CLEARWATER COMPLIANCE

Clean the house: Cyber-hygiene to safeguard patient information and ensure patient safety

October 31, 2017

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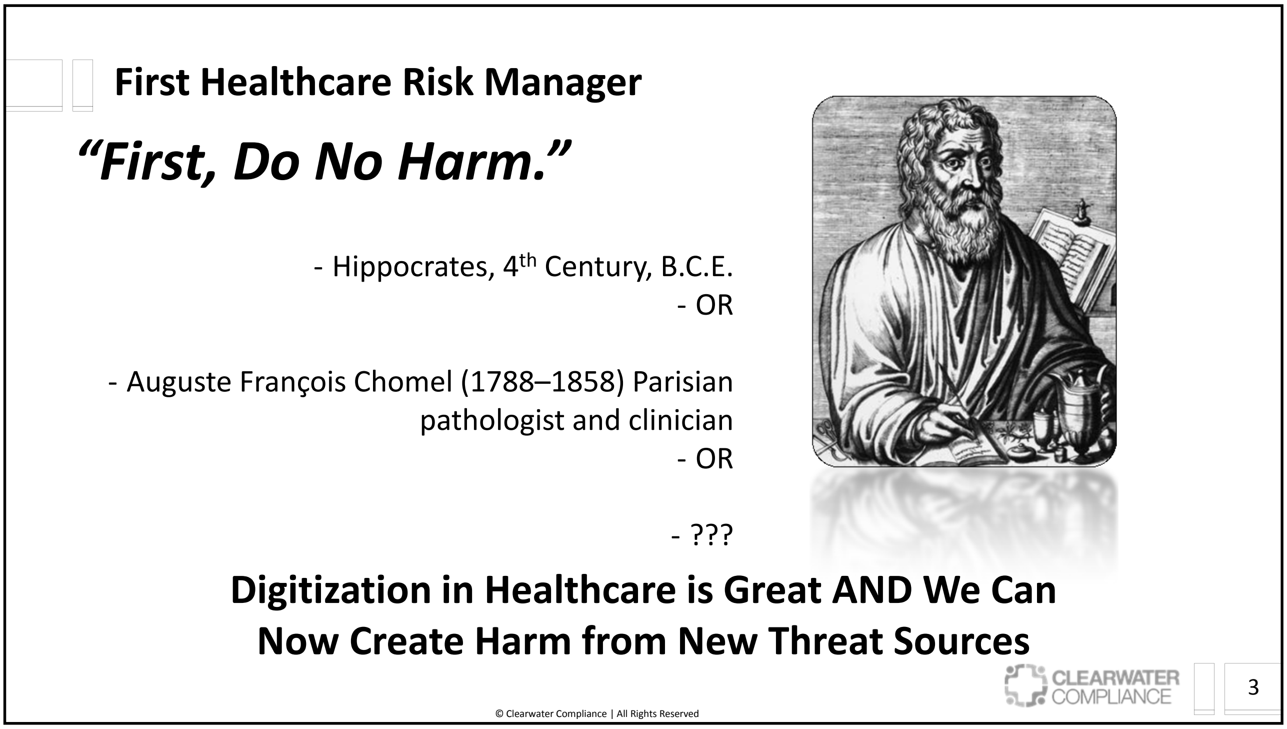
Discussion Flow

1. Connecting the Dots
2. Beyond Traditional IT Assets
3. Bona Fide Risk Analysis and Risk Management



First Healthcare Risk Manager

"First, Do No Harm."

- Hippocrates, 4th Century, B.C.E.
- OR

- Auguste François Chomel (1788–1858) Parisian pathologist and clinician
- OR

- ???

Digitization in Healthcare is Great AND We Can Now Create Harm from New Threat Sources

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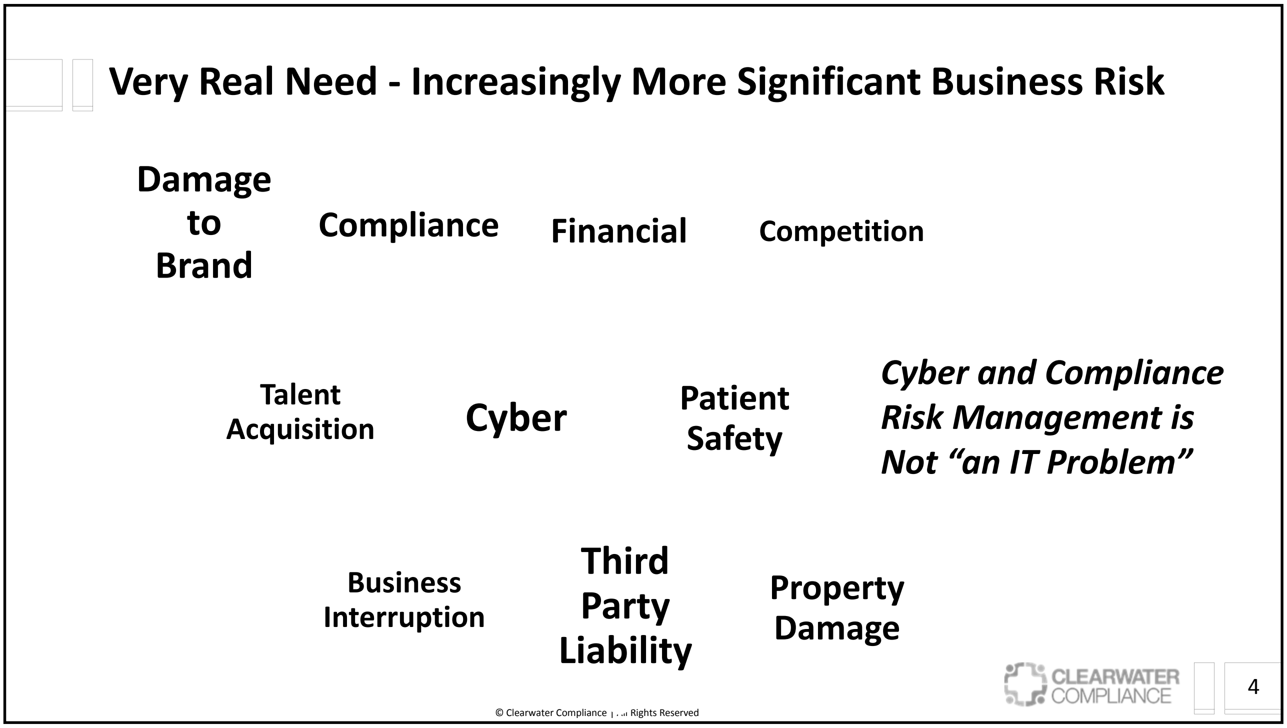

Very Real Need - Increasingly More Significant Business Risk

Damage to Brand

Compliance

Financial

Competition

Talent Acquisition

Cyber

Patient Safety

Cyber and Compliance Risk Management is Not "an IT Problem"

Business Interruption

Third Party Liability

Property Damage

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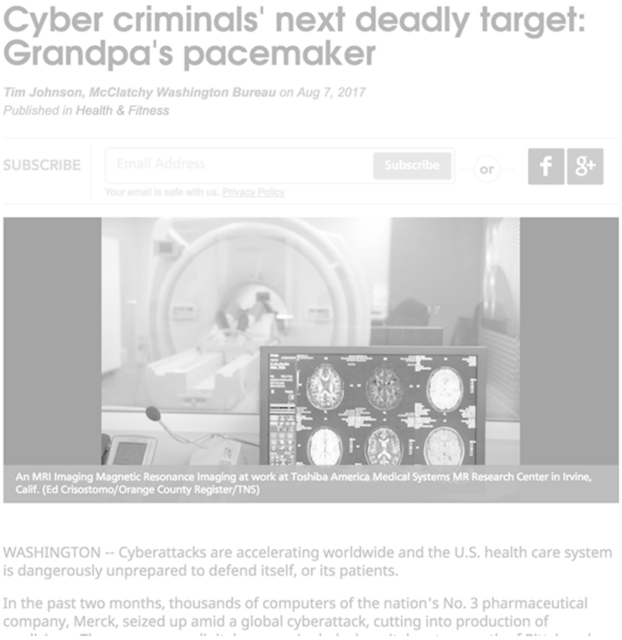

Cyber criminals' next deadly target: Grandpa's pacemaker

Tim Johnson, McClatchy Washington Bureau on Aug 7, 2017
Published in Health & Fitness

An MRI Imaging Magnetic Resonance Imaging at work at Toshiba America Medical Systems MR Research Center in Irvine, Calif. (Ed Crisostomo/Orange County Register/TNS)

WASHINGTON -- Cyberattacks are accelerating worldwide and the U.S. health care system is dangerously unprepared to defend itself, or its patients.

In the past two months, thousands of computers of the nation's No. 3 pharmaceutical company, Merck, seized up amid a global cyberattack, cutting into production of

"We're going to have our digital D-Day, our cyber D-Day, if you will, in medical, and there's going to be patients that die. It's going to be a big deal," said Dr. Christian Dameff, an emergency room physician and expert on cyber vulnerabilities.

https://www.arcamax.com/healthandspirit/health/healthtips/s-1985471?fs

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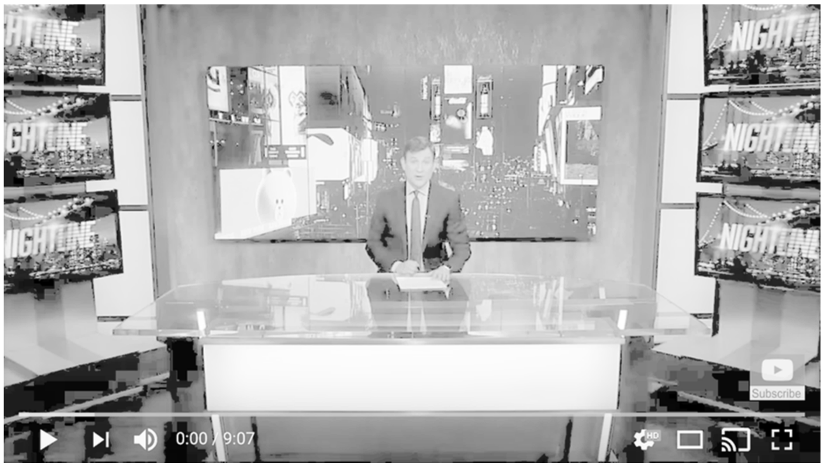
Fears of hackers targeting hospitals, medical devices | ABC News | June 29, 2017



https://www.youtube.com/watch?v=pU3NQ3GkC_0

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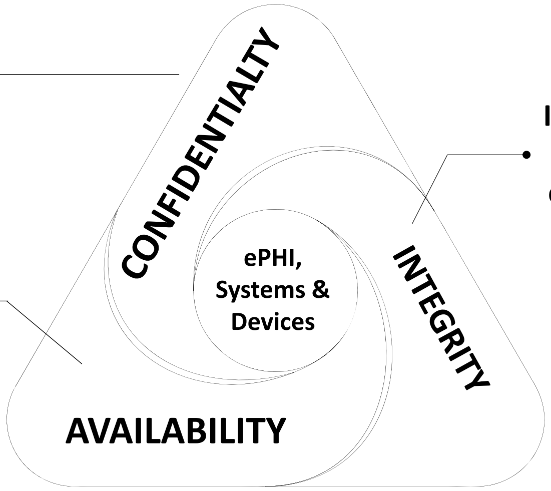
The Risk Problem We're All Trying to Solve



What if my Sensitive Information is shared?

What if my Sensitive Information, Systems, or Devices are not complete, up-to-date and accurate?

What if my Sensitive Information, Systems, or Devices are not there when it is needed?

Don't Compromise CIA!

Don't Forget: **PII, PCI Data, MNPI, Trade Secrets, Business Plans, Software Code, Etc.**

Discussion Flow

1. Connecting the Dots
2. Beyond Traditional IT Assets
3. Bona Fide Risk Analysis and Risk Management

Must Include Every Information Asset in Every Location/LOB

Clinics
Hospitals
LTC Facility
ASC
CHC

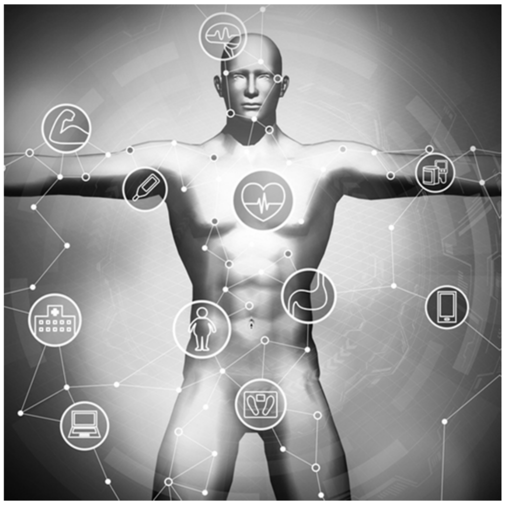
Hospice
Insurance
Home Health
EMS
Rehab Clinic

Imaging Center
Rural Clinic
Dialysis Clinic
Behavioral
Research

Traditional Assets – IT Systems and Applications

- Electronic Health Record Applications
- Clinical Information Applications
- Lab And / Or Medical Specialty Applications
- Medical Billing/Claims Processing Applications
- Email Applications
- Company Intranet Websites
- HR Management Applications
- Network File Sharing Applications
- EDI Applications
- Fax Applications
- Payment Processing Applications
- Financial Management/Reporting Applications
- Any Other Software Used To Manage Sensitive Electronic Information

Biomedical Assets – Pumps, PACS, etc.

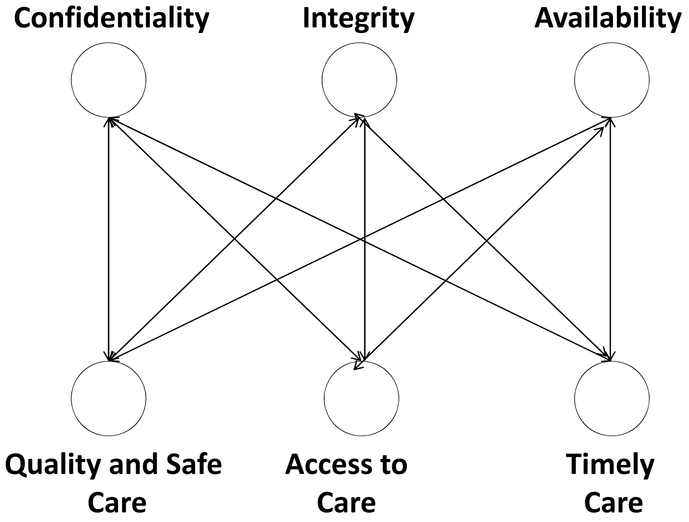


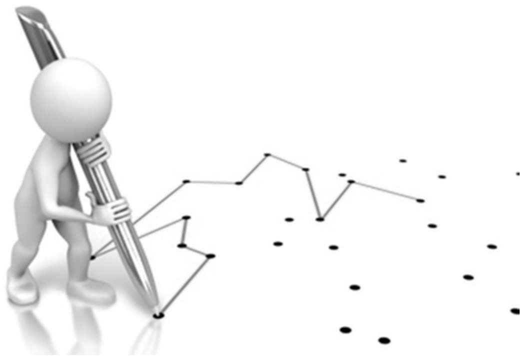
- Patient monitoring devices, monitors and smart rooms
  - Smart medical devices, infusion pumps, ventilators, incubators, telemetry, smart stethoscopes and medical imaging
  - Electrocardiogram (ECG), heart rate, pulse oximetry, ventilators, capnography monitors, depth of consciousness monitors, regional oximetry, biopatch technology and respiratory rate
  - Smart beds, hand hygiene and fall detection
  - Remote ICU telemetry, Tele-ology (any medical science done remotely — for example, tele-neurology or tele-dermatology)
- Remote wellness and chronic disease management
  - Pacemakers, defibrillators and neuro-stimulators
  - Wearable wristbands, bio-patches, smartwatches and ear buds
  - Remote clinical monitor spirometer, pulse oximeter, ECG, glucometer and fall detection

IoT Assets – Facilities, Infrastructure, etc.

- Facilities Security, Building Management
  - Video surveillance, door locks and entry systems, and fire alarms
  - Power monitoring, power distribution, energy consumption and management, and elevators
  - HVAC, lighting, room control, water quality, humidity monitoring, and tissue and blood refrigerators
- Real-time location services (RTLS) for Assets, Employees, Patients and Visitors
  - Wheelchairs, infusion pumps, smart cabinets, medication carts, par-level management and rental management
  - Physicians, nursing staff and ancillary staff
  - Infant abduction and wandering systems
  - Wayfinding and digital signage
- Networking Hardware, Software, Security, Services
  - Routers, Switches, LAN cards, Wireless routers
  - Operating systems, Network Security and Services

Don’t Compromise CIA of any Traditional, Biomedical, IoT Assets





Patient Information AND Patient Health

Medical Device Security: An Industry Under Attack and Unprepared to Defend

- 67% of medical device manufacturers believe one of their devices will be attacked in the next 12 months
- Two-thirds of healthcare organizations are unaware of adverse effects to patients due to an insecure medical device
- Only 17% of medical device makers are taking significant steps to prevent attacks

Ponemon INSTITUTE

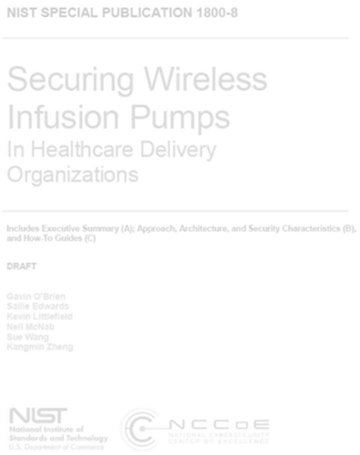
Medical Device Security: An Industry Under Attack and Unprepared to Defend

Sponsored by Synopsys
Independently conducted by Ponemon Institute LLC
Publication Date: May 2017

Ponemon Institute© Research Report

https://www.synopsys.com/software-integrity/resources/analyst-reports/medical-device-security-report.html

Include Biomedical Devices in Risk Analyses



NIST SPECIAL PUBLICATION 1800-8

Securing Wireless Infusion Pumps
In Healthcare Delivery Organizations

Includes Executive Summary (A); Approach, Architecture, and Security Characteristics (B), and How-To Guides (C)

DRAFT

Gavin O'Brien
Sallie Edwards
Kevin Littlefield
Neil McNab
Sue Wang
Kangmin Zheng

NIST National Institute of Standards and Technology U.S. Department of Commerce

NCCoE NATIONAL CYBERSECURITY CENTER OF EXCELLENCE

- NIST is increasing activity and work products
- First Practice Guide published May 2017
- Government and industry collaboration
- NIST-based risk assessment performed

B|BRAUN Baxter BD cisco CLEARWATER COMPLIANCE digicert Hospira intercede MDISS PFP RAMPARTS smiths medical Symantec TD

https://nccoe.nist.gov/sites/default/files/library/sp1800/hit-infusion-pump-nist-sp1800-8-draft.pdf

Discussion Flow

1. Connecting the Dots
2. Beyond Traditional IT Assets
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NIST Risk Management Process[1]

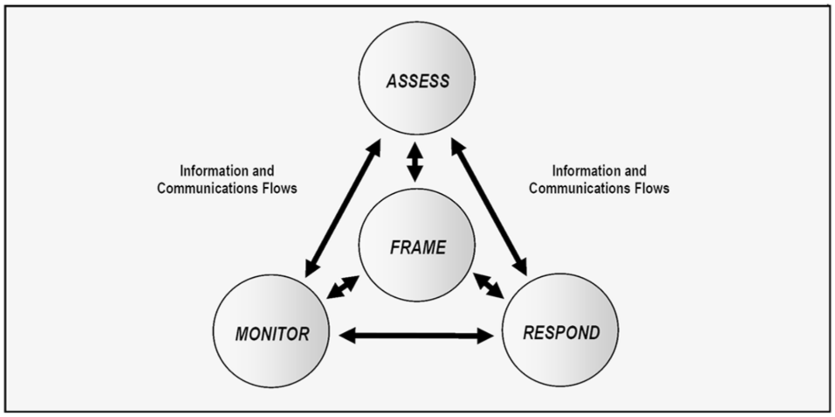
ASSESS
Information and Communications Flows
Information and Communications Flows
FRAME
MONITOR
RESPOND

FIGURE 1: RISK MANAGEMENT PROCESS

[1] http://clearwatercompliance.com/wp-content/uploads/SP800-39-final.pdf

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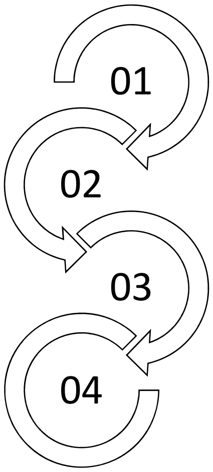
NIST Risk <u>Assessment</u> Process



Finalize Information Asset Inventory

Identify Threats & Vulnerabilities

Determine Likelihood & Impact

Determine Risk Level

What Are All the Possible Ways in Which We May Compromise Sensitive Information?

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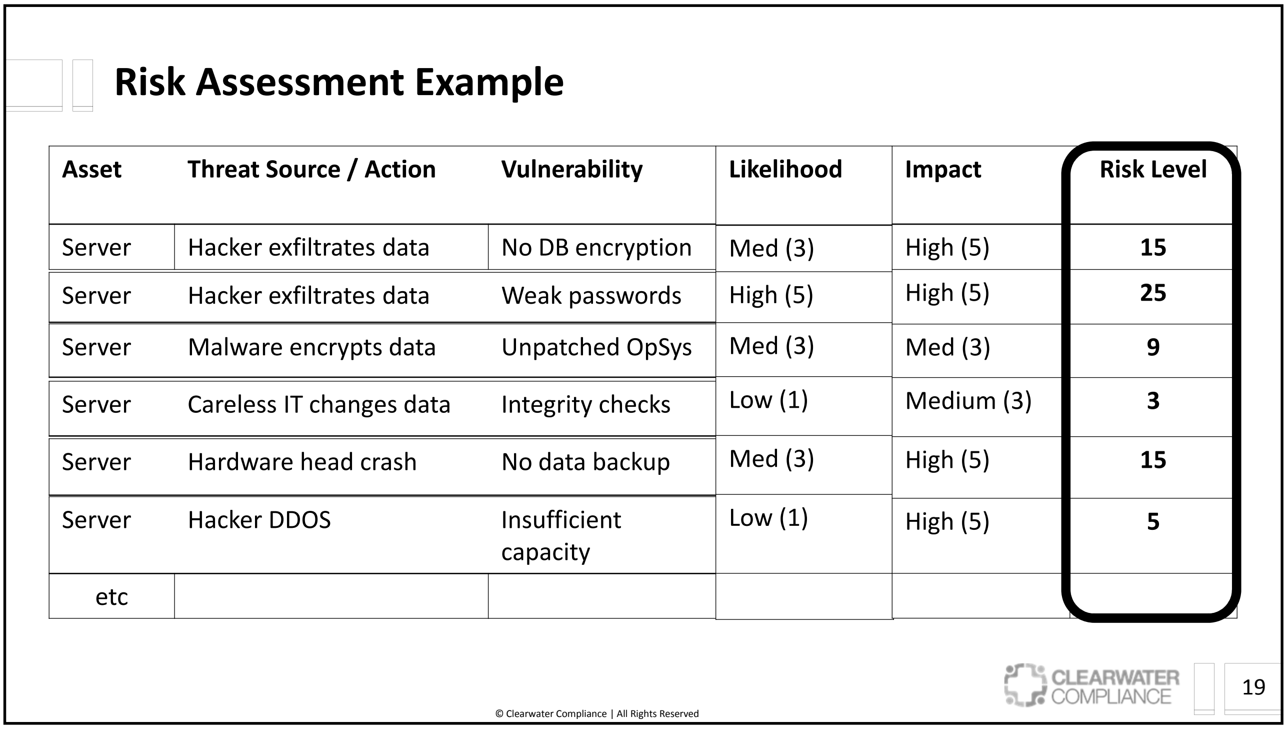

Risk Assessment Example

Asset	Threat Source / Action	Vulnerability	Likelihood	Impact	Risk Level
Server	Hacker exfiltrates data	No DB encryption	Med (3)	High (5)	**15**
Server	Hacker exfiltrates data	Weak passwords	High (5)	High (5)	**25**
Server	Malware encrypts data	Unpatched OpSys	Med (3)	Med (3)	**9**
Server	Careless IT changes data	Integrity checks	Low (1)	Medium (3)	**3**
Server	Hardware head crash	No data backup	Med (3)	High (5)	**15**
Server	Hacker DDOS	Insufficient capacity	Low (1)	High (5)	**5**
etc					

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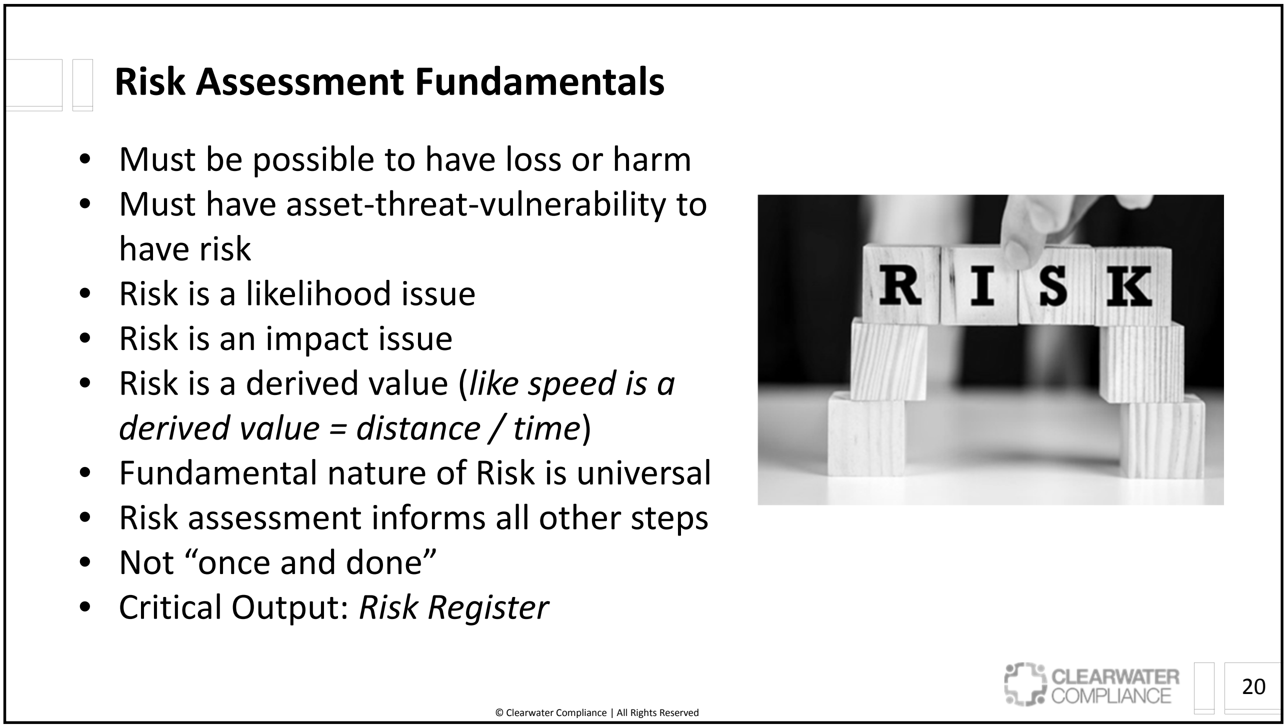

Risk Assessment Fundamentals

- Must be possible to have loss or harm
- Must have asset-threat-vulnerability to have risk
- Risk is a likelihood issue
- Risk is an impact issue
- Risk is a derived value (*like speed is a derived value = distance / time*)
- Fundamental nature of Risk is universal
- Risk assessment informs all other steps
- Not “once and done”
- Critical Output: *Risk Register*

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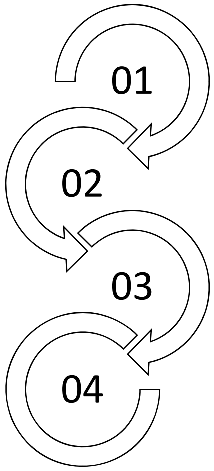
NIST Risk Response Process



Identify Risk Responses

Evaluate Alternatives

Make Risk Response Decision

Implement Risk Response

What decisions do we need we need to make to treat or manage risks?

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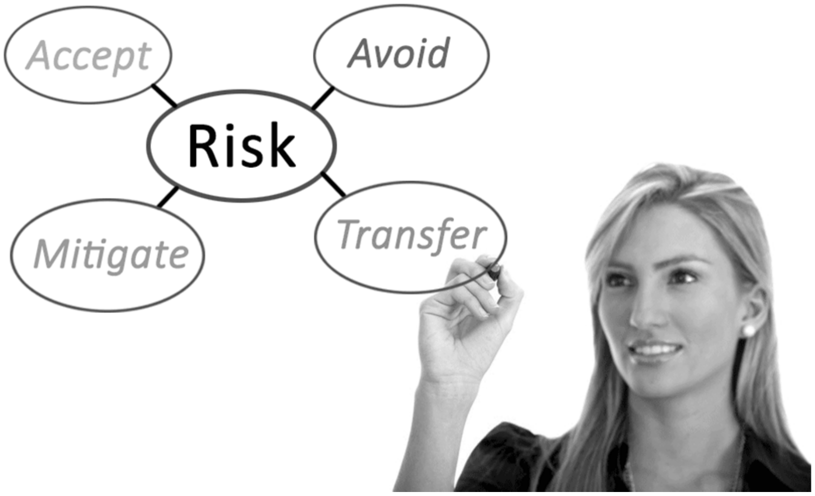
Decide on Response or Treatment



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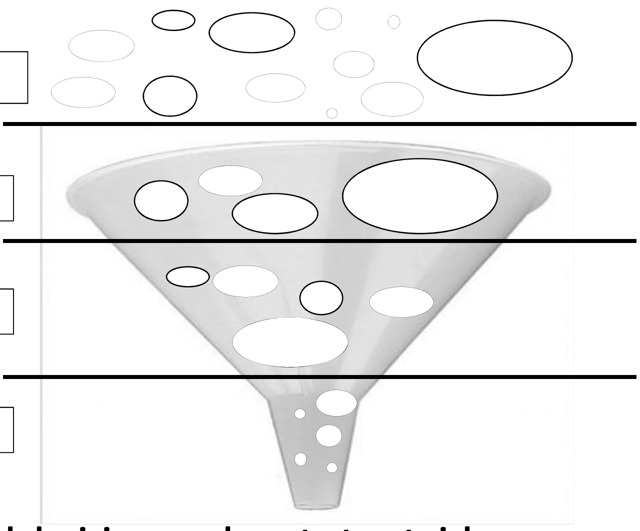
Thinking Like a Risk Manager

Risks of all types & sizes exist



Risk Assessment ➔

Risk Response

Avoid / Transfer Risks

Mitigate / Transfer Risks

Accept Risks

Risk Response is making informed decisions on how to treat risks.

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Risk Response Fundamentals

- *Real* Risk Response Requires *Real* Risk Analysis
- All Risks Need a Response
- Not All Risks Must Be Mitigated
- Risk Response Requires Setting Your Risk Appetite
- Risk Response Requires Real Risk Framing
- Risk Management is Informed Decision Making – What's New?
- Risk Response Informs All Other Steps
- Critical Output: *Risk Management Plan*

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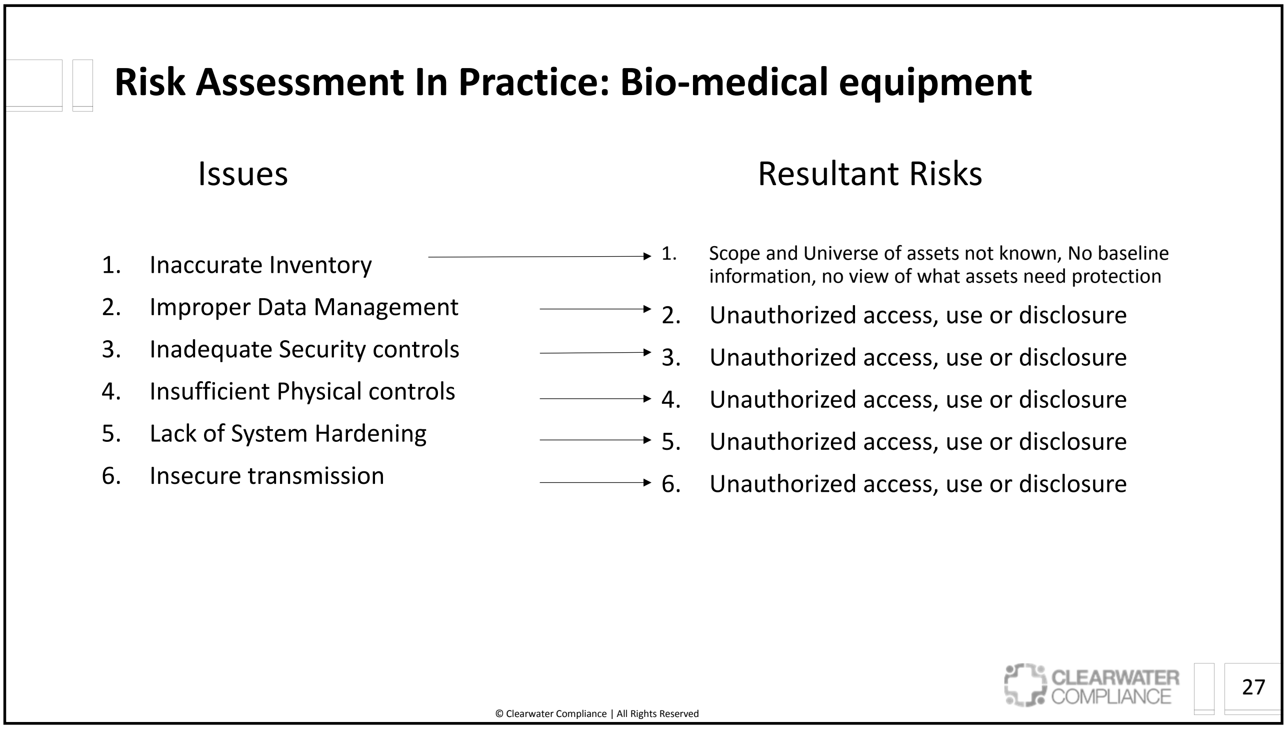
Key Elements of Risk Action Plan

- Control Gap
- Recommendation
- What is Affected? (assets, ePHI, etc.)
- Responsibility for Implementation
- Priority
- Due Date
- Actual Completion Date
- Current Status
- Documentation

Risk Assessment In Practice: Bio-medical equipment

- Scenario: A mid-size hospital system with one ambulatory care unit and a small long-term care unit wants to start an audit of their bio-medical devices. Such an audit has never been performed before.

Challenge: Where to begin? How do I assess risk?



Risk Assessment In Practice: Bio-medical equipment

Issues		Resultant Risks	
1.	Inaccurate Inventory	1.	Scope and Universe of assets not known, No baseline information, no view of what assets need protection
2.	Improper Data Management	2.	Unauthorized access, use or disclosure
3.	Inadequate Security controls	3.	Unauthorized access, use or disclosure
4.	Insufficient Physical controls	4.	Unauthorized access, use or disclosure
5.	Lack of System Hardening	5.	Unauthorized access, use or disclosure
6.	Insecure transmission	6.	Unauthorized access, use or disclosure

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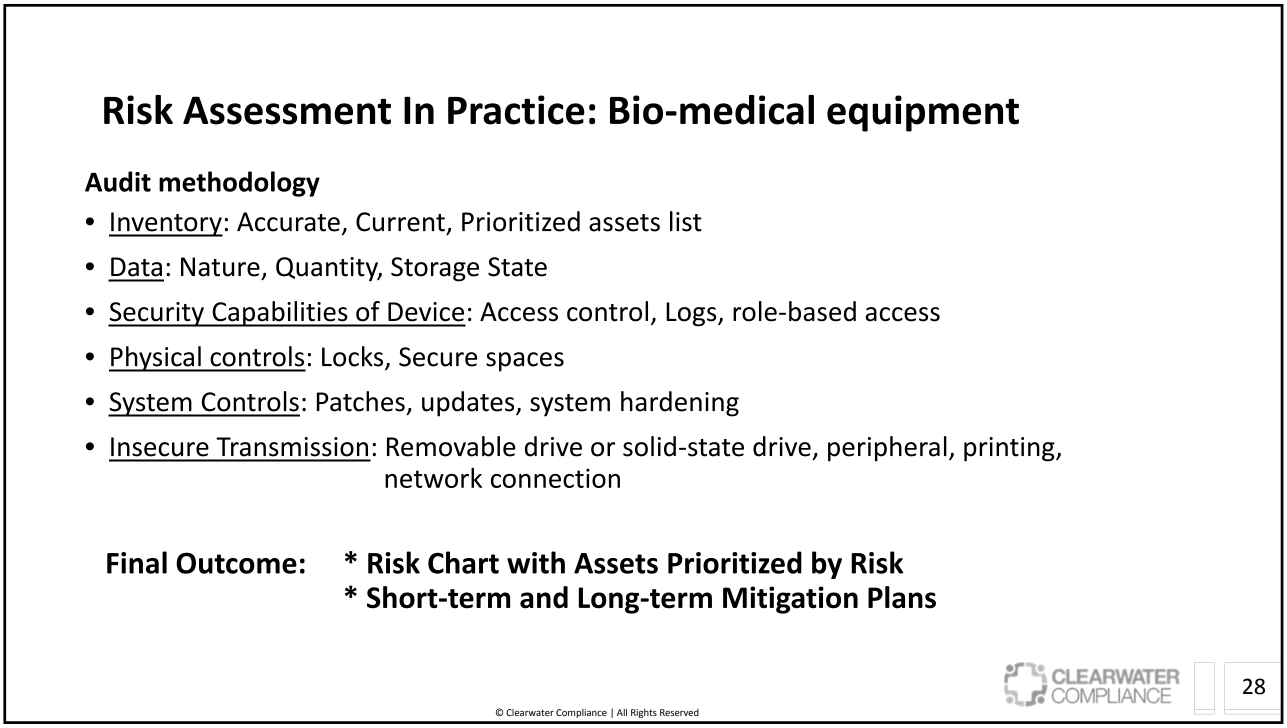

Risk Assessment In Practice: Bio-medical equipment

Audit methodology

- Inventory: Accurate, Current, Prioritized assets list
- Data: Nature, Quantity, Storage State
- Security Capabilities of Device: Access control, Logs, role-based access
- Physical controls: Locks, Secure spaces
- System Controls: Patches, updates, system hardening
- Insecure Transmission: Removable drive or solid-state drive, peripheral, printing, network connection

Final Outcome: * Risk Chart with Assets Prioritized by Risk
*** Short-term and Long-term Mitigation Plans**

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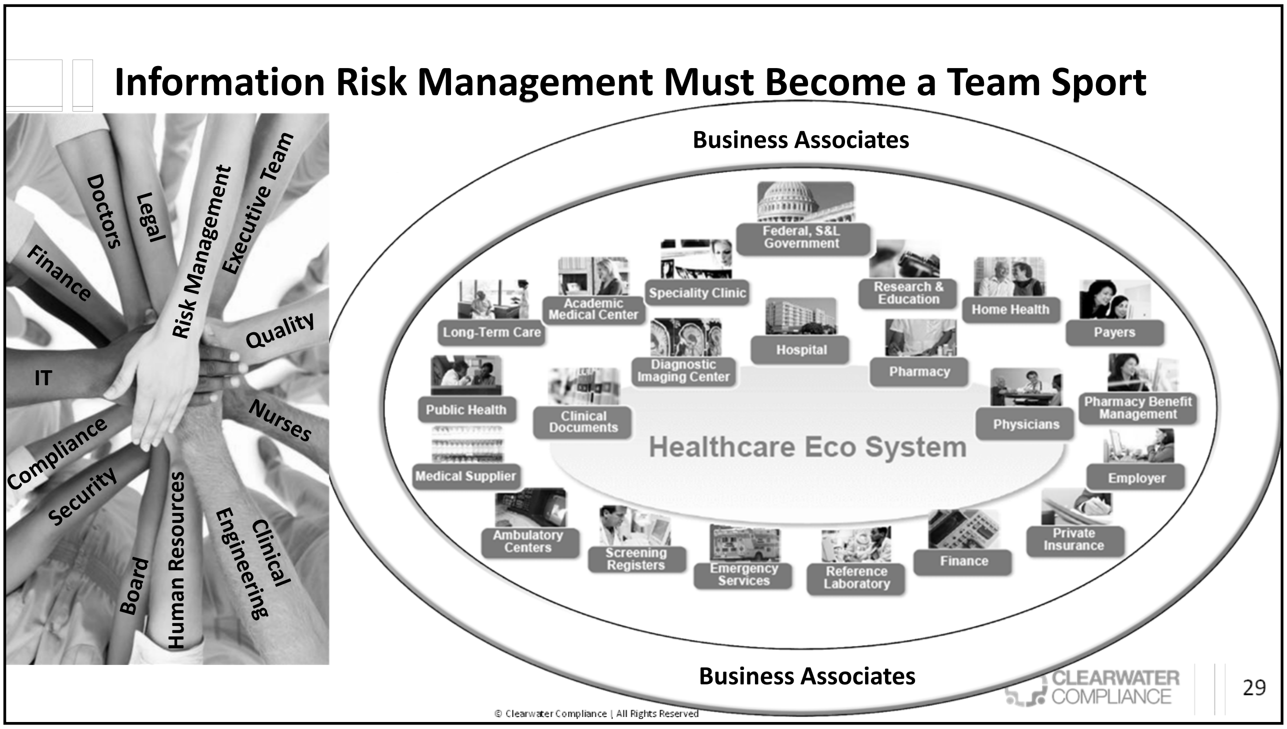

Information Risk Management Must Become a Team Sport

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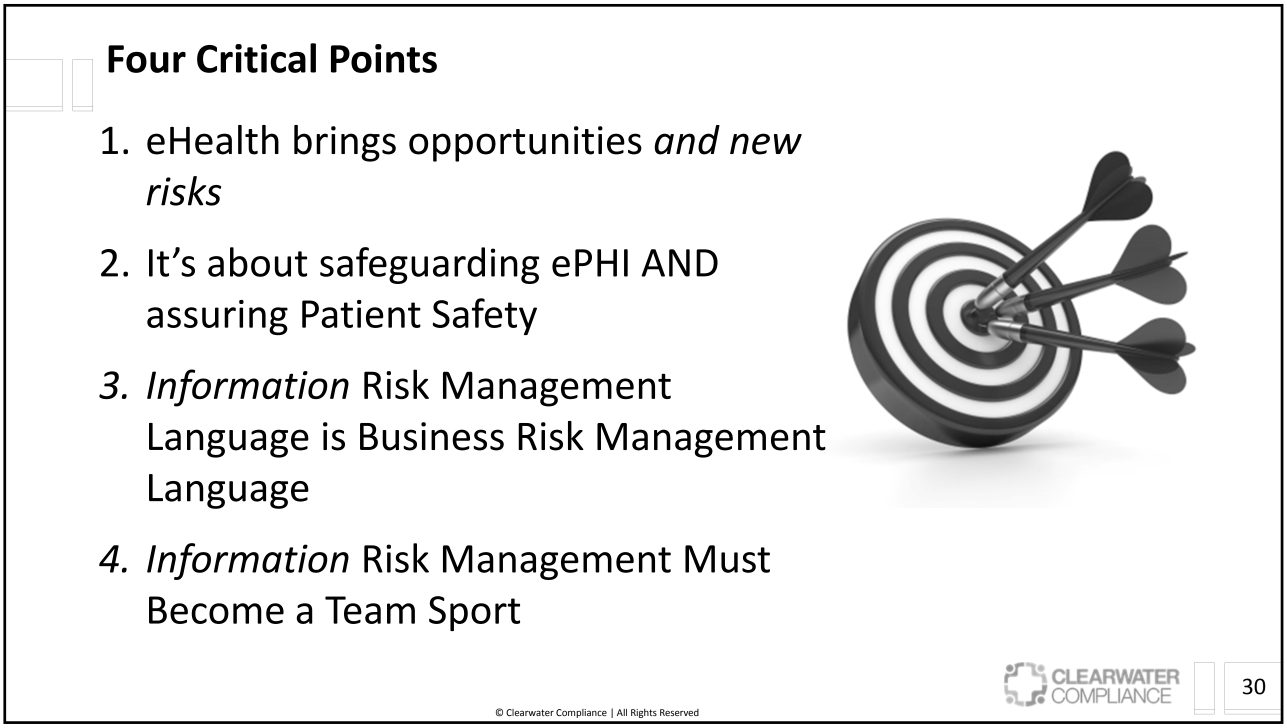

Four Critical Points

1. eHealth brings opportunities *and new risks*
2. It’s about safeguarding ePHI AND assuring Patient Safety
3. *Information* Risk Management Language is Business Risk Management Language
4. *Information* Risk Management Must Become a Team Sport

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Backup slides

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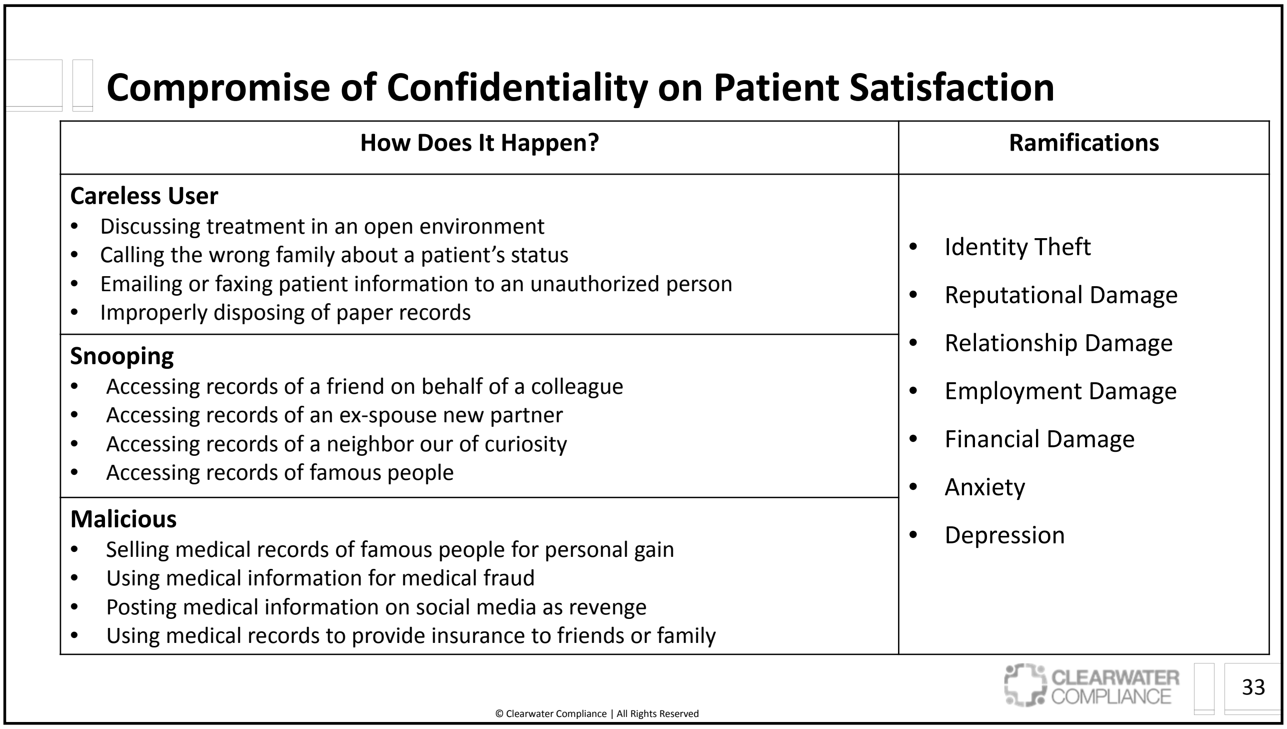
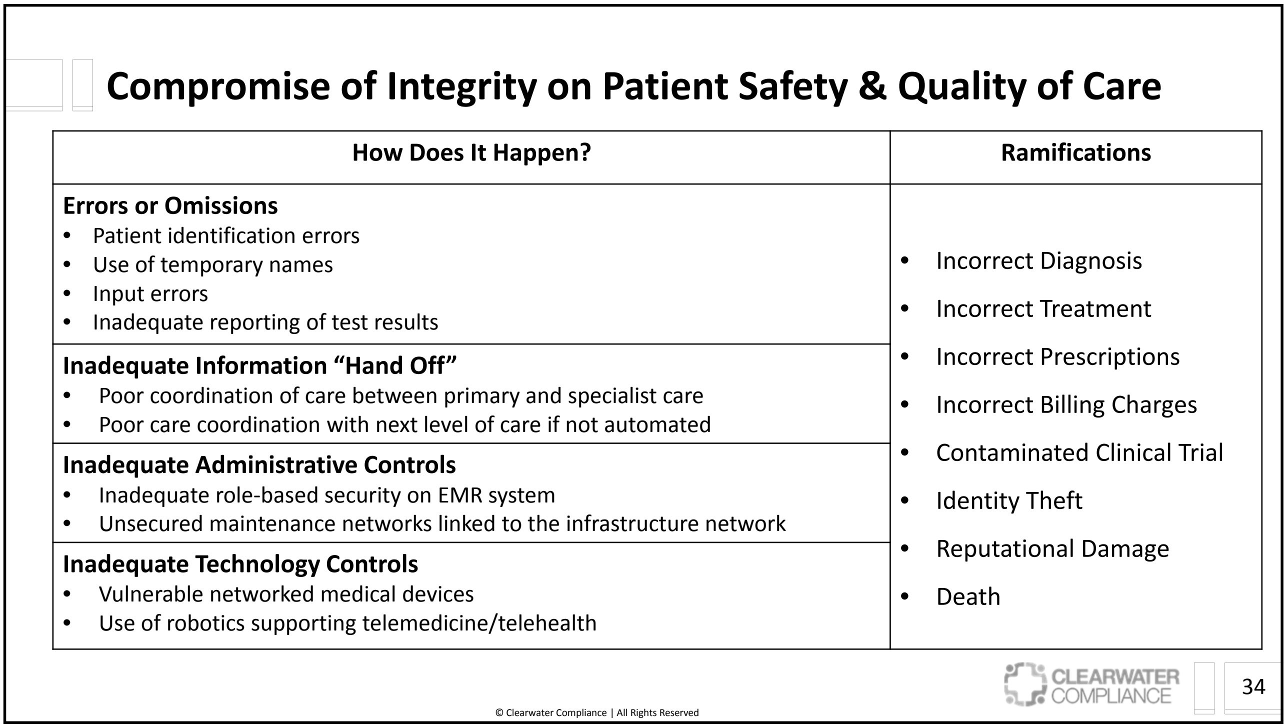


Compromise of Confidentiality on Patient Satisfaction

How Does It Happen?	Ramifications
Careless User • Discussing treatment in an open environment • Calling the wrong family about a patient's status • Emailing or faxing patient information to an unauthorized person • Improperly disposing of paper records	• Identity Theft • Reputational Damage • Relationship Damage • Employment Damage • Financial Damage • Anxiety • Depression
Snooping • Accessing records of a friend on behalf of a colleague • Accessing records of an ex-spouse new partner • Accessing records of a neighbor our of curiosity • Accessing records of famous people	
Malicious • Selling medical records of famous people for personal gain • Using medical information for medical fraud • Posting medical information on social media as revenge • Using medical records to provide insurance to friends or family	



Compromise of Integrity on Patient Safety & Quality of Care

How Does It Happen?	Ramifications
Errors or Omissions • Patient identification errors • Use of temporary names • Input errors • Inadequate reporting of test results	• Incorrect Diagnosis • Incorrect Treatment • Incorrect Prescriptions • Incorrect Billing Charges • Contaminated Clinical Trial • Identity Theft • Reputational Damage • Death
Inadequate Information "Hand Off" • Poor coordination of care between primary and specialist care • Poor care coordination with next level of care if not automated	
Inadequate Administrative Controls • Inadequate role-based security on EMR system • Unsecured maintenance networks linked to the infrastructure network	
Inadequate Technology Controls • Vulnerable networked medical devices • Use of robotics supporting telemedicine/telehealth	

Compromise of Availability on Patient Safety & Quality of Care

How Does It Happen?	Ramifications
Incomplete or untested remediation plans • Disaster Recovery Plans • Business Interruption Plans • Business Continuity Plans	• Delayed Admittance • Delayed Diagnosis • Delayed Surgery • Delayed Prescriptions • Delayed Discharge • Diagnosis Errors • Treatment Errors • Death
Inadequate Processes • Untimely or incomplete back-up procedures • Disconnected Systems • Unpatched applications	
Inadequate Security Controls • Back-up connected to infrastructure network • Untrained workforce members on social engineering tactics	