Breaking Down Barriers

The White Paper and Action Plan 2002-2003
of Thematic Working Group 6 of the
European Health Telematics Association

This document has been prepared by Thematic Working Group 6 ("T6") of the European Health Telematics Association ("EHTEL"). It reports on the results of the Green Paper consultation exercise that was undertaken by T6 from 2000 – 2001 and sets out the action plan that T6 will implement over the next 18 months in order to tackle the issues that those responding to the Green Paper have identified as being most urgent.

This document is aimed at the Board of Directors of the EHTEL Association, at the individual and institutional members of the Association and at the European Commission. It will also be of interest to anyone with an interest in and knowledge of information and communication technologies in healthcare.

Three further publications, three workshops, two seminars and one large-scale international conference will be produced by T6 as a result of the action plan set out in this White Paper.

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Foreword by the Chairman of Thematic Working Group 6

At the first Annual General Meeting of the European Health Telematics Association in March 2000 a total of 15 separate working groups were created to address the issues that presently concern the many different professionals and organisations involved in supplying and using information and communication technologies in healthcare.

I was very honoured to be able to actively support the creation of the EHTEL Association and to subsequently be asked to lead a working group that would tackle the legal, ethical, privacy and security issues that relate to health telematics.

The resulting group – Thematic Working Group 6 – or simply "T6" benefits from the involvement and commitment of lawyers, ethicists and other experts from throughout and beyond Europe, as well as the involvement of the EHTEL Association members themselves. I have had the privilege of being the Chairman of this group since its creation and am delighted not only that so many talented individuals participate in the work of T6, but also that I have the assistance of an excellent Vice Chairman: Leif Erik Nohr of the National Centre for Telemedicine in Tromsø, Norway.

One of the first initiatives undertaken by the group was the publication of a Green Paper on *Legal Aspects of Health Telematics* that identified the legal issues arising from the development and implementation of information and communication technologies for healthcare and invited readers to provide their own comments, criticisms and reflections on how these issues impact upon health telematics and what, if anything, can be done to improve matters.

This White Paper *Breaking Down Barriers* reports on the results of that Green Paper consultation exercise and sets out the action plan that T6 will implement over the next 18 months in order to tackle the issues that those responding to the Green Paper have identified as being most urgent. It commences with a summary of the comments received in response to each individual section of the Green Paper and makes recommendations for action for each of those sections. It concludes with a detailed timetable and action plan.

In setting out our priorities for the coming 18 months, the T6 group has prioritised four specific areas of concern: (1) technical and data security standards; (2) reimbursement and responsibility; (3) Internet pharmacies and electronic prescribing; and (4) privacy and security issues in healthcare.

These are not, of course, the only legal and ethical issues that arise from using health telematics applications, but they are the ones that have been identified as most pressing by the individuals and institutions that have responded to the Green Paper.

In respect of issues (1) and (2) the group will research and draft two reports to the European Commission which will be validated by two high level workshops that will take place in March and May 2002 respectively.

The group will also promote understanding and awareness of the legal and ethical issues arising from the use and supply of health telematics applications by hosting two further events. A seminar on general legal issues in health telematics will take place at the World Congress of Medical Law in August 2002 and a session on issues relating to Internet pharmacies and electronic prescribing (our third priority area) will take place at the International Society for Telemedicine's annual conference in September 2002.

The group will then focus on priority area (4) through the production of a workshop and handbook on privacy and security in healthcare aimed at enabling health professionals at every level to put into practice the organisational and technical measures that will protect patient privacy and promote good information security management. The handbook will be published in June 2003.

Our eighteen month action plan ends with a major European conference on privacy and security in healthcare to be held in June 2003.

The action plan is clearly ambitious and will require the ongoing support and commitment of both the members of the EHTEL Association and the individual experts who work within T6. Three further publications, three workshops, two seminars and one large-scale international conference will be produced by T6 as a result of the action plan set out in this White Paper.

I have no doubts at all that T6 will be able to rise to this challenge and in so doing, provide a valuable programme of real benefits to the members of the EHTEL Association and the European healthcare community at large.

Benedict Stanberry

Chairman, Thematic Working Group 6

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1 THE GREEN PAPER CONSULTATION EXERCISE

Introduction

'T6 – is benefiting the members of the EHTEL Association and the European Union at large by taking positive steps to minimise, remove, clarify or resolve legal and ethical issues which impede the use of information and communication technologies in healthcare.'

1.1 The legal, ethical, privacy and security issues that arise from the use of information and communication technologies in healthcare is a central theme of the work of the European Health Telematics Association (EHTEL). To this end one of the fifteen working groups of the Association – Thematic Working Group 6 ("T6") – is benefiting the members of the EHTEL Association and the European Union at large by taking positive steps to minimise, remove, clarify or resolve legal and ethical issues which impede the use of information and communication technologies in healthcare.

1.2 In furtherance of the mission of T6, the group published a Green Paper on *Legal Aspects of Health Telematics* at the Association's first annual conference, held in Lille, France in November 2000. That paper had four broad aims:

- to identify what the actual legal issues affecting the evolution and use of health telematics in Europe were;
- to assess how and to what extent each of these issues presents (or would present in the future) a real barrier or impediment to health telematics;
- to suggest workable ways of reducing or removing those barriers and identify the various institutions and bodies that must co-operate in this process; and
- to promote reflection and debate and to invite all those with an interest in health telematics to submit their written comments and observations on the questions raised in the Green Paper.

1.3 The purpose of this White Paper is to set out the results of the consultation exercise that took place following the publication of the Green Paper and to set out the action plan that T6 will pursue in order to address the issues raised in the Green Paper which the health telematics and healthcare community in Europe has identified as being most urgent.

The Green Paper

'... the Green Paper was praised by all those who read it as being an accurate and helpful summary of the legal position of health telematics in Europe at the present time.'

1.4 On the whole, the Green Paper was praised by all those who read it as being an accurate and helpful summary of the legal position of health telematics in Europe at the present time. In particular, the paper has been referenced by the European Commission in its forthcoming *Communication on Legal Aspects of eHealth* that will be published in June 2002, and is likely to be referenced in other, similar documents. An abridged list of those responding to the Green Paper is contained in the Annex to this White Paper.

1.5 Each section of the Green Paper summarised the law relating to an area of specific concern in the field of health telematics. The individual sections of the Green Paper covered the legal issues arising from: technical standards, protecting electronic patient information, best practice, cross-border practice, malpractice and product liability, reimbursement and bridging the digital divide. Each section ended with a number of questions aimed at stimulating readers to respond to the issues raised in that section.

1.6 In general the responses received to the Green Paper came from "high level" individuals in health authorities, government ministries and data protection commissions. "Low level" responses from individual health professionals, mangers and patient groups were rare. It would appear that at this level the Green Paper was used as a reference document on the legal issues arising from using information and communication technologies in healthcare and that readers at this level did not therefore respond to the questions raised at the end of each section. Indeed, many individuals felt unqualified or too inexperienced

to respond to the paper and we have hence not received as many responses from these individuals as we would have liked.

1.7 Notwithstanding the above observations, we feel that the Green Paper exercise has been very successful in that it has placed T6 in a position to pursue a number of specific actions that will accelerate the uptake of health telematics applications throughout Europe and remove some of the barriers to its further implementation.

2 TECHNICAL STANDARDS

The Issues

'The lack of products complying with open, published technical standards is widely recognised as being one of the main reasons for the slow uptake of information and communication technologies in healthcare.'

2.1 The lack of products complying with open, published technical standards is widely recognised as being one of the main reasons for the slow uptake of information and communication technologies in healthcare. Those technologies that have demonstrated significant uptake are those in which there are open, published standards and technical specifications: such as HL7 for transmitting patient-related data and DICOM for image transmission.

2.2 The Green Paper recognised that European legislation already promotes standards in health telematics to the extent that such standards are required in order to fulfil the legal requirements of legislation such as the Data Protection Directive (95/46/EC), the Directive on Electronic Signatures (99/93/EC) or the Medical Devices Directives (93/42/EEC). It also recognised that using legislation to set specific standards for health telematics may constitute an anti-competitive and illegal interference in what should be a user led process of natural selection.

Responses to the Green Paper

2.3 The issue of standards attracted a number of responses from both the health telematics industry and users. It is apparent from the responses received that there is no clear relationship between those determining health policy and those responsible for the development of standards, nor is there a clear link between research and development and standardisation, nor any mechanism by which the outcomes of research projects can be assessed with a view to producing standards. There is uncertainty over what types of technology or application should be standardised on an international level and what should be standardised on a European or national level. Many of those responding to the Green Paper

felt that since health telematics applications were still in a highly embryonic stage in many European countries, the absence of standards was not a significant barrier to uptake at the present time. Others felt, however, that the lack of interoperability and common standards was making expansion of the health telematics industry all but impossible.

'Existing standards are felt to be expressed in a form that is too abstract to be easily implemented. Moreover, there are few if any incentives for suppliers of health technologies to adopt such standards'

2.4 Existing standards are felt to be expressed in a form that is too abstract to be easily implemented. Moreover, there are few if any incentives for suppliers of health technologies to adopt such standards, though there is a clear desire on the part of national health authorities to know what incentives would be both suitable and effective to stimulate the development and implementation of standards.

2.5 Both the suppliers of health technologies and users are totally unaware of the formal legal status of ISO (International Standards Organisation) and CEN (European Standardisation Committee) standards, although they all agree that such standards should be respected. They are generally unacquainted with the relevant European legislation on standardisation in the field of information and communication technologies for healthcare. There is also confusion regarding what the so-called "New Approach" to standardisation that has been adopted by the European Commission actually means in practice and to how the different encryption standards used in healthcare can be brought closer together, thus promoting interoperability.

Recommendation

2.6 It is the recommendation of the T6 group, therefore, that a more detailed investigation into the matter of technical and data security standards takes place and that a formal publication be prepared by T6, aimed at addressing in some depth the issues raised in response to the Green Paper such as interoperability and electronic signatures. The T6 group has agreed that a draft of this publication should be validated by a joint workshop, held in conjunction with

Thematic Working Group 1 (T1 - Health Information Society Europe) and Actors' Working Group 1 (A1 – Health Authorities).

Action

- Host a joint workshop with T1 and A1 on legal aspects of technical and data security standards.

- Publish a report (including recommendations where appropriate) on legal aspects of technical and data security standards.

3 PROTECTING ELECTRONIC PATIENT INFORMATION

The Issues

3.1 The privacy and security of patient information remains a paramount concern for both the users and providers of health technologies. Increasingly, healthcare providers expect to use patient information for the purposes of epidemiological research, auditing the quality of care and making health policy decisions. Patients, however, still have the intrinsic right to have their privacy respected. These rights are enshrined in the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950, Recommendation No. R 5 of 15 February 1997 on the protection of medical data and the Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data (95/46/EC).

'… the responses to the Green Paper almost unanimously agreed that patients know very little about their rights and that, moreover, patient associations are not effectively communicating those rights to patients or representing them effectively in the health technology arena.'

Responses to the Green Paper

3.2 Despite this plethora of regulations and recommendations, however, the responses to the Green Paper almost unanimously agreed that patients know very little about their rights and that, moreover, patient associations are not effectively communicating those rights to patients or representing them effectively in the health technology arena.

3.3 Many people responding to the Green Paper expressed their great dissatisfaction with the decision of the United Kingdom's Court of Appeal in *R v. Department of Health, ex part Source Informatics Limited*. Some respondents believe that the court's decision in that case – that the use of anonymised patient information does not breach any duty of confidentiality owed to the patient – is fundamentally flawed and in breach of the European Convention on Human Rights. Concern was also expressed regarding the much debated health database established by the government of Iceland and its potential for misuse.

3.4 Respondents also expressed concern over how genetic information held within a patient record is used and shared. Many respondents feel that genetic information should be subject to specific rules and that it should be possible to take legal action against those who misuse such information.

3.5 The level of concern expressed both by users and health authorities marks privacy and security issues out as being one of the greatest barriers to the widespread acceptance of electronic, linkable, shareable health records and databases.

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Recommendation

3.6 The T6 group was surprised and concerned that the field of privacy and security in healthcare has given rise to a great deal of legislation and regulation – at both a national and European level – but that there remains widespread ignorance on the part of both patients and healthcare professionals of their respective rights and responsibilities.

3.7 There appears to be a significant gap between the requirements laid down in national and European laws and the actual implementation of appropriate technical and organisational measures to prevent the misuse or misappropriation of health information. T6 therefore proposes to research, edit and publish a handbook on privacy and security in healthcare which will assist both patients and health professionals to understand and exercise their rights and responsibilities. The handbook will be published by EHTEL in 2003 and made widely available to patients and health professionals throughout the European Union.

3.8 Furthermore, the T6 group will plan and produce both a small-scale joint workshop and a large-scale European conference on privacy and security in healthcare, aimed at all the actors involved in promoting and delivering privacy and security in healthcare: patients, health professionals, health authorities and

industry. This major event will aim to achieve an attendance of 1,000 people and will take place in mid-2003. The conference programme will be accompanied by a commercial exhibition of information security products and services.

Action

- Publish a handbook on privacy and security in healthcare.
- Host a workshop on privacy and security in healthcare.
- Organise a large-scale European conference on privacy and security in healthcare to take place in mid-2003.

4 BEST PRACTICE

The Issues

'… lack of guidelines on what the correct standards of care are for medical practitioners that use health technology is seen as an inhibiting factor in ensuring that patients receive the same quality of care in telemedicine and ehealth facilitated encounters with healthcare professionals, as they do in face-to-face encounters.'

4.1 Health telematics is not yet in sufficiently widespread use for a body of medical opinion to have evolved regarding what constitutes good or best practice in the use of information and communication technologies in healthcare. This lack of guidelines on what the correct standards of care are for medical practitioners that use health technology is seen as an inhibiting factor in ensuring that patients receive the same quality of care in telemedicine and ehealth facilitated encounters with healthcare professionals, as they do in face-to-face encounters.

4.2 There are not, at the present time, institutions in the European Union that are able to publish standards for medical practice using health telematics technologies or which can undertake assessment and accreditation activities. Yet many respondents felt that such an approach is already needed in Europe to ensure that patients receive the highest possible standards of care. The JCAHO ("Joint Commission for the Accreditation of Health Care Organisations") system used in the USA was identified as a potentially suitable model for use in Europe.

Responses to the Green Paper

4.3 One area in which there was a high level of satisfaction with the present situation was concerning the quality of health information available on the Internet. It was generally felt that rating and filtering services offered a reasonable form of protection against sub-standard sites and that the ethical codes that many sites subscribed to were felt to be both adequate and sufficient.

4.4 The use of email communications between doctors and patients was recognised as an application that would inevitably grow in popularity but that carried a number of substantial risks, both in terms of the security and confidentiality of

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the transmission and the risks associated with giving a patient medical advice without having had a face-to-face consultation. Most respondents believed that the competent bodies that oversee the practice of medicine in the different member States of the European Union should issue specific guidelines on the benefits and risks inherent in online consultations and in prescribing medications by email.

Recommendation

4.5 The T6 group agreed that while there are a number of European initiatives taking place in relation to the quality of health information on the Internet, a number of other issues – most notably Internet pharmacies and electronic prescriptions – were highly topical but had not been examined properly as respects their inherent legal aspects. It was therefore agreed that T6 would host a workshop or seminar on the subject of Internet pharmacies and electronic prescribing as part of a suitable, larger congress or conference taking place within the next 18 months.

4.6 It was further agreed by the T6 group that a more detailed investigation into the matter of responsibility in telemedicine and ehealth consultations should take place to fill the tangible knowledge gap that exists with regards to where responsibilities lie in teleconsultations an ehealth consultations The T6 group has agreed that a draft publication on this subject should be validated by a joint workshop, held in conjunction with Thematic Working Group 2 (T2 – Telemedicine and eHealth) and Actors' Working Group 2 (A2 – Health Professionals).

Action

- Host a seminar on Internet pharmacies and electronic prescribing.

- Host a joint workshop with T2 and A2 on reimbursement and responsibilities in health telematics.

- Publish a report (including recommendations where appropriate) on reimbursement and responsibilities in health telematics.

5 CROSS-BORDER PRACTICE

The Issues

'Most respondents felt that a system by which online health professional could be identified, accredited and supervised was necessary if health telematics is to expand in Europe.'

5.1 Information and communication technologies can be used to break down traditional geographic and national barriers to medical practice: online consultations can take place between patients and health professionals located in different countries or even in different continents. Although professional medical qualifications awarded in one European country are recognised elsewhere in Europe, this does not give rise to an automatic right to practice medicine anywhere in the European Union. It remains necessary to register as a medical practitioner with the competent national or regional authority that supervises medical practice, providing attested copies of original diplomas and whatever other documentation is required are made available for inspection and validation.

5.2 Cross-border medical practice therefore gives rise to both supervisory problems – the need to ensure that health professionals have the necessary licence and qualifications to practice and that they conform to an appropriate standard of care – and also to accreditation problems: the need for patients to identify with certainty that an online healthcare professional really does possess the qualifications he claims to have.

Responses to the Green Paper

5.3 Most respondents felt that a system by which online health professional could be identified, accredited and supervised was necessary if health telematics is to expand in Europe. However, a number of respondents – in particular the competent authorities from several members states – felt that cross-border practice will never be common enough to require such a system and that,

moreover, the risks involved in cross-border medical practice using health telematics technologies were so high as to be make it unthinkable.

'… the emphasis of European policy in this area ought now to switch from resisting such services to finding ways to properly supervise and accredit them.'

5.4 The T6 group firmly believes that the spectrum of established and emerging health telematics applications is becoming broader by the day whilst, at the same time, these applications are finding themselves more and more at odds with the established, traditional way in which healthcare delivery is regulated. Logically, the emphasis of European policy in this area ought now to switch from resisting such services to finding ways to properly supervise and accredit them.

5.5 There is a clear challenge facing Europe's health professionals and policy-makers therefore: to carefully craft the development of new approaches to the supervision of medical and pharmaceutical practice, based not only upon the ultimate goal of raising consumer confidence in cross-border healthcare, but at ensuring that the mechanisms are put in place whereby health professionals themselves can benefit from using health telematics applications, while still ensuring the highest standards of medical practice.

Recommendation

5.6 The T6 group have concluded that while the legal issues raised by cross-border practice present significant barriers to the implementation of health telematics services, there is at present little or no will, on the part of national competent authorities, to enter into any dialogue or understanding on this subject. We have therefore concluded that the issues raised by cross-border practice should be readdressed by the group in 18 months time, but not treated as a priority for action at present.

6 MALPRACTICE & PRODUCT LIABILITY

The Issues

6.1 Throughout Europe similar legal tests are used with regards to malpractice. Generally, health professionals are required to act in accordance with the standards that are required by their profession. Clearly, patients themselves have the right to receive the same high standard of treatment and advice when their relationship with a healthcare professional is facilitated by information or communication technologies, as when they are in a face-to-face consultation with that professional.

Responses to the Green Paper

6.2 The Green Paper exercise unearthed a number of conflicting views regarding medical practice that is facilitated using health telematics applications. Many health authorities and individual healthcare providers remain deeply sceptical about telemedicine and ehealth's suitability as a medium for communication between health professionals and patients. Others are, on the whole, open-minded but nonetheless have deep-seated reservations regarding the risks involved. Many health professionals find it difficult to get straightforward and clear answers from their malpractice liability insurers or defence organisations regarding the acceptability of using health telematics applications in their day-to-day practice.

'Concerns over malpractice liability clearly prevent many health professionals and health authorities from pursuing their interest in health telematics applications'

6.3 Concerns over malpractice liability clearly prevent many health professionals and health authorities from pursuing their interest in health telematics applications – such reticence is closely related to the lack of standards for good practice and the lack of guidance available from their own national or regional competent authorities.

Recommendation

6.4 T6 therefore proposes that issues of medical responsibility and standards be addressed as part of the deliverable on responsibility in telemedicine and ehealth that is described in paragraph **4.6**. The draft of this publication being validated by a joint workshop with groups T2 and A2 of the EHTEL Association.

Action

- Include issues of medical responsibility and standards in the joint workshop and report on reimbursement and responsibilities in health telematics **(see Section 4)**.

7 REIMBURSEMENT

The Issues

'Without the creation of reimbursement processes and a corresponding regulatory framework for healthcare services delivered using health telematics technologies, the market for such services cannot grow.'

7.1 Reimbursement of medical services delivered remotely using information and communication technologies is a key issue in health telematics. Without the creation of reimbursement processes and a corresponding regulatory framework for healthcare services delivered using health telematics technologies, the market for such services cannot grow.

7.2 The impact of reimbursement policies varies tremendously between European countries. Where healthcare is funded by the state (such as in the United Kingdom and Denmark) and is therefore free to citizens at the point of delivery, reimbursement is of little concern, since the policies regarding the use of health telematics technologies are set by national and regional health authorities and funded according to the policies and priorities set by those authorities.

7.3 However, in those countries where payment for consultations, investigations and treatment is made directly to the health service provider by an insurance body, or a patient pays part or all of the cost of treatment and is later indemnified, reimbursement is a pivotal issue.

Responses to the Green Paper

7.4 Many of the respondents to the Green Paper consultation exercise stated that there is no reimbursement process in place in their country or region for healthcare services provided through health telematics applications. Opinions seem to differ regarding whether or not such services should be reimbursed. One national health authority expressed the view that only emergency consultations should be reimbursable. The underlying rationale for this view seems to be that insurers are not prepared to pay for treatments unless they are both economical

and safe, yet there is still insufficient evidence of this to convince them to reimburse such treatments.

'Key barriers to cross-border reimbursement include differing national standard fees for specific treatments which could make treatment in one country more expensive for the insurer than an identical treatment in their home country, as well as the differences in treatment nomenclatures and classifications that exist from country to country.'

7.5 There was a widespread view that reimbursement for cross-border telemedicine consultations would be almost unworkable, except for emergency consultations. Key barriers to cross-border reimbursement include differing national standard fees for specific treatments which could make treatment in one country more expensive for the insurer than an identical treatment in their home country, as well as the differences in treatment nomenclatures and classifications that exist from country to country.

Recommendation

7.6 The T6 group has concluded that issues of reimbursement remain a significant barrier to the use of health telematics applications and that, in particular, there is very little understanding on the part of industry and health professionals regarding how health authorities can be encouraged to be more inclusive of telemedicine and ehealth facilitated healthcare.

7.7 Issues of reimbursement, including an in-depth examination of three healthcare reimbursement systems and the proposal of models for the reimbursement of health telematics delivered services, will therefore also be a part of the deliverable on responsibility in health telematics delivered care, committed to in paragraph **4.6**. As has already been stated, a draft publication will be validated by a joint workshop with groups T2 and A2 of the EHTEL Association.

Action

- Include issues of reimbursement and reimbursement models in the joint workshop and report on reimbursement and responsibilities in health telematics **(see Section 4)**.

8 EQUITY & ACCESS: BRIDGING THE DIGITAL DIVIDE

The Issues

8.1 The accessibility of health telematics technologies to European citizens depends, to a great extent, upon bridging the digital divide that separates those who have access to appropriate technologies and affordable broadband telecommunication networks and those who do not.

8.2 Although there are European Union Directives promoting the universal accessibility of telecommunications services, regardless of a citizen's address, these do not extend to the provision of affordable, broadband services to healthcare institutions and citizens. Moreover, a significant number of European citizens are unable to benefit from the creation of online health services and resources because they do not have access to the Internet.

'The Green Paper consultation exercise exposed widespread disagreement among governments, healthcare authorities, industry and users regarding where responsibility for creating the infrastructure necessary to support health telematics applications should lay.'

Responses to the Green Paper

8.3 The Green Paper consultation exercise exposed widespread disagreement among governments, healthcare authorities, industry and users regarding where responsibility for creating the infrastructure necessary to support health telematics applications should lay. Many respondents believe that industry has a responsibility to lower its prices, whereas others believe that only through national governments, healthcare institutions and telecommunication companies working in partnership can the right conditions be achieved whereby citizens and healthcare providers can properly benefit from health telematics technologies.

Recommendation

8.4 Clearly there is a need for greater dialogue among the concerned actors for any clear understanding to be reached regarding how health telematics technologies

can best benefit the poorest and most underserved communities in Europe. Yet the facilitation of such dialogue was felt to be a responsibility that should be addressed at the highest levels of government and in which the EHTEL Association could, if it so chooses, take a very active role. It was not, however, felt to be an area of specific priority for T6 at the present time and will therefore be reviewed as a target for T6 actions in 18 months time.

9 SUMMARY OF RECOMMENDATIONS

9.1 Technical Standards - T6 should carry out a study of technical and data security standards, with particular emphasis on interoperability and electronic signatures, that will lead to a publication that will be validated by a joint workshop, held in conjunction with Thematic Working Group 1 (T1 - Health Information Society Europe) and Actors' Working Group 1 (A1 – Health Authorities).

9.2 Protecting Electronic Patient Information – T6 should research, edit, publish and disseminate a handbook on privacy and security in healthcare, aimed at "low level" users such as patients and their representatives, health professionals, managers and administrators working within the healthcare environment. Furthermore, T6 should plan both a small joint workshop and produce a large-scale conference and commercial exhibition on privacy and security in healthcare to be held in mid-2003.

9.3 Best Practice, Malpractice & Product Liability and Reimbursement – T6 shall carry out a study of responsibility, reimbursement and best practice in health telematics applications, that will lead to a publication that will be validated by a joint workshop, held in conjunction with Thematic Working Group 2 (T2 – Telemedicine and eHealth) and Actors' Working Group 2 (A2 – Health Professionals). T6 will also hold a workshop or seminar on the specific issue of Internet pharmacies and electronic prescribing.

9.4 Cross-Border Practice – T6 should not treat this as a priority issue at the present time. T6 will reconsider its position on cross-border practice and what actions are necessary on this issue in July 2003.

9.5 Equity & Access: Bridging the Digital Divide - T6 should not treat this as a priority issue at the present time. T6 will reconsider its position on equity and access to health telematics applications and what actions are necessary on this issue in July 2003.

10 ACTION PLAN 2002 - 2003

10.1 In the light of the conclusions reached by the T6 group following the Green Paper consultation exercise and the recommendations we have reached in this White Paper in response to those conclusions, T6 have agreed to adopt the following Action Plan for the period 1 January 2002 to 30 June 2003:

10.1.1 In respect of recommendation **9.1** regarding technical standards, our first report on the legal aspects of technical and data security standards will be delivered on 5 April 2002 following a joint workshop on that theme to be held in Bonn, Germany in the period 7 / 8 March 2002. A T6 standing committee meeting will also take place at that time.

10.1.2 In respect of recommendation **9.3** regarding best practice, malpractice & product liability and reimbursement, our second report on reimbursement and responsibilities in health telematics, will be delivered on 30 June 2002, following a workshop on that theme, to be held in Paris, France in the period 22 / 23 / 24 May 2002. A T6 standing committee meeting will also take place at that time.

10.2 In order to promote the activities of T6 and assist in recruiting more experts into the group and more members into the EHTEL Association, we shall host a workshop or seminar on the subject of the legal aspects of telemedicine and ehealth as part of the 12th World Congress of Medical Law, to be held in Maastricht, The Netherlands, in the period 11 / 12 / 13 / 14 August 2002. The papers presented by T6 will be published as part of the official congress proceedings. A T6 standing committee meeting will also take place at that time.

10.3 In respect of the second part of recommendation **9.3**, the T6 group will host a workshop or seminar on Internet pharmacies and electronic prescribing as part

of the International Society for Telemedicine's (ISfT) annual conference on the medical aspects of telemedicine, to be held in Regensburg, Germany, in the period 22 / 23 / 24/ 25 September 2002. The papers presented by T6 will be published as part of the official proceedings. A T6 standing committee meeting will also take place at that time.

10.4 In respect of recommendation **9.2** regarding protecting privacy and security in healthcare, our handbook on privacy and security in healthcare will be developed during the period 1 October 2002 – 31 May 2003 and published on 1 June 2003. The development of that handbook will be guided by the outcome of an EHTEL Association joint workshop. Our international conference on privacy and security in healthcare will take place in a major European city in mid-June 2003. T6 standing committee meetings will take place in late January/early February

10.5 The chronology and delivery dates for all of these actions are set out in Table 1, below.

10.6 The T6 group have expressed their general satisfaction with their mission statement and constitution, as set out in Section 11.

Table 1: T6 Schedule of Meetings and Deliverables for 2002 - 2003

January 2002

11 & 12 January 2002 – London, UK
T6 Standing Committee meeting

February

31 January 2002:
Publication of "Breaking Down Barriers: the White Paper & Action Plan 2002-2003"

March

7 & 8 March 2002 – Bonn, Germany
T6 Standing Committee meeting
T6 Joint Open Workshop (with T1 & A1) on "Legal Aspects of Technical and Data Security Standards"

April

5 April 2002:
Publication of "Report and Recommendations on Legal Aspects of Technical and Data Security Standards"

May

21 – 24 May 2002 – Paris, France
T6 Standing Committee meeting
T6 Joint Open Workshop on "Reimbursement and Responsibilities in Health Telematics"

June

30 June 2002:
Publication of "Report and Recommendations on Reimbursement and Responsibilities in Health Telematics"

July

11 – 14 August 2002 – Maastricht, The Netherlands
T6 Standing Committee meeting
T6 to host a seminar on "Legal Aspects of Telemedicine & eHealth"
at the 14th World Congress of Medical Law: Papers to be published in the Official Proceedings

August

22 – 25 September 2002 – Regensburg, Germany
T6 Standing Committee Meeting
T6 to host a seminar on "Internet Pharmacies & Electronic Prescribing" as a special session of the International Society for Telemedicine's (ISfT) annual conference on Medical Aspects of Telemedicine: Papers to be published in the Official Proceedings

September

late November 2002 – tba
T6 Standing Committee meeting.
T6 Joint Open Workshop on "Privacy and Security in Health Telematics"

October

November

December

January 2003

late January / early February 2003 – tba
T6 Standing Committee meeting

February

March

late March / early April 2003 – tba
T6 Standing Committee meeting

April

May

1 June 2003:
Publication of "EHTEL Handbook on Privacy and Security in Healthcare"

June

mid June 2003 - tba
EHTEL T6 International Conference on Privacy and Security in Healthcare

11 MISSION STATEMENT & CONSTITUTION

Mission Statement

11.1 Thematic Working Group 6 ("T6") of the European Health Telematics Association ("the Association") will benefit the members of the Association and the European Union at large by taking positive steps to minimise, remove, clarify or resolve legal and ethical issues which impede the use of information and communication technologies in healthcare.

Principle Objectives

11.2 T6 will achieve this by:

11.2.1 Undertaking such activities within the context of the PROEHTEL project, and any other such projects as T6 may from time-to-time be involved in, as are conducive to the mission of the group.

11.2.2 Acting as a point of reference for both the members of the EHTEL Association and the European Union at large on issues of law and ethics relating to the use of information and communication technologies in healthcare. In furtherance of this objective, T6 will consider legal and ethical issues referred to it in writing and produce wherever possible a written, reasoned opinion.

11.2.3 Promoting publications and events designed to educate the members of the EHTEL Association and the European Union at large on the legal and ethical issues that arise from the use of information and communication technologies in healthcare and promoting fora for the discussion and resolution of these issues.

11.2.4 Lobbying relevant individuals, institutions and authorities within member States and the European Union on matters of law and ethics, in order to achieve the most positive outcomes possible for the advancement of information and communication technologies in healthcare.

Constitution

11.3 In order to best address the unique challenges that legal and ethical issues present to the advancement of information and communication technologies in healthcare, T6 will consist of both a Standing Committee of Experts – comprised of leading lawyers, jurists, ethicists and moral philosophers – as well as an Open Forum, consisting of both the Standing Committee of Experts and members of the EHTEL Association at large.

11.4 In order to best exert influence on a global level and promote the international standing of both the EHTEL Association and T6 there shall also be a Virtual Forum.

11.5 A Chairman will be responsible for the day-to-day administration and management of T6, the preparation of its publications and events and all liaison between the group and the Executive / Board of Directors of the EHTEL Association. He or she will be supported by a Vice Chairman.

11.6 The Standing Committee of Experts will consist of up to 2 (two) representatives of each European country, together with representatives of such other countries as shall be necessary for the execution of the objectives of T6. The present membership of the Standing Committee is contained in Table 2. The group shall actively work to recruit representatives from those countries that are not presently represented on the Standing Committee.

11.7 Every member of the Standing Committee shall be an internationally recognised expert in the legal, ethical, privacy or security aspects of using information and

communication technologies in healthcare. The Chairman of T6 shall act as the Chairperson of the Standing Committee and shall also be responsible for ensuring that accurate minutes are kept of T6 meetings.

11.8 The Standing Committee will be responsible for the achievement of the principle objectives of T6. This shall include, among other things, carrying out the sub-projects assigned to it under the PROEHTEL project; considering the legal and ethical issues referred to the group and producing written, reasoned opinions wherever possible; producing relevant publications and events; undertaking lobbying activities and generally conducting or commissioning whatever administrative or professional work is necessary for the achievement of these tasks.

11.9 The Open Forum will consist of the Standing Committee of Experts, plus all those members of the EHTEL Association with an interest in the activities of T6.

11.10 The Open Forum shall, together with the Standing Committee and the Board of Directors of the EHTEL Association, agree and oversee the strategic direction of T6.

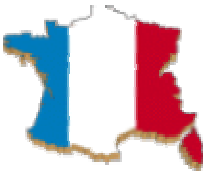
11.11 The Virtual Forum will consist of any individual or organisation that wishes to receive news and information and exchange views on the activities of T6 electronically.

11.12 The Standing Committee shall meet at least 4 (four) times a year. Such meetings will take place at times, dates and venues that are agreed by the Committee as most convenient to the majority of its members.

11.13 The Open Forum shall meet at least 4 (four) times a year to participate in workshops, seminars or such other activities that will advance the mission and objectives of T6.

11.14 A list of past meetings of the Standing Committee and Open Forum is contained in Table 3.

Table 2: Members of the Standing Committee of Experts

Country:	Name:	Job Title:
United Kingdom 	Benedict Stanberry *(Chairman)*	Managing Director, Avienda Limited
	Dr Kevin Dalton	Consultant in Obstetrics & Gynaecology and Legal Medicine, Addenbrooke's Hospital. Fellow of St. Catherine's College, Cambridge.
France 	Dr Anne Strauss	Director, Groupe de Recherche en Imagerie Biomédicale
Belgium 	Professor Stefaan Callens	Professor of Law. Lawyer, Callens Advocatenkantoor
Germany 	PD Dr iur Dr med Christian Dierks	Lawyer, Messrs Dierks & Bohle, Berlin.
Greece 	Dr Zoi Kardasiadou	Independent Legal Consultant. Researcher at the Centre for International and European Economic Law, Thessaloniki.

The Netherlands 	Dr Sjaak Nouwt	Center for Law Public Administration and Informatization, Tilburg University.
Norway 	Leif Erik Nohr *(Vice Chairman)*	Legal Adviser, National Centre of Telemedicine, University Hospital of Tromsø.
	Ellen Christiansen	Legal Adviser, National Centre of Telemedicine, University Hospital of Tromsø.
Austria 	Mag. Brigitte Gastinger	Research Fellow, ISM-Austria GmbH.
	Mag. Michaela Pieringer	Research Fellow, ISM-Austria GmbH.
Israel 	Rina Hakimian	Senior Researcher, Gertner Institute for Epidemiology and Health Policy Research, Unit for Ethics and Health Rights, Sheba Medical Center, Tel Hashomer.
USA 	Dr Joseph McMenamin	Attorney-at-Law, Messrs McGuireWoods LLP, Richmond, Virginia.
European Commission Observer 	Dr Petra Wilson	Scientific Officer, Directorate-General for the Information Society, European Commission, Brussels, Belgium.

Table 3: Meetings of Thematic Working Group 6

Date:	Venue:	Attendees:
Monday 28 August 2000	London, United Kingdom	Standing Committee of Experts
Monday 30 October 2000	London, United Kingdom	Standing Committee of Experts
Thursday 16 – Friday 17 November 2000	Lille, France	Open Forum (EHTEL Conference)
Thursday 8 March 2001	Thessaloniki, Greece	Open Forum (Health Online 2001)
Sunday 17 - Monday 18 June 2001	Uppsala, Sweden	Open Forum (ISfT 2001)
Friday 11 – Saturday 12 January 2002	London, United Kingdom	Standing Committee of Experts

Annex:

Respondents to the Green Paper

Name:	On behalf of:
Theo Hooghiemstra	Data Protection Authority, The Netherlands.
Yves Poullet	Working Group on the Legal and Ethical Aspects of the Electronic Medical Record, Belgium.
Andrew Vaux	Direct Visual Group plc, United Kingdom.
Susanne Westfold-Scott	Imperial College, University of London, United Kingdom.
Christiano Paggetti	Research and Development Director, MEDEA - MEDical and Engineering Applications, Florence, Italy.
Gavin Tong	Infostructure Coordinator, Canadian Institute for Health Information (CIHI), Toronto, Canada.
James Harrison	European Technical Consultant - Health Telematics Philips Medical Systems - Cardiac & Monitoring Systems, Bracknell, United Kingdom.
Nicholas Robinson	Telemedicine Lead, NHS Direct, United Kingdom.
Stefan Hebenstreit	Universiy of Bielefeld, School of Public Health - WHO Collaborating Center, Dept. 5: Management in Health Care, Bielefeld, Germany.
Erik Hoencamp	The Netherlands.
Michael Darling	Michael Darling, Senior Manager Telehealth, Information Management Group, Corporate Shared Services, Ministry of Health Planning and Ministry of Health Services, Victoria, British Columbia, Canada.
Alberto Tomasich	Italy.

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