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The Application of ICT Standards Phase Two: Conjoining ICT Policy Makers in Europe with Standards Makers

**A project report by EHTEL Thematic Working Group “Health
Information Society Europe” (T1) in collaboration with the Actors
Working Group “Healthcare Authorities” (A1)**

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Executive Summary

The project comprised two phases.

Phase 1 was a questionnaire survey to ascertain the priorities across Europe for the application of ICT to health.

Phase 1 report was published in October 2002. It established extensive commonality in priorities the highest being:

- health / patient records;
- communications with particular emphasis on e-prescriptions;
- protecting personal information with emphasis on Public Key Infrastructure and associated professional and patient data cards;
- prescribing with emphasis on e-prescriptions.

Policy makers declared a commitment to international standards but reality demonstrates that the commitment is very weak. One reason is that the links between policy makers in ministries of health or equivalent, and international standards makers, is elusive and very indirect.

Phase 2 of the project seeks to establish whether there is a means for bringing together European policy makers as a group with standards makers so as to make a reality of expressions of commitments to, and legal obligations towards, international standards.

Phase 2 involved face-to-face meetings. Those seen are detailed in Annex A. All those seen would support a meeting between policy makers and standards makers but the value to attendees would depend on the agenda. It would need to be focused on a real, realisable objective which aligned with country priorities and undertaken to a timetable aligned with such priorities.

Possible steps might cover all or some of the following:

- 1) Policy makers to identify the priority application area which will be pursued with standards makers. The top candidate appears to be e-prescribing including PKI and professional and patient data cards. It might be preferable to focus even further either on the e-prescription or PKI or professional and patient data cards for identification and access control / security (maybe encompassing the e-Europe health card / E111). Although electronic health records were a shared high priority, it was generally felt that attempting this application might be too ambitious.
- 2) Refine the definition of the chosen application perhaps by a high level process and information model / diagram.
- 3) Identify the areas which require international standards.

- 4) Determine what international standards exist that might suit the requirements and what new or amended standards would be necessary.
- 5) Create a profile of existing and proposed new standards with a view to interoperability.
- 6) Decide on how best to 'commission' the drafting of any new standards in a manner which would lead to international standards.
- 7) Decide whether funding is desirable or necessary to assist standards drafting and if so, identify the source and secure commitment.
- 8) Commission the drafting of new or amended standards to a timetable determined by policy makers.
- 9) Agree the means for testing interoperability of standards within the standards profile for the chosen application.
- 10) Agree the means for piloting the application utilising the standards.
- 11) Feed back and amend standards as appropriate.

A meeting of policy makers and standards makers could take place some time after stage 3. The EU commission DG Enterprise and DG SANCO should be involved and the way the organisation integrating the Healthcare Enterprise (IHE) operates could be a model for testing interoperability.

Introduction

This project comprised two phases.

Phase 1

Phase 1 sought to establish:

- what policy makers in Europe regarded as the priorities for the application of ICT in different countries;
- whether there was a commonality in priorities;
- the general views of policy makers on standards matters;
- what international standards were available potentially to meet needs.

The Phase 1 report was published in October 2002. It established that there was extensive commonality in priorities across Europe for the application of ICT. The top priorities, by far, were:

- health / patient records;
- communications with particular emphasis on e-prescriptions;
- protecting personal information with emphasis on Public Key Infrastructure and associated professional and patient data cards;
- prescribing with emphasis on e-prescriptions.

The middle rank priorities were:

- support for clinical processes through telemedicine;
- support for public / patients;
- support for clinical decisions;
- epidemiology / statistics;
- support for professionals (web);
- hospital PAC / RIS;
- ensuring semantic meaning.

When asked, policy makers agreed the importance of standards in realising their priority applications and expressed the general desire that these be international standards wherever practicable.

The Phase 1 report included a list of health informatics standards published, or in the work programme of, CEN, ISO, HL7, DICOM and IEEE. It demonstrated that standards from these bodies did exist to support some, if not all, of the applications which European policy makers regarded as high priority.

Phase 2

This report deals with Phase 2 of the project. Phase 2 is founded on the main conclusions from Phase 1 namely that:

- there is significant commonality within Europe regarding priorities for the application of ICT; and,
- there is a general commitment in principle to utilising international standards in achieving these priorities.

In a number of countries policy makers defer / refer to some form of national technical orientated body for standards advice and / or standards writing. Where such a body exists it may be the country's formal National Standards Organisation but that is very rare. However the body usually does have contacts with the formal National Standards Organisation and through the National Standards Organisation to CEN and ISO and other standards bodies with international standing e.g. DICOM, HL7, IEEE.

By policy makers is meant those who are responsible in a country for policy on ICT applied to health. They will typically be located in the country's Ministry or National Board responsible for health or a regional authority equivalent.

Both CEN and ISO have a Technical Committee dealing with Health Informatics each supported by four or five Working Groups. The Technical Committee is responsible for policy and comprises delegations formally nominated by a country's Member Body (the formal National Standards Organisation). Membership of Working Groups is fairly open but formally comprises people nominated by their National Member Body. All proposals for the drafting of a standard must be approved by vote through the Technical Committee albeit such proposals usually derive from the Working Groups and are not often rejected.

The standards programme of CEN and ISO (and of other like bodies) seems thereby to have a very elusive and weak connection with national policy makers. This is the case even where members of a national body to which policy makers defer / refer are members of the Technical Committee and/or a Working Group. It is rare for a proposal for a new standard to include a statement such as 'a standard for this purpose is required by policy in my country'. Indeed it is rarely clear that proposers of a new standard can provide any commitment to implement or trial the standard in their country when it is complete.

Policy makers espouse a commitment to international standards. However the remoteness of policy makers from the international standard organisations means that this commitment appears weak and is rarely explicitly demonstrated. Although EU Directives mandate the use of international standards (particularly European standards) in procurements this obligation appears little known and largely ignored. This is not surprising given that policy makers have such loose ownership of the products of international standards organisations and exercise very remote, if any, influence on what they do.

Whereas participants in international standards making and representatives of National Member Bodies may have good knowledge of ICT policy in their country and, in that sense, may reflect this in what they do and how they vote, they usually seem to carry no mandate from policy makers or report back to them. The standard makers' lack of the means to implement or nationally trial or test the standards they produce is a considerable weakness and accounts in part for the generally weak involvement of suppliers.

This is not to say that the international standards which are produced are not applied. Most, but not all, are implemented to various extents. However the general absence of a route back from the standards makers to the countries' policy makers and to those that implement the policies they create, mean that implementation may be patchy and its extent usually unknown.

Most of Europe's policy makers have much the same aims and priorities for ICT applied to health - as EHTEL Phase 1 demonstrated. They recognise that they need standards for the applications they pursue and desire these to be international. On the other hand the international standards organisations are willing and ready to produce the standards which policy makers require and indeed have produced some standards in the areas which have highest priority for policy makers. This should therefore be fertile territory for success but success is apparently being denied because of a communication gap between the parties. The purpose of Phase 2 of the EHTEL T1 / A1 project is to explore whether there are ways of bridging that gap.

Project Approach

Phase 1 was based primarily on a questionnaire approach with policy makers mainly being represented by EHTEL A1 members.

Phase 2 was based on face-to-face meetings of about one to one and half hours duration. All A1 members were contacted with a view to a meeting but because authorisation for project start was greatly delayed, the time available for scheduling meetings meant that arrangements to meet with all A1 members was not possible. Some A1 members suggested meetings with persons other than themselves. Additionally there were meetings with a few authoritative persons who were not members of A1.

Annex A provides details of those persons with whom meetings took place together with a very brief note on the meeting conclusions. Individuals were seen from the following countries: Belgium, Denmark, Germany, Italy, Netherlands, Norway, Sweden and the United Kingdom. Finland sent in views by email.

Obligations to the EU and International Agreements

There are a number of EU Council Decisions and EU Directives which refer to, or are devoted to, national obligations to use international standards rather than national standards. The EHTEL Thematic Group T6 report "Legal Aspects of Standardisation in Health Telematics" by Ben Stanberry covered many of these aspects.

For example the Council Decision 87/95/EEC states that:

"Member States shall take the necessary steps to ensure that reference is made to European standards and international standards in public procurement orders relating to information technology". The meaning of a 'public procurement' is very wide and certainly covers procurements by health authorities and others such as 'any body governed by public law'. This in turn means "any body financed, for the most part, by the State, or regional or local authorities, or subject to management supervision by those bodies, or having an administrative, managerial or supervisory board, more than half of whose members are appointed by the State, regional or local authorities".

That encompasses very many European health institutions. To back this up Member States must ensure that National Standards Bodies do not adopt national standards in conflict with European ones.

In EU "New Approach" Directives the EU will consider compliance with international standards as the means for compliance with the Directive's requirements.

The World Trade Organisation (WTO) agreements also commit signatories to use of international standards rather than national ones.

From a very large volume of published agreements, Decisions and Directives there is no doubt whatever that Governments in the EU, and the wider world, look to nations to commit themselves to international standards

Despite these obligations commitment to European health informatics standards, and wider international standards, is weak and often ignored. International standards certainly encompass CEN, and ISO but whether standards from HL7, IEEE and DICOM are formally / legally encompassed is not clear.

Phase 2 seeks means whereby these obligations to utilise international standards might be made a reality. This would appear all the more important as a number of countries are moving towards implementing of national strategies involving extremely substantial expenditure e.g. €3.5 billion extra investment in ICT for health in the English National Health Service over the next three or four years.

Content of the Meetings

Meetings generally comprised:

- a discussion of the ICT policy / strategies being followed in the relevant country;
- an explanation of how such policies / strategies were being implemented, particularly in relation to any bodies entrusted with the implementation task or the creation or choice of standards;
- attitudes to utilisation of international standards;

- the value, if any, of bringing together European policy makers as a group, and standards makers as a group, with a view to increasing the relevance of, and the strengthening commitment to international standards.

Meeting generally concluded with consideration of the following questions;

- Would there be value in arranging a meeting or meetings between policy makers as a group with standards makers as a group?
- Would EHTEL, through the A1 / T1 groups, be a suitable vehicle for such a meeting(s)?
- If such a meeting(s) were to take place what should be the nature of the agenda?
- If the meeting (s) resulted in a commission / agreement to create a standard(s) would it be agreeable in principle for policy makers to contribute to a small shared fund to help drafting?
- If a meeting(s) were to take place would individuals be prepared to assist in the agenda setting and attend?

Commitment to International Standards

All those seen acknowledged the importance of agreeing standards if their national priorities were to be met. It was also generally accepted that standards should be international as far as practicable. Nevertheless the commitment to that principle was generally on the weak side. For some the creation of international standards appeared to be too slow and many of those which existed too complex with a critical absence of guidelines for implementation. Overall there was very little commitment to European Directives and Decisions which mandate use of international standards in procurements.

There were exceptions. For example, Denmark has a firm commitment to the European Directives and has implemented a number of CEN TC251 standards notably in messaging. This success has been in the past due to the creation of good implementation guides. Norway, through the organisation KITH, seemed also to be well connected with CEN TC251 in the context of uptake of its standards.

This having been said, there was a general willingness to take on international standards if some common weaknesses, or perceptions of weaknesses, could be overcome notably:

- speed of production to match scheduled priorities;
- relevance to priorities and ease of implementation;
- supplier involvement;
- assured interoperability.

Value of a Meeting of European Policy Makers and Standards Makers

All those seen would be prepared to attend a meeting of European policy makers and standards makers if one were arranged but with conditions:

- the agenda would need to be tightly focused on an achievable result without setting sights too high;
- there would need to be a real and tangible outcome;
- if the outcome was to be a commission for a standard(s), the latter would need to be produced to an agreed and relevant timetable and be driven by policy makers' requirements.

The value of such a meeting to any particular country would depend on its aims and outcome. For example Denmark is very far advanced in e-prescriptions and may realise little value if that were the focus although they would be prepared in principle to attend to contribute their experience. Thus although there was a willingness to attend, the degree of enthusiasm or otherwise for a meeting was tempered, and for some heavily tempered, by hesitation in the absence of a clear agenda. Nevertheless overall there was agreement that the proposed meeting(s) was worth pursuing further.

EHTEL as the Forum for Meeting(s)

The lack of firm and meaningful commitment to European Directives and international standards is in part due to the absence of a forum which directly brings together European policy makers and standards makers. As this project illustrates, EHTEL could provide such a forum.

The Working Group A1 has successfully brought together policy makers from a number of countries and those seen agreed that it could thereby be a suitable forum for the proposed meeting with standards makers and for follow through of the wider proposals of this report. However there are a number of countries not represented in A1 and some are represented by individuals one step removed from policy makers per se. Additionally ICT policy makers from the EU Commission are not members. Whereas EHTEL A1 could provide the means for bringing together policy makers that did not presently apply to standards makers. The manner in which standards makers might be brought into the process is discussed later.

An alternative suggested vehicle for a meeting was the EU Commission. EHTEL was preferred because the agenda would be entirely in the hands of A1 i.e. the European policy members themselves, rather than decided by the Commission.

The main uncertainty surrounded the question over the continued viability of EHTEL as an organisation.

Focus for (a) Meeting(s)

It was generally agreed that any meeting(s) between policy makers and standards makers would need to focus tightly on an application which was a shared priority for most, if not all, countries.

The meetings with policy makers confirmed that the highest priorities were those identified in Phase 1 namely:

- health / patient records;
- communications with particular emphasis on e-prescriptions;
- protecting personal information with emphasis on Public Key Infrastructure and associated professional and patient data cards;
- prescribing with emphasis on e-prescriptions.

Of these, the much preferred focus was electronic prescribing (perhaps including aspects of the medication record) and associated Public Key Infrastructure with professional and patient data cards for identification / access control / authorisation / security.

It would be possible, and in the views of some preferable, to focus initially on some aspects of the above rather than attempt the whole. In that case the preference would be for:

- standards for the e-prescription per se; or
- standards for PKI including standards for professional and patient data cards within that context.

The second option could be further divided into:

- standards for PKI;
- standards for professional and patient data cards for the purposes of identification and access authorisation.

If standards for patient cards identification / access control were a focus then it might be advantageous to include the proposed European Health Card and electronic E111.

Before any meeting with standards makers it would clearly be necessary for policy makers to agree on the application area on which the meeting(s) should focus.

Objective of Meeting(s)

The objective of any meeting of policy makers and standards makers would be to agree the means by which international standards could be brought to bear successfully to enable the application chosen by policy makers to a time table meeting the requirements of policy makers.

The process, commencing with an agreed outcome and schedule for the chosen application might be:

- clarify the chosen application by means of a high-level process and information model / diagram and description;
- identify the areas for which international standards are required;
- identify any existing international standards which might meet any of the requirements;
- identify where new or amended international standards might be required including, where applicable, guidance for the implementation of standards;
- agree the means by which any new or amended standards would be created and by when;
- create a profile of the set of standards which are required successfully to enable the application in a manner which displays necessary interoperability;
- agree a means to testing interoperability of standards and in the chosen application;
- pilot the whole and amend standards as appropriate.

Creating New Standards

There are a number of options by which policy makers could 'commission' the creation of new standards to their requirements for example;

- each to nominate individual experts from their country thus creating an 'expert group' who would be commissioned for the task;
- commission a standards making body to undertake the task e.g. TC251, ISO TC215 or HL7 (either direct if practicable or by drawing on national HL7 affiliates). In this option policy makers could nominate experts from their country to participate;
- issue an open or closed invitation to tender (implying availability of finance – see later).

If a commission were placed other than with, or through, one of the international standards bodies then arrangements would need to be made to align the work with an international standards body so that the draft could be taken into a process for acceptance as an international standard.

Creating a Profile of Standards

Any application is likely to require a set of standards some existing and some perhaps new. A profile of such standards with a view to identifying interoperability issues could be required. This might be created through any of the options listed above for creating new standards with the first of the options appearing preferable.

Funding

If collaborating policy makers were each to nominate, utilise and appropriately support experts from their own countries for any necessary tasks, the question of collective financing need not arise.

Finance would undoubtedly speed processes if work is commissioned through contracts and it would enable better control to be exerted. The possibility of sharing costs through a pooled fund might therefore be explored and was not ruled out by those seen. Within CEN TC251 the cost of a project team to create a standard averaged about €60,000 albeit they no longer have funds.

Standards Makers

In terms of involving standards makers, there are a number of bodies to consider e.g. CEN TC251, ISO TC215, HL7 (HL7 country affiliates), DICOM, IEEE. However the 'chosen' application may not require consideration of all these, e.g. DICOM and IEEE. It should be noted that heads of delegations from European standards bodies to CEN TC251 and ISO TC215 tend to be the same.

Phase 2 included a meeting with the chairperson of CEN TC251, Gunnar Klein. He would support an initiative to bring together European policy makers and CEN TC251 standards makers.

Interoperability Testing and Piloting

As already noted, any application is likely to require a set of standards to interoperate. The standards may comprise a mix from different international standards bodies.

Since success will require the set of standards to interoperate, a means for testing that they do so with a suitable range of vendor products would be necessary.

The organisation IHE (Integrating the Healthcare Enterprise) has successfully demonstrated interoperability across vendors using a set or profile of different standards and could be therefore be a model to examine. However, despite ambitions to the contrary, IHE (and its European arm IHE Europe) are focused primarily on applications surrounding imaging and, within that context, primarily DICOM and HL7.

Since the underlying prescription is that the 'chosen' application area will be one of high priority to collaborating policy makers, interoperability testing should be practicable through bodies within the policy makers' countries on a collaborative basis. The same could be applied to piloting of the whole application.

Vendors

None of the proposals presented in this report will succeed unless relevant vendors are on board. Involvement of vendors on a representative basis can be difficult because of the absence of European vendor organisations in the health ICT field. Nevertheless policy makers may have effective contacts within their own countries that they could persuade to become involved. It is asserted that if policy makers were to make clear that any initiative taken in this field was with real and determined intentions, vendors would quickly seek to participate.

International Telecommunications Union (ITU)

The ITU has long had an interest in health applications and in the standards to support them. At a well attended ITU conference in May 2003, it was decided to create a small group to seek to coordinate e-health standards from ITU, ISO, CEN, DICOM, HL7, IEEE and perhaps others such as WHO. They are also expressed interest in creating 'stacks' or profiles of standards for applications.

Contact with ITU may thus be advantageous and might even represent a funding or technical resource given the 'right' application.

EU Commission

Any initiative would wisely include the EU Commission DG Enterprise and DG SANCO.

At a meeting understood to involve health ministers in May 2003 in Brussels, the importance of standards was recognised and it is reported that DG Enterprise was requested to support health standards. As a consequence discussions between DG Enterprise and CEN TC251 have recently opened and may offer an opportunity on which to build.

Possible Next Steps

There appears to be general support for exploring opportunities to bring together European policy makers as a group with international standards makers. In so far as this involved a meeting(s) those seen would be prepared to attend but the value to each attendee and thus their commitment would depend on the agenda. It would need to be focused, pursuing a real and significant output, and conducted to a sharp timetable. In the context of this report the EHTEL A1 / T1 groups will accordingly need to decide whether to proceed further.

If further steps are to be taken suggested possible stages are:

- 1) Policy makers to identify the priority application area which will be pursued with standards makers. The top candidate appears to be e-prescribing including PKI and professional and patient data cards. It might be preferable to focus even further either on the e-prescription or PKI or professional and patient data cards for identification and access control / security (maybe encompassing the e-Europe health card / E111). Even though electronic health records were a shared high priority, it was generally felt that attempting this application might be too ambitious.
- 2) Refine the definition of the chosen application perhaps by a high level process and information model / diagram.
- 3) Identify the areas which require international standards.
- 4) Determine what international standards exist that might suit the requirements and what new or amended standards would be necessary.
- 5) Create a profile of existing and proposed new standards with a view to interoperability.
- 6) Decide on how best to 'commission' the drafting of any new standards in a manner which would lead to international standards.
- 7) Decide whether funding is desirable or necessary to assist standards drafting and, if so, identify the source and secure commitment.
- 8) Commission the drafting of new or amended standards to a timetable determined by policy makers.
- 9) Agree the means for testing interoperability of standards within the standards profile for the chosen application.
- 10) Agree the means for piloting the application utilising the standards.
- 11) Feed back and amend standards as appropriate.

In pursuing the above steps, policy makers should consider at what stage, or stages, a meeting(s) should take place with standards makers and how the latter would be represented. Since any meeting would need to be highly focused with a valued and valid outcome, careful preparation will be necessary. A meeting no earlier than stage 3 but possibly not until after stage 7 would seem appropriate. Stages up to stage 7 could be reached by bringing together and utilising experts drawn from the policy makers' countries.

The extent of involvement of the EU Commission (DG Enterprise and DG SANCO) and at what stages will need to be decided.

The means for obtaining involvement and commitment from relevant vendors will need consideration at an early stage.

Contact with, and involvement of, bodies such as IHE(E) and ITU should be considered probably some time after stage 4.

Acknowledgements

Thanks and acknowledgments are made to those who agreed to meet and gave their time to consideration of the matters which this report covers.

ANNEX A

Notes on Meetings

The people with whom meetings took place during Phase 2 are given below. Although detailed notes were of course made of each meeting they are not duplicated here. Only very brief indications of overall background conclusions relevant to the proposals in this report are given.

Unfortunately, because of the tight timetable required for Phase 2, it proved impossible to arrange a meeting with the A1 members Michele Thonnet, France; Gottfried Dietzel, Germany; and Ralf Ekebom, Finland. However Ralf Ekebom sent some views by email. The A1 members Frank Flier, who has changed responsibilities, proposed a meeting with Gert-Jan Boven rather than himself and Alfred Enrenclou, who is now in Canada, proposed a meeting instead with Irene Henrikson Aune. Meetings with these alternatives were undertaken.

Germany

Dr Dorothee Dengler

Dr Dengler is an EHTEL A1 member. She is responsible for health matters in the Lander of Hamburg and is a member of the Working Group comprising those responsible for ICT in all Germany's Lander. She would not speak for all the Lander but recognised the importance of standards and the international context albeit her focus was more local. She would support an initiative to bring together policy makers and standards makers and regarded EHTEL as appropriate forum for this.

Dr Nino Mangiapane

Dr Mangiapane is a member of EHTEL A1. He works for Techniker Krankenkasse, the third biggest health insurance company operating at a federal level. He is his company's liaison person with the German Federal Government in Berlin and part of the Planning Committee of insurance companies, clinical doctors and pharmacists planning a health telematics platform for 2006. The latter will be driven by electronic prescribing with smart cards for health professionals and patients for identification and access control within a PKI system with encrypted messages and electronic signatures.

The strategy is currently before the Lander for imminent agreement which looks likely. Standards would preferably be at Federal level and preferably international, but have yet to be decided. This may be the task of the Health Telematics Forum from Germany (ATG). A new high-level appointment to oversee the proposed new strategy has very recently been made in the Ministry of Health, Bonn (Herr Paland). Unfortunately neither a meeting with Herr Paland nor Gottfried Dietzel in the Ministry of Health proved possible.

In so far as standards will be required in these areas soon then initiatives for identifying / creating them are needed. If an initiative through EHTEL could assist that process within the time constraints and led to the standards being international that would be welcomed by those with a national viewpoint. However pharmacists and physicians tended to think only locally and probably would do so for many years.

The Netherlands

Dr Gert-Jan van Boven

Dr Frank Flier, until recently the A1 chairperson had changed responsibilities. At his suggestion a meeting was instead held with Dr Gert-Jan van Boven the Director of NICTIZ (the National ICT Institute for Healthcare). The latter is funded for five years by the Netherlands Ministry of Health with the remit to implement the total infrastructure for health informatics strategy for the Netherlands by 2006. His organisation will be responsible for the necessary standards which NICTIZ will themselves create if required. They may fund the Netherlands National Standards Body (NEN) to draft standards for them e.g. on security aspects.

Included within the Netherlands strategy is:

- the question of a national health number for identification / authorisation (Parliamentary approval to be sought at end 2003);
- national pharmacy medication files / e-prescribing with a 2004 goal in many regions and nation-wide by 2006;
- health professional cards for all professionals by 1 January 2006 (a national or even European citizens card is being debated).

NICTIZ would use European standards if they were relevant and implementable and were available in time. In general NICTIZ was looking towards HL7 Version 3.

Dr van Boven would support the idea of a meeting under the auspices of EHTEL of European policy makers and standards makers but only if it is focused on real needs with delivery of results quickly and in time. Possible applications on which to focus were:

- medication records / e-prescribing;
- PKI including professional cards;
- an electronic patient record structure standard.

In principle NICTIZ would be prepared to contribute to shared funding of a standard(s) for the 'right' initiative.

Dr Frans van Bommel

A very brief conversation took place with Dr van Bommel who chairs the Health Informatics Committee in NIN and leads the Netherlands delegation to CEN TC251. He confirmed commitment to international standards provided they were relevant

and implementable and supported an initiative to bring together European policy makers and standards makers.

Belgium

Prof Francis Roger France

Prof France is the President of the Belgium Commission on Norms for Telematics in the Healthcare Sector, head of the Belgium delegation to CEN TC251 and professor of medical informatics at the Catholic University de Lovain, Brussels. The Commission on Norms was created by Royal Decree in 1999. It does not create standards but recommends to the Ministries of Social Affairs and Public Health what standards should be adopted. Besides general and messaging security the major foci are:

- electronic health records;
- an accreditation system for GP systems;
- professional and patient data cards with associated electronic signatures.

Prof Roger France would support the idea of a meeting between European policy makers and standards makers provided there was a carefully identified need with a practical real solution.

Any meeting should include local national experts and not solely CEN TC251 members. A preliminary meeting might be the way to start. Candidate areas for consideration might be:

- secure identification of patients and professionals with data cards and PKI;
- electronic health records;
- electronic prescribing / pharmacy/ medication records.

Dr Marc Bangels

Dr Marc Bangels is an EHTEL A1 member and has responsibilities for ICT strategy within the Federal Public Services (FPS) for Health, Food Chain Safety and Environment. He provides the secretariat for the Belgium Commission on Norms for Telematics in the Healthcare Sector. Dr Bangels was due to attend the meeting with Prof Roger France but had to cancel at the last minute. The conclusions of the meeting with Prof Roger France (as above) were communicated to him and he expressed support. His candidates for consideration were:

- electronic healthcare records with a focus on the emergency record as a minimum European data set;
- patient and healthcare professional identification, authentication and electronic (digital) signature.

Both these were real European public health challenges.

Electronic prescribing would be supported since it represented common needs but was not regarded as a pan-European priority.

Sweden

Dr Bo Jordin and Mr Mats Larson (joint meeting)

Dr Jordin is a member of EHTEL A1 and has responsibility for medical informatics matters in the National Board of Health and Welfare. The latter is an autonomous government agency with no operational responsibilities. The latter lie with the twenty one Swedish county authorities. The Board of Health and Welfare provides a knowledge base for parliament and government and issues guidelines and recommendations. It has responsibilities for terminologies. Dr Jordin's approach to standards was that they were solely a means to facilitate processes. The starting point should be the problem and EHTEL A1 might formulate that view.

Mats Larson is a member of the EHTEL Board. He is also responsible for the EHTEL-network of national European organisations (ELO's) in the field of ICT and Health. He is Chief executive Officer of Carelink which owned by Swedish healthcare. It was founded three years ago to stimulate collaboration in ICT between the stakeholders in health and is focused on a national infrastructure to allow digital information to be transferred. It cannot mandate but recommends. Among priorities are:

- providing a national broadband-infrastructure (Sjunet) for safe and secure communication between healthcare actors in Sweden;
- a roll out of electronic prescriptions which is well advanced (20% presently and soon 30%);
- rolling out a PKI system for healthcare professionals.

Although Carelink has interests in international standards and some of its members are involved in Working Groups within the Swedish National Standards Body (SIS), Mr Larson felt standards should primarily emerge from industry wherein they might be international. It might however be necessary to facilitate implementation of standards through guidelines.

E-prescribing has advanced through discussions between suppliers, counties and SIS and, through the latter, e-prescriptions relate to a CEN TC251 standard.

In regards to electronic patient records, only one or two counties have a common format and interest within others is relatively low. EPR's are used in primary care (95%) and in all hospitals – with a coverage ranging from 100% - 20% of the departments.

Whereas Dr Jordin and Mr Larson would attend a meeting which brought together European policy makers and standards makers, little value was foreseen for Sweden at the present time given the current position in ICT and the highly devolved responsibilities for ICT.

Norway

Dr Irene Henrikson Aune and Dr Ellen Strålberg (joint meeting)

Dr Alfred Enrenclou was until recently Norway's representative on EHTEL A1. He is now in Canada and Dr Henrikson Aune is his replacement on A1. She is Senior Advisor in the Norwegian Directorate for Health and Social Affairs which is funded by both Ministries. Dr Henrikson Aune is responsible for Norway's ICT strategy for health. Within the latter the recent current focus has been the creation of a virtual private network for health with special access arrangements connecting the five existing regional networks. In summer 2003 it will open for e-prescriptions, email, GP to hospital communications and other applications. Dr Ellen Strålberg is responsible for this network within the Directorate for Health and Social Affairs.

The Directorate funds a special standards programme in an organisation called KITH (a not for profit organisation founded in 1990 and owned by government and the Norwegian Association of Local and Regional Health Authorities). The strategy is concentrating on:

- electronic patient records;
- prescriptions;
- discharge and referral messages;
- electronic bookings;
- terminological matters.

KITH has firm links with CEN TC251 through the Norwegian national standards body and is committed to European standards.

In PKI the National Insurance Association are leading and e-pharmacy is being facilitated by pharmacies with KITH support.

Whereas Dr Henrikson Aune would attend a meeting bringing together European policy makers and standards makers, she and Dr Strålberg were reserved about its value to Norway since they were already committed to European CEN standards.

Prof Bjarte Solheim

Prof Solheim is chairperson of the Health Informatics Committee of the Norwegian National Standards Institution and heads the Norwegian delegation to CEN TC215. In Norway standards linked to EU Decisions and Directives are taken seriously and they try to implement CEN and ISO standards. Relationships with KITH are good and the National Standards Institution provides a conduit to CEN TC251 and ISO TC215.

Electronic patient records are used in 95% of GP practices. Five vendors dominate the market. Three systems dominate in hospitals. The CEN TC251 standard 13606 is actively implemented.

For electronic prescriptions there were active attempts to work with CEN TC251 standards. In the area of patient cards, the National Health Insurance body is collaborating with European groups regarding a card for health insurance purposes. They are also considering patient identification aspects for prescriptions.

All healthcare professional are to have professional data cards with electronic signatures within a PKI with third party certificates.

Prof Solheim would support an initiative to bring together European Policy Makers and standards makers.

Italy

Dr Alessandra Pastorino

Dr Pastorino works within the Italian National Standards Institution (UNI) and chairs its Health Informatics Committee. She heads the Italian delegation to ISO TC251. She cannot speak for the Italian Ministry of Health although she has a strong contact with Dr Walter Bergamaschi who is responsible in the Ministry for ICT matters.

Italy is actively considering its health ICT strategy. A significant conference on the strategy, including standards needs, would take place 9 June 2003. It will involve the Ministry of Health, Federation of GPs, insurance companies, DG SANCO, UNI and many others of influence. The outcome of the conference will be very significant for standards.

Italy has a new centre for Services and Products for Health (CONSIP), for procurements and all public administrations must purchase through them. They will be very influential in selection and implementation of standards.

Dr Pastorino would support an initiative to bring together European policy makers and standards makers. Guidelines for the use of a standard are important. However standards makers should not be represented solely by CEN TC251. DG Enterprise and DG SANCO should be involved. In terms of policy makers Dr Walter Bergamaschi could be the appropriate representative in the A1 context but Dr Pastorino could not commit him.

Denmark

Mr Jan Petersen

Mr Petersen leads the Danish delegation to ISO TC251 and works for the National Board of Health. The latter advises the Ministry of Health institutions and different ministries, counties and municipalities on health issues. Within the National Board, Dr Arne Kverneland heads the Department of Health Informatics.

Denmark has just published its second ICT strategy for 2003 to 2007. In the first strategy e-prescriptions were pursued and are successfully implemented with well

over half of prescriptions being electronic. They are based on EDIFACT and the CEN TC251 messaging standards (as are referrals, discharges, laboratory results, reimbursement etc). The second strategy will seek to move these messages to an XML environment. A logical view of the medication record is under development.

The main foci of the second strategy will be a national electronic healthcare record and development of a Public Health Information portal. An information structure for the health record has been developed rather than a record structure as in CEN TC251 standard 13606. All countries have committed to implementing an Electronic Health Record by 2006 based on the specification.

Recommendations on security have been made but a suggestion of all embracing citizens' card has met opposition. Proposals for a medication record database have been put forward by pharmacists.

Denmark takes EU Directives very seriously and seeks to comply with CEN TC251 standards. When seeking standards for an application it looks to CEN and ISO rather than attempt to develop their own standards. Public specifications are obliged to refer to international standards. The Health Informatics Committee in the national standards body contains many vendors and the chairperson is the Director responsible for ICT in the National Board of Health.

Mr Petersen would support an initiative to bring together European policy makers and standards makers and would seek to participate in any meeting(s). Denmark would bring extensive experience in adopting CEN standards and in GP to hospital messaging and e-prescriptions.

United Kingdom

Mr Jeremy Thorp

Mr Thorp has recently been elected chair of EHTEL A1. He is a senior member of the National Health Service Information Authority within the National Design Authority which is implementing the national health information and ICT strategy. The Authority will determine which standards to use.

Any application will require a profile of standards which may come from multiple sources. The challenge then is interoperability. IHE's approach to testing interoperability is a good model albeit focused on imaging applications.

The UK has taken the strategic decision to seek to apply HL7 Version 3 standards but there are very few of these at present and HL7 does not cover all areas of interest. The UK may therefore become engaged in creating Version 3 HL7 standards for input to HL7.

The major focus of the present strategy to 2007 is electronic health records, GP to hospital messaging, electronic bookings and e-prescriptions. A PKI structure will cover security. The role of patient and professional data cards has yet to be

determined. The strategy involves £2.3 billion sterling of centrally controlled funding (about €3.5 billion) and consortia are bidding to oversee implementation.

Mr Thorp would support an initiative to bring together policy makers and standards makers. The focus should include standards profiles for key shared priority applications, interoperability and guidance for the implementation of standards. (CEN standards are generally well thought out but complex and difficult to understand). Vendors must be on board. Any initiative must be driven by realistic, relevant and timely target dates.

Sights should not be set too high. Possible areas to consider might be:

- information required to support patients who cross national borders;
- PKI;
- Professional and patient data cards for identification, access control etc.

This should be in the context of integration of different standards into coherent profiles and interoperability testing.

Finland

Dr Ralf Ekebon

It was not possible to arrange a face-to-face meeting with Dr Ekebon but he expressed some views by email.

Whilst that he was not an expert in the standards field he was aware that there has been a lot of disappointment with the slow progress of the standardisation work that has taken place, and that the uptake by industry of work completed has been less than encouraging.

At the same time interoperability between different systems is of crucial importance (for the time being at least on a national level) and interoperability will also need some kind of - at least de facto - standards. Dr Ekebon would therefore be interested in participating/ supporting work that envisages a realistic solution to these challenges.

Regarding possible priority areas he noted that for e-prescribing Finland will start the piloting phase of a national project early in the autumn. On PKI he thought that there would be a solid basis established already (incorporating also the health care sector). Finland seeks to achieve interoperability of EPR by 2007.

Without a clear outline for a project and without having discussed possibilities with colleagues or superiors, Dr Ekebon was not be in a position to make any promises regarding financial resources.

CEN TC251

Gunnar Klein

Dr Klein is the chairperson of the CEN Health Informatics Technical Committee TC251. He is based in the Swedish National Standards Institution which holds the secretariat.

Dr Klein would support an initiative which brought together European policy makers as a group and standards makers. It would be important to bring suppliers and users on board. Candidate applications which have been suggested as a focus such as e-prescribing and / or medication record or PKI, or professional and patient data cards or electronic health records were supported. However the area of IEEE based standards applied to medical devices which has been very successful e.g. as applied to ECGs, should not be ignored. There is 'open ECG' EU project (€400,000) which is essentially promoting these standards.

In the security area the ISO work on a guide to the implementation of ISO 17799 might be considered.

Account should be taken of views in DG Enterprise and DG SANCO where interest in health standards is strengthening.

It is understood that the EU High Level Policy Group has issued a new version of its document on health ICT and its stance on standards would be important. There is also the question of an electronic European Health Passport.