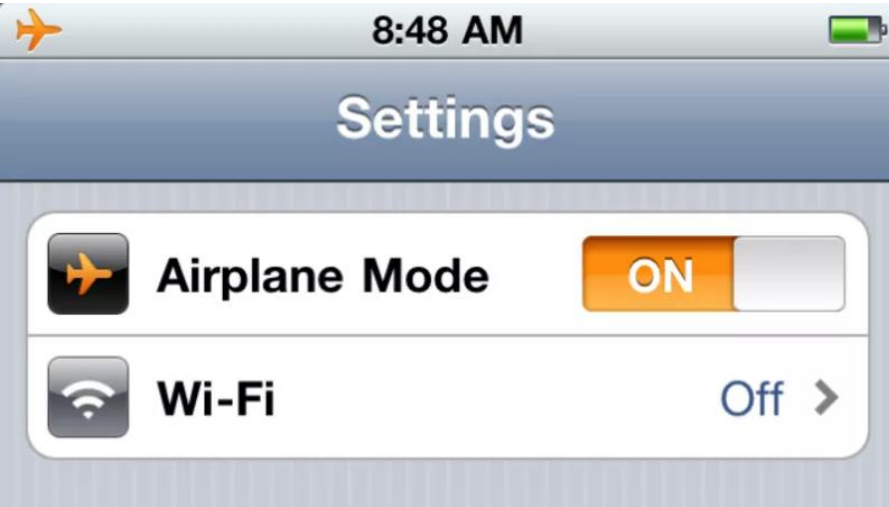


Three Paradoxes and the Need for a Paradigm Shift—A CIO Perspective



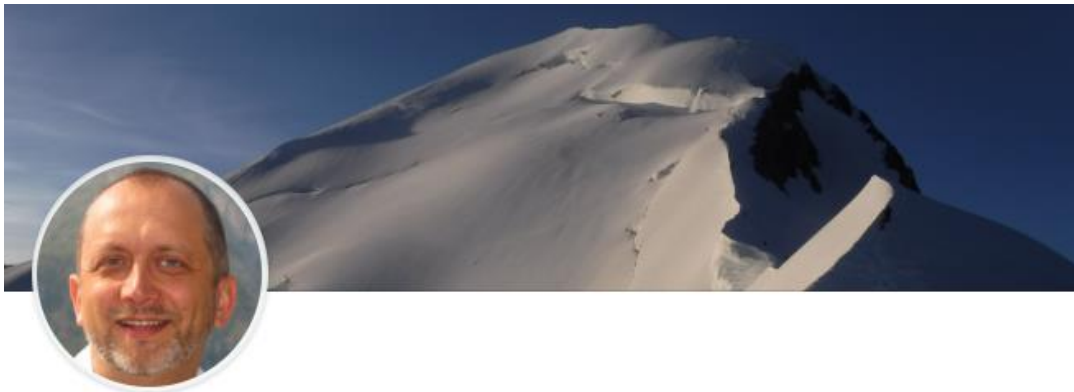
Pre-flight safety briefing



Introducing myself...

Giuliano Pozza

- President of A.I.S.I.S. (Italian Association of Healthcare Information Systems Professionals– www.aisis.it)
- C.I.O. Ospedale S. Raffaele
- Biomedical Engineer





Giuliano Pozza

Chief Information Officer at Ospedale San Raffaele -
Presidente di AISIS (Ass.ne Italiana Sistemi Informativi in
Sanità)

Milan Area, Italy

 Ospedale San Raffaele

 Politecnico di Milano

 See contact info

 See connections (500+)

Chief Information Officer with experience in IT strategy definition and execution in complex and challenging environments.

AREAS OF SPECIALTY

- Governance of Enterprise IT
- Change Management
- Program and Project Management
- Cybersecurity & IoT: Governance of cyber risk in Healthcare
- Health Care Information Systems (Hospital Information Systems, EHR/EPR...)
- Organization Development and Process Improvement

I have specific industry knowledge in Healthcare and Pharmaceutical Industry.

I am the President of the "Italian Association of Healthcare Information Systems" (AISIS).

I am external lecturer for SDA Bocconi University (eHealthAcademy) and for Istituto A.C. Jemolo.

My hobbies are hiking, reading and sometimes writing.

www.linkedin.com/in/gpozza/

www.yottabronto.net

About AISIS

The Italian organization of healthcare information systems managers (AISIS) was founded in 2003 to promote the development of IT professionals and the strategic role of Information Technology in healthcare. It currently has over 500 members ranging from CIOs to non-technical e-Leaders. AISIS organizes events, training courses (AISIS eHealth Academy), research programs (eHealthLab) and is also active in the promotion of a social and philanthropic approach to healthcare IT (AISIS4Social). AISIS operates in association with other national and international organizations. For more information, please visit www.aisis.it.

ACTIVE COLLABORATION with POLIMI:

AISIS4Social - www.aisis.it/aisis4social

(2019: 2 scholarships)

Main Partnerships:

- AICA
- AIIC
- ASSD
- CHIME (<https://chimecentral.org/chime-and-aisis-announce-plans-to-launch-chapter-in-italy/>)
- Ethos.it
- FIASO
- GHT
- HIMSS
- Istituto Superiore Sanità
- LifeTech Forum
- Osservatorio Innovazione Digitale in Sanità del Politecnico di Milano
- SDA Bocconi School of Management
- ...

Course Objectives

- Understand the context of cybersecurity in healthcare
- Analyze from a risk management/accountability perspective (as required by GDPR) the most dangerous cyber threats
- Define mitigation scenarios

Agenda

- (15 min) Context: cybersecurity & IoT in Healthcare
- (15 min) Three paradoxes
 - Are There More Things in Shadow IT Than in Official IT?
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- (15 min) Q&A

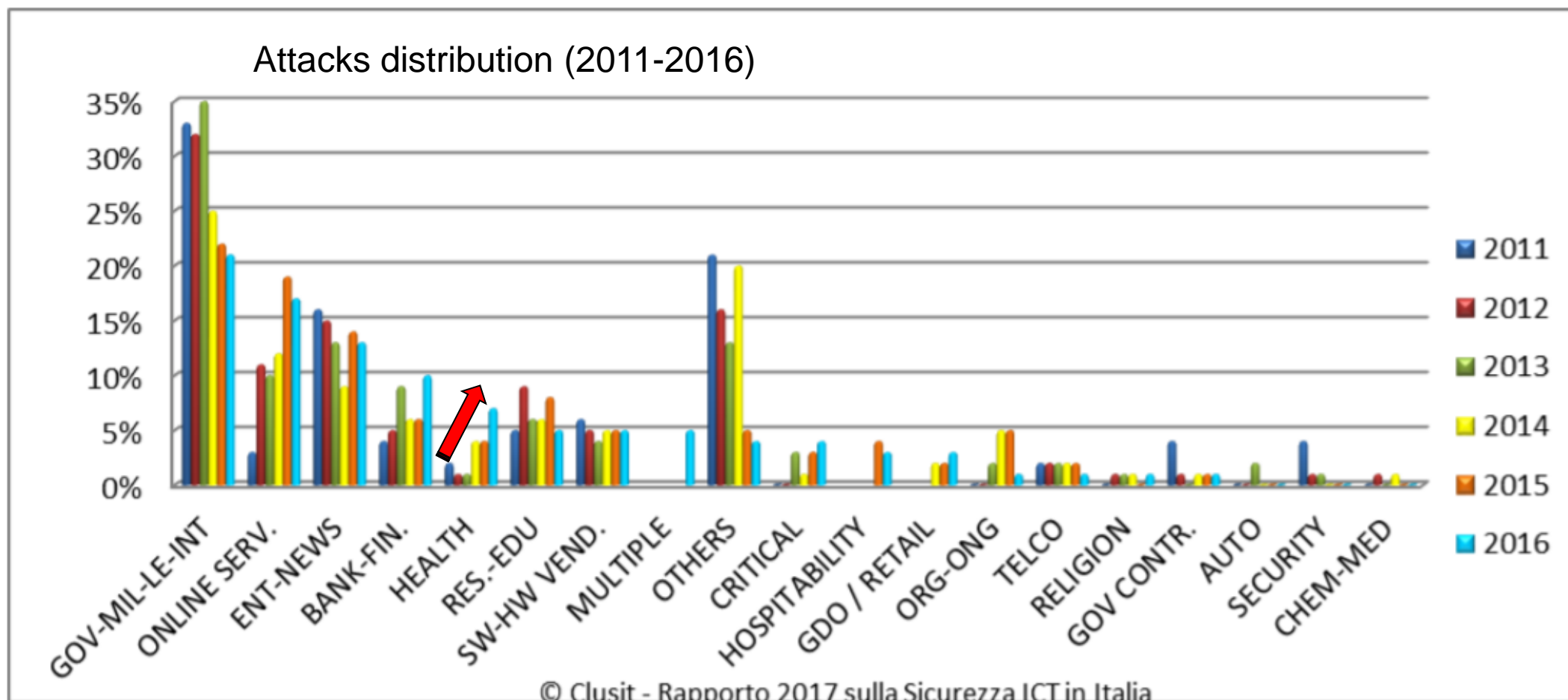
War games...



(<https://threatmap.fortiguard.com> - <http://www.norse-corp.com/map/> - www.digitalattackmap.com)

Healthcare under attack (1/2)

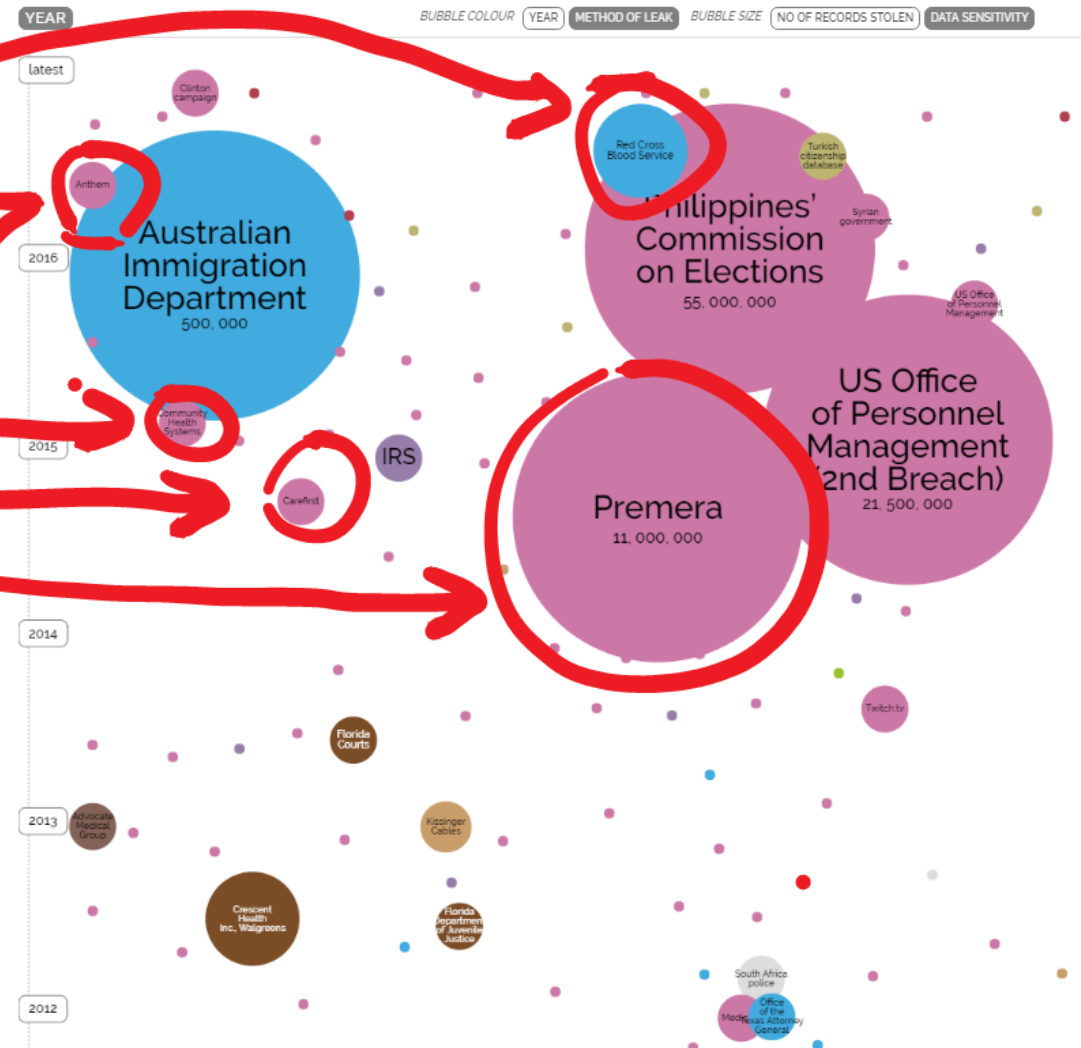
Source: Rapporto CLUSIT 2017



Healthcare under attack (2/2)

World's Biggest Data Breaches (Healthcare & Government)

Selected losses greater than 30,000 records
(updated 15th Oct 2016)



Health Data

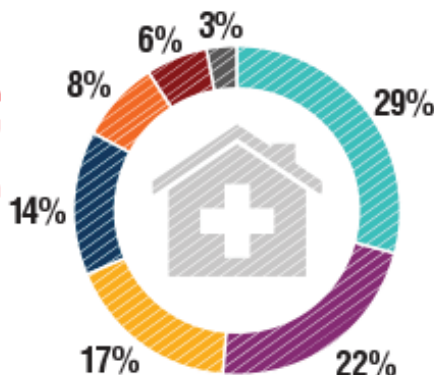
Source: www.informationisbeautiful.net

Internet of Things (1/3)

Source: EvaluateMedTech® World Preview 2016, Outlook to 2022

MEDICAL DEVICE INDUSTRY

Value of total exports
based on North American Industry
Classification System (NAICS)



THE U.S. LEADS

- World production of medical devices
- Global consumption of medical devices
- Medical device market with a value of \$140+ billion; ~45% of the global market



\$43 BILLION
with
1.5% ANNUAL GROWTH

2015 total value of U.S. industry product shipments under medical NAICS categories

booz&co.

M-HEALTH

PHYSICIAN USE OF MOBILE TECHNOLOGY

DOCTORS ♥ TABLETS

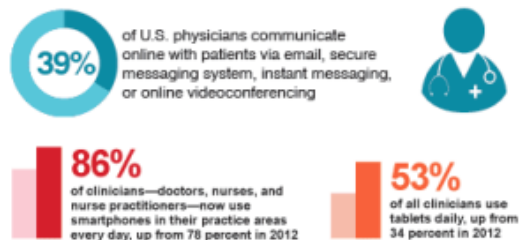
250% MORE LIKELY TO OWN A TABLET THAN ANY OTHER CONSUMERS



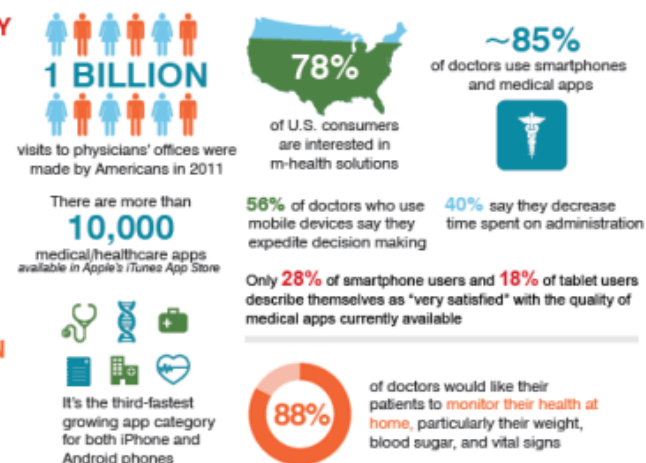
U.S. PHYSICIAN SMARTPHONE ADOPTION



ONLINE PATIENT-PHYSICIAN COMMUNICATION



The emerging field of mobile health (m-health) has enabled consumers to use smartphone technology to answer their own health-related questions with the quick tap of a touch screen. Here's a look at m-health and the impact it's making on our culture and our well-being:



PATIENT USE OF MOBILE TECHNOLOGY



Source: IDC, Gartner, Forrester, Frost & Sullivan, YouGov, comScore, CISCO Global Cloud Index 2013, CISCO Visual Networking Index Study 2013, Intel, AMD, IMS Research, Manhattan Research 2012, Rock Health Digital Funding Mid Year 2013, Paw Internet and American Life Project, Health Online 2013, Epocrates 2013 report, and American EHR Partners 2013 survey

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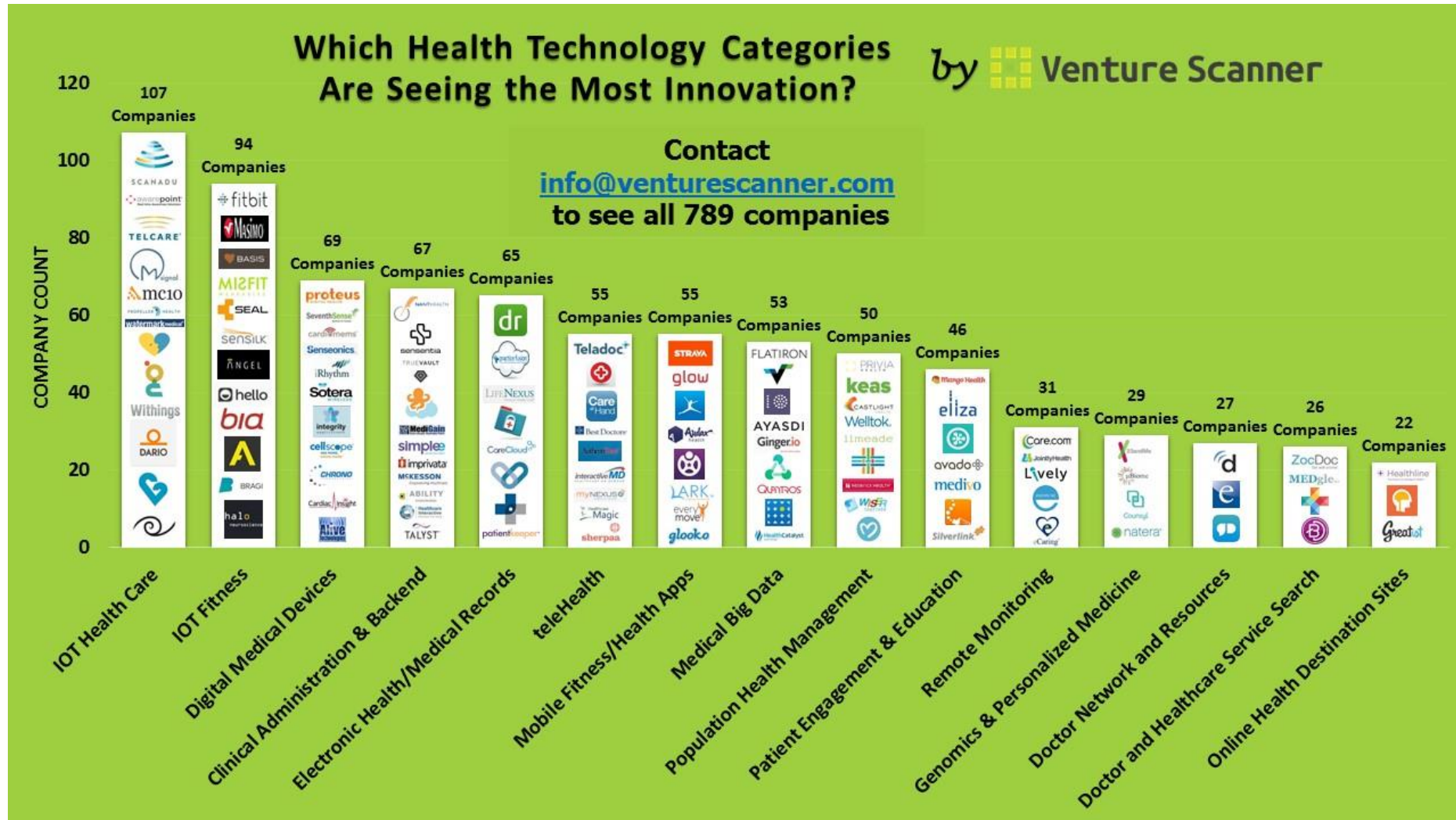
Internet of Things: wearable (2/3)

Patient Generated Data
(PGD)



Patient Generated Data
(PGD)

Internet of Things & wearable (3/3)



Healthcare: The perfect storm

IT SECURITY:



INNOVAZIONE "TECNOLOGICA"
(DIAGNOSTICHE, ROBOTICA...)



INNOVAZIONE "DI SISTEMA"
(EHR, EMR...)

THE PERFECT
OPPORTUNITY



THE PERFECT STORM
(WHEN THEY BREAK, THEY
BREAK HARD - JOHN SNOW)



INNOVAZIONE "SOCIALE"
(APPS, SOCIAL MEDIA,
AN HEALTH, HEALTH IoT...)

SOSTENIBILITÀ
ECONOMICA
(DOMANDA "ESPLOSIVA"
DA CRONICI e FRAGILI)

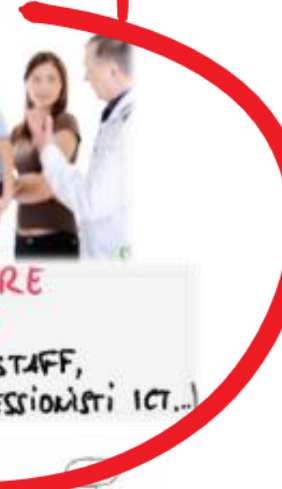


DIVERSE CULTURE
POCO "IT SAVVY"
(MEDICI, INFERMIERI, STAFF,
OPER. SOCIALI, PROFESSIONISTI ICT...)



CAMBIAMENTI
ORGANIZZATIVI
(CENTRALIZZAZIONI
SPESO CON SCARSO GOVERNO)

HEALTH
CARE



Healthcare: The perfect opportunity

Cross Regional EMRAM Score Distribution (2017 Q4)					
Stage	Asia Pacific	Middle East	United States	Canada	Europe*
Stage 7	1.2%	1.2%	6.4%	0.3%	0.2%
Stage 6	7.4%	21.6%	33.8%	1.7%	3.0%
Stage 5	7.9%	18.5%	32.9%	3.9%	32.1%
Stage 4	1.8%	2.5%	10.2%	1.5%	5.2%
Stage 3	1.0%	16.0%	12.0%	30.3%	5.7%
Stage 2	31.2%	19.1%	1.8%	29.4%	32.7%
Stage 1	5.0%	6.2%	1.5%	15.2%	9.1%
Stage 0	44.5%	14.8%	1.4%	17.6%	12.0%

N = 834

N = 162

N = 5,487

N = 646

N = 1,132

Data from HIMSS Analytic
*Data from Q2 2017

ITALY:
- 6 LEVEL 6
HOSPITALS

- ALMOST ALL
BELOW LEVEL 3


PS: EMRAM Scale

BEFORE 2018



AFTER 2018

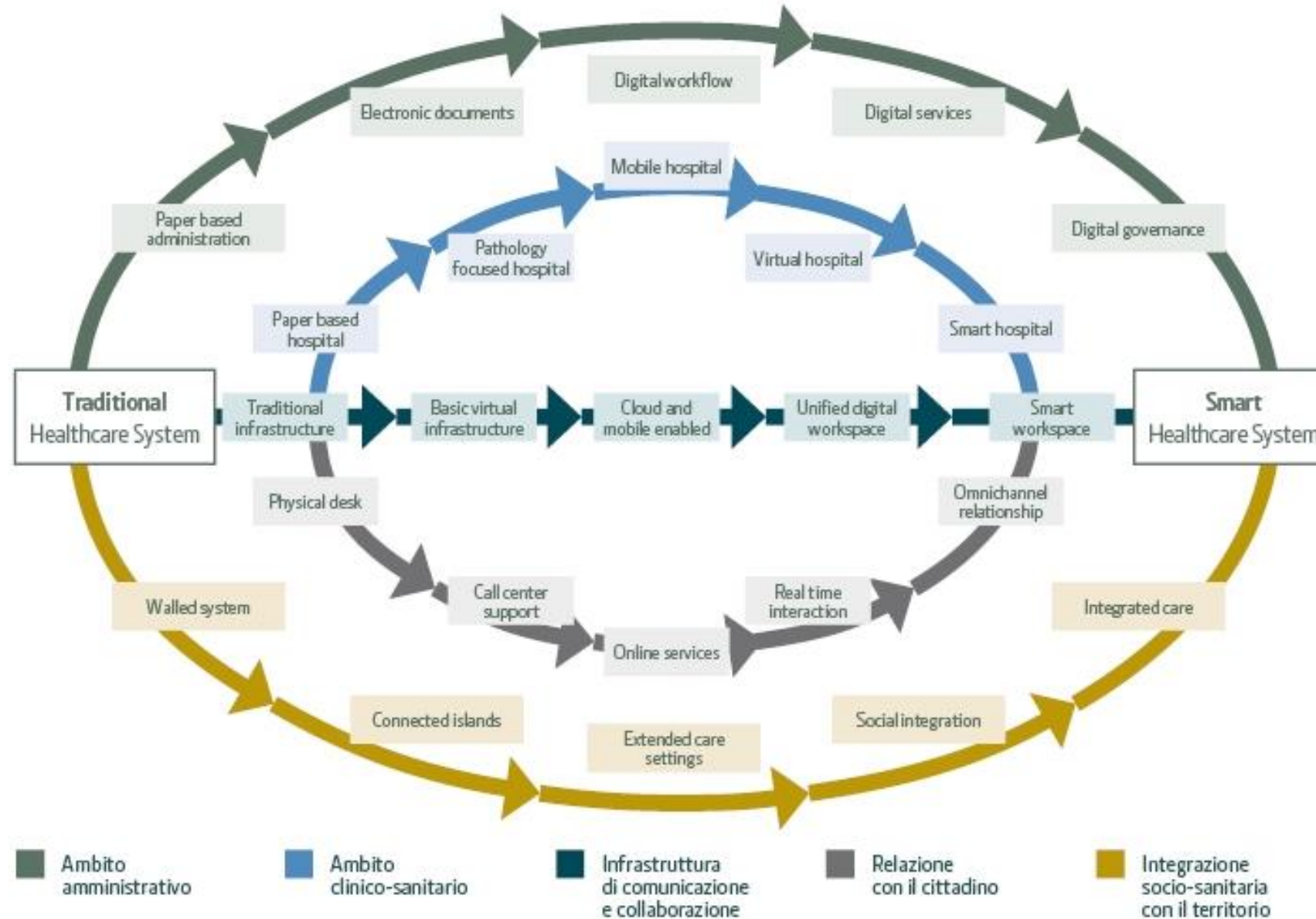
US EMR Adoption Model SM	
Stage	Cumulative Capabilities
Stage 7	Complete EMR; CCD transactions to share data; Data warehousing; Data continuity with ED, ambulatory, OP
Stage 6	Physician documentation (structured templates), full CDSS (variance & compliance), full R-PACS
Stage 5	Closed loop medication administration
Stage 4	CPOE, Clinical Decision Support (clinical protocols)
Stage 3	Nursing/clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology
Stage 2	CDR, Controlled Medical Vocabulary, CDS, may have Document Imaging; HIE capable
Stage 1	Ancillaries - Lab, Rad, Pharmacy - All Installed
Stage 0	All Three Ancillaries Not Installed

STAGE	 EMR Adoption Model Cumulative Capabilities
7	Complete EMR; External HIE; Data Analytics, Governance, Disaster Recovery, Privacy and Security
6	Technology Enabled Medication, Blood Products, and Human Milk Administration; Risk Reporting; Full CDS
5	Physician documentation using structured templates; Intrusion/Device Protection
4	CPOE with CDS; Nursing and Allied Health Documentation; Basic Business Continuity
3	Nursing and Allied Health Documentation; eMAR; Role-Based Security
2	CDR; Internal Interoperability; Basic Security
1	Ancillaries - Laboratory, Pharmacy, and Radiology/Cardiology information systems; PACS; Digital non-DICOM image management
0	All three ancillaries not installed

+ DIFFUSION

Other maturity models...

Fonte: Osservatorio Innovazione in Sanità del Politecnico di Milano



Agenda

- (15 min) Context: cybersecurity & IoT in Healthcare
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Paradox #1

Are There More Things in Shadow IT Than in Official IT?

Report CISCO 2015: Do You Know the
Way to Ballylickey? Shadow IT and the
CIO Dilemma – N. Earle

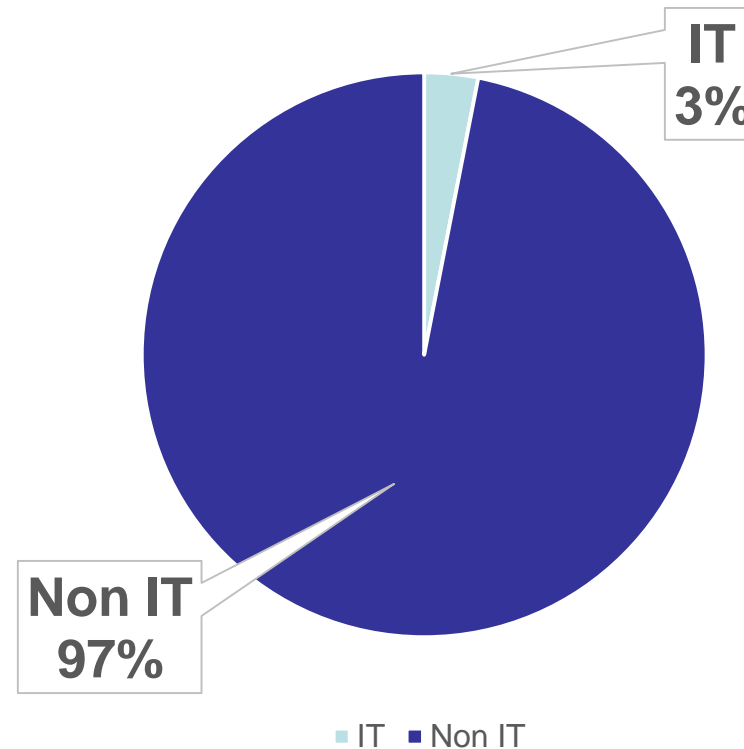


Paradox #1

Are There More Things in Shadow IT Than in Official IT?

Real life example: diagnostic imaging in an hospital:
20TB Managed by IT (RIS-PACS), 631TB not managed by IT (or not managed?)

Diagnostic imaging (per year value in TB)



Paradox #2

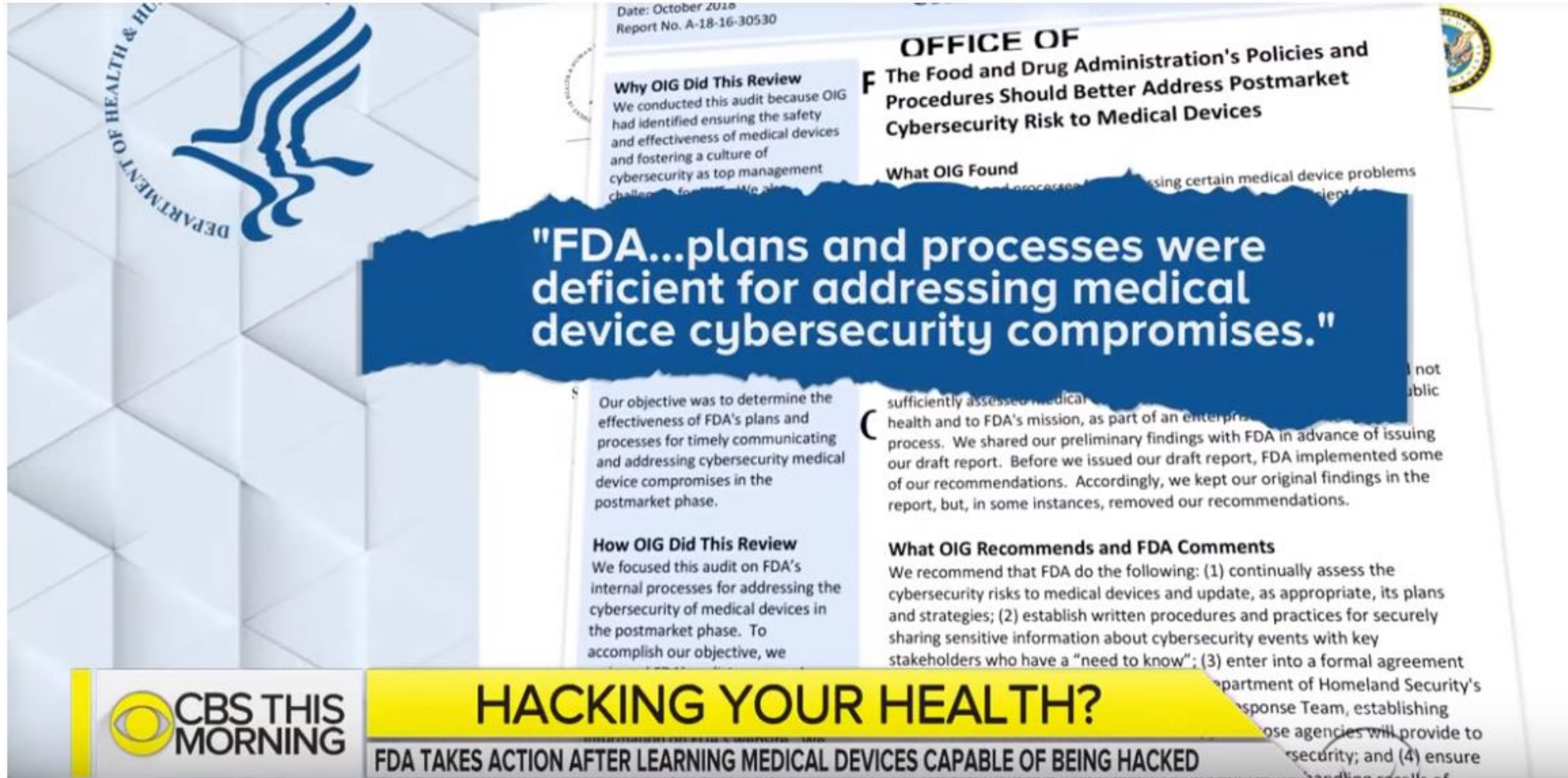
In Healthcare, a Large and Growing Amount of Sensitive Data and the Most Dangerous and Potentially Life-Threatening Systems Are, From the Security Perspective, in a “No Man’s Land”



Paradox #2: Hacking a medical Device



hacking medical devices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Date: October 2018
Report No. A-18-16-30530

OFFICE OF
The Food and Drug Administration's Policies and Procedures Should Better Address Postmarket Cybersecurity Risk to Medical Devices

Why OIG Did This Review
We conducted this audit because OIG had identified ensuring the safety and effectiveness of medical devices and fostering a culture of cybersecurity as top management challenges for FDA. We also...

What OIG Found
...certain medical device problems...

"FDA...plans and processes were deficient for addressing medical device cybersecurity compromises."

Our objective was to determine the effectiveness of FDA's plans and processes for timely communicating and addressing cybersecurity medical device compromises in the postmarket phase.

How OIG Did This Review
We focused this audit on FDA's internal processes for addressing the cybersecurity of medical devices in the postmarket phase. To accomplish our objective, we...

What OIG Recommends and FDA Comments
We recommend that FDA do the following: (1) continually assess the cybersecurity risks to medical devices and update, as appropriate, its plans and strategies; (2) establish written procedures and practices for securely sharing sensitive information about cybersecurity events with key stakeholders who have a "need to know"; (3) enter into a formal agreement with the Department of Homeland Security's Incident Response Team, establishing a joint response team; (4) ensure that all medical device manufacturers provide to the FDA and the Department of Homeland Security's Incident Response Team, establishing a joint response team; and (5) ensure that all medical device manufacturers provide to the FDA and the Department of Homeland Security's Incident Response Team, establishing a joint response team.

CBS THIS MORNING

HACKING YOUR HEALTH?
FDA TAKES ACTION AFTER LEARNING MEDICAL DEVICES CAPABLE OF BEING HACKED

<https://www.youtube.com/watch?v=smhPhmNsvVc>

Paradox #2

FROM THE BUYER SIDE:

Clinical Engineers evaluate and manage medical devices but...lack competencies in cybersecurity (and sometimes awareness of the risk level)

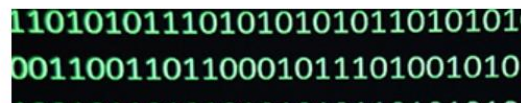


[Regulatory Focus™](#) > [News Articles](#) > [Abbott Recalls 465,000 Pacemakers for Cybersecurity Patch](#)

Abbott Recalls 465,000 Pacemakers for Cybersecurity Patch

Posted 30 August 2017 | By Michael Mezher

Medical device maker Abbott on Monday announced it is voluntarily recalling some 465,000 pacemakers to install a firmware update to patch cybersecurity vulnerabilities



FROM THE SUPPLIER SIDE:

Historically Engineering department of medical device manufacturers did not embed cyber security measure in device design process (security by design). Everything OK for “closed” devices. Then... wi-fi and remote control were so tempting... (PS: PHASE OUT on Implanted devices is a problem!)

Paradox #2

- Clinical Engineering and ICT cannot be considered separate fields anymore
- Almost every equipment/medical device has a software component
- Clinical Engineering is the first buyer of IT Systems in many hospitals



Top 10 Health Technology Hazards for 2018 ECRI Institute

1. **Ransomware and Other Cybersecurity Threats to Healthcare Delivery Can Endanger Patients**
2. Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk
3. Mattresses and Covers May Be Infected by Body Fluids and Microbiological Contaminants
4. Missed Alarms May Result from Inappropriately Configured Secondary Notification Devices and Systems
5. Improper Cleaning May Cause Device Malfunctions, Equipment Failures, and Potential for Patient Injury
6. ...

Paradox #3

CIOs Are Working Hard to Fortify the Walls of the Citadel, but There Is no Citadel to Defend

WE (C.I.O.s) THINK
WE ARE HERE



BUT... —→ WE ARE HERE



BEST ANALOGY: WWW.THREATSPROJECT.EU

Paradox #3

Holistic Approach (local hyper-security is dangerous)

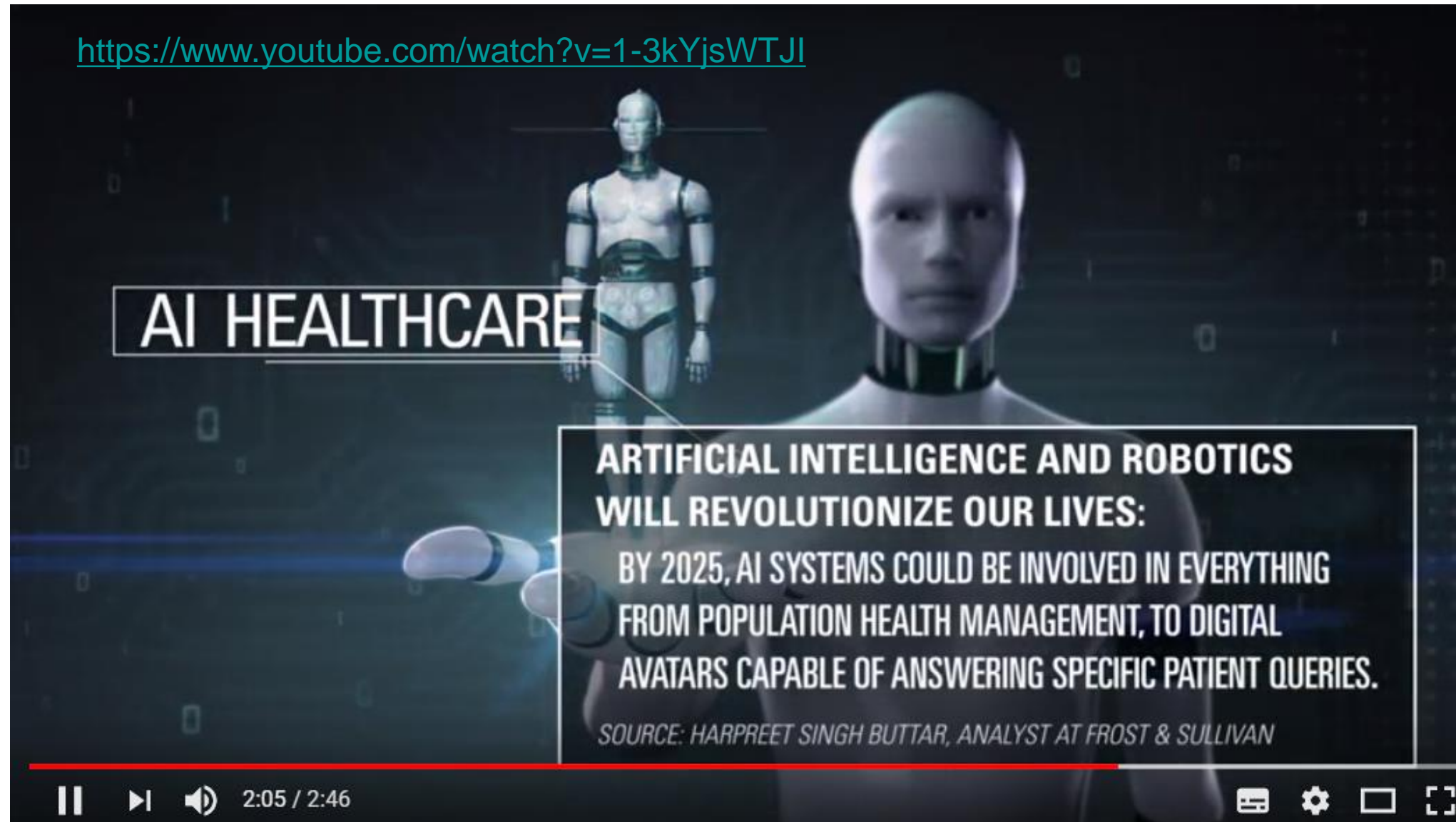


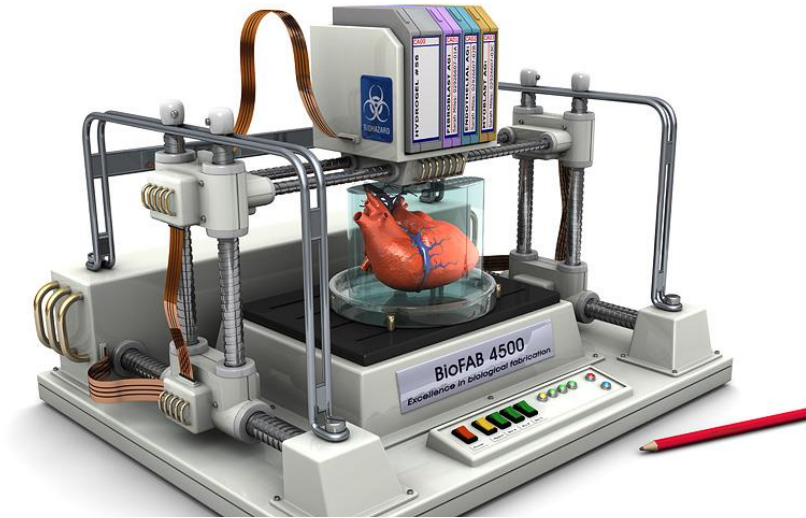
- **Maginot line** was not crazy: it was ment to be part of a global (holistic) strategy
- Local Hyper security (what IT Department are doing now) is a problem because absorbs most of the resources without mitigating risk (se next slides...)

Agenda

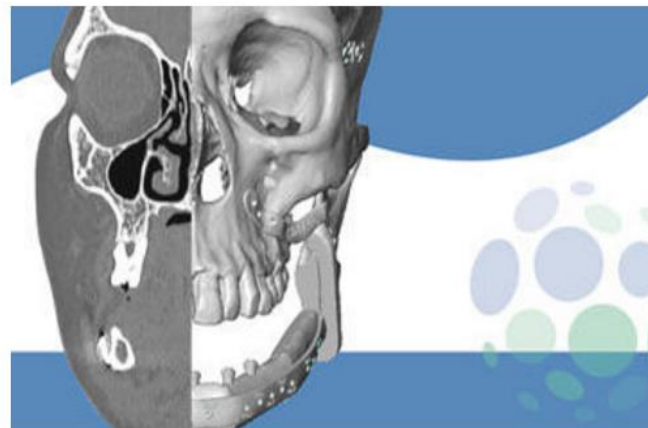
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- (15 min) Q&A

It's all about data and information! (1/4)





⌚ Le nuove frontiere dell'industria biomedicale



18 Dic 2016

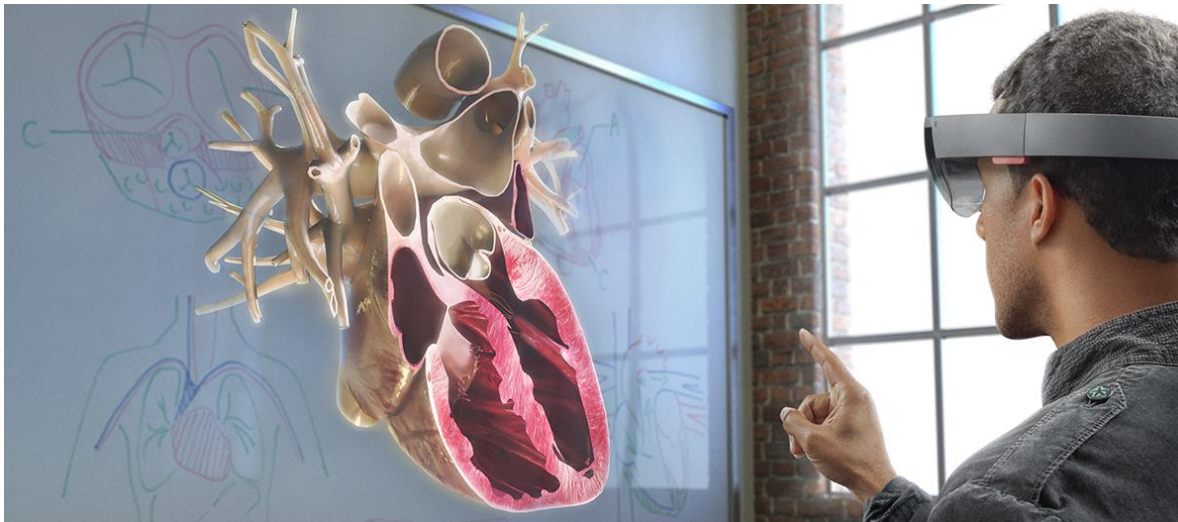
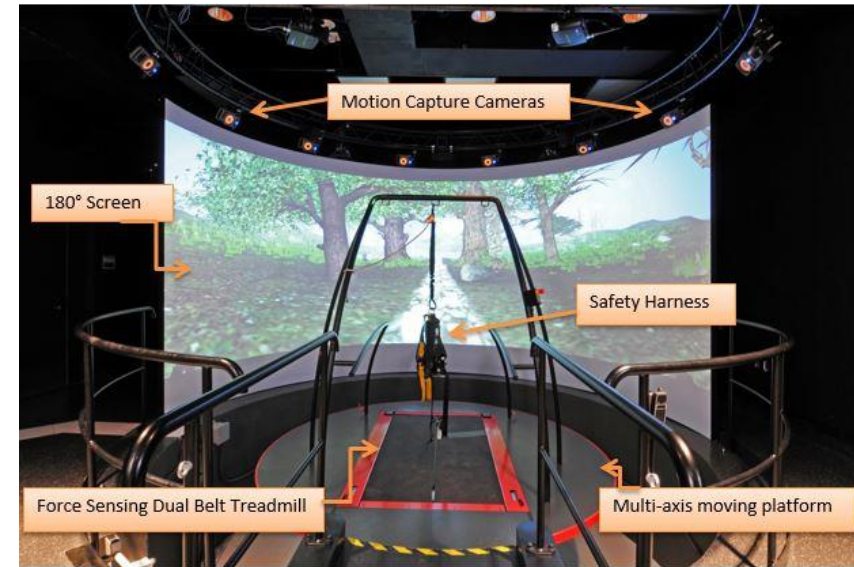
Radio24

A Padova è stato effettuato pochi mesi fa il primo trapianto di mandibola con una **protesi artificiale** realizzata da una stampante 3D. In generale, la manifattura additiva sta rivoluzionando l'intera industria delle protesi, che sarà personalizzata, in pezzi unici.

La mandibola di Padova è stata realizzata da Sintac, società del Gruppo GPI, una conglomerata da circa 150 milioni di euro di ricavi nel settore delle tecnologie medicali. Radio24 ne parla con Fausto Manzana, Presidente di GPI.

It's all about data and information! (3/4)

- Healthcare applications
 - Education (Hololens)
 - «Flight simulators» for surgeons
 - Rehabilitation (The Ottawa Hospital)



It's all about data and information! (4/4)



Protecting data: GDPR & Risk

6 THINGS GDPR IS.

**RISK BASED
APPROACH**

1

**A Total Data
Protection Game
Changer!**

Global Applicability – applies to organisations anywhere who control or process EU citizen data

2

**Applies Equally in
all EU member
states**

As a regulation, the GDPR is directly effective, and does not leave room for jurisdictional interpretation of all its rules

3

**Legislation with
teeth!**

For Irish organisations, this is a whole new world. The current Data Protection Act lacks the teeth to really punitively effect wrongdoers. New powers will be given to the Data Protection Commissioner to impose fines to a maximum of 4% of turnover/€20 million. Individuals will also be entitled to claim for compensation where they have suffered a loss.

4

**Encouraging of a
risk based
approach to
systems, strategies,
product
development etc.**

The fundamental rights and freedoms of individuals to privacy must be balanced against the operations of the organisation. Risk assessments and in-built privacy considerations are to factor in every new approach taken by organisations.

5

**Making
organisations
accountable.**

The requirements for Data Protection Officer, Mandatory Breach Reporting and documenting compliance are pushing the onus on the data controllers and processors to prove they are taking individuals' fundamental rights seriously.

6

Long over due!

Privacy has never been so challenged and technology has never been so advanced. Legislators are finally catching up!

Risk

Definition

Risk

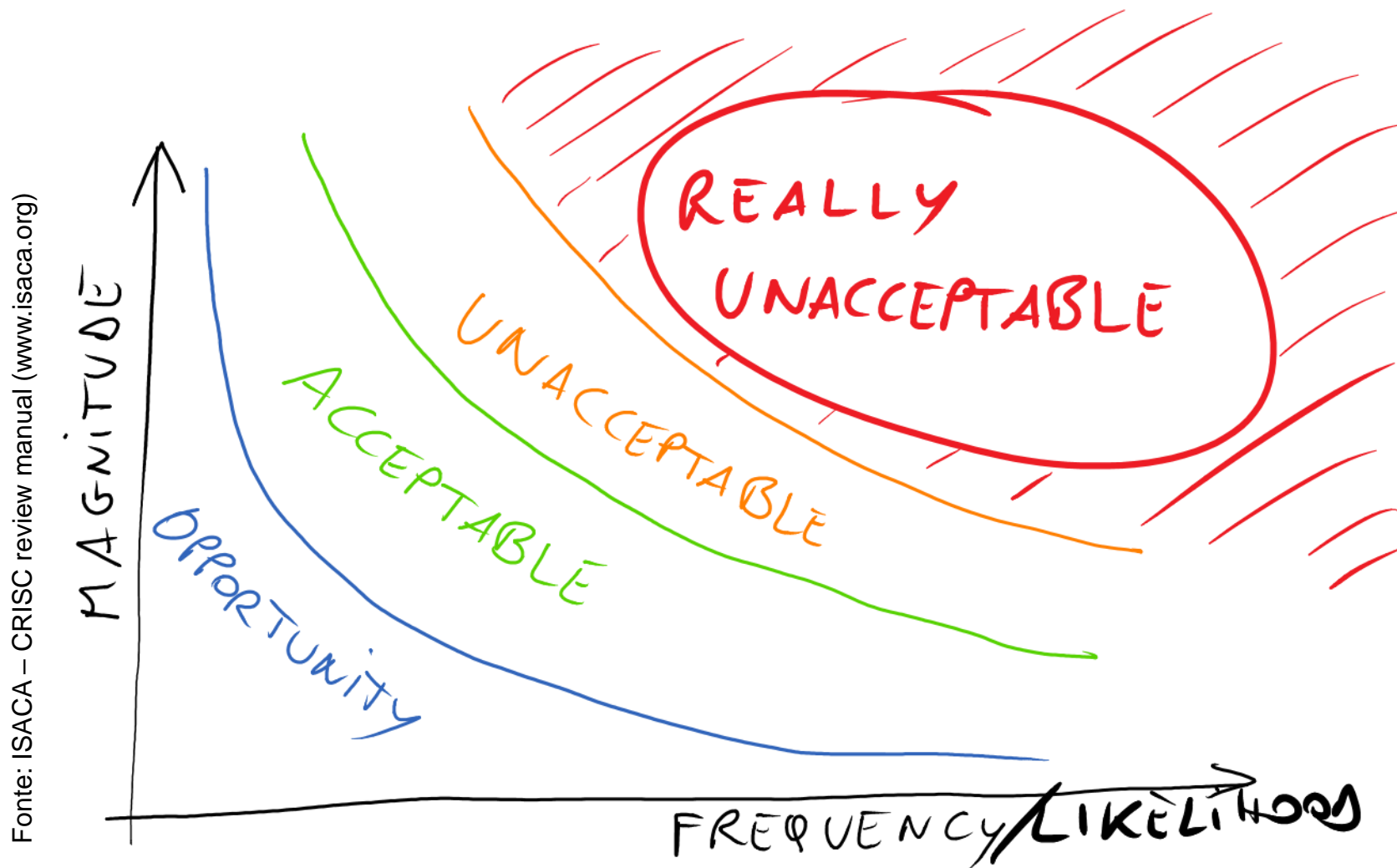
The possibility of loss or harm in exposure to a chance of damage involving uncertain danger in the creates or suggests a hazard or the degree of probability of suc

**RISK =
PROBABILITY x IMPACT**

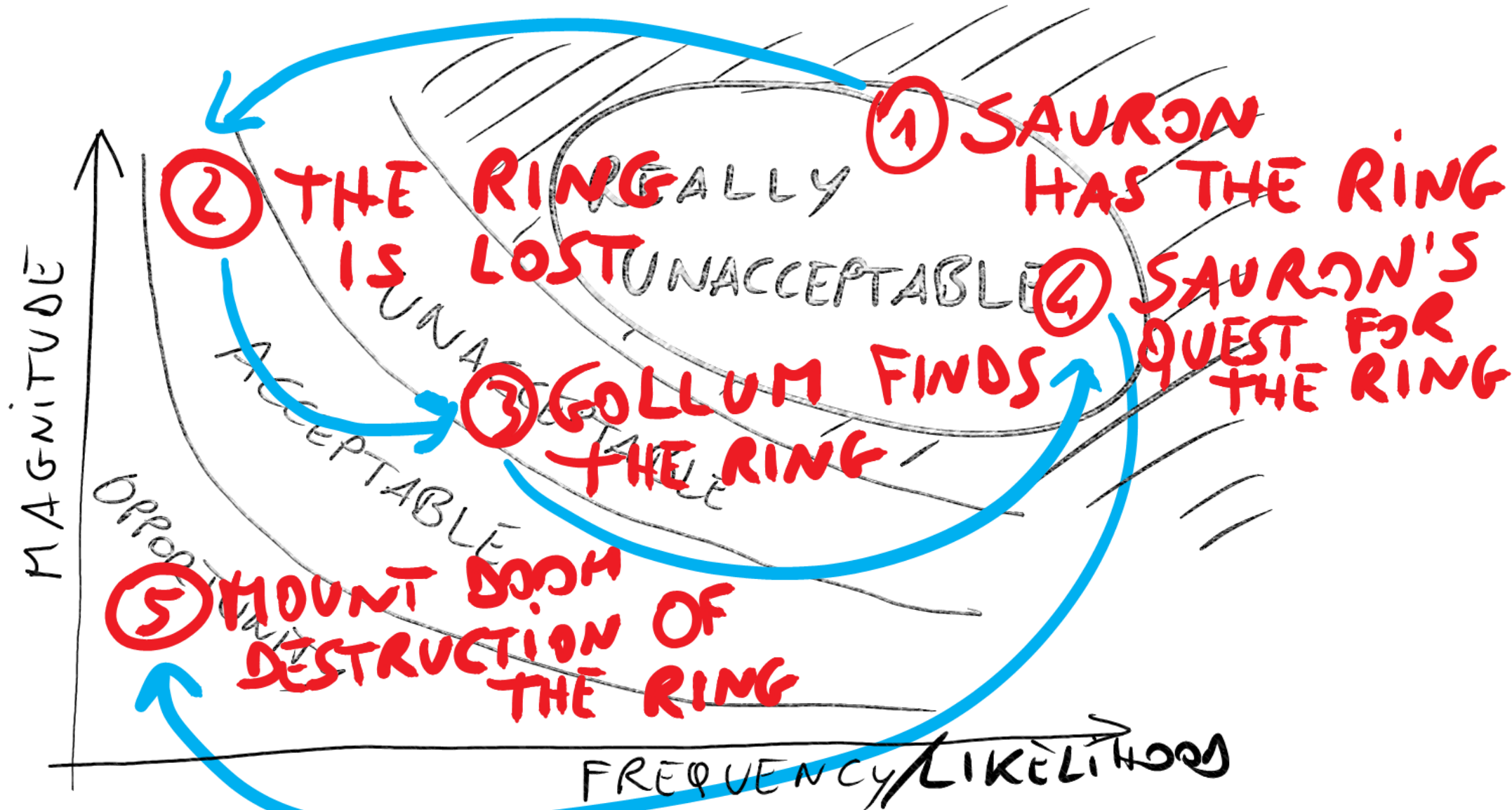
		Impact				
		Trivial	Minor	Moderate	Major	Extreme
Probability	Rare	Low	Low	Low	Medium	Medium
	Unlikely	Low	Low	Medium	Medium	Medium
	Moderate	Low	Medium	Medium	Medium	High
	Likely	Medium	Medium	Medium	High	High
	Very likely	Medium	Medium	High	High	High

Risk map

Risk Optimization

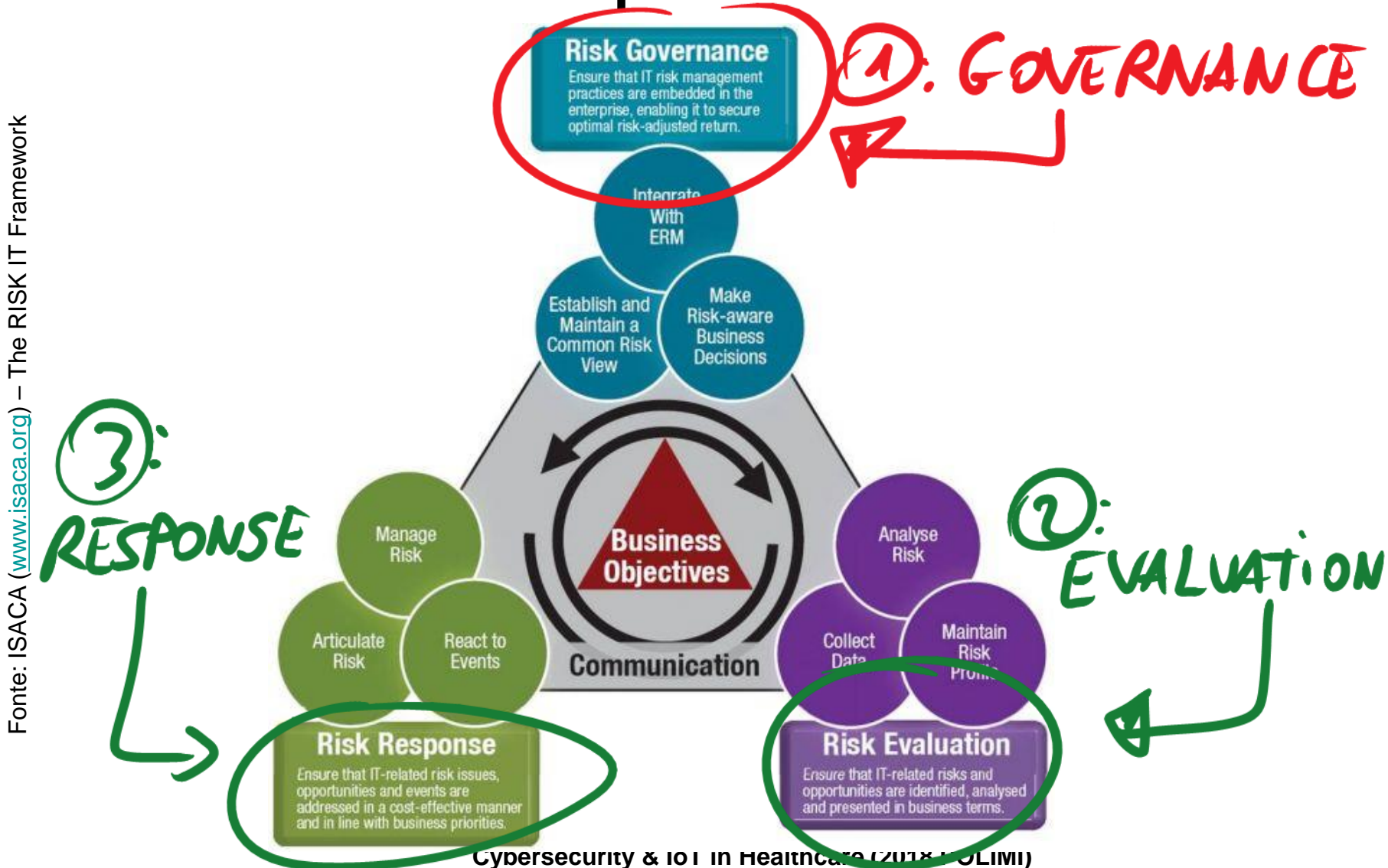


Risk map - example

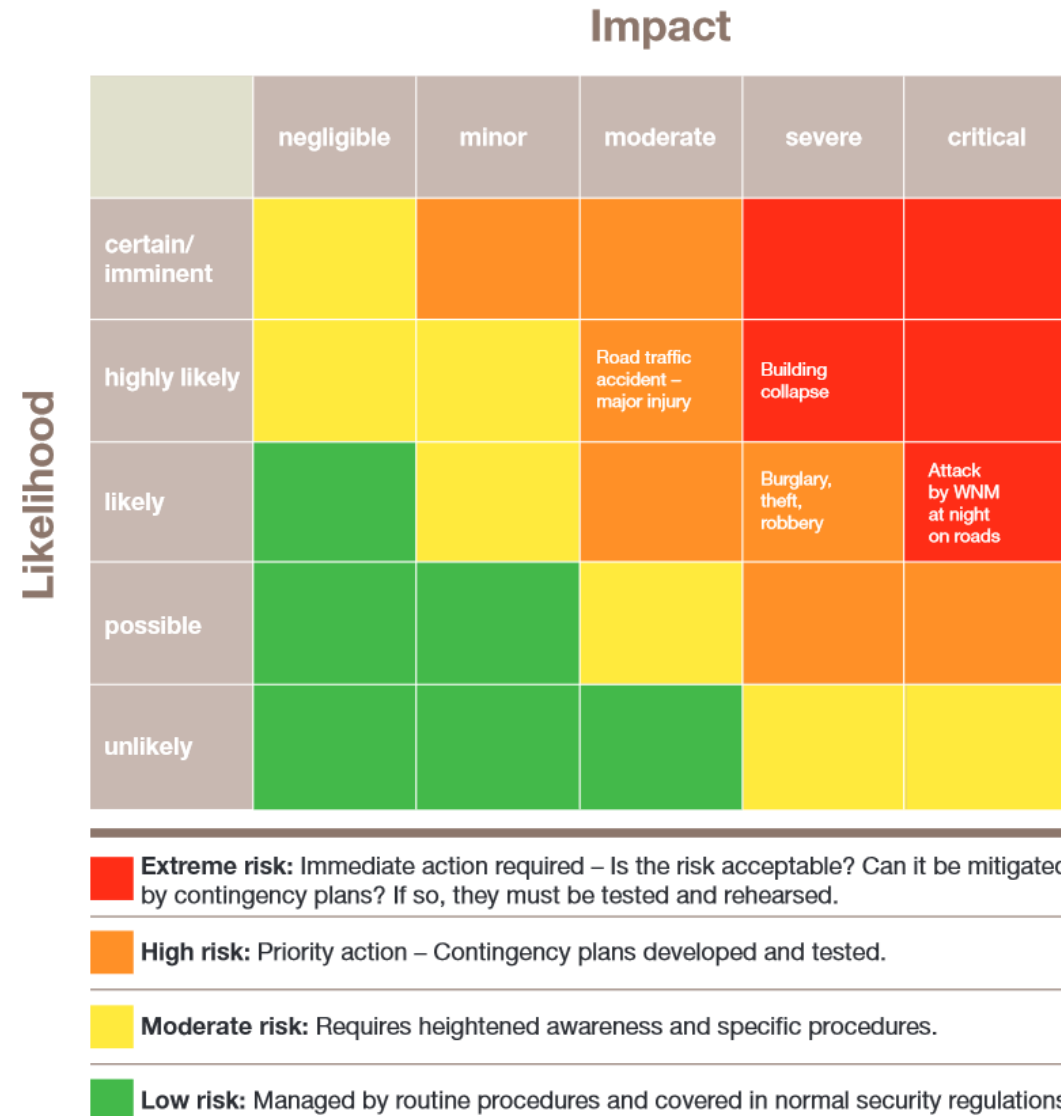


Enterprise Risk Management

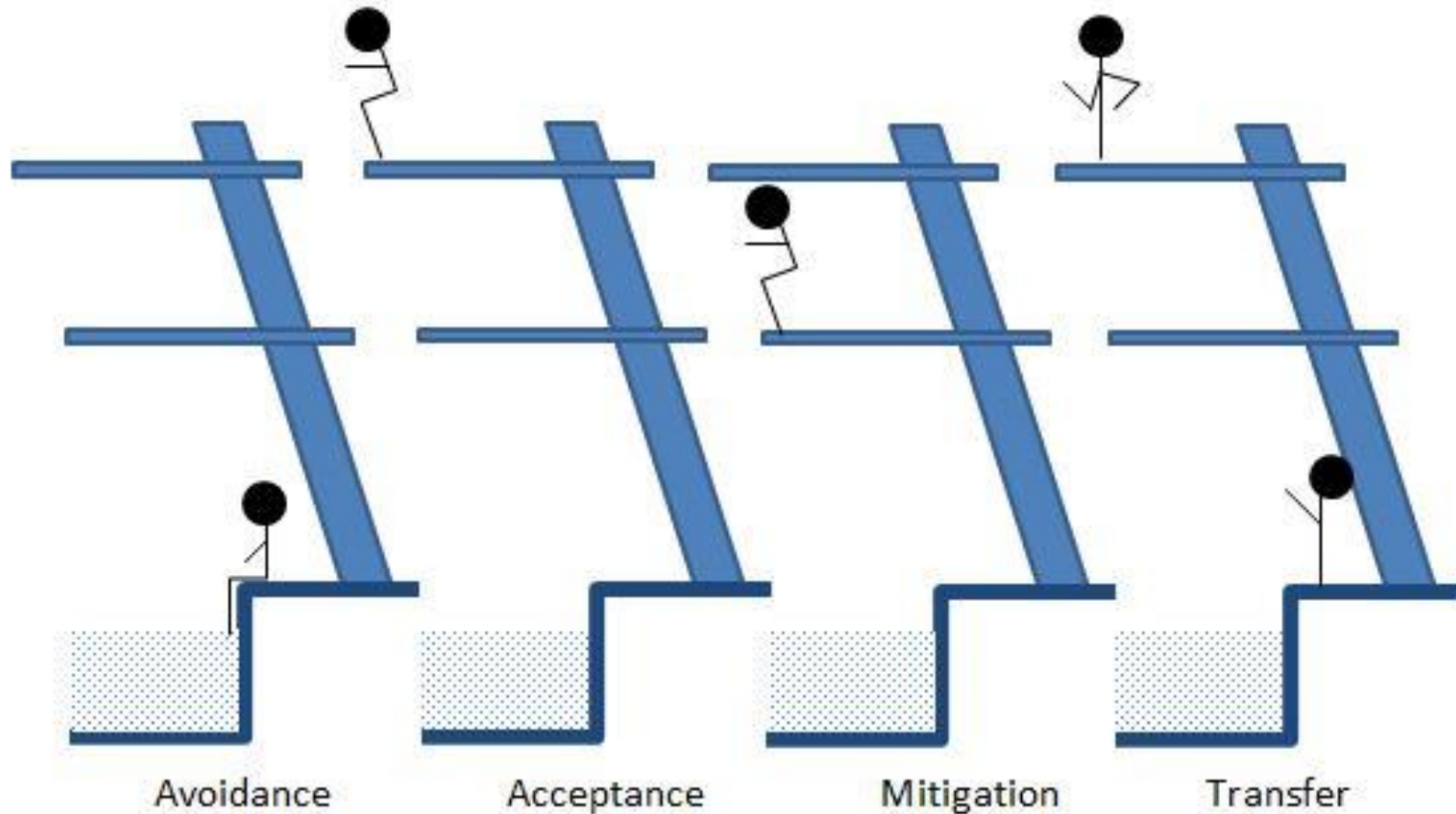
Risk Optimization



Risk evaluation – Heat map



Risk response strategies

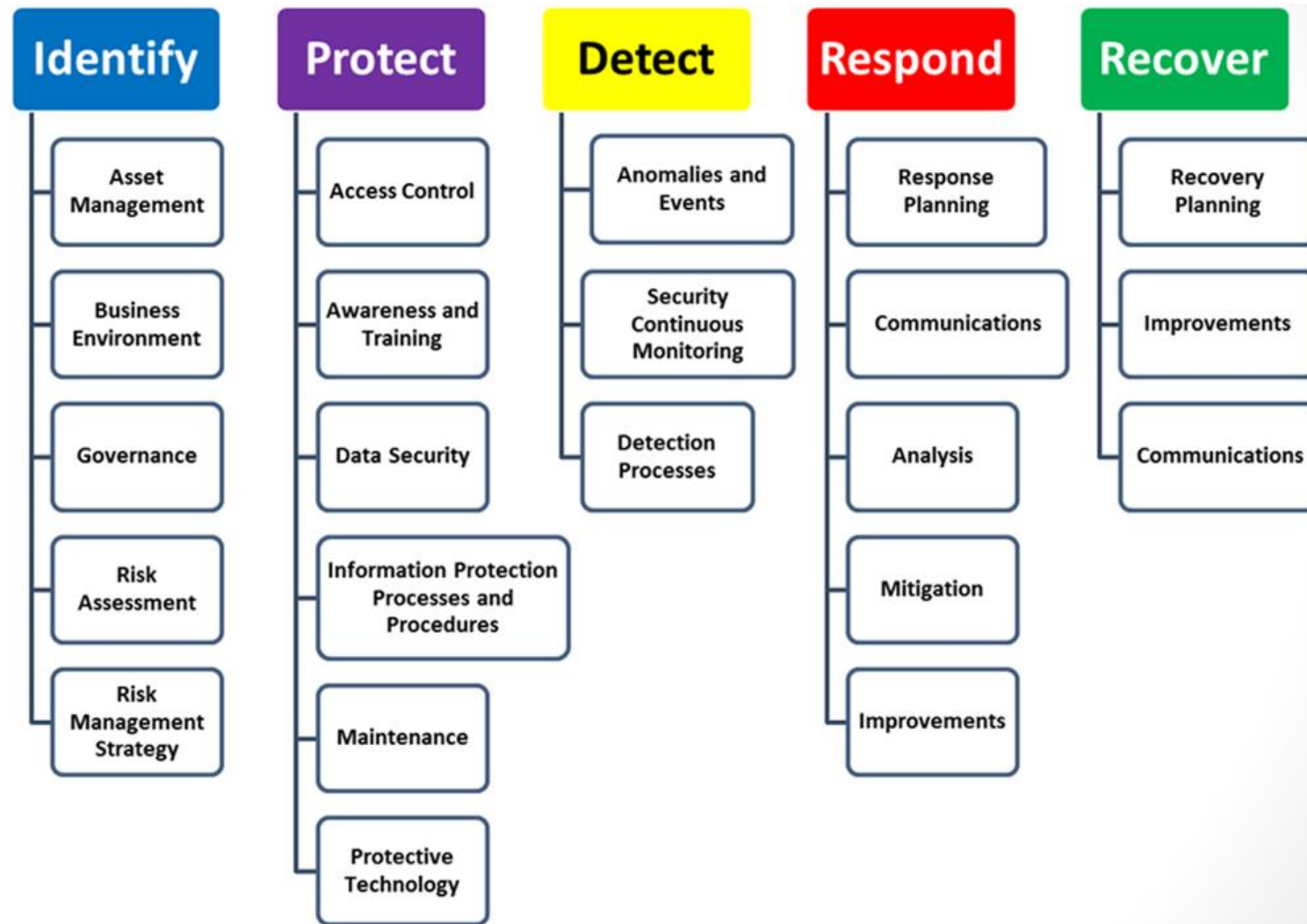


Strategies for dealing with risk

R. Jaffe

NIST CSF & Risk

Source: www.nist.gov/cyberframework



Other frameworks

This table shows the most popular cyber security frameworks in healthcare, according to the **2018 HIMSS Cybersecurity Survey**.

Table 17: Security Frameworks

Framework	N	percent
NIST	103	57.9%
HITRUST	47	26.4%
Critical Security Controls	44	24.7%
ISO	7	18.5%
COBIT	13	7.3%
Other	9	5.1%
No security framework has been implemented at my organization	30	16.9%
Don't know	15	8.4%

Q. Which of the following security framework(s) does your organization use? Please select all that apply.

HIMSS surveyed 239 healthcare information security professionals from Dec. 2017 through Jan. 2018 for the report. When asked to list the network security frameworks used at their organizations, respondents could select multiple answers.

Source: <https://www.calypsix.com/hipaa/top-5-cyber-security-frameworks-in-healthcare/>

Beyond the frameworks: S.T.O.P.

To address cybersecurity in healthcare we need to review:

STRATEGY:

- **No citadel to defend:** protection of an open city with a wide attack surface
- **Move from a siloes approach to an integrated and holistic approach to security.** All the information and automation technologies in the hospital must be addressed, regardless of who is responsible for what

TECHNOLOGY:

- **In technology assessment and acquisition, it is important to ensure that security is one of the basic requirements,** included by design in the technology under evaluation
- **In selecting the tools and services to support security, the IT department should incorporate an architectural vision** more than a mere evaluation of a single product in a traditional best-of-breed approach

PROCESSES:

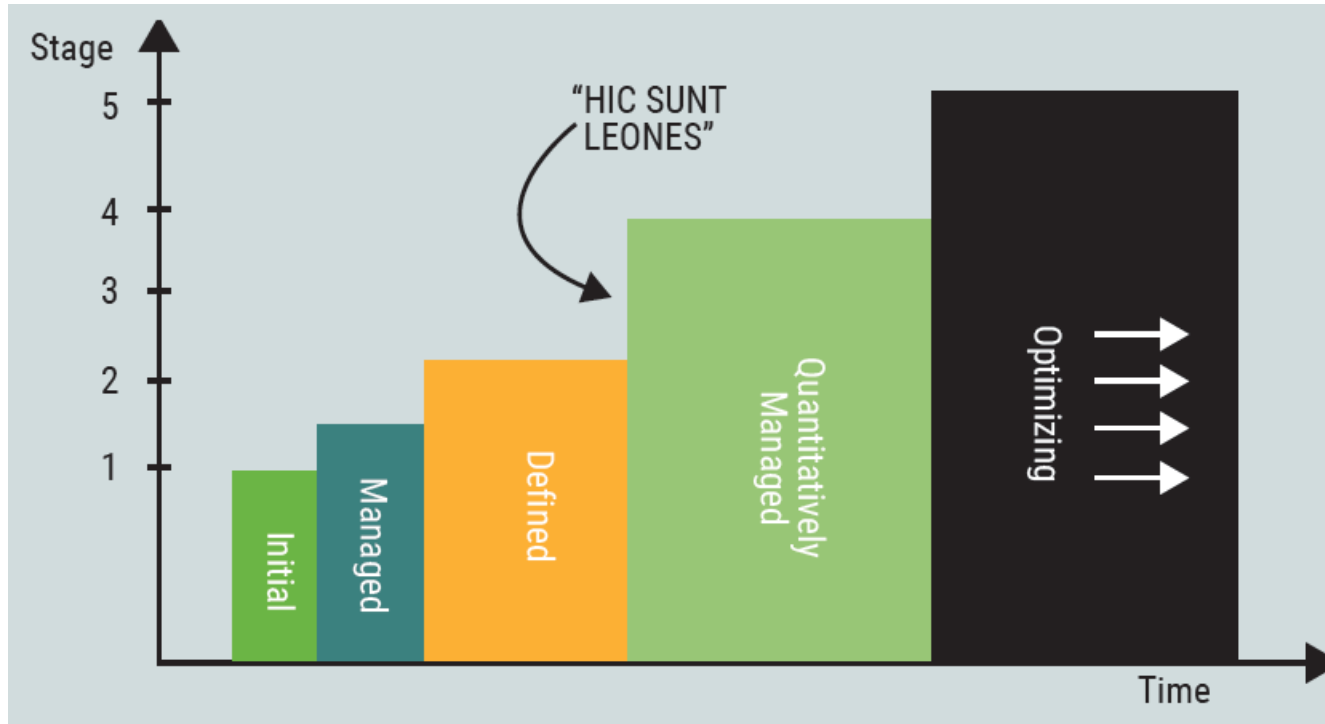
- **New methodology needed!** Beyond IT methodologies (IT Infrastructure Library [ITIL], COBIT® 5, International Organization for Standardization [ISO]/International Electrotechnical Commission [IEC] 27001) and Clinical Engineering Methodologies (health technology assessment [HTA])

ORGANIZATION:

- **Unification/coordination of different technology departments is a must!** The three typical technology departments in a hospital (facility, clinical engineering and IT) were born when buildings were walls and bricks, medical devices were dumb machines, and IT managed a well-defined set of applications and data.
- **Cross-fertilization and hybridation is a value!**

Final considerations: a proposal

Source: G. Pozza - Healthcare Security—Three Paradoxes and the Need for a Paradigm Shift (ISACA Journal – Vol. 3 2018)



The stages can be defined as follows:

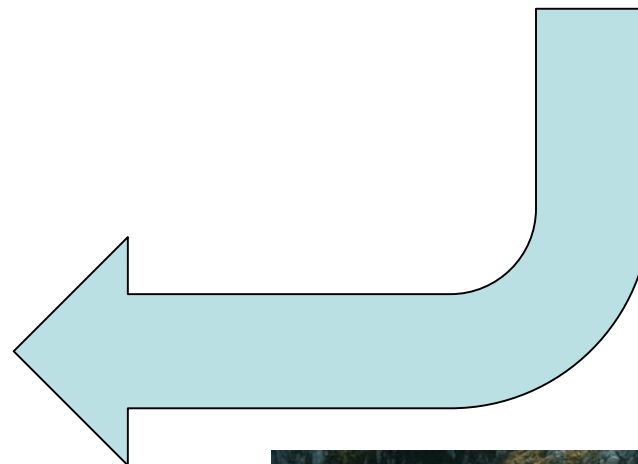
- **Stage 1 (Initial)**—“Local,” not structured, security management exists.
- **Stage 2 (Managed)**—Structured security management for ICT is in place. There is general awareness about security in other technical areas (using the ICT department as the internal expert on call). Risk assessment present.
- **Stage 3 (Defined)**—Coordination efforts and policies on security are in place among different technology areas (ICT, facility, clinical engineering), but no dedicated cross-border organization on security exists. A structured framework is used.
- **Stage 4 (Quantitatively Managed)**—A cross-border role on security (e.g., the CISO reporting to the CEO) oversees security strategy and policies with a 360-degree approach. At the departmental level, security is well managed, with key performance indicators (KPIs) and monitoring processes.
- **Stage 5 (Optimizing)**—Converged security strategy and the organization. The technology departments in the hospital are under a unified responsibility. Security and governance are managed with a holistic approach.

Final considerations: AISIS & AIIC

Sommario

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<u>Cybersecurity</u>	7
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That's one small step for a man, one giant leap for mankind!



The first joint document by C.I.O.s (AISIS) and Clinical Engineers (AIIC) on Cybersecurity & IoT in Healthcare!



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Takeoff tracks (personal bibliography)

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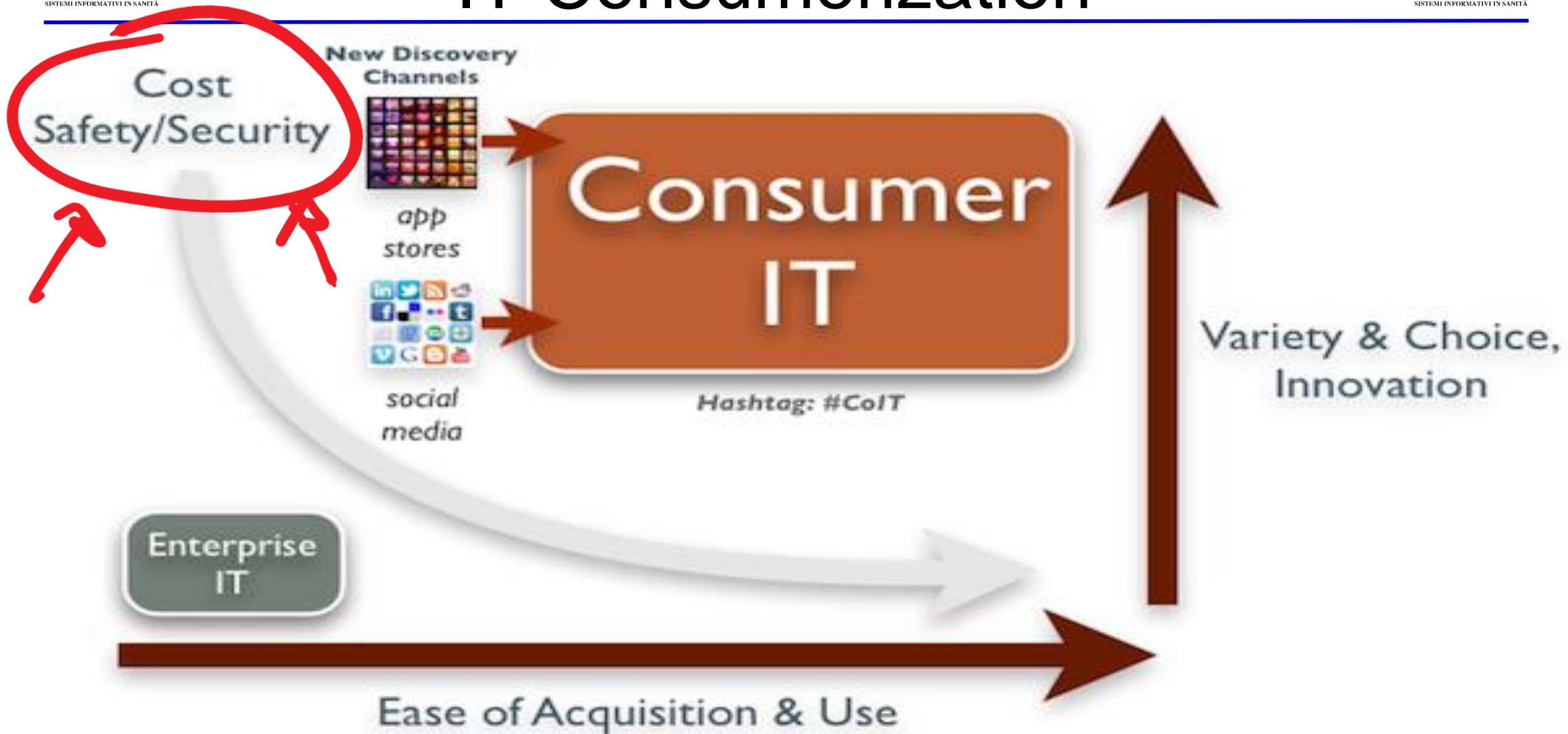
Q&A

Contact Info: giuliano.pozza@gmail.com or www.yottabronto.net



Back-up slides

IT Consumerization



Video-break: IBM Vision



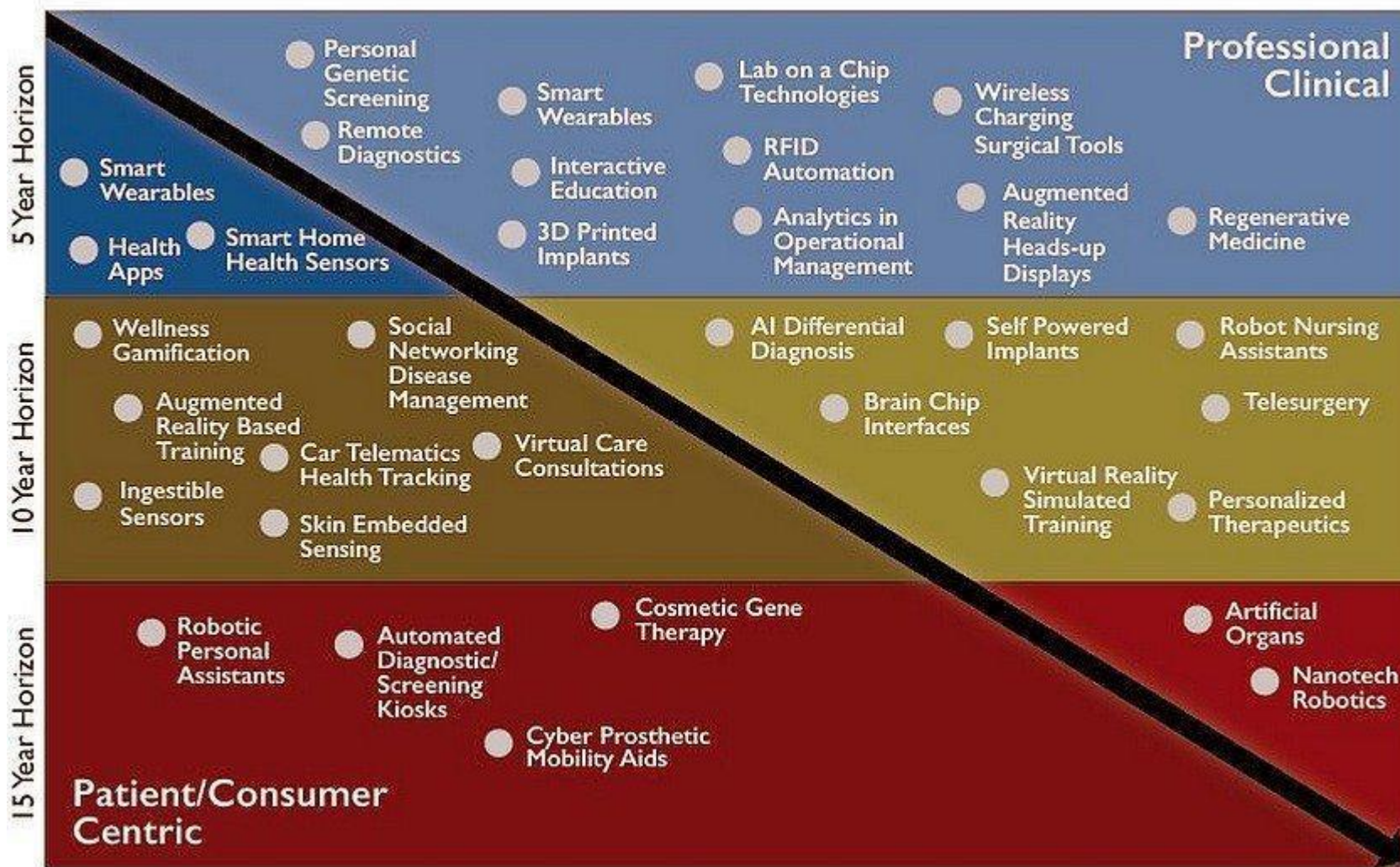
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Video-break: Microsoft Vision



<https://www.youtube.com/watch?v=-HWJ4sIzpXE>

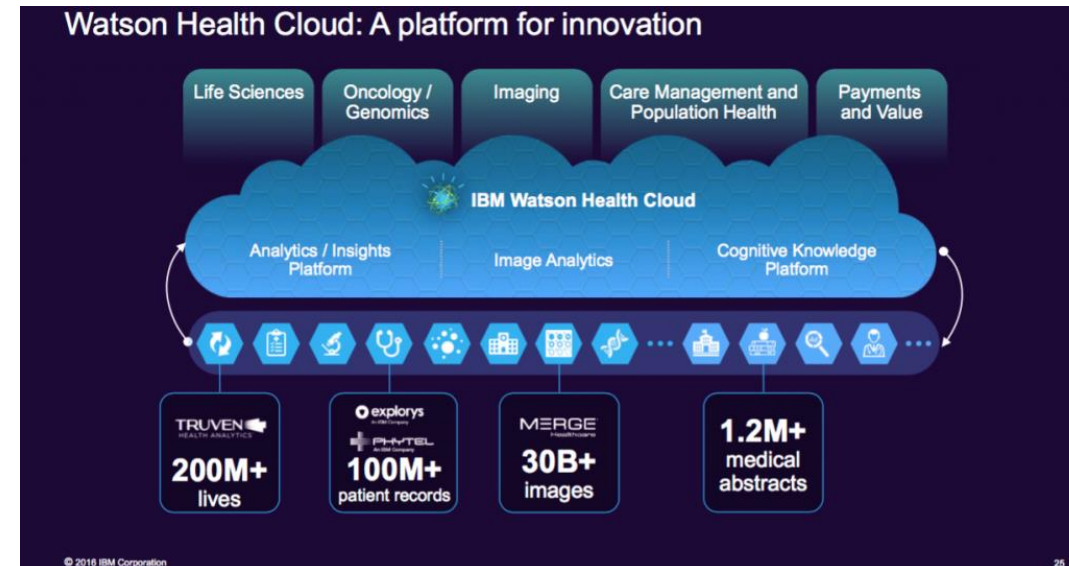
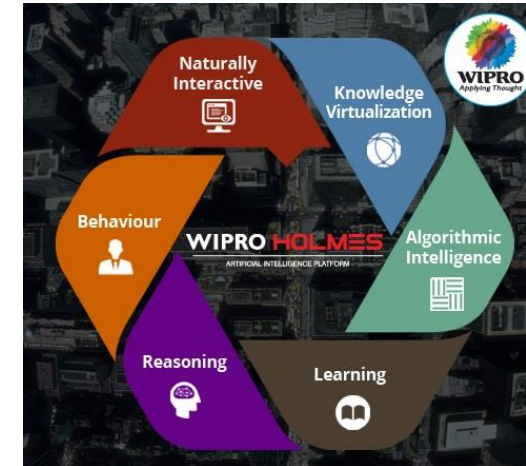
Appendice: Future of eHealth



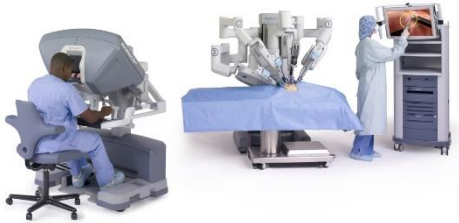
Source: Frost & Sullivan

Artificial/Augmented Intelligence

- Keywords (buzzwords):
 - AI weak or strong
 - Cognitive Computing
 - Machine Learning

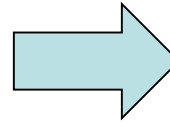


- Not new:
 - «Da Vinci»



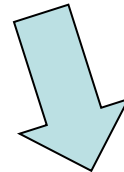
- New:
 - Medical emergency drones
 - HAL (Hybrid Assistive Limb)
 - Nanorobots (drugs targeted dispatching)
 - Tele-presence robots





DU and Guardtime Partner with Dubai's NMC Hospital to Revolutionize Electronic Health Records with Blockchain Technology

By Richard Kastelein - January 14, 2017



Estonia using Blockchain to secure health records

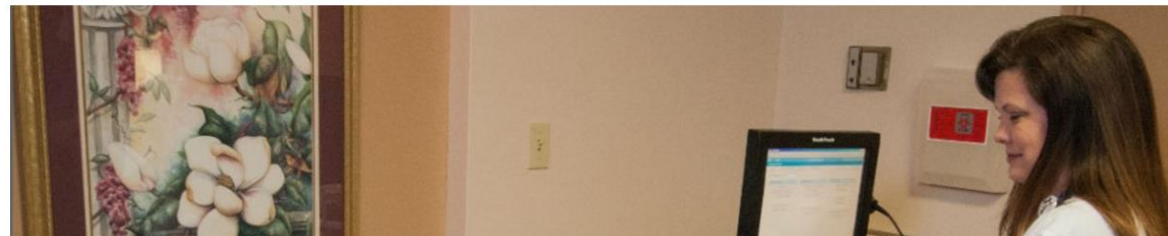
Blockchain's public sector use goes beyond payments.



By Medha Basu

6 MAR 2016

INNOVATION



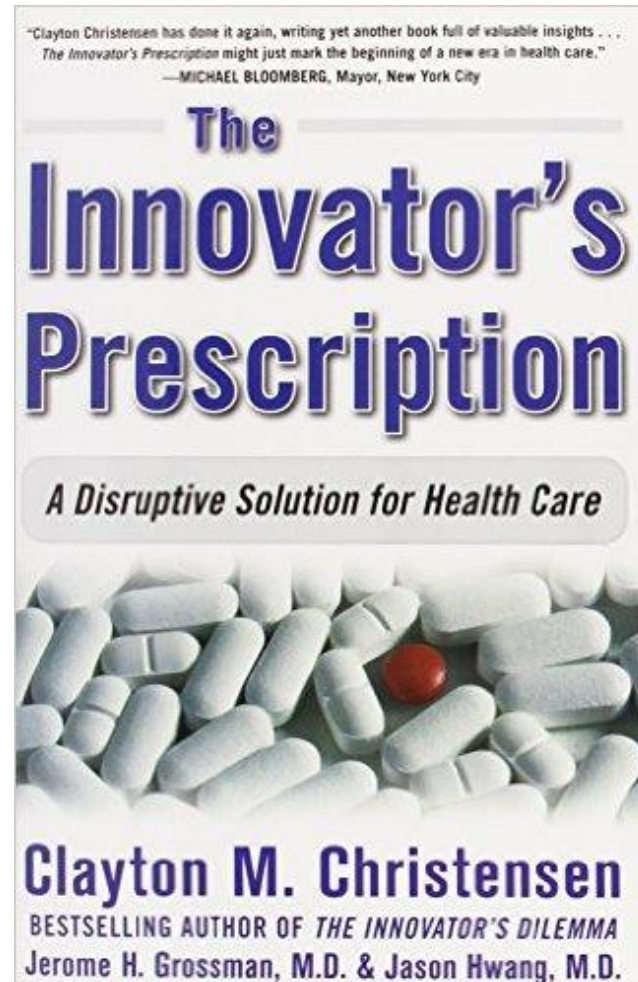
Video-break: Healthcare 2020

Oltre le tecnologie dell'informazione, medical devices, genomica, nanotecnologie...



<https://www.youtube.com/watch?v=totMfYaq8O8>

Nota: Innovator's Prescription



https://www.youtube.com/watch?v=tmKqt6jf_H0