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The Tensions Shaping the Emergence of Standard Bodies: The Case of a National Health Informatics Standards Body

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Abstract *This study applies New Institutional theory to identify the social processes shaping the emergence of a standard setting body. Meyer and Rowan's classification of the mechanisms that lead to the creation of institutional rules—relational networks, degree of collective organisation and leadership—is applied to a health informatics private standard consortia operating in the UK. The study identifies a number of conflicts within the institutional contexts within which the standard body operates. Such conflicts undermine the institutionalised rules that frame the emergence of the standard body and lead to the erosion of the institutionalised standardisation practice.*

Keywords: standards; institutional theory; health informatics.

Introduction

The importance of standardisation in the evolution of Information Technology (IT) has been increasingly recognised.[1] One reason for the growth of interest in standardisation is the increasing use of IS as a foundation for inter-organisational integration.[2] The development of information and communication technology (ICT) standards, including the standardisation of messages and their meanings, must precede the implementation of inter-organisational IT systems. The institutional context in which standard setting organisations operate is highly relevant to the outcome of the standard development process[3] and consequently to the shape of any inter-organisational system. The environment provides such standards organisations with institutional rules for how standardisation should proceed, beliefs about what is important in the process of creating standards, and assumptions about the standards environment.[4]

With the rise of Internet technologies and associated XML based standards, the number of competing models for standards development and standards bodies has increased dramatically.[5] The organisational and institutional milieu in which XML-based standards are developed has thus become complex and dynamic. The emerging

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institutional structure is a significant issue because the outputs of the process are models of standard business processes that many users may have to accept. The institutional rules which frame the process of standard development significantly influence the development of e-business and, due to path dependency, once a business model is institutionalised in a standard it may become difficult to develop alternative standards.

While most of the accounts of standard development adopt an economic perspective, this study argues that an alternative approach is required to identify and explain the rich social processes that shape an emerging standard consortium. We have turned to New Institutional theory[6] to provide a theoretical framework to analyse this empirical case study. The focus of the study is to analyse the institutional mechanisms that frame the emergence of a standard setting body. The analysis uses Meyer and Rowan's[7] classification of the mechanisms that shape the creation of institutional rules—relational networks, degree of collective organisation and leadership—and applies the classification to the study of a health informatics private standard consortium operating in the UK. The study identifies significant conflicts within the institutional environment in which the new standard body operates, for example tensions between the system vendors and the health providers. Such conflicts, far from supporting ideas of convergent and stability of organisational forms within the standardisation domain, are evidence of the interplay between diverse institutionalised contexts that erodes the institutionalisation of standardisation practices.

Evolution of Standards Organisations: the Emergence and Institutionalisation of Consortia

To address the tensions between actors in the development of standards we have to consider, the arenas in which standards development takes place. David and Greenstein[8] proposed a distinction between *de jure* standards, developed in formalised institutional collaborations, and *de facto* standards, developed by single organisations but then institutionalised through their adoption by the market of intermediate and final users. This classification does not distinguish between the standards but between the processes within which they are developed and disseminated. The distinction is analogous to the comparison between standards setting through markets and standards setting through committees,[9] in which the focus is on how constituencies of users form. Until the 1990s, formal Standards Development Organisations (SDOs), such as ANSI in the United States, BSI in the United Kingdom and DIN in Germany, provided representatives to global SDOs, notably ISO (International Organisation for Standardisation), and were responsible for standards development. However, by the 1990s the institutional basis of standards setting was being eroded by the formation of consortia of interested actors developing standards outside the formal process.[10] Exogenous factors that have been suggested as triggering this change include the 1993 National Co-operative Research and Production Act in the United States, which reduced the anti-trust risks of informal inter-organisational alliances,[11] the emergence of the Single European Market[12] and the Agreement on Technical Barriers to Trade.[13] The success of the Internet—for example the victory of the Internet standardisation model over OSI in the early 1990s—has also flagged the possibility of alternative standard development models.[14] It has also been claimed that the formal bureaucratic-structures had become increasingly perceived as being slow and cumbersome.[15]

This unresponsiveness was regarded as particularly problematic in IT standardisation, where flexibility and speed of development are important to potential users.[16] The danger that organisations would defect from the formal standardisation bodies led the standardisation bodies to reform their procedures to increase the speed of standards development and the quality of the standards produced.[17]

However, for organisations interested in standards, it is not only a choice between involvement in the existing formal standards bodies and developing their own idiosyncratic standards: they can co-operate with other firms. The greatest growth in standards development in the last 10 years has been an explosive growth in the number of consortia, groups of organisations co-operating to develop standards outside the processes of ISO and other formal standards bodies. The ISO process has been described as encompassing four principles of organisation: *expertise*, *representation*, *user orientation* and *participation*, but in practice the process is dominated by intermediaries, for example consultants who can see the experience gained through participation becoming marketable, rather than by expert organisational users who participate to develop standards that meet their needs.[18] Schmidt and Werle[19] identified that the hierarchical structure of national representation had become regarded as a barrier to the development of standards and had led to organisations co-operating to form 'para-standardisation' bodies, citing as an early example the European Computer Manufacturers Association (ECMA) founded in 1961. At what point standards produced collaboratively cease to be *de facto* and become *de jure* is determined by the recognition of the legitimacy of the processes within which the standards are developed. As a standards body becomes more organisationally defined it can claim to be the dominant standards development organisation within its area, and become the legitimate standard bodies in their areas if formal standards bodies, such as ISO or ANSI, recognise this claim or ratify the standards. This 'symbiotic co-existence'[20] reduces formal standards development organisations to the rubber-stamping of standards developed outside their processes. This process of legitimation is repeating the historical process by which the national standards bodies formed early in the twentieth century as collaborations between industrial firms, who could see benefits in collaborating on standards, and whose nascent organisations were then recognised by national governments.[21]

The mainstream literature has addressed standards creation from an economic perspective. Economic models have been used to compare different standard setting processes[22] or to analyse the factors affecting a firm's choice between the standard setting processes available.[23] The economic literature conceptualises the process of standard creation within standard setting bodies as an 'interactive cooperative behaviour of learning agents within clubs'.[24] The focus is on the firm's choice between alternative forms of standard settings which is based on efficiency criteria and it is analysed employing a game-theory model.[25] In general, the economic argument claims that standardisation within standard bodies is more efficient but slower than market standardisation.[26] Firms choose the most efficient form of standardisation based on the firm's features, the nature of technology, the significance of standards, and the characteristics of available standard settings bodies[27] such as cost of vote recruiting, number of actors and procedural mechanisms.[28]

The economic models of standardisation are based on the assumption that the actors involved in the standard setting process are seeking economic benefits. A critical variable in the economic analysis is the payoff for the firms involved, where

payoffs represent economic returns.[29] However, although firms do seek economic benefits, the underlying reasons for their choices, such as what standard to adopt, and which standard settings to participate in, are far from clear. Such choices depend upon expectations about the unproven outcomes, the behaviour of the other participants,[30] and the power relationships between the participants[31] which are ignored in the economic analysis. Economic theory can produce generalised explanations of why standardisation takes place within committees rather than other forms of standard setting, why such committees exist and why firms choose to participate in them. However, the exclusive economic focus restricts its ability to explain how these committees are organised, how actors are enrolled and the factors that shape the standardisation process once the firms have chosen a particular form of standard setting. To address the rich social processes that characterise the standardisation process and which cannot be captured in an economic account, standardisation researchers have increasingly drawn from institutional theory[32] or institutional theory in combination with social constructivism.[33]

This paper approaches the standardisation process from an institutional perspective in order to identify the social processes that shape standard development within a standard consortium—in particular, the emergence of institutional rules that frame the standard development process within a health informatics standards consortium—and which cannot be captured by the economic account. A brief account of the institutional theory is included in the next section, followed by an overview of the existing research into the institutionalisation of standard settings.

Theoretical Background—Institutional Theory

Institutional theory emerged in reaction to the economic and resource dependency approaches, which conceptualise organisations either as production functions or as exchange systems, shaped either by their technologies and transactions or by the interdependency resulting from these exchanges within the system. Environments are conceived as a stock of resources and exchange partners.[34] In contrast, institutional theory focuses on the taken for granted assumptions at the core of social action.[35] Organisations are seen as captives of the institutional environment in which they exist. In order to survive, they conform to what is defined as appropriate and efficient in this social environment, largely disregarding the actual impact on organisational performance.[36] Particular emphasis is given to legitimation processes, and to the tendency of institutionalised organisational structures and procedures to be taken for granted or viewed as legitimate by the organisations that adopt and perpetuate them.[37] The process of legitimation is seen as a source of formal structure. By gaining legitimacy, the elements of formal structure, such as policies, positions and governance structures become manifestations of institutional rules in their respective domains.[38]

In contrast with the economic view, within institutional theory organisational success is seen as depending on an organisation's ability to accommodate institutional expectations rather than on the efficient coordination and control of productive activities.[39] Being consistent with the assumptions,[40] or what Meyer and Rowan[41] call the 'rationalised myths', within the institutional environment, becomes critical for an organisation's survival, and not task performance. Conformity is not only based on the 'taken for granted' quality of the institutionalised beliefs,[42] but also on the fact that organisations are rewarded by doing so through increased legitimacy, resources and survival capabilities.[43]

According to Meyer and Rowan[44] there are three processes through which these rationalised myths, which become the institutional rules, emerge:

1. through the elaboration of complex relational networks: as relational networks in an industry or domain become denser and more interconnected, the number of rationalised myths of organisational structure that generate institutional rules increases;
2. their emergence depends on the degree of collective organisation of the environment: whereas relational networks have legitimacy based on the assumption they are rationally effective, institutional rules can also gain official legitimacy based on a legal mandate. Such a legal mandate has to be issued by a central and acknowledged organisation within the environment;
3. they are facilitated by the leadership efforts of local organisations: organisations not only adapt to their institutional context, they also play an active role in shaping it. These efforts translate into a powerful organisation either forcing others to adapt to its structure and processes or into the organisation attempting to use institutional rules (standards) as a means of propagating its own goals and processes.

The process of accommodation to a set of institutionalised beliefs leads organisations within the same institutional environment to adopt similar organisational forms.[45] This understanding is central to institutional theory: conformity to institutional rules creates structural similarities, termed isomorphism, between organisations.[46] DiMaggio and Powell define isomorphism as 'a constraining process that forces one unit in a population to resemble other units that face the same set of environmental conditions'.[47]

In general, institutional theorists differentiate between three main processes that cause organisations to change their structures in ways that make them conform to an institutional pattern:[48]

1. coercive isomorphism resulting from pressures exerted on organisations by other organisations upon which they are dependent and by cultural expectations;
2. mimetic isomorphism, a consequence of adopting the successful elements of other organisations when uncertain about alternative; and
3. normative transmission of social facts, generally from external sources such as professions.

Through coercive, mimetic and/or normative pressures, organisations within the same population facing the same set of environmental constraints will tend to be isomorphic to one another and to their environment.[49]

Institutional theory has usually been applied to explain the similarity and stability of organisational forms. This premise that conformity to institutional rules creates isomorphism across organisations is seen as central to New Institutional theory.[50] The focus on isomorphism has been criticised for placing too much emphasis on the homogeneity of organisations rather than on the processes that may not create this outcome[51] such as organisational change.[52] In response to these criticisms, a number of researchers have applied institutional theory to study the discontinuity of an institutionalised organisational activity[53] and firm heterogeneity within a particular field.[54] Oliver[55] studies the erosion of an institutionalised

organisational activity due to the gradual deterioration in the acceptance and use of a particular institutionalised practice. According to Oliver,[56] political, economic and social pressures that operate both at the organisational and environmental levels can precipitate the process of deinstitutionalisation. Building on the work of Oliver,[57] following studies argue that both change and stability can be understood by addressing the interaction of organisational actors with the institutional context.[58] Such studies stress the crucial role of intra-organisational dynamics in accepting or rejecting institutionalised practices.[59] Firm heterogeneity can hence be accounted for since organisational response to the same institutional context differs due to intra-organisational dynamics,[60] individual actions[61] and different organisational structure, culture and action.[62] Additionally, the institutional fields that define the legitimate practice are found to be diverse and complex, which translate into different outcomes—heterogeneity—at the organisational level.[63]

As a result, institutional theory addresses both the institutionalisation process—the social process by which individuals and organisations come to accept a shared definition of social reality[64]—and the deinstitutionalisation process—where this shared definition of social reality became challenged.[65] Isomorphism is still the dominant theme in institutional research.[66] However, institutional theory is gradually being developed to explain heterogeneity within an institutional field[67] and to address the processes through which the institutional environment that sustained and perpetuated isomorphism becomes dissipated as a result of either internal organisational dynamics[68] or political, social and economic forces from the outer environment.[69]

Institutional Theory and Standard Creation

In contrast with the economic account of standardisation, there is only limited research approaching standardisation from an institutional perspective. When considering standard creation, Schmidt and Werle[70] analysed the organisations coordinating standards development as emerging institutions, stressing the institutional settings and rules that help to achieve such coordination. The study considers 'technology as socially constructed' where the 'technological choices can be explained as the outcomes of the interactions between intentional actors'.[71] However, the authors argue that in the social constructivism approach the location of relevant social groups has largely been neglected and that institutional and organisational factors have to be included in the analysis to identify the membership and boundaries of such groups.[72] Both the artefacts in the social constructivism view and the institutions in the institutional theory are seen as channelling, framing and contextualising the actions and interactions of the actors involved in standard creation. The authors conceive the standardisation field as highly institutionalised. The standardisation environment provides SDOs with institutional rules that determine their 'general procedure, the decision process, sometimes the legitimacy of arguments, and the value of consensus',[73] and shape the negotiation process within standard committees. In this way, institutions contextualise situations by providing specific rationales for actions to the actors involved in the standardisation process.[74] The authors emphasise the influence that institutional rules have on the way actors coordinate standards development.

In a later work, Werle[75] examined the institutional aspects related to different forms of SDOs. Building on earlier work,[76] Werle[77] identified the co-existence of several competing forms of SDOs. Despite this competition, many of the SDOs

share similar institutional features: negotiation, voluntary participation, consensus-based decision making and inclusiveness of committees. Therefore, even though SDOs differ in institutional settings and in their internal organisational structure, Werle[78] points out that SDOs have developed both mimetic and coercive isomorphism. According to Werle, it is this institutional isomorphism that explains the peaceful coexistence of so many different SDOs with overlapping jurisdiction.

Isomorphism develops not only between organisations that develop standards, but also among organisations that use these standards. Lawrence[79] found that standards led to coercive (standards imposed through regulation) and mimetic (as in the case of *de facto* standards) isomorphism for the organisations that adopt them. According to Lawrence,[80] standardisation in general is concerned with the establishment of technical, legal or informal standards that define what is 'normal' for a practice, product or service either through regulation or through enactment of less formalised norms or standards. The author argues that standardisation strategies are not about organisations adopting practices which are already normatively sanctioned in order to legitimate their own existence, but about the movement of practices from the realm of technical rationality to that of institutional rationality. In other words, standardisation strategies involve the institutionalisation of practices, products or services through the assignment of value beyond their technical value either through social or cultural mechanisms. Lawrence's[81] study also emphasises the importance of leadership, and of technical, legal and political expertise as critical resources in standardisation strategies.

Such an analysis can explain isomorphism in the context of standard setting[82] and standard user[83] organisations, and the role that institutional context plays in framing the standard development process.[84] However, existing institutional research in the standardisation arena focuses on the similarities between emerging standard setting bodies rather than on their broad variety. Hawkins[85] in contrast emphasises the broad diversity within the private standard consortia realm and identifies as their only shared feature the informal character of their 'formal structure'. At the same time, even the established, traditional SDOs are in a process of constant change as they are attempting to adapt to the increasing competition and new demands for a faster and more efficient standardisation process.[86] In this context, questions that standards research has still to address include: how does the institutional context(s) shape the emergence of a new standard consortium? And in this context where both stability and change trends are apparent, what are the mechanisms that shape the creation of institutional rules that frame the standard creation process?

This study aims to shed some light on these questions. The paper analyses the mechanisms that frame the emergence of institutional rules within a specific context: the development of standards for clinical data messaging in the health sector in England within the Health Level Seven (HL7) UK standard body. The study is not intended to identify general patterns that apply across all settings and types of standards, but rather to gain an in-depth understanding of the processes that underline standards development in this particular setting.

Research Methodology

This work uses a case study approach to examine how HL7 standards are developed in the NHS in England. The case study approach was chosen because the research focuses on 'how and why' type of questions.[87] This case explores the way in which

institutional rules and frames are generated within the HL7 standard consortium. It demonstrates how the NHS in England is developing the HL7 standard. Yin suggests that case study research is appropriate when the events being studied are still underway, which is true of the standards development process described here, and when it is not possible for researchers to control the events being studied, which is also true for this project: although we were able to interview managers taking part in the events described, the researchers had no influence over the process of standards development. The case described here is a 'single instrumental case':[88] the focus of the research is on gaining in-depth insights into the social processes that underline the emergence of the HL7 UK consortium, and the mechanisms that lead to the creation of institutional rules which frame standard development within the HL7 UK consortium. A single instrumental case study research design allows us to understand the dynamics present within a single setting,[89] which matches the objective of this research, and is not intended as a means of generalisation. This research thus aims to understand the processes through which institutional frames and rules develop within a particular context—the HL7 consortium in the English health market—and not to identify general patterns that apply across a multitude of standards settings and countries.

The case study uses three of the sources of information identified by Yin:[90] documentation, observation and interviews. The purpose of the interviews was to answer questions that were raised as a consequence of detailed analysis of the survey of documentation. The primary resource for study of documentation was the HL7 website for HL7 UK members, found at www.hl7.org, and the internal e-mail list for HL7 UK members. One member of the research team became a member of HL7 in order to gain access to the detailed documentation provided on the members-only area of the HL7 website. As a consequence of her membership it was possible to view all the relevant documentation on the website and also to observe on-line discussions as they developed. In this context the observation was of a virtual community. As is often the case for standards consortia, the members' area of the HL7 website, and especially the internal e-mail list, represents the primary means of interaction/communication between the HL7 UK members.

Interviews were carried out using an 'interview guide'[91] with a focus on the development processes of HL7, but leaving the interviewer free to build the conversation and to develop questions spontaneously as specific information emerged. The approach employed opportunistic sampling,[92] following leads given by interviewees to identify other appropriate contacts. The purpose was to explore the experiences of the interviews and their interpretations of the standards development process. Interviewees were selected for their capability to act as key informants.[93] Respondent validation was used to ensure the accuracy of the data obtained in the interviews.[94]

The interview process included four respondents, chosen to represent the different constituencies involved in HL7 standards development within the NHS in England. The four interviewees were: an independent consultant involved in developing the HL7 specifications for the UK market and also involved in coordinating the technical work within HL7 UK (IC); a key member of the National Programme for Information Technology within the NHS (NPfIT); a senior member of one of the leading IT suppliers in the English health market (ITS); and an individual member of HL7, representing the Scottish NHS in the HL7 UK consortium (IM).

Following Stake's[95] recommendation, the analysis of the case was based on making detailed descriptions of the materials and the case settings. The data

analysis followed techniques outlined by Miles and Huberman,[96] making comparisons, noting relationships between variables and developing patterns and themes. The different patterns and relationships identified in the case were brought together by building a logical chain of evidence. The relationships in the chain have been verified by those interviewed and against countervailing evidence (if such evidence was apparent, then it was checked and accounted for).

Clinical Data Messaging Standards Development—HL7 UK

Context

Within the UK the state NHS is divided into four, largely autonomous, bodies: the NHS for England, the Scottish NHS, NHS Wales and the Health and Social Services Northern Ireland.[97] This paper concentrates on developments of standards for clinical data messaging in the NHS in England. In England the NHS Information Authority (NHSIA) is the body responsible for the development and implementation of information technology initiatives.

In 1998, the NHSIA launched the National Programme for Information Technology (NPfIT), a radical approach to IT service provision strategy based on a centrally devised new system. The plan is to have a number of nationwide applications (e-booking, electronic transmission of prescriptions and an integrated patient care system) running over a new, nationwide broadband infrastructure, called the 'spine'. The spine will link the national applications with a range of services developed and specified locally within five clusters of strategic health authorities in England.

A crucial requirement for the development of this new system was a unique standard for clinical data messaging that would allow a consistent approach to communication and messaging of clinical data across the NHS. Such a standard is required to describe not only the network protocols and the XML messaging, but also the information flows between the various parts of the NHS, including referral and discharge letter, appointment booking, and test results.

In 2000, the NHSIA announced the adoption of HL7 version 3 as the national standard for clinical and administrative data in health care. The standard setting body responsible for the development of HL7 version 3 for the NHS is HL7 (Health Level Seven) UK. The case below discusses the tensions between the different relational networks operating within the HL7 UK, the degree of organisation and the role of leadership that shaped the emergence of the HL7 UK consortium.

HL7 UK

HL7 UK was established in January 2000 as an international affiliate of HL7, a US-based private standards consortium. The HL7 US consortium was created in 1987 as an open consortium of health care providers and system vendors developing standards for clinical and administrative data in healthcare. In an effort to increase its recognition as an international SDO in health informatics, in 1994 HL7 became ANSI accredited. Its cooperation agreements with other official SDOs, such as ISO and CEN, have also helped HL7 to gain legitimacy as an SDO.

At present, there are two functional versions of the HL7 standard: version 2.0 specifically developed for the US healthcare requirement and widely implemented in the US, and version 3[98] which is driven by the international healthcare market requirements.

HL7 Adoption in NHS England

The NHSIA's choice of HL7 version 3 was primarily driven by its strong support from the system vendors operating in the English market, in contrast with the ISO and CEN standards for health messaging. According to one of the interviewees: '[for CEN] there was less of a community committed to their development … and the supplier buy-in was an attraction [for HL7]' (IC). The reasons for such a strong vendor support was that vendors' influence within formal, official SDOs such as ISO and CEN is constrained by the system of national representation.[99] In contrast they can directly influence the development within a private standard consortium such as HL7, and consequently, prefer HL7 standards to standards developed in official SDOs.

Similarly, by choosing a private consortium standard, the NHS can retain influence over the process of standard development. This influence is exemplified by the direct participation of the NHS not only in the UK affiliate but also in the parent organisation.

Consequently, the institutional break from national representation through national standards bodies suited the ambition of the NHS to develop a standard that is supported by software suppliers in the long term, and influenced directly by the needs and requirements of the NHS. Thus the emphasis in the standardisation process has moved from the need to ensure legitimacy through the formal SDOs to the need to ensure that the socio-economic interests of the actors are represented during the process.

Standard Setting

HL7 UK was created by coalitions of large US-based health system vendors. According to one respondent, HL7 UK 'was set up by some of the larger suppliers … saying they wanted to get a version 2 implementation guide agreed for the UK so that they could tell their customers that they would do interfaces for any other system so long as they implemented the agreed UK version 2 standard' (IC). HL7 UK's role was to support the vendors' HL7 version 2 compliant products, hence increasing their market share, rather than to make an active local contribution to the development of a national version of the standard. However, following the commitment of the NPfIT to version 3, HL7 UK focused on version 3 development, and the work on version 2 was abandoned after only six months.

Participation in HL7 UK appears to be balanced between the different types of members: 'There's a mix of representation of a reasonable number of independent consultants, middleware firms, some of the big ones such as IDX [systems] and some NHS representatives from different bits of the NHS' (IC).

In contrast with the HL7 US development context, where work appears to be driven by suppliers rather than by healthcare providers, within HL7 UK the NHS has become one of the major drivers of standards development work, with a very large representation within HL7 UK. According to one interviewee, 'The NHS is a very big beast. It means that there are different bits of the NHS, so there's the Information Authority, there's the National Programme [NPfIT], there's the trusts, … there's the ISB [Information Standard Board], there's a whole range of organisations within the NHS that have an interest and that have a legitimate proper interest … so there's reasonably healthy engagement from across the NHS' (IC). However, the greatest involvement from the NHS comes not from the trusts but

instead from the central authorities responsible for the IT strategy and standards, such as the NPfIT and the NHS Information Standards Board. In addition, the NHS has also become actively involved in the parent organisation, being the only international healthcare provider organisation that is a benefactor member of HL7 in the US (which means that it pays the largest fee and has the right to the largest number of votes).[100]

Despite the balanced representation of suppliers, healthcare providers and independent consultants in the working groups, the actual development work appears to be done almost entirely by independent IT consultants, driven by NHS requirements. As one of the HL7 members mentioned: 'The suppliers tend to come to meetings and they're supportive and they'll stump up sponsorship money, but in terms of actually contributing and doing the work, and standing for all responsibilities and that sort of thing, they haven't been (actively involved) … (development work) tended to be driven by the independent consultants … We'd like to get more active engagement from the suppliers' (IC). This low vendor involvement in HL7 UK seems counterintuitive, especially since it was the system vendors who created HL7 UK in order to support their HL7 version 2 compliant products. One explanation for this is the difference between the traditional context of HL7 standards development in the US and the context of HL standard development and implementation in the UK. Whereas traditionally HL7 has been 'a fairly open network and people throw in ideas, here's this draft …, a little working group will produce a draft, all the manufacturers will go away and try them out and suggest changes' (IM), in the UK the implementation of HL7 version 3 is compulsory. The NHS mandate to adopt HL7 version 3 influences not only the implementation process, but it also shapes the development setting. In practice, HL7 UK is developing standards for the NHS which, according to an HL7 UK member, means that 'what the design authority are doing is [saying], "there it is, use it". It's a different way of working and it's not bringing the manufacturers along […] It's not an open process, an open agreement process, it's a dictatorial process' (IM).

Additionally, there is a significant tension between the open and collaborative nature of standards development within the HL7 consortium, and the norms and rules characterising the NHS approach. As discussed by one of the interviewees, 'The NHS largely focuses around centrally-led things, … closed steering groups or closed programme boards and things, which are a handful of invited people and they're not open, you can't get on there if you want to. Alternatively they're professional-led so you've got the Royal Societies and the Clinical Colleges and these kind of groups, and they've got their own structures and hierarchies and their own committees and things like that, so things will be done through a particular college' (IM). One of the outcomes of the difference in the characteristics of NHS and HL7 institutions is the lack of transparency during the standards development process. In order to protect the confidentiality that surrounds NPfIT only a very limited number of documents about the HL7 UK standards development process are publicly available, and access is severely restricted even for HL7 UK members. Such an opaque approach to standards creation is in contrast not only to the official SDOs procedures,[101] but also to other private consortia.[102]

The work within HL7 UK is dominated entirely by IT professionals, with no clinicians directly involved in any of the development processes. According to one of the HL7 UK members, 'historically there haven't been any pure doctors turning up to those (HL7 UK) meetings. Part of that is because the meetings have been

very technical … the main thrust has been how can version 3 be established as an appropriate basis for the development of standards in the UK … the focus … was getting the infrastructure in place so that the standards could be developed' (IC). The lack of clinical involvement thus appears to be due to the highly technical focus of the HL7 UK meetings, where the main emphasis was on developing the HL7 architecture and the underlying messages rather than, for example, on identifying the user requirements. Such tasks require IT experts rather than clinicians. However, the lack of clinicians involved in the process may create difficulties not only in the process for identification of business requirements, which is driven by IT experts, but also in terms of the adoption of the standard. As one of the members of HL7 UK mentioned describing the English approach to standardisation, '[the NHS] developed their own [messaging standards] in the 90s and actually people didn't use them. They're now developing their own extremely rapidly and they are not bringing the clinical community along with that' (IM).

Discussion

The decision by the NHS to adopt HL7 version 3, a set of private consortium standards, rather than the standards emerging through official SDOs such as CEN or ISO, places HL7 at the centre of health IT strategy in England. This decision was taken early in the process of development of both HL7 version 3 and the competing ISO and CEN standards, and implies that the decision was centred on a choice between competing institutional structures rather than between competing standards. The reason given for the choice was that the institutional structure of HL7, as a private consortium, offered the NHS the strong support of suppliers and the ability to directly influence the development of standards.

As discussed at the beginning of this paper, institutional frames emerge through three types of processes: relational networks, degree of collective organisation and leadership of a central organisation.[103] The emergence of the HL7 UK consortium is shaped by two competing institutional contexts characterised by conflicting relational networks and a strong degree of collective organisation that lead to competing institutional rules framing the standard creation process. These two mechanisms are discussed next.

First, there is a significant conflict between institutional frames that operate within HL7 UK as a consequence of different, often competing, relational networks. These conflicts can be placed in two dimensions:

1. *HL7 and NPfIT*: the traditional HL7 US process operates based on the norms within the standards domain, demonstrating open and transparent operations, and including a consensus-based voting system. This observation is in line with findings from earlier studies on standards development, which found that private standards consortia share many of the attributes of formal, traditional, SDOs.[104] In agreement with the work of Schmidt and Werle[105] because the development of HL7 is driven by vendors, different competitive interests exist. However, because a single party does not drive the requirements, the work is based on consensus, and collaboration is necessary. Because the NHS in England has made the adoption of HL7 version 3 standards mandatory, it has become one of the major driving forces at the level of HL7 UK. However, the relational networks that characterise the NHS are based on different norms to those usually observed in the standards setting arena. The groups are closed,

have a very restricted membership and operate with little or no transparency. There is a significant conflict between the underlying norms, rules and assumptions that characterise HL7 and those that characterise the NHS. Such conflict is undermining the structure of the HL7 UK, with vendors becoming gradually more and more disengaged from the development of the standards that their applications will be required to adopt.

2. *HL7 UK and the NHS*: there are significant differences between the professional networks involved in standards setting (HL7 UK) and those found in the implementation context (the NHS). In the context of the NHS in England and HL7 UK, standards setting is dominated by IT professionals whereas the implementation will be carried out within the clinical domain. As a result, development of standards and implementation are occurring within different institutional frames. Within HL7 UK there has been no apparent effort to reconcile the two networks, for example through the inclusion of clinicians in the standards setting process. This lack of overlap between the two frameworks within which HL7 standards will operate in England raises concerns about the extent to which the practitioner health community will adopt the standards. Concerns regarding the lack of alignment between users and standardisers have been raised in previous studies,[106] though in these cases the focus has been on benefits (or the lack of benefits) of user involvement, and the concerns raised about standards coordination, and not on the alignment of the different underlying relational networks.

A similar institutional tension between two different relational networks was found in an earlier study of forensic accounting standardisation in Canada.[107] The study found that the tension between forensic and accounting relational networks led to competing institutional rules undermining the elaboration of standardisation strategies. In the case of HL7 UK, the tension is between the standards developers and the NPfIT who are charged with implementation rather than between two competing professional networks within the standards setting arena.

Second, both institutional contexts within which HL7 UK operates are characterised by a strong degree of collective organisation:

1. The standards domain is characterised by large number of standards developing bodies, some more formal than others. However, there are a limited number of SDOs that are acknowledged as central organisations, and that are generally accepted as 'the official' SDOs. ANSI is one of the central players, together with ISO and CEN, with the latter particularly active in the European standards arena. Official recognition from such central organisations provides a 'legitimate mandate' for any standards body.[108] HL7 has gained legitimacy by becoming accredited by ANSI and by forging agreements with such 'legitimate' SDOs as ISO and CEN. To gain legitimacy consortia can also draw on the institutional framework of existing well-established SDOs,[109] including in HL7's case having national affiliates and open decision-making. As suggested by Schmidt and Werle,[110] despite the rise of private standards consortia, a limited number of SDOs still appears to occupy pre-eminent positions within the standardisation field. The position of these SDOs enables them to operate with an authority akin to a legitimate mandate. The legitimacy of SDOs, and thus the institutional rules that frame the work of such organisations, is still significant for business organisations, not least, according to Schmidt and Werle,[111]

because high levels of legitimacy increase the likelihood of implementation and compliance. By establishing itself as the recognised legitimate body, HL7 has been able to enrol new members. For both vendors and users it is apparent that the standards developed will be the standards that will be adopted, so the risk of investing resources in a standard that does not gain acceptance is reduced and any knowledge gained will be exploitable in products or during implementation.

2. In the UK healthcare sector, the institutionalisation of user needs, with the dominant position of the NHS IA as the institutionalised user representative, reduces the incentive for users to invest their resources in participation in the standard development process. In a relatively homogenous sector where there is a recognised legitimate users' representative the users will be willing to allow their interests to be fed into the process through that representative.

Finally, the third mechanism that Meyer and Rowan[112] list as leading to the creation of institutional rules is the leadership of central organisations. This study revealed the crucial role that leadership efforts play in shaping the institutional context, thus supporting Lawrence's[113] earlier findings. The NHS is driving the standards development in HL7 UK and is trying to gain access to the higher levels of the overall HL7 standards body in an effort to build its goals, processes and requirements into the standards.

Conclusion

This paper has claimed that the conventional economic account to understand standard setting is incomplete due to its inability to engage with the social processes that underlie the creation of standards. An economic analysis, with its focus on the costs and benefits to actors of engaging with a standards development process, is valuable in understanding the decisions by actors to enrol, but tells us little about how the standards organisations available to them emerged. As an alternative approach, this paper has adopted an institutional framework to explain the mechanisms that frame the emergence of standard setting organisations. A naïve institutional analysis of standards development would expect isomorphism to lead to homogeneity between standards processes. However, we have seen that standardisation does not take place in institutional isolation. In addition to institutions drawn from global standards processes, such as consensus decision-making and open communities, the process will also be influenced by the institutional milieu of the context in which the standards will be used. These local institutions may be more obdurate and resilient than the global standards institutions, leading to heterogeneity in standards development processes. The description of HL7 UK illustrates the conflict between a globally highly institutionalised process for standard development (HL7) and a local highly institutionalised organisation (NHS) that shapes the development of health informatics standards within a new standards consortium in the UK. The standardisation environment as well as the British health service are characterised by conflicting relational networks and a strong degree of collective organisation leading to competing institutional rules. In this way, rather than characterised by similarity and stability, the standard setting is characterised by different, often divergent, institutional environments that lead to the emergence of a hybrid organisation. The heterogeneity of the standard setting

organisations can thus be explained based on the multiplicity of the institutional contexts in which they operate.

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