

Archetype-based electronic health records: a literature review and evaluation of their applicability to health data interoperability and access

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Abstract

Health Information Managers (HIMs) are responsible for overseeing health information. The change management necessary during the transition to electronic health records (EHR) is substantial, and ongoing. Archetype-based EHRs are a core health information system component which solve many of the problems that arise during this period of change. Archetypes are models of clinical content, and they have many beneficial properties. They are interoperable, both between settings and through time. They are more amenable to change than conventional paradigms, and their design is congruent with clinical practice. This paper is an overview of the current archetype literature relevant to Health Information Managers. The literature was sourced in the English language sections of ScienceDirect, IEEE Explore, Pubmed, Google Scholar, ACM Digital library and other databases on the usage of archetypes for electronic health record storage, looking at the current areas of archetype research, appropriate usage, and future research. We also used reference lists from the cited papers, papers referenced by the openEHR website, and the recommendations from experts in the area. Criteria for inclusion were (a) if studies covered archetype research and (b) were either studies of archetype use, archetype system design, or archetype effectiveness. The 47 papers included show a wide and increasing worldwide archetype usage, in a variety of medical domains. Most of the papers noted that archetypes are an appropriate solution for future-proof and interoperable medical data storage. We conclude that archetypes are a suitable solution for the complex problem of electronic health record storage and interoperability.

Keywords (MeSH):

Medical Informatics; Decision Making, Computer-Assisted; Review; Medical Records; Database Management Systems; Information Storage and Retrieval

Supplementary keywords:

Archetype-based Electronic Health Records; Semantic Interoperability

As we develop as an information society, many occupations which formerly dealt with physical things now deal increasingly with information. This change was originally experienced by desk-bound office workers, but it is now spreading out, affecting the work of teachers to police, farmers to fishermen. While HIMs have always been information workers, the information revolution does not bypass the other clinical disciplines. As such, in the health arena, both information production and information demand are growing

at a great rate. This trend is evidenced by overflowing medical record filing rooms, and multiple medical files specific to various purposes (e.g. the situation where there are multiple files held for a single patient, such as where a patient has a file with each of the Royal District Nursing Service [RDNS], community health services, and acute/inpatient care facilities). Electronic health records (EHRs) solve this problem, but the solution itself has potential to incur trauma. The pain of implementing an EHR, including the systemic change

necessary to accommodate it, will be followed by further challenges in future years, when the system needs to be reconfigured to accommodate the changing health landscape. It appears that health information managers face the task of accommodating a continually changing set of systems that will fulfil health information needs.

This bleak outlook is coincident with current EHR implementations. The paper medical record did not have this problem; in the past, although innovations were comparatively few, accommodation of change was dealt with simply through the addition of a new paper form, pinned neatly into the record. Change in the paper record is much easier than that in the current EHR contenders, where changes are often expensive, slow to implement, and unsatisfying, at least until they are accepted by the users through a combination of continued use and gradual system modification.

The name of the discipline itself, *health information management*, means that HIMs will bear some responsibility for this unhappy situation, whether they like it or not. Health information management means different things in its various contexts, but at a bare minimum, HIMs are responsible for storing health information. In addition, the demands on health information are increasing and changing; there are pressures for health information to interoperate between services and to be useful for decision support. As information proliferates and information demands increase, the situation worsens, and the current health information management toolset does not serve well.

This paper discusses archetype-based EHR systems (henceforth *archetype systems*). Archetype systems are tools that address the above problems; they specify open and standard medical information access and exchange protocols, thereby making the information interoperable and accessible. The standard is designed to be future-proof; while it can be extended to accommodate future demands, historical data also remain accessible, and more importantly, retain their semantic meanings. Information stored in an archetype system interoperates both between different institutions, and between present and future of a single institution.

Archetype systems are also designed to accommodate the rapid change in health knowledge; this means that, while change in medical knowledge still occurs, the resulting change in the information system is much less painful. In addition to this, the standardisation of archetype systems means that decision support interfaces do not have to be rebuilt for every healthcare situation; instead, the infrastructure can be used across the sector, which avoids the reinvention of the wheel. Finally, there is a standard archetype query language, allowing easy access to custom reports and views, easing the pressure for custom reports (Ma et al. 2007).

Archetype systems, as a component of EHR, were first proposed by an Australian team in 1998, working on extending the Good Electronic Health Record (GEHR) project (*openEHR* Foundation 2009a). This paper traces archetype system research conducted over the past 10 years, referring to both case studies and descriptions of tools for building and working with archetype-based data. We discuss and define archetype systems, pointing out the problems they are meant to solve and their provenance, structure, and usage. Specifically, we explore their suitability to health data storage requirements and talk about how they address these problems. The results section has three parts, showing archetype system comparisons, application domains, and places where archetypes are being used.

Paper-based medical records are useful because of their flexibility, allowing an informal recording of information (Coiera 2003). This is useful in the medical realm, because the structure of such information is changing rapidly. This informality is flexible, but as health information systems become more tightly coupled, this informality does not serve us well; the data recorded in paper based medical records are not easily interoperable. As well, the data are not machine processable, leading to difficulties with aggregation (as in epidemiology applications) and computerised decision support and clinical guidelines. Interoperability is crucial in the medical realm. Medicine is complex and interconnected, and will become more so; communication is essential. The problem is that the interoperating systems must agree about

the data that are to be transferred at semantic, structural, and format levels, and traditional solutions to this problem make for high levels of engendered interdependency. This agreement tends to make the interdependent systems brittle and difficult to change; a change in the data sender necessitates changes in all the listeners, and vice versa. This problem is compounded by the fact that health data are constantly changing.

Health information systems are not easy to design and implement, due to the complexity and breadth of the domain, and the speed at which it changes. Moreover, such systems contain two types of knowledge: computer technical and domain medical. Communication between these domains is necessary for successful system construction, but it increases system implementation difficulty. It also imposes a future cost, due to internal interoperability constraints; changes in the medical realm impact on the technical realm, and vice versa. It makes sense to have a minimal coupling between these domains, to minimise the effects of changes.

Interoperability problems are solved by all the players carrying out compatible actions; one way to ensure this compatibility occurs is through standards for representing and communicating with EHRs. Such standards structure and mark up the clinical content for the purpose of exchange (Eichelberg et al. 2005). However, standards are only a partial solution to this problem, as they cannot cover (a) the area of medical knowledge that is changing, and (b) the part of the medical organisation that is learning. For this reason, health data need a method that can accommodate such change. The stated overall problem lies in syntax, format, and semantics. Syntax and format are problems in their own right, and there are standards that address these problems. The present paper addresses the semantics problem; the data need to have common meaning between communicating entities. It should be noted that such communicating entities can be separate institutions, or they can be the same institution, separated by time. Archetype systems address both these cases.

The semantic problem has been addressed by both the European Committee for Standardisation (CEN), and the International Standards Organisation (ISO). On the recommendations of

an EU report on EHR (empirica GmbH 2008), CEN has recently adopted archetype systems as the basis for their EHR communication standard, CEN 13606. This work then formed the basis for the ISO standard, ISO13606, made up of 5 parts (International Standards Organisation 2009). We focus on that standard, both its provenance and features of systems based on the standard. There is also work within the HL7 organisation to make their infrastructure compatible with the standard (Schloeffel et al. 2006). This exercise in congruence continues to date, but there remain differences between ISO 13606 and HL7 archetype-based models that have not yet been overcome. Key components of ISO 13606 are a reference model (RM) and archetypes. We explain these components and detail systems based on these concepts. For the present purposes, we use the term *archetype systems* when referring to systems based on both the RM and archetype concepts and the word *archetypes* to mean clinical archetypes.

The health archetype concept

The health archetype concept was first mentioned as part of the Australian project GEHR. The work was continued by the *openEHR* foundation, which is an international not-for-profit body, campaigning to make the interoperable, life-long EHR a reality and to improve health care in the information society (*openEHR* Foundation 2009b). The foundation has done substantial work with the archetype-based health system concept; it publishes specifications, maintains a repository for completed archetypes, and has recently released *The Clinical Knowledge Manager*¹, a web-based tool for collaborative development, management and publishing of archetypes (and related resources) (*openEHR* Foundation 2003).

A more detailed survey and analysis of EHR standards is presented in Eichelberg et al. (2005), who discussed HL7 and Digital Imaging and Communications in Medicine (DICOM) in addition to CEN and *openEHR*. These authors compared the standards in terms of the content structure, the access service, the security features, the combination of EHR

¹ <http://www.openehr.org/knowledge/>

content and communication protocol standards, and the market share. Eichelberg et al. argue that *openEHR* and CEN 13606 converge into a harmonised EHR architecture. Our paper will review archetype system research to date, focusing on *openEHR*-based work. Due to the similarity of archetype-based models, the discussion is relevant to, and sometimes refers to, the other models.

Archetype systems are designed to store medical data. A key feature of an archetype system is that it is made up of a two-level architecture: the RM, which is a reference object model, and archetypes, which are constraint models that accord with the RM. Archetypes are clinical knowledge objects, designed to model standard ways of storing chunks of health information. The RM consists of a set of reference types, and each archetype is based on one of these types (Kalra & Ingram 2006). The two-level architecture means that technical concerns are separated from clinical (Garde et al. 2006). The RM is an object-oriented model used to represent the generic and stable properties of health record information. It contains a set of primitive types, a set of classes that define the building blocks of EHRs, and a set of auxiliary classes that describe the context information to be attached to an EHR annotation (Moner et al. 2006).

The RM defines a basic structure for the data that will be stored, consisting of a relatively small number of classes that support medico-legal requirements and record management functions. The functionality of the reference type is passed on to the child archetypes that inherit from it. For example, if a reference type has a *patient* element, its children will also have a *patient* element. The RM provides the infrastructure for storing and validating generic archetypes. The clinical knowledge is not hard coded into the database or the application, but contained within the archetypes themselves. This means that archetypes can evolve, without having to change the RM.

The archetypes then define a model structure for specific sets of health data. They then specify both the types of data that can be put in the structure (e.g. number, text, or even other archetypes), and validation rules for it. The cluster of data in a single archetype is contextualised. For example, *heart attack* in a family

history archetype has different semantics from *heart attack* in a presenting problem archetype. Other basic archetypes include Observation, Evaluation, Instruction, and Action archetypes.

The archetypes can then be further constrained and combined to make up larger, more functional templates, generating artefacts that represent useful clinical elements, such as forms (Román, Roa et al. 2006). For example, a blood pressure archetype has components that could be used in a nursing observations template.

An archetype consists of various sections (Fernández-Breis et al. 2008).

- header - containing the archetype names and the specialisation information
- description - containing authoring information, lifecycle status, and archetype purpose
- definition - the clinical concept that the archetype represents, described in terms of reference model entities
- ontology – containing links to terminologies and bindings. (It is to be noted that while archetypes themselves are terminology-neutral, they can link to external terminologies like SNOMED CT [Garde et al. 2006]).

Archetype systems are the application of the frame logic concept (Kifer, Lausen & Wu 1995) to health information. These ideas were further explored by Beale (2002), where he provides the motivation for archetype systems, and describes a formal archetype language, identification and specialisation features and querying capabilities. A summary of the theoretical model, and a justification for the top level reference model categories can be found in Beale & Heard (2007).

The ISO 13606 standard is a subset of the *openEHR* work. The *openEHR* architecture specification consists of three components: the reference model, the archetype model, and the service model. The reference model provides identification, access to knowledge resources, data types and structures, versioning semantics, and support for archotyping. The archetype model package contains the models necessary to describe the semantics of archetypes and templates, and their use within *openEHR*. The service model includes definitions of basic services that allow access to the data contained in the previous two models (Fernández -Breis et

al. 2008). ISO 13606 excludes the service model (Martínez-Costa et al. 2009).

As mentioned earlier, clinical information systems need to be interoperable among external entities due to, for example, shared care (Garde, Knaup et al. 2007). Also, data need to be interoperable between independent internal entities, for example, between the data set and a decision support system. Finally, they have to be interoperable through time in a single entity's information storage, to make a health system future proof. Román, Roa et al. (2006) noted that archetype systems provide knowledge-level interoperability, that is, the ability of systems to reliably communicate at the level of knowledge concepts.

Under this paradigm, the interoperability problem is solved by (a) having a common RM, and (b) using common archetypes. Templates then are used to combine archetypes, strip out unneeded optional elements of archetypes and further constrain archetypes – so that they can be used in a concrete clinical setting. Because archetypes are a maximal data structure, they are designed to not need expansion or modification due to local circumstance. This gives them stability and standard structure, with the data stored in a standard, accessible format. That said, health information systems (HIS) need to be able to readily accommodate change.

Change is accommodated in an archetype system in a number of ways: by further constraining an archetype, or by combining custom archetypes with standard archetypes. Both of these situations leave the original archetype intact, with the data stored in a standard, known structure. With appropriate governance of these archetypes, a safe evolution of data structures is provided, with the meaning preserved: archetypes preserve semantic interoperability, semantic interoperability, and syntactic interoperability (Garde, Knaup et al. 2007). The stored data remain accessible, and therefore, more useful. Finally, archetypes can be readily communicated and stored, because they are each based on types from the common RM. Archetype systems were designed to not only solve the interoperability problem. Garde et al. (2006) listed eight problems that apply to the current ways we store clinical data, even when these data are

stored in a standardised format. These include missing common data types and presentation format, missing proper structure, lacking integrity constraints, and inability to represent time series and context. Archetype systems address these issues.

Method

For the present paper, we gathered references appropriate for an audience interested in implementing archetype systems. For this purpose, we sourced papers in the areas of archetype system definition, relationships to international standards, comparisons with existing paradigms, examples of archetype system usage and design. We excluded papers that use archetype systems as a basis for more complex processing, such as integration with ontologies.

We sourced conference papers, journal articles, book chapters, and theses published between 2000 and 2008. We carried out a literature search in ScienceDirect, IEEE Explore, Pubmed, and ACM Digital library and other databases using the terms 'archetype', 'openEHR', and 'CEN 13606'. As mentioned, the *openEHR* Foundation is the peak body for archetype systems worldwide, while ISO 13606 is the international archetype-based standard. We gathered references from the *openEHR* website, and from the reference lists of papers found by the above methods. Finally, we asked for recent unpublished work, through both the *openEHR* mailing list and via direct email with authors who have published widely in the field.

In our search, we found 115 references. Using the criteria mentioned above, 68 were beyond the scope of our topic, as judged by either the article title or abstract. We sourced 47 papers appropriate to our topic. The papers show that the archetype systems research area is rich and diverse, and that archetype systems are being applied in a variety of settings and locations.

Table 1 – Archetype Systems Application Areas

AREA	NOTES
Aged care (Hovenga & Garde 2007)	Looks at the advantages of openEHR in aged care and describes a process for developing archetype systems in this setting.
CAM (complementary and alternative medicine) practitioners (Smith & Kalra 2008)	Describes the applicability of archetypes to represent EHR data in the CAM domain
Nursing (Hovenga, Garde & Heard 2005)	Looks at openEHR archetype system applicability in nursing. The authors noted that nursing could benefit from the domain expert empowerment that comes from archetype usage.
Disease surveillance (Bellika, Hasvold & Hartvigsen 2007)	This example used an archetype system in the implementation of an open source communicable disease surveillance system (the Snow Agent System). In addition to interoperability, archetypes were useful because they were able to validate both user-supplied data and provide definitions for concepts such as 'possible disease X', 'probable disease X', and 'confirmed disease X'.
Discharge summaries (Moner et al. 2008)	This paper describes a tool, LinkEHR-Ed, used to standardise existing hospital discharge summaries and convert them into archetype format.
Security concerns (Sucurovic 2007)	Focuses on the security aspect of MEDIS, a web-based EHR system based on ENI 3606 standards. They noted that the distribution rules defined in the reference model contains sufficient information to precisely constrain access control.

Table 2 - Worldwide Archetype Use

PLACE	NOTES
Germany	Describes a state-of-the-art integrated system, integrating both archetypes and HL7 paradigms in a hospital setting (Blobel 2006).
Australia	A case study as part of a Master degree thesis, describing a roadmap for implementation of archetype based EHR in the Austin Hospital Emergency Department, Melbourne. This included history, architecture, and the relationship of archetypes to other data standards (Gök 2008).
Australia	Description of the Australian General Practice Computing Group (GPCG) archetype system based field trials in South Australia (Bird, Goodchild & Tun 2003).
UK	UK archetype system progress report circa 2007 (Leslie 2008).
Denmark	This article describes the transition from the standard health model to a more modular archetype system model. The authors note that archetype systems 1) allow users to take control of granularity, 2) implement EHR systems, and 3) are helpful for user interface composition purposes (Bernstein et al. 2005).
Netherlands	Reports of two archetype systems, built around the PropeR platform. They are for treatment of stroke, and haematology. This work shows that archetypes can be used for complex integrated care both within and outside of hospitals in an acute care setting. Their system also has an integrated DSS. Tange et al. 2002; van der Linden, Boers et al. 2003; van der Linden, Tange et al. 2003; van der Linden et al. 2004; van der Linden et al. 2005).
Brazil	Brazil has a national project for electronic data interchange between health plans and providers using the openEHR methodology ¹ , and is doing research into heterogeneous systems ² .
Latin America	Is using archetype systems in ontological research in the areas of clinical care and practice modeling, and for clinical protocol standards. ³

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- 1 Personal communication, Rigoleta Dutra, 26 March 2006
- 2 Personal communication, Marceo Rodrigues dos Santos, 29 March 2009
- 3 Personal communication, Dr Carol Hullin Lucay Cossio, 9 March 2009

Results

Currently, archetype systems have been reported to be used in a variety of settings and with respect to various clinical disciplines. Table 1 displays the domain areas where archetype systems have been used, while Table 2 shows their geographic range.

Because health is a complex arena with multiple competing standards, archetype systems are often described in comparison to other existing standards. These discussions include:

- a comparison between archetype systems and variously, guidelines, standards, and terminologies (Hovenga & Garde 2007)
- the relationship between CEN 13606, HL7, and *openEHR* (Schloeffel et al. 2006)
- a comparison between the usability of HL7 and *openEHR* when used for the purpose of developing local templates (Hoy et al. 2009)
- a comparison between the archetype systems designed for the Danish Aarhus project with the *openEHR* models. The authors noted that there is a trade-off between ease of use and flexibility of the model, depending on the comparative sizes of each of the models. A larger reference model (such as found in the Aarhus project) makes it easier to model, as more choices have been pre-made at the reference level, but the resulting model is less flexible (Michelsen et al. 2005)
- a contrast between *openEHR* archetype systems with the Julius archetype system, part of the Swedish Swedestar system. Julius implements a smaller scale of archetype than *openEHR*. The author recommended switching to the *openEHR* model to gain connection to terminologies and increased interoperability (Chen, Enberg & Klein 2007).

In an ideal world, all data would be in a single standard format, and there would be few interoperability issues. In the real world, data are used for different purposes and exist in different formats. Román, Roa et al. (2006) proposed a federated decentralised demographic information system based on an archetype system. They described the reconciliation of archetype-based information with other demographic standards.

While the base driver for archetype systems is interoperability, their consistent and self-describing structure provides support for various analysis tasks such as quality management and

health policies. Gall et al. (2008) noted how archetypes facilitate data integration, cohort formation, variable selection (including context related variables), time course analysis, and query formulation. As well, the availability of archetype structure leads to interesting applications. Sundvall et al. (2007) described an information visualisation tool for time varying health data based on archetypes.

Electronic decision support systems (DSS) are another driver for EHR use. Archetype systems especially support DSS, because the data are well-structured. Also, the archetype's standard format, across a variety of settings, makes the DSS tools more widely available (Niès, Steichen & Jaulent 2007). Such an application can be found in Barretto, Warren & Goodchild (2004), who described the delivery of evidence-based care using guidelines and archetype-based EHR. Here, an archetype system also encouraged appropriate information collection, provided a base data source for guidelines, and helped structure the care workflow.

Archetype system design is not a trivial task. Archetypes can be obtained from an archetype repository, but developing these archetypes needs domain knowledge-governance processes (Garde, Hovenga et al. 2007; Garde, Knaup et al. 2007). Alternatively, archetypes and templates can be developed locally, as detailed in Hoy et al. (2009). A business process to facilitate archetype development is described in Kohl, Garde & Knaup (2008), whereas a method for validating designed archetypes can be found in Chen et al. (2008). At a larger level, Lopez and Blobel (2009) proposed an interoperable system-modelling methodology incorporating archetypes.

Discussion

One problem with HIS implementation is the necessary coordination between technical and medical domain experts. We noted that this problem can be addressed by having minimal coupling between the domains. Archetype systems have this property. Archetypes are meant to be designed by domain experts, whereas the reference model design is largely a technical task.

According to Glass's law, 'requirement deficiencies are the prime source of project failures' (cited in Qamar & Rector 2007: 16).

The adoption of archetypes and templates replaces the need for providing detailed technical requirements at the clinical level. An additional bonus is that archetype systems can be designed in parallel, with reference design happening concurrently with archetype design. This separation also empowers domain specialists, allowing them to define the informational concepts they work with and to have direct control over their information systems.

The structure associated with archetypes has other follow-on effects. First, clinical terminology use is simplified because the archetypes allow the segmenting of terminologies (Garde, Hovenga et al. 2007). Second, because the archetype-based data are well-described, querying can be facilitated, based on this known structure (Ma et al. 2007; Román, Madinabeitia & Reina 2006). Archetype systems have a logical theoretical framework, are well-designed, and are gradually being used in systems worldwide. Tools and methodologies to aid in archetype system usage are being developed, and various governments are sponsoring their usage. That said, archetype systems are not ubiquitous, despite the clear benefits that would result from such ubiquity.

Adoption of archetype-based systems is impeded by the nature of complex systems. Successful complex systems do not arise 'holus bolus', they evolve from less complex systems. Archetypes are data storage components, and changing system data storage is large scale change. A more gradual upgrade path is needed. Another problem with archetype adoption is the lack of practical benefits, as interoperability is largely theoretical until multiple sites are using archetypes. Also, a future proof system can only be experientially validated over time.

Archetype adoption could be aided through government support; their use could be specified via contractual terms. Archetype use of standard and open data models means that vendor lock-in is eliminated. This would disadvantage the powerful established systems vendors, and this is a problem.

The health data environment is inarguably a large complex system. There are multiple players, complex interdependent data, unknown current and future applications, and unknown future data. Due to these uncertainties and

interdependencies, being the first mover down the archetype path has real costs. In some sense, archetype developers are waiting on systems developers, and vice versa, slowing progress. However, progress is being made. Hullin Lucay Cossio² reported that there are unpublished/unused archetypes, waiting for applications to use them. McCauley³ reported that members of the medical software industry of Australia are implementing archetypes. Another solution is to build concurrently the domain knowledge and the technical implementation. Atalag⁴ is developing an open-source endoscopic reporting software implementation project, along with an extensive (translated into 10 languages) archetype for colon endoscopic findings.

Archetype systems will exist in a heterogeneous data storage world, with many different applications, and data storage appropriate for each. Due to this, there is much research based on dual model systems, such as the delivery of RM conformant extracts from existing non-archetype based systems⁵. Other current archetype-based research problems include⁶:

- the boundary problems between the archetype system model and terminology systems;
- convertibility between major archetype and non-archetype standards;
- knowledge management with respect to archetype based EHR development, and
- machine reasoning based on combined semantics of EHR models and ontologies.

Conclusion

The present review, based on 47 papers published between 2000 and 2008, describes the state of archetype research and implementation progress. It shows where and for what purpose archetypes are being used, and it demonstrates both their appropriateness as a solution to the interoperability problems and their usefulness in other areas of health information. While the review found no examples of substantial archetype-based health infrastructure, there were many instances

2 Personal communication, Dr Carol Hullin Lucay Cossio, 9 March 2009

3 Personal communication, Vincent McCauley, 10 March 2009

4 Personal communication, Koray Atalag, 17 March 2009

5 Personal communication, Georg Duftschmid, 9 March 2009

6 Personal communication, Rong Chen, 3 April 2009

of archetype-centred research and widespread pilot usage. This is appropriate, as the change necessary when moving to an archetype-centred health system is substantial. However, such change is occurring and will continue to do so. It is a virtuous cycle: as archetype systems gain in popularity their value becomes increasingly more apparent; and as researchers and practitioners gain more experience in archetype use, archetypes become even more useful.

Widespread implementation of archetype-based systems will greatly simplify and enrich the health information environment, easing the process of future change and making the current situation much more tractable. For the promise of computer-enhanced medicine to be realised, we will need this or something with similar characteristics: well-designed structure, future proof, open standard. However, the inertia and entrenched positions associated with the current health information system slows the adoption process.

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