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Study on Legal Framework of
Interoperable eHealth in Europe

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Study on Legal Framework of Interoperable eHealth in Europe

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1 Documents

1.1 Applicable Documents

[AD1]	Services Contract 30-CE-0162056/00-04

1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
[RD3]	Recommendation of the Commission on eHealth interoperability, http://ec.europa.eu/information_society/activities/health/docs/policy/200807_02-interop_recom.pdf
[RD4]	Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, http://www.euro.who.int/observatory/Hits/TopPage
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, http://www.euro.who.int/observatory/Publications/20060522_4
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: http://ec.europa.eu/information_society/europe/i2010/docs/benchmarking/

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	<p>gp_survey_final_report.pdf, Country profiles: http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm</p>
[RD9]	<p>Communication from the European Commission, “A Community framework on the application of patients' rights in cross-border healthcare”, 2 July, 2008, http://ec.europa.eu/health-eu/doc/com2008415_en.pdf</p>
[RD10]	<p>Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, http://ec.europa.eu/health-eu/doc/com2008414_en.pdf</p>
[RD11]	<p>European Commission, IDABC, eID interoperability for public government services (with country profiles): http://ec.europa.eu/idabc/en/document/6484/5938</p>
[RD12]	<p>European Commission, IDABC, eSig-Web (Electronic signatures applications in public government services – country overviews): http://ec.europa.eu/idabc/en/chapter/6000</p>
[RD13]	<p>Legally eHealth, Study on Legal and Regulatory Aspects of eHealth, http://www.ehma.org/projects/default.asp?NCID=140</p>
[RD14]	<p>Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML</p>
[RD15]	<p>Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf</p>
[RD16]	<p>International Encyclopedia of Medical Law (editor: Herman Nys), http://www.ielaws.com/medical.htm, (with country monographs)</p>

2 Glossary

2.1 Definitions

In the course of this Study, a number of key notions are frequently referred to. To avoid any ambiguity, the following definitions apply to these notions and should also be used by the correspondents.

- **Authorization:** refers to:
 - the permission of an authenticated entity (e.g. a person) to perform a defined action or to access a defined resource/service
 - or: the process of determining, by evaluation of applicable permissions, whether an authenticated entity is allowed to perform a defined action or has access to a defined resource.
- **Data authentication:** information provided for verification, with more or lesser degrees of certainty, of the origin and the integrity of data.
- **eHealth:** a very broad term that encompasses many different activities related to the use of the information and communication technology (ICT) for healthcare. Many of these activities focus on administrative functions such as claims processing or records storage. However, there is an increasing use of e-health related to patient and clinical care.
- **Electronic health record:** a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes;
- **Electronic signature:** data in electronic form which are attached or logically associated with other electronic data and which serve as a method of data authentication.
- **ePrescription:** a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC47, issued and transmitted electronically
- **Healthcare:** the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions. Health care embraces all the goods and services designed for people's health, including preventive, curative and palliative infections, whether directed to individuals or to populations.
- **Health professional:** a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on

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the recognition of professional qualifications or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC.

- **Identification:** using claimed or observed attributes of an entity (e.g. a person) to distinguish the entity in a given context from other entities it interacts with (= entity authentication).
- **Identifier:** attribute or set of attributes of an entity (e.g. a person) which uniquely identifies the entity in a given context.
- **Identity management:** Identity management (ID management) is a broad administrative area that deals with identifying entities in a system (such as a country, a network, or an enterprise) and controlling their access to resources within that system by associating user rights and restrictions with the established identity.
- **Patient:** any natural person who receives or wishes to receive health care in a Member State;
- **Patient summary:** subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription;
- **Registration:** process in which a partial identity is assigned to an entity and the entity is granted a means by which it can be authenticated in the future.
- **Telemedicine:** exchange of medical information from one site to another via electronic communications with the purpose to improve patients' health status.

2.2 Acronyms

CBSS	Crossroads Bank for Social Security
EHR	Electronic Health Record
eID	Electronic Identity
eIDM	Electronic Identity Management
FINEID	Finnish Electronic Identification
FINUID	Finnish Electronic Unique Identifier
GP	General Practitioner
HiT	Health in Transition
KANTA	Finnish National Healthcare Data Archive

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KELA	The Social Insurance Institution of Finland
OCSP	Online Certificate Status Protocol
PKI	Public Key Infrastructure
NRN	National Register Number
SIS	Social (security) Information System
SSCD	Secure Signature Creation Device
SSIN	Social Security Identification Number
TEO	Finnish Authority for Medico-Legal Affairs
TTP	Trusted Third Party
TUPAS	Finnish Bank Association PIN/TAN Authentication Scheme

3 Introduction

3.1 General overview of the Finnish healthcare system

A comprehensive (2002) overview of the Finnish healthcare system can be found in the Finnish HiT country report published by the European Observatory on Health Systems and Policies (written by Jutta Järvelin). <http://www.euro.who.int/Document/e74071.pdf> (102 p.)

An updated (2004) general overview of the Finnish healthcare system is published by the Finnish Ministry of Social Affairs and Health:

<http://www.stm.fi/Resource.phx/publishing/store/2004/12/aa1106916032942/passthru.pdf>

From the 2004 Ministry report , we reproduce the following important observations:

Municipalities in Finland have, by law, the main responsibility for arranging basic social and health services. At the beginning of 2008 Finland counts 415 municipalities. Primary health care is provided by health centres established by a single municipality or jointly by neighbouring municipalities. Municipalities may buy services from other municipalities or from the private sector. Health centre services include medical consultations and provision of dental care, preventive care and environmental health care. Health centres run maternity and child health clinics, and arrange school and occupational health services.

Finland is divided into 20 hospital districts, each providing specialist consultation and care for its population. Local municipal authorities are responsible for funding specialist treatment provided to inhabitants of their areas. Each hospital district has a central hospital with departments for most main specialties. Finland has five university hospitals. These provide the most advanced medical care, including highly specialized surgery and treatment for rare diseases. The university hospitals are also mainly responsible for the clinical training of medical students, and for medical research.

Private medical treatment supplements care provided by municipalities and the state.

Particularly in cities, many doctors, dentists, and physiotherapists offer private care. There are also a few small private hospitals. More than 10% of Finnish doctors earn their living solely as private practitioners. About one third of doctors run a private practice in addition to working in a hospital or health centre.

From the 2002 HiT report , we reproduce the following important observations:

“Central government and the municipalities are the two main players in the organization of health care. Hospital districts, comprising associations of municipalities, are in charge of some management functions in the hospital sector, and constitute critical instruments to overcome the efficiency and equity problems associated with the small scale of the main health care governing bodies, i.e. the municipalities. At the national level, the Ministry of Social Affairs and Health issues framework legislation in health and social care policy and monitors implementation. There are several agencies and institutions attached to the ministry, namely the National Research and Development Centre for Welfare and Health; the National Authority for Medico-legal Affairs; and the National Agency for Medicines. Finland is

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divided in five provinces and the Åland Islands, which promote national and regional objectives of the central administration. They are responsible for the approval of capital investment plans and guide and supervise public specialized and primary health care.”

“Municipalities negotiate annually on the provision of hospital services within their corresponding hospital district, which defines prices. The purchaser-provider split has not fully been introduced in Finland, and therefore hospital districts do not act as classical third-party purchasers. There is an equalization mechanism operating within hospital districts, which spreads the risk of high cost patients between the municipalities included within each district.

Finally, employers sometimes organize their own private plans. This builds on the 1979 Occupational Health Care Act, which obliged employers to provide preventive occupational health care for their employees.”

“The Finnish health care system provides comprehensive coverage to all the resident population and it is mainly tax-financed. Both the state and municipalities have the right to levy taxes. The existence of several public funding sources creates difficulties with coordination so that it seems the public financing system needs to be clarified and simplified. The increase in out-of-pocket payments has led to an increase in the total share of private financing. The role of private health insurance is still relatively insignificant in Finland, and has grown only recently.

“Hospital physicians and most doctors in municipal health centres are salaried employees. They usually have a basic monthly salary and an additional remuneration for being on call or for certificates of health status. Under the personal doctor system, physicians are paid a combination of a basic salary (approx. 60%), a capitation payment (20%), fee-for-service (15%) and local allowances (5%).” This situation has recently changed; companies offer frequently primary care and emergency services. They are chosen by giving out calls for tender, and the personal doctor systems has been getting more and more rare.

“In 1993, the resource allocation system to municipalities which channels state subsidies was reformed so that funds are prospectively set (and paid in advance) and cease to be earmarked. Municipal allocations are calculated mainly according to the number of inhabitants, age structure and morbidity, under a weighted capitation system. As regards capital investments, future prospects point to a gradual reduction of state subsidies (to 25% of the costs from the year 2002 onwards). Municipalities are allowed to borrow money to finance capital investments or for other purposes.

Services are defined and prices calculated in very different ways, hospitals and hospital districts have become increasingly interested in using diagnostic related groups (DRGs) as the basis for billing municipalities.”

“Pharmaceutical products enter the market by permission of the National Agency of Pharmaceuticals. The Pharmaceuticals Pricing Board regulates the prices of those drugs that are reimbursed by the NHI. The majority of drugs are reimbursable. Pharmacies are privately owned but require a licence from the National Agency of Pharmaceuticals.

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3.2 Use of ICT in the Finnish healthcare sector

A recent (2007) status of the use of ICT by *general practitioners* in Finland has been drafted in the framework of the European Pilot Study on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe' (Empirica):

http://ec.europa.eu/information_society/europe/i2010/benchmarking/index_en.htm

From the Finnish country brief, we take over the following key findings:

“In terms of infrastructure Finland is among the top performers as 100% of GP practices are equipped with one or more PCs. This result puts Finland on a par with three other EU countries where a computer availability rate of 100% is attained. The same share, that is 100% of the practices, disposes of an Internet connection. In Finland, broadband represents the most common form of access to the Internet with 93% of GP practices resorting to broadband connections.

The storage of electronic medical patient data is universal in Finland as 100% of the GP practices register at least one type of patient data. Finland scores above the EU27 average use rates not only for some, but for all types of data under observation.

Finland is among the top performers as 100% of GP practices are equipped with one or more PCs. This result puts Finland on a par with three other EU countries where a computer availability rate of 100% is reached.

Electronic patient data storage is universal in Finland as 100% of the GP practices register at least one type of patient data. Lab result, medical history, examinations and results, are stored in 98% of all GP practices. Nearly all practices that use local EHRs also store radiological images (95%), symptoms/ reasons for encounters (96%), medications 96%, vital signs measurement, treatment outcomes (88%) and diagnosis (81%).

Finland scores above the EU27 average use rates for all but one type of data under observation. Even the storage of treatment outcomes and radiological images, which is a lot less common on average (65% and 34% respectively), is made use of in just about all GP practices in Finland. The only other EU27 Member State showing a similar usage pattern is Denmark.

A computer is available in all Finnish GPs, which is the highest score for EU27.

Data transfer via networks concerns not only medical data, but can also be used for administrative purposes, i.e. for data exchanges between the GP practice and reimbursers or other care providers. 21% of the Finnish GPs use networks to exchange administrative patient data with other carers, compared to the average rate of 10% reached in the EU27. Among the 27 EU members, shares differ between 0% (Latvia and Luxembourg) and 72% (Denmark). Finland thus positions itself behind Denmark (72%) and the Netherlands (28%). With a usage rate of 8% for the exchange of administrative patient data with reimbursers, Finland scores below the EU average of 15%.

The only area under observation which is only averagely well developed concerns the exchange of administrative patient data. EPrescribing is not made use of by Finnish GPs.

The National Insurance Agency (KELA) is very well connected and there is an electronic communication between KELA and pharmacies. This does currently not include administrative patient data transfer for GPs, which is in line with the findings of this study. A

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similar situation can be found in relation to ePrescribing: Kela was hosting a pilot database that was shut down and the real database is under construction. First connectors to this will be public GPs and they will start sending ePrescriptions in late 2008 in 2 pilot areas. At the moment the system is in its final testing.) GPs or anybody else are currently not included in this system and accordingly usage rates are low. The pilot system was shut down in end of 2006 so it is no possible to say that “usage rates are low”; there is not system running and so there is no usage at all since it is not technically possible.

For more information, there is also a comprehensive survey on the use of ICT by Finnish hospitals for secondary or tertiary care, primary care health care centres and a sample of private sector service providers, published by the Centre of Excellence for Telehealth at the University of Oulu and the National Research Centre for Welfare and Health (STAKES) in 2007.

<http://www.stakes.fi/verkkojulkaisut/raportit/R1-2007-VERKKO.pdf>

3.3 National eHealth strategy

An overview of the Finnish eHealth policy can be found in the September 2007 ERA Report “eHealth strategy and implementation activities in Finland” (Authors: Persephone Doupi, Päivi Hämäläinen, Pekka Ruotsalainen): <http://www.ehealth-era.org/database/database.html#finland>

For our Study, the following observations, adapted from the ERA report, are important: The Finnish eHealth strategy was first laid down in 1996 and updated in 1998 by putting emphasis on the adoption of digital patient and client records in all levels of healthcare and social services, combined with nationwide interoperability between distributed legacy systems; support of high level security and privacy protection, allowing citizens access to their patient records via the Internet, as well as maintenance of a personal digital health and welfare record; and, improved management of service chains. In 2002 the Government decided that “a national electronic patient record” should be introduced by the end of 2007. The strategy for the national EPR was published in January 2004.

The legislation on electronic handling and archiving of electronic health care records, ePrescriptions and on the division of eHealth responsibility areas between different institutions were laid down during 2006 and placed in effect in 2007. The national projects and initiatives for the Finnish ICT infrastructure for social and healthcare are:

- A national digital archive for patient documents KANTA operated and maintained by the Social Insurance Institution (KELA). The legislation obliges all health organizations to join the national IT architecture for health, which should be built by the end of 2011.
- Establishment of one logical connectivity centre for eHealth communication in KANTA also operated by KELA.

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- Establishment of a national ePrescription database in KANTA and archive service operated by KELA.
 - Development of citizen access point service to KANTA for managing and editing personal data, managing consent information and reviewing of referrals, results, readings and access log information.
 - Setting up of a national PKI system for health care professionals. The system will be administered by the National Authority for Medico-legal Affairs (TEO), which operates as a Qualified Certificate Authority for all healthcare professionals (<http://www.valtteri.fi/>).
 - Creation of a national health portal for citizens. The prototype of the portal is demonstrated at a public website (www.terveysuomi.fi). The portal is planned to be finalised during 2008. It is hosted by the National Public Health Institute, which will merge in 2009 with STAKES and form a new research and expert institute on health and welfare in Finland. The major portal for health professionals is Terveystieto (www.terveysportti.fi), maintained by the Finnish Medical Society Duodecim. A decision support system for professionals has been built and is being offered as part of the Terveystieto services.
 - Development of semantic interoperability in the national EPR project. The interoperable core data set has been published in the national code server and is available without cost to all health care providers with different software solutions. The headings of the EPR and its metadata are being harmonised as well as the main data types. STAKES maintains the code server where all relevant codes and classifications are stored and from which they can also be downloaded electronically. ISO-OID-system is used for identification of the code systems.
 - Implementation of HL7 standards, which started in 2004. At present HL7 CDA R2-family standards are widely used. In the future Finland is exploring the use of HL7 version 3 RIM-based standards in ISO-standards: University of Kuopio, IT Centre, Health Information Systems (HIS) <http://his.uku.fi>

All citizens above 16 year have the health insurance card issued by KELA. This card is a plastic card with one-dimensional bar codes. About 400.000 EHC plastic cards have been distributed (30). Finland has made a policy decision that no health related information is stored in the e-cards. Cards are used only for identification. The citizen eID card (FINEID) with PKI-based Citizen Certificates is issued by the Finnish Population Register Centre, which is the only qualified level Certificate Authority in Finland. Approximately 180.000 valid FINEID cards were in use in May 2008. Upon request, citizens may have the KELA health insurance functions included in the FINEID cards, but this is not in electronic form. The Decision-in-Principle by the Council of State on Securing the Future of Healthcare was given on 11 April 2002. The document states that “nationwide electronic patient records will be introduced by the end of 2007” (www.terveysshanke.fi/eng.pdf). The National Health

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Project Programme was launched and an electronic patient record (EPR) project was included in the programme. The Ministry of Social Affairs and Health formed a working group (Ministry of Social Affairs and Health 2003), which produced a definition of electronic patient records and their implementation strategy.

A strategy document by the Ministry of Social Affairs and Health from 2003 describes how the implementation of the nationwide electronic patient record system can be completed by 2007. The common content and structure that should be used in every EPR system in all organisations was defined. It includes a clinical consensus on core patient data, some national services such as a code server, open standards for interoperability, and national guidelines for the safeguarding of data. The basic elements of the architecture needed for the construction of a national data transfer system and its mechanisms were also described.

The Act on Electronic Handling and Archiving of Electronic Healthcare Records (so called Client Data Act 2007/159) mandated the Social Insurance Institution KELA to provide for all the so called KANTA services for handling of electronic patient information. KANTA services cover archive services, encryption and certification services, and the patient's access to the data. The services will be regulated by KELA, the National Authority for Medico-legal Affairs TEO and the National Research and Development Centre for Welfare and Health STAKES. The creation of a common archiving system is expected to promote patient and client care, confidentiality, and an increase in the efficiency of healthcare services. The Act mandates the National Authority for Medico-legal Affairs TEO to act as Certificate Authority for all medical professionals and healthcare institutions; and the National Research Centre for Welfare and Health STAKES to maintain the code server of core data and other electronic patient record structures and ISO-OID codes of health care organisations.

The law makes mandatory the incorporation of all public health care units into the electronic archiving system, as well as private health care units that do not use paper-based archives.

There is a newly released Roadmap paper (2007) from the Ministry of Social Affairs and Health, which provides concrete action elements in order to achieve the National eHealth Strategy:

<http://www.stm.fi/Resource.phx/publishing/store/2007/02/pr1172737292558/passthru.pdf>

The following target areas listed in the eHealth Roadmap are important:

- Healthcare ICT Interoperability
- Identification and authentication of patients and citizens
- Identification and authentication of health care professionals
- Naming, identification and authentication of operating units
- Electronic signature
- Healthcare ICT infrastructure and information networks
- Healthcare e-services and information for citizens
- Quality of the work of professionals and patient safety

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- Developing health care statistics and monitoring

The Roadmap document foresees that patient information will be available in real time whenever the treatment relationship and patient consent allow, and this will improve the continuity, quality and patient safety of services. Structurally uniform entry, storage and transfer of data make data easier to find and easier to reuse. Structured information will also enable the introduction of smart support systems for decision-making directly in medical care situations. The supra-organizational availability of data will enable the introduction of new procedures and agreements on cooperation and division of duties between organizations in the health care system. The centralized archive system will enable patients to view data and usage logs pertaining to them. This will increase the potential for citizens to participate in their medical treatment and, consequently, increase confidence in the system. Centralized services make planning, monitoring (including real-time statistics) and management much easier and also open up new opportunities for research. International cooperation is easier to organize when national systems are uniform. Uniformity also means that the IT infrastructure can be built more cost-effectively while ensuring a high level of data security.

Finland has long used individual personal identity numbers (SSIN) for every citizen, which is widely used for electronic services. Use of the SSIN is restricted by different privacy laws and regulations, therefore citizens have been issued with an electronic unique identifier (FINUID) each time a citizen applies for a FINEID card. Patients can be identified and authenticated with two methods: either using a FINEID PKI card or authentication based on one-time codes (TUPAS), issued by banks.

Online banking services are used by about 2 million citizens. The public administration is introducing a joint platform for online identification and payment (VETUMA), financed out of the central government budget. The platform will accommodate FINEID, TUPAS identifiers, user ID + password combinations and, at a later date, mobile certificates (Wireless FINEID). The Client Data Act (2007/159) requires that users are strongly authenticated. A forthcoming Decree will specify the minimum requirements for identification and authentication in various applications. The extensively used TUPAS identifiers have also been tried on a limited scale in certain health care transactions projects. The development of chip cards and mobile certificates, and progress on the European Health Insurance Card (eHIC) are being monitored. Data security is an important aspect of development in the National Health Programme. Units in the health care sector are required to apply a uniform data security policy based on the ISO 27799 standard.

The Client Data Act (2007/159) requires the National Authority for Medico-legal Affairs (TEO) to administer a certification service for health care professionals. This service will involve a smart card and a national PKI system. Over half of all hospital districts are already introducing a professional ID card enabling strong authentication. In the future national architecture, use of TEO certification service will be compulsory. The determination and administration of user authorizations will be left to be implemented at the local level. The aim is to introduce role-based and rule-based authorization management based on international ISO standards. Single Sign-On (SSO desktop integration) must also be implemented at the

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local level; at the regional level, directory-based user-rights management (LDAP) will also be needed.

The KANTA system will be managed by KELA, but its role is restricted to technical management alone: the stakeholders in the healthcare sector (all different medical services and pharmacies) are responsible for providing data in due manner and form.

3.4 Regulatory framework for patients' summaries

Finland has legal provisions in the area of patients' summaries in the form of The Act on Electronic Handling and Archiving of Electronic Healthcare Records (so called Client Data Act 2007/159).

In the §6 of the Client Data Act 2007/159, the Summarized Electronic health Record is defined as a structured data system, which enables the electronic Use, Releasing, Storing and Safeguarding of patient data within the framework of the national Electronic Healthcare Record and Archive service defined in §14 of that Act. The §14 sets the responsibilities for creating and managing the national Electronic Healthcare Record and Archive service KANTA, with KELA being in charge of the complete system. Roles of the National Authority for Medico-legal Affairs TEO and the National Research and Development Centre for Welfare and Health STAKES are also defined in §14.

3.5 Regulatory framework for telemedicine

The Executive Board of the Finnish Medical Association has approved ethical guidelines in telemedicine in 1997. The guidelines define the following domains: medical competence, patient - doctor relationship, physician's responsible, quality, security and safety in telemedicine, handling of patient documents, and rules and practices for medical ethics, patient consent and confidentiality.

The Act on Electronic Handling and Archiving of Electronic Healthcare Records (so called Client Data Act 2007/159) sets provisions with regard to telemedicine, but also other laws are relevant for eHealth service provisioning.

The Client Data Act does not have any specific information about telemedicine. In the Finnish eHealth infrastructure the telemedicine services do not go via the eArchive (possibly teleradiology in a longer period of time, not 2011) and are running as regular services in several regions.

There are no limitations related to physical presence of the physician as long as professional accreditation, authorisations and patient consent can be performed according to law. This remains though a substantial challenge for telemedicine service providers, as well as users. There is no jurisprudence in Finland with regard to the liability of physicians who provided medical advice to patients by telephone but the rules applied are in line with the traditional liability for negligence (e.g. if a physician didn't have all relevant information about the patient's health because he was not physically present).

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Basing our analysis on the year reports (www.teo.fi) from the National Authority for Medicolegal Affairs TEO, most jurisprudence related to telemedicine concerns liability for negligence for not providing healthcare service in due delay. Long delays coincide with long distances thus the use of telephony and distance monitoring services for out-patients and homecare is growing and generally seen as a positive solution rather than a risk.

Telemedicine services are usually used when geographical distances become a real risk for patient safety and telemedicine is often seen as the only solution to tackle the requirements of medical service accessibility and availability, and large geographical distances. As a comparison, Finland counts several municipalities that are as large as Belgium, but with only a few thousand inhabitants, who by law are entitled to the same healthcare services as any other citizen in the country.

3.6 Regulatory framework for electronic prescriptions

Finland has adopted legislation for electronic prescriptions in 2007 (Act on Electronic Prescription 2007/61). Electronic prescribing is allowed only for medicines destined to humans and veterinary drugs are omitted from the current legislation. The electronic prescription system is composed of a centrally managed database provided by the Social Insurance Institution KELA within the KANTA archive service, and local client systems integrated within respective EPR systems in use. The KANTA system is in development phase and is scheduled to be ready by the end of 2011, which coincides with the transition period allowed by the Act 2007/61 for pharmacies and medical services to integrate the national e-prescription database and communication service. For more details we refer to Chapter 8 of this report.

3.7 Overview of relevant legislation

Once the KANTA service will be ready, the provisions of the Act on Electronic Handling and Archiving of Electronic Healthcare Records 2007/159 and the Act on Electronic Prescription 2007/61 will fully enter into force. The main topics of the two laws relate to:

- patient record registering and directory services
- electronic archiving of patient data
- consent management services, logging and monitoring services
- prescription database
- access to personal data

The general laws with relevance to eHealth in Finland are:

- Act on the Protection of Privacy in Electronic Communications (2004/516)
<http://www.finlex.fi/fi/laki/ajantasa/2004/20040516>

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in English: <http://www.finlex.fi/en/laki/kaannokset/2004/en20040516.pdf>

- Personal Data Act (1999/523)
<http://www.finlex.fi/fi/laki/ajantasa/1999/19990523>
in English: <http://www.tietosuoja.fi/uploads/hopxtvf.HTM>
- Act on Services in the Information Society (2002/458)
<http://www.finlex.fi/fi/laki/ajantasa/2002/20020458>
- Act on Electronic Communication with Public Authorities (2003/13)
<http://www.finlex.fi/fi/laki/ajantasa/2003/20030013>
- Act on Electronic Signatures (2003/14)
<http://www.finlex.fi/fi/laki/ajantasa/2003/20030014>
in English: <http://www.finlex.fi/en/laki/kaannokset/2003/en20030014.pdf>
- Act on the Recognition of Professional Qualifications (2007/1093)
<http://www.finlex.fi/fi/laki/ajantasa/2007/20071093>
- Act on the Openness of Government Activities (1999/621)
<http://www.finlex.fi/fi/laki/ajantasa/1999/19990621>
in English: <http://www.finlex.fi/pdf/saadkaan/E9990621.PDF>
- Law on the Population Register (1993/507)
<http://www.finlex.fi/fi/laki/ajantasa/1993/19930507>

Healthcare and eHealth specific laws in Finland are:

- Act on Status and Rights of the Patient (1992/725)
<http://www.finlex.fi/fi/laki/ajantasa/1992/19920785>
- Act on Specialized Medical Care (1989/1062)
<http://www.finlex.fi/fi/laki/ajantasa/1989/19891062>
- Act on Electronic Handling and Archiving of Electronic Healthcare Records (2007/159)
<http://www.finlex.fi/fi/laki/ajantasa/2007/20070159>
- Act on Electronic Prescriptions (2007/61)
<http://www.finlex.fi/fi/laki/ajantasa/2007/20070061>
- Decree on Storing of Patient Data (2001/99)
<http://www.finlex.fi/fi/laki/alkup/2001/20010099>
- Act on Patient Damages (1986/585)
<http://www.finlex.fi/fi/laki/ajantasa/1986/19860585>

Of particular interest to eHealth are the laws on Electronic Handling and Archiving of Electronic Healthcare Records (2007/159), Electronic Prescriptions (2007/61), Status and Rights of the Patient (1992/725) and the Personal Data Protection Act (1999/523).

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The Decree on Storing of Patient Data (2001/99) regulates the management of medical records. Healthcare professionals and service providers receive complementary and regularly updated guidelines and best practices published by the Data Protection Ombudsman. Other organisations such as STAKES, the Ministry of Social Affairs and Health, the Association of Finnish Municipalities and private organisations such as the Finnish Medical Association's publisher Duodecim contribute largely on the development and dissemination of guidelines and best practices for data privacy protection and proper handling of patient data.

Indirectly relevant are the laws on the Openness of Government Activities (1999/621) for its regulations on the requirements for collection and management of personal data; the Act on Electronic Communication with Public Authorities (2003/13) for its regulations on the requirements on types and methods of electronic communication with authorities; the Act on Electronic Signatures (2003/14) and the Act on Population Register (1993/507), which establishes the use of the social security identification number SSIN.

For further information on the use of the SSIN number, the electronic identity card and the legislation with regard to electronic documents and electronic signatures, see Reference Documents under RD9 and RD10.

4 Regulatory framework for the healthcare profession

The National Authority for Medico-legal Affairs TEO is responsible for ensuring the adequacy of services provided by health care professionals and health care operating units through guidance and supervision. TEO's role and mandate are instituted in the Law 1992/1074, and it is placed under the authority of the Ministry of Social Affairs and Health. The Decree on Healthcare Professionals 1994/559 legislates on the qualification of medical professionals, on the supervision of medical professions, and on the conditions enabling sharing of information and cooperation between medical professionals.

TEO's tasks include also the processing of complaints, notifications and other supervisory matters related to the adequacy of services, which may arise as a result of official requests for opinion. A further key area is the provision of information, specialist guidance and training. In addition, the Authority issues insurance medical statements on the causality of injuries to other authorities, upon their request.

4.1 Legal conditions for the practice of healthcare

The regulation of the education leading to the various professions in the healthcare sector in Finland is a competence of the Ministry for National Education. The educational programs have been adapted to the European directives in this area. For the medical profession in particular, the Council Directives 86/457 on specific training in general medical practice and 93/16/EEC concerning the coordination of provisions in respect of activities of doctors, have influenced education leading to general medical practice or medical specialization in Finland. The practice of medicine is regulated by the Act on Health Care Professionals 1994/559 and the Decree on Health Care Professionals 1994/564

Licensed professionals

Under Finnish law 1994/559 §4 and §5, licensing is granted to the following professions: physician, dentist, pharmacist, psychologist, speech therapist, dietician, dispenser, nurse, midwife, public health nurse, physiotherapist, medical laboratory technologist, radiographer, dental hygienist, occupational therapist, optician and dental technician (17 titles in total). The practice of these professions is restricted to licensed professionals only. Licensing is granted, upon application, by TEO.

Authorised professionals

The National Authority for Medico-legal Affairs may grant an authorisation to practice to nationals of countries outside the EU/EEA and who have obtained their qualifications in a country outside of the EU/EEA. The authorisation is valid for a fixed period of time and may be restricted to a specific place of employment.

Protected occupational titles

The protected occupational titles as defined in the Decree on Health Care professionals are: orthopaedic technician, podiatrist, trained masseur, chiropractor, naprapath, osteopath, practical nurse for social and health care, psychotherapist, hospital physicist, hospital geneticist, hospital chemist, hospital microbiologist and hospital cell biologist (13 titles).

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According to the law 1994/559 no person may practice medicine unless he holds a legal diploma of physician. This monopoly is exclusive, which means that with the exclusion of all others, physicians are competent to practice medicine. It is also all-embracing, which means that it covers every activity that has to be considered as belonging to medicine. Physicians with the proper education are listed in §4 of the aforementioned law: generalist practitioner, dentist, specialised practitioner and specialised dentist. Medical degree courses are offered by five universities (Helsinki, Tampere, Turku, Oulu, and Kuopio). The basic medical course lasts for some six and a half years and leads to the degree of Licentiate of Medicine.

To practice medicine in Finland, the following requirements have to be fulfilled:

- Possession of the legally required diploma: diplomas awarded in other EU Member States are assimilated in accordance with the provisions of Council Directive 75/363.
- Accreditation by the National Authority for Medico-legal Affairs and registering to the Terhikki medical professional registry database
- Doctors from within the EU or EEA can obtain a licence to practise medicine in Finland on the basis of directives concerning mobility of doctors and mutual recognition of diplomas. The National Authority for Medico-legal Affairs assesses and approves the education of health-care professionals and recognises degrees.
- Doctors and dentists must obtain an insurance policy against malpractice claims, accidents and patient compensation claims. The law provides fines for not signing voluntarily to an insurance policy. In public healthcare the insurance is covered by the healthcare unit and for private physicians, the insurance is included in their FMA membership or it can be purchased separately.
- Licensing of doctors from within the EU and EEA does not involve the meeting of any language-proficiency requirements but employers, e.g. municipalities, may require certificates relating to linguistic skills. Treating patients would be difficult without knowledge of Finnish.
- To receive a licence to practice medicine in Finland, a doctor from outside the EU or European Economic Area (EEA) has to undergo practical training and pass a three-part examination, including questions on administration, legislation and clinical medicine, and a practical section testing ability to cope with normal clinical situations. There is also a separate language test. Licences are granted in stages. The initial licence is valid only for hospital work. It can subsequently be extended to cover health-centre work, and then work in other institutions and in private practice. The licences are always granted for specific periods of time. If a holder of an extended licence is granted Finnish citizenship, the National Authority for Medico-legal Affairs can authorize him or her to practice medicine independently as a licensed physician.

The Finnish Medical Association (FMA) is a professional organisation and an independent trade union representing physicians from all branches of medicine in Finland. Membership is voluntary, but nearly all doctors who practise in Finland choose to be members. Entire classes

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of medical students join the Association after their fourth year of study, i.e. when they can practise medically for the first time. Doctors from abroad can join the Association if they have a licence to practise medicine in Finland and the senior doctor in their place of employment recommends them for membership.

An act belongs to the field of medicine whenever it has the purported purpose, in respect of a human being:

- To examine the state of health;
- To detect diseases and disabilities;
- To establish a diagnosis;
- To introduce or administrate any treatment of a pathological condition;
- To carry out a vaccination;
- To supervise pregnancy and childbirth as well as any related procedure.

4.2 Control over the practice of medicine

The National Authority for Medico-legal Affairs grants, upon application, the right to practice as a licensed or authorised professional and authorises the use of the occupational title of healthcare professional. The National Authority for Medico-legal Affairs is a competent authority, which receives applications and issues decisions on the above matters, also in cases where training has been undertaken outside of Finland. A person practicing as a healthcare professional in Finland without a licence may be sentenced to a fine or imprisonment.

The Ministry of Social Affairs and Health has the main responsibility to control the practice of medicine. This responsibility is delegated to provincial authorities that are in charge of supervising healthcare practices: healthcare service delivery, healthcare professional malpractice claims and patient mentions and complaints. The National Authority for Medico-legal Affairs TEO is the competent agency that acts upon the Ministry's responsibilities. TEO supervises the provincial authorities and acts independently in the following cases (Act 1994/559, art.5):

- Issues with general principle or global reach;
- Malpractice claims where death or permanent injury is invoked;
- Issues related to forensic studies;
- Issues that may involve punitive sanctions;
- Issues where the provincial authority is biased to act;

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4.3 Professional liability

The Law on Patient Damages 1986/585 defines compensation to patients and professional liability. The law on Medical Professionals 1994/559 defines that every medical professional must acquire a insurance policy as defined in the Act 1986/585.

The law 1994/559 accords TEO the responsibility to conduct investigations and evaluation of a healthcare professional's competence and capacity to perform. Competence and capacity has to be attested by the subject in case and if this cannot be attested, TEO may apply punitive sanctions such as suspension of right to provide healthcare services (§25).

- Malpractice or wrong doings by a healthcare professional are defined by the law (§26) as follows:
- A healthcare fails to observe its obligations as defined in the same law;
- Performs acts that exceed qualification or professional competence;
- Acts otherwise wrongfully or unlawfully;

In such cases TEO may decide upon different sanctions varying from reprimands to temporary or permanent suspension of authorised title or right to perform healthcare services. In case the healthcare professional is found guilty of a crime or serious crime not related to his or her professional activity, TEO may nevertheless suspend temporarily or permanently the subjects rights as healthcare professional.

The Criminal Code is applicable in case of unlawful impersonation of a healthcare professional (art. 44) and in case of failing to observe data privacy and patient confidentiality regulations (art.38 and 40).

Medical malpractice complaints are rising yearly, between 2006 and 2007 the number of complaints rose at average 20%

(<http://www.teo.fi/SiteCollectionDocuments/Toimintakertomus2007.pdf>)

The Finnish Medical Association FMA offers its members patient injury insurance coverage for doctors in private practice.

4.4 Professional secrecy

One of the most important legal obligations owed by a physician to a patient is the protection of confidences revealed by the patient to the physician. Articles 16 and 17 of the Law on Healthcare Professionals 1994/559 stipulates that handling of and archiving of patient medical records has to be in accordance with the law on Patient Status and Rights 1992/785 (§13) and that professional secrecy covers every all social transactions and that secrecy must be kept even after the physician is no longer performing his or her profession.

Criminal sanctions in the case if a physician fails to observe professional secrecy regulations are defined in Articles 38 and 40 of the Criminal Code. Failure to observe due diligence procedures while handling sensitive patient data, or failing to respect patient consent information is sanctioned with fines (Customer Data Act 2007/159, Article 23).

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The obligation of non-disclosure applies not only to information acquired directly from the patient, but also to information concerning the patient which the doctor learns from other sources.

The duty of medical secrecy is not limited to physicians who are providing healthcare to the patient. A physician, who medically investigates a person at the request of an employer or an insurance company, is also bound by the duty, although he may inform in such a case the employer or the insurer within the limits of his mission. The Act on Patient Status and Rights 1992/785 Article 13 defines the limits and boundaries of disclosure and confidentiality. As a general observation, the right to disclose patient data is restricted to data relevant to providing care services and statistical study, not to disclose data with financial or other non-medical implications.

Articles 38 and 40 of the Criminal Code have a large field of application and not only applies to physicians alone but to everyone who, in the course of his professional practice, is being informed of confidential information. Not only physicians but also nursing and paramedical personnel as well as different professions in the field of social services are bound to a duty of secrecy. Because all the members of a medical team are obliged to respect the confidentiality of the patient's information, one accepts that this information may circulate within the team (so-called "shared medical secret") as long as this is in accordance with patient consent and the principle of the need-to-know basis.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Since 1999 Finland has a general legislation protecting the individual with regard to automatic processing of personal data. The Act on Personal Data of 22 April 1999/523 was created in order to transpose the provisions of the European Directive 95/46/EC, and it substituted the previous Personal Data Record Act of 1987/471. Soon after adoption, the Act was amended to clearly include the provisions of articles 3, 25 and 26 of the Directive. The new amended Act came into force on the 1st of December 2000.

The Finnish Personal Data Act is similar to the European directive:

- the definitions of the essential concepts: personal data, processing, controller, processor, third party, recipient and consent (art. 2 of the Directive);
- the rules regarding data quality (art. 6 of the Directive) but, accordance with the Directive, the Finnish legislator has enacted detailed rules on the further processing of personal data for scientific, historical or statistical purposes;
- the criteria for making personal data processing legitimate (art. 7 of the Directive) with additions in concerning data processing for customer relations and corporate human resources;
- the information to be given by the controller to the data subject (art. 10-11 of the Directive);
- the data subject's rights (art. 12, 14 and 15 of the Directive);
- the provisions with regard to confidentiality and security of processing (art. 16-17 of the Directive);
- the notification of the processing to the data protection supervisory authority (art. 18-19 of the Directive);
- the status and competences of the data protection supervisory authority (art. 20, 21, 22 and 28 of the Directive: Finland has two data protection authorities; the Data Protection Ombudsman and the Data Protection Board. The Data Protection Ombudsman provides direction and guidance on the processing of personal data, supervises the processing in order to achieve the objectives of the Personal Data Act (523/1999), as well as makes decisions concerning right of access and rectification. The Data Protection Board deals with questions of principle relating to the processing of personal data, where these are significant to the application of the Personal Data Act. The Board has also the power to grant permissions and issue orders. More details about the Finnish Data Protection Ombudsman and Board can be read at <http://www.tietosuoja.fi>
- liability for damages as a result of unlawful processing (art. 23 of the Directive);

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-
- Transfer of personal data to third countries, outside the EU (art. 25-26 of the Directive).

5.2 Transposition of article 8 of Directive 95/46/EC

As far as the processing of special categories of personal data is concerned (transposition of art. 8 of Directive 95/46/EC) the Finnish law 1999/523 contains additional provisions for a) sensitive personal data concerning health and insurance institutions, b) data concerning social services, and c) use of personal data for special reasons.

Art. 3 of the Finnish law regulates the processing of data concerning health and is formulated as follows:

§ 11 Processing of sensitive personal data:

- 4. The processing of health-related personal data shall be prohibited.
- 5. The processing of data related to social services and benefits shall be prohibited

§ 12. The prohibition of processing data referred to in § 11 shall not apply in the following cases:

- 1. processing of data where the data subject has given an express consent;
- 2. processing of data necessary for the safeguarding of a vital interest of the data subject or someone else, if the data subject is incapable of giving his/her consent;
- 3. processing of data where based on the provisions of an Act or necessary for compliance with an obligation to which the controller is subject directly by virtue of an Act;
- 4. processing of data for purposes of historical, scientific or statistical research;
- 5. a health care unit or a health care professional from processing data collected in the course of their operations and relating to the state of health, illness or handicap of the data subject or the treatment or other measures directed at the data subject, or other data which are indispensable in the treatment of the data subject;
- 6. an insurer from processing data collected in the course of its insurance activity and relating to the state of health, illness or handicap of the policyholder/claimant or the treatment or other measures directed at the policyholder/claimant, or data on the criminal act, punishment or other sanction of the policyholder/claimant or the person causing the damage, where necessary for the determination of the liability of the insurer;
- 7. a social welfare authority or another authority, institution or private producer of social services granting social welfare benefits from processing data collected in the course of their operations and relating to the social welfare needs of the data subject or the

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benefits, support or other social welfare assistance received by the person or otherwise indispensable for the welfare of the data subject;

§ 13. Sensitive data shall be erased from the data file immediately when there no longer is a reason for its processing. The reason and the need for processing shall be re-evaluated at five-year intervals at the longest, unless otherwise provided in an Act or stated in a permission of the Data Protection Board. A personal identity number may be processed in activities relating to health care, in social welfare activities or other social services and in matters relating to the civil service.

5.3 Information and access rights of data subjects

§ 28 of the Data Privacy Act states that subjects have an access right to their personal information:

2) The controller shall without undue delay reserve the data subject an opportunity to inspect the data referred to in § 26 or, upon request, provide a hard copy of the data. The data shall be given in an intelligible form. If the controller refuses to provide access to the data, a written certificate to this effect shall be issued. The certificate shall also mention the reasons for the refusal. A failure by the controller to give a written response to the data subject within three months of the request is deemed equivalent to a refusal to provide access to the data. In this event, the data subject may bring the matter to the attention of the Data Protection Ombudsman.

3) Anyone who wishes to have access to the data on himself/herself in the files of the health care authorities and institutions, physicians and dentists or other health care professionals and relating to their state of health or illness, shall make a request to this effect to a physician or another health care professional, who shall then see to the obtainment of the data with the consent of the data subject and provide him/her with access to the entries in the file. The provisions in paragraph (2) apply to the procedure in the realisation and refusal of the right of access.

6 Rights and duties of healthcare providers and patients

The Finnish legislation covering the rights of patients is contained in the Act on Status and Rights of the Patients 1992/785 and it applies to every part of the general health care system and to health care services provided in social welfare institutions. Finland became in 1993 the first country in Europe to enact legislation relating to the status and rights of patients.

The Act rules that:

- treatment requires the consent of the patient;
- the patient's agreement must also be obtained as to the forms of treatment;
- patients must, if they so request, be given information on their state of health, the extent of the proposed treatment, any risk factors, and possible alternative forms of treatment;
- patients are entitled to see and correct the information entered in their own patient histories;
- those on a waiting list for treatment must be told the reason for the delay and its estimated duration;
- patients dissatisfied with their treatment are entitled to lodge a complaint with the establishment concerned;
- establishments providing medical treatment must have a patient ombudsman, whose duty is to inform patients of their rights and assist them, if necessary, in submitting a complaint, appeal or claim for indemnity;
- the opinion of young patients must be taken into account if they have reached a stage of development at which they are able to express an opinion. A doctor or other professional person assesses the stage of development;
- a child's parent or guardian is not entitled to refuse treatment that would avert a health risk or save the life of an underage person.

<http://www.stm.fi/Resource.phx/eng/subjt/healt/right/index.htx>

6.1 Scope of the law

Patient means a person to whom healthcare services are provided or otherwise subject to. Healthcare means “the services that a health professional provides in order to promote, determine, preserve, restore or improve a patient’s state of health, in a healthcare service unit.” Health professionals in the current state of the legislation are: physician, dentist, pharmacist, psychologist, speech therapist, dietician, dispenser, nurse, midwife, public health nurse, physiotherapist, medical laboratory technologist, radiographer, dental hygienist, occupational therapist, optician and dental technician.

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6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is not further specified by the law. In §6, where the patient's right of self-determination is defined, importance is paid to proper recording and understanding of the patient's and his or her proxy's consent to treatment.

6.3 Right to quality care

In §6, the law 1992/785 provides that every permanent resident in Finland is entitled to the health and medical care that her or his state of health requires, within the limits of resources available for healthcare. Patient care must be arranged in such a way that the dignity of the patient is not impaired. Each patient's privacy must be respected. The mother tongue of the patient, and the patient's individual needs and culture must be taken into account in providing treatment.

6.4 Right to free choice

The Finnish legislation does not provide any right for the patient to freely choose his health professional or to change that choice. Only references made to the choice of healthcare service provider are in the recently amended (1.3.2005) Law on Public Health 1972/66 (§15b) and Law on Specialised Healthcare (§31a), which provide the patient the option to choose a private or European (EU/EEA) healthcare provider in case the time to receive treatment exceeds 3 months. The patient can of course choose any healthcare service provider at his or her own expenses.

6.5 Rights related to information about the state of health

A patient has the right to receive from the health professional all relevant information necessary to assess his or her state of health and prognosis. Information must be given about the necessity of treatments, the different treatment options, possible effects and side-effects of treatments, and all other information that can be relevant to the patient in order to decide upon a treatment or cure.

Communication with the patient must take place in clear language, adapted to the individual needs and in accordance with the language legislation, providing both Finnish and Swedish speaking patients to be informed in their preferred language. Also interpretation services have to be used if the patient and physician do not share any common language or idiom. The patient may request that the information be confirmed in writing and the patient is entitled to see what information is recorded on him or her.

Information is not provided to the patient if the latter explicitly requests not to know. The explicit request not to know can be given in writing or orally, in which case it has to be noted in the medical record.

It is accepted that a patient has a right to relinquish his right to information, but this relinquishing must be voluntary and certain. In this case the healthcare professional is no longer required to inform.

In exceptional cases the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient and on condition that the

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health professional has sought the opinion of another health professional (so-called “therapeutic exception”).

6.6 Right to give consent

The patient has the right to consent well informed, freely and in advance to any service provided by a health professional. The consent is only valid for the medical intervention consented to. Consent must be given expressly, except when the health professional, after having adequately informed the patient, can reasonably infer consent from the patient’s behaviour; The consent has to be recorded and added to the medical record at the patient’s or the professional’s request and with the health professional’s or patient’s approval. The information to be given to the patient prior to the consent is specified in the law on Customer Data 2007/159. Patients have the right to refuse or withdraw consent for any service. A recorded consent can cover the whole treatment “chain”, but only for a maximum period of 12 months if not refreshed sooner.

6.7 Rights related to the patient’s medical record

The patient has the right to a medical record, carefully updated and safely stored by the health professional. A medical record about every patient is produced and stored by the record keeper, which until the end of 2011 is the hospital, primary health care centre or private practice, where the patient receives treatment. The medical record shall contain information relevant to organisation of treatment, planning and execution of treatment and securing of treatment follow-up (1992/785 §12).

The Customer Data Act 2007/159 contains more detailed rules concerning the so-called General Medical Record (GMR), the medical records in hospitals and archiving of medical records within the framework of the national health data system KANTA. Every medical record has to be uniquely identifiable to a physical person and only one single copy of a record can be kept. There are special regulations concerning copying and keeping of copies of patient records.

The §11 of the Act contains precise rules about the content of the GMR. There should be one GMR per patient, kept by the general practitioner in charge of treating the patient. A patient can freely choose by which services have access to his or her medical record and can modify this choice at any moment. At this moment this is not yet possible since the KANTA system is not yet operational.

According to the Act 2007/159, a medical record (not only the GMR) has to be kept in electronic format. The Act foresees that different archiving periods apply for different data and that archiving periods can be defined by decree of the Ministry of Social Affairs and Health.

The Act 2007/159 regulates that the “patient’s record” includes the GMR and a patient consent record. The GMR has to include search information. The search information include the following: patient unique identifier, healthcare service provider information, patient record information, treatment period information or out-patient call information, their start

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and end dates, information about whether the GMR contains laboratory results, medical images or similar results, and a identifier for treatment service entity.

The Act 2007/159 states that the medical record is kept in electronic format and that by the end of 2011 all healthcare service providers will have to integrate into the national KANTA system. Some of the documents in the medical record need to be signed by the physician(s) who provided care to the patient, some by the patient (consent record) and some using a system certificate (time stamping, and attestation of messaging integrity)

The Social Insurance Institution KELA has the obligation to archive the electronic records of all patients in a central database, with a unique number per patient. The archive will be accessible to physicians who are involved in the provision of care to the patient and also to the patients who have a right to view his or her medical information. At the moment, before KANTA becomes operational, nobody is allowed to archive electronic patient records. If all legislation is followed they should be printed out and archived as paper documents. Some of the central hospitals follow the rules accordingly and all providers print the documents and store the as paper documents after the death of the patient.

Patients have the right to have a view access to their own medical records. A patient's request to access his medical record shall be granted as soon as possible and not later than 14 days following the request.

Patients have a right to obtain a copy of their medical records, in whole or in part, at no cost, as soon as possible and not later than 14 days following the request. Each copy shall clearly indicate that it is strictly personal and confidential. A health professional can refuse to supply a copy if there are clear signs that the patient has been pressured to ask a copy of his medical record at the instigation of a third party. Also if a patient requests another copy of his or her record in a short period of time, the copy will be charged at a cost to be defined by the Ministry.

The law 1992/785 determines the conditions under which the next of kin may consult the deceased patient's medical record.

6.8 Right to protection of privacy and intimacy

Patients have the right to the protection of their privacy in any medical service, particularly in respect of the information about their health. They have also a right to the protection of their intimacy. Not other persons than those whose presence is required for the delivery of medical services shall be allowed to assist in the provision of care, without the patient's consent.

6.9 Right to representation in case of incompetence

The law 1992/785 contains rules to protect the rights of patients who are legally or factually not capable of exercising their rights as a patient. In the case of minor patients, the patient rights are exercised by the parents asserting authority over the minor or by the patient's guardians. The minor patient will be involved in exercising his rights, bearing in mind his age and level of maturity. Minor patients who are deemed capable of reasonably grasping their situation may exercise their rights on their own behalf.

7 Identity management in the health sector

A co-ordinated identity management system for the Finnish healthcare sector including the identities of patients, healthcare professionals and other stakeholders is not yet available. There is a decision to use the Finnish FINEID system for patient identity management also in the healthcare sector, but the issue is unsolved in practice since the dissemination of FINEID cards to the public has been very slow. If the distribution process is not significantly speeded-up, patient identity management will not be resolved based on the FINEID, in the delays accorded by the law. The information in this chapter is based on our IDABC-report referenced under [RD9].

7.1 Overview

The Finnish eIDM system is based on the Finnish Electronic Identification card FINEID, which is a facultative electronic identity card that is intended to facilitate access to eGovernment services for all Finnish citizens. Detailed information is available through the official FINEID website (<http://www.fineid.fi>; available in Finnish, Swedish and English).

The card contains a chip with a PKI application holding two certificates: one for authentication and encryption purposes, and one for qualified signatures.

The FINEID is issued by the Finnish Population Register Centre (*Väestörekisterikeskus VRKI*) and it is linked with the population register service, which contains a key set of authentic attributes and information for citizens. Many of the attributes stored in the authentication certificate of the eID card are obtained directly from the Population Register.

The Population Register stores the SSIN of all citizens and the FINUID identifier used in the FINEID certificate. The SSIN is not transmitted in electronic services nor published in public directories since it contains privacy sensitive value and data. The FINUID is not privacy sensitive, therefore it was introduced as a replacement to the SSIN in electronic services. The SSIN is nevertheless the *de facto* unique identifier for Finnish citizens in eGovernment services since only very few applications support the use of FINUID, which by default has to be resolved to a SSIN.

Apart from being the main access key to the National Register, the SSIN is also used directly within the TUPAS bank Identification scheme. The TUPAS scheme is an alternative paper based PIN/TAN token which is issued by Finnish banks. The Federation of Finnish Financial Services (www.fkl.fi) is the holder of the proprietary TUPAS scheme (now version 2) but every bank has a separate TUPAS identity provider and issuing system and service.

Authentication using TUPAS PIN/TAN paper tokens is very popular since nearly all adult Finns have TUPAS credentials and TUPAS credentials are commonly used in numerous e-commerce and e-government services.

The TUPAS scheme offers several practical advantages to consumers and service providers, but it also contains several security and functional challenges: it is not X509.v3 based, it is issued by banks to their customers and with the bank policy, it is not “personal” since the credentials belong to the issuer, TUPAS authentication cannot be federated within an identity

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management framework due to contractual liability clauses, the credentials are unique only within one bank causing therefore a risk for conflicting identity credentials, TUPAS credentials use privacy sensitive SSIN for authentication, which is not allowed by the current legislation on Personal Data, and the service is charged with variable rates. For all of the above mentioned reasons, the Act 2007/159 does not allow the use of TUPAS credentials to be used for accessing medical patient data by patients, and only use of the FINEID card or mobile FINEID certificate is allowed.

7.2 The KELA Card

The purpose of the KELA card is to prove eligibility for health insurance in Finland. For example in order to benefit from price reductions on medicines, eligibility for health insurance has to be proven when purchasing medicines at a pharmacy.

All permanent residents in Finland are issued a regular KELA card (without a photo). Pre-printed with all necessary information, the card is ready to use once the cardholder (if at least 16 years of age) has personally signed it. KELA sends you automatically a new card if users name is changed (e.g. marriage). Personal information about the insurance holder is directly communicated from the Population Register service which provides authorised source information.

The format for the Finnish identity card issued by the police allows the possibility of adding health insurance information to the FINEID card. An identity card that includes the bearer's personal health insurance details is accepted as KELA card at pharmacies, medical centres and other locations.

The identity card is valid for a period of five years, whereas the simple KELA card has no set validity time. Also FINEID KELA card applications must be filed personally with the police or a local KELA office that has a joint-service agreement with the police. Applicants need a valid passport or identity card, two passport-sized photo-graphs and 40 euros when they apply for a combined FINEID KELA card. The regular KELA card is free of charge to the user and does not require applying or registering after first application (namely foreigners). Anyone moving permanently from Finland must return their card to a KELA office.

The following information is printed visibly on the card: the social security number, last name and two first names, and issuing date of the card. Birth date and gender information are comprised in the Finnish SSIN, therefore it is not printed on the card. On the back side of the card information about the card bearer's additional insurance coverage and chronic diseases are printed as well as the SSIN in both plaintext and bar-coded.

7.3 Patient data archive service KANTA

The KANTA service will be maintained by the Social Insurance Institution (KELA). The legislation which obliges all health organizations to join the national IT architecture for health came to effect in July 2007 (2007/159). The system should be ready by the end of 2011. In the new legislation, the Ministry of Social Affairs and Health has a stronger role in steering eHealth Activities in close cooperation with other national authorities such as the Social

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Insurance Institution (KELA) and the National Authority for Medico-legal Affairs and the National Research and Development Centre for Welfare and Health (STAKES).

- The whole KANTA service is composed of the following systems and services:
- A national digital archive for patient documents
- One logical connectivity centre for eHealth communication between organisations will be conducted on a national basis and not regionally
- A code server and EHR-registration services

7.4 Patient identifier

Identification of the citizen is based on his or her SSIN number. Use of this number is strictly monitored, and subject to regulations supervised by the Data Privacy Ombudsman (<http://www.tietosuoja.fi>). This same number is also used all governmental systems in order to exchange social security personal data between administrations. Patients with FINEID cards are also assigned a unique FINUID identification number, which can be used for identification. The FINUID identifier is mainly used only for securing privacy and systems need to resolve the FINUID into a SSIN in order to transfer personal information from the Population Register.

The law 2007/159 establishes that the KANTA service is authorized to have access to the Population Register and to use the SSIN in accordance to the provisions of the Personal Data Act 1999/523.

Patients have the right to view and assess their personal health records in the KANTA system, but the law has not defined whether users should register to the KANTA service before they can be granted access. The KANTA system will need to support identity discovery and self-provisioning functionality if the legislator opts for not requiring initial registration. Identity discovery would be based on the use of the SSIN in conjunction with the Population Registry service. The Decree on Patient Records 2001/99 is under the process of amendment in June 2008.

7.5 Authentication of healthcare professionals

Healthcare professionals using electronic patient record systems, electronic patient data archiving systems and services and electronic prescription systems have to be identified and authenticated reliably using strong authentication methods. Patient records and electronic prescriptions require signing using advanced electronic signature certificates. All personnel employed in healthcare service units and all other people included in the process of providing healthcare services to patients will need to be authenticated using PKI certificates issued by the National Authority for Medico-legal Affairs TEO CA services. Each healthcare provider and service unit is responsible for user identity management (authorisation, provisioning and de-provisioning).

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Healthcare professional certificates are issued to healthcare professionals defined in the law 559/1994, and also to students completing studies to become physician, dentist and pharmacist. According to the law 159/2007 TEO CA certificates are also issued to all personnel working in and for healthcare service units, to other healthcare service providers and to healthcare applications and equipment. TEO CA certificates are to be used for accessing patient data systems, signing of electronic prescriptions and other applications. More information on the TEO CA activity is available in Finnish at: <http://www.valtteri.fi> In accordance with the Law on Medical Professionals 559/1994 and 1030/2000, healthcare professionals are registered in the nation register (so-called “Terhikki”) of healthcare professionals, established by the National Authority for Medico-legal Affairs. This register contains information about the diploma and the specialization of a health care provider identified through his social security identification number (SSIN). The Terhikki register contains amongst personal data also mentions about possible court convictions and medical malpractices, and information about granted medical procedure authorisations and denial of previously granted medical procedure authorisations. A registry service is also created by TEO for private healthcare and social service providers (“Ysteri”).

More information about the Terhikki register is available in Finnish at:

<http://www.teo.fi/FI/Ammattioikeudet/Terhikki-rekisteri/Sivut/etusivu.aspx>

The Terhikki register is available online and it is used as a so-called validated authentic source by the all healthcare service units to verify authorizations with regard to medical records and other data or applications. Other validated authentic sources which are used in this context is the National Population Register database. The Population Register service provides authorised personal information such as age, citizenship, permanent residence address etc. The Terhikki register also contains healthcare professional SSIN numbers; therefore it is managed in accordance with the provisions of the Data Privacy Act 523/1999. Management requirements for the register service are provided in the Act on the Openness of Government Activities 621/1999.

7.6 Exchange of health-related data

On the national level there is electronic communication between KELA and pharmacies for drug reimbursement, between KELA and service providers for the ordering of drugs and materials and between service providers and the National Research and Development Centre for Welfare and Health (STAKES) for national statistical data collection. Regional information transfer is based on regional directory services and interoperable systems, which are already operational in 6 of the 21 hospital regions. The most commonly used communication standards in Finland are derived from the HL7- family (at present the HL7 CDA R2.x family standards). eHealth services used on a regular basis include regional level telemedicine services such as transfer of images, e-Referrals, laboratory results and care summaries between primary and secondary care, e-Consultations, billing and e-Booking. Exchange of healthcare data is possible only between healthcare service providers (§10). The SSIN is included in the search criteria for data exchange via the KANTA system. For healthcare professionals, access and data exchange is based on search criteria, authorisation,

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patient consent and other professional attributes that are a combination of attributes from the Terhikki registry and role or circumstantial attributes provided by the local healthcare unit. The search criteria are defined in the law 2007/159. The KANTA system or service log handling cannot be outsourced to any other party than KELA.

8 Electronic prescription

A national ePrescription pilot was launched in Finland during 2002. The piloting of the system took place in 2004-2006 and with the Act on Electronic Prescriptions 2007/61, permanent ePrescription legislation is now in effect. The legislation was drafted based on the experiences of the pilot-project. The ePrescription is based on a national database hosted by KELA, strong authentication and a smart ID-card for professionals with advanced electronic signature implementation and SSL-secured messages from health care providers and pharmacies to the database.

The Finnish e-Prescribing is aimed to be fully integrated with the different EPR systems and a centralised receipt data file, to cover all pharmacies, and to contain continuously updated knowledge about all prescribed drugs of the patients, by using highly secured networks. The application to be built offers a usable platform for decision support for the drug safety. The pertinent legislation came into effect in April 2007 and setting up of the system has started. The Act on Electronic Prescriptions §7 determines that the electronic prescription needs to be signed using an advanced electronic signature issued by The National Authority for Medicolegal Affairs. The healthcare service unit has to ensure that the physician is authorised to prescribe the medicine before allowing application of the signature. Several electronic prescriptions written to a single patient during one session can be signed once, and multiple electronic prescriptions can be signed as a batch. An amendment to the current Act has been introduced in June 2008. The act was given out in July 2008 and is in effect now. Some of the changes occur in the definition of the signatory role and authorisation, which was very challenging to implement under the provisions of the former legislation. In the current legislation, a physician or a dentist has a “personal” right to sign electronic prescriptions, but the healthcare unit has a legal obligation to control to whom and in which circumstances the physician can and cannot effectively sign prescriptions.

The electronic prescription’s information content includes:

- Patient name and SSIN, or date of birth for non-Finnish
- Information about the medicine with pharmacological database reference and composition description
- Information necessary for delivery and taking of the medicine
- Information necessary for identifying the physician or dentist giving out the prescription and the healthcare service unit in question
- All necessary information needed by insurance institutions
- Identifier for the electronic identifier

A patient’s consent is not required for writing an electronic prescription, but a patient can deny the use of an electronic prescription. The patient has to be informed about the electronic prescription and the national database service in order for the patient to be aware of the new data exchange and archiving services and to be able to understand what are the privacy and

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safety issues involved. Informing the patient is recorded in the patient record and this event frees the healthcare service providers to repeatedly query consent information.

The electronic prescription is secret and it has to be encrypted using certificates. The patient can allow decrypting but this service will become available only once the transition period of electronic prescription transition is over (end 2011). The electronic prescription can be modified, revoked and renewed if patient consent is acquired, by the prescribing physician or a pharmacist, after due consultation. All modifications have to be signed by the healthcare professional applying the modification, as well as all renewals also. Any pharmacy in the country has access to the electronic prescription database and access is granted by the user or his or her assigned proxy. The patient has to identify herself and a proxy must have a signed assignment. The pharmacy will use information discovery services in order to retrieve patient care specific data from the database, such as use of proxy, insurance details etc. A paper information sheet is always delivered together with the medicines, unless the patient explicitly denies reception.

Limitations to secrecy are defined in §15 of the Act and they cover the following cases: information related supervision of healthcare professionals, medical safety guidance development, study and research. When not necessary, patient identifiers are automatically omitted from the data and all organisations requesting information on electronic prescriptions, have to justify their request according to the Act on the Openness of Government Activities 1999/621 §28.

The patient has right to view and audit his or her personal data stored in the electronic prescription database. The patient has right to request viewing of the data and access log data from any of the parties involved in the process: KELA, the pharmacy or the healthcare unit. The access log data has to contain all information related to the access, use, transfer or other handling of the electronic prescription data.

Electronic prescriptions are first stored in an active electronic prescription centre, where they are readily available for up to 30 month. After this period, the electronic prescriptions are automatically transferred to a long term electronic archive, where they are stored for 10 more years, after which the data is destroyed.

The Act on Electronic Prescriptions also defines the technical implementation of the electronic prescription system. The technical definition requires that users are strongly authenticated and access is only granted based on authorisation, prescription data matches with medical data, only legally compliant electronic prescriptions are introduced to the prescription centre, electronic prescriptions are signed and encrypted, the prescription centre service is resilient and operations gather relevant log information for audit purposes, finally that all equipment used in the process are compliant with relevant standards.

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Finally, the use electronic prescriptions will become mandatory for all medical service providers in main-land Finland (exception are the Åland islands) by the end of 2011.

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9 General assessment

The Finnish regulatory framework is ready for a full implementation of eHealth projects such as the exchange of patient's summaries, telemedicine or electronic prescriptions. The KANTA health data exchange and archiving service and the citizen health portal are scheduled to be ready and online between 2009 and 2011. By then a lot of different eHealth service enablers will have to be launched or reactivated with the healthcare PKI-card deployment and large citizen eID dissemination being perhaps the biggest individual challenges. As a lot of the upcoming eHealth and healthcare ICT systems and services rely on certificate based signatures and identity management for security, confidentiality and privacy, the deployment of professional and citizen eID's needs to take place very quickly. Both projects have faced major setbacks and risk is that the regulatory requirements and the new online services will be following separate tracks with regards to citizens' capacity to use the new services once they are available.

Finland is a technology forerunner in several eHealth domains: a lot of emphasis is put on very advanced technology services such as OID based code services for health data classification, semantic web technologies to support the citizen health portal, and special importance is paid to healthcare system communication and structural interoperability. Nevertheless, basing our analysis on available documentation, we suspect that there are serious challenges that are not addressed clearly enough for the successful implementation of the eHealth strategy. We have listed some areas that should be more clearly defined:

- Health care professional identity management and federation interoperability with regards to technology standards and national initiatives. Role management problematic has been addressed on a target level, but no scalable overall solution has been defined so far: authority and ownership of identity validation and meta-directory services are not clearly defined.
- Citizen or patient identity management and federation interoperability with regards to technology standards and national initiatives. Identity management is generally limited to system authentication, which is not sufficient for achieving cross-platform single-sign on and identity federation, which are at the heart of a seamless service delivery.
- Role of the TUPAS identity scheme is not settled and only use of FINEID cards is regarded as "strong authentication".
- Web Service Security standards for secure data exchange. The standards were not defined before the KANTA system development started. As the system provider is providing the definitions, the Public Authority's possibility to independently define the implementations is considerably narrowed down. This may result into a creation of a gap between expectations and capabilities.
- Technology standards for user-centric, user-controlled and persistent privacy control mechanism. For user privacy safeguard, only use of PKI is offered as solution. This

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tendency is widely questioned since a lot of essential information should, but cannot be included in a public certificate.

- Digital signature usage and quality levels for system signatures and role-based user signatures.
- Digital signature interoperability in a cross-platform and cross-border context. No signature standard formats or Web Service integration profile standards have been proposed as a requirement.
- Role management and policy enforcement with regards to authorising of digital signatures for ePrescriptions (only certificate based solutions are envisioned)

For the development of cross-border eHealth services, the Finnish legal landscape contains no specific peculiarities. The transposition of the European data protection directive into Finnish law follows quite closely the terminology of the Directive and no major additional requirements, compared to the EU Directive, have been added for the processing of personal data concerning health.

From the perspective of cross-border interoperability, the connection of the health sector to the identity management system used for public government services, will logically lead to the adoption of similar solutions in that area as well. The solution which will ultimately be chosen to make public government services interoperable on a EU level, will automatically also be valid in the domain of eHealth.

Teemu Rissanen
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Annex: Contact details of National Correspondents

9.1 Primary Contact

Country	Finland
Name	Teemu Rissanen
Organisation	Conseils Oy
Position	Managing Director
Mailing Address	Hämeentie 153 B, FI-00560 Helsinki
Work Phone	+358 (0)9 229 19 47
Mobile Phone	+358 (0)50 379 53 43
Fax	
E-Mail	teemu.rissanen@conseils.fi

9.2 Alternative Contact

Country	Finland
Name	Tapio Rissanen
Organisation	EuroConseils sprl
Position	CEO
Mailing Address	Avenue Colonel Daumerie 5, BE-1150 Brussels
Work Phone	+32 2 779 0503
Mobile Phone	+32 485 330 102
Fax	+32 2 779 8401
E-Mail	tapio.rissanen@conseils.fi