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Towards an Evaluation Framework for Ubiquitous, Self-Evolving Patient Identification Solutions in Health Information Systems

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Abstract

The increasing adoption of Health Information Systems (HIS) does not seem to have resolved the ongoing lack of ubiquitous, dependable and accurate patient information so as to effectively prevent medical errors. Previous work has identified multiple causes, including but not limited to improper or incomplete HIS implementation, incompatibility in healthcare standards, lack of proper data input and validation, and accelerating evolution of technology triggering instability of candidate solutions depending on it. This paper continues the research by describing high-level non-functional requirements that any solution should satisfy relying on current best-practice, and subsequently customizing an established international standard so as to define an evaluation framework that can be used to assess candidate HIS architectures. The ultimate aim of the research is to support selection of stable, sustainable long-term architectural solutions and thus to assist HIS strategic decision making and self-evolution supporting agility.

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Keywords: health information system; healthcare standard; architecture evaluation; patient identification; non-functional requirements.

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1. Introduction

Patient safety in healthcare is an essential problem which, despite ongoing efforts, is still not properly resolved [1-3]. An essential aspect of this problem is patient identification, which supports the many critical points in medical care (such as transfer, handover, diagnosis, medication management etc.), thus ensuring patient safety. Today's increasingly complex, dynamic, busy and often under-resourced health systems lead to issues such as patient identification turning into 'wicked' problems [4] – multifaceted, without a clear solution, occurring within dynamic and volatile environments [5]. This problem is further exacerbated by natural- or man-made catastrophic events typically having medical consequences such as pandemics, earthquakes, fires, flooding, etc.

An unfortunate consequence of the above problem is that, despite technological advances and initiatives, patients often receive their proper treatment only after a serious error that may result in their harm [1, 6]. Root causes of patient misidentification include: incorrect patient identification at registration, time pressure in treatment, insufficient training and awareness, duplicate medical records in the same of different systems, human error, 'silo' issues across departments or processes, inadequate safety procedures, over-reliance on own identification systems and patient behavioral issues [7, 8].

Potential solutions to the above-mentioned problem have to consider its 'wicked' aspect - thus dealing with the complexity, unclarity and constantly evolving aspects. An important aspect are also the *constraints* imposed on potential solutions, with an emphasis on architecturally significant requirements [9], or so-called '-ilities' that should feature in sustainable HIS architectures such as promoted by the World Health Organisation (WHO) [10]. Previous work has spelled out preliminary requirements and has sketched how these *significant* -ilities might be structured and built into a sustainable long-term HIS architectural solution [11]. This paper aims to expand on the requirements and corresponding evaluation processes that would be part of a healthcare architectural *evaluation framework* usable to assess self-evolving, ubiquitous Patient identification solutions.

2. Required Properties of Patient Identification Solutions

Any candidate patient identification solution needs to be assessed against a set of desired systemic properties. Previous work in the HIS non-functional requirements area includes Lowry's [12] report on technical evaluation of the usability of Electronic Health Records (EHR) and Horbst's systematic review on EHR quality requirements [13]. There is also an extensive literature on non-functional requirements and associated processes; however, its intended target and applicability is focused mainly on systems engineering [14, 15] or more specifically software systems engineering [16-18], rather than enterprises. As the 'health enterprise' and its HIS form a typically large scale, complex and evolving *System-of-Systems* (SoS) with a long-term viability requirement, the priorities and relevance of the existing -ilities will differ. Thus, the value and novelty of the present work stems from a) the adaptation and enrichment of a generic list of -ilities into the set required for systems providing solutions to the healthcare domain, and b) the structuring of the ways these -ilities can be assessed into an *evaluation framework*.

2.1. Quality Attributes of Systems of Systems

The international Standard ISO 25010-2011 [19] provides guidance on quality attributes of systems and additional attributes relevant to system use. Section 4.1 of the Standard (see **Erro! A origem da referência não foi encontrada.**) also describes sub-categories of quality attributes of systems. In the authors' opinion this provides a suitable starting point for a set of attributes that all solutions should satisfy. This section presents these attributes while also briefly explaining some essential aspects.

Table 1. Categories of quality attributes (with sub-categories in italics).
(Source: the publicly available informative section of ISO25010 [19])

- Functional suitability: *Functional completeness, Functional correctness, Functional appropriateness;*
- Performance efficiency: *Time behaviour, Resource utilization, Capacity;*
- Compatibility: *Co-existence, Interoperability;*
- Usability*;*

- 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*.

Thus, Functional Suitability expresses the fact that the candidate solution should be complete, correct and appropriate from the point of view of the intended use. As nowadays patients are increasingly mobile and often being treated in multiple healthcare institutions, a complete, correct and appropriate candidate solution should be able to uniquely identify patients across all involved providers and access their information from all relevant locations [20].

Performance Efficiency: As the candidate system is expected to be suitable for all scenarios, including emergencies, it should be able to respond in useful time e.g. so as to be able to support rescue services. In addition, as patient identification may be required in the field in isolated locations, the system may need to run on mobile platforms typically having limited memory, computing and power resources. The candidate system should also have adequate capacity so as to be able to handle the entire envisaged scope, which may vary from a ward to a cluster of hospitals. The aspiration should be that the solution is in fact a System-of-Systems whose components are fully interconnected, integrated and interoperate seamlessly [21] in order to cater for patients worldwide. Moreover, as interoperability is currently still inadequately implemented [22], the proposed evaluation framework must also assess the effectiveness of this quality attribute.

Compatibility: Many hospitals have historic in-house, self-developed patient identification proprietary solutions. Over-reliance on such home-grown systems is identified as a risk to patients [8] as they are usually incompatible with other systems, sometimes even within the same medical institution, exposing patients to medical errors. A suitable candidate solution should be able to co-exist with legacy solutions and be interoperable with these at least so as to enable a deliberate stable and planned transition to the new system.

Usability is 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” [23]. As such, the candidate solution should be fit for purpose, recognisable, easy to learn and operate, offer user error protection (e.g. flag potential semantic problems based on heuristics [24]), display user interface aesthetics and have accessibility features catering for the entire range of intended users.

Due to dealing with human life, the candidate solution has to be *reliable*, i.e. display a high level of *effective* (i.e. performing its intended duties within parameters) uptime while featuring fault tolerance and ability to gracefully exit and recover from errors [25]. Security is a very important non-functional requirement for a candidate ubiquitous patient identification solution due to the requirements for data privacy (which have been inadequate in many EHR systems [26]) and the risks involved in potential identify theft [27] and data corruption. Thus, the candidate system has to ensure information confidentiality but also be able to authenticate users, preserve data integrity and enable accountability [28].

An acceptable candidate solution must also be highly maintainable. Due to the nature of the domain which can become unpredictable (e.g. in emergencies such as pandemics), the system should be able to be readily improved whereby its composing modules are easy to analyse and upgrade / replace as seen fit, ideally during normal operation of the system as a whole. Multi-platform availability and ease of installation would also be required for a system able to uniquely identify patients irrespective of the available hardware and current location.

Satisfaction of the users should not be underestimated as a perfect solution that is not used is pointless and will not ‘stick’ (i.e. users will eventually revert to previous practice). In particular, *trust* is an essential human-specific aspect that cannot be imposed or rushed [29]. From the patient’s point of view, trust is also influenced by cultural norms that may vary between patient cohorts (e.g. the acceptance of certain biometric identification methods).

2.2. A Working List of -ilities for Assessment

In practice, for a particular endeavour (such as e.g. the use of a specific technology in patient identification) impacting a certain HIS, it would typically be unfeasible to assess the entire set of -ilities of the HIS in question. Therefore, the authors propose an evaluation regime that trims the initial -ilities set and thus supports meaningful comparisons and associated implementation decisions.

Boehm et al. define a 'means-ends hierarchy of IDIO (Initial Definition of an -Ilities Ontology) stakeholder value-based -ilities' [30]. Here, the -ilities defined summarize the class hierarchy of the primary stakeholder -ility end-value classes of Mission Effectiveness, Resource Utilization, Dependability and Flexibility, joined by their primary means-ends subclasses, and the primary composite ilities of Affordability and Resilience [ibid.].

Based on the set of requirements shown in **Erro! A origem da referência não foi encontrada.** and on Boehm et al.'s above-mentioned hierarchy, the authors propose a working list of -ilities for assessment shown in **Erro! A origem da referência não foi encontrada.**. This set adds *ubiquity* (the capacity of being used irrespective of location), *evolvability* (understood as adaptive (self-)evolution [31]) and *viability* (namely, the system's capability of long-term survival), all very relevant system quality attributes considering the candidate solutions that the proposed evaluation framework is aimed at.

Similar to Boehm et al.'s work, the selection of -ilities is also based on the INCOSE Systems Engineering Handbook's definition of systems engineering as "an interdisciplinary approach and means to enable the realization of successful systems" [32], as well as the Fundamental System Success Theorem [33], which states that the success of a system directly depends on the achievement level of its success-critical stakeholders, such as operational stakeholders and those investing key resources in the definition, development operation and maintenance of the system.

Table 2. Categories of quality attributes (with sub-categories in italics).

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
• *Evolvability*
• *Ubiquity*
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*

An important purpose of the final -ility list is to contain compulsory criteria for long term HIS infrastructure decisions. As such, it can be used to filter out solutions favoured by some stakeholders concerned with a shorter horizon that may in fact *hinder* the achievement of long-term strategic goals.

3. A Generic Architecture Evaluation Standard

ISO42030 [34] aims to organize and record architecture evaluations for the enterprise, systems and software fields of application. This is done by using a process that supports architectural decision-making and thus improving architecture governance maturity. The standard attempts to generalize previous work on architecture evaluation, such as the Architecture Trade-off Analysis Method – ATAM [35], the Method Framework for Engineering System Architectures (QASAR) [36], and Analysis of Alternatives – AoA [37]. Note that a related standard, ISO 42020 'Architecture processes' [38] has been used in *conceptualizing* the architecture of HIS [39], while the focus of the present work is on one of the architecture processes, namely architecture evaluation.

According to ISO42030, the evaluation of alternatives should be performed in *two passes*: 1) eliminate proposals that do not satisfy mandatory non-functional requirements, and 2) compare candidate solutions using an *appropriate* decision-making method. ISO 42030 requires that, based on business goals, architecture governance derives the *evaluation objectives,* specifying *what kind of answers are expected from the architecture evaluation*. Objectives may e.g. include the desire to determine whether the solution will reduce the total cost of ownership (and if so then to what extent), or if it will improve current capability and/or service quality.

The comparison of potential solutions is to be performed by defining factors that influence the answers, and selecting methods known to deliver these answers. *Evaluation factors* (typically obtained from business drivers) may contain cost, schedule, quality, risk etc. Corresponding evaluation methods on this level typically include referring to existing analysis reports, or using expert panels – hence not very formal. This is an important aspect because in practice often there is an extensive number of objectives and factors which need to be filtered using prompt and reasonable methods.

It is also often the case that the answers to the above are unclear, and to accomplish a meaningful comparison of architectural solutions one also needs to ask e.g. *what is the value* of a particular architecture. For example, it may be necessary to establish whether the quality requirements are met, or there is a possible trade-off, or an opportunity to optimize; or, the way architectural decisions contribute to the expected quality attributes.

As part of this value assessment process, it must be determined how and to what extent the chosen architecture contributes to achieving the business goals. The value of the chosen approach may be shown using key performance indicators based on adequately selected metrics such as velocity, throughput, cost, etc. The findings of architecture evaluation performed using value assessment factors are then to be compiled using value assessment methods.

Further *architectural analysis* is needed if the desired measures are not readily available when inspecting the proposed architecture; this may require the development of e.g. simulation models usable for *sensitivity analyses*. For example, one can perform quantitative statistical analysis based on simulation models so as to establish the extent to which the candidate architectural solution meets the desired quality attributes. Some other systemic properties (availability, changeability, robustness, evolvability, complexity) may be expressed using graph properties of the system, or by entropy calculations, etc. Note that architecture analysis endeavors typically also include the analysis of alternatives [40] and therefore they are quite costly in resources and time; hence, such work should only performed as a last resort.

4. A Framework to Evaluate Proposed Ubiquitous Patient Identification Solutions

Solutions advocated at any one time by protagonists (e.g. the use of certain biometrics for patient identification) must be able to be evaluated against the desired criteria discussed in Section 2. While the generic framework of ISO 42030 international standard gives guidance, a practical application requires the identification of domain-specific objectives, evaluation factors and methods.

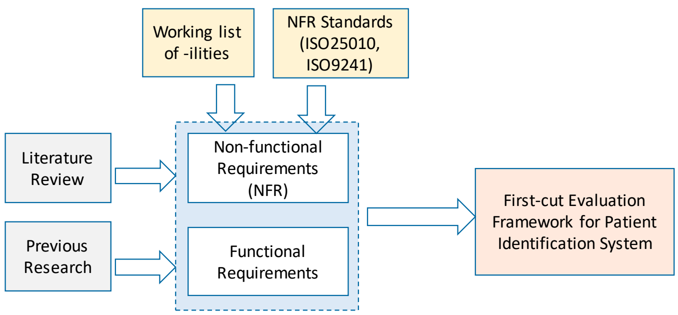

Fig. 1. Building the first-cut Evaluation Framework.

According to ISO42030 recommendations (see Section 3), a first-cut version of the evaluation framework intended for a specific domain such as patient identification can be developed based on the systemic properties discussed and found desirable for any proposed patient identification solution (see Fig. 1). Following the proof-of-concept stage, the proposed list of artefacts must be validated with stakeholders, refined and possibly trimmed or expanded by the architecture governance processes. Fig. 2 shows the subsequent process of defining evaluation objectives, factors and methods and, if required, performing value and architecture analysis.

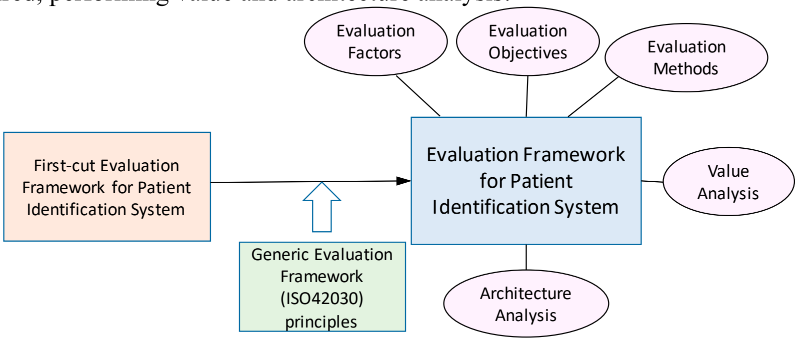

Fig. 2. Evaluation Framework components

4.1. Evaluation Objectives

In discussing the relevant evaluation objectives for the architecture of a patient identification solution to be embedded on multiple levels into the healthcare SoS, the first difficulty encountered is that in the healthcare ecosystem there is no single 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, evaluation objectives must include the mandate to answer the following fundamental questions:

- Does the architecture of the healthcare SoS display a structure enabling continuous long-term change and improvement to ensure long term *viability*?

- 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*.

- Is there a guarantee that system changes satisfy the end user quality of service requirements? For example, the reasons for the presence of *usability* in the mandatory list of -ilities include the recurrent reports about lack of usability and / or good user experience design result in poor adoption by medical staff and a number of adverse effects that prevent the full benefits from being realised [12].

Note that other evaluation objectives could be defined and used based on the -ilities listed in Tables 1 and 2; however, the scope of this paper is mainly the viability aspect.

Given that the evaluation concerns the architecture of a systems of systems (SoS), these objectives are relevant for each level and constituent of the healthcare ecosystem, according to the theory of the Viable Systems Model [41]. 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 health- and allied health care providers).

4.2. Evaluation Factors

Architecture evaluation factors are often categorized as Political, Economic, Social, Technological, Environmental and Legal (PESTEL). This categorization (originating from the work of Aguilar [42]) helps the designer of the evaluation to find relevant factors and determine what methods to use. For example, an economic factor of viability is whether the patient identification 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 modularizing the system architecture to separate patient identification technology choice from the service user, thus localizing the change effects).

In addition, when evaluating systems for usability, one must again include economic factors; for example, it needs to be understood whether the use of the patient identification solution requires extra work, extra resources, or otherwise may slow down the medical service.

4.3. Evaluation Methods

Depending on the evaluation factors at hand, there can be a number of options to use, including medical expert reviews, references to existing strategic analyses from authoritative sources (e.g. WHO), and others. If the identified methods cannot give a conclusive answer, then *architecture evaluation* needs to be employed so as reconsider the evaluation of the relevant factor(s) of the solution using a viewpoint based on the value contributed to business goals.

An important technicality in this evaluation effort is that while patient identification solutions may be often technology-focused, there is no corresponding articulation of how technology objectives support the broader population health and well-being business goals. To address this problem, the derivation of the evaluation objectives may have to use methods specially developed for business–technology alignment. Directives regarding how to derive technology objectives from business goals can be found in COBIT [43] and ISO3850 [44].

It is to be noted that the quality of the evaluation objectives depends on the capability and maturity of architecture governance and architecture management. As a result, adopting an architecture evaluation framework and method may be futile if there is no equal emphasis on improving the maturity of governance and management processes.

As a result of the evaluation, a *synthesis report* is produced, identifying the extent the architecture satisfies business goals, as well as identifying risks due to uncertainty or lack of available information.

4.4. Value Analysis

Value analysis has its own objectives, factors and methods, with the resulting reports incorporated into the subsequent architecture evaluation synthesis report. Space and scope limitations do not allow a factors and methods listing here; however, it must be noted that value assessment should try to use existing sources of information, such as historical records of past projects. Should the outcomes of value assessment methods be inconclusive, a third layer of architecture evaluation, i.e. 'architecture analysis' is necessary.

Value analysis objectives may be classified in several ways. A natural way to do this is to organize the objectives by stakeholders, i.e., include questions such as: what is the (qualitative and quantitative) value for the health services provider, for the patient, and for health services management? For each of these stakeholder categories the value may be positive or negative, and care must be taken that in addition to a value statement, a value analysis must follow.

Given patient identification as the running example, it is apparent that the same solution may have both positive and negative value for a stakeholder depending on the factors considered, such as a doctor may perceive the extra administrative load as producing negative value if considered *workload* as a factor, but at the same time given *ethical impact* as an evaluation factor may be seen as providing positive value (e.g., preventing iatrogenic errors).

The value may not be easy to determine: e.g. if the quantitative workload impact can only be determined by analyzing the processes before and after the adoption of the solution, this situation leads to engaging the next layer, namely Architecture Analysis.

4.5. Architecture Analysis

Architecture analysis also has its own objectives, factors and methods, with 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 patient identification-related process cannot be ascertained from the point of view of workload as a factor, then business process *modelling* and *simulation* may be required to model the economic impact of the architectural change resulting from the solution being rolled out. Factors that may be considered as parameters are for example: the time taken to perform patient identification, the number of administrative tasks (and the time needed to perform them) associated with the new method (including back office tasks related to the privacy and security of storing and using personally identifiable information) and the cost to have the previous factors within acceptable boundaries. *Experimentation* may also be employed e.g. by creating a proof of concept of a pilot implementation, which then will be used to conduct usability experiments in healthcare environments.

From the above factor descriptions and the proposed working list of -ilities in Section 2 (and according to [40]) it can be seen that the various dimensions of the healthcare universe of discourse can be in tension. Hence, architecture evaluation also aims to identify the *key trade-offs* and their consequences so as to deliver the most stable and robust patient identification architectural solution.

It is important to acknowledge that to ensure one has covered a significant part of the healthcare ‘tradespace’ [40], *alternative architectures* may also need to be considered, which will further expand the required effort and as such must be approached based on proper rationale. Note that in this context, the authors use Martin’s [ibid.] definition of tradespace as the collection of enterprise, program and system parameters, attributes and characteristics which are necessary in order to satisfy a variety of stakeholder concerns throughout a system’s lifecycle, notably while staying within relevant constraints.

5. Evaluation Process

As shown in previous work [45], patient identification techniques are useful to various degrees in different scenarios and have their own features, requirements, difficulties and advantages. Due to the need to adopt future-proof systems in the presence of uncertainty, an evaluation framework should be able to assess proposed solutions both in terms of a) the long term sustained performance of technical systems that provide patient identification services (such as those using biometrics), 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 the patient identification point of view, both the healthcare ecosystem and the system(s) providing patient identification service need to be considered.

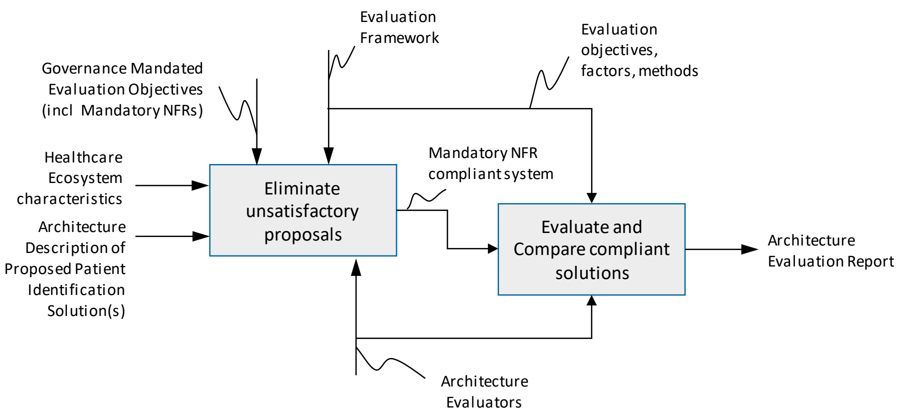

Fig. 3. Proposed Evaluation Process

Fig. 3 shows the evaluation endeavour in form of an IDEF0 [46] activity model. Thus, the Healthcare Ecosystem characteristics and the architecture description of the proposed Patient Identification solution are the inputs to the evaluation process, the architecture evaluators are the resources used to perform the evaluation, the evaluation objectives (as stated by governance) and the Evaluation Framework control the assessment activity, whereupon the result is an Evaluation Report (which may include proposals to either accept, reject or modify the solution, discussion of trade-offs, etc.). Note that the process may be used to assess and compare multiple solution proposals so as to appropriately cover the relevant tradespace.

The evaluation objectives relate to the concerns of a wide range stakeholders, which includes those who use, manage, conceive, specify, evaluate, develop, operate, support, maintain, and improve the patient identification service – in other words the entities involved in the whole of life of the service, and therefore the development of evaluation objectives is an important (albeit also onerous) responsibility of architecture governance.

6. Evaluation Process

This paper has proposed an evaluation framework for self-evolving, ubiquitous architectural solutions aiming to address the currently still unsolved patient identification issues. The paper builds on previous work, performs new research and uses several relevant standards, notably attempting to specialise the International Standard for Architecture Evaluation (ISO 42030) for the problem in question.

A key finding is that the difficulty of managing the solution space of the patient identification problem has multiple roots:

i) The Healthcare Ecosystem is a *System of Systems*, without an ultimate central authority to control its evolution;

ii) A patient identification infrastructure must remain *viable* on a very long term; currently, there is only episodic experience with successful long-term IT infrastructure building, with significant social and political factors influencing its success;

iii) Technology changes at an increasing 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 entities involved in the governance and management of the Healthcare Ecosystem, such as government agencies (e.g. health departments, health district management), Non-Governmental Organizations (such as the WHO, standards bodies, etc.) and even HIS vendors. Due to the complexity involved, such entities would seek to base their decision-making on a disciplined and structured approach provided by the application of a domain-specific architecture evaluation framework to candidate solutions.

Further work aims to assess the proposed evaluation framework using case studies selected to expose and test its various elements while further developing it based on feedback. It is also envisaged that the framework will be subject to validation by selected experts from key success stakeholder groups.

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