A Framework to Evaluate Architectural Solutions for Ubiquitous Patient Identification in Health Information Systems

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Keywords: Enterprise Architecture, Architecture Principles, Patient Identification, Architecture Evaluation.

Abstract: The lack of accurate, reliable and consistent patient information is a major issue in healthcare, despite a relatively high Health Information System (HIS) adoption level worldwide. The main reason for this appears to be patient records lacking accurate particulars, including links to associated care programs, disease classification and treatment plans. The causes for this are multiple, including incompatibility of healthcare standards between version releases, inconsistent HIS implementation, lack of effective data input / validation, and the rapid evolution of and absence of a single 'universal' technological solution. Sustainable, stable and long-term architectural solutions are required. This research builds on previous work identifying major challenges and root causes of the problem and proposing essential non-functional requirements for HIS architectures. The paper elaborates on non-functional requirements and proposes an evaluation framework (based on a new international standard) that can be used to assess aspiring HIS architectures for long term stability and self-evolution and thus to support strategic decision making from within the evolving HIS.

1 INTRODUCTION

Having accurate, reliable and consistent patient information is still a major issue in healthcare despite a high Health Information System (HIS) penetration worldwide (Fernandes and O'Connor 2015). The root cause of this appears to be a lack of accurate records of patient particulars, associated care programs, disease classification and treatment plans. While the effect on HIS efficacy and patient medical security is obvious, there exist important flow-on effects on healthcare management and policy-making.

A plethora of triggers result in erroneous patient records – see. Arts et al. (2002). In previous work, the authors elaborated on a selection of causes deemed to be some of the most important and difficult to address (Memon et al. 2017). For example, the incompatibility of healthcare standards themselves, the inconsistent manner that HISs are implemented, episodic unavailability of HIS leading to duplication and inconsistency of information, lack of effective data input and validation, patients spoofing or hiding information from the system for various reasons, etc.

Previous research identified four main categories of challenges in implementing portable patient identification in HIS (technical, cultural, social and ethical), and spelled out architecturally significant requirements (Chen 2013), or so-called 'ilities' that should feature in sustainable HIS architectures such as promoted by the World Health Organisation. The paper builds on previous work and findings from literature on use cases and case studies (Aller 2016; Lowry et al. 2015) using a conceptual-analytical method to demonstrate how the *significant* 'ilities' can be structured and built into a sustainable long-term HIS architectural solution. This is then taken one step forward by proposing a healthcare architectural *evaluation framework* usable to underpin strategic decision making in a sustainable manner, i.e. from within the evolving HIS itself.

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Memon, Z., Noran, O. and Bernus, P.
A Framework to Evaluate Architectural Solutions for Ubiquitous Patient Identification in Health Information Systems.
DOI: 10.5220/0007696305800587
In *Proceedings of the 21st International Conference on Enterprise Information Systems (ICEIS 2019)*, pages 580-587
ISBN: 978-989-758-372-8

2 PATIENT IDENTIFICATION CHALLENGES

Beyond conceptual problems, e.g., incompatibility of healthcare standards and inconsistent HIS of implementation around the world, (Anderson 2007; LO 2006; Memon et al. 2017; Rinehart-Thompson and Harman 2006) identified several categories of challenges as explained below.

2.1 Cultural and Social Barriers

In some (often developing) countries, directly sharing personal information outside family or larger group is forbidden. Instead, the family or tribe 'head' is to pass on information, which can result in incompleteness and inaccuracy (misinterpretation originating due to lack of proper background, fear of stigma, 'shame', etc.). People outside of the group may not be allowed contact with members of health care providers; thus, patient identification may be subject to errors but also pose a threat to the health workers' security (Almutairi and Moradi 2012).

In addition, language barriers and lack of 'cultural competence' (Georgetown University 2011; Sulaiman 2017) may impair communication and cooperation at the core of patient information management (Schyve 2007), so training may need to be provided and techniques used carefully chosen to match the cultural environment and afferent degree of EHR acceptance (Brown 2012; Zoonen 2013).

2.2 Ethical Issues

An essential advantage of HISs is making Electronic Health Records (EHRs) universally available (when they are *indeed* usable and interoperable, as argued by Reisman (2017)). However, this intrinsically generates privacy and security concerns – 'hacking', identity theft, unauthorized access or data alteration (Devon et al. 2010; Ngafeeson 2014). Improper use of data for serious diseases has the potential to create significant preconceptions and inequity in workplace and society (Harman et al. 2012; Ozair et al. 2015; Sharona 2012). Therefore, 'information ethics' as espoused by Fessler and Grémy (2001) must be thoroughly observed. This is no trivial task, considering the effort and costs (Noble et al. 2009) in the socio-economic and cultural context present in some geographical areas, especially in developing countries.

2.3 Technical Problems

Ubiquitous patient identification typically relies on electrical power availability, local or worldwide networking capability, possibly aiming towards Internet of Things (IoT)-based *pervasive healthcare* (Arnrich et al. 2010; Zdravković et al. 2014), and based on Wireless Sensor Networks (Ko et al. 2010). These requirements may present significant barriers in developing countries or remote areas in general. Data may require local storage (avoid information loss or duplication on power loss), and processing/ conditioning (reduce transmission bandwidth need). Traditionally patient identification has been text-based, but it is fraught with numerous pitfalls, such as duplication or unavailability of essential data (e.g. unique identifiers (names, dates of birth) due to geographical and cultural factors (Aller 2016), or the possibility to intentionally provide false information (e.g. for doctor- and/or drug 'shopping').

Alternative technologies proposed are based on barcodes and/or radiofrequency identification (RFID) tags, both often used with wristbands, or *biometric* identification using body features unique to individuals (Alyssa 2012; Doll Martin Associates 2008; García-Betances and Huerta 2012). In the latter category, among the most used are iris pattern, palm vein and fingerprint (Aller 2016).

Iris pattern can be sensed from a distance (important if physical contact is a problem due to e.g. cultural or fomite (infectious transmission) perceptions, and can be done in infrared (hence less conspicuous). However it requires a good image, may be confused with facial recognition (which may be feared by some members of the public) and may fail due to rare but existing pigment dispersion conditions (Pillai et al. 2011; Ross 2010)

Fingerprint technology has been used for decades and evolved to be able to identify fake or dead prints and improved reliability by using 3D. While it is an accepted method in many areas and countries, it does require good quality readers, may imply a negative social perception (Wickins 2007) (e.g. due to being associated with Police work), and may lack accuracy for young patients or those who practice specific manual trades affecting finger ridges (Aller 2016).

Palm vein identification is more recent (Zhang et al. 2007), uses separate templates in each patient network and is more secure, but this hinders data consolidation. It can also be affected by ambient light and palm position, must be refreshed yearly for young patients and can constitute a fomite (Aller 2016; Patil and Ajmire 2018).

As can be seen, biometric technologies exhibit a large variety and are in constant evolution. Each technique is useful in specific conditions and appears to have its weaknesses; therefore, a combination is perhaps the solution. Also, in order to triangulate and to verify results and thereby minimise patient misidentification, text-based identification may also be used, but only as a back-up measure and to facilitate interoperability (e.g., with legacy systems).

Note that 'blockchain' technology is also being considered for compliance, information integrity preservation, privacy and interoperability, although the technology is in its infancy (Krawiec 2016).

In view of the above, a question remains: how to prepare for a long-term ubiquitous solution in view of the continuous evolution and heterogeneity of solutions and different levels of technology adoption worldwide? The solutions must meet patient identification functional requirements as well as essential *non-functional* requirements (HIMSS 2015) due to the special role of patient identification in the lives of patients in health services management.

In conclusion, a stable, long-term solution must specify architectures, rather than specific solutions or technologies. This creates a problem: *how do we know that such architectures are in fact of 'good quality'?* The authors argue that there is also a need for an *evaluation framework* for assessing the quality of such architectures. The remainder of this paper addresses the above two essential questions.

3 DESIRED SYSTEMIC PROPERTIES OF A SOLUTION

There is an extensive literature of non-functional requirements (the system 'ilities'), in the software engineering (Chung et al. 2000; Jan et al. 2016; Penzenstadler et al. 2014) and systems engineering literature (INCOSE 2011; ISO/IEC/IEEE 2011). However, the authors were unable to find a comprehensive list that applies to *enterprises*.

Many ilities known from the systems engineering literature apply to enterprises including health care (public health, health care provision & management (Anyanwu et al. 2003)), but the relevance and priorities of these properties are expected to be different from those that apply to a software system (including an HIS). This is expected, as the health enterprise is a complex evolving *system of systems* (SoS) both on national- and global scales - and the time horizon on which the long-term viability of this enterprise needs to be secured is very long (in fact, open ended).

In recent years, evidence accumulated (at least in the HIS area) pointing to the need to pay increasing attention to non-functional requirements. E.g., Lowry et al. (2015) list as a top priority to "... consistently display information critical to patient identification in a reserved area to avoid wrong patient errors".

Establishing a framework for an open-ended long term solution to patient identification is facing a problem that has been documented in the systems engineering literature (Jain et al. 2009; Warren 2018) namely that stakeholders are *not* a good (or reliable) single source of information when it comes to determining non-functional requirements of a system. Accordingly, system ilities are usually not on the radar of stakeholders (or only trivial ones are considered): the architects must become protagonists and educate stakeholders about what they should be requiring. E.g., maintainability is not in the focus of typical HIS stakeholders, even though when a system becomes too expensive to maintain a costly redesign and re-development will be necessary.

As described by Bellomo et al. (2015), the software architecture community identified a list of systemic (non-functional) requirements that dominate the landscape of software systems architecture. However, the patient identification problem context is provided by a 'system' that is not software, but rather an *evolving socio technical system of systems* (SoS). This SoS consists of a combination of policies, laws and processes performed by humans, supported by a various technologies, and involve independently managed and evolving services. So, while lessons learnt from the systems and software engineering must be considered, we must make adaptations and look at experiences from other domains.

3.1 Quality Attributes of Systems of Systems

The international Standard ISO 25010 - Quality Model (2011) provides guidance on quality attributes of systems (such as: functional suitability, reliability, performance efficiency, usability, security, compatibility, maintainability and portability), and additional attributes relevant when the system is in use (effectiveness, efficiency, satisfaction, freedom from risk and context coverage). Section 4.1 of this standard includes a finer-grained and comprehensive list of sub-categories (see Table 1).

Despite these quality characteristics being important, these concentrate on a shorter time scale / horizon than a patient identification system would require, because traditional architectural decisions for software and other technical systems are made assuming that the systems will be designed, built and used, without necessarily considering very long term changes (abrupt or evolutionary) in the domains of technology, or in the socio-economic environment.

Table 1: Categories of quality attributes, with sub-categories in italics. (Source: the publicly available informative section of ISO25010 (2011)).

- Functional suitability: *Functional completeness, Functional correctness, Functional appropriateness,*
- Performance efficiency: *Time behaviour, Resource utilization, Capacity;*
- Compatibility: *Co-existence, Interoperability,*
- Usability (defined by ISO9241 as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"): *Appropriateness, Recognisability, Learnability, Operability, User error protection, User interface aesthetics, Accessibility;*
- Reliability: *Maturity, Availability, Fault tolerance, Recoverability*;
- Security: *Confidentiality, Integrity, Non-repudiation, Accountability, Authenticity;*
- Maintainability: *Modularity, Reusability, Analysability, Modifiability, Testability, Portability, Adaptability, Installability, Replaceability*;
- Effectiveness;
- Efficiency;
- Satisfaction: *Usefulness, Trust, Pleasure, Comfort,*
- Freedom from risk: *Economic risk mitigation, Health and safety risk mitigation, Environmental risk mitigation;*
- Context coverage: *Context completeness, Flexibility*.

Therefore, as demonstrated in previous work by two of the authors (Noran and Bernus 2017; Turner et al. 2018) the solution must be approached as a *long-term infrastructure building endeavour,* where during the lifetime of this infrastructure many changes are to be expected while preserving continuity. For this reason the authors propose a working list of ilities (See Table 2) that adds *viability* (which is in fact the ultimate long-term system survival capability) to Boehm's (2014) set.

We argue that to decide on the introduction of sustained use of biometrics in patient identification it would be impractical to assess *all* of the ilities of HISs impacted by the relevant technology choice(s). Section 4 below proposes reducing the size of the decision tree to arrive at an evaluation regime that prunes the options so meaningful comparisons and associated implementation decisions can be made.

Such a reduced list would contain mandatory criteria for very long term HIS infrastructure decisions to eliminate solution options possibly attractive to some stakeholders (given a shorter term investment horizon) but which do not satisfy essential non-functional requirements and go against the achievement of long term strategic goals.

4 A GENERIC ARCHITECTURE EVALUATION FRAMEWORK STANDARD

ISO42030 'Architecture Evaluation Framework' ((ISO/IEC 2018) contributes to the maturity of architecture governance because it systematises the elements to be considered by a process that supports architectural decision making. The standard builds on the concepts of previous work on architecture evaluation, but generalises these. Such previously published methods include Architecture Trade-off Analysis Method – ATAM (Kazman et al. 2000), the Method Framework for Engineering System Architectures (QASAR) (Firesmith 2010) and Analysis of Alternatives (U.S. Air Force 2008).

Accordingly, the evaluation of alternatives should be performed in *two passes*: i) eliminate proposals that do not satisfy mandatory non-functional requirements, and ii) compare candidate solutions using and appropriate decision-making method. ISO 42030 (ISO/IEC 2018) requires that based on business goals architecture governance derive the *evaluation objectives,* i.e., *what kind of answers do we expect from the architecture evaluation?* Objectives may include the desire to determine whether the solution will reduce the total cost of ownership, to what extent, or if it will improve current capability/service quality.

Comparing alternative solutions would be performed by defining *factors* that influence the answers, and selecting *methods* known to deliver these answers. *Evaluation factors* (derived from business drivers) may include cost, schedule, quality, risk etc., whereupon evaluation methods on this level would not be very formal (referring to existing analysis reports, or using expert panels are typical examples). This is important, because in practical situations there are too many objectives and factors and it is necessary to eliminate many of these using fast and affordable methods.

Table 2: Categories of ilities (based on (Boehm 2014)).

Individual ilities

- Quality of Service: Performance, Accuracy, Usability, Scalability, Versatility
- Resource Utilization: Cost, Duration, Personnel, Scarce Quantities (size, weight, energy, …)
- Protection: Safety, Security, Privacy
- Robustness: Reliability, Availability, Maintainability
- Flexibility: Modifiability, Tailorability / Extendability, Adaptability
- Composability: Interoperability/Portability, Openness/Standards Compliance, Service-Orientation

Composite ilities

- Comprehensiveness/Suitability: all of the above
- Dependability: Quality of Service, Protection, Robustness
- Resilience: Protection, Robustness, Flexibility
- Affordability: Quality of Service, Resource Utilization
- Viability

Often though, the answers are unclear, and to compare architectural solutions one also needs to assess the architecture by asking *what is the value of this architecture* (the quality requirement may not be met? is there a trade-off or opportunity to optimise?, how do architectural decisions contribute to the expected quality attributes?).

As part of this value assessment process, one must determine how/to what extent the chosen architecture contributes to achieving the business goals? The value of the chosen approach may be demonstrated using suitably selected metrics (value factors that have measurable characteristics), such as speed, throughput, cost, etc. Given the value assessment factors, value assessment methods are needed to compile the findings of architecture evaluation.

Often the desired measures are not readily available by inspecting the proposed architecture, so further *architectural analysis* is needed, and this may require models to be developed.

Analytical models may be suitable for sensitivity analyses, e.g., perform quantitative statistical analysis using simulation models that can be put to test and provide evidence of the extent the architectural solution meets the desired quality attributes. Some systemic properties (availability, changeability, robustness, evolvability, complexity) may be expressed using graph properties of the system, or by entropy calculations, and so on. Architecture analysis exercises are for the above reason the most costly and time consuming; therefore it is prudent to eliminate the need for such analytic work if possible.

5 A FRAMEWORK TO EVALUATE PROPOSED UBIQUITOUS PATIENT IDENTIFICATION SOLUTIONS

Solutions advocated at any one time by protagonists (namely to use biometrics for patient identification) must be able to be evaluated against the desired criteria discussed in Section 3. While the generic framework of ISO 42030 (ibid.) draft international standard gives guidance, a practical application requires the identification of domain-specific objectives, evaluation factors and methods.

A first-cut version of a *specific* evaluation framework can be developed based on the systemic properties discussed and found desirable for any proposed solution. Note that in real application the proposed artefacts must be re-visited, validated with stakeholders and possibly expanded using the end user's architecture governance processes.

As shown in Section 2.3, biometric identification techniques are useful to various degrees in different circumstances and have their own characteristics, requirements, weaknesses and strengths. Thus, given the uncertainties and the need to adopt future-proof systems, it is important to have an evaluation framework at hand that can assess proposed solutions both in terms of a) the long term sustained performance of technical systems (such as those using biometrics) that provide patient identification services, and b) in terms of how these contribute to the viability of seamless use of patient identification functions within relevant processes of the complex healthcare SoS (the 'healthcare ecosystem'). Thus, from patient identification point of view, both the healthcare ecosystem and the system(s) providing patient identification service need be considered.

5.1 Evaluation Objectives

In discussing the relevant evaluation objectives for the architecture of the healthcare SoS, the first difficulty encountered is that in the healthcare ecosystem there is no central decision making authority that has complete control over the system as a whole (not even on the country or region level).

However, there exist significant players that can develop and disseminate policies, principles and standards that influence decision makers in desirable directions. Accordingly, an evaluation must answer the following fundamental questions:

i) Does the architecture of the healthcare SoS display a structure enabling continuous long-term change and improvement (viability)?
ii) Is there a guarantee that the above can happen without the need for reinventing the way this essential function is provided by the patient identification services available at any one time, now and in the future? Thus, the authors propose to also investigate *evolvability*.
iii) Is there a guarantee that system changes satisfy the end user quality of service requirements (such as usability)? The reason for *usability* to make the mandatory list of ilities is the recurrent reports about lack of usability and / or good user experience design result in poor adoption and a number of adverse effects that prevent the full benefits from being realised (Lowry et al. 2015).
iv) Other evaluation objectives could be defined and used (based on the ilities listed in Tables 1 and 2), but the focus here is on the viability aspects.

Given that the evaluation concerns an SoS, these objectives are relevant for each level and constituent of the healthcare ecosystem, according to the theory of the Viable Systems Model (Beer 1972). Although the architectural measures taken to ensure viability, evolvability and usability may not be the same on every system level, government level measures (laws, policies, principles and mandatory compliance processes) *must* be traced to corresponding decision making instruments on lower levels of the ecosystem (e.g. various and allied health care providers).

5.2 Evaluation Factors

Architecture evaluation factors are often categorised as Political, Economic, Social, Technological, Environmental and Legal (PESTLE) (Law 2009), which helps the designer of the evaluation to find relevant factors and determine what methods to use. For example, an economic factor of viability is that the system is affordable to operate, while an economic factor for evolvability is that changing the system by adding a new technology is affordable (e.g. by modularising the system architecture to separate technology choice from the service user, thus localising the change effects). When evaluating systems for usability, one must include economic factors: it needs to be understood whether the use of patient identification system requires extra work or otherwise slows down the medical service.

5.3 Evaluation Method(s)

Depending on the evaluation factors at hand, there can be a number of options to use, including expert reviews, references to existing strategic analysis from respectable sources, etc. If the identified methods cannot give a conclusive answer, then architecture evaluation needs to evaluate each relevant factor of the solution from the point of view of the value it contributes to business goals. The result is a *synthesis report* identifying the extent the architecture satisfies business goals, as well as identifying risks due to uncertainty or lack of available information.

5.4 Value Analysis

Value analysis has its own *objectives*, *factors*, and *methods*, and reports are created that can be incorporated into the eventual architecture evaluation synthesis report. Space and scope limitations do not allow a factors and methods listing, albeit it must be noted that value assessment should try to use existing sources of information, such as historical records of past projects. However, in case the outcomes of value assessment methods are inconclusive, a third layer of architecture evaluation 'architecture analysis' is necessary.

5.5 Architecture Analysis

Architecture analysis also has its own *objectives*, *factors* and *methods*, and the results incorporated into an eventually produced 'synthesis report'.

The main difference between this layer and the first two is that the factors considered are such that the analysis methods require the use of *modelling* and/or *experimentation*; therefore, the cost and time involved may be significant. For example, if the value of a new process cannot be ascertained, business process modelling and simulation may be required to model the economic impact of the architectural change.

Experimentation may involve the creation of a proof of concept of a pilot implementation, which then will be used to conduct usability experiments.

6 CONCLUSIONS AND FURTHER WORK

This paper proposes an architectural solution for the currently unsolved patient identification problem, based on an International Standard for Architectural Evaluation (ISO 42030) and should be considered as an example demonstrating the use of this standard. The difficulty of the problem lies in the following:

i) The Healthcare Ecosystem is an SoS without an ultimate central authority to control its evolution;
ii) A patient identification infrastructure must be viable on a very long term, and there is only scarce experience with successful long term IT infrastructure building, with significant social and political factors influencing its success;
iii) The technologies of today will change at an accelerated rate; therefore, a long term solution must incorporate the ability of the system to *evolve* without causing unacceptable disruption.

The proposed framework is a tool that may be used to assess patient identification improvement proposals in view of addressing the most significant stakeholder concerns, which are not always explicitly espoused in essential non-functional requirements. End users of this framework may include government agencies (e.g. health departments, health district management), NGOs (such as the WHO, standards bodies, etc.) and even HIS vendors.

Further work will include development of the details of the evaluation framework and its validation by selected experts from stakeholder groups.

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