Understanding the Evolution of Standards: Alignment and Reconfiguration in Standards Development and Implementation Arenas[1]

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ABSTRACT: The paper focuses on the various frameworks that have been advanced for socio-economic analysis of compatibility standards in information systems, and their adequacy in addressing a set of key issues and challenges. The paper draws upon the concepts developed within the social shaping of technology perspective to approach the standardization process in a dynamic fashion. A dynamic approach to the analysis of standards development is proposed which examines together the settings of standard development and use. The analysis addresses the entire life cycle of a standard, which is conceived in terms of a series of versions of a particular standard, and the displacement of one standard by another. These issues are explored empirically through the case study of healthcare messaging standards in the English and Scottish healthcare sectors.

1. Introduction: laying out the context

The crucial role that standards play for Information and Communication Technologies (ICT) development, especially in relation with technological innovation processes, has been largely documented in the socio-economic literature on standard development. Standardisation has been found to have a major impact on technology innovations (Jakobs, 1998), to represent an endogenous factor that shapes technology development (Egyedi, 1996), and to affect the rate and direction of innovation (David and Steinmueller, 1994). A growing body of literature has thus emerged investigating the factors shaping the standards development process and its outcomes.

This paper addresses some analytical challenges and shortcomings evident in this literature. For methodological, practical and theoretical reasons, many socio-economic studies of standard development have involved case-studies of particular instances and fora for the agreement for a particular standard, and focusing on the interplay between the various interests involved in relation to a particular standard.

The result has been a markedly static conception of the standardisation process. The interaction between the various stages in a standard life cycle and its influence on the evolution of standards over time has been largely ignored in existing research. Examples include the analysis by Graham et al (1995) of the global development of the EDIFACT standard, and the

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discussion by Egyedi and Loeffen (2002) regarding the transition from SGML to XML and Schmidt and Werle (1998) analysis of telecommunications standard development. While providing useful insights into the socially shaped nature of the standard development process, for example by illustrating the conflict and alignment of interests between the actors (Graham et al, 1995), and the mixed socio-technical nature of the process (Egyedi & Loeffen, 2002), such studies do not address the dynamic analysis of standards as they evolve over time.

We argue that such a static focus has restricted the ability of existing socio-economic analytical frameworks to conceptualise and fully investigate the ongoing relation between the various stages in the standard life cycle and interaction between standards and their evolution over time.

1.2. The objectives of the paper

The reasons for these shortcomings in existing studies of standardisation are various, and include practical considerations (for example resource constraints mean that direct investigation of standard setting contexts is limited in time and social/geographical space) as well as the prevalence of actor-centred accounts within much contemporary technology studies (which, with their concern to explore the influence of actors on standard development have tended to focus on the immediate locales of standard setting) (Williams, 1997). We suggest that the framework of analysis has to be enlarged in order to account for a dynamic evaluation of standard development. The aim of this paper is to articulate a more complex conceptual framework that can address the dynamics of standards as they evolve over time. Two major objectives are addressed in this paper.

(1) First, the paper examines the standards development and implementation stages together, even if they operate in very different kinds of socio-technical settings.

(2) Second, the analysis of standardisation process is approached from an evolutionary perspective, where the life-cycle of standards is conceived in terms of series of versions of a particular standard, and the displacement of one standard by another.

The next section will lay out the theoretical argumentation which justifies a dynamic approach to understand standards development and use. Such a move clearly presents a number of challenges for research, which needs to take on board longitudinal study and to address the interaction between a number of social locales. The theoretical discussion will be exemplified in the following section with a short discussion of the evolution of healthcare messaging standards in the British health service. A discussion of the findings of the study concludes this paper.

2. Theoretical approach and framework

2.1. Background

In the broad sense, a standard can be defined as "*a set of specifications to which all elements of product, processes, formats, or procedures under its jurisdiction must conform*" (Tassey, 2000, pg. 588). David and Steinmueller (1994) differentiate between four categories of standards, reference standards, minimum quality standards, technical interface design standards, and compatibility standards. This paper focuses on the latter category, i.e. standards that "*assure the user that a component or sub-system can successfully be incorporated, and be 'inter-operable' with other constituents of a large system of closely specified inputs and outputs.*" (David and Steinmueller, 1994, pg. 218). Compatibility standards are addressed in relation with network

ICTs, in which case they are crucial in that they enable data exchange between components within a particular system or between different inter-organisational information systems.

The development and implementation of compatibility standards not only technically defines a method of interoperation between the different components in a network, but most importantly it represents a proposal for the future of complex socio-technical systems, that is the shape of a inter-organisational network. According to Graham et al (1995), the standardisation process also represents an attempt to align interests, business practices and expectations of an array of people with an interest to develop and use the system that is to be standardised. Therefore, standardisation is not only about providing workable solution, but most importantly, it refers to articulating and aligning expectations and interests (Williams, 1997).

A number of different analytical frameworks have been used in the existing standardisation literature to address the development and, less often, the implementation and use of standards. An overview of these frameworks is presented in the table below, together with some examples of the studies in which they have been, implicitly or explicitly, used:

Table 1. Analytical frameworks in standardisation research

Analytical framework	Basic premises	Studies in standardisation
Technocratic ideology	Standard setting is seen as neutral, and the actors are seen as "interest free" engineers who collaborate in order to develop the best technical solution to a technical problem.	Thompson, 1954
Bureaucratic ideology	It is similar to the technocratic ideology framework in that participants in the standardisation process are seen as collaborating toward the development of the best technical solution. However, standard setting is seen as following specific rules and procedures in order to ensure that standards emerge through a democratic process (e.g. due process, fairness, transparency and openness, consensus voting system).	Bensen and Farrell, 1991
Simple interest model	Standard setting is seen as a game of power and dominance between the participants. The framework usually attempts to model the interplay between the interests of the actors.	Farrell and Saloner, 1985, 1988; Cohen, 2003; Park, 2003.
The social shaping model of standard setting	The standard setting is conceptualised as actor networks, and the focus of the analysis is on mapping the different relevant groups involved in the process.	Schmidt and Werle, 1998
The social shaping model of emerging standards: Actor-network theory	The various interests of the actors involved are seen as negotiated constructs, forged in the process of alliance building. The actors involved (which according to ANT include humans and non-humans) try to translate their interests into the standard, hence the outcome of standardisation is seen as the result of a negotiation process. The process of technological change and its outcomes, and in particular the development of standards, is seen as locally constructed, negotiable and contingent. However, the framework has difficulties in accounting for the influence of prior history, and for taken for granted relations, routines and the broader context and structures.	Graham et al, 1995 Spinardi et al, 1996 Monteiro and Hanseth, 1995
Re- conceptualisation of the social shaping – the development arena	The debates around the role of action versus structure and of particular actors, communities and broader social milieu in shaping technological innovation have provoked a rethinking of the social shaping perspective to pay attention to the complex interactions in innovation amongst a wide range of players and across diverse settings (Sorensen and Williams, 2002). In the area of standardisation, one concept that has emerged to theorise these interactions is the development arena (Jorgensen and Sorensen, 1999). The development arena concept has enabled a multi-level analysis that encompasses the interactions between various actors networks involved in standards development.	Williams and Edge, 1996; Sorensen and Williams, 2002; Jorgensen and Sorensen, 1999; Hwang, 2003

Over the years, the literature on standardisation has shown an evolution of the analytical frameworks employed to study the process of standards development. However, as discussed during the introduction, most of these frameworks employ a static perspective and address the development process in isolation from the context of standards use. The challenge in analysing the standardisation process is to produce an adequate evolutionary account of the complex dynamics surrounding the standards, account which includes both the standard development and use settings.

2.2. Standardisation process - a dynamic approach

To understand the dynamic nature of the standardisation process, this paper draws upon Jorgensen and Sorensen (1999) concept of "development arena" to articulate the dispersed and heterogeneous nature of the space where standards develop and are eventually used. A "development arena" is defined as a space which holds together the settings and relationships that comprise the context where a standard develops, and includes three distinct elements: (1) a number of elements such as actors, artefacts and standards, (2) a variety of locations for action, knowledge and vision, and (3) a set of translations that shape and play out the stabilisation and destabilisation of relation and artefacts.

The notion of "development arena" emphasises the idea that a particular product or process is shaping and changing throughout its life time, and that the processes of market creation, user positioning, recruitment and interaction are as important as the early stage of development in shaping the product (Jorgensen and Sorensen, 1999). The "development arena" concept is very similar to the Actor Network notion of "actor worlds" (Callon, 1986). However, Callon's "actor world" describes how actor networks are built, maintained, and how they break down, but it does not address the problem of competition between them, i.e. how different such actor networks compete in building different actor worlds. In contrast, Jorgensen and Sorensen develop the notion of "development arena" specifically to address the issue of competition and co-operation between different actor networks, that is to explain how different actor networks co-exist and interfere with each other within a certain space. In this way, the notion of "development arena" can be applied to explain the evolution of standards as a result of competition and co-operation between different networks of actors (Jorgensen and Sorensen, 1999).

Consequently, the notion of "development arena" can be used to bring together the different stages of standard development, and at the same time to emphasise the competition and co-operation processes that underline the evolution of standards, both in terms of different versions of standards and as standard replacements. In this way, the concept is useful to address both objectives of this paper.

2.2.1. Standards development and implementation stages

The different stages of the standard life cycle operate in very different socio-technical settings. The locus of standardisation, as well as the actors involved in the process, and their attributes are different in the two stages. For example, in the case of official SDOs or even for private consortia[2], standards are developed within the standard organisation technical committees, whereas the implementation is (at least in principle) done in the entire market that those standards address. Precisely because of this reason, the existing socio-economic analysis has looked at standard development in isolation from standard implementation. However, to understand the standardisation process "in making", i.e. how it evolves and how it is shaped and structured over time, these different socio-technical settings must be considered together under the umbrella of the "development arena" concept.

Such an approach allows to identify not only the factors that shape each of the two stages, but also the linkages that are forming between the development and implementation stage as a result of the interaction between these factors. For example, the level of formality of the standard setting may depend on the organisational culture in which standards are to be implemented, as it was the case for clinical standard messaging in the Scottish health service (see section 4.1). In this way, the development process can be informed by implementation issues such as the organisational nature in which implementation takes place,

[2] For the distinction between traditional SDOs and private consortia, see Hawkins, 1999. The distinction between market (de facto) and committee based (SDOs and consortia) standardisation is explained in Farrell and Saloner, 1988.

the requirements of the users, the size of the potential market, the willingness of the players to align with it, and the existence of competing proprietary standards. At the same time, the success or failure of a standard implementation may depend not only on factors pertaining to the implementation context, but also on the nature of the setting in which the standard has been developed. For example, the extent to which the standard settings allow for the involvement of the users may influence the extent to which the emerging standards fit such users' requirements, hence facilitating the implementation process.

Moreover, such an approach which brings together the implementation and development stage highlights the role that the various kinds of intermediaries such as technology suppliers, and user representatives play in linking these domains of development and use more or less effectively. As a result, the approach allows to identify the complex interaction existing between the two domains[3].

2.2.2. Standards life cycle

The second purpose of the paper is to address the analysis of the standards life-cycle as conceived in terms of a series of versions of a particular standard, and the displacement of one standard by another. Such an approach allows for the dynamic nature of standard development to be unveiled.

Whereas standard development, their adoption and diffusion has been the preoccupation of a number of researchers, there is almost no research done in what concerns standards in use, which addresses the entire life cycle of a standards. Notable exceptions are Moreton et al (1995) and Sloane (2000) who have looked at the factors that influence the change in the standards used in organisations. They develop a model of standards life cycle as a number of routes between the need for and the obsolescence of a standard. The model differentiates between six types of standards for information management and technology[4] and the different routes and conditions that lead to the formation of a particular standard. However, their model looks at standard development and implementation in isolation, not addressing the interaction between the two stages.

The whole process of standard development has to be conceived as a process of shaping, of evolution and of "becoming" which cannot be limited only to established standards. The standards life cycle has to address both the replacement of one standard by another, as well as the evolution within a standard as a succession of different versions. As discussed in the previous section, such a life cycle has to conceptualise the two stages in the standardisation process together, addressing the complex interactions between them as they evolve over time.

In this way, this paper seeks a more effective understanding of the way standards evolve over time not only through interaction with the environment in which they are developed, but equally important with the environment where they are applied (i.e. the market context).

3. Empirical research: messaging standards in the UK health service

The theoretical argument is exemplified with a discussion of the evolution of standards for communication of clinical data in the Scottish and English healthcare market. The empirical research follows a multi case study research design. Two cases are included into the analysis: the process of standardising health care messaging in the UK National Health Service (NHS). These two cases are selected because they allow for

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[3] For example, in the British long term insurance industry, the standardisation of B2B processes between insurance companies and the financial advisers market (IFAs market) is driven by the large insurance companies. However, the use of standards involves both the insurers and the IFAs, where the latter buy the technology incorporating the standards from system suppliers, and deal with most of the insurers through service providers (portals). Such system suppliers and service providers become the IFAs proxies in the standard development process, and play a crucial role in linking the end users of the standards (IFAs market) with the providers of the standards (the insurance companies who drive standard development).

[4] Moreton et al (1995) classifies the standards for information management and technology in closed, proprietary, de facto, de jure, open and consortium.

the exploration of two very different instances of the phenomenon under study (a pragmatic and informal approach to standardisation in Scotland versus a highly formalised approach in England) although in two similar contexts (same standard, and same country). The two cases represent very different pathways for the development and implementation of compatibility standards for the same application domain: clinical data messaging.

The two case studies illustrate the two objectives of this research:

(1) The NHS Scotland case exemplifies the complex interactions that exist between the standard development and implementation stages.

(2) The NHS England and Wales case explores the factors that explain the evolution within the HL7 standard, a standard for clinical data messaging developed within an American based consortium.

Semi-structured interviews have been used for data collection, complemented with secondary data sources such as internal documentation and publicly available reports. Over a period of 6 months, 15 interviews have been conducted[5].

At the end of the last decade, both NHS Scotland (2000) and NHS England and Wales (1998) were announcing radical changes in their approach to information technology. Both approaches were aiming at to take advantage of the promised benefits of the new Internet technologies by developing an integrated electronic patient care system, where the IT systems would be designed and delivered around the needs of the patients, and not around the NHS institutions. Such an integrated electronic system for patient care was seen as a significant effort to increase the efficiency of the health service. Whereas the objectives were the same, the manner in which they were to be achieved were significantly in the two regions of the UK.

- The National Programme for Information Technology (NPfIT) was a radical approach to change the entire strategy for information service provision in the NHS England and Wales. The plan is to have a foundation layer of nationwide applications running over a new broadband infrastructure. Three main applications are build on this new infrastructures: a national e-bookings system which enable the patient to participate in where and when an appointment is made, an electronic transmission of prescriptions which will enable prescriptions to be send electronically between GPs and retail pharmacies, and a national integrated patient care service. The infrastructure is delivered by a national infrastructure provider, whereas the national services will be delivered by one national application service provider (BT). This national patient record system, comprising a medical snapshot of every patient, will be fed into a national “spine”, delivered by BT, on top of the IT infrastructure. The spine will link the full range of the IT services specified locally and provided by Local Service Providers. NHS England is split in five clusters of strategic health authorities, and the rights to supply software and support services have been awarded to Accenture (Eastern Cluster and North East Cluster), the Capital Care Alliance led by BT (London Cluster), Computer Sciences (North West and West Midlands Cluster) and Fujitsu Alliance (Southern Cluster). As a result, electronic patient records will be hold centrally, and will be available from all parts of the NHS, with improved debugging, duplication and management facilities compared with today's distributed, fragmented systems.
- In NHS Scotland, the information strategy followed the same objectives as the NPfIT, i.e. integrated electronic patient care system, electronic booking and electronic transmission of prescriptions. However, the strategy followed an incremental approach rather than a radical change of the IT provision in Scotland. Rather than building a common spine across the NHS, in Scotland the electronic patient records would be kept regionally at the level of the health boards. The patient record repository is called SCI (Scottish Care Information) store and was developed

[5] The interviews cover 2 respondents involved in devising the new e-health strategy for the NHS Scotland and one member involved in the information standard group, 5 respondents involved in the development of new information systems from the NHS Scotland (SCI and ECCI programmes) and from the supplier companies involved, 3 respondents involved in the implementation of the standardised systems in the NHS Scotland health care trusts, a supplier member of the standard group in Scotland, the chair of the standard group in Scotland which was also member of the HL7 UK group, the Chair of the Technical Committee in the HL7 UK and one representastive of the NPfIT in the HL7 UK.

in partnership between NHS Scotland and SemaSchlumberger. To facilitate the exchange between SCI Store and the existing legacy systems within the local hospitals, and between the local hospitals and GPs, 5 additional SCI products are already (SCI Clinical, Gateway, Integration and Outpatients) or will be (SCI Prescriptions) developed. These are presented in the figure below.

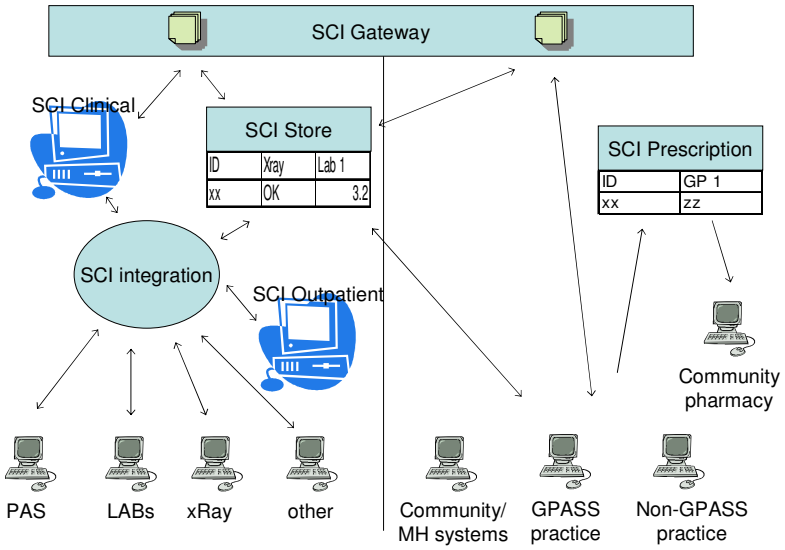

Figure 1. SCI products and their role in the Scottish NHS

Between all the SCI products, only SCI Store and SCI Gateway are compulsory, the local boards being free to choose the products, and thus the suppliers for the other applications.

The exchange of information between the various components in the integrated patient care system, either within the English spine or the Scottish SCI, requires the existence of common standards for clinical data messaging throughout the NHS. Such standards are required to specify the structure and content of the clinical data exchanged between the various IT systems in the NHS. The standards cover not only the network protocols (e.g. HTTM or SMPT) and the XML messaging (e.g. SOAP), but also the information flows between the various components of the NHS system (e.g. referral and discharge letter, clinical letter, appointment booking, lab results, test ordering).

The following two sections will discuss the approach to standardisation in the two UK regions of the NHS.

3.1. Standardisation in NHS Scotland: linking development with implementation and use of standards

Standard development was approached in NHS Scotland in a pragmatic manner, and *"the idea was to move ahead and actually getting something that works, with the realisation that there will be change, it can try and demonstrate the benefits relatively quickly, do something, get it adopted perhaps with change"* (Technical Architect). The emphasis in standards development was thus placed on speed rather than on the technical quality of the standards: the aim of the development effort was to build a "good enough standards" which "works fast" rather than investing the time and effort in developing the "gold standard" within an existing SDO (such as CEN or the HL7 consortium). As a result, the approach has been for the Scottish NHS to develop their own standards for clinical data messaging, where the structure and the content was based on existing standards such as the CEN pre-standard, the American HL7 and the NHS data dictionary type standards, and SIGN, READ and SNOMED codes, and existing NHS Information

Statistics Division published standards. Work on standard development has been done in parallel with system development and implementation: *"rather than going away and sitting in a sealed room and completing something, and then exposing it to the development, they (the standard development team) were sort of drip-feeding the (system) development"* (Technical Lead). As a result, standards development was constantly informed by the system development and the following implementation: *"[the] standard was always intended to grow, and it was always intended to evolve, and there was always intended to be a mechanism of people feeding into it"* (Technical Lead). Standards development has been thus approached in a gradual fashion, taking advantage of successive implementations. At the same time, optionality was gradually removed, and standards were becoming more prescriptive in terms of what end users, i.e. the clinicians using the standardised systems, can do.

The mechanism charged with controlling and monitoring the change in standards was the XML Steering Group (SG). SG was set up in 2000 as an informal group within the Information Statistics Division in NHS Scotland. Its members include the representatives of the NHS Scotland IT programmes, software suppliers for the NHS Scotland, NHS Scotland contractors and clinicians. Participation is open to everybody interested, no membership fees exist, and there are no formal procedures in place to regulate its proceedings. However, the involvement of system suppliers is less significant than in England for example, and their primary interest is in gaining awareness of what is happening and marketing their name, rather than a genuine interest in developing the standards: *"a lot of time they're coming here to get sort of intelligence, market advantage, networking but not actually committed to developing [the standard]."* (Technical Lead).

In conclusion, the development effort is characterised by a pragmatic and gradual approach, by a constant feedback with the development and implementation of systems and by open access and informal procedures. As it will be discussed next, this standards development setting is informed by the context in which standards are implemented and subsequently used, i.e. the NHS Scotland healthcare trusts. The various ways in which the settings in which standards are used shape the development process are illustrated in the figure below:

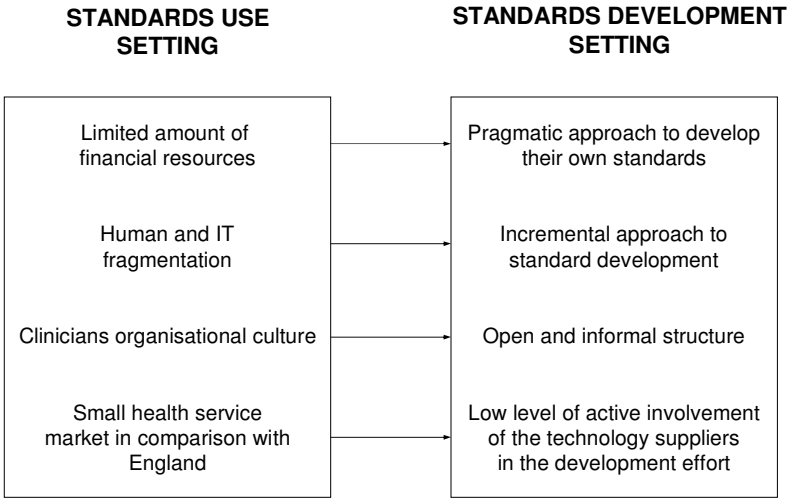

Figure 2. The influence of context of use over development of standards in NHS Scotland

- First of all, NHS Scotland is a relatively small market (especially in comparison with the NHS England and Wales), with a (comparatively) small budget allocated to IT developments and consequently, to standardisation. However, participation in SDOs requires significant financial effort not only in terms of participation fees, but also in terms of the time and travel costs for sending experts to the meetings[6]. As such participation costs do not depend on the size of the participant (e.g. NHS organisations from smaller health markets such as Scotland have to pay the same amount as those from larger markets such as America or England and Wales if they are to be actively involved in the standardisation efforts), they are high in the case of NHS Scotland relative to its total budget. As a result, rather than allocating the time and resources to get involved into an existing standardisation effort (e.g. CEN or HL7), NHS Scotland has preferred the pragmatic approach to develop their own standards.
- Second, healthcare across the world is generally characterised by a significant fragmentation in terms of clinical culture. Clinicians are seen to belong to a very diverse and highly independent community. Scotland is no exception: *"if you get 100 clinicians in a room you'll get 101 different views. I guess they're quite sort of independent-minded 'I have a way of doing things and it's the right way' kind of mentality, which means that it's quite hard to extract the common approach to something"* (SCI Technical). At the same time, the UK NHS (as many other national healthcare systems across the world) is populated by a large number of stand alone IT systems that do not interact with one another and where there is almost no reuse of data or software components. In Scotland, such a fragmentation is less visible in the primary care sector as GPASS (a GPs IT system) has achieved around 80% representation. However, in hospitals, interoperability is still a significant concern. As the standards concern not only the technical aspects of messaging between systems, but also the structure and content of the data exchanged between clinicians, they are relevant for the working practices of these clinicians. Standardising what data is to be exchanged, when, and in what manner thus affect not only the IT systems, but also the work of nurses, junior doctors, consultant, lab people and GPs which exchange such data. Therefore, in Scotland an incremental approach to standard development was seen as the best approach to deal with such a fragmented organisational culture, and with the existence of independent legacy systems. The reason was that such an incremental approach would allow the time for a parallel change in clinicians culture and working practice, as well as the time for replacing/upgrading the IT systems.
- Third, the open and informal structure of the SG has been a conscious choice in order to facilitate the involvement of clinicians in the process of standards development "*to make sure that the schema that we are producing are as widely applicable and as acceptable to the NHS community*" (member SG). The reasons are linked to the nature of the context in which standards are used: the clinicians see their work as "*an art rather than a science. So the more you say you need to specify this, you need to revise this data, then the more resistant they are.*" (Technical Lead). In this context, the clinicians would not accept a change in their working practices unless they themselves are shaping the decisions leading to that change. Consequently, the involvement of clinicians in the SG was seen as a way to facilitate their input into the standard process, to enable them to retain ownership over something that might affect their work, and eventually to support the adoption of the standards.
- Finally, the passive involvement of suppliers in the process of standard development can be understood better in the light of the context in which standards are implemented and then used. In general, technology suppliers have a strong input into standardisation efforts[7]. However, most of the technology suppliers for NHS Scotland also operate in the much bigger and more profitable English market, and are therefore more inclined to commit themselves to the English model

[6] Existing empirical studies have shown that due to this high participation costs, SMEs often find themselves restricted in their ability to get involved in formal standard development in contrast with large organisations which can afford the time and financial effort that such formal standard settings requires (Jakobs, 2000).

[7] See for example the HL 7 consortia, or any other private ICTs standard consortia created during the last decade.

where the potential payoffs are higher[8]: "*to be fair to the commercial system suppliers, Scotland's a tiny market, they're much bigger in England and probably huge in America.*" (Technical Lead). In this context, there are few incentives for them to invest resources and time in the development effort for a Scottish standard for clinical messaging. As they have little motivation to support two different standards, "*suppliers … will be forced to be committed to the English model and so the upgrade paths that will be available … will automatically support the English messaging*" (supplier member of SG). Consequently, the character of the context where standards are used explains for the lack of active involvement from the part of the technology suppliers in the standardisation effort.

As a result, the nature of the standard development process is significantly affected by the characteristics of the context in which implementation and subsequent use take place. To analyse the development stage in isolation, would have meant to ignore a number of factors that explain how standards are developed.

3.2. The NHS England and Wales approach to health messaging standardisation: the evolution within a standard

In contrast with Scotland, the NHS England and Wales has invested considerable resources and time in developing the "gold standard", emphasising the quality objective rather than speed. In 2000, a number of different standards were used for clinical messaging across England, such as CEN ENV 13606 the European pre-standard, and HL7 version 2.

Rather than focusing their resources on developing their own standards to support their integrated patient care systems, NHS England and Wales has decided to get involved in one of the existing standardisation initiatives: the Health Level Seven (HL7), a private standard consortium. An American based organisation, the HL7 consortium was founded in 1987 as an open consortium of health providers and vendors developing standards for clinical and administrative data in healthcare. In 2000, the National Programme for Information Technology in England and Wales (NPfIT) adopted HL7 version 3 as the national standard for clinical and administrative data across NHS England and Wales, and became heavily involved in the work of the HL7 UK, one of the 23 international affiliates of the HL7. In contrast with the existing competing standards for health messaging (e.g. CEN and ISO), HL7 version 3 enjoyed a considerable support from system suppliers operating in the English market: "*[for CEN] there was less of a community committed to their development … and the supplier buying was an attraction [for HL7]. The fact that suppliers would rather work with a standard that was international …*" (HL7 UK member1). As arguably the CEN and ISO standards were also aimed at the international market, it is more likely that the suppliers were supporting HL7 because:

(1) the existing HL7 version 2 at the time (2000) was widely used in America, thus providing a large market for technology suppliers; and

(2) as a private consortium, HL7 allowed the suppliers to become actively involved in shaping the standard, in contrast with the CEN counterpart initiative for clinical data message communication where participation is based on the system of national representativeness rather than commercial considerations.

At the present, there are 3 versions of the HL7 standard. Version 1.0 draft standard was presented in October 1987 but never implemented, and followed in 1988 by the version 2.0 which is widely implemented in America. There have been a number of revisions of the 2.0 version up to the 2.4. version in 2000. Since 1996, work has started to create a new generation of standards known as version 3, which at the present is still under development.

The migration between version 2 and 3 of the HL7 standards and in particular the development of version 3 in the English health system can be understood by looking at the context in which such standards are

[8] The English NHS has adopted the HL7 version 3 standard which is widely used in America, thus providing a huge market for system suppliers.

developed and in which they are implemented and used. The factors that explain the evolution of the HL7 from a primarily American focused standard to an international standard are summarised in figure 2.

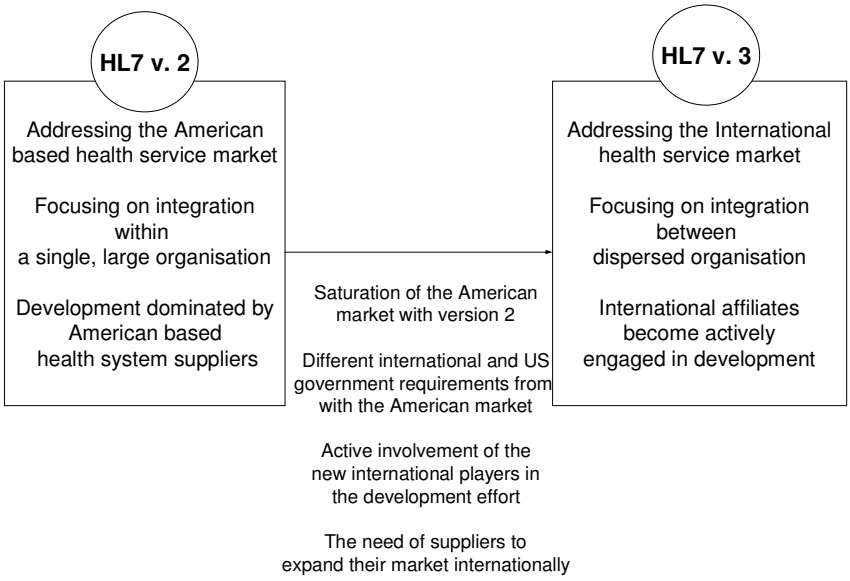

Figure 3. HL7 version 2 versus HL7 version 3

The settings where version 2 and version 3 are implemented and used are very different:

- Since its inception in the late 1980s, HL7 version 2 has been geared towards the American market where the demand was for the integration of systems within single, independent organisations. Consequently, HL7 version 2 has focused on the development of standards for clinical data messaging within hospitals: "*version 2 is mainly designed for implementation within a single organisation across different departments, and so that is what it was suited for*" (NPfIT). In the mid 1990s, the HL7 version become widely implemented in America: "*in the US … their market is fairly saturated with version 2, except for a few exceptions … and that basically was well adopted in the US but there are only a few areas within the US, mainly at the government levels, where they need that higher level of integration across organisations*" (NPfIT). However, due to the strong focus on the American market's requirements, version 2 did not reach large coverage in the international market, particularly in the English market: *"HL7 had them in the States, nobody in the UK implemented HL7 standards in the version 2 format hardly anybody and still to a large extent hardly anyone's actually implemented it."* (HL7 UK member2).
- As the american market became saturated with version 2, HL7 consortium was planning to expand internationally. Such a change to move outside the American market has been sustained by the health system suppliers driving the HL7 consortium which were looking to expand into other markets. As a result, in 1996 work has started on version 3 which was designed in such a way to address the international market for health informatics standards: "*over the last few years it's the new HL7 adopters, particularly at the government or nationwide levels like in Canada or the Netherlands or the UK who are really anxious for version 3 to complete its development*" (NPfIT). The implementation context for health informatics standards in the US is significantly different from the international context that HL7 version 3 addresses where the health service is usually public (such as in UK) and where communication and integration is required between disparate systems in different organisations rather than within single organisations: "*at the level*

of the national programme … integration it required across so many different organisations and suppliers" (NPfIT). As a result, version 3 has been developed in such a way as to "*allow multiple organisations to integrate across organisational boundaries* [*… and to*] *provide a model that is comprehensive and it is generic enough to allow to be implemented across many different organisations*" (NPfIT).

The change in the standard has been mirrored by a parallel change in the nature of the settings in which HL7 standards are developed.

- Because of the focus of version 2 on the American market, the development setting for HL7 version 2 has been dominated by American based system suppliers. International affiliates were created by coalitions of such American based large health system suppliers in order to coordinate the implementation of version 2 in the respective countries and thus actively support their HL7 version 2 compliant products, rather than to have an active local contribution to the development of national version of the standard. For example, in 2000 HL7 UK "*was set up by some of the larger suppliers with a possible assistance to the UK, saying they wanted to get a version 2 implementation guide agreed for the UK*" (HL7 UK member1).
- However, following the commitment of the NPfIT to version 3, HL7 UK focused on contributing to the development of version 3, while the work on defining the implementation guidelines for version 2 was abandoned after only 6 months. A similar change has happened across the world, and the structures and procedures of the HL7 consortium have evolved allowing for the active involvement of the newly formed international affiliates in the development process. As a result, the role of the HL7 international affiliates has changed from coordinating the implementation guidelines of an existing standard to active involvement into the development of a new version: "*in fact, the UK, the Netherlands and Canada have probably been the drivers behind version 3 so far, rather than the US*" (NPfIT). The members of the international affiliates have became major players in driving the development efforts: "*the Australians and New Zealand are taking the lead in developing certain portion under referral messaging, … the Netherlands is contributing a lot in transport protocols … Canada, they're leading a financial management type of claims oriented messaging … So everybody decides on what their priorities are and then they contribute to that. In UK we may be the first to contribute our particular requirement for e-booking.*" (NPfIT). As a result, the development context has changed from a predominantly American based health system suppliers community to a large international one, involving not only international health system suppliers, but also national health service organisations such as NHS England: "*the last* [*HL7*] *meeting in January, half the delegates were internationals, about 500 people there. That's quite a lot of international input although it's geographically in the US.*" (HL7 UK member1).

The expansion ambitions of the technology suppliers, the different requirements of the American and international implementation context of the standard, and the changes in the development process supporting the active involvement of the international players are major factors that explain the evolution of the HL7 standard.

4. Conclusions

The search for a more dynamic approach in the study of messaging standards in the UK health services has been useful as it has allowed us to:

(1) extend the analysis to incorporate both the development and the implementation part of the standardisation process. Such an extension of the "arena" has unveiled the complex interactions that exist between the two stages of the process, which shape the evolution of standards.

(2) identify the competition patterns that exist between the different networks of actors within the arena (i.e. between the Scottish and the English system), and the role that key actors plays in

shaping these patters (i.e. the commitment of the system suppliers to the English model which questions the future of the Scottish standards).

The analysis of the evolution of clinical data messaging standards in the UK has also revealed two contrasting system development and implementation strategies:

(1) A search for early agreement and implementation of 'good enough' standards and their incremental evolution amongst a small informal alliance of players in NHS Scotland; and

(2) The protracted development of a 'gold standard' through participation in the a more formal standard developing organisation leading to the internationalisation of the US HL7 standard by the NHS England and Wales.

The former offers the benefits of early adoption, but incurs continued upgrading costs for system enhancements, as well as risks that its solutions will subsequently be outmoded by the English standardisation, which as a larger market will be better placed to attract and lock-in suppliers. In contrast, the latter trades the high costs and delays related to the participation in an international and formal organisation for the benefits associated with a standard that enjoys a wide support from technology suppliers.

The case shows how the historical context of standard setting shapes players' perceptions about plausible courses of action. It points to the complex alignments of players from the immediate and broader setting of standards development and implementation. However, the context does not determine particular paths of action. The cases reveal how the complex interactions and strategic games amongst the various players such as, for example between IT suppliers and NHS users, have shaped the standard setting. The two cases described here illustrate two different ways of reconciling one of the central dilemmas in standard setting: whether to devote time and effort to agreeing a comprehensive standard and defer system implementation and its associated benefits accordingly, or to seek rapid agreement on a set of standards with a more limited coverage, functionality and longevity. The English case represents the former, whereas the Scottish case illustrates the latter option. The distribution of anticipated costs and benefits of the two strategies over time are very different. Though the formal norms of standard setting would tend to favour the slow but comprehensive prior standard-setting process of the HL7 version 3, at this stage it is perhaps too soon to determine which strategy will prove the most effective and offer the best cost-benefit balance overall.

Jorgensen's concept of the "development arena" idea has been useful in this respect as it highlights the complexity of the spaces in which standards development/implementation processes are worked out, and the possibility that developments will set off radical reconfigurations of the relationships between players and of the overall arena itself. However, the "arena" concept, though a step forwards from simplified conceptualisations of the spaces where actors interact (e.g. actor-network analyses), does not wholly resolve the conceptual and epistemological issues that such actor-centred explanations face. We raise two examples.

(1) First, as our case of messaging standards in the UK health service shows, there is a continued uncertainty as to the correct level of analysis; is the "development arena" best conceived as the Scottish (or English) standard nexus, or the UK or indeed the global health message standards community? All are germane to developments in the field, though their salience may depend upon the goals of the research and also the particular time when a study is undertaken (given the possibility that the maturation of the UK HL7v3 standard might induce a realignment of Scottish XML efforts).

(2) Second, the inclusion of implementation as an important focus in the biography of standards necessarily brings in a large, highly dispersed and somewhat amorphous array of actors and locales. Those building information systems may be making choices about which standards to implement and how (and thus shaping the uptake of standards), however they are far removed from standard-setting contexts (Voß et al, 2002), they may not see themselves as acting in relation to standards systems insofar as these aspects may be ancillary to their main concern to

build systems (and may indeed be bundled up inside the choice of particular artefacts and systems). It will be important to develop a language that can more effectively capture the multi-level analysis needed to do justice to a dynamic analysis of standards.

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