# A Systematization of Cybersecurity Regulations, Standards and Guidelines for the Healthcare Sector

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#### Abstract

The growing adoption of IT solutions in the healthcare sector is leading to a steady increase in the number of cybersecurity incidents. As a result, organizations worldwide have introduced regulations, standards, and best practices to address cybersecurity and data protection issues in this sector. However, the application of this large corpus of documents presents operational difficulties, and operators continue to lag behind in resilience to cyber attacks. This paper contributes a systematization of the significant cybersecurity documents relevant to the healthcare sector. We collected the 49 most significant documents and used the NIST cybersecurity framework to categorize key information and support the implementation of cybersecurity measures.

### 1 Introduction

Worldwide, the *digital transformation of health services* is seen as an important and influential process, increasing the integration of technology in healthcare organizations, ranging from the use of computers and electronic health records to home monitoring of patients, electronic medical devices, and decision support systems [71].

Digital transformation affects many aspects of healthcare systems and allows for the improvement of service quality. For example, it is known that the adoption of telemedicine decreases hospital mortality rates without a significant increase in cost [19, 32].

However, the extensive integration of technologies into existing organizations has caused cybersecurity incidents to become an increasing challenge. Therefore, preventing, mitigating, responding to, managing emergencies, and recovering from cyber-attacks are critical responsibilities in the health domain nowadays.

To answer the above needs, several regulations, standards, and best practices on healthcare security have been proposed worldwide to help and guide health organizations in improving their cybersecurity preparedness. However, the correct application of regulations, standards, and best practices poses several issues. Firstly, these guidelines have been designed by different actors for various purposes, and their fragmented nature makes integration and application challenging (*issue1*). Furthermore, they often provide a high-level overview of security measures in a discursive manner without specifying the technical security policies that need to be implemented (*issue2*). Moreover, there is significant overlap among documents published by different sources, and different terminology is used to refer to the same concepts (*issue3*). Finally, the extensive use of legal jargon and cross-references to other regulations makes it difficult to parse and extract security-focused elements (*issue4*).

This paper proposes a systematization of the corpus of documents mentioned above to overcome these issues. We extract succinct and informative excerpts related to security and data protection from non-technical sources, and then provide a consistent view of the stated security measures by analyzing the degree of overlap and filling the gaps in coverage of security-related

aspects. To accomplish this, we began by analyzing a corpus of 68 documents to identify relevant ones. From these, we extracted excerpts of interest and mapped them to the NIST Cybersecurity Framework [65]. Based on each mapped excerpt, we defined a set of cybersecurity controls that can be effectively used to build cybersecurity plans.

We also present the methodology used to conduct our study and exemplify its application in the healthcare sector, discussing findings that highlight possible areas for improvement.

The paper is organized as follows: Section 2 provides background information on cybersecurity regulations, standards, and best practices issued worldwide in the healthcare sector and illustrates related proposals; Section 3 introduces our novel methodology for systematizing such corpus of documents, and describes its results; Section 4 discusses important findings identified through this systematization; Section 5 concludes the paper.

### 2 Background and Related Work

The corpus of documents that govern cybersecurity and data protection for healthcare organizations can be grouped into three categories: *Regulations, Standards*, and *Best Practices*. Each category is briefly described in the following.

**Regulations** are issued by an executive authority or regulatory agency and have the force of law. They can be national or international (for the national ones, in this paper we refer to the Italian regulations). One of the first security regulations for the healthcare sector is the U.S. *Health Insurance Portability and Accountability Act (HIPAA)* [38], 1996. The main goal of HIPAA was to protect Personally Identifiable Information (PII) and to preserve privacy while allowing individuals to access their medical records. HIPAA was updated in 2003 and 2013, adding requirements for managing Electronic Protected Health Information and implementing penalties for privacy violations. The EU *General Data Protection Regulation (GDPR)* [68], 2018, regulates the processing and circulation of personal data; GDPR recognizes health data as special data that requires greater protection and specific security measures. The European Union issued the *Regulation on Medical Devices (MDR)*, 2017, that presents cybersecurity requirements of medical devices [69].

**Standards** are documents set up by authority or general consent as a model or example to be compliant with. In the last few years, several Standards have been released to promote the development of security requirements for the healthcare sector, for example, the *ISO 27799 Health informatics* [47], 2016, provides an implementation guide for the controls described in ISO/IEC 27002 and supplements them where necessary. More recently, the *ISO/TR 21332 - Health informatics* [55], 2021, provides an overview of the security and privacy of Electronic Health Records (EHR) in a cloud computing service and the *IEC 80001-1* [42], 2021, specifies security requirements for connecting medical devices.

**Best Practices** are guidelines to be used in a particular business or industry (such as healthcare) to meet cybersecurity objectives and to be compliant with regulations. For example, the *NIST Security Rule -SP 800-66* [64], 2008, summarizes HIPAA security standards to support healthcare organizations to be compliant with HIPAA regulations. In Europe, ENISA published several documents; we mention the *Procurement guidelines for cybersecurity in hospitals*, 2020, [26] and the *European Commission's (EC) Medical Devices Coordination Group (MDCG)* published in 2020 a guide on how to fulfill all the essential cybersecurity requirements issued by the MDR and IVDR (In Vitro Diagnostic Medical Devices Regulation) regulations [61].

**Related work.** In the last ten years there has been a significant increase in the pace of publication about cybersecurity and healthcare [18]. The interest is motivated by the key role of Cybersecurity in the healthcare sector: any disruption in health services can be a disaster for patients' health, not only for organizations. In the following, we focus on studies that aim to provide a systematization for the large number of cybersecurity documents in the healthcare domain.

Jalali et al. [58] conducted a broad work on scientific literature: they surveyed 472 scientific contributions extracted from Pubmed and Web of Science at the intersection of cybersecurity and healthcare. Their findings show that most contributions focus on technological aspects, while 32% focus on managerial and policy-making topics. Differently from our work, they do not consider regulations, standards, and best practices, making their work complementary to our approach. Mohammed [62] discusses the compliance issues and challenges for healthcare organizations in the U.S., focusing on HITECH and HIPAA. The author lists among major challenges the vagueness and ambiguity of many of the prescriptions of those documents, similar to what we identified before.

Furthermore, it has been observed how cybersecurity standards and regulations are still uncertain, overlapping, and do not entirely address healthcare-specific concerns; as a consequence complying with cybersecurity rules is a challenging activity that involves time and expense for healthcare organizations, hindering their ability to develop adequate cybersecurity programs [23, 14, 20, 60, 21]. In [59] and [73] regulations and standards for medical device software are considered focusing on the device manufacturer as the intended target; our goal is to inform the management (i.e., CISOs and DPOs) inside healthcare organizations.

As a consequence of the aforementioned considerations, it is necessary to support healthcare organizations in navigating and making sense of these documents to support the extraction and modeling of cybersecurity measures.

### 3 Methodology

This section outlines a novel four-step methodology for the systematization of cybersecurity regulations, standards, and best practices that have been published over time for the healthcare sector. In the first step, we thoroughly searched public repositories to find documents of interest. In the second step, the documents are analyzed to identify excerpts that refer to technical security and governance measures. In the third step, cybersecurity excerpts are mapped on the Subcategories of the NIST Framework [65], and in the last step, a control definition procedure is carried out for each subcategory.

All the results and additional materials are available at this link: https://github.com/carelloSapienza/Systematization-healthcare.

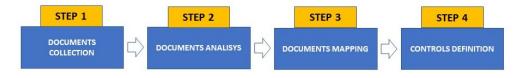


Figure 1: Methodology Steps

#### 3.1 Documents Collection

We explored the information available on the main official sources of European, International, and National regulators (e.g., ENISA, NIST, Salute.gov) using main searched keywords such as cybersecurity, privacy, electronic health record (EHR), medical device, telemedicine, cloud for healthcare.

A second round of research was conducted using the main indexing platforms (e.g., Elsevier Scopus, Google scholar, IEEE Xplore), and the primary searched keywords were: *cybersecurity* in healthcare, healthcare cybersecurity legislation, telemedicine security and privacy, cybersecurity of medical devices; security framework for healthcare. We performed a forward and backward analysis for each document or paper collected. Afterward, to refine the research, we constrained each collected document to two key requirements: (i) the regulation must be in effect, (ii) the document must address data security, privacy issues, or cybersecurity measures for healthcare organizations or public administrations. Therefore, we did not include works that address only manufacturers of medical devices, external service providers, or government agencies.

Examples of documents excluded, as not deemed of interest, are *ISO/TR* 17522:2015 Health informatics — Provisions for health applications on mobile/smart devices [45], focused only on interoperability, and *ISO* 14971:2019 Medical devices — Application of risk management to medical devices [50] that is specifically addressed to manufacturers of medical devices.

**Results.** This step allowed us to gather 68 potential documents of interest first, then narrowed to 49 documents by considering the key requirements. The final corpus, therefore, is composed of 11 regulations, 21 best practices, and 17 standards gathered by European (9), international (19), and national (21) sources.

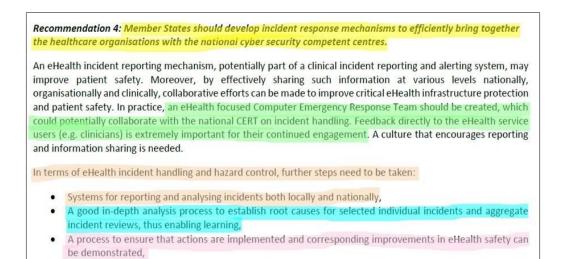
#### 3.2 Documents Analysis

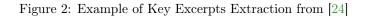
In this step, each of the 49 documents previously collected is accurately analyzed to identify key excerpts of text that refer to technical security and governance measures. A key excerpt of text is a sentence in a document that refers to areas of cybersecurity or data protection, such as information security policies, data privacy, incident management, etc. The identification has been performed manually by at least two members of our team with expertise in security governance, cybersecurity, and data protection. Once identified, the excerpt is extracted from its original document and collected in a table as output for the next step. Another group of information security specialists has regularly examined the collected excerpts to verify their relevance.

This step mitigates *issue* 4 helping to organize the texts and to extract only the relevant contents (security and data protection).

**Results.** Figure 2 shows an example of key excerpts identification on the document *Security* and *Resilience in eHealth Infrastructures and Services* [24].

To identify relevant key excerpts from non-relevant ones, consider the first sentence: "An eHealth incident reporting mechanism, potentially part of a clinical incident reporting and alerting system, may improve patient safety". This excerpt does not give any technical information and therefore is not a key excerpt. Conversely, the sentence highlighted in green asserting that "Computer Emergency Response Team should be created" and "could potentially collaborate with the national CERT" has been considered a relevant excerpt since it provides clear cybersecurity indications.





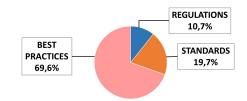


Figure 3: Documents Analysis: excerpts distribution

Based on the analysis of the 49 documents collected, we extracted approximately 2,800 excerpts distributed as depicted in Figure 3.

### 3.3 Documents Mapping

The excerpts identified in the previous step are listed in a table in their original form. To systematize them, we choose the **NIST Cybersecurity Framework v1.1** that provides a common ground and standard terminology for cybersecurity functionalities. However, since several key excerpts refer to data security and privacy, it was necessary to extend it. We leveraged the Italian Cybersecurity Framework [15, 16], retro-compatible with the NIST framework, that includes categories and subcategories dedicated to data protection. Each excerpt has been accurately assessed for its semantic content and linked to one or more subcategories of the framework.

For each excerpt, the *Function* it belongs to is first determined, followed by the assumed *Category* and then the appropriate *Subcategory*. An example of mapping is shown in Table 1. This step mitigates *issue* 3 by identifying, quantifying, and resolving overlap.

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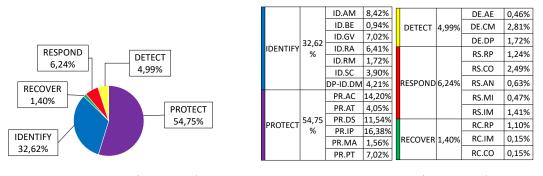


Figure 4: Mapping (Functions)

Figure 5: Mapping (Categories)

**Results.** The 2,800 excerpts have been mapped mostly in the *Protection* and *Identify* functions. Very few excerpts address *Respond*, *Detect*, and *Recover* functions, as visible in Figures 4.

#### 3.4 Controls Definition

In this step, the excerpts previously mapped are refined and modeled as cybersecurity controls. It is necessary to refine the excerpts to be syntactically uniform because they were retrieved from documents of various types, origins, and writing styles. For example, Best Practices have a purely technical nature and are made by sentences more direct and concise. In contrast, Regulations have a syntax typical of the legal world and are therefore made by sentences more discursive.

To define the controls and get a consistent and similar structure, *three key constraints* were enforced during their definition:

- 1. **Self-contained**: the control contains every element that is essential for its semantic completeness;
- 2. Homogeneous: the control faithfully complies with the semantics of the excerpt;
- 3. Verifiable: an application of the control must be verifiable through a well-defined quantitative or qualitative approach.

A unique identifier then enumerates each control to retain its traceability. By analyzing each excerpt in Table 1 and applying the constraints, one or more controls have been defined. For example, a thorough semantic analysis of the excerpt E2 led to the definition of three controls: ID.GV-2-01 and ID.GV-2-02 directly derived from the original text while ID.AM-6 has been added as an implicit requirement deriving from the former controls.

This step mitigates *issues 1 and 2* by uniforming the contents and supporting the implementation of technical security measures.

**Results.** At the end of this step, the approximately 2800 sentences extracted from the previous phase led to the definition of approximately **3,320 controls**.

The control definition's 15% increase over the sentences extracted confirms the heterogeneity and fragmentation of the excerpt's content. The distribution of controls is uniform among the framework's categories (see Table 1).

Excerpt Detail	Subcategory	Control Definition
E1: Member States should develop	PR.IP-9	PR.IP-9-01: Healthcare organi-
incident response mechanisms to ef-		zations develop incident response
ficiently bring together the health-		mechanisms to bring together with
care organizations with the national		the national cybersecurity compe-
cyber security competent centers.		tent centers
E2: An eHealth-focused Computer	ID.GV-2;	ID.GV-2-01: A Computer Emer-
Emergency Response Team should	ID.AM- 6	gency Response Team (CERT) has
be created, which could potentially		been created focused on eHealth.
collaborate with the national CERT		ID.GV-2-02: The CERT collabo-
on incident handling. Feedback di-		rates with the national CERT on
rectly to the eHealth service users		incident handling.
(e.g., clinicians) is extremely im-		ID.AM-6-01: Roles and responsibil-
portant for their continued engage-		ities are defined within the Com-
ment.		puter Emergency Response Team
E3: In terms of eHealth incident	RS.AN-5	RS.AN-5-01: Systems for report-
handling and hazard control, fur-		ing and analyzing incidents both lo-
ther steps need to be taken: Sys-		cally and nationally have been im-
tems for reporting and analyzing in-		plemented
cidents both locally and nationally.		

Table 1: Excerpts ext. & Controls Definition Document [24] Recommendation 4

### 4 Findings

Cybersecurity Controls Coverage. The first finding, depicted in Fig 3, is the large gap among the number of relevant excerpts extracted from Regulations and Standards compared to Best Practices.

The gap is mostly due to the nature of the documents themselves: *Regulations* have the lowest percentage of extracted excerpts (10,7%) because they are mostly discursive and do not address technological or procedural security measures, only stating general goals; *Best Practices*, on the other hand, have the highest percentage of excerpts (69,60%), since they are intended to serve as guidance for deploying cybersecurity measures, and therefore feature more technical and in-depth cybersecurity controls (*Finding 1*).

While Healthcare organizations experienced significant security incidents in recent years, with the majority of them caused by either phishing or ransomware attacks [14], there is still a lack of focus on how to address such threats. This is evidenced by the very low percentages of controls mapped on *Detect* (4,99%), *Respond* (6,24%), and *Recovery* (1,40%) functions, as shown in Figure 5. As a result, the documents focus mainly on the identification of cybersecurity perimeter and assets protection, with *Protect* (54,75%) and *Identify* (32,62%) being the most covered functions, rather than the detection and management of cybersecurity incidents during and after their deployment (*Finding 2*).

**Cybersecurity Topics Coverage.** The previous findings, were derived using the NIST Cybersecurity Framework. As it is a mostly operative framework, it gave us an idea of the less covered actions. To provide additional insights focused on evaluating the coverage of key cybersecurity and data protection areas, we used a second taxonomy suggested by the Report A Proposal for a European Cybersecurity Taxonomy [63], issued by the European Commission. We selected the most pertinent topics for the healthcare sector (eight) and used a three-stage approach to evaluate the coverage level for each topic. Firstly, the team assigned each subcate-

gory of the NIST Framework to one of the taxonomy's security topics. Secondly, we counted the number of controls that fell into a specific subcategory for each document based on the mapping performed in the Control Definition Step. Thirdly, we developed three levels of coverage based on the number of occurrences: *Low* if there were 1 to 3 controls that address the topic, *Medium* (4 to 6 controls), and *High* (more than 6 controls). Thresholds were derived from a statistical analysis of the distribution of extracted controls per document per subcategory. Figure 6 shows the topics addressed and the level of coverage for each document gathered, ranging from dark green for high coverage to white for no coverage. Using this approach, we provide an overview of documents coverage of cybersecurity topics and derive several findings.

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Administration Digital Code[4]		<u> </u>		6			1		
Tech.Measures Storage System 333]				10	-2 E		В		
Electronic Health Records (EHR) [5]									
Health Records Retention [1]		1			1				
Medical Dev. Incidents report.[36]		8		1	1				
Manag. Infor. hospital resign.[2]									
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Interoperability of EHR[6]			1		2	1			
Administrative Documentation [3]									
HIPAA [38]									
Medical Devices Reg. 2017/745 [69]		3	3		2				
ISO / IEC 20000 [53]									
ISO 27799[47]									
ISO 2 70 17[46]					X X		1		
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ISO 18638[49]									
ISO 2 2857[44]		3							-
ETSI TS 101 533-1 V1.2.1 [30]									-
ISO/TS 21547 [56]					5. S				-
ISO/TR 11636[43]		1	8		8				-
IEC 62 304 [41]			-						-
Cybersecurity Best Practices [52]		-							H
Electronic Health Records[37]					-	-			F
Disaster Recovery PAILU									
Secure Code Development[11]									
Software Frameworks Security[8]		-							-
Threats Modeling[9]				-					
Access Point Security for PA[12]			8	3	\$ \$				-
Manag. and Storing of DOC[13]									
Data Protection Code Conduct [66]		1	1	1					
Data Breach Notification[31]			2	1	ň.				
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MDCG 2019-16[61]			Ĩ.	)					
Health Cybersec. Task Force[39]	}	3			3				
SecureMedical DeviceDeploy. [67]									
HITRUST CSF[40]					li and a second				
NIST SP 800-66 Rev. 1[64]					÷				

Figure 6: Mapping Taxonomy

T1: Security Management and Governance (Figure 6 column A) is the most addressed topic (around 85%) demonstrating the high regard by the documents collected. Moreover, the security measures are addressed by many publications issued by different sources, implying that the topic's contents are heavily overlapping (*Finding 3*). In addition, many documents go deeper in their analysis (deep green color), and as a result, it could prove challenging to homogenize the security measures extracted. Unlike T1, T8: Assurance, Audit, Certif. (Figure 6 column B) is the least addressed topic, with some scattered contributions from standards and best practices, even if focused. Surprisingly, regulations do not provide cybersecurity controls in this area. Similar considerations can be made for topics T6: Incident Handling & Digital Forens. and T7: Education & Training. T6 presents a shallower coverage than T7, raising the possibility that the resulting security measures could be incomplete (Finding 4).

Analyzing Figure 6 from a document-based perspective, the coverage area is determined by the document typology: Regulations and Standards are more focused on specific topics, leaving others completely or partially uncovered, while Best Practices are broad and cross-topics. For instance, the standard ISO 17090 [48] (row C) focuses on a single topic (T2), analyzing it in depth and providing specific security measures. On the other hand, the National Best Practice for Electronic Health Record [37] (row D) covers a wider range of topics, where most of them are only given a shallow level of analysis, implying that the contents are overly generic (*Finding*) 5). An interesting analysis is to compare international and national coverage mappings (see Figure 7). Even among the National corpus of documents, the most popular topics are T1, T2: Data Security & Privacy, and T3: Identity Management. It indicates that the national context tends to mirror the trend of international publications on these topics. On the contrary, the remaining topics result less covered, both in terms of the number of controls and depth of analysis. Critical topics are T7 and T8, with the first addressed in less than 20% of the documents and the second addressed by only one best practice (Finding 6). Notice that there is a lack of standards in the list of national documents since all standards gathered during the collection step are issued by international entities.

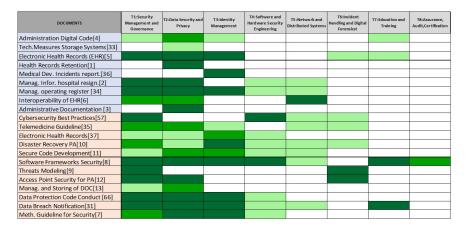


Figure 7: National Mapping Taxonomy

**Temporal trends.** The temporal analysis by date of publication confirms that cybersecurity is emerging as a top priority in the healthcare sector, with a steady increase in the pace of cybersecurity regulations, standards, and best practices publication since 2008.

As shown in Figure 8 there is a peak of publications in 2017 which may be related to the 2016

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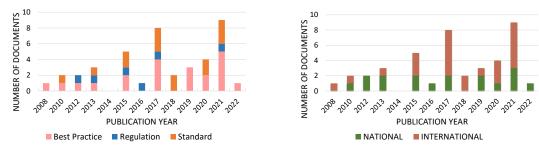
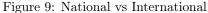


Figure 8: Analysis by document type



Hollywood Presbyterian ransomware attack (the first highly publicized cyberattack incident against a hospital) [17] and a second peak in 2021, when, among others, regulations on medical devices, along with related guidelines and standards, have been published (*Finding 7*). Furthermore, Figure 9 illustrates that national publications tend to follow a similar trend,

indicating that national authorities are attempting to keep up and align national regulations with international ones (*Finding 8*).

Actors. A healthcare system is an organization of people, institutions, and resources that delivers services for the population. We modeled, referring to literature, the healthcare sector as composed of five main providers, sorted by descending size:

- *Hospital*: an institution that provides diagnoses of disease, medical and surgical treatments, and nursing care for sick or injured people;
- *Private Structure* (e.g., Care Homes, Diagnostic Centers, etc. ): structure that performs several health services but cannot perform hospitalizations;
- Local Sanitary Unit: the integrated primary health care public service covering a well-defined population;
- *Clinical laboratory*: healthcare facility providing a wide range of laboratory procedures for diagnosis and treatment;
- *Medical practitioner*: a self-employed or publicly employed health professional who works independently.

For each provider, we defined the delivered services classified as primary (compulsory to provide) mapped in green, secondary (optional to provide) indicated in yellow, and services not provided indicated in red (see Figure 10).

Afterward, for each primary service, we analyze which cybersecurity controls, defined in the Controls Definitions Step, could be fitting for securing the service.

As a result, for each provider, we obtain the number of cybersecurity controls that should be coped with to improve the providers' cybersecurity posture distributed by functions and originating sources type (see Figure 10).

Due to the fewer services offered, Medical Practitioners need to cope with less than 60% controls compared to a hospital organization. Overall, Identify and Protect remain the most addressed functions, and there is a uniform distribution of controls derived from Regulations, Standards, and Best Practices (*Finding 9*). We notice that the number of controls to cope remains high, disregarding the target actor. More effort should be put in place to streamline their implementation, considering their priority and the security of secondary services.

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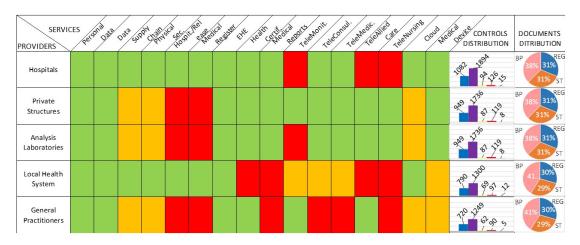


Figure 10: Healthcare Providers and Services

### 5 Conclusions

This paper systematized healthcare sector cybersecurity and data protection regulations, standards, and best practices, analyzing 49 documents and categorizing them using the NIST Framework. This resulted in 3200 security controls and nine findings, including that best practices present more technical controls than Regulations. We found an uneven distribution of controls for cybersecurity and data protection topics, particularly in the areas of Detect, Respond, and Recover. Future plans include updating the systematization with new documents, like NIS2, and utilizing the controls for cyber-posture assessments.

## References

- Circolare n. 61 del ministero della sanità del 19 dicembre 1986 n. 900 conservazione dei dati sanitari (1986)
- [2] Disciplina del flusso informativo sui dimessi dagli istituti di ricovero pubblici e privati (2000)
- [3] Testo unico sulla documentazione amministrativa (tuda) (2000)
- [4] D.Lgs. 7 marzo 2005, n. 82 (c.d. «Codice dell'Amministrazione Digitale ») (2005)
- [5] D.p.c.m. 29 settembre 2015 n 178 regolamento in materia di fse (2015)
- [6] Decreto 4 agosto 2017: Modalità tecniche e servizi telematici resi disponibili dall'infrastruttura nazionale per l'interoperabilità del fse (2017)
- [7] AGENAS: Indicazioni metodologiche sicurezza (2022)
- [8] AGID: Linee guida per la configurazione per adeguare la sicurezza del sw di base
- [9] AGID: Linee guida per la modellazione delle minacce
- [10] AGID: Linee guida per il disaster recovery delle pubbliche amministrazioni (2013)
- [11] AGID: Linee guida per lo sviluppo di codice sicuro (2013)
- [12] AGID: Linee guida sul punto di accesso telematico ai servizi della pubblica amministrazione (2021)
- [13] AGID: Linee guida sulla formazione, gestione e conservazione dei documenti informatici (2021)
- [14] Akinsanya, O.O., Papadaki, M., Sun, L.: "current cybersecurity maturity models: How effective in healthcare cloud ?". In: CERC. pp. 211–222 (2019)

- [15] Angelini, M., Ciccotelli, C., Franchina, L., Marchetti-Spaccamela, A., Querzoni, L.: Italian national framework for cybersecurity and data protection. In: Privacy Technologies and Policy: 8th APF, Lisbon, Portugal, Springer (2020)
- [16] Angelini, M., Lenti, S., Santucci, G.: Crumbs: a cyber security framework browser. In: IEEE Symp. on Visualization for Cyber Security (VizSec). pp. 1–8. IEEE (2017)
- [17] Argaw, S.T., Bempong, N.E., Eshaya-Chauvin, B., Flahault, A.: The state of research on cyberattacks against hospitals and available best practice recommendations: a scoping review. BMC medical informatics and decision making 19(1), 1–11 (2019)
- [18] Argaw, S.T., Troncoso-Pastoriza, J.R., Lacey, D., Florin, M.V., Calcavecchia, F., Anderson, D., Burleson, W., Vogel, J.M., O'Leary, C., Eshaya-Chauvin, B., et al.: "cybersecurity of hospitals: discussing the challenges and working towards mitigating the risks". BMC medical informatics and decision making 20(1), 1–10 (2020)
- [19] Armaignac, D.L., Saxena, A., Rubens, M., Valle, C., Williams, L.M., Veledar, E., Gidel, L.: Impact of telemedicine on mortality, length of stay, and cost among patients in progressive care units: Experience from a large healthcare system. Critical Care Medicine 46, 728 – 735 (2018)
- [20] Biasin, E., Kamenjašević, E.: Cybersecurity of medical devices: new challenges arising from the ai act and nis 2 directive proposals. International Cybersecurity Law Review 3(1), 163–180 (2022)
- [21] Burke, W., Oseni, T., Jolfaei, A., Gondal, I.: Cybersecurity indexes for ehealth. In: Proc. of the Australasian computer science week multiconference. pp. 1–8 (2019)
- [22] CEN: 16850 societal and citizen security guidance for managing security in healthcare facilities (2015)
- [23] Coventry, L., Branley, D.: Cybersecurity in healthcare: A narrative review of trends, threats and ways forward. Maturitas 113, 48–52 (2018)
- [24] ENISA: Security and resilience in ehealth infrastructures and services (2015)
- [25] ENISA: Healthcare certification (wp2018) (2018)
- [26] ENISA: Procurement guidelines for cybersecurity in hospitals (2019)
- [27] ENISA: Cloud security for healthcare services (2021)
- [28] ENISA: Nis investments (2021)
- [29] ENISA: Psirt expertise and capabilities development health and energy (2021)
- [30] ETSI: Ts 101 533-1 v1.2.1 technical specification, electronic signatures and infrastructures; information preservation systems security (2011)
- [31] GPDP: Linee guida in materia di dossier sanitario 4 giugno 2015 n164 notifiche data breach (2015)
- [32] Haleem, A., Javaid, M., Singh, R.P., Suman, R.: "telemedicine for healthcare: Capabilities, features, barriers, and applications". Sensors international 2, 100117 (2021)
- [33] Health, M.: Dpcm 3 dicembre 2013 regole tecniche in materia di sistema di conservazione (2013)
- [34] Health, M.: Decreto 7 dicembre 2016, n. 261 guida alla corretta compilazione e tenuta del registro operatorio (2016)
- [35] Health, M.: Linee guida telemedicina (2018)
- [36] Health, M.: Circolare del 8 luglio 2021 vigilanza sui dispositivi medici indicazioni per la segnalazione di incidenti occorsi dopo l'immissione in commercio (2021)
- [37] Health, M.: Fascicolo sanitario elettronico linee guida (2022)
- [38] HHS: Administrative simplification (2013)
- [39] HHS: Healthcare industry cybersecurity task force (2019)
- [40] HITRUST: Health information trust alliance common security framework
- [41] IEC: 62304 medical device software software life cycle processes (2006)
- [42] IEC: 80001-1 2021 application of risk management for it-networks incorporating medical devices (2021)

- [43] ISO: 11636 health informatics dynamic on-demand virtual private network for health information infrastructure (2009)
- [44] ISO: Health informatics guidelines on data protection to facilitate trans-border flows of personal health data. (2013)
- [45] ISO: 17522health informatics provisions for health applications on mobile/smart devices (2015)
- [46] ISO: 27017 information technology security techniques code of practice for information security controls based on iso/iec 27002 for cloud services (2015)
- [47] ISO: 27799 health informatics-information security management in health using iso/iec 27002 (2016)
- [48] ISO: 17090:2017 health informatics public key infrastructure (2017)
- [49] ISO: 18638:2017 health informatics guidance on health information privacy education in healthcare organizations (2017)
- [50] ISO: 14971 medical devices (md); application of risk management to md (2019)
- [51] ISO: 12967 health inform. service architecture-p.1: Enterprise viewpoint (2020)
- [52] ISO: 12967 health inform. service architecture-p.2: Information viewpoint (2020)
- [53] ISO: 20000-information technology-service management-system requirements (2020)
- [54] ISO: 22696-health informatics-guidance on the identification and authentication of connectable personal healthcare devices (2020)
- [55] ISO: 21332 health informatics cloud computing considerations for the security and privacy of health information systems. (2021)
- [56] ISO: 21547:2010 health informatics security requirements for archiving of electronic health records. (2021)
- [57] ISS: Buone pratiche per la sicurezza informatica nei servizi sanitari (2019)
- [58] Jalali, M.S., Razak, S., Gordon, W., Perakslis, E., Madnick, S.: Health care and cybersecurity: Bibliometric analysis of the literature. J Med Internet Res (2019)
- [59] Lechner, N.H.: An overview of cybersecurity regulations and standards for medical device software. In: Central European Conference on Information and Intelligent Systems. pp. 237–249. Faculty of Organization and Informatics Varazdin (2017)
- [60] Martin, G., Martin, P., Hankin, C., Darzi, A., Kinross, J.: "cybersecurity and healthcare: how safe are we?". Bmj 358 (2017)
- [61] MDCG: Guidance on cybersecurity for medical devices (2022)
- [62] Mohammed, D.: Us healthcare industry: Cybersecurity regulatory and compliance issues. Journal of Research in Business, Economics and Management 9(5), 1771–1776 (2017)
- [63] Nai-Fovino, I., Neisse, R., Hernández-Ramos, J., Polemi, N., Ruzzante, G., Figwer, M., Lazari, A.: A proposal for a european cybersecurity taxonomy. Publications Office of the European Union (2019)
- [64] NIST: Nist security rule (sp 800-66 rev. 1)-an introductory resource guide for implementing the hipaa security rule (2008)
- [65] NIST: Cybersecurity framework v1.1 (2018)
- [66] of organizations, C., istitutions: Proposta di codice di condotta per la protezione dei dati personali in sanità (2019)
- [67] OWASP: Secure medical device deployment (2017)
- [68] PARLIAMENT, E.: General data protection regulation (2016)
- [69] Parliament, E.: Regolamento (ue) 2017-745 sui dispositivi medici mdr (2017)
- [70] PARLIAMENT, E.: Directive of the european parliament and of the council on measures for a high common level of cybersecurity across the union, repealing directive 2016/1148 (2022)
- [71] Ricciardi, W., Pita Barros, P., Bourek, A., Brouwer, W., Kelsey, T., Lehtonen, L.: How to govern the digital transformation of health services. European J. of Public Health 29(Suppl. 3), 7–12

(2019)

- [72] Rule, H.A.E.I.F.: Hitech act health information technology for economic and clinical health act (2009)
- [73] Thomasian, N.M., Adashi, E.Y.: Cybersecurity in the internet of medical things. Health Policy and Technology **10**(3), 100549 (2021)