Module 2: eHealth Data Privacy, Security, Legal Frameworks & Ethics

DigHealth –

Micro-credentials in digital health for Ethiopia and Somalia

Proj. Ref. Num. 101179425

Capacity Building in the field of Higher Education

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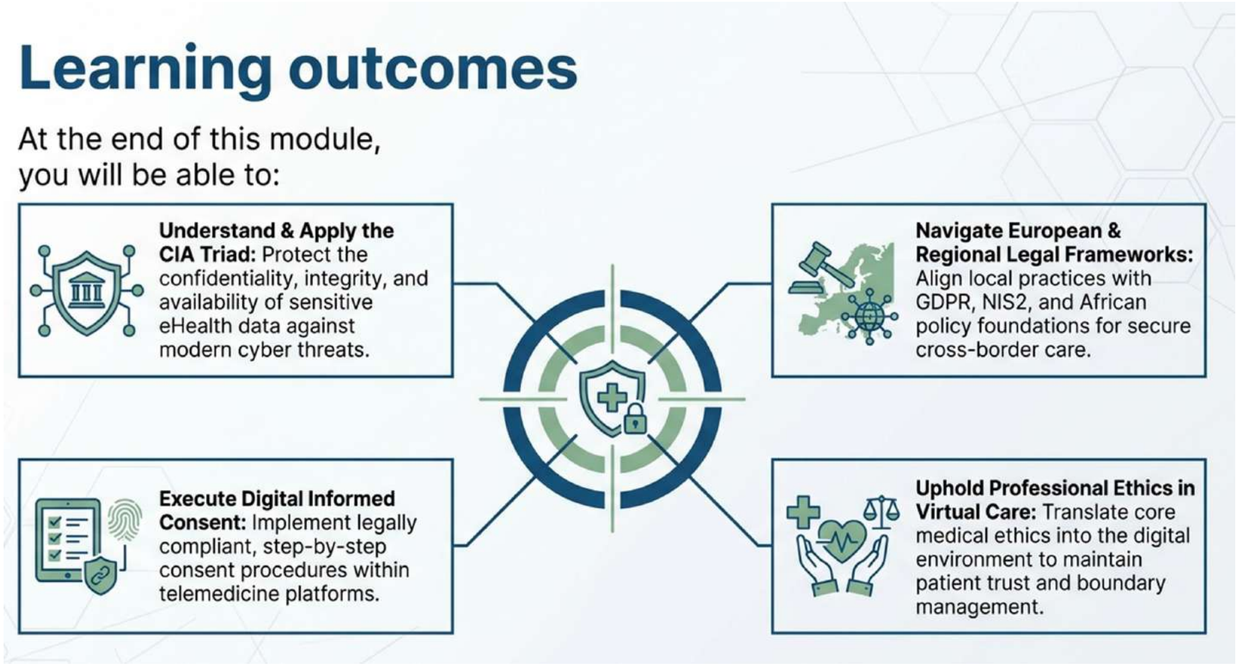
Learning outcomes

At the end of this module, you will be able to:



- Explain the CIA triad (Confidentiality, Integrity, Availability) and apply it to eHealth scenarios.
- Identify common cybersecurity threats in healthcare and select appropriate technical and organisational mitigation strategies.
- Describe the European legal frameworks (GDPR, Patients' Rights Directive, NIS2, EU AI Act) and how they interact in digital health.
- Adapt NIS2 principles to African legal and policy contexts (Malabo Convention, regional frameworks).
- Design and implement valid informed consent procedures in telemedicine, including for cross-border and AI-assisted services.
- Apply core ethical principles and professional conduct standards in virtual consultations.

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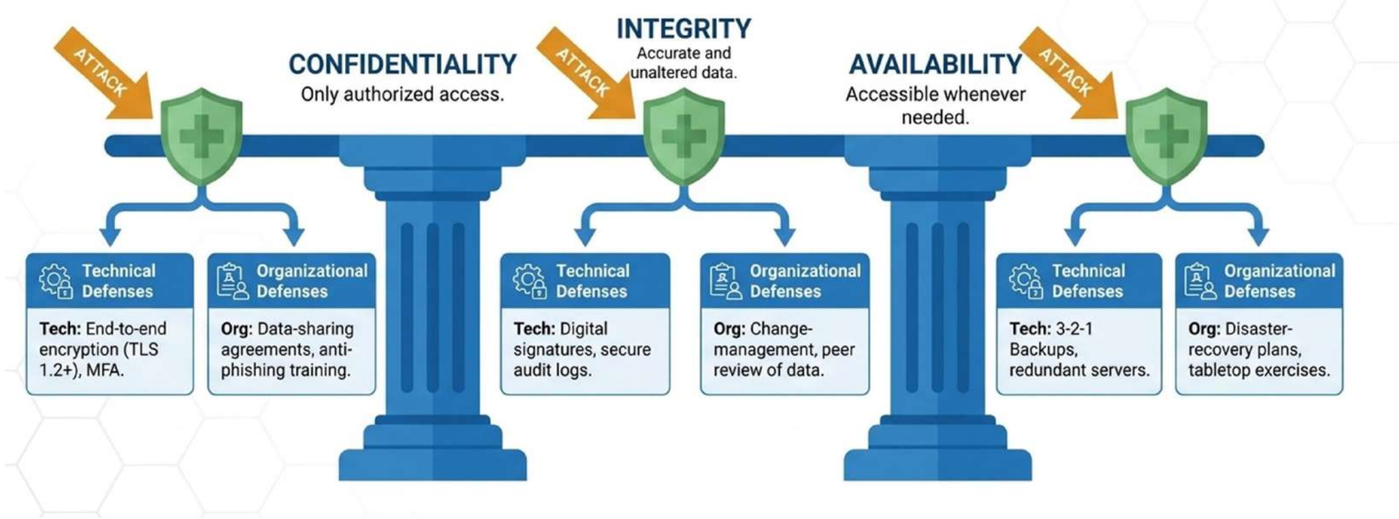
Unit 1 — Core Principles of Data Protection

• Confidentiality • Integrity • Availability

- Digital health (telemedicine, EHRs, AI diagnostics) transforms care but creates new risks for privacy, accuracy and availability of patient data.
- Every professional must understand the fundamental security principles before exploring threats or legal duties.
- This unit introduces the CIA triad — three pillars of data protection — and provides a common language for risk assessment, incident response, and compliance with GDPR and NIS2.
- Health data is among the most valuable personal information: targeted by criminals, strictly regulated, and critical for patient safety.
- A weakness in any one of the three pillars can compromise patient trust, disrupt care, and trigger heavy legal and financial penalties.



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1.2 The CIA Triad — Definitions

Three pillars of eHealth data protection

- **Confidentiality — Only authorised persons can access data.**
  - Example: A telemedicine platform allows only the attending physician and the patient to view video and test results.
- **Integrity — Data remain accurate, complete and unaltered from creation to use.**
  - Example: Electronic prescriptions are digitally signed so they cannot be modified without detection.
- **Availability — Data and services are accessible to authorised users whenever needed.**
  - Example: Remote-monitoring devices continuously upload readings to a cloud server clinicians can access 24/7.
- **Key Point: Protecting all three pillars simultaneously is critical. Strong encryption is useless if systems are unavailable in an emergency, and perfect uptime is meaningless if data can be secretly altered.**

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1.3 Practical Controls

- **Technical and organisational measures for each pillar**

- **Confidentiality — Technical:**
  - End-to-end encryption, multi-factor authentication (MFA), role-based access control.
- **Confidentiality — Organisational:**
  - Data-sharing agreements, staff training on phishing and social engineering.
- **Integrity — Technical:**
  - Digital signatures, checksums, version control, secure audit logs.
- **Integrity — Organisational:**
  - Change-management procedures, peer review of data corrections.
- **Availability — Technical:**
  - Daily backups, redundant servers, disaster-recovery plans.
- **Availability — Organisational:**
  - Business-continuity planning, periodic recovery drills and tabletop exercises.

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1.4 Case A — Confidentiality Breach

- **Lost laptop with patient records**

- **Scenario:**
  - A clinical researcher copied patient datasets onto a personal laptop for home analysis. The laptop, containing unencrypted files, was stolen on a train.
- **CIA Impact: Confidentiality — health records of hundreds of patients exposed.**
- **Mitigation Plan:**
  - Enforce full-disk encryption on every portable device — even if hardware is lost, data remain unreadable without the key.
  - Activate remote-wipe technology so IT can erase data as soon as a device is reported missing.
  - Restrict export of patient data to personal equipment; require secure remote-access tools (VPN) instead of local copies.
  - Train staff regularly on safe handling of mobile devices, with annual simulated 'lost device' incidents.

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1.4 Case B — Integrity Failure

- **Altered clinical-trial data**

- **Scenario:**
  - An insider with administrator privileges manipulated lab results in an online clinical-trial database to improve perceived effectiveness of an experimental drug.
- **CIA Impact: Integrity — accuracy and reliability of clinical data compromised.**
- **Mitigation Plan:**
  - Apply principle of least privilege — grant only minimum rights per role.
  - Require MFA and heightened monitoring for all privileged accounts.
  - Maintain secure, tamper-evident audit logs of every data change; trigger automated alerts on unusual editing patterns.
  - Require dual approval / peer review for critical data changes.
  - Run periodic integrity audits with hash-based dataset verification.

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1.4 Case C — Availability Outage

- **Hospital ransomware attack**

- **Scenario:**
  - Ransomware encrypted core hospital servers, shutting down EHRs, lab systems and scheduling for 3 days. Staff reverted to paper, delaying surgeries and emergency care.
- **CIA Impact: Primarily Availability; confidentiality and integrity also at risk because attackers had full network access.**
- **Mitigation Plan:**
  - Robust patch-management programme to close known vulnerabilities.
  - Endpoint Detection and Response (EDR) tools that monitor and isolate infected machines automatically.
  - 3-2-1 backup strategy: 3 copies, 2 media, ≥1 offline; quarterly restoration tests.
  - Network segmentation so an infection in one department cannot spread.
  - Incident-response plan with 24/72-hour reporting timelines (GDPR/NIS2), rehearsed via tabletop exercises.

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1.4 Case D — Multi-Pillar Breach

- **Third-party cloud compromise**

- **Scenario:**
  - A cloud provider hosting a national telemedicine platform was hacked. Attackers accessed appointment schedules and disabled the service, leaving thousands of patients unable to reach doctors.
- **CIA Impact: All three pillars — confidentiality (leaks), integrity (risk of unauthorised modification), availability (downtime).**
- **Mitigation Plan:**
  - Strong vendor-risk management: ISO 27001 / SOC 2, annual security audits, fast breach notification clauses.
  - End-to-end encryption for all data exchanged with the cloud.
  - Continuous monitoring and anomaly detection on vendor interfaces.
  - Redundant hosting / fail-over so telemedicine can migrate to a secondary provider.
  - Joint incident-response exercises with vendors to clarify roles and reduce recovery time.

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1.5 Unit 1 — Key Points

Summary of Core Principles

- A single incident can compromise more than one CIA pillar; controls must address all three simultaneously.
- Effective protection requires both technical safeguards (encryption, backups, monitoring) and organisational measures (policies, contracts, staff training).
- A well-rehearsed incident-response plan dramatically reduces harm and regulatory penalties when a breach occurs.

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Unit 2 — Cybersecurity Threats & Mitigation

- **Threats, case studies and layered defences**

Threat	CIA Impact	Layered Defenses
Phishing & Ransomware (e.g., WannaCry, HSE Ireland)	**Impact:** Availability & Confidentiality.	**Shield:** Patch management (<7 days), EDR offline backups, network segmentation.
Insider Threats (e.g., Vastaamo breach, altered trial data)	**Impact:** Integrity & Confidentiality.	**Shield:** Least-privilege access, multi-factor authentication, tamper-evident audit logs.
Supply-Chain / Cloud Compromise (e.g., SolarWinds)	**Impact:** Complete CIA Triad failure.	**Shield:** ISO 27001/SOC 2 vendor requirements, zero-trust architecture, continuous anomaly detection.

- **This unit covers four areas:**
  - Common cybersecurity threats in healthcare.
  - Real-world case studies showing impact.
  - Technical controls to reduce risk.
  - Organisational measures to sustain security.
- Healthcare faces the same threats as other sectors, but the stakes are higher because lives may be at risk.

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2.1 Common Cybersecurity Threats in eHealth

Most frequent attack types

- **Phishing & Social Engineering — fraudulent emails or calls trick users into revealing credentials or clicking malicious links.**
  - Impact: compromised EHR access, stolen credentials.
- **Ransomware — malicious software encrypts data and demands payment for decryption.**
  - Impact: hospital-wide downtime, cancelled appointments, potential patient harm.
- **Insider Threats — employees or contractors intentionally or accidentally compromise data.**
  - Impact: unauthorised data export, patient-record tampering.
- **Distributed Denial of Service (DDoS) — overwhelms servers with traffic to make services unavailable.**
  - Impact: telemedicine platform outages during critical consultations.
- **Supply-Chain Attacks — attackers compromise trusted vendors or software updates.**
  - Impact: malicious code injected into medical-device software or cloud services.
- **IoT / Medical Device Exploits — weakly secured connected devices become attack entry points.**
  - Impact: manipulated telemetry readings, unsafe device behaviour.

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2.2 The CIA Triad in Threat Context

Mapping threats to CIA pillars helps prioritise controls

- Phishing threatens Confidentiality by stealing credentials.
- Insider attacks often harm Integrity by altering records.
- Ransomware and DDoS primarily threaten Availability by disrupting services.
- Supply-chain attacks can compromise all three pillars at once via trusted channels.
- IoT exploits often harm Integrity (manipulated readings) and Availability (unsafe device behaviour).
- Mapping each threat to one or more CIA pillars allows organisations to design layered, prioritised controls.

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2.3 Case A — WannaCry & UK NHS (2017)

Global ransomware hits >80 NHS trusts

- **Scenario:**
  - WannaCry exploited an unpatched Windows vulnerability (MS17-010) and disrupted >80 NHS hospital trusts, cancelling ~19,500 appointments and diverting ambulances.
- **CIA Impact:**
  - Primary: Availability — critical systems inaccessible. Secondary: confidentiality risk from data exfiltration.
- **Root Causes:**
  - Delayed application of Microsoft's security patch and a flat network structure allowed the malware to spread rapidly.
- **Mitigation Plan:**
  - Robust patch management with critical updates applied within days.
  - Network segmentation to contain outbreaks; offline, tested backups.
  - Deploy EDR to isolate infected machines automatically.
- References: UK National Audit Office report on WannaCry; Microsoft security update MS17-010.

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2.3 Case B — Düsseldorf University Hospital (2020)

Ransomware contributes to patient death

- **Scenario:**
  - Ransomware disabled hospital IT, forcing emergency patients to be diverted. A critically ill patient died after a delayed transfer.
- **CIA Impact: Availability — emergency services interrupted.**
- **Root Causes:**
  - Exploited vulnerabilities in external-facing systems and inadequate emergency downtime procedures.
- **Mitigation Plan:**
  - Maintain downtime protocols (paper-based intake, alternative communications).
  - Conduct regular tabletop exercises.
  - Continuous vulnerability scanning with rapid patching.
- References: Europol press release; BSI Germany advisory 2020-1360.

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2.3 Case C — Vastaamo, Finland (2018-2020)

Mental-health records extorted

- **Scenario:**
  - Attackers accessed psychotherapy records and extorted both the clinic and individual patients, threatening to publish therapy notes.
- **CIA Impact: Confidentiality — highly sensitive mental-health data exposed.**
- **Root Causes:**
  - Inadequate database security and delayed breach detection.
- **Mitigation Plan:**
  - Encrypt sensitive records at rest; apply strict role-based access.
  - Continuous log monitoring with automated alerts for unusual database queries.
  - Establish a rapid breach-notification and victim-support process.
- References: Finnish Police press release; Data Protection Ombudsman case summary.

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2.3 Case D — Irish HSE (2021)

National-scale ransomware attack

- **Scenario:**
  - The Conti ransomware gang infiltrated Ireland's national health service, forcing a nationwide shutdown of hospital IT. Recovery cost hundreds of millions of euros.
- **CIA Impact: Availability — national-scale disruption; Confidentiality — data theft suspected.**
- **Root Causes:**
  - Prolonged attacker dwell time and insufficient network segmentation.
- **Mitigation Plan:**
  - Deploy a Security Operations Centre (SOC) with real-time threat detection.
  - Enforce MFA for all administrative accounts.
  - Use network segmentation to limit lateral movement.
- References: HSE Incident Report; Irish Government post-incident review.

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2.3 Case E — SolarWinds Supply-Chain (2020)

Trusted-update compromise affecting healthcare

- **Scenario:**
  - Attackers inserted malicious code into a widely used IT-management product. Many hospitals and research institutions were exposed.
- **CIA Impact: Confidentiality, Integrity, Availability — all potentially compromised.**
- **Root Causes:**
  - Over-reliance on trusted vendor updates and lack of verification mechanisms.
- **Mitigation Plan:**
  - Strengthen vendor risk management with third-party security certifications.
  - Signed-update verification and annual penetration tests.
  - Adopt zero-trust architecture to minimise damage even if a vendor is compromised.
- References: CISA advisory AA20-352A; SolarWinds security advisory.

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2.4 Technical Mitigation Strategies (1/2)

Layered defences — encryption, MFA, patching

- **Encryption**
  - Protect data at rest and in transit using strong, current algorithms (TLS 1.2+).
  - Encrypt backups and removable media.
- **Multi-Factor Authentication (MFA)**
  - Require at least two independent proofs of identity (password + authenticator app) for all privileged and remote accounts.
  - Stops most credential-theft attacks even if passwords are stolen.
- **Patch and Vulnerability Management**
  - Maintain an asset inventory and apply critical patches within 7 days of release.
  - Use automated vulnerability scanning to detect missing updates.
- **Network Segmentation**
  - Separate clinical from administrative networks; create secure 'jump boxes' for privileged access.

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2.4 Technical Mitigation Strategies (2/2)

Backups, monitoring, zero-trust, secure development

- **Secure Backups and Recovery**
  - Follow the 3-2-1 rule: 3 copies, 2 media, at least 1 offline.
  - Test restoration quarterly.
- **Logging and Monitoring**
  - Centralise logs and retain at least 90 days of records.
  - Automated alerts for unusual login patterns or data transfers.
- **Zero-Trust Architecture**
  - 'Never trust, always verify' — continuously authenticate users and devices.
- **Secure Development Practices**
  - For in-house software: code reviews, static analysis, and penetration tests before deployment.

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2.5 Organisational Mitigation Strategies (1/2)

Policy, risk, incident response, continuity

- **Information Security Policy**
  - High-level document approved by leadership; sets security objectives, responsibilities and reporting lines.
- **Risk Assessment & Treatment**
  - Annual risk assessments to identify critical assets, likely threats and mitigation priorities.
- **Incident Response Plan (IRP)**
  - Define roles, communication channels and actions for detection, containment, recovery and reporting.
  - Include 24/72-hour reporting procedures to comply with GDPR and NIS2.
- **Business Continuity & Disaster Recovery**
  - Plans to keep essential services running during outages.
  - Include paper-based fallbacks for patient registration and prescriptions.

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2.5 Organisational Mitigation Strategies (2/2)

- **Vendor security, DPIAs, training, accountability**

- **Vendor and Supply-Chain Security**
  - Include security clauses and breach-notification deadlines in all contracts.
  - Require vendors to demonstrate compliance with ISO 27001 or SOC 2.
- **Data Protection Impact Assessments (DPIAs)**
  - Mandatory under GDPR for high-risk processing such as telemedicine or AI diagnostics.
  - Identify potential risks before launching new services.
- **Training and Awareness**
  - Run regular phishing simulations; continuous education on safe data handling.
  - Reward staff for reporting suspicious incidents.
- **Management Accountability**
  - Boards and senior executives review cybersecurity KPIs quarterly and allocate adequate budgets.

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Unit 3 — European Legal Frameworks for eHealth

GDPR, Patients' Rights, NIS2, EU AI Act

GDPR	Patients' Rights (2011/24/EU)	NIS2 Directive (2022/2555)	EU AI Act (2024)
Focus: Personal-data protection.	**Focus:** Cross-border patient care.	**Focus:** Cybersecurity of critical services.	**Focus:** Safety & transparency of AI.
Core Duty: Lawful processing & explicit consent.	**Core Duty:** Access to safe care, clear info & secure data exchange.	**Core Duty:** Risk management & 24/72-hour incident reporting.	**Core Duty:** High-risk management, human oversight, conformity testing.
Penalty: Up to€20M or 4% turnover.	**Penalty:** National penalties.	**Penalty:** Up to €10M or 2% turnover.	**Penalty:** Up to €35M or 7% turnover.

- Modern eHealth services depend on a complex mesh of EU laws.
- Four core frameworks must be considered together: GDPR (data protection), Patients' Rights Directive (cross-border care), NIS2 (cybersecurity of critical services), and the EU AI Act (safety and transparency of AI).
- DigHealth partners must integrate all four to ensure legal compliance, patient trust, and secure cross-border collaboration.

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3.1 GDPR — General Data Protection Regulation

Regulation (EU) 2016/679

- **Definition: The EU's primary law on personal-data protection. Applies to any organisation processing data of EU residents, even if based outside the EU.**
- **Key principles (Article 5):**
  - Lawfulness, Fairness, Transparency — valid legal basis, clearly explained.
  - Purpose Limitation — specific, explicit purposes.
  - Data Minimisation — only necessary data collected.
  - Accuracy — data kept up to date.
  - Storage Limitation — retain only as long as needed.
  - Integrity and Confidentiality — protect against unauthorised access or loss.
  - Accountability — controllers must demonstrate compliance.
- **Health data is special category data — requires explicit consent or another strong legal basis.**
- **Individual rights: access, correction, deletion, portability, objection.**
- **Penalties: up to €20 M or 4% of global annual turnover — whichever is higher.**

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3.2 Patients' Rights Directive

Directive 2011/24/EU

- **Definition: Guarantees EU citizens can receive safe, high-quality healthcare across Member States and obtain reimbursement from their home country.**
- **Key Provisions:**
  - Patients may seek treatment abroad and claim reimbursement, subject to national rules.
  - Member States must provide clear information on providers, quality standards and reimbursement procedures.
  - Healthcare providers must ensure secure exchange of medical data for cross-border care.
- **Example:**
  - A Greek patient receiving telecardiology services from a German hospital must be informed about costs, service quality and data-exchange safeguards.

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3.3 NIS2 Directive

Directive (EU) 2022/2555 — minimum cybersecurity standards

- **Definition: Sets minimum cybersecurity standards and rapid incident-reporting obligations for critical sectors — healthcare, universities, digital infrastructure.**
- **Scope: Essential entities (hospitals, major telemedicine platforms) and Important entities (university research centres).**
- **Core Obligations:**
  - Risk Management — encryption, access control, supply-chain security, incident response.
  - Incident Reporting — early warning ≤24 h, detailed report ≤72 h, final report ≤1 month.
  - Management Accountability — senior leadership approves security policies and can be personally liable.
- **Penalties: up to €10 M or 2% of global turnover for essential entities.**
- **Example: A university hospital in a DigHealth pilot must show network segmentation, MFA and a 24/72-hour reporting process to comply with NIS2.**

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3.4 EU AI Act (2024)

Risk-based regulation of AI systems

- **Definition: World's first comprehensive AI law — risk-based approach to regulate AI systems that could harm health, safety or fundamental rights.**
- **Risk Categories:**
  - Unacceptable Risk — prohibited uses (e.g., social scoring).
  - High Risk — AI used in medical diagnosis, triage or treatment recommendations.
  - Limited / Minimal Risk — subject only to transparency rules.
- **Obligations for High-Risk AI:**
  - Risk-management systems and high-quality, representative datasets.
  - Human oversight and transparency — users know they are interacting with AI.
  - Pass a conformity assessment before deployment in the EU.
- **Example: An AI tool recommending cancer treatment must document training data, allow human override, and undergo formal EU conformity testing.**

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3.5 How the Frameworks Interact

One eHealth project may need to comply with all four

- **GDPR — focus on personal-data protection; max fine €20 M or 4% turnover.**
- **Patients' Rights Directive — cross-border patient care; national penalties.**
- **NIS2 — cybersecurity of critical services; max fine €10 M or 2% turnover.**
- **EU AI Act — safety and transparency of AI; max fine €35 M or 7% turnover (severe breaches).**
- **Example: an AI-based telemedicine service must:**
  - Obtain GDPR-compliant consent for patient data.
  - Provide cross-border access and reimbursement under the Patients' Rights Directive.
  - Implement NIS2 cybersecurity measures and 24/72-hour incident reporting.
  - Pass a high-risk AI conformity assessment under the AI Act.

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Unit 3 — Key Points

- **Integrated EU compliance for eHealth**

GDPR protects personal and health data and grants patients strong control over their information.	The Patients' Rights Directive ensures safe, reimbursable cross-border healthcare.	NIS2 sets minimum cybersecurity standards and strict incident-reporting timelines.	The EU AI Act regulates AI by risk level, imposing strict controls on high-risk medical applications.	DigHealth partners must integrate all four frameworks for legal compliance, patient trust and secure cross-border collaboration.

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Applying NIS2 Principles in African Countries

Introduction

- NIS2 (Directive (EU) 2022/2555) sets common cybersecurity standards and fast incident-reporting requirements for critical sectors in the EU — healthcare, higher education and digital infrastructure.
- Although legally binding only in the EU, its principles can guide African governments, universities and health authorities that want to:
  - Strengthen cybersecurity.
  - Align with international best practice.
  - Facilitate secure cross-border cooperation with European partners.

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NIS2 in Africa — 1. Core Ideas of NIS2

Technology-neutral concepts adaptable to African contexts

- **Risk-management measures: encryption, MFA, network segmentation, supply-chain security.**
- **Incident reporting: early warning ≤24 h; detailed report ≤72 h; final report ≤1 month.**
- **Management accountability: senior leadership approves cybersecurity policies and can face penalties.**
- EU Official text: Directive (EU) 2022/2555 (EUR-Lex).
- These concepts — sector classification, minimum controls, rapid reporting, top-level accountability — are technology-neutral and can be adapted to African contexts.

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NIS2 in Africa — 2. Legal & Policy Foundations

Existing African frameworks as legal gateways

- African Union Convention on Cyber Security and Personal Data Protection (Malabo Convention) — continental treaty in force June 2023.
- AU Digital Transformation Strategy for Africa 2020-2030 — secure digital infrastructure and harmonised cyber policies.
- Smart Africa Cybersecurity Blueprint — continental blueprint for CSIRTs and regional cooperation.
- ECOWAS Directive on Fighting Cybercrime (2011) and Supplementary Act on Personal Data Protection (2010).
- SADC Model Laws on Data Protection & Cybercrime (2012) — templates for Southern African states.
- EAC Cybersecurity Framework — guidelines for harmonised cyber legislation in East Africa.

These instruments provide a legal backbone for NIS2-style obligations.

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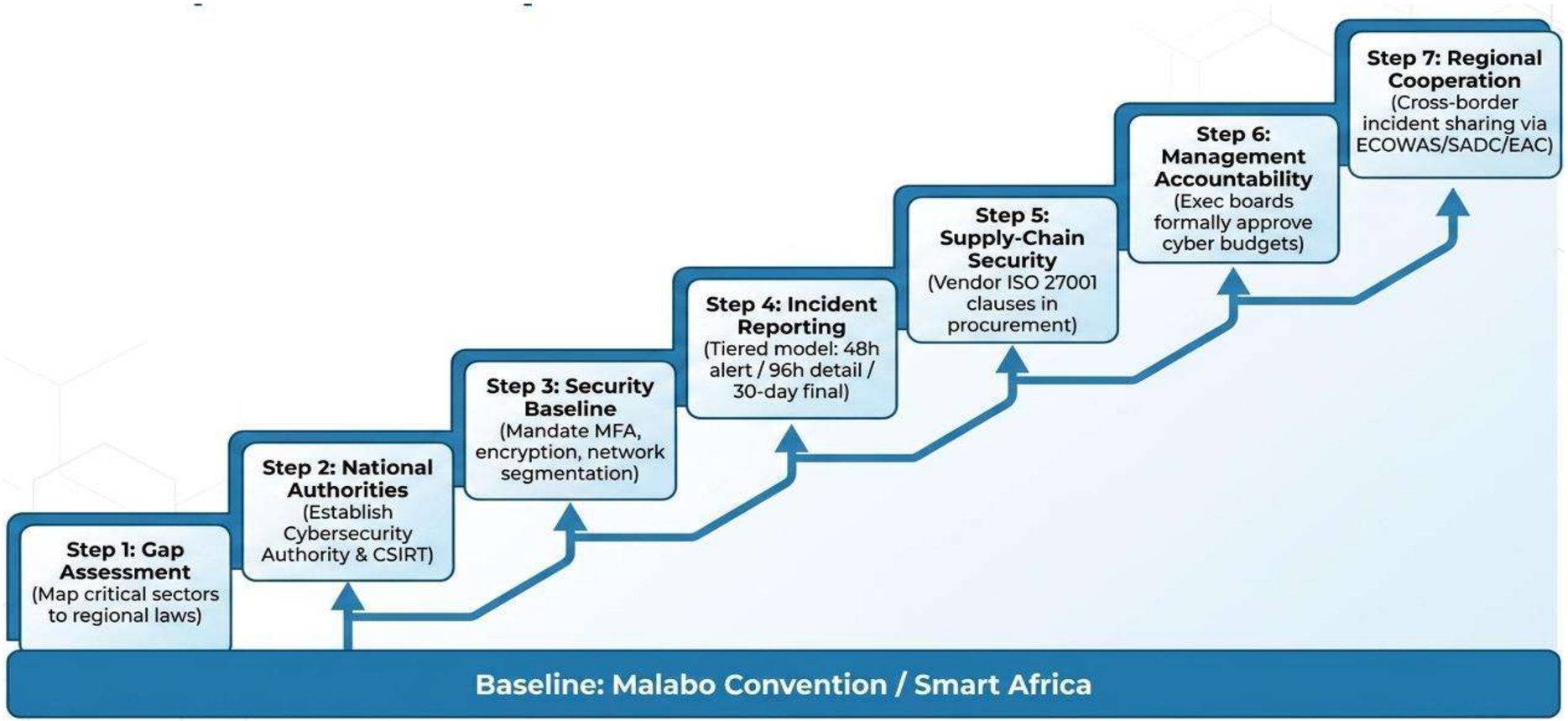
NIS2 in Africa — 3. Step-by-Step Adaptation



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NIS2 in Africa — 3. Step-by-Step Adaptation (1/2)

Phases 1-3

Phase 1 — Gap Assessment

- Map existing national laws against the Malabo Convention and regional model laws.
- Identify critical sectors (health, energy, transport, education) and key operators (hospitals, telecoms, research universities).

Phase 2 — Establish National Authorities

- Designate or strengthen a National Cybersecurity Authority and a CSIRT to receive incident reports.
- Examples: Kenya's KE-CSIRT or South Africa's CSIRT as focal points.

Phase 3 — Minimum Security Baseline

- Publish national guidelines requiring core controls (MFA, encryption of health data, patch management, network segmentation).
- Align with NIS2 Annex I & II risk-management measures for critical and important entities.

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NIS2 in Africa — 3. Step-by-Step Adaptation (2/2)

Phases 4-7

Phase 4 — Incident Reporting Scheme

- Tiered reporting (e.g., 48 h early alert, 96 h detailed, 30 d final), mirroring NIS2 24/72-hour standard.
- Secure national portal for reporting and threat-intelligence sharing.

Phase 5 — Supply-Chain Security

- Government contracts and healthcare procurement: vendor security clauses, ISO 27001 / SOC 2, breach-notification duties.

Phase 6 — Management Accountability

- Boards and senior executives of hospitals, universities and critical providers approve cybersecurity budgets and risk reports.

Phase 7 — Regional Cooperation

- Connect national CSIRTs to Smart Africa or regional networks (ECOWAS, SADC, EAC) for cross-border incident sharing and joint exercises.

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NIS2 Toolkit — A. Minimum Security Baseline (1/2)

Identity, data, vulnerability, backups

- **A1. Identity & Access Management**
  - MFA everywhere for privileged, remote, email and VPN accounts.
  - Least-privilege roles; quarterly access reviews; immediate de-provisioning on exit.
  - Dedicated break-glass accounts stored offline and audited.
- **A2. Data Protection**
  - TLS 1.2+ on all web services; HSTS enabled.
  - Encrypt data at rest for databases, object storage, backups, laptops.
  - Pseudonymise for research / secondary use; document key management.
- **A3. Vulnerability & Patch Management**
  - Complete asset inventory (servers, apps, endpoints, IoT/medical devices).
  - Critical patches within 7 days, high severity within 14 days; quarterly authenticated scans.
- **A4. Backups & Recovery**
  - 3-2-1 rule (3 copies, 2 media, 1 offline/immutable); quarterly restore drills with measured RTO/RPO.

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NIS2 Toolkit — A. Minimum Security Baseline (2/2)

Network, monitoring, IR, supply chain

- **A5. Network Security**
  - Segment clinical/OT, corporate IT and guest environments.
  - Jump-hosts for admin access; disable direct admin logins.
  - EDR on servers and workstations with integrated alerting.
- **A6. Logging & Monitoring**
  - Centralised logs (auth, firewall, EDR, application) ≥90 days online / 1 year archive.
  - Alerts on failed MFA bursts, new admin creation, large data extractions, malware quarantines.
- **A7. Incident Response (IR)**
  - At least three one-page playbooks: phishing, ransomware, data leak.
  - 24/7 contacts list; communications templates; tabletop exercises every 6 months.
- **A8. Supply-Chain Security**
  - Procurement: MFA for vendor admins, encryption, breach-notification SLA, annual independent security test letter.
  - Cloud: region/location pinning and, where possible, customer-managed keys.

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NIS2 Toolkit — B. Incident Reporting Scheme

Adoptable timers and minimum fields

Who reports?

- Essential Entities: national hospitals, national eHealth platforms, national research networks.
- Important Entities: universities handling health data, regional hospitals, major ISPs supporting health.

When?

- Early Alert: ≤48 h of awareness (target 24 h as maturity grows).
- Detailed Notification: ≤96 h with initial root cause and impact.
- Final Report: ≤30 days with corrective actions and lessons learned.

Minimum fields:

- Entity, contacts, affected services/systems, CIA impact, number of patients/data records affected, event timeline, immediate containment, assistance requested, preliminary root cause, cross-border implications.

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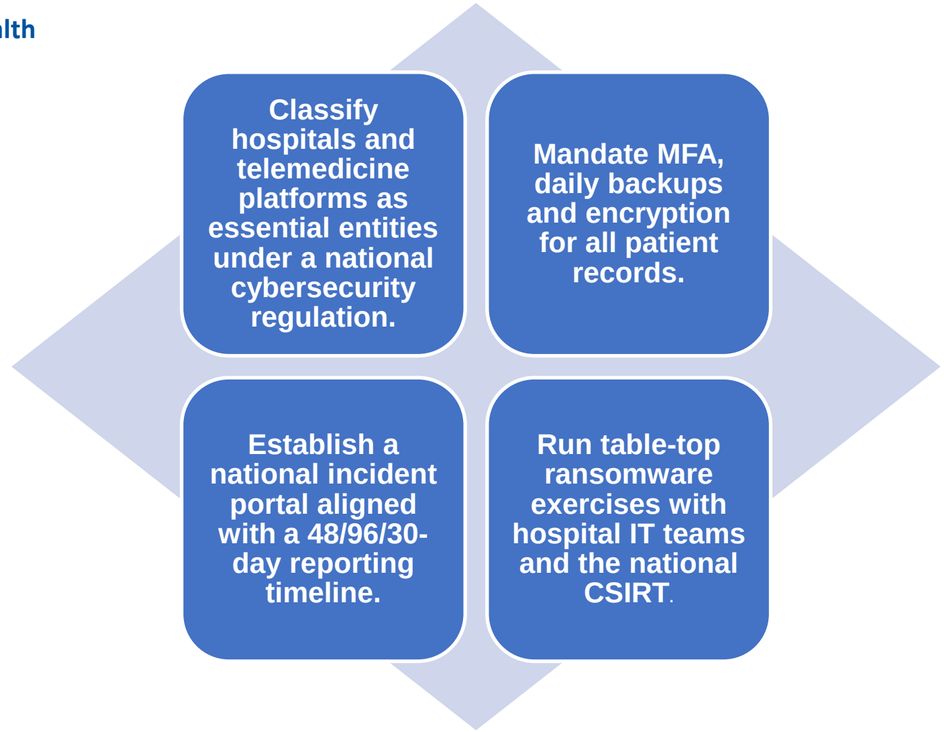
NIS2 in Africa — 4. Health Sector Pilot

- **Practical example for a Ministry of Health**



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NIS2 in Africa — 5. Benefits of Adoption

Why it matters for African health systems

- ✓ Improved resilience of health systems against ransomware and data breaches.
- ✓ Stronger international cooperation — easier participation in EU-funded research and Erasmus+ projects.
- ✓ Legal harmonisation with global partners, facilitating cross-border data exchange and telemedicine.

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Unit 4 — Informed Consent in Telemedicine

Introduction

- Informed consent is a cornerstone of ethical healthcare and a key legal requirement under GDPR, the Patients' Rights Directive and international medical ethics codes.
- Telemedicine — where consultations, diagnosis and treatment occur remotely — presents new challenges:
  - Patients may never meet their provider in person.
  - Digital platforms can obscure how and where data are stored.
  - Cross-border services create overlapping legal obligations.

This unit explains how to obtain and document valid informed consent in digital health environments.

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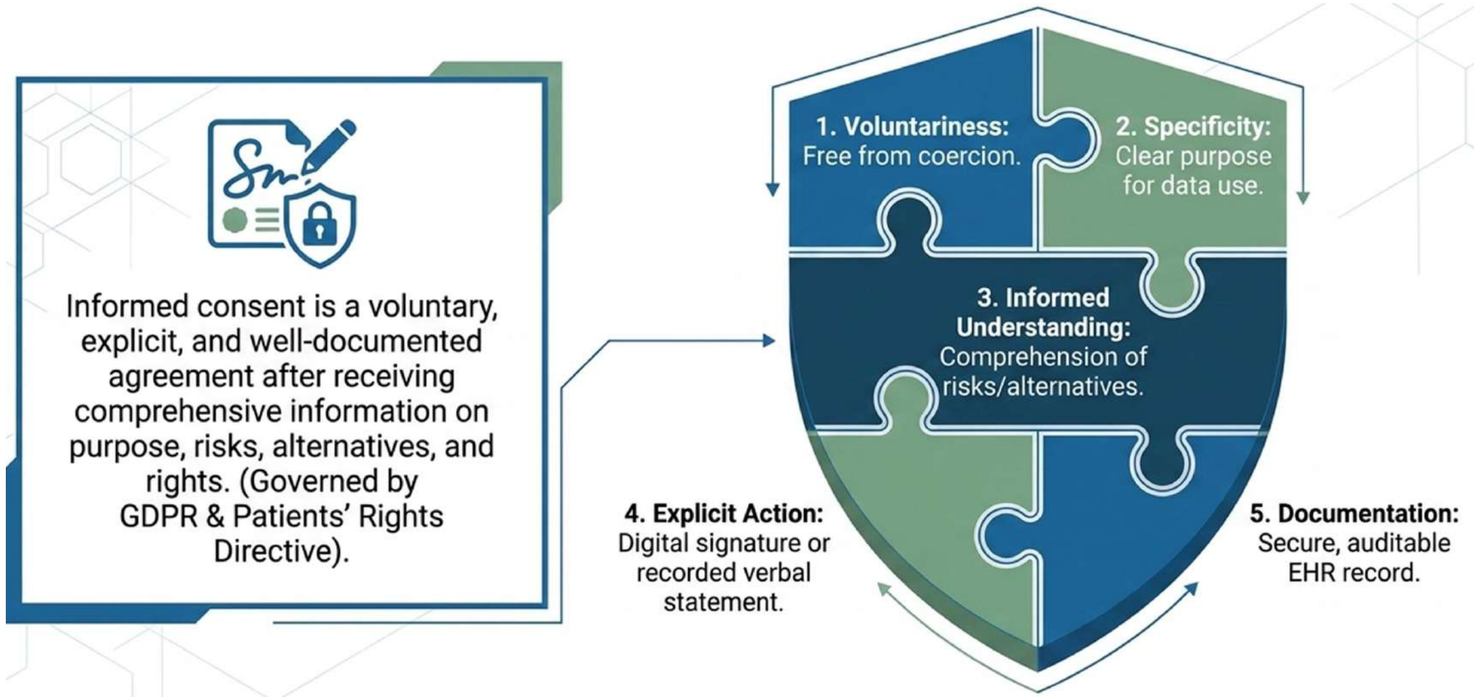
4.1 Definition of Informed Consent

Five required elements



Informed consent is a voluntary, explicit, well-documented agreement by a patient to allow a provider or researcher to perform a service or process personal data after receiving comprehensive information on purpose, risks, benefits, alternatives and rights of withdrawal.

- **Voluntariness — the decision is free from coercion or undue influence.**
- **Specificity — the consent clearly states each purpose for which data will be used.**
- **Informed understanding — the patient comprehends procedure, risks and alternatives.**
- **Explicit action — a clear affirmative step (digital signature, recorded verbal statement).**
- **Documentation — a secure, auditable record of the consent and any subsequent withdrawal.**

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4.2 Legal Foundations

Key instruments for telemedicine consent

GDPR — requires explicit consent for processing health data and mandates clear withdrawal mechanisms.

Reference: eur-lex.europa.eu/eli/reg/2016/679/oj.

Patients' Rights Directive (2011/24/EU) — guarantees access to clear information and informed decision-making in cross-border healthcare.

Reference: eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0024.

World Medical Association — Declaration of Helsinki — international ethical standards for medical research and clinical care.

Reference: wma.net/policies-post/wma-declaration-of-helsinki-…

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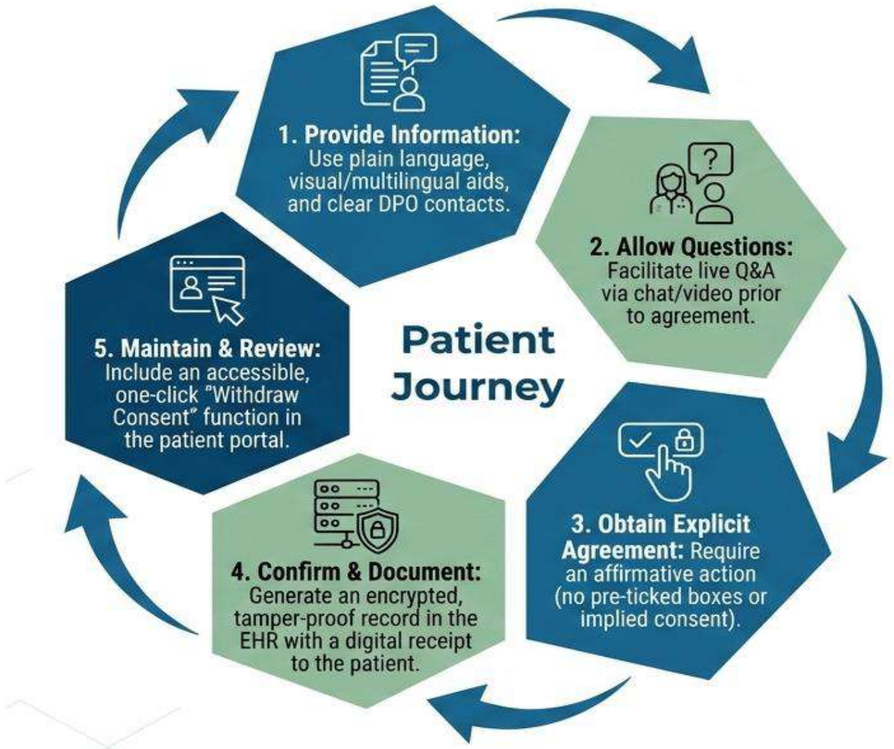
4.3 Step-by-Step Digital Consent Process

Five steps from information to withdrawal



- **1. Provide Information — clear explanation of the service, purpose of data collection, risks, benefits, retention, DPO contact.**
  - Plain language and visual aids; multilingual versions; audio/video formats for low literacy.
- **2. Allow Questions — give the patient time to ask questions via chat, phone or video before consent.**
  - Keep a record of Q&A to improve future materials.
- **3. Obtain Explicit Agreement — affirmative action: ticking a checkbox, signing digitally, recorded verbal consent.**
  - No pre-ticked boxes or implied consent.
- **4. Confirm and Document — provide a digital receipt or PDF; store a tamper-proof record in the EHR.**
  - Use audit trails and encryption.
- **5. Maintain & Review — allow withdrawal at any time; log all withdrawals.**
  - Include a one-click 'Withdraw Consent' function on patient portals.

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4.4 Digital Tools for Consent

Practical instruments for telemedicine

- Secure e-signature platforms (e.g., DocuSign, Adobe Sign) compliant with eIDAS and GDPR.
- Integrated EHR consent modules that automatically log timestamps and user IDs.
- Video consent recording for patients with low literacy, stored on encrypted servers.
- Multilingual mobile apps allowing patients to read or listen to consent information in their preferred language.

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4.5 Case 1 — Tele-Psychiatry Service

Recordings without clear retention or purpose

- **Scenario:**
  - A provider records therapy sessions for 'research purposes' but fails to specify retention periods, security measures or secondary uses.
- **Risks:**
  - Patients cannot make a fully informed decision (GDPR Articles 6 & 9).
  - Unclear retention and purpose create risk of unlawful processing and reputational damage.
- **Mitigation:**
  - Rewrite consent notice — list each purpose, storage duration, DPO contact; provide plain-language and multilingual versions.
  - Re-collect consent via secure email / patient portal, with explicit affirmative action.
  - Encrypt all recordings at rest and in transit (AES-256/TLS 1.2+); store keys separately.
  - Build a 'withdraw consent' button that triggers removal from active research sets, deletion/anonymisation, confirmation email and audit log.
  - Quarterly retention-log audits to verify deletion / anonymisation rules are applied.

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4.5 Case 2 — Cross-Border Cardiology

Tele-consultation across jurisdictions

- **Scenario:**
  - An Ethiopian patient receives a tele-consultation from an EU cardiology clinic. Different jurisdictions and unclear data-transfer safeguards create legal uncertainty.
- **Risks:**
  - GDPR applies to the EU clinic; local privacy laws may impose additional duties.
  - Cross-border transfer without safeguards may violate GDPR Chapter V.
- **Mitigation:**
  - Map data flows; identify safeguards (Standard Contractual Clauses, Binding Corporate Rules, or explicit consent for transfer).
  - Cross-border consent: patient is informed that data is transferred to/from the EU, the legal basis, and rights under both GDPR and local law.
  - Provide a dedicated EU-based DPO contact; create a dual-channel withdrawal process (EU provider or local partner).
  - Review the arrangement annually; document all transfers in the clinic's Article 30 Records of Processing.

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4.5 Case 3 — AI Diagnosis

Triage AI without transparency to patients

- **Scenario:**
  - An AI triage tool generates treatment suggestions, but the provider does not explain the AI's role to the patient.
- **Risks:**
  - Lack of transparency breaches GDPR Articles 13–15 and EU AI Act high-risk obligations.
  - Patients may misunderstand the human oversight in decision-making.
- **Mitigation:**
  - Transparency statement — what the AI does, its limitations, that a clinician reviews all AI outputs.
  - Consent form: separate checkbox confirming the patient understands and agrees to AI involvement; link to detailed explanation.
  - Human-oversight protocol: clinicians validate every AI recommendation; log overrides and justifications.
  - Risk assessment under EU AI Act high-risk requirements; document training data, accuracy metrics and bias testing.
  - Offer patients the option to receive care without AI support — opting out must not delay or diminish service.

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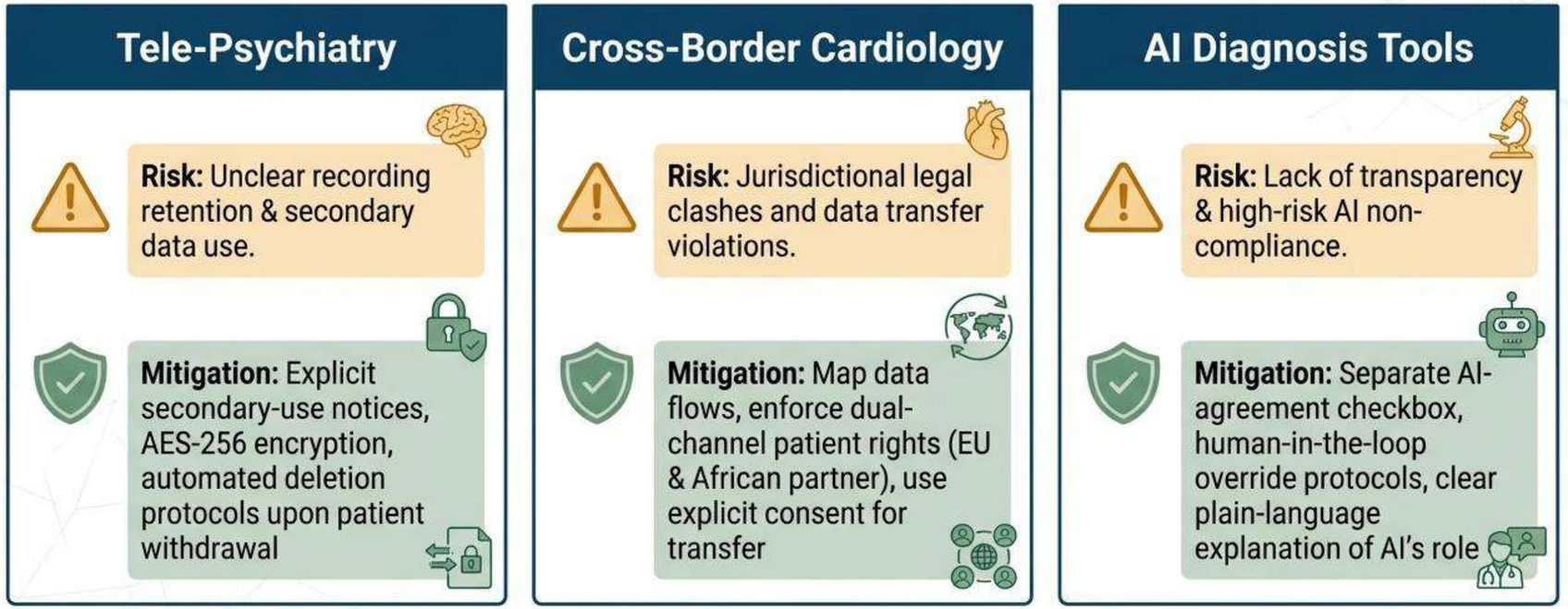
Cases — Diagnosis



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4.6 Ethical Considerations

Beyond legal compliance

- **Respect for Autonomy: consent is an ongoing dialogue, not a one-time signature.**
- **Equity :accessible materials for persons with disabilities and diverse languages.**
- **Transparency :disclose use of third-party platforms or AI algorithms.**
- **Data Minimisation : collect only data strictly necessary for the consultation.**

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4.7 Checklist for Telemedicine Providers

Confirm before every virtual consultation

- ❑ Patient identity and location are verified.
- ❑ Platform is encrypted and compliant with GDPR security standards.
- ❑ Consent has been obtained and is documented in the EHR.
- ❑ Patient is informed about data processing, retention and DPO contact.
- ❑ Withdrawal mechanism is available and clearly explained.
- ❑ For cross-border care: legal basis for transfer, applicable safeguards and dual-channel contact are in place.
- ❑ For AI-assisted care: transparency statement, human oversight and opt-out option are provided.

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Ethics in Virtual Consultations — Introduction

From in-person to digital ethics

- Virtual consultations — telemedicine platforms, mobile apps, video calls — are now a core part of healthcare delivery.
- Benefits: accessibility, continuity of care, cost savings.
- New ethical challenges:
  - Maintaining professional boundaries when consulting from a patient's living room.
  - Preserving confidentiality when platforms transmit sensitive health data.
  - Building trust when human cues are limited to a screen.

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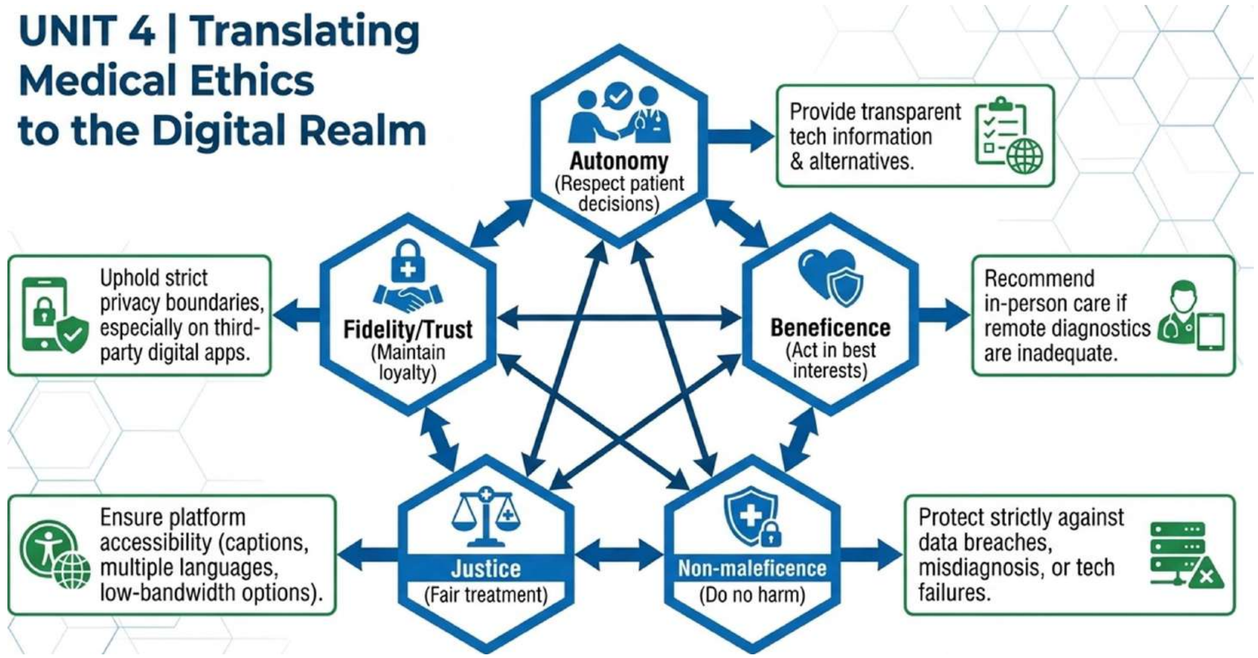
5.1 Core Ethical Principles

Digital interpretation



- **Autonomy — respect the patient's right to make informed decisions.**
  - Provide complete, understandable information about the telemedicine process, technology and limitations.
- **Beneficence — act in the patient's best interest.**
  - Ensure the chosen modality is clinically appropriate; recommend in-person care if remote care is inadequate.
- **Non-maleficence — do no harm.**
  - Protect against data breaches, misdiagnosis from poor video quality, or delays from technical failures.
- **Justice — fair and equal treatment.**
  - Provide accessible platforms (multilingual, captions, disability accommodations) and equitable scheduling.
- **Fidelity / Trust — uphold privacy and security promises, even when using third-party platforms.**

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5.2 Professional Conduct (1/2)

Challenge vs. Standard	Action Checklist
Environment & Prep:	**USE** a private, well-lit space. **TEST** equipment and network connections beforehand. 
Patient Verification:	**VERIFY** identity (using 2 identifiers) and physical location to enable emergency routing. 
Communication:	**OBTAIN** verbal consent confirmation at the start. **AVOID** technical jargon; maintain eye contact via the camera. 
Confidentiality:	**USE** only encrypted, GDPR-compliant platforms. **NEVER** store session data or video on personal devices. 
Boundaries:	**DOCUMENT** all communication in the official EHR. **AVOID** informal messaging or social media contact with patients. 

- **1. Preparation and Environment**
  - Private, quiet, well-lit space free from interruptions.
  - Test camera, microphone and network before the consultation.
  - Patient records and diagnostic tools accessible.
- **2. Patient Verification**
  - Confirm identity using at least two identifiers (name and date of birth).
  - Verify location for jurisdictional compliance and emergency response capability.
- **3. Communication Etiquette**
  - Explain the structure of the visit; obtain verbal confirmation of consent.
  - Speak clearly, maintain eye contact through the camera, use plain language.

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5.2 Professional Conduct (2/2)

Challenge vs. Standard	Action Checklist
Environment & Prep:	**USE** a private, well-lit space. **TEST** equipment and network connections beforehand.
Patient Verification:	**VERIFY** identity (using 2 identifiers) and physical location to enable emergency routing.
Communication:	**OBTAIN** verbal consent confirmation at the start. **AVOID** technical jargon; maintain eye contact via the camera.
Confidentiality:	**USE** only encrypted, GDPR-compliant platforms. **NEVER** store session data or video on personal devices.
Boundaries:	**DOCUMENT** all communication in the official EHR. **AVOID** informal messaging or social media contact with patients.

- **4. Confidentiality and Data Handling**
  - Remind patients to join from a private location and use a secure device.
  - Use only encrypted, GDPR-compliant platforms; never store recordings on personal devices.
- **5. Boundary Management**
  - Maintain the same professional boundaries as in-person visits — no informal messaging on personal accounts, no social-media contact.
  - Document all communications in the official EHR.
- **6. Emergency Protocols**
  - Clear plan for urgent situations (sudden deterioration).
  - Directory of local emergency numbers and patient location at the start of the session.

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5.3 Practical Challenges and Mitigation

Bridging technology, equity and law

Technical failures — risk of interrupted care or miscommunication.	Data breaches — exposure of sensitive health data.	Digital divide — exclusion of patients with limited internet or devices.	Cross-border jurisdiction — conflicting legal requirements.
• Mitigation: fallback options (telephone, reschedule), test equipment beforehand.	• Mitigation: end-to-end encrypted platforms, MFA, strict access controls.	• Mitigation: hybrid options (community tele-kiosks, telephone consultations), clear guidance and tech support.	• Mitigation: verify patient location, inform about applicable laws, obtain consent for cross-border transfers.

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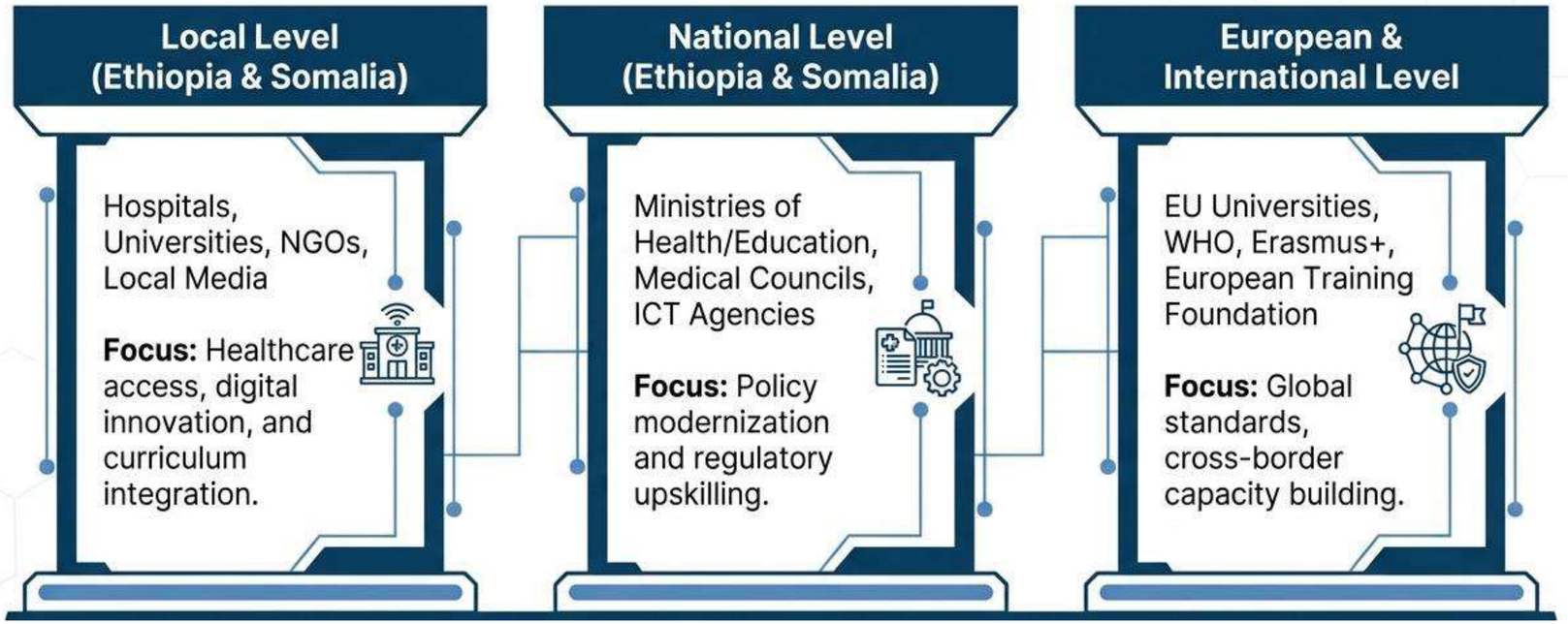
Target Groups for DigHealth Dissemination



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Summing up

1. **CIA Triad** — Confidentiality, Integrity and Availability are the three pillars of eHealth data protection — controls must address all three simultaneously.
2. **Threats & Mitigation** — Phishing, ransomware, insider threats, DDoS, supply-chain and IoT attacks need layered technical and organisational defences.
3. **EU Legal Frameworks** — GDPR, the Patients' Rights Directive, NIS2 and the EU AI Act interact — eHealth services must integrate all four for compliance.
4. **Consent & Ethics** — Valid informed consent, transparency for AI, cross-border safeguards and ethical conduct are essential in virtual care.

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In Summary the Action Plan

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