XML-based clinical data standardisation in the National Health Service Scotland

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ABSTRACT

The objective of this paper is to clarify the role that socio-economic factors played in shaping the development of XML-based clinical data standards in the National Health Service in Scotland from 2000 to 2004. The paper discusses the NHS Scotland approach to clinical data standardisation, emphasising the actors involved, their choices during the standard development process and the factors that have shaped these choices. The case suggests that the NHS Scotland approach to clinical data standardisation is shaped by strong political pressures for fast development of an integrated electronic patient care system, economic pressures for high efficiency and cost reductions, and organisational requirements for strong clinical support. Such economic, political and organisational pressures explain the informal approach to standard development, the emphasis on fast system development and strong clinical involvement. At the same time, market factors explain the low commitment of the IT vendors, which might have otherwise put significant pressure on NHS Scotland to pursue a more formalised standardisation approach within an internationally recognised standard-setting body.

Keywords: clinical data standardisation, data exchange standards

Introduction

Since the development of the Electronic Data Interchange (EDI) systems and EDIFACT standards in the 1970s and 1980s, evidence has emerged to suggest that the development of data exchange standards is as much a social process as it is a technical exercise. For example, an examination of EDIFACT standards development showed that the technical choices made during standard development were driven by social factors and were embodiments of social relationships between the users involved, while earlier research on EDI standardisation revealed that the conflict and alignment between the interests of the various users were critical in shaping the development of EDI standards.

In the clinical context, organisational and political factors were shown to shape EDI development in the National Health Service (NHS) in Scotland, and tensions between divergent institutional environments were found to influence clinical data standardisation in the NHS in England. This paper investigates the NHS Scotland clinical data standardisation strategy based on the XML schemas with the aim of understanding the social processes that characterise data standard development. Two parts of this strategy are explored here. First, the paper investigates the reasons behind the adoption of eXtensible Markup Language (XML) to develop clinical data standards. Second, the paper examines the approach taken by NHS Scotland
to the standardisation process itself by identifying the objectives, the methods of co-ordination and the level of actors’ participation.

The study follows a qualitative research methodology strategy built around a single case study research design. The data were collected using semi-structured interviews with the participants involved in standard development, including five NHS IT policy makers, two representatives of the major IT programmes in NHS Scotland, two IT consultants involved in standard development, two IT vendors and three end-users. The data from the interviewees were supplemented with secondary data including internal documentation, conference and workshop presentations, newspapers and other published studies focused on NHS Scotland.

Background

Developed in 1998, XML is a standard for data representation and exchange over the internet. Since the mid-1970s, automatic data exchanges between organisations relied on EDI systems and associated standards, such as ANSI X12 in the US and UN/EDIFACT on an international scale. EDI standards were aiming to develop a uniform format for inter-organisation data exchange, where such data refer to business transactions. EDI systems and the associated standards were developed to operate within value-added networks (VANs). Using XML to support data exchange has a number of advantages over EDI standards: it has the support of a wider variety of applications (as it is backed by all major IT vendors); it is relatively easy to write programs which process XML documents; its text (rather than binary) format allows the document to be sent and read easily across the internet; and it can be compressed when bandwidth is a concern. As the Internet is a public network based on open standards (such as TCP/IP protocol), data exchange over the Internet is significantly cheaper than over private VANs. Consequently, the use of XML to write inter-organisational data exchange standards promised to overcome the limitations of EDI standardisation.

Clinical data standards using XML schemas 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 GPASS (the General Practice Administration System for Scotland), the dominant primary care system in Scotland (where it is used in 85% of the general practices). As a result of the GPASS interest in the project, at the end of 1999 real discharge letters were produced as XML documents and exchanged between a number of general practitioners (GPs) and hospitals.

In 2000, the Scottish health minister in the recently created Scottish Parliament laid out the foundations for a new strategy for information* based upon the concept of an ‘online appointment booking’ system. This concept translates into the broader objective to provide electronic support for direct and integrated health care. The strategy included 21 national programmes for IT, among which Scottish Care Information (SCI) and the Electronic Clinical Communication Implementation (ECCI) programmes were the two main beneficiaries of XML standardisation efforts.

The SCI programme involved the development of the clinical and communication systems that would form the core of the new electronic patient care system, and enable integration with existing systems. The backbone of this new system was SCI Store, developed initially in co-operation with Sema and later with AtosOrigin, which would store the electronic patient record at the level of the health boards. To facilitate the exchange between SCI Store and the existing local systems, and between the GPs and the health trusts, five other SCI products were planned to be developed: SCI Gateway, SCI Outpatient, SCI Clinical, SCI Integration and SCI Prescriptions.

Whereas SCI was delivering the products, ECCI was meant to support the organisational and cultural change required by the introduction of the new integrated electronic patient care systems. ECCI was aimed at informing and training clinicians in using the SCI products. One of the major hurdles in the rollout of ECCI was that when the programme was initiated, many of the SCI products were not yet fully developed.

The new national IT strategy for the NHS recommended the adoption of XML as the technology to support clinical data exchange standardisation. The choice for XML-based standards was informed by the following rationales:

- developed in 2000, e-GIF mandated the adoption of XML as the primary standard for data integration and presentation tools for all public sector systems
- a strong ministerial commitment to online booking systems
- the success of the 1997 XML pilot project for discharge letters proved that XML documents could be used as the basis for developing the integrated electronic record
- the limited scale of EDIFACT use in NHS Scotland meant that there was not an installed base of EDIFACT users. As documented in previous research,

* Minor changes to the strategy were made in 2003 to ensure a stronger ministerial involvement (for example, the minister is the chair of the e-health programme board).
a wide-scale adoption of EDI standards in NHS Scotland failed for organisational and political reasons.3 Consequently, the decision to adopt standardised clinical data using XML in NHS Scotland was both a top-down initiative (ministerial commitment and compliance with the e-GIF) and a bottom-up effort (the success of an early XML pilot and EDIFACT failure).

The NHS Scotland approach to standard development

Standard development

As discussed by one of the interviewees, data standardisation was directed by the need to 'move ahead and get something that works: demonstrate the benefits quickly and perhaps change it along the way'. Driven by the strong political commitment to achieve rapid progress with the electronic integrated patient care system, standard development has been approached pragmatically. The focus was on the fast development of 'good enough' standards that meet the present requirements of the systems as they are developed, and that are intended to evolve over time in parallel with the systems. As explained by one of the respondents, from the beginning of the process:

[T]here was an acceptance that we weren't going to get, if you like, a gold standard, so this isn't going to be the final word in the standard that's going to be fixed forever and a day, which is really what the EDIFACT tried to do, a one-off that was going to cure everything. So [it was] a deliberate policy of we just need to get enough to get us over the particular problem we've got.

The objective of the standardisation effort was thus to achieve fast system development, rather than to develop a highly robust 'gold standard' that would stand the test of time. The main goal of the standardisation process was to get the system working as fast as possible. Standardisation was '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 focus on speed meant that standard development was done incrementally, in parallel with system development and 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'. Standards were thus intended to evolve over time in parallel with the systems, taking advantage of gradual refinements over successive rounds of implementations.

While this might be true for all kinds of data exchange standardisation processes, the difference here was the highly unstructured nature of this incremental process, which was described by one of the respondents as follows:

'I spoke to a system supplier in England and they were interested in the discharge message, and I gave them a copy of it and they came back and said this is very good but we've found some faults with it. I said that's great, we'll change it, and they couldn't believe that we were just so accommodating, because in England they would have refused'.

In contrast with formal standard development processes (such as HL7 or CEN), NHS Scotland had significantly fewer formal procedures and rules in place to co-ordinate the changes in standards that result from the ongoing interactions between implementation and development stages. This approach to standard 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, resulting in a standard that better fits the needs of the users. On the other hand, the parallel synchronicity between system and standard development requires a continuous change and upgrading of the standards. This can potentially lead to significant problems in terms of maintaining the interoperability between the various versions of the same standards. To address this problem, NHS Scotland set up an XML Steering Group (SG) to control the change process.

Steering Group

The 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 clinical data standards. Participation is open to everyone interested, no membership fees exist, and there is no formal procedure in place to regulate its proceedings. This comes in stark contrast with the typical format in which standard development is co-ordinated elsewhere: for example, committees based within standard-setting organisations (for example, HL7 standards are developed within the HL7 organisation). Such standards committees and organisations are generally governed by procedures and rules with varying degrees of formality. Membership is restricted and/or subject to paying a fee, and access to committee deliberations is generally not open to the public.9 The open and informal structure of the SG was chosen deliberately in order to facilitate the involvement of clinicians in the process of standard development. According to the
interviewees, ‘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 emphasis placed on clinical involvement is also illustrated by SG efforts to train and educate the clinical community regarding the crucial significance of data standards through seminars and workshops.

The SG includes system vendors, representatives from the clinician community (trusts and GPs) and from the major projects within NHS Scotland (that is, ECCI and SCI). There is a divergent set of interests that motivates the actors to get involved. ECCI and SCI are actively involved since they are the major users of the standards. The clinicians involved in the SG share a particular interest in IT and XML and acknowledge the need to retain ownership over the development of standards that could possibly affect their working practice.

In contrast, the involvement of system vendors was much more limited, and not necessarily related to a direct interest in standard development. According to one respondent,’[Suppliers] come over here to find out about things but unless somebody’s going to pay them there’s no interest in them doing it. So a lot of the time they’re coming here to get sort of intelligence, market advantage, networking but [they are] not actually committed to developing [the standard]’.

According to one of the suppliers interviewed, their involvement in the SG enabled them to have some input into what is going on in Scotland, but the major rationales behind this involvement were mostly to keep aware of what is happening in the Scottish market, and to make sure that the company’s name remains visible. Involvement in the SG had more to do with the need to avoid a competitive disadvantage, rather than with gaining competitive advantage by early participation in the Scottish standardisation efforts: ‘By offering a bit of our time and assistance, it’s not going to harm us when it comes to bidding for new contracts in Scotland’.

There are two principal reasons to explain the limited supplier commitment in the early stages of standard development. First, up to 2004, the NHS Scotland SCI products were the only products that had to use the standards, which meant that up to that point, suppliers’ products did not have to comply with the NHS Scotland XML-based standards for clinical data exchange. Only after 2004 did SCI Store and SCI Gateway become mandatory, and by 2005 they were in use in all of the local trust boards, although in different stages of implementation. As system suppliers would have to integrate their products with the standardised mandatory SCI products, they would have to adhere to the NHS Scotland standards and it was expected that they would become more actively involved in standardisation efforts.

There were two recent developments that support this expectation. In what concerns primary care, since 1999, the NHS has issued the Scottish National Requirement for Accreditation (RFA), which set out the minimum specification for a GP computer system to be used in the NHS in Scotland, and included, for example, the requirements for the transmission of clinical data via EDIFACT and X.400(88) (but not via XML). In 2006, another tranche of RFA was released, stipulating that primary care system suppliers that operate in the Scottish market must comply with the defined Scottish national XML standards (among others). This requirement is likely to stimulate the interest of primary care suppliers in participating in standard development, as they need to work towards compliance with the RFA standards. In the secondary care environment, in December 2005 AxSys was named as the successful bidder for the NHS Scotland’s national generic clinical system (GCS) procurement. One of the principal aims of the GCS is to ensure that the local clinical systems that support different specialties are underpinned by common standards. The AxSys system – Excelcare – will be integrated into the national SCI products including SCI Store and SCI Gateway. The supplier will thus have to work with the NHS national IT programmes towards developing common standards for data exchange.

Second, the Scottish health market is relatively small in comparison with its English and most importantly US counterparts. However, most IT vendors operate also in the much larger, and potentially more profitable, English and US health markets. Both the English and US markets support the HL7 standards developed by the US-based HL7 consortium. Under significant competitive pressures, suppliers prefer to channel limited resources towards larger markets to avoid duplication of effort when the potential rewards for doing so are limited. As discussed by one of the interviewees: ‘To be fair to the commercial system suppliers, Scotland’s a tiny market, they’re much bigger in England and probably huge in America’. As there are few incentives for suppliers to invest in the development of a Scottish standard, they would rather commit themselves to those markets where they can achieve economies of scale (such as the English health market, which supports HL7 standards). The expectation in NHS Scotland was that 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’.

**NHS Scotland**

There are two characteristics of the Scottish health service that explain this pragmatic approach to XML standard development in NHS Scotland.
First, the introduction of clinical data standards, whether XML or not, requires more than just the standardisation of message exchanges. The clinical data messages (such as the discharge letter) embody the practice of the users, and clinical data standards have to capture not only the content of the message, but also the working practice itself (such as filling in a discharge letter by entering the data into a computer rather than writing it on a piece of paper). However, the context in which these standards are supposed to be introduced – health care – is far from conducive to standardisation.

Health care across the world is generally characterised by a significant fragmentation, and Scotland is no exception. 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 not only against their existing practice, but also against their beliefs and assumptions regarding what their work entails. As one of the interviewees argued, ‘the more you say they [clinicians] have to specify something, the more resistant they get’. Such an active pursuit of diversity is less extensive in primary care, where GPASS for example achieved almost complete uniformity in Scotland (85%), and where during the 1980s, GPs were instrumental in getting the Read Code terminology* accepted as the UK standard for recording medical information in a machine readable form. However, secondary care is characterised by a huge diversity of clinical practice within the individual specialties, which makes any kind of standardisation a very difficult task. For example, a study of clinical terminology conducted in 1999† found that the major reason why standardising medical language and terminology is so difficult is the scale and the diversity of use that clinical terminology is expected to serve.

The variety in clinical practice is paralleled by a similar variety in the supporting IT systems, especially in secondary care. Hospitals are populated by a large number of stand-alone systems that do not interact with one another and where there is almost no reuse of data or software components. While this variety in systems can be explained based on the diversity of processes that they have to support (that is, diversity between the individual clinical specialties), the interviewees emphasised that the same is true even within the same specialty, where the working practices are supposed to be more similar. In the example given by one of the interviewees, in one Scottish trust there were 65 different cancer systems. The explanation was that clinicians want to retain ownership over the IT system they use: ‘If they [clinicians] want to get an IT system it’s their own IT system, there’s never a concept of “let’s see what somebody else is using and reuse that”’.

In this context, the introduction of clinical data standards would change not only the clinicians’ working practice, but also their underlying beliefs and assumptions regarding what their work involves; it would also require a huge investment effort in terms of replacing and/or integrating with existing legacy systems. A move from a relative lack of standardisation to having a standard that specifies not only the content and structure of the messages but also the practice itself would have thus required a sudden and radical cultural change together with the commitment of huge financial resources. Both were highly unlikely to happen. For this reason, NHS Scotland chose to follow a gradual approach to XML standard development, so as to allow time for a parallel change in clinicians’ culture and working practice, which was supported through the ECCI programme.

Second, at the time when the strategy was devised (in 2000) there were few alternatives for clinical data standards from which NHS Scotland could choose. As mentioned before, EDIFACT failed to be widely adopted in Scotland. At the same time, England announced that it would support the HL7 version 3 and set up significant support for the HL7-UK group (through strong participation of the NHS Information Authority in the group). However, in 2000 HL7 version 3 was only in an incipient form and commitment to HL7 would have meant that NHS Scotland would have had to wait for the standard to be developed through the formal procedures within the HL7 consortium. Participating in a formal standardisation effort would have considerably delayed the development process as compared with developing the standards themselves. As such a delay was in contrast with the strong ministerial commitment for fast electronic integrated patient care development in Scotland, NHS Scotland decided to develop the clinical data standards themselves via the SG.

* Read Code is a clinical coding system that was first developed in 1982 for use in general practice by a GP, Dr James Read. The original list was gradually extended as more GPs began using the codes. In 1990, the NHS bought the intellectual property rights for Read Code and adopted them as a standard coding system in the UK.
† 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 to enable the standardisation of message exchanges.
‡ At that time, a number of standards were used in NHS England, including HL7 version 2.
Discussion: implications for NHS Scotland

The ‘good enough’ approach to standard development, outside the formal procedures of an established standards body, means that NHS Scotland was far ahead of England in terms of messaging standardisation in 2004. A combination of limited resources, strong ministerial commitment to support fast system development, and a successful experience with XML-based messaging standardisation has ensured a rapid development and implementation of standards. Additionally, the open and informal nature of the SG created better conditions for clinical participation during standards development, which in turn facilitated adoption. Nevertheless, the limited commitment of the suppliers could have threatened standards implementation once they were used outside NHS Scotland’s in-house products. Such a threat has been partially avoided in primary care with the implementation of the Scottish National RFA in 2006 and in secondary care with the GCS procurement exercise at the end of 2005. This helps transform the standards developed within NHS Scotland into de facto standards, as their adoption becomes a prerequisite for all primary care suppliers operating in the Scottish health market.

On the negative side, as the standardised SCI products become mandatory, a more formal approach to standard development is required to better manage the change process and its effects on an increasing number of users. Although the open and informal nature of the SG encourages clinical involvement, the lack of a clear methodology to control changes in the standards undermines interoperability between different versions. At the same time, formal system testing and accreditation is required in order to identify which systems will be affected by a change in the standards, the effects that this change will have on them, and most importantly to ensure that the systems comply with the new versions of the standards.

As the standardised mandatory products are more widely implemented, IT suppliers will need to become more actively involved in standard development and implementation. A formalisation of the standardisation process is required to effectively manage the change process and its effects on an increasing number of actors. In addition, whereas there is a strong political commitment and a clear vision to the IT strategy, a clear vision regarding the standardisation process is lacking. Standard development was driven by system development, and lacks clear governance, management and a defined strategic direction. A standardisation roadmap in NHS Scotland is required to support the actors involved in understanding the plan and challenges at the strategic level. The need for such a more formalised and strategic approach has been addressed recently, as the XML Steering Group has been replaced with a Scottish Interoperability Working Group as part of the roadmap to a full accreditation authority for national systems.

Finally, the commitment of the system suppliers to the English model will put Scotland in the position to make a difficult choice: move to the HL7 English standards or develop compatible standards. Both alternatives will require changes to the standards, and implicitly, to systems that are already in place and working in NHS Scotland. The development of a clear standardisation strategy would help to make this transformation process easier.

Conclusions

The NHS Scotland study highlighted the importance that political, organisational and economic factors play in shaping data exchange standardisation. GPASS involvement in the XML discharge project ensured the success of XML use on a larger scale than initially envisioned. A combination of this early success with a strong political commitment to XML and Internet technologies meant that NHS Scotland selected XML to standardise electronic messaging and system integration. The nature of the health service environment together with the characteristics of the Scottish health market meant that standard development was approached in an informal and loosely structured manner, with a focus on speed. The case also illustrated the complexity of the interactions between these various factors. For example, in the absence of a strong political commitment to fast system development, the small size of the Scottish health market might have determined a different course of action for clinical data standardisation, such as waiting for an English standard to emerge.

In conclusion, the approach to XML-based clinical data 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 (participating in HL7, a global standard setting consortium in health care, versus a much more informal form of standard co-ordination via the SG), the approach taken within this standard setting (‘good enough’, gradual and loosely structured), and finally the outcome, that is, the standard.
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CONFLICTS OF INTEREST

None.

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XML-based clinical data standardisation in the National Health Service Scotland

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The description of the XML Steering Group in Scotland, as described in the paper by Raluca Bunduchi, refers to the state of play between 2000 and 2004. I would like to update readers on the present circumstances. The Steering Group has been disbanded as its main functions have now been superseded. It had developed and published standards for referrals, discharges and investigations. Now, in 2006, all main laboratory test results are reported back to all GP practices via the standard schema; approximately 70% of all referrals are sent electronically in Scotland, many protocol-based using the standard schema, with a target of 90% next year. Around 80% of GP practices can send and receive GP summary records when patients move practice. The success of these and other developments is one of the benefits of having strong clinical involvement in IM&T.

The Steering Group also helped develop understanding of XML itself, with training workshops and conferences. Now XML is a routine technology for which there are plenty of ways for IT staff to gain knowledge. Finally, the business world has changed: interoperability between systems was relatively unknown in 2000, but now there is an expanding spaghetti of systems from different programs and suppliers communicating with each other. Developing new standards is not the main issue – managing change is.

The Steering Group was disbanded in 2005 and replaced by an Interoperability Working Group comprising invited representatives from each of the main national systems suppliers and project sponsors. The role of the new group is to manage changes to standards affecting interoperability. Problems of interoperability which cannot be sorted amicably within the group are escalated to the financial and political levels.

The philosophy of clinical involvement in developing data standards has matured and we now have a programme developing patient data standards for electronic health records: the National Clinical Datasets Development Programme.

Website: www.isdscotland.org