

# XML standards and standard settings. The case of XML standards in the NHS Scotland.

Raluca Bunduchi<sup>\*</sup>, Ian Graham<sup>\*\*</sup>, Robin Williams<sup>\*</sup>, Neil Pollock<sup>\*\*</sup>, Alison Smart<sup>\*\*\*</sup>

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## 1. Introduction

The development of the Internet during the last decade has been one of the fastest trends in the business world. In less than ten years, Internet technologies have become a global phenomenon, and have pervaded all organisations regardless of their national and industrial context. At the core of this phenomenon is the development of open Internet based standards that hold out the promise of allowing diverse computers and information systems of different organisations to exchange information more or less seamlessly<sup>1</sup>. To overcome the limitations of HTML for presenting information on the Internet, a new standard was developed for data representation and exchange on the Internet - XML - which separated the content from the style of presentation. However, the development of XML has more consequences than only redefining the way humans interact with a web server through a browser. Whereas browsing the web can be still seen as reading the data from the browser (with or without XML), the use of XML has redefined the way

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\* Research Centre for Social Science, University of Edinburgh

\*\* Management School, University of Edinburgh

\*\*\* Manchester Business School

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<sup>1</sup> For example, one of the most crucial attributes of the Internet which explains its rapid adoption is its TCP/IP standard which allowed connectivity between different platforms. This meant that Internet technologies could run on any type of platforms, Unix, as well as on Macintosh and Windows.

communication takes place between computers, and has thus enabled the use of Internet technologies for supporting electronic transactions between organisations. XML standards and the use of Internet technologies for B2B exchanges promised to overcome the limitations that surrounded the earlier development and implementation of Electronic Data Interchange (EDI) standards and systems, i.e. their high implementation and maintenance costs, inflexibility and complexity in use (Medjahed et al, 2003; Turban et al, 2000).

The development of the Internet during the last decade has been accompanied not only by a change in the type of standards developed for B2B exchange (i.e. XML standards replacing the EDIFACT EDI standards), but also by important alterations in the process and locales of standard setting. This paper discusses one instance of such a change in standard setting, the approach to XML standards development in NHS Scotland.

The paper is structured as follows: section 2 examines the different options that exist in approaching standard development. Section 3 briefly discusses the theoretical approach and the objectives of the study. The case study is presented in section 4. A discussion of the findings from the case study and their theoretical relevance concludes the paper.

## **2. Different approaches to standard settings**

Standards are produced through a variety of means, which can be broadly classified into de jure and de facto (Antonini, 1994). For the purpose of this paper<sup>2</sup>, de jure standards are defined as

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<sup>2</sup> One of the first classification of de jure and de facto standardisation defined de jure standards as those standards that are elaborated by committees and mandated by standard setting agencies, whereas de facto standards emerge through market forces (Antonini, 1994). However, this categorisation of standard making obscures the range of various modes in between the two extremes through which standardisation happens. For example, Egyedi (1996) notices the impreciseness in the term “de jure” which suggests that standardisation takes place in a regulatory

those standards which are elaborated by standard setting organisations, as opposed to de facto standards which emerge purely through market forces (Jakobs, 2000). The discussion in this paper concerns only de jure standard setting.

Before the 1990s, standard setting was dominated by (but not limited to<sup>3</sup>) **traditional formal standard developing organisations (SDOs)**. According to Egyedi (2001), formal standardisation is defined as “*the voluntary consensus processes that take place in technical committees under the auspices of national, regional, and international standard bodies*” (Egyedi, 2001, pg. 11). These formal SDOs are public standard bodies, recognized and often supported by governments (Werle, 2001) such as ISO, ITU-T, ETSI and CEN.

All the formal SDOs share the same principles underlining their procedures and working practices: due process, fairness and transparency, consensus, and voluntarism. According to David and Shrumer (1996), these set of principles reflect the *technocratic idealism* which characterises formal SDOs practices. This technocratic idealism reflects the assumption (or desire) that the standards process should lead to the best technical solution, independent of the commercial interests of the vendors and users (David and Shrumer, 1996).

The 1990s have witnessed an extraordinary move away from the formal SDOs’ slow and cumbersome standard development process, which was seen as incapable of dealing with the

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context, whereas the formal standard setting agencies emphasise the voluntary application of the standard. On a similar note, Bonini and Spring (1999) distinguish between regulatory (what they name “de jure” standards) and voluntary or consensus standards to differentiate between the standards that have the force of law, and standards which are developed in a public forum where all those interested can become involved. However, this dispute regarding the meaning of de jure and de facto standards, is beyond the objective of this paper.

<sup>3</sup> ECMA, one of the first examples of standard consortia, was founded in 1963. However until the late 80s, early 90s, the number of such standard consortia outside the formal standard setting bodies was limited (Hawkins, 1999).

issues of inter-operability, the need for anticipatory IT standards, and the need to cope with the shortening life cycle for IT products and services (David and Shrumer, 1996; Hawkins, 1999). Though what we call now industry standard consortia or private standard bodies existed well before the 1990s (e.g. ECMA), they showed significant growth during the 1990s, when in less than a decade more than 140 ICTs standard consortia were created (Rada and Ketchell, 2000).

A **standards consortium** is defined as “*an informal alliance of firms, organisations, and (sometimes) individuals that is financed by membership fees for the purpose of co-ordinating technological and market development activities*” (Hawkins, 1999, pg. 161). The majority of these consortia do not have any official status, they are simply private consortia and fora<sup>4</sup>.

According to David and Shurmer (1996), a key characteristic of these consortia is that commercial considerations explicitly play a crucial role in influencing standards development, which stands in contrast with the technocratic idealism of the formal SDOs. Through consortia frequently follow the consensus principle, as with formal SDOs, they include a smaller range of actors, and thus narrower array of technical and commercial interests. In addition, their lack of official status means that there is no need to follow strictly all the stages in the bureaucratic process, in the way that formal SDOs must. Consequently, consensus is easier to achieve and standard development is quicker (Hawkins, 1999).

The discussion above is one of the critical issues in current standards research, which aims to understand the process of IT standard development in this increasingly complex and diverse setting. By and large, the argument centres on the dichotomy between formal versus informal, and public versus private SDOs (Egyedi, 2001; David and Shrumer, 1996; Hawkins, 1999;

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<sup>4</sup> However, some of the older unofficial SDOs have received a quasi official status, for example such as ECMA which in a settlement with ETSI and CENELEC in 1991 was recognized as a SDO in its own rights.

Werle, 2001). However, increasingly new types of standard settings fora have emerged, which transcend the traditional dichotomy between public and private forums. Outside the market realm, standards are produced through a variety of means which do not necessarily fit these two categories. There are only a limited number of studies in the mainstream standards literature that explore the development of standards outwith the context of a clearly established SDO. This paper represents such a study which focuses on the standard setting process in between (or outside) the formal SDOs and the standard consortia. The approach taken to explore this process is described in the following section.

### **3. The process of standard development**

Standards are claimed to play a crucial role in the business world: they reduce transaction costs, facilitate international trade, reduce risks and uncertainty, and increase user value (Austin and Milner, 2001) (David and Shrumer, 1996). In particular, the development of the XML based standards that enable the use of Internet technologies for facilitating business exchanges are claim to allow for cheap, flexible and easy integration between organisations, hence overcoming the limitations of the EDI (Turban et al, 2000). However, the ability to gain such positive outcomes depends also on the process through which such standards are developed. In other words, understanding the outcomes of standards adoption requires an understanding of the process through which they develop.

Following Williams et al (1993), the development of a standard is seen as shaped by the choices that the actors involved make at every stage during the process. These choices are influenced by a wide array of factors which include, but are not limited to, technical ones (see also Jakobs, 2000). The context, the culture, and the technical and economic factors that influence the choices of the

actors frame the development process, and ultimately its outcome, the standard. Explaining standard development entails understanding the interactions between all these factors.

The role that social-economic and technical factors play in shaping standards development has been documented in previous research. Spinardi et al (1997) analyse the EDI development in the Scottish Health Service and show the importance that organisational and political factors have in shaping the EDI development process. Graham et al's (1995) study of EDIFACT finds that the "technical choices" are driven by social factors and are embodiments of social relationships between the actors involved, whereas Williams et al (1993) highlight the role that the conflict and alignment between the actors' interests have in shaping the development of EDI.

The objective of this paper is to clarify the role that socio-economic factors play in shaping the process of XML standard development in NHS Scotland. This requires an understanding of **the choices** made by the actors during the development process, **the factors** that have influence these choices, and the **outcomes** that the standard development, framed by these choices, has on NHS Scotland. The paper analyses the development of XML standards in NHS Scotland. The study follows a qualitative research methodology strategy built around a single case study research design. NHS Scotland is been chosen as the case study because of its unusual approach to standard developing, which takes place outside the boundaries of a clear SDOs, whether a formal body or a standard consortium.

The primary source for data collection was semi-structured interviews with the participants involved in standard development, NHS IT policy makers, representatives of the major IT programmes in NHS Scotland, and end users of the standards. The data from the interviewees was supplemented with secondary data such as internal documentation, presentations of the NHS IT members at conferences and workshops, newspapers and other published studies focused on

NHS Scotland. Data analysis followed the recommendations of Miles and Huberman (1998) for qualitative analysis, descriptive and explicatory matrix displays.

## **4. Hybrid standard settings: the XML standard development in the NHS Scotland**

### 4.1. Background – the initial motives for XML adoption in NHS Scotland

XML standards first arrived on the scene in NHS Scotland in the late 1990s, with a small scale project starting in 1997 for a pilot distribution of electronic discharge letters in one of the Scottish hospitals. In 1998 the project became bound up with the development of the GPASS (the General Practice Administration System for Scotland) which is the national primary care system in Scotland<sup>5</sup>. As a result of GPASS interest in the project, at the end of 1999 real discharge letters were produced as XML documents and exchanged between a number of GPs and hospitals.

In 2000, the Scottish health minister in the recently created Scottish Parliament laid the foundations for a Strategy for Information in NHS Scotland. This new strategy was based upon the idea of an “online appointment booking” system for NHS Scotland, which was a concept which translates into electronic media broader objective to support direct and integrated health care. Minor changes to the strategy have been made in 2003 to ensure a stronger ministerial involvement into NHS Scotland (e.g. directly involving the minister as the chair of the e-health programme board). 21 national programmes for IT have spun off from this new strategy for information - programmes which were meant to translate into practice the ministerial commitment for integrated information systems and integrated health care in Scotland. Among these programmes, SCI (Scottish Care Information) was aimed at developing clinical and

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<sup>5</sup> GPASS is practically the dominant system in primary care, used in around 80% of the Scottish GPs.

communication systems and enabling integration with existing systems, and the ECCI (Electronic Clinical Communication Implementation) programme was meant to support the exchange of clinical messages between primary and secondary care. These two programmes were the two main beneficiaries of XML standardisation efforts.

In the new national strategy, XML standards were adopted as the standard for achieving the envisioned integrated health care system. The choice for XML standards was based on a number of factors.

- First, the success of the XML pilot project for discharge letters proved that XML documents can be used as the basis for developing the integrated electronic record.
- Second, XML was e-GIF (the national framework for e-government) compliant. E-GIF was developed around the same time, i.e. 2000, and mandated the adoption of XML as the primary standard for data integration and presentation tools for all public sector systems.
- Third, at the time of its adoption in the NHS Scotland (2000), XML standards had little competition in the health service. There was a US-originated industry standard consortium – HL7<sup>6</sup>. However, HL7 version 3 was still under way<sup>7</sup>, whereas the existing version 2 was

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<sup>6</sup> HL7 is a standard for healthcare messaging produced by an Health Level Seven (HL7), an American based organisation. HL7 was founded in 1987 as an open consortium of health providers, and vendors developing standards for clinical and administrative data in healthcare. HL7 has international affiliates in 23 countries. HL7 UK was founded in 2000 in by vendors and health providers operating in the UK health market in order to support the development and implementation of HL7 standards in UK. At the present, there are 3 versions of the HL7 standard. Version 1.0 draft standard was presented in October 1987, and followed in 1988 by the version 2.0 which is widely implemented in America. There have been a number of revisions of the HL7 version 2.0. up to the version 2.4. in 2000. Since 1996, work has started to create a new generation of standards known as version 3 which is more geared toward the international community. At the present, version 3 is still under development.

<sup>7</sup> For example, the HL7 v 3 reference model become standardised only in 2002.



geared toward internal system integration rather than integration between various systems. Consequently, HL7 did not satisfy the integration needs of the Scottish health service at that time. In a similar way, ENV 13606, the CEN pre-standards for clinical data messaging, was never implemented on a large scale in UK. At the same time, EDIFACT was not seen as suited to the health market, and it was never really used extensively in the NHS Scotland. The reasons were its costs (too expensive to buy proprietary technology to handle messaging) and its lack of flexibility. EDIFACT required specifying every element within the message, which is difficult to achieve in the highly diverse and fragmented health system (see next section). In contrast, XML has the advantage of being much cheaper to implement than EDIFACT (it does not require to pay charges for access to a value added network - VAN) and it provides the required flexibility in terms of data types and structure.

In this way, the decision to adopt XML as the standard for system integration and electronic communication in NHS Scotland was not only a top down initiative (the ministerial commitment to online booking systems and the compliancy with the e-GIF framework) but was also driven from the bottom-up by the difficulties of implementing EDIFACT in the Scottish health service and the success of the early XML discharge letters pilot.

## 4.2. The approach to standard development

### 4.2.1. Characteristics of the development process

XML standardisation was driven by the need to *“move ahead and getting something that works: demonstrate the benefits quickly and perhaps change it along the way”*. The focus was not on building *“a gold standard that’s going to be fixed forever”*, but rather developing a *“good enough”* standard that meets the present requirements of the systems as they are developed, and

that is intended to evolve over time in parallel with the systems. Consequently, **pragmatism** appears to characterise the Scottish approach to XML standards developing process, approach described by the interviewees as based on “*a deliberate policy of we just need to get enough to get us over the particular problem that we’ve got*”.

The need to constantly meet the requirements of the systems as they develop means that standard development is done in parallel with system development and implementation. Standard development thus becomes an ongoing process, where the standards change as the actors (developers, system suppliers, and end users) constantly feed back into the process as a result of previous implementation of systems and standards. This **parallel synchronicity** between standards development and their implementation, and between standardisation and the development and implementation of the software systems can be seen to be driven by the *primacy of systems over standards development*. Standardisation appears to play a secondary role in NHS Scotland, subordinated to system development. As one of the interviewees mentioned, standardisation “*is not a high priority activity, it’s not a great push to get more XML done, it’s a great push just to get this bit of the system working and that’s why we need the XML to make it work.*” The main goal of the process is to get the system working, and the development of standards is seen as supporting this goal.

Apart from the changes that are due to this synchronicity with systems development, standardisation is also characterised by a **gradual** refinement towards more specific and narrow standards. Initially developed as broad and generic specific specification, including ample free text to accommodate a diversity of users’ specific requirements/working practices, the standards become gradually more specific and narrow. Optionality is gradually removed, and standards become more prescriptive in terms of what users can do.

This pragmatic approach to standard development in parallel with system development has both advantages and disadvantages.

On one hand, the ongoing feedback between standard development and implementation means that *changes in business requirements can be readily incorporated into the standard*. The standard can be easily changed to accommodate the needs of the various users. For example, a request from a system supplier for a change in the standard can easily be satisfied. At the same time, the users and their requirements can be easily and quickly included in the development of standards. As the users can easily get involved in the standardisation process, the result is a standard that better fits the needs of the users.

On the other hand, this parallel synchronicity between software and standards development requires a *continuous change and upgrading of the standards*. Without a mechanism that controls these changes, the interoperability between the various versions of the same standards would be difficult to maintain. The mechanism that controls this change process in this case is the Steering Group (SG).

#### 4.2.2. Steering Group – monitoring and controlling standard development

SG was set up in 2000 and runs as an **open and informal** standards forum designed to monitor and control the changes in the XML standards. Participation is open to everyone interested, no membership fees exist, and there is no formal procedure in place to regulate its proceedings. Thus, the SG appears to be different from an informal standard consortium, according to the definition of such consortia in the literature (see section 2). The decision to adopt such an open and informal structure rather than the “common” type of close and highly formal groups existing

in NHS Scotland<sup>8</sup> was based on the lessons learned from the history of standardisation efforts in health care. According to the chairman of the SG, “*to make standards really work you have to get the community on board and involved in the development otherwise they tend to be things put on bookshelves.*” The open and formal structure was meant to get the clinician community to buy into the standards, get them involved in the process and thus raise their acceptance of the standards. The importance that is placed on involving the clinician community is also emphasised by the efforts of the SG to provide training and to educate the health community about the role of XML standards through seminars and workshops.

The **members** of the SG include system suppliers, representatives from the clinician community (trusts and GPs) and from the major projects within NHSS (i.e. ECCI, SCI). There is a divergent set of interests which motivates the actors to get involved. ECCI and SCI are actively involved since they are the major users of the standards: ECCI focuses on supporting the electronic transmission of clinical messages between primary and secondary care, and the SCI programme is in charge with actually developing the pieces of software that will use the XML standards/schema. The clinicians who are involved in the SG are those with a particular interest in IT and XML and who acknowledge the need to retain ownership over the development of standards which could possibly affect their working practice.

For system suppliers, the interest in participating in the SG appears to be in gaining competitive advantage and increasing market share as an indirect result of being involved in the SG, rather than in the development of the standards per se. As discussed in detail in the next section, Scotland is a small market in comparison with the total market that these system suppliers

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<sup>8</sup> The common type of steering groups in the health community which include professional bodies or advisory committees where participation is restricted.

address (most of them are involved in the much larger English market), and their focus is on the standards developed in England. According to one of the suppliers, the reasons to get into the SG were to have some input into what is going on in Scotland, but mostly keep aware of what is happening in the Scottish market, and make sure that the company's name remains visible. The low level of commitment of system suppliers for standard development is also due to the fact that SCI products, (which are developed by the NHS Scotland either in house or in partnership with two of the vendors) were until recently the only products that had to use the standards. However, two of the SCI products (SCI store and gateway) have become mandatory in the NHS Scotland, and they are presently in use in all of the local trust boards, although they are in different stages of implementation. As system suppliers will have to integrate their products with the standardised SCI store and gateway, they will have to adhere to the standards that these products use. According to the interviewees, this change has translated into a higher interest from system suppliers into the XML standards in the last six months.

#### 4.2.3. Characteristics of the Scottish NHS context

There are two characteristics of the Scottish health service that seem to explain the reason for such an approach to XML standard development in NHS Scotland, which does not fit the working procedures of either an official standard body (e.g. CEN), or a standard consortia (e.g. HL7).

First, the Scottish health care is **highly fragmented both in terms of human and IT systems**. Clinicians are a very diverse community who *“work for themselves and are actively encouraged to do things differently”*. As a result, any form of standardisation goes against not only their existing practices, but also against their beliefs and assumptions regarding what their work entails. One of the interviewee involved in standard development argued that *“the more you say*

*they have to specify something, the more resistant they [clinicians] get*". When variety is seen as a strength rather than as a weakness, a standard that prescribes what clinicians should do (for example a standardised form for creating discharge letters which are usually scribbled on a piece of paper) will certainly meet a significant degree of resistance. There were a number of attempts to standardise the clinical data content, which is essential for XML standardisation, and a number of standards existed such as READ, SIGN guidelines and more recently SNOMED which was meant to replace the READ codes. However, the use of these guidelines imposed only a relative degree of standardisation, for example the SIGN guidelines provided only headings that should appear in the discharge or referral letters, rather than prescribing the detailed structure of the clinical documents required for an effective XML standard.

In addition to the fragmentation in the general working practices of all clinicians, the NHS is characterised by a clear separation in the working practices of the secondary and primary care clinicians. The relationships between GPs and hospitals was often said to be characterised by severe lack of communication and trust. In the conditions in which the introduction of a common standard for electronic communication would lead to an uneven distribution of the benefits and the costs between the primary and the secondary care, the poor relationship between the parties increases the resistance to accept it. For example, in the case of referrals letters, GPs would have to change their practice and produce a standardised letter (which takes time), whereas the entire benefits would be on the part of the hospitals who would have better data on which to base their decision to admit or not a patient in the hospital (improving their service quality and saving time).

IT systems in the health service are characterised by a similar fragmentation especially in secondary care. Whereas the GPASS has managed to achieved almost complete uniformity in the

primary care (used in more than 80% of GPs), the IT systems in secondary care are characterised by huge diversity characteristics. In hospitals in a large number of stand alone systems abound that do not interact with one another and where there is almost no re-use of data or software components. According to one of the interviewees, this situation is partially due to the fact that clinicians want to retain ownership over the IT system they use, “*if they (clinicians) want to get an IT system is their own IT system*”. The assumptions, beliefs and values that form the health service context (individually oriented, variety rather than commonality) reflect in this way on the nature of the IT systems in health service. As a result, in addition to the human resistance, the fragmentation in the IT system creates additional challenges in the adoption of a common standard for their integration.

As a result of this fragmentation of the health service, a move from a relatively lack of standardisation to having an XML standard that specifies everything would require a sudden and radical cultural change. This cultural change would imply a transformation of the working practice of the clinicians (e.g. filling in standardised clinical documents, GPs would make direct appointments for their patient in the hospitals), as well as a change in their approach to what they’re doing, i.e. their beliefs and assumptions regarding what their work has to be (e.g. support common practices rather than diversity). For this reason NHS Scotland chose to follow a ***gradual approach to XML standard development***, so to allow the time for a parallel change in clinicians culture and working practice and thus ensure the adoption of standards.

Second, the **Scottish health market is a relatively small market**, and is **limited in its financial resources** in comparison with the English health market. This means that a lower level of funds is allocated to IT in NHS Scotland. In addition, most of the system suppliers that operate in the Scottish health market are also involved in the larger (and more profitable) English health market,

which focuses on HL7 version 3. Suppliers have little interest into developing different products based on different standards. Therefore, once the HL7 standard is fully developed and implemented, system suppliers will be committed to the English model, and the upgrade paths for their products will support the HL7 standard. As the system supplier applications will drive forward the English standard, it is expected that Scotland will either have to ensure compatibility of its standards with HL7 or eventually adopt the English standards.

However, in 2000 HL7 version 3 was only in an incipient form. For the Scottish NHS, the alternative to develop the required XML standards for electronic messaging and system integration would have been to wait for a standard to be developed in the English NHS. This approach was in contrast with the ministerial commitment in the early 2000 for achieving electronic integrated patient care in Scotland. Consequently, NHS Scotland had to have information standards, and had to develop them themselves, since at that time there was not a definite standard for health care available. The lack of extensive financial resources and the strong political commitment meant that Scotland, rather than investing time and money in getting the perfect standard, has followed a *pragmatic approach to standard development*, aiming toward quickly developing a standard that support system development.

#### 4.3. Discussion: Implications for NHS Scotland

The pragmatic approach to standard development, outside the clear procedures and methodologies of an established SDO, rather than the pursue of “the best standard” within SDOs such as HL7 or CEN, meant that the Scottish health service is much ahead of England in terms of standardisation of messaging. Thus a combination of lack of financial resources but strong ministerial commitment to support electronic integrated patient care based on XML standards has helped to ensure the rapid development and implementation of standards. At the same time, the



open and informal nature of SG, and its overall focus on involving the clinician community into the standardisation process are meant to create the conditions for the standards to be adopted by their intended users. Nevertheless, the low level of commitment from the system suppliers due to their divergent interests in the English and Scottish market will pose a threat to the implementation of XML standards as they will have to be used outside the NHS Scotland in-house developed products (e.g. the SCI).

On the negative side, as the standard based IT products become mandatory, a more formal and rigorous approach to standard development is required to better manage the change process and its effects on an increasingly large number of users. Whereas the open and informal nature of SG encourages users/clinicians involvement into the process, the lack of a formal mechanism (i.e. clear methodology, defined working procedures) to control changes in the standards creates the danger of a lack of interoperability between the different versions of the same standard. This in turn means lack of interoperability between the various systems that implement different versions of the standards, hence undermining the very purpose of standardisation. At the same time, a formal control mechanism that includes a formal system testing and accreditation is required in order to identify which products and systems will be affected by a change in the standards, and what the effects on these systems will be. As the standardised mandatory products are implemented in most of the local boards, system suppliers will need to become more actively involved in both the use and development of standards. A more formal and rigorous approach to standardisation, that is a formalization of the nature of the SG, is required in order to manage the change process and their effects on an increasingly larger number of actors.

At the same time, whereas there is a strong political commitment and a clear and defined vision to the IT strategy in NHS Scotland, it appears that a clear vision regarding the standardisation

process is lacking. Standards development has been driven by system development, and lacks a clear governance, management and a defined strategic direction. A roadmap for XML standards in NHS Scotland is required that states the direction where standards are going in order to help the actors involved in the process to understand what the plan and problems are at the strategic level.

Finally, the commitment of the system suppliers to the English model will put Scotland in a difficult choice: move to the HL7 English standards or develop compatible standards. This process will raise challenges in terms of changing the standards/systems that are already in place and working in NHS S. The development of a clear standardisation strategy would help to make this transformation process easier.

## **5. Conclusions**

In the context in which standards are essential in order to achieve the promise of e-business technologies, understanding the development of standards becomes extremely important. If empirical research focuses solely on standardisation processes within the established SDOs arena, be them formal SDOs or informal standard consortia, then they may fail to achieve an adequate understanding of standard development where standards development and related activities are taking place in multiple and informal arenas.

The analysis of XML standard development in the NHS Scotland has provided some insight into the process of standard development outside the clear boundaries of a established SDO. The NHS Scotland case study has highlighted the importance that political, organisational, and economic factors play in shaping the development of standards. The involvement of GPASS in the XML discharge project ensured the success of XML use on a larger scale than initially envisioned. This success and the strong political commitment to XML and Internet technologies to achieve

integrated care records meant that NHS Scotland chose XML as the standard used for electronic messaging and system integration. The existing nature of the health service environment - cultural and organisational factors - together with the characteristics of the Scottish health market - economic factors - meant that the actors involved in the development of XML standards followed a gradual and pragmatic approach to standards development. The case has also illustrated the complexity of the interactions between these various factors. For example the lack of financial resources, combined with the *absence* of a strong political involvement could have lead to a different approach, and consequently a different standard, e.g. waiting for the English market to adopt/develop a standard. Consequently, the outcomes that the use of XML standards had in NHS Scotland are deeply rooted into the process that led to their formation.

There are also a number of choices that the NHS Scotland will have to make in the future, such as responding to the changes in the English NHS standardisation strategy, choices which will shape the future development of XML standards in NHS Scotland.

In conclusion, the approach to XML standard development in NHS Scotland is the result of the combination of and interaction between an array of political, organisational, cultural and technical factors. These factors have influenced the initial choice for a particular form of standard setting (between an industry consortium, i.e. HL7, and a hybrid form of standard setting, i.e. the SG), the approach taken within this standard setting, and finally the outcome, i.e. the standard.

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