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Traveling Standards and the Development of Danish Electronic Patient Records

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Introduction

In the last decades organizational theorists have paid attention to the closely-knit and interdependent relationships between institutions and the technological environments in which they are embedded (e.g. Dosi 1982, Hughes 1983). Increasingly, they have pointed to the importance of standardization in ensuring this interrelatedness. They have also focused on the institutional requirements of standard-setting and development itself (e.g. Schmidt and Werle 1998, Garud, Jain and Kumaraswamy 2002). By unpacking these aspects of standardization, they have challenged the received understanding, which see this process as driven solely by economic requirements and technological progress (see e.g. Besen and Farrell 1994).

There is a substantial overlap between this agenda and the research into standardization emerging out of Science and Technology Studies (STS), which have analyzed the varied social, material, and institutional requirements for successful technological standardization, development, implementation and use (e.g. Timmermans and Berg 1997, 2004). In spite of this congruence some important

differences remain. These can be glimpsed from the following excerpt from Schmidt and Werle's book *Co-ordinating Technology*:

> Large technical systems especially rely on coordination: not only with respect to construction and maintenance but also with respect to operation and use. Technical standards serve as a medium of coordination. They are technical rules that specify relational properties of artifacts. Compliance with these rules ensures compatibility and thus ensures the artifacts' smooth interoperation in a system (Schmidt and Werle 1998: 25)

From the point of view of STS-studies, the first sentences of this citation are unobjectionable in their emphasis on the ongoing work required to build, implement and maintain effective standards. It is the conclusion to the paragraph that jars. Here, it is suggested that "compliance with rules" ensures "smooth interoperation in a system". With this formulation in mind, a lack of agreed-upon standards can then be seen as *disabling* the co-ordination of activities between different companies, institutions, and organizations; as representing chaos rather than order. This premise makes standardization seem commercially and politically attractive or, indeed, as a crucial societal aim. As we shall see below, this view is not limited to academic analysis, but is widely shared among politicians and technologists involved with current efforts to implement electronic patient records in Danish health care. Below I use this agreement as an occasion to consider some shared assumptions that tie together the otherwise dissimilar endeavours of institutional theory and political envisioning.

The present paper engages questions of standardization from both a theoretical and an empirical angle. It discusses how institutional studies of standard-setting, in spite of their interest, retain determinist pre-suppositions from earlier economic and technical analyses of standardization, which lead them to overestimate the co-ordinating capacities of standards. By way of an empirical study of the standardization of electronic patient record in Danish health care, it then suggests that standards may be seen as *travelling entities*. Standards move between practices in the attempt to facilitate co-ordination, but often they do so with great difficulty. Their success is neither guaranteed by institutionalized procedures, nor ensured by technical sophistication. Furthermore, I argue that standards do not co-ordinate an

inert infrastructure. Rather, they enter into a highly *active* infrastructure. In turn, this means that standards must themselves be co-ordinated with existing organizational, political, and technical arrangements. The paper argues that this complicated and labour-intensive work is what enables standards to *actually standardize*.

In the effort to make standards successfully travel, organizational, political and technical issues become increasingly intertwined. This has consequences that remain invisible from perspectives that claim to clearly be able distinguish between these domains. In the following I refer to this important aspect of standardization as the *travel expenditures* of standards.

Standardization from Determinism to Institutionalism

Standardization has not generally created a lot of excitement among social scientists, not to mention among the broader public. One reason for this predicament is probably that they have been seen as neutral infrastructural technologies. The consequence of this is that analyses of standardization have often focused on the factors supposedly underlying standardization, rather than on the standards themselves.

In the case of medical standards sociological critics have mainly argued that standardization inherently reduces the richness and complexity of work practices. As Cambrosio and Keating sum up this line of critique: "it is maintained that medical technologies have downgraded or eliminated skills embodied in what is termed "clinical judgment," forcing diagnosing physicians to become increasingly subservient to technologies whose development they cannot control" (Cambrosio and Keating, 2003: 324).[1] In such analyses technological standardization is seen as a symptom of a general marketization of health care, which deprive doctors of their embodied skills.

[1] See e.g. Heath and Luff (1996), Wilkinson (1983).

However, institutional studies of standardization have begun to question whether standards embody any general rationality. Ceasing to view standards as deterministic entities has consequences for both critics and proponents of standardization. On the one hand, contrary to what is argued by critics, studies show that standards do not follow a logic, which automatically deprive humans of agency (e.g. Timmermans and Berg 2004). On the other hand – indeed, for the same reason - the idea that standardization *ensures* optimal co-ordination becomes questionable. For one thing, determinist studies of standards often lack attention to issues of power. As Schmidt and Werle argued:

> One crucial weakness of economic approaches to explaining the evolution and functioning of committee standardization is, of course, their tendency to neglect power. They do not regard prevailing resource and power differentials between countries, or between organizations or individuals, as crucial variables affecting the phenomena under considerations. Instead they emphasize deficiencies and failures of markets such as network externalities (Krasner 1991). Aspects that are not purely economic, especially political interests and motives, are dismissed as external (Schmidt and Werle 1998: 61)

This argument takes issue with the assumption of economic rationality in standardization research. However, exactly the same type of argument applies to technological rationality and determinism. Thus, information studies researcher Rob Kling writes: "a remarkable fraction of [computer and information scientists'] accounts are infused with a hyper-rational and under-socialized view of people, computer systems, organizations, and social life in general…Further computer systems are portrayed as powerful, and often central, agents of organizational change" (Kling 1998: 50; see also e.g. Agre 1990, Forsythe 2001, Star 1995, Suchman 1987, 1988). Brian Winston ties the two determinisms together by pointing out that: "Information revolutionists, in predicting the future, take exactly such a technologically determined view. If the technology makes it possible, they seem to be saying, then it will happen (normally, most of them seem to add; through the beneficence of the market" (Winston 1986: 13). These researchers advocate a broadening of perspectives, which enables research into standardization to not only take into account narrowly technical and economic concerns, but also

situate standardized technologies socially, institutionally and politically. In short, they allow researchers to grapple with the liveliness of standards.

Schmidt and Werle term their approach *actor-centered institutionalism*, and explain that they "relate meso-level elements (institutions) to micro-level elements (actors). Jointly, these elements constitute the social setting that shapes technology" (Schmidt and Werle 1998: 16). Focusing on the relations between institutions and actors is a good starting point if one wants to develop an understanding of standardization as a contingent and unpredictable process shaped by multiple interests and agendas. Yet, some critical points can be advanced. For example, while Schmidt and Werle emphasize the necessity of going beyond narrow economic understandings of standardization processes, both also continue to rely on certain metaphors and images from this tradition. In their book Schmidt and Werle devote considerable attention to diverse game-theoretical scenarios and their relevance for analyzing the construction of standards in the CCITT (Comité Consultatif International Téléphonique et Télégraphique), an organization that sets international communications standards. They conclude that standardization by committee most often resembles the scenario called 'battle of the sexes' or the 'dilemma of common aversions', in which "actors have a strong common aversion to a particular outcome (in our case, incompatibility) but they lack a common recipe for preventing it" (Schmidt and Werle 1998: 104). Rather than making their detailed empirical study an occasion for questioning the appropriateness of, and assumptions behind, this rather thin model of human (and technical!) interactions, Schmidt and Werle adopt it as an explanatory device throughout their study. Likewise, they accept without question Hardin's economic analysis of the challenges faced by standards development. This analysis is named 'the tragedy of the commons' and is also described as the 'free-rider problem', which Garud *et al* gloss in the following way:

> For a sponsor, adopting such an open systems strategy implies placing part of its private knowledge in the public domain. A property of such public goods is that even those who have not contributed to their creation can benefit from them (Olson, 1965). Typically, such a situation creates a free rider problem resulting in the

> underdevelopment of the public good or in the degradation of the "commons" (Hardin, 1982) (Garud, Jain and Kumaraswamy 2002: 201)

In Schmidt and Werle's analysis the consequences of free-riding are that:

> In fact, the implementation of a standard, especially if switching from an old to a new one is involved, may turn out to be another public-goods problem. Early adopters help to initiate widespread adoption, but they risk incurring losses if others do not follow and adoption does not become widespread (Dybvig and Spatt 1983). Here free riding means delaying until many others have implemented the new standard. It is therefore not surprising that, on the one hand, committee standards are public goods and that, on the other hand, they entail a normative commitment to comply (Schmidt and Werle 1998: 60)

From the point of view of STS, however, a dose of scepticism appears in order with respect to the virtues of this analysis. In the case of the 'tragedy of the commons', Peter Taylor has detailed how Hardin's interpretation of social interaction was closely circumscribed in order to make it amenable to an analysis based on the rationalist and individualist presuppositions of classical economic theory. As Taylor sums up:

The conventional strategies in science gives priority - in method, theoretical development, and aesthetics - to posing simple principles behind complex appearances. A lot of new thinking can be opened up by inversion of this relationship, by recognizing that simple models should be read as entailing complex social constructions (Taylor 1998: 449).

Notable among the new thinking facilitated by this inversion is that it no longer seems certain that the commons are tragic *as such*. Rather this question would be open for empirical exploration of the ways in which socio-technical processes make them so or otherwise.

Schmidt and Werle are explicit about their theoretical agenda; they want to draw on ideas from STS without letting go of what they see as important insights from economic and political analysis. Their reliance on metaphors such as the 'battle of the sexes' and the 'free-rider problem' instantiates this eclecticism. However, as Taylor's criticism of those same ideas indicates, it is not conceptually straightforward to mix theoretical models with different basic assumptions. Nor does it make Schmidt and Werle perceptive to the full variety of sites and actors

involved in standardization, or to the technologically mediated *transformation* of political and institutional relationships, which take place as standards travel from committees and deeper into the health care system.

Constructivism and Travelling Standards

Constructivist studies of science and technology view the social, the political and the technical not as distinct spheres, but as mutually constitutive processes, which unfold in socio-technical networks. This suggestion, which results from an ongoing dialogue at the boundary of IS research, medical informatics and STS (see e.g. Berg 1995, Markussen 1996, Suchman 1987), has led to a research agenda, highlighting the local and varied requirements for successful technological standardization, development, implementation and use. In turn, this has suggested the importance of closely analyzing the genealogies and the multidimensional implications of different standardization processes and outcomes (Timmermans and Berg 1997, 2004).

Thus, researchers have looked carefully not only at the development of standards but also at standards at work.[2] Where do they come from? Who makes them? And what happens as they move between practices? As many studies have shown, standards come in practice in many forms and shapes. They come from different places and relate to many different problems. Some relate to the same problem but propose incongruent solutions. This is not surprising since the implementation of a standard can be an effective way of reconfiguring work-practices by changing and re-defining what competences and tasks are relevant from within.

The term "configuring the user" was proposed by Steve Woolgar (1991) and subsequently applied and refined by other researchers, in order to show how the presumed needs of institutions, organizations and individuals are often elaborate constructions, which result from the activities of e.g. designers, managers or

[2] The list includes Berg and Timmermans (2000), Bowker and Star (1999), Hughes (1983), Porter

politicians (see also Cooper and Bowers 1995; Oudshorn et al. 2004). The point of these studies, however, was not to criticize designers or managers. Rather, it was to note how their activities create organizations and people, with real needs, which they previously did not have. Jean-Francois Lyotard concisely summarizes this type of situation: "just as the flow of uses can be controlled, so can the flow of information… As a need is diverted and a motivation created, an addressor is led to say something other than what he or she was going to say" (Lyotard 1988: 12). Preferences and needs of users are conceived in these studies not as static but as dynamic and transformational. For example, certain organizations and people have literally diverted needs and created motivations for the development of health care standards in Europe and Danmark, and health care users have been reconfigured in the process. In this process, people make standards but standards also make people. Of course, whether such needs and preferences are subsequently met and whether new standards become in reality capable of moving between and co-ordinating practices; that is a different question, which must be investigated by following standardization in action.

Marc Berg has suggested that: "the most "successful" implementation processes appear to be those in which an obsession for control and planning is replaced by an obsession for experimentation and mutual learning" (Berg 2001: 154). In terms of developing an analysis of standardization, this requires flexible tools, which are not tied up with abstract and pre-specified definitions of what a standard *really* is, or how it can optimally be made to work. Geoffrey C. Bowker and Leigh Star has developed the following broad and heuristic characterisation of standards, with the attainment of such flexibility in mind:

> A "standard" is any set of agreed-upon rules for the production of objects.
>
> A standard spans more than one community of practice. It has temporal reach as well in that it persists over time.

(1997), Schaffer (1994), Slaton and Abbate (2001) and Wise (1995).

> Standards are deployed in making things work together over distance and heterogeneous metrics.
>
> Legal bodies often enforce standards, be these mandated by professional organisations, manufacturer's organisation or the state.
>
> There is no natural law that the best standard shall win. (Bowker and Star 1999: 13-4)

The following case-study of the standardization of electronic patient records in Danish health care will particularly exemplify and qualify the fifth suggestion, which may be seen as a challenge to pseudo-Darwinist conceptions, according to which the best standard *must* win, simply because of its better economical or technical fit.

At the same time Bowker and Star's characterization implies an answer to those criticizing standardization for enforcing an abstract and reductive technological rationality, for it points to the variability both of standards and their effects. With an eye for sociotechnical detail, standardization comes alive; its consequences turning out to be come to be contingent and unpredictable.

In the following, I try to capture this liveliness by referring to standards as *travelling entities*. This use is literal to the extent that standards in reality have to move between practices, and that their success is related to their geographical spread. As we shall see, however, the focus on travelling standards, also allows me to highlight the problem of *travel expenditure*. This is particularly relevant, because just such expenditure tends to be forgotten in political and managerial discourses that separate technological and political issues, and choose to focus exclusively on the technical possibilities of standardization. Teasing out the various expenditures of travelling standards, in the end, facilitates a more broadminded analysis of the *sociotechnical* costs and benefits of standardization .

The present case deals with the development of standards for electronic patient records at the Comité Européen de Normalisation (CEN), at the Danish National Board of Health, and in the EPR Development Project in the Aarhus Region in Denmark. This is therefore not a microsociological study, but, contrary to Garud *et al* and to Schmidt and Werle, it is also difficult to characterize it as either *meso* or *macro*, because it does not focus narrowly on institutions and their relations (Jensen

2007). Rather, it details some of the tensions and incompatibilities which arose as standards were created at CEN, from where they were required to travel elsewhere; across national, institutional, political, practical, professional, technical, and disciplinary borders, and into Danish health care. It discusses how the hoped-for smooth co-ordination of health care practices has been enabled by the standards only to a limited extent. Rather than simply co-ordinating technologies, EPR standards have themselves had to be co-ordinated with Danish health care practices and institutions through a sustained and still ongoing effort.

Standardizing the Electronic Patient Record

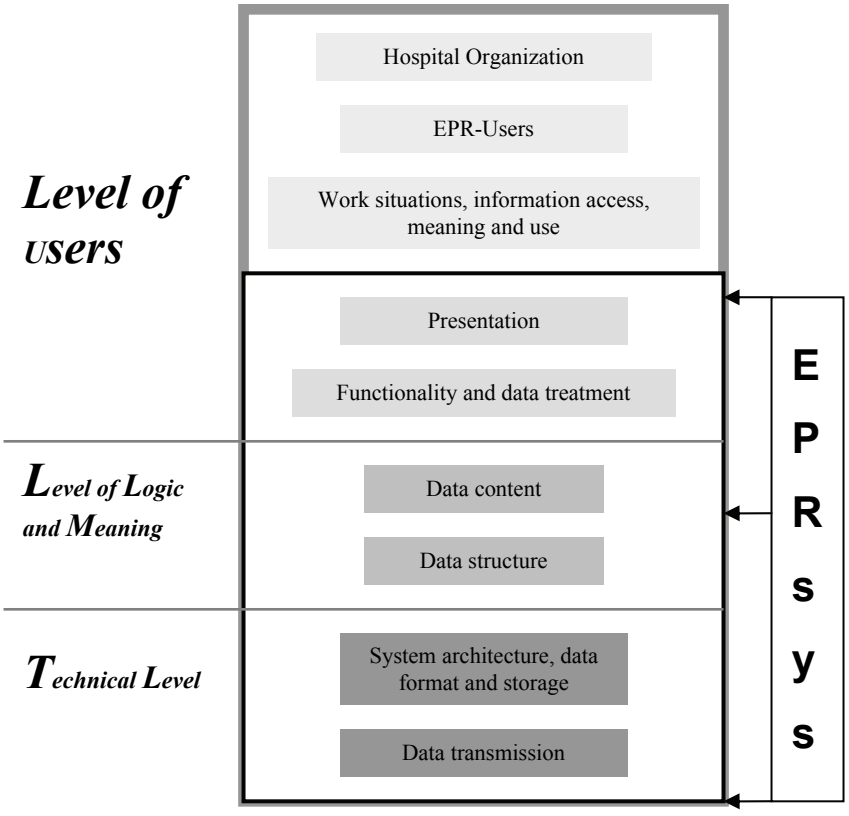
In Denmark, the development of electronic patient records has been one of most debated topics within the health services for several years. Debates on how these records are, and ought to be, developed, often revolve around questions of standardisation, considered in terms of general evaluations of economic feasibility or technical efficiency.[3]

To get a better understanding of the heterogeneity of practical issues in standardization and the tensions that arise as standards travel I shall discuss the activities and concerns of a number of practices involved in or affected by the current initiatives to construct a standardized EPR.

The level of semantic standardization, which will be the main focus in the following, is developed primarily at CEN - the European Standardization Committee - , and I briefly introduce its technical committee TC 251. Schmidt and Werle convincingly argue that it is important to understand the nature of the work, which takes place in standardization committees, in order to understand why standards become failures or successes. But this explanation is only partial. A standard is not a success merely because it has been finalized in a committee; it

[33] See for instance the report on the "use-value of the EPR" made by the national board of health. Available from www.dsi.dk/Fagomraader/ Sundhedsinformatik/EPJ%20rapport.pdf, accessed January 24th, 2005.

must be taken up and used in many other practices elsewhere. In this study I therefore follow one semantic standard as it travels from CEN's offices and into those of the National Board of Health in Denmark and I show how the standard does not stay unaffected as it moves. I trace the standard as it moves even further into Danish territory, more specifically to the electronic patient records development project in the Aarhus county. And I illustrate how ever more flexibility and transformation is required by the standard as it attempts to do its job of co-ordinating Danish health care. To get this genealogy started, however, I first present a semi-official reference-model constructed developed by the Danish EPR-observatory as a representation of the standards at play in the development of EPR's (EPJ-Observatoriet 2000: 14):[4]



[4] The EPR-Observatory is a Danish project under the auspices of V-Chi (Virtual Center for Health Informatics) funded by the Ministry of Health, with the purpose of surveying the developments initiated in Denmark with the purpose of making an EPR.

This model has three and a half levels. The *user* level relates to hospital organisation, work situations and information access. The *intermediary* level between users and software refers to interface-presentation and functionality. The *logical and conceptual* level concerns data-content and structure. Finally, the *technical* level has to do with system architecture, data formatting and transmission.[5] All of these levels can be standardised in many different ways, but not all have been equally contentious.

The most unproblematic level of standardisation, from the point of view of many developers of electronic patient records, is the technical level. The reason for this is that standards for transmission are not domain specific; that is, they do not have to be developed specifically with the health care sector in mind. The technical level is dominated by de facto standards[6] developed by multinational corporations. However, the situation is quite different at other levels of the model. The user level has been neither formally nor de facto standardised. And although the Danish National Board of Health and hospitals have been struggling with the question of how to ensure that information reaches only correct health care personnel a solution to this problem has not been easily forthcoming. Likewise, neither de facto, nor satisfying formal standards have been easy to develop at the level of interfaces. Finally, standardization has been challenging at the logical and conceptual level. This level, which relates to issues having to do with data structure and semantics, have been taking up as of particular concern by formal

[5] An obvious analytical move from the point of view of STS would be to deconstruct precisely such models in order to point to the technicalities of what is taken for granted as the social level of the model and show the many layers of social embedding, which enters into the putatively technical level. In this paper, however, I take seriously the discourse of medical informatics, which generates these distinctions, and follow the threads of one level of the model. This approach, too, quickly points to the co-construction of the technical and social, albeit from a somewhat different angle.

[6] De facto standards are often developed by market consortia whereas formal or de jure standardisation is what takes place under the quasi-democratic auspices of standardisation organisations such as ISO, CEN, ANSI, CCITT and similar initiatives (see e.g. Lehr 1992; Schmidt and Werle 1998).

standardisation bodies as it has been understood that "especially in Europe, where the information crosses management boundaries and, in many cases, regional and national boundaries, agreement on information content and message structures is necessary" (de Moor 1994: 3). Clearly "harmonisation" of EPR standards in Europe is a complicated business. How is it carried out?

The European Standardization Process

In 1990 CEN approved the establishment of a technical committee on healthcare informatics (TC 251), which was subsequently split up in seven working groups (de Moor 1994). As in the case of other international standardization organizations, the working methods and goals of CEN include that:

- participation is voluntary and not remunerated,
- participation is, within certain membership rules, open to those who are "substantially interested",
- the work is committee-based, cooperative, and consensus-oriented,
- organization and working procedures are impartial, unsponsored, and politically independent ("due process"),
- the work is based on technological knowledge and follows the principle of parsimony of standard options,
- standards are international, nonmandatory "public goods"
(Schmidt and Werle, 1998: 58)

The first working group of TC 251 concentrated on specifying a logical information structure for medical records. When a CEN-standard is ratified any task for which companies are invited to submit tenders within the EU has to be in compliance with it. The work of standardization is therefore of interest to a large and diverse group of people. Consequently it is by no means a simple task - and not just for technical reasons, but also for organizational, political, and, of course, economical ones.

The TC 251 consists of members from the different national standardisation organisations. Thus, Danish Standards set up a so-called 'mirror group', DS/S-273, to follow and participate in the work done at CEN. Members of DS/S-273 are from public and private institutions and organisations, primarily software companies and

health care organisations, with an interest in being actively engaged in the standardisation work (DS Hæfte 4 1995). But there are many other actors to take into account. CEN TC 251 has worked closely with the medical expert group of the European Workshop for Open Systems (EWOS/EG-MED), the Western European EDIFACT Board's Message Development Group for Healthcare (WEEB MD9) and many others. Internationally, the committee has been in contact with ISO (International Organisation for Standardisation), ANSI/HISB (American National Standards Institute/Healthcare Informatics Standards Board), which is the American equivalent of CEN/TC 251, and has developed the well-known HL 7 communication protocol. Contacts were also established with Japanese and Australian standardisation initiatives. These were rarely full-fledged instances of co-operation, but "exchanges of experience" (DS Hæfte 4 1995:27), which ensure that individual standardisation groups do not "re-invent … the wheel" (DS Hæfte 4 1995:54). Due to the extraordinary amount of actors and interests it is not surprising that formal standardisation bodies move slowly (see discussions by e.g. Sherif 2003, Warner 2003).

In 1996, the first standard for electronic patient records, EHCRA (Electronic Healthcare Record Architecture), was ratified by the national standardisation organisations. This, however, was not a final standard, but a pre-standard; an Europäischer Norm-Vorausgabe. In contrast with a final standard a pre-standard is characterised by not carrying any legislative force (e.g. for the submission of tenders). It is, instead, delivered to national organisations, software companies and other interested parties for testing in practice over a two-year period after which it is re-evaluated.

Travelling From CEN to the Danish National Board of Health

In Denmark the National Board of Health works to develop and implement health political initiatives coming from the government. In 1997 the board set up an office for medical informatics and became actively involved in the debates on the standardization of electronic patient records. From the point of view of the National

Board of Health the main issue was to ensure homogeneity of the standards adopted in Danish councils, which (then) represented the political level responsible for the health care systems. Carrying out this task was complicated by the fact that a number of concrete development initiatives were already under way in different councils. In the fall of 2000 the National Board of Health published a report on the proposed basic semantic structure of the Danish EPR. This structure was tested at two wards at Copenhagen Regional Hospital[7] that resulted in the publication of a version called G-EPJ 1.0 from December 2001, which has been updated several times since. An improved pre-standard was also published by TC 251 in 1999. The juxtaposition of TC 251 initiatives and those from the Danish National Board of Health points immediately to certain tensions involved in making standards travel. The CEN committee has been putting a concerted effort into its standardisation process, yet this did not prevent the National Board of Health from translating its results, by tailoring these standards to fit the peculiarities of the Danish health care system. Meanwhile several Danish councils worked on local projects, some of which began years before the office for medical informatics was set up at the National Board of Health, and started to advocate specific standards. Similarly to what is documented in other cases (e.g. Berg 2001, Graham *et al* 1995) the European and Danish landscape of EPR standardisation seems variable and heterogeneous. Additionally, it appears difficult to remove this problem by further standardization. For, indeed, the proliferation of groups, committees, initiatives, projects and organisations which span countries, continents and councils has partly been constructed as an attempt to reduce divergences and ensure broader co-operation between standardisation efforts. This very organization may thus be seen as an acknowledgment that standardization is not only a techno-economical issue, but one which involves multiple (political and organizational) interests and agendas.

[7] The pilot-wards were Thorax surgery R and Cardiology P.

And yet, we may ask; why, if these activities were organized to achieve consensus, do we still encounter the seeming incongruence between the concrete initiatives taking place in TC 251, the National Board of Health and EPR projects at local hospitals? What might superficially seem like simple obstruction becomes less clear-cut as we move closer to the Danish health care system. The National Board of Health is indeed very interested in the work of TC 251 as evidenced from the fact that it published an abridged version of the pre-standard ENV 13606 in co-operation with Danish Standards. Thus, the board did not try to promote its own structure as an alternative to the European standardisation work. On the contrary it was actively trying to 'raise consciousness' about this standard the context of Danish health care. In fact the board viewed its effort as a matter of re-specification. Precisely because of the internationally co-operative approach used in CEN, the standards produced there become abstract. The EPR standard defined the terminology to be adopted, and specified the general data structure through the use of UML (Unified Modeling Language). And this model could in principle be used directly in each of the Danish counties. However, the problem with this approach is that the level of abstraction of the CEN-standard was so high that the probable outcome would be the construction of numerous local translations of it, which still might be unable to communicate with each other. The CEN-standard, then, ensures technical and logical compatibility, but it does not guarantee compatibility in practice. Ensuring practical compatibility, according to the National Board of Health, requires the specification of national semantic standards. This task cannot in principle be accomplished by international committees, because semantic standardisation has to reflect the actual organisation of the national health care sectors – and these are exceedingly diverse.

To illustrate this problem, consider that Denmark, as many other countries, relies on the latest international classification of diseases, ICD 10. The codes given in this classification, however, are translated into the Danish SKS-classification, which is

used for standardised documentation of the treatment of patients in the National Register of Patients.[8] Other procedures, for instance for surgery, are developed in co-operation with the Nordic countries, whereas x-ray and clinical protocols are made in Denmark. The National Board of Health defines itself as a crucial mediator between international standardisation efforts and the Danish health care sector, precisely because of the extremely complicated information infrastructure into which the EPR has to fit. Furthermore, the necessity of making local specifications is also acknowledged by TC 251. They explicitly limit their competence to develop standards, which are able to maintain and communicate medical knowledge without trying to delimit what a health care professional can or should do in context. As they express it: "TC 251 does not work with the content of a classification – classification is a job to be carried out by experts from the medical specialty" (DS Hæfte 4 1995:34). This argument is replicated by the National Board of Health, which also claims to provide only a standardized frame, the content of which must be filled out by hospitals and clinicians.

Danish EPR-Projects

The 2001-report from the EPR-Observatory identified 52 Danish EPR-projects. Most of these were small, based in a single ward, some involved two or more wards within a single hospital, a dozen were coordinated between several hospitals, and two involved all hospitals in their respective councils (EPJ-Observatoriet 2001: 7). Thus, local Danish hospitals were in full swing developing systems that were widely diverging – among themselves, and in relation to the European standardisation work (see e.g. Svenningsen 2002). In public debates in Denmark

[8] The national register of patients contains approximately 40 million pieces of information about patients. It is the duty of all public and private hospitals in the country to make monthly reports of all hospitalisations, ambulatory treatments and visits to the casualty wards to LEC [the software company running the register]. The national register of patients is a unique register, in Europe and world-wide, because it contains patient data (diagnoses, surgery, treatments etc.) of high quality, covering a time-span of more than 25 years. Available from http://www.lec.dk/indhold/lec9072.htm, accessed May 20th, 2002.

such initiatives were regularly referred to as irrational, selfish or political.[9] They were seen as promoting the autonomy of individual counties at the peril of patient's free choice of hospital, of improved inter-regional communication and presumed qualitative and economical benefits, which would follow from having a single national system. But the counties used different lines of argument in defence of their projects.

As noted, EPRs seriously entered the political imaginary only in the mid- to late-nineties, while a number of clinicians and informaticians had been spokespersons for their importance years earlier. The sudden high profile of these systems made money available for development projects, which, from the perspective of these projects, it would have been pointless to let slip away. Furthermore, official state-funded projects like HEP (Action-plan for the Electronic Patient Record), actively encouraged local initiatives and experimentation with the construction of such systems even though they emphasised that standardisation would have to follow. Late in 1995 the Ministry of Health wrote:

Although initiatives have now been taken towards national standards for electronic patient records, there is no reason to stop local or regional initiatives. The IT-development moves very quickly, and slowing down initiatives already effectuated could cause the loss of accumulated knowledge along with the commitment of the people working on the cause (Sundhedsministeriet 1996: 54)

Moreover local developers pointed out that the slowness of formal standardisation made it unfeasible to delay projects until these standards were ratified and ready for use. In this they replicated many other proponents of market driven generation of standards, but the point is more specific than that. As mentioned, some hospitals had been working with smaller development and implementation projects for

[9] For instance by the National Board of Health, or by the Danish Board of Technology, whose former president Erik Bonnerup has declared: "Then each region has to invent the wheel for themselves, ten times. A central system is also more flexible as regards staff. With a centralised system, the nurse from Hjørring [a provincial town in Northern Jutland] can go to work at the National Hospital [in Copenhagen] without having to take a course in its patient system. Available

years. For them the National Board of Health moved exceedingly slowly, not even setting up an office related to the problem of electronic patient records until 1997. And although TC 251 had been in existence since 1990 it had yet to ratify a final standard for the document architecture of the EPR. For these reasons, local developers aimed at making their own systems work, even though on a less grand scale than subsequently imagined by visionary politicians and designers.[10]
In the EPR-report from 2001 the incongruities between local development initiatives and national standardization efforts led the authors to argue the need for detailed "migration-plans". These would describe how the proposed national standard could be validated against the heterogeneous systems under development, and explain how the standard would be able to migrate (travel to), enter into, and co-ordinate these emerging information infrastructures. However, no initiatives were taken in this direction, while political and economical pressure was applied to ensure compliance from "rogue counties". The result, was that several counties put their projects on hold, while a few high profiled projects, notably in Aarhus and Copenhagen continued the development of their sophisticated "2nd generation" EPRs. Their hope was that other counties would follow suit by using their models, or, at least, ensuring compatibility with them. Let us therefore look closer at the development project in the Aarhus county.

The Aarhus Project

As mentioned this project, along with one in Copenhagen, figured as the most ambitious in Denmark. Its seeds were sown in late 1995 with the publication of a regional IT-strategy. Practical development work commenced in 1999, after a complicated organization structure had been put in place, involving wards and personnel from all regional hospitals, along with several IT-developers, hired to

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from http://www.prosa.dk/Nyheder/sundhedsvaesnenet270401.shtml, accessed May 20th, 2002.
[10] For example, is it strictly necessary to create inter-regional compatibility between systems in Denmark, when the number of patients that cross the border of a council is comparably diminutive?

develop independent but compatible modules, such as medication, orders-entry, and notes (see Jensen 2003). Early in the project, Aarhus was not interested tying its development too closely to the standardized EPR structure proposed to them by the National Board of Health, as they foresaw that it would become workable only in a distant future.

As project management wanted to move quickly, to be able to present results and to gain competitive advantage, it decided to build its own model, which was based on an 'integration machinery', constructed around a so-called domain object model (DOM). The DOM "describes a general frame for concepts and processes as well as their interrelations... The model is thus a … metamodel of the clinical world in which the EPR is meant to operate" (Vurdering, 2004: 29). The project also developed so-called 'event description definitions' (HBD's), as a dynamic tool for clinical modelling, which could easily be changed or upgraded to reflect ongoing transformation in clinical knowledge and organization.

As time progressed and the National Board of Health improved on their G-EPJ structure, the Aarhus project and the board also began to negotiate a process of convergence. It was decided by project management that Aarhus ought indeed to live up to the terminological specification in the G-EPJ. In 2004, one medical ward at an Aarhus hospital participated in a pilot under the GEPKA (G-EPJ Prototypes and Clinical Testing)-project, run by the Board of Health. But in spite of such efforts, adoption has not been easy. Why not? Let us look at some of the conclusions from an evaluation report on the Aarhus project, written by the EPR-observatory.

In response to the economic troubles of the project this report was commissioned by the Aarhus council as a 'critical and unbiased evaluation', although some regional politicians pointed out that this description (and the commissioning itself) was 'unfortunate' given the "co-incidence between members of the steering committee of the EPR-observatory and managers of the regional EPR project."[11]

One interviewee suggested that "making an EPR does not un-invent the telephone or fax machine."

[11] Aarhus Amt: dagsorden for oekonomiudvalgets moede 4.maj 2004. Dagsordenens punkt 2.

However, in light of the problems indicated by the evaluation the concern that the report would take an overly optimistic perspective on the project appears not to have been borne out.

The report explains that different modules are compatible with each other and with the G-EPJ to varying degrees. For instance, the medication module which was being tested as part of the GEPKA-pilot, has been developed and modelled "in close dialogue with the National Board of Health. [It] is therefore mainly based on the G-EPJ" (fuld ref. 48); the notes module has also been built up around this structure. However, this is not the case with the patient administrative module (PAS). Hence, "guaranteeing that data, which is registered in notes/GEPKA, can be used for re-imbursement and reporting from PAS" (29) is a concern. Specifically, "Events in PAS and notes/GEPKA must be harmonized, so correct data transfer is ensured" (29).

The report further explained that modelling in the Aarhus project had been made difficult because G-EPJ specifications were continually changed as a consequence of delays and complications in the standardization processes taking place at CEN and at the National Board of Health.[12] But DOM and the dynamic HBD's used in the Aarhus project were developed precisely to easily deal with such ongoing definitional changes. What then is the problem? To understand these we need to once again move closer to technical and organizational issues in Aarhus.

As may be recalled the project was built up around the simultaneous development and integration of multiple modules, and the construction of the flexible integration machinery. Just this flexibility turned out to be troublesome, because it used up too much computer power. During pilots in 2002 these technical difficulties became increasingly visible in the shape of 'performance problems' especially related to long log-on times and generally to slow system responses. System performance

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Offentliggjort paa Aarhus Amts WWW-server af Amtsraads- og udvalgssekretariat 29. april 2004. Available at http://www.aaa.dk/dagsor/ok/040504/2.htm, accessed Dec 5th, 2004.

[12] Olesen (2004).

caused the delay of development schedules, piloting and implementation since then. Of course, many attempts to solve these technical problems have been made. In many cases solutions were made *ad hoc* by means of what has been referred to as 'hacks'; that is, the hard-coding into a module of some specific procedure. In turn, this meant that the functionality of various parts of different modules ceased to be based on the common and generic part of the original model. This compromised flexibility and led to a situation in which, according to the evaluation report, changes in the model largely necessitated the re-programming of modules (49). In consequence, contrary to plans and expectations: "the system is not very robust when it comes to enabling convergence with the G-EPJ and possible changes in it" (49).

Such technical difficulties and delays were immediately and directly linked with economics, politics, and media relations. Following the publication of the evaluation report, the magazine *Computerworld* wrote, on June 11th 2004, that "Aarhus is on its way to the parking lot of big IT scandals" and claimed that the economic part of the nightmare started "a long time ago".[13] The article explains how the earliest estimated price of 50M Danish Crowns will have been surpassed with almost 500% as the latest round of additional funding put the price at 240M. It characterized the lack of co-ordination of modules as 'farcical' and pointed out that missing conceptual integration meant that double-entry is necessitated, although a major original aim and justification was to get rid of just this task (both to lessen workload and to minimize potential sources of error).

Computerworld was not alone with criticism. Other IT-vendors went on the attack, but aimed more broadly, pointing fingers also at the National Board and the Minister of Health. Thus, the CEO of CSC Scandihealth, Martin Holm, argued that the Danish state could save millions just by making use of the 'globally used

[13] Dorte Toft, *Computerworld*, "Slagsmål om EPJ-projektet til kvart millard", 11. Juni 2004.

standard HL7' rather than the 'not very used European HISA standard, which has not yet been approved'.[14]

Predictably, attacks were met with defences. For example, the software developer Systematic deflected the severe criticism launched against the Aarhus project by arguing that complications and delays were to be expected, since Aarhus was "years ahead of what the big international players in the market, IBM and Oracle, offer with their integration platform". Systematic even linked its EPR project with ideals such as humanism and 'third-world' development: "Why shouldn't Denmark be able of delivering a completely new hospital system to reconstruction in Iraq or as development aid? We are very humanistic in our thinking".[15]

In December 2004, veteran health informatics consultant Peter Sylvest Olesen published a damning critique of the standardization efforts of the National Board of Health (Olesen 2004). Discussing in detail numerous problems with the G-EPJ structure, including its highly complicated classification-system, its exclusionary development process, and its problematic assumptions concerning clinical work practice, Olesen explains his intervention in the following way:

> In principle, there is no need for me to care about the shape of the GEPJ. I have written my last record a long time ago, and I am not a future user of an EPR-system based on GEPJ. The reason why I have nevertheless chosen to develop a sustained critical analysis, is the simple one that I feel morally obliged to direct attention to a very large, expensive, and socially important project, which it is my belief has gone astray (Olesen 2004: 6)

Olesen's "moral obligations", as well as Systematic's "humanistic concerns" and, indeed, Computerworld's outrage at the expenses of the Aarhus project all indicate that standardization, far from being neutral territory, may become "at once the technical obsession and the political and moral problem" (Schaffer 2000: 78).

A 'note' published by the board of health in response to Olesen's report aimed to undermine his moral viewpoint and defuse his criticisms by insisting that their

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[14] Available from http://www.erhvervsbladet.dk/nyhedsservice/npShowArticle.asp?strArtID=11345, accessed Dec 5th, 2004.

[15] Dorte Toft, *Computerworld*, "Drømmen om Verdens bedste EPJ", 11. Juni 2004.

standard was simply a neutral technological tool. Further, they argued that the identified problems were "irrelevant if the EPR-systems can access data reciprocally." However, the board offered no answer to the question of how the messy situation identified by Olesen could possibly be transformed into such ideal form. Below I broach the implications of this omission by discussing the *travel expenditures* of EPR-standards.

Travel Expenditures

As exemplified by the article from *Computerworld*, EPR development increasingly took on a scandalous aura as standards remained unfinished, projects were delayed and costs increased. From determinist points of view allocating responsibility for this situation should be relatively easy, because they assume that optimal solutions can be identified by means of rational analysis. When the challenges of standardization are formulated primarily in terms of game theory or Hardin's free-rider problem this assumption is involved. In this understanding everybody wants some good, such as a shared standard, but each actor would prefer others to provide it for them. Looking concretely at the activities around EPR standardization, however, suggests that standardization does not have one overarching goal, but many varying ones. Only in the abstract can the efforts taking place at CEN, the National Board of Health, the project in Aarhus, and at the specific ward testing the medical module be said to be *about the same thing*. The standardization landscape may perhaps be more adequately characterized by Lyotard's (1988) notion of cultural differentials, which point to situations involving heterogeneous actors and goals, with no ready-made commonalities, which should in principle facilitate their convergence.

As we have seen, standards do not simply fall from on high and land in local practices without problems. Rather, there is a distinctly recursive quality to the situation. Hospital-based and regional EPR projects have taken place simultaneously with Danish and European standardization efforts, and they have worked actively to influence them as well, for instance through Danish Standards.

Rather than moving from standardization committees at the top and down to local hospital practices, the activities have thus taken place in parallel and connected only at certain times and places.

This allows for some critical reflection on the idea that the political, the technical, and the economic remain in principle distinct domains. Schmidt and Werle's study, for example, argues that "politics remains blind to the technicality of standards" and "helps to achieve an agreement precisely because it does not consider technical detail" (Schmidt and Werle 1998: 271). However, while it is true that "official" politics rarely interrogates the technicalities of standard-setting, the crucial point from the present point of view is that standardization surreptitiously *transforms* relationships, for example between the National Board of Health and the Aarhus development project. Such transformed relationships have consequences that may cut across economical, political and organizational domains and therefore mostly remain invisible to traditional economical and technical analysis. I refer to these consequences as the travel expenditures of standardization.

An illustration of the hidden travel costs of standards is provided by the CEN-standard laboriously constructed at European level only to be re-specified by the National Board of Health, through an intensive translational effort, so as to fit with the Danish health system. Indeed, this effort was not sufficient, since it was recognized that further tailoring of the standard would be required by various medical specialties. The example indicates how technical standards – even if developed with painstaking care – are incapable of travelling to other practices without change. Further, though, it was not just the technology that changed since new organizational relationships had to be developed to enable co-ordination of the standardization effort at regional and national levels. Indeed, it was not just organizational relations that changed either since doctors and nurses argued passionately that new semantic standards and new work routines brought along by the technologies would profoundly affect the nature of their work as well as their professional identities. Aside from technical, organizational and professional relationships, attention must finally be paid to the transformation of economical

and political relations as an integral dimension of the travel expenditures of standards. As we have seen the National Board of Health threatened "non-compliant" and "rogue" regions with economical sanctions, should they fail to live up to the requirements of their standards. Yet, this was a viable strategy only because the board (chose to) forget that the Ministry of Health previously provided strong encouragement to local and regional development initiatives. A final, noteworthy, travel expenditure has been that these initiatives ceased to be seen as pioneering development efforts. Instead, the commitment to locally developed solutions gradually came to be viewed as demonstrating a stubborn insistence on "re-inventing the wheel" in each region. No wonder that standards became not only the "technical obsession" but also "the political and moral problem."

Conclusion

This study has proposed that existing infrastructures are not inert and passive receptacles awaiting the arrival of new standards. Instead they bring along their own histories and pose their own challenges. If this is the case the many activities at CEN, in Aarhus, and at other locations may be seen as efforts to ensure that existing infrastructures are co-ordinated with new standards, thus allowing them to actually *standardize*. But in this process the involved practices also become entangled in ways that give rise to new organizational, political and technical issues and problems, as illustrated by the changing relationship between the National Board of Health and the Aarhus Project. This exceedingly complicated situation can be captured by Star and Ruhleder's suggestion that "infrastructure happens" – as an effective achievement - or does not happen, as new systems "wrestle with" old ones (Star and Ruhleder 1996: 113). If one pays attention to standardization as infrastructural achievement, then one is also forced to notice the price of successful standardization; its *travel expenditures*.

When standardization is understood solely as a matter of technical improvement, and standards are seen as all 'form' leaving the 'content' of clinical work, not to mention health care politics, entirely aside, then these travel expenditures remain

invisible. On the one hand, this paper is therefore an argument for analyses, which make such expenditures visible by bringing into light effects of standardization that stem from the "hybridization" of the technical, political and organizational. On the other hand, it likely that such analyses will be perceived as unwieldy and unmanageable, precisely by those managers and designers whom one might hope would act on them (Jensen 2006). The question of how STS analyses of standardization might relate to standardization itself thus remains unanswered.
Yet, this uncertainty as regards effects ties up with the uncertainties of standardization itself. Thus, Schmidt and Werle acknowledge that "sometimes [technical and economic aspects] can be determined only analytically' and that it "is not always possible to determine efficiency unequivocally" (275), and Bowker and Star (1999) noted as one central characteristic of standards: "There is no natural law that the best standard shall win".
From the point of view of the present study this observation is indeed crucial: The mutual political and technical *infiltration of practices* make the unproblematic designation of responsibilities for 'scandalous' situations to individual actors, organizations, or institutions difficult to maintain in general and certainly hopeless as an analytical stance. This poses the challenge to standardization research of how to disentangle these responsibilities, without simply falling back on the old distinctions between the economical, political, and technical. It also suggests that one task would be to follow the movements of standards and account for the various kinds of expenditure that are generated through their infrastructural travels.

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