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Review article

HL7 Fast Healthcare Interoperability Resources (HL7 FHIR) in digital healthcare ecosystems for chronic disease management: Scoping review

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ABSTRACT

Background: The prevalence of chronic diseases has shifted the burden of disease from incidental acute inpatient admissions to long-term coordinated care across healthcare institutions and the patient's home. Digital healthcare ecosystems emerge to target increasing healthcare costs and invest in standard Application Programming Interfaces (API), such as HL7 Fast Healthcare Interoperability Resources (HL7 FHIR) for trusted data flows.
Objectives: This scoping review assessed the role and impact of HL7 FHIR and associated Implementation Guides (IGs) in digital healthcare ecosystems focusing on chronic disease management.
Methods: To study trends and developments relevant to HL7 FHIR, a scoping review of the scientific and gray English literature from 2017 to 2023 was used.
Results: The selection of 93 of 524 scientific papers reviewed in English indicates that the popularity of HL7 FHIR as a robust technical interface standard for the health sector has been steadily rising since its inception in 2010, reaching a peak in 2021. Digital Health applications use HL7 FHIR in cancer (45 %), cardiovascular disease (CVD) (more than 15 %), and diabetes (almost 15 %). The scoping review revealed that references to HL7 FHIR IGs are limited to ~ 20 % of articles reviewed. HL7 FHIR R4 was most frequently referenced when the HL7 FHIR version was mentioned. In HL7 FHIR IGs registries and the internet, we found 35 HL7 FHIR IGs addressing chronic disease management, i.e., cancer (40 %), chronic disease management (25 %), and diabetes (20 %). HL7 FHIR IGs frequently complement the information in the article.
Conclusions: HL7 FHIR matures with each revision of the standard as HL7 FHIR IGs are developed with validated data sets, common shared HL7 FHIR resources, and supporting tools. Referencing HL7 FHIR IGs cataloged in official registries and in scientific publications is recommended to advance data quality and facilitate mutual learning in growing digital healthcare ecosystems that nurture interoperability in digital health innovation.

1. Introduction

Chronic diseases are conditions, including cancers, cardiovascular diseases (CVD), diabetes, chronic lung illnesses, and renal disease, frequently resulting in long-term treatment and care [119]. Their prevalence imposes significant challenges on healthcare systems representing around 70 % of disability-adjusted life years according to the Global Burden of Disease [1] and accounting for 74 % of all deaths worldwide according to the World Health Organization [2]. Escalating health costs forces health systems to restructure and invest in digital transformation [3].

Rationale: Managing chronic diseases calls for continuous monitoring and coordinated care involving citizens at home, leisure, or work [4]. Digital health products and services interconnected through digital

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health platforms facilitate communication among multiple health providers and institutions. [5]. In the resulting digital healthcare ecosystems, Application Programming Interfaces (APIs) ensure seamless and secure information sharing through standard interfaces and terminology, a fundamental requirement for the success of eHealth initiatives, according to the European Institute of Innovation and Technology [6]. The rising HL7 FHIR (Health Level Seven Fast Healthcare Interoperability Resources) popularity as a healthcare API makes it pertinent to understand, its role and impact in the disease management literature [7].

HL7 FHIR is an open standard developed in 2010 to exchange health data among healthcare information systems. It innovates from previous monolithic model-based HL7 versions by defining “resources” that represent clinical concepts that can be “profiled” to support complex healthcare scenarios. HL7 FHIR resources are used to store, exchange, and process data, supporting healthcare providers in making better-informed decisions. HL7 FHIR provides open RESTful (Representational State Transfer) APIs standards for health data exchange based on Internet standards. It works seamlessly with terminology standards such as ICDx, SNOMED and LOINC [7] and supporting services to convey the meaning of different terms associated with chronic diseases [120–124]. Value-based care and outcomes research are closing the loop with HL7 FHIR, facilitating process innovation, increasing care efficiencies and data quality [8]. HL7 FHIR is maintained regularly and its recent releases are Draft Standard for Trial Use 2 (DSTU2, 2014–15), Standard for Trial Use 3 (STU3, 2015–19) and Release 4 (R4, 2018–9, R4B, 2021–22 and Release 5 in 2023) [165].

In the digital health transformation view, HL7 FHIR as a healthcare API can play a transformative role in chronic disease management by allowing for the data integration from various sources including health providers and institutions, as well as health and wellness devices collecting patient-generated data [9]. Providers can access a comprehensive view of the patient’s condition, ensuring timely interventions and personalized care plan development, while, patients actively participate in their care by accessing and sharing their data and providing feedback [10]. HL7 FHIR Implementation Guides (IGs) play a crucial role in this ecosystem by providing detailed instructions on how to use HL7 FHIR for specific use cases, ensuring consistency and interoperability across diverse healthcare environments [11,12]. Platforms like SMART on FHIR provide a foundation for apps to run across diverse healthcare systems, ensuring that clinicians can access contextually relevant tools and information [13]. The HL7 FHIR impact extends to Clinical Decision Support Systems (CDSS) [14]. CDS Hooks using HL7 FHIR facilitate CDSS integration with digital health applications for real-time CDS [15] preparing the ground for Artificial Intelligence (AI) models deployment in federated architectures. The contribution of HL7 FHIR to chronic disease management also expands to clinical research and public health. Its open format facilitates the data aggregation and analysis across populations, conveying information in dashboards leading to new insights driving improvements in prevention and treatment [16,17].

The chronic diseases impact on the resilience of health systems and the prominent HL7 FHIR role in digital health ecosystems call for comprehensive understanding of the existing evidence, methodologies, and interventions that are essential to align independent efforts and advance interoperability. A scoping review offers an ideal approach mapping the existing literature to understand the range and nature of the evidence and qualify the HL7 FHIR impact on chronic disease management. Exploring different study designs, methodologies, and perspectives, a rigorous and systematic review at the confluence of HL7 FHIR and chronic disease management targets areas where technology, healthcare policies, and clinical practices converge. In this way, we hope to identify gaps and inform future research directions in policy-making and practice by highlighting areas where evidence is limited or inconsistent. Reflecting on the current knowledge, the groundwork for further in-depth studies and policy actions can be prepared, aligning with needs and opportunities in advancing healthcare interoperability and standards. As noted by J Pavão et al. [18], considering only scientific literature is a limitation, because industry studies that are not published in indexed journals or conferences can be excluded. Taking in account these considerations, this scoping review objective is extended to address this limitation and investigate HL7 FHIR IGs registries supporting chronic disease management to support digital innovation and entrepreneurship.

The next two sections detail the methodology and key results. The discussion section reflects on our results in the context of health policy and digital healthcare ecosystems, and it reports the limitations of our research. The paper concludes with our recommendations and acknowledgements of our research.

2. Methods

This scoping review is in strict compliance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) framework, a guideline designed to enhance transparency [19] (see Fig. 1). The following research questions (RQs) were applied to the scientific literature and HL7 FHIR IG registries aim to assess the potential impact of HL7 FHIR in chronic disease management:

- RQ1 – How many scientific papers and HL7 FHIR IGs apply HL7 FHIR in managing chronic diseases per year and in which geographic area?
- RQ2 – To what extent do scientific papers report use of HL7 FHIR IGs compared to listings in HL7 FHIR IG registries over time?
- RQ3 – What chronic diseases are managed by platforms based on HL7 FHIR?
- RQ4 – Which versions of HL7 FHIR dominate chronic disease management?
- RQ5 – What are the main reasons for using HL7 FHIR in chronic disease management platforms?

The methodological approach underpinning this research encompasses an exhaustive survey of scholarly literature, focusing specifically on research papers that use HL7 FHIR in chronic disease management. The databases employed in literature search were PubMed, Scopus, ISI Web of Science, and IEEE. As a referring period, we considered 2017–2023 because of the fast moving field; the first candidate Normative version R4 was released in 2018 and some researchers could use R4 for trial use some year before the final Normative release in 2019 [165]. The PubMed search query presented in Fig. 2 for reference, was adapted to the search of the other databases.

The query results were collected in August 2023. The following eligibility criteria were applied: (a) HL7 FHIR version, DSTU2 or later, HL7 FHIR IG publication date publication, 2016 or later; (b) HL7 FHIR implementation in the chronic disease management area including the sensor and device use in telemonitoring environments; (c) reference to one of six disease categories: cancer, CVD, diabetes, neurology including Parkinson’s and dementia, chronic lung disease, and renal; (d) disease management applies to the patient journey starting with prevention; (e) article or HL7 FHIR IG written in English with full text available; (f) scientific articles referring to communicable diseases, e.g. patients infected by HIV, were not in scope.

The paper selection process followed three steps (Fig. 1):

- **Step 1 – Identification**: the query was performed in the selected databases and duplicates were removed.
- **Step 2 – Screening**: title and abstract were reviewed to select articles that met the eligibility criteria. When in doubt, authors read the articles in full to confirm they did.
- **Step 3 – Inclusion**: selected articles were analyzed to extract the publication year, the HL7 FHIR version, whether HL7 FHIR IGs were

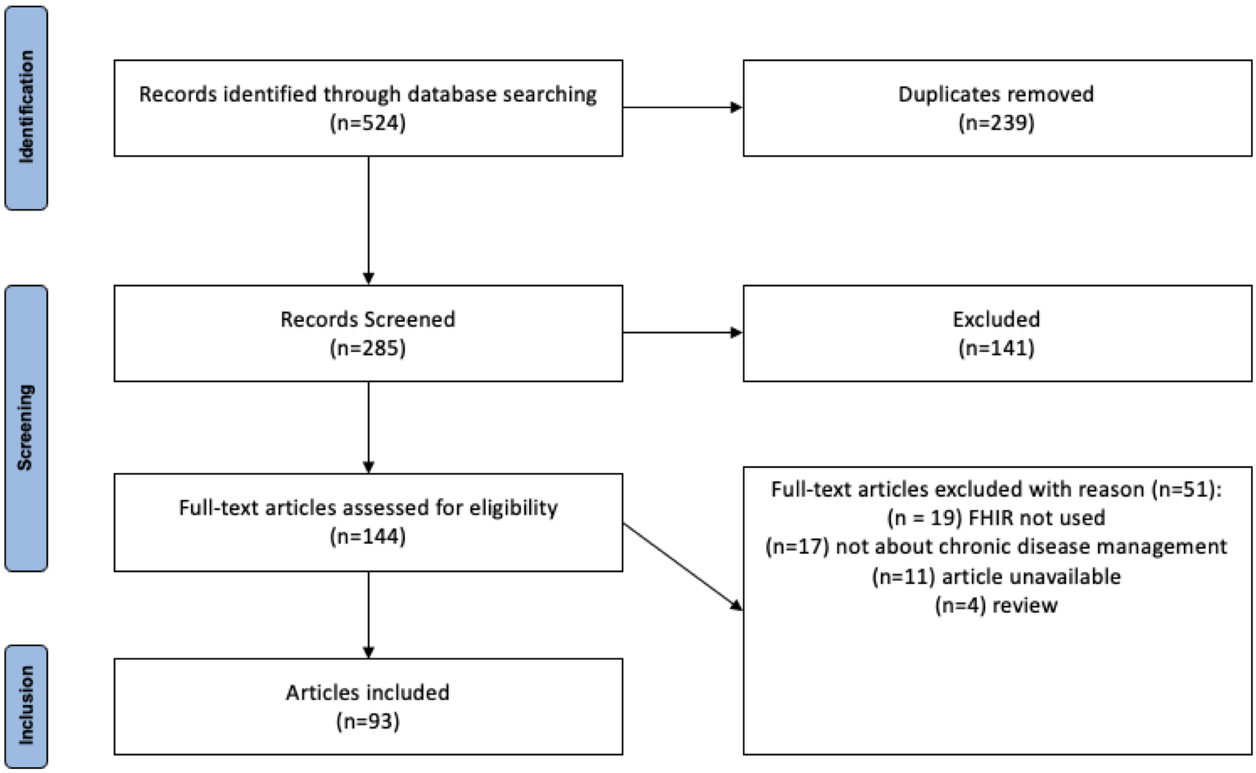

Fig. 1. Steps in article selection process and corresponding results according to the PRISMA-ScR method.

("FHIR"[All Fields] OR "Health Level 7"[All Fields] OR "Fast Healthcare Interoperability Resource"[All Fields] OR "Fast Health Interoperability Resource"[All Fields] OR "HL7"[All Fields]) AND ("Disease Management"[All Fields] OR "Managing disease"[All Fields] OR "Care coordination"[All Fields] OR "Chronic care management"[All Fields] OR "Health management"[All Fields] OR "Medical management"[All Fields] OR "Condition management"[All Fields] OR "Case management"[All Fields] OR "Healthcare coordination"[All Fields] OR "Illness management"[All Fields] OR "Treatment management"[All Fields] OR "cardiovascular"[All Fields] OR "stroke"[All Fields] OR "Coronary"[All Fields] OR "Heart Failure"[All Fields] OR "cardiology"[All Fields] OR "Dementia"[All Fields] OR "parkinson"[All Fields] OR "Alzheimer"[All Fields] OR "Cognitive"[All Fields] OR "COPD"[All Fields] OR "Chronic lung disease"[All Fields] OR " Chronic obstructive pulmonary disease"[All Fields] OR "respiratory"[All Fields] OR "pulmonar"[All Fields] OR "pneumo"[All Fields] OR "asthma"[All Fields] OR "oncology"[All Fields] OR "Cancer"[All Fields] OR "tumour"[All Fields] OR "kidney"[All Fields] OR " renal disease"[All Fields] OR " renal failure"[All Fields] OR "diabetes mellitus"[All Fields] OR "Diabetes"[All Fields] OR " DM2"[All Fields] OR "DM1" [All Fields] OR "T2DM" [All Fields] OR "T1DM" [All Fields]) AND (2017:2023[pdat])

Fig. 2. The reference query for this scoping review in PubMed syntax.

developed or used, applicable chronic disease, and geographic regions.

During the screening process, we worked collaboratively yet independently. In the event of divergence, consensus was achieved through discussion amongst us. HL7 FHIR IG registry [20], Simplifier [21], gray literature, and word of mouth were used as additional information sources for HL7 FHIR IGs applicable to chronic disease management. To perform this analysis, we queried HL7 FHIR registries for keywords related to chronic disease management or any of the six disease areas to retrieve HL7 FHIR IGs in the period 2016–2023 to cover DSTU2, STU3 or R4 [165].

3. Results

The research queries resulted in 161 records from PubMed, 218 from Scopus, 127 from ISI Web of Science, and 18 from IEEE, for 524 records in total (Fig. 1). After eliminating duplicate entries, 285 papers remained. Review of titles and abstracts based on selection criteria resulted in 144 articles for full-text review. Full-text review led to 93 articles stratified based on the HL7 FHIR version, HL7 FHIR resource profiling for disease management, HL7 FHIR IG use or development, and geographical scope. Table 1 reports the analysis results. The research queries performed on HL7 FHIR IG registries and other sources resulted in 35 HL7 FHIR IGs (Table 2). The summary of RQ results appears on Table 4.

HL7 FHIR and HL7 FHIR IGs in the scientific and gray literature: The HL7 FHIR version was specified in ~ 50 % of the articles: ~30 % used R4, ~15 % STU3, and ~ 5 % DSTU2. Only 3 articles (~3%) adopted a combination of its versions. However, ~80 % of articles did not indicate if HL7 FHIR IGs were adopted. In articles that used HL7 FHIR IGs, R4 was common. Considering the 35 HL7 FHIR IGs studied, more than 70 % were based on R4, ~20 % STU3, and 3 % DSTU2.

Why HL7 FHIR? In more than 50 % of the articles, it was used to broadly support *interoperability*, followed by ~ 30 % to feed *CDSS* and ~ 15 % to enable *data export*. When HL7 FHIR supported *interoperability* and *CDSS*, its version was frequently omitted. R4 was primarily mentioned in *data export*.

Was HL7 FHIR used uniformly for chronic diseases? In scientific literature, it was used primarily in cancer (~45 %) [22–617682], CVD

Table 1
Evidence of HL7 FHIR use in scientific literature, purpose of use, chronic condition, and geographical region.

Category	N/A (N = 46)	DSTU2 (N = 6)	STU3 (N = 12)	R4 (N = 26)	>1(N = 3)	Total (N = 93)
Main use of HL7 FHIR						
CDSS	14 (30 %)	2 (33 %)	3 (25 %)	5 (19 %)	3 (100 %)	27 (29 %)
Export	4 (9 %)	1 (17 %)	0 (0 %)	9 (35 %)	0 (0 %)	14 (15 %)
Interoperability	28 (61 %)	3 (50 %)	9 (75 %)	13 (46 %)	0 (0 %)	52 (56 %)
HL7 FHIR IG Creation or Use reported						
No	41 (91 %)	5 (83 %)	10 (83 %)	16 (61 %)	1 (33 %)	73 (79 %)
Yes	4 (9 %)	1 (17 %)	2 (17 %)	11 (39 %)	2 (67 %)	20 (21 %)
Category of Disease						
Cancer (or with diabetes)	19 (41 %)	1 (17 %)	**5 (42 %)**	14 (54 %)	2 (67 %)	41 (44 %)
Cardiovascular (or + cancer)	7 (15 %)	0 (0 %)	**4 (33 %)**	4 (15 %)	1 (33 %)	16(17 %)
Diabetes (or + renal or + CVD)	**7 (15.2 %)**	2 (33 %)	1 (8 %)	**3 (12 %)**	0 (0 %)	13 (13 %)
Chronic Disease management	4 (9 %)	2 (33 %)	0 (0 %)	2 (8 %)	0 (0 %)	8 (9 %)
Neurology (Dementia or Parkinson's)	5 (11 %)	0 (0 %)	0 (0 %)	1 (4 %)	0 (0 %)	6 (7 %)
Chronic Lung Disease (or + CVD)	2 (4 %)	1 (17 %)	1 (8 %)	2 (8 %)	0 (0 %)	6 (7 %)
Renal disease	2 (4 %)	0 (0 %)	1 (8 %)	0 (0 %)	0 (0 %)	3 (3 %)
Country or Geographic Region						
Europe > 3 countries	3 (6 %)	1 (17 %)	1 (8 %)	2 (4 %)	0 (0 %)	6 (7 %)
Germany	9 (20 %)	0 (0 %)	3 (25 %)	4 (15 %)	0 (0 %)	16 (17 %)
Italy	6 (13 %)	1 (17 %)	1 (8 %)	2 (8 %)	0 (0 %)	10 (11 %)
Netherlands	1 (2 %)	0 (0 %)	0 (0 %)	1 (4 %)	0 (0 %)	2 (2 %)
Spain	1 (2 %)	0 (0 %)	0 (0 %)	1 (4 %)	0 (0 %)	2 (2 %)
Norway	2 (4 %)	0 (0 %)	0 (0 %)	0 (0 %)	0 (0 %)	2 (2 %)
France	0 (0 %)	0 (0 %)	1 (8 %)	1 (4 %)	0 (0 %)	2 (2 %)
UK	0 (0 %)	0 (0 %)	2 (17 %)	0 (0 %)	0 (0 %)	2 (2 %)
Other Europe	2 (4.3 %)	0 (0 %)	0 (0 %)	2 (8 %)	0 (0 %)	4 (4 %)
Europe	***24 (52 %)***	***2 (33 %)***	***8 (67 %)***	***13 (48 %)***	***0 (0 %)***	***47 (50 %)***
USA	14 (30 %)	3 (50 %)	1 (8 %)	8 (31 %)	3 (100 %)	29 (31 %)
Colombia	0 (0 %)	0 (0 %)	2 (17 %)	0 (0 %)	0 (0 %)	2 (2 %)
Other America	1 (2 %)	0 (0 %)	0 (0 %)	2 (7.7 %)	0 (0 %)	3 (3 %)
America	***15 (33 %)***	***3 (50 %)***	***3 (25 %)***	***10 (37 %)***	***3 (100 %)***	***34 (36 %)***
South Korea	4 (9 %)	0 (0 %)	1 (8 %)	0 (0 %)	0 (0 %)	5 (5 %)
Other Asia	3 (7 %)	0 (0 %)	0 (0 %)	3 (12 %)	0 (0 %)	6 (7 %)
Asia	***7 (15 %)***	***0 (0 %)***	***0 (0 %)***	***3 (12 %)***	***0 (0 %)***	***11 (12 %)***
Rest of the World	7 (15 %)	0 (0 %)	1 (8 %)	3 (11 %)	0 (0 %)	12 (12 %)
International	0 (0 %)	1 (17 %)	0 (0 %)	1 (4 %)	0 (0 %)	2 (2 %)

(~15 %) [62–79], diabetes (~15 %) [7380–93], general chronic disease management (~10 %) [94–101], followed by neurology [102–107], chronic lung disease [71108–112], and renal disease [90113–115]. Table 3 reports the papers we found for each category of disease with the corresponding HL7 FHIR version adopted. R4 was frequently referenced in articles for cancer, while articles on diabetes treatment often cited DSTU2 and STU3. In HL7 FHIR IG registries, the most prominent were cancer (40 %), chronic disease management (~25 %), and diabetes (~20 %). Only ~ 5 % of HL7 FHIR IGs supported CVD and ~ 5 % neurology. We found one HL7 FHIR IG for diabetes + CVD and one for pulmonary. Most HL7 FHIR IGs for cancer were in R4, whereas in diabetes R4 and STU3 were equally used. There was also an HL7 FHIR IG for diabetes in DSTU2.

CDSS: Out of 27 papers on CDSS, 6 were on specific cancer types, i.e., breast cancer [22,40,45], cervical cancer [48,53], colorectal cancer [34], ovarian cancer [44], and melanoma [52]. There were also references to platforms for computable clinical guidelines [42,43,51,52,54,59] and supporting tools of care processes in oncology [29,34,44,54,99]. CDSS also addressed CVD [62,64,65,70,78], diabetes [81,90,92,93], chronic lung disease [112], and renal disease [113]. HL7 FHIR was used in multimorbidity i.e., cancer and diabetes [73,82] and cancer and CVD [76]. The semantic interoperability topic was also quite advanced in cancer research, with work in ontologies, semantic data models [32,56], minimal datasets (mCODE) [24], and OSIRIS [37]. ACTION-EHR [32] focused on exporting cancer data using HL7 FHIR. Frameworks or platforms also used it to facilitate secondary data use in public health registries and clinical trials [31,36,39,53,60,61]. Finally, there are works that address cancer patient-facing applications [29,41,49,57,58]. HL7 FHIR was used to integrate devices and systems for CVD + diabetes [49] and CVD + pulmonology [108]. HL7 FHIR-based integration was the topic of articles [62–65,67–72,75,78,86,95].

HL7 FHIR IG Registries: Table 2 shows the 35 FHIR IGs available to support chronic disease management. Only a third of the them, as represented in Table 3, were also referenced in the scientific literature with specific focus on patient reported outcomes [48,58], living environments [50,64,104,48,116,117], mhealth [95], personal health devices [32,71], and HL7 FHIR integration with genomics [23,26,28,46,55,61]. The most cited FHIR IGs are produced by HL7 International: HL7 Genomics Reporting followed by mCODE, Personal Health Devices, HL7 Clinical Practice Guidelines and oncology dktk on HL7 FHIR.

HL7 FHIR adoption across geographic regions: 50 % of the retrieved scientific articles report on research performed in Europe: Germany (~20 %), Italy (~10 %) or across Europe (more than 5 %), followed by more than 30 % in America, especially in USA. More than 10 % of the scientific papers report works in other regions and only two articles on international initiatives that involve different continents. Considering the geographic regions across the world, Table 2 shows that more than 50 % of the HL7 FHIR IGs identified were developed in Europe, i.e. Germany (~40 %), and across Europe (more than 10 %), followed by ~ 20 % at international level. America (all the USA) and the rest of the world cover each one more than 10 % of the identified HL7 FHIR IGs.

Table 2
Technical artifacts repositories in English found in the period 2016–2023.

Name	FHIR Version	Category of Disease	Country	First publication year	Considerations
Open mHealth to HL7 FHIR [128]	R4	Chronic Disease Management	International	2016	Security is not well addressed. It provides integration with mHealth data.
POWER2DM [129]	DSTU2	Diabetes	Across Europe	2016	Documentation is very poor. Address diabetes management.
rcpa [130]	STU3	Cancer	Australia	2017	Not available anymore.
InsulinOnFHIR [131]	STU3	Diabetes	Austria	2017	Documentation is very poor. Track insulin.
ClinicalIntegrationHub. CancerCareRecord [132]	STU3	Cancer	Germany	2018	Proprietary models used in the German healthcare system. Cancer Care Record.
HealthyMe [133]	STU3	Cardiovascular	Across Europe	2018	Focused on hypertension management, seems not maintained anymore. Solution is aimed at supporting self-management for specific groups of patients and their care providers.
nGHRUNCDStudy [134]	STU3	Diabetes	South Asia	2018	No info available. It claims Study into Diabetes and CVD prevention and control in South Asia.
FHIR Patient-Reported Outcomes [135]	R4	Chronic Disease Management	International	2018	Not available anymore.
Personal Health Device [136]	R4	Chronic Disease Management	International	2018	It's not clear if it can cover secondary use of data FHIR resources to convey measurements and supporting data from communicating Personal Health Devices (PHDs), strong documentation.
HL7 Genomics Reporting [137]	R4	Chronic Disease Management	International	2018	It seems It does not address the workflows around how reports are requested, created, approved, routed, delivered, amended, etc. This guide covers many aspects of genomic data reporting, it also has exhaustive documentation.
de.dktk.oncology [138]	R4	Cancer	Germany	2019	No functional details available. Data model of the German Cancer Consortium (DKTK) and the Comprehensive Cancer Center Network.
CCOR4.eClaims [139]	R4	Cancer	Canada	2019	No functional details available. Profiling regarding claims and patient information management.
HL7 FHIR Clinical Guidelines [140]	R4	Chronic Disease Management	International	2019	Clinical Practice and E**am**BM.
HL7 Clinical Practice Guidelines [141]	R4	Chronic Disease Management	International	2019	Clinical Practice and EBM.
oncology dktk on Fhir [142]	R4	Cancer	Germany	2019	No functional details available. Several aspects of cancer treatment information management.
Mcode [143]	R4	Cancer	USA	2019	MCode Initiative from US, to enable interoperability of oncology EHRs.
cca [144]	R4	Cancer	New Zealand	2020	It allows representation of cancer treatment regimens created by the Cancer Control Agency of New Zealand.
dmpd2 [145]	STU3	Diabetes	Germany	2020	No functional details available. Written in German, self-management of Diabetes Type 2.
BBMRI.de/GBA [146]	R4	Chronic Disease Management	Germany	2020	German Biobanks Alliance, linked with biobanks both within their consortium as well as with international biobank infrastructures such as BBMRI-ERIC.
GATEKEEPER FHIR [147]	R4	Chronic Disease Management	Across Europe	2020	It includes mapping of AI services in the FHIR operations.
central-cancer-registry-reporting [148]	R4	Cancer	USA	2021	Exchange of Cancer Registries and Patient Outcomes in the US between the Centers for Disease Control and Prevention.
colonoscopyreport.no [149]	R4	Cancer	Norway	2021	No functional details available. Norwegian Colonoscopy Report.
cancer-reporting [150]	R4	Cancer	USA	2021	Resources useful for Cancer Pathology, they also include specifications for conformance.
de.uk-koeln.nngm.registrationform [151]	R4	Cancer	Germany	2021	Almost no info available. Semantic part regarding cancer.
Portabiles-HCTParkinsonGoExportFormat [152]	R4	Neurology	Germany	2021	Poor Description. Profiling of resources regarding parkinson disease.
PanoramixGatekeeperIntegration [153]	R4	Neurology	Across Europe	2021	No functional details available.
iATROSPlatform [154]	R4	Cardiovascular	Germany	2021	No functional details available. App for the self-management of hypertension and related diseases.
mebix-app [155]	STU3	Diabetes + Cardiovascular	Germany	2021	Poor Description. Technical details of information exchange regarding hypertension.
Vitadio [156]	R4	Diabetes	Czech Republic, Germany	2021	Poor Description. App for the self-management of Type 2 Diabetes.
PanCareSurPass [157]	R4	Cancer	Across Europe	2022	It includes a Maturity Model for the artifacts that are ready to be tested.
codex-radiation-therapy [158]	R4	Cancer	USA	2022	It includes Conformance rules.
Una-Health [159]	R4	Diabetes	Germany	2022	No functional details available. App for the self-management of Type 2 Diabetes.
KataInhalation [160]	R4	Pulmonary	Germany	2022	Limited Description of the Guide not provided at the hl7.org web page. Profiling for asthma related data export.
Breast Cancer [161]	R4	Cancer	International	2022	No Security Implemented. Solution implementing PROMs for Breast Cancer and well detailed.

(*continued on next page*)

Table 2 (*continued*)

Name	FHIR Version	Category of Disease	Country	First publication year	Considerations
lung.ca.screen.assignment [162]	R4	Cancer	Thailand	2023	No functional details available. Educational purposes.
SugarTracker [163]	R4	Diabetes	Germany	2023	Little description and data. Examples of FHIR resources to be used in a blood sugar tracker app.

Table 3
Chronic disease management in scientific literature and HL7 FHIR IGs.

Category of Disease	FHIR Version	Scientific papers	Applicable HL7 FHIR IGs
Cancer	Multiple	[42,54]	–
	R4	[23,24,28,29,30,32,36,37,39,45,46,48,50,55,56,58,59,60,61]	[23,32,46,55,61] cited [137,60] cited [142,24,32,39] cited [143,36] cited [161,50] cited [140,48] cited [141,29] cited [146,32] cited [136] Not cited [138,139,144,148,149,150,151,157,158,162]
	STU3	[22,26,49,52,67]	Not cited [130,132]
	DSTU2	[44]	–
	N/A	[25,27,31,33,34,35,38,40,41,43,47,51,52,53,54,57,76,82]	–
Cardiovascular	Multiple	[64]	[64] cited [141]
	R4	[62,65,72,74]	Not cited [154]
	STU3	[63,67,71]	Not cited [133,155]
	N/A	[66,68,69,70,73,75,76,77,78,79]	–
Diabetes	R4	[88,87]	Not cited [156,159,163]
	STU3	[93]	Not cited [131,134,145,155]
	DSTU2	[84]	[84] cited [129]
	N/A	[73,80,81,82,83,85,86,89,90,91,92]	–
Chronic Disease management	R4	[58,71,95,100]	[23,32,46,55,61] cited [137,50] cited [140,48,64] cited [141,29] cited [146,32] cited [136,116,117] cited [147,95] cited [128,71] cited [135,71] cited [136]
	DSTU2	[94,101]	–
	N/A	[96,97,98,99]	–
Neurology	R4	[104]	Not cited [152,153]
	N/A	[102,103,105,106,107]	–
Chronic Lung Disease	R4	[108,110]	[71] cited [135,71] cited [136] Not cited [160]
	STU3	[71]	–
	DSTU2	[11]	–
	N/A	[109,110,112]	–
Renal disease	STU3	[114]	–
	N/A	[90,113,115]	–

HL7 FHIR in time: Fig. 3 depicts the scientific publications number in the chronic disease management area that apply HL7 FHIR in the period 2017–2023, against HL7 FHIR IGs developed in the period 2016–2023. The HL7 FHIR popularity peaks in 2021, is reflected in the scientific literature and the publication of HL7 FHIR IGs. Fig. 3 shows an increase in scientific publications starting from 2020 (13 papers) with a

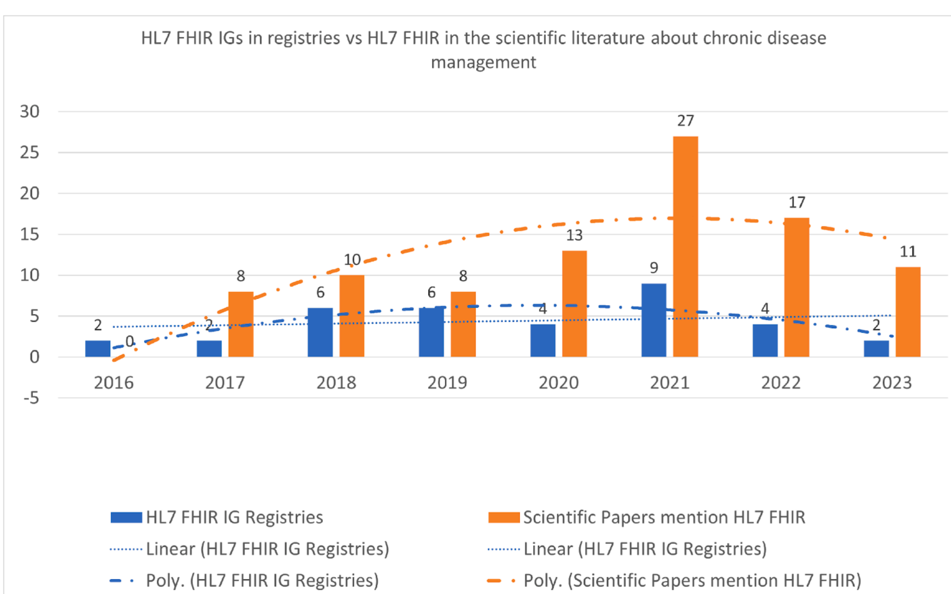

Fig. 3. Scientific papers per year on the use of HL7 FHIR in chronic disease management against published HL7 FHIR IGs.

peak in 2021 (26 papers) and a decrease in 2022 (17 papers) and in 2023 (11 papers).

4. Discussion

This scoping review was initially inspired by different European projects where HL7 Europe worked with stakeholders in the industry, government, and health care to develop HL7 FHIR IGs to support the management of some chronic diseases. The GATEKEEPER project, aimed to promote a healthier independent life of aging populations, many of which suffer from chronic disease [116,117], the PanCareSurPass project, aimed to optimize the Survivorship Passports generation for childhood cancer survivors [59], and the IDEA4RC project aimed to facilitate the re-use of health data on rare cancers among clinical centers [166]. Pointing at consolidating HL7 FHIR developments on chronic disease management as inspired by GATEKEEPER use cases and the Global Burden of disease [2], CVD, neurology, diabetes, and chronic lung disease, cancer and renal disease were considered, focusing on coordination and alignment between scientific work and development of HL7 FHIR.

HL7 FHIR version adopted: in more than half the scientific articles it was not mentioned, indicating limited focus on sustainability, except in cases where multiple diseases were considered. In the presence of an HL7 FHIR IG, the version could be identified. As this review refers to 2017–2023, we expected that R4 released in 2018 would be widely used as 55/93 articles were published after 2021 (Fig. 3). Despite that, 21 articles used previous HL7 FHIR releases. This indicates that it takes time for a new release to be adopted even in the research area, while it takes even longer in the real world.

Publication year: 2021 was surprising the year with the most published works in HL7 FHIR concerning chronic disease management. With 14 papers and 5 HL7 FHIR IGs published in 2020, COVID-19 highlighted the technology's role in addressing their unmet needs, as pointed out by P. Choudhary et al. [83]. The number of articles for 2023 concerns papers published by August and is thus underestimated. Looking at PubMed, the publication number on HL7 FHIR is steadily increasing, with 115 in 2023 versus 104 in 2022. This may mean that chronic disease management is maturing and of limited interest to research. HL7 FHIR IGs in registries can be updated to a newer HL7 FHIR version. In Table 2, the most recent update is considered.

HL7 FHIR use: its adoption for interoperability was most frequently the rationale, strengthening the its perception as a *tool to guarantee interoperability by design*. HL7 FHIR supported CDSS in 27 articles suggesting that SMART on FHIR or CDS Hooks were important facilitators for CDSS to integrate seamlessly with digital health applications and provide clinicians contextually relevant information. HL7 FHIR was used in 14 papers illustrating its role in reusing healthcare data and for that purpose R4 was most widely used.

FHIR IGs use: they were used in ~ 20 % of the articles, suggesting that the HL7 FHIR base specifications are robust, comprehensive and versatile for most use cases limiting the need for resource profiling. This is a testament to the foresight and the progressive HL7 FHIR design, given that chronic disease management includes complex disease pathways and care workflows. Only a third of the HL7 FHIR IGs were cited by a scientific paper. This is an indication that HL7 FHIR IG creation is driven by industry rather than research/academia. Finally, HL7 FHIR IGs developed by HL7 International were most frequently cited confirming its authority.

Lesson learned: in 93 scientific articles reviewed, best practices for employing interoperability standards exemplified by HL7 FHIR emerged. In reporting HL7 FHIR use, authors should maintain clarity, precision, and comprehensiveness. They should: (a) detail the HL7 FHIR version, as the standard continually evolves; (b) describe the HL7 FHIR resources, profiles, and IGs used to provide readers with a clear understanding of HL7 FHIR components in the study; (c) contextualize the HL7 FHIR choice within the research study objectives to offer insights into its relevance and utility; (d) document profiles and HL7 FHIR resources extensions to ensure reproducibility and transparency; (e) list HL7 FHIR IG in one of the public registries.

Following these best practices, an HL7 FHIR IG can advance interoperability with reproducibility and further development of the results reported. Such practices facilitate peer reviews, replication studies, and further advancements in the field, upholding integrity, and credibility of the research. Following the systematic HL7 FHIR application in academic research, we can foster a collaborative environment where knowledge is built upon shared foundations, driving innovation, and enhancing patient care in the digital health landscape. Some preliminary results in this direction have already appeared in social media [118]. In this context collaboration among scientific societies and standards developing organizations is key to advancing interoperability in digital health ecosystems.

Chronic Disease categories: most articles addressed issues with cancer and the same holds true for HL7 FHIR IGs, a fact that can be attributed to the burden of disease, and the academic funding available. However, the HL7 FHIR IG number to support diabetes was higher than the number of academic papers on diabetes reporting use of HL7 FHIR. This difference could be related to providers of insulin monitors that have developed an HL7 FHIR IG to differentiate quality in their products. This aspect confirms what was indicated by J. Pavão et al. [18], who observed that only focusing on scientific literature may exclude potential interesting industrial studies that were not published in indexed journals or conferences.

Country and Geographic Region: even though we considered only articles in English, top regions were USA, Germany, and Italy. Among broader geographic regions, most articles were published by Europeans, sometimes linked to European Commission funded research. There were very few international studies. In HL7 FHIR IGs despite language limitations, Germany was most active, followed by international initiatives across Europe or USA. HL7 FHIR IG registries had more international initiatives than those reported by scientific articles. Europe was the continent with the most implemented HL7 FHIR IGs. Thus, international initiatives to define global specifications are needed to support interoperability in chronic disease management. HL7 FHIR accelerators play an important role in that setting.

Next steps and future works: a track during the HL7 Europe WGM2024 and FHIR Marathon focused on cancer mission projects to compare existing European FHIR Cancer-related scenarios and Implementation Guides was organized.

4.1. Limitations

Our results are limited in several ways. First the scope review queries are limited to full text articles available in English. This limitation precludes in part insights into national health system developments and could be the result of a separate study. Second, HL7 FHIR IGs are limited to those available in global HL7 FHIR IG registries, when several countries maintain their own HL7 FHIR IG registries. This limitation impedes insights into national standards activities and HL7 FHIR profiles. Lastly, our analysis excludes technical infrastructure challenges e.g. data privacy and security, as our scoping focus has been HL7 FHIR IG and supporting tools for interoperability in chronic diseases, which are an increasing burden for the health systems world wide. Implementing HL7 FHIR entails additional challenges such as interoperability issues between varied healthcare systems, ensuring data privacy and security, and keeping up with evolving standards, for which tangible guidance has eluded this review.

5. Conclusions

This review revealed gaps in using HL7 FHIR for chronic disease management. Interest in the topic picked up in 2021, as shown in Fig. 3. Articles usually omitted the FHIR version (Table 1, column "N/A"), and

R4 was the most adopted HL7 FHIR version in literature followed by STU3 (Table 1, column "R4" and "STU3"). Results highlighted increasing international community interest in HL7 FHIR as a tool to guarantee interoperability by design to allow CDSS to integrate seamlessly with digital health applications and to enable data re-use (Table 1, section "Main use of HL7 FHIR"). On the other hand, the need for the definition of HL7 FHIR IGs was not sufficiently evident in research. In fact, the available HL7 FHIR IGs were not cited (Table 1, section "HL7 FHIR IG Creation or Use reported", row "No"). Among chronic diseases, cancer-related articles used HL7 FHIR the most (Table 1, section "Category of Disease", row "Cancer (or with diabetes)"), also creating or using HL7 FHIR IGs (Table 2, column "Category of Disease", value "Cancer"). A significant HL7 FHIR IG number supported diabetes, illustrating the importance of HL7 FHIR IG registries and following best practices (Table 2, column "Category of Disease", value "Diabetes").

Europe with Germany and Americas with the USA are top in academic research (Tabel 1, section "Country or Geographic Region", rows "Europe", "Germany" and "USA") and HL7 FHIR IGs development (Table 2, column "Country", value "Across Europe", "Germany", "USA"). However, the low number of academic articles with an international focus suggests that more is needed for HL7 FHIR IGs to support interoperability globally (Table 1, section "Country or Geographic Region", row "International"). The HL7 International FHIR IGs were most cited in the literature since information on HL7 FHIR IGs was not in scope.

Considering the evolution of HL7 FHIR IGs in time and its specific use in chronic disease management, we observed HL7 FHIR resources are re-used, and complex concepts are thoroughly explored as the scientific community explores standardization of personalized care pathways standardization, combined with genomics and AI use. While significant progress has been made, a substantial need for ongoing research, policy-making, and clinical practice improvements remains. Future efforts must align with the domain's most pressing needs and opportunities in the domain, ensuring that the full HL7 FHIR potential is realized in the quest for better healthcare outcomes. Thus, the foundations laid by this review will act as a springboard for informed decision-making, facilitating further studies and policy development that are attuned to the nuances of chronic disease management in the digital age.

The HL7 FHIR implications in chronic care are evolving, offering possibilities for enhancing healthcare delivery and outcomes. As technology and healthcare become intertwined, HL7 FHIR becomes a vital connector. Its implementation streamlines communication between various stakeholders and promotes efficient, effective, and patient-oriented chronic disease management. Integration with legacy systems, variability in global adoption, and the necessity for specialized training pose additional hurdles that healthcare systems must navigate to optimize the HL7 FHIR use in improving patient outcomes.

The reported methods and results may be transferable to other areas in the health sector landscaping the standard use and identifying gaps (see Table 4). Future studies and perhaps synergies with scientific societies in medical informatics could inform topics such as communicable diseases, behavioral change, and clinical research, particularly in the context of cross-border exchange context [125–127,164] and the health data spaces (HDS) like the recent provisionally approved European HDS.

Table 4
Summary of Findings.

Research Question	*Result*
RQ1 – How many scientific papers and HL7 FHIR IGs apply HL7 FHIR in managing chronic diseases per year and in which geographic area?	From 595 papers, after applying the eligibility criteria we ended up with 93 scientific papers and 35 HL7 FHIR IGs
RQ2 – To what extent do the scientific papers report use of HL7 FHIR IGs compared to listings in HL7 FHIR IG Registries over time?	There was a pick for scientific papers using HL7 FHIR in 2021 (27). The number of HL7 FHIR IGs for chronic disease management present a much lower pick (9) in the same year.
RQ3 – What chronic diseases are managed by platforms based on HL7 FHIR?	Cancer, diabetes, pulmonology
RQ4 – Which version of HL7 FHIR dominates chronic disease management?	R4 followed by DSTU2 and STU3
RQ5 – What are the main reasons for using HL7 FHIR in chronic disease management platforms?	(a) Support interoperability (b) feed data to CDSS (c) enable data export

CRediT authorship contribution statement

Roberta Gazzarata: Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Joao Almeida:** Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Lars Lindsköld:** Writing – review & editing, Methodology, Investigation, Data curation, Conceptualization. **Giorgio Cangioli:** Writing – review & editing, Investigation. **Eugenio Gaeta:** Writing – review & editing, Validation, Data curation, Conceptualization. **Giuseppe Fico:** Writing – review & editing, Validation, Resources, Methodology, Conceptualization. **Catherine E. Chronaki:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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