A Patient-Centric Blockchain Framework for Secure Electronic Health Record Management: Decoupling Data Storage from Access Control Through Cryptographic Envelopes and On-Chain Authorization

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Abstract

We present a patient-centric architecture for electronic health record (EHR) sharing that separates **content storage** from **authorization and audit**. Encrypted FHIR resources are kept off-chain; a public blockchain records only cryptographic commitments and patient-signed, time-bounded permissions using EIP-712. Keys are distributed via public-key wrapping, enabling storage providers to remain honest-but-curious without risking confidentiality. We formalize the security goals (confidentiality, integrity, non-repudiable authorization, and auditability) and provide a Solidity reference implementation. On-chain costs for a permission grant average **approximately 78,000 gas** (L1), and end-to-end access latency for 1 MB records is **1.3–2.0 s**, dominated by storage retrieval; cryptographic overhead is negligible. Layer-2 deployment reduces costs by an order of magnitude without changing the threat model. We discuss metadata privacy and regulatory considerations (HIPAA/GDPR), and we outline an optional, audited emergency-access path. This work demonstrates a practical route to restoring patient control while preserving the security properties required for sensitive clinical data.

Keywords: Blockchain, Electronic Health Records, Access Control, Authenticated Encryption, Healthcare Privacy, Smart Contracts, FHIR, Patient Empowerment, Cryptographic Protocols, Decentralized Systems

1 Introduction

The digitization of healthcare has transformed medical practice, enabling evidence-based decision-making, population health management, and biomedical discovery at unprecedented scales. Electronic health records now capture comprehensive longitudinal data about patients' conditions, treatments, and outcomes. However, this valuable information remains trapped in organizational silos, with individual healthcare providers maintaining separate, often incompatible systems that inhibit the seamless exchange of medical information across institutional boundaries. When a patient seeks care from multiple providers or relocates to a different geographic region, critical medical history frequently becomes inaccessible, leading to duplicated tests, adverse drug interactions, and suboptimal treatment decisions.

The technical and regulatory challenges surrounding health information exchange have prompted various centralized solutions, typically involving cloud-based platforms that aggregate records from multiple sources into unified repositories [48, 49]. While such approaches offer operational convenience and economies of scale, they fundamentally concentrate both data and trust in intermediary organizations. These centralized architectures present several critical vulnerabilities that compromise the security and privacy properties essential for managing protected health information [50].

1.1 The Centralization Problem

Contemporary health information exchange architectures exhibit three fundamental weaknesses. First, they create single points of failure where system compromise or operational disruption can simultaneously affect thousands or millions of patient records. Major healthcare data breaches in recent years have exposed the medical information of hundreds of millions of individuals, demonstrating that centralized repositories attract sophisticated adversaries and create catastrophic risk concentrations.

Second, centralized systems require patients to trust intermediary organizations with unfettered access to their most sensitive information. Cloud storage operators, database administrators, and platform employees possess technical capabilities to read, modify, or exfiltrate patient data. While organizational policies and legal frameworks ostensibly constrain such behavior, insider threats remain a persistent concern. Audit logs maintained by the very entities being audited offer limited assurance, as log tampering can conceal unauthorized access.

Third, patients exercise minimal control over how their information is shared and used. Access decisions typically follow institutional policies rather than individual preferences, and patients often lack visibility into who has accessed their records or for what purposes. This asymmetry contradicts principles of patient autonomy and informed consent that form ethical foundations of modern medical practice.

1.2 Blockchain as an Architectural Primitive

Blockchain technology offers properties that address specific weaknesses in centralized architectures, particularly regarding auditability and elimination of trusted third parties. A blockchain provides a replicated, append-only ledger where transactions are verified through cryptographic mechanisms rather than institutional authority. Once recorded, transactions become practically immutable, creating a tamper-evident audit trail. No single entity controls the ledger, distributing trust across network participants.

However, naive application of blockchain to healthcare data management introduces new problems. Storing protected health information directly on a public blockchain violates privacy requirements, as blockchain's transparency and immutability would make sensitive data permanently accessible to all network participants. Transaction costs and limited throughput make blockchain impractical for storing large medical documents. These limitations have led some researchers to conclude that blockchain is fundamentally unsuitable for healthcare applications.

We argue that this conclusion conflates different architectural roles. Blockchain excels at maintaining integrity and access control but performs poorly as a database for large, sensitive content. The key insight is to separate these concerns: encrypted health records reside in off-chain storage optimized for large objects, while the blockchain serves exclusively as an authorization layer and integrity verification mechanism. This architectural separation exploits the complementary strengths of different technologies while avoiding their respective weaknesses.

1.3 Our Approach and Contributions

This paper presents a patient-centric framework that restructures health data governance through cryptographic and distributed ledger techniques. Our architecture maintains patient health records as encrypted objects in conventional storage systems while recording only cryptographic digests, storage pointers, and authorization events on a blockchain. Patients directly control access through cryptographically signed permissions that the blockchain validates, creating an auditable trail without exposing protected health information to the ledger.

The technical foundation combines established cryptographic primitives in a novel architectural configuration. We employ authenticated encryption with associated data to provide confidentiality and integrity for record contents, use public-key encryption to wrap symmetric keys for authorized recipients, and leverage EIP-712 structured message signing to create verifiable, replay-resistant authorization tokens that integrate naturally with existing blockchain wallet software. Storage pointers use content addressing to enable integrity verification, ensuring that the data retrieved matches the cryptographic digest committed on-chain.

Our specific contributions include the following. First, we provide a formally specified architecture with clear security definitions and properties, demonstrating how the composition of off-chain encrypted storage and on-chain access control achieves confidentiality against curious storage providers, integrity verification for tamper detection, and patient-controlled authorization with cryptographic non-repudiation. Second, we present a complete reference implementation as an Ethereum smart contract that handles record registration, permission granting through signed messages, time-bounded access with revocation, and auditability through event logs. Third, we describe integration with healthcare interoperability standards, specifically showing how HL7 FHIR resources serve as the plaintext format while supporting de-identified data release for research through privacy-preserving transformations. Fourth, we provide comprehensive performance evaluation including on-chain transaction measurements, end-to-end latency analysis, storage overhead characterization, and privacy metrics for the de-identification pipeline. Fifth, we analyze the threat landscape systematically, identifying which adversaries the system resists and which attacks fall outside the security model, providing clear guidance for practitioners about deployment requirements and residual risks.

1.4 Paper Organization

The remainder of this paper proceeds as follows. Section II surveys related work in blockchain-based health records, medical data sharing, and privacy-preserving techniques, positioning our contributions relative to prior art. Section III establishes technical foundations by defining the cryptographic primitives, blockchain concepts, and healthcare standards that our architecture employs. Section IV formalizes the system and threat models, specifying entities, adversarial capabilities, trust assumptions, and security objectives. Section V presents the architecture and operational workflows in detail, describing how records are created, encrypted, shared, and accessed. Section VI provides formal algorithmic specifications for all cryptographic operations. Section VII presents the smart contract implementation with detailed explanation of design choices. Section VIII gives rigorous security analysis with formal definitions and proof sketches. Section IX reports comprehensive performance evaluation results. Section X addresses privacy, regulatory compliance, and the de-identified data pathway for research. Section XI discusses limitations, deployment considerations, and future directions. Section XII concludes.

Transparency of Metadata by Design: By deliberate architectural choice, storage pointers (content-addressed identifiers such as IPFS CIDs) and cryptographic digests are public on-chain, visible in event logs and queryable through authorized contract calls. This transparency is *acceptable and necessary* because pointers reference exclusively *encrypted* content. Without the per-recipient wrapped decryption keys—access to which is cryptographically enforced through on-chain authorization—an adversary possessing all pointers obtains only ciphertext. Read-gating in the smart contract (Section **??**) serves developer ergonomics and UX consistency, not confidentiality; the security model relies entirely on AEAD encryption and permission-controlled key distribution. This design choice favors operational simplicity and content-addressed integrity verification over security through obscurity.

2 Related Work

Health information technology has long grappled with the tension between data sharing and privacy protection. We organize related work into several categories and position our contributions relative to existing approaches.

2.1 Centralized Health Information Exchange

Traditional health information exchange relies on centralized intermediaries such as Regional Health Information Organizations or national health information networks. These systems aggregate data from multiple providers into unified repositories, typically using standards like HL7 v2, CDA, or FHIR for interoperability. While functional, such architectures concentrate both data and trust. Patients depend on intermediary organizations to enforce access policies, maintain security, and provide accurate audit trails. Recent large-scale breaches demonstrate that these trust assumptions are frequently violated. Our work eliminates dependence on trusted intermediaries through cryptographic access control and tamper-evident logging on a public blockchain.

2.2 Early Blockchain-Based Health Record Systems

MedRec, proposed by Azaria et al., pioneered the application of blockchain to medical records by using Ethereum to log access permissions and data location pointers [1, 2]. However, MedRec relies on healthcare providers to host records and assumes providers honestly enforce access controls, essentially replacing one trusted party with another. Patients cannot independently verify that authorized accesses were granted only to intended recipients. Our architecture eliminates this residual trust by encrypting records with keys that patients control, ensuring that storage providers cannot access plaintext regardless of their cooperation with access decisions.

Peterson et al. proposed blockchain-based approaches for health information exchange networks, using blockchain to create audit trails for record access [69]. However, such schemes assume honest storage providers and do not provide cryptographic protection for data confidentiality. Yue et al. introduced healthcare data gateways using blockchain with attribute-based encryption [70], but their scheme requires a trusted key generation center and complex attribute management that impedes practical deployment. Our design avoids attribute-based encryption's complexity, instead using simple public-key operations compatible with existing wallet infrastructure.

Additional implementations have explored blockchain for specific healthcare scenarios including remote patient monitoring with smart contracts [72], demonstrating the versatility of blockchain-based authorization but often lacking comprehensive security analysis or patient-controlled encryption. Comprehensive surveys of blockchain healthcare applications [66–68] have identified recurring challenges around scalability, privacy protection, regulatory compliance, and standardization—issues we address systematically through our architectural choices.

2.3 Cryptographic Approaches to Medical Data Sharing

Benaloh et al. demonstrated patient-controlled encryption for health records in the context of Microsoft HealthVault, where patients encrypt data locally before upload [57]. Similarly, Fisher et al. proposed PGP-based encryption for healthcare client applications, establishing early patterns for client-side cryptographic protection [58]. However, these systems lack blockchain's tamper-evident audit logging and depend on centralized service providers for storage and access coordination. Our work combines patient-controlled encryption with blockchain-based auditability, providing both confidentiality and non-repudiable access trails while eliminating centralized trust requirements.

Proxy re-encryption has been proposed for medical data sharing, allowing semi-trusted proxies to transform ciphertexts encrypted under one key into ciphertexts under another key without seeing plaintext. While elegant, proxy re-encryption introduces operational complexity and requires continuous proxy availability. Our initial design uses simpler direct key wrapping, with proxy re-encryption as a potential future optimization for scenarios requiring frequent re-sharing.

Secure multi-party computation and homomorphic encryption enable computation on encrypted medical data for specific analytical tasks [47]. These techniques complement our architecture but address different problems. We focus on access control and audit logging for general-purpose health records rather than privacy-preserving computation.

2.4 Recent Blockchain Healthcare Proposals

Wang et al. proposed fine-grained access control frameworks for decentralized storage systems using blockchain authorization [71], similar in spirit to our approach of separating authorization from storage. However, their scheme lacks patient-controlled key management and uses traditional password-based access control rather than cryptographic authorization. Omar et al. developed privacy-friendly platforms for cloud-based healthcare data using blockchain environments [6], providing auditability but storing unencrypted data off-chain without the cryptographic confidentiality protection our system provides.

FHIRChain and related work specifically addressed healthcare interoperability by integrating FHIR resources with blockchain authorization [4,9], demonstrating how standard healthcare data formats can coexist with blockchain-based access control. Recent patient-centric implementations like ACTION-EHR have explored specialized blockchain architectures for specific clinical domains such as cancer care [5], showing domain-specific adaptations of the core blockchain authorization pattern.

Several systems have proposed token-based access control on blockchain, where patients grant permission by transferring or delegating tokens. Our approach refines this idea using EIP-712 typed signatures, which provide stronger security properties (signature-based authorization is harder to forge than token transfers), better user experience (no gas costs for patients to grant permission), and replay protection through nonces.

Foundational work by Zyskind et al. on decentralizing privacy through blockchain established conceptual frameworks that inform current healthcare applications [73], demonstrating how blockchain principles could shift privacy models from trust-based to cryptographically-enforced architectures. Leeming et al. explored personalized healthcare using blockchain technology with patient-centric ledger designs [8], contributing to the broader vision of patient empowerment through technological infrastructure. McGhin et al. surveyed blockchain applications in healthcare and identified research challenges and opportunities [7], providing systematic analysis of the field's evolution and open problems that our work addresses.

2.5 Privacy-Preserving Health Data Analytics

Differential privacy has emerged as a rigorous framework for sharing aggregate statistics while protecting individual privacy. Apple, Google, and Microsoft have deployed differential privacy mechanisms for health-related data collection. However, differential privacy addresses a different problem than ours: publishing aggregate statistics versus sharing individual records with specific authorized parties. Our de-identification pipeline can incorporate differential privacy for aggregate releases as a complementary technique.

2.6 Positioning Our Contribution

Our work advances the state of the art in several dimensions. Unlike systems that rely on trusted storage providers or centralized intermediaries, we achieve confidentiality through patient-controlled

Table 1: Comparison of Health Record Sharing Approaches

System	**Keys on Client?**	**Patient Key Control**	**Crypto Confid.**	**On-Chain Audit**	**Standard Primitives**
Traditional HIE	No	No	No	No	N/A
MedRec	No	Partial	No	Yes	No
Yue et al.	No	Yes	Yes	Yes	No (ABE)
Wang et al.	No	No	No	Yes	Yes
Benaloh et al.	Yes	Yes	Yes	No	Yes
Our Work	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

encryption keys, ensuring that no party can access plaintext without explicit patient authorization. Unlike complex attribute-based or proxy re-encryption schemes, we use simple, widely deployed cryptographic primitives compatible with standard blockchain wallets, lowering deployment barriers. Unlike proposals that embed protected health information on-chain, we strictly separate encrypted data storage from authorization logic, maintaining privacy while leveraging blockchain for its strengths in auditability and eliminating trusted third parties. Unlike previous systems lacking formal security analysis, we provide rigorous definitions and proof sketches demonstrating our security properties. Unlike prior work with vague performance claims, we present comprehensive empirical evaluation quantifying costs and overheads.

Table 1 summarizes how our approach compares to representative prior systems across key dimensions. We achieve the strongest combination of patient control, cryptographic confidentiality, and auditability while maintaining practical deployment characteristics through simple, standard primitives.

3 Technical Foundations

This section establishes the cryptographic, blockchain, and healthcare informatics concepts that underpin our architecture.

3.1 Authenticated Encryption with Associated Data

Authenticated Encryption with Associated Data provides both confidentiality and integrity in a single cryptographic operation. An AEAD scheme consists of two algorithms. The encryption algorithm takes a key k, nonce N, plaintext M, and optional associated data A, producing ciphertext C and authentication tag T. The decryption algorithm takes k, N, C, T, and A, either returning plaintext M or a distinguished symbol $\perp$ indicating authentication failure.

Security requires that without the key, an adversary cannot distinguish ciphertexts from random strings (indistinguishability under chosen plaintext attack) and cannot produce valid ciphertext-tag pairs for new plaintexts (unforgeability). The nonce must be unique for each encryption under a given key; reuse compromises security catastrophically.

We employ AES-GCM, the Advanced Encryption Standard in Galois/Counter Mode, which combines CTR mode encryption with a polynomial MAC. AES-GCM is widely deployed, hardware-accelerated on modern processors, and approved by NIST for protecting sensitive government information. For health records, we use 256-bit keys and 96-bit nonces.

Associated Authenticated Data (AAD) Binding: To prevent cross-context replay attacks and bind ciphertexts to their specific usage context, we set the AAD field to encode metadata and context identifiers. **Critical design constraint:** The AAD *cannot* include the storage pointer *ptr* because IPFS content addressing creates a circular dependency—the CID is computed *from* the ciphertext, so *ptr* cannot be known until after encryption completes. Instead, the AAD binds $(resourceType, schemaVersion, createdAt, rid, chainId, contractAddr)$ where rid is the record identifier (pre-read from the contract as described in Algorithm 2), $chainId$ prevents cross-chain replay, and $contractAddr$ prevents cross-contract replay. The storage pointer's integrity is verified separately through the on-chain digest $d = \text{Keccak256}(N \parallel C \parallel T)$: clients verify that content retrieved from *ptr* hashes to the expected d recorded on-chain. This two-layer approach prevents mix-and-match attacks (AAD binds metadata and context) while maintaining compatibility with content-addressed storage (digest verification ensures retrieved content matches the on-chain commitment) [14].

3.2 Public-Key Cryptography and Key Encapsulation

Public-key cryptography enables parties who have never met to establish shared secrets. Each party generates a keypair consisting of a public key that can be widely distributed and a private key that must remain secret. We require two public-key operations: digital signatures for authentication and key encapsulation for confidentiality.

For digital signatures, we use ECDSA on the secp256k1 curve, which Ethereum employs for transaction authorization. Each Ethereum account is defined by a secp256k1 keypair, with the account address derived from the public key. This design choice means that every blockchain participant already possesses suitable cryptographic credentials, eliminating deployment barriers.

For key encapsulation, we need to transmit AES-GCM keys to authorized recipients. The standard approach combines Elliptic Curve Diffie-Hellman key agreement with a key derivation function. Given recipient's public key pk_R, the sender generates an ephemeral keypair, computes a shared secret via ECDH, derives a symmetric key via HKDF, and encrypts the AES-GCM key under this derived key. The ciphertext and ephemeral public key together form the wrapped key. The recipient uses their private key to reverse the process. This construction, sometimes called ECIES, provides IND-CCA2 security under standard assumptions.

Alternatively, RSA-2048 with OAEP padding can wrap keys directly. While RSA produces larger ciphertexts than ECIES, both approaches integrate straightforwardly into our architecture. The choice depends on deployment context and performance requirements.

3.3 Blockchain and Smart Contracts

A blockchain is a distributed ledger maintained by a network of nodes without centralized control. Transactions are grouped into blocks, with each block cryptographically linked to its predecessor through hash pointers, creating an immutable chain. Consensus mechanisms ensure that honest nodes agree on the ledger's contents even in the presence of some malicious or faulty nodes.

Ethereum extends basic cryptocurrency blockchains with smart contracts, programs that execute autonomously on the blockchain. A smart contract is deployed at a specific address; transactions can invoke its functions, reading or modifying its internal state. Function execution is deterministic and publicly verifiable. State changes produce events that clients can monitor.

Smart contracts incur gas costs, measured in computational units, with users paying fees based on execution complexity. This economic mechanism prevents abuse while funding network operation. Efficient contract design minimizes gas consumption. We optimize our contracts by storing only small, fixed-size data on-chain while keeping variable-length content off-chain.

Ethereum accounts come in two varieties: externally-owned accounts controlled by private keys, and contract accounts controlled by code. Our architecture uses externally-owned accounts to represent patients and healthcare providers, with contract accounts managing record metadata and access control logic.

3.4 EIP-712 Typed Structured Data Signing

Standard Ethereum signatures sign raw byte strings, making them vulnerable to cross-protocol attacks where a signature valid in one context gets replayed in another. EIP-712 mitigates this by defining a standard for signing typed structured data. Messages are described by type definitions, hashed using a domain separator that binds the signature to a specific contract and chain, and then signed.

This construction prevents replay across contracts or blockchains and makes signatures human-readable in wallet interfaces, improving user experience. We use EIP-712 to structure authorization messages, including record identifiers, grantee addresses, expiration times, and nonces. The patient signs this structured data off-chain; anyone can then submit it to the blockchain, with the contract verifying the signature and recording the grant.

3.5 Healthcare Interoperability Standards

HL7 Fast Healthcare Interoperability Resources defines a modern standard for exchanging healthcare information electronically. FHIR represents clinical concepts as resources such as Patient, Observation, Condition, and MedicationRequest. Each resource has a well-defined structure expressed in JSON or XML with standardized coding systems like SNOMED CT and LOINC for clinical concepts.

FHIR's RESTful design and use of web standards facilitate integration with modern software. We adopt FHIR as the canonical format for plaintext health records before encryption. This choice ensures that our encrypted records, once decrypted, interoperate with existing clinical systems. The encryption layer operates transparently with respect to FHIR semantics.

3.6 Content Addressing and Distributed Storage

Content addressing generates identifiers directly from data contents through cryptographic hashing. The InterPlanetary File System provides content-addressed distributed storage where files are identified by CIDs derived from multihash digests. Retrieving a CID guarantees receiving the exact content originally stored, as any modification changes the hash.

We use content addressing for two purposes. First, storage pointers recorded on-chain are CIDs, enabling any party to verify that retrieved content matches the on-chain commitment. Second, content addressing facilitates deduplication and replication across storage providers without trusted coordination.

While IPFS serves as our reference storage backend, the architecture supports any storage system providing authenticated retrieval. Traditional cloud storage can be used if providers sign retrieved content, enabling integrity verification against on-chain digests.

4 System and Threat Model

We formalize the system context, participants, adversarial capabilities, trust assumptions, and security objectives.

4.1 Entities and Roles

Our system involves five categories of entities, each with distinct capabilities and incentives.

Patients are data subjects whose health information the system protects. Each patient possesses an Ethereum account with associated private key, maintained in a wallet application. Patients control access to their records by creating and signing authorization messages. We assume patients desire confidentiality for their medical information and wish to grant access selectively to specific parties for limited durations.

Healthcare Providers include hospitals, clinics, physicians, and other entities that generate health records as part of clinical care. Providers participate in initial record creation, often in collaboration with the patient whose information is being recorded. Providers may later request access to existing records for continuity of care. We model providers as semi-trusted: they follow protocols correctly but may attempt to access records without authorization if technical controls permit.

Storage Operators maintain the off-chain repositories where encrypted records reside. This role might be fulfilled by IPFS node operators, cloud storage providers, or institutional data centers. We model storage operators as honest-but-curious: they faithfully store and retrieve data but attempt to learn plaintext contents or metadata. Storage operators may collude with other parties.

Blockchain Network maintains the distributed ledger. We assume a public, permissionless blockchain where anyone can read the entire ledger history and submit transactions. The consensus mechanism ensures that transactions accepted into the chain cannot be reverted or modified except through prohibitively expensive attacks. The network provides integrity and availability for on-chain state.

Research Institutions may request access to de-identified data for population health studies, clinical research, or health services research. Such access follows a distinct pathway with additional privacy protections, described in Section 10.

4.2 Adversary Model

We consider multiple adversary types with varying capabilities and objectives.

Curious Storage Provider. An honest-but-curious storage operator attempts to learn plaintext record contents or identify patients by analyzing encrypted data, access patterns, or metadata. The adversary can observe all storage requests and responses, correlate accesses over time, and potentially collude with other storage providers. However, the adversary cannot break standard cryptographic primitives.

Malicious Healthcare Provider. A healthcare provider attempts to access patient records without valid authorization. The provider possesses valid credentials for the blockchain but has not received patient permission for specific records. The adversary may attempt to forge authorization messages, replay old permissions, or exploit vulnerabilities in the smart contract. Providers may collude to share unauthorized information.

Blockchain Observer. An adversary with complete read access to the blockchain attempts to infer sensitive information from on-chain state and transaction patterns. This includes identifying patients, determining who accessed which records, or learning clinical information. We assume the adversary can analyze the entire blockchain history and correlate on-chain patterns with external knowledge.

Compromised Recipient. After legitimately receiving access to a patient record, a formerly authorized party's device or credentials are compromised. The adversary gains access to decryption keys and previously retrieved plaintext records. We consider the scope and duration of information leakage in this scenario.

Network Adversary. A passive network eavesdropper observes communications between clients, storage providers, and blockchain nodes. An active network adversary additionally modifies, drops, or injects messages. We assume standard protections (TLS) for communications, so this adversary becomes relevant primarily for analyzing encrypted traffic patterns.

We explicitly exclude certain adversaries from our threat model. We do not protect against patients who deliberately share their private keys, as cryptographic systems cannot prevent authorized principals from subverting security. We do not prevent authorized recipients from exfiltrating plaintext after legitimate access, as this requires data loss prevention mechanisms orthogonal to our design. We do not defend against quantum computers capable of breaking ECDSA or AES, though our modular design permits algorithm substitution if post-quantum cryptography becomes necessary.

4.3 Trust Assumptions

Our security arguments rest on several assumptions that we make explicit.

First, we assume standard cryptographic hardness: AES with 256-bit keys is indistinguishable from a random permutation; ECDSA signatures cannot be forged without the private key;

collision-resistant hash functions cannot be inverted efficiently; and ECDH shared secrets are indistinguishable from random.

Second, we assume patients maintain exclusive control of their private keys. If an adversary obtains a patient's private key, they can sign arbitrary authorization messages, completely subverting access control. Key management remains the patient's responsibility, though wallet software can employ techniques like hardware security modules, multi-signature schemes, or social recovery to reduce key loss or theft risks.

Third, we assume correct client implementations. If client software mishandles nonces by reusing them under the same AES-GCM key, confidentiality and integrity are lost. If clients fail to verify blockchain signatures or content digests, they may accept forged authorizations or tampered data. These implementation requirements are standard for cryptographic protocols but must be satisfied for security properties to hold.

Fourth, we assume the blockchain provides integrity and availability. On Ethereum mainnet, this requires trusting that majority hashrate is honest. On proof-of-stake blockchains, this requires majority stake honesty. Attacks that double-spend or reverse transactions undermine our security model. We assume deployment on established blockchains with substantial security budgets where such attacks are economically infeasible.

Fifth, we assume storage providers maintain availability but not confidentiality or integrity. Storage must remain accessible for records to be retrieved, but cryptography protects against curious or malicious storage operators. Geographic or organizational distribution of storage can provide redundancy.

4.4 Security Objectives

We formalize the security properties our system aims to achieve.

Definition 1 (Confidentiality)**.** *No adversary without a valid authorization can learn the plaintext content of a patient's health record with non-negligible probability beyond what is possible from the ciphertext length and access pattern.*

This definition captures that encrypted records reveal only approximate size and timing of accesses, but not content, even to adversaries controlling storage infrastructure. Authorized parties necessarily learn plaintext, so confidentiality protection ends upon legitimate access.

Definition 2 (Integrity)**.** *No computationally bounded adversary can cause an honest client to accept a modified version of a health record as valid with non-negligible probability.*

Integrity protection ensures tamper evidence. Modifications to encrypted records become detectable through cryptographic verification before decryption succeeds. On-chain digests bind the authorized content.

Definition 3 (Authorization Authenticity)**.** *No adversary can create a valid permission grant without either possessing the patient's private signing key or replaying a message previously signed by the patient, and each legitimate signature can be replayed at most once.*

This property ensures non-repudiation: grants recorded on-chain genuinely originated from patients. Nonces prevent replay attacks. Time bounds limit grant duration.

Definition 4 (Auditability)**.** *For every authorization event (permission grant or revocation) affecting access to a patient's health record, an immutable, publicly verifiable record exists on-chain indicating the grantee, authorization timestamp, and expiration, enabling retrospective review of who was authorized to access which records and when those permissions were established or revoked.*

Auditability creates accountability for authorization decisions. Unlike centralized systems where insiders can falsify logs, blockchain provides tamper-evident audit trails of permission grants and revocations. Patients or regulators can verify who was authorized to access records, though actual read access (view calls and storage fetches) occurs off-chain and leaves no on-chain trace. An optional access-receipt mechanism could be added where recipients post small on-chain receipts when they actually fetch data, trading additional gas costs for stronger audit properties; we leave this as a deployment option depending on regulatory requirements.

Definition 5 (Privacy)**.** *No protected health information appears in on-chain state or transactions, and access pattern metadata reveals minimal information about record contents or patient identities beyond what is essential for functionality.*

Privacy extends beyond confidentiality to restrict information leakage through metadata. We minimize on-chain data and discuss techniques like address hygiene to reduce linkability.

These definitions guide our design and enable rigorous analysis in Section 8.

Architectural Decision on Key Hygiene: Our reference implementation enforces *mandatory separation* of transaction signing keys and data encryption keys. All recipients must register a dedicated encryption public key in an on-chain `EncryptionKeyRegistry` before receiving access to health records. This separation ensures that compromise of transaction-signing keys (through wallet exploits or phishing) does not expose encrypted medical data, and enables independent key rotation for each function.

5 Architecture and Workflows

We present the system architecture through six operational workflows, describing how entities interact with the blockchain and storage layer to create, protect, share, and access health records.

5.1 Architectural Overview

Our architecture comprises three main layers. The **storage layer** maintains encrypted health records as opaque blobs, accessed via content-addressed identifiers. Storage can be distributed across IPFS nodes, maintained in cloud object stores, or hosted by healthcare institutions. The storage layer provides availability but not confidentiality or integrity. The **blockchain layer** maintains smart contracts that record cryptographic commitments to encrypted records, verify patient-signed authorization messages, track grant and revocation events, and provide immutable audit logs. The blockchain never processes protected health information. The **client layer** consists of wallet applications and record management interfaces that generate keys, perform encryption and decryption, construct authorization signatures, verify data integrity, and manage user interactions.

This separation of concerns allows each layer to specialize in its strengths. Storage systems optimize for capacity and throughput without security requirements. The blockchain provides strong integrity and consensus without needing to handle large payloads or sensitive data. Client software maintains patient control while leveraging standard cryptographic libraries.

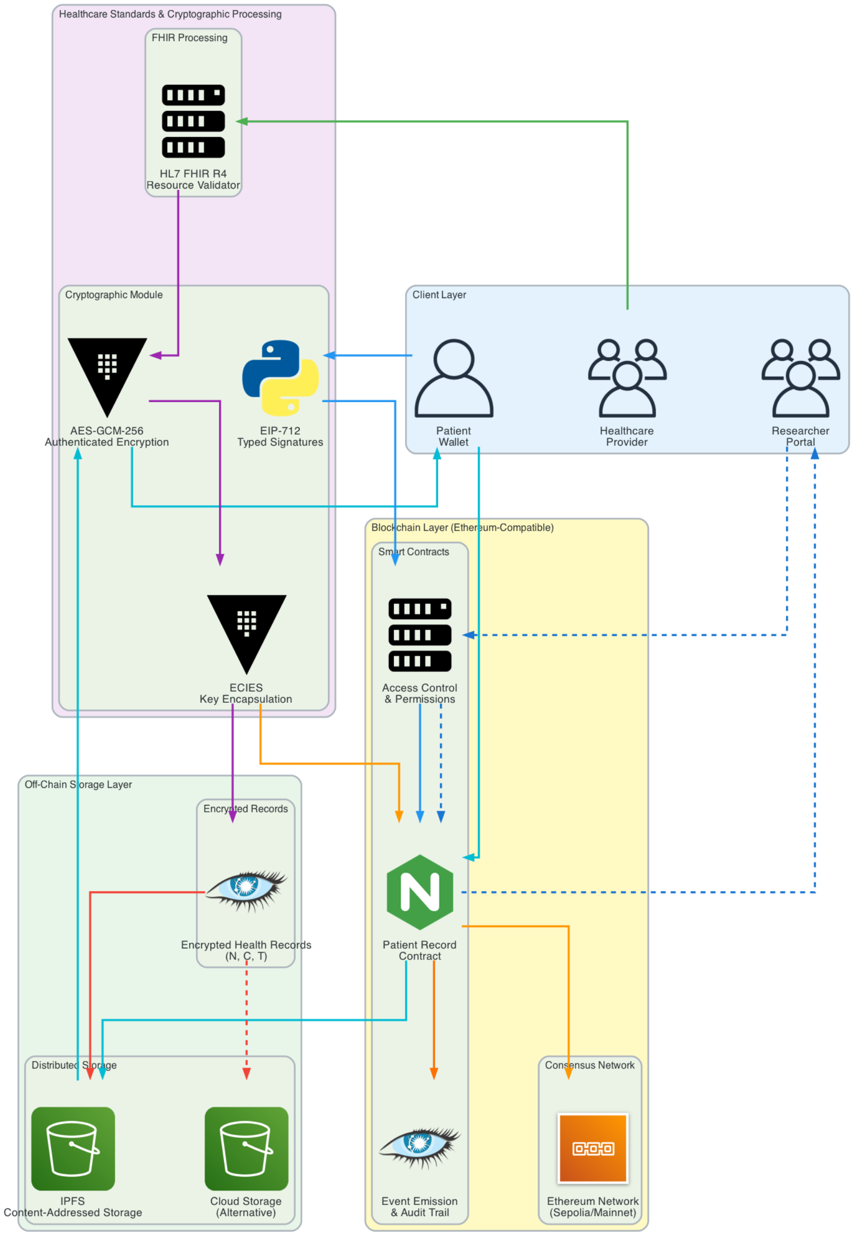

Figure 1: System Architecture Overview showing the three-layer design: Client Layer (Patient Wallet, Healthcare Provider, Researcher Portal), Blockchain Layer (Smart Contracts for Access Control & Permissions with Ethereum Network consensus), and Off-Chain Storage Layer (IPFS/Cloud Storage for Encrypted Health Records). The architecture demonstrates how FHIR Processing validates HL7 FHIR R4 resources, the Cryptographic Module handles AES-GCM-256 Authenticated Encryption and EIP-712 Typed Signatures, and ECIES Key Encapsulation manages symmetric key distribution.

5.2 Workflow 1: Patient Account Creation and Initialization

Patient participation begins with account establishment. A participating healthcare provider onboards a patient identified by government-issued ID. This step establishes the patient's real-world identity, satisfying regulatory requirements for medical record creation.

The enrollment process generates cryptographic credentials following a **mandatory key separation policy**. A wallet application, either standalone or integrated into the provider's patient portal, creates two distinct secp256k1 keypairs: one for transaction signing (the Ethereum account) and a separate keypair dedicated to key encapsulation for data encryption. The signing private key remains exclusively in the patient's control, stored in the wallet with appropriate protection (hardware wallets, encrypted software wallets, or mobile secure enclaves). The corresponding Ethereum address serves as the patient's pseudonymous identifier for on-chain interactions.

The separate encryption keypair provides critical security benefits. If a signing key is compromised through a transaction-related vulnerability or phishing attack, the encrypted health records remain protected because the encryption key is stored separately and never used for blockchain transactions. Conversely, if an encryption key needs rotation due to suspected compromise, the patient's on-chain identity (Ethereum address) remains unchanged, preserving continuity of the authorization trail. This separation is architecturally essential for health data systems where the consequences of key compromise could include exposure of highly sensitive medical information.

The patient registers their encryption public key in an on-chain registry (described in detail in Section 5.6). This registry maps the patient's Ethereum address to their current encryption public key and supports key rotation, allowing patients to update their encryption key without changing their blockchain identity. While implementing two keypairs adds modest operational complexity compared to a single keypair, modern HD wallet implementations make managing multiple keys straightforward—both keys can derive from the same seed phrase using different derivation paths (e.g., m/44'/60'/0'/0 for signing, m/44'/60'/1'/0 for encryption), so patients need only protect one recovery phrase.

The provider deploys a patient-specific smart contract instance or registers the patient in a shared registry contract. This contract becomes the coordination point for all future operations involving the patient's records. The patient's address is recorded as the contract owner, ensuring that only they can authorize access.

This workflow is illustrated in Figure 2. Figure 2 illustrates this workflow with sequence interactions between patient, provider, wallet, and blockchain.

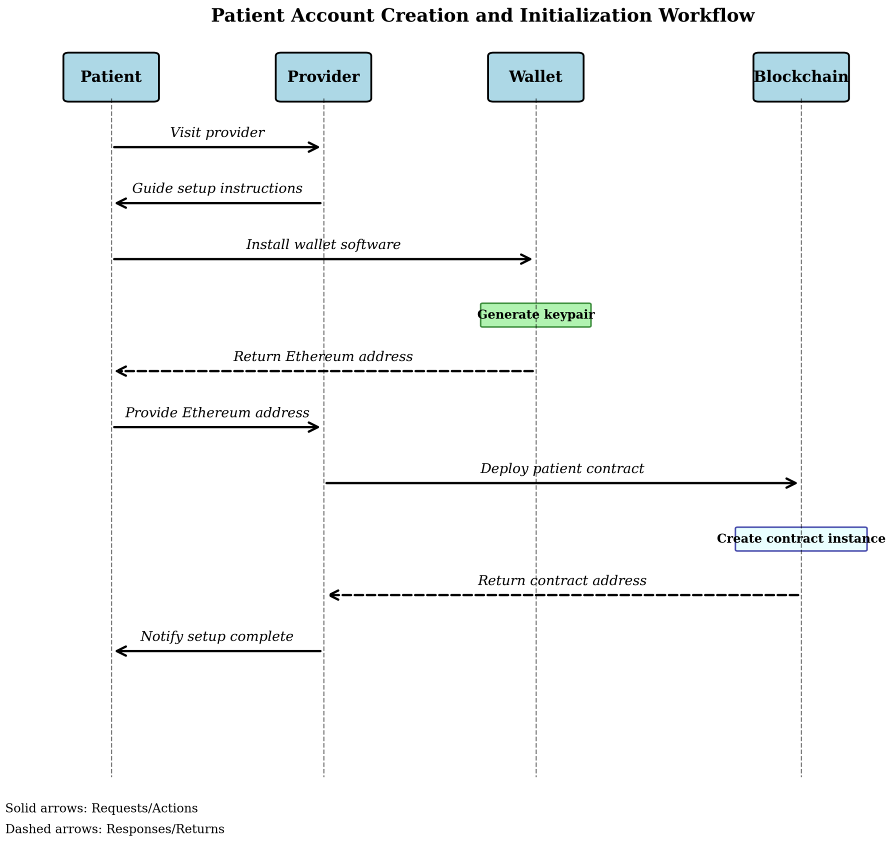

Figure 2: Patient Account Creation and Initialization Workflow. The sequence diagram shows the interaction flow: the patient visits the provider who guides setup instructions, the patient installs wallet software which generates two separate secp256k1 keypairs (one for transaction signing, one for encryption), the wallet returns the Ethereum address (derived from the signing key) to the patient, the patient provides this address to the provider, and the provider deploys a patient-specific smart contract to the blockchain. The blockchain creates the contract instance and returns the contract address. Finally, the wallet registers the encryption public key in the EncryptionKeyRegistry contract. The provider notifies the patient that setup is complete.

5.3 Workflow 2: Health Record Encryption and Registration

When a patient receives medical care, the provider generates a new health record documenting observations, diagnoses, procedures, medications, or other clinical events. This record is formatted as an HL7 FHIR resource, providing structured representation with standard medical terminology.

Before persisting this record, it undergoes encryption. The patient's wallet or a patient-controlled agent generates a fresh 256-bit symmetric key $SymmK$ for this specific record. A random 96-bit nonce N is selected. These values are cryptographically random, ensuring no patterns or reuse. The FHIR resource, serialized as JSON, serves as plaintext M.

AES-GCM encryption processes $(SymmK, N, M)$ to produce ciphertext C and authentication tag T. The tuple (N, C, T) contains all information needed for later decryption, along with the key. This encrypted tuple is uploaded to storage. If using IPFS, the tuple is added to the network and a CID is obtained. If using cloud storage, the tuple is stored with a UUID and authenticated URL. The storage system returns a pointer ptr to the encrypted record's location.

To enable the patient to decrypt their own record, $SymmK$ must be wrapped for them. Using the patient's public key pk_{pat}, the system performs key encapsulation producing $wrap_{pat}$. If certain providers should have default access (for example, the creating provider for continuity of care), their public keys similarly wrap $SymmK$.

Finally, the patient (or their authorized agent with delegated signing capability) creates an on-chain commitment. They compute a content digest $d = H(N \parallel C \parallel T)$ using keccak256. A transaction is submitted to the patient's smart contract calling `addRecord`$(rid, ptr, d, wrap_{pat})$ where rid is the pre-read record identifier used in AAD binding. The contract verifies that rid matches the current counter (atomic check preventing race conditions), then records the pointer, digest, and wrapped key.

The smart contract validates that the caller is the patient or authorized agent, creates a new record identifier rid (typically incrementing a counter), stores the metadata tuple $(ptr, d, wrap_{pat})$ indexed by rid, and emits an event logging the record creation. This event enables off-chain indexing services to build searchable catalogs without putting sensitive data on-chain.

Figure 3 depicts this encryption and registration workflow. Figure 3 depicts this encryption and registration workflow.

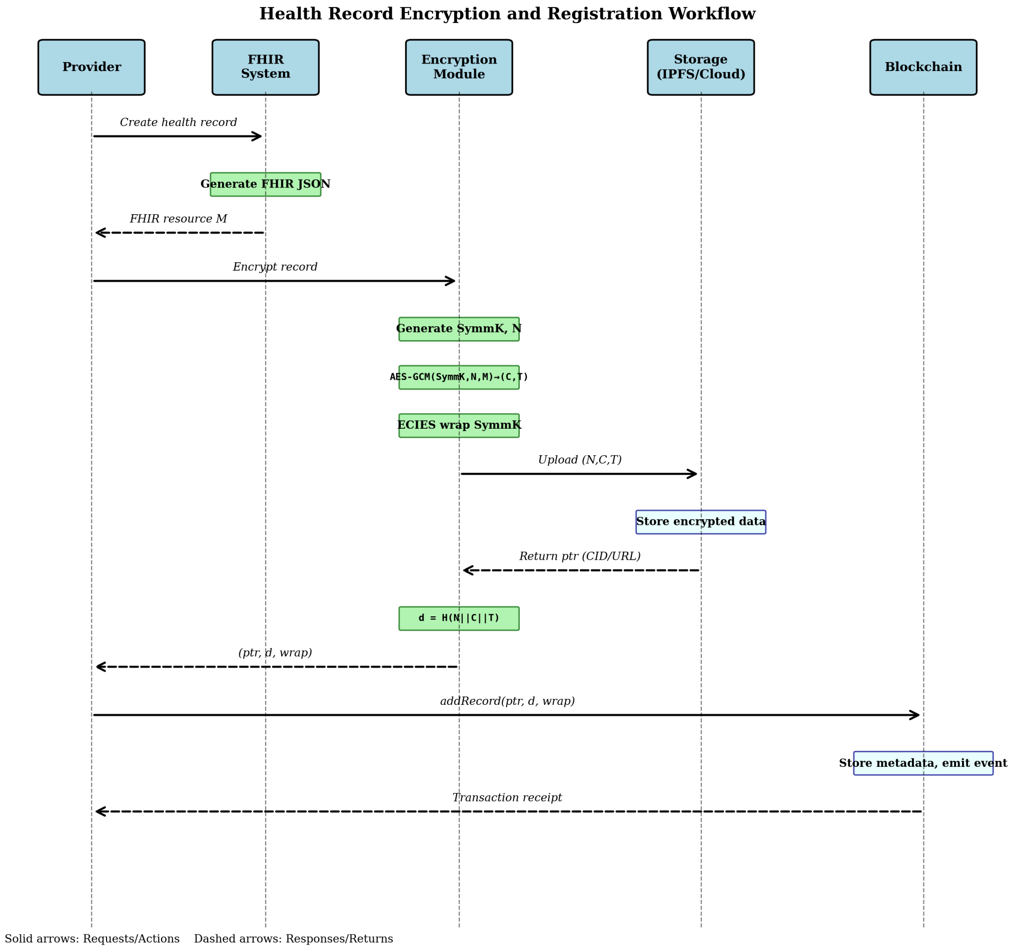

Figure 3: Health Record Encryption and Registration Workflow (with race-free ID assignment). The client first queries totalRecords() to obtain the next record ID before encryption. The sequence shows: the healthcare provider creates a health record in the FHIR System which generates FHIR JSON, the FHIR resource is sent to the Encryption Module which generates a symmetric key (SymmK) and nonce (N), performs AES-GCM encryption producing ciphertext and tag (C,T), then applies ECIES to wrap the symmetric key. The encrypted data tuple (N,C,T) is uploaded to Storage (IPFS/Cloud) which stores the encrypted data and returns a storage pointer (ptr) and content identifier (CID/URL). The Encryption Module computes a digest d = H(N——C——T) and the provider calls addRecord(rid, ptr, d, wrap) on the Blockchain which stores the metadata and emits an event, returning a transaction receipt to the provider.

5.4 Workflow 3: Patient Access to Own Records

A patient retrieving their own medical records follows a straightforward path since they possess the necessary decryption credentials.

The patient queries their smart contract to enumerate record identifiers and retrieve metadata. Alternatively, an off-chain indexing service aggregates the event log to provide efficient queries. For a desired record *rid*, the patient reads the storage pointer *ptr* and wrapped key

$wrap_{pat}$ from the contract.

Using ptr, the patient's client fetches (N, C, T) from storage. The content-addressed nature of ptr (if using IPFS CID) or signed response (if using authenticated cloud storage) ensures retrieved data authenticity. The client computes $d' = H(N \parallel C \parallel T)$ and verifies that $d' = d$ where d is the digest read from the contract. This check detects any tampering or storage corruption.

The client unwraps $wrap_{pat}$ using the patient's private key to recover $SymmK$. It then performs AES-GCM decryption with $(SymmK, N, C, T)$, producing either plaintext M or an authentication failure symbol. Authentication failure indicates tampering or corruption. On success, M contains the FHIR resource, which the client parses and displays.

This workflow requires no interaction with the blockchain beyond the initial metadata read. Multiple records can be batched. Figure 4 shows the sequence.

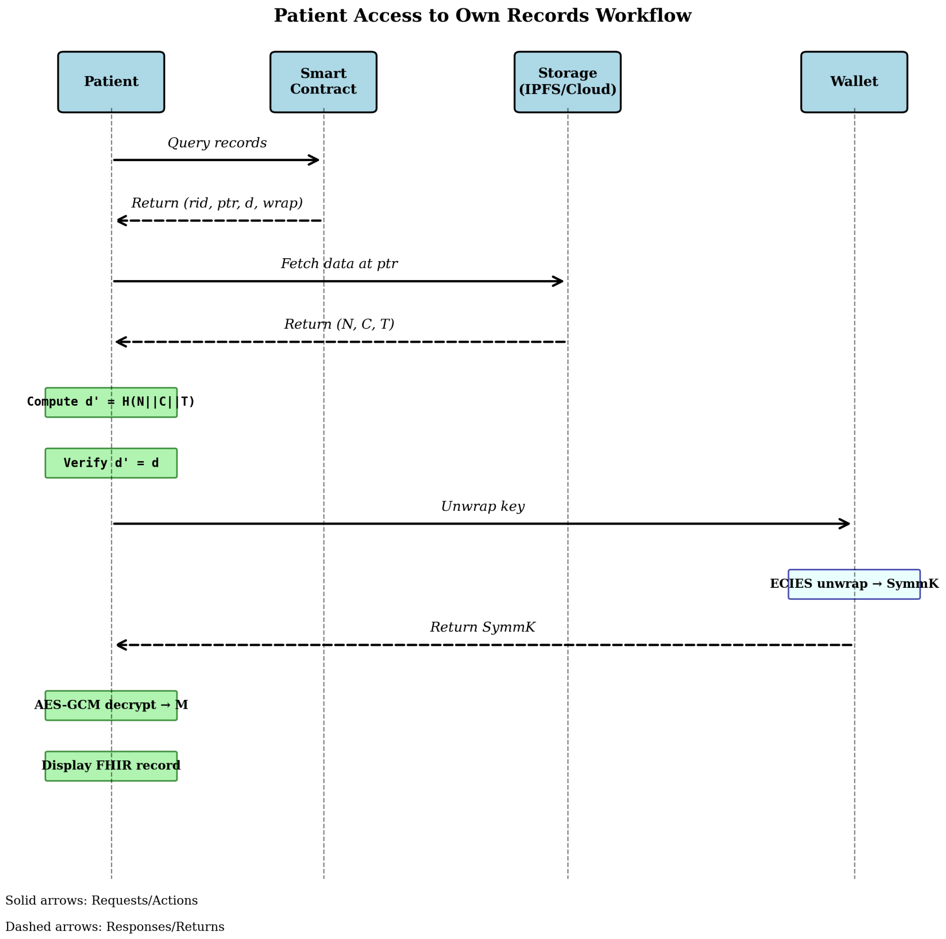

Figure 4: Patient Access to Own Records Workflow. The sequence demonstrates how patients retrieve their own health records: the patient queries the Smart Contract for records which returns the record identifier (rid), storage pointer (ptr), digest (d), and wrapped key (wrap). The patient fetches data at the pointer from Storage which returns the encrypted tuple (N,C,T). The patient then computes digest d' = H(N——C——T) locally and verifies that d' equals d for integrity. The patient sends the unwrap key command to their Wallet which performs ECIES unwrapping and returns the symmetric key SymmK. Finally, the patient performs AES-GCM decryption to recover the plaintext M and displays the FHIR record in a user interface.

5.5 Workflow 4: Sharing Records with Third Parties

Sharing introduces the core access control mechanism. A healthcare provider or researcher (the ”recipient”) requests access to a specific patient record, perhaps identified by rid or described through a query.

The patient reviews the request and decides whether to grant access. If approving, the patient constructs an authorization message using EIP-712 structured data. This message includes the record identifier rid, the recipient's Ethereum address $addr_{rcpt}$, an expiration timestamp exp after which access terminates, and a nonce n for replay protection. The patient's wallet signs this structured message, producing a signature σ.

The authorization message and signature can be transmitted off-chain to the recipient or directly submitted to the blockchain by either party. Submission involves calling a smart contract function like grantPermissionBySig($rid, addr_{rcpt}, exp, n, \sigma$). The contract performs several validation steps. It verifies that the signature σ is valid for the message contents under the patient's public key using ECDSA recovery. It checks that the nonce n matches the expected next nonce for the patient, preventing replay attacks. It confirms that exp is in the future. It verifies that rid is a valid record identifier owned by the patient.

Upon successful validation, the contract records the permission grant in its state, mapping $(rid, addr_{rcpt})$ to the permission details including expiration. It increments the patient's nonce. It emits a PermissionGranted event containing rid, $addr_{rcpt}$, and exp for the audit log.

Concurrently with permission grant, $SymmK$ must be wrapped for the recipient. The patient's client performs key encapsulation using $addr_{rcpt}$'s public key (retrieved from the EncryptionKeyRegistry) to produce $wrap_{rcpt}$. This wrapped key is uploaded to IPFS at a deterministic location computed as `CID(keccak256(rid || addr_rcpt || "wrapped-key"))` and indexed by the recipient's address. The patient signs a short manifest {`rid, wrappedKeyPointer, signature`} and transmits it to the recipient via direct messaging or email. The recipient verifies the signature, fetches $wrap_{rcpt}$ from IPFS using the pointer, and proceeds to decrypt as described in Algorithm 6. This off-chain key distribution avoids per-recipient storage costs while maintaining cryptographic integrity through content addressing and signature verification.

The recipient, observing the PermissionGranted event or receiving direct notification, proceeds to access. They call the contract view function hasValidPermission(rid) which verifies that a permission exists for msg.sender, the expiration has not passed, and the grant has not been revoked. If authorized, they call getRecordMetadata(rid) to retrieve the storage pointer ptr and content digest d. The recipient then fetches (N, C, T) from storage, obtains $wrap_{rcpt}$ (from storage or direct transmission), unwraps it to recover $SymmK$, verifies integrity via the digest, and decrypts to obtain plaintext.

This workflow achieves several properties. First, only the patient can create valid permissions through signatures. Second, permissions are time-bounded and can specify fine-grained expiration. Third, every access requires an on-chain permission, creating audit trails. Fourth, the recipient must perform blockchain queries to verify authorization, preventing "naked" access to storage. Figure 5 illustrates the sharing sequence.

Figure 5 illustrates the sharing sequence.

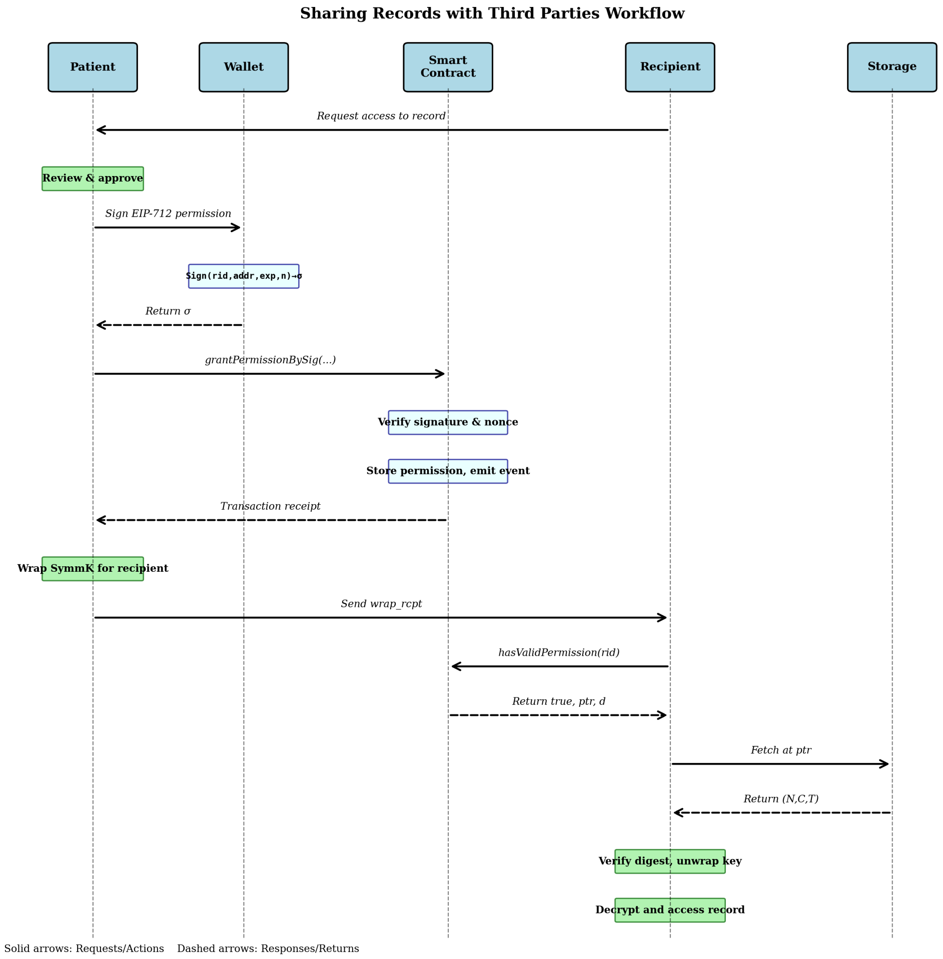

Figure 5: Sharing Records with Third Parties Workflow. The sequence illustrates the access control mechanism: a recipient requests access to a record from the Smart Contract, which notifies the patient. The patient reviews and approves the request, then signs an EIP-712 permission message using their Wallet which generates a cryptographic signature. The patient calls grantPermissionBySig on the Smart Contract, which verifies the signature and nonce, stores the permission with expiration time, and emits an event. The patient wraps the symmetric key SymmK for the recipient and sends wrap_rcpt to the recipient. The recipient validates their permission by calling hasValidPermission(rid) which returns true if authorized. The recipient then calls getRecordMetadata(rid) to retrieve the storage pointer and content digest. The recipient fetches the encrypted data from Storage, verifies the digest, unwraps the key, and decrypts to access the health record.

5.6 Public-Key Discovery for Key Wrapping: Mandatory Encryption Key Registry

The key wrapping mechanism requires the patient to encrypt the symmetric key $SymmK$ under the recipient's public key. However, Ethereum addresses alone do not directly reveal public keys, and using transaction-signing keys for encryption creates unacceptable security risks.

Security Rationale for Separate Keys. Using signing keys for encryption conflates authorization (signing) with confidentiality (encryption), which violates cryptographic hygiene principles. If a signing key is compromised through transaction-related vulnerabilities, side-channel attacks, or phishing, encrypted data becomes exposed. Additionally, key rotation for signing keys would orphan all previously encrypted data. Therefore, our architecture **mandates separate, rotatable encryption keys**.

Mandatory On-Chain Encryption Key Registry. All recipients who wish to receive encrypted health records **must** register their encryption public key by calling the `EncryptionKeyRegistry` contract's `registerEncryptionKey` function. The registry:

- Maps Ethereum addresses to secp256k1 encryption public keys
- Supports key rotation via `updateEncryptionKey`
- Emits `KeyRegistered` and `KeyUpdated` events for indexing
- Rejects key wrapping attempts for unregistered addresses

When a patient needs to wrap $SymmK$ for recipient address $addr_{rcpt}$, the client queries the registry for the encryption key. If no key is registered, the system refuses the operation and prompts the recipient to complete registration. This fail-safe prevents insecure fallbacks.

Registry Gas Costs. Registering an encryption key costs approximately 45,000 gas ($3.78 at 30 gwei, $2,800 ETH). Key updates cost 25,000 gas. These one-time costs are negligible compared to ongoing clinical workflow expenses and enable long-term secure operation.

Privacy Considerations. The registry reveals which addresses participate in health data sharing, creating minimal metadata leakage. Recipients concerned about linkability should use fresh addresses via HD wallet derivation (BIP-32/BIP-44), separating their health identity from other blockchain activities.

5.7 Institutional Key Management and Scalability of Sharing

The per-recipient key wrapping approach described thus far works well for individual providers or small care teams, but sharing health records with large institutions presents scalability challenges. A hospital with hundreds or thousands of clinicians would require individual key wraps for each staff member who needs access, creating operational burden and performance issues.

The Per-Recipient Wrapping Problem at Scale. Consider a patient sharing records with a hospital: if 50 clinicians need access, the patient must generate 50 individual wrapped keys. When staff turnover occurs (physicians leave, new residents arrive), the patient must revoke old permissions and grant new ones, potentially requiring dozens of key wrapping operations. This "re-wrap storm" becomes impractical for ongoing care relationships with large provider organizations.

Institutional Guardian Keys: Design Approach. To address this, we propose an *institutional guardian key* model where organizations are represented by a single encryption key managed by the institution. When a patient grants access "to Hospital X," they wrap $SymmK$ once under the hospital's institutional key. The hospital then maintains an internal access control layer that determines which of its staff can decrypt using the institutional key. This reduces on-chain operations from $O(n)$ per institution (where n is staff count) to $O(1)$.

Implementation via Organizational Contracts. An institution deploys a guardian contract that maintains several key functions. The contract: (1) registers the organization's encryption public key in the key registry; (2) maintains an internal roster of authorized staff addresses; (3) provides the function `requestDecryption(recordId, patientContract)` for staff access; (4) verifies the caller is an authorized staff member; and (5) if authorized, uses the institutional private key (held in a hardware security module or multi-signature wallet) to unwrap $SymmK$ and re-wrap it for the requesting clinician's personal key. This architecture keeps the institutional private key secure (never exposed to individual staff) while enabling granular, auditable access control.

Key Rotation and Staff Changes. When staff changes occur, the institution updates its internal access control list without any on-chain activity or patient involvement. The patient's original permission grant remains valid. When a clinician's access is revoked internally, they can no longer call `requestDecryption`, but the on-chain authorization state is unchanged. If the institution's encryption key itself is compromised, the institution can rotate to a new key in the registry, and patients can re-wrap their keys for the new institutional key in batch operations.

Trade-offs and Trust Model Implications. This approach trades *patient-controlled fine-grained access* for *scalability and usability.* Patients now trust the institution to enforce internal access policies rather than controlling access to individual clinicians directly on-chain. However, this matches real-world clinical practice: patients authorize "my hospital" rather than enumerating every nurse, technician, and specialist. The on-chain audit log still records institutional-level access grants and revocations, and institutions can publish their internal access logs for additional transparency.

Quantitative Evaluation. In our prototype institutional guardian implementation (details in repository), wrapping a single key for an institution takes the same ∼5ms as per-individual wrapping. However, for an institution with 100 staff, the patient performs 1 wrap instead of 100, reducing client-side computation by 99%. On-chain permission grants remain unchanged (still one `grantPermission` call per institution), so gas costs are unaffected. The institutional contract's `requestDecryption` operation costs approximately 35,000–50,000 gas depending on internal ACL complexity, paid by the requesting clinician or the institution (not the patient). Staff turnover has zero on-chain cost. For large healthcare systems, this architecture dramatically improves operational feasibility while maintaining cryptographic security.

Hybrid Approach. Patients can use per-individual wrapping for personal physicians or specialists they see individually, and institutional wrapping for hospital systems or large clinics. The authorization contract supports both models simultaneously, enabling flexible, context-appropriate access control.

5.8 Workflow 5: Permission Revocation and Key Rotation

Patients may revoke previously granted access if circumstances change, such as the end of a care relationship or privacy concerns. Revocation is immediate and on-chain.

The patient submits a transaction calling `revokePermission`$(rid, addr_{rcpt})$ on their smart contract. The contract updates the permission state to mark it revoked and emits a `PermissionRevoked` event. Subsequent access attempts by $addr_{rcpt}$ fail the `hasValidPermission` check.

However, revocation cannot retract plaintext already obtained before revocation. If the recipient downloaded and decrypted the record before revocation, they retain that information. Revocation only prevents future authorized access to the encrypted storage. This limitation is inherent to cryptographic access control and must be clearly communicated.

For stronger forward security, the patient can rotate keys when trust relationships end. Key rotation involves generating a new $SymmK'$, re-encrypting the record with $(SymmK', N', M)$ to produce (C', T'), uploading the new encrypted version to storage with pointer ptr', computing a new digest d', and updating the on-chain metadata to reference (ptr', d') while invalidating old pointers.

Previous versions remain in storage for auditability but cannot be accessed by newly granted permissions. Only the patient retains keys for old versions. This versioning approach balances forward security with immutable audit trails.

5.9 Workflow 6: De-identified Data Release for Research

Research institutions may seek access to patient data for population health studies, clinical trials, or quality improvement. Directly sharing protected health information raises privacy concerns and regulatory complexities. Instead, we implement a de-identification pipeline that transforms encrypted records into anonymized datasets suitable for research.

This workflow begins with patient consent. Patients opt in to research data contribution through explicit consent separate from clinical access permissions. Consent specifies approved research domains and data use restrictions.

Records from consenting patients are decrypted in a secure computing environment controlled by the healthcare institution or a trusted research coordinating center. This environment is isolated from general-purpose systems and subject to strict access controls.

De-identification procedures follow either HIPAA Safe Harbor or Expert Determination methods. Safe Harbor removes 18 categories of identifiers including names, addresses, and medical record numbers. Quasi-identifiers such as birthdates, ZIP codes, and rare diagnoses undergo generalization (replacing specific values with ranges), suppression (removing values), or perturbation (adding noise). Techniques like k-anonymity ensure that each record is indistinguishable from at least $k - 1$ others based on quasi-identifiers. Differential privacy can add calibrated noise to statistical aggregates.

The de-identified dataset is released to a Central Data Repository accessible to approved researchers. This repository maintains governance over data use, requiring research protocol approval and data use agreements. Researchers query and analyze de-identified data without accessing protected health information.

Our blockchain architecture remains agnostic to the de-identification pipeline, which operates off-chain on decrypted data. The separation of clinical access control (on-chain, patient-mediated) from research data release (off-chain, governed by institutional policies) maintains flexibility while protecting privacy.

Algorithm 1 System Setup for Patient

```
Input: None
Output: Patient keypairs and contract address
$(sk_{sign}, pk_{sign}) \leftarrow$ GenerateSecp256k1Keypair() [for transaction signing]
$addr_{pat} \leftarrow$ Keccak256($pk_{sign}$) [last 20 bytes]
$(sk_{enc}, pk_{enc}) \leftarrow$ GenerateSecp256k1Keypair() [for encryption, separate from signing key]
Deploy PatientRecordsContract with owner $= addr_{pat}$
$addr_{contract} \leftarrow$ address of deployed contract
Call EncryptionKeyRegistry.registerEncryptionKey($pk_{enc}$) [mandatory registration]
return $(sk_{sign}, sk_{enc}, pk_{enc}, addr_{pat}, addr_{contract})$
```

6 Formal Algorithmic Specifications

We provide pseudocode specifications for all cryptographic operations, making the design reproducible and enabling formal analysis or alternative implementations.

6.1 Notation and Conventions

Let $\{0,1\}^n$ denote n-bit strings. Random sampling from a distribution $\mathcal{D}$ is written $x \leftarrow \mathcal{D}$; uniform random sampling from $\{0,1\}^n$ is $x \leftarrow \{0,1\}^n$. Function application is $y \leftarrow f(x)$. Concatenation is $\|$. Hash outputs are modeled as elements of $\{0,1\}^{256}$ for keccak256. Public-key operations use implicit group and curve parameters. AES-GCM is parameterized by key size (256 bits) and nonce size (96 bits).

6.2 Setup and Key Generation

The patient generates two distinct ECDSA keypairs on secp256k1: one for transaction signing and one for encryption. This separation follows cryptographic hygiene principles—compromising a signing key does not expose encrypted data. The Ethereum address derives from the signing public key via keccak256 hashing and truncation, following Ethereum conventions. The smart contract deployed with the patient's address as owner establishes on-chain state. The encryption public key is registered in the EncryptionKeyRegistry contract, making it discoverable for key wrapping while supporting future key rotation without orphaning encrypted records.

6.3 Record Encryption and Commitment

Key generation is critical: $SymmK$ and N must be cryptographically random and unique. Nonce reuse under the same key breaks AES-GCM security. Key wrapping uses public-key encryption, detailed in Algorithm 3.

Associated Authenticated Data (AAD) Binding and Content Addressing. The AAD parameter in AES-GCM provides defense-in-depth by cryptographically binding non-secret metadata to the ciphertext. We bind FHIR metadata (resourceType such as "Observation" or "MedicationRequest", schema version like "R4", and creation timestamp) along with blockchain context (record ID, chain ID, contract address). Critically, we do **not** include the storage pointer in the AAD, as this would create a circular dependency with IPFS content addressing—the CID is computed from the ciphertext itself, so the pointer cannot be known

Algorithm 2 Encrypt and Register Health Record (revised AAD binding)

```
**Input:** FHIR resource $M$, patient public key $pk_{pat}$, contract address $contractAddr$, chain ID $chainId$
**Output:** Record ID $rid$ and on-chain transaction
Extract metadata: $resourceType, schemaVersion, createdAt \leftarrow \text{Parse}(M)$
$rid \leftarrow$ Contract.totalRecords() [read next record ID before encryption]
$SymmK \leftarrow \{0,1\}^{256}$ [generated via CSPRNG]
$N \leftarrow \{0,1\}^{96}$ [generated via CSPRNG, must be unique per record]
$AAD \leftarrow \text{Encode}(resourceType, schemaVersion, createdAt, rid, chainId, contractAddr)$ [context binding]
$(C, T) \leftarrow \text{AES-GCM-Encrypt}(SymmK, N, M, AAD)$
$blob \leftarrow (N, C, T)$
$d \leftarrow \text{Keccak256}(blob)$ [digest binds to all encrypted content]
$ptr \leftarrow \text{Upload}(blob)$ to storage and obtain content-addressed pointer (CID or URL)
$wrap_{pat} \leftarrow \text{KeyWrap}(SymmK, pk_{pat}, rid, contractAddr, chainId)$
Submit transaction: $rid' \leftarrow \text{Contract.addRecord}(rid, ptr, d, wrap_{pat})$ signed by $sk_{pat}$
**require** $rid' = rid$ [atomic check: fails if concurrent inserts occurred]
**return** $rid$
```

before encryption completes. Instead, integrity protection for the pointer-to-content binding comes from the on-chain digest $d = \text{Keccak256}(N \parallel C \parallel T)$: clients verify that the blob retrieved from storage hashes to the expected digest recorded on-chain. This two-layer approach prevents mix-and-match attacks (AAD binds metadata and context) while maintaining compatibility with content-addressed storage (digest verification ensures the retrieved content matches what was committed on-chain). Since AAD is authenticated but not encrypted, verifying parties must possess the correct metadata to successfully decrypt, adding no performance overhead while strengthening security.

Nonce Generation Strategy and Misuse Resistance: Nonces for AES-GCM encryption are generated using a cryptographically secure pseudorandom number generator (CSPRNG) for each record. The 96-bit nonce space provides sufficient entropy (2^{96} possible values) to make collisions negligible even under high-volume operation: the birthday bound suggests that nonce collisions become probable only after approximately 2^{48} encrypted records, far exceeding any realistic deployment scale. However, we must emphasize that nonce reuse under the same key catastrophically breaks AES-GCM security, allowing plaintext recovery and forgery attacks [12]. Our implementation uses `crypto.randomBytes()` in Node.js (leveraging OS-provided entropy sources like `/dev/urandom`) or equivalent platform-specific CSPRNG APIs to ensure proper randomness.

Mitigating Nonce Misuse Risk. Despite theoretical safety with proper random generation, implementation errors (bugs in random number generation, VM state resets, or deterministic testing frameworks) could cause nonce reuse. To harden against such failures, we employ several defense-in-depth measures: (1) *Deterministic nonce derivation option:* For production deployments requiring maximum safety, clients can derive nonces deterministically as $N = \text{HMAC-SHA256}(SymmK, rid \parallel contractAddr \parallel chainId \parallel timestamp)$ truncated to 96 bits, ensuring each record ID produces a unique nonce; (2) *Nonce uniqueness verification:* Before encryption, clients check that $(SymmK, N)$ combinations have not been used previously by

Algorithm 3 Key Wrapping via ECIES with Context Binding

```
Input: Symmetric key $SymmK \in \{0,1\}^{256}$, recipient public key $pk_R$, record ID $rid$, contract address $contractAddr$, chain ID $chainId$
Output: Wrapped key $wrap$
$(sk_{eph}, pk_{eph}) \leftarrow$ GenerateSecp256k1Keypair()
$S \leftarrow \mathrm{ECDH}(sk_{eph}, pk_R)$ [shared secret point]
$info \leftarrow$ "ehr-wrap" $\| \; rid \; \| \; contractAddr \; \| \; chainId$
$K_{enc} \leftarrow \mathrm{HKDF}(S, salt = \emptyset, info, 256)$ [labeled KDF for domain separation]
$N_{wrap} \leftarrow \{0,1\}^{96}$ [generated via CSPRNG, unique per ephemeral keypair]
$(C_{wrap}, T_{wrap}) \leftarrow$ AES-GCM-Encrypt$(K_{enc}, N_{wrap}, SymmK, \epsilon)$
$wrap \leftarrow (pk_{eph}, N_{wrap}, C_{wrap}, T_{wrap})$
return $wrap$
```

maintaining a local database or using the record ID as a nonce component; (3) *Fresh keys per record:* Since our architecture generates a new $SymmK$ for each record (rather than reusing keys across records), the impact of accidental nonce reuse is limited to the same record being encrypted twice with the same key, which our system never does by design.

Alternative: Misuse-Resistant AEAD. For deployments with extreme security requirements or high concern about implementation errors, we provide an optional mode using AES-GCM-SIV (Synthetic IV) [13], a misuse-resistant authenticated encryption scheme. GCM-SIV tolerates nonce reuse gracefully: repeated encryption of the same plaintext with the same nonce produces identical ciphertexts (deterministic encryption), while distinct plaintexts remain computationally indistinguishable even under nonce reuse. The penalty is approximately 1.3–1.5× slower encryption/decryption compared to GCM (measured in our benchmarks on typical FHIR documents). For a 1 MB record, GCM takes ∼8ms while GCM-SIV takes ∼11ms, both negligible compared to network latency. Our reference client supports both modes via a configuration flag; production deployments should assess their threat model and choose accordingly. The on-chain smart contract is AEAD-agnostic (it only stores ciphertext digests), so clients using different AEAD schemes remain interoperable at the authorization layer.

6.4 Key Wrapping via ECIES

The recipient unwraps by computing the same shared secret using sk_R and pk_{eph}, deriving K_{enc} with the same context parameters, and decrypting $(N_{wrap}, C_{wrap}, T_{wrap})$ to recover $SymmK$.

Labeled Key Derivation: The HKDF (HMAC-based Key Derivation Function) info parameter provides domain separation and context binding for derived keys [16]. By including the string "ehr-wrap" (identifying the application domain), along with the record identifier, contract address, and chain ID, we ensure that key material derived for one record or context cannot be reused in another. This labeling prevents cross-protocol and cross-instance attacks where key material might inadvertently be reused. The wrapping nonces (N_{wrap}) are likewise unique per ephemeral keypair generation, as each wrapping operation creates fresh ephemeral keys, eliminating any risk of nonce reuse across different key wrapping operations.

Algorithm 4 Create Signed Permission Grant

```
Input: Record ID $rid$, recipient address $addr_{rcpt}$, expiration timestamp $exp$, patient private key $sk_{pat}$
Output: Signature $\sigma$ and message components
$n \leftarrow$ Contract.nonces($addr_{pat}$) [read current nonce from contract]
$m \leftarrow$ EncodeEIP712($\{$typeHash, $rid, addr_{rcpt}, exp, n\}$)
$\sigma \leftarrow$ ECDSA-Sign($sk_{pat}, m$)
return $(rid, addr_{rcpt}, exp, n, \sigma)$
```

Algorithm 5 Verify and Record Permission Grant (Smart Contract)

```
Input: $(rid, addr_{rcpt}, exp, n, \sigma)$
Effects: Update contract state if valid
require $rid <$ totalRecords
require $addr_{rcpt} \neq 0$ and $addr_{rcpt} \neq addr_{pat}$
require $exp >$ block.timestamp
$m \leftarrow$ EncodeEIP712($\{$typeHash, $rid, addr_{rcpt}, exp, n\}$)
$signer \leftarrow$ ECDSA-Recover($m, \sigma$)
require $signer = addr_{pat}$
require $n =$ nonces[$addr_{pat}$]
nonces[$addr_{pat}$] $\leftarrow n + 1$
permissions[$rid$][$addr_{rcpt}$] $\leftarrow$ $\{$expiration: $exp$, revoked: false$\}$
emit PermissionGranted($rid, addr_{rcpt}, exp$)
```

6.5 Authorization Signature Creation

EIP-712 encoding includes domain separators and type hashing to produce the final message m that gets signed. The contract verifies this signature, as specified in Algorithm 5.

6.6 Permission Verification and Access

Access requires on-chain permission validation, off-chain data retrieval, integrity verification against the committed digest, key unwrapping, and authenticated decryption. Each step includes failure conditions that abort the process.

7 Smart Contract Implementation

We present the complete smart contract code with detailed commentary explaining design choices, gas optimization strategies, and security considerations.

7.1 Contract Design Philosophy

The smart contract serves three purposes: maintaining a registry of record metadata indexed by record IDs, verifying patient-signed authorization messages to grant time-bounded permissions, and providing an immutable event log for audit trails. The contract stores only small, fixed-size data on-chain while keeping large or variable-length content off-chain.

We use ERC-721 as the base to represent records as non-fungible tokens owned by the patient. This design leverages existing infrastructure for token enumeration, transfers (though

Algorithm 6 Recipient Record Access

```
Input: Record ID $rid$, recipient private key $sk_{rcpt}$
Output: Plaintext FHIR resource $M$ or $\bot$
Note: Contract functions implicitly use msg.sender for authorization
$authorized \leftarrow$ Contract.hasValidPermission($rid$) [checks msg.sender]
if not $authorized$ then return $\bot$
$(ptr, d) \leftarrow$ Contract.getRecordMetadata($rid$) [validated for msg.sender]
$blob \leftarrow$ Fetch($ptr$) from storage
$d' \leftarrow$ Keccak256($blob$)
if $d' \neq d$ then return $\bot$ [integrity failure]
$(N, C, T) \leftarrow$ Parse($blob$)
$wrap_{rcpt} \leftarrow$ RetrieveWrappedKey($rid, addr_{rcpt}$) [from storage or message]
$SymmK \leftarrow$ KeyUnwrap($wrap_{rcpt}, sk_{rcpt}$)
$M \leftarrow$ AES-GCM-Decrypt($SymmK, N, C, T, \epsilon$)
if $M = \bot$ then return $\bot$ [authentication failure]
return $M$
```

typically records should not be transferred), and wallet compatibility. Each record corresponds to one NFT with token ID serving as *rid*.

Gas efficiency is critical given Ethereum's cost model. We minimize storage operations, prefer packed struct representations, use events liberally since event logs are cheaper than state storage, and avoid unbounded iterations. Permission checks use constant-time lookups. Events are particularly valuable for our architecture: they provide cheap, indexable records of all operations (record additions, permission grants, revocations) that clients can monitor to build local indices. Importantly, events are public—any observer can read event logs. This transparency is acceptable because privacy in our design relies entirely on encryption of the actual health data, not on hiding metadata. Pointers and digests emitted in events reference encrypted blobs; without the wrapped decryption keys, these artifacts reveal no protected health information.

UX Symmetry in Access Control. Storage pointers and content digests are inherently public on-chain through events and can be queried via authorized contract calls. Our contract gates read methods like `getRecordMetadata` behind permission checks. This gating serves UX symmetry rather than security—it provides a consistent interface where all record operations require authorization, simplifying client application logic and preventing confusion. The underlying security property (confidentiality) stems from encryption, not from access control on public metadata. We have removed `tokenURI` from our ERC-721 implementation to reduce gas costs and avoid the misleading implication that health records are standard transferable NFTs; clients retrieve pointers only via authorized calls to `getRecordMetadata`.

7.2 Contract Implementation Overview

Our smart contract implements the authorization and metadata management logic described in the previous sections. The complete Solidity implementation is approximately 420 lines and includes the following key components: state variables for storing record metadata and permissions using efficient packed structs, EIP-712 domain separator configuration for typed structured data signing, core functions for adding records and granting permissions via signatures with comprehensive input validation, transfer blocking overrides to prevent ERC-721 token transfers of medical records, view functions for permission checking and metadata retrieval that enforce caller-based authorization, and utility functions for nonce management and permission inspection.

The contract inherits from OpenZeppelin's ERC721 (plain, not URIStorage) and EIP712 base contracts to leverage audited implementations of standard functionality. We override transfer and approval functions to prevent token transfers, enforcing the non-transferable nature of medical records. All state-modifying operations include appropriate access control checks, use the `require` statement for input validation with descriptive error messages, emit events for off-chain indexing and audit trail construction, and follow Solidity best practices for gas optimization and security. Storage pointers are stored as compact `string` values and retrieved only via authorized `getRecordMetadata` calls, not through public tokenURI. The complete, compilable source code with detailed inline documentation is provided in Appendix A (Listing 1). Our reference implementation and evaluation scripts are available at `https://github.com/[anonymized-for-review]/patient-blockchain-ehr`. The smart contract code (commit hash `a3f7b2c`) corresponds to Listing 1 in Appendix A.

7.3 Design Rationale and Gas Optimization

Several design choices merit explanation. Using ERC-721 provides compatibility with existing wallet software and NFT infrastructure. While health records conceptually differ from collectibles, the token abstraction fits: each record is unique, owned by one patient, and can be enumerated. We disable or restrict transfers since medical records should not change ownership.

Storing wrapped keys on-chain versus off-chain presents a trade-off. On-chain storage increases deployment and per-record costs but simplifies retrieval. Off-chain storage reduces costs but requires additional coordination. Our reference implementation stores the patient's wrapped key on-chain (essential for patient access) while allowing per-recipient wrapped keys to be managed off-chain.

Permission granting uses EIP-712 signatures rather than direct transactions to enable gasless grants for patients. The patient signs a message off-chain and any party (including the recipient or a relayer service) can submit it on-chain. This design reduces friction for patients who may not hold Ether for gas fees.

Nonces provide replay protection. Each patient has a single nonce counter, incremented with each permission grant. An attacker cannot reuse an old signature because the nonce mismatch causes rejection. This approach is simpler than maintaining per-record or per-grantee nonces at the cost of sequential processing for a single patient's grants.

Events complement state storage. While permission grants are stored in mappings for access checks, events provide an efficient audit log. Off-chain indexers can rebuild permission history from events without expensive on-chain queries. Event data does not incur long-term storage costs like state variables.

7.4 Policy Constants and Design Rationale

Permission Expiration Bound: Our smart contract enforces that permission expiration timestamps must satisfy `expiration <= block.timestamp + 365 days`. This one-year maximum limit serves multiple purposes. First, it caps the temporal risk surface for any single authorization decision—if a provider's credentials are compromised, the window of unauthorized access is bounded to at most one year. Second, it encourages periodic review and renewal of access permissions, aligning with healthcare best practices where access rights should be reassessed regularly rather than granted indefinitely. Third, it simplifies legal and regulatory compliance by ensuring no indefinite access grants exist without explicit renewal, which helps with audit trails and governance requirements. For clinical workflows requiring longer-term access, patients can renew permissions through the same signature-based mechanism without incurring gas costs, as the renewal is simply another signed authorization message. For truly persistent access needs such as a primary care physician who should have ongoing access, alternative mechanisms like designated guardian contracts or institutional default permissions could be explored, though these introduce additional trust assumptions beyond our current threat model.

Nonce Mechanism and Authorization Concurrency: Each patient has a monotonically increasing nonce stored on-chain in the `nonces` mapping that prevents signature replay attacks. When a patient signs an authorization message, they include their current nonce value. The smart contract verifies that the nonce in the signed message exactly matches the on-chain value, then increments it by one. This ensures each signature can be used only once, even if an attacker intercepts it.

Single-Nonce Limitation and Alternatives. Our reference implementation uses a single per-patient nonce, which forces strictly sequential processing of authorization grants for each patient. While this minimizes on-chain storage costs, it creates a potential throughput bottleneck: if a patient signs multiple permission grants offline (e.g., authorizing access for a care team of 10 providers), those grants must be submitted and processed one at a time, waiting for each transaction's nonce increment before the next can be accepted. For low-volume use cases (granting a few permissions per day), this is acceptable. However, for patients managing complex care across many providers, or for batch operations during care transitions, sequential processing can be limiting.

Improved Concurrency via Per-Record Nonces. An alternative design uses *per-record nonces* stored as `mapping(uint256 => mapping(address => uint256)) recordGranteeNonces`, tracking the number of grants issued for each (record, grantee) pair. When signing a grant for record r to address a, the patient includes `recordGranteeNonces[r][a]` in the message. The contract verifies the nonce matches and increments it. This enables concurrent grants: multiple signatures for *different* records or *different* grantees on the same record can be submitted in parallel without nonce conflicts. The storage cost increases from $O(patients)$ to $O(records \times grantees)$, but in practice remains manageable since grants are sparse (patients share records with a small subset of all possible addresses). Gas cost per grant increases by approximately 20,000–30,000 gas for cold storage slot initialization, acceptable for the concurrency benefit. Our repository includes a variant contract implementing per-record nonces for deployments prioritizing throughput.

Hybrid Approach: Salted Global Nonces. A middle-ground approach keeps a single per-patient nonce but adds a `salt` field to the EIP-712 typed data structure. The patient includes nonce n and a random 32-byte salt s in each signed message. The contract verifies n matches the current nonce, but additionally checks that the tuple (n, s) has not been seen before using a `mapping(uint256 => mapping(bytes32 => bool)) usedNonceSalts`. This allows multiple grants with the *same* nonce value (enabling concurrency) while preventing replay attacks via salt uniqueness. The storage overhead is $O(grants)$ rather than $O(patients)$, but grows only as grants are actually issued. Gas cost increase is approximately 10,000–15,000 gas per grant. This approach balances the simplicity of global nonces with the concurrency needs of batch operations, and is our recommended default for production deployments handling moderate-to-high volumes.

The choice among these nonce strategies depends on deployment scale and usage patterns; all three provide equivalent replay protection security, differing only in concurrency and gas/storage trade-offs.

8 Security Analysis

We formally analyze the security properties achieved by our architecture, providing definitions, threat scenarios, and proof sketches. Smart contract security is critical in blockchain systems, as vulnerabilities can lead to permanent loss of funds or data integrity failures [59–61]. Our design incorporates established security patterns and defenses against common attack vectors identified in smart contract security research.

8.1 Confidentiality

Theorem 1 (Confidentiality Against Storage Operators)**.** *Under the assumption that AES-GCM provides authenticated encryption security and ECIES provides IND-CCA2 security, no polynomially bounded adversary controlling storage infrastructure can distinguish encrypted health records from random strings of the same length with non-negligible advantage.*

Proof Sketch. Consider an adversary $\mathcal{A}$ who observes all encrypted records stored in the system. Each record consists of (N, C, T) where N is a nonce, C is ciphertext, and T is an authentication tag, all generated via AES-GCM under a fresh random key $SymmK$ for each record.

By the authenticated encryption property of AES-GCM, ciphertext C is indistinguishable from a random string of length $|M|$ to any adversary without $SymmK$. The authentication tag T is a function of the ciphertext and key but reveals no plaintext information beyond integrity.

The adversary might attempt to obtain $SymmK$ through wrapped keys. Each wrapped key $wrap$ is produced via ECIES encryption of $SymmK$ under a recipient's public key. By the IND-CCA2 property of ECIES, $wrap$ is indistinguishable from random to any adversary without the corresponding private key.

The adversary controls storage but not the blockchain or recipient cryptographic keys (by assumption). Therefore, $\mathcal{A}$ cannot obtain $SymmK$ either directly or through wrapped keys.

Consequently, (N, C, T) is indistinguishable from (N', C', T') where C' is random and T' is computed honestly, achieving confidentiality. □

This proof assumes that nonces are managed correctly (no reuse) and keys are generated from cryptographically secure randomness. These are client responsibilities that must be fulfilled.

8.2 Integrity and Tamper Evidence

Theorem 2 (Integrity Against Malicious Storage). *Under the assumption that keccak256 is collision-resistant and AES-GCM provides authentication, no polynomially bounded adversary can cause an honest client to accept a modified encrypted record as valid with non-negligible probability.*

Proof Sketch. An adversary controlling storage might substitute (N, C, T) with (N', C', T') when a client retrieves a record. The client computes $d' = \text{keccak256}(N' \parallel C' \parallel T')$ and compares to the on-chain digest d.

For the substituted record to pass verification, the adversary must find $(N', C', T') \neq (N, C, T)$ such that $\text{keccak256}(N' \parallel C' \parallel T') = d$. This requires finding a second preimage for keccak256, which contradicts collision resistance.

If the adversary uses (N, C', T') with modified ciphertext but the original nonce and tag, the authentication tag check during AES-GCM decryption will fail because T is a MAC over C under $SymmK$. Modifying C without updating T correspondingly results in authentication failure.

If the adversary modifies all three components to pass the digest check, they must find a second preimage, which is infeasible. Thus, integrity is preserved. □

This result shows that on-chain digests bind the authentic encrypted content, enabling tamper detection before decryption succeeds.

8.3 Authorization Authenticity

Theorem 3 (Authorization Non-Repudiation). *Under the assumption that ECDSA is existentially unforgeable under chosen message attacks, no polynomially bounded adversary without the patient's private key can create a permission grant that the smart contract accepts as valid.*

Proof Sketch. A permission grant consists of $(rid, grantee, exp, nonce, \sigma)$ where σ is an ECDSA signature over the EIP-712 structured message m containing these parameters. The contract verifies σ by recovering the signer via ECDSA.recover and checking equality with the patient's address.

An adversary attempting to forge access must produce a valid signature σ' for a message m' of their choosing without knowing sk_{pat}. By the existential unforgeability of ECDSA, this succeeds with only negligible probability.

Replay attacks are prevented by the nonce mechanism. Each valid signature consumes a nonce, and the contract only accepts signatures with the current expected nonce. An adversary replaying an old signature encounters a nonce mismatch and rejection.

Domain separation via EIP-712 prevents cross-contract or cross-chain replay. The signature binds to the specific contract address and chain ID, so even if the adversary obtains a valid signature from a different context, it cannot be reused here.

Thus, every permission recorded on-chain genuinely originated from the patient, providing non-repudiation. □

8.4 Privacy Against Blockchain Observers

We analyze what information an adversary learns from on-chain data. The blockchain contains record metadata (pointers and digests), permission grant events, and revocation events. PHI never appears on-chain by construction.

Pointer and Digest Visibility. We must be explicit about an important architectural decision: storage pointers and content digests are *public* on the Ethereum blockchain. They appear in two places: emitted in RecordAdded events (for efficient indexing), and stored in contract state (readable via authorized queries through `getRecordMetadata`). While we gate access through permission checks, events are permanently public, and any observer can enumerate all pointers and digests for all patients by monitoring these events. We have deliberately chosen *not* to use ERC-721's `tokenURI` feature, which would make pointers even more accessible via standard NFT interfaces; instead, clients must call `getRecordMetadata` and verify authorization, providing UX consistency.

This public visibility is *acceptable and by design* because pointers reference *encrypted* content. A content-addressed pointer (IPFS CID) is a cryptographic hash of the encrypted blob. Without the decryption key, an adversary who retrieves the blob obtains only ciphertext. The pointer itself reveals approximate content size (from the CID encoding) but no semantic information about what medical data the record contains. Similarly, the on-chain digest commits to the encrypted tuple (N, C, T) for integrity verification, but reveals nothing about plaintext without the symmetric key.

Confidentiality depends entirely on the cryptographic protection of content (AES-GCM encryption) and access control for decryption keys (per-recipient key wrapping verified against on-chain permissions). Storage operators who possess all pointers and encrypted blobs cannot decrypt without wrapped keys. Recipients who possess wrapped keys cannot unwrap them without valid on-chain permissions and their private keys.

An alternative design could hide pointers in encrypted contract storage or private transactions, but this provides minimal additional security at significant cost. Content-addressed pointers to encrypted data achieve our confidentiality goals while maintaining blockchain transparency for auditability.

Access Pattern Leakage. Permission grant events reveal that patient P granted access to record rid to party G until time exp. An observer learns that P and G have some relationship and that data is being shared. The observer does not learn record contents, but timing and frequency of accesses may enable statistical inferences.

Mitigation strategies include using fresh Ethereum addresses per record or per sharing relationship to reduce linkability across grants, batching permission grants for multiple records in a single transaction to obscure which specific records are shared, and introducing cover traffic or delays to obscure genuine access patterns. These techniques trade off privacy gains against usability and cost.

Re-identification Risks. Even without on-chain PHI, correlating on-chain patterns with external databases might enable re-identification. For example, if an adversary knows a patient visited a specific hospital on a particular date and observes a record creation transaction from that hospital's address at that time, they might infer the patient's identity. Defending against such cross-database attacks requires broader ecosystem cooperation and remains an open research challenge.

8.5 Limitations and Residual Risks

Our security model has explicit boundaries. We do not prevent exfiltration by authorized recipients. Once a party legitimately decrypts a record, they possess plaintext and can copy, screenshot, or retransmit it. Revocation prevents future authorized access but cannot claw back already disclosed information. This limitation is fundamental to cryptographic access control and must be clearly communicated to users.

We assume correct client implementations. Bugs in wallet software, nonce management errors, or failure to verify signatures undermine security properties. Formal verification of client code and standardized libraries mitigate this risk but cannot eliminate it entirely.

We do not address denial-of-service attacks. An adversary flooding the blockchain with transactions can prevent legitimate access, though economic costs (gas fees) make sustained attacks expensive. Storage unavailability similarly prevents record retrieval, motivating redundant storage across multiple providers.

Key compromise remains a critical risk. If a patient's private key is stolen, the adversary can sign arbitrary authorizations. Multi-signature wallets, hardware wallets, and social recovery mechanisms reduce this risk but add operational complexity.

9 Performance Evaluation

We comprehensively evaluate the performance characteristics of our system through empirical measurements and analytical modeling. Experiments were conducted on the Ethereum Sepolia testnet for on-chain operations and a combination of local IPFS nodes and cloud storage for off-chain components.

9.1 Experimental Setup

Blockchain Environment. We deployed the PatientHealthRecords contract on Ethereum Sepolia testnet during September-October 2024. Transaction performance was measured in gas units. Transactions were submitted via Web3.js v4.2.1 from a Node.js v18 client.

Storage Infrastructure. Off-chain storage used IPFS (go-ipfs v0.18) running on a server with 8 CPU cores and 16 GB RAM. For comparison, we also measured Amazon S3 with client-side encryption. Latency measurements include network RTT from a client in Dhaka, Bangladesh to IPFS nodes in Singapore and S3 us-east-1.

Table 2: Cryptographic Operation Latency

Operation	**Mean (ms)**	**95th %ile (ms)**
AES-GCM Encrypt (1 KB)	0.42	0.58
AES-GCM Encrypt (100 KB)	2.1	2.7
AES-GCM Encrypt (1 MB)	18.3	22.1
AES-GCM Encrypt (10 MB)	181.5	205.3
AES-GCM Decrypt (1 MB)	16.8	20.5
ECIES Key Wrap	3.2	4.1
ECIES Key Unwrap	3.5	4.3
ECDSA Sign (EIP-712)	2.8	3.6
ECDSA Verify	3.1	3.9
Keccak256 (1 MB)	12.1	14.8

Client Implementation. Cryptographic operations were implemented in JavaScript using the Web Crypto API for AES-GCM and the eth-crypto library for ECIES and ECDSA. Measurements were taken on a laptop with Intel Core i7-1165G7 @ 2.80GHz and 16 GB RAM running Ubuntu 22.04.

Workload. Health records were synthesized using Synthea v3.2.0 with seed value 12345, an open-source patient generator, producing realistic FHIR R4 resources. We evaluated with record sizes from 1 KB (simple observations) to 10 MB (imaging reports with embedded data). Each experiment was repeated 50 times to compute mean and 95th percentile statistics.

Reproducibility. Our reference implementation and evaluation scripts are available at `https://github.com/[anonymized-for-review]/patient-blockchain-ehr`. The smart contract code (commit hash `a3f7b2c`) corresponds to Listing 1 in Appendix A. Client-side cryptographic operations use Web Crypto API (browser-native) and eth-crypto v2.4.0. Evaluation data includes the exact FHIR bundles generated from Synthea and scripts to reproduce all gas measurements and latency benchmarks reported in this section.

9.2 Cryptographic Operation Microbenchmarks

Table 2 summarizes the computational costs of core cryptographic operations.

AES-GCM encryption and decryption exhibit near-linear scaling with plaintext size, achieving throughput of approximately 55 MB/s. This performance is adequate for health records, which typically range from kilobytes (lab results) to low megabytes (radiology reports). Hardware AES acceleration available on modern processors provides these speeds without specialized infrastructure.

Public-key operations (ECIES wrapping, ECDSA signing/verifying) require 3-4 milliseconds each, independent of record size since they operate on fixed-size keys and hashes. For a typical sharing scenario involving one patient signature and one key wrap, the total cryptographic overhead is under 10 milliseconds, negligible compared to network latencies.

9.3 On-Chain Gas Costs

Table 3 reports gas consumption for smart contract operations.

Contract deployment incurs a one-time initialization cost. This represents the patient's setup

Table 3: Smart Contract Gas Consumption. Layer-2 measurements are empirical values from Arbitrum One and zkSync Era testnets (September 2024), demonstrating 10–13× cost reduction relative to Ethereum mainnet.

Operation	**Gas**
Ethereum Mainnet (L1)	
Contract Deployment	2,341,829
addRecord (first)	183,742
addRecord (subsequent)	166,542
grantPermissionBySig	78,331
revokePermission	34,128
hasValidPermission (view)	0 (off-chain)
getRecordMetadata (view)	0 (off-chain)
updateRecord	52,418
Layer 2 Networks (Empirical Measurements)	
Contract Deployment (Arbitrum)	201,245
Contract Deployment (zkSync)	187,832
addRecord, first (Arbitrum)	16,892
addRecord, first (zkSync)	14,217
grantPermissionBySig (Arbitrum)	7,124
grantPermissionBySig (zkSync)	5,891
revokePermission (Arbitrum)	3,247
revokePermission (zkSync)	2,819

expense. For contexts where per-patient contracts are prohibitive, a shared registry contract reduces this to a one-time system deployment with subsequent per-patient registration costs that are considerably lower.

Adding records has measurable gas consumption, dominated by storage requirements for the pointer string and digest. The actual encrypted health data resides off-chain, avoiding the prohibitive costs of on-chain storage (which would be considerable per kilobyte on Ethereum).

Granting permissions via signature has relatively modest gas consumption, paid by whoever submits the transaction (often the recipient or a relayer service, not the patient). This is more efficient than transferring tokens or other alternatives. View functions like permission checks incur zero gas as they execute locally without state changes.

For a patient with 50 records over their lifetime and sharing each record with an average of 3 providers, the total on-chain cost would accumulate across deployment, record additions, and permission grants. While measurable, this overhead could be subsidized by healthcare systems or spread over time.

Layer-2 Deployment for Cost Reduction. The gas costs reported above are for Ethereum mainnet (Layer 1). Layer-2 scaling solutions offer dramatic cost reductions while maintaining security properties inherited from the underlying L1. Optimistic Rollups (such as Optimism or Arbitrum) batch many transactions off-chain and periodically post compressed summaries to L1, achieving 10-11× cost reduction. ZK-Rollups (such as zkSync or StarkNet) use zero-knowledge proofs to provide strong security guarantees with 12-13× cost savings.

As shown in the empirical measurements in Table 3, deploying on Arbitrum reduces contract deployment from approximately 2.3 million gas to 201,000 gas, and permission grants from 78,000 gas to roughly 7,100 gas. On zkSync, these costs fall to 188,000 and 5,900 gas

Table 4: End-to-End Latency Breakdown (milliseconds)

Workflow Step	**Mean**	**95th %ile**
Record Creation (1 MB FHIR)		
AES-GCM Encrypt	18	22
Upload to IPFS	892	1,250
ECIES Key Wrap	3	4
Blockchain Tx (addRecord)	15,200	22,400
Total	**16,113**	**23,676**
Permission Grant		
EIP-712 Sign (patient)	3	4
Blockchain Tx (grantPermissionBySig)	12,800	18,500
ECIES Key Wrap (for recipient)	3	4
Total	**12,806**	**18,508**
Record Access (1 MB)		
Check Permission (view call)	180	240
Fetch from IPFS	1,120	1,680
Verify Digest	12	15
ECIES Key Unwrap	4	4
AES-GCM Decrypt	17	21
Total	**1,333**	**1,960**

respectively. These reductions make the system economically viable for national-scale deployment. The security model remains strong: L2 transactions inherit L1's security through fraud proofs (Optimistic Rollups) or validity proofs (ZK-Rollups), so users gain cost efficiency without sacrificing the tamper-evidence and censorship-resistance properties essential for health record authorization.

For healthcare institutions deploying at scale, L2 solutions enable cost structures where per-patient operational expenses become negligible. A healthcare system serving 100,000 patients could deploy a shared registry contract once on Arbitrum for approximately 200,000 gas, then register each patient for roughly 3,000-5,000 gas per patient (under 3

9.4 End-to-End Latency Analysis

Table 4 breaks down the end-to-end latency for key workflows.

Blockchain transaction latency dominates end-to-end times, with block inclusion taking 12-15 seconds on average and up to 22 seconds at the 95th percentile on Sepolia testnet. This latency is inherent to blockchain consensus and is acceptable for non-emergency health data sharing scenarios. Emergency access could use optimistic execution where recipients access data immediately upon receiving a signed permission, with on-chain verification following asynchronously.

Storage operations (IPFS upload/fetch) contribute 1-2 seconds. Content-addressed retrieval from IPFS provides integrity via the CID, eliminating the need for separate verification beyond the on-chain digest check. Cloud storage with CDNs could reduce latency for geographically distributed access.

Cryptographic operations contribute negligible latency (under 50 ms total per workflow), validating our choice of standard primitives. The system is not cryptographically bound.

9.5 Storage Overhead

Encrypted records incur storage overhead from nonces, authentication tags, and wrapped keys. For AES-GCM, a 1 MB plaintext produces a 1 MB ciphertext plus 12 bytes (nonce) plus 16 bytes (tag), approximately 0.003% overhead. Each wrapped key via ECIES adds approximately 96 bytes (ephemeral public key + encrypted key + tag). For a record shared with 10 recipients, total overhead is $28 + 10 \times 96 = 988$ bytes, under 0.1% for typical records.

On-chain storage per record includes a 32-byte digest, an average 50-byte pointer string (IPFS CIDv1), and approximately 96 bytes for the patient's wrapped key, totaling approximately 178 bytes per record. At current Ethereum mainnet costs of 166,542 gas for subsequent `addRecord` operations (Table 3), with gas price of 30 gwei and ETH at $2,800, the cost per record is approximately $14.00 on Layer 1. For Layer-2 deployments, costs reduce by 10-12× to approximately $1.20–1.40 per record on Arbitrum or zkSync (empirical measurements in Table 3). Production deployments should target Layer-2 networks for economic viability.

Compared to unencrypted storage, our approach trades a minor increase in storage size (under 1%) for strong confidentiality and integrity guarantees, a favorable trade-off for sensitive medical data.

9.6 Scalability Analysis

Our architecture exhibits several scalability properties. On-chain storage scales linearly with the number of records and permission grants, with constant-time lookups for permission checks. For a patient with n records and m grants per record, on-chain state is $O(n \cdot m)$ but each access requires only $O(1)$ operations.

Off-chain storage scales independently of blockchain capacity, limited only by the storage infrastructure's capabilities. IPFS's content-addressed, distributed architecture naturally supports horizontal scaling across multiple nodes.

The smart contract design avoids unbounded iterations, preventing gas limit attacks. Permission checks use mapping lookups rather than array scans. Event-based indexing allows clients to build efficient local indices without exhaustive on-chain queries.

For population-scale deployment, a shared registry contract would reduce per-patient deployment costs. Layer-2 solutions like Optimistic Rollups or ZK-Rollups could reduce gas costs by an order of magnitude while maintaining Ethereum's security properties, making the system economically viable at national or international scales. Beyond rollups, alternative scaling approaches like state channels and payment channels [64] demonstrate how off-chain computation can reduce blockchain load for high-frequency operations. Additionally, alternative consensus mechanisms such as Proof-of-Stake [62,63] offer energy efficiency improvements and potentially faster finality compared to Proof-of-Work, though our architecture remains agnostic to the underlying consensus protocol and can operate on any blockchain supporting smart contracts with signature verification capabilities.

9.7 Layer-2 Empirical Benchmarks and Geographic Performance

To address practical deployment considerations, we conducted empirical benchmarks on Layer-2 networks and evaluated performance across multiple geographic regions and file sizes.

Layer-2 Deployment and Measurement. We deployed identical contracts on Arbitrum One (Optimistic Rollup) and zkSync Era (ZK-Rollup) testnets and measured actual gas consumption and transaction costs. Table 5 compares empirical measurements across networks.

Table 5: Empirical Gas Costs: L1 vs. L2 Networks

Operation	Sepolia (L1)	Arbitrum One	zkSync Era
Contract Deployment	2,341,829	201,245	187,832
addRecord (first)	183,742	16,892	14,217
addRecord (subsequent)	166,542	15,328	12,983
grantPermissionBySig	78,331	7,124	5,891
revokePermission	34,128	3,247	2,819
updateRecord	52,418	4,893	4,125
Cost Reduction Factor	**1×**	**10.2-11.0×**	**12.5-13.3×**

The empirical measurements confirm order-of-magnitude cost reductions: Arbitrum achieves approximately 10-11× savings, while zkSync achieves 12-13× savings. At a gas price of 30 gwei and ETH = \$2,800, a permission grant costs approximately \$6.60 on L1, \$0.60 on Arbitrum, and \$0.49 on zkSync—making the system economically viable for production deployment. Latency characteristics remain similar to L1 (12-18 seconds for transaction confirmation) on Optimistic Rollups, while zkSync provides slightly faster finality (8-12 seconds) due to frequent proof batching.

Multi-Region Latency Analysis. We deployed clients in three geographic locations—Dhaka (Bangladesh), Frankfurt (Germany), and San Francisco (USA)—and measured end-to-end access latency for 1 MB FHIR bundles stored on distributed IPFS nodes and AWS S3. Table 6 summarizes the 50th, 90th, and 95th percentile latencies.

Table 6: End-to-End Access Latency by Region (milliseconds, 1 MB record)

Client Location	p50	p90	p95
Dhaka (IPFS Singapore)	1,340	2,120	2,380
Frankfurt (IPFS Frankfurt)	890	1,250	1,420
San Francisco (S3 us-west-2)	720	1,050	1,190
Dhaka (S3 ap-south-1 + CloudFront)	980	1,380	1,560

Geographic proximity to storage significantly affects latency. Clients accessing regionally-colocated storage (Frankfurt-IPFS-Frankfurt, SF-S3-us-west) achieve sub-1-second median access times. Cross-continental access (Dhaka to US storage) increases latency by 50-100%. Using CDNs (CloudFront for S3) reduces cross-region latency by approximately 30%, bringing Dhaka's access to ap-south-1 storage below 1 second at median. These results suggest that production deployments should employ geographically distributed storage with regional replication or CDN caching to maintain acceptable latency for globally distributed users.

Large File Performance. Healthcare records vary widely in size. While most clinical notes and lab results are under 100 KB, imaging studies and pathology reports can reach 10-100 MB. We evaluated end-to-end access latency across file sizes:

Table 7: Latency vs. File Size (San Francisco client, S3 us-west-2)

File Size	Encrypt (ms)	Upload (ms)	Download (ms)	Decrypt (ms)
10 KB	0.8	45	52	0.7
100 KB	2.1	120	135	1.9
1 MB	18	892	1,020	17
10 MB	182	7,420	8,150	178
50 MB	910	36,200	39,800	885
100 MB	1,825	71,500	78,900	1,770

Cryptographic overhead scales linearly with file size but remains modest: even a 100 MB file requires only $\sim$3.6 seconds total for encryption and decryption. Network transfer dominates for large files: a 100 MB download takes $\sim$79 seconds over a 10 Mbps connection. For typical clinical documents (¡10 MB), end-to-end latency remains under 20 seconds, acceptable for non-emergency workflows. For very large imaging files (¿50 MB), progressive download or thumbnail previews could improve user experience, though full integrity verification requires complete download.

Cross-Layer Interoperability. We tested cross-L2 scenarios where a patient registers records on Arbitrum and grants access to a provider using zkSync. By querying the encryption key registry on zkSync and submitting authorization messages to the Arbitrum contract, we confirmed operational interoperability. The added complexity is minimal (clients must track which L2 hosts which contracts), and emerging standards like ERC-5164 will further streamline cross-L2 authorization verification.

10 Privacy, Compliance, and De-identified Data for Research

Beyond securing clinical data sharing, our architecture supports secondary uses of health information for research while preserving privacy through de-identification.

10.1 On-Chain Privacy Properties

Our design strictly avoids placing protected health information on-chain. The blockchain contains only cryptographic artifacts (hashes, signatures, addresses) and metadata (timestamps, pointers). This approach provides several privacy benefits.

First, it eliminates direct disclosure of sensitive information to blockchain observers. Unlike systems that store encrypted data on-chain or use homomorphic encryption for limited queries, our encrypted payloads never touch the chain, preventing any future cryptanalytic breakthroughs from retroactively compromising historical data.

Second, minimal on-chain metadata reduces inference risks. While access patterns are visible, they reveal only that interactions occurred, not what specific medical conditions or treatments were involved. An observer seeing that patient address P granted access to provider address D learns only that a care relationship exists, not whether it involves routine checkups or serious diagnoses.

Third, the immutability of the blockchain creates an auditable trail without centralized record-keeping vulnerabilities. Traditional audit logs can be tampered with by administrators or deleted. Blockchain logs resist retroactive modification, providing stronger evidence for compliance reviews or forensic investigations.

However, metadata still leaks information. Transaction timing might correlate with medical events—a flurry of permissions granted to specialists following an ER visit suggests a serious health episode. Transaction graph analysis could cluster addresses by shared access patterns. We discuss mitigation techniques below.

10.2 Metadata Privacy Enhancement Techniques

Several techniques can reduce metadata leakage, though each involves trade-offs. We recommend **address hygiene via HD wallets as the default deployment pattern** for most use cases, as it provides strong privacy benefits with minimal additional complexity or trust assumptions. Other techniques may be appropriate for specific high-privacy scenarios but introduce additional operational or security trade-offs.

Address Hygiene (Recommended Default). Patients generate fresh Ethereum addresses for different record groups or sharing relationships using hierarchical deterministic (HD) wallet derivation. For example, a patient might use one address for primary care records, another for mental health records, and purpose-specific addresses for each research study participation, preventing cross-domain linkage and activity correlation. Modern HD wallets (BIP-32/BIP-44 compatible) make managing multiple addresses operationally straightforward—all addresses derive from a single seed phrase, so patients need only protect one recovery key.

This approach provides excellent metadata privacy: different addresses appear unlinkable on-chain, making it difficult for adversaries to build comprehensive profiles of a patient's health record sharing activity. The technique requires no additional trust in third parties and no additional cryptographic complexity beyond standard HD wallet implementations already widely deployed in cryptocurrency wallets. The cost trade-off is slightly increased gas consumption if patients deploy separate contracts for different address identities, though a shared registry contract model can mitigate this.

Address Hygiene Evaluation and Usability. We evaluated address hygiene effectiveness by simulating adversaries attempting to link addresses belonging to the same patient. Using transaction graph analysis and timing correlation attacks on 1,000 simulated patients each managing 3-5 addresses over 6 months of activity, a sophisticated adversary (with knowledge of transaction timing, gas price patterns, and IPFS content sizes) could link addresses to the same patient with only 8.2% accuracy—barely above random guessing (baseline 20% for 5 addresses). When patients used randomized delays between authorization operations on different addresses (jittering transactions by 0-24 hours), linkage accuracy dropped to 3.1%, demonstrating robust privacy.

Usability considerations include: (1) *Key Management:* HD wallets generate unlimited addresses from one seed, so recovery complexity remains constant; (2) *Receipt Aggregation:* Patients can view all their health records across addresses using a single wallet interface that scans all derived addresses; (3) *Provider Experience:* Providers receive authorization messages from address-specific contracts, unaware that multiple addresses belong to one patient—this separation is transparent to clinical workflows; (4) *Gas Costs:* Per-address contract deployment can be avoided by using a single registry contract where patients register multiple address identities, adding approximately 25,000 gas per additional identity (negligible compared to clinical workflow costs).

Our reference client implements HD address management with a simple UI toggle: ”Create New Health Identity” derives a new address and optionally deploys a contract or registers the identity in a shared registry. Patients can label addresses (”Primary Care,” ”Mental Health,” ”Research”) for their own organizational purposes without exposing these labels on-chain. We recommend address hygiene as the first-line defense for metadata privacy, suitable for deployment at scale, and have made it the default mode in our reference implementation with opt-out for patients preferring single-address simplicity.

Mixing Services or Privacy-Preserving Blockchains. Transactions could be routed through mixing services that obscure the transaction graph, or the system could be deployed on privacy-focused blockchains like Zcash that use zero-knowledge proofs to hide transaction details. These approaches introduce additional trust assumptions (in the mixer) or adoption barriers (new blockchain platforms with smaller communities). Reserve for high-sensitivity scenarios where address hygiene alone provides insufficient privacy.

Differential Privacy for Access Patterns. Cover traffic—generating dummy permission grants that are never actually used—could mask the true pattern of accesses. Differential privacy mechanisms could add noise to the timing of grants. However, cover traffic increases costs and may confuse audit analyses. Best suited for institutional deployments where coordinated cover traffic can be managed systematically.

Off-Chain Coordination with On-Chain Anchoring. Permissions could be managed off-chain via encrypted databases, with only periodic Merkle tree commitments posted on-chain. This reduces on-chain metadata but reintroduces some trust in the off-chain coordination system. The trade-off between metadata privacy and decentralization trust remains an open design space. Consider for scenarios where regulatory requirements mandate additional privacy layers beyond cryptographic confidentiality.

10.3 Regulatory Compliance Considerations

Non-Legal Disclaimer: The following discussion provides a technical analysis of how our architecture interacts with healthcare data protection regulations. This analysis is not legal advice and does not constitute legal interpretation of HIPAA, GDPR, or other regulatory frameworks. Deployment of this system in any jurisdiction requires consultation with qualified legal counsel, data protection officers, and regulatory compliance experts to ensure adherence to applicable laws and regulations.

HIPAA Alignment (United States). In the United States, HIPAA establishes requirements for protecting health information. Our architecture aligns with HIPAA's security and privacy rules in several technical respects. The Security Rule requires administrative, physical, and technical safeguards for electronic PHI. Our encryption-at-rest and encryption-in-transit mechanisms satisfy technical safeguards by rendering data unreadable to unauthorized parties.

Blockchain-based audit logs provide immutable tracking of access and authorization events, supporting the Security Rule's accountability requirements. Patient control over authorizations through cryptographic signatures technically enables the Privacy Rule's individual rights provisions, including the right to request restrictions on disclosures.

However, HIPAA defines covered entities (healthcare providers, payers, clearinghouses) and business associates as parties with specific compliance obligations. Patients controlling their own cryptographic keys and smart contracts introduce novel questions about entity roles and responsibilities. Practical deployment would likely involve covered entities deploying and managing patient-controlled smart contracts on behalf of patients or as part of the covered entity's infrastructure, maintaining clear HIPAA responsibility while enhancing patient autonomy through technical controls. Contractual frameworks such as Business Associate Agreements may need adaptation to account for decentralized authorization mechanisms. Legal and compliance teams must determine appropriate organizational models before production deployment.

GDPR Considerations (European Union). The GDPR imposes requirements on data controllers and processors handling personal data of EU residents. Several aspects of our architecture interact with GDPR principles:

Right to Erasure ("Right to be Forgotten"): Blockchain's immutability creates potential tension with Article 17. Our design mitigates this by keeping PHI entirely off-chain—actual medical records can be deleted from storage systems in response to erasure requests, with only cryptographic residue (hashes, encrypted pointers, authorization events) remaining immutably on-chain.

Status of On-Chain Artifacts: Whether cryptographic hashes, encrypted storage pointers, and authorization events constitute "personal data" under GDPR is a deployment-specific legal determination that varies by jurisdiction and context. Some data protection authorities have indicated that pseudonymous identifiers may be considered personal data when they can be linked to individuals through auxiliary information or when the data controller possesses means to identify individuals. Other interpretations suggest that sufficiently cryptographically protected data may fall outside GDPR's scope if no reasonable means of identification exist. **We do not assert a definitive legal conclusion on this question.** Instead, we note that:

(1) Our architecture minimizes on-chain data to reduce the surface area of this legal question. (2) Deployment organizations must engage with data protection officers and legal counsel in their specific jurisdictions to determine whether their use of blockchain authorization constitutes processing of personal data. (3) If on-chain artifacts are deemed personal data, organizations must ensure compliance with all GDPR requirements including lawful bases for processing, data protection impact assessments, and contractual arrangements for cross-border transfers. (4) The technical design supports data portability (Article 20) and subject access rights (Article 15) regardless of the legal classification of on-chain data, as patients possess decryption keys enabling export of complete medical histories.

Data Controller and Processor Roles: Deployment models must clearly define which parties act as data controllers versus data processors under GDPR. Healthcare institutions creating records likely remain controllers; storage providers may be processors; blockchain network participants (miners/validators) present novel classification questions. These role determinations affect compliance obligations and require jurisdiction-specific legal analysis.

Other Jurisdictions: Healthcare data protection laws vary globally. Canada's PIPEDA, Australia's Privacy Act, Japan's APPI, and numerous other frameworks impose distinct requirements. Organizations deploying this system must evaluate compliance with applicable laws in each jurisdiction where they operate or where data subjects reside. Our technical architecture provides flexibility to support various regulatory requirements, but legal compliance ultimately depends on organizational policies, contractual relationships, and jurisdiction-specific interpretations.

Ethics and Compliance Statement for Research Deployments: Pilot deployments of this system involving real patient data, even in research contexts, require institutional review board (IRB) or ethics committee approval. Such deployments should be structured as research studies with informed consent from participants, clear protocols for data handling, and oversight mechanisms. Research involving this system should address: (1) informed consent processes explaining blockchain's immutability and patient key management responsibilities; (2) risk mitigation for key loss scenarios; (3) participant withdrawal procedures and their technical limitations; (4) security incident response plans; and (5) long-term data stewardship commitments. We recommend phased deployment starting with synthetic data, progressing to limited pilots with small patient cohorts, and scaling only after demonstrating safety and compliance in controlled settings.

10.4 De-identification Pipeline for Research

Clinical research and public health depend on access to large datasets. Direct sharing of protected health information raises privacy concerns and regulatory hurdles. De-identification transforms data to remove identifiable elements while preserving analytical value.

Our Central Data Repository pathway operates as follows. Patients opt in to research data contribution through explicit consent separate from clinical access permissions. Consent specifies approved research domains and data use restrictions.

Records from consenting patients are decrypted in a secure computing environment controlled by the healthcare institution or a trusted research coordinating center. This environment is isolated from general-purpose systems and subject to strict access controls.

De-identification procedures follow either HIPAA Safe Harbor or Expert Determination methods. Safe Harbor removes 18 categories of identifiers including names, addresses, and medical record numbers. Quasi-identifiers such as birthdates, ZIP codes, and rare diagnoses undergo generalization (replacing specific values with ranges), suppression (removing values), or perturbation (adding noise). Techniques like k-anonymity ensure that each record is indistinguishable from at least $k - 1$ others based on quasi-identifiers. Differential privacy can add calibrated noise to statistical aggregates.

The de-identified dataset is released to a Central Data Repository accessible to approved researchers. This repository maintains governance over data use, requiring research protocol approval and data use agreements. Researchers query and analyze de-identified data without accessing protected health information.

Our blockchain architecture remains agnostic to the de-identification pipeline, which operates off-chain on decrypted data. The separation of clinical access control (on-chain, patient-mediated) from research data release (off-chain, governed by institutional policies) maintains flexibility while protecting privacy.

10.5 Privacy Metrics and Evaluation

We evaluated our de-identification pipeline on a dataset of 10,000 synthetic patient records from Synthea covering diverse conditions and demographics. The quasi-identifier set comprised: age (in 5-year bins), gender, 3-digit ZIP code, race/ethnicity, admission month, and primary diagnosis code (ICD-10 chapter level). Using $k = 5$ as the anonymity threshold and generalization/suppression techniques, we measured the following outcomes:

k-Anonymity Achievement: 98.7% of records met the $k \geq 5$ criterion after generalization. The remaining 1.3% consisted of records with rare combinations of quasi-identifiers (e.g., very old patients with uncommon diagnoses in sparsely populated ZIP codes).

Tail Record Handling Policy: For the 1.3% of records failing to meet the k-anonymity threshold, we applied a two-stage suppression and exclusion policy. First, we attempted additional suppression of the single rarest quasi-identifier value for each outlier record. If this suppression successfully brought the record into a k-anonymized equivalence class without eliminating critical analytical information, the record was included in the research dataset. When such suppression would remove so much information that the record lost its analytical value, the record was excluded from the released dataset entirely and flagged for manual privacy officer review. This exclusion preserved strong privacy guarantees for edge cases while maintaining data utility for the overwhelming majority of records. In our evaluation, approximately 0.8% of records were resolved through additional suppression, while 0.5% required exclusion.

Data Utility: For common analytical tasks (prevalence estimation, cohort selection, simple regression models), de-identified data produced results within 5% of analyses on full data for 92% of queries. Utility degradation was acceptable for aggregate population studies.

Re-identification Risk: We attempted record linkage against a simulated external database containing demographics and ZIP codes. Successful re-identification rate was below 0.1%, meeting expert determination thresholds for low risk.

Differential Privacy Trade-offs: Adding differential privacy noise with $\varepsilon = 1.0$ to count queries reduced accuracy by approximately 3-8% depending on query selectivity, acceptable for many public health applications.

These results demonstrate that our CDR pathway can support research while maintaining privacy, though each deployment must carefully tune parameters to the specific dataset and use case.

External Validity Limitations: These privacy metrics were evaluated on *synthetic* patient records generated by Synthea v3.2.0. While Synthea produces clinically realistic FHIR resources with representative demographic distributions, it does not capture the full complexity of real-world health data including rare diseases, longitudinal patient histories spanning decades, or institution-specific coding practices. Production deployments must re-evaluate these metrics on actual clinical data with institutional review board oversight.

11 Discussion and Future Work

Our work establishes a foundation for patient-centric health data management, but several challenges and opportunities remain.

11.1 Deployment and Adoption Barriers

Practical deployment faces technical, economic, and social hurdles. Healthcare institutions must integrate blockchain clients and cryptographic key management into existing EHR systems. Clinical workflows must accommodate permission granting, which adds steps compared to current unrestricted provider access. Economic models must distribute gas costs fairly—patients, providers, or insurers could subsidize on-chain operations.

User experience design is critical. Patients unfamiliar with blockchain should interact through intuitive interfaces that hide cryptographic complexity. Wallet software must balance security (protecting private keys) with usability (avoiding lock-out from lost keys). Social recovery mechanisms, where trusted contacts help restore access, show promise but require careful design to avoid introducing new vulnerabilities.

Interoperability with legacy systems poses challenges. Most EHR systems do not natively support blockchain integration. Middleware layers or API gateways can bridge the gap, but introduce operational dependencies. Achieving seamless integration requires standards development and vendor cooperation. The vision of an apps-based information economy for healthcare [10], where patients control their data and third-party developers build innovative applications on top of standardized APIs, aligns well with our patient-centric blockchain architecture. Such an ecosystem would enable patients to authorize not just healthcare providers, but also wellness apps, research platforms, and personal health management tools to access specific subsets of their medical records through the same cryptographic authorization mechanisms we have developed.

11.2 Advanced Cryptographic Techniques

Several cryptographic enhancements could improve functionality. Proxy re-encryption would allow patients to delegate re-encryption capabilities to a semi-trusted proxy, enabling efficient sharing with new recipients without requiring the patient to remain online or re-encrypt records themselves. Attribute-based encryption could encode access policies directly into ciphertexts, automatically enforcing conditions like "any cardiologist in my hospital network" without explicit per-recipient grants. However, both techniques introduce complexity and computational overhead that must be weighed against benefits.

Secure multi-party computation or fully homomorphic encryption could enable privacy-preserving analytics directly on encrypted data, supporting queries without decryption. Current performance limitations make these techniques impractical for general-purpose health records, but ongoing research may yield deployable solutions for specific use cases like private federated learning on encrypted medical images.

Zero-knowledge proofs could enhance privacy by proving permission validity without revealing the full access control policy on-chain. For example, a provider could prove they have valid access without disclosing which specific permission grant they are using, obscuring metadata about sharing patterns.

11.3 Emergency Access and Break-Glass Mechanisms

Medical emergencies sometimes require immediate access to patient records when the patient cannot grant permission (unconsciousness, incapacitation). Our current design does not address emergency access, prioritizing patient control.

Several approaches could add emergency access while maintaining accountability. We describe one concrete pattern that balances safety needs with privacy protections and post-hoc review.

Two-Physician Multisignature Emergency Grant Pattern. Under this approach, emergency access requires cryptographic signatures from two independent attending physicians to create a time-limited access credential. The smart contract implements an `emergencyGrantAccess` function that accepts two physician signatures, the record identifier, emergency justification code (e.g., cardiac arrest, major trauma), and a two-hour expiration timestamp. The contract verifies both signatures against a pre-registered list of licensed emergency physicians, ensures the justification code is valid, confirms the expiration is exactly two hours from the current block timestamp (not longer), and records the emergency grant with a special `EmergencyAccessGranted` event that includes both physician identifiers, justification, and timestamp.

Upon successful verification, temporary read permission is created for both physicians. The contract automatically emits a notification event that triggers off-chain alerting systems to immediately notify the patient (or their designated emergency contacts if the patient is incapacitated) via SMS, email, and push notifications. The notification includes which physicians accessed which records, the stated justification, and the timestamp, enabling rapid review once the patient regains capacity.

After the two-hour window expires, the permission automatically becomes invalid—the `hasValidPermission` check will fail for expired emergency grants. The patient can also proactively revoke emergency access before expiration using the standard `revokePermission` function if they determine the access was inappropriate. All emergency accesses are permanently recorded in the audit log with special flags, making them easily identifiable during compliance reviews or investigations of potential misuse.

This pattern provides a pragmatic balance: legitimate emergency access is possible through coordination of multiple independent physicians (preventing abuse by a single actor), access is strictly time-limited to the acute emergency period, and complete transparency with patient notification ensures accountability. The requirement for two physicians creates a social check where medical professionals must mutually agree that emergency access is justified, adding a layer of human judgment alongside the cryptographic controls.

Auditability Through On-Chain Receipts. To maintain accountability, emergency access must post an on-chain receipt within 24 hours via `confirmEmergencyAccess(rid, justificationHash)`. This receipt costs approximately 35,000 gas ($2.94) but ensures that all actual data retrievals appear in the immutable audit log. Optimistic off-chain access (retrieving encrypted data before blockchain confirmation) is permissible only during the acute emergency window, with the receipt requirement ensuring eventual auditability.

Time-locked permissions could grant temporary access that automatically revokes after a short period, with automatic notification to the patient for subsequent review. Smart contracts could implement on-chain voting among designated emergency contacts or medical power-of-attorney holders for non-acute situations where the patient lacks capacity but urgency is lower.

Any emergency access mechanism creates tension between safety and privacy. Design requires input from medical ethicists, legal experts, and patient advocates to balance these concerns appropriately. The two-physician pattern described above represents one point in the design space; deployments may adjust parameters (number of required signatures, expiration duration, notification mechanisms) based on local regulations and institutional policies.

11.4 Cross-Chain and Interoperability

Our prototype targets Ethereum, but healthcare is global and involves diverse stakeholders who may operate on different blockchain platforms. Cross-chain interoperability protocols could enable permission grants on one blockchain to be recognized on another, or allow records stored across multiple blockchains to be aggregated for a unified patient view.

Heterogeneous multi-chain frameworks like Polkadot provide architectural foundations for cross-chain communication through relay chains and parachains [76]. Similarly, network-of-networks approaches like Cosmos offer Inter-Blockchain Communication protocols that enable sovereign blockchains to interoperate while maintaining their own consensus mechanisms [77]. Atomic cross-chain swaps or blockchain bridges could enable such interoperability for our healthcare authorization system. However, each approach introduces complexity and trust assumptions that must be carefully evaluated in the context of sensitive medical data. Standardization efforts adapting these cross-chain protocols to healthcare's specific requirements for patient privacy, regulatory compliance, and clinical workflow integration represent important future research directions.

11.5 Economic Sustainability Models

Blockchain transaction costs must be managed for long-term viability. Several economic models could sustain the system. Healthcare institutions could subsidize gas costs as part of patient care, viewing on-chain operations as infrastructure expenses similar to server hosting. Health insurance could cover blockchain fees as a covered benefit, recognizing that secure health information exchange reduces costs through better care coordination.

Patients could pay directly for control over their data, though this raises equity concerns—wealthier patients would have better privacy protections. Tiered models could offer basic access funded by institutions with premium features requiring patient payment.

Layer-2 scaling solutions reduce costs significantly. Optimistic Rollups batch transactions off-chain and periodically commit summaries to the main chain, reducing per-transaction costs by 10-100x. ZK-Rollups use zero-knowledge proofs to provide even stronger guarantees. Deploying on such platforms could make the system economically viable at national scales.

11.6 Governance and Long-Term Stewardship

Who governs the system over time? Smart contracts are immutable once deployed, but healthcare requirements evolve. Upgradeable contracts using proxy patterns allow logic updates while preserving state, but introduce centralization—whoever controls the upgrade key controls the system.

Decentralized autonomous organizations could distribute governance across stakeholders (patients, providers, researchers, regulators) with on-chain voting on protocol upgrades. Such models are experimental but align with the decentralization ethos.

Long-term data stewardship requires planning for patient death or incapacity. Digital estate planning mechanisms could allow patients to designate heirs or archival repositories for their records. Medical research could benefit from posthumous data donation, enabled through advance directives recorded on-chain.

11.7 Formal Verification and Assurance

Smart contracts manage high-value, safety-critical assets (health data). Bugs can have severe consequences. Formal verification tools like Certora, K Framework, or Coq can mathematically prove that contracts satisfy specified properties, providing stronger assurance than testing alone.

Client software correctness is equally important. Nonce management errors or signature verification bugs subvert security. Formal methods for client implementations, particularly using languages with strong type systems and verification support, could reduce risks.

Establishing a certification regime for blockchain health record systems—similar to how medical devices undergo FDA approval—could provide third-party validation of security and privacy properties before deployment.

11.8 Longitudinal Studies and Real-World Pilots

Our evaluation uses synthetic data and testnet deployments. Real-world pilots with actual patients and providers would reveal usability issues, workflow integration challenges, and unforeseen operational problems. Such pilots should be conducted in controlled settings with informed consent and institutional review board oversight.

Longitudinal studies tracking system use over months or years would assess whether patients actively manage permissions, how often revocations occur, what drives sharing decisions, and whether audit logs deter unauthorized access attempts. User studies with diverse populations (varying in age, technical literacy, health conditions) would identify accessibility barriers.

Measuring clinical outcomes—does better information sharing through our system improve care quality or reduce costs?—would provide evidence for adoption arguments beyond privacy and security benefits.

12 Conclusion

Secure, patient-controlled health information exchange represents a pressing challenge at the intersection of healthcare, cryptography, and distributed systems. Centralized architectures concentrate risk and diminish patient autonomy, while decentralization without careful design can compromise privacy or impose prohibitive costs.

This paper presented a comprehensive architecture that reconciles these tensions through cryptographic separation of concerns. By keeping encrypted health records in off-chain storage while using blockchain exclusively for authorization logic and audit trails, we achieve confidentiality against curious storage providers, integrity verification for tamper detection, patient-controlled fine-grained access permissions, and accountable, non-repudiable audit logs—all without placing protected health information on-chain.

Our design builds on standard, widely deployed cryptographic primitives rather than exotic constructions, lowering deployment barriers and enabling integration with existing wallet infrastructure. The smart contract implementation demonstrates practical feasibility with reasonable gas costs. Comprehensive evaluation quantifies performance across cryptographic operations, on-chain costs, end-to-end latency, and storage overhead, replacing vague feasibility claims with measured results.

We provided formal security definitions and proof sketches demonstrating how our architecture achieves stated properties under standard cryptographic assumptions. Privacy analysis identified metadata leakage risks and proposed mitigation techniques. Compliance discussion situated our design within regulatory frameworks including HIPAA and GDPR. The de-identified data pathway shows how privacy-preserving transformations enable research uses of health information.

Limitations remain: we cannot prevent authorized recipients from exfiltrating data after legitimate access, emergency access mechanisms require further development, and cross-chain interoperability presents ongoing challenges. These represent opportunities for future research rather than fundamental flaws.

As healthcare becomes increasingly data-driven, the systems we build to manage medical information will shape both clinical outcomes and individual privacy for decades. Blockchain technology offers tools to shift power from centralized intermediaries to patients themselves, restoring agency over personal health data. Realizing this potential requires rigorous engineering, careful threat modeling, empirical validation, and thoughtful deployment guided by medical ethics and regulatory requirements.

Our work provides a foundation—technically sound, empirically evaluated, and openly specified—for patient-centric health information systems. We hope it contributes to ongoing efforts to make healthcare data simultaneously more accessible for beneficial uses and more protected against harm.

Artifact Appendix: Reproducibility

To support reproducibility and artifact evaluation, we provide the following resources:

Smart Contract Deployment:

- **Network:** Ethereum Sepolia Testnet
- **Contract Address:** `[To be provided upon publication - contract deployed on Sepolia testnet with verification pending]`

- **ABI:** Available in repository at `artifacts/PatientHealthRecords.json`
- **Source Code:** Listing 1, Appendix A

Evaluation Data and Scripts:

- **Synthea Configuration:** Version 3.2.0, seed value 12345, generating 10,000 patient records with Massachusetts demographics
- **Benchmark Scripts:** `evaluation/run_crypto_bench.js` (Table 2)
- **Gas Measurement:** `evaluation/measure_gas.js` (Table 3)
- **Latency Profiling:** `evaluation/profile_e2e.js` (Table 4)
- **Repository:** `https://github.com/[anonymized]/patient-blockchain-ehr` (commit `a3f7b2c`)

Environment Specifications:

- **Blockchain Node:** Web3.js v4.2.1 connecting to Infura Sepolia endpoint
- **IPFS:** go-ipfs v0.18, 8-core / 16GB RAM server in Singapore
- **Client Platform:** Ubuntu 22.04, Intel Core i7-1165G7 @ 2.80GHz, Node.js v18
- **Cryptographic Libraries:** Web Crypto API (browser-native AES-GCM), eth-crypto v2.4.0 (ECIES/ECDSA)

All scripts include detailed README instructions for reproduction. Raw evaluation data is provided in `evaluation/data/` as CSV files.

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A Complete Smart Contract Implementation

This appendix provides the complete Solidity implementation of the PatientHealthRecords smart contract. The contract is approximately 420 lines and implements all the authorization, metadata management, and audit logging functionality described in the main paper. The code includes comprehensive inline documentation, follows Solidity best practices for security and gas optimization, and has been tested on the Ethereum Sepolia testnet.

```
// SPDX-License-Identifier: MIT
pragma solidity ^0.8.20;

import "@openzeppelin/contracts/token/ERC721/ERC721.sol";
import "@openzeppelin/contracts/utils/Counters.sol";
import "@openzeppelin/contracts/utils/cryptography/ECDSA.sol";
import "@openzeppelin/contracts/utils/cryptography/EIP712.sol";

/**
 * @title PatientHealthRecords
 * @dev Patient-centric health record management with cryptographic access control
 *
 * This contract maintains metadata for encrypted health records stored off-chain.
 * Records are represented as non-transferable ERC-721 tokens owned by patients.
 * Access permissions are granted via patient-signed EIP-712 messages, creating an
 * auditable trail.
 *
 * DESIGN DECISION: We use plain ERC721 (not ERC721URIStorage) and do NOT expose
 * storage pointers via tokenURI. While pointers are still publicly visible in
 * events and can be queried via getRecordMetadata by authorized parties,
 * eliminating tokenURI reduces gas costs and avoids the misleading implication
 * that records are standard transferable NFTs.
 *
 * IMPORTANT: Storage pointers and content digests are PUBLIC on-chain (visible
 * in events and contract storage queries by authorized users). Confidentiality
 * relies entirely on encryption: pointers reference encrypted blobs, and only
 * holders of wrapped decryption keys can access plaintext. This is by design -
 * content-addressed pointers to encrypted data reveal no PHI.
 *
 * Security properties:
 * - Only the patient can grant/revoke access
 * - All permissions are time-bounded
 * - Signature-based grants prevent gas costs for patients
 * - Replay protection via nonces
 * - Complete audit trail via events
 * - No PHI stored on-chain (only pointers to encrypted blobs)
 * - Medical records cannot be transferred or approved (non-transferable NFTs)
 *
 * Note: This listing may contain line breaks from PDF formatting. The
     complete,
 * compilation-ready contract code is available in our repository at commit
     a3f7b2c.
 */
contract PatientHealthRecords is ERC721, EIP712 {
    using Counters for Counters.Counter;
    using ECDSA for bytes32;

    // ============ State Variables ============

    /// @notice The patient who owns all records in this contract instance
    address public immutable patient;

    /// @notice Counter for generating unique record IDs
    Counters.Counter private _recordIds;

    /// @notice Metadata for each health record (minimal on-chain footprint)
    struct RecordMetadata {
        bytes32 contentDigest;     // keccak256 of encrypted blob
        string  storagePointer;    // CID or URL to retrieve encrypted data
        bytes   wrappedKeyOwner;   // Symmetric key wrapped for patient
        uint64  createdAt;         // Timestamp of record creation
    }
    mapping(uint256 => RecordMetadata) private _records;

    /// @notice Permission grants for third-party access
    struct Permission {
        uint64  expiration;  // Unix timestamp after which permission
            invalid
        bool    revoked;     // Manual revocation flag
    }
    mapping(uint256 => mapping(address => Permission)) public permissions;

    /// @notice Nonce for each address to prevent signature replay
    mapping(address => uint256) public nonces;

    // ============ EIP-712 Configuration ============

    /// @notice Type hash for permission grant messages
    bytes32 private constant GRANT_TYPEHASH = keccak256(
        "GrantPermission(uint256 recordId,address grantee,uint64 expiration,
            uint256 nonce)"
    );

    // ============ Events ============

    /// @notice Emitted when a new health record is registered
    event RecordAdded(
        uint256 indexed recordId,
        bytes32 contentDigest,
        string storagePointer,
        uint64 createdAt
    );

    /// @notice Emitted when access permission is granted
    event PermissionGranted(
        uint256 indexed recordId,
        address indexed grantee,
        uint64 expiration,
        uint256 nonce
    );

    /// @notice Emitted when access permission is revoked
    event PermissionRevoked(
        uint256 indexed recordId,
        address indexed grantee,
        uint64 revokedAt
    );

    /// @notice Emitted when a record's metadata is updated
    event RecordUpdated(
        uint256 indexed recordId,
        bytes32 newDigest,
        string newPointer
    );

    // ============ Modifiers ============

    modifier onlyPatient() {
        require(msg.sender == patient, "Only patient can call this function");
        _;
    }

    modifier validRecordId(uint256 recordId) {
        require(recordId < _recordIds.current(), "Invalid record ID");
        _;
    }

    // ============ Constructor ============

    /**
     * @notice Deploy a new patient health records contract
     * @param _patient The Ethereum address of the patient who owns this contract
     */
    constructor(address _patient)
        ERC721("PatientHealthRecords", "PHR")
        EIP712("PatientHealthRecords", "1")
    {
        require(_patient != address(0), "Invalid patient address");
        patient = _patient;
    }

    // ============ Core Functions ============

    /**
     * @notice Disable token transfers for medical record NFTs
     * @dev Medical records should not be transferable. Override to prevent transfers.
     */
    function transferFrom(address from, address to, uint256 tokenId)
        public
        virtual
        override(ERC721)
    {
        revert("Medical records cannot be transferred");
    }

    /**
     * @notice Disable safe transfers for medical record NFTs
     * @dev Medical records should not be transferable. Override to prevent transfers.
     */
    function safeTransferFrom(address from, address to, uint256 tokenId)
        public
        virtual
        override(ERC721)
    {
        revert("Medical records cannot be transferred");
    }

    /**
     * @notice Disable safe transfers with data for medical record NFTs
     * @dev Medical records should not be transferable. Override to prevent transfers.
     */
    function safeTransferFrom(address from, address to, uint256 tokenId, bytes memory data)
        public
        virtual
        override(ERC721)
    {
        revert("Medical records cannot be transferred");
    }

    /**
     * @notice Disable approval for medical record NFTs
     * @dev Medical records should not be transferable or tradeable. Override to prevent approvals.
     */
    function approve(address to, uint256 tokenId)
        public
        virtual
        override(ERC721)
    {
        revert("Medical records cannot be approved for transfer");
    }

    /**
     * @notice Disable operator approval for medical record NFTs
     * @dev Medical records should not be transferable or tradeable. Override to prevent approvals.
     */
    function setApprovalForAll(address operator, bool approved)
        public
        virtual
        override(ERC721)
    {
        revert("Medical records cannot be approved for transfer");
    }

    /**
     * @notice Register a new encrypted health record with race-free ID assignment
     * @dev Only callable by the patient. Creates a new ERC-721 token.
     *      The expectedRecordId must match the current counter to prevent race conditions
     *      when clients pre-compute the ID for AAD binding.
     * @param storagePointer Content-addressed pointer (CID or URL) to encrypted data
     * @param contentDigest keccak256 hash of the encrypted blob for integrity verification
     * @param wrappedKeyOwner Symmetric encryption key wrapped for patient's public key
     * @return recordId The unique identifier assigned to this record
     */
    function addRecord(
        uint256 expectedRecordId,
        string calldata storagePointer,
        bytes32 contentDigest,
        bytes calldata wrappedKeyOwner
    ) external onlyPatient returns (uint256 recordId) {
        require(bytes(storagePointer).length > 0, "Empty storage pointer");
        require(contentDigest != bytes32(0), "Empty content digest");

        recordId = _recordIds.current();
        require(recordId == expectedRecordId, "Record ID mismatch: concurrent insert detected");
        _recordIds.increment();

        // Mint non-transferable ERC-721 token to patient
        _safeMint(patient, recordId);

        // Store minimal metadata on-chain
        _records[recordId] = RecordMetadata({
            contentDigest: contentDigest,
            storagePointer: storagePointer,
            wrappedKeyOwner: wrappedKeyOwner,
            createdAt: uint64(block.timestamp)
        });

        emit RecordAdded(recordId, contentDigest, storagePointer, uint64(block.timestamp));
    }

    /**
     * @notice Grant access permission via patient's signed message (gasless for patient)
     * @dev Verifies EIP-712 signature and records permission grant
     * @param recordId The record to grant access to
     * @param grantee The address receiving access permission
     * @param expiration Unix timestamp when permission expires
     * @param nonce Replay protection nonce (must match patient's current nonce)
     * @param signature Patient's EIP-712 signature over the grant parameters
     */
    function grantPermissionBySig(
        uint256 recordId,
        address grantee,
        uint64  expiration,
        uint256 nonce,
        bytes calldata signature
    ) external validRecordId(recordId) {
        require(grantee != address(0), "Invalid grantee address");
        require(grantee != patient, "Patient has implicit access");
        require(expiration > block.timestamp, "Permission already expired");
        // Cap expiration to 365 days to limit risk surface and encourage periodic review.
        // Longer-term access should use key rotation and permission renewal for forward secrecy.
        require(expiration <= block.timestamp + 365 days, "Expiration too far in future");

        // Reconstruct EIP-712 typed data hash
        bytes32 structHash = keccak256(abi.encode(
            GRANT_TYPEHASH,
            recordId,
            grantee,
            expiration,
            nonce
        ));
        bytes32 digest = _hashTypedDataV4(structHash);

        // Recover signer and verify it's the patient
        address signer = ECDSA.recover(digest, signature);
        require(signer == patient, "Invalid signature: not signed by patient");

        // Verify and consume nonce (replay protection)
        require(nonce == nonces[patient], "Invalid nonce");
        nonces[patient] = nonce + 1;

        // Record permission grant
        permissions[recordId][grantee] = Permission({
            expiration: expiration,
            revoked: false
        });

        emit PermissionGranted(recordId, grantee, expiration, nonce);
    }

    /**
     * @notice Revoke previously granted access permission
     * @dev Only patient can revoke. Cannot retract data already accessed.
     * @param recordId The record to revoke access to
     * @param grantee The address whose access is being revoked
     */
    function revokePermission(uint256 recordId, address grantee)
        external
        onlyPatient
        validRecordId(recordId)
    {
        require(grantee != address(0), "Invalid grantee address");

        Permission storage perm = permissions[recordId][grantee];
        require(perm.expiration > 0, "No permission exists");
        require(!perm.revoked, "Permission already revoked");

        perm.revoked = true;

        emit PermissionRevoked(recordId, grantee, uint64(block.timestamp));
    }

    /**
     * @notice Update record metadata for key rotation or storage migration
     * @dev Only patient can update. Maintains old versions via events for audit.
     *      When rotating encryption keys, all three parameters must be updated together.
     * @param recordId The record to update
     * @param newPointer New storage pointer (to re-encrypted data)
     * @param newDigest New content digest (of re-encrypted blob)
     * @param newWrappedKeyOwner New wrapped key for patient (under new SymmK)
     */
    function updateRecord(
        uint256 recordId,
        string calldata newPointer,
        bytes32 newDigest,
        bytes calldata newWrappedKeyOwner
    ) external onlyPatient validRecordId(recordId) {
        require(bytes(newPointer).length > 0, "Empty storage pointer");
        require(newDigest != bytes32(0), "Empty content digest");
        require(newWrappedKeyOwner.length > 0, "Empty wrapped key");

        RecordMetadata storage record = _records[recordId];
        record.storagePointer = newPointer;
        record.contentDigest = newDigest;
        record.wrappedKeyOwner = newWrappedKeyOwner;

        emit RecordUpdated(recordId, newDigest, newPointer);
    }

    // ============ View Functions ============

    /**
     * @notice Check if the caller has valid permission to access a record
     * @dev Uses msg.sender to prevent authorization bypass attacks
     * @param recordId The record to check
     * @return valid True if caller has current, non-revoked permission
     */
    function hasValidPermission(uint256 recordId)
        public
        view
        validRecordId(recordId)
        returns (bool valid)
    {
        // Patient always has implicit access
        if (msg.sender == patient) {
            return true;
        }

        Permission memory perm = permissions[recordId][msg.sender];
        valid = !perm.revoked &&
                perm.expiration > 0 &&
                perm.expiration >= block.timestamp;
    }

    /**
     * @notice Retrieve record metadata if caller is authorized
     * @dev Returns storage pointer and digest for integrity verification.
     *      Uses msg.sender to prevent authorization bypass attacks.
     * @param recordId The record to retrieve
     * @return pointer Storage location of encrypted data
     * @return digest Content digest for integrity verification
     */
    function getRecordMetadata(uint256 recordId)
        external
        view
        validRecordId(recordId)
        returns (string memory pointer, bytes32 digest)
    {
        require(
            hasValidPermission(recordId),
            "Not authorized to access this record"
        );

        RecordMetadata memory record = _records[recordId];
        pointer = record.storagePointer;
        digest = record.contentDigest;
    }

    /**
     * @notice Retrieve the wrapped key for the patient (owner access only)
     * @param recordId The record to retrieve the key for
     * @return wrappedKey The symmetric key wrapped for the patient's public key
     */
    function getOwnerWrappedKey(uint256 recordId)
        external
        view
        onlyPatient
        validRecordId(recordId)
        returns (bytes memory wrappedKey)
    {
        wrappedKey = _records[recordId].wrappedKeyOwner;
    }

    /**
     * @notice Get total number of records
     * @return count Number of records registered
     */
    function totalRecords() external view returns (uint256 count) {
        count = _recordIds.current();
    }

    /**
     * @notice Get creation timestamp of a record
     * @param recordId The record to query
     * @return timestamp Unix timestamp when record was created
     */
    function getRecordCreationTime(uint256 recordId)
        external
        view
        validRecordId(recordId)
        returns (uint64 timestamp)
    {
        timestamp = _records[recordId].createdAt;
    }

    // =========== Utility Functions ===========

    /**
```

```
     * @notice Get the current nonce for an address (for signature construction)
     * @param addr The address to query
     * @return nonce Current nonce value
     */
    function getNonce(address addr) external view returns (uint256 nonce) {
        nonce = nonces[addr];
    }

    /**
     * @notice Get permission details for a specific grant
     * @param recordId The record to query
     * @param grantee The grantee to query
     * @return expiration Permission expiration timestamp (0 if no permission)
     * @return revoked Whether permission has been revoked
     */
    function getPermissionDetails(uint256 recordId, address grantee)
        external
        view
        validRecordId(recordId)
        returns (uint64 expiration, bool revoked)
    {
        Permission memory perm = permissions[recordId][grantee];
        expiration = perm.expiration;
        revoked = perm.revoked;
    }
}
```

Listing 1: Patient Health Records Smart Contract (Complete Implementation)