

xShare

Expanding the European EHRxF to share and effectively use health data within the EHDS

WP3

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List of abbreviations

Please refer to the i~HD Glossary: <https://glossary.ramit.be/public/index.cfm>

Abbreviation	Term
BAT	Business, Data, Application and Technology
BPMIN	Business Process Model and Notation
CCG	Computable Clinical Guidelines
CDSS	Clinical Decision Support System
CQL	Clinical Quality Guideline
DAK	Digital Adaptation Kit
DCP	Dynamic Care Planning
DMN	Decision Model and Notation
EHDS	European Health Data Space
EHRxF	European Electronic Health Record Exchange Format
FHIR	Fast Healthcare Interoperability Resources
HID	Health Information Domain
IPS	International Patient Summary
LLM	Large Language Model
SMART	Standard-based, Machine-readable, Adaptive, Requirement-based and Testable
WHO	World Health Organization
X-Bundle	xShare Interoperability Bundle

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Executive summary

The European Health Data Space (EHDS) establishes a common European framework for the exchange and use of health data. While the current European Electronic Health Record Exchange Format (EHRxF) defines several priority categories of health information, it does not explicitly address Care Plans as a distinct Health Information Domain (HID).

This deliverable presents the initial xShare proposal for a Care Plan HID within the EHDS ecosystem. The proposal is based on the observation that healthcare systems across Europe are increasingly required to support patients with chronic diseases, multimorbidity and long-term care needs. These patients frequently receive care from multiple healthcare professionals and organisations over extended periods of time, creating a need for coordinated, longitudinal and patient-centred care planning. The deliverable argues that Care Plans should be regarded as more than narrative documents. Instead, they should be represented as structured, standardised, guideline-informed, machine-readable and interoperable health information artefacts capable of supporting coordinated care, clinical decision support, patient involvement and future computable healthcare services.

To support this vision, the document proposes a conceptual definition of a Care Plan HID and presents a logical information model consisting of a small set of core elements, including conditions, goals, activities, observations and responsibilities. The model is intended to provide a technology-neutral foundation that can be aligned with existing interoperability frameworks and standards.

The proposal is informed by practical experiences from existing care planning initiatives, including the nationally deployed Danish chronic care planning solution and selected international examples. The document further explores how Care Plans may be linked to Computable Clinical Guidelines (CCGs) and discusses the relationship between Care Plans, WHO SMART Guidelines and emerging approaches to guideline-informed clinical decision support.

A review of current interoperability standards demonstrates that technologies such as HL7 FHIR, openEHR and IHE integration profiles already provide important building blocks for interoperable and computable care planning. These standards and initiatives provide valuable experience that can support the future development and implementation of a Care Plan HID within the EHDS.

As part of the xShare framework, the deliverable also introduces an initial Care Plan X-Bundle and a corresponding Implementation Guide. Together, these artefacts provide a foundation for future implementation activities and demonstrate how Care Plans can be represented and exchanged using open and internationally recognised interoperability standards.

Finally, the deliverable highlights several implementation considerations related to governance, organisational maturity, incentives, care delivery models and cross-border interoperability. These considerations illustrate that successful adoption of a Care Plan HID depends not only on technical specifications, but also on broader organisational and policy contexts.

This deliverable should be regarded as an interim proposal intended to stimulate discussion, validation and further refinement. The work will continue towards the final deliverable, incorporating feedback from stakeholders, implementation experiences and ongoing developments within the EHDS and EHRxF ecosystems.

0. Introduction

The European Health Data Space (EHDS) represents a transformative step toward a unified European framework for the primary and secondary use of electronic health data. By establishing common rules, standards and infrastructures for cross-border data exchange, EHDS aims to improve continuity of care, strengthen patient rights, enhance care quality, support innovation and evidence-based policymaking across Member States.

A central instrument for achieving interoperability within EHDS is the European Electronic Health Record Exchange Format (EHRxF). The EHRxF defines priority categories of electronic health data to be exchanged across borders under Article 5 and Annex I of the EHDS Regulation. These categories include patient summaries, ePrescriptions, laboratory results, medical imaging reports and discharge reports.

However, while these categories cover essential clinical documentation, they do not explicitly address structured, longitudinal and coordinated care planning as a distinct Health Information Domain (HID). The EHRxF priority categories capture what has happened to a patient — a retrospective record — but do not specify what should happen next, by whom, by when, and toward what goal; this is the function of a shared care plan, and its absence from the architecture is a critical gap for the 105 million Europeans living with multimorbidity.

The xShare Care Plan multidisciplinary expert group brings together health informatics specialists, policymakers and clinicians. Based on experiences from different healthcare systems and care planning initiatives, the group has identified a common need for care planning approaches that are structured, interoperable and capable of computational support. Narrative or locally defined care plans alone are insufficient to support coordinated care, cross-border health data exchange, quality measurement and digital decision support within the European Health Data Space.

Within the xShare project, the vision is to expand and operationalise the European EHRxF to support technologically effective and clinically meaningful exchange of health data in the EHDS context. As part of this work, Deliverable 3.7 proposes the definition of a new Health Information Domain for Care Plans.

The core conceptual position of this deliverable is that:

A Care Plan HID should be defined as a structured, standardised, guideline-informed, machine-readable, human-understandable and interoperable model for coordinated patient care.

This implies that Care Plans are not merely narrative documents, but structured and semantically defined constructs capable of supporting:

- Integrated and coordinated care across providers, organizations and specialties
- Transparent linkage to evidence-based clinical guidelines
- Rule-based, machine-readable and verifiable clinical decision support
- Continuity of care across organizations, regions and national borders
- Secondary use of structured care data for research, monitoring, policymaking and quality improvement

The objectives of this deliverable are therefore to:

- Define the conceptual foundations of a Care Plan as a Health Information Domain
- Clarify its relationship to the EHDS and EHRxF
- Outline its architectural and governance implications
- Propose the basis for a corresponding Care Plan X-Bundle
- Propose use cases based on existing experiences

This document is intended as a discussion and positioning paper for the broader European interoperability community. It aims to stimulate structured dialogue on how coordinated, computable and interoperable care planning can be integrated into the evolving EHDS framework.

The proposal is further informed by practical experience from existing digital care planning initiatives across Europe, including the Danish chronic care programmes that support the implementation of the Danish Health Reform and the introduction of chronic care packages as a patient right from 1 January 2027. It is also inspired by WHO's work on Smart Guidelines, which demonstrates how digital care plans may in the future be linked to computable clinical guidelines based on open international standards such as HL7 FHIR.

1. Policy Context

1.1 European Health Data Space and Interoperability Challenges

The European Health Data Space (EHDS) establishes a common European framework for the primary and secondary use of electronic health data. A key element of this framework is the European Electronic Health Record Exchange Format (EHRxF), which defines priority categories of health data for interoperable exchange across Member States, including patient summaries, ePrescriptions, laboratory results, medical imaging reports and discharge reports.

While these categories cover important parts of clinical documentation, they do not explicitly define Care Plans as a separate Health Information Domain. Elements of care planning may appear in patient summaries, discharge reports or other clinical documents, but there is currently no common European model for representing a Care Plan as a structured, longitudinal, interoperable and computable health information object.

This represents an important gap. Healthcare delivery across Europe is increasingly characterised by long-term management of chronic conditions, multidisciplinary and cross-sectoral care, outcome-oriented models of healthcare, and stronger patient involvement and self-management. These developments require care planning approaches that can be shared, updated and understood across systems, organisations and borders.

A dedicated Care Plan HID would therefore complement the existing EHRxF priority categories by representing not only what has happened to the patient, but also what is planned, by whom, by when, and toward which goals.

1.2 The Problem We Want to Solve: Supporting Better Outcomes, Not Just Data Exchange

Although care planning is widely recognised as an essential component of coordinated healthcare, current digital implementations across Europe remain fragmented, inconsistent and largely non-interoperable. As a result, care plans are often difficult to share, update and use across healthcare organisations, sectors and national borders.

The challenges are not primarily related to the exchange of health data itself, but to the ability to support coordinated, longitudinal and guideline-informed care processes. To realise the ambitions of the EHDS, care planning must evolve from locally defined and often narrative approaches towards structured, interoperable and computable models.

The key challenges can be summarised as follows:

- Care Plans are often narrative and not computable
- Lack of a defined Health Information Domain for Care Plans
- Limited integration with Clinical Guidelines
- Insufficient use of structured and coded data
- Known clinical issues due to absence of integrated Care Plans and clinical guidelines
- Telemedicine Context

These challenges are described in more detail in the following paragraphs.

1.2.1 Care Plans are often narrative and not computable

In many healthcare systems, care plans are documented as free text or through locally defined templates that vary between organizations, regions and countries. In addition, many Electronic Health Record (EHR) systems provide limited functionality for creating, maintaining and sharing structured care plans. As a result, care planning information is often embedded within clinical documents such as discharge reports rather than represented as a distinct and reusable information object.

While such approaches may support local clinical workflows, they present significant limitations for interoperability, care coordination and digital decision support. Narrative care plans are typically not:

- Standardised across organisations and jurisdictions
- Semantically interoperable
- Machine-readable
- Directly linked to computable decision support

Consequently, care plans cannot easily be exchanged, updated, analysed or reused across healthcare systems. This limits their value for coordinated care, quality monitoring, population health management, cross-border health data exchange and the implementation of guideline-driven care processes.

To support the ambitions of the EHDS, care plans must evolve from narrative documents towards structured, interoperable and computable health information artefacts.

1.2.2 Lack of a defined Health Information Domain for Care Plans

While care planning is widely recognised as an essential component of modern healthcare, there is currently no common European definition of what constitutes a Care Plan as a shareable and interoperable health information object.

Without a dedicated Health Information Domain (HID), care plans are represented differently across healthcare systems, organisations and countries. As a result, there is no common conceptual model, no agreed information structure and no shared semantic framework aligned with the EHRxF.

This creates significant challenges for interoperability. Care plan information may be exchanged as part of clinical documents, patient summaries or local care management solutions, but it cannot be reliably shared, interpreted and maintained as a coherent care planning artefact across systems and organisational boundaries.

The absence of a dedicated Care Plan HID also limits the ability to establish common implementation guides, interoperability specifications and reusable digital assets that can support care planning across Europe.

Consequently, continuity of care, multidisciplinary collaboration and cross-border healthcare remain dependent on local implementations rather than on a shared European approach.

Establishing a Care Plan HID would provide the conceptual and semantic foundation required to represent, exchange and manage care plans consistently across the EHDS ecosystem. In this way, EHDS can become the foundation of shared findings and lessons learned.

1.2.3 Limited integration with Clinical Guidelines

Clinical guidelines provide the foundation for evidence-based healthcare and are widely used to support clinical decision-making and care planning. However, most guidelines are still published as narrative documents intended for human interpretation.

Even when guidelines are available in digital form, they are rarely transformed into:

- Explicit and verifiable rule sets
- Computable clinical logic
- Standardised decision algorithms linked to patient data

As a result:

- Care planning remains largely manual and variable
- Guideline adherence is difficult to measure and monitor
- Clinical decision support is inconsistently implemented
- Opportunities for automation and workflow support are limited
- AI-supported solutions may lack transparency and traceability if they are not grounded in explicit, evidence-based clinical logic

Care plans represent the operational layer where guideline recommendations are translated into patient-specific goals, activities and follow-up actions. However, in most healthcare systems there is currently no systematic and computable connection between clinical guidelines and digital care plans.

There is therefore a need to establish transparent and standards-based mechanisms for linking Care Plans with Computable Clinical Guidelines (CCGs), enabling evidence-based recommendations to be incorporated directly into digital care planning processes.

1.2.4 Insufficient use of structured and coded data

Effective care planning depends on access to high-quality, structured and coded patient data. Care plans do not exist in isolation; they rely on information originating from other health information domains, including diagnoses, laboratory results, medications, observations and clinical reports.

However, significant challenges remain across healthcare systems:

- Data may be incomplete, inconsistent or unavailable
- Terminologies and coding systems are not always harmonised
- Structured data is often supplemented by narrative information that cannot easily be processed by digital systems
- Access to authoritative and up-to-date data sources may be limited

These challenges reduce the reliability of digital decision support and limit the ability to implement computable care planning processes.

The successful implementation of a Care Plan HID therefore depends on effective integration with other EHDS health information domains and on the availability of high-quality structured and coded health data. While addressing these issues is beyond the scope of this deliverable, they represent important prerequisites for interoperable and computable care planning.

1.2.5 Known clinical issues due to absence of integrated Care Plans and clinical guidelines

The limitations described above are not merely technical challenges. They have direct implications for the quality, consistency and coordination of patient care.

There is substantial evidence that healthcare systems continue to face challenges related to diagnostic errors, variations in clinical practice and incomplete adherence to evidence-based guidelines. Studies have shown that both healthcare professionals and patients frequently deviate from recommended care pathways, and that patients often receive only a subset of recommended interventions. Similarly, adherence to clinical guidelines remains variable across healthcare settings.

While these issues have multiple causes, fragmented care planning and the limited integration of clinical guidelines into digital workflows contribute to the problem. When care plans are not structured, shareable and computable, it becomes more difficult to ensure that evidence-based recommendations are consistently translated into coordinated clinical actions.

Structured and interoperable Care Plans have the potential to reduce variation in care delivery by supporting transparent communication, coordinated follow-up and more consistent application of evidence-based recommendations across healthcare organisations and care settings.

The objective is not to replace clinical judgement, but to provide healthcare professionals and patients with a shared framework that supports continuity of care and improves the implementation of guideline-informed care processes.

1.2.6 Telemedicine Context

The ongoing digital transformation of healthcare is expanding the use of telemedicine, remote monitoring and virtual care services across Europe. These developments are particularly relevant for the management of chronic conditions, where care is often delivered over extended periods and across multiple healthcare providers.

Experience from telemedicine programmes has demonstrated the importance of continuity of care, shared understanding of treatment goals and effective coordination between healthcare professionals and patients. However, fragmented information, unclear responsibilities and limited visibility of planned interventions remain common challenges in distributed care settings.

In this context, structured and interoperable Care Plans can provide an important mechanism for documenting care goals, planned activities, responsibilities and follow-up actions across organisational boundaries.

While telemedicine is only one of many use cases, it illustrates the broader need for longitudinal, shareable and computable care planning capabilities within the EHDS ecosystem.

1.3 Policy Alignment

The proposal for a Care Plan HID is aligned with the objectives of the European Health Data Space (EHDS), in particular Article 5 and Annex I, which define the priority categories of electronic health data to be exchanged through the European Electronic Health Record Exchange Format (EHRxF). While these categories include Patient Summaries, ePrescriptions, Laboratory Results, Medical Imaging Reports and Hospital Discharge Reports, Care Plans are not currently defined as a dedicated Health Information Domain.

Existing European guidelines for Patient Summaries and Hospital Discharge Reports already include limited care planning information. However, these documents primarily provide episodic or point-in-time clinical information and do not support the longitudinal, dynamic and collaborative characteristics required for coordinated care planning. The proposed Care Plan HID therefore complements existing EHRxF artefacts rather than replacing them.

A structured and interoperable Care Plan HID would directly support several strategic objectives of the European Health Data Space.

By providing a common framework for representing planned and coordinated care, a Care Plan HID would strengthen the primary use of health data by supporting continuity of care across healthcare organisations, sectors and national borders. It would complement the existing EHRxF priority categories by enabling the exchange of care intentions, goals, planned interventions and follow-up activities in a consistent and interoperable manner.

A Care Plan HID would further support:

- Cross-jurisdiction continuity and coordination of care
 - European interoperability through alignment with the EHRxF
 - Implementation of evidence-based and guideline-informed care pathways
 - Digital transformation of chronic disease management
 - Patient engagement and shared decision-making
 - Secondary use of structured care planning data for research, quality improvement and policymaking

The proposal for a Care Plan HID should therefore be regarded not as an isolated technical initiative, but as a strategic enabler for achieving the broader objectives of the EHDS.

1.4 Strategic Rationale

The analysis presented in this chapter demonstrates that current approaches to care planning are insufficient to support the long-term ambitions of the European Health Data Space. While care plans play a central role in coordinated and patient-centred care, they are typically implemented through heterogeneous and often non-interoperable solutions.

To support continuity of care, multidisciplinary collaboration, guideline-informed care processes and future computable healthcare services, care planning must become structured, interoperable and computable.

A dedicated Care Plan Health Information Domain (HID) provides the conceptual and semantic foundation required to achieve these objectives. It establishes a common European framework for representing, exchanging and maintaining care plans across healthcare organisations, systems and national borders.

The following chapters therefore describe the proposed Care Plan HID and its relationship to the broader EHDS and EHRxF ecosystem.

2. Conceptual Definition of Care Plans as a HID

2.1 Rationale for a Dedicated Care Plan HID

Within the European Health Data Space (EHDS), Health Information Domains (HIDs) represent structured and semantically defined categories of health data intended for interoperable exchange.

A Care Plan differs from most existing health information artefacts because it is inherently longitudinal, collaborative and action oriented. Rather than documenting what has happened, a Care Plan describes what is planned, why it is planned, who is responsible, and how progress will be evaluated over time.

For this reason, Care Plans should not be treated merely as content embedded within other documents such as patient summaries or discharge reports. Instead, they should be recognised as a distinct Health Information Domain capable of supporting coordinated, interoperable and computable care processes across the EHDS ecosystem.

Existing EHDS and EHRx artefacts such as Patient Summaries and Hospital Discharge Reports may contain or refer to care planning information. However, these artefacts are primarily designed to provide snapshots of a patient's health status at a specific point in time.

A Care Plan differs fundamentally from these document types. It is a longitudinal, continuously evolving and collaborative artefact that supports the planning, coordination and evaluation of care over extended periods of time.

Unlike a Patient Summary or a Discharge Report, a Care Plan:

- can be updated independently of clinical documents
- maintains explicit relationships between conditions, goals, activities, observations and responsibilities
- supports coordinated care across multiple healthcare providers and organisations
- enables monitoring of progress towards agreed goals
- provides a foundation for guideline-informed and computable care processes

For these reasons, care planning should not be regarded merely as a section within existing Health Information Domains. Instead, it should be represented as a dedicated Health Information Domain capable of supporting longitudinal, interoperable and computable care management within the EHDS ecosystem.

2.2 Definition

For the purposes of this deliverable, a Care Plan HID is defined as:

“A structured, standardised, guideline-informed, machine-readable, human-understandable and interoperable model for coordinated patient care.”

This definition implies that a Care Plan is:

- Structured – composed of clearly defined information elements
- Standardised – aligned with European interoperability frameworks, standards and terminologies
- Guideline-informed – informed by evidence-based clinical recommendations and care pathways
- Machine-readable – suitable for computational processing, automation and decision support
- Human-understandable – understandable and actionable by healthcare professionals, patients and caregivers
- Interoperable – exchangeable across systems, organisations, sectors, jurisdictions and national borders

The Care Plan HID is therefore not merely a documentation format, but a semantic and architectural construct that supports coordinated, longitudinal and patient-centred care.

2.3 Scope and Boundaries

A Care Plan HID should include the information elements necessary to coordinate, manage and evaluate patient care across healthcare providers and over time.

Core elements typically include:

Clinical context

- Diagnosis or problem definition
- Relevant clinical conditions, signs and symptoms
- Relevant observations and assessments
- Risk stratification or eligibility criteria

Goals

- Clinical goals (e.g., target blood pressure, HbA1c levels)
- Functional goals
- Patient-defined goals (e.g., lifestyle changes and quality-of-life objectives)

Planned activities and interventions

- Consultations and referrals
- Monitoring activities and follow-up appointments
- Laboratory tests and diagnostic procedures
- Treatments and therapies
- Self-management activities

Responsibilities and roles

- Assigned healthcare professionals
- Care coordinator (where applicable)
- Patient and caregiver responsibilities

Evaluation and outcome tracking

- Measured outcomes
- Progress towards goals
- Adjustments to the care plan

The Care Plan HID does not replace other Health Information Domains such as patient summaries, laboratory results, prescriptions or medical imaging. Instead, it references, links and orchestrates information originating from these domains within a coordinated care structure.

The purpose of the Care Plan HID is therefore not to duplicate existing health information, but to provide a longitudinal framework that connects clinical information, patient goals, planned activities and outcomes in support of coordinated, patient-centred care.

2.4 Longitudinal and Dynamic Nature

A Care Plan differs from episodic clinical documentation because it is inherently longitudinal and dynamic. Rather than representing a single clinical event or encounter, it supports the planning, coordination and evaluation of care over extended periods of time.

A Care Plan is typically:

- Iterative
- Adaptive
- Continuously updated
- Context-sensitive

It may evolve in response to:

- New clinical findings
- Changes in patient preferences and circumstances
- Changes in risk status
- Updates to clinical guidelines and recommendations
- Progress towards agreed goals and outcomes

As part of a coordinated care process, a Care Plan supports shared decision-making between healthcare professionals, patients and, where appropriate, caregivers. It provides a common and continuously updated view of agreed goals, planned activities and responsibilities.

The Care Plan HID must therefore support versioning, traceability and structured updates over time. These capabilities are essential for maintaining transparency, accountability and continuity of care across healthcare organisations, sectors and national borders.

2.5 Relationship to EHRxF

The Care Plan HID should be aligned with the European Electronic Health Record Exchange Format (EHRxF) to ensure semantic and technical interoperability across the European Health Data Space.

The Care Plan HID is not intended to replace existing EHRxF priority categories. Rather, it complements them by providing a structured framework for coordinating and managing care over time.

While existing EHRxF categories primarily describe clinical events, observations, results and outcomes, the Care Plan HID represents the planned and coordinated aspects of care, including goals, interventions, responsibilities and follow-up activities.

The Care Plan HID should therefore be capable of referencing and incorporating information originating from other Health Information Domains, including:

- Patient Summaries
- Laboratory Results
- ePrescriptions and eDispensations
- Medical Imaging Reports
- Hospital Discharge Reports
- Other relevant clinical documents and datasets

In this way, the Care Plan HID acts as a coordinating and longitudinal layer that connects information from multiple health information domains within a patient-centred care process.

Alignment with the EHRxF also provides a foundation for the development of common implementation guides, interoperability specifications and reusable digital assets that can support care planning across Europe.

The Care Plan HID should therefore be regarded as a complementary extension of the EHRxF ecosystem, supporting continuity of care, multidisciplinary collaboration and future computable healthcare services.

2.6 Governance and Semantic Integrity

The value of a Care Plan HID depends not only on technical interoperability, but also on semantic consistency and governance. Information exchanged between healthcare organisations, regions and countries must be interpreted in a consistent and predictable manner.

To support semantic interoperability, Care Plan information elements should be based on internationally recognised standards, terminologies and information models where appropriate. Existing semantic frameworks such as EN ISO 13940 (ContSys) provide an important reference for establishing consistent definitions and relationships between care planning concepts. ContSys offers a common conceptual foundation for continuity of care, including concepts such as health issues, healthcare goals, healthcare activities and the actors involved in the care process. The proposed Care Plan HID is conceptually aligned with these principles. This includes the use of standardised coding systems and clearly defined information structures to ensure that care planning information retains its meaning when exchanged across systems and jurisdictions.

Governance mechanisms are equally important. A Care Plan HID requires agreed definitions, maintenance processes and change management procedures to ensure consistency over time and to support future evolution of the EHDS ecosystem.

Semantic integrity is particularly important for guideline-informed care planning, clinical decision support and future computable healthcare services. Ambiguities in definitions, coding or information structures may lead to inconsistent interpretation, reduced interoperability and variation in care delivery.

The Care Plan HID should therefore be governed as a shared European information asset part of the EEHRxF, supported by transparent governance processes, agreed semantic specifications and alignment with existing European interoperability frameworks.

2.7 Positioning Within the EHDS Vision

The proposed Care Plan HID supports the broader vision of the European Health Data Space by extending interoperability beyond the exchange of clinical records and towards the coordination of care processes.

While existing Health Information Domains primarily focus on documenting clinical events, observations and outcomes, the Care Plan HID introduces a longitudinal and patient-centred perspective that supports the planning, coordination and evaluation of care across healthcare organisations, sectors and national borders.

By providing a common conceptual and semantic framework for care planning, the Care Plan HID can contribute to:

- Improved continuity and coordination of care
- Greater patient involvement and shared decision-making
- More consistent implementation of evidence-based care pathways
- Enhanced support for multidisciplinary and cross-sector collaboration
- Future integration with computable clinical guidelines and digital decision support services

The Care Plan HID should therefore be regarded as a strategic component of the evolving EHDS ecosystem. It provides a foundation for interoperable, guideline-informed and patient-centred care planning, while enabling future implementation through common specifications, implementation guides and Care Plan X-Bundles.

The following chapters describe the clinical, business and technical perspectives that support the proposed Care Plan HID and its implementation within the European Health Data Space.

3. Clinical and Business Perspective on Care Planning

This chapter describes the clinical and organisational context that forms the basis for the logical information model for Care Plans presented in the following chapter.

3.1 Clinical user stories

Care planning is fundamentally a clinical activity that supports the management of chronic diseases and long-term health conditions. In daily clinical practice, care plans are used by healthcare professionals to structure consultations, define treatment goals together with the patient, and coordinate follow-up activities across healthcare providers.

To ensure that the proposed Care Plan Health Information Domain reflects real clinical needs, a set of clinical user stories has been collected and analysed as part of the preparatory work. The user stories have been developed and refined through collaboration with healthcare professionals involved in the management of chronic diseases in primary care and across sectors.

User stories describe typical clinical situations from the perspective of the user. They capture what healthcare professionals and patients need to achieve in a specific context and the value that the functionality should provide. A typical user story follows the structure:

As a [role], I want to [perform an action] when [context], so that [value].

Examples of user stories include situations where a general practitioner wishes to:

- obtain a structured overview of the patient's relevant measurements and treatment goals during an annual consultation
- receive guideline-based recommendations when evaluating a patient's clinical status
- adjust treatment goals based on an individual assessment together with the patient
- identify patients in need of a care plan or follow-up consultation
- coordinate treatment goals and interventions with other specialists through a shared care plan

From the patient perspective, user stories typically focus on transparency, understanding, and participation in the care process. Patients may wish to:

- see their care plan and agreed treatment goals
- contribute personal goals and preferences to the care plan together with their care team
- understand how their measurements evolve over time
- track their progress toward treatment goals and see when targets are achieved
- be reminded of follow-up consultations
- report symptoms, measurements, or concerns between consultations
- share their care plan with healthcare professionals across care settings.

Taken together, the clinical user stories illustrate that care plans function as dynamic tools that support decision-making, care coordination and patient engagement. They also demonstrate that

care plans must integrate information from multiple sources, including diagnoses, clinical measurements, treatment goals and planned activities.

The analysis of these user stories provides an important foundation for identifying the core business needs and information elements that must be supported by a structured and interoperable Care Plan Health Information Domain.

3.2 Core business needs

The analysis of clinical user stories reveals several recurring functional and organizational needs that must be supported by digital care planning solutions. These needs represent the core business requirements for care planning and provide an important foundation for the development of a structured and interoperable Care Plan Health Information Domain.

Although the specific implementation of care plans varies across healthcare systems, the underlying needs are largely consistent. Care planning must support clinicians in organizing patient care, monitoring progress and coordinating activities across healthcare providers and sectors. At the same time, care plans should provide patients with transparency and support their active participation in the management of their own health.

Based on the collected user stories and the experience from existing care planning implementations, four overarching categories of business needs can be identified. Together, these categories describe the fundamental capabilities that digital care planning solutions must support, irrespective of healthcare setting or organisational model.

3.2.1 Documentation and registration

Care planning requires structured documentation of relevant clinical information. This includes diagnoses, clinical measurements, treatment goals, lifestyle factors and other patient-related information that forms the basis for clinical decision-making and follow-up. Structured documentation ensures that relevant information is consistently recorded and accessible to healthcare professionals involved in the patient's care.

3.2.2 Patient identification and follow-up

Healthcare professionals must be able to identify patients who may benefit from a care plan and organize systematic follow-up over time. This includes identifying patients who require annual reviews, monitoring patients with chronic diseases and ensuring that relevant consultations or interventions are scheduled. Digital solutions should therefore support population-based identification of patients and facilitate structured follow-up activities.

3.2.3 Clinical decision support

One of the central purposes of care planning is to support evidence-based clinical decision-making. Care plans should provide healthcare professionals with access to relevant clinical data and guideline-based recommendations that can assist in defining treatment goals, evaluating patient progress, recommend referrals and consultations and adjusting treatment when necessary. Clinical decision support helps promote consistency in care and reduce unwarranted variation in treatment across healthcare providers.

3.2.4 Communication and collaboration

Care plans are frequently used across multiple healthcare providers and organizational boundaries. Effective care coordination therefore requires that care plans can be shared and understood across care settings, including primary care, hospitals, municipal health services and patients themselves. Digital care plans should support transparency and facilitate collaboration among healthcare professionals while also enabling patients to access and understand their own care plans.

Together, these business needs demonstrate that care plans are not merely static documents but dynamic tools that support clinical workflows, decision-making and coordination of care. A Care Plan Health Information Domain must therefore provide a structured representation of the key elements required to support these processes.

3.3 Care planning workflow

Care planning is closely integrated into the daily clinical workflow of healthcare professionals and typically occurs as part of regular consultations and follow-up activities for patients with chronic conditions or complex care needs. Rather than being a one-time documentation task, care planning represents a continuous and iterative process that evolves over time as the patient's condition; preferences and treatment goals change.

In clinical practice, the care planning process often begins with the identification of patients who may benefit from structured follow-up and coordinated care. This may occur through population-based screening, clinical assessment during consultations or identification of patients with specific diagnoses or risk profiles.

Once a patient is identified, the care planning process typically involves several steps. First, relevant clinical information is reviewed, including diagnoses, clinical measurements, medication and other relevant patient data. This information provides the clinical context for evaluating the patient's current health status and determining appropriate treatment and prevention strategies.

Based on this information, healthcare professionals define treatment goals together with the patient. These goals may include clinical targets, such as specific values for blood pressure or glycemic control, as well as patient-defined goals related to quality of life, daily functioning or lifestyle changes. Shared decision-making plays an important role in this phase, ensuring that the plan reflects both clinical recommendations and the patient's individual circumstances and preferences.

Once goals have been established, specific activities and interventions are planned to achieve these goals. These activities may include medical treatments, lifestyle interventions, monitoring activities or referrals to other healthcare providers. Responsibilities for these activities are often distributed across different healthcare professionals and care levels.

The final step in the workflow involves monitoring and evaluation. Patient values and other outcome indicators are reviewed during follow-up consultations to assess progress toward the defined goals. Based on these evaluations, the care plan may be adjusted by modifying goals, introducing new activities or revising treatment strategies.

This cyclical workflow illustrates the dynamic nature of care planning. Care plans evolve continuously as new information becomes available and as the patient's situation changes. Digital care planning solutions must therefore support iterative updates, structured tracking of goals and outcomes, and coordination across healthcare providers while providing decision support.

4. Logical Model for Care Plans

4.1 Purpose of the Logical Model

The previous chapter described the clinical and organizational context in which care planning takes place. It highlighted how care plans are used in clinical workflows to structure consultations, define treatment goals, coordinate activities and monitor patient outcomes.

To support interoperability within the European Health Data Space (EHDS), these clinical processes must be represented through a structured and shared information model. A logical model provides a technology-neutral description of the key information elements required to represent a Care Plan and the relationships between them.

The purpose of the logical model presented in this chapter is therefore to identify and describe the core information elements that constitute a Care Plan and that must be supported by interoperable digital systems. These elements reflect the fundamental components of care planning identified through clinical practice, user stories and business requirements described in the previous chapter.

The logical model does not prescribe a specific technical implementation. Instead, it provides a conceptual structure that can later be mapped to existing interoperability standards and exchange formats. In particular, the model is intended to support alignment with the European Electronic Health Record Exchange Format (EHRx) and with widely adopted health information standards such as HL7 FHIR.

By defining a clear logical structure for Care Plans, it becomes possible to represent care planning in a consistent and interoperable manner across healthcare systems, enabling coordinated care, improved decision support and more effective data sharing within the EHDS.

4.2 Core Information Elements of a Care Plan

Care planning involves the organization of clinical information and activities around the management of a patient's health condition over time. To support structured and interoperable care planning, it is necessary to identify the core information elements that consistently appear across care planning workflows.

Analysis of clinical practice, user stories and business requirements shows that care plans typically revolve around a small set of fundamental elements that together describe the patient's situation, the objectives of care and the actions required to achieve them.

At the centre of the model is the **Care Plan**, which represents the structured plan for managing a patient's health condition. The Care Plan provides an overview of the clinical situation, the agreed goals for treatment and the activities planned to achieve these goals.

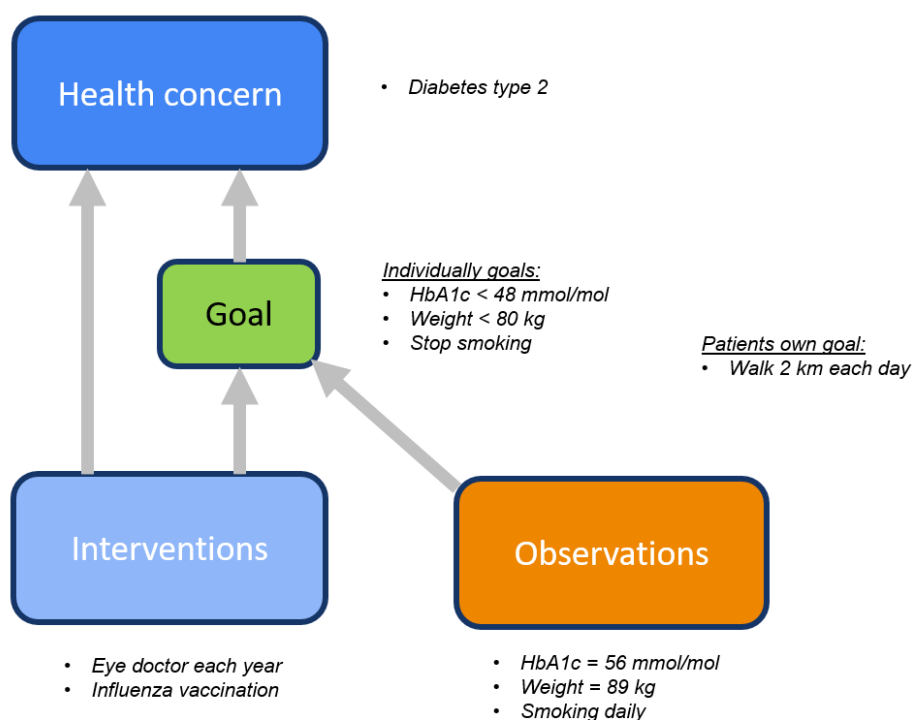


Figure 1. Core Information Elements of the Care Plan Logical Model.

The figure illustrates the principal information elements that constitute a Care Plan and their relationships. A Condition or Problem typically serves as the trigger for establishing a Care Plan. Goals define the intended outcomes, Activities describe the interventions required to achieve these goals, and Observations provide the information needed to evaluate progress over time. Actors and Responsibilities identify the individuals or organisations responsible for carrying out and coordinating care activities.

A Care Plan is typically associated with one or more **Conditions or Problems** that describe the underlying clinical situation requiring structured care planning. These may include chronic diseases, long-term conditions or other health-related problems that require coordinated management over time. A Condition or Problem will serve as the trigger for establishing a Care Plan and provides the clinical context for defining goals, activities and follow-up.

Based on the identified condition, healthcare professionals and patients define **Goals** that describe the intended outcomes of care. Goals may include clinical targets, such as improved disease control or specific measurement values, as well as patient-centred objectives related to quality of life, daily functioning or lifestyle changes.

To achieve these goals, the care plan defines a set of **Activities or Interventions**. These activities represent clinical actions, treatments or follow-up measures that must be carried out by healthcare professionals, patients or other actors involved in the care process.

Care planning also requires the monitoring of **Patient Values or Observations**, which provides information about the patient's health status over time. These may include clinical measurements,

patient-reported outcomes or other indicators used to evaluate whether the defined goals are being achieved.

Finally, care plans often involve multiple healthcare professionals and organizations. The logical model therefore also includes **Actors and Responsibilities**, representing the individuals or organizations responsible for performing specific activities within the care plan.

Together, these elements form the core structure of a Care Plan. They provide the foundation for representing care planning in a structured way and enable consistent interpretation of care plans across healthcare systems.

4.3 Longitudinal Structure of Care Plans

Care planning is inherently longitudinal. Unlike many other clinical documents that capture a specific clinical event or encounter, a Care Plan represents an evolving structure that supports the management of a patient's health condition over an extended period.

For patients with chronic diseases or long-term conditions, care planning typically spans months or years and involves repeated consultations, monitoring activities and adjustments to treatment strategies coordinated among multiple healthcare professionals. As the patient's condition changes, the Care Plan must be updated to reflect new clinical information, revised goals and modified activities.

This longitudinal nature means that Care Plans are not static artefacts but dynamic structures that evolve throughout the care process. Goals may be adjusted, new activities may be introduced, and responsibilities may shift as different healthcare professionals become involved in the patient's care.

Monitoring patient values and observations plays a central role in this process. Measurements, patient-reported outcomes and other indicators provide information about the patient's progress and support the evaluation of whether the defined goals are being achieved. These observations may trigger updates to the Care Plan, including modification of goals or the introduction of new interventions.

The longitudinal structure of Care Plans also supports continuity of care across healthcare providers and organizational boundaries. Because care plans extend over time and across multiple care encounters, they provide a shared reference point for healthcare professionals involved in the patient's treatment within the care team.

From an interoperability perspective, the longitudinal nature of Care Plans implies that digital care planning solutions must support versioning, updates and the consistent representation of changes over time. The logical model therefore needs to accommodate the evolving structure of care plans while preserving the relationships between conditions, goals, activities, observations and healthcare professionals.

4.4 Alignment with existing standards

The logical model presented in this chapter provides a conceptual representation of the key information elements required to support structured care planning. While the model is intentionally

technology-neutral, it has been designed to align with existing health information standards and interoperability frameworks to support practical implementation.

The logical model is also conceptually aligned with EN ISO 13940 Health Informatics – System of Concepts to Support Continuity of Care (ContSys). ContSys provides a European reference model for describing healthcare processes, health issues, healthcare goals, planned healthcare activities and the relationships between the actors involved in continuity of care.

Several of the core concepts identified in the proposed Care Plan HID, including conditions, goals, activities, observations and responsibilities, are consistent with the conceptual approach defined in ContSys. While the purpose of this deliverable is not to provide a formal mapping to ContSys, the standard provides an important semantic foundation for the development of interoperable and longitudinal care planning within the EHDS ecosystem.

Within the context of the European Health Data Space (EHDS), the logical model for Care Plans should be compatible with the European Electronic Health Record Exchange Format (EHRx). EHRx defines a set of priority health data categories and interoperability specifications intended to facilitate the exchange of health data across European healthcare systems. A structured representation of Care Plans should therefore be able to integrate with this broader interoperability framework.

At the same time, the logical model aligns with widely adopted international standards for health information exchange, particularly those defined by HL7. In many digital health systems, care planning functionality is already supported by resources within the HL7 FHIR standard, including the **CarePlan**, **Condition**, **Goal**, **Observation**, and **Task** or **ServiceRequest** resources. These resources provide technical representations of the core elements identified in the logical model.

The purpose of the logical model is not to replicate or replace existing standards but to provide a coherent conceptual structure that can guide the consistent use of these standards in the context of care planning. By identifying the core elements and their relationships, the model supports the development of interoperable implementations that remain compatible with existing standards.

This alignment is particularly important for enabling the development of a Care Plan Health Information Domain and a corresponding Care Plan X-Bundle within the xShare framework. The logical model therefore serves as an intermediate layer between the clinical concepts described in earlier chapters and the technical specifications discussed in the following chapters.

4.5 Relationship with Clinical Guidelines

Care planning is closely connected to the use of clinical guidelines. In clinical practice, healthcare professionals frequently rely on evidence-based recommendations when defining treatment goals, selecting interventions, and determining appropriate follow-up for patients with chronic diseases and long-term conditions.

Clinical guidelines provide structured knowledge about recommended care pathways, diagnostic criteria, treatment options and monitoring strategies. However, in many healthcare systems these guidelines remain primarily narrative and are therefore not directly integrated into clinical information systems for enabling the creation of personalized care plans.

Care Plans provide a practical mechanism for translating guideline recommendations into patient-specific treatment strategies. While clinical guidelines describe general recommendations for groups of patients, care plans represent the individualized application of these recommendations for a specific patient.

Within the care planning process, guideline recommendations may influence several elements of the Care Plan. They may inform the identification of relevant clinical conditions, support the definition of treatment goals and guide the selection of appropriate clinical activities and monitoring strategies. In this way, care plans act as the operational layer where guideline recommendations are applied in everyday clinical practice.

The growing development of computable clinical guidelines further strengthens this relationship. When guideline knowledge is represented in machine-readable formats, it becomes possible to integrate guideline-based decision support directly into digital care planning tools. This can support healthcare professionals in defining treatment goals, identifying appropriate interventions and monitoring patient progress in accordance with evidence-based recommendations.

The logical model presented in this chapter provides a structured representation of the elements required to support such integration. By clearly defining the relationships between conditions, goals, activities and observations, the model creates a foundation for linking care planning with computable guideline knowledge.

5. The current landscape

This chapter provides an overview of the current use and implementation of care plans across selected countries. The purpose is to establish a shared understanding of how care planning is currently applied in practice, including clinical use, organisational setup, and technical implementation.

5.1 Denmark

Denmark has a well-established and widely adopted model for digital care plans in primary care. These care plans are maintained in general practice for patients with chronic conditions such as chronic obstructive pulmonary disease (COPD), type 2 diabetes, and ischaemic heart disease.

Digital care plans were introduced nationally in 2018 as part of a joint initiative involving the Ministry of Health, the Regions and general practitioners. Today, the solution is in daily routine operation in all general practice clinics across the country, with a high level of adoption among general practitioners and a significant number of care plans created annually. This demonstrates that care planning is not a theoretical construct in Denmark, but an integrated and operational part of everyday clinical practice.

5.1.1 Clinical purpose and structure

In the Danish context, care plans are developed and maintained by the patient's general practitioner and serve as a structured tool to support the management of chronic disease. The plan is intended to strengthen patient self-management while ensuring systematic follow-up and adherence to clinical guidelines.

A care plan typically includes four core elements:

- The patient's condition or diagnosis
- Individualised treatment goals (both clinical and patient-defined)
- Planned activities and interventions
- Patient data and measurements used for monitoring progress

The care plan is not static but continuously updated during routine consultations, particularly during annual check-ups. It functions as a shared reference point for dialogue between the clinician and the patient and supports clinical decision-making based on current data and guideline recommendations.

5.1.2 Decision support and clinical integration

A key characteristic of the Danish solution is the integration of clinical decision support. Relevant patient data (e.g. laboratory results, vital signs, medication) are used in combination with national clinical guidelines to provide recommendations on treatment goals and potential adjustments.

This means that the care plan is not merely a documentation tool, but an active clinical instrument used during consultations. It supports the clinician in interpreting patient data, identifying deviations from recommended targets, and suggesting appropriate interventions.

The solution is tightly integrated with general practice systems, ensuring that clinicians can access and update care plans within their existing workflow. Data entered during the consultation are synchronised with the patient record, reducing duplication and supporting efficient clinical processes.

5.1.3 Technical architecture and data sharing

The current Danish care plan solution is based on a common care plan module where relevant patient data are extracted from each general practice systems.

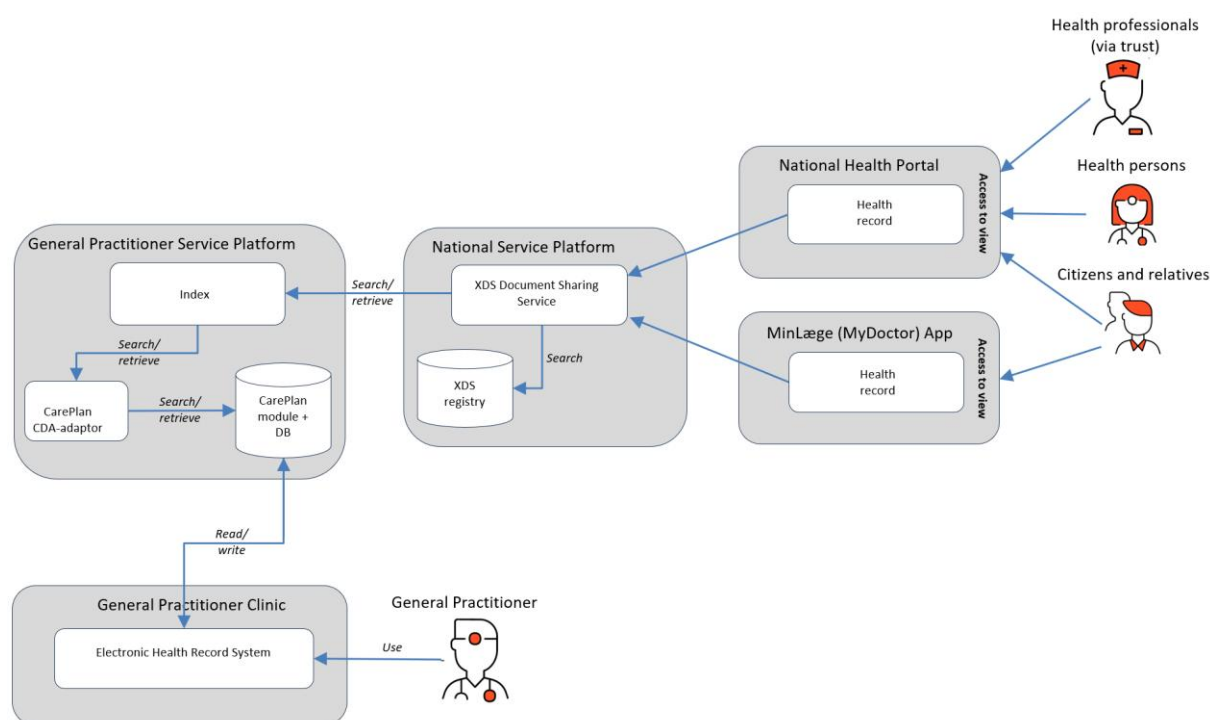


Figure 2. Care Plans are shared via the Danish Health Care Infrastructure.

Care plans can be accessed not only by general practitioners but also by other healthcare actors through the national health portal, Sundhedsjournalen. This enables sharing of care plans with hospitals, municipalities, and patients, supporting coordination across sectors.

5.1.4 Strengths and limitations

The Danish care plan solution has several notable strengths:

- High national adoption and routine clinical use
- Strong integration with general practice workflows
- Embedded clinical decision support based on national guidelines
- Ability to share care plans across sectors and with patients

At the same time, experience from implementation has highlighted important limitations:

- Complexity in data exchange and reliance on data copying rather than real-time access

- Limited scalability when introducing new disease-specific care plans
- Tight coupling between clinical content and technical implementation
- Dependence on specific technical solutions and limited use of open standards

These limitations have led to a recognised need for modernisation towards a more modular, standardised, and interoperable architecture.

5.1.5 Policy direction and chronic care packages

Recent policy developments in Denmark further reinforce the importance of structured care planning. As part of the national health reform agreed in 2024, *chronic care packages* are being introduced as a new patient right.

These packages aim to ensure that patients with chronic conditions receive a coherent, proactive, and coordinated care pathway across sectors. In the first version care plans plays a central role as the tool that structures and documents this pathway, supports follow-up, and enables collaboration between general practice, hospitals, and municipalities.

While the detailed implementation of chronic care packages is still under development, they signal a clear policy direction: care planning will become an even more central element of the Danish healthcare system, with increased expectations regarding standardisation, interoperability, and support for coordinated, patient-centred care.

5.2 The Netherlands

5.2.1 Care Plans and the Health Care Information Models (HCIMs)

In the Netherlands, Healthcare Information Models (HCIMs, or “Zorginformatiebouwstenen”) are nationally defined, reusable building blocks that describe clinical concepts—such as problems, medications, allergies, and care plans—in a structured and standardized way.

The two Dutch HCIM links included here point to overviews of how these building blocks have been mapped to FHIR Care Plan resources. The first link shows which HCIMs are implemented in the FHIR CarePlan profile for FHIR STU3, and the second link provides the corresponding mapping for FHIR R4, allowing the reader to see which Dutch HCIM concepts are represented and how they are carried over between FHIR versions.

- [Nictiz STU3 Zib 2017 | nl-core-careplan - SIMPLIFIER.NET](#)
- [Nictiz R4 Zib2020 - SIMPLIFIER.NET](#)

Here are two examples of patient care plans modeled in FHIR in the Dutch national core profiles:

- An NL Core STU3 example of a CarePlan with a context, goal and activities: [Nictiz STU3 Zib 2017 | CarePlan for Paul XXX Mesker - SIMPLIFIER.NET](#)
- An NL Core R4 example of a CarePlan: [Nictiz R4 Zib2020 | CarePlan for Patient, Johanna Petronella Maria \(Jo\) van Putten-van der Giessen - SIMPLIFIER.NET](#)

5.2.2 The Santeon Shared Care Planning (SCP) Implementation Guide

Santeon (a collaboration of seven top-clinical hospitals in the Netherlands) created an implementation guide for “shared care planning” that builds on the FHIR CarePlan and CareTeam resources: <https://santeonnl.github.io/shared-care-planning/>. The original concept started as an experiment: use the existing clinical workflow as the engine that gradually assembles a care team around a patient and let the CarePlan be the resulting artifact rather than the starting point.

In the Santeon design, the care plan is not manually curated in a separate application. Instead, it emerges from the patient’s journey across organizations: each referral, order or service request between providers becomes input for the shared care planning service. That service is the single place where the CarePlan resource lives and is updated. Other actors – such as a GP or a hospital specialist – don’t all maintain their own copy. They submit tasks or service requests that function as “requests for change”: for example, to add or remove a team member or to mark an activity as completed. The shared care planning service has the “service role insight” to evaluate these requests and update the CarePlan and CareTeam accordingly, including setting members inactive when their treatment relationship ends.

Functionally, this model tries to use CarePlan and CareTeam as they are intended in FHIR: not only as documentation, but as the backbone for access control and coordination. Membership in the CareTeam drives who is allowed to see and act on the patient’s data. In theory, once the network of providers and relationships is captured, you could start to layer computable guidelines on top of it: computer-interpretable care pathways could generate or update parts of the CarePlan automatically, based on high-quality data and standardized workflows.

However, Santeon’s experience also underlines how hard this is to implement in a federated health system like the Netherlands. The current Santeon specification involves many transactions and dependencies between organizations. Looking back, the original design is considered as quite advanced and could be a bridge too far for broad implementation in today’s infrastructure. The underlying FHIR workflow building blocks (subscriptions, Task, ServiceRequest, and the evolving clinical order workflow IG) are still in flux, and most real-world implementations can only support a limited subset reliably.

As a result, Santeon’s shared care planning has so far been used in a limited, hospital-to-hospital context rather than as a fully realized, cross-sector national solution. The workflow portion – exchanging orders and referrals and driving Tasks between systems – is the part expected to see adoption first, as newer versions of the workflow and authorization specifications mature. The more ambitious vision – dynamically building a shared CareTeam across the whole care network and using it as the enforcement point for data access – remains a “maybe someday, maybe never” scenario. Nonetheless, it is a useful reference point for EHDS discussions: it shows both what a CarePlan-centric model could enable, and how quickly complexity explodes once you require multiple, heterogeneous organizations to participate in the same shared plan.

Here is an example of a process focused CarePlan (with a care team and tasks, but no goal and problem) as modelled in FHIR according to this model: [1.04.3 CarePlan creation - JSON Representation - Shared Care Planning \(SCP\) Implementation Guide v0.3.0](#)

6. The role of AI

Artificial intelligence, and in particular large language models (LLMs), is increasingly being explored in healthcare for tasks such as clinical documentation, summarisation, workflow support, guideline interpretation and decision support. These developments are relevant to the future evolution of digital care planning, but they also introduce important concerns related to reliability, transparency, explainability, accountability and clinical safety.

In the context of this deliverable, AI should not be understood as a replacement for structured care planning, clinical guidelines or professional clinical judgement. Rather, AI may support selected tasks around the Care Plan lifecycle, provided that its use is grounded in explicit, evidence-based and verifiable clinical logic.

This chapter therefore focuses on the potential role of AI in relation to Care Plans and Computable Clinical Guidelines. The central position is that AI may assist with structuring narrative guidelines, supporting workflow orchestration and improving usability, but patient-specific recommendations should remain based on deterministic, auditable and clinically validated rules.

Although AI may support care planning processes, several risks and limitations must be considered before AI-generated outputs can be trusted within clinical workflows.

Risk	Solution
Hallucinations in LLMs occur when a model generates data that is incorrect and not grounded in facts and not based on training data.	LLM accuracy can be improved by incorporating domain-specific knowledge through external documents. This process updates the model's knowledge base with relevant information, enabling it to base its responses on the new knowledge base. This technique is called Retrieval-augmented generation (RAG).
Bias can be introduced in LLM responses when the training data contains bias. Such biases can generate incorrect outputs.	Different techniques, such as self-supervision training can be utilized by AI vendors when training new LLM models.
Explainability: although LLM model can provide an accurate output, it is often impossible to accurately follow the logical path it took to reach that conclusion because the decision is based on billions of parameters and complex statistical probabilities.	RAG technique improves but not solves explainability. Improvement is achieved by forcing models to show their step-by-step reasoning, using tools that highlight which specific data influenced the final response most, and anchoring these insights to verified medical rules.
Loss of human expertise: constant relying on AI methods impact human decision making and	To prevent the loss of human expertise, systems based on AI methods must implement "human-in-the-loop" workflows and continuous training programs that

Risk	Solution
reasoning, which is manifested in the loss of human expertise.	encourage clinicians to critically challenge AI outputs using explainability tools, ensuring that domain expert remains the final, skilled decision-maker.

Artificial intelligence is already being applied in a wide range of healthcare scenarios, including clinical documentation, medical imaging, diagnostics, workflow support and patient communication. While these applications demonstrate the potential of AI to improve efficiency and support clinical practice, the use of AI in care planning requires particular attention because care plans directly influence clinical decisions, patient follow-up and coordination of care.

For this reason, the integration of AI into care planning should be considered within the broader context of clinical guidelines, decision support and patient safety. The following sections examine how AI may support the interpretation of clinical guidelines, the generation of structured clinical rules and the management of digital Care Plans.

6.1 Care Plan and Clinical guidelines in the Era of AI

Clinical guidelines stand as an evidence-based gold standard for everyday work in clinical practice. Any actual clinical guideline stands on the work of previous iterations and year after year increment updates based on research and clinical practice. Care Plans are often the result of applying and interpreting clinical guidelines where clinicians synthesise medical history, genetic factors, family history, lifestyle factors and other relevant considerations to tailor specific patient centric care plan.

As previously noted, 90% of clinical guidelines are unstructured, therefore limiting efficient integration into clinical workflows and the creation and management of structured Care Plans.

With the advent of AI, new possibilities emerge regarding clinical workflows empowered with

- a. clinical decision making assisted with LLM
- b. clinical guideline rules generation with LLM

Some of the ideas have already been scientifically and practically validated.

6.2 LLM as a decision support system

Several studies evaluate large language models used directly as clinical decision support systems, where LLMs generate diagnostic or management recommendations from patient data without executable guideline logic at runtime. In a real-world, EMR-embedded deployment across 16 primary-care clinics in Kenya, an LLM-based CDSS produced recommendations judged largely guideline-aligned, yet potentially harmful advice occurred in 7.8% of encounters, and clinician adoption was inconsistent, highlighting the absence of local guardrails, structured oversight, and explicit guideline linkage. Similarly, a prospective evaluation of an LLM-based CDSS for medication safety across 16 clinical specialties showed variable performance when used autonomously,

with improved outcomes only when deployed in a human-in-the-loop co-pilot configuration, underscoring the limitations of unconstrained LLMs as standalone CDSS components.

These findings are particularly relevant for digital care planning, where incorrect recommendations may directly influence treatment goals, planned activities and patient follow-up. They therefore highlight the importance of combining AI capabilities with structured Care Plans and explicit clinical rules.

6.3 LLM used to generate, apply, or navigate structured clinical rules

In contrast, other studies employ LLMs to generate, apply, or navigate structured clinical rules, rather than acting as autonomous decision-makers. A deterministic LLM framework for haemodialysis anaemia management demonstrated that when clinical protocols were explicitly encoded and enforced, guideline adherence increased from 32% under loose prompting to 100%, eliminating unsafe recommendations, with the LLM functioning as a constrained executor and explanation layer rather than an autonomous clinical decision-making system.

Complementary rule-generation and benchmarking studies show that while LLMs can assist in drafting or traversing guideline logic, they struggle to reliably follow multi-step, conditional clinical rules without explicit decision structures. Such approaches may provide an important foundation for future Care Plan systems, where guideline knowledge can be transformed into structured, computable and patient-specific care planning processes.

6.4 The challenges of probabilistic AI evidence

Recent analyses have highlighted a potential imbalance between the maturity of clinical evidence and the pace of adoption of different AI approaches in healthcare.

Several studies have argued that multiple randomized and externally validated AI systems capable of improving detection, risk stratification, and accuracy have not been systematically embedded into care workflows, whereas generative AI tools are increasingly relied upon for diagnostic reasoning without comparable real-world evidence. Complementary critiques of foundation models further argue that this imbalance reflects a structural mismatch, as probabilistic, general-purpose models are poorly aligned with the regulatory, auditable, and guideline-driven nature of clinical decision-making.

For Care Plan systems, these observations reinforce the importance of combining AI capabilities with structured data models, computable guidelines and transparent decision logic to ensure safe and consistent care planning.

6.5 Implications for Care Plans and Clinical Decision Support

Presented evidence indicates that LLMs can approximate clinical guideline logic and generate plausible clinical recommendations; however, this capability remains inherently unreliable when used without explicit structural constraints.

Across multiple studies, LLMs were shown to occasionally omit critical guideline steps, introduce unsafe recommendations, or diverge from intended care pathways, while clinicians often could not reliably distinguish correct from incorrect outputs.

Although LLMs can assist in generating clinical rules, translating narrative guidelines into conditional logic, and reasoning over decision paths, the resulting rule sets are:

- frequently inconsistent,
- non-deterministic,
- and sensitive to prompt formulation, with identical inputs producing divergent logic and corner cases or safety constraints commonly missed.

Consequently, human oversight remains necessary to validate and refine LLM-generated logic. Findings suggest that while LLMs can meaningfully support clinicians and guideline engineers by accelerating rule authoring and interpretation, safe clinical use requires that LLM-generated recommendations operate within strictly defined, deterministic clinical rules and logic, provided by CDSS systems, rather than acting as autonomous decision-making systems.

6.6 Where AI can help

6.6.1 Structuring of narrative clinical guidelines by LLMs

Current evidence supports exploring a workflow in which LLMs can be used to assist in the transformation of predominantly narrative clinical guidelines into structured, machine-interpretable clinical rules, while the application of those rules to individual patient contexts is performed by deterministic clinical decision support systems (CDSS).

LLMs are well suited to extracting decision logic, conditional pathways, and rule candidates from unstructured guideline text, thereby reducing the manual effort required to produce structured representations.

However, because LLM-generated logic is non-deterministic and may omit safety-critical constraints, these outputs require expert validation before use. Once validated, the structured rules can be ingested into CDSS platforms, which apply them consistently to patient-specific data to generate context-appropriate outputs, such as CarePlans, recommendations, or alerts.

This separation of concerns preserves the strengths of LLMs in guideline interpretation and knowledge structuring, while ensuring that patient-level decision making remains deterministic, auditable, and safe across both human-centered and AI-enabled clinical workflows.

6.6.2 Clinical workflows orchestration by LLMs

In advanced clinical architectures, LLMs can be used to orchestrate clinical workflows (rather than to replace clinical logic), coordinate guideline application, CarePlan lifecycle management, and interoperability transactions. In such a setup, the LLM operates at the workflow level—triggering and sequencing actions such as executing predefined IHE profile transactions, validating exchanged clinical information, and invoking deterministic CDSS services to generate or update patient-specific CarePlans. The use of IHE profiles is critical in this context, as they provide well-defined, semantically constrained transactions that align AI-driven workflows with established health information exchange (HIE) practices.

Example scenario:

In a newborn care scenario, an **IHE NANI** (Newborn Admission Notification Information) transaction can act as the initial trigger for the clinical workflow at birth, communicating core newborn demographics and admission context to downstream systems and initiating guideline-driven care processes.

From that point, an LLM can be used at the orchestration layer to coordinate interoperable actions, while deterministic clinical logic and standardized transactions remain authoritative by using **IHE CCG** (Computable Care Guidelines) transactions enabling standardized discovery, retrieval, and application of executable guideline logic.

Clinical logic is transferred to **IHE DCP** (Dynamic Care Planning) transactions which are used to create, update, and manage the newborn CarePlan as clinical events evolve (screening, vaccinations, monitoring).

Illustrative workflow:

- **Birth event and workflow initiation**
 - IHE NANI transaction notifies the health information exchange of a newborn admission and serves as a reliable event trigger for downstream clinical workflows
- **Guideline retrieval and execution**
 - An initial Care Plan template is generated and populated through workflow orchestration based on guideline recommendations and patient context.
 - LLM searches for appropriate guidelines in Guideline Repository with IHE CCG transaction (QRPH-61)
 - Neonatal guidelines are retrieved (QRPH-62) and applied (QRPH-64) by a CCG Engine to the newborn's clinical context.
- **Patient-specific care planning**
 - CCG Engine generates recommendations which LLM uses to update existing Care Plan by using IHE DCP (PCC-41) transaction.
 - As clinical events evolve (screening, vaccinations, monitoring) Care Plan is updated accordingly. LLM reacts to event-driven notifications received from point-of-care applications. E.g. nurses perform measurements and upon storing them in EHR LLM re-evaluates Care Plan by applying appropriate clinical logic via IHE CCG transactions and IHE DCP transactions for searching, retrieving and updating Care Plan.
- **Clinical document exchange and validation**
 - Screening results, discharge summaries, and other clinical documents are exchanged using IHE MHD (Mobile access to Health Documents) transactions, providing lightweight, standards-based access to clinical documents across systems and devices.

- **Workflow coordination and closure**

- The LLM coordinates the sequence of these steps—validating inputs, invoking CCG and DCP services, and tracking workflow state—without altering clinical logic.
- As required neonatal care activities are completed, the Care Plan reaches closure and the newborn transitions to routine care.

7. Care Plans and Computable Clinical Guidelines

7.1 Example implementations

7.1.1 WHO

The World Health Organization's SMART Guidelines (Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable) are a framework and methodology for transforming WHO clinical and public health recommendations into structured, digitally actionable content (i.e., computable clinical guidelines). Their purpose is to bridge the gap between evidence-based normative clinical and public health recommendations and real-world implementation in digital health systems. Rather than publishing guidance only as narrative PDF documents, SMART Guidelines encode clinical recommendations in formats that can be directly consumed by software, health information systems, and decision-support tools, enabling consistent, accurate, and scalable deployment of WHO standards across diverse country contexts in a transparent manner.

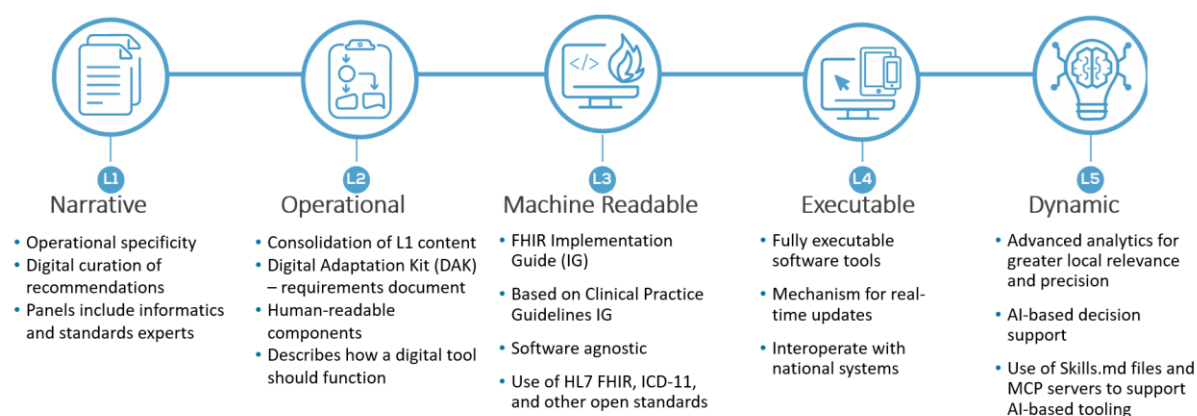


Figure 3. WHO SMART Guidelines architecture (L1–L5)

Layer 1 — Narrative guidelines (L1): This layer represents the narrative, human-readable, evidence-based clinical and programmatic recommendations as published WHO guidelines. It forms the authoritative source of normative content from which all subsequent layers are derived. WHO guidelines follow a rigorous living guideline development methodology through Cochrane systematic reviews and expert panels.

Layer 2 — Operational guidelines & Digital Adaptation Kits (L2): This layer translates narrative recommendations into structured business requirements and operational workflows. It defines the 'who does what, when, how and why' following human-centered design methodologies and standard business process modelling and decision modelling notation standards (BPMN and DMN). This results in a Digital Adaptation Kit with generic personas, user scenarios, business process workflows, a data dictionary, functional and non-functional requirements, and decision support logic and scheduling logic representing the normative clinical and public health recommendations in a semi-structured format.

Layer 3 — Machine-readable recommendations (L3): This layer encodes the clinical logic from L2 into computable, interoperable formats using HL7 FHIR and Clinical Quality Language (CQL). This includes FHIR resources such as PlanDefinitions, ActivityDefinitions, and Questionnaires, as well as

CQL libraries that express decision logic, eligibility criteria, and indicators in a form that systems can execute directly. It is software agnostic and provide evidence-based recommendations in discrete components that can be combined into a comprehensive care plan based on individuals' health status.

Layer 4 — Executable guidelines (L4): This layer establishes executable static algorithms and interoperable digital components to deliver the operational and functional requirements outlined in L2 using standards-based software agnostic content provided in L3. This also includes the testing and validation infrastructure to confirm that L3 machine-readable content correctly implements the original guideline intent.

Layer 5 — Dynamic Guidelines (L5): The emerging frontier of the framework, L5 layer envisions adaptive, AI-augmented guidelines and a precision health model that can learn and update based on real-world data, enabling continuous improvement cycles. This layer represents the integration of evidence generation, feedback loops, and potentially AI-driven clinical decision support into the living guideline ecosystem.

WHO SMART Guidelines applicability to care plans

SMART Guidelines machine-readable content (L3) is explicitly designed to interoperate with established health informatics standards rather than replace them. At its core, L3 leverages HL7 FHIR standard as the canonical representation standard, enabling WHO recommendations to be expressed as native FHIR resources that slot directly into existing national and facility-level FHIR-conformant infrastructure. This interoperability is particularly important for the modern concept of care plans, which require consistent representation of goals, interventions, activities, and outcomes across systems.

Care plans are a central mechanism in this integration: the FHIR Care Plan resource and its governing PlanDefinition act as the computable scaffold that sequences interventions, links clinical logic, and tracks patient-level progress against a WHO-recommended care pathway. A PlanDefinition encodes the population-level protocol — defining when and how to apply interventions — while a Care Plan instantiates it for an individual patient, binding the WHO guidance to a specific clinical encounter or longitudinal journey. By encoding guideline-driven decision pathways and data elements in machine-readable formats aligned with FHIR (including Care Plan, Condition, Observation, and ActivityDefinition resources), SMART Guidelines ensure that digital care plans remain evidence-based, updatable, and harmonized across platforms. This alignment enables countries to create longitudinal, person-centered, interoperable care plans that faithfully operationalize WHO recommendations within broader digital health architectures.

This architecture aligns with IHE profiles and other existing open standards allowing SMART Guidelines-derived content to be consumed by FHIR-native EMRs, CDS Hooks-enabled clinical decision support services, and terminology servers using ICD-11, LOINC, or SNOMED GPS. The result is a standards-layered approach where WHO normative content flows seamlessly into the same data and workflow infrastructure that countries are already building, ensuring that care plan execution reflects current WHO guidance without requiring bespoke system integrations.

The WHO SMART Guidelines framework demonstrates that guideline-informed and computable care planning is becoming an internationally recognised direction for digital health. The proposed Care Plan HID can be regarded as a complementary European initiative that supports similar objectives within the EHDS ecosystem.

7.2 Current landscape of standards

Current care planning initiatives are increasingly supported by open international standards that enable interoperability, structured data exchange and computable healthcare processes. Several standards and frameworks already provide capabilities relevant to the representation of Care Plans and Computable Clinical Guidelines (CCGs), although they differ in scope, maturity and intended use.

The purpose of this section is not to compare standards or recommend a single implementation approach, but to provide a brief overview of the most relevant standards currently used to support care planning, clinical workflows and guideline-based decision support. Understanding the strengths and limitations of these standards is important when considering the future implementation of a Care Plan HID and associated X-Bundles within the EHDS ecosystem.

Among the standards most relevant to care planning are openEHR, HL7 FHIR and the IHE integration profiles built on top of FHIR. Each addresses different aspects of digital health interoperability and provides capabilities that may contribute to the implementation of interoperable and computable Care Plans.

7.2.1 openEHR

openEHR is an open health data platform that focuses on the structured representation and long-term management of clinical information. Through its archetype-based modelling approach, openEHR provides mechanisms for representing care planning concepts, clinical observations and longitudinal patient information.

openEHR contains care plan archetypes ([Care Plan](#) and [Care Pathway Management](#)) in its core Clinical Knowledge Manager, but both are still in early alpha status.

A notable Care Plan implementation is the Dutch “[Ons Plan](#)” pilot on the Nedap Ons® platform, which has been in production for two years and plans to scale to over 2,000 customers. A cross-vendor hackathon is planned, and the Dutch elderly care branch organization ACTIS is considering governance of the model.

The Shared Care Plan initiative in London uses OpenEHR but mainly focuses on shared advance care planning and emergency protocols.

A key lesson from these efforts is that different clinical disciplines use different care plan structures, requiring models generic enough to accommodate all. For example:

- NANDA-NIC-NOC for nursing
 - Diagnosis (NANDA-I): Identify the patient's issue (e.g., Acute Pain).
 - Outcome (NOC): Establish expected results (e.g., Pain Control, with scores from 1-5).
 - Intervention (NIC): Select nursing actions to achieve outcomes (e.g., Pain Management: administering analgesics, teaching relaxation).
- SFMPC for elderly care physicians
 - Somatic, Functional, Mental, Psychosocial, Communication domains

For [guidelines](#), openEHR offers the [Guideline Definition Language v2](#) (GDL2), but this is limited to calculation rules and risk scores and is not suitable for complex decision trees or process workflows. Experimental [process support](#) has been paused due to implementation complexity.

Aandachtsgebied	Doel	Actie
5 Pijn, zwelling en complicaties	Verminderen van pijn en zwelling en het voorkomen van complicaties	Verzorgende - Wisselgigging Diëet - Voedingsadvies ter bevordering van wondgenezing Diëet - Medische Dienst (ij) - Zorg - Pijnbestrijding, wondzorg en controle op complicaties
Gemetastaseerd darmCA	Introductie vast voedsel	Zorg - Pijnscore bijhouden Diëet - Medische Dienst (ij) - Specialist Ouderengeneeskun... - 3x daags vast voedsel
Spijkracht	Verbeteren van mobiliteit en spierkracht	Zorg - zelfstandig transfers uitvoeren Diëet - Zorg - zoutarm dieet
gehoor	gehoorbescherming	Specialist Ouderengeneeskun... - inzetten
F Dagelijkse activiteiten	Herwinnen van zelfstandigheid in dagelijkse activiteiten (ADL)	Ergotherapie - Training in zelfzorg, hulpmiddelenadvies, oefenen van huishoudelijke taken Zorg - Stimuleren van zelfredzaamheid bij ADL client wast zichzelf heeft hulp nodig bij douchen kan zichzelf aankleden
Mobiliteit	Verbeteren van balans en stabiliteit 22 maart 2024 - Fysiotherapie bespreken	Fysiotherapie - Oefeningen voor spierkracht en coordinatie
	Opbouwen van mobiliteit en loopvaardigheid	Fysiotherapie - Oefeningen voor loopvaardigheid
Patient kan nog niet traplopen, maar dit wordt beter	zelfstandig kunnen traplopen	Fysiotherapie - oefeningen zelfstandig oefenen met traplopen Maatschappelijk werk - krachttraining

Figure 4. A visual representation of the first part of an SFMPC-structured care plan

7.2.2 HL7 FHIR / CQL

HL7 FHIR is currently the most widely adopted international standard for health data exchange and forms the foundation for many current and emerging EHDS interoperability initiatives. FHIR provides native resources for representing care planning concepts, making it particularly relevant for the implementation of a future Care Plan HID.

HL7 FHIR provides the [CarePlan resource](#) as part of its core specification since at least R4.

Multiple care plan models exist in the FHIR ecosystem: the International Patient Summary (IPS) includes [a narrative section with optional CarePlan references](#); the EU is developing [logical information models](#) and profiled CarePlan resources for [hospital discharge reports](#) and [imaging study reports](#); and the Netherlands has a [Shared Care Planning Implementation Guide](#) (built on IHE's Dynamic Care Planning profile), though adoption remains limited.

For computable guidelines, FHIR's [Clinical Practice Guidelines](#) (CPG) specification and [Clinical Quality Language](#) (CQL) are gaining traction, supported by PlanDefinition and ActivityDefinition resources that can encode clinical pathways and decision logic.

7.2.3 IHE CCG Profile

IHE has specified two relevant integration profiles on top of FHIR.

[Dynamic Care Planning](#) (DCP) defines transactions and actor roles for creating, updating, subscribing to, and sharing care plans and care team information across contributors and services.

[Computable Care Guidelines](#) (CCG) specifies how guideline-based clinical decision support can be distributed and applied. It does face some adoption challenges: the lead specifier of CCG has retired, some implementations exist in Denmark and Germany, and there is ongoing debate about the added value of the specification's folder/card concept over base FHIR capabilities.

Together, DCP and CCG provide complementary capabilities for sharing Care Plans and applying guideline-driven decision support, making them particularly relevant for future Care Plan implementations within the EHDS ecosystem.

8. Care Plan X-Bundle

The previous chapters have described the rationale for a Care Plan Health Information Domain (HID), its conceptual foundations, logical information model, and relationship to existing standards and computable clinical guidelines.

To support practical implementation within the European Health Data Space (EHDS), these concepts must be translated into reusable interoperability assets that can be discovered, implemented and governed across different healthcare systems and jurisdictions.

Within the xShare framework, this is achieved through the concept of X-Bundles¹. An X-Bundle provides a structured collection of artefacts, specifications and implementation assets that support a specific Health Information Domain and its associated business use cases.

This chapter introduces the proposed Care Plan X-Bundle and outlines how it can support the implementation of interoperable, guideline-informed and machine-readable Care Plans within the EHDS ecosystem. Particular attention is given to the relationship between the Care Plan HID, the xShare X-Bundle Registry and the xShare Care Plan Implementation Guide.



Figure 5. X-Bundle registry: care plan use case

¹ **X-Bundle registry** published in <https://x-bundles.ehr-exchange-format.eu/>. Please refer to xShare deliverable D2.8 section 4 for details about the **X-Bundle registry**.

The **Care Plan X-Bundle** is available in the **registry** and includes references to different categories of assets (see the following figure).

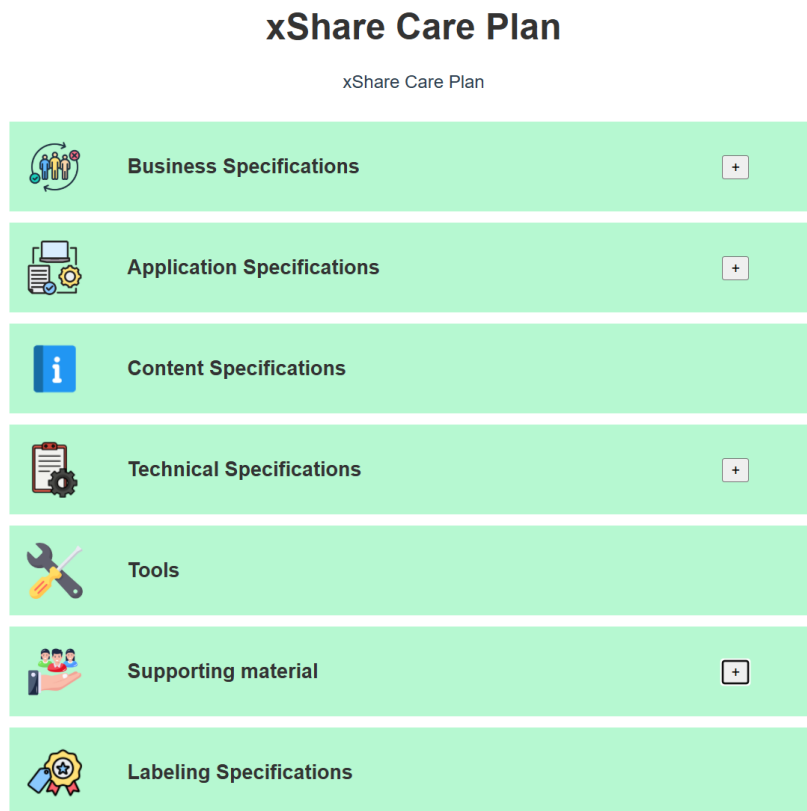


Figure 6: Care Plan artefacts categories

Taking as example the Content Specification (see figure below) two artefacts have been referred the current Xt-EHR logical model and the **xShare Care Plan Implementation Guide** collecting the relevant information needed for implementing this use case.

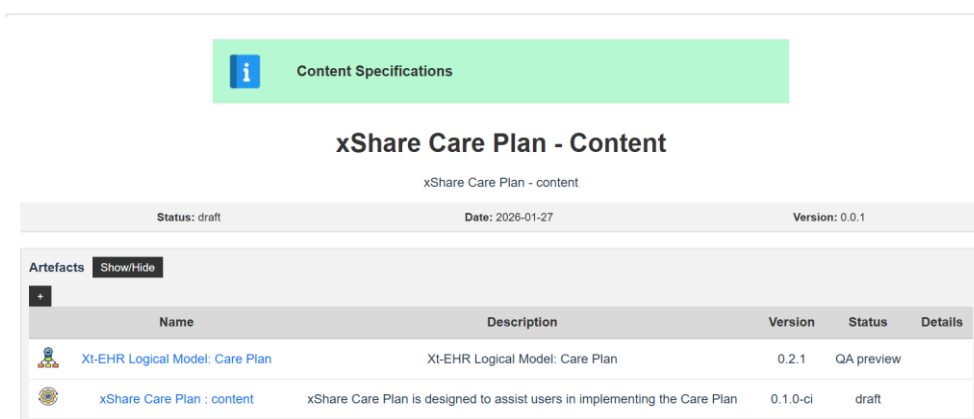


Figure 7: Care Plan X-Bundle : content specifications.

8.1 xShare Care Plan Implementation Guide

The **xShare Care Plan Implementation Guide** has been structured according to the BDAT model (Business, Data, Application, and Technology), as illustrated in the figure below.

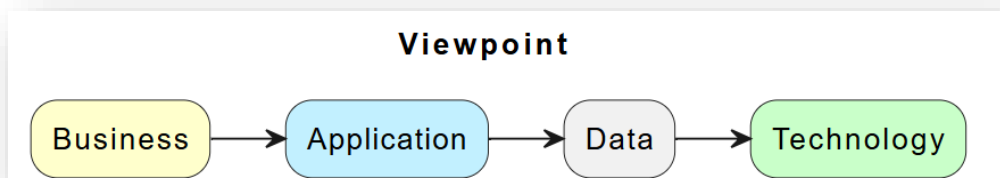


Figure 8: The xShare Yellow Button Implementation Guide approach

It provides in fact a:

- A **business viewpoint** describing the goals, business processes, how products are labeled, and rules of the xShare Care Plan.
- An **application domain** section describing what are the logical (software) components involved in the business processes and how they interact, collaborate, or are coordinated.
- The **data domain** page describes instead data models, the exchange formats and how the model is mapped into the profiles. In this section a **logical model for Care Plans extending the current XT-EHR** model has been developed and its representation in HL7 FHIR specified, providing also a formal forward mapping from the model to the HL7 FHIR Profile.
- And finally, a **technology** domain section describing the technology stack and the FHIR Profiles Used

In addition to this, the guide offers new readers a "**get started**" explaining in a simple and concise way to best utilize this guide.

Key Elements Table	Differential Table	Snapshot Table	Statistics/References	All	
Name	Flags	Card.	Type	Description & Constraints	Filter: ?
XShareCarePlan		0..*	EHDSCarePlan	Care Plan (Logical Model)	
header		1..1	Base	Elements defined in Ancestors: header, title, description, period, addresses[x], activity[x], goal	
title		0..1	string	Basic metadata for this information	
description		0..1	string	Human-friendly name for the care plan	
period		0..1	Period	A description of the scope and nature of the plan.	
addresses[x]		0..*		Indicates when the plan did (or is intended to) come into effect and end. Conditions/problems/concerns/diagnoses /etc whose management and/or mitigation are handled by this plan.	
activity[x]		0..*	Reference()	Binding Description: (preferred): ICD-10, SNOMED CT, Orphacode	
goal		0..*	CodeableConcept	The details of the proposed activity represented in a specific resource.	
realize[x]		0..*		Describes the intended objective(s) of carrying out the care plan.	
category		0..*	Instantiated Guideline		
careTeam		0..*	Category		
supportingInfo		0..*	Base	Care team / organization in charge	
goalDetails		0..*	Reference()	Evidence / supporting information	
category		0..1	Base	Goal	
target		0..*	CodeableConcept	Category (e.g., treatment, patient goal)	
due		0..1	Base	Goal target	
detailsActivity		0..*	date	Goal due date	
workflowStatus		0..1	Base	Activity	
narrative		0..1	code	Workflow status	
progress		0..*	markdown	Narrative	
performed		0..*	Annotation	Outcome, Progresses	
		0..*	Reference()	Performed activity	

Figure 9: The xShare Care Plan Logical Model

Name	Flags	Card.	Type	Description & Constraints	Filter: ?
CarePlan		0..*	CarePlan	Healthcare plan for patient or group	
instantiatesCanonical		0..*	canonical(PlanDefinition Questionnaire Measure ActivityDefinition OperationDefinition)	Instantiated Canonical	
instantiatesUri		0..*	uri	Instantiated URI	
status		1..1	code	Status of the care plan	
category		0..*	CodeableConcept	Kind of plan	
title		0..1	string	Care Plan Title	
description		0..1	string	Description of the care plan	
subject		1..1	Reference(Patient (EU core))	Who the care plan is for	
period		0..1	Period	Time period covered by the plan	
created		0..1	dateTime	Date the plan was created	
author		0..1	Reference(Patient Practitioner PractitionerRole Device RelatedPerson Organization CareTeam)	Who the plan is attributed to	
careTeam		0..*	Reference(CareTeam)	Participants in the care plan	
addresses		0..*	Reference(Condition (EU core))	Health issues this plan addresses	
supportingInfo		0..*	Reference(Resource)	Information considered as part of the	

Figure 10: The xShare Care Plan Profile

Mapping Context • Source logical model: XShareCarePlanModel • Target FHIR profile: XShareCarePlan						
XShareCarePlanModel to xShare CarePlan map						
XShareCarePlanModel (Logical Model)		Relationship	Target FHIR representation			
Element	Description	Relation	Resource	Element	Description	Notes
header	Basic metadata for this information.	related-to	CarePlan	.	Header-level metadata represented by native CarePlan resource metadata and elements.	The parent header is a grouping element; its child elements are mapped individually below.
header.subject	The patient whose intended care is described in the plan.	equivalent	CarePlan	subject	Who the care plan is for.	
header.identifier	Identifier for the care plan.	equivalent	CarePlan	identifier	External identifiers for the care plan.	
header.author[x]	The responsible party (custodian) for the care plan.	equivalent	CarePlan	author	Who authored or is responsible for the care plan.	
header.date	Date and optionally time of authoring/issuing.	equivalent	CarePlan	created	Date the plan was created.	
header.status	Indicates whether the plan is currently being acted upon, represents future intentions, or is now a historical record.	equivalent	CarePlan	status	Current status of the care plan.	
header.source	Source of information, e.g. patient, patient's representative, or health professional.	narrower	CarePlan	contributor	Who provided the content of the care plan.	

Figure 11: The xShare Logical model to FHIR Profile Mapping

9. Implementation Considerations for a Care Plan HID

The proposal for a Care Plan Health Information Domain (HID) extends beyond technical interoperability considerations. Successful implementation also depends on organisational, governance, policy and financing factors that influence how care planning is adopted and used within healthcare systems.

The experiences reviewed in previous chapters demonstrate that interoperable Care Plans can support care coordination, continuity of care and guideline-informed clinical practice. However, implementation across Europe will take place in healthcare systems with different levels of digital maturity, organisational structures, financing models and policy priorities.

This chapter discusses several key implementation considerations that may influence the adoption and long-term sustainability of a Care Plan HID within the EHDS ecosystem. The objective is not to provide definitive solutions, but to highlight factors that should be considered in future policy, governance and implementation activities.

9.1 Policy Intervention Disguised as Technical Specification

The proposal for a Care Plan HID is primarily presented as an interoperability initiative. However, the introduction of structured and shared Care Plans may also influence how healthcare systems organise and coordinate chronic care.

Care Plans support integrated and coordinated care processes by making goals, activities, responsibilities and outcomes visible across care settings. Their implementation may therefore encourage greater alignment between clinical practice, care coordination and health policy objectives.

The Care Plan HID is not intended to be regarded as a policy instrument. Nevertheless, its successful adoption may depend on broader policy frameworks that support coordinated and patient-centred care.

9.2 Maturity Heterogeneity Across and Within Member States

The digital maturity of care planning solutions varies significantly across Europe. Some Member States have already implemented national or regional care planning solutions, while others are still developing the necessary infrastructure, governance models and interoperability capabilities.

This diversity makes it difficult to define a single implementation pathway for a Care Plan HID. A flexible and incremental adoption approach is therefore likely to be more realistic than a mandatory implementation model.

The proposed Care Plan HID should provide a common interoperability framework while allowing Member States to adopt and implement Care Plan capabilities according to their national priorities, organisational structures and level of digital maturity. The Care Plan HID can provide a framework of sharing experiences and perhaps also data of high quality under EHDS.

9.3 Capacity and Incentive Gaps as Adoption Barriers

Successful implementation of a Care Plan HID depends not only on technical specifications but also on organisational capacity and incentives within healthcare systems.

Across Europe, healthcare organisations and Member States differ significantly in terms of digital infrastructure, workforce capabilities, governance structures and implementation experience. While some countries have already established mature care planning solutions, others are still developing the foundations required to support structured and interoperable care planning.

In addition, the benefits of coordinated care planning may not always align with existing organisational and financial incentives. Implementing shared Care Plans often requires investments in technology, workflow redesign, training and cross-organisational collaboration before the benefits become visible.

The adoption of a Care Plan HID should therefore be supported by appropriate governance arrangements, implementation guidance and capacity-building activities. Recognising these differences will be important for achieving sustainable and scalable implementation across the EHDS ecosystem.

9.4 Interdisciplinary vs. Multidisciplinary Care Models

Care planning is implemented within different organisational models across European healthcare systems. In some settings, healthcare professionals work primarily within discipline-specific processes and coordinate through referrals and clinical communications. In others, care is organised through integrated teams with shared goals, responsibilities and coordinated follow-up.

These differences influence how Care Plans are created, maintained and governed. Some care planning approaches emphasise coordination between independent providers, while others rely on shared ownership and collaborative decision-making within multidisciplinary care teams.

A future Care Plan HID should be sufficiently flexible to support different organisational models while maintaining a common structure for representing goals, activities, responsibilities and outcomes. This is important to ensure interoperability across healthcare systems with varying organisational traditions and levels of care integration.

The Care Plan HID should therefore be regarded as an interoperability framework rather than a prescription for a specific model of care delivery. The choice of organisational model remains outside the scope of the Care Plan HID and is a national, regional or local implementation decision.

9.5 Cross-Border and National Implementation Perspectives

The European Health Data Space is strongly associated with cross-border health data exchange. However, many care planning activities are primarily organised and managed within national, regional and local healthcare systems.

For patients with chronic conditions and long-term care needs, Care Plans are often closely linked to local care pathways, organisational responsibilities and healthcare services. As a result, the primary

value of a Care Plan HID may initially be realised through improved coordination and interoperability within national healthcare systems.

At the same time, the use of common European information models and interoperability specifications can support future cross-border use cases where appropriate. A shared Care Plan HID may therefore provide value both as a national interoperability framework and as a foundation for future European collaboration.

The balance between national implementation needs and future cross-border interoperability should be considered as part of the ongoing evolution of the EHDS ecosystem.

10. Conclusions and Next Steps

This is an interim version of the deliverable on Care Plans as a priority health data category in the EHDS. The next version, which will be the final one, will include more examples across Europe and will present also examples and use cases from the open calls.