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FOR INFORMATION ☒
The Health Telematics Working Group of the High Level Committee on Health was asked to review the introduction of information and communications technology (ICT) in the health sector, the factors promoting or inhibiting its development, and areas where Community legislation could be beneficial. The Group was invited to consider particular applications of ICT in health, namely health cards, virtual hospitals and provision of health-related information to health professionals and patients.

Information is a vital resource for the effective running of all major businesses. The health sector is arguably one of the most information-dependent businesses of all. Its information requirements can be classified as:

- Information for citizens
- Patient education services
- Health Management Information
- Personal Health Data
- Decision support systems for health care professionals
- Life long learning for health care professionals

Modern information and communication technologies, including the Internet, offer an opportunity to meet these needs and others, and to reengineer and revitalise the processes and procedures currently in place. At the same time, eHealth must support appropriate developments in health policy. There is a large and growing body of health-related information on the World Wide Web, to which citizens and patients, hungry for information, are increasingly turning. However, the information available via the Internet is of highly variable quality and many people still do not have access to the Internet, or have difficulties in finding information in a language they understand. Population level public health/health management data is still not of a quality or comparability to support confident inferences about public health policy. These are issues which the European
Union is already addressing through its new public health programme and successive eEurope actions.

At the same time, modern health care is not provided by one institution or by one group of healthcare professionals alone. New service models like “seamless care”, “shared care”, “tailored care”, “integrated care” “mobile care”, “home hospitals” and “customer-centred care” all contain the same basic notion: that of the patient at the centre of a network of service providers, forming “pathways of care” as s/he moves between institutions and care providers. Such models all require access to patients’ health histories from any place.

Furthermore, in emergency situations, basic information may be vitally important in administering immediate care. In an ideal world, a citizen requiring urgent medical attention whilst away from home (including temporary trips abroad) would be confident that the clinicians treating them would have fast and secure access to all relevant information from their medical record in order to facilitate treatment. This would be immediately accessible over secure networks using agreed standards and protocols and by communicating with their usual treatment providers in a language understandable for both the patient and the professionals. The appropriate care could be provided quickly and effectively and necessary follow-up arrangements agreed for when the person returns home.

The reality is that within Europe none of this is yet possible. There is no easy way of identifying the citizen’s physician, nor aspects of their medical history, nor current medical conditions or medication which ought to be taken into account in determining current treatment. There is not even any guarantee that medication prescribed in one Member State can be easily identified in another.

In practice, therefore, communication between different healthcare providers is too often still done manually due to basic non-interoperability of the many systems in place. Information is communicated using mail, phone, fax or carried by the patient and the bulk of information is printed out from one information technology system, mailed and finally re-keyed into another IT system used in another institution. Chronically ill patients often have to tell their medical history over and over again This form of communication is expensive, takes time and gives rise to failures because of errors, inaccuracies and incomplete availability or loss of medical information.

This area of health care policy is within Member States competence. However, there are important synergies between the generation of electronic data in the health care system and the collation of population level data such as is envisaged in the development of a Health Information and Knowledge System of the new public health programme. Furthermore, these are common problems and Member States would benefit from the opportunity to exchange ideas and experiences in tackling them.

They are also issues which would benefit from concerted action at European and international level. The cornerstone of a system for sharing information about patients between care providers is the electronic health record (EHR). This in turn can support
advanced systems of electronic prescribing and medication management. There are, however, substantial problems in sharing data. These relate to the non-interoperability of health care and IT systems. Interoperability is not just about getting the right technologies in place. Many privacy and confidentiality issues remain to be resolved and legal data confidentiality requirements are clearly inseparable from the need for technological security when data is transmitted electronically. To make the shared access and use of patient health information possible a secure platform is needed, incorporating the use of qualified electronic signatures and asymmetric encryption.

Other issues concern the need to agree on a common data set and how to organise and codify it.

There are new developments in health telematics which are helping to ameliorate or resolve the problem of non-interoperability of ICT systems. For example, the use of interoperability technologies and Open Source software makes it easier to share data between systems. Such initiatives need to be promoted and encouraged. Telemedicine and telecare are not just growing in use, but are helping to provide the shared information necessary for shared care. However, there remain legal uncertainties about liability and reimbursement which need to be solved at European level. Health services planning may be undertaken on the basis of regional networks and European level initiatives have already been supporting developments in this area.

Furthermore, there are various national and international bodies active in the area of health telematics standards at international level, particularly the CEN (Comité Européen de Normalisation), and the International Standards Organisation (ISO).

There needs to be concerted action to address common standards, particularly in the development of interfaces between rival and incompatible systems. This area would benefit from further study.

In conclusion, therefore, there are many issues to be addressed before the available technologies can be harnessed effectively. They will require careful planning and will be facilitated by a high level of international co-operation and agreement.

At EU level, albeit within limited legal competences, much is ready being done, but more could be attempted. There is extensive ongoing support for the development of new applications in health under the Sixth Framework Programme managed by DG Information Society. In future, however, project selection should be better informed by health policy issues. There is also a need to develop better means of assessing the cost-effectiveness of new technologies and this is also one of the objectives of the new public health programme. A joint action with DG INFSO is also foreseen under the new public health programme in the area of eHealth, particularly on follow up work to explore the possibility of developing European seals of approval for health-related web sites. Under the information objectives of the new public health programme European level databases will be established. Projects already supported by the Health Monitoring Programme are devoted to exploring the generation of data from within the primary health care and
hospital sectors. Dissemination of information to patients, professionals, citizens and Member States’ authorities will be a key aspect of these activities.

At the same time, the need for concerted action at European and international level to achieve interoperable and secure IT systems within health care has to be coordinated, managed and resourced. Given DG INFSO’s limited remit, such activity should be located within, or under the supervision of, the Commission’s Public Health Directorate. There is, simultaneously, a need for a forum in which Member States can meet and exchange experience in implementing ICT strategies in national health care systems. One option would be to support the use of the A1\(^1\) Group of the European Health Telematics Association (EHTEL), although other possible measures could be envisaged. There is provision in the 2003 Work Programme of the new public health programme for an ICT newsletter which might go some way towards achieving this aim.

\(^1\) EHTEL A1 Group = Group of healthcare authorities representatives
1. INTRODUCTION

1.1. Terms of Reference

The Health Telematics Working Group of the High Level Committee on Health was asked to review the introduction of information and communications technology (ICT) in the health sector, the factors promoting or inhibiting its development, and areas where Community legislation could be beneficial. The Group was invited to consider particular applications of ICT in health, namely health cards, virtual hospitals and provision of health-related information to health professionals and patients.

Since the Working Group was established, there have been new initiatives at European level which overlap its mandate. The eEurope initiative stressed the use of the Internet, which is of growing importance in the field of health, and the eEurope Action Plan for 2002 included an eHealth chapter which made provision for, among other things, a report on the establishment of ICT infrastructures and regional networks in member States and a publication of a Commission document on Legal Issues in eHealth. This has now been followed by a further eEurope Action Plan for 2005. Both are discussed in more detail elsewhere in this report. In the light of these and other new and ongoing activities, for example the Sixth Framework Programme and the proposal to replace paper-based E-forms authorising cross-border care in the EU, the Working Group felt that it would be appropriate to provide a strategic overview of all ongoing health telematics activities and to make general recommendations for future action in this field at European level.

In addition, significant progress has now been made in the process of Enlargement. Many candidate countries are also making important steps in the use of ICT in health, and some have highly advanced systems from whose experience existing Member States could benefit. The experience of candidate countries has not been taken into account explicitly in the work of the Working Group, but its conclusions and recommendations apply in equal measure to an enlarged European Union.

The following report is, therefore, about the development of eHealth in its widest sense. This can be described as the use of information and communication technology and the Internet to:

- connect citizens, health information providers and governments
- inform, educate and empower citizens, patients, health care professionals, managers and policymakers
- stimulate innovation in health policy development, health promotion and prevention of ill-health
- improve the quality and management of health data as well as care delivery and health system management
Legal competence at European level is restricted in some of these areas, particularly where the delivery of health services is concerned, this being a Member States competence. Therefore, the different fields of ICT may require quite different types of response at European level.

In addition, European-level interest in ICT spans different Directorates General, and non-government organisations, and in the past there has not always been sufficient coordination between them, or read-across from one to the other. It also seemed important to the Working Group, therefore, to discuss the criteria for different types of response, and to propose models for possible future fields of activity, organisation, collaboration and co-ordination of health telematics, between Member States and the European Union.

2. INFORMATION AND HEALTH

2.1. The Uses and Purposes of Health-Related Information

Information is a vital resource for the effective running of all major businesses. Banks, insurance companies, retail chains, travel companies etc. all invest heavily to ensure that they are adequately empowered with comprehensive and timely information which will enable them to meet their business requirements. They are acutely aware that without such information they will struggle to survive, and will be overtaken or swallowed up by those of their competitors who have ready access to relevant information. Information is therefore regarded as a key business enabler that is perhaps second only to human resources in terms of value to the organisation. The health sector is arguably one of the most information-dependent businesses of all.

The development of societies where health considerations permeate all policies can only take place if modern information and communication technologies are also fully utilised. With the help of these technologies citizens’ participation in the definition of health and health relevant policies can be enhanced.

Availability of, and access to, reliable information is also crucial for health promotion and prevention which are gaining an ever more important role both on the global, European and national levels. There is a great deal of information available from evidence-based research and other types of evaluation, but gathering, assessing, summarising and disseminating it requires coordinated efforts. The provision of high quality, efficient, cost-effective health care can only be truly realised through the collaborative efforts of various health professionals, health care planners, funding providers, administrators and, very importantly, the public themselves. Real added value can be gained through systematic exchange of information and collaboration regarding the development of infrastructure for reliable information systems.
2.1.1. Information for citizens

The general ageing of the population requires increased attention to all possibilities for increasing citizens’ working and functioning capacity, or more broadly, the health potential, of the population. There is good evidence for the view that a promotional, cross-sectoral health and welfare policy can be effective in the long term. Thus prevention and early detection of disease will be an increasingly important aspect of health care delivery. In addition, individual citizens are expecting, and being expected, to play a greater role in ensuring their own well being and are looking for high quality and reliable information on how to stay healthy. This development can be supported by increased availability of reliable information and through new types of interactive telematic services. Non-governmental organisations and the activities of so-called self-help groups are important for this development. For citizens to be able to influence developments on both a local, national and European level, solid information concerning health determinants and other health policy issues is needed.

It is essential that the citizen/patient should be able to have confidence in the accuracy and validity of health-related information. There is a large and growing body of health-related information on the World Wide Web. However, the information available via the Internet is of highly variable quality. The growing use of such information by patients, is also affecting the old type of relationship between patient and doctor. Currently, the Internet provides numerous possibilities for obtaining a second opinion with relatively little effort. Initiatives to produce “health portals” or "call-centres" aimed at citizens are increasingly evident.

At the same time, many people do not have access to Internet facilities. There are also social and literacy considerations that need to be taken into account. Therefore the Internet should be seen as complementary to other initiatives at national level to provide health information services to citizens.

2.1.2. Patient education services

Patient education includes education on treatment choices and medicines, health education and clinical health promotion. It also covers patient's rights and ethical issues. Patient education can improve the management of chronic diseases and conditions as well as improve quality of life, and it plays a major role in helping to meet the needs of the ageing population and the increasing prevalence of chronic diseases. The Internet and mobile communications will in the future be essential tools in patient education.

2.1.3. Health Management Information

Health policy makers and care providers need information on the health status and trends of the population, to be able to predict future needs and challenges. Information is also required to assess the overall effectiveness of health promotion, prevention and on treatments and approaches in use, as well as to evaluate the best means of ensuring that high quality and value for
money are achieved. Accountability and further improvement can only be achieved through the careful measurement of the approaches in place and the outcomes achieved. Comprehensive, aggregate and reliable information, drawn from a wide variety of sources is essential to realise this objective.

All member states make major investments in the collection of health data, but with different approaches, methods and indicators. Consequently, anonymous health data are in general not easily available for statistical, research or policy purposes and, even if they are, they are frequently not comparable, lack standardisation and do not allow proper cross-country comparisons. As described below, redressing this problem is a principal objective of the new EU public health programme, where significant added-value is achievable with careful planning, relying on the best available expertise and participation of the relevant authorities of the member states. Efficient planning and evaluation of health policy as well as a cost effective delivery of health care all require the speedy, accurate and comprehensive exchange of data. Inefficient procedures lead to unnecessarily high administrative costs for care providers and financiers.

2.1.4. Personal Health Data

In the case of the health professional involved in the treatment of an individual, it is vital that all relevant information regarding the person’s condition is available. Much of this information will be historic and may have been gathered over many encounters with the health service, due to contacts with professionals in different locations and systems. Where such information is unavailable, the result may be delay, additional costs, and perhaps even inadequate or inappropriate treatment.

At the same time there are important data security and privacy considerations to be taken into account when communicating personal health data over open networks. Besides the purely technical challenges of this task there are also legal issues (e.g. ownership of data) and ethical and cultural considerations. The concept of the patient as owner of data is an important starting point for defining patient access to available personal data and establishing a correct line of responsibility for authorising its use elsewhere.

2.1.5. Decision support systems for health care professionals

It has become apparent in recent years that too few clinical practices are based on rigorous evaluation of effectiveness and cost-effectiveness. Growing emphasis on evidence-based medicine has highlighted the importance to all health professionals of decision support systems for helping them to determine the optimal treatment for the particular set of circumstances with which they are presented. Such tools are also of particular help to professionals dealing with complex and unusual conditions. Relevant information may be available locally, based on evidence gathered together, but very frequently clinicians will require access to national and international sources of information. In reality, in many
countries easy electronic access to the guidelines for best practice is unavailable.

There are modern medical protocols relying on international networks of authorised partners, (for example, organ transplantation; reacting to different types of health threats) which need safe cross border identification of authorised contact points.

2.1.6. Life long learning for health care professionals

Health care professionals need sufficient continuous on-the-job training, and education in the adoption and use of health telematics technologies. Technical tools for improving the educational possibilities include 24-hour access to scientific and technical databases and electronic libraries, access to clinical meetings and conferences by video, and access to agreed quality criteria, processes and procedures of prevention and care, and supervision of services.

The search for higher quality of health care processes and outcomes is putting pressure on health care providers in most European countries to develop their systems for postgraduate professional training towards better structured, sponsor-independent and outcome-oriented programs. When closely blended with personal and practice oriented teaching methods like hands-on seminars and supervision, e-Learning offers opportunities to increase the standards of postgraduate professional education. In this context, mutual recognition of diplomas and harmonization of curricula according to the Bologna Declaration are important prerequisites for the advancement of e-Learning in health care, since they provide for common levels of knowledge and curricula for postgraduate continuing education across Europe.

The increasing use of multimedia-based teaching at universities will ensure the acceptance of e-Learning among younger professionals. However, for a sustainable quality improvement of health care, the fast integration of older professionals in these modern methods of life long learning is vital.

Easy and frequent access to electronic databases, libraries and e-Learning tools can be enhanced by a seamless integration into digital diagnostic hardware, clinical management and decision support systems. It is important to develop information and education for patients, health care providers and assisting professions which are based on the same clinical guidelines and scientific evidence, and according to technical specifications which are widely accepted across e-Learning-providers. However, current platforms and systems for the distribution and integration of structured knowledge in health care lack the required ease of use, accessibility and necessary economic sustainability. Growing legal requirements for postgraduate continuing education and quality assurance will foster the utilization of these technologies.
3. **HEALTH TELEMATICS: KEY SERVICES**

Modern information and communication technologies offer an opportunity to meet these needs and others, and to reengineer and revitalise the processes and procedures currently in place. At the same time, ICT must support appropriate developments in health policy. Modern health care is not provided by one institution or by one group of healthcare professionals alone. It requires the close co-operation of many different professional groups working together and using their specialised expertise in a common effort to deliver the best quality service and most cost-effective care as possible. Without this specialisation it would not be possible to apply advanced techniques and the many distinct functions provided by healthcare. Due to this specialisation and division of labour, the need for cross-sector information in health care is growing.

Across Europe, health care is also changing from that of service ‘islands’ to integrated services and from having a local character to being regional and even international. New service models like “seamless care”, “shared care”, “tailored care”, “integrated care” “mobile care”, “home hospitals” and “customer-centred care” all contain the same basic notion: that of the patient at the centre of a network of service providers, forming “pathways of care” as he moves between institutions and care providers. Such models all require access to patients’ health histories from any place.

In emergency situations, basic information may be vitally important in administering immediate care. Such information may save both time and costs and can result in more appropriate treatment. In some cases it may even save lives. It is crucial for the delivery of an effective, efficient, quality service with the objective of putting the citizens’ needs at the top of the agenda. In an ideal world, a citizen requiring urgent medical attention whilst away from home (including temporary trips abroad) would be confident that the clinicians treating them would have fast and secure access to all relevant information from their medical record in order to facilitate treatment. This would be immediately accessible over secure networks using agreed standards and protocols and by communicating with their usual treatment providers in a language understandable for both the patient and the professionals. The appropriate care could be provided quickly and effectively and necessary follow-up arrangements agreed for when the person returns home.

This co-operation and division of labour is not new to healthcare. What is new is that for the first time it will be possible to have real-time access to relevant health information stored in electronic form by other health care providers. In the future it is also perceived that ehealth services will be extended outside the limits of the healthcare institutions, giving citizens better access to health information or services from their home or other locations.

The reality is that within Europe none of this is yet possible. Much material was provided to the Health Telematics Working Group by Member States describing their overall ICT strategies and also providing some information on the extent to
which ICT tools and applications were used in health delivery at national level. A wide range of potential applications of information and communications technologies are now available in the health, particularly the health care, field and they have been implemented to varying degrees within Member States. These include patient management and scheduling systems in hospitals and primary care practices, pharmacy systems, accident and emergency systems, inventory management, advanced imaging and multimedia data handling systems, especially digital radiology.

Generally, however, only a small proportion of GPs keep the full clinical record electronically, although this situation is changing rapidly in response to national regulatory policies which may, for example, require the physician to submit claims electronically. Furthermore, the “stand-alone” clinical systems that store patient data, even though they may support access to the Internet, do not share or communicate information and cannot support collaborative work and seamless care involving data transfer, messaging and archiving. There is no easy way of identifying the citizen’s physician, nor aspects of their medical history, nor current medical conditions or medication which ought to be taken into account in determining current treatment. There is not even any guarantee that medication prescribed in one Member State can be easily identified in another.

In practice, therefore, communication between different healthcare providers is too often still done manually due to basic non-interoperability of the many systems in place. Information is communicated using mail, phone, fax or carried by the patient and the bulk of information is printed out from one information technology system, mailed and finally re-keyed into another IT system used in another institution. Chronically ill patients often have to tell their medical history over and over again. This form of communication is expensive, takes time and gives rise to failures because of errors, inaccuracies and incomplete availability or loss of medical information.

3.1. The Electronic Health Record (EHR) - archiving and legal rules

The cornerstone of a system for sharing information about patients between care providers is the electronic health record (EHR). The method for documenting patients’ health history and episodes of illness varies from country to country. Typically there is within a single institution a structured record including both clinical and administrative data. The data content of the electronic health record (EHR) is regulated and often reflects the organisational structure of the health care service system. There may also be regulations governing longitudinal patient health documentation. This health documentation can be episode-based or even cumulative within a service provider or region.

The information contained in the EHR is typically used within a single organisation for the purpose of planning and delivering care. EHR systems currently in use have limited communication capabilities. There are also legal barrier to the access and transfer of, patient information between different health care organisations. However, there already exist today
technologies which provide the ability to network the distributed EHR in a secure way. The principal benefit of the networked EHR is the possibility it provides for 24-hour access to a comprehensive set of patient health information. The result could be a regional or nation-wide virtual patient record, which is a basic building block for the modern, tailored care procedures described above.

3.2. **Electronic Prescribing and Medication Management**

Stand alone computerised systems already have the capability of producing a prescription electronically, but the benefits can only be achieved on a large scale through the creation of advanced systems of drug prescribing and prescription transfers. Medication management and electronic prescribing improve both the production of the medical prescription itself and the processing of the accompanying data. They link drug information systems with the electronic health record, thereby enabling the decision on therapy to be better informed. Unwanted interactions can be controlled and individual incompatibilities taken into account.

Simultaneously, the electronic prescription facilitates more efficient and faster communication between physicians, pharmacists, and health insurance funds. The pharmacist can link the prescription data with data from product databases in order to advise patients. The social insurance funds can simplify and accelerate the accounting procedure with the electronic prescription.

These systems are also have the capacity to generate population-level information relating diagnoses to treatments and describing utilisation of medicines at national level.

4. **ADDRESSING THE PROBLEMS OF SHARING DATA**

4.1. **Key Issues**

As described above, many, if not most, IT systems currently used in health systems are stand-alone, developed by a multitude of suppliers and are incompatible with one other. This *non-interoperability of IT systems* represents perhaps the biggest single problem in transferring data securely between different parts of the healthcare system. It is a problem to be found not just across national borders, but between regions and even localities.

Interoperability is not just about getting the right technologies in place. For example, no technology can directly provide an organization with the ability to ensure uniform use of interoperability standards. Effective use of interoperability technologies cannot be fully separated from policies for using and administering sharable resources. After all, a technology that enables sharing of data, software, parts, or people will be of little benefit if the policies (or lack of policies) that control those resources makes such sharing difficult or impossible. There is no easy answer to this problem.. Collaborative action at European level would reduce the risks and favour the effective realization of potential solutions.
There are a number of policy issues which have to be addressed before networked information can be delivered.

### 4.1.1. Trust and confidentiality in an e-health environment

Many privacy and confidentiality issues remain to be resolved. The data content of an EHR is of the utmost sensitivity. Therefore issues concerning both the ownership of, and the rules for managing, the data contained in the EHR are issues that demand clear policies.

Because a person’s health information is sensitive, its utilisation is strongly regulated in all European countries. This means that information may not be made available or disclosed to unauthorised individuals, entities or processes. The way in which personal data may be processed in the EU across the whole range of Information Society Services such as electronic communications are set out in Directive 95/46/EC on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Directive 97/66/EC concerning the processing of Personal Data and the Protection of privacy in the Telecommunications Sector. The objective of Directive 95/46/EC is to harmonise data protection legislation in the Member States, which currently varies significantly, in order to facilitate the free movement of goods, services and people, thereby removing the possibility of one Member State objecting to the transfer of personal data to another because of differing standards of data protection. As its title suggests, the Directive is a framework directive, setting standards of data protection for all sectors where personal data are processed. In addition, articles 7 and 8 of the Charter of Fundamental Rights of the European Union also provide for the protection of the rights to privacy and data protection.

Another problem is that patients still do not have easy access to their own health record. Tools enabling a more active role for citizens to follow their own health-related documents – including patient health cards - would allow them to have a more active involvement in their own health promotion and, in addition, would increase their ability to influence the medical decision-making concerning their own lives and health.

### 4.1.2. Components in Security Systems

The need for technological security when data is transmitted electronically is clearly inseparable from legal data confidentiality requirements. The unprotected electronic transmission of personal patient data via open networks like the Internet has been rejected in the European Union. Instead, hard cryptography (highly secure encryption procedures) has been deemed a necessary element of an adequate security infrastructure for the electronic transmission of health data. To make the shared access and use of patient health information possible a secure platform is needed, incorporating the use of qualified electronic signatures and asymmetric encryption. The PKI (Public Key Infrastructure) platform is a general solution for e-health services in an otherwise insecure environment such as the Internet.
PKI is a blend of technology, policy and administrative procedures to enable the secure exchange of sensitive data in an insecure environment by using diverse components like TTP ((Trusted Third Party - see below) which would offer services to prove the identity, roles, functions and respective responsibilities of each partner. The foundation for any solid PKI architecture is a security policy that all partners can accept. Authentication, encryption, digital signature and certificates are core services of the PKI platform. In a health care environment the PKI is also used to ensure data integrity and the identification of the origin of the data as well as for managing consent. PKI is also needed for secure long term digital archiving. Because authentication in health care is role-based, that is attaches to a type of professional, the PKI system has been able to manage diverse situations related to the same person in both their professional and work-based roles.

Many European states are currently planning or installing secure PKI-based infrastructures for health care (e.g. UK, Finland, Sweden, France, Norway, Hungary and the Netherlands). ISO TC 215 has published a health care PKI standard in autumn 2001. However, there are also other different data security systems across Europe, reflecting different national legislation, although all rely on the concept of encryption techniques based on asymmetric algorithms (as in the field of banking) and involving public key infrastructures (PKI) in which there is a public and private key, the public key being held by a Trusted Third Party (TTP). In order to operate a TTP system in Europe, there would need to be political agreement about who would be the TTP, and how long the key could be. Very long keys are favoured by some Member States (the longer the key the more secure the encryption) but are not allowed in others (nor in the US). Or at least, there would need to be cross-border consensus and recognition of a security policy between the MS, with respect for mutual rights and duties.

4.1.3 Identifying the Patient, the Professional and the health care organisation as well as other service providers

An important aspect of security concerns authorisation for who can access what in the medical record. Currently across Europe legislation about what patients can see is not consistent, whilst under the Data Protection Directive it should in theory be possible for patients to see their whole record.

Different professionals will have different access rights and requirements. Access rights can be checked with the help of the Public Key. The certification service of this infrastructure verifies the identity of an other entity/person (authentication). The electronic signature function is a key feature of a PKI which makes it possible different functionalities such as: safeguarding data integrity and assuring the non-repudiation of a message by its authenticated sender. The confidentiality of data can be protected through encryption.

The recent Directive on a Community Framework for Electronic Signatures (99/93/EC) defines the requirements for electronic signature certificates and certification services so as to ensure minimum levels of security and allow their free movement throughout the EU. Of particular importance in the health field, the Directive stipulates that an electronic signature cannot be
legally discriminated against solely on the grounds that it is in electronic form. If a certificate and the service provider as well as the signature product used meet the specific requirements set out in the Directive, there will be an automatic assumption that any resulting electronic signatures are as valid legally as a hand-written signature.

Another alternative is to use another type of identification card, such as a driving licence or passport linking a person to a Master Person Index (MPI). Yet another option is biometric identification in which hand, face, finger, retina or other unique human parts are scanned in order to identify a person. In both these cases, however, some countries may actually not want a patient identifier that links the patient to systems other than the health care system.

4.1.4 The data set: what to include? How to organise it?

As will be evident from the above discussion, there exist very many different models of what data is exchanged, ranging from purely administrative data to a small sub-set of the full medical record (e.g. for the exchange of information about specific conditions like diabetes, pregnancy, immunisation record, emergency health data) to the full medical record (which will include imaging, medication, laboratory results, etc.). In order for there to be a full exchange of data between Member States there must be agreement about what data is to be exchanged and in what format. For example, communication would be facilitated by “intermediation services” which would automatically and transparently offer for users, translation or transcodification between different kinds of data representation or coding (for example, cross-identification, recognition, mutual acceptance of a confidentiality policy, transcoding between ICD 10 and SNOMED coding systems) in order to realise a real interchange between heterogeneous systems.

4.1.5 Nomenclature: how to codify the data

There needs to be a standardised terminology by which to code diseases and clinical interventions. There are diverse coding systems in operation, which have different purposes and are intended for use by different types of health care professionals. Two of the best known are ICD 10 (the WHO international, standardized, diagnosis-oriented codification for specialist medical doctors) and SNOMED CT (a syndrome-oriented classification for GPs). However, there is as yet no international or European body for the standardisation of coding systems for medical procedures.

How the health data is organised and encoded also affects how flexibly it can be used, storage capacity and the ability to represent the information in different languages.
4.2. Possible Solutions

4.2.1. Technological possibilities

An interoperability technology is an integrated, automated set of capabilities that makes it easier to share resources. The shared resources are usually data, but interoperability technologies may also promote the sharing of software, physical components, or even people. Solutions to interoperability challenges, are being defined and adopted by International Standard Organizations. There are a number of emerging interoperability technologies to support the migration from monolithic ad-hoc ICT architectures to an open environment. These new technologies have some risks (they may not fully deployed) but high potential (full deployment may greatly increase benefits to all users). Information-related emerging interoperability technologies include: high-portability programming languages; Java; Jini; JavaBeans and InfoBus; EJB (Enterprise Java Beans); Microsoft COM (Common Object Model); DCOM (Distributed Component Object Model) and COM+; Microsoft SOAP (Simple Object Access Protocol); WAP (Wireless Application Protocol); CORBA (Common Object Request Broker Architecture); Java RMI (Remote Method Invocation); XML (eXtensible Markup Language); COE (Common Operating Environment); and Linux.

One possibility for data transfer/access to data is the use of health cards, which can themselves be used as stand-alone carriers of health data, or as identification cards. However, it is now widely accepted that health cards alone can only ever offer a partial solution. The best option may be a combination of cards providing the means of accessing electronic networks for the secure transfer of clinical and patient administrative data – for which the Internet offers important possibilities. On this scenario the card would carry identification details and limited health data, and also provide the access key to the Electronic Health Record, wherever it may be stored.

Whichever system is chosen, a key prerequisite is clearly that there should be functional interoperability, or at least documented standardized interfaces (on content, structures formats and codifications) between all the hardware and software systems in use by healthcare professionals (primary care workers), organisations (hospitals, etc.), funding and other administrative bodies.

4.2.2. Open Source

Open source is copyright software with a source code, a licence to use for any purpose, a licence to modify for own use, a licence to redistribute and sell and a licence (sometimes a requirement) to redistribute the modified source. This type of software therefore gives licence holders the opportunity to modify the software to render it compatible with other systems in use. Its use, therefore, promotes standardisation and interoperability.
4.2.3. Telemedicine

Telemedicine refers to the use of electronic communication and information technologies, including diagnostic and treatment tools, to provide or support medical care at a distance. It cannot and should not replace traditional patient-professional contacts because face-to-face interpersonal contact between the health professional and the client has supportive properties that can be important for successful care. As a supplement to traditional patterns of care delivery, it encompasses a wide range of applications from co-operative work of professionals sharing medical expertise, to home care systems. Thus, it can be used in hospital settings, to create networks of specialists and to improve access by primary care practitioners to specialists so as to improve the quality of diagnostics and treatment. It is also being used to improve access to medical care in nursing and care for the elderly. And experiments are underway to investigate the viability of using telecare to improve patients and relatives’ access to medical knowledge and information about health care.

In the past, telemedicine has been confined to “point-to-point” technology-driven projects. Increasingly, however, telemedicine is being seen as a multi-disciplinary, multi-networking tool, to be deployed in response to users’ needs, and oriented not just to improving access to individual care providers and institutions, but also for enhancing the continuity and quality of care throughout the health care systems by means of its capacity to interface with other networking technologies. Some Member States (Sweden is one example) have now developed telemedicine strategies and integrated these into their ICT strategies. Evaluation on the impact, design and cost-effectiveness of telemedicine and telecare is ongoing, but much work still needs to be done.

At national level, specific legislation, as well as the law of contract and the law of negligence (tort/derelict) will govern the relationship between a practitioner and patient so that the patient can claim compensation when injured as a result of a telemedical treatment. There are, however, legal and regulatory barriers to implementing trans-European telemedicine activities, including issues about licensing, liability for malpractice, and procedures for reimbursement. In particular, there is at present, no European-level legislation which directly addresses the liability of the telemedicine practitioner, although Directives in the area of product liability (Directive 85/374/EEC) and medical devices (Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices and Directive 98/79/EC on in vitro diagnostic medical devices) may also be important.

4.2.4. Regional Networks

The development of regional networks represent one limited solution to the problem of interoperability of IT systems. Even within highly devolved health care systems, specialised healthcare is planned on a the basis of sub-sectors of the population of between half a million and five million, depending on the level of specialisation involved (for example secondary or
tertiary care). Since the beginning of the nineties, there have been national and European research and development activities on regional health care networks, a few at the beginning of the decade, and several more recent years. These activities have resulted in pilot projects and operational regional health care networks in several European regions, all quite different in scale, and each providing different services (from simple messaging to shared electronic health care records). In the last part of the decade, many European countries have started building Regional Health Care Networks using different types of technology, and a broader approach mainly around shared patient records supporting continuity of care.

Besides these national developments, the European Commission has been supporting the developments of regional health telematics networks. In the 4th R & D Framework Programme (running 1994-98), six projects have been working on building Regional Health Care Networks. These activities have been continued in the 5th Framework Programme. All these regional, national and European projects and programmes have to a large degree developed bespoke (i.e. specifically developed) regional health care services for local use, in the same way as was done for IT solutions to hospitals and laboratories in the beginning of the seventies. By using standardized information transfer schemes, interoperability of the transmission can now be assured. There is, however, a need to assess, compare and interconnect some relevant regional health care networks all around Europe and to consider and follow-up the cross border projects in order to expand the networks and increase the continuity of care which they can provide.

4.2.5. Standardisation activities and organisations

There are various national and international bodies active in the area of health telematics standards at international level of which the main ones are the CEN (Comité Européen de Normalisation) with TC 251, and the International Standards Organisation (ISO). Another body which is internationally active in the field of standardisation for health informatics is the US-based HL (Health Level) 7.

Since August 1998, the standardization of “Health Informatics” has been done by the ISO TC 215 and its five working groups (Working Group 5 on “Health Cards” was set up in April 1999). CEN and ISO are now formally co-operating with one another in the field of health telematics. HL7 is now recognised as an important part of the de facto standardisation organisation for health informatics.

There has been much activity in the standards arena, but for a number of reasons this has so far failed to meet the needs:

- there needs to be a process for prioritising work on standards and for establishing a formal link between those responsible for health policy either at the Commission or in Member States, and those responsible for the development of standards;
• there is no real linkage between research activities and standardisation work. The European Commission has funded a large number of research projects through the Framework Programme, but there is no mechanism by which the outcomes from these projects are formally assessed with a view to producing standards for use across Europe.

• the current process for agreeing standards needs to be speeded up. Many of the CEN standards have taken a number of years to be delivered.

• many standards are not in a form that can easily be implemented and some are considered to be irrelevant. This may be because they are too abstract (and hence need added work on implementation guidelines before they can be used). Suppliers need to be more involved, and hence able to inform the standards process with a view of what is pragmatic and feasible.

• there appear to be huge difficulties in implementing internationally-agreed standards. Once a standard has been agreed there seem to be few ways in which national authorities can ensure that these standards are used. This leads to confusion and frustration amongst users and suppliers.

There needs to be concerted action to address common standards, particularly in the development of interfaces between rival and incompatible systems. This area would benefit from further study.

**Summary**

In conclusion, therefore, there are many issues to be addressed before the available technologies can be harnessed effectively. It is crucial to ensure that systems of the future are sufficiently secure to deliver the data protection rights of individuals and professionals. There is a need to obtain agreement to, and deployment of, widely accepted technical standards. These are significant challenges to be overcome. They will require careful planning and will be facilitated by a high level of international co-operation and agreement.

5. HEALTH TELEMATICS IN THE EU

5.1. European versus national competences

Article 152 of the Amsterdam Treaty stipulates that:

"Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care." Because of this legal constraint, there have been no EU initiatives to date to develop specific legislation concerning health systems delivery in the Community. Thus, the implementation of IT in health systems lies principally within the legal competence of Members States, subject to the EU legislation described above. All European level initiatives are currently expressed in non-binding terms.
The same article also gives the following mandates "A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities. Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health … by promoting …health information and education". This, on the other hand, gives the community a mandate which none of the health authorities of the member states have.

5.2. The New Public Health Programme

It is expected that the new action programme on public health, which comes into operation on 1 January 2003, will provide a new basis for the implementation of this key role of the Community, including its proposals to develop a Health Knowledge and Information System. Collaboration between relevant authorities of Member State, inclusion of the civil society, co-ordination by a Community level expert body and use of new technologies will create new opportunities for the implementation of this task. In particular, the initiative on the public health portal will provide a flexible IT platform that can be used to launch various health information projects, including advice on health issues, health data publishing, health information storing and sharing of experience. The portal will bring relevant EU Public Health Information Network (Euphin) components together in a user-friendly way, taking into account all security needs of different components.

The Health Telematics Working Group also considers that it will be important to progress ongoing work on international health management information networks, to include:

- organ exchange
- communicable diseases
- poisons network
- blood donation

liasing with other European database initiatives as appropriate.

5.3. DG Information Society Research Projects

The new public health programme makes several specific references to the importance of exploiting information technologies in health and health care for the benefit of citizens, liasing closely with the eEurope programmes of action (Recitals 26,27) and proposes joint strategies, joint actions and links as appropriate, with all other relevant Community programmes (Article 4). The work of DG Information Society, in promoting research into health telematics applications through the EU’s Research Framework Programmes has been of particular importance. A consistent effort is now required to ensure that the results of projects already completed under those programmes
are implemented where relevant to the development of the Community’s Health Information System. Furthermore, DG Information Society research activities and priorities should in future be more closely informed by health policy objectives and priorities as the present emphasis of the Framework Programmes on technological innovation diminishes the possibility for research into the development of innovations in health care by the use of ICT. There is a particular need to develop methodologies for the rigorous appraisal of cost-effectiveness of potential health telematics applications.

5.4. eHealth 2002

The European Council held in Lisbon in March 2000 set the ambitious objective for Europe to become the most competitive and dynamic economy in the world. It recognised an urgent need for Europe to quickly exploit the opportunities of the new economy and in particular the Internet. In response, the eEurope Action Plan of 2002, which the Feira Council adopted in June 2000, was drawn up using an open method of co-ordination and based on the benchmarking of national initiatives. The eHealth chapter urged Member States to develop an infrastructure of user-friendly, validated and interoperable systems for health education, disease prevention and medical care and set out the following specific actions, some of which were to be undertaken by Member States and some by the European Commission:

- Ensure that primary and secondary healthcare providers have health telematics infrastructure in place, including regional networks
- Identify best practices in electronic health services in Europe
- Publish a Communication on Quality Criteria for health related websites
- Publish a paper on Legal Issues in eHealth
- Establish health technology and data assessment networks

Most of the Member States already support these activities

5.5. eHealth 2005

An extension of eEurope 2002 has now been agreed at the Sevilla Summit of 2002. The eEurope 2005 Action Plan contains the following proposals for the health sector:

- supporting a common approach to patient identifiers and electronic health record architecture through standardisation and supporting the exchange of good practices on possible additional functionalities, such as emergency medical data and secure access to personal health information.
- Member States to develop health information networks between points of care with broadband connectivity where relevant
• Commission to set up European-wide information networks of public health data and co-ordinate actions for Europe wide rapid reactions to health threats

Commission and MS to ensure that online health services are provided to citizens (eg information on health living and illness prevention, electronic health records, teleconsultation, e-reimbursement). Commission to monitor actions taken by MS to make health information as accessible as possible to citizens as well as initiatives to implement quality criteria for web sites.

5.5.1. Recent case law of the European Court of Justice and coordination of social security

Recent rulings of the European Court of Justice concerning patients’ rights to reimbursement for health care obtained without prior approval in other Member States have highlighted the importance of guaranteeing appropriate treatment and continuity of publicly-funded health care systems across borders. Increased movement of citizens within the Community, giving rise to more treatments being provided to patients other than by their own Member State will also create a need for a new type of information exchange for the purpose of reimbursement and patient care.

The Commission is already sponsoring cross-border health projects in EU border regions under the Interreg Programme. In these projects, administrative barriers to cross-border trade in health care have been deliberately lowered to encourage patients to use health care facilities abroad, particularly where there is a common language and culture, and/or where facilities across the border are nearer than in the Member States of the insured patient. One Euregio project already incorporates a health telematics pilot project. Others could be deployed in the future using the concept of regional networks, described above.

EU regulations 1408/71 allow for reimbursement of the costs of cross-border care for migrant workers (E106), where emergency care is required in the course of tourist or short term business trips (E111) and where applications are approved by member States for elective care abroad (E112). A system for reciprocal reimbursement of costs incurred by Member States when treating patients from abroad is operated through the Administrative Commission for Social Security for Migrant Workers. Electronic means to support and to speed up this reimbursement process should be considered.

The Barcelona Council of March 2002 endorsed a proposal to launch a new European insurance card to replace the paper E-forms by means of which authorisation for health care between EU Member States is given. These forms are used for the purpose of transferring information between Member States about the status of the assured person. Details of the scheme have yet to be decided, but various technologies are being considered. The mandate delivered by the Barcelona Council does not extend to the integration of health information in the new insurance card.

In fact, projects related to the usage of chip cards and smart cards in the healthcare sector have a long history in the policy of the European
Institutions and Member States. In the recent study “A European Health Card”, which was commissioned by the Scientific and Technological Options Assessment (STOA) Programme of the European Parliament there is documentation of related activities dating back to 1981. Thus the recent study is part of some long-standing political commitment to this issue. The concept of a European Health Card might vary from that of one card to many, interoperable and standards-based cards, including national information around a core European dataset (administrative data concerning eligibility and medical data such as a European emergency data set). Such a concept would be in line with the Barcelona summit decisions and with the vision of eEurope 2005.

In addition, within the eEurope Action Plan 2002, a series of “trailblazer” projects was established to contribute to the European-wide operability of smartcards. Trailblazer 11 is concerned with the European-wide interoperability of healthcare cards. This applies to patient data cards as well as to professional cards and their usage in networks. It covers administrative as well as clinical data.

The Working Group believes that the initiative to introduce card-based E-forms represents an opportunity to launch discussions on how to reengineer the existing system of authorisation for the benefit of citizens and patients and has particular concerns about the current proposals:

- There is now extensive historical debate and research into the use of card technologies as a means of identifying patients, and/or storing personal and medical data and/or keying into an electronic health record held at a distance from the patient.

- Replacement of the E-forms, by itself adds no obvious benefit to the existing system of authorisation of cross-border health care. As studies have shown, additional quality improvements in health care, and substantial cost savings, can be expected if medical data are also communicated or can be accessed

- at the time of drafting this report, Member States were being consulted on the current initiative principally through the forum of the Administrative Commission on Social Security for Migrant Workers, at which they are mostly represented by social security departments. The health policy aspects of this initiative are too important for it to be debated by such a narrow constituency and the Commission should help to widen the debate by involving health departments as well, for example through the involvement of the Council Working Group on Health.

Cross-border treatment and medical care of patients travelling in other member states can be hampered by inaccessible personal medical information. It is a long term challenge for the Member States to define and implement a legal, ethical, technical and even linguistic framework which fulfils the operational and security requirements of all healthcare systems, including the need for an interoperable PKI-architecture so as to provide the means to link to the Electronic Health Record of a person, thereby giving access to emergency data, covering e.g.
- blood group
- allergies
- donor status
- contact information to next of kin and personal doctor

Current medication, however relevant, should only be put on a health card at a later stage, pending resolution of the as-yet-unresolved problems of the responsibility and accountability for maintaining the information up to date. The other items identified above could be included in a card as they contain more stable information.

If conditions in a Member State do not currently permit the introduction of a state-of-the-art health card, a step-by-step procedure might be foreseen, starting with the replacement of the E-forms and adding higher functionalities later. This should be a first step towards the introduction of a fuller electronic health card and should be done in such a way that will enable its extension rather than requiring the total replacement of a solution of limited scope.

6. NEXT STEPS AND POSSIBLE FUTURE CO-ORDINATION MECHANISMS

6.1 The Tasks Ahead

We live in an exciting era where ICT can potentially be harnessed to achieve many of the requirements of modern health care systems which could only have been dreamed of in the past. We are all aware of the way in which the Internet and satellite technologies, for example, have changed the everyday lives of many people over the past few years. These and other available technologies also have the potential to modernise, indeed perhaps even revolutionise, the manner in which health is promoted. However, as described above, there are many issues to be addressed before these technologies can be harnessed effectively. The Working Group has defined three specific areas of future work.

6.1.1 Continuation of European-level initiatives where the Community has an existing mandate or could deliver results which it would be difficult to achieve by Member States acting alone

The opening sections of this report noted a number of diverse fields of information gathering and dissemination relevant to this objective.

*Information for citizens and patients* is a field where the Community is already active. The recently-adopted Communication on Quality Criteria for Health-related web sites should provide a basis for further debate with and between Member States about the possible implementation of community seals of approval for health-related
web sites, as foreseen in both eEurope 2005 and the Community's new action programme in the field of public health. The development and dissemination of information and analyses for citizens and patients is also foreseen under the proposals for an Information and Knowledge system under the new public health programme and will be furthered in part by means of the development of health portals by DG SANCO, and by DG INFSO in the context of the development of the second generation Europa web sites. There are, finally, a number of projects supported by DG INFSO under the Research Framework Programmes in support of information to patients whose implementation should be undertaken as part of the work of the new public health programme.

As described above, the collation of high quality, timely, comparable Health Information, particularly population-level, health-related information, is a central objective of the Information Strand of the new public health programme. This will be done drawing on work already undertaken under the former Health Monitoring programme, and coordinating with international work in this field, including that undertaken by the WHO, OECD and EUROSTAT, to mention just three international databases. The principal sources of such data at national level are health information surveys, registry data and hospital data.

By contrast, the development of systems for storing and networking Personal Health Data is a Member States’ competence. There is an important synergy between the two, however, since the electronic health record is a potentially invaluable source of population-level data on health services, as well as on treatment (including prescribing) patterns. Several Member States have recently reported their experience in developing pilot projects experimenting with the collection of data using the EHR as a source.

6.1.2 The need to work together at European and international level to achieve interoperable and secure ICT systems within health

Preceding sections of this report have identified a number of policy issues which need to be addressed at national level in support of interoperable ICT systems supporting the networking of information which is essential for optimal models of health care delivery. These relate to decisions implementing patient identification, security of confidential data and the Electronic Health Record with a common data set and coding systems. An appropriate forum needs to be developed in which to take these issues forward.

In addition, this report has referred to a number of legal issues which impinge on important aspects of eHealth. These are to be explored more fully in the Legal Issues Working Paper which is being prepared under the eHealth 2002 Action Plan. They relate in particular to the ownership, security and confidentiality of personal health data and to the use of electronic signatures.

The Working Group has noted areas where further work on legal aspects of eHealth is required. One is in the development of a legal framework for establishing liability
in the case of cross-border practice of medicine and, in particular, the use of telemedicine.

The Working Group has also noted two important legal issues regarding standardisation in health telematics. One relates to the legal status of the (pre)standards of CEN/TC 251 and ISO/TC 215 and whether they fall under Council Decision 87/95/EEC of 22 December 1986. The second question is whether health telematics could be governed by a New Approach Directive, whereby essential requirements are laid down in EU directives and CEN then asked to develop standards (so-called harmonised standards) which meet those essential requirements. If so, the so-called New Approach policy on standardisation could be a useful tool for increasing interoperability in health telematics. The European Commission is invited to comment further on these two points.

6.1.3 The need for a forum in which Member States can meet and exchange experience in implementing ICT strategies in national health care systems

EU Member States’ health systems are facing similar challenges and mostly share common IT objectives, even though the organisation of their health systems differs. It is clear that they are adopting common solutions and developing similar strategies. Themes such as the implementation of a unique patient identifier, electronic health record, the development of regional networks and support for increased use of telemedicine featured regularly in round table country updates during the Working Group’s discussions. Decision support systems and continuous medical education for health care professionals is also an area to be covered by the new public health programme and supported by DG INFSO under the 6th Framework Programme, which also envisages the development of clinical risk management tools.

The opportunity to have these cross-country experiences in the various specific domains described above is invaluable. This report proposes that the creation of a forum or platform for the exchange of information and practices would be extremely advantageous in the area of health telematics where national administrations are all grappling with similar problems at local level.

6.2. Possible Coordination Mechanisms

It will be clear from the above discussion that the implementation of telematics in health care is principally an issue for Member States, and second that no single Directorate General in the Commission, or other EU-level institution, has overall responsibility for health telematics at EU level, which in consequence is scattered between a variety of players, giving rise to problems of duplication, potential inconsistency and lack of overall strategic direction. Given this mix of competencies, responsibilities, initiatives and players, the Working Group has also considered, therefore, how the process of policy debate and recommendation could be streamlined in the future. It has identified a need for new organisational solutions to the problem of co-ordination. Some potential activities are complementary.
(1) Develop health telematics at European level with priority given to public health and information systems and other initiatives within European competence by establishing a Health Telematics Unit in the Public Health Directorate. As foreseen in the Decision on the new public health programme, this would require extensive coordination with the eEurope initiatives. There are further synergies, described above, between the ongoing activities of DG INFSO under the 6th Framework Programme and the information objectives of the new Public Health Programme. These should be reflected in an organisational structure which supports the further development of cooperation between these two Directorates General and which, moreover, ensures that health policy concerns underpin the selection of research projects under the INFSO programmes.

(2) An alternative solution would be to set up a mechanism similar to the working parties proposed in the Public Health Work Programme for 2003 in the area of operating the information system.

(3) The Working Group notes the proposal in the 2003 Work Programme for DG Sanco to initiate a newsletter for the exchange of information and experience.

(4) It would also be possible to use the policy group A1 of European Health Telematics Association (EHTEL) as a body for stimulating discussion between health care authorities representatives in order to facilitate consensus between all actors concerned with health telematics in the delivery of care, and to help the Commission to follow-up in this domain.

2 See Footnote 1 above