

Architectural Key Dimensions for a Successful Electronic Health Record Implementation

Eduardo Pinto and António Carvalho Brito

*INESC TEC, Faculdade de Engenharia, Universidade do Porto
Rua Dr. Roberto Frias, 4200-465 Porto, Portugal*

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Abstract: The availability of patient clinical data can be vital to a more effective diagnosis and treatment, by a healthcare professional. This information should be accessible regardless of context, place, time or where it was collected. In order to share this type of data, many countries have initiated projects aiming to implement Electronic Health Record (EHR) systems. Throughout the years, some were more successful than others but all of them were complex and difficult to materialise. The research involves the study of four international projects – in Canada, Denmark, England and France – launched with the goal of fostering the clinical data sharing in the respective countries, namely by implementing EHR-like systems. Those case studies served as data to identify the critical issues in this area. To address the challenge of sharing clinical information, the authors believe to be necessary to act in three different dimensions of the problem: (1) the engagement of the stakeholders and the alignment of the system development with the business goals (2) the building of complex systems of systems with the capability to evolve and easily admit new peers (3) the interoperability between different systems which use different conventions and standards.

1 INTRODUCTION

Healthcare is one of the areas where new Information Technologies (IT) caused huge impact. Throughout the years, the society's dynamic changed appearing an increasing necessity for sharing clinical information among different healthcare institutions (Haux, 2006). Several projects were launched in many countries, such as in England or Canada for instance, with the goal of creating the well-know Electronic Health Record (EHR) systems. An EHR is a “longitudinal collection of electronic health information about individual patients and populations” (Gunter and Terry, 2005). The main objective is to provide clinical information about a patient where it needs to be consulted, independently of its origin or location, helping to avoid clinical errors or duplication of efforts and resources. Usually, these initiatives are not confined to the EHR concept. In this sense, the last years brought an emergent paradigm in which the patients have the control over the information about themselves as long as their involvement in the process also grows (Ball et al., 2007). The Personal Health Records (PHR) – which are systems whereby individuals can access,

manage and share their health information which can be accessed by others in a private, secure, and confidential environment (Connecting for Health, 2003) – are the best example of it. On the other hand, the excess of information might be a trouble in different situations. For that reason, some countries adopted concepts like Patient Summary (PS) (epSOS, 2012) which is a set of information that allows a healthcare professional to have a quick and easy overview over a clinical history.

This research intends to understand the extent of the challenge that constitutes the implementation of a system like an EHR as a facilitator of clinical data sharing among several institutions, from an architectural point-of-view. In order to do so, four international cases were selected: Canada, England, Denmark and France. Basically, these projects were selected for different reasons: Canada has a lot of information publicly available and that stands as official information; the English project was always a very famous, controversial and apparently not so well succeeded project; Denmark is known as one of the most successful countries in this area and France has been investing in this field for the last decade. These case studies were analysed and dissected based on

information from official on-line documentation and scientific articles. Along with that, the authors expose the current methodologies, models and technologies that better address those challenges.

The paper starts with a description of the international case studies and their experience of these implementations at Section 2. From that analysis, the authors extract the main challenges in these projects and describe the state-of-the-art that allows to respond to those challenges, at Section 3. Finally, the paper's conclusions are presented at Section 4.

2 RELATED WORK

Several initiatives to implement EHR projects have been created over the years in several countries. Some countries have achieved more than others, but the common experience says that it stands not only as a technological challenge, but way beyond that (Anderson et al., 2006; Jha et al., 2008; Protti et al., 2009).

2.1 Canada Case Study

In Canada, its First Ministers created a non-for-profit organization called Canada Health Infoway back in 2001 and the effort would exceed 1.5 billion dollars (Canada Health Infoway, 2009). In order to guide the development of the systems in each different province, Infoway provided a set of principles, guides and components, called EHRS Blueprint. EHRS Blueprint advocated the creation of a shared reference information source that is populated by several health-care organizations around Canada and is maintained externally from every health-care organization (or Points of Service, as designated in EHRS Blueprint). The Points of Service (PoS) are able to reference or pull data from the shared repository. In fact, there is not one single EHR, there are several (EHRi) replicated through the country, with the same structure, that are responsible for interacting with the local entities (PoS). The EHRi information is stored as copy of the original one and the EHR Blueprint was built following a Services-Oriented Architecture.

The critiques started to raise up when one of the Infoway's goals of having 50 per cent of Canadians with an electronic health record available by 2010 was not met. McGrail et al. (McGrail et al., 2010) argued that "after billions of dollars and nearly a decade of work by Infoway and the provinces, Canada is well back of the electronic records pack" and that Canada's "laggard position is certainly not a question of software design or lack of access to user-friendly technologies". On the other hand, the same study

pointed out some issues of lack of clinicians engagement, e-health policy and a focus on national perspective rather than the regional one. Along with that, six provincial auditors joined and produced a report raising the possibility that the programme needs more funds (Legislative Audit Offices, 2010). More recently, Webster (Webster, 2011) advocated a change of strategy following British recommendations for not keep going with a top-down approach that is crafted with insufficient engagement of clinical users.

2.2 Denmark Case Study

At the end of 1994 the project organisation MedCom was created and mandated to establish a nationwide health care data network based on the Electronic Document Interchange (EDI) concept. The project was to be completed within a period of two years (The Danish Ministry of Health, 1996) and was the beginning of the Danish Health Data Network. In Denmark, the doctors known as general practitioners serve as the "gatekeepers" of patients to other specialists and health professionals (Kuo et al., 2010). This context has enhanced the message-like solution that took place later. More than a national-wide solution, the programme was concerned about achieving value in the local regions by allowing fast and simple communication between the different stakeholders. The communication flow was based on six interactions, always with the general practitioner as a nodal point: request laboratory results from hospital; prescription with pharmacies; reimbursement by assurance public health care; messages to emergency community care; radiology exams; referral and discharge information. This approach led to a "tremendous rise in messaging from 3 million per month in 2005 to 5 million per month in 2009 was much higher than expected" (Protti and Johansen, 2010). Denmark has a National Patient Registry (DNPR) which has served as a data set of hospital contacts since 1977. Despite of being an administrative tool, the DNPR allowed the creation of a number of shared services, including the National Patient Index (NPI) that gathers all relevant information about individual patients.

Some authors argue that there were two key developments that led to the success of the Danish programme: "(1) creation of a nation-wide electronically accessible patient summary record, and (2) creation of a secure national health data network" (Kuo et al., 2010). Moreover, in 2006, Edwards (Edwards, 2006) states some critical factors that led to success, such as: monetary incentives to the adoption of MedCom standards; precise standards worked out with the clinicians; gradual approach and realistic time frames;

incentives to vendors; culture of consensus and a project-based approach. In the late years, Denmark has shine with the national health network (MedCom) being “used by over 3/4 of the healthcare sector, altogether more than 5000 different organizations” (Protti et al., 2009).

2.3 England Case Study

The National Health Service National Programme for IT (NPfIT) was initiated in 2005. It was born as the world’s largest civil information technology project, committing 12.4 billion pounds over 10 years (Brennan, 2005). The NPfIT was made of eight specific-purpose systems: a big and national healthcare data repository, a national healthcare network, an electronic appointment booking system and five local service providers covering England’s territory. In order to implement the five local clusters, five providers were contracted and made responsible for delivering the local services. The program defined a set of standards, frameworks and implementation to guide and favour the interoperability between local systems and across them, called NHS Interoperability Toolkit (ITK). The step-by-step maturity model was meant to allow the organization to incrementally progress from sharing binary data to sharing fully-coded CDA documents. The NHS Care Records contemplated two different types of records: 1) Summary Care Records — records held nationally and is an implementation of the concept known as Patient Summary; 2) Detailed Care Records — records held locally and a more comprehensive record which might store data from past exams and details, avoiding the necessity for repeating them, for example.

Since its beginning the project was the target of many critiques. Back in 2004, John Powell advocated the importance of involving the clinicians in the changes as well as showing the value to patient care (Powell, 2004). A report by the King’s Fund in 2007 also criticised the government’s “apparent reluctance to audit and evaluate the programme”, questioning their failure to develop a capable strategy (Wanless et al., 2007). Several authors wrote about the problems’ causes and things that could and should be learned (Coiera, 2007; Clegg and Shepherd, 2007), from lack of clinicians’ engagement till wrong metrics, weak political leadership and one-size-fits-all solutions.

2.4 France Case Study

France is a country with one of the best healthcare systems in the world, having been classified inclu-

sively as the “best health system in the world” by the World Health Organization (WHO) in June 2000. Following a set of initiatives in the late-nineties, in 2004 a law is approved to establish a Personal Medical Record (Dossier Médical Personnel - DMP) which aims to enable: (1) coordination of care (2) improve quality of care (3) continuity of care. However, that law was not only about the DMP, it had other directives to reform all the hospital sector that were “important enablers of healthcare delivery modernisation in France” (Artmann and Giest, 2010). In 2009, the “Rapport Fieschi” outlines semantic interoperability as the key goal and challenge of health information systems.

The General Practitioner (GP) assumed a critical role in the DMP, being able to access it via the GP software or via the Internet but also accredited to transfer important documents into the DMP and hide document data upon request by the patient. Moreover, a number of patient-centred services are also envisaged (Artmann and Giest, 2010): consumer portal allowing the patient to access their healthcare record, to see the list of professionals who accessed their DMP and be informed of data updates; patient being able to manage the access rights of health professionals and update their personal information space as well as masking data. In terms of the storage of the EHR, France is “the best example of a country that went with a host-based electronic health record system” (Stroetmann et al., 2011). The French patients are allowed to choose whichever data-host they want for their health record. Obviously, as prescribed by the French Decrees on Data Hosts, hosts have to be certified in order to be allowed to store clinical information. Another interesting fact is that, in France, an electronic health record can only be created after the consent of the patient (“opt-in” strategy). In terms of standards, the French Dossier Medical Personnel adopted the IHE standards that were combined with the use of HL7 CDA for the Clinical Document Architecture.

The Table 1 shows a brief summary of the four countries presented, from an architectural perspective. There are four classification parameters: (1) strategy - classify the process of implementation in terms of management approach, (2) architecture - understand where it stands between the two extremes (completely distributed or completed centralized), (3) communication - state the approach used to allow the share of information and (4) standards - some of the used standards in that country either nomenclatures or encoding ones. It is easy to understand the variety of solutions that is possible to adopt only by these four examples. In terms of strategy we have

Table 1: Brief summary of the four countries from an Architectural Perspective.

	Canada	Denmark	England	France
Strategy	Top-down	Bottom-up	Top-down	Big-bang
Architecture	Distributed: fetched in real-time	Distributed	Hybrid: PS held national; the rest held locally	Distributed: host-based, fetched in real-time
Communication	SOA	Message-oriented	SOA	Document exchange
Standards	DICOM; SNOMED CT; HL7 v3; ICD10-CA	EDI (internal); CEN; SNOMED CT; DICOM	HL7 CDA; SNOMED CT	HL7 CDA; IHE profiles; SNOMED CT

two projects (Canada and England) that were conceived from high-level to low-level contexts. By the opposite, in Denmark the strategy sprouted from the developments that were being made at a local level. In terms of architecture, at least with regard to these cases, the tendency is clear about the distribution of the data. That is, there is not a completely centralized repository with all the clinical data. Usually, most of the data is held locally, where it was produced, and some set of it is selected to be accessible in a more centralized and easy way. In terms of communication, the solutions vary a bit, since it is possible to find a strategy based in messages like in Denmark, two SOA-based solutions and France relying on the exchange of structured clinical documents. Finally, in terms of standards we can identify SNOMED CT as the common one, but then it is difficult to find significant similarities.

3 KNOWLEDGE DOMAIN MODEL

The presented case studies show that the problems/challenges vary from high-level strategy to chosen standards. Despite of some of the issues discussed are not properly architectural problems, the fact is that all these problems are coupled, depend or affect some-how the architectural decisions. Therefore, the authors summarized the fundamental problems into three research questions:

- How to maintain the closeness between the system and the business goals guaranteeing the system's acceptance/adoption?
- How to build such complex and component-crowded systems in a way they would be able to change and evolve?
- How to make such different systems to communicate and understand each other bringing forth pa-

tient care value?

3.1 Aligning the Business Goals with the System Development

Twenty years ago, the systems complexity was growing with an exponential velocity. The software development was facing two problems at a time: in one hand, the systems were becoming huge and hugely complex; on the other hand, the systems were developed with few concerns about business orientation (Sessions, 2007). At that time, the concept of Enterprise Architecture appeared to address this problem. A lot of enterprise architecture models appeared and disappeared over the years. Three of the most known Enterprise Architecture frameworks are: The Zachman Framework, The Open Group Architecture Framework (TOGAF) and The Federal Enterprise Architecture Framework (FEAF). The Zachman Framework (Zachman, 1987) aims to guarantee that all stakeholders' perspectives are being taken into account when developing a complex software system. In general terms, it is important to understand if all the artefacts are sufficiently focused and if the existing artefacts clarify all the players, from the business owner till the database designer, keeping all the visions aligned. First developed in 1995, TOGAF was based on the US Department of Defense Technical Architecture Framework for Information Management (TAFIM) (Josey, 2011). TOGAF might be seen as a process for building an Enterprise Architecture. This framework states this building process as a continuous process of building multiple architectures from highly generic to highly specific ones, until reaching the organizational architecture level (Sessions, 2007). Finally, the Federal Enterprise Architecture Framework appeared with the objective of serving as a platform for sharing processes, information and documentation among the U.S. Federal Agencies and other government agencies. This framework

gathers two main characteristics of the two previous: in one hand, it defines a taxonomy – similar to the Zachman Framework – for artefacts classification; on the other hand, it suggests a process for building and implementing the architecture like TOGAF does.

3.2 Architecting Complex-Crowded Systems

The concept of Systems-of-Systems (SoS) is closely related to this idea of achieving value through the connecting and integration between several peer systems. A system is classified as an SoS when there is an “assemblage of several components which individually may be regarded as systems” and with two additional properties (Maier, 1998): (1) operational independence of the components – each component is able to fully continue operating even when disassembled from the system (2) managerial independence of the components – the component systems do operate independently in fact. Maier suggests some architectural principles to deal with this kind of system like stable intermediate forms, policy triage, leverage at the interfaces and ensuring cooperation. In addition to the obvious dependence of several systems, the fact of being a complex and large kind of project also deserves special attention and methodologies. In this field, the Ultra-Large-Scale Systems (Northrop et al., 2006) and the Large-scale complex IT systems (Somerville et al., 2012) are two terms that refer to the same type of systems. Independently of the designation used, these are systems identified by extreme size in every imaginable dimension: lines of code, stakeholders, number of systems, etc. Northrop, et al. state some characteristics as decentralized control, “unknowable” and conflicting requirements, continuous evolution and others (Northrop et al., 2006).

If we lower the abstraction level, it makes sense to refer some architecture styles like Service-Oriented Architectures (SOA) and Resource-Oriented Architectures (ROA). SOA is an “architectural style that emphasizes implementation of components as modular services that can be discovered and used by clients” and that “emphasis on loose coupling between interacting services” (Srinivasan and Treadwell, 2005). On the other hand, the ROA defines an easy access to the entities as well as the way that access should be done (Overdick, 2007).

3.3 Transforming Data into Information

Several registries are created and updated all over the healthcare institutions. The process of transforming that data into information is an essential step. Plus,

the share of that information creating the knowledge necessary to offer better healthcare services is the ultimate challenge before creating real value to the patient. The pursuit of interoperability is not possible without a clear definition of common languages and communication channels. In this sense, multiple standards can be found and compared (Atalag et al., 2010).

One of the most known organizations in this area is Health Level Seven International (HL7), which produced HL7 Messaging Standard. The Integrating Healthcare Enterprise (IHE) Profiles are other example, in this case these profiles define the systems involved, the specific standards used, and the details needed to implement the solution. Also, the Digital Imaging and Communications in Medicine (DICOM) is an worldwide used standard for medical image communication, providing data structures and services and allowing the exchange of medical images and related information. Another standard is openEHR which develops specifications for implementing full EHR systems, pronouncing more in persistence as opposed to messaging, with the goal of achieve lifelong, patient centred, secure and shareable EHR. The standards referred above are more about how to transfer the information. Another underlying question is the codification of that clinical information. In that case, the research is about terminologies and ontologies: SNOMED CT, ICD, LOINC.

3.4 The Peer-Generated Value

Despite the healthcare arena is an old-fashion one, it is interesting to understand how the new models of development could fit it. As known, the businesses are evolving from a product-oriented perspective to a relation-oriented one. This change of paradigm brought the client to the middle of the business, helping to create value. The Metropolis Model (Kazman and Chen, 2009) appears as an attempt of describing really huge complex systems built from two basilar concepts: Open-source Software (OSS) and Community-Based Service Systems (CBSS). The Metropolis Model presents a new unified vision between the CBSS and the OSS, focusing deliberately in the crowd value generation through the definition of two levels: the kernel services and the periphery services. In the healthcare, there is also a vast community ready to produce value and to be involved in the improvements that need to be done. The question is if the systems will be able to support and incentive that contribute.

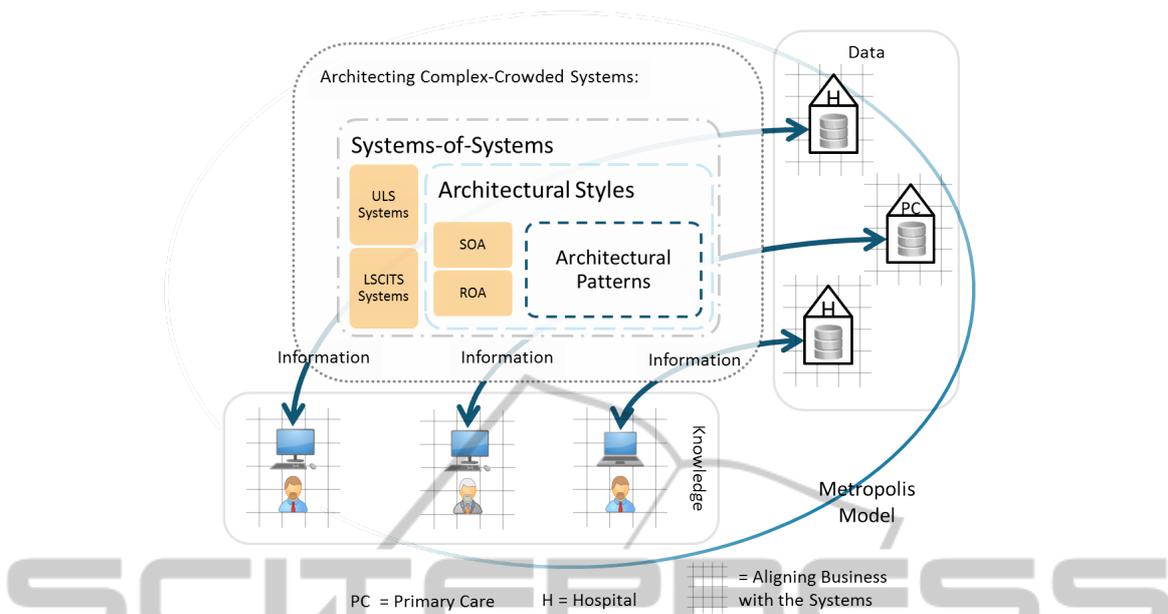


Figure 1: The Knowledge Domain Model proposed as an integrated view of the clinical data sharing domain.

3.5 Discussion

From the literature review it was possible to find some methodologies that address a subset of the three questions. For instance, the BITAM (Chen et al., 2005) which stands as a methodology for aligning business and IT strategy with special focus on “detecting, gauging and ameliorating the effects of misalignment”. In fact, it address in broad terms the first two concerns elicited above but does not goes into details of interoperability questions. However, we believe that the three dimensions are critical. The Figure 1 presents an integrated view of how all this knowledge can be gathered. With it, we pretend to show that the process of transforming the existing clinical data into information is, in fact, a very complex process. It starts with the production of the data at a local level, usually in an hospital or a primary care unit. At this level, the main concern is about aligning the systems with the healthcare processes. That alignment is what improves the quality and quantity of data available to be shared. The next step is about fetching the information at the local repositories and transfer or make it available to other professionals. Obviously, this step requires a significant effort since it can require operations like locating the origin repository or transform the information into a codification the destiny will be able to interpret. Not to mention that this central structure might need to balance a high volume of requests. Thus, the construction of a platform like this requires a wide knowledge from the concepts of Systems-of-Systems to the Architectural Patterns that work at a much lower level, as presented in the fig-

ure. All these processes aim to transform the data into information, which basically means to present the data in a way and within a proper context to be consumed by a healthcare professional. The interpretation and use of that information by the professional is implicitly transforming it into knowledge and ultimately into value to the patient when the healthcare services are improved because of that. Once again, when providing that information to the professionals one big concern must be the alignment between those systems and the processes, otherwise all the effort may be in vain.

From the analysis of the English project, it is possible to say that the first dimension might have been overlooked. The strategy followed (top-down) implies from the beginning a certain distance between the implementation team and the local stakeholders. Despite the division of the project in 5 “local providers”, it would be necessary a much greater effort to bring clinicians and other healthcare professionals to the centre of the implementation process. Apparently, the lack of this engagement had as consequence the raising of multiple resistances either supported in the system’s existing fails or the natural inertia to change and adapt. The other two dimensions – the architecture of the hole system and the interoperability – appear to have been better studied. Although, some articles report the appearance of critical failures which might result from architectural issues. The step-by-step maturity model to the adoption of fully-coded CDA documents is an example of the importance given to interoperability, indeed evi-

denced by the existence of the NHS Interoperability Toolkit. Most of the critiques raised against the Canadian project are related to the first dimension also, accusing the responsible of insufficient engagement of clinical users. Plus, some authors criticized the focus on national perspective rather than the regional one which is highly influenced by the chosen architecture. In terms of the third dimension, the chosen standards and the architecture based on PoS was not subject to major criticism and seemed a good concept. In Denmark, the lower-profile project was built from the local perspective to a national one, which seems to have facilitated the engagement of the stakeholders (first dimension). Moreover, the standards and conventions were negotiated with the clinicians and its use was encouraged with monetary incentives. In fact, the strategy was able to distribute the efforts between the three dimensions making this project one of the most successful case studies in this area. The French case is another example of balance between the three dimensions. Despite the launching in a national reform, the responsible were able to: 1) engage the different players of the market by fostering a solution of local hosts 2) find an interesting solution in architectural terms to balance the data centralization/distribution issue 3) select and define the standards of communication (IHE profiles and HL7 CDA).

The Knowledge Domain Model presented above refers an extra dimension which we believe can improve the implementation of these projects in terms of adoption velocity and stakeholder participation. From the case studies referred the only one where this dimension might have been a bit explored was in France. In fact, the establishment of standards and the allowance of private certified hosts for clinical data storage stands as a good small example of what a more open strategy can bring to these complex projects.

4 CONCLUSIONS

The implementation of an EHR or a project that aims to foster clinical data sharing in a country is a challenge that congregates wide issues, from strategy and business processes to technology and interoperability problems. Despite the necessary technology exists, most country healthcare systems might not seem ready to fully exploit all its benefits.

The authors believe that these projects have three critical dimensions: (1) keep the stakeholders engaged as well as guaranteeing the system to be aligned with the business goals, using principles of Enterprise Architectures (2) adopt an agile architecture that is

able to gathers new peers but also to allow the system to evolve and get better, following research in System-of-Systems and Software Architecture (3) allow the institutions (peers) to effectively share clinical data creating value to the patient care services, taking advantage of the several standards and conventions existing in this area. It is not about technology that needs to be invented, it is about how one is able to bring all this knowledge together and deliver not the “biggest computer program in the world” but the most valuable one. From the literature review, most of the projects usually addressed two of the three concerns referred above. The more high-level ones usually describe the components of the system and may or may not describe the strategies to engage stakeholders. The ones more focused on local perspectives are usually more concerned about defining the ways of interaction and interoperability but fail to define a transversal strategy.

4.1 Future Work

This work is the basis for the research project in which the authors want to specify an Architecture Framework (AF) for this area of clinical data sharing at a large scale. Thus, the next steps involve a progressive breakdown of this model towards the creation of that AF as a guide to the implementation of these kind of systems. The AF is expected to: 1) describe the model in terms of a set of building blocks 2) show how the building blocks fit together 3) provide a common vocabulary 4) include a list of recommended standards 5) include a list of compliant products that can be used to implement the building blocks. Meanwhile, a Quality Attribute Workshop (QAW) (Lattanze et al., 2003) with Information Systems specialists from Portuguese healthcare institutions will be organized in order to validate the main strategy and the key aspects of the model. In addition, the validation process of the framework may include the development of a prototype.

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