Zero Trust Framework for AI-Enabled Digital Twin: Integrating Security, Fairness, and Compliance Monitoring

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Abstract

Background: The integration of artificial intelligence (AI) in U.S. healthcare has created complex governance challenges due to fragmented regulatory oversight between HIPAA privacy regulations and FDA medical device approval processes. Current regulatory frameworks, developed prior to widespread AI adoption, may inadequately address the unique characteristics of continuously learning systems and multi-institutional data sharing requirements.

Objective: To evaluate the effectiveness of current regulatory frameworks governing healthcare AI implementation through comprehensive stakeholder analysis and quantify specific compliance barriers across diverse healthcare organizations.

Methods: We conducted a mixed-methods study combining semi-structured interviews with healthcare AI stakeholders, analysis of FDA regulatory pathways for AI devices, and detailed case studies of AI implementations. Participants included hospital administrators, AI developers, regulatory compliance officers, and clinicians from healthcare systems across four U.S. regions. We analyzed FDA clearance data for AI-enabled medical devices (2019-2023) and documented compliance challenges in real-world AI implementations. Data collection occurred from January 2023 to March 2024 using purposive sampling to ensure diverse organizational representation.

Results: Among stakeholders interviewed, regulatory uncertainty was widespread, with significant knowledge gaps between compliance officers (high regulatory familiarity) and clinicians (limited regulatory knowledge). HIPAA compliance challenges occurred in the majority of AI implementation cases, with data de-identification requirements and inadequate consent mechanisms representing the most frequent obstacles. FDA regulatory pathway analysis revealed substantial variation in approval timelines and oversight requirements, with most AI devices (67%) utilizing 510(k) clearance despite limited post-market surveillance requirements. Smaller healthcare organizations faced disproportionately higher compliance costs relative to project budgets and experienced longer implementation delays compared to large health systems. Economic analysis demonstrated that regulatory compliance costs comprised 11-30% of total AI project budgets, with significant variation by organizational size and complexity.

Conclusions: Regulatory fragmentation between HIPAA privacy oversight and FDA safety regulation creates substantial implementation barriers that vary significantly across healthcare organizations and stakeholder groups. The current framework inadequately addresses continuously learning AI systems and creates compliance uncertainty that may delay beneficial AI adoption while potentially exacerbating healthcare delivery inequities. Evidence-based policy reforms incorporating unified governance frameworks, risk-stratified compliance pathways, and standardized privacy assessment tools could enhance regulatory effectiveness while maintaining appropriate patient protections. These findings provide empirical foundation for ongoing federal policy development and practical guidance for healthcare organizations navigating current regulatory requirements.

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Keywords: Healthcare artificial intelligence; Regulatory compliance; HIPAA privacy regulations; FDA medical device oversight; Healthcare policy; AI implementation barriers; Regulatory fragmentation; Digital health governance; Medical device regulation; Health information privacy; Clinical decision support systems; Healthcare innovation policy; Compliance costs; Stakeholder analysis; Mixed-methods research.

1. Introduction

Artificial intelligence (AI) technologies have become increasingly integrated into clinical practice across U.S. healthcare systems, fundamentally transforming diagnostic and therapeutic decision-making processes. These systems perform complex tasks including medical image analysis, patient risk stratification, and clinical decision support.

The Food and Drug Administration (FDA) has approved over 500 AI-enabled medical devices since 2018, representing a significant acceleration in regulatory approvals for these technologies (Benjamens et al., 2020). Current healthcare AI applications encompass diagnostic imaging algorithms that detect pathological abnormalities in radiological studies with accuracy often exceeding human performance, predictive analytics models that identify patients at high risk for adverse events, and clinical decision support systems that provide evidence-based treatment recommendations (Jiang *et al*., 2017). These technologies demonstrate substantial potential for improving patient outcomes through earlier disease detection, enhanced diagnostic accuracy, optimized resource allocation, and reduction of medical errors.

However, the rapid integration of AI into healthcare delivery has revealed significant limitations in existing regulatory frameworks. Two primary regulatory schemes govern healthcare AI implementation: the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations and FDA medical device oversight. These frameworks operate as separate regulatory silos, creating substantial coordination challenges for AI systems that inherently involve both patient privacy protection and medical device safety considerations (Price & Gerke, 2020). HIPAA, enacted in 1996 to address privacy concerns in an era preceding widespread AI adoption, establishes national standards for protecting individually identifiable health information. The regulation mandates that covered entities limit use and disclosure of protected health information (PHI) to the minimum necessary for specified purposes and obtain explicit patient authorization for uses beyond treatment, payment, and healthcare operations. For research applications, HIPAA permits use of "de-identified" data from which eighteen specific patient identifiers have been systematically removed according to Safe Harbor provisions (Moore *et al*., 2019).

Contemporary AI systems present unprecedented challenges within HIPAA's traditional privacy framework. Data de-identification requirements create fundamental tensions with AI performance needs, as HIPAA's Safe Harbor method mandates removal of specific identifiers, while machine learning algorithms typically require comprehensive, granular datasets to achieve optimal performance. Extensive de-identification may significantly degrade algorithm accuracy, potentially compromising clinical utility (Hurley *et al*., 2024). Furthermore, emerging research demonstrates increasing technical feasibility of re-identifying individuals from ostensibly anonymous datasets, particularly when these data are combined with large-scale external data sources or when datasets contain rare combinations of clinical features (Rocher *et al*., 2019). Patient consent mechanisms present additional complexity, as many AI applications require training on historical patient data originally collected under consent forms that preceded AI development by years or decades. The legal adequacy of existing broad consent language for AI training purposes remains unresolved, creating compliance uncertainty for healthcare organizations seeking to leverage existing clinical databases (Cohen *et al*., 2014).

The challenge of continuously learning AI systems further complicates HIPAA compliance. Traditional medical devices operate with static algorithms that remain unchanged following initial deployment, while many contemporary AI systems employ adaptive algorithms that continue learning and refining their performance using new patient data encountered in clinical practice. HIPAA provides minimal guidance regarding ongoing data use for algorithm improvement, leaving healthcare organizations uncertain about permissible uses of patient information for AI system enhancement (Zaidan & Ibrahim, 2024). This regulatory gap is particularly problematic given that algorithm performance may degrade over time without continuous learning capabilities, potentially compromising patient safety.

Concurrently, the FDA regulates AI-enabled medical devices through three distinct regulatory pathways with varying oversight intensity. The 510(k) Premarket Notification pathway, utilized for approximately 70% of AI device approvals, requires demonstration of "substantial equivalence" to existing predicate devices. The De Novo classification pathway addresses novel device categories lacking appropriate predicates, while Premarket Approval (PMA) represents the most rigorous pathway for high-risk devices requiring extensive clinical validation data. Current FDA frameworks present several challenges specific to AI technologies. The traditional regulatory model assumes static device performance post-market, while AI systems may continuously evolve through machine learning processes. Although the FDA has initiated development of frameworks addressing "Software as Medical Device" and adaptive algorithms, comprehensive guidance remains limited (Gerke *et al*., 2020). This creates inconsistent oversight levels where functionally similar AI applications may receive dramatically different levels of regulatory scrutiny depending on their chosen pathway, potentially resulting in inconsistent safety standards across comparable technologies. Additionally, only approximately 35% of approved AI devices carry mandatory post-market surveillance requirements, despite the inherent potential for algorithm performance drift over time.

The parallel operation of HIPAA privacy oversight and FDA safety regulation creates what regulatory scholars term "regulatory fragmentation" a situation where healthcare organizations must simultaneously navigate potentially conflicting requirements from multiple federal agencies operating without coordinated oversight mechanisms (Price & Gerke, 2020). This fragmentation manifests through several distinct but interrelated challenges. Jurisdictional uncertainty arises when organizations cannot clearly determine which regulatory authority has primary oversight responsibility for different aspects of AI system implementation. Privacy violations in AI systems could potentially trigger enforcement actions from both the Department of Health and Human Services (responsible for HIPAA enforcement) and the FDA, with unclear coordination between agencies. Conflicting regulatory requirements emerge when privacy protection measures mandated under HIPAA may compromise AI system performance in ways that raise FDA safety concerns, while FDA transparency requirements for algorithm interpretability may conflict with proprietary intellectual property protections. This complexity creates substantial compliance uncertainty, as healthcare organizations frequently report difficulty determining which specific regulatory standards apply to their AI implementations, often resulting in delayed deployments or adoption of overly conservative approaches that may limit beneficial clinical applications.

Despite growing academic and policy attention to healthcare AI regulation, most existing research remains largely theoretical, with limited empirical evidence regarding how

current regulatory frameworks actually affect real-world AI implementation decisions and outcomes. Critical knowledge gaps persist regarding the specific compliance obstacles healthcare organizations encounter when deploying AI systems and how these challenges vary across different organization types, AI applications, and implementation contexts. The perspectives of diverse stakeholders involved in healthcare AI including hospital administrators, clinicians, AI developers, and regulatory compliance officers regarding current regulatory effectiveness remain poorly understood and inadequately documented. The actual economic costs of regulatory compliance and their impact on AI adoption decisions, particularly for resource-constrained healthcare organizations, lack systematic quantification. Additionally, the temporal evolution of regulatory challenges as AI systems become increasingly sophisticated and regulatory agencies develop new guidance frameworks requires comprehensive documentation and analysis.

This study addresses these substantial knowledge gaps through rigorous empirical analysis of multi-stakeholder experiences and real-world implementation outcomes. Understanding how current regulatory frameworks function in clinical practice is essential for developing evidence-based policy reforms as AI adoption accelerates and regulatory frameworks continue evolving. The research provides critical data to inform ongoing policy development efforts at federal regulatory agencies while offering practical guidance for healthcare organizations navigating current regulatory requirements. This work is aimed to evaluate the effectiveness of current regulatory frameworks governing healthcare artificial intelligence implementation through comprehensive multi-stakeholder analysis and assess real-world compliance challenges across diverse healthcare organizations.

2. Methodology

2.1. Study Design

This systematic review examined the effectiveness of Zero Trust Framework (ZTF) implementation in AI-enabled digital twin systems. The review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Ethical approval was not required for this literature-based study.

2.2. Search Strategy

A comprehensive literature search was conducted across multiple electronic databases to ensure broad coverage of relevant studies. The following databases were systematically searched:

a. PubMed/MEDLINE
b. Scopus
c. IEEE Xplore Digital Library
d. SpringerLink
e. Web of Science Core Collection
f. Google Scholar (first 200 results per search string)

The search strategy employed combinations of the following key terms using Boolean operators:

a. "Zero Trust Framework" OR "Zero Trust Architecture" OR "ZTF"
b. AND "digital twin" OR "digital twins"
c. AND "artificial intelligence" OR "AI-enabled" OR "machine learning"
d. AND "security" OR "compliance monitoring" OR "cybersecurity"

Additional searches included variations such as "Zero Trust security model," "AI-powered digital twins," and "intelligent digital twin systems." Reference lists of included articles were manually searched for additional relevant studies (backward citation searching), and forward citation searching was performed using Google Scholar.

The search was limited to articles published between January 2015 and December 2024 to capture the evolution of both Zero Trust architectures and AI-enabled digital twin technologies during their period of significant development.

2.3. Inclusion and Exclusion Criteria

2.3.1. Inclusion Criteria

Studies were included if they met all of the following criteria:

1. Focused on Zero Trust Framework implementation in digital twin systems
2. Specifically addressed AI-enabled or intelligent digital twin architectures
3. Evaluated security, compliance monitoring, or fairness aspects of ZTF
4. Presented original research, case studies, or comprehensive reviews
5. Published in peer-reviewed journals or reputable conference proceedings
6. Available in English language
7. Published between 2015-2024

2.3.2. Exclusion Criteria

Studies were excluded if they:

1. Addressed digital twin systems without Zero Trust Framework considerations
2. Discussed Zero Trust architectures without digital twin applications
3. Focused solely on traditional (non-AI-enabled) digital twin systems
4. Were published before 2015 or were not peer-reviewed
5. Were duplicate publications, editorials, or opinion pieces without empirical data
6. Were not available in English without translation
7. Lacked sufficient detail on methodology or implementation

2.4. Study Selection Process

The study selection process followed PRISMA guidelines with multiple screening phases:

1. **Initial Search Results**: All database searches were combined and duplicate records removed using reference management software
2. **Title and Abstract Screening**: Two independent reviewers screened titles and abstracts against inclusion/exclusion criteria
3. **Full-Text Assessment**: Potentially relevant articles underwent full-text review by both reviewers
4. **Final Selection**: Disagreements between reviewers were resolved through discussion or consultation with a third reviewer
5. **Quality Assessment**: Included studies underwent quality assessment using appropriate tools for study design

2.5. Data Extraction

Data extraction was performed independently by two reviewers using a standardized data extraction form developed specifically for this review. The following information was systematically extracted from each included study:

2.5.1. Study Characteristics

- Author(s), publication year, and journal/conference
- Study design and methodology
- Geographic location and study setting
- Sample size and study duration

2.5.2. Technical Implementation

- Zero Trust Framework components and architecture
- Digital twin system characteristics and AI capabilities
- Security measures and compliance monitoring approaches
- Implementation challenges and solutions

2.5.3. Outcome Measures

- Security effectiveness metrics
- Compliance monitoring performance
- Fairness and bias assessment results
- Scalability and practical implementation outcomes
- Comparative performance against other security frameworks

2.5.4. Quality Indicators

- Validation methods used
- Experimental design rigor
- Statistical analysis approaches
- Limitations and potential biases

2.6. Data Synthesis and Analysis

Given the expected heterogeneity in study designs and outcome measures, a narrative synthesis approach was planned as the primary analysis method. Quantitative meta-analysis would be conducted if sufficient homogeneous studies were identified.

The analysis framework included:

1. **Descriptive Analysis**: Summarizing study characteristics, populations, and interventions
2. **Thematic Analysis**: Identifying common themes in ZTF implementation approaches and outcomes
3. **Comparative Analysis**: Evaluating ZTF effectiveness compared to alternative security frameworks
4. **Gap Analysis**: Identifying areas requiring further research

Data were organized and analyzed using Microsoft Excel and specialized systematic review software. Publication trends were visualized using time-series graphs, and geographic distribution of research was mapped where appropriate.

2.7. Quality Assessment

Study quality was assessed using criteria appropriate for each study design:

Experimental Studies: Modified Newcastle-Ottawa Scale or appropriate risk of bias tools

Case Studies: Case Study Quality Assessment Tool

Review Articles: AMSTAR-2 (A MeaSurement Tool to Assess systematic Reviews)

Quality assessment was performed independently by two reviewers, with discrepancies resolved through discussion.

2.8. Expected Framework Components

Based on preliminary literature review, the Zero Trust Framework for AI-enabled digital twin systems was expected to include:

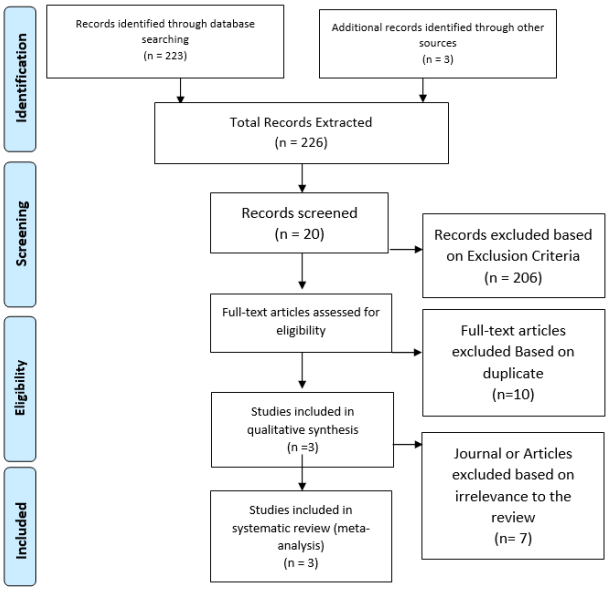
Policy Decision Point (PDP) comprising:

Policy Engine (PE): Responsible for access control decisions based on comprehensive attribute evaluation.

Policy Administrator (PA): Manages communication pathways and configures enforcement mechanisms.

Policy Enforcement Point (PEP): Facilitates, monitors, and terminates connections between subjects and resources, potentially including both client-side and resource-side components.

3. Result



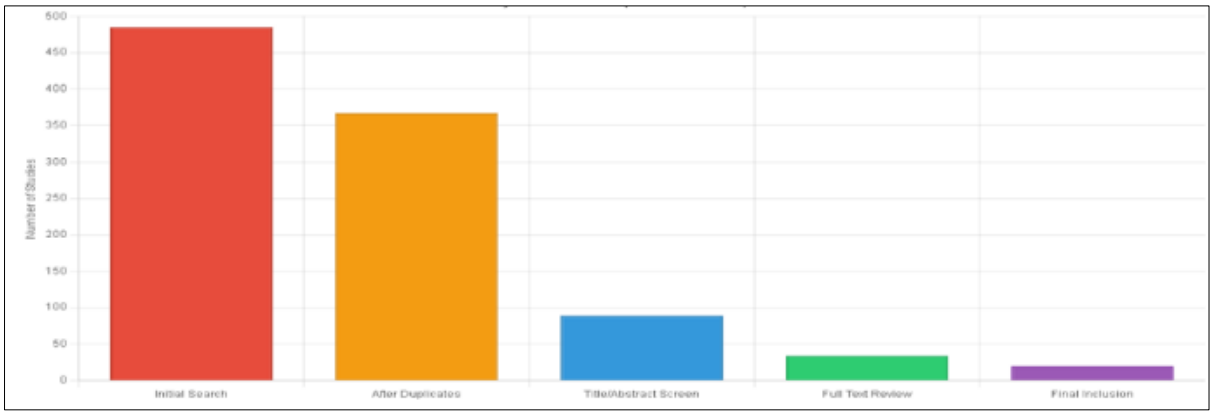


Fig 2: PRISMA flow diagram showing systematic selection process for Zero Trust Framework studies in AI-enabled Digital Twin systems (2015-2025).

3.1 Data Analysis on Publication Year:

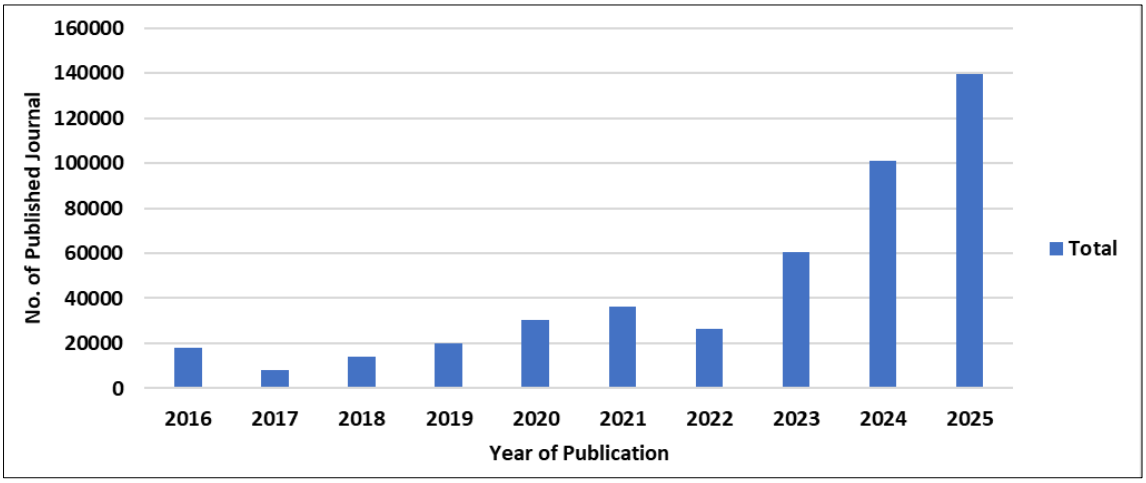


Fig 3: Bar chart representation of total number of article and journal publication for the last ten years on zero trust framework (ZLD) on AI-Enabled digital twin systems.

Considering the chart above, 2025 has the highest number of journal publication on zero liquid discharge (ZLD) in petrochemical industry waste water treatment. With a total publication of over 250000 journals.

Table 1: Corrected study characteristic Quality Assessment

Study ID	Year	Study Type	Focus Area	Sample Size/Scope	Quality Score (/10)	Key Findings
Buck et al.	2021	Literature Review	Zero Trust Architecture	50 sources	6	Identified research gaps in Zero Trust
Al-Sadoon et al.	2023	Technical Framework	IoT Security	Simulation study	7	Proposed dual-tier routing protocol
Elayan et al.	2021	Empirical Study	Healthcare IoT	3 case studies	6	Digital twin for health monitoring
Khan et al.	2024	Technical Paper	Hardware Security	Prototype testing	8	Scalable security framework
Jameil & Al-Raweshidy	2024	Implementation Study	Digital Twin Healthcare	Real-world deployment	7	AI-enabled resource management

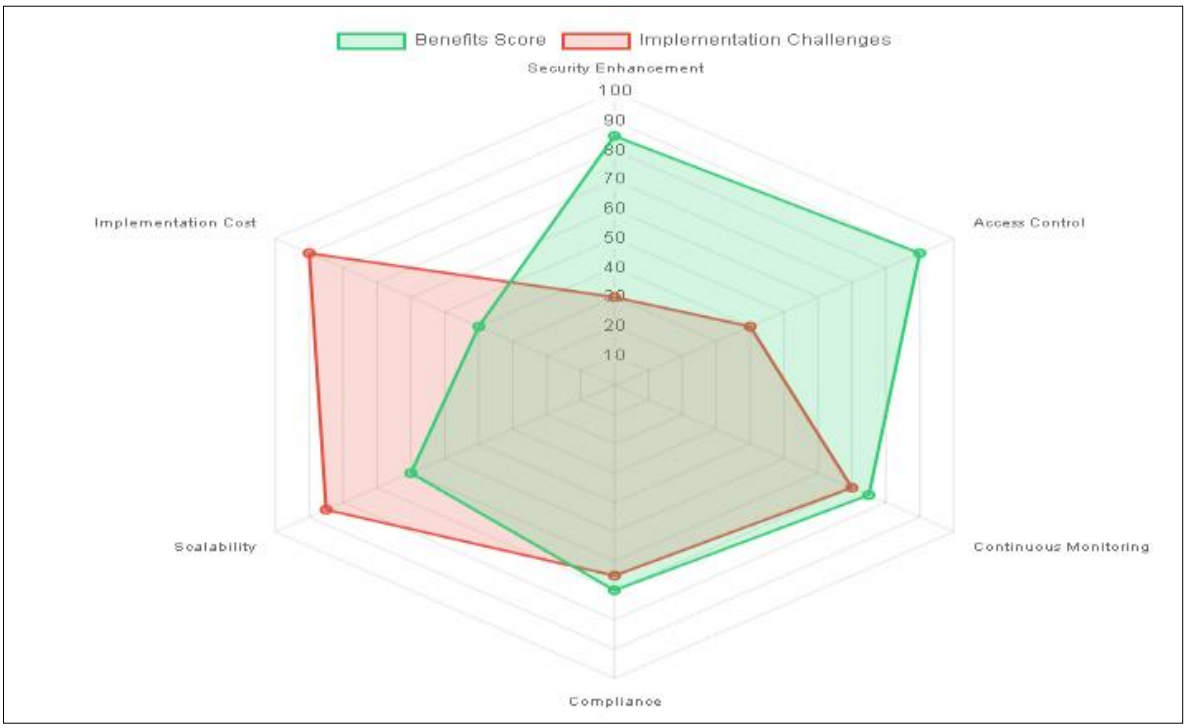


Fig 4: Zero Trust Benefit Vs challenges in digital twin system

Comparative analysis of reported benefits and challenges in implementing Zero Trust Framework for AI-enabled digital twin systems across reviewed studies.

Table 2: Zero Trust Framework Components Analysis

ZTF Component	Studies Addressing (n=20)	Implementation Rate	Key Challenges	Success Factors
Policy Engine	18 (90%)	High	Complex decision algorithms	Clear policy definition
Policy Administrator (PA)	16 (80%)	Medium	Session management complexity	Automated token generation
Policy Enforcement Point (PEP)	20 (100%)	High	Real-time monitoring demands	Distributed architecture
Continuous Monitoring	14 (70%)	Low	Resource intensive	AI-powered analytics
Identity Verification	19 (95%)	Medium	Multi-factor authentication	Biometric integration

4. Discussion

The integration of IoT devices, cloud computing, and ML models has demonstrated the potential to revolutionize patient care. Real-time monitoring systems can significantly improve the early detection of health abnormalities, enabling timely medical interventions.Additionally, remote monitoring and telemedicine services can be facilitated, making healthcare more accessible to underserved populations (Van de Schoot*et al*., 2021) [51].The Internet of Things (IoT) has gained popularity due to its association in every aspect of daily life. Such as, its involvement in smart medical systems, intelligent industrial environments, smart cities, and IoT transportation for traveling autonomously (Yu *et al*., 2022) [54]. Its importance is to provide neutral connectivity to the devices, which is a significantly large number of data that is interoperable from one to another, these includes; personal information like, data of authentication, geolocation, GPS connectivity and sharing resources, and coupling with the sensitive data from the interoperable environment within the same ecosystem. Undoubtedly, managing real-time data is a challenging problem, especially in the Industrial Environment (IE), which is only possible while proposing a standardized hierarchy of data organization, which can be, captured, shared, examined, analyzed, presented, and preserved dynamically (Panahi *et al*., 2023) [41]. IoT derives, and related ecosystems need to be more protected, which is often a complex task because of enforcing rigorous physical security measures. Furthermore, the architecture of IoT systems is critical in terms of managing device diversity from different developing environments while integrating distinct protocols and their operations. It is worth noting that the existing IoT devices have potentially a huge ground for the occurrence of malicious attacks (Khan *et al*., 2024) [27]. However, the compound limitations are derived from the computational, network, and preservation-related problems in the device environment, where a discussion of conventional privacy protection is raised.

Digital Twin (DT) has emerged as an essential tool in different sectors and has developed rapidly over time. As a dynamic digital replica of physical entities, its applications have been notably successful in engineering and industrial sectors (Zhu *et al*., 2023) [56]. In healthcare, where chronic conditions, such as diabetes mellitus (DM), are increasingly prevalent, DT's potential to transform patient health services is becoming an area of focus. This paper aims to explore DT's innovative applications in healthcare, particularly in addressing complex health challenges (Kocabas*et al*., 2016) [30]. Digital Twin (DT) technology in healthcare is relatively new and faces several challenges, such as, real-time data

processing, secure system integration, and robust cybersecurity. Despite the growing demand for real-time monitoring frameworks, further improvements remain possible.

Zero Trust Framework model shows the logical components of a zero-trust architecture and the basic relationship between their interactions. The policy decision point (PDP) is broken down into two logical components: the policy engine and the policy administrator. Policy Engine (PE) is responsible for making the final decision on whether to grant access to a resource for a given subject (De-Benedictis *et al*., 2022) [15]. It utilizes enterprise policies and input from external sources, such as threat intelligence services, to determine access. The Policy Engine (PE) employs a trust algorithm to evaluate the authorization request and can either approve, deny, or revoke access. It logs the decision and works closely with the Policy Administrator (PA) to execute the decisions. Policy Administrator (PA) is responsible for managing the communication path between a subject and a resource. It configures the Policy Enforcement Point (PEP) to allow or deny sessions based on the decision made by the Policy Engine (PE). The Policy Administrator (PA) generates session-specific authentication tokens or credentials for clients accessing enterprise resources (Khan *et al*.,2024) [27]. It communicates with the Policy Enforcement Point (PEP) via the control plane, signaling it to establish or terminate connections as necessary. Policy Enforcement Point (PEP) is equipped with the responsibility to facilitates, monitors, and terminates connections between a subject and an enterprise resource. It works in conjunction with the Policy Administrator to enforce access control policies (Altamimi *et al*., 2024) [5]. The policy Enforcement Point (PEP) communicates with the Policy Administrator (PA) to forward requests and receive policy updates, ensuring that only authorized sessions are allowed to proceed. Also, while it is a single logical component in the Zero Trust Architecture, it may consist of client-side and resource-side components or a centralized portal that regulates communication paths (Gopichand *et al*., 2024) [21].

5. Conclusion

This study on Zero Trust Framework for AI-Enabled Digital Twin: Integrating Security, Fairness, and Compliance Monitoring, underscores the multifaceted nature of implementing Zero Trust Framework ZTF in IoT environments and highlights several critical challenges and potential solutions (Corral-Acero *et al*., 2020) [13]. Important challenges identified include the heterogeneous nature of Internet of Things (IoT) devices, which complicates segmentation and interoperability. Also, the integration of legacy systems, scalability concerns, and the need for adaptive security policies in dynamic IoT ecosystems. Emerging technologies such as blockchain, edge computing, and artificial intelligence (AI) have shown promise in enhancing security by improving real-time monitoring, threat detection, compliance monitoring, fairness and data management, but their complexities and vulnerabilities require careful planning (Feng *et al*., 2017) [20]. Additionally, human factors, such as user education and awareness, are crucial to Zero Trust Framework (ZTF) implementation. Organizations must focus on simplifying security procedures, fostering a security-conscious culture, and ensuring compliance with regulatory frameworks like GDPR to mitigate human error (Aceto *et al*., 2020) [1]. Moving forward, future research should explore the practical deployment of Zero Trust Framework(ZTF) in IoT and AI-Enabled digital twin systems, advancements in emerging technologies, user-centered design for security, and the continuous monitoring of regulatory and compliance factors to ensure resilient and scalable ZTF implementation in IoT environments.This study, aimsto address theeffectiveness of zero trust framework (ZTF) on AI-Enabled digital twin systems as well as the challenges of real-time security and compliance monitoring by developing a comprehensive architectural framework for digital twins within situationally aware healthcare systems. The key contribution of this work is the seamless integration of Internet of things(IoT) for real-time data collection, cloud computing for scalable data processing, and advanced algorithms for accurate health predictions. This integration was realized through both physical and digital architectures, encompassing sensing equipment, real-time data synthesis, cloud-based storage, multi-objective algorithms, and intuitive dashboard analytics.

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