
3. Decrease risk to patients and HCW's
4. Meet requirements of Government, Insurers and Certifying bodies

Incident Management & Investigation

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Higher Reliability in Healthcare…

"Experience fewer than anticipated accidents or events of harm, despite operating in highly complex, high-risk environments."

The 5 Principles of High Reliability Organizations (HRO):

- Preoccupation with Failure. ...
- Reluctance to Simplify. ...
- Sensitivity to Operations. ...
- Commitment to Resiliency. ...
- Deference to Expertise.

"If we do not strive to understand what went wrong
we cannot possibly expect to prevent it from happening again"

Incident Management & Investigation

Primary Goals

- Determine the cause(s) of the incident

- Implement recommendations to prevent recurrence

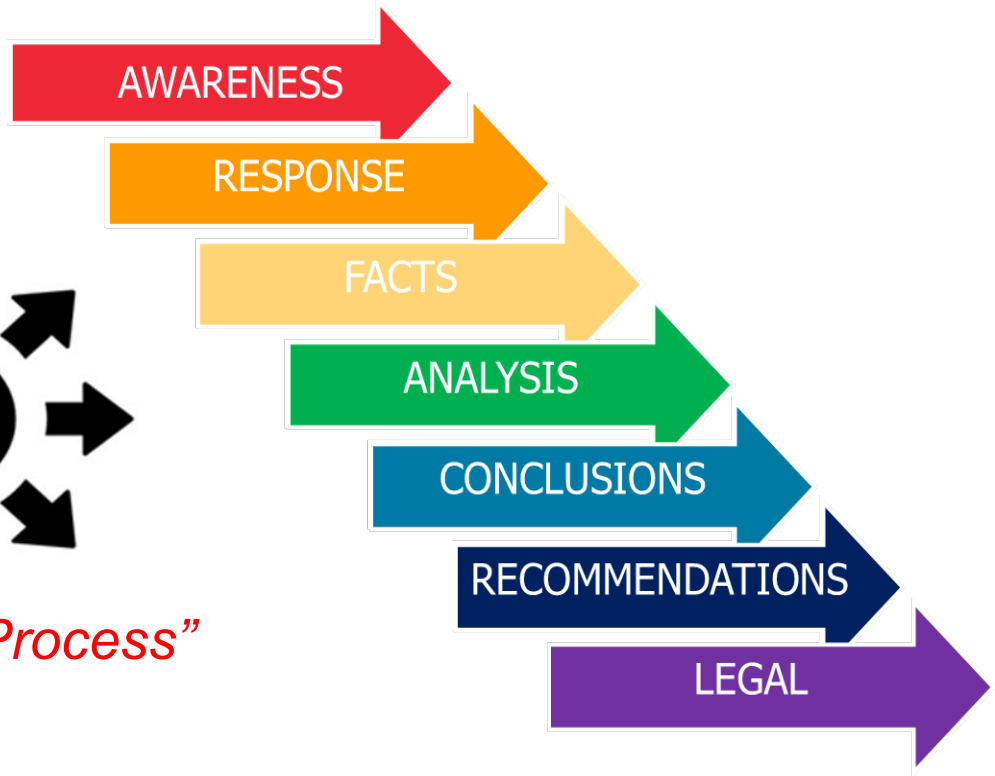
Incident Management & Investigation

Difficulties

- Diversity of technologies – Over 10,000 devices
- Numerous causes of injuries
- Lines of communication can break down
- Patient-specific factors can vary
- Limited information from Equipment Manufacturer
- Sustained compliance with recommendations

“Master the Process”

Incident Management & Investigation Plan
"The IMI Plan"



"Master the Process"

The IMI Plan

Point #1 AWARENESS ***Strange place to start?***

An organization can only analyze and act on incidents that that they are aware of…

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Point #1 AWARENESS — *Sources of Awareness*

INTERNAL

- Clinical Staff notices:
  - Unexpected complication
  - Injury
  - Death
  - “Near miss” or “Close call”.

EXTERNAL

- Patient or Family Member
- Medical Device Manufacturer
- Regulatory Agencies (FDA, CDC)
- Legal Action or Insurance Claim
- Independent Reporting Agencies

The IMI Plan

Point #1 AWARENESS *Types of Awareness*

AWARENESS

Concurrent

Immediately Aware

Subsequent

Aware some time later

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Point #1 AWARENESS → ***Culture of Reporting***

"Delayed awareness can have profound effects on the investigation process"

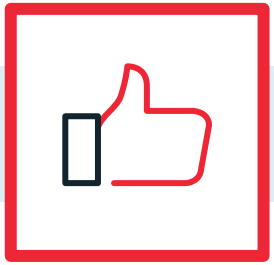
Accessories Discarded…

Loss of Stored Info…

Can Happen Again…

The IMI Plan

Point #1 AWARENESS → ***Culture of Reporting***



Make reporting SAFE

Encourage open communication

No fear of repercussions

Confidential

Make reporting EASY

Well-defined process

Consistent across departments

Build into the workflow

Educate & Train Staff

What should be reported & to whom

The importance of awareness & timely reporting

Acknowledge & Support

Thank reporter & assure them it will be acted on

Support caregivers

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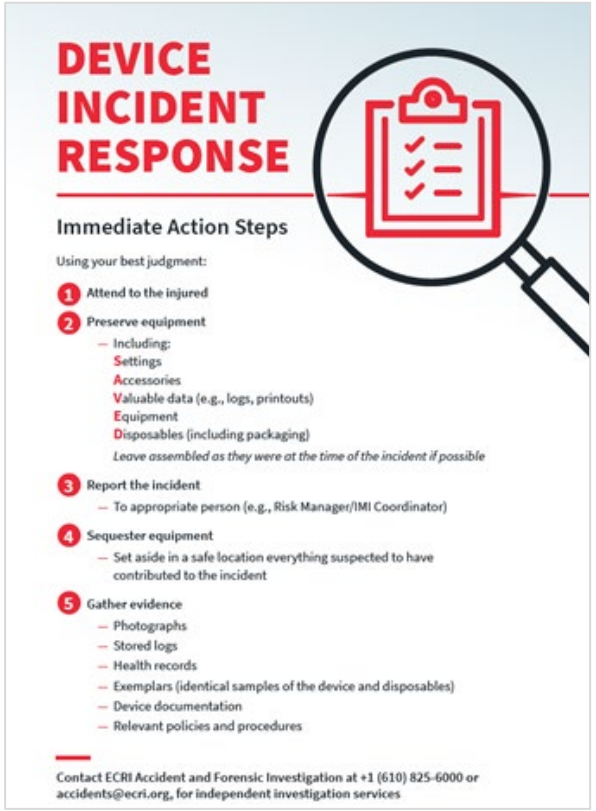
Point #2 RESPONSE

Immediate Action Steps

1. **Attend to the injured**
   - **Patient**
   - **Clinician**
   - **Visitor**



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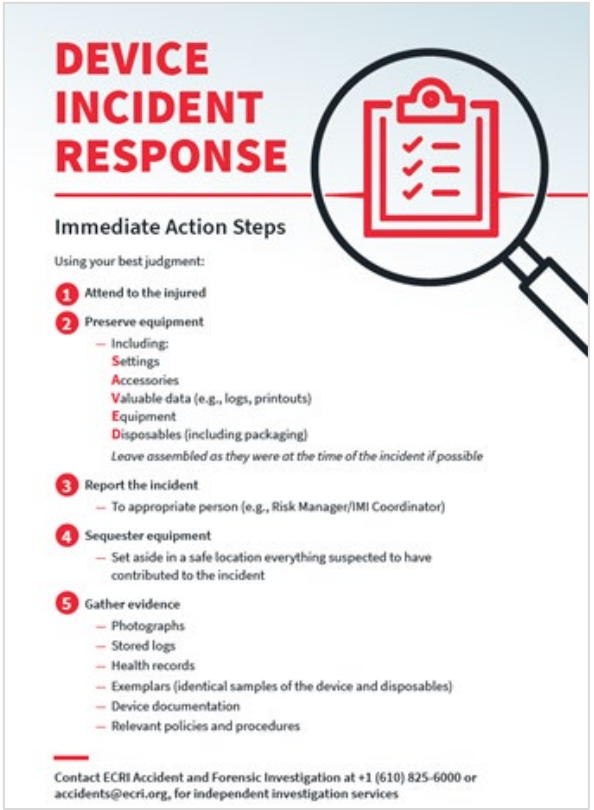
Point #2 RESPONSE

Immediate Action Steps

1. Attend to the injured
2. **Preserve equipment & environment**
   - **Anything that may have caused or contributed**



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Point #2 RESPONSE → *Preservation of Evidence*

Settings

Accessories

Valuable Data/Logs

Equipment

Disposable & Packaging

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Point #2 RESPONSE → *Preserve the Environment*

May want to consider:

- Temperature
- Lighting
- Electrical Power
- Medical Gas
- Odors

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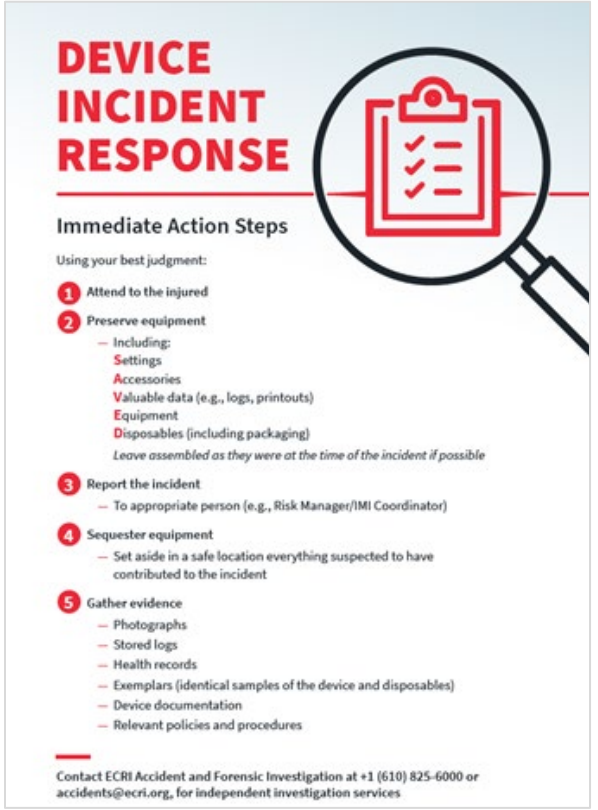
Point #2 RESPONSE

Immediate Action Steps

1. Attend to the injured
2. Preserve equipment/environment
3. **Report the incident**
   - **To appropriate person**
   - **Facility can only analyze & act on events that are reported**



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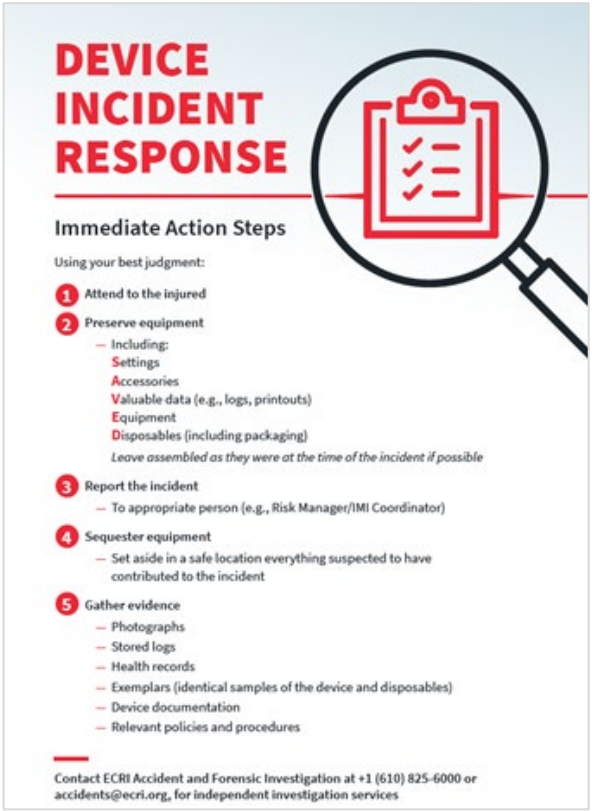
Point #2 RESPONSE

Immediate Action Steps

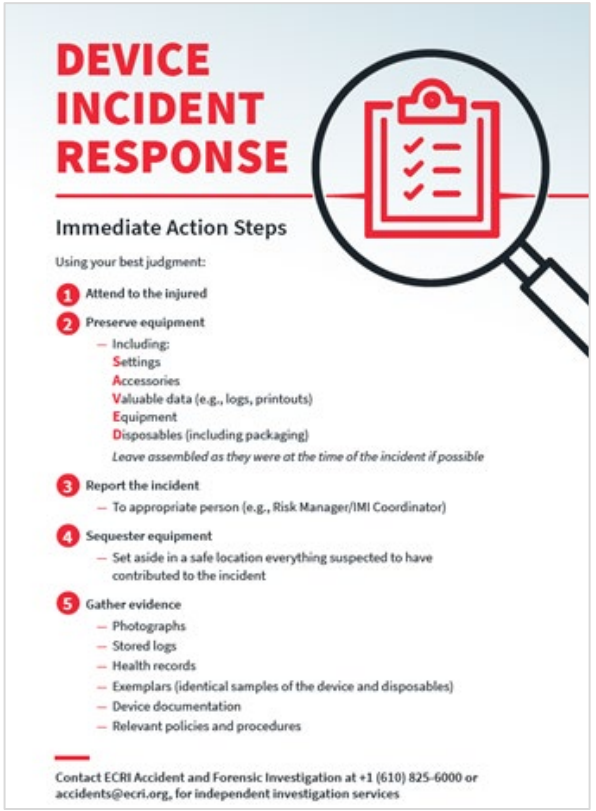
1. Attend to the injured
2. Preserve equipment/environment
3. Report the incident
4. **Sequester equipment**
   - **Prevents defective devices being used on other patients**
   - **Secures devices and data until they can be examined & tested**



Point #2 RESPONSE

Immediate Action Steps

1. Attend to the injured
2. Preserve equipment/environment
3. Report the incident
4. Sequester equipment
5. **Gather evidence**
    1. **Photos**
    2. **Stored Data**
    3. **Health Record**
    4. **Exemplars**
    5. **Device Documents**
    6. **Policies & Procedures**



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Point #2 RESPONSE → *Takes a TEAM*

National Transportation Safety Board (NTSB)

NTSB News Release

National Transportation Safety Board Office of Public Affairs

NTSB Launches Go-Team to Investigate Today's Amtrak Accident

1/31/2018

- Designated investigator in charge
- Designated media relations specialist
- Multi-disciplinary team consisting of human performance, highway factors, survival factors, vehicle factors, truck operations, train operations

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Point #2 RESPONSE → *TEAM Approach*

The IMI Committee (IMIC)

Safe Medical Center Internal Memo

To: Investigation Team

From: High Reliability and Patient Safety Office

Safe Medical Center Launches Go-Team to Investigate Today's Surgical Incident

- Designated investigator in charge
- Designated communications lead
- Multi-disciplinary team consisting of clinical leadership, anesthesiology, surgery, nursing, clinical engineering, IT, human factors, and patient safety/risk management

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Point #2 RESPONSE → ***The IMI Committee***

IT Legal Counsel Risk & Quality Independent Experts Clinical Engineering

Facilities Insurance Clinical Staff Hospital Executives

Investigation Coordinator

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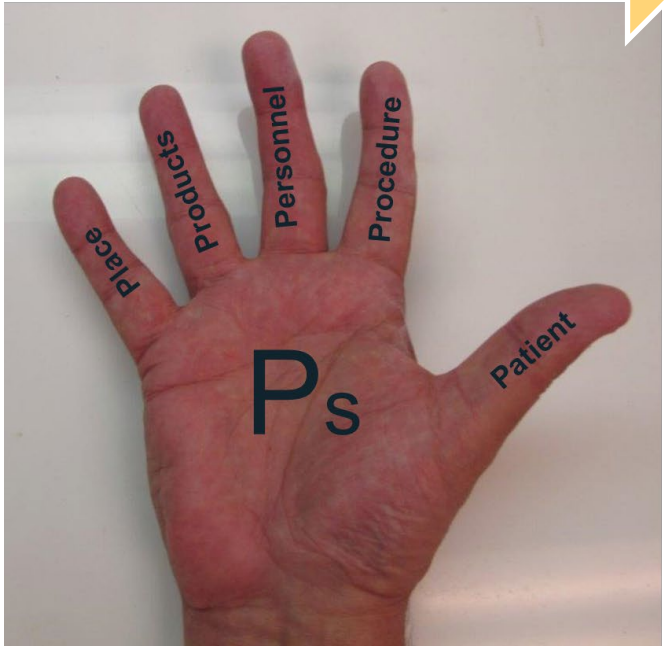
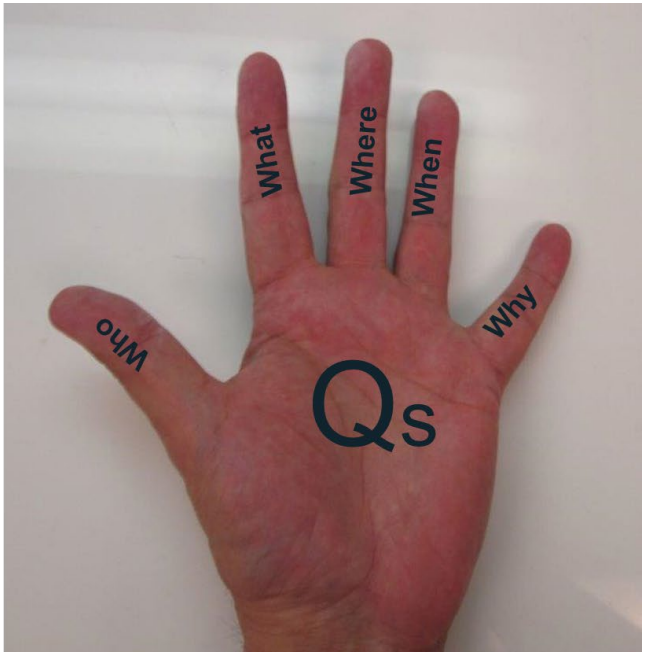
Point #3 FACTS

Begins in parallel with Steps 1 & 2





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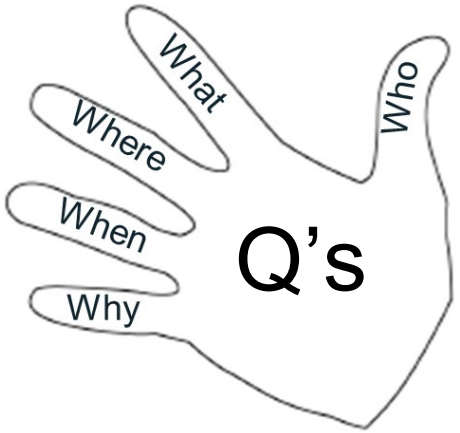
Point #3 FACTS

Clear Incident Description



- **WHO** was involved?
- **WHAT** happened?
- **WHERE** did the incident occur?
- **WHEN** did it happen (be specific)?
- **WHY** did it happen?

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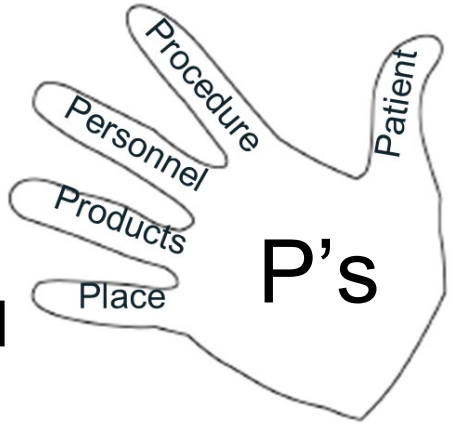
Point #3 FACTS



Gather information related to:

- **PLACE** where incident occurred
- **PRODUCTS** in use
- **PERSONNEL** involved
- **PROCEDURE** being performed
- **PATIENT**

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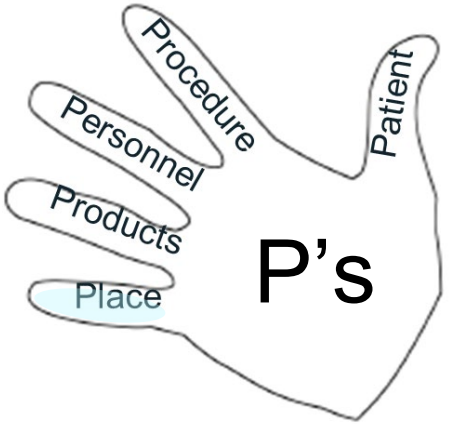
Point #3 FACTS



PLACE where incident occurred

- Consider physical and structural aspects
  - ✓ Electrical power
  - ✓ Medical gas
  - ✓ Lighting
  - ✓ Noise
  - ✓ Recent changes?
- Obtain security video (if available)

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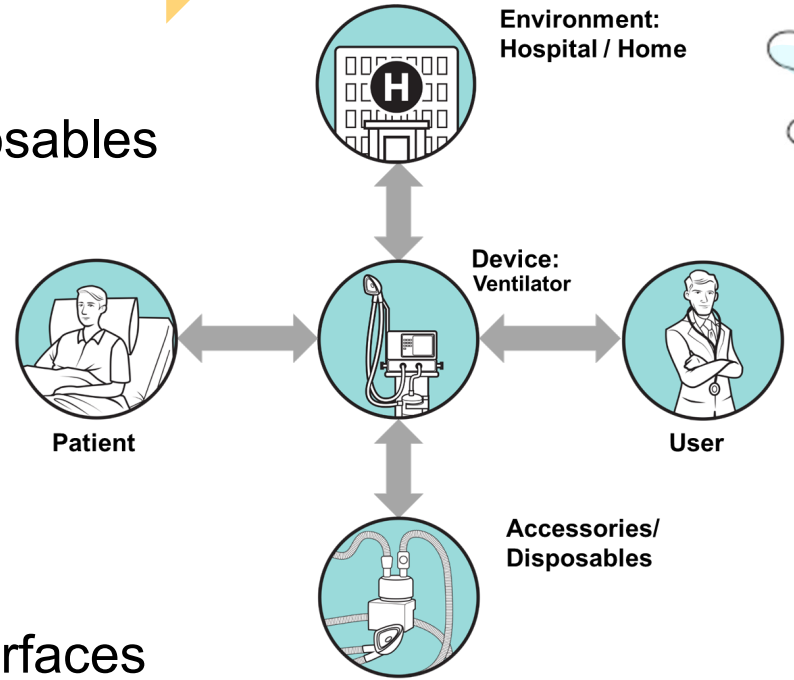
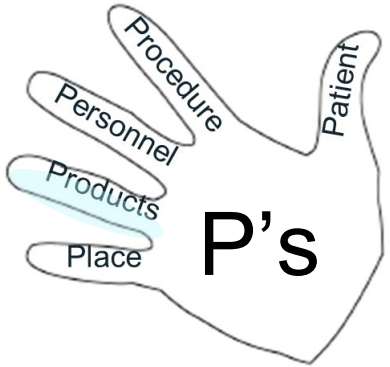
Point #3 FACTS

PRODUCTS in use

- Accessories & Disposables
- Instrument Settings
- Device Ownership
- Maintenance
  - ✓ IPM records
  - ✓ Service records
- Recalls/Alerts
- Consider device Interfaces





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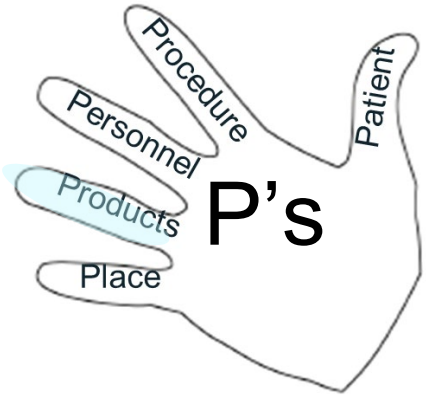
Point #3 FACTS



PRODUCTS - Evaluation Methods

- Gross Inspection
- Microscopic Examination
- Data Recovery (Device Logs, any stored data)
- Verification of Proper Operation
- Incident Simulation
- Advanced Methods (SEM, FTIR, GC-MS, metallurgy)

Can perform some/all as Joint Inspection with device manufacturer

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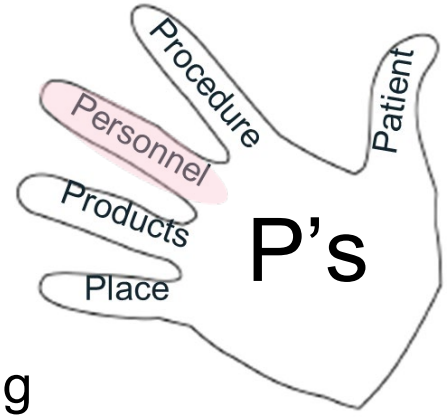
Point #3 FACTS



PERSONNEL involved

- Conduct interviews
- Consider staffing levels, credentialing, and training
- Were there any contract service personnel involved?
- Was a device manufacturer representatives present?

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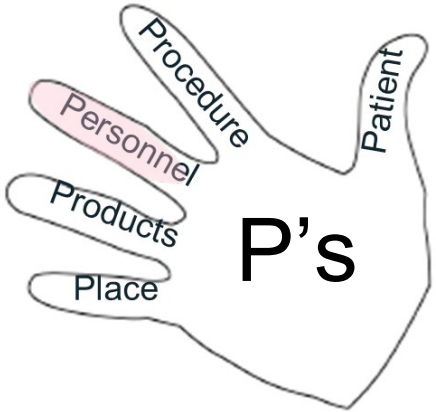
Point #3 FACTS



PATIENT

- Type of Injury
- How it was treated
- Consider their medical history
- Susceptibility to injury
- Result of post-mortem examination (if done)
- Attitude of the patient's family?

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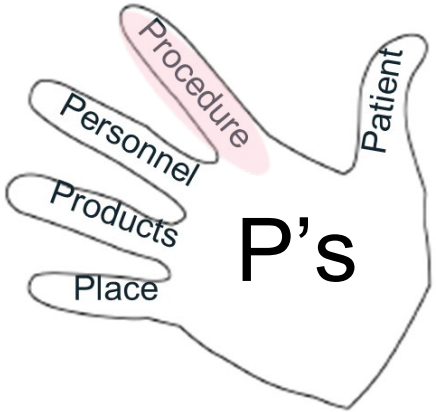
Point #3 FACTS



PROCEDURE being performed

- What was being done.
- Was it a “new” procedure?
- Consider policies and procedures.
- Were standards of practice followed?
- Understand the workflow
- Create Event Timeline

The IMI Plan

Point #3 FACTS

“Facts are investigative bedrock; assumptions and opinions are shifting sand.”

- Remain open-minded
- Avoid hasty conclusions
- Determine causes, don’t assign blame
- Standardize the process as much as possible

The IMI Plan

Point #4 ANALYSIS

Goal – Determine Causation

1. Analyze the Facts
2. Consider possible causes
3. Rule-out causes that are inconsistent with the facts
4. Rank cause(s) based on degree of certainty

Note: There is almost always more than 1 cause

The IMI Plan

Point #4 ANALYSIS

Common causes of healthcare incidents

- Device defects (Design, Manufacturing, Labeling)
- Device Malfunction
- Device modification by the user
- Installation and maintenance errors
- Improper storage
- Staff overload and fatigue
- Misuse
- Failure to properly train and credential

The IMI Plan

Point #4 ANALYSIS

Root Cause Analysis (RCA) is a process used to try to identify the basic or causal factors that underlie variation in performance.

Therefore, RCA can be considered part of the Analysis step of the broader IMI Plan in that it seeks to determine causation.

The IMI Plan

Point #5 CONCLUSIONS

What was the outcome of the investigation?

- Clearly describe what caused and contributed
- Used to:
  - ✓ Inform/revise the message
  - ✓ Inform actions and recommendations
  - ✓ Inform reporting both Internally and to outside agencies (FDA, TJC, DOH, CMS, ECRI)
- Forms the basis for legal expert opinion

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Point #6 RECOMMENDATIONS

Goal - Prevent Recurrence

- Clear and concise
- Considerate of workflow
- Consistent with best practices
- Collaborative
- Compliance verified

"A recommendation that cannot or will not be followed is not helpful"

The IMI Plan

Point #6 RECOMMENDATIONS

Compliance Verified

- Verify implementation
- Monitor effectiveness
- Follow-up to ensure compliance at determined intervals
- Update as needed

"If compliance is not achieved the recommendation has little value"

The IMI Plan

Point #7 LEGAL — *Claims*

Malpractice or negligence

Provider failed to:

- Meet a standard of practice
- Follow established policies or procedures

Product liability

Defective:

- Design
- Manufacture
- Labeling

Spoliation of Evidence

If devices are:

- Discarded
- Altered
- Stored data is lost

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Point #7 LEGAL → Consider for every point

Liability Assessment

- Should be done for all 5 P's
- Consider negligence or criminal acts
- Requires asking probing questions, but is essential to incident management
- Helps inform insurers
- Assists in legal defense preparation

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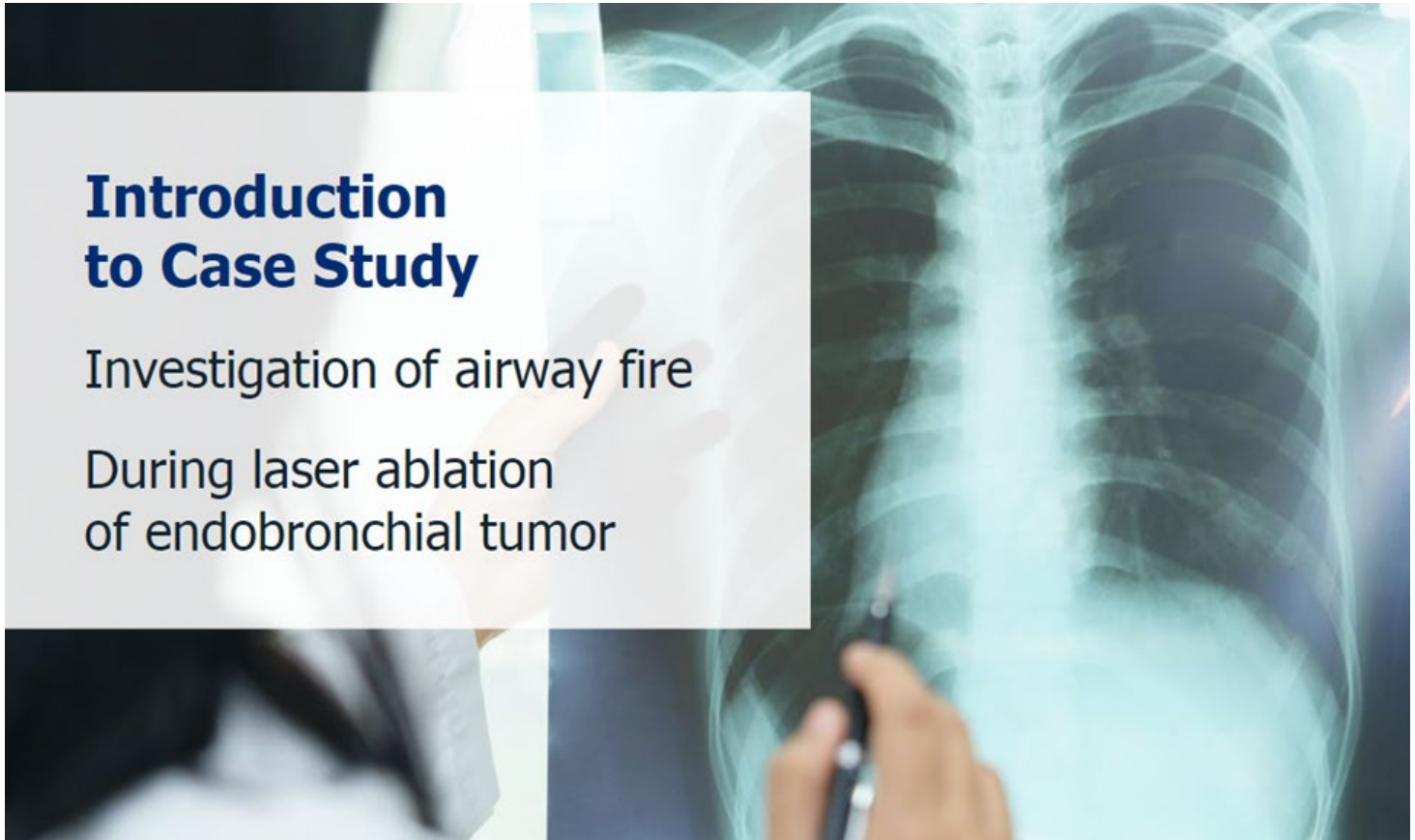
Point #7 LEGAL — *External Reporting*

- Federal reporting under SMDA
  - ✓Report deaths caused by medical technology to FDA
  - ✓Report serious injury to the manufacturer
- State requirements (vary)
- Accreditors (like Joint Commission)
- Voluntary reporting (ECRI's Problem Reporting Network))
- Patient Safety Organizations (ECRI PSO)
  - ✓PSWP is not discoverable

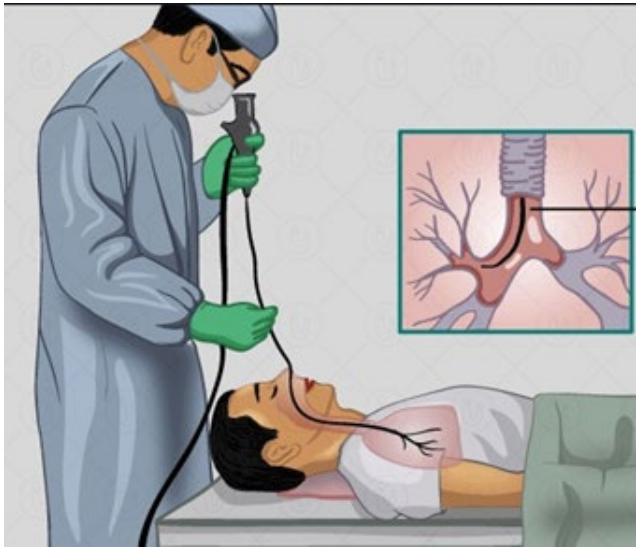
Investigation – Airway Fire



Investigation – Airway Fire

Incident Circumstances

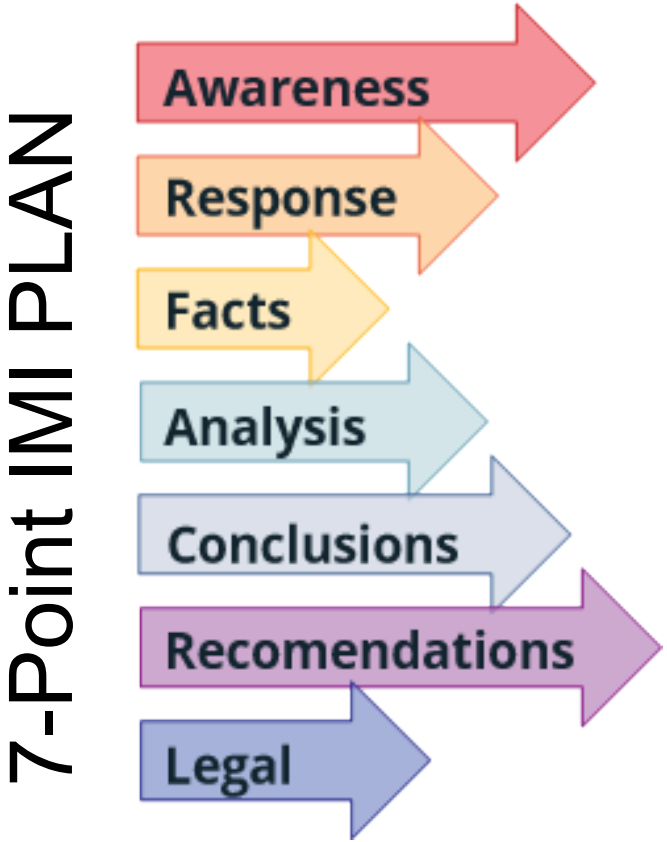
- ET tube placed
- 100% O_2 administered
- Bronchoscope inserted
- Visualized the tumor
- Laser fiber inserted
- Ablation performed



Investigation – Airway Fire

Incident Circumstances

Investigation - Airway Fire



Investigation - Airway Fire

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Point #1 AWARENESS

Concurrent

Immediately Aware

INTERNAL

- Clinical Staff notices:
  - Unexpected complication
  - Injury
  - Death
  - “Near miss” or “Close call”

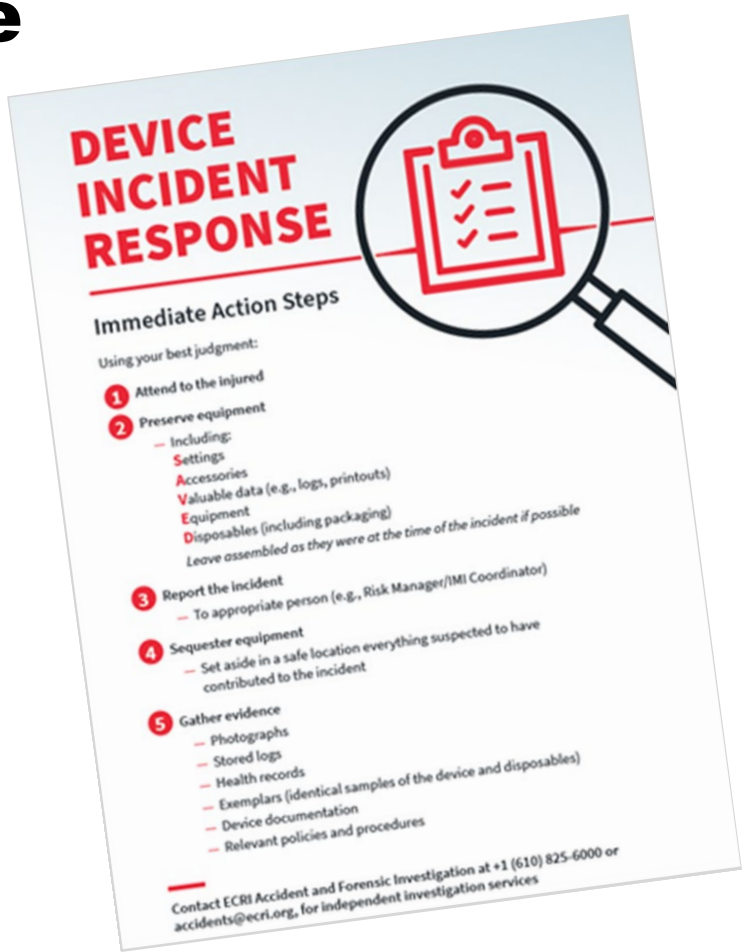
Investigation – Airway Fire

Point #2 RESPONSE

IMMEDIATE RESPONSE

1. Attended the injured
   - Withdrew scope/ET tube
   - Irrigated airway with saline.
   - Ventilated & re-intubated.
   - Examined airway
   - Re-administered O_2

Patient suffered throat & lung damage



Investigation – Airway Fire

Point #2 RESPONSE

IMMEDIATE RESPONSE

2. Preserved Equipment
   - Devices
     - — Anesthesia machine, bronchoscope, laser
   - Accessories & Disposables
     - — ET tube & laser fiber
   - Saved Logs & records
3. Reported the incident

Investigation – Airway Fire

Point #2 RESPONSE

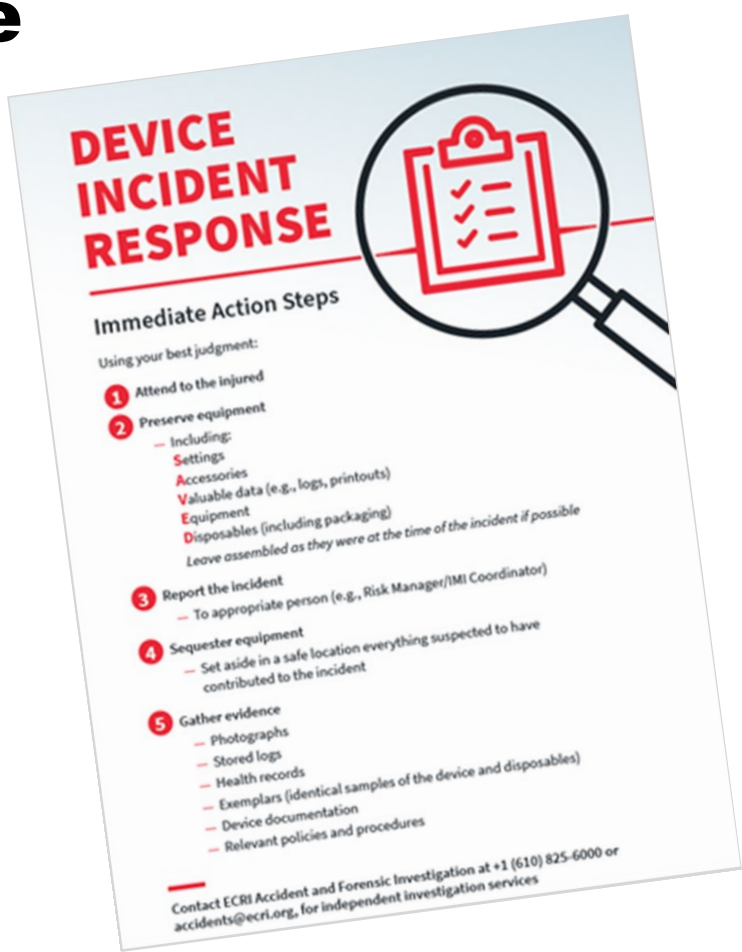
IMMEDIATE RESPONSE

4 Sequestered equipment

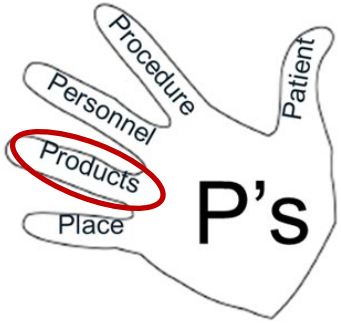
5 Gathered evidence

- Took Photographs
- Downloaded info from EHR
- Called ECRI

Overall Good Response

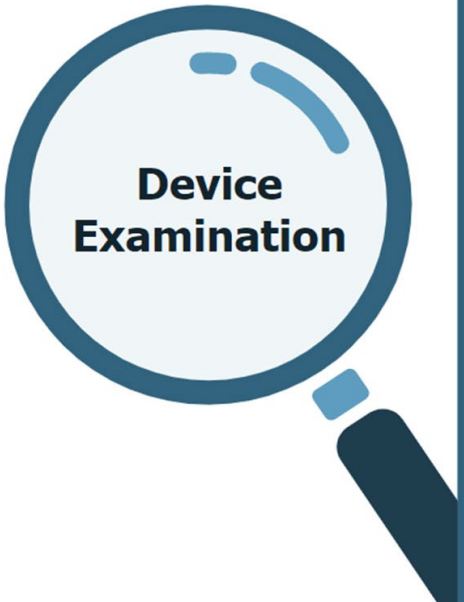


Investigation – Airway Fire



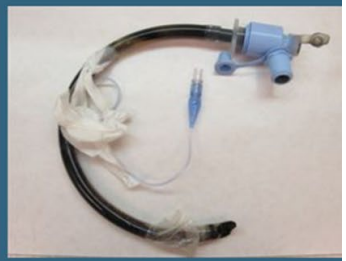
Point #3 FACTS

Products



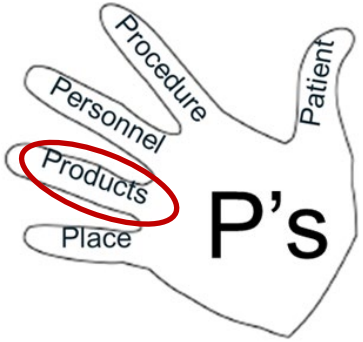
Distal tips of ET tube and bronchoscope showed severe thermal damage

ET tube had soot throughout the entire lumen



Coating near the end of the laser fiber had been burned away

Investigation – Airway Fire



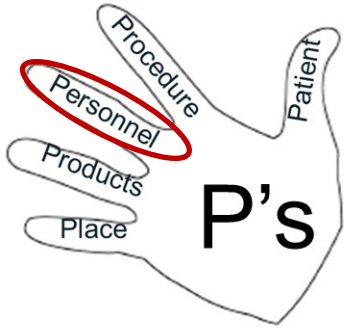
Point #3 FACTS

Products

Anesthesia machine and laser worked properly

Device logs did not show malfunction, or alarms during procedure

Investigation – Airway Fire



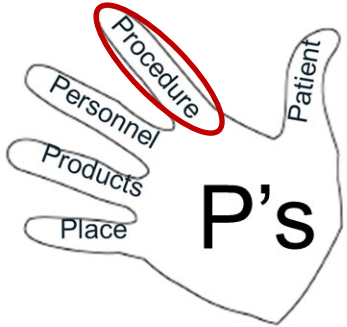
Point #3 FACTS

Personnel - Conducted Interviews

- **Surgical staff** – thought laser in standby at the time
- **Anesthesiologist** - reduced the O_2 concentration to <30% during ablation
- **Physician** - indicated when ablation was complete
- **Surgical team** - heard a loud pop before they saw smoke.

O_2 Concentration >30%
increase fire risk when energy source is activated

Investigation – Airway Fire



Point #3 FACTS

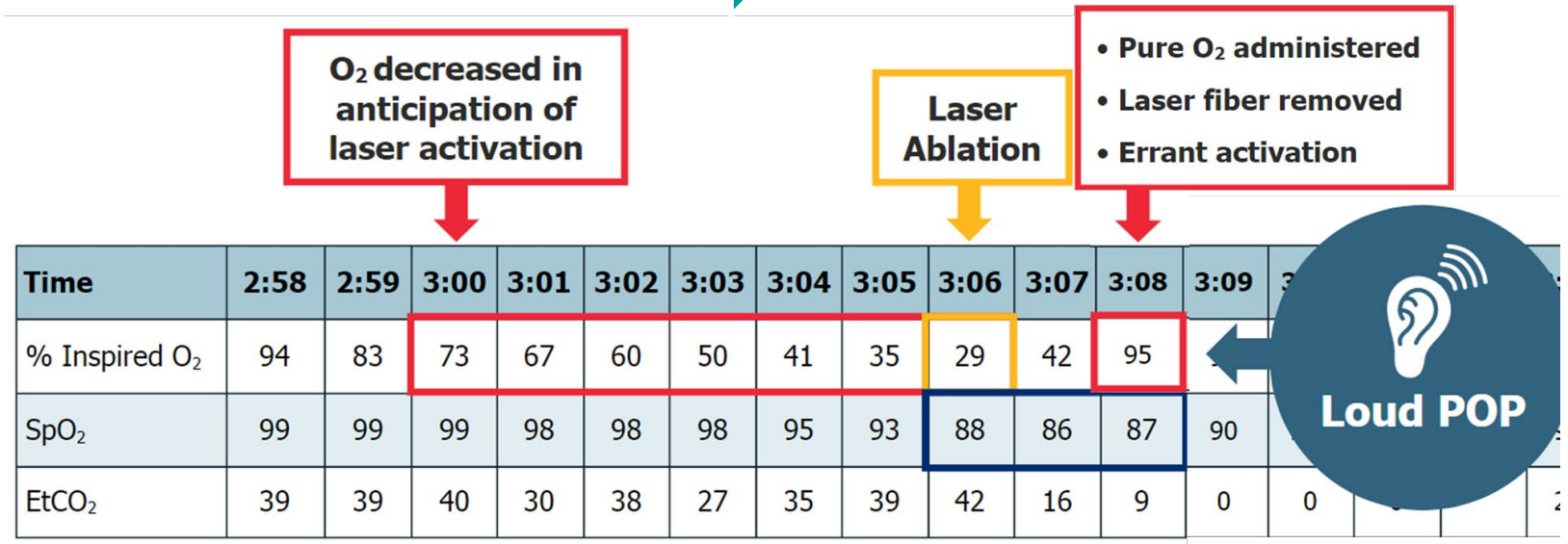
Procedure

- Reviewed intraoperative report
- Hospital policies and procedures surrounding laser use and safety.
- The anesthesia record

Investigation – Airway Fire

Point #4 ANALYSIS

Timeline of Events

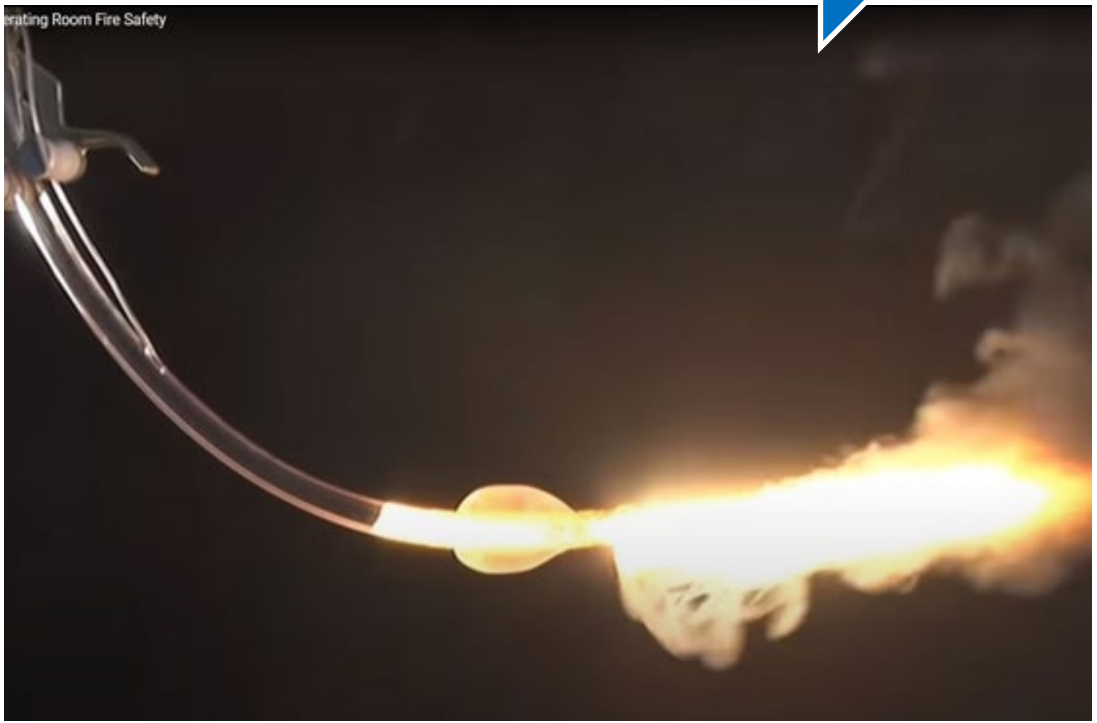


Time	2:58	2:59	3:00	3:01	3:02	3:03	3:04	3:05	3:06	3:07	3:08	3:09	3
% Inspired O_2	94	83	73	67	60	50	41	35	29	42	95		
SpO_2	99	99	99	98	98	98	95	93	88	86	87	90	
$EtCO_2$	39	39	40	30	38	27	35	39	42	16	9	0	0

Analyzed the anesthesia record

Investigation – Airway Fire

Point #5 CONCLUSIONS



No device malfunction

Error in communication and responsibilities

- Laser not immediately placed in standby
- O_2 was increased resulting in O2 enrichment
- Laser was accidentally fired during removal

Resulted in fire that burned the patient

Investigation – Airway Fire

Point #6 RECOMMENDATIONS

Update and Monitor
Surgical Fire Pre-Operative Time-out

Specifically:

- Ensure laser is placed on standby when ablation (or other energy activation) is complete
- Confirm <30% O_2 concentration before each laser firing
- Fully withdraw laser fiber before announcing ablation is complete
- Confirm ignition source is removed from patient and placed in standby before increasing O_2 concentration (if needed).

Investigation – Airway Fire

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Point #7 LEGAL

- Ruled out device malfunction
- Helped hospital reconcile with the patient

Incident Management & Investigation

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What We Learned

- The importance of incident investigation
- The 7-point IMI Plan
- How to apply the plan

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We value your feedback!

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Thank You!

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