UNIVERSITY OF GENOA

MASTER'S PROGRAM IN BIOENGINEERING

Thesis submitted in partial fulfillment of the requirements for the title of Master of Bioengineering

Artificial Intelligence in Healthcare Systems: Clinical Impact, Economic Evaluation, and Policy Implications

Danilo Caserza

July 2026

Thesis advisor: Prof Marcello Montefiori

Abstract

Artificial intelligence (AI) and telemedicine are increasingly promoted as tools to improve efficiency, accessibility, and equity in healthcare. Yet their effects on care organisation and service use remain debated, especially in a region like Liguria. This thesis examines AI and telemedicine in the Ligurian healthcare system through three analyses: a review of European and international AI regulation; a regional survey on digital innovation adoption, conducted with Regione Liguria; and a specific analysis of telemedicine's impact among cardiology patients of ASL3.

The regulatory review places Italy and Europe within a comparison with the United States, China, and the European Union, up to the EU AI Act and Italy's national AI legislation. The survey, covering nine Ligurian healthcare institutions, shows uneven diffusion of digital innovation: AI accounts for 57% of the projects identified, but this result is driven almost entirely by a single institution, while telemedicine is more evenly distributed. Although cardiology is among the clinical areas most involved in digital innovation projects, no active AI applications are reported in this field, unlike the concentration of AI initiatives in image-based diagnostics.

The empirical core evaluates telemedicine among 10,295 cardiology patients treated within ASL3 in 2024. Using propensity score matching and negative binomial regression, telemedicine use is associated with a significant increase in total specialist visits and cardiology-specific visits, with no statistically significant effect on urgent or planned hospitalisations. These findings suggest that telemedicine complements, rather than replaces, traditional care, strengthening outpatient follow-up without reducing hospital-based services. Overall, the results support policy recommendations on data governance, stable funding for telemedicine as a continuity of care tool, and closer alignment between AI investment and clinical needs.

Index

5 Interpretation of Results and Policies

References

1 Introduction to Artificial Intelligence in Healthcare

Artificial intelligence (AI) is a branch of computer science that builds programs able to carry out tasks that normally need human intelligence, recognising patterns, learning from experience, or making decisions. It brings together several related areas, including Representation Learning (RL), Machine Learning (ML), Deep Learning (DL) and Natural Language Processing (NLP), all aimed at getting computers to imitate how humans think and solve problems (shul et al., 2015).

Often "Artificial Intelligence" and "Machine Learning" are confused with the same meaning, but they are not identical: AI is the broader idea, and Machine Learning is one way of achieving it. In medicine, AI uses computer algorithms to pull useful information out of raw data, helping doctors make more accurate decisions (Char et al., 2020).

Machine learning is the part of AI that focuses on finding patterns in data automatically, without being told exactly what rules to follow. Rather than following fixed instructions, an ML model learns from examples. This makes it possible to work with huge amounts of information, far more than a person could realistically go through by hand, which is especially useful in medicine, where data can include patient records, lab results, and images.3

Building a machine learning model usually follows the same basic steps: choosing a suitable algorithm, training it on a dataset where the outcomes are already known, and testing how well it performs on new data. A medical dataset might include a patient's age, symptoms, test results, or scans; these individual pieces of information are called "features," and the model uses them to spot patterns and make predictions, for example, about how well a treatment might work.4

There are two main ways a model can learn. In supervised learning, the model is trained on data where the correct answer is already known, for instance, whether a patient has a disease, making it well suited to tasks like diagnosis or drug discovery. In unsupervised learning, the model is given data with no predefined answers and must find structure on its own, for example by grouping similar patients together (Vamathevan et al., 2019). This is useful for spotting disease subtypes, catching unusual patterns in scans that might be missed by eye, or making sense of continuous data from wearable devices such as heart rate or blood sugar monitors.

Which method works best depends largely on the size and type of data available. Simpler, traditional methods, like decision trees or logistic regression, tend to work well with smaller datasets and are

easier to understand, which matters in medicine, where knowing why a model decided can be as important as the decision itself.

Deep learning is better suited to very large and complex data, such as medical images or genetic sequences, but needs much more data and computing power, and its results are harder to explain, often described as a "black box." Because this lack of transparency is a real concern in healthcare, researchers are increasingly working on "explainable AI" methods that try to show which factors are driving a model's predictions (Shaban-Nejad et al., 2021).

The data feeding these models come from many sources, electronic health records, genetic databases, smartphones, sensors, and wearable devices. This has allowed AI to move well beyond its earliest and best-known use, reading medical images such ECGs, plain radiographs, computed tomographic (CT) and magnetic resonance imaging (MRI) and X-rays, where it already helps doctors by flagging anything abnormal. Today, AI is also used to spot infectious disease outbreaks, combine clinical and genetic data to catch rare conditions, and support day-to-day hospital operations.

Cardiovascular medicine has become one of the most active areas for applying artificial intelligence in clinical practice. Because so many cardiology decisions rely on digitised, patient-specific data, ECGs, echocardiograms, CT and MRI scans, it is a natural fit for AI methods that can process large volumes of complex data and identify connections a clinician might not spot by eye (Sau et al., 2023).

As in other medical fields, the AI methods used span supervised approaches (artificial neural networks, support vector machines), unsupervised approaches (clustering), and deep learning methods (convolutional and recurrent neural networks), each suited to different tasks.

The most established use of AI in cardiology is analysing the standard 12-lead ECG, a cheap, widely available test whose interpretation has traditionally depended heavily on the reading clinician's experience. AI models can detect subtle patterns in the ECG signal invisible to the human eye, with promising diagnostic accuracy across several conditions. For valvular heart disease, AI-enhanced ECG has been used to screen for aortic stenosis in asymptomatic patients, an area where conventional echocardiography is too costly to use as a general screening tool.

Similar approaches detect atrial fibrillation even when a patient's rhythm looks normal at the time of testing, coronary artery disease, reduced heart pump function in heart failure, cardiomyopathy, and, in prenatal ultrasound, congenital heart disease.

A consistent theme emerges: AI does not replace the gold-standard test, but offers a low-cost, scalable way to flag patients needing further evaluation, particularly valuable for conditions that are often asymptomatic until relatively advanced.

AI is also making established imaging techniques faster and more consistent. In echocardiography, AI models can automatically calculate left ventricular ejection fraction, traditionally a manual, time-

consuming task, with accuracy comparable to trained clinicians, and can flag abnormal wall motion suggestive of prior myocardial infarction. Comparable approaches improve the speed and accuracy of coronary CT angiography and cardiac MRI, including automated quantification of stenosis, myocardial blood flow, and plaque burden.

AI, typically unsupervised clustering, is also used to identify clinically meaningful subgroups within otherwise heterogeneous patient populations: for example, identifying which heart failure patients are most likely to benefit from cardiac resynchronisation therapy, characterising atrial fibrillation phenotypes linked to different prognostic risk, or distinguishing hypertension subtypes that call for different management. The rationale is that one-size-fits-all treatment strategies often underperform in populations that are biologically heterogeneous; AI-based clustering offers a data-driven way to better match patients to the treatments most likely to help them.

AI models have also been developed to predict longer-term cardiovascular outcomes, frequently using ECG data as an input, including models predicting one-year all-cause mortality from ECG waveforms, "ECG-derived age" as a marker of vascular ageing linked to future cardiovascular events, and risk scores incorporating retinal imaging, coronary calcium scoring, and outcome prediction following cardiac surgery.

Remote monitoring (RM) of cardiac implantable devices, pacemakers, defibrillators, and resynchronisation devices has become increasingly important as the number of implants and the complexity of patient follow-up have grown. RM devices automatically send data on device function and clinical parameters to a secure web platform, alerting the care team if something goes wrong, without ever allowing the device itself to be reprogrammed remotely (Ricci et al., 2015).

Clinical trials have repeatedly shown RM to match or outperform traditional in-person follow-up: studies report 50-56% fewer hospital visits, earlier detection of arrhythmias such as atrial fibrillation (often months sooner than scheduled checks), fewer inappropriate shocks, longer device battery life, and, in several large studies, improved patient survival.

In Italy, RM is typically organised through a "primary nurse" model, in which a dedicated nurse manages each patient's ongoing care under a doctor's supervision. Despite these clinical and organisational benefits, Italy, unlike Germany, the UK, or the US, still has no formal reimbursement for RM services, which remains a real barrier to its wider use, even though an estimated 30,000 Italian patients are already followed this way (Ricci et al., 2015). This gap is directly relevant to the broader diffusion of telemedicine services, including televisits, examined in this study.

Several limitations affect this clinical adoption. As with AI in medicine more broadly, the interpretability of deep learning models remains a central concern: because their internal workings are not easily understood even by their developers, it is often unclear which features drive a given

prediction, limiting clinicians' confidence in adopting them (Sun et al., 2023). Most existing evidence also comes from single-centre studies with relatively narrow patient populations, meaning larger, more diverse validation is still needed. Finally, the cost-effectiveness of integrating AI tools into routine cardiology practice remains an open question.

2 Regulatory and Legal Framework

2.1 The European AI Act: Establishing the Legal Framework for Digital Health

The European AI Act is the first-ever comprehensive legal framework on AI worldwide. The aim of these rules is to promote trustworthy AI in Europe, introducing risk-proportionate compliance obligations that bind both the developers of the models and the deployers who implement them in specific use cases (Regulation (EU) 2024).

It all began on April 21, 2021, when the European Commission presented the first formal draft of the regulation. After a review and negotiation process, the final text was approved by a large majority in the European Parliament on March 13, 2024, subsequently receiving the decisive unanimous approval from the Council of the European Union on May 21, 2024. On July 12, 2024, the regulation was officially published in the Official Journal of the European Union.

The AI Act entered into force in August 2024 and was fully applicable 36 months after its entry into force, in August 2027. However, regulated entities were required to comply with the initial set of rules by February 2025. This marks a turning point in the regulatory oversight of AI systems in the EU, designed to give companies and institutions time to progressively adapt to the new European regulatory framework (Regulation (EU) 2024).

The Regulation aims to support the adoption of AI technologies across various social and economic sectors while ensuring a uniform level of protection for public interests regarding health, safety, and fundamental rights throughout the European Union. This legislative milestone is particularly significant for the healthcare sector, where the use of AI products for diagnosis, treatment, and patient care is rapidly increasing. (Article 113 EU AI Act.)

The second milestone occurred in August 2025, the date when specific transparency rules and obligations for General Purpose AI (GPAI) models become applicable, and when Member States are required to officially designate their national supervisory authorities.

The turning point for the entire regulatory framework will occur on August 2, 2026, twenty-four months after its entry into force: on this date, the AI Act will become applicable in its general structure. Transparency obligations will take effect (such as mandatory labelling for deepfakes and AI-generated content), and, above all, the strict requirements for "stand-alone" high-risk systems will enter into force.

The implementation cycle will definitively conclude on August 2, 2027. Thirty-six months after the start of the process, the strictest rules will also be extended to all the high-risk systems listed (Regulation (EU) 2024/)

For the healthcare domain, the AI Act is particularly important for application of the technologies adopting artificial intelligence in their practices.

Other existing legislations, such as the Medical Device Regulation (MDR) that regulates products with an intended medical purpose on the EU market, classifying them from low-risk Class I (e.g., bandages) to high-risk Class III (e.g., implantable pacemaker)) or the In Vitro Diagnostic Medical Device Regulation (IVDR; regulates in vitro diagnostic devices with an intended medical purpose on the EU market, categorising them from Class A (low-risk) to Class D (high risk), but these do not explicitly cover medical AI applications (European Commission, 2021).

To fully implement the safety objectives established by the European MDR, Italy is establishing the National Unique Registry of Implantable Medical Devices (RUNDMI) to monitor high-risk devices such as pacemakers. This centralized database strictly obliges physicians and manufacturers to register data for every implant, ensuring the immediate traceability of patients in the event of adverse incidents or technical defects. By doing so, the State bridges a regulatory gap, equipping itself with a robust tool to independently assess long-term clinical safety and optimize healthcare expenditure (Presidenza del Consiglio dei Ministri, 2026).

In addition, not all AI applications that can be adopted in the healthcare sector necessarily fall within the scope of the MDR or IVDR, e.g., general-purpose large language models (LLM) such as ChatGPT2,3 (European Commission, 2021). While regional frameworks like the AI Act and MDR aim to ensure safety and compliance within Europe, the global nature of AI innovation also demands broader international coordination, a need that was recently addressed at the AI Action Summit

The AI Action Summit is an international event held at the Grand Palais in Paris in February 2025, under the French and Indian presidency.

The summit followed the AI Safety Summit, hosted in 2023 at Bletchley Park in the United Kingdom, and the AI Seoul Summit, held in 2024 in Seoul, South Korea. The Declaration agreed at Paris, signed by fifty-seven states and bodies such as the UN, the OECD, and the European Commission, reflected common concerns around the impact of AI on values such as sustainability, human rights, inclusivity and the future of work.

The declaration was signed by 61 countries (including China, France, and India): the document, entitled *Statement on Inclusive and Sustainable Artificial Intelligence for People and the Planet*, envisions the creation of an open, inclusive, and ethical artificial intelligence, as well as global coordination and dialogue to prevent excessive market concentration. The text presents declarations of principle, but no concrete action plan to be taken. (13)

European Commission President Ursula von der Leyen emphasized that "AI needs the trust of citizens and must be safe," but she also acknowledged concerns regarding regulatory burdens.

He also announced that the "InvestAI" initiative has reached a total of €200 billion in AI investments across Europe, including €20 billion dedicated to gigafactories.

2.2 Regulatory Tiers and Compliance in the AI Act

The AI Act adopts a risk-based approach, as illustrated in Figure 1, establishing clear classifications and regulatory frameworks. Specifically, it prohibits AI practices that pose an unacceptable risk while defining strict compliance obligations for high-risk systems and general-purpose AI (GPAI) models. Conversely, AI systems presenting limited, minimal, or no risk are subject to minimal transparency requirements or operate without specific legal obligations. While AI systems are supervised by national market surveillance authorities, the supervision of GPAI models and systems is carried out by a newly established AI Office at the EU level.

Most rules in the AI Act apply to providers that are the developers of AI systems. This means that most of the time, the provider obligations only apply to the tech company that developed the AI software, tool, or device and placed it on the market (4).

However, as some healthcare organisations such as hospitals and long-term care homes are developing AI systems for their own use, these rules also apply to them. This means that health professionals using AI for healthcare activities must comply with the rules stipulated for deployers. The same goes for public deployers such as public health authorities. The obligations of deployers are however limited (4).

In the higher level of risk there are certain AI practices that are prohibited from the AI-act due to their unacceptable risks. Examples are including purposefully manipulative and deceptive practices, exploitation of vulnerabilities, biometric categorisation, social scoring, 'real-time' remote biometric identification, risk assessments for criminal offences, and facial recognition and emotion inference (4).

Non-compliance with these prohibitions can lead to severe penalties of up to 35 million EUR or 7% of annual turnover for companies. However, the AI Act provides some exceptions for medical uses. For example, the prohibitions on manipulative and exploitative practices do not affect lawful practices in the context of medical treatment, such as psychological treatment for mental illness or physical rehabilitation, when carried out following applicable laws and medical standards and with the explicit consent of individuals or their legal representatives.

Similarly, facial recognition and emotion recognition systems may be permitted for medical reasons (4).

AI Systems classified with High-risk (e.g. AI diagnostic tools), must comply with certain safety and quality requirements, and operators have specific obligations regarding their use. In the healthcare sector, these obligations primarily apply to AI medical devices that are required to undergo a third-party conformity assessment by the EU MDR Article 6 AI Act). Generally, this means that only medical devices of risk class IIa or higher, used for medical purposes of diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, injury, or disability, that are using AI, are considered high-risk AI systems. More additional health-related uses of AI are also considered high-risk, such as AI to evaluate and classify emergency calls or dispatch emergency first response services, including medical aid (5). General-purpose AI systems can fall into the high-risk.
High-risk AI sistems are bound to stringent requirements, such as risk management, data governance, and human oversight. For AI medical devices, these obligations supplement the rules provided for in the EU MDR, which require a third-party conformity assessment. The AI Act thus creates an extra level of regulation for AI medical devices which will be integrated into the regular conformity assessment for medical devices. (5)
A system falling under these circumstances may be exempted from high-risk system obligations if it performs limited and preparatory functions, without replacing or influencing human assessment without adequate supervision. Consequently, common administrative tasks in the medical field, such as ICD-10 coding or the structuring of radiological reports, are not generally classified as high-risk.
General Purpose AI models can be deployed as standalone high-risk systems or as components of other AI systems, regardless of their risk classification. For this reason, they are always subject to specific requirements, given their capability to perform a multitude of tasks (6). GPAI models are classified into presenting systemic risks, a risk that is specific to the high impact.
Most other health-related AI tools that do not serve a purely medical purpose and thus do not fall under the definition of the EU MDR, are considered low-risk AI. This also applies to medical devices that are not required to undergo a third-party conformity assessment (Class I).
These systems only need to comply with certain transparency requirements because of their direct interaction with individuals, such as chatbots providing advice on wellbeing. There are no rules for minimal-risk AI systems that do not interact directly with individuals such as AI for hospital administration (7).
Irrespective of the risk classification, all models, including GPAI, must fulfil additional transparency obligations if they are intended to interact with natural persons or to generate content, such as text, image, and video content. In the healthcare sector, this could be the case for virtual health assistants and chatbots.

The concrete impact of the AI Act on medical AI development remains partially unclear. Prohibited practices are unlikely to affect the healthcare sector, given the explicit exemptions for lawful medical purposes. However, the high-risk classification will have a significant practical impact: approximately 75% of all commercial AI-enabled medical devices on the market are radiology-related, virtually all of which are classified as Class ≥ IIa under the MDR, and thus automatically qualify as high-risk AI systems. These devices must comply with the high-risk requirements within 12 months of the AI Act entering into force (8).

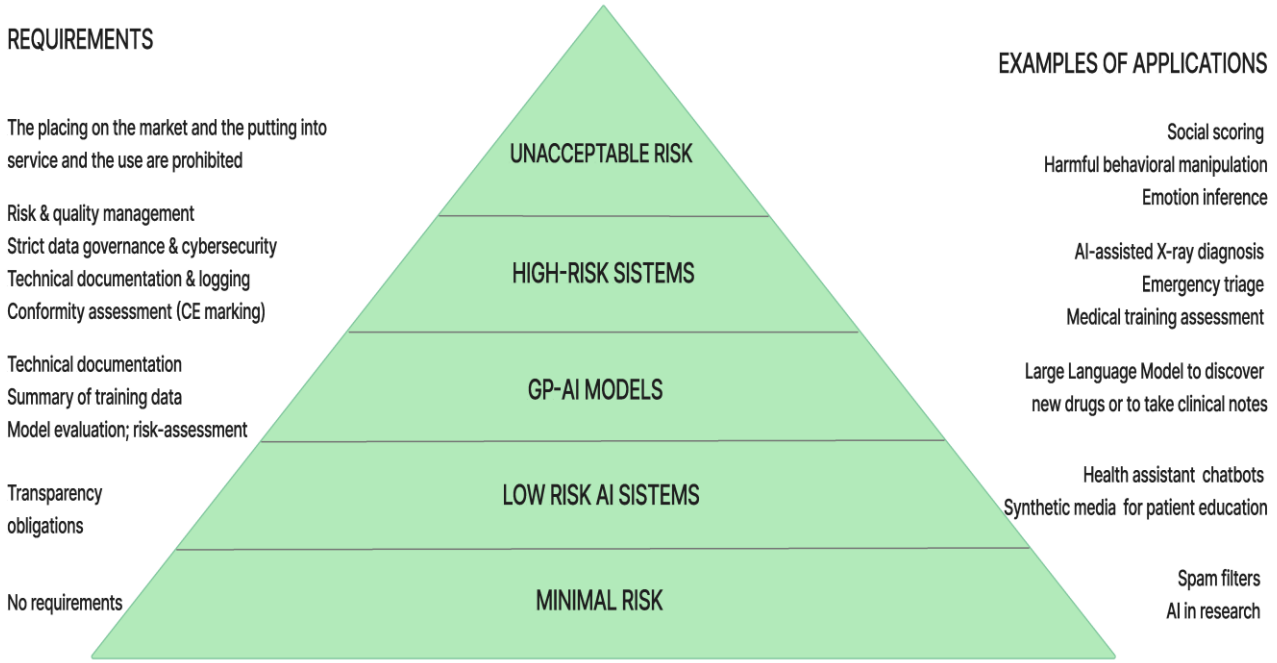


***Figure 1**: Pyramid diagram illustrating the EU AI Act's risk categories, detailing the corresponding compliance obligations and practical healthcare use cases ranging from minimal-risk tools to high-risk diagnostic systems.*

2.3 Data Protection Frameworks: Privacy Challenges in AI-Driven Healthcare

Formally Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR) is the EU's general legal framework governing how personal data of individuals is processed, structured across eleven chapters with 173 recitals and 99 articles defining terms and cross-references. It was adopted in April 2016 with a two-year transition period before becoming binding on 28 May 2018, replacing the earlier Directive 95/46/EC. Its reach applies to any organization worldwide that processes the personal data of people in the EU, not just EU-based companies (Chung et al., 2025).

Everything is based on seven principles set out in Article 5: lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy; storage limitation; security (integrity and

confidentiality); and accountability, meaning organizations must actively demonstrate compliance rather than just assert it.

Three roles anchor the system: the data controller, who decides why and how data is processed, the data processor, who acts on the controller's behalf and the data subject, the individual concerned. Data subjects hold a corresponding set of enforceable rights covering access to their data, correction, erasure, restriction of or objection to processing, portability, and protections around purely automated decision-making (European Commission, 2019a).

The regulation has hard penalties that can reach €20 million or 4% of a company's global annual turnover (Bloomberg Law, s.d.).

Health information gets GDPR's strictest tier of protection. Article 9 designates data concerning health, along with genetic and biometric data, as a "special category," and processing it is prohibited by default unless a specific listed exception applies (GDPR Regulation n.d.).

The exceptions healthcare organizations rely on are explicit patient consent; processing necessary for preventive or occupational medicine, medical diagnosis, health or social care treatment, or managing health systems; public health purposes; and archiving, research, or statistics in the public interest. In practice, this means every use of patient data needs a general lawful basis under Article 6 plus a matching special-category condition under Article 9, both of which must be documented (Secure Privacy Team, 2026).

Extra obligations stack on top for the sector: a Data Protection Officer and Data Protection Impact Assessments are generally required for organizations processing sensitive data at scale or deploying high-risk systems like health data warehouses, and retention isn't governed by one EU-wide number but by national clinical rules, commonly a decade or more for adult records, until legal adulthood plus extra years for children's records, and even longer for maternity and reproductive data, while exporting health data outside the EU/EEA faces particularly close scrutiny applies (GDPR Regulation n.d.).

Building and training AI systems require a vast amount of accurate data, which can contain sensitive medical information in healthcare services and medical research. Therefore, data protection is a critical legal matter, especially in the European Union (EU), under the GDPR. The GDPR prohibits solely Automated Decision Making (ADM) and processing of health data, with a few exemptions, such as if it is done with the patient’s consent or for the public interest. Hence, using health data with AI systems for ADM can face significant legal restrictions (Malgieri et al, 2019). However, the GDPR encourages innovation and technological developments, especially in scientific research, where there are several broad exemptions.

The GDPR only partly covers the regulation of AI systems, with rules on processing personal data and protecting data subjects against ADM. It does not provide comprehensive protection against AI systems. Thus, AI regulation has become a central policy question in the EU (European Commission, 2019a), moving from a soft-law approach, with its non-binding guidelines, to a legislative approach that calls for a new regulatory framework on AI by proposing the AI Act. The proposal aims to establish horizontal rules for the development and application of AI-driven products, services and systems in the EU.1 With the proposed AI Act, the EU aims to establish a technology-neutral definition of AI systems in EU law and to lay down a classification system for AI systems with different requirements and obligations tailored to a "risk-based approach" (European Commission, 2019a).

2.4 National Implementation: Law No. 132/2025 and AI Adoption in Italy

With the approval of Law No. 132/2025, Italy became the first EU Member State to introduce a national framework law fully aligned with the European AI Act, establishing dedicated governance authorities and sector-specific rules for the development and use of AI.

The law was enacted to complement the European AI Act (Regulation EU 2024/1689) and establishes national principles for the development, deployment, and governance of AI systems in Italy. It promotes a human-centred approach to AI, ensuring that technological innovation remains consistent with fundamental rights, constitutional principles, transparency, security, data protection, and non-discrimination (Repubblica Italiana, 2025).

The law emphasizes that AI systems must support rather than replace human decision-making, particularly in sensitive sectors such as healthcare, public administration, justice, and employment. To guarantee compliance and safety, Italy has designated the Agency for National Cybersecurity (ACN) and the Agency for Digital Italy (AgID) as the national authorities responsible for supervision, monitoring, and implementation of AI-related policies.

The Italian AI Law is expected to have significant implications for healthcare and medical practice. By promoting the safe and transparent use of AI, the legislation supports the adoption of AI-based tools for diagnostics, clinical decision support, predictive analytics, and personalized medicine, while maintaining human oversight over medical decisions. AI systems can assist physicians in detecting diseases earlier, analysing medical images more accurately, and optimizing treatment strategies through the processing of large volumes of clinical data (Senato della Repubblica, 2024).

Furthermore, the law establishes safeguards concerning patient privacy, cybersecurity, and the responsible use of health data. The requirement for transparency and human accountability aims to

reduce risks related to algorithmic bias, diagnostic errors, and the lack of explainability in automated medical decisions (Di Giacomo, 2025).

2.5 Data Controllership in Connected Medical Devices: The Bologna Pacemaker Case

Modern cardiac implantable devices pacemakers, defibrillators, and the remote-monitoring platforms attached to them continuously generate, transmit, and store patient data that increasingly feeds diagnostic algorithms and predictive models. This makes the question of who legally "owns" that data a foundational precondition for any subsequent AI-driven use of it, not a peripheral compliance detail. Regulation (EU) 2016/679 answers this through the distinction between the data controller (Art. 4(7)), the party that determines the purposes and means of processing, and the data processor (Art. 4(8)), which processes data solely on the controller's documented instructions, formalised through an Article 28 contract. In healthcare procurement, the provider almost always retains the controller role, since only the hospital determines why patient data is collected and how it is used clinically; the company supplying the device and its monitoring infrastructure acts as processor.

The Capitolato Speciale for pacemaker supply issued by the Azienda Ospedaliero-Universitaria di Bologna offers a concrete illustration of this allocation in practice. Article 15 ("Obbligo di Riservatezza dei Dati") confirms that the hospital retains full controllership throughout, while the supplier is formally appointed data processor for the contract's duration only, with the appointment lapsing automatically on completion. This time-bound structure is significant: it prevents a supplier's access to patient data, including telemetry passing through its own monitoring equipment, from outliving the clinical relationship that justified it.

Several concrete obligations follow from this processor designation: confidentiality extending to the supplier's employees, consultants, and subcontractors; a prohibition on any use of the data beyond what contract execution strictly requires, absent express authorisation; conditional authorisation for public-cloud storage; mandatory return of all data, software, and documentation at contract expiry with no retained copy; data protection by default (Art. 25 GDPR), limiting processing to what each specific purpose requires; cooperation on the hospital's Data Protection Impact Assessment (Art. 35 GDPR) and maintenance of a processing register; and, finally, an audit right for the hospital together with immediate termination and damages in case of breach.

Read together, these clauses show that titularity of data in an AI-in-medicine context is a structural safeguard rather than an abstract label: by keeping the hospital as sole controller and binding the

device manufacturer to a narrow, time-limited, auditable processor role, the contract ensures that any later step, secondary use of monitoring data for research, or its incorporation into a predictive algorithm, must pass back through the controller's authorisation rather than being decided unilaterally by whoever holds the hardware.

2.6 The Fragmentation of International AI Governance

Unlike data protection, where the GDPR at least gives the EU one shared reference point, artificial intelligence governance has no equivalent unifying instrument at the global level. Each country sets its own norms, on its own timeline, following its own institutional logic, so what emerges is a patchwork of national approaches rather than a single coherent regime, and the map, scored on a 3-to-36 scale, makes that unevenness visible briefly.

The United States sits at the very top of the scale, shaded darker than any other country shown and standing out as the single most active jurisdiction in the dataset. A second tier — visibly darker than the surrounding regional average, includes Canada, Australia, China, Turkey, and Saudi Arabia: a group with little in common institutionally, spanning common-law democracies, a one-party state, and an absolute monarchy, which is itself worth commenting on, since it shows that a high score here doesn't track any single political or legal model. A broader middle band, including the UK, Brazil, Poland, and parts of Southeast Asia, shows moderate activity, while most of Western and Southern Europe, India, and the rest of South America register comparatively low, pale values despite being far from inactive in absolute terms. Just as telling is what's missing entirely: Russia, almost all of Africa, and Central Asia appear in grey, meaning the dataset records no comparable value for them at all an absence that is itself a form of fragmentation, since it points to the lack of the kind of formalized, trackable national framework already present elsewhere.

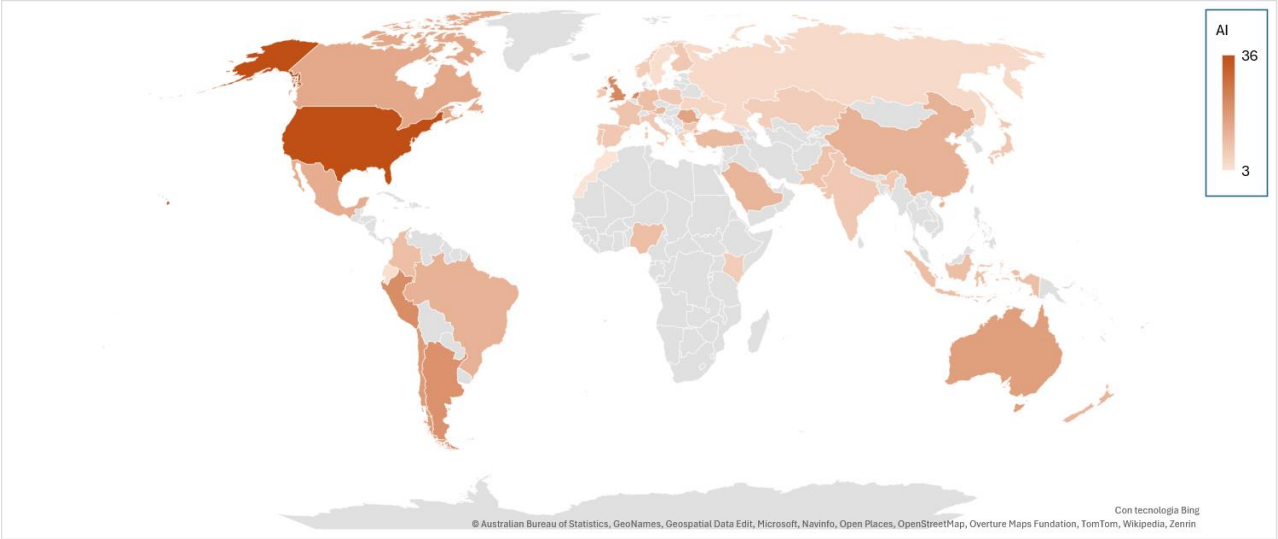


Figure 2: Global mapping of regulatory density regarding Artificial Intelligence.

Data source: https://regulations.ai/map

2.7 Comparative Regulatory Frameworks: Contrasting AI Regulatory Trajectories in the EU, China, and the USA

Figure 3 provides a comparative overview of the relationship between the growth of scientific interest in healthcare AI and the regulatory responses adopted by the European Union, China and the United States between 2020 and 2025. The graph on the left shows a rapid increase in AI-related healthcare publications across all three regions, confirming the accelerating adoption of artificial intelligence in the medical sector. However, the right side of the figure highlights that this technological expansion has been accompanied by markedly different regulatory strategies.

China exhibits the most significant growth in scientific output, increasing from an indexed value of 100 in 2020 to 685 in 2025. This trend is consistent with the country's increasingly structured regulatory framework. As reported in Table X, the National Medical Products Administration (NMPA) introduced dedicated review requirements for deep-learning medical software as early as 2019, followed by classification principles in 2021 and registration guidelines in 2022. The upcoming 2025 directives further strengthen lifecycle management and approval mechanisms for high-end medical devices and medical robots. This demonstrates China's attempt to combine technological competitiveness with centralized regulatory oversight.

The European Union follows a different trajectory. Although publication growth is slightly lower than that observed in China, the EU has developed the most comprehensive and precautionary regulatory framework. The milestones presented in Figure X and detailed in Table X show a progressive

evolution from the implementation of the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) to the entry into force of the AI Act in 2024. Additional measures concerning transparency requirements and prohibited AI practices reinforce the EU's risk-based approach, which prioritizes safety, accountability and fundamental rights throughout the lifecycle of AI systems.

The United States occupies an intermediate position in terms of scientific production but follows a substantially different regulatory philosophy. According to the milestones summarized in Table X, the Food and Drug Administration (FDA) has progressively developed guidance documents for AI-enabled medical devices, including the AI/ML Software as a Medical Device framework, Good Machine Learning Practice principles and Predetermined Change Control Plans (PCCPs). Nevertheless, unlike the European Union and China, the broader U.S. governance model remains heavily influenced by political changes and market-oriented priorities. As discussed previously, recent federal policies have favoured deregulation and innovation over comprehensive mandatory oversight, resulting in a fragmented landscape where state-level regulations coexist with limited federal intervention.

Taken together, the figure illustrates how increasing scientific interest in healthcare AI has been matched by different governance models. The European Union emphasizes risk management and regulatory certainty, China combines strong state coordination with industrial strategy, while the United States prioritizes innovation and market flexibility. These divergent trajectories highlight the ongoing challenge of balancing technological advancement with patient safety, transparency and accountability in healthcare AI.

Table 1. *Comparative overview of the main regulatory milestones for Artificial Intelligence in healthcare across the United States, China, and the European Union.*

AREA	YEAR	MONTH	DESCRIPTION	REGULAMENTATION
USA	2019	April	Describes a potential approach to premarket review for artificial intelligence and machine learning-driven software modifications	U.S. Food and Drug Administration, 2019
	2021	January	Outlines a total product lifecycle oversight approach to deliver safe and effective AI/ML-based medical software functionality, improve patient care and enhance care quality, structured around five pillars: PCCPs, GMLP, transparency, bias/robustness, and real-world performance monitoring	U.S. Food and Drug Administration, 2021
		October	Joint FDA–Health Canada–MHRA guidance identifying 10 principles to inform Good Machine Learning Practice (GMLP) and promote safe, effective and high-quality AI/ML-enabled medical devices	U.S. Food and Drug Administration et al., 2021
	2022	December	Establishes the statutory basis for Predetermined Change Control Plans for devices, allowing manufacturers to prospectively specify and seek FDA authorization for planned modifications that may be implemented without additional marketing submissions when consistent with an authorized PCCP	U.S. Food and Drug Administration, 2024
	2023	April	Provides recommendations for including PCCPs in FDA submissions, allowing planned AI/ML software modifications to be reviewed in advance while maintaining device safety and effectiveness	U.S. Food and Drug Administration, 2025a
		October	Identifies 5 guiding principles for PCCPs in ML-enabled medical devices, building on GMLP Principle 10: focused and bounded, risk-based, evidence-based, transparent, and total product lifecycle-oriented	U.S. Food and Drug Administration et al., 2023
	2024	March	Represents the FDA's coordinated approach to AI. This paper is intended to complement the "AI/ML SaMD Action Plan"	U.S. Food and Drug Administration, 2025b
		June	Builds on GMLP Principles 7 and 9, framing transparency around six dimensions (who, why, what, where, when, and how) to support clear information for relevant audiences, including users, patients, and decision-makers	U.S. Food and Drug Administration et al., 2024
		December	Provides recommendations for PCCPs tailored to AI-enabled devices, supporting iterative modifications while maintaining safety and effectiveness through planned changes, validation methods and impact assessment	U.S. Food and Drug Administration, 2025c
	2025	January	Provides lifecycle management and marketing submission recommendations for AI-enabled medical devices, highlighting relevant recommendations from other FDA guidances and adding AI-specific recommendations to support manufacturers	U.S. Food and Drug Administration, 2025b
		April	Omits proposed guardrails on the use of AI in Medicare Advantage prior authorization, including rules on non-discrimination, internal coverage criteria and more granular reporting	Patil & Graham, 2025
CHINA	2019	July	Provides comprehensive review requirements for deep learning–assisted medical software, covering the entire AI product lifecycle from requirement analysis and algorithm development to verification and validation	Liu et al., 2024
	2021	July	Defines classification principles for AI-based medical software products, strengthening NMPA supervision and supporting high-quality industry development	National Medical Products Administration, 2021

	2022	March	Provides general guiding principles for the registration review of AI medical devices, supporting lifecycle management, registration materials preparation, technical review and quality management system verification, with applicability depending on product characteristics and risk	Center for Medical Device Evaluation, 2022
	2025	October	Strengthens review and approval mechanisms and whole life-cycle regulation for high-end medical devices (including medical robots, high-end medical imaging equipment, AI-powered medical devices and novel biomaterial-based devices) to support the application of new technologies, materials, processes and methods in healthcare, better meet public health needs and enhance China's international competitiveness	National Medical Products Administration, 2025
EU	2017	April	Adoption of the MDR (Regulation 2017/745) and IVDR (Regulation 2017/746)	European Parliament & Council of the European Union, 2025a; European Parliament & Council of the European Union, 2025b
	2021	May	Application of the MDR	European Commission, n.d.
	2022	May	Application of the IVDR	European Commission, n.d.
	2024	August	The AI Act enters into force, setting requirements for high-risk AI systems, including AI-based software intended for medical purposes, such as risk-mitigation systems, high-quality data sets, clear user information and human oversight.	European Parliament & Council of the European Union, 2024; European Commission, n.d.b
	2025	February	General provisions (definitions & AI literacy) and prohibitions apply	European Commission, n.d.c
		April	Expected to be finalised, addressing transparency, copyright-related rules and risk management for providers of general-purpose AI models	European Commission, n.d.b
		August	GPAI obligations and AI Act governance rules become applicable, including national competent authorities, penalties and EU-level governance bodies	European Commission, n.d.c
	2026	August	Most AI Act rules enter into application, including rules for Annex III high-risk AI systems, transparency obligations, innovation support measures, AI regulatory sandboxes and national/EU enforcement	European Commission, n.d.c
	2027	December	High-risk AI rules apply to certain high-risk areas, including biometrics, critical infrastructure, education, employment, migration, asylum and border control (AI Omnibus political agreement)	European Commission, n.d.d
	2028	August	High-risk AI rules apply to AI systems integrated into products, such as lifts or toys (AI Omnibus political agreement)	European Commission, n.d.d

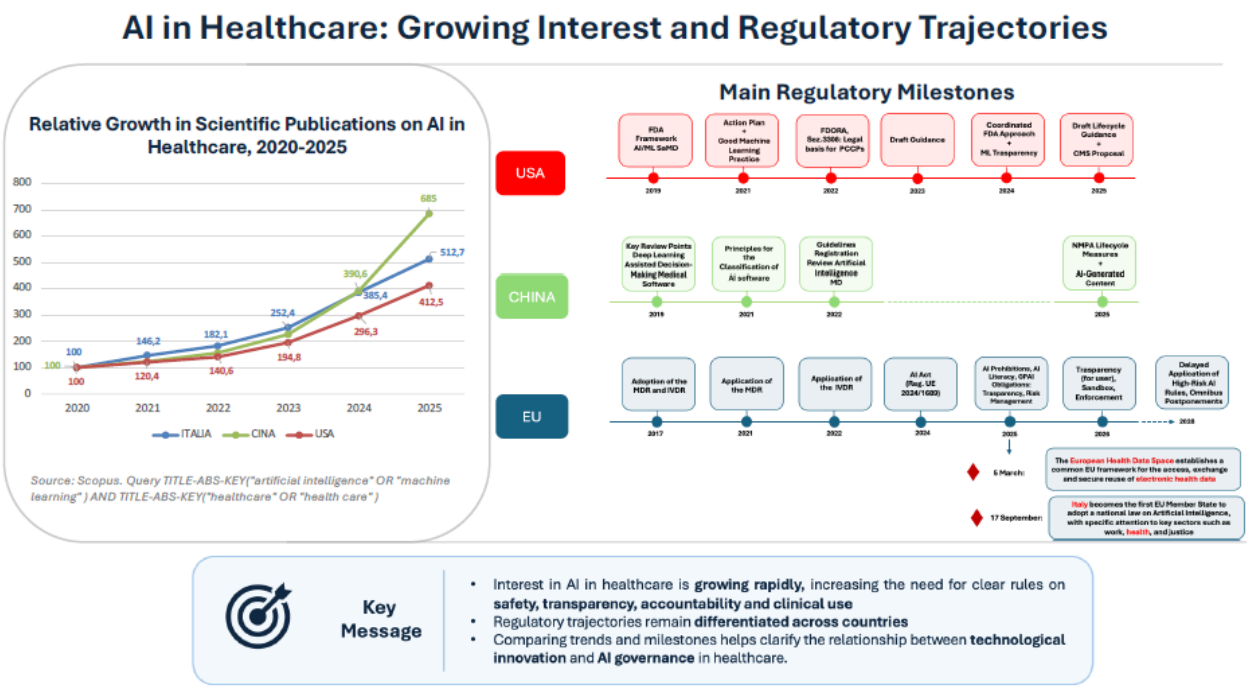


***Figure 3**: Dashboard illustrating the global trajectory of AI in healthcare, featuring the relative growth of scientific publications (2020–2025) alongside key regulatory milestones in the United States, China, and the European Union.*

3 Qualitative Analysis of Regional Technology Adoption

3.1 Digital Innovation Analysis: A Questionnaire-Based Evaluation

This study was carried out in cooperation with Regione Liguria, which made it possible to collect data through the administration of structured questionnaires all the healthcare organizations in the region. Specifically, the survey involves five Local Health Authorities (ASLs) and four hospitals, for a total of nine entities within the Ligurian Regional Health System.

Including both local health authorities and hospitals is intended to provide a complete picture of digital technology adoption in the regional healthcare system, capturing differences between specialized institutions and community-based services, where tools like Artificial Intelligence (AI) and telemedicine can significantly improve patient management and continuity of care.

It's worth noting that one institution, reporting the highest number of active projects, submitted two separate questionnaires, one focusing on artificial intelligence and one on telemedicine. Given that the present study centres on AI adoption, only the AI-related questionnaire is considered for analysis.

Before starting with the analysis, it is important to highlight that the questionnaires administered are structured as self-assessments, requiring institutions to provide their own subjective evaluation of their level of digital adoption. This approach, while widely used in health systems research for its practicality and scalability (Nazione et al., 2014), inevitably introduces well known methodological limitations. In line with this, Nair et al. (2024) highlight that self-assessment instruments are inherently affected by two interrelated limitations: respondent bias, where individuals tend to portray themselves more favourably than their actual behaviour would suggest, and the lack of direct observation, as data rely exclusively on self-declared information with no external verification of real-world conduct. A further source of variability lies in the interpretation of complex concepts such as artificial intelligence or telemedicine, which may differ considerably depending on the background and professional perspective of the respondent, an issue particularly relevant in multidisciplinary healthcare settings (Riens et al., 2025).

The findings presented in this study should therefore be read with these limitations in mind, considering the data collected as a representation of the internal perception of the participating institutions, rather than an objective verified measure of their actual technological level.

Within this setting, the study pursues two specific objectives:

- To establish a comprehensive overview of the level of digital innovation across the Ligurian territory, identifying which technologies have reached the most advanced stage of adoption and development.
- To conduct a focused analysis on institutions that have already integrated AI into their workflows, comparing them with those that have not, in order to assess potential implementation opportunities in other clinical areas, such as cardiology.

3.2 Methodology: Survey Design and Thematic Framework

As illustrated in Table 1, the questionnaire consists of 13 questions, organised into six thematic sections, each addressing a specific aspect of the digital technology adoption process in healthcare. The questions include categorical items, multiple-choice fields, and open free-text responses, the questionnaire is organized to provide a comprehensive overview of the digital landscape, detailing the specific questions and focus areas for each section. These sections start from initial strategic motivations and governance structures to technical implementation and the final evaluation of clinical and organizational impacts:

1. General context and project objectives: This section maps the landscape of digital innovation within the institutions, focusing on the initiatives currently active in clinical practice. Information is also collected regarding the primary motivating factors driving their launch. Starting from this point, respondents are asked to identify and refer exclusively to a single project considered their 'best practice' for the remaining questions. The analysis specifically explores the domains involved, with particular attention to the clinical areas of application.
2. Organizational aspects and governance: This section explores the organizational and professional dimensions of digital transformation, investigating which clinical and administrative figures are involved in project design and operations, and which change management strategies are adopted to support staff engagement.
3. Technologies and data: This section examines the specific technologies deployed, as well as the level of interoperability achieved between.
4. Financing and sustainability: This section investigates the financial sources sustaining the projects.

5. Results and impacts: This section assesses the outcomes observed following project implementation, covering both organizational-managerial effects and clinical impacts on patients, as well as the main implementation challenges encountered.
6. Evaluation and transferability: This final section explore whether the identified best practices are considered potentially scalable across the Ligurian regional healthcare system, and the motivations to justify it. Then they are asked a synthetic description of the project and whether they have undergone formal evaluation for it.

Table 2: Structural framework of the survey questionnaire: sections, analyzed items, and corresponding question types.

Section	Item / Question Number	Type of Question
1. General Context and Objectives	AI/Virtual Hospital project adoption	Closed-ended (Dichotomous)
	Number of active projects	Free text
	Main motivations for adoption	Multiple choice
	Clinical areas and patient categories	Multiple choice
2. Governance and Change Management	Structures and professional figures involved	Multiple choice
	Management of organizational change	Multiple choice
3. Technology and Data	Implemented technologies and partners involved	Multiple choice
	Information systems integration	Multiple choice
	Dedicated digital innovation structures	Closed-ended
4. Funding and Sustainability	Sources of funding	Multiple choice
5. Results and Impacts	Organizational-managerial effects	Multiple choice
	Clinical effects on patients	Multiple choice
	Implementation criticalities	Multiple choice
6. Evaluation and Transferability	Best practice selection	Closed-ended (Single)
	Reasons for best practice selection	Multiple choice
	Formal evaluation and indicators	Multiple choice

3.3 Mapping Digital Innovation and Artificial Intelligence across the Regional Healthcare System

The data collected from the questionnaires are analyzed to describe the state of digital innovation in the Ligurian healthcare sector. The study then focuses on artificial intelligence applications, adopting a double comparative approach: first, between structures equipped with AI and those without it, and subsequently, between two centers of excellence that already utilize it. This methodology is applied to examine the differences on the maturity level of the solutions, governance, and expansion potential across the entire regional system.

Out of the nine healthcare facilities that provide a complete response, seven out of nine (78%) report at least one active digital innovation project, while the remaining two have not yet launched any initiative at the time of the survey, and will therefore not be considered in the following analysis.

Across the seven active participating organizations, as shown in Table 2, AI emerges as the most reported digital technology, accounting for 30 projects and representing 57% of all declared technological initiatives.

However, this quantity is strongly influenced by a single highly active entity, which alone accounts for 24 of the total AI-related projects.

Beyond AI, televisit is reported by 9 organizations (17%), Teleconsultation and tele reporting follow with 5 organizations apiece, 9% each. By contrast, telemonitoring remains notably underdeveloped, present in only 3 organizations (6%), and wearable devices by just 1 (2%).

Across the overall sample of participating structures, clinical motivations emerge as the most frequently reported driver for the adoption of digital and innovative solutions, being selected by all seven institutions. Organizational motivations follow, cited by four structures, while economic considerations are reported by two institutions and regulatory motivations by one.

Table 3: Overview of implemented digital health technologies by number of active projects and relative percentage.

Technology	Active projects	%
Artificial intelligence	30	57%
Televisits	9	17%
Teleconsultation	5	9%
Telereporting	5	9%
Telemonitoring	3	6%
Wearable devices	1	2%

In this section the survey invites each organization to select a single active project considered representative of their best practice in digital innovation, and to answer all subsequent questions with reference to that specific initiative.

With reference to the technologies implemented within the project identified by each organization as a best practice, telemedicine solutions emerge as the most recurrent choice.

Five out of seven healthcare structures report the adoption of at least one telemedicine-related technology. Ai is selected by three structures, while more specific solutions, including teleconsultation, wearable devices, virtual reality (VR) and telemonitoring, are each reported by a single organization.

Conversely, although telemedicine accounts for a lower absolute number of reported projects compared with Artificial Intelligence, it appears to be more widely distributed across the selected

best-practice projects. In other words, AI shows a higher project intensity, but this is largely concentrated in a limited number of institutions, whereas telemedicine seems to have a broader organizational diffusion across the regional healthcare system.

The subsequent analysis is conducted on the entire sample of seven structures that reported at least one active project, to preserve a comprehensive regional perspective. At the same time, a particolar focus is dedicated to the three structures that select Artificial Intelligence among the technologies implemented, with the aim of exploring in greater detail the characteristics and differences with other digital tools. Where relevant, their results are set against those of the other four non-AI-adopting structures.

Table 3 summarizes the main characteristics of the surveyed projects across four dimensions: clinical targets, patient populations, observed benefits, and main criticalities, reporting for each variable the number of structures and, in parentheses, the subset of AI-adopting institutions.

At the European level, the WHO Regional Office for Europe has documented the diffusion of AI across clinical domains. The most consolidated application remains AI-assisted diagnostics, present in 64% of member states, with radiology, dermatology, and ophthalmology leading adoption. Other significant areas include conversational platforms for patient assistance (50%), automation of administrative and logistical workflows (40%), and AI-assisted surgical robotics and symptom checkers (both at 38%), while remote patient monitoring and prognosis prediction are progressively entering clinical practice.

A similar pattern emerges at the regional level in Lombardy, where diagnostic support accounts for most AI applications (54%), followed by prognostic tools (48%). Notably, diagnostic applications in radiology have generally reached routine clinical use, whereas prognostic tools remain more frequently in pilot or development phases (Ardito et al, 2025).

The trend of the survey is consistent with the clinical areas targeted by the projects, with cardiology and radiology emerging as the most frequently cited domains, each reported by three out of seven structures, indicating that imaging-based specialties and cardiovascular care currently represent the leading areas of technological innovation within the regional healthcare landscape. Three additional areas neurology, pneumology, and diabetology are each reported by two organizations, while psychology is identified by only one.

Analysing AI-adopting institutions specifically, the picture aligns closely with the European and Lombardy evidence: all three AI-adopting structures converge on image-based clinical applications, with radiology and neuroradiology emerging as the dominant areas, and neurology accounting for one further application.

Across these experiences, AI solutions are primarily applied to support diagnostic workflows based on medical imaging. Selected examples include the implementation of AI systems for automated fracture detection on emergency radiographic images integrated within existing RIS-PACS infrastructures, the use of neurovascular AI platforms designed to accelerate diagnosis and clinical decision-making in acute stroke and neurovascular conditions, and the development of an in-house AI tool for the detection and volumetric quantification of epidural haemorrhages from paediatric Computer Tomography (CT) scans, built in collaboration with an academic research department.

Cardiology, by contrast, despite being equally represented among the clinical areas surveyed, reports no AI implementation at all, a gap that stands out against the growing AI applications in the European trajectory in electrocardiogram interpretation and pace-maker monitoring.

About patient targeting, the analysis reveals a strong focus on fragile and clinically complex populations. Frail or high-complexity patients represent the most frequently addressed group, selected by five out of seven organizations, followed by patients with chronic conditions, identified by four structures. Acute patients and paediatric patients were each targeted by two organizations.

Overall, these patterns indicate that digital innovation initiatives within the Ligurian healthcare system are primarily oriented toward patient groups characterized by high clinical complexity and long-term care needs. This orientation closely reflects the demographic and epidemiological profile of Liguria, which has both the oldest population in Italy and a high prevalence of chronic and multimorbid patients (Osservasalute, 2019; ISTAT, 2024; Ansaldi & Astengo).

Figures 4 and 5 highlight the connection between the need in enhancing continuity of care and clinical outcomes among chronic cardiac patients (Eurlings et al., 2019).

None of the AI-adopting structures identifies chronic patients as the main target of their projects, instead, acute patients were the most frequently addressed group.

These findings are consistent with existing literature, which highlights that AI technologies have achieved greater clinical validation and operational impact in acute and emergency settings where timely diagnostic support can generate immediate clinical value (Ahmed et al., 2025). At present, this relative maturity contrasts with more limited AI deployment in long-term chronic care pathways, which often require sustained monitoring, complex care coordination, and broader organizational integration**.**

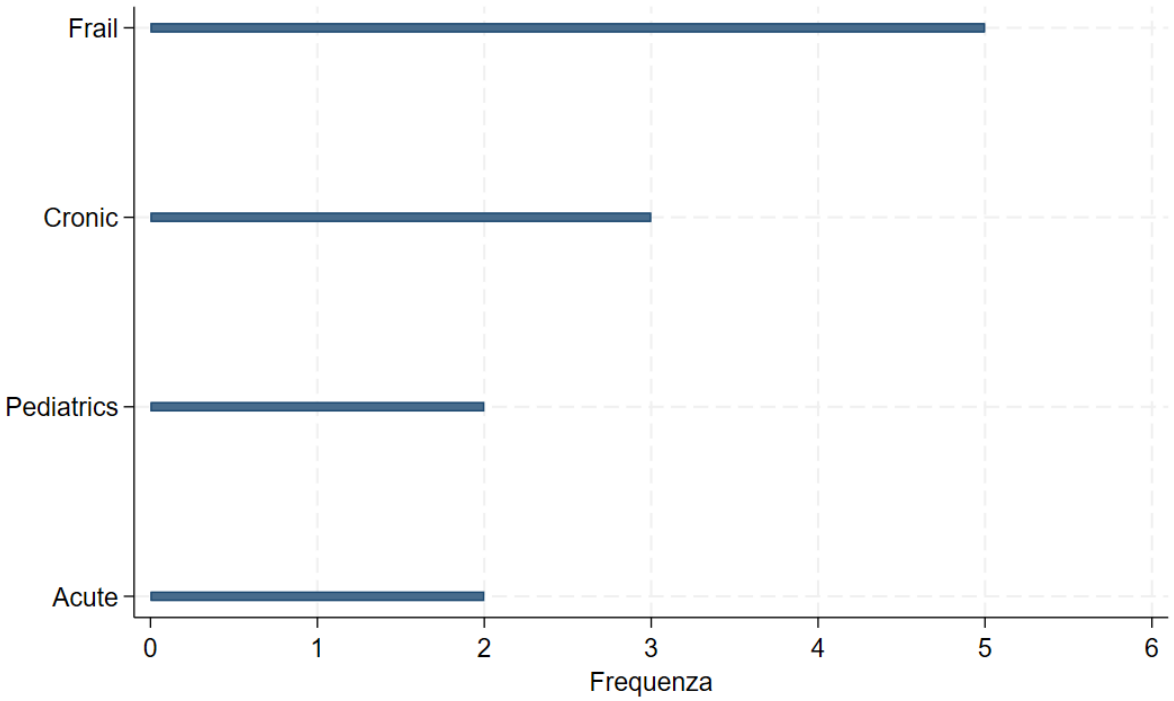


Figure 4: *Frequency distribution of target patient populations (Frail, Chronic, Pediatric, Acute) in the analyzed healthcare interventions.*

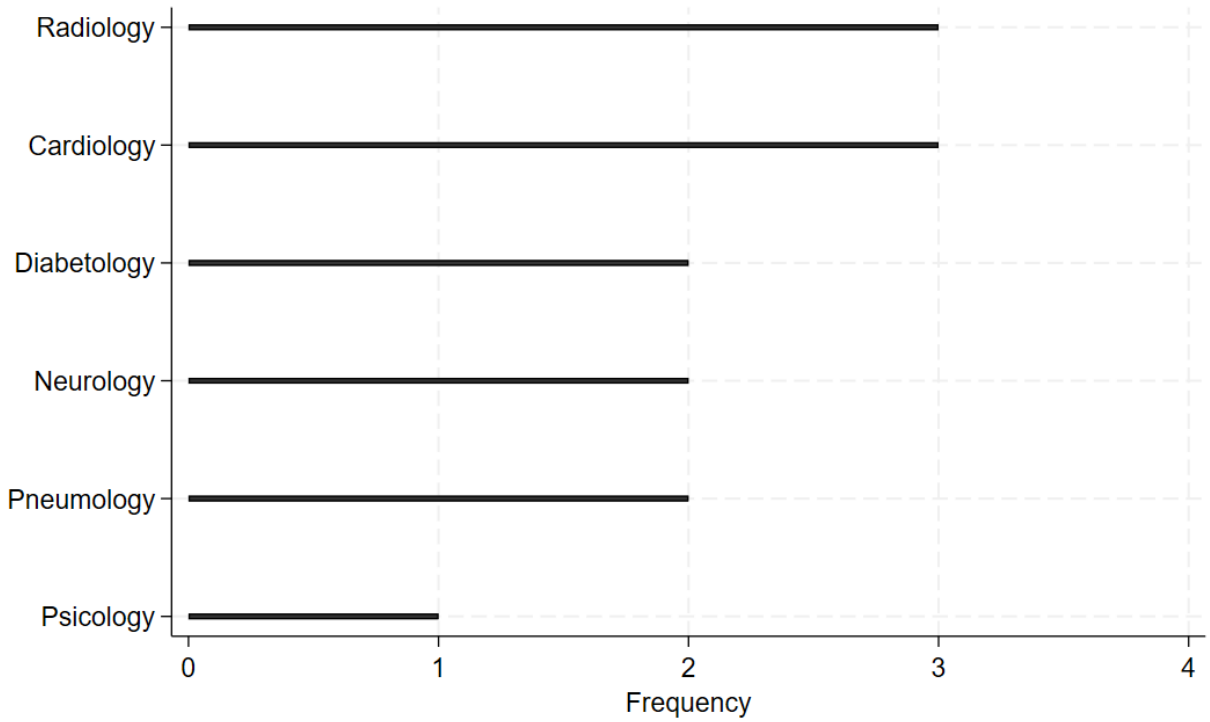


Figure 5: *Frequency of telemedicine and AI interventions by medical specialty.*

3.4 Organizational and Clinical Benefits and Main Barriers of Artificial Intelligence

The reported positive outcomes are observed in two aspects: one organizational, concerning how structures manage resources and workflows, and one clinical, reflecting the tangible effects on patient outcomes.

Among the benefits reported by the overall structures, the most frequently cited are the optimization of operational efficiency and enhanced pathological control emerge each mentioned.

Notably, AI-adopting institutions are correlated in both cases, three out of five for operational efficiency and two out of five for pathological control, suggesting that AI implementation may be a contributing factor to improve the performance of both clinical and operational performances.

Outcome reported in institutions using other digital tools are: increased therapeutic adherence and optimization of quality's life.

The reported benefits specific to AI-adopters are improved diagnostic speed and precision, the reduction in emergency department discharge times and shorter lengths of stay. While the numbers are too small to draw any conclusions, the last two outcomes touch on a point that is particularly relevant in Liguria. The region combines with the oldest population in Italy, generating sustained demand on hospital resources in terms of admissions, bed occupancy, and care continuity (Osservasalute, 2019; ISTAT, 2024). Regional data from 2022 and 2023 show hospitalization rates for heart failure and acute myocardial infarction broadly in line with national figures, though with notable variability across local health districts (Osservasalute, 2023; Agenas, 2024) a pattern that reflects underlying inequalities in both disease burden and service capacity. The use of digital tools showing a modest contribution to reducing unnecessary hospital stays or emergency pathways would carry meaningful implications, and the tentative signal emerging from the survey, however limited, is worth pursuing in future, more structured investigations.

The most reported difficulties relative to AI is the absence of established guidelines or defined protocols. This finding reflects one of the most consistently documented barriers in the literature on AI implementation in healthcare. A recent scoping review (Nair et al., 2024) highlights how the absence of comprehensive regulatory frameworks actively limits AI adoption in healthcare. The widespread uncertainty surrounding AI governance and unresolved questions about medical liability make clinicians hesitant to rely on these tools. This hesitation is further compounded by a lack of established accuracy benchmarks for clinical approval and missing protocols for privacy-compliant data management. Ultimately, this regulatory hole directly dictates if and how institutions feel secure enough to implement AI (Nair et al., 2024).

Limitations regarding other digital tools are resistance to change among healthcare staff and technological limitations of adopted solutions mentioned by three structures, coordination difficulties between teams or departments and limited involvement of specific professionals, present in two.

Among AI adopters specifically, the challenges shift toward the concrete and operational: difficulty in evaluating available AI solutions on the market, economic and cost-sustainability assessments, problems in data collection and management, and, specific to neuroradiology, a lack of protected research time and pressure to reduce imaging interpretation times. These concerns are qualitatively different from the institutional resistance reported by non-adopters, and in many ways mirror precisely the governance gaps identified in the literature: without validated evaluation frameworks, clear cost-benefit methodologies, and structured data protocols, even institutions that have already adopted AI find numerous difficulties.

Table 4: The table summarizes the main features of the selected best-practice projects across four dimensions: clinical areas of application, target patient populations, reported benefits, and main implementation barriers. The table also distinguishes between AI-adopting and non-AI-adopting institutions, allowing a comparison of clinical focus, organizational outcomes, and critical issues associated with different digital health technologies.

	Structures (AI adopters)
Clinical target	
Radiology/Neuroradiology	3 (2)
Cardiology	3 (0)
Neurology	2 (1)
Diabetology	2 (0)
Pneumology	2 (0)
Psicology	1 (0)
Patients target	
Frail / High-complexity patients	5 (1)
Cronics	4 (0)
Acute	2 (2)
Pediatrics	2 (1)
Observed benefits	
Optimization of operational efficiency	5 (3)
Enhanced pathological control	5 (2)
Increased therapeutic adherence	3 (0)
Optimization of quality's life	2 (0)
Better resource allocation	3 (1)
Reducing discharge times from the Emergency Department	1 (1)
Speed up length of stay	1 (1)
Improved diagnostic speed and precision	1 (1)
Main criticities	
Absence of established guidelines or defined protocols	3 (2)
Resistance to change among healthcare staff	3 (0)
Technological limitations of the adopted solutions	3 (0)
Limited involvement of specific professionals	2 (0)
Coordination difficulties between teams or departments	2 (0)
Economic evaluation and cost-sustainability check	1 (1)
Reduction of interpretation time of neuroradiological imaging	1 (1)
Evaluating available AI solutions	1 (1)
Problems in data collection or management	1 (1)
Lack of protected research time	1 (1)

3.5 Strategic Implementation, Sustainability, and Scalability of Digital Health Models

Clinical professionals emerge as a constant across all surveyed organizational structures: all of seven institutions include them among the figures actively involved in digital innovation processes. Other figures include the presence of an IT teams in six cases, senior management in five and the involvement of external partners in three cases.

Particularly worth noting is the presence in two different institutions of a Data Protection Officers and AI- specialized researchers engaged in the project.

Regarding implementation initiatives, staff training and the active involvement of clinical professionals emerge as the most reported practices across the overall sample and are present in two of the three institutions that have adopted AI. In contrast, although senior management support and internal feedback mechanisms are broadly relevant within the wider sample, they do not appear among the AI adopters. Notably, one of the AI-adopting institutions has developed a structured collaboration with a university**.**

Data was also collected regard the management of interoperability and integration across different information systems. Almost all the institutions, six out of seven, report collaborations with technology partners, with two of them being AI adopters.

Four organisations report the integration between internal hospital departments. It is worth noting that all three institutions that have adopted AI fall within this group. This pattern suggests that internal interoperability may play an important role in the adoption of advanced technologies.

Integration between hospital and community care services, is reported also by four organisations, and half of these have adopted AI.

Finally, the least reported is the integration between hospitals present in two organisations, but only one of these has adopted AI. Overall, the findings highlight that AI adoption is closely associated with internal integration, while external forms of integration remain, for the time being, more limited in their development.

The fourth section is dedicated to the financial resources and founds involved to sustain the selected digital project. The initial expectation was that a significant share of implementation costs would be covered through the National Recovery and Resilience Plan (PNRR). The PNRR represents the main instrument through which Italy allocates Next Generation EU (Recovery and Resilience Facility) funds over the 2021-2026 period, with disbursements tied to the achievement of predefined semi-annual milestones and target (Armocida, B. et al.). Within the healthcare sector, Mission 6 (Health)

places particular emphasis on strengthening territorial care and, on upgrading and modernising the technological and digital infrastructure of the National Health Service (ISTAT, 2019).

However, the survey data shows that most participating organizations (5 out of 7) rely on internal institutional resources to finance their digital innovation initiative. Only 2 out of 7 indicate the use of PNRR funds, while 1 out of 7 report dedicated regional funding, and 1 out of 7 mention participation in competitive calls. Notably, all three organisations that have adopted artificial intelligence fall within the first group, suggesting that the development of AI initiatives is currently being driven largely by internal resources rather than external funding options.

Among the surveyed structures, five out of the seven consider their identified best practice project potentially transferable at a regional scale, while two have not yet conducted a formal assessment. The absence of any negative responses suggests a broadly favourable disposition toward scaling digital innovations across the Ligurian health system.

When examining the reasons behind these transferability judgments, the ease of integration into existing processes emerged as the most critical factor, selected by four institutions. Economic sustainability was the second most relevant consideration (three organizations), followed by the achievement of significant clinical outcomes and a high level of acceptance among healthcare professionals and patients (two organizations each). Finally, improvements in organizational efficiency were mentioned by a single institution.

If we isolate the responses of the organizations that have already adopted AI, a specific pattern appears. These AI-adopting facilities make up most of those prioritizing practical and economic factors: they account for three of the four institutions that highlighted process integration, and two of the three that stressed financial sustainability. This indicates that for organizations dealing with complex technologies, easier workflow integration and clear financial viability are perceived as the primary prerequisites for successful scaling.

These empirical findings closely align with established theoretical models in digital health, most notably the NASSS framework (Non-adoption, Abandonment, Scale-up, Spread, and Sustainability), developed to predict and evaluate the success of health and social care technologies (Greenhalgh, Trisha et al. 2017).

According to the authors, systemic complexity remains the primary obstacle to scalability: programs exhibiting high complexity across multiple NASSS domains rarely transition into routine practice or achieve long-term sustainability. Furthermore, the model highlights that digital technologies frequently fail when designed around simplified models of disease, ignoring the reality of patient comorbidities and varying social contexts. Crucially, the NASSS framework identifies professional

staff acceptance as a critical determinant for the local success or failure of a new technology. . (Greenhalgh, Trisha et al. 2017).

This theoretical premise perfectly mirrors the survey results previously discussed, where the ease of integration into existing clinical workflows and the high level of acceptance among healthcare professionals emerged as fundamental prerequisites for effectively scaling AI-driven solutions across the regional health system.

3.6 Comparative Analysis of AI Adoption Strategies: "Make" vs. "Buy" Models

This section compares two hospitals that reported the adoption of artificial intelligence, with the aim of highlighting differences in implementation strategy, governance, outcomes and scalability. As shown in Table 4 and Figure 6, the comparison is summarised through a radar chart based on six dimensions of AI implementation maturity: AI project intensity, in-house development capacity, interdisciplinary governance, workflow integration, clinical-organizational impact, and regional scalability/sustainability. Each dimension was converted into a synthetic score from 1 to 5, where 1 indicates low maturity and 5 indicates high maturity. These scores should not be interpreted as direct quantitative measurements, but as a structured qualitative assessment derived from the questionnaire findings.

Hospital 1 “In-house” AI model represents the most advanced case in the sample, with 24 active projects and an original AI system developed in collaboration with an academic institution. By contrast, Hospital 2 “Commercial AI” model reports 4 active projects based mainly on commercially available AI tools, reflecting an earlier stage of AI integration.

These two cases illustrate the distinction between the “make” and “buy” approaches to AI adoption. The in-house model allows greater customization, closer alignment with specific clinical needs and stronger control over data governance, but requires substantial initial investment in technical infrastructure, specialised staff and research capacity. Conversely, commercial AI solutions can accelerate adoption and require lighter internal infrastructure, although they may involve higher dependency on external providers, pass-through costs and potential concerns related to data protection and clinical reliability. In this sense, both pathways are legitimate, but they differ in terms of costs, risks and long-term sustainability.

This distinction is also reflected in the radar profile. Hospital 1 scores higher in AI project intensity, in-house development capacity and interdisciplinary governance, reflecting a more mature and research-driven implementation model. Hospital 2 shows lower internal development capacity, but

maintains a relatively strong profile in workflow integration and regional scalability, consistent with the advantages of adopting pre-built commercial solutions.

The outcomes reported by the two hospitals partially overlap. Both report improvements in operational efficiency and pathological control. However, Hospital 1 reports a broader range of effects, including significant clinical results and resource optimisation, consistent with its more mature and internally developed model. The barriers also differ: Hospital 1 mainly identifies the lack of protected research time for clinicians involved in AI development, while Hospital 2 highlights the absence of established guidelines and protocols, reflecting the broader regulatory uncertainty that still limits AI adoption in healthcare.

Finally, both hospitals consider their projects potentially transferable at regional level, although for different reasons. Hospital 1 emphasises clinical results, economic sustainability and readiness for certification, whereas Hospital 2 highlights ease of integration into existing workflows, one of the main advantages of commercial AI solutions. Overall, the radar chart suggests that regional scalability may be achievable through both in-house and commercial pathways, but with different requirements, timelines and levels of institutional maturity.

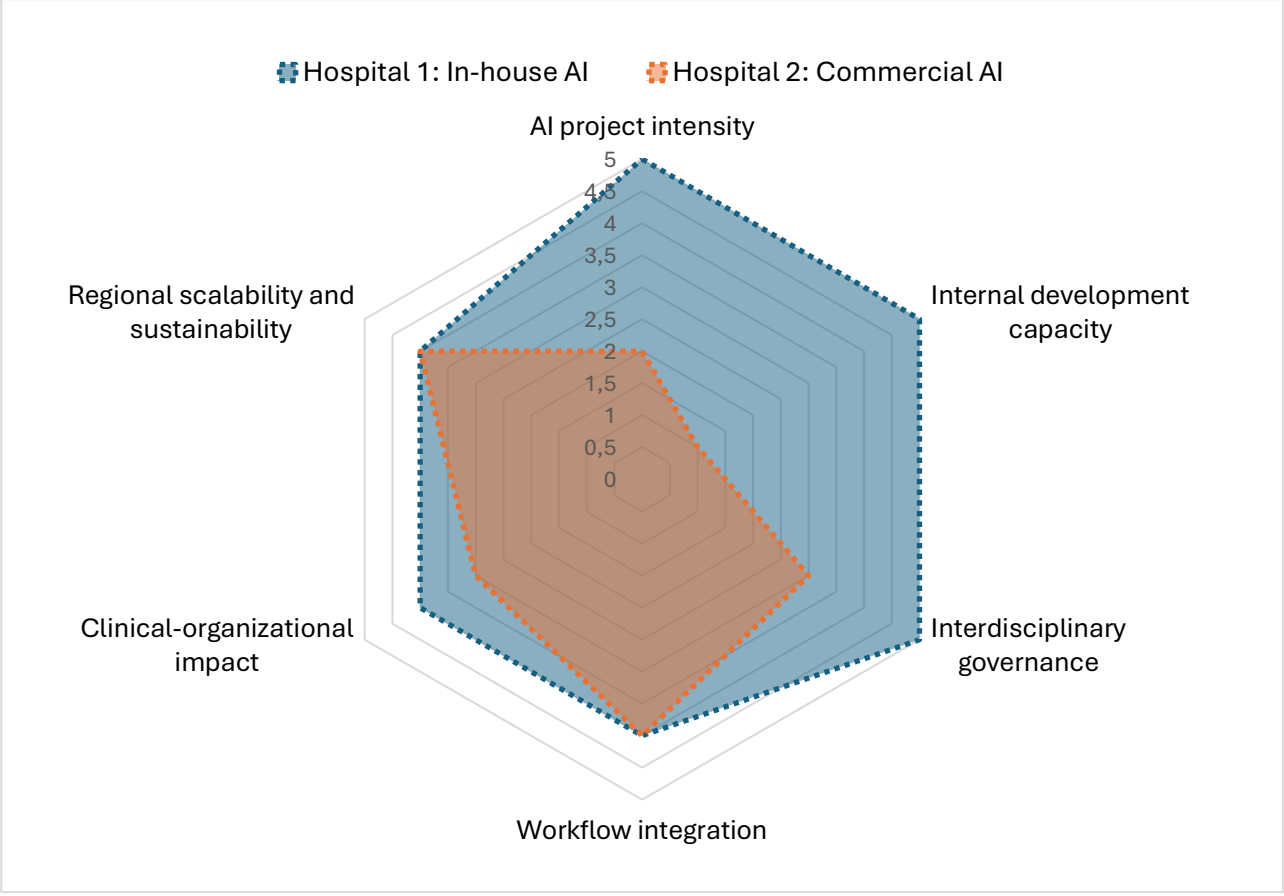
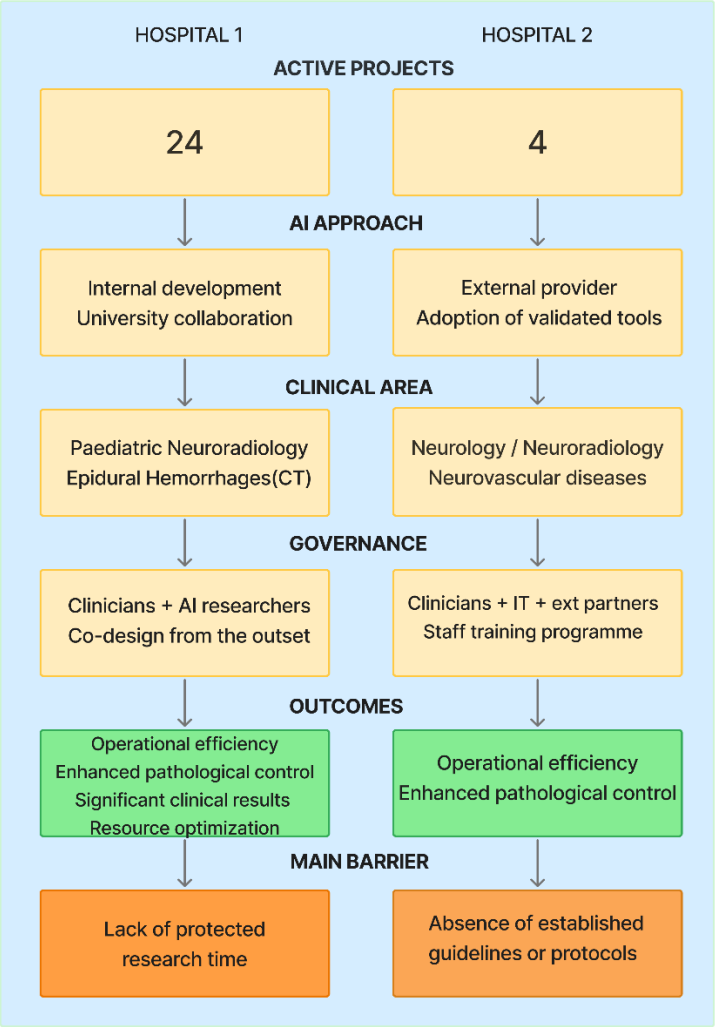


***Figure 6**: Radar chart of AI implementation maturity. The radar chart compares the two AI adoption models across six dimensions, highlighting the stronger internal development profile of Hospital 1 and the workflow-oriented scalability of*

Hospital 2. Scores range from 1 = low maturity to 5 = high maturity and summarize the implementation profile of two anonymized hospitals adopting respectively an in-house and a commercial AI model.

Table 5: *Comparative maturity profile of AI adoption models that summarize the implementation profile of two anonymized hospitals adopting respectively an in-house and a commercial AI model.*



4 Quantitative Analysis of Healthcare Service Utilization

4.1 Introduction to Telemedicine

Cardiovascular diseases (CVDs) remain a leading global cause of morbidity, disability, and mortality. Accounting for an estimated 19.8 million global deaths in 2022 (32% of all mortality), most of these events are driven by ischemic heart disease and stroke (Mohammadzadeh et al., 2022; WHO, 2021). Beyond the clinical toll, CVDs exert severe socioeconomic pressure through absenteeism, early retirement, and surging healthcare expenditures, with EU costs escalating from €169 billion in 2003 to €210 billion in 2017 (Luengo-Fernandez et al., 2023). In Italy, CVDs continue to be the primary cause of death. Recent estimates attribute approximately 209,948 deaths to cardiovascular events in 2023, alongside an overall prevalence of over 9.1 million cases (IHME, 2024).

Historical data reveals a dual epidemiological trend within the Italian population. Between 2000 and 2022, age-standardized cardiovascular mortality declined by 2.6%, largely reflecting advancements in acute care and prevention. Furthermore, the disease burden expressed in Disability-Adjusted Life Years (DALYs) decreased by 13.6%. Paradoxically, this improvement in survival has catalyzed a sharp 25.6% increase in CVD prevalence over the same period (IHME, 2024). This mirrors a broader European paradigm shift: a transition from acute mortality to prolonged chronicity. As the population ages, the sustained healthcare demand generated by complex, multimorbid cardiovascular patients threaten the sustainability of traditional in-person care models, necessitating urgent organizational innovation.

In response to these systemic pressures, telemedicine has emerged as a cornerstone of digital healthcare innovation (Halm-Pozniak et al., 2023). Telemedicine encompasses a spectrum of remote services, ranging from teleconsultations to continuous home telemonitoring, that enhance accessibility, reduce cross-infection risks, and alleviate hospital infrastructure strain (WHO, 2019; Hawrysz et al., 2021). Within this domain, telecardiology and virtual hospital models represent a highly promising frontier. Technological advancements now permit the real-time transmission of continuous physiological data, enabling proactive interventions for conditions such as heart failure and arrhythmias. Crucially, this continuous data stream paves the way for the integration of artificial intelligence (AI). AI-augmented cardio telerehabilitation can synthesize vast amounts of remote monitoring data, providing clinicians with predictive decision-support tools that identify sub-clinical deteriorations before they require urgent hospitalization. Studies already indicate that remote

cardiovascular monitoring is cost-effective, yielding favourable Incremental Cost-Effectiveness Ratios (ICER) and improved Quality-Adjusted Life Years (QALYs) well within acceptable European thresholds (Mokri et al., 2025; European Commission, 2018).

Despite robust emerging evidence, the successful implementation of telemedicine is highly dependent on localized demographics and healthcare infrastructures. The Liguria region serves as a highly relevant testing ground. It features the oldest population demographic in Italy and reports a high prevalence of chronic cardiovascular conditions, resulting in significant pressure on regional hospital admission rates and lengths of stay (Osservasalute, 2023; Agenas, 2024). Furthermore, the Ligurian context is complicated by profound geographic and logistical barriers. Its longitudinal, coastal morphology, constrained between the sea and mountainous terrain creates stark disparities in healthcare accessibility between high-density metropolitan hubs like Genoa and isolated rural areas. Compounded by the fact that 16.3% of Italians live alone (ISTAT, 2025), these geographic and social vulnerabilities can amplify health inequities (Di Novi et al., 2020; Succi et al., 2023). Telemedicine offers a critical tool to bridge this spatial divide.

While the theoretical benefits of virtual wards and cardio telerehabilitation are well-documented, there remains a critical shortage of comparative, data-driven studies utilizing standardized clinical databases (Norman et al., 2023; Vallée & Arutkin, 2024). Current evidence is frequently limited to fragmented qualitative initiatives. This study aims to objectively evaluate the clinical and organizational effects on the outcomes of telemecine-supported cardiologic pathways compared to traditional face-to-face care. By analysing real-world clinical databases within the complex demographic and geographic framework of the Liguria region, this research seeks to provide evidence-based insights to support policymakers in designing equitable, sustainable, and high-impact digital healthcare interventions.

4.2 Administrative Data Sources and Extraction

This study aims to evaluate the impact of telemedicine on cardiological patients compared to traditional in-person care. The analysis relies on administrative healthcare data provided by the Local Health Authority 3 (ASL 3).

The comprehensive dataset, processed using STATA software, consists of six distinct administrative data flows: specialist outpatient care, demographic registries, hospital discharge records (SDO), healthcare exemptions, pharmaceutical records, and pathological anatomy. Table 2 details the specific characteristics of the datasets actively utilized in this analysis.

While these administrative records span a longitudinal period from 2019 to 2024, the regression analysis was strictly limited to data from the year 2024. This methodological restriction was necessary because the Regional Unique Code (CUR), the essential variable required to accurately distinguish telemedicine consultations from conventional in-person visits, was only introduced and systematically recorded in the 2024 dataset.

***Table 6**: Description of the data used in the analysis with their variables*

Outpatient Care Database	Contains regional outpatient care records, detailing specialist visits and diagnostic procedures. In this study, it is used to track the volume, timing, and modality (telemedicine vs. in-person) of cardiovascular follow-up care.	-ID -Date (prescription, execution and prenotation) -Prestation code -Quantity -Branch -Tariff -ID medic -Year -Semester -CUR (regional unique code)
Health Demographic Registry	Provides demographic and vital status information for the regional population. It is utilized to extract baseline patient characteristics (such as age, sex, and residence) and to track survival status throughout the observation period	-ID -Gender -Birth year -Date of death -Enrollment date -End enrollment date -Health authority pin -Self certification -Province of residence code -Month -Year
Hospital Discharge Records	Collects standardized clinical and administrative data on all hospital admissions and day-hospital stays. It is essential for identifying urgent versus	-ID -Facility code -Admission type -Admission date

	planned cardiovascular hospitalizations and for calculating baseline clinical complexity (e.g., Charlson Comorbidity Index) via ICD-9-CM diagnostic codes.	-Discharge date -Admission and discharge wards -Transfer details (wards and dates) -Admission regime -Discharge status -Primary and secondary diagnoses -Primary and secondary procedures -Day hospital accesses -DRG (Diagnosis Related Group) -Tariff -Source of admission -Education level -Marital status –Quarter -Year

4.3 Analytic Sample Construction and Inclusion Criteria

Two distinct samples were analysed.

The first sample (n = 15,173) includes all telemedicine encounters identified in the specialist outpatient file (CUR), corresponding to televisits and remote monitoring/control activities of all the branches. This sample was used to provide a general demographic overview of telemedicine diffusion across the entire ASL3 population. To identify the telemedicine, we searched key words in the descriptions of the specialistic file like “tele”, “remote” and “distance”.

The second sample focuses specifically on cardiology patients. It was constructed by selecting, from the specialist file, all visits matching one of the following three clinical pathways: general cardiologic visit, Pacemaker check and Heart failure follow-up each identified by a televised CUR code

(C02265500, C02269600, C02265600) and its corresponding in-person comparator (C00348200, C00481700, C01064900).
The total number of cardiologic encounters is 13,010 observations.

4.4 Healthcare Service Utilization Outcome Variables

Healthcare service utilization was measured by counting the events recorded in a 12-month window following each patient's individual index date. Therefore, unlike a difference-in-differences design across multiple calendar years, our analysis adopts a cross-sectional perspective with a fixed individual follow-up, comparing, via propensity score matching (PSM), patients who utilized televisits with clinically comparable patients who did not. Outcome variables were extracted from two administrative data flows: hospital discharge records (SDO) for hospitalisation-related outcomes, and outpatient specialist care records for visit-related outcomes.
Four main outcomes were formally modelled via negative binomial regression:

- Total Specialist Visits: The total number of specialist visits (total_consultations), extracted from outpatient specialist care records, allows us to evaluate whether the effect of the telemedicine extends to the patient's overall healthcare consumption or remains confined to the cardiological scope.
- Cardiological Visits: For this purpose, the subset of cardiological visits (cardio_consultations) was isolated separately. This is useful for distinguishing an intensification effect in specific specialist follow-up from a more general effect on healthcare consumption.
- Urgent Admissions: The number of urgent inpatient admissions (urgent_hospitalizations) is extracted from the Hospital Discharge Records. It approximates the occurrence of acute events that tighter monitoring, made possible by televisits, could help prevent or anticipate.
- Planned Admissions: The number of planned, elective inpatient admissions (planned_hospitalizations), extracted from the same Hospital Discharge Records, complements the analysis of urgent admissions.

The overall number of accesses to the cardiological pathway (n_accesses) was additionally used, at an earlier descriptive stage of the analysis, as an aggregate measure of service utilization intensity informing the propensity score matching step, though it was not retained among the four outcomes formally modelled above. Day hospital admissions (dh_adm) were also constructed from the same HDR flow but have not yet been included in the presented models, representing a natural direction for future extension of the analysis.

4.5 Clinical and Demographic Control Variables

To account for the main confounding factors in the relationship between telemedicine services use and healthcare utilisation intensity, the following covariates were included: patient sex (*male*), age class (categorised into <60, 60-69, 70-79, and ≥80 years), the type of cardiac condition, coded into categories including, among others, pacemaker carriers and patients with heart failure), and the Charlson Comorbidity Index (*charlson_score*), calculated for each patient as a summary indicator of comorbidity burden and associated clinical risk (Charlson et al., 1987). For descriptive purposes, the Charlson Index was further categorised into three classes (No comorbidity, Mild, Severe), while in the regression models it was retained in continuous form.

4.6 Analytical Strategy: Propensity Score Matching and Negative Binomial Regression

Our analysis focuses on cardiology patients enrolled in the ASL3 pathway during 2024 who received at least one remote consultation as part of their clinical follow-up. This approach is based on the hypothesis that telemedicine can support closer and more continuous monitoring of cardiac patients, including pacemaker carriers and patients with heart failure, whose conditions require ongoing surveillance to prevent acute exacerbations, while also raising the question of whether such remote contact substitutes for, or instead adds to, traditional in-person specialist care.

The analysis is based on twelve-month administrative data extracted from the hospital discharge records (SDO) and outpatient specialist care flows, covering hospitalisations, urgent and planned admissions, and specialist visits occurring within a fixed follow-up window from each patient's individual index date.

Four outcome variables were considered: the total number of specialist visits. the subset of cardiology-specific visits, the number of urgent hospitalisations and the number of planned hospitalisations. Patients are divided into two groups: those who received at least one telemedicine service during the observation period (the treated group) and those who did not (the control group). Consistent with an absorbing treatment definition, each patient is classified once, at the patient level, rather than tracked across repeated discrete periods, since the design evaluates cumulative utilisation within a fixed post-index window rather than a multi-period panel. We additionally include a set of confounding patient characteristics expected to influence healthcare utilisation, namely sex, age class, type of cardiac condition, and the Charlson Comorbidity Index. Statistical analyses were performed using Stata (StataNow SE 19.5).

Given the characteristics of our outcome data, a high proportion of zero counts, particularly for urgent hospitalisations, right-skewed distributions, and clear evidence of overdispersion, negative binomial regression emerged as the most appropriate model for assessing the impact of telemedicine on healthcare utilisation, consistent with established guidance on modelling overdispersed count data (Ver Hoef and Boveng, 2007). Unlike panel-data designs with repeated observations per individual over time, our design does not require individual random effects or time interactions, since each outcome is modelled as a single cumulative count over the fixed follow-up window. To address the non-random assignment of patients to telemedicine, which was based on clinical judgement and device compatibility rather than randomisation, we adopt a two-stage estimation strategy combining propensity score matching (PSM) with negative binomial regression. In the first stage, the probability of receiving telemedicine is estimated through a logistic regression model on observed patient characteristics (Rosenbaum and Rubin, 1983):

$$\mathbf{e}(\boldsymbol{Xi}) \;=\; \mathbf{Pr}(\mathbf{T}\boldsymbol{i} \;=\; \mathbf{1} \mid \boldsymbol{Xi}) \;=\; \boldsymbol{\Lambda}(\boldsymbol{\beta_0} + \boldsymbol{\beta_1}\mathbf{A} + \boldsymbol{\beta_2}\mathbf{S} + \boldsymbol{\beta_3}\,\mathbf{Pt} + \boldsymbol{\beta_4}\mathbf{C})$$

where Λ(·) denotes the logistic cumulative distribution function, T denotes the telemedicine, A is the age class, S is the gender, Pt is the type of pathology and C is the Charlson score. Based on the estimated propensity score, treated patients are matched to control patients through nearest-neighbour matching, one-to-one and without replacement, minimising the absolute distance between propensity scores within each matched pair.

In the second stage, negative binomial regression is estimated on the matched sample for each outcome variable Yi in turn:

$$\boldsymbol{E}[\boldsymbol{Y_i}|\,\boldsymbol{X_i}\,] \;=\; \boldsymbol{e}^{(\boldsymbol{\beta_0}+\boldsymbol{\beta_1}\,\mathrm{T}_i\,+\boldsymbol{\beta_2}\,\boldsymbol{A_i}+\boldsymbol{\beta_3}\,\boldsymbol{S_i}\,+\boldsymbol{\beta_4}\boldsymbol{P_i}+\boldsymbol{\beta_5}\,\boldsymbol{C_i})}$$

$$\mathbf{Var}(\,\boldsymbol{Y_i}|\boldsymbol{X_i}\,) \;=\; \mathbf{E}[\boldsymbol{Y_i}\mid\boldsymbol{X_i}] \;+\; \boldsymbol{\alpha}\,[\mathbf{E}[\boldsymbol{Y_i}|\,\boldsymbol{X_i}]]^{\mathbf{2}}$$

where α is the overdispersion parameter: values of α significantly different from zero indicate that the conditional variance exceeds the conditional mean, justifying the negative binomial specification over a standard Poisson model.

To assess the validity and robustness of our findings, we complemented the main specification with several checks. First, covariate balance between treated and matched control patients was formally tested after matching, to verify that the matching procedure had adequately reduced observable differences between groups prior to outcome estimation. Second, rather than relying on a single outcome, we estimated the treatment effect across four related but conceptually distinct measures of

healthcare utilisation, allowing us to assess whether telemedicine operates as a general intensifier of contact with the healthcare system or acts more specifically on cardiology-related follow-up, while leaving hospital-based urgent care comparatively unaffected. Third, the overdispersion parameter was formally tested through a likelihood-ratio test against the nested Poisson specification for each outcome (e.g., $\chi^2(1) = 43.95$, $p < 0.001$ for urgent hospitalisations), confirming that the negative binomial model was preferable to a Poisson alternative across all estimated models.

4.7 Preliminary Demographic Analysis of Telemedicine Diffusion

To perform this analysis, outpatient visit records were extracted from the specialist healthcare dataset. To accurately identify and distinguish tele-visits, we utilized a specific data layout provided by the University of Genoa (UNIGE), which contains the complete Regional Catalogue of Services. The unique regional codes and their corresponding service descriptions were imported into STATA and integrated with the specialist outpatient records through a deterministic merge procedure.

As illustrated in Figure 1, which reports the top 10 most frequently provided telemedicine services, ophthalmological and metabolic follow-up dominate the overall volumes. Remote follow-up visits for Ophthalmology rank first with 2,741 services, closely followed by Diabetology (2,245) and Radiotherapy (1,430).

Endocrinology (869) and Teleradiography (589) complete the upper half of the ranking. Cardiology ranks sixth overall with 484 services, a comparatively modest absolute volume relative to the top specialties, yet still a stable and clinically meaningful presence within the top ten. The remaining places in the ranking are occupied by Telespinography (440), Pain Management (422), Internal Medicine (371), and Nephrology (342).

Before turning to the causal analysis of telemedicine on cardiology patients, we examined how telemedicine activity is distributed across clinical specialties more broadly. For three telemedicine branch, four utilisation indicators were computed: total frequency of contacts (the aggregate volume of telemedicine activity), care intensity (the average level of use per patient within the branch), the return/repeat-visit rate (the ratio of total contacts to unique patients, expressing how often the same patient returns to the same telemedicine service), and the number of unique patients served.

Individual specialty codes were subsequently aggregated into a smaller set of main clinical branches, among which Cardiology, Diabetology, and Radiology are considered the most relevant in the Ligurian context. This prominence is deeply rooted in the region's unique demographic profile, which features the highest proportion of elderly residents in Europe, thereby driving a structural demand for

the continuous remote management of age-related cardiovascular and metabolic conditions (ISTAT, 2022).

All four indicators were normalised on a common 0-100 scale to allow direct visual comparison across branches with markedly different absolute volumes, and the results were jointly displayed in a radar chart (Figure 4).

The resulting pattern reveals three distinct utilisation profiles. Radiology stands out for its breadth of reach: it records the highest total frequency of contacts, the highest number of unique patients, and the highest overall intensity of use among the three branches, but the lowest return/repeat-visit rate. This is consistent with the episodic nature of radiological telemedicine activity, typically organised around single diagnostic exams rather than a continuous relationship with the same patient. Cardiology displays close to the opposite profile: despite reaching comparatively fewer unique patients and recording only moderate total frequency and intensity of use, it shows by far the highest return/repeat-visit rate of the three branches, indicating that cardiology patients who engage with telemedicine tend to do so repeatedly rather than only once. This pattern is consistent with the chronic, monitoring-oriented nature of cardiology follow-up, particularly for pacemaker carriers and heart failure. Diabetology occupies an intermediate position, reaching a relatively high number of unique patients and a high total frequency, but showing comparatively low intensity of use and a low return/repeat-visit rate, a pattern closer to occasional contact than to sustained follow-up.

It should be noted that the four indicators were normalised jointly across four clinical branches (Cardiology, Diabetology, Radiology, and Neurology), with Neurology subsequently excluded from the final visualisation, because of its minimal volume. Because the 0-100 scale for each indicator is anchored to the minimum and maximum values observed across all four branches, values close to 0 for the three displayed branches should be interpreted as being close to Neurology's value on that indicator, rather than as an absolute absence of activity.

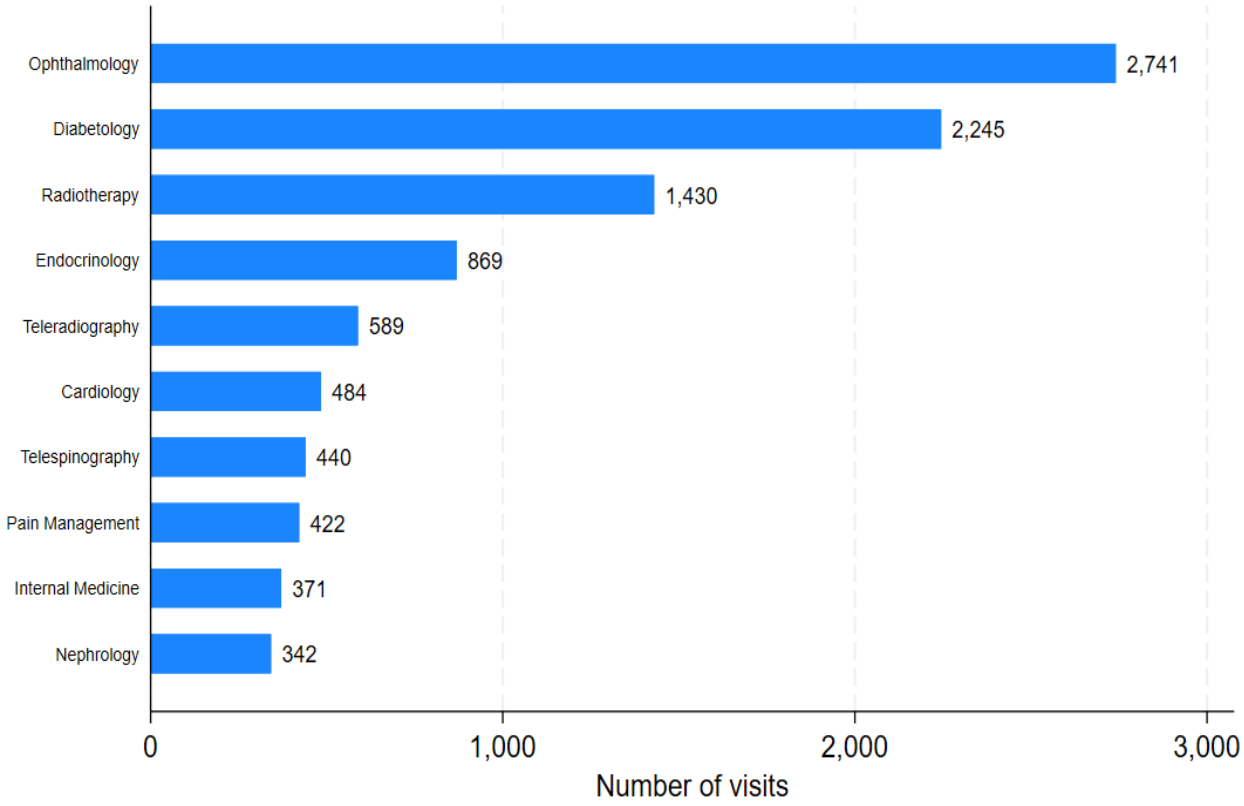


***Figure 7**: Top 10 most frequently provided telemedicine services by volume, ASL3, 2024.*

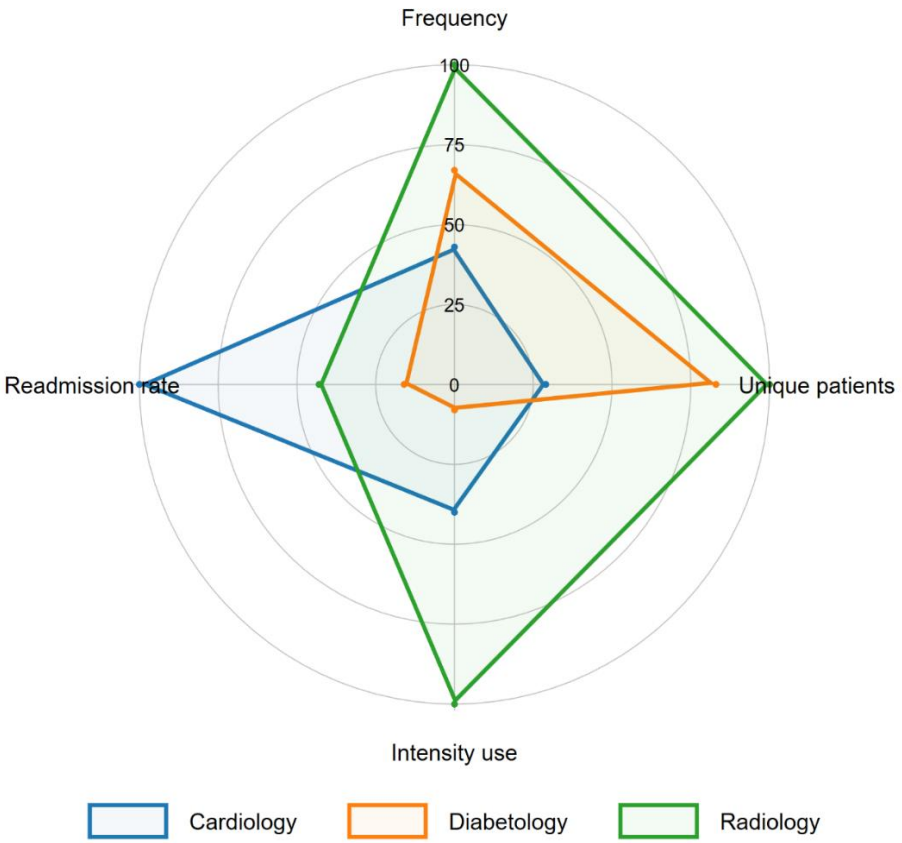


***Figure 8**: Telemedicine utilisation profile by clinical branch (Cardiology, Diabetology, Radiology): frequency, intensity of use, return rate, and unique patients served, normalised on a 0–100 scale.*

4.8 Cardiology Cohort Construction and Baseline Characteristics

The construction of the analytic sample began with the extraction of all cardiology-related outpatient visits recorded during 2024, identified through the relevant CUR (*Catalogue Unico Regionale*) procedure codes described in the Inclusion Criteria section. This extraction yielded a total of 14,113 visits, distributed across three clinical categories: General Cardiology, Pacemaker follow-up, and Heart Failure and two care modalities, in-person and telemedicine.

Figure 3 illustrates the distribution of visits by category and modality. General Cardiology accounts for most of the activity, with 8,818 in-person and 484 telemedicine visits (9,302 visits in total, approximately 66% of the full sample), followed by Pacemaker follow-up, with 4,203 in-person and 314 telemedicine visits (4,517 visits, approximately 32% of the sample).

Heart Failure represents by far the smallest category in absolute terms, with only 186 in-person and 108 telemedicine visits (294 visits, roughly 2% of the sample). However, when visits are examined in relative rather than absolute terms, a markedly different pattern emerges telemedicine accounts for only 5.2% of General Cardiology visits and 7.0% of Pacemaker visits, but for 36.7% of Heart Failure visits, more than five times the share observed in the other two categories. This asymmetry suggests that, despite its low absolute volume, telemedicine is disproportionately directed towards heart failure patients, consistent with the chronic, monitoring-intensive nature of this condition and with the higher clinical value of frequent, low-burden remote contact for patients at elevated risk of acute decompensation.

Following the initial extraction, the visit-level dataset was linked to two additional administrative sources. First, the registry file (*anagraphic*) was merged in to retrieve patient sex and to compute age, derived from year of birth relative to 2024. Second, the hospital discharge records (SDO) were used to compute, for each patient, the Charlson Comorbidity Index (Charlson et al., 1987). Importantly, the Charlson Index was constructed using only hospitalisations occurring in the 12 months preceding each patient's individual index date, rather than the post-index follow-up window used for the outcome variables. This design choice is methodologically deliberate: since the Charlson Index enters the analysis as a pre-treatment control variable, both in the propensity score model and in the subsequent negative binomial regressions, it must reflect the patient's comorbidity burden *prior to* telemedicine assignment, so as to avoid contaminating a confounding variable with post-treatment information. For each hospitalisation within this pre-index window, the Charlson Index was computed from the primary and secondary discharge diagnoses using the user-written charlson command in Stata, applying the Enhanced ICD-9-CM coding algorithm and the standard Charlson comorbidity weights. Where a patient had more than one hospitalisation within the 12-month pre-index window, the maximum Charlson score observed across admissions was retained, representing the patient's most severe recorded comorbidity burden prior to treatment; the continuous score was subsequently grouped into three categories: None (0), Mild (1-2), and Severe (≥3) for descriptive purposes.

Of the initial 14,113 visits, 320 (approximately 2.3%) could not be matched to either the registry file or the hospital discharge records and were therefore excluded, yielding a final analytic sample of 13,793 visit-level observations. Collapsing this sample to the patient level retaining one row per patient, as visit-level attributes such as age, sex, and Charlson score are

constant within patient produced a total of 10,295 unique patients, of whom 607 (5.9%) received at least one televisit during the observation period and 9,688 (94.1%) did not.

Table 2 summarises the descriptive characteristics of the two groups prior to matching. Telemedicine users are disproportionately male (65.9% versus 58.4% among non-users) and are more concentrated in the 60-79 age bracket (62.1% versus 45.2%). Conversely, the oldest patients (≥80 years) are comparatively under-represented among telemedicine users (25.3%) relative to non-users, for whom this age group constitutes the largest single category (39.6%). Average Charlson scores are slightly lower among telemedicine users (0.292) than among non-users (0.356). Taken together, these imbalances, particularly with respect to age distribution, indicate that telemedicine use was not randomly assigned across the patient population, but instead followed a pattern plausibly related to clinical judgement, technological accessibility, or both. This descriptive evidence motivates the propensity score matching strategy adopted in the following section, which is used to construct a balanced comparison group before estimating the effect of telemedicine on healthcare utilisation outcomes.

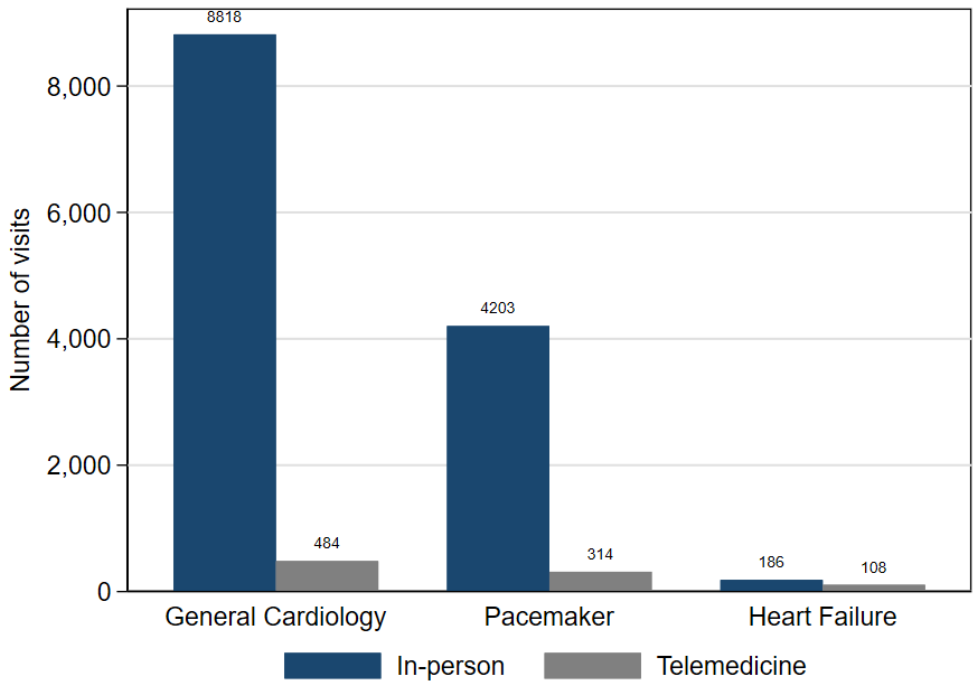


***Figure 9**: Distribution of cardiology visits by clinical area and delivery modality (in-person vs. telemedicine).*

Table 7: *Descriptive characteristics of cardiology patients by telemedicine status (sex, age class, Charlson Comorbidity Index), pre-matching sample (n = 10,295; 607 treated, 9,688 controls).*

		Telemedicine	
		Yes	No
Sex	Female	207 (34%)	4029 (41.5%)
	Male	400 (66%)	5659 (58.4%)
Age class	<60	76 (12.5%)	1462 (15.1 %)
	60-79	377 (62.1%)	4382 (45.2%)
	≥80	154 (25.3%)	3844 (39.6 %)
Charlson Index	Average	0.292	0.356
Number		607	9688

4.9 Temporal Longitudinal Trends in Healthcare Access

Before complementing the negative binomial regression results estimated on the 12-month cumulative outcomes, healthcare utilisation was additionally examined at a finer temporal resolution by disaggregating each outcome into four consecutive quarters relative to the patient's individual index date (Q1: days 1-91, Q2: days 92-182, Q3: days 183-273, Q4: days 274-365). For each patient and each quarter, hospitalisation counts (urgent and planned) were computed from the hospital discharge records (SDO), while visit counts (total and cardiology-specific) were computed from the outpatient specialist care flow, applying the same event definitions used for the cumulative 12-month outcomes. Patients with no recorded events in each quarter were assigned a value of zero, yielding a complete patient-by-quarter panel. Quarterly averages were then computed separately for the treated and control groups and plotted as line graphs to visualise the raw, unadjusted evolution of healthcare utilisation across the follow-up period (Figure 4).

The quarterly trends offer a more granular picture of the patterns identified in the regression analysis. For urgent hospitalisations, both groups display a marked downward trend over the follow-up period, converging to comparably low levels by Q4; the two lines remain close throughout, with no consistent or widening gap between treated and control patients. Cardiology visits show the opposite pattern: treated patients report a consistently higher quarterly average than controls in every quarter, with the gap most pronounced in Q1 and Q3, indicating that the intensification of cardiology-specific follow-up associated with telemedicine is sustained throughout the year rather than concentrated in a single period.

Total visits follow a similar pattern, with treated patients again consistently above controls across all four quarters, although both groups show declining utilisation from Q1 to Q4, suggesting that overall care intensity, for both groups, is front-loaded toward the beginning of the follow-up window.

Planned hospitalisations display a more irregular pattern: control patients start from a higher level in Q1 and decline steadily, while treated patients increase from Q1 to Q3 before dropping sharply in Q4, with the two lines crossing around Q3.

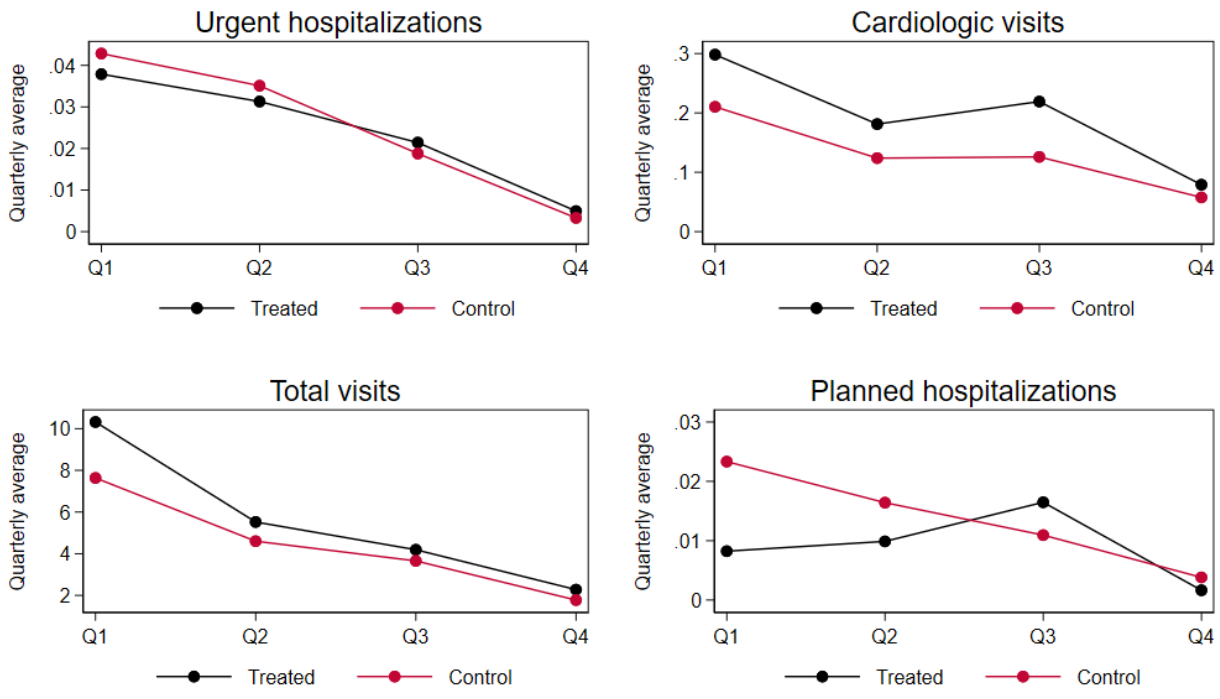


Figure 10: *Longitudinal trends of average quarterly healthcare utilization outcomes (urgent hospitalizations, cardiologic visits, total visits, and planned hospitalizations) for treated and control groups over a four-quarter follow-up period.*

4.10 Propensity Score Matching Evaluation and Covariate Balance Diagnostics

Propensity score matching was implemented to address the non-random assignment of telemedicine, motivated by the descriptive imbalances already documented in Table 2 and further confirmed by the balance diagnostics reported here. Before matching, a likelihood-ratio test on the logit propensity score model was highly significant (LR $\chi^2(8) = 59.80$, $p < 0.001$), confirming that treated and control patients differed systematically on observed characteristics, that is, telemedicine assignment was not independent of age, sex, condition type, and comorbidity burden. Individual covariates showed varying degrees of imbalance: sex displayed the largest standardized bias among the continuous/binary covariates (15.5%, $p < 0.001$), while among condition-type categories, the smallest clinical subgroup corresponding to heart failure patients, showed the most pronounced imbalance (22.5%, $p < 0.001$), with telemedicine users markedly overrepresented in this category relative to controls. Age and Charlson score displayed comparatively smaller, non-significant pre-matching imbalances (-2.5% and -6.7% respectively).

Nearest-neighbour matching, implemented one-to-one and without replacement, reduced the initial sample of 607 treated and 9,688 control patients to a matched sample of 607 treated and 607 control patients. Balance diagnostics recomputed on the matched sample indicate a substantial improvement across all summary indices: mean standardized bias fell from 9.2% to 1.2%, and median bias from 7.1% to 0.9%. Rubin's B (the standardized difference of the linear propensity index between groups) fell from 29.4 to 4.3, and Rubin's R (the ratio of propensity score variances) moved from 2.47 to 1.35, both indices falling within the conventionally accepted thresholds ($B < 25$; R between 0.5 and 2) after matching, having exceeded them beforehand. Critically, the joint likelihood-ratio test on the matched sample is no longer significant (LR $\chi^2(8) = 0.57$, $p = 0.989$), indicating that, after matching, observed covariates no longer predict treatment assignment, consistent with the two groups being statistically indistinguishable on observables.

At the level of individual covariates, bias reduction was most pronounced for the variables that had shown the largest pre-matching imbalance: sex (93.4% bias reduction) and the heart-failure condition-type category (100% reduction, from 22.5% to 0.0%), followed by the pacemaker category (90.4% reduction) and Charlson score (54.0% reduction). Age, which

was already only modestly imbalanced before matching, showed a smaller absolute improvement (31.9% reduction, from -2.5% to -1.7%), while the general-cardiology category, already well-balanced pre-matching, showed a negligible increase in bias after matching (from -0.5% to -0.7%), which remains well within an acceptable range in absolute terms.

These results are summarised graphically in Figure 5, which displays the standardized percentage bias for each covariate before (unmatched) and after (matched) the matching procedure. Covariates that were furthest from the zero-bias reference line under the unmatched sample, most visibly sex and the heart-failure category, converge closely to zero under the matched sample, visually confirming the improvement in covariate balance reported in the accompanying balance table. Overall, these diagnostics support the validity of the matched sample as a basis for the subsequent negative binomial regression analysis, since the treated and control groups are, on the covariates considered, no longer distinguishable from one another prior to outcome estimation. The resulting matched sample comprises 1,214 patients (607 treated, 607 controls), forming the analytic dataset for the negative binomial regression models presented in the following section. Before turning to these results, it is useful to examine the distribution of the four healthcare utilisation outcomes within this matched sample (Figure 6), since their shape directly motivates the choice of estimator. As shown in Figure 6, all four outcomes display a pronounced concentration of observations at zero, together with a long right tail extending to a comparatively small number of high-count patients. For urgent and planned hospitalisations, the overwhelming majority of patients recorded zero events during the follow-up period, with very few experiencing one or more hospitalisations; cardiology and total visit counts show a similar, though less extreme, concentration at zero alongside a markedly longer tail. Correspondingly, the sample variance substantially exceeds the sample mean for every outcome (urgent hospitalisations: mean = 0.11, variance = 0.16; planned hospitalisations: mean = 0.04, variance = 0.05; cardiology visits: mean = 0.62, variance = 2.02; total visits: mean = 19.64, variance = 744.65) a pattern inconsistent with the equidispersion assumption (mean equal to variance) underlying the Poisson model, and indicative of overdispersion. This combination of excess zeros and overdispersion is characteristic of healthcare utilisation counts more broadly and provides the empirical justification for modelling these outcomes with negative binomial regression rather than standard Poisson or linear regression. Notably, while zero-inflated extensions of the negative binomial model exist specifically for this type of data, Lee et al. (2023), evaluating comparable zero-inflated healthcare-utilisation outcomes in a telemedicine trial, found that conventional negative binomial regression performed comparably to and, by information-criteria comparisons, often outperformed its zero-inflated counterpart even under

substantial zero inflation, supporting the use of the standard negative binomial specification adopted here.

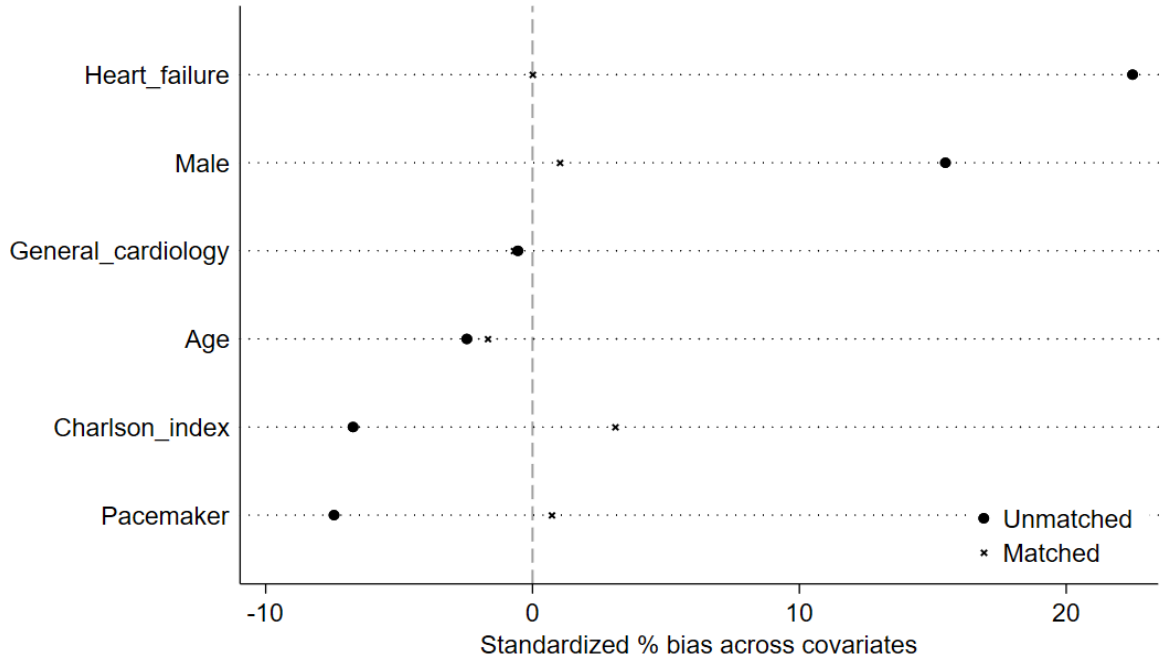


***Figure 11**: Assessment of covariate balance. The plot illustrates the reduction in standardized bias across patient characteristics (age, sex, clinical condition, and Charlson Index) achieved through the matching procedure.*

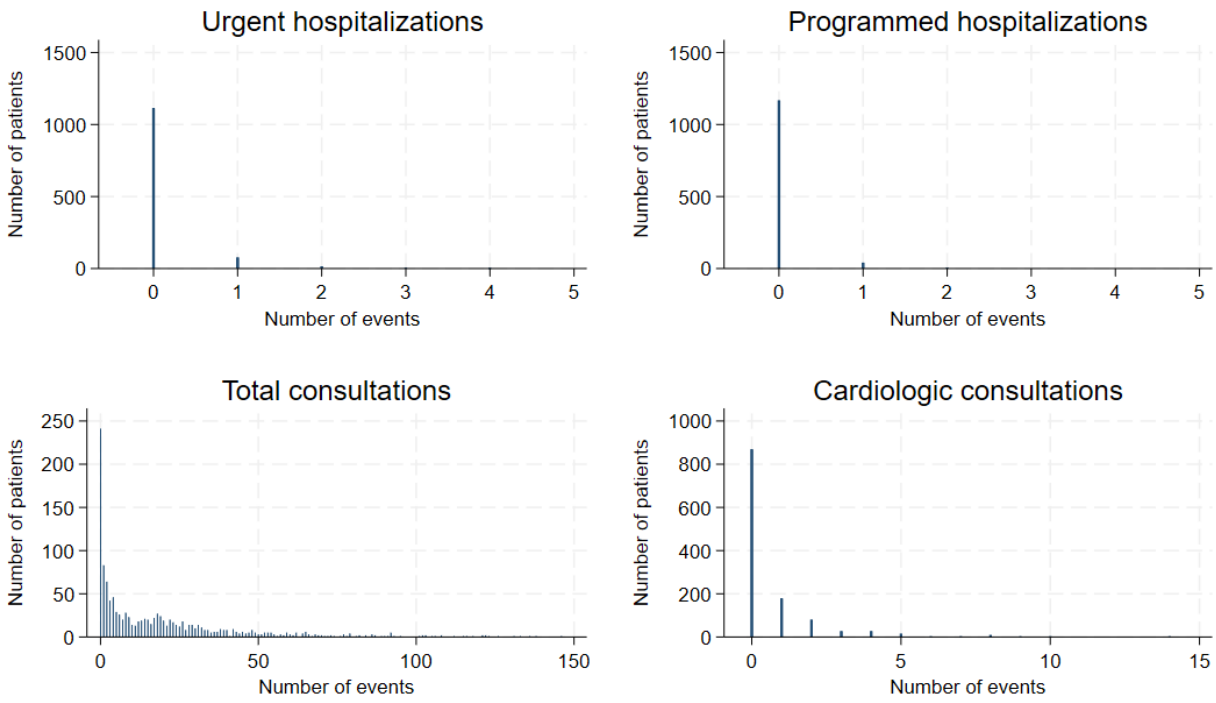


***Figure 12:** Distribution of the four healthcare utilisation outcomes in the matched sample (n = 1,214). Each panel shows the number of patients (y-axis) recording each observed count of events (x-axis) during the follow-up period, for urgent hospitalisations, planned hospitalisations, total consultations, and cardiologic consultations.*

4.11 Negative Binomial Regression Estimates

Table 3 reports the results of four negative binomial regression models estimated on the matched sample (n = 1,214), each modelling a distinct healthcare utilisation outcome as a function of telemedicine service use, age class, sex, condition type, and Charlson comorbidity score. Across all four models, the overdispersion parameter was estimated well above zero (with lnalpha = 2.13 for total visits, 2.92 for cardiology visits, 3.45 for urgent hospitalisations, and 3.12 for programmed hospitalisations), with a likelihood-ratio test explicitly rejecting the Poisson restriction for the urgent hospitalisations model ($\chi^2(1) = 43.95$, $p < 0.001$), confirming that the negative binomial specification is appropriate given the overdispersed, zero-heavy nature of the count outcomes.

Cardiology consultations show the strongest and most consistent association with telemedicine use: treated patients recorded 52.9% more cardiology visits than matched controls (IRR = 1.53, 95% CI: 1.19–1.96, p = 0.001). Among the covariates, only condition type reached significance: pacemaker carriers recorded more than double the cardiology visits of the reference category (IRR = 2.04, p < 0.001), consistent with the structured, device-monitoring-intensive follow-up this subgroup requires. Notably, neither age, sex, nor Charlson score were significant predictors of cardiology-specific visit frequency once telemedicine and condition type were accounted for.

Total consultations show a smaller, though still significant, effect of telemedicine (IRR = 1.26, 95% CI: 1.07–1.49, p = 0.007), corresponding to a 26.2% increase, about half the magnitude of the cardiology-specific effect. Age and Charlson score were both significant predictors of overall visit volume (patients aged ≥80 recorded 62.8% more total visits than the reference group, p = 0.001; each additional point of Charlson score was associated with an 11.3% increase, p = 0.037), while pacemaker carriers showed a divergent pattern from the cardiology-specific model, recording significantly fewer total visits than the reference category (IRR = 0.80, p = 0.020).

Urgent hospitalisations show no significant association with telemedicine (IRR = 0.81, 95% CI: 0.53–1.23, p = 0.316); the point estimate is directionally consistent with a protective effect, but the confidence interval is wide and includes 1, precluding any firm conclusion in either direction. In this model, the strongest predictors are clinical rather than technological: male sex is associated with an approximate doubling of urgent hospitalisation risk (IRR = 2.00, p = 0.007), and each additional point of Charlson score raises the risk by 52.7% (IRR = 1.53, p < 0.001), by far the strongest covariate effect observed across all models, consistent with the Charlson Index's established role as a predictor of acute clinical deterioration.

Programmed hospitalisations similarly show no significant association with telemedicine use (IRR = 0.73, 95% CI: 0.41–1.33, p > 0.05). Much like urgent admissions, the primary driver for elective

inpatient care is baseline clinical complexity rather than remote monitoring exposure: the Charlson comorbidity score is the only statistically significant predictor in this model, increasing the expected rate of programmed hospitalisations by 38.3% for each additional point (IRR = 1.38, 95% CI: 1.08–1.77, $p < 0.001$).

***Table 8**: Negative binomial regression estimates for healthcare utilisation outcomes (total visits, cardiology visits, urgent hospitalisations, and programmed hospitalisations) on the matched sample (n = 1,214). *Note: Incident rate ratios (IRR) are reported with 95% confidence intervals in brackets. *p < 0.05, **p < 0.01, **p < 0.001.*

	Total consultations	Cardio consultations	Urgent hospitalizations	Programmed hospitalizations
Telemedicine	1.262*** [1.067,1.494]	1.529*** [1.191,1.964]	0.805 [0.527,1.230]	0.733 [0.405,1.325]
Age classes				
60-69	1.058 [0.787,1.423]	1.517* [0.968,2.377]	1.021 [0.434,2.399]	1.122 [0.358,3.516]
70-79	1.424** [1.083,1.873]	1.396 [0.919,2.122]	1.620 [0.759,3.457]	1.747 [0.629,4.853]
≥80	1.628*** [1.217,2.177]	1.183 [0.758,1.847]	1.949* [0.883,4.300]	0.922 [0.289,2.947]
Male	1.066 [0.893,1.272]	1.207 [0.928,1.570]	1.998*** [1.210,3.298]	1.256 [0.661,2.389]
Pacemaker	0.797** [0.658,0.965]	2.035*** [1.556,2.663]	1.221 [0.770,1.934]	0.659 [0.318,1.366]
Heart failure	1.069 [0.713,1.602]	1.643* [0.919,2.936]	1.265 [0.491,3.259]	1.434 [0.433,4.754]
Charlson index	1.113** [1.007,1.231]	1.038 [0.898,1.200]	1.527*** [1.262,1.847]	1.383*** [1.082,1.768]
Lnalpha	2.125*** [1.959,2.305]	2.915*** [2.401,3.539]	3.445*** [2.010,5.905]	3.120* [0.929,10.473]

4.12 Graphical Summary: Incidence Rate Ratios and Predictive Margins

Figures 7 and 8 display these results graphically for the two outcomes where telemedicine reaches statistical significance, cardiology consultations and total consultations, plotting, for each covariate, the estimated incidence rate ratio and its 95% confidence interval; hospitalisation outcomes are not shown graphically here, as neither model yields a significant telemedicine effect and both are already fully reported in the text above.

The two figures make one pattern especially visible: pacemaker carriers occupy opposite positions across the two models. In the cardiology consultations model (Figure 7), pacemaker shows the single largest effect of any covariate (IRR = 2.04, 95% CI: 1.56–2.66), positioned furthest to the right and clearly excluding 1. In the total consultations model (Figure 8), the same covariate falls on the other side of the reference line (IRR = 0.80, 95% CI: 0.66–0.97), the only covariate across either model with a confidence interval entirely below 1.

The two figures also differ in which covariates reach significance. In the cardiology consultations model (Figure 7), only telemedicine and pacemaker have confidence intervals excluding 1; age, sex, heart failure, and Charlson score are all non-significant, with even the oldest age category (≥80) crossing 1. In the total consultations model (Figure 8), a wider set of covariates is significant: alongside telemedicine, both older age categories (70-79 and ≥80) and Charlson score exclude 1. Telemedicine itself is the only covariate significant in both models, with a visibly wider confidence interval and a higher point estimate in the cardiology consultations model, consistent with the larger, more precisely estimated effect that are already reported above. Figure 9 complements these results by displaying the model-predicted absolute values for each outcome (rather than relative IRRs), holding covariates at their sample means. The pattern mirrors the significance results already reported: for total and cardiology consultations, the two confidence intervals are clearly separated, visually confirming the significant telemedicine effect; for urgent and programmed hospitalisations, by contrast, the intervals overlap substantially, illustrating why neither effect reaches statistical significance despite both point estimates trending downward.

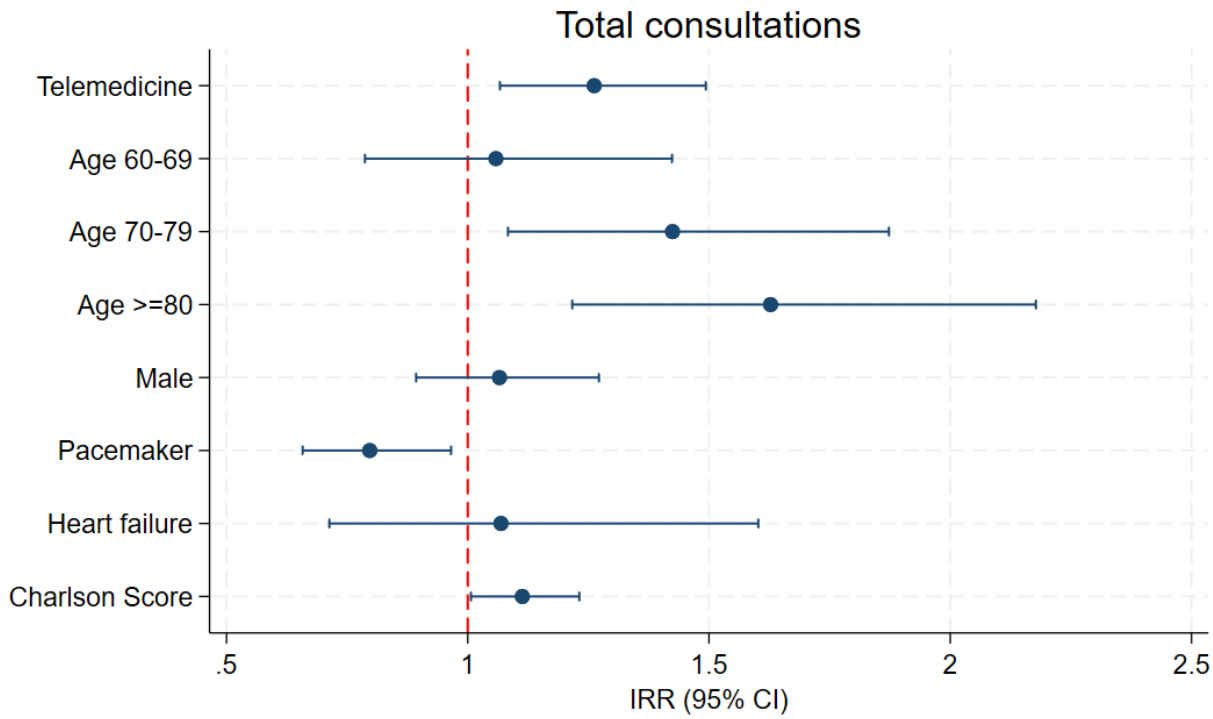


***Figure 13**: Negative binomial regression coefficients for total consultations (IRR, 95% CI), matched sample (n = 1,214). The dashed red line marks IRR = 1 (no effect); covariates whose interval crosses this line are not statistically significant.*

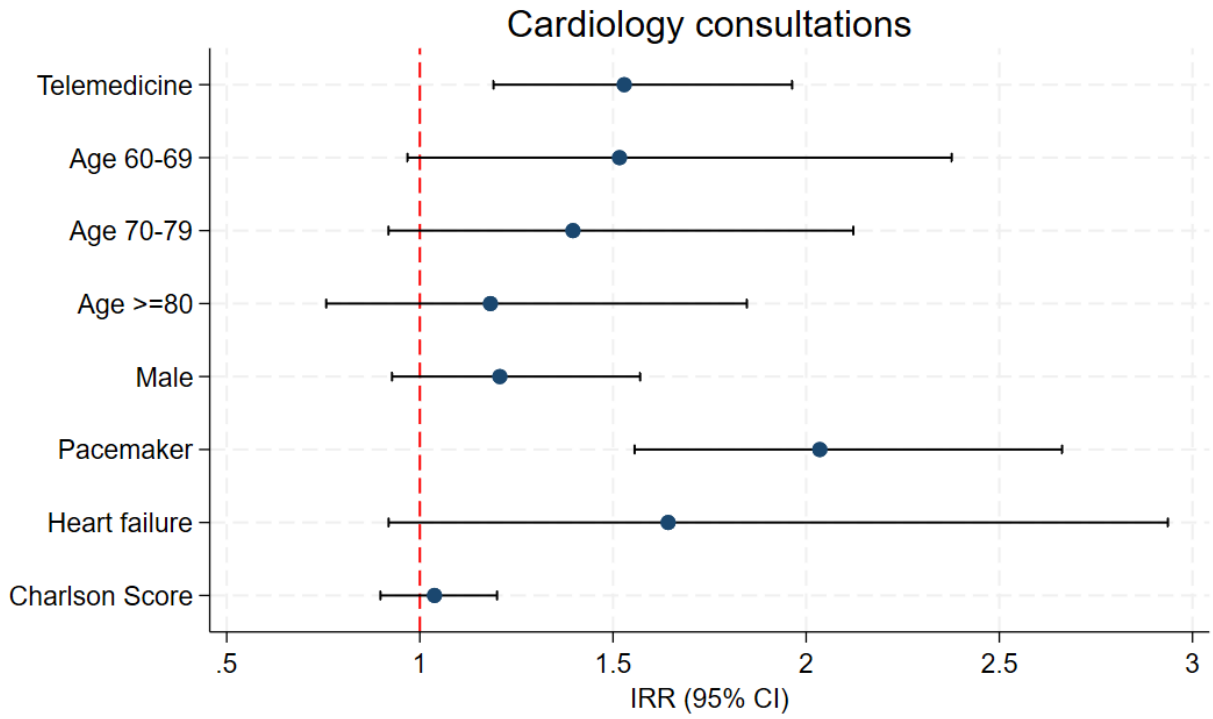


***Figure 14**: Negative binomial regression coefficients for cardiology consultations (IRR, 95% CI), matched sample (n = 1,214). The dashed red line marks IRR = 1 (no effect); covariates whose interval crosses this line are not statistically significant.*

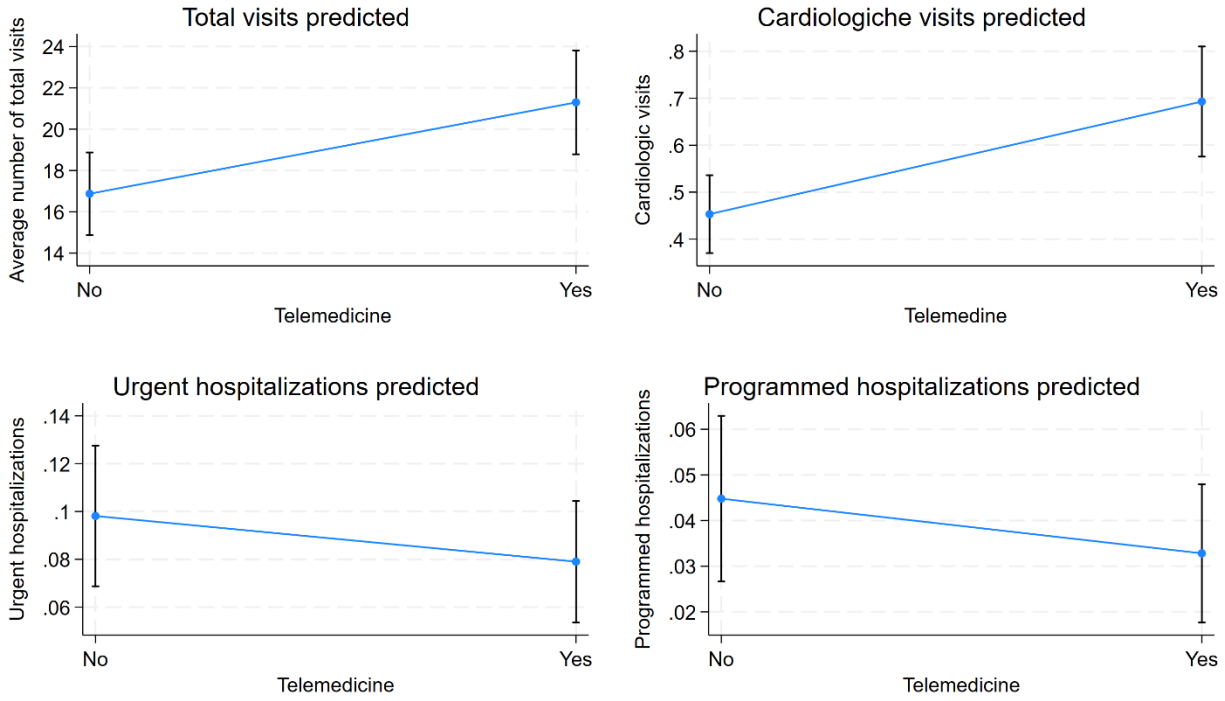


***Figure 15**: Predictive margins of healthcare utilisation outcomes with 95% confidence intervals, comparing matched patients with (Yes) and without (No) telemedicine follow-up.*

4.13 Conclusion: The Role of Telemedicine in Cardiological Follow-up Pathways

The principal pattern emerging from this analysis, a significant increase in ambulatory follow-up alongside a statistically null effect on both urgent and programmed hospitalisations, points toward telemedicine operating primarily as a complement to, rather than a substitute for, traditional in-person cardiology care. Rather than replacing existing contact between patients and the healthcare system, telemedicine appears to add to it: patients who use telemedicine are seen more often, particularly within cardiology, without a corresponding reduction in hospital-based care. This interpretation is consistent with a substantial body of telemedicine literature. Dahlgren et al. (2023, 2024), studying direct-to-consumer telemedicine in Sweden, found that telemedicine users increased their overall healthcare consumption relative to matched controls, an effect that persisted from the short term into the following months. Similarly, Zeltzer et al. (2024) documented a rise in primary care visits following expanded telemedicine access in Israel, while Cantor et al. (2022) showed that telehealth expansion during the COVID-19 pandemic sustained, rather than displaced, utilisation of preventive and non-urgent services. Most directly comparable to the present setting, the ASL3/Liguria telemonitoring programme, evaluated in a Ligurian cardiology population closely resembling the one

studied here, found that telemonitoring left short-run hospital admission volumes unchanged while increasing cardiology visit volumes by 60-70%, a magnitude in the same range as the 52.9% cardiology-specific effect estimated in this analysis.

At the same time, a competing theoretical perspective frames telemedicine as a substitute for in-person care, capable of reducing hospital utilisation by enabling earlier detection and intervention, or by making follow-up sufficiently accessible that acute deterioration is caught before it requires hospitalisation. Achelrod et al. (2017), using a difference-in-differences design on population-level German data, found that home telemonitoring significantly reduced COPD-related hospitalisations and mortality, while Walter et al. (2023) reported that a standardised virtual care programme in the U.S. Military Health System reduced both length of stay and inpatient costs without compromising clinical outcomes. If telemedicine functioned this way in the present setting, one would expect to observe a measurable reduction in urgent hospitalisations among telemedicine users, a pattern the point estimate is directionally consistent with (IRR = 0.81) but which the data cannot confirm with statistical confidence (95% CI: 0.53–1.23).

Reconciling these two perspectives, the evidence assembled here, together with comparable studies such as Ashwood et al. (2017), who found that only 12% of direct-to-consumer telemedicine visits actually replaced an in-person visit, and Ellegård et al. (2021), who documented only partial substitution in the Swedish context, suggests that complementarity and substitution are not mutually exclusive, but instead operate at different margins of care. Consistent with the ASL3/Liguria findings, the present results indicate complementarity at the extensive margin: telemedicine expands the volume of clinical contact, particularly within cardiology, where the structured and recurrent nature of device and condition follow-up lends itself naturally to remote consultation. At the intensive margin of acute, hospital-based care, however, the evidence is more properly described as null rather than substitutive: telemedicine neither measurably reduces nor increases the likelihood of urgent or programmed hospitalisation in this sample. This may reflect a genuine absence of effect but may equally reflect limited statistical power given the comparatively small number of hospitalisation events observed within a single-year follow-up window, a limitation discussed further below. What the data do rule out, with reasonable confidence, is a scenario in which telemedicine simply substitutes for in-person cardiology visits on a one-to-one basis had this been the case, total and cardiology-specific visit counts would be expected to remain stable or decline among telemedicine users, not increase significantly as observed.

Beyond telemedicine, the covariate pattern across the four models offers a coherent secondary narrative. Age is a significant predictor of total visit volume, patients aged 80 and above recorded 62.8% more total visits than the youngest reference group, but is not significant in the cardiology-

specific model, suggesting that the age-driven intensification of care operates mainly through general specialist and primary contact rather than through cardiology follow-up specifically, which appears to be governed more by condition type than by age per se. Male sex shows a markedly different role: it is not a significant predictor of visit frequency in any of the three ambulatory models, but is associated with an approximate doubling of urgent hospitalisation risk (IRR = 2.00, p = 0.007), the second-strongest effect observed in that model. This asymmetry, sex mattering for acute hospital risk but not for routine follow-up intensity, is consistent with established cardiovascular epidemiology, where male sex is a well-documented independent risk factor for acute cardiac events, without necessarily translating into differential care-seeking behaviour at the ambulatory level.

Pacemaker status displays the most striking pattern in the analysis: carriers record substantially more cardiology visits (IRR = 2.04) but significantly fewer total visits (IRR = 0.80) than the reference category. Rather than reflecting a general reduction in healthcare contact, this divergence more plausibly reflects a concentration of care: pacemaker follow-up is technically structured, protocol-driven, and recurrent, drawing a disproportionate share of these patients' overall specialist contact into cardiology specifically, potentially at the expense of engagement with other specialties. Heart failure, by contrast, does not reach significance in any of the four models, despite point estimates trending in clinically plausible directions (elevated IRRs for cardiology visits and programmed hospitalisations). Given that heart failure represents by far the smallest of the three condition-type categories in this sample, this is more likely attributable to limited statistical power than to a genuine absence of association and should be interpreted with corresponding caution rather than as evidence of no effect.

Finally, the Charlson comorbidity score emerges as the most consistent predictor of hospitalisation risk across the analysis, significantly increasing both urgent (IRR = 1.53 per point) and programmed (IRR = 1.38 per point) hospitalisation rates, while showing a smaller, only marginally significant association with total visits and no significant association with cardiology-specific visits. This pattern is clinically intuitive: overall comorbidity burden is a well-established driver of hospitalisation risk in general, largely independent of the specific technology used for ambulatory follow-up, whereas cardiology-specific visit frequency in this sample appears to be shaped more by condition type, and by telemedicine use itself, than by general comorbidity

5. Interpretation of Results and Policy Implications

5.1 Interpretation of AI Results

The questionnaire analysis shows that digital innovation is already present across most healthcare organizations in Liguria. Among the technologies reported, AI represents the most frequently mentioned area of innovation. However, its adoption remains highly concentrated in a limited number of specialized institutions, while telemedicine appears to be more broadly distributed across the regional healthcare network.

AI adoption in the surveyed organizations is mainly concentrated in radiology, neuroradiology and diagnostic imaging, where algorithmic tools can be more easily integrated into existing clinical workflows. By contrast, cardiology, despite being one of the most frequently represented specialties among the surveyed projects, did not report AI-based best-practice initiatives

From an organizational and clinical perspective, AI-adopting institutions reported benefits such as improved diagnostic speed and precision, enhanced pathological control, reduced emergency department discharge times, shorter length of stay and greater operational efficiency. Although the small number of AI-adopting organizations prevents any causal interpretation, these results suggest that AI may generate value primarily in diagnostic support, workflow optimization and clinical decision-making.

At the same time, the analysis highlights several barriers to AI implementation. These include the absence of standardized guidelines and protocols, uncertainty regarding clinical responsibility, difficulties in evaluating available AI solutions, challenges in data collection and management, and concerns about economic sustainability. These barriers indicate that technological availability alone is not sufficient: successful AI adoption requires clear governance structures, validated evaluation processes and robust data management frameworks.

The comparison between the two AI-adopting hospitals further illustrates that implementation can follow different strategic pathways. The in-house AI model appears associated with stronger internal expertise, closer collaboration with academic institutions and greater customization of the technology. However, it also requires substantial resources, technical infrastructure and protected research time. Conversely, the commercial AI model allows faster adoption and easier integration into existing workflows but may generate greater dependence on external providers and fewer opportunities for internal knowledge development. Both approaches appear potentially scalable, but they require different organizational conditions, investment strategies and governance mechanisms.

5.2 Interpretation of Telemedicine Results

The main finding is that telemedicine was associated with an increase in total outpatient visits and cardiology-specific visits, while no statistically significant reduction was observed in urgent or programmed hospitalizations.

This suggests that, in the observed setting, telemedicine operates primarily as a complement rather than a substitute for traditional care. Instead of replacing in-person contacts, telemedicine seems to increase the overall frequency of follow-up, particularly in cardiology. This result is clinically relevant because cardiological patients, especially those with chronic conditions or implantable devices, often require continuous monitoring and recurrent specialist assessment.

Age also deserves specific attention. Older patients tend to have greater healthcare needs and may benefit substantially from remote monitoring and easier access to follow-up. At the same time, elderly patients may face greater barriers in using digital tools, including limited digital literacy, difficulty using devices, lack of caregiver support or reduced confidence with remote communication. Therefore, telemedicine policies should not assume that access to technology automatically translates into effective use. Dedicated support strategies are needed to avoid reinforcing inequalities among older and more fragile patients.

Overall, the telemedicine findings suggest that remote care can improve continuity and intensity of cardiological follow-up, but its long-term impact on hospitalizations, clinical outcomes and patient quality of life requires further evaluation.

5.3 Policy Implications

One of the most important policy priorities concerns data governances. AI and telemedicine rely on the collection, processing and exchange of sensitive health data. For this reason, each healthcare organization should ensure the systematic involvement of a Data Protection Officer (DPO) in all digital innovation projects from the earliest design phase.

The role of the DPO should actively contribute to evaluating privacy risks before implementation and ensuring transparency in the use of patient data.

This is particularly important for AI projects, where data reuse, algorithmic training, external vendors and automated decision-support tools may create additional legal and ethical risks.

The questionnaire findings reveal that the absence of established guidelines and protocols remains one of the main barriers to AI adoption. Therefore, regional health authorities should develop operational guidelines for AI implementation in healthcare settings.

The telemedicine results suggest that remote care can increase follow-up intensity, especially in cardiology. However, the elderly population may face specific barriers in using digital services. This issue is particularly relevant in Liguria, given the high proportion of older residents and the prevalence of chronic conditions.

Policy should therefore support patient-oriented digital education programs, including simple training sessions before activation of telemedicine services; caregiver involvement when appropriate;

The survey indicates that AI adoption is associated with stronger internal integration between hospital departments and information systems. This suggests that interoperability is a precondition for advanced digital innovation.

Future regional policies should prioritize shared data standards; integration between hospital and territorial care systems; interoperable electronic health records;

The questionnaire results show that many digital innovation projects, including AI initiatives, are financed mainly through internal institutional resources rather than dedicated external funding mechanisms. This may create inequalities between large, research-oriented hospitals, which are more able to mobilize internal resources, and smaller healthcare organizations with more limited financial and technical capacity.

Regional policy should therefore introduce targeted funding mechanisms for digital health innovation, while also ensuring that part of these resources is specifically allocated to PNRR compliance, data governance and privacy-by-design procedures

5.4 Limitations

Several limitations should be acknowledged:

The questionnaire data are based on self-assessment. This means that the responses reflect the internal perception of each organization rather than externally verified measures of technological maturity. As a result, reporting bias and differences in interpretation may have influenced the findings.

The radar chart and maturity scores used to compare the two AI-adopting hospitals represent a synthetic qualitative assessment. They are useful for structuring the comparison, but they should not be interpreted as objective quantitative measurements.

The telemedicine outcome window captures one year, that may be too short to capture long-term effects on hospitalizations, mortality, quality of life or disease progression. Some benefits of improved follow-up may emerge only over a longer time horizon.

5.5 Conclusions

The findings of this study provide a multidimensional picture of digital innovation within the Ligurian healthcare system, highlighting both the opportunities and the current limitations associated with the adoption of Artificial Intelligence (AI) and telemedicine.

In conclusion, the integration of telemedicine and AI represents a promising direction for the management of diseases in an aging population. Telemedicine can increase continuity of care and generate structured longitudinal data, while AI can help transform these data into predictive and clinically actionable information. If supported by adequate governance and policy frameworks, this combination could contribute to a more proactive, personalized and sustainable model of healthcare delivery.

References

Schuld, M.; Sinayskiy, I.; Petruccione, F. An introduction to quantum machine learning. Contemp. Phys. **2015**, 56, 172–185.

Char, D.S.; Abràmoff, M.D.; Feudtner, C. Identifying ethical considerations for machine learning healthcare applications. Am. J.Bioeth. **2020**, 20, 7–17.

Elsebakhi, E.; Lee, F.; Schendel, E.; Haque, A.; Kathireason, N.; Pathare, T.; Syed, N.; Al-Ali, R. Large-scale machine learning based on functional networks for biomedical big data with high performance computing platforms. J. Comput. Sci. **2015**, 11,69–81.

Bashir, S.; Qamar, U.; Khan, F.H.; Naseem, L. HMV: A medical decision support framework using multi-layer classifiers fordisease prediction. J. Comput. Sci. **2016**, 13, 10–25.

Vamathevan, J., D. Clark, P. Czodrowski, I. Dunham, E. Ferran, G. Lee, B. Li, A. Madabhushi, P. Shah, M. Spitzer, and S. Zhao.

Applications of machine learning in drug discovery and development.*Nat. Rev. Drug Discov.* 18(6):463–477, 2019.

Shaban-Nejad, A., M. Michalowski, J. S. Brownstein, and D.L. Buckeridge. Guest editorial explainable AI: towards fairness,accountability, transparency and trust in healthcare. *IEEE J. Biomed. Health Info.* 25(7):2374–2375, 2021.

Sau A, Pastika L, Sieliwonczyk E et al.(Artificial intelligence-enabled electrocardiogram for mortality and cardiovascular risk estimation: a model development and validation study) The Lancet Digital Health, 6, e791-e802

Ricci, R. P., Locati, E. T., Campana, A., Cavallaro, C., Giammaria, M., Landolina, M., Marzegalli, M., & Melissano, D. (2015). *Monitoraggio remoto dei dispositivi cardiaci impiantabili: Health Technology Assessment*. *Giornale Italiano di Cardiologia, 16*(5), 295–303

Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC).

Article 113 EU AI Act.

European Commission. (2021, accessed 14 June 2024). https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=celex%3A52021PC0206.

Van Kolfschooten, H., & Van Oirschot, J. (2024). The EU artificial intelligence act (2024): implications for healthcare. *Health Policy*, *149*, 105152.

Singhal K. Large language models encode clinical knowledge. Nature 2023;620 (7972):172–80. https://doi.org/10.1038/s41586-023-06291-2.

Kolfschooten Hvan. The AI cycle of health inequity and digital ageism: mitigating biases through the EU regulatory framework on medical devices. J Law Biosci 2023;10(2). https://doi.org/10.1093/jlb/lsad031. lsad031.

Singhal K. Large language models encode clinical knowledge. Nature 2023;620 (7972):172–80. https://doi.org/10.1038/s41586-023-06291-2.

MedTech Europe. Medical Technology Industry Perspective on the Final AI Act (2024, accessed 15 June2024). https://www.medtecheurope.org/wcontent/uploads/2024/03/medicaltechnology-industry-perspective-on-the-final-ai-act-1.pdf.

Redazione. (2025, 3 dicembre). *Legge 132/2025 sull'Intelligenza Artificiale: dalla teoria alla pratica nelle aziende italiane*. ICT Security Magazine. https://www.ictsecuritymagazine.com/articoli/legge-132-2025/

Di Giacomo, L. (2025, October 10). *Legge AI: in vigore la legge delega italiana sull'Intelligenza Artificiale*. Diritto.it. https://www.diritto.it/approvata-legge-delega-italiana-intelligenza-artifi/

Repubblica Italiana. (2025). *Legge 23 settembre 2025, n. 132. Disposizioni e deleghe al Governo in materia di intelligenza artificiale*. Gazzetta Ufficiale della Repubblica Italiana, n.223.https://www.gazzettaufficiale.it/eli/id/2025/09/25/25G00143/SG

Senato della Repubblica. (2024). *Disegno di legge n. 1146: Disposizioni e deleghe al Governo in materia di intelligenza artificiale*. https://www.senato.it/leggi-e-documenti/disegni-di-legge/scheda-ddl?did=58262

Shoaib, M., Shamim, M. U., Iqbal, S., & Mahmood, G. F. (2024). Evolving AI strategies: A comparative analysis of U.S. policies under the Obama, Trump, and Biden Administrations. *Contemporary Journal of Social Science Review*, *2*(4), 2179–2185.

Redazione. (2026, 9 giugno). *Regolamentazione dell'intelligenza artificiale, un nuovo ordine esecutivo sui "modelli di frontiera"*. ICT Security Magazine. https://www.ictsecuritymagazine.com/notizie/regolamentazione-intelligenza-artificiale/

BenJaMins, V. R., & Salazar García, I. (2019). Towards a framework for understanding societal and ethical implications of Artificial Intelligence. In *Vulnerabilidad y cultura digital: Riesgos y oportunidades de la sociedad hiperconectada*.

Agenda Digitale. (s.d.). *AI Action Summit 2025: l'Ue alla sfida della governance globale dell'IA*. https://www.agendadigitale.eu/cultura-digitale/ai-action-summit-2025-lue-alla-sfida-della-governance-globale-dellia/

The White House, Office of the Vice President. (2025, 11 febbraio). *Remarks by Vice President Vance at the Artificial Intelligence Action Summit*

World Health Organization. (2021, June 11). Cardiovascular diseases (CVDs). World Health Organization. https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-%28cvds%29

Luengo-Fernandez, R., Walli-Attaei, M., Gray, A., Torbica, A., Maggioni, A. P., Huculeci, R., ... & Leal, J. (2023). Economic burden of cardiovascular diseases in the European Union: A population-based cost study. *European Heart Journal, 44*(45), 4752–4767.

Eurlings et al. (2019) highlighted that telemedicine can improve the management and monitoring of patients with chronic heart failure

Institute for Health Metrics and Evaluation (IHME). (2024). *GBD Results Tool*. University of Washington. https://vizhub.healthdata.org/gbd-results/

Halm-Pozniak, A., Lohmann, C. H., Zagra, L., Braun, B., Gordon, M., & Grimm, B. (2023). Best practice in digital orthopaedics. *EFORT open reviews*, *8*(5), 283–290. https://doi.org/10.1530/EOR-23-0081

Hawrysz, L., Gierszewska, G., & Bitkowska, A. (2021). The research on patient satisfaction with remote healthcare prior to and during the COVID-19 pandemic. *International Journal of Environmental Research and Public Health, 18*(10), 5338. https://doi.org/10.3390/ijerph18105338

Mokri, H., van Baal, P., & Rutten-van Mölken, M. (2025). The impact of different perspectives on the cost-effectiveness of remote patient monitoring for patients with heart failure in different European countries. *The European Journal of Health Economics, 26*(1), 71–85. https://doi.org/10.1007/s10198-024-01690-2

Osservasalute (2019) Osservatorio Nazionale sulla Salute nelle Regioni Italiane. https://www.osservatoriosullasalute.it/wp-content/uploads/2019/02/Focus-1-Osservasalute-La-cronicità-in-Italia-feb-2019.pdf

Osservatorio Nazionale sulla Salute nelle Regioni Italiane. (2023). *Rapporto Osservasalute 2023*. https://osservatoriosullasalute.it/osservasalute/rapporto-osservasalute-2023

ISTAT. (2025, 31 marzo). *Demographic Indicators: Year 2024* [PDF]. https://www.istat.it/wp-content/uploads/2025/03/DEMOGRAPHIC-INDICATORS_YEAR-2024.pdf

Di Novi C, Leporatti L, Montefiori M. Older patients and geographic barriers to pharmacy access: When nonadherence translates to an increased use of other components of health care. Health Economics. 2020;29(S1):97–109. https://doi.org/10.1002/hec.4031

Norman, G., Bennett, P., & Vardy, E. R. (2023). Virtual wards: A rapid evidence synthesis and implications for the care of older people. *Age and Ageing, 52*(1), afac319. https://doi.org/10.1093/ageing/afac319

Charlson, Pompei, Ales, Mackenzie, “A new method of classifying prognostic comorbidity in longitudinal studies: development and validation,” Journal of Chronic Diseases, vol. 40, no. 5, pp. 373-383, 1987

Ver Hoef, J.M. and Boveng, P.L. (2007), QUASI-POISSON VS. NEGATIVE BINOMIAL REGRESSION: HOW SHOULD WE MODEL OVERDISPERSED COUNT DATA? Ecology, 88: 2766-2772. https://doi.org/10.1890/07-0043.1

U.S. Food and Drug Administration. (2019). Proposed regulatory framework for modifications to artificial intelligence/machine learning (AI/ML)-based software as a medical device (SaMD):

Patil, N., & Graham, C. (2025). The Trump administration's first regulatory action on Medicare Advantage omits some prior authorization guardrails. Georgetown University McCourt School of Public Policy, Center on Health Insurance Reforms, Medicare Policy Initiative. https://medicare.chir.georgetown.edu/the-trump-administrations-first-regulatory-action-on-medicareadvantage-omits-critical-prior-authorization-guardrails-april-14-2025/

Liu, Y., Yu, W., & Dillon, T. (2024). Regulatory responses and approval status of artificial intelligence medical devices with a focus on China. NPJ digital medicine, 7(1), 255.

National Medical Products Administration. (2021). NMPA announcement on guidance for the classification defining of AI-based medical software products. https://english.nmpa.gov.cn/2021-07/08/c_660267.htm Center for Medical Device Evaluation. (2022). 国家药监局器审中心关于发布人工智能医疗器械注册审查指导原则的通告（2022年第8号） [Announcement of the Center for Medical Device

Evaluation of the National Medical Products Administration on issuing the Guideline for the registration review of artificial intelligence medical devices (No. 8 of 2022)]. CIRS Group.

https://www.cirs-group.com/cn/md/gjyjjqszxgyfbrgznylqxzcsczdyzdtg-2022nd8h

National Medical Products Administration. (2025). Announcement of the National Medical Products Administration on issuing measures to optimize whole life-cycle regulation in support of the innovative development of high-end medical devices ([2025] No. 63). China Daily. https://english.nmpa.gov.cn/2025-10/14/c_1138492.htm

European Parliament & Council of the European Union. (2025a). Consolidated text: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. EUR-Lex. https://eurlex.

European Commission. (n.d.a). Nuovi regolamenti. Public Health. https://health.ec.europa.eu/medical-devices-sector/new-regulations_it

European Parliament & Council of the European Union. (2024). Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) No 2018/858, (EU) No 2018/1139 and (EU) No 2019/2144 and Directives

2014/90/EU, (EU) No 2016/797 and (EU) No 2020/1828 (Artificial Intelligence Act). Official Journal of the European Union, L 2024/1689. https://eur lex.europa.eu/eli/reg/2024/1689/oj/eng

Panetta, R. (2025, September 24). Italy becomes first EU member state to pass an AI law. International Association of Privacy Professionals. https://iapp.org/news/a/italy-becomes-first-eu-memberstate-to-pass-an-ai-law

European Commission. (n.d.). European Health Data Space Regulation (EHDS). Public Health. Retrieved June 30, 2026, from https://health.ec.europa.eu/ehealth-digital-health-and-care/europeanhealthdata-space-regulation-ehds_en

AKNOWLEDGEMENTS

I would like to thank Regione Liguria and ASL3 for sharing the data. A special thanks to Giorgia Rieti for her help, and to Centro Aphec for their support.