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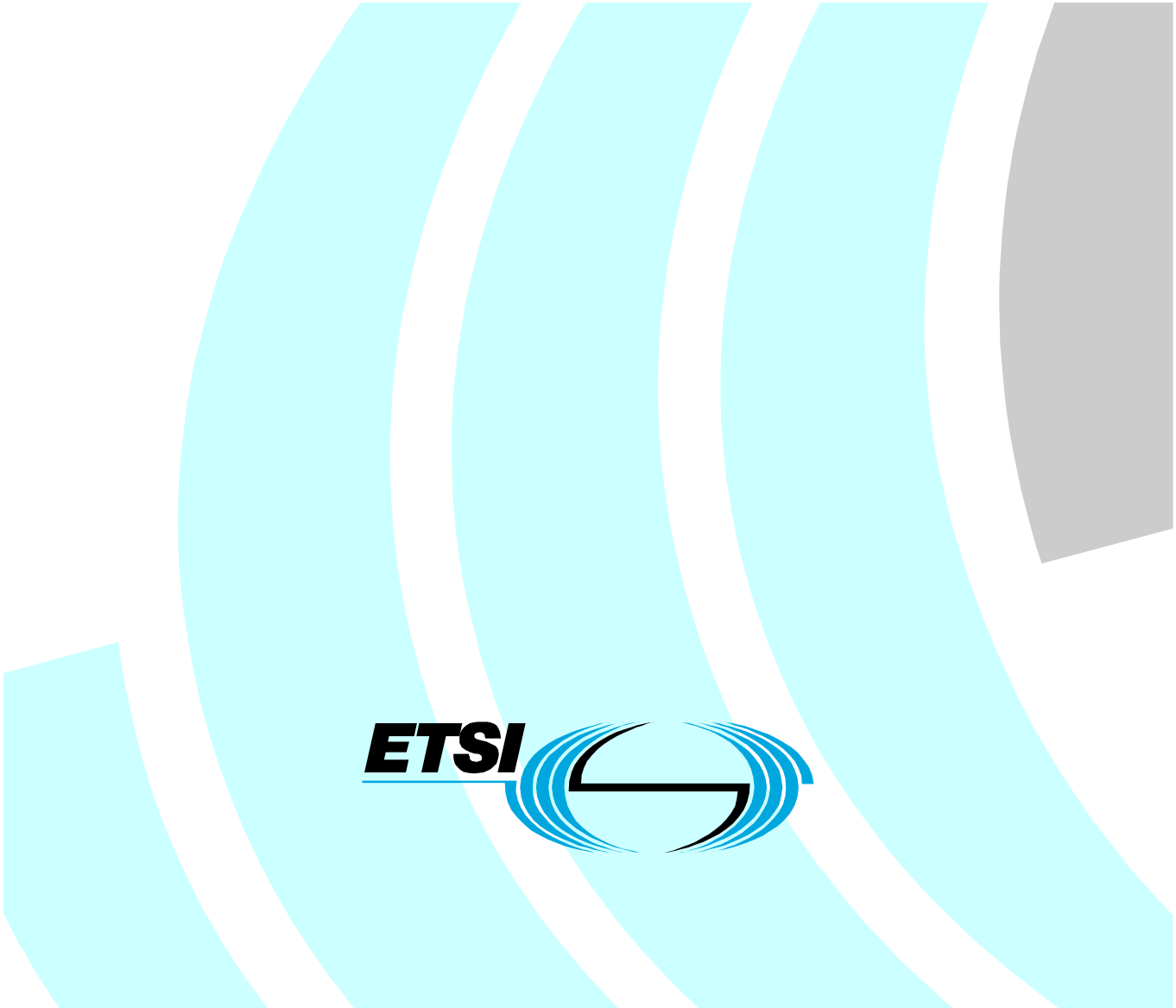
Special Report

Applicability of existing ETSI and ETSI/3GPP deliverables to eHealth



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Contents

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Foreword

This Special Report (SR) has been produced by Advisory Committee Operational Co-ordination Group (OCG).

Intended readers of the present document are:

- standards developers;
- developers and equipment manufacturers and providers in the eHealth related area;
- developers and providers of eHealth related services.

Introduction

eHealth includes the application of information and communications technologies across the whole range of functions that affect the health sector in an international (e.g. cross-border) perspective, from the doctor to the hospital manager, including nurses, data processing specialists, social security administrators and - of course - the patients. eHealth systems include tools for health authorities and professionals as well as personalized health systems for patients (individuals) and citizens (community). Examples include health information networks, electronic health records, telemedicine services, personal wearable and portable communicable systems including those for medical implants, health portals, and many other ICT-based tools assisting disease prevention, diagnosis, treatment, health monitoring and lifestyle management. (This description is based on text at the Europe's Information Society eHealth portal [210].)

The paper on "Home telehealth-Current state and future trends" presented in the "International Journal of Medical Informatics" [224] summarizes the important overall problems regarding healthcare services that most countries are facing such as:

- increased demand of healthcare due to an increased number of elderly and changed life styles leading to an increase in chronic diseases;
- demand for increased accessibility of care outside hospitals, moving health services into the patient's own homes;
- need for increased efficiency, individualization and equity of quality-oriented healthcare within limited financial resources;
- difficulties of recruiting and retaining personnel in the healthcare services in general and in home and elderly care in particular.

It is expected that eHealth will provide partial but significant solutions to the above issues, as it has been recognized as a potential tool to provide access to timely, efficient, and high quality healthcare. Driving forces exist for implementing new solutions such as the migration to self-managed care and allowing increased patient mobility at an international level (e.g. cross border). However, there are numbers of hindrances and restrictions when it comes to practical and sustainable use of eHealth. One of the major problems identified by the participants in the World of Health IT event held in October 2006 in Geneva is the lack of ICT standards especially for interoperability related to the eHealth area. The present document addresses work within the ETSI domain necessary for solving identified problems.

A key ambition of the EU policy is the provision of better care services at the same or lower cost. eHealth is regarded as [210] "today's tool for substantial productivity gains, while providing tomorrow's instrument for restructured, citizen-centred health care systems and, at the same time, respecting the diversity of Europe's multi-cultural, multi-lingual health care traditions. There are many examples of successful e-Health developments including health information networks, electronic health records, telemedicine services, wearable and portable monitoring systems, and health portals."

eHealth related work has been done in several ETSI Technical Bodies: however, there is currently no specific committee structure for eHealth standardization work. It is felt that the importance of the subject matter could justify the creation of a new ETSI Technical Body, but before taking this step, it is necessary to further analyse the work to be performed. The present document provides the results of an analysis of the applicability of existing ETSI and ETSI/3GPP deliverables for eHealth matters, and specifies the need for further work in this area. Based upon the present document, further actions may be undertaken.

1 Scope

The scope of the present document is to define which ETSI and ETSI/3GPP deliverables are applicable to the eHealth domain and identify gaps where there is a need for future standardization work.

The present document provides an outline architecture to identify relevant standards, standardization activities and stakeholders interests that may be relevant to the eHealth area. However, investigation about the status of standards in other organizations, and identification of necessary External Relationships will be the task of the ETSI Technical Body and is not covered under the scope of the present document.

2 References

For the purposes of this Special Report (SR), the following references apply:

NOTE: While any hyperlinks included in this clause were valid at the time of publication ETSI cannot guarantee their long term validity.

Radio:

[1] ETSI EN 301 839-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods".

[2] ETSI EN 301 839-2 (V1.2.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[3] ETSI EN 302 195-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 1: Technical characteristics and test methods".

[4] ETSI EN 302 195-2 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[5] ETSI EN 302 208-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio Frequency Identification Equipment operating in the band 865 MHz to 868 MHz with power levels up to 2 W; Part 1: Technical requirements and methods of measurement".

[6] ETSI EN 302 208-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio Frequency Identification Equipment operating in the band 865 MHz to 868 MHz with power levels up to 2 W; Part 2: Harmonized EN under article 3.2 of the R&TTE Directive".

[7] ETSI TR 101 445: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD) intended for operation in the 862 MHz to 870 MHz band; System Reference Document for Radio Frequency Identification (RFID) equipment".

[8] ETSI TR 102 436: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD) intended for operation in the band 865 MHz to 868 MHz;. Guidelines for the installation and commissioning of Radio Frequency Identification (RFID) equipment at UHF".

[9] ETSI TR 102 449: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Overview of Radio Frequency Identification (RFID) Tags in the telecommunications industry".

[10] ETSI EN 301 489-27: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)".

[11] ETSI EN 301 489-31: "Electromagnetic compatibility and Radio spectrum Matters (ERM);ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)".

[12] ETSI EN 300 220-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW; Part 1: Technical characteristics and test methods".

[13] ETSI EN 300 220-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW; Part 2: Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive".

[14] ETSI EN 300 220-3: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW; Part 3: Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive".

[15] ETSI EN 300 330-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Part 1: Technical characteristics and test methods".

[16] ETSI EN 300 440-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 2: Harmonized EN under article 3.2 of the R&TTE Directive".

[17] ETSI EN 300 328: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive".

[18] ETSI EN 301 489: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services".

[19] ETSI EN 302 510 (Parts 1 and 2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories ".

[20] ETSI EN 302 536 (Parts 1 and 2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 315 kHz to 600 kHz".

[21] ETSI EN 302 537 (Parts 1 and 2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz".

WiMAX:

[22] ETSI TS 102 385-1: "Broadband Radio Access Networks (BRAN); HiperMAN; Conformance Testing for WiMAX/HiperMAN 1.2.1; Part 1: Protocol Implementation Conformance Statement (PICS) proforma".

[23] ETSI TS 102 385-2: "Broadband Radio Access Networks (BRAN); HiperMAN; Conformance Testing for WiMAX/HiperMAN 1.2.1; Part 2: Test Suite Structure and Test Purposes (TSS&TP)".

[24] ETSI TS 102 385-3: "Broadband Radio Access Networks (BRAN); HiperMAN; Conformance Testing for WiMAX/HiperMAN 1.2.1; Part 3: Abstract Test Suite (ATS)".

[25] ETSI TS 102 177 (RTS/BRAN-0040001r5): "Broadband Radio Access Networks (BRAN); HiperMAN; Physical (PHY) layer".

[26] ETSI TS 102 178 (RTS/BRAN-0040002r4): "Broadband Radio Access Networks (BRAN); HiperMAN; Data Link Control (DLC) layer".

[27] ETSI TS 102 545-1 (DTS/BRAN-004T008-1): "Broadband Radio Access Networks (BRAN); HiperMAN; Conformance Testing for WiMAX/HiperMAN 1.3.1; Part 1: Protocol Implementation Conformance Statement (PICS) pro forma".

[28] ETSI TS 102 545-2 (DTS/BRAN-004T008-2): "Broadband Radio Access Networks (BRAN); HiperMAN; Conformance Testing for WiMAX/HiperMAN 1.3.1; Part 2: Test Suite Structure and Test Purposes (TSS&TP)".

[29] ETSI TS 102 545-3 (DTS/BRAN-004T008-3): "Broadband Radio Access Networks (BRAN); HiperMAN; Conformance Testing for WiMAX/HiperMAN 1.3.1; Part 3: Abstract Test Suite (ATS)".

UWB:

[30] ETSI TS 102 455: "High Rate Ultra Wideband PHY and MAC Standard [ECMA-368/December 2005, modified]".

[31] ETSI TR 101 994-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Technical characteristics for SRD equipment using Ultra Wide Band technology (UWB) Part 1: Communications applications".

[32] ETSI TS 102 456 (DTS/ECMA-00301): "MAC-PHY Interface for ECMA-00300".

[33] ETSI EN 301 489-33 (DEN/ERM-EMC-230-33): "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 33: EMC requirements for UWB communications devices".

[34] ETSI TR 102 495-5 (DTR/ERM-RM-044-5): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Technical characteristics for SRD equipment using Ultra Wide Band Sensor technology (UWB); System Reference Document Part 5: Object Identification for Surveillance applications operating in the Frequency range from 2.2 GHz to 8 GHz".

[35] ETSI TR 101 994-1 (RTR/ERM-RM-048-1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Technical characteristics for SRD equipment using Ultra Wide Band technology (UWB) Part 1: Communications applications".

[36] ETSI DTS/ERM-TG31A-E-001: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short-range location application for emergency services in the frequency range from 3 GHz to 5 GHz; Short-range location application for emergency services".

[37] ETSI EN 302 065 (DEN/ERM-TG31A-0112-1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD) using Ultra Wide Band technology (UWB) for communications purposes".

[38] ETSI DTR/ERM-TG31A-0113: "Electromagnetic compatibility and Radio spectrum Matters (ERM) Short Range Devices (SRD) using Ultra Wide Band technology (UWB) for communications purposes; UWB communications technologies".

[39] ETSI DTS/ERM-TG31A-0114: "Electromagnetic compatibility and Radio spectrum Matters (ERM) Short Range Devices (SRD) using Ultra Wide Band technology (UWB) for communications purposes; Mitigation techniques for UWB communications technologies".

[40] ETSI DTR/ERM-TG31A-0115: "Electromagnetic compatibility and Radio spectrum Matters (ERM) Short Range Devices (SRD) using Ultra Wide Band technology (UWB) for communications purposes; RF Complianced test methods for UWB communications technologies".

Network:

[41] 3GPP TS 22.259: "3rd Generation Partnership Project; Technical Specification Group Service and System Aspects; Service requirements for Personal Network Management (PNM); Stage 1 (Release 8)".

Interoperability:

[42] ETSI white paper: "Achieving Technical Interoperability - the ETSI Approach".

NOTE: Available at: http://portal.etsi.org/docbox/OCG/OCG_IOP/IOP%20White%20Paper/

Testing:

[43] ETSI TS 101 324: "Telecommunications and Internet Protocol Harmonization Over Networks (TIPHON); Numbering; Scenarios 1, 2, 3 and 4".

[44] ETSI TS 102 265: "Digital Enhanced Cordless Telecommunications (DECT); DECT access to IP networks".

[45] ETSI TR 102 419: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Security analysis of IPv6 application in telecommunications standards".

[46] ETSI TR 123 923: "Universal Mobile Telecommunications System (UMTS); Combined GSM and Mobile IP mobility handling in UMTS IP CN (3GPP TR 23.923)".

[47] ETSI MI/UMTS-00009: "Universal Mobile Telecommunications System (UMTS); The use of IPv6 in UMTS".

Smart cards:

[48] ETSI TS 102 221: "Smart cards; UICC-Terminal interface; Physical and logical characteristics ".

[49] ETSI TS 102 223: "Smart cards; Card Application Toolkit (CAT)".

[50] ETSI TS 131 102: "Universal Mobile Telecommunications System (UMTS); Characteristics of the Universal Subscriber Identity Module (USIM) application (3GPP TS 31.102)".

[51] ETSI TS 151 011: "Digital cellular telecommunications system (Phase 2+); Specification of the Subscriber Identity Module - Mobile Equipment (SIM-ME) interface (3GPP TS 51.011)".

[52] ETSI TS 100 812-2: "Terrestrial Trunked Radio (TETRA); Subscriber Identity Module to Mobile Equipment (TSIM-ME) interface; Part 2: Universal Integrated Circuit Card (UICC); Characteristics of the TSIM application".

[53] ETSI TS 131 103: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Characteristics of the IP Multimedia Services Identity Module (ISIM) application (3GPP TS 31.103)".

[54] 3GPP2 C.S0023-0: "Removable User Identity Module (R-UIM) for cdma2000 Spread Spectrum Systems".

[55] ETSI TS 102 222: "Integrated Circuit Cards (ICC); Administrative commands for telecommunications applications (Release 7)".

[56] ETSI TS 102 225: "Smart Cards; Secured packet structure for UICC based applications (Release 7)".

[57] ETSI TS 102 226: "Smart Cards; Remote APDU structure for UICC based applications (Release 6)".

[58] ETSI TS 102 240: "Smart Cards; UICC Application Programming Interface and Loader Requirements; Service description; (Release 6)".

[59] ETSI TS 102 241: "Smart Cards; UICC Application Programming Interface (UICC API) for Java Card (TM) (Release 6)".

[60] ETSI TS 102 310: "Smart Cards; Extensible Authentication Protocol support in the UICC".

[61] ETSI TS 102 230: "Smart cards; UICC-Terminal interface; Physical, electrical and logical test specification".

[62] ETSI TS 102 124: "Smart Cards; Transport Protocol for UICC based Applications".

[63] ETSI TS 101 220: "Smart Cards; ETSI numbering system for telecommunication application providers".

[64] ETSI TR 122 907: "Universal Mobile Telecommunications System (UMTS); Terminal and smart card concepts".

[65] ETSI TR 102 151: "Smart Cards; Measurement of Electromagnetic Emission of SIM Cards".

Application services - Open Service Access (OSA);Parlay X Web Services:

[66] ETSI ES 202 391-1: "Open Service Access (OSA); Parlay X Web Services; Part 1: Common (Parlay X 2)".

[67] ETSI ES 202 391-2: "Open Service Access (OSA);Parlay X Web Services; Part 2: Third Party Call (Parlay X 2)".

[68] ETSI ES 202 391-3: "Open Service Access (OSA); Parlay X Web Services; Part 3: Call Notification (Parlay X 2)".

[69] ETSI ES 202 391-4: "Open Service Access (OSA); Parlay X Web Services; Part 4: Short Messaging (Parlay X 2)".

[70] ETSI ES 202 391-5: "Open Service Access (OSA); Parlay X Web Services; Part 5: Multimedia Messaging (Parlay X 2)".

[71] ETSI ES 202 391-6: "Open Service Access (OSA); Parlay X Web Services; Part 6: Payment (Parlay X 2)".

[72] ETSI ES 202 391-7: "Open Service Access (OSA); Parlay X Web Services; Part 7: Account Management (Parlay X 2)".

[73] ETSI ES 202 391-8: "Open Service Access (OSA); Parlay X Web Services; Part 8: Terminal Status (Parlay X 2)".

[74] ETSI ES 202 391-9: "Open Service Access (OSA); Parlay X Web Services; Part 9: Terminal Location (Parlay X 2)".

[75] ETSI ES 202 391-10: "Open Service Access (OSA); Parlay X Web Services; Part 10: Call Handling (Parlay X 2)".

[76] ETSI ES 202 391-11: "Open Service Access (OSA); Parlay X Web Services; Part 11: Audio Call (Parlay X 2)".

[77] ETSI ES 202 391-12: "Open Service Access (OSA); Parlay X Web Services; Part 12: Multimedia Conference (Parlay X 2)".

[78] ETSI ES 202 391-13: "Open Service Access (OSA); Parlay X Web Services; Part 13: Address List Management (Parlay X 2)".

[79] ETSI ES 202 391-14: "Open Service Access (OSA); Parlay X Web Services; Part 14: Presence (Parlay X 2)".

QoS:

[80] ETSI TS 122 105: "Universal Mobile Telecommunications System (UMTS); Services and service capabilities (3GPP TS 22.105 version 6.4.0 Release 6)".

[81] ETSI TS 123 107: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Quality of Service (QoS) concept and architecture (3GPP TS 23.107 version 6.4.0 Release 6)".

[82] ETSI TS 123 207: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); End-to-end Quality of Service (QoS) concept and architecture (3GPP TS 23.207)".

[83] ETSI EG 202 057-1: "Speech Processing, Transmission and Quality Aspects (STQ); User related QoS parameter definitions and measurements; Part 1: General".

[84] ETSI EG 202 057-2: "Speech Processing, Transmission and Quality Aspects (STQ); User related QoS parameter definitions and measurements; Part 2: Voice telephony, Group 3 fax, modem data services and SMS".

[85] ETSI EG 202 057-3: "Speech Processing, Transmission and Quality Aspects (STQ);User related QoS parameter definitions and measurements; Part 3: QoS parameters specific to Public Land Mobile Networks (PLMN)".

[86] ETSI EG 202 057-4: "Speech Processing, Transmission and Quality Aspects (STQ);User related QoS parameter definitions and measurements; Part 4: Internet access".

[87] ETSI EG 202 009-1: "User Group; Quality of Telecom Services; Part 1: Methodology for identification of parameters relevant to the Users".

[88] ETSI EG 202 009-2: "User Group; Quality of telecom services; Part 2: User related parameters on a service specific basis".

[89] ETSI EG 202 009-3: "User Group; Quality of telecom services; Part 3: Template for Service Level Agreements (SLA)".

[90] ETSI TR 102 049: "Power Line Telecommunications (PLT);Quality of Service (QoS) requirements for in-house systems".

[91] ETSI TR 102 157: "Satellite Earth Stations and Systems (SES);Broadband Satellite Multimedia; IP Interworking over satellite; Performance, Availability and Quality of Service".

[92] ETSI TR 102 521: "Speech Processing, Transmission and Quality aspects (STQ); Support to TC EMTEL for QoS and Transmission Quality aspects for end-to-end services".

[93] ETSI TS 102 250-1: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 1: Identification of Quality of Service aspects".

[94] ETSI TS 102 250-2: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 2: Definition of Quality of Service parameters and their computation".

[95] ETSI TS 102 250-3: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 3: Typical procedures for Quality of Service measurement equipment".

[96] ETSI TS 102 250-4: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 4: Requirements for Quality of Service measurement equipment".

[97] ETSI TS 102 250-5: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 5: Definition of typical measurement profiles".

[98] ETSI TS 102 250-6: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 6: Post processing and statistical methods".

[99] ETSI TS 185 001: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Next Generation Network (NGN); Quality of Service (QoS) Framework and Requirements".

[100] ETSI TR 102 479: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Review of available material on QoS requirements of Multimedia Services".

[101] ETSI TS 102 462: "Satellite Earth Stations and Systems (SES); Broadband Satellite Multimedia (BSM); QoS Functional Architecture".

ECMA/ETSI (Mobility and single-sign-on):

[102] ETSI TR 102 477: "Corporate telecommunication Networks (CN); Mobility for enterprise communication".

Location based services:

[103] ETSI TS 122 071: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Location Services (LCS); Service description; Stage 1 (3GPP TS 22.071)".

[104] ETSI TS 123 271: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Functional stage 2 description of Location Services (LCS) (3GPP TS 23.271)".

[105] ETSI TS 123 032: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Universal Geographical Area Description (GAD) (3GPP TS 23.032)".

Broadcast, multicast and satellite (Bms):

[106] ETSI TS 122 246: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Multimedia Broadcast/Multicast Service (MBMS) user services; Stage 1 (3GPP TS 22.246)".

[107] ETSI TS 123 246: "Universal Mobile Telecommunications System (UMTS); Multimedia Broadcast/Multicast Service (MBMS); Architecture and functional description (3GPP TS 23.246)".

[108] ETSI EN 301 790: "Digital Video Broadcasting (DVB); Interaction channel for satellite distribution systems".

[109] ETSI TR 101 790: "Digital Video Broadcasting (DVB); Interaction channel for Satellite Distribution Systems; Guidelines for the use of EN 301 790".

[110] ETSI EN 300 468: "Digital Video Broadcasting (DVB); Specification for Service Information (SI) in DVB systems".

[111] ETSI EN 300 744: "Digital Video Broadcasting (DVB); Framing structure, channel coding and modulation for digital terrestrial television".

[112] ETSI EN 301 192: "Digital Video Broadcasting (DVB); DVB specification for data broadcasting".

[113] ETSI TS 101 154: "Digital Video Broadcasting (DVB); Implementation guidelines for the use of Video and Audio Coding in Broadcasting Applications based on the MPEG-2 Transport Stream".

[114] ETSI EN 302 304: "Digital Video Broadcasting (DVB); Transmission System for Handheld Terminals (DVB-H)".

[115] ETSI TS 123 041: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Technical realization of Cell Broadcast Service (CBS) (3GPP TS 23.041)".

[116] ETSI TR 102 444: "Emergency Communications (EMTEL); Analysis of the Short Message Service (SMS) and Cell Broadcast Service (CBS) for Emergency Messaging applications; Emergency Messaging; SMS and CBS".

Multimedia:

[117] ETSI TS 122 228: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Service requirements for the Internet Protocol (IP) multimedia core network subsystem (IMS); Stage 1 (3GPP TS 22.228)".

Priority:

[118] ETSI EN 300 392-10-16: "Terrestrial Trunked Radio (TETRA); Voice plus Data (V+D); Part 10: Supplementary services stage 1; Sub-part 16: Pre-emptive Priority Call (PPC)".

Address book:

[119] ETSI TS 102 334-1: "Network Address Book on fixed network; Part 1: Overview".

[120] ETSI TS 102 334-2: "Network Address Book on fixed network; Part 2: Service description".

[121] ETSI TS 102 334-3: "Network Address Book on fixed network; Part 3: vCard 2.1 profile for contact exchange by SMS/EMS for fixed network".

[122] ETSI TS 102 334-4: "Network Address Book on fixed network; Part 4: Data synchronization".

Device control:

[123] ETSI TS 123 240: "Universal Mobile Telecommunications System (UMTS); 3GPP Generic User Profile (GUP) requirements; Architecture (Stage 2) (3GPP TS 23.240)".

[124] ETSI TS 127 005: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Use of Data Terminal Equipment - Data Circuit terminating Equipment (DTE-DCE) interface for Short Message Service (SMS) and Cell Broadcast Service (CBS) (3GPP TS 27.005)".

SMS:

[125] ETSI TS 123 040: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Technical realization of Short Message Service (SMS) (3GPP TS 23.040)".

[126] ETSI TS 124 011: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Point-to-Point (PP) Short Message Service (SMS) support on Mobile Radio Interface (3GPP TS 24.011)".

[127] ETSI TS 123 042: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Compression algorithm for SMS (3GPP TS 23.042)".

[128] ETSI TR 122 940: "Universal Mobile Telecommunications System (UMTS); IP Multimedia Subsystem (IMS) messaging; Stage 1 (3GPP TR 22.940)".

[129] ETSI TS 122 340: "Universal Mobile Telecommunications System (UMTS); IP Multimedia Subsystem (IMS) messaging; Stage 1 (3GPP TS 22.340)".

[130] ETSI TR 181 007: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Overview of Messaging Services".

[131] ETSI TS 123 038: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Alphabets and language-specific information (3GPP TS 23.038)".

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3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the following terms and definitions apply:

active RFID Tag: RFID tag that has its own power source

assistive technologies: any product, instrument, equipment or technical system used by a disabled person to prevent, compensate, relieve or neutralize an impairment, disability or handicap

assistive technology device: device used by a disabled person to prevent, compensate, relieve or neutralize any resultant handicap and which has the ability to interface to an ICT device

AT: two character abbreviation used to start a command line sent from terminal equipment to a terminal adaptor

auditability: ability to track the consumption of resources by users and applications

authentication: provision of assurance of the claimed identity of an entity, confirmation that a user who is requesting services is a valid user of the network services requested

authorization: administrative act of granting 'access rights'; refers to granting access to specific types of service (including "no service") to users, based on their authentication, services requested, and state of the system

availability: degree to which a system, subsystem, or equipment is operable and in a committable state at a random point in time

caregiver: individual who provides care to the client, mediated through or assisted by the eHealth service

caretaker: individual receiving the eHealth service, to support independent living and/or using eHealth services for the care of his or her own health

confidentiality: property that information is not made available or disclosed to unauthorized individuals, entities, or processes

address book: entity that contains a number of records describing potential contacts of the user

design for all: design of products to be usable by all people, to the greatest extent possible, without the need for specialized adoption

home care: care arranged by social and/or health related services and delivered to individuals in their own homes

eHealth: application of ICT across the whole range of functions that affect health

NOTE: Also written e-health, e-Health, E-Health, E-health in other publications.

ICT devices and services: devices or services for processing information and/or supporting communication, which has an interface to communicate with a user

impairment: any reduction or loss of psychological, physiological or anatomical function or structure of a user (environmental included)

informal caregivers: relatives, neighbours, friends or volunteers providing care for the person in need

integrity: condition in which data is identically maintained during any operation

intelligent home: See **smart house.**

localization: involves taking a product and making it linguistically and culturally appropriate to the target locale (country/region and language) where it will be used and sold (Definition from LISA)

mobility: See **personal (user) mobility** and **service mobility**.

passive RFID Tag: RFID tag that does not have its own power source

personal (user) mobility: ability for the user to access personal services and data independent of the device and access network used (including user's fixed and mobile devices), while maintaining their personal communication environment

residential care: personal and/or nursing care that is provided to a person in a formally managed care home, in which the person is also provided with accommodation that includes appropriate staffing, meals, cleaning services, furnishings and equipment, for the provision of that care and accommodation

Public Safety Answering Point (PSAP): physical location where emergency calls are received under the responsibility of a public authority

role based access control: approach to restricting system access to authorized users

safety: degree to which a system may operate without causing harm, which includes its tamper resistance

service mobility: possibility for services to be accessed and delivered independently of network, terminal or geographical location attributes

single sign-on: procedure by which a user gains access to all authorized communication services

smart card: card that has a microprocessor and storage capability embedded in it

NOTE: Also written smartcard, Smart Card, SmartCard other publications.

smart house: house with a communication infrastructure, allowing interconnectivity of systems and devices in that home

telecare: delivery of health and social care to individuals within the home or wider community, with the support of systems enabled by ICT

traceability: ability to ensure that the operations associated with the resources are recorded and can be subsequently reproduced

usability: effectiveness, efficiency and satisfaction with which specified users can achieve specified goals (tasks) in a particular environment

NOTE: It includes the concepts of learnability and flexibility.

user profile: set of user related settings and information

3.2 Abbreviations

For the purposes of the present document, the following abbreviations apply:

3G	3rd Generation
3GPP	3rd Generation Partnership Project
A-GPS	Assisted GPS
AT command	ATtention Command
AT	Access and Terminals (Technical committee AT)
CAT	Card Application Toolkit
CEPT	European Conference of Posts and Telecommunications
DECT	Digital Enhanced (formerly European) Cordless Telecommunications
DVB-H	DVB Handheld system
EBU	European Broadcasting Union
ECMA	European Computer Manufacturers Association
EHR	Electronic Health Record
EMTEL	EMergency TELecommunications
EOTD	Enhanced Observed Time Difference
ETP	European Technology Platform
GDP	Gross Domestic Product
GPRS	General Packet Radio Service
GPS	Global Positioning System
GSM	Global System for Mobile telecommunication
GW	GateWay
ICC	Integrated Circuit Cards

ICT	Information and Telecommunication Technologies
IdP	Identity Provider
IMS	IP Multimedia Subsystem
ISP	Internet Service Provider
ITS	Intelligent Transport Systems
IP	Internet Protocol (also known as TCI/IP)
IPv6	Internet Protocol version 6
JTC	Joint Technical Committee
LAP	Liberty Alliance Project
LI	Lawful Interception
LCS	LoCation Services
MAN	Metropolitan Area Networks
MBMS	Multimedia Broadcast/Multicast Service
M2M	Machine to Machine
ML	Markup Language
MMI	Man-Machine Interface
NAA	Network Access Application
NGN	Next Generation Networks
OCG	Operations Coordination Group (a body in ETSI coordinating TB's)
OMA	Open Mobile Alliance
PAN	Personal Area Network
PAS	Publicly Available Specification
PIN	Personal Identity Number
PWS	Public Warning System
PSAP	Public Safety Answering Point
PSTN	Public Switched Telephone Network
QoS	Quality of Service
RBAC	Role Based Access Control
RFID	Radio Frequency IDentification
SAML	Security Assertion Markup Language
SCP	Smart Card Platform
SDO	Standards Development Organization
SIP	Session Initiation Protocol
SMS	Short Message Services
STQ	Speech processing, Transmission and Quality aspects
SUPL	Secure User PLane
TB	Technical Body
TC	Technical Committee
TETRA	TErrestrial Trunked RAdio
TISPAN	Telecommunication and Internet converged Services and Protocols for Advanced Networking
TVRA	Threat Vulnerability Risk Assessment
UCI	Universal Communications Identifier
UICC	Universal Integrated Circuit Card
UMTS	Universal Mobile Terrestrial System, also known as 3G (Third Generation)
URC	Universal Remote Console
U-TDOA	Uplink Time Difference Of Arrival
UWB	Ultra Wide Band
VoIP	Voice over Internet Protocol
WAPECS	Wireless Access Policy for Electronic Communication Services
WCDMA	Wideband Code Division Multiple Acces
WiFi	Wireless Fidelity ISO/IEC local area network standard (IEEE 802.11 family)
WiMax	IEEE 802.16 (common name)
XML	eXtensible Markup Language

4 Background

4.1 Socio-economic development

It is estimated that in 2051, 40 % of the European population will be 65 years or older [215], [225]. Responding to demands for better healthcare raised by an ageing population can increase the cost at a time when health care spending is already on the increase. In 1970, the healthcare related spending of the Organization for Economic Co-operation and Development (OECD, www.oecd.org) countries averaged 5 % of GDP. This increased to 7 % in 1990, currently exceeding 10 % in Germany, Sweden, Switzerland and the United States.

In order to control the increasing expenses, OECD recommends actions that include the introduction of automated health data systems, strategies providing improved quality of care through better access to information and the application of new technologies.

4.2 Current situation and requirements

The European Commission study "eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites" [219] is one of the first attempts to assess the real impact of eHealth applications, their benefits and safety aspects. The 10 case studies clearly demonstrate that eHealth matters, that it is well worth the investment, and that it can lead to substantial economic and social benefits. eHealth can lead to improved treatment quality, better access to care, avoidance of unnecessary public expenditure. Information and Communication Technologies (ICT) can greatly benefit all aspects of delivering healthcare.

The report on "Home telehealth - Current state and future trends" [224] has identified a number of hindrances and restrictions when it comes to practical and sustainable use of ICT-based home healthcare. The report also suggests further research work and lists the following identified issues and research areas.

The issues [224] include:

- the lack of standards to combine incompatible information systems;
- the lack of an evaluation framework considering legal, ethical, organizational, economical, clinical, usability and technical aspects;
- the lack of proper guidelines for practical implementation of potential home telehealth solutions.

Therefore, research is critical in order to determine the impacts and benefits, and limitations, of potential solutions. In an international research perspective, there is a need [224] for:

- new cross-disciplinary evaluation methods for home telehealth tools and services;
- better design solutions considering usability aspects for future users (such as, e.g. elderly);
- better tools for self-managed care (patient empowerment), tools for family caregivers and relatives and individual services to support a healthier lifestyle;
- better methods for introduction of home telehealth tools and services into clinical practice;
- better integration of new knowledge about diagnosis and treatment into evidence-based decision support tools at the point of care;
- further development of wireless tools and devices (e.g. smart clothing);
- more research on privacy and confidentiality issues, payment and reimbursement issues as well as legal and ethical issues.

4.3 Policies and strategies

The EU Policy encourages EU Member States to seek a balanced status among the detected needs of providing quality care and social services to citizens, being compliant to standards, containing costs at a national level, and managing services at a local level. The eHealth Action Plan [207] states that "eHealth is today's tool for substantial productivity gains, while providing tomorrow's instrument for a restructured, citizen centred health system and, at the same time, respecting the diversity of Europe's multicultural, multilingual healthcare traditions". A key ambition is better care services at the same or a lower cost.

e Health has been identified as one of the priority objectives of the eEurope 2005 [206] and i2010 Action Plans, while the eHealth Action Plan [207] has identified and set up the practical steps required to build a "European eHealth area":

- Basic level: by mid 2004, a European Health Identity Card (EHIC) shall be introduced.
- National level: by 2005, EU member states are required to develop national and regional e Health strategies.
- Interoperability level: by 2006, national healthcare networks should be well advanced in their efforts to exchange information, including client identifiers.
- Networked level: by 2008, health information and services such as e prescription, e referral, telemonitoring and telecare, are to become commonplace, accessible over both fixed and mobile broadband networks.

4.4 Shift in Health System Paradigms

The challenges to healthcare systems in Europe and beyond mentioned above motivate a two-fold paradigm shift:

a) from symptom-based to preventive healthcare; and

b) from hospital-centred to person-centred health systems.

Achieving this paradigm shift will ensure continuity of care at all levels, from prevention to rehabilitation, and at all places where citizens or patients may need care, whether inside clinical settings or in ordinary living and working environments (*"follow me" healthcare*). It will also enable provision of personalized care, from lifestyle and health status management to individualized medicines and treatment. ICT for Health [215] can be instrumental in supporting this paradigm shift by developing systems and services to:

- Accelerate the advancement of medical knowledge and improve the understanding of disease-related processes (e.g. by using HealthGrids).
- Empower citizens to become actively involved in managing their own health status.
- Improve prevention and early diagnosis of many diseases, thus reducing overall healthcare costs and improving the citizens' quality of life.
- Enhance patient safety.
- Enable cost-effective management of chronic diseases.
- Facilitate active ageing and independent living for the ageing population.

From a technical perspective, the person-centred paradigm typically involves homecare, mobile and continuous patient monitoring, personal sensor/body area network equipment, etc. The related infrastructure has to be primarily secure, while being user-oriented, context-sensitive, process-driven, workflow-controlled and semantically interoperable.

As the relevance of individual lifestyle, wellness and prevention is emphasized, private financial responsibility and expenditures for health-related services and products will increase. The developing new private health market co-exists and partly overlaps with the traditional, mainly insurance-based regulated health system. A number of business models in the eHealth area encourage a wide range of third-party service providers to play an important role in providing eHealth application services and content to end-users. The eHealth business cases and opportunities will greatly benefit from the availability of eHealth-related standards.

5 eHealth action plan

The aim of the eHealth action plan [207] is to provide user-friendly and interoperable information systems for patients and health professionals across Europe.

The eHealth action plan [207] states major challenges for wider implementation, including (among others):

- "Issues relating to the **mobility of patients, including the cross border circulation of goods and services, among which e-Health services are of growing importance**. In this light, a European strategy is needed - which forms part of the current Communication on patient mobility - to ensure that citizens can exercise their rights to seek care in other Member States if they wish, and that European cooperation can help systems to work together to meet better the challenges they face. Regulation 1408/71 [208] has been recently updated to take these issues into account: it provides a streamlined framework for the assumption of costs arising from cross border healthcare, based on the tariffs and fees in force in the Member State where the healthcare is delivered. However, to benefit from this equal treatment provision, the social security institutions may be allowed, in certain circumstances (most notably hospital care), to grant an authorization prior to the delivery of the care. In addition, in January 2004, the Commission adopted a proposal for a directive on services in the internal market which deals with the cross border provision of health care services."

- "**Confidentiality and security issues**. Firstly, the confidentiality and protection of patient data is governed by the general European Union rules of data protection, as well as by the requirements of ePrivacy legislation regarding communications infrastructure. The requirement for confidentiality makes health information systems security critical. There is a provision within the general data protection directive to create a code of conduct for special domains such as health, but this has not yet been taken forward. Another important legal issue is liability in the event of problems - such as technical malfunctions of the system, network, or provision of the service itself - that result in serious harm to a patient. While there are currently no specific guidelines or liability rules, as with any emerging or growing area of practice, only the increased use of e-Health applications and the performance of eHealthcare will make its potential fully visible as well as raising any remaining legal uncertainties. The electronic commerce Directive, which creates a legal framework for the provision of information society services, also applies to the provision of online health services. The Directive, principally by virtue of its internal market clause, contributes to the legal certainty and clarity needed for the provision of online information society services throughout the entire Community. In particular, its provisions on information and transparency requirements, commercial communications, the liability of intermediary service providers, and the basic principles it establishes regarding electronic contracts, provide for high standards in the provision of online services in all Member States, thus also increasing consumer confidence. Further steps might be considered if they could show that even greater legal certainty would reinforce patient confidence in e-Health services. Similar safeguards for qualifications might also be useful. Building trust is a prerequisite to the development of an information society, in e-Health probably more than anywhere else. **Citizens prefer services and information tailored to their needs and requirements, while knowing that their right to privacy is protected**."

- "**Interoperability of e-Health systems**. Interoperability should enable the seamless integration of heterogeneous systems. This will allow secure and fast access to comparable public health data and to patient information located in different places over a wide variety of wired and wireless devices. However, this depends on standardization of system components and services such as health information systems, health messages, electronic health record architecture, and patient identifying services. Work has been launched within European standards organizations to answer this issue partly, but the take-up of e-Health interoperability standards has been slow and - in addition - to achieve actual interoperability is a separate task. Interoperable e-Health solutions should also support the technical platform for the implementation of such initiatives as the creation of a European network of centres of reference to promote co-operation across medical institutions across the Community".

- "**Lack of regulation and fragmentation of e-Health market in Europe**. Most e-Health solutions in the Union have either been designed by small- and medium-sized businesses or are developed internally by specific health organizations. The **lack of standards and accreditation of products**, **together with different national regulations, have pushed up the cost of development and customization**. This has held the e-Health industry back from more substantial investment in e-Health solutions. Overall, health care systems are highly regulated through different forms of national regulation yet, at the same time, there is a need for improving legal certainty regarding the conditions for reimbursement of medical costs incurred in another Member State."

- "**User friendliness of e-Health systems and services.** A top priority for health providers in using an e-Health system is speed in getting the desired, high-quality results. There is an absolute need for fast connection, connectivity, and high speed. This highlights the importance of ensuring broadband connection for online health services and infrastructure for regional health information networks. Configuring personal preferences to ensure usability is also key."

- "**Needs and interests of users**. The take-up of e-Health systems and services would take place more rapidly were the needs and interests of the user communities (health professionals, patients, and citizens) to be taken on board. In general, these should be better integrated into the development and promotion of e-Health."

- "**Access for all to e-Health**. The equal access of all groups of society to health services is an important goal in the public health policy field. There is a risk that certain parts of society - such as lone parents of families, isolated communities, inner city communities, individuals with literacy and numeracy challenges, groups of immigrants, homeless persons, elderly persons and disabled persons - could remain excluded from the possibilities offered by e-Health (including Internet-based health services) if special efforts are not made to counterbalance such trends. On the other hand, e-Health can offer considerable possibilities for the provision of health services to such individuals, groups, and communities."

- "**Common understanding and concerted efforts by all stakeholders**. No single stakeholder can carry through implementation successfully on its own without the active co-operation of all the others. Each of the stakeholders, health authorities, professionals, consumers, industry, has the power to veto an implementation, if it is not perceived as beneficial. Only through concerted efforts by all stakeholders, can we ensure a successful implementation where all partners benefit, thereby creating a win-win situation."

6 Deliverables related to eHealth

6.1 Various types of deliverables

The present document refers to a range of ETSI and ETSI/3GPP deliverable, which are all named as "ETSI" deliverables. Annex B on "Technical Standards, Specifications, Reports, Guides" provides information on the various types of deliverables.

6.2 Selection of deliverables

The eHealth area is a very wide domain, and there are a wide number of ETSI and ETSI/3GPP deliverables. The aim of the present document is to select a set of ETSI and ETSI/3GPP deliverables relevant to the eHealth domain. There might be eHealth related deliverables not considered in this report, due to their very large and constantly growing number. The intention is not to mention ETSI and ETSI/3GPP deliverables that are not related to the eHealth domain.

6.3 Mapping of issues

The following table provides an overview of areas related to eHealth and their relations to eHealth action plan [207] and ETSI and ETSI/3GPP deliverables. It refers to further details described in the following clauses.

Table 1: Mapping of issues to action plan and ETSI and ETSI/3GPP deliverables

Issues	eHealth Action Plan	ETSI and ETSI/3GPP deliverables/clauses
radio	- mobility - confidentiality and security issues - interoperability of eHealth systems	7 radio
network	- confidentiality and security issues - interoperability of eHealth systems - mobility	8 network
interoperability	- interoperability of eHealth systems	9 interoperability and testing
cards and readers	- access for all to e-Health - confidentiality and security issues - interoperability of eHealth systems - mobility	10 smart cards platform
application services	- access for all to e-Health - needs and interests of users - user friendliness of e-Health systems and services	11 application services
emergency	- interoperability of eHealth systems - mobility - user friendliness of e-Health systems and services	12 emergency communications
usability	- access for all to e-Health - needs and interests of users - user friendliness of e-Health systems and services	13 usability
security	- confidentiality and security issues	14 security
testing	- interoperability of eHealth systems	9 interoperability and testing
regulation	- regulation and integration of e-Health market in Europe	15 regulation
methodology for future work	- common understanding and concerted efforts by all stakeholders	16 Future e-Health standardization activities

7 Radio

7.1 ERM

7.1.1 Overview

ETSI ERM (EMC and Radio Spectrum Matters) is a "horizontal" technical committee that is responsible for the standardization of ElectroMagnetic Compatibility (EMC) and radio spectrum matters on behalf of all other technical bodies of ETSI.

See the ETSI ERM and other Radio web pages at: http://portal.etsi.org/radio/.

7.1.2 Medical telemetry and telecontrol

Telemetry is a technology that allows the measurement and reporting of information of interest to a remote operator or system. Remote systems that need instructions and data sent to them in order to operate require the counterpart of telemetry, telecontrol. Telemetry and telecontrol typically refer to wireless communications, but can also refer to data transfer over other media, such as a telephone or computer networks.

Wireless medical telemetry can be used to monitor patient physiological parameters (e.g. cardiac signals) over a distance via radio-frequency (RF) communications between a transmitter worn by the patient and a central monitoring station. This has the advantage of allowing patient movement without tethering the patient to a bedside monitor with a hard-wired connection.

Telecontrol is a technology allowing the remote control of a medical device, including the programming of various operational parameters.

For Medical Implant Communications Systems (MICS) using Ultra Low Power - Active Medical Implants (ULP-AMI) and ULP-AMI-P (peripheral devices for ULP-AMI) applications, the 402 MHz to 405 MHz frequency band has been allocated. ULP-AMI/ULP-AMI-P applications permit telemetry and telecontrol applications including continuous transmission of relevant parameters as well as data download for mass storage.

ETSI ERM_TG30 is responsible for standards applicable to wireless medical devices. The following standards are the responsibility of ERM_TG30:

- ETSI EN 301 839-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods" [1].

- ETSI EN 301 839-2 (V1.2.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM);Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive" [2].

- ETSI EN 302 195-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM);Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 1: Technical characteristics and test methods" [3].

- ETSI EN 302 195-2 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM);Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive" [4].

Standards that have finished Public Enquiry, and as at November 10, 2006 are awaiting Resolution Meeting:

- ETSI EN 302 510 (Parts 1 and 2): "Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories" [19].

Standards approved at TC_ERM and as at November 10, 2006, are under Public Enquiry:

- ETSI EN 302 536 (Parts 1 and 2): "Ultra Low Power Animal Implanted Devices operating in the frequency range 315 kHz to 600 kHz" [20].

- ETSI EN 302 537 (Parts 1 and 2): "Ultra Low Power Active Medical Implanted Devices operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz" [21].

The following EMC standards are applicable and are the responsibility of TC ERM-EMC:

- ETSI EN 301 489-27: "Electromagnetic compatibility and Radio spectrum Matters (ERM);ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)" [10].

- ETSI EN 301 489-31: "Electromagnetic compatibility and Radio spectrum Matters (ERM);ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)" [11].

Additional radio standards applicable in eHealth include:

- ETSI EN 300 220-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW; Part 1: Technical characteristics and test methods" [12].

- ETSI EN 300 220-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW; Supplementary parameters not intended for regulatory purposes" [13].

- ETSI EN 300 220-3: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW; Part 3: Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive" [14].

- ETSI EN 300 330-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Part 1: Technical characteristics and test methods" [15].

- ETSI EN 300 440-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 2: Harmonized EN under article 3.2 of the R&TTE Directive" [16].

- ETSI EN 300 328: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive" [17].

- and their associated EMC standards (EN 301 489 [18], parts 1 and other product specific parts).

7.1.3 RFID in eHealth

Radio Frequency IDentification (**RFID**) is an automatic identification method, relying on storing and remotely retrieving data using devices called RFID tags or transponders. An RFID tag is an object that can be attached to or incorporated into a product, animal, or person for the purpose of identification using radio waves. Chip-based RFID tags contain silicon chips and antennas. Passive tags require no internal power source, whereas active tags require a power source.

The use of RFID has been described in clause 14.8 on "Identification and tracking of products". The past 18 months have seen progressive improvement in the performance of RFID, in some very demanding situations. This will ensure compatibility between RFID systems operating in adjacent sites and augers well for RFID's operational deployment (see ETSI newsletter on the 29th September 2006 http://www.etsi.org/pressroom/Previous/2006/2006_09_rfid.htm).

In the short term, TG34 will generate a Technical Specification which will describe the operation of synchronization. Ultimately, TG34 anticipate seeking the abrogation of listen before talk (LBT) in ERC/REC 70-03 [205] and the generation of a revised version of the standard EN 302 208, see more details about the standard at:

- ETSI EN 302 208-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Radio Frequency Identification Equipment operating in the band 865 MHz to 868 MHz with power levels up to 2 W; Part 1: Technical requirements and methods of measurement" [5].

- ETSI EN 302 208-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Radio Frequency Identification Equipment operating in the band 865 MHz to 868 MHz with power levels up to 2 W; Part 2: Harmonized EN under article 3.2 of the R&TTE Directive" [6].

The following ETSI technical reports on RFID are also available:

- ETSI TR 101 445: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Short-Range Devices (SRD) intended for operation in the 862 MHz to 870 MHz band; System Reference Document for Radio Frequency Identification (RFID) equipment" [7].

- ETSI TR 102 436: "Electromagnetic compatibility and Radio spectrum Matters (ERM);Short Range Devices (SRD) intended for operation in the band 865 MHz to 868 MHz; Guidelines for the installation and commissioning of Radio Frequency Identification (RFID) equipment at UHF" [8].

- ETSI TR 102 449: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Overview of Radio Frequency Identification (RFID) Tags in the telecommunications industry" [9].

7.2 TErrestrial Trunked RAdio (TETRA)

TErrestrial Trunked RAdio (TETRA) is the digital Private Mobile Radio (PMR) and Public Access Mobile Radio (PAMR) technology for police, ambulance and fire services, security services, utilities, military, fleet management, transport services and a host of other communities.

TETRA provides secure and crystal-clear voice calls and delivers a wide range of highly resilient and secure data services - Over its own frequencies - to front-line health and emergency professionals.

More information about ETSI TETRA Standards is at http://portal.etsi.org/radio/TETRA/tetra.asp

Future PMR requirements are also being looked at in Project MESA, a Partnership on future Public Safety initiatives.

NOTE: See http://www.projectmesa.org/.

7.3 WiMAX

WiMAX is defined as Worldwide Interoperability for Microwave Access by the WiMAX Forum, formed in June 2001 to promote conformance and interoperability of the IEEE 802.16 standard, officially known as Wireless Metropolitan Area Network. The Forum describes WiMAX as "a standards-based technology enabling the delivery of last mile wireless broadband access as an alternative to cable and DSL". Accordingly, the term WiMAX does not strictly specify a technology, but rather a certification mark, or "stamp of approval" given to equipment that meets certain conformity and interoperability tests for the IEEE 802.16 family of standards. HIPERMAN stands for High Performance Radio Metropolitan Area Network and is the alternative European ETSI Broadband Radio Access Networks (BRAN) standard for WiMAX.

Conformance testing deliverables on WiMAX are in particular:

- ETSI TS 102 385-1: "Broadband Radio Access Networks (BRAN); HiperMAN/WiMAX; Conformance testing for the Data Link Control Layer (DLC); Part 1: Protocol Implementation Conformance, Statement (PICS) proforma" [22].

- ETSI TS 102 385-2: "Broadband Radio Access Networks (BRAN); HiperMAN/WiMAX; Conformance testing for the Data Link Control Layer (DLC); Part 2: Test Suite Structure and Test Purposes (TSS&TP) specification" [23].

- ETSI TS 102 385-3: "Broadband Radio Access Networks (BRAN); HiperMAN/WiMAX; Conformance testing for the Data Link Control Layer (DLC); Part 2: Abstract Test Suite (ATS)" [24].

Ongoing ETSI work on WiMAX:

- ETSI TS 102 177 (RTS/BRAN-0040001r5): "Broadband Radio Access Networks (BRAN); HiperMAN; Physical (PHY) layer" [25].

- ETSI TS 102 178 (RTS/BRAN-0040002r4): "Broadband Radio Access Networks (BRAN); HiperMAN; Data Link Control (DLC) layer" [26].

- ETSI TS 102 545-1 (DTS/BRAN-004T008-1): "Broadband Radio Access Networks (BRAN); Conformance Testing for the WiMAX/HiperMAN 1.3.1 Part 1: Protocol Implementation Conformance Statement (PICS) proforma" [27].

- ETSI TS 102 545-2 (DTS/BRAN-004T008-2): "Broadband Radio Access Networks (BRAN); Conformance Testing for the WiMAX/HiperMAN 1.3.1 Part 2: Test Suite Structure and Test Purposes (TSS&TP)" [28].

- ETSI TS 102 545-3 (DTS/BRAN-004T008-3): "Broadband Radio Access Networks (BRAN); Conformance Testing for the WiMAX/HiperMAN 1.3.1 Part 3: Abstract Test Suite (ATS)" [29].

7.4 UWB

Ultra-Wideband (UWB) is a technology for transmitting information spread over a large bandwidth that should be able to share spectrum with other users. A February 14, 2002 Report and Order by the Federal Communications Commission (FCC) authorizes the unlicensed use of UWB in 3.1-10.6 GHz. This is intended to provide an efficient use of scarce radio bandwidth while enabling both high data rate personal-area network (PAN) wireless connectivity as well as longer-range, low data rate applications as well as radar and imaging systems. Most devices already certified under the FCC UWB rules are radar, imaging or positioning systems. Deliberations in the International Telecommunication Union Radiocommunication Sector (ITU-R) have resulted in a Report and Recommendation on UWB in November of 2005. Various national regulations for UWB are in preparation.

There are a number of advantages of UWB over narrow band systems that are also relevant for eHealth applications, making it a particularly attractive possible technology for use in body area / personal area networks: A typical UWB link has a far greater channel capacity (maximum data rate) than a narrow band link that uses the same transmission power. Accordingly, a UWB link will have a larger reach than a narrow band link using the same transmission power and data rate. To fulfil privacy requirements, it is possible to use UWB signals that look like background noise to a receiver that is unaware of the signal's coding. In addition, UWB transmission can most efficiently handle multipath transmission conditions typical for ad-hoc communication scenarios.

Using the extremely low emission levels allowed by regulatory agencies, UWB system ranges using omnidirectional antennas are typically less than one kilometre-although tight beam links with highly directive antennas can go many miles using microwatts. However, their easily accomplished high data rates can be readily traded for range by simply scaling the number of pulses per data bit.

Among ETSI deliverables on UWB, the following seem to be particularly relevant:

- ETSI TS 102 455: "High Rate Ultra Wideband PHY and MAC Standard [ECMA-368/December 2005, modified], UWB PHY & MAC" [30].

- ETSI TR 101 994-1 :"Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Technical characteristics for SRD equipment using Ultra Wide Band technology (UWB) Part 1: Communications applications" [31].

Relevant ongoing ETSI work on UWB:

- ETSI TS 102 456: "MAC-PHY Interface for ECMA-00300" [32].

- ETSI EN 301 489-33 (DEN/ERM-EMC-230-33): "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 33: EMC requirements for UWB communications devices" [33].

- ETSI TR 102 495-5 (DTR/ERM-RM-044-5): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Technical characteristics for SRD equipment using Ultra Wide Band Sensor technology (UWB); System Reference Document; Part 5: Object Identification for Surveillance applications operating in the Frequency range from 2.2 GHz to 8 GHz" [34].

- ETSI TR 101 994-1 (RTR/ERM-RM-048-1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Technical characteristics for SRD equipment using Ultra Wide Band technology (UWB); Part 1: Communications applications" [35].

- ETSI DTS/ERM-TG31A-E-001: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short - range location application for emergency services in the frequency range from 3 GHz to 5GHz; Short-range location application for emergency services" [36].

- ETSI EN 302 065 (DEN/ERM-TG31A-0112-1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD) using Ultra Wide Band technology (UWB) for communications purposes" [37].
- ETSI DTR/ERM-TG31A-0113: "Electromagnetic compatibility and Radio spectrum Matters (ERM) Short Range Devices (SRD) using Ultra Wide Band technology (UWB) for communications purposes; UWB communications technologies" [38].
- ETSI DTS/ERM-TG31A-0114: "Electromagnetic compatibility and Radio spectrum Matters (ERM) Short Range Devices (SRD) using Ultra Wide Band technology (UWB) for communications purposes; Mitigation techniques for UWB communications technologies" [39].
- ETSI DTR/ERM-TG31A-0115: "Electromagnetic compatibility and Radio spectrum Matters (ERM) Short Range Devices (SRD) using Ultra Wide Band technology (UWB) for communications purposes; RF Complianced test methods for UWB communications technologies" [40].

7.5 Suggested future work

Recommendation 7.5.a: Most standardized wireless technologies and protocols have not been designed for transport of health-related / medical information and the support of corresponding QoS requirements. Ongoing joint CEN TC251 / ISO TC 215 / IEEE 11073 / HL7 work aims at profiling specific off-the-shelf standardized RF technologies with regard to their use among medical equipment. It is expected that this concept of profiling would be similarly applicable to technologies specified by ETSI standards, particularly UWB, WIMAX, and RFID.

Recommendation 7.5.b: Another most relevant issue that should be addressed by future work is coexistence or even (functional) interoperability between different technologies operating on a common unlicensed frequency band and /or network. This is especially important when considering the operation of multiple health-related components from different manufacturers, each with different QoS requirements, on a single shared IT network infrastructure

Recommendation 7.5.c: eHealth implies transparency between all clinical and healthcare-related institutions and stakeholders. To enable all this, communication infrastructure has not only to provide for functional, but also for semantic interoperability (see also clause 9). Concepts for cross-technology semantic interoperability create a demand for common abstractions from particular transport technologies, e.g. by some "abstraction layer" on IP level. As related efforts are in an early stage, ETSI contributions could be most relevant.

Recommendation 7.5.d: Specifications to provide semantic interoperability with (clinical) information systems could also be an issue for ETSI-specified radio technologies where health-related / medical use was anticipated, in particular ULP-AMI and TETRA.

Recommendation 7.5.e: When considering functional (radio) and semantic interoperability issues, security, privacy and reliability (see clause 14) are essential parameters when using standards for wireless networks.

Recommendation 7.5.f: Further investigation is required on existing PAN standards for patient monitoring applications, e.g. Bluetooth and Zigbee.

8 Network

This clause provides an overview of network issues, but it will only list deliverables related to Internet Protocol IPv6 and Next Generation Networks in order not to provide duplications with deliverables that are listed in the other clauses of the present document.

8.1 Introduction

This clause provides an overview of network issues. Mainly aiming at Network layer protocol deliverables, in particular relating to Internet Protocol and specifically its version 6 (IPv6), it contains a clause (8.2 Taxonomy of Networks) which provides a set of definitions for the whole range of computer networks, but will not list deliverables in order not to provide duplications as the relevant deliverables are listed in the other clauses of the present document.

As originally defined in the ISO OSI Model, the Network layer solves the problem of getting packets across a single network. With the advent of the concept of internetworking, additional functionality was added to this layer, namely getting data from the source network to the destination network. This generally involves routing the packet across a network of networks, known as an internetwork or (lower-case) internet. In the Internet protocol suite, IP performs the basic task of getting packets of data from source to destination.

8.2 Taxonomy of Networks

A **Personal Area Network (PAN)** is a computer network used for communication among computer devices (including telephones and personal digital assistants) close to one person. The reach of a PAN is typically a few meters. PANs can be used for communication among the personal devices themselves (intrapersonal communication), or for connecting to a higher level network and the Internet (an uplink). Personal area networks may be wired with computer buses such as USB and FireWire. TS 22.259 [41] defines scenarios and requirements for PANs to operate within 3GPP networks. A **Wireless Personal Area Network (WPAN)** can also be made possible with network technologies like Bluetooth.

A **Local Area Network (LAN)** is a computer network covering a local area, like a home, office, or group of buildings. Current LANs are most likely to be based on switched IEEE 802.3 Ethernet running at 10 Mbit/s, 100 Mbit/s or 1,000 Mbit/s or on wireless LAN (WLAN, WiFi) technology.

A **home network** is a residential local area network, and is used to connect multiple devices within the homes.

In Internet terminology, a **private network** is a network that uses RFC 1918 ("Address Allocation for Private Internets") IP address space. Computers may be allocated addresses from this address space when it is necessary for them to communicate with other computing devices on an internal (non-Internet) network but not directly with the Internet. Private networks are quite common in office local area networks, as many organizations do not see a need for globally unique IP addresses for every computer, printer and other device that the organizations use. Another reason for the extensive use of private IP addresses is the shortage of publicly registerable IP addresses. IPv6 was created to alleviate this shortage.

Metropolitan area networks or **MAN**s are large computer networks usually spanning a city. They typically use wireless infrastructure or optical fibber connections to link their sites.

A **Wide Area Network or WAN** is a computer network covering a broad geographical area. Contrast with personal area networks (PANs), local area networks (LANs) or metropolitan area networks (MANs) that are usually limited to a room, building or campus. WANs are used to connect local area networks (LANs) together, so that users and computers in one location can communicate with users and computers in other locations. Many WANs are built for one particular organization and are private. WANs are most often built using leased lines. The largest and most well-known example of a WAN is the Internet.

The **Public Switched Telephone Network (PSTN)** is the concentration of the world's public circuit-switched telephone networks, in much the same way that the Internet is the concentration of the world's public IP-based packet-switched networks. Originally a network of fixed-line analogue telephone systems, the PSTN is now almost entirely digital, and now includes mobile as well as fixed telephones.

The **Global System for Mobile Communications**, **GSM** (original acronym: Groupe Spécial Mobile) is the most popular standard for mobile phones in the world. GSM is a cellular network, which means that mobile phones connect to it by searching for cells in the immediate vicinity. GSM networks operate in four different frequency ranges. Most GSM networks operate in the 900 MHz or 1800 MHz bands. Some countries (including the United States and Canada) use the 850 MHz and 1900 MHz bands because the 900 MHz and 1 800 MHz frequency bands were already allocated.

Universal Mobile Telecommunications System (UMTS) is a third-generation (3G) mobile phone network technology. It uses WCDMA (Wideband Code Division Multiple Access) as the underlying technology, is standardized by the 3GPP project, and relates to the ITU requirements for 3G cellular radio systems. 3GPP has began work on Long Term Evolution (LTE) which includes enhanced performance with a new radio access network and evolved system architecture.

DECT or **Digital Enhanced (formerly European) Cordless Telecommunications** is an ETSI standard for digital portable phones, commonly used for domestic or corporate purposes. DECT can also be used for wireless data transfers. DECT is recognized by the ITU as a 3G phone network technology.

The **cdma2000** networks are specified by 3GPP2.org. They are predominant in Asia in the Americas. They are not predominant in Europe although there are cdma2000 networks operating in 450MHz bands notably in Eastern Europe.

8.3 IPv6 networks

Internet Protocol version 6 (IPv6) is a network layer IP (Internet Protocol) standard used by electronic devices to exchange data across packet-switched networks. It follows IPv4 as the second version of the Internet Protocol to be formally adopted for general use.

The main improvement brought by IPv6 is the increase in the number of addresses available for networked devices, allowing, for example, each cell phone and mobile electronic device to have its own address. Where IPv4 supports 4.3 billion addresses, which is inadequate for giving even one address to every living individual, IPv6 supports 50 octillion addresses - more than enough to give an IP address to every kind of physical object at any point in the world. In the eHealth context - and in combination with adequate radio technologies - IP-addressing of all objects relevant for monitoring and affecting the health status of every individual becomes a realistic option.

IPv6 was adopted by the Internet Engineering Task Force in 1994, when it was called "IP Next Generation" (IPng). However, the replacement of IPv4 by IPv6 has been slowed by the introduction of classless inter-domain routing (CIDR) and network address translation (NAT), each of which has partially alleviated the impact of address space exhaustion.

The main feature of IPv6 is the larger address space: addresses in IPv6 are 128 bits long (versus 32 bits in IPv4) which can be efficiently manipulated by 64 bit processors most future network products are expected to be based on. The drawback of the large address size is that IPv6 is less efficient in bandwidth usage, affecting mobile / Personal / Body Area Network applications where bandwidth is limited.

Another, security-related advantage of the larger address space is that it makes scanning certain IP blocks for vulnerabilities significantly more difficult than in IPv4.

The following list of deliverables related to IPv6 does not cover the extensive material related to IPv6 protocol testing:

- ETSI TS 101 324: "Telecommunications and Internet Protocol Harmonization Over Networks (TIPHON); Numbering; Scenario 1 + Scenario 2" [43].
- ETSI TS 102 265: "Digital Enhanced Cordless Telecommunications (DECT); DECT access to IP networks" [44].
- ETSI TR 102 419: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Security analysis of IPv6 application in telecommunications standards" [45].
- ETSI TR 123 923 [46]: "Universal Mobile Telecommunications System (UMTS); Combined GSM and Mobile IP mobility handling in UMTS IP CN (3GPP TR 23.923)" [46].
- ETSI MI/UMTS-00009: "Universal Mobile Telecommunications System (UMTS); The use of IPv6 in UMTS" [47].

8.4 Next Generation Network (NGN)

According to an ITU definition, a Next Generation Network (NGN) is a packet-based network able to provide services including telecommunication services and able to make use of multiple broadband, QoS-enabled transport technologies and in which service-related functions are independent from underlying transport-related technologies. NGN offers unrestricted access by users to different service providers. NGN supports generalized mobility which will allow consistent and ubiquitous provision of services to users.

Building upon the work already done by 3GPP in creating the SIP-based IMS (IP Multimedia Subsystem), TISPAN and 3GPP are now working together to define a harmonized IMS-centric core for both wireless and wireline networks.

This harmonized ALL IP network has the potential to provide a completely new telecom business model for both fixed and mobile network operators. Access independent IMS will be a key enabler for fixed/mobile convergence, reducing network installation and maintenance costs, and allowing new services to be rapidly developed and deployed to satisfy new market demands.

NGN Release 1 was launched by TISPAN in December 2005, providing the robust and open standards that industry can use as a reliable basis for the development and implementation of the first generation of NGN systems. TISPAN is now working on Release 2, with a focus on enhanced mobility, new services and content delivery with improved security and network management.

Apart from a large amount of TISPAN deliverables (some are mentioned in other clauses in the present document) in this area, the following deliverables are potentially relevant:

- ETSI TS 102 330: "Access and Terminals (AT); Portable Service Format (PSF) for Interactive Home Devices - Multi-platform service description" [139].
- ETSI TS 102 261: "Open Network Services and Architecture (ONSA); Abstract architecture and reference points definition; Mapping of functional architectures and requirements for NGN - NGN functional architecture" [194].

The following ongoing work on regulatory issues is further explained in clause 15 on "Regulation":

- ETSI DSR/OCG-00017: "Electronic Communications Networks and Services Consequence on the NGN standardization activity from the EU ECN&S regulatory view point" [195].

8.5 Suggested future work

Recommendation 8.5.a: Important factors at network level are security and QoS, including latency. The Health service provider responsibility is to guarantee that the systems will satisfy QoS and security requirements. Future ETSI deliverables in this area could give support by application-related requirements and profiles.

Recommendation 8.5.b: The handling of specific information (such as alarms and alerts) between health professional environments (e.g. hospitals) and private individuals (who are either mobile or at home) is not yet sufficiently foreseen by current concepts, but its specification is essential for future personal health applications.

9 Interoperability and testing

9.1 Relevance

Health information integration (e-Health) implies interoperability among all clinical and healthcare-related institutions and stakeholders. Electronic Health Records (EHR) comprise relevant demographic, diagnostic and therapeutic information. It is generated, stored and used by different stakeholders at different places and different points in time. Nevertheless, it may be required and processed simultaneously in a specific situation during a patient's treatment. Other typical e-Health applications involve multiple stakeholders, partly on an ad-hoc basis: hospitals, general practitioners and specialists, pharmacies, labs and care service providers, insurance companies etc. An adequate infrastructure - being currently developed or introduced in all industrialized countries - has to provide for adequate functional and semantic interoperability.

Standards are essential for interoperability of communicating systems and integration of information. Communication architectures, interfaces, transmission protocols and codes tend to be unnecessarily limited to specific components, applications, manufacturers or domains, resulting in barriers, efforts and costs when exchanging information or even just replacing components. Motivated by this situation, groups of health professionals from different areas started work on standardization of medical data exchange and communication, primarily to improve the situation in their particular environments. Resulting standards established in specific domains are generally based on incompatible concepts reflecting not only typical domain-specific requirements and conceptual paradigms, but also their development history. However, these originally clinical standards have to be utilized for e-Health.

Interoperability is particularly necessary to achieve mobility of eHealth services and mobility of European citizens who should be able to receive medical treatment based on their medical history throughout Europe. It will be important to achieve not only functional and semantic interoperability but also legal and administrative harmonization of the procedures behind the eHealth systems in Europe.

The eHealth Action Plan [207] has identified interoperability as one of the major challenges for wider implementation of eHealth services. The action plan states that "Work has been launched within European standards organizations to answer this issue partly, but the take-up of e-Health interoperability standards has been slow and - in addition - to achieve actual interoperability is a separate task. Interoperable e-Health solutions should also support the technical platform for the implementation of such initiatives as the creation of a European network of centres of reference to promote co-operation across medical institutions across the Community".

Interoperability, although considered desirable for some areas of eHealth, offers challenges in the field of security. Security (including reliability) of communication is itself split into a number of areas, viz:

- Prevention of unauthorized interception of information.
- Prevention of the transmission of unauthorized information (including malign transmissions which may have patient safety implications).
- Reliability of the transmitted or received information in terms of error free communication.
- Latency of communication.

9.2 Interoperability activities

Interoperability is an area that could be considered as being supported by ETSI and ETSI/3GPP deliverables developed in all committees. However, there is one particular group, the OCG ad hoc IOP, which is responsible for the horizontal co-ordination of issues related to interoperability: see http://portal.etsi.org/ocg/OCG_ad-hoc_Interop.asp. The OCG IOP group addresses the following:

- Act as a steering group for the interoperability STFs of generic interest.
- Ensure alignment regarding related activities of PTCC.
- Ensure closer alignment of the Plugtests™ events with the ongoing standards development work within ETSI.

The main aim of standardization is to enable interoperability in a multi-vendor, multi-network, multi-service environment. The absence of interoperability must not be the reason why final services for which there is great demand do not come into being. ETSI is very much aware of these developments and market demands. It knows what the inhibitors to interoperability are that can be encountered during the standards development process. The ETSI white paper "Achieving Technical Interoperability - the ETSI Approach" (which can be downloaded for free from http://www.etsi.org/etsi_radar/whitepaper/wp_3.htm) gives an overview of the approach that ETSI has taken to address these inhibitors to interoperability and how the institute ensures that interoperable standards of high quality and relevance to the marketplace are developed.

The white paper highlights one issue that could be mentioned when considering the use of existing standards for the eHealth area; "If standards are adapted or used beyond their original context, then it is important that the consequences for interoperability are fully understood and addressed. This is especially pertinent in the environment of multi-organizational standardization" and the whitepaper further states that; "Using standards beyond their original purposes: it is becoming more common for standards developed with one context in mind to be used in another. A well-engineered standard will be robust and flexible enough to make the transition. But in many cases changes or additions to the original specifications to make them suitable for the new environment bring compromises in interoperability. The risks of this occurring can be reduced if those changes are made in a considered and well-planned way: regrettably this is not always the case as things are often done in an ad-hoc manner. It is highly likely to happen if those changes are decided by individual implementers of the standard."

The white paper lists a number of ETSI initiatives and support entities to enable the production of interoperable standards. These include:

- the appointment by the ETSI Board of a Champion for Interoperability;
- series of interoperability workshops;
- the well-established Technical Committee MTS;
- the ETSI Protocol and Testing Competence Centre; and

- the ETSI Plugtests™ service.

These ETSI initiatives and support entities could play an important role for future eHealth interoperability and testing activities.

9.3 Testing

ETSI is increasingly committed to providing resources for interoperability and conformance testing activities. The ETSI white paper on Achieving Technical Interoperability (http://www.etsi.org/etsi_radar/whitepaper/wp_3.htm) describes the ETSI Protocol and Testing Competence Centre PTCC, which is a unique resource available to ETSI Technical Committees for the application of leading-edge specification, validation and testing techniques in ETSI deliverables. The task of the PTCC is to help the ETSI membership produce the very best technical standards and test specifications possible. A large part of the PTCC work is to assist in the planning and development of conformance and interoperability test specifications. The ETSI Plugtests™ Service is a professional unit of ETSI specializing in organizing and running interoperability test events for a wide range of telecommunications, Internet, broadcasting and multimedia converging standards.

9.4 Suggested future work

Recommendation 9.4.a: Given the urgent need for conformance and interoperability testing in all areas of health-related / medical communication and networking on the one hand, and the tremendous expertise of ETSI regarding interoperability and testing on the other hand, this domain requires action as it shows great promise of building upon existing successful ETSI activities.

While most of the functional interoperability issues may be covered with existing expertise within the related ETSI bodies, providing application-specific expertise for the preparatory specification aspects, semantic interoperability testing and assurance is a demanding new activity, which is not yet sufficiently covered by any institution, organization or company.

Recommendation 9.4.b: Further to ETSI activities in this field, there will be necessary requirements beyond telecommunication functional and semantic aspects, to achieve legal and administrative interoperability of the procedures behind the eHealth systems in Europe, so that industrial market volumes sufficiently high to commercially justify the necessary efforts in standardization and certification infrastructure may be achieved.

10 Smart cards platform

10.1 Relevance

When information has to be held by a human being, an appropriate media is needed to store data structures and applications providing the required functionality as well as to communicate data items between partners inside or outside the healthcare domain. This generally applies ranging from the use of a simple hardware token for specific functions such as identity-related services up to more or less comprehensive portable information systems carried by the information subject. Being a personal token, only token-holder related information should be stored on the respective device.

Launched by the European Commission, the EuroCard project investigated use of cards in the healthcare domain as well as future deployment opportunities. As a result, the following application domains have been defined:

- administrative cards that have administrative purposes;
- cards for medical professionals;
- cards for emergencies;
- cards for patients.

A Smart Card is a plastic card incorporating an integrated circuit. The card stores information that can be securely and accurately read by card readers in various terminals such as mobile phones (SIM cards), ATMs, ticket machines etc. There are smart cards that need to be inserted into a slot, and there are also contactless cards that work at a distance of up to 10 cm, which can be more convenient as no insertion operation is required. This is convenient for all people and of particular importance for those who may have difficulties placing a card in a slot, such as wheelchair users, those with Parkinson's disease or arthritis, and people with a visual disability. There are smart cards provided with RFID (e.g. in Sweden) which extends the range in which the card can be read, and linked to eHealth information stored online, which can be made available in appropriate situations.

Major advantages of smart cards are, e.g.:

- robust security;
- increased storage capacity;
- flexibility and intelligence in transaction processing;
- support for multiple applications and multiple functions.

In the healthcare filed, further advantages have been fixed, such as:

- enforcement of security policies;
- integration with existing facility access control;
- support for information authenticity, accountability, availability, integrity, and confidentiality;
- support for strong privacy policies;
- securing patient information on a wireless network.

Smart cards are currently used in several European Countries for storing very basic information related to health care (e.g. information related to health insurance and payment). However, there are many different systems with many different cards in Europe.

With increasing international mobility, people expect to be able to obtain health service independent of their location. The first step to eHealth mobility is the introduction of the European Health ID Card (EHIC) which identifies the person and provides about payment information.

10.2 ETSI Smart Card Platform

The ETSI technical committee Smart Card Platform (SCP) is working with a wide range of experts from all over the world to ensure that the next generation of Smart cards meets the standard (see www.etsi.org/scp). A series of ETSI specifications have been established describing integrated circuit cards (ICC) in general, universal integrated circuit cards (UICC), but also toolkits for creating card-based applications.

ETSI deliverables provide generic UICC (Universal Integrated Circuit Card) specifications including for example size, contacts, electric parameters, basic initialization, data transmission protocols, file structures, logical channels, security features, commands, typical procedures, events etc. as specified in:

- ETSI TS 102 221: "Smart cards; UICC-Terminal interface; Physical and logical characteristics (Release 6)" [48].
- TS 102 221 [48] describes the essentials for smart cards and their communication with any terminal in a generic way using vendor-independent interface specifications. In detail:
  - the requirements for the physical characteristics of the UICC;
  - the electrical interface between the UICC and the terminal;
  - the initial communication establishment and the transport protocols;
  - the model which serves as a basis for the logical structure of the UICC;
  - the communication commands and the procedures;

- the application independent files and protocols;

have been defined in this standard, providing the basic specification for the interactions with ICCs used in smart cards.

Application-specific aspects are out of scope of TS 102 221 [48]. This also concerns special functionalities in the context of 3G telecommunication networks such as the Universal Subscriber Identity Module (USIM) application, which is specified in TS 131 102 [50] or administrative commands for a telecommunication card, specified in TS 102 222 [55] in compliance with ISO/IEC 7816 [201].

- ETSI TS 102 223: "Smart cards; Card Application Toolkit (CAT) (Release 7)", [49].

The Card Application Toolkit (CAT) specified in TS 102 223 [49] defines the generic interface between the UICC and the terminal, especially focusing on mandatory terminal procedures for network access independent of the access technology of the network, also called Network Access Application (NAA). The following NAA are supported by the CAT:

- a USIM application, as defined in TS 131 102 [50], which can reside only on a 3G platform;
- a SIM application, as defined in TS 151 011 [51], which can reside either on a 3G or a 2G platform;
- a TSIM application, as defined in TS 100 812-2 [52], which can reside only on a 3G platform;
- a ISIM application, as defined in TS 131 103 [53], which can reside only on a 3G platform;
- a RUIM application, as defined in TIA/IS-820-A [200], 3GPP2 C.S0023-0 [54], which can reside on a 2G platform; or
- other applications residing on a 3G platform or a 2G platform. Specifying the interface is to ensure interoperability between an ICC and a terminal independently of the respective manufacturers and operators.

The TS also specifies mechanisms in order to expand the generic set of commands and procedures by access technology specific ones. In TS 102 223 [49], commands, application protocol, and mandatory requirements on the ICC and terminal for each procedure are defined. The applications supported by the TS range from profiles, data and event downloads to the UICC, the support of proactive UICCs, the provision of security services such as data confidentiality, data integrity, and data sender validation, or any subset of these as well as many other services.

Message structure and command specifications for card remote (over-the air OTA) management are described in:

- ETSI TS 102 224: "Smart Cards; Security mechanisms for UICC based applications - Functional requirements (Release 7)" [181].

ETSI TS 102 224 [181] defines requirements for securing Card Application Toolkit (CAT) related communication over the network, (e.g. SMS, USSD, and future transport mechanisms) with the level of security chosen by the network operator or the application provider. Security requirements the TS is dealing with concern authentication, message integrity, replay detection and sequence integrity, proof of receipt and proof of execution, message confidentiality, and the indication of the security mechanisms used.

- ETSI TS 102 225: "Smart Cards; Secured packet structure for UICC based applications (Release 7)" [56].
- ETSI TS 102 226: "Smart Cards; Remote APDU structure for UICC based applications (Release 6)" [57].

TS 102 225 [56] and TS 102 226 [57] deal with security aspects of communication. TS 102 226 [57] defines the remote management of the UICC based on the secured packet structure specified in a general format in TS 102 225 [56].

JAVA specifications for platform independent applications are specified in:

- ETSI TS 102 240: "Smart Cards; UICC Application Programming Interface and Loader Requirements; Service description; (Release 6)" [58].

  Completing the UICC specification set, TS 102 240 [58] specifies a generic UICC Application Programming Interface.

- ETSI TS 102 241: "Smart Cards; UICC Application Programming Interface (UICC API) for Java Card (TM) (Release 6)" [59].

The following deliverables describes further smart card aspects:

- ETSI TS 102 310: "Smart Cards; Extensible Authentication Protocol support in the UICC" [60].
- ETSI TS 102 230: "Smart cards; UICC-Terminal interface; Physical, electrical and logical test specification" [61].
- ETSI TS 102 222: "Integrated Circuit Cards (ICC); Administrative commands for telecommunications applications" [55].
- ETSI TS 102 124: "Smart Cards; Transport Protocol for UICC based Applications" [62].
- ETSI TS 101 220: "Smart cards; ETSI numbering system for telecommunication application providers" [63].
- ETSI TR 122 907: "Universal Mobile Telecommunications System (UMTS); Terminal and smart card concepts" [64].
- ETSI TR 102 151: "Smart Cards; Measurement of Electromagnetic Emission of SIM Cards" [65].

10.3 Suggested future work

Recommendation 10.3.a: Currently, no solution exists for security tokens such as the Electronic European Health Insurance card and its readers; ETSI will need to deal with such needs in conjunction with other SDOs.

Recommendation 10.3.b: In the field of biometrics, few specifications currently exist, and thus ETSI will need to be pro-active in promoting development in this area.

Recommendation 10.3.c: Extension and adaptation of existing and emerging ISO or CEN specifications should be performed following the example of TS 102 222 [55].

11 Application services

11.1 Third-party service providers

11.1.1 Relevance

Third-party service providers are expected to play an important role in providing eHealth application services and content to end-users. eHealth business cases and opportunities would encourage a wide range of (third party) service providers who could develop interoperable eHealth services. The application developers would thus need to use network functionality through an open standardized interface. Where any part of the networks involve radio then WAPECS principles may be applicable (http://rspg.groups.eu.int/doc/documents/meeting/rspg8/rspg_05_102.pdf).

11.1.2 Deliverables

The following multi part deliverable has been produced by TISPAN and is based on Parlay X 2 Web Services specification for Open Service Access (OSA). The OSA specifications define an architecture that enables application developers to make use of network functionality through an open standardized interface, i.e. the OSA APIs, see the multi part deliverable, as identified below:

- ETSI ES 202 391-1: "Open Service Access (OSA); Parlay X Web Services; Part 1: Common (Parlay X 2)" [66].
- ETSI ES 202 391-2: "Open Service Access (OSA); Parlay X Web Services; Part 2: Third Party Call (Parlay X 2)" [67].
- ETSI ES 202 391-3: "Open Service Access (OSA); Parlay X Web Services; Part 3: Call Notification (Parlay X 2)" [68].
- ETSI ES 202 391-4: "Open Service Access (OSA); Parlay X Web Services; Part 4: Short Messaging (Parlay X 2)" [69].
- ETSI ES 202 391-5: "Open Service Access (OSA); Parlay X Web Services; Part 5: Multimedia Messaging (Parlay X 2)" [70].
- ETSI ES 202 391-6: "Open Service Access (OSA); Parlay X Web Services; Part 6: Payment (Parlay X 2)" [71].
- ETSI ES 202 391-7: "Open Service Access (OSA); Parlay X Web Services; Part 7: Account Management (Parlay X 2)" [72].
- ETSI ES 202 391-8: "Open Service Access (OSA); Parlay X Web Services; Part 8: Terminal Status (Parlay X 2)" [73].
- ETSI ES 202 391-9: "Open Service Access (OSA); Parlay X Web Services; Part 9: Terminal Location (Parlay X 2)" [74].
- ETSI ES 202 391-10: "Open Service Access (OSA); Parlay X Web Services; Part 10: Call Handling (Parlay X 2)" [75].
- ETSI ES 202 391-11: "Open Service Access (OSA); Parlay X Web Services; Part 11: Audio Call (Parlay X 2)" [76].
- ETSI ES 202 391-12: "Open Service Access (OSA); Parlay X Web Services; Part 12: Multimedia Conference (Parlay X 2)" [77].
- ETSI ES 202 391-13: "Open Service Access (OSA); Parlay X Web Services; Part 13: Address List Management (Parlay X 2)" [78].
- ETSI ES 202 391-14: "Open Service Access (OSA); Parlay X Web Services; Part 14: Presence (Parlay X 2)" [79].

11.2 Service capabilities and Quality of Services

11.2.1 Relevance

The outcome of eHealth services will depend on which services the user has access to. Moreover, it is not enough to have access to a specific range of services but it is also crucial that the quality meets the user requirements and system requirements. If the quality does not meet the requirements, the consequences may be fatal. The ETSI and ETSI/3GPP deliverables on Quality of Services (QoS) will therefore be described in the following clauses.

eHealth services that were very successful with "simple technology" using SMS have turned out to be less successful when being replaced by 3G services. As a conclusion, a reliable established technology may prove a better choice than a new technology which is not necessarily as widely available.

11.2.2 Technical bodies dealing with QoS

QoS is addressed in various technical bodies such as 3GPP, TISPAN, USER and AT.

STQ is ETSI's technical committee for Speech, Transmission Planning, and Quality of Service (http://portal.etsi.org/stq/Summary.asp). It was intended initially as a centre of expertise on speech quality issues but has broadened its scope to handle more general quality issues. STQ has three main areas of activity:

- Speech quality and end-to-end speech transmission performance.
- General quality of service parameters for fixed and mobile networks.
- Distributed speech recognition algorithms (the Aurora project).

11.2.3 Deliverables

The following Technical Specification describes how and what kind of UMTS services the user has access to.

- ETSI TS 122 105: "Universal Mobile Telecommunications System (UMTS); Services and service capabilities (3GPP TS 22.105 version 6.4.0 Release 6)" [80].

The following technical specification provides the framework for Quality of Service within the 3GPP system:

- ETSI TS 123 107: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Quality of Service (QoS) concept and architecture (3GPP TS 23.107 version 6.4.0 Release 6)" [81].

  The main purpose of TS 123 107 [81] is to specify the list of attributes applicable to the UMTS Bearer Service and the Radio Access Bearer Service, as well as describe the Quality of Service architecture to be used in the 3GPP system.

The following document provides the framework for end-to-end Quality of Service involving GPRS and complements TS 123 107 [81] which describes the framework for Quality of Service within UMTS.

- ETSI TS 123 207: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); End-to-end Quality of Service (QoS) concept and architecture (3GPP TS 23.207)" [82].

The following STQ deliverables address user related parameters starting with parts on general parameters and parameters for telephony, fax and modem data services.

- ETSI EG 202 057-1: "Speech Processing, Transmission and Quality Aspects (STQ); User related QoS parameter definitions and measurements; Part 1: General" [83].
- ETSI EG 202 057-2: "Speech Processing, Transmission and Quality Aspects (STQ); User related QoS parameter definitions and measurements; Part 2: Voice telephony, Group 3 fax, modem data services and SMS" [84].
- ETSI EG 202 057-3: "Speech Processing, Transmission and Quality Aspects (STQ); User related QoS parameter definitions and measurements; Part 3: QoS parameters specific to Public Land Mobile Networks (PLMN)" [85].
- ETSI EG 202 057-4: "Speech Processing, Transmission and Quality Aspects (STQ); User related QoS parameter definitions and measurements; Part 4: Internet access" [86].

The ETSI USER group has developed the following QoS deliverables:

- ETSI EG 202 009-1: "User Group; Quality of Telecom Services; Part 1: Methodology for identification of parameters relevant to the Users" [87].
- ETSI EG 202 009-2: "User Group; Quality of telecom services; Part 2: User related parameters on a service specific basis" [88].

- ETSI EG 202 009-3: "User Group; Quality of telecom services; Part 3: Template for Service Level Agreements (SLA)" [89].

eHealth systems in homes will be important and therefore would the following technical report be useful:

- ETSI TR 102 049: "Power Line Telecommunications (PLT); Quality of Service (QoS) requirements for in-house systems" [90].

  The scope of the report is to achieve a consistent view on the quality of a service (QoS) on a PLC home network. The main focus will be on CE applications in the home, typical examples for CE-in-home applications are Voice, Audio/Video and Data services.

  The scope of the following document is on the provisioning of Internet QoS over Broadband Satellite (BSM) Networks. It will investigate how standardized QoS parameters and management mechanisms apply to BEMs and how to ensure that their required performance is met:

- ETSI TR 102 157: "Satellite Earth Stations and Systems (SES); Broadband Satellite Multimedia; IP Interworking over satellite; Performance, Availability and Quality of Service" [91].

The following deliverable from STQ is for TC EMTEL on QoS and Transmission Quality aspects for end-to-end services:

- ETSI TR 102 521: "Speech Processing, Transmission and Quality aspects (STQ); Support to TC EMTEL for QoS and Transmission Quality aspects for end-to-end services" [92].

The following multipart deliverable specifies QoS aspects for popular services in GSM and 3G networks:

- ETSI TS 102 250-1: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 1: Identification of Quality of Service aspects" [93].

  Part 1 identifies QoS aspects for popular services in GSM and 3G networks. For each service chosen QoS indicators are listed. They are considered to be suitable for the quantitatively characterization of the dominant technical QoS aspects as experienced from the end-customer perspective.

- ETSI TS 102 250-2: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 2: Definition of Quality of Service parameters and their computation" [94].

  Part 2 defines QoS parameters and their computation for popular services in GSM and 3G networks. The technical QoS indicators, listed in part 1, are the basis for the parameter set chosen. The parameter definition is split into two parts: the abstract definition and the generic description of the measurement method with the respective trigger points. Only measurement methods not dependent on any infrastructure provided are described in the present document. The harmonized definitions given in the present document are considered as the prerequisites for comparison of QoS measurements and measurement results.

- ETSI TS 102 250-3: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 3: Typical procedures for Quality of Service measurement equipment" [95].

  Part 3 describes typical procedures used for QoS measurements over GSM, along with settings and parameters for such measurements.

- ETSI TS 102 250-4: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 4: Requirements for Quality of Service measurement equipment" [96].

  Part 4 defines the minimum requirements of QoS measurement equipment for GSM and 3G networks in the way that the values and trigger-points needed to compute the QoS parameter as defined in part 2 can be measured following the procedures defined in part 3. Test-equipment fulfilling the specified minimum requirements, will allow to perform the proposed measurements in a reliable and reproducible way.

- ETSI TS 102 250-5: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 5: Definition of typical measurement profiles" [97].

  Part 5 specifies test profiles which are required to enable benchmarking of different GSM or 3G networks both within and outside national boundaries. It is necessary to have these profiles so that when a specific set of tests are carried out then customers are comparing "like for like" performance.

- ETSI TS 102 250-6: "Speech Processing, Transmission and Quality Aspects (STQ); QoS aspects for popular services in GSM and 3G networks; Part 6: Post processing and statistical methods" [98].

  Part 6 describes procedures to be used for statistical calculations in the field of QoS measurement of GSM and 3G networks using probing systems.

  The following TISPAN deliverable specifies the generic QoS concepts for NGN and provides a QoS Framework Model:

- ETSI TS 185 001: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Next Generation Network (NGN); Quality of Service (QoS) Framework and Requirements" [99].

  TS 185 001 [99] is release independent. TISPAN deliverables which have a bearing on QoS should indicate, which QoS requirements are met for each release. The QoS requirements include QoS classes, codecs, QoS control mechanisms, QoS architecture, QoS signalling.

  The following document provides an overview of factors that influence user perceived quality in TISPAN compliant systems supporting multimedia applications:

- ETSI TR 102 479: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Review of available material on QoS requirements of Multimedia Services" [100].

  TR 102 479 [100] defines the audio and video quality requirements for a variety of multimedia applications involving conversational and streaming media flows and the transmission quality requirements to support these in TISPAN systems. Video applications are restricted to those involving screens of medium size (12') and upwards. A classification system is included to describe the quality aspects of multimedia systems, their media components and the transmission quality requirements in TISPAN systems.

11.2.4 Suggested future work

Recommendation 11.2.4: It will be important to investigate the QoS aspects for eHealth services, in particular critical situations where failures to meet QoS requirements may have very serious consequences. Deliverables specifying technical requirements as well as guidelines on the choice and use of various technologies for eHealth services will be required.

11.3 Mobility and single sign-on

11.3.1 Relevance

A large number of terms are frequently used to describe different types of mobility, often both with different terms being given the same meaning, and the same meaning being applied to different terms. Mobility in the sense of "Issues relating to the mobility of patients, including the cross border circulation of goods and services, among which e-Health services are of growing importance" has been addressed by the eHealth action plan [207] (see also clause 5 on "eHealth action plan". Generalized mobility as stated in [102] includes four mobility types: terminal, user, session and service mobility, which refer to different functionalities that the Mobility Management (MM) of networks can provide.

NOTE: The functionality of these mobility types is complementary, but not independent, i.e. session and service mobility can not be used without terminal or user mobility.

Single sign-on is important when achieving a higher degree of mobility, as it allows the user to avoid repeated authentication, regardless of how many eHealth servers are deployed in their environment. Many reports describe single sign-on as an important area that is expected to play an important role in future eHealth systems. One of a great number of reports which has pointed out the need for single sign-on is "The National strategy for eHealth" in Sweden [213]:

- Patients often move between different care settings and providers. Access to information and communication must therefore be made secure by using procedures and tools which ensure that only authorized personnel can exchange and make use of the information. The technical infrastructure must therefore include as an essential component common security solutions featuring some form of electronic identification (e-ID). Electronic identification also enables care professionals to access different information systems easily with a single sign-on.

- Health care professionals will be able to access the ICT systems they need with a single sign-on to the usual system environment. Secure identification and authentication systems will enable doctors to access a patient's EHR and medical history, ongoing treatment and courses of medication - after securing the latter's consent - no matter where this information is stored.

- Existing ICT-based tools must not only be user-friendly but also simplify routine health care procedures. Tools should preferably have a common user interface and shared sign-on, security and communication functions. There is room for improvement and a need for closer inter-service cooperation in this area.

11.3.2 Deliverables

This following report on mobility and single sign-on has been produced by ECMA and ETSI:

- ETSI TR 102 477: "Corporate telecommunication Networks (CN); Mobility for enterprise communication" [102].

The report [102] provides the following examples of mobility for eHealth applications:

- Easy ad-hoc access to patient data (for authorized personnel only) - anywhere.

- Voice over WLAN for nurses and doctors.

- Information on where to find personnel within premises.

The report [102] provides information on single sign-on, which in the eHealth related domain could be described as follows; In case of provisioning of services across network boundaries authentication of service access by a single sign-on is of high importance for user acceptance of mobility.

The Liberty Alliance Project (LAP) provides such a single-sign on solution for HTTP traffic. The basic is that ISPs do not perform user authentication themselves but relies on an Identity Provider (IdP). The LAP does not mandate any particular mechanism for user authentication, e.g. 3GPP AKA may be used. The IdP generates Security Assertion Markup Language (SAML)-based authentication assertions related to multiple authentication contexts and provides these to ISPs. Ultimately the ISP authorizes end-user access to ISP services.

The mobility of eHealth users demands that multiple choices are available to complete any desired communication. Part of that is the increasing capability of end user devices and their ability to communicate in personal area networks. In most cases not all of a user's devices will contain the same authentication capabilities, so eHealth user mobility requires that any supporting networks and services allow the flexible execution of authentication and identification processes, such as the identification of a user's SIM card on one device through a network connection on another device within their PAN.

The report [102] explains that user profiles [162] are very valuable in flexible communications. User profiles allow the various services individual and corporate users interact with to provide customized capabilities with very little user interaction or self-provisioning. Proper handling of the profiles also provides the security and privacy users and employers desire. With the support of enhanced applications profiles are also capable of carrying customized policy information that can be applied during any interactive session or during handover to new networks or devices.

A user profile active when a user is on the move, under a visited network, may also carry various authentication data and information on the relationship between the two parties, such as the existence of a non-disclosure agreement, which may allow greater trust in the visited network.

A wide range of security related ETSI and ETSI/3GPP deliverables are relevant to refer to when describing mobility and single sign-on issues, see further details in clause 14 on "Security".

11.4 Location based services

11.4.1 Relevance

eHealth services will use the available communications and positioning infrastructures to enhance the well-being of mobile citizens. Possible applications, listed in the ITPS report on "Location-Based Healthcare Services", (http://www.jrc.es/home/report/english/articles/vol81/ICT2E816.htm) could include:

- Optimizing rescue and first aid missions by providing accurate location data to the emergency services so they can reach victims of accidents, etc. faster and more efficiently.
- Information services (either public or private) to enhance healthcare provision, for instance by giving information about the nearest medical facilities and the fastest and most convenient routes by car or public transport, notifying users who need to obtain medication when walking past a chemists or indicating the location of the nearest public toilet to incontinence sufferers.
- If sufficiently accurate, navigation services could signal the way to blind people with sounds or to show the path back home to the mentally disabled who have become lost.
- A degree of protection against toxins or viruses could be provided by alerting citizens when they are about to enter an area where a catastrophe has just occurred (for instance, in the event of bioterrorist attack) or which is affected by an epidemic.
- Tracking at-risk individuals could assist drug and alcohol detoxification programmes by warning patients against entering certain areas or alerting support teams when a patient is in the wrong place. Tracking services could also be used to remind people suffering from Alzheimer's disease to do the right things in the right places. Tracking could also support a medical team treating an unconscious patient by informing them where that person has been.
- Scientific research could also benefit by tracking samples of people and analysing the progression of different body parameters at different locations, times and situations (this could be done in ways that protect individual's privacy by ensuring their anonymity in similar ways to those used in drug trials, for instance).
- Tracking objects could also be useful as a means of monitoring the location and use of limited equipment in hospitals, avoiding theft of expensive material or tracking the path taken by certain medicines. This could also be combined with other information such as that from sensors checking temperature and humidity conditions so as to issue a warning if equipment or medicines have been left in an inappropriate environment.
- As other information and communication technologies advance, mobility and location will support commitments to reduce the digital divide and enhance the quality of life of the ageing population, for instance, by facilitating daily life, travelling, social networking, leisure and safety.

11.4.2 Deliverables

The standardized positioning technologies in 3GPP are assisted GPS (A-GPS), EOTD, U-TDOA and cell-id. The IPTS report should also mention A-GPS, which is in fact the most accurate of the positioning technologies. Assisted Galileo is also planned in 3GPP.

3GPP is standardizing control plane solutions but a Secure User Plane (SUPL) solution is being standardized in Open Mobile Alliance (OMA), see http://www.openmobilealliance.org/release_program/supl_v1_0.html.

The following document provides the Stage One description of Location Services (LCS). A Stage One description provides an overall service description, primarily from the service subscriber's and user's points of view, but not dealing with the details of the Man Machine Interface (MMI):

- ETSI TS 122 071: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Location Services (LCS);Service description" [103].

The following document specifies the stage 2 of the LoCation Services (LCS) feature in UMTS and GSM, which provides the mechanisms to support mobile location services for operators, subscribers and third party service providers. This stage 2 service description covers the LCS system functional model for the whole system, the LCS system architecture, state descriptions, message flows, etc.

- ETSI TS 123 271: "Digital cellular telecommunications system (Phase 2+);Universal Mobile Telecommunications System (UMTS);Functional stage 2 description of Location Services (LCS) (3GPP TS 23.271)" [104].

The following document defines an intermediate universal Geographical Area Description which subscriber applications, GSM or UMTS services can use and the network can convert into an equivalent radio coverage map. This specification also provides a description of velocity that may be associated with a universal Geographical Area Description when both are applied to a common entity at a common time:

- ETSI TS 123 032: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Universal Geographical Area Description (GAD) (3GPP TS 23.032)" [105].

11.4.3 Suggested future work

Recommendation 11.4.3: There is a wide range of potential health-related services which take the user's location into account. Mainstream eHealth development, however, is not yet focussing on this area, leaving ETSI in a role to potentially promote novel applications.

11.5 Broadcast, multicast and satellite communication services

11.5.1 Relevance of broadcast and multicast communications services

There are situations when information need be sent to several people, for example:

- in an emergency situation, information can be sent via SMS and cell broadcast to people in a certain geographic area;
- for educational purposes (e.g. medical training) to people in various geographic locations, remote and/or isolated areas, rural areas;
- for telemedicine, when distant specialists are consulted, broadband satellite communication services can be used for transmission of exams such as radiology, pictures and ECG records.

The clauses below address these areas and describe relevant activities and deliverables.

11.5.2 Joint Technical Committee (JTC) Broadcast

The Joint Technical Committee Broadcast is a tripartite body between European Broadcasting Union (EBU), CENELEC and ETSI was established to co-ordinate the drafting of standards for broadcasting and related fields.

EBU is an association of broadcasting organizations that co-ordinates its members' activities in the technical, legal, programme-making and programme-exchange domains. The Union has 70+ Members in Europe and 40+ Members in the rest of the world.

JTC BROADCAST is responsible for broadcast systems (emission-reception combination) for television, radio, data and other services via satellite, cable and terrestrial transmitters. JTC BROADCAST assesses the work performed within organizations like DVB Project and WorldDAB.

11.5.3 Satellite communication services

Satellite communication and satellite-based Internet services are used in locations where terrestrial network access is not available or in locations which move frequently. Communication services via satellite are available worldwide. They enable qualified health information and support services in geographic areas which are lacking medical staff and expertise.

There are basically three types of satellite communication services:

- one-way multicast:
  One-way multicast satellite systems are used for Internet IP multicast-based data, audio and video distribution. Note that most Internet protocols will not work correctly over one-way access, since they require a return channel. However, Internet content such as web pages can still be distributed over a one-way system by "pushing" them out to local storage at end user sites, though full interactivity is not possible.

- one-way with terrestrial return:
  One-way terrestrial return satellite Internet systems are used with traditional dial-up access to the Internet, with outbound data travelling through a telephone modem, but downloads are sent via satellite at a speed near that of broadband Internet access.

- two-way satellite access:
  There are several types of two-way satellite services depending on how they share the satellite bandwidth among several of many users - both in the upstream (forward channel) and in the downstream (return channel). Dedicated and shared bandwidth technologies allow different service classes, targeted at diverse user groups. Satellite phone services provide data services at the comparatively slow speed of 2 400 bit/s. Uplink speeds rarely exceed one megabit per second and latency can be up to one second. Two-way satellite Internet sends data from remote sites via satellite to a hub, which then sends the data to the Internet.

The large number of ETSI deliverables relating to satellite communications cover various technical domains and originate accordingly from different Technical Committees. The Joint Technical Committee Broadcast (see clause 11.5.2) is active in broadcasting, particularly working on DAB and DVB, the ETSI Technical Committees ERM (EMC and Radio Spectrum Matters, see clause 7.1) deals mainly with electromagnetic compatibility aspects, and the ETSI Technical Committee SES (Satellite Earth Stations and Systems, see below) - contribute the majority of deliverables -is generally responsible for all aspects relative to satellite communications.

11.5.4 TC Satellite Earth Stations (SES)

The Satellite Earth Stations (SES) is the ETSI technical committee dealing with Satellite Earth Stations and Systems standardization. Their scope includes:

- all types of satellite communication services and applications (including mobile and broadcasting);

- all types of earth stations and earth station equipment, especially the radio frequency interfaces and network and/or user interfaces;

- protocols implemented in earth stations and satellite systems.

11.5.5 Deliverables

Multimedia Broadcast/Multicast Service (MBMS) is specified in the following technical specifications:

- ETSI TS 122 246: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Multimedia Broadcast/Multicast Service (MBMS) user services; Stage 1 (3GPP TS 22.246)" [106].

- ETSI TS 123 246: "Universal Mobile Telecommunications System (UMTS); Multimedia Broadcast/Multicast Service (MBMS); Architecture and functional description (3GPP TS 23.246)" [107].

Digital Video Broadcasting

- ETSI EN 301 790: "Digital Video Broadcasting (DVB); Interaction channel for satellite distribution systems" [108].

- ETSI TR 101 790: "Digital Video Broadcasting (DVB); Interaction channel for Satellite Distribution Systems; Guidelines for the use of EN 301 790" [109].

- ETSI EN 300 468: "Digital Video Broadcasting (DVB); Specification for Service Information (SI) in DVB systems" [110].

- ETSI EN 300 744: "Digital Video Broadcasting (DVB); Framing structure, channel coding and modulation for digital terrestrial television" [111].

- ETSI EN 301 192: "Digital Video Broadcasting (DVB); DVB specification for data broadcasting" [112].

  The deliverable EN 301 192 [112] explains that DVB System provides a means of delivering MPEG 2 Transport Streams (TS) via a variety of transmission media. These specifications have traditionally been oriented to containing MPEG 2 Video and Audio. Data broadcasting is seen as an important extension of the MPEG 2 based DVB transmission standards. Examples for data broadcasting are the download of software over satellite, cable or terrestrial links, the delivery of Internet services over broadcast channels (IP tunnelling), interactive TV, etc.

- ETSI TS 101 154: "Digital Video Broadcasting (DVB);Implementation guidelines for the use of Video and Audio Coding in Broadcasting Applications based on the MPEG-2 Transport Stream" [113].

DVB-H (Digital Video Broadcasting - Handheld) is used for bringing broadcast services to handheld receivers and is described in:

- ETSI EN 302 304: "Digital Video Broadcasting (DVB); Transmission System for Handheld Terminals (DVB-H)" [114].

DVB-H and MediaFLO are being developed outside 3GPP for broadcasts to mobile phones (see floforum.org). The MediaFLO System (http://www.floforum.org/) complements existing networks and expands the ability to deliver the multimedia customers desire without impacting the voice and data services they expect.

The following deliverables specify Cell Broadcast Service (CBS):

- ETSI TS 123 041: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Technical realization of Cell Broadcast Service (CBS) (3GPP TS 23.041)" [115].

The applicability of CBS for Public Warning Services has been considered by ETSI EMTEL, for example the following technical report (see also clause 12.2 on "ETSI Special Committee EMTEL"):

- ETSI TR 102 444: "Analysis of the Short Message Service (SMS) and Cell Broadcast Service (CBS) for Emergency Messaging applications; Emergency Messaging; SMS and CBS" [116].

3GPP is currently studying PWS, see clause 12.8 on "Ongoing 3GPP study on Public Warning System".

Performance, availability and Quality of Service (QoS) for satellite IP interworking including recommendations for future standardization are described in:

- ETSI TR 102 157: "Satellite Earth Stations and Systems (SES); Broadband Satellite Multimedia; IP Interworking over satellite; Performance, Availability and Quality of Service" [91].

The QoS architecture for Broadband Satellite Multimedia (defining how IP protocols and packet markings are interpreted and transmitted, which satellite independent protocols are used and how they in turn trigger the satellite dependent functions) is subject of the ETSI SES deliverable:

- ETSI TS 102 462: "Satellite Earth Stations and Systems (SES); Broadband Satellite Multimedia (BSM); QoS Functional Architecture" [101].

Deliverables on cell broadcast (CBS) related to location services and SMS services are mentioned in clause 11.11.4 on "Deliverables on SMS".

11.5.6 Suggested future work

Recommendation 11.5.6: Satellite-based communication can under certain circumstances fill gaps in the terrestrial infrastructure when aiming at ubiquitous supply with health-related / medical information and services. Economic and technical considerations, such as transmission delays, may impose specific technical limitations. Further work is required to define specifications applicable to satellite based services and systems in the eHealth field.

11.6 Multimedia applications

11.6.1 Relevance

IP multimedia applications including for example speech communication, real time multimedia applications, shared online whiteboards etc, which could be used by caregivers for on-line discussions between various stakeholders.

11.6.2 3GPP standard on IP multimedia applications

The following TS defines the service requirements from users' and operators' perspective for the support of IP multimedia applications including for example speech communication, real time multimedia applications, shared online whiteboards etc.:

- ETSI TS 122 228: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Service requirements for the Internet Protocol (IP) multimedia core network subsystem (IMS); Stage 1 (3GPP TS 22.228)" [117].

11.6.3 Guidelines for real-time person-to-person communication services

The following reports provide guidelines for real-time person-to-person communication services:

- ETSI TR 102 535: "Human Factors (HF);Guidelines for real-time person-to-person communication services; Future requirements" [171].
- ETSI TR 102 274: "Human Factors (HF);Guidelines for real-time person-to-person communication services" [172].

11.6.4 Suggested future work

Recommendation 11.6.4.a:. Existing and future multimedia information exchange mechanisms may prove adequate in terms of QoS for eHealth applications, but adequate provisions for functional and semantic interoperability will be required in applicable standardization work.

Recommendation 11.6.4.b: The future requirements related to real-time person-to-person communication services, listed in [171] could potentially be further developed in an eHealth perspective.

11.7 Priority services

11.7.1 Relevance and deliverables

There may be situations where the need for giving priority to urgent eHealth services may become important, for example services used when long-distance operations are made. Other priority issues have been addressed by the following document:

- ETSI EN 300 392-10-16: "Terrestrial Trunked Radio (TETRA); Voice plus Data (V+D); Part 10: Supplementary services stage 1; Sub-part 16: Pre-emptive Priority Call (PPC)" [118].

The document defines the stage 1 specifications (overall service description from the users point of view) of the Supplementary Service Pre-emptive Priority Call (SS-PPC) for the Terrestrial Trunked Radio system (TETRA). It specifies the service description of the supplementary service and the procedures to be expected with successful and unsuccessful outcomes. The document is not expected to be directly useful as is, for the eHealth domain, but it would rather serve as input for further work on priority issues in the eHealth domain.

Priority related requirements are also addressed in emergency documents, see clause 12 on "Emergency communications".

11.7.2 Suggested future work

Recommendation 11.7.2: The need for priority services requires further investigations. For data transmission, QoS as well as semantic interoperability aspects need to be considered.

11.8 Address book

11.8.1 Relevance

Several eHealth stakeholders are expected to deal with a number of people and it will therefore be useful to collect contact information that can be available from various places. It will therefore be useful to have an address book stored in the network. The possibility of sharing address book entries (e.g. among family members) is also expected to be useful and is described in published deliverables. However, the need for further work is expected in order to allow multiple parties sharing address book entries.

11.8.2 Deliverables

The technical committee TC Access and Terminals, AT-Features has developed technical specifications on Network address book:

- ETSI TS 102 334-1: "Access and Terminals (AT); Network Address Book on fixed network; Part 1: Overview" [119].
- ETSI TS 102 334-2: "Access and Terminals (AT);Network Address Book on fixed network; Part 2: Service description" [120].
- ETSI TS 102 334-3: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Network Address Book on fixed network; Part 3: vCard 2.1 profile for contact exchange by SMS/EMS for fixed network" [121].
- ETSI TS 102 334-4: "Access and Terminals (AT); Network Address Book on fixed network; Part 4: Data synchronization" [122].

The work on UCI describes how UCI contacts (as well as non-UCI contacts) can be dealt with in address books:

- ETSI EG 202 249: "Universal Communications Identifier (UCI); Guidelines on the usability of UCI based systems" [176].

The deliverable on user profiles addresses personalization aspects and address book management:

- ETSI EG 202 325: "Human Factors (HF);User Profile Management" [162].

11.8.3 Suggested future work

Recommendation 11.8.3: Further work on address books will be required in order to allow multiple parties (e.g. eHealth related service users such as patients and doctors) sharing address book entries.

11.9 Grid

11.9.1 Relevance

The next generation breakthroughs in healthcare critically depend on large multidisciplinary and geographically dispersed research teams and health provision units, wherein the network has become an integral part of the eHealth infrastructure. The distributed Grid technology (http://en.wikipedia.org/wiki/Grid_Computing) is an alternative, indeed, to costly (centralized or parallel) computing clusters, while it penetrates and spans the healthcare disciplinary spectrum, The Grid technology can either significantly reduce the cost or time to produce results and evidence for practice, research, and techniques of diagnosis, or, beyond, even provide resources that are able to deliver services that cannot be economically delivered using conventional networked information systems. It provides a ubiquitous and transparent computing tool, which is inherently distributed in resources including the medical data, computation infrastructure, software and personnel, or facilities. It fully represents the vision of a more and more computational intensive, interactive, and collaborative technology excellence for eHealth through a broad sharing of resources. Several eHealth areas (listed in the European Commissions eHealth Newsletter [221]) can be beneficially affected by Grid technology, such as:

- medical imaging and image processing;
- modelling the human body for therapy planning;
- pharmaceutical research and development;
- epidemiological studies;
- genomic research and treatment development.

The European Commission's brochure on Grids [223] states the following on the impact of Grids for the eHealth domain: "Grids will have an enormous impact on the healthcare sector, from accelerating the development of medicines to improving the analysis of health factors across entire populations. Healthcare will be revolutionized in the 21st century by the mapping of the human genome, and proteomics, the analysis of protein functions. Both disciplines are creating massive new databases in laboratories across the world. Without the right bioinformatics tools to share and use this data, however, the promise may never be realized.

Of key importance, and particularly so in the healthcare domain, is the concept embodied in "Grid" of "Virtual Organizations" (VO). These permit the sharing of resources (computing, data, human) belonging to different physical organizations within a "virtual organization" established in pursuit of a specific goal or objective. In the health context, this could mean, for example, the VOs established around each single patient to deliver the care appropriate to that patient. Grids will allow laboratories around the world, working together in virtual organizations, to search the data and create new molecules in silico with desired characteristics (multi-drug resistance, toxicity, etc.) for testing. As another example in healthcare, Grids allow the federation of databases of mammograms from across Europe, along with software tools to improve breast cancer screening and diagnosis."

A Grid infrastructure used for health is also called HealthGRID, which is also the name of a non-profit research association formed from a wide community of European researchers and institutions sharing expertise in Health Grids, see http://www.healthgrid.org .

The HealthGrid White Paper [222] has recognized the need for standardization and states, among other, that although Grids cannot by themselves resolve the problem of heterogeneity in data formats and communication protocols, they are expected to motivate the establishment of standards in this field. From the original experiments investigating possibilities offered by broadband networks, Grid technologies have entered into a phase where production capabilities are available, such as NASA's Information Power Grid, the EGEE project led by CERN and NSF's TeraGrid. However, the vision of large scale resource sharing has not yet become a reality in many areas". The whitepaper [222] explains that this can be attributed especially to the lack of commonly accepted standards, as well as to the diversity and fragmentation of available Grid middleware, tools, and services. Originally coming from the computer science community (and scientific networking), the Open Grid Forum (OGF), with participants from industry, research, and academia appears as the main body driving global standardization efforts for Grid services, protocols, and interfaces.

Future developments of Grid technologies will be characterized by a full adoption of the network intensive, automated, service-oriented Grid paradigm in a dynamically specified end-to-end resource provisioning environment, including a complete virtualization of resources and services, and the increased utilization of semantic information and ontologies (cf. Semantic Grid). Significant efforts will have to be undertaken in order to provide appropriate high-level tools and environments that hide the complexity and reduce the costs of Grid application development.

The availability and adoption of advanced security standards, support for Quality of Service, and the establishment of associated large-scale Grid business models and processes will be pre-requisites for the large penetration and adoption of Grid technologies in the every-day life of European citizens.

ETSI and ETSI/3GPP deliverables on for example security (see clause 14), QoS (see clause 11.2) and Web Services technologies (see clause 11.1) would therefore be expected to be useful and further need for standardization in areas related to Grid should be further investigated.

11.9.2 ETSI Technical Committee GRID

The ETSI Technical Committee GRID (http://portal.etsi.org/fixed/Technology/grid.asp) was created by Board#57 on 22 June 2006. The TC GRID will address the lack of interoperable GRID solutions built by the IT and telecommunications industry. It will start with writing of test specifications and progress towards a broader range of GRID standards to integrate the use of telecommunications infrastructures in networked computing.

The ETSI TC GRID is coordinating their activities with other organizations such as (among others):

- The Global Grid Forum (GGF), with participants from industry, research, and academia is the main body driving global standardization efforts for Grid services, protocols, and interfaces, see www.ogf.org . The Open Grid Forum is the "new" organization that resulted from the merger of the Global Grid Forum (GGF) and the Enterprise Grid Alliance (EGA). ETSI TC GRID is discussing cooperation with OGF on GRID testing standards and interoperability. Within the OGF, the Grid Interoperability Now (GIN) has been very active in pursuing interoperation between existing production grid systems, (see https://forge.gridforum.org/projects/gin and https://forge.gridforum.org/sf/wiki/do/viewPage/projects.gin/wiki/HomePage).

- The testing tools and repository of the ETICS project (http://etics.web.cern.ch/etics/) has been adopted by EGEE, VDT, OMII, DILIGENT and a number of other grid projects.

- ETSI and ITU-T have signed, on June 2000, a Memorandum of Understanding (MoU) to enhance their co-operation in the development of telecommunications standards (http://webapp.etsi.org/AgreementView/AgreementDetail.asp?AgrID=62). The ETSI TC GRID Chairman presented ETSI TC GRID activities at the ITU-T NGN-GRID workshop (Geneva, 23-24 October 2006) and said that it would be a must to see ETSI, ITU-T and OGF working close together with all SDOs and foras on solving ICT GRID interoperability gaps (http://www.itu.int/ITU-T/worksem/grid/presentations/s3p5-fisher.pdf).

- NESSI (http://www.nessi-europe.com/), which has an eHealth working group (among others).

The eHealth sector is expected to have requirements related to the ETSI TC GRID's work.

11.9.3 Suggested future work

The HealthGrid White Paper [222] has recognized the need for standardization in several areas where ETSI is active, and that paper might be useful input for planning future ETSI activities in this domain. It might also be good to consider participation in the HealthGrid association, in order to collect requirements and input for further work in this area.

Recommendation 11.9.3a: There is a number of relevant health-related / medical applications of Grid technology. Given the similarities with using non-Grid infrastructure from an application point-of-view, however, the need for specific standardization in eHealth areas related to Grid should be further investigated.

Recommendation 11.9.3b: Given the high relevance of Grid within ETSI, continuous coordination with Grid activities is highly recommended

11.10 Device control

11.10.1 Relevance

AT commands that can be used to enable assistive devices to interwork with mobile terminals for use of eHealth services.

11.10.2 Current standards as input

AT commands has matured from being a modem control technology to be a comprehensive and pervasive middleware platform for mobile devices. AT commands provide control of calls, the SIM card, phone information, packet domain, network services, and mobile termination in the mobile ICT device.

AT commands are specified in:

- ETSI TS 123 240: "Technical Specification Group Core Network and Terminals; AT command set for User Equipment (UE) (3GPP TS 27.007)" [123].
- ETSI TS 127 005: "Technical Specification Group Core Network and Terminals; Use of Data Terminal Equipment - Data Circuit terminating Equipment (DTE - DCE) interface for Short Message Service (SMS) and Cell Broadcast Service (CBS) (3GPP TS 27.005)" [124].

Another technology that could be of interest is the Universal Remote Console (URC) [199] can be used for remote control of a great number of devices including mobile phones. The URC framework has been released as a family of ANSI standards in 2005. It defines an XML-based, network-neutral framework of components for remote control of electronic and ICT devices and services. Conformant products can be controlled by any software or device implementing the URC technology, including voice-enabled controllers and assistive devices.

11.11 Messaging services

11.11.1 Relevance

11.11.2 SMS

SMS is useful in the eHealth domain, for example:

- SMS can be used for sending personalized messages to the patients, for example reminding them to take their medication, or of their appointments.
- An external device associated with an implanted device can send an SMS to warn of health problems. When such an SMS is received, health professionals may review the warning and take appropriate actions.
- Parents of children who have diabetes can receive blood glucose measurements by SMS.

11.11.3 Email

Email services can also be useful for sending eHealth related information and documents. However, it may be important to assure the email is an authentic email from the correct sender. Therefore is it expected that electronic signatures will play an important role when sending eHealth related emails, see clause 14.7.2 on "Security - electronic signatures".

11.11.4 Deliverables on SMS

The following deliverable is about the technical realization of SMS with UMTS:

- ETSI TS 123 040: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Technical realization of Short Message Service (SMS) (3GPP TS 23.040)" [125].

- ETSI TS 124 011: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS);Point-to-Point (PP) Short Message Service (SMS) support on Mobile Radio Interface (3GPP TS 24.011)" [126].

- ETSI TS 123 042: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Compression algorithm for SMS (3GPP TS 23.042)" [127].

The following deliverable is related to SMS for fixed line terminals:

- ETSI TR 103 180: "Access and Terminals (AT); Study on Emergency Communications; Aspects related to fixed line terminals", annex B [135].

SMS and IP Multimedia Subsystem (IMS):

- ETSI TR 122 940: "Universal Mobile Telecommunications System (UMTS); IP Multimedia Subsystem (IMS) messaging; Stage 1 (3GPP TR 22.940)" [128].

- ETSI TS 122 340: "Universal Mobile Telecommunications System (UMTS); IP Multimedia Subsystem (IMS) messaging; Stage 1 (3GPP TS 22.340)" [129].

An overview of messaging services is presented in the following TISPAN report:

- ETSI TR 181 007: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Overview of Messaging Services" [130].

The following document defines the character sets, languages and message handling requirements for SMS, CBS and USSD. The specification for the Data Circuit terminating Equipment/Data Terminal Equipment (DCE/DTE) interface (TS 127 005 [124]) will also use the codes specified in the following document, for the transfer of SMS data to an external terminal.

- ETSI TS 123 038: "Digital cellular telecommunications system (Phase 2+); Universal Mobile Telecommunications System (UMTS); Alphabets and language-specific information (3GPP TS 23.038)" [131].

Messaging and cell broadcast (e.g. for sending information to a group of people in a given area):

- ETSI TR 102 444: "Analysis of the Short Message Service (SMS) and Cell Broadcast Service (CBS) for Emergency Messaging applications; Emergency Messaging; SMS and CBS" [116].

- ETSI TS 124 012: "Cell Digital cellular telecommunications system (Phase 2+) (GSM); Universal Mobile Telecommunications System (UMTS);Short Message Service Cell Broadcast (SMSCB) support on the mobile radio interface (3G TS 24.012)" [133].

- ETSI TS 127 005: Digital cellular telecommunications system (Phase 2+);Universal Mobile Telecommunications System (UMTS);Use of Data Terminal Equipment - Data Circuit terminating Equipment (DTE-DCE) interface for Short Message Service (SMS) and Cell Broadcast Service (CBS) (3GPP TS 27.005)" [134].

11.12 Intelligent houses

11.12.1 Relevance

The delivery of health and social care services to people being at home is expected to increase, so eHealth services are therefore expected to have requirements related to the connected (intelligent) homes, which is an area that ETSI has been dealing with in the technical committee AT NGN@Home (now within TISPAN and ATTM).

11.12.2 ETSI AT and TM NGN@Home

NGN@Home (http://portal.etsi.org/at/ATNGNSummary.asp) refers to existing Network Access technologies and will cover the characteristics and functionality of devices on the Internet that may use the various access networks to transport information across the Home Access Network to the end devices on the Home Local Network. NGN@Home facilitates interoperability between the various Home Network end devices and various home hub technologies and will provide a standardized approach to Next Generation Networks at Home and in home intelligent device technologies. NGN@Home was part of ETSI AT and is currently part of TISPAN ATTM.

The following report provides an overview of AT (access and terminals) issues and deliverables when used for emergency communications and provides some issues that would also be relevant to the eHealth domain:

- ETSI TR 103 180: "Access and Terminals (AT);Study on Emergency Communications; Aspects related to fixed line terminals" [135].

The following NGN@Home deliverables could be relevant for eHealth services:

- ETSI EG 201 973-1: "Access and Terminals (AT);Public Switched Telephone Network; Support of legacy terminals by Broadband IP networks and equipment; Part 1: General (common part covering both PSTN Analogue and ISDN TE)" [136].
- ETSI EG 201 973-2: "Access and Terminals (AT);Public Switched Telephone Network; Support of legacy terminals by Broadband IP networks and equipment; Part 2: Analogue PSTN terminals" [137].
- ETSI EG 201 973-3: "Access and Terminals (AT);Public Switched Telephone Network; Support of legacy terminals by Broadband IP networks and equipment; Part 3: ISDN terminals" [138].
- ETSI TS 102 330: "Access and Terminals (AT);Portable Service Format (PSF) for Interactive Home Devices" [139].

The following NGN@Home draft could be relevant for eHealth services:

- ETSI TR 102 160-3 (DTR/AT-040002-03): "Access and Terminals (AT); Home Area Networks and the support of Next Generation Services; Part 3: Current and developing home networking technologies" [140].

11.12.3 Suggested future work

In NGN (TISPAN and ATTM) there is no requirements to have battery back-up residential GW, so in case only IP telephony is available and there is a power failure, then calls will be possible, which could have serious consequences for eHealth and emergency situations.

Recommendation 11.12.3: Investigations of eHealth requirements related to the NGN@Home area is required. One identified issue within the NGN@Home area is how to deal with power failures. This issue is almost certainly one which will be critical for eHealth systems, including emergency calls.

12 Emergency communications

12.1 Relevance

Both the emergency committees and eHealth need to address the requirements of emergency responders bearing in mind that serious consequences of the provision of incorrect or insufficient information. It is therefore relevant to coordinate the future eHealth work with ETSI emergency committees.

Many people have medical conditions which should be immediately known to emergency personnel. An emergency situation could happen due to external conditions (e.g. car crash, fire) or due to internal conditions (e.g. heart attack).

12.2 Future scenario

An e-health system could detect an emergency situation due to a patient's health condition. Wearable technology, (e.g. sensors in a shirt) and a personal monitoring system could be used to collect relevant data from of a user. The monitoring system could collect and transmit the data to a personal digital assistant (PDA) via a Bluetooth communication module. A detection algorithm could be performed in the PDA in order to recognize an emergency from the received data and the PDA could, if necessary, forward the data to an eHealth monitoring centre. If an emergency alarm is generated, the operators will try to contact the patient to determine if the patient is in an urgent situation, and, if necessary, contact the emergency services.

NOTE 1: Consideration needs to be given to emergency situations where radio communications may be deliberately jammed e.g. by security authorities intent on preventing the possible detonation of terrorist devices, and the result that personal radio based eHealth communications in the local area may not be available. Under such circumstances, reliance on eHealth communications for emergency warning may prove more dangerous than not having such communications in the first place.

NOTE 2: Bluetooth is only one possible technology for linking sensor devices to a mobile phone. There are several more in IEEE 802.15 [198], done by the group dealing with Personal Area Networks (PANs) and they have scenarios similar to the above scenario.

12.3 ETSI Special Committee EMTEL

ETSI's Emergency Telecommunications committee (EMTEL) addresses a broad spectrum of aspects related to the use of telecom services in emergency situations. Both public and private services benefit from the ETSI Special Committee (SC) EMTEL work (http://portal.etsi.org/fixed/Security/EmergencyCommunications.asp). These include emergency call services, caller location enhanced emergency services, telemedicine, the car industry, and specific public safety communication systems - to mention but a few examples. EMTEL is attended by a large number of representatives of emergency organizations, which makes it ideally placed to identify user needs and is therefore a key coordinator in collecting requirements on Emergency Communications. EMTEL provides requirements on issues of network security, network integrity, network behaviour in emergency situations, and emergency telecommunications needs in networks. Its scope includes national security and Public Protection and Disaster Relief (PPDR) and the activities include the preparation of ETSI deliverables used to describe requirements for Users, Network Architectures, Network Resilience, Contingency planning, Priority Communications, Priority Access Technologies (e.g. Twisted Pair, Cable/ HFC, Satellite, Radio Frequencies/ fixed and mobile, new solutions) and Network management.

All EMTEL deliverables could be relevant to eHealth, especially the revision of SR 002 180 [141] where health images could be sent to PSAPs and on to the Emergency services before arrival on the scene.

The EMTEL deliverables covering the communication needs of citizens and authorities in emergency situations would also be considered relevant in the eHealth domain, including the following:

- ETSI SR 002 180: "Requirements for communication of citizens with authorities/organizations in case of distress (emergency call handling)" [141].
- ETSI TS 102 181: "Emergency Communications (EMTEL);Requirements for communication between authorities/organizations during emergencies" [142].
- ETSI TR 102 182: "Emergency Communications (EMTEL); Requirements for communications from authorities/organizations to the citizens during emergencies" [143] (it will be replaced by TS 102 182: Emergency Communications (EMTEL); Requirements for communications from authorities/organizations to individuals, groups or the general public during emergencies)

The following EMTEL report covering European regulatory principles would also be considered relevant in the eHealth domain (see also clause X on "Regulation"):

- ETSI SR 002 299: "Emergency Communications; Collection of European Regulatory principles" [144].

The suitability of SMS and CBS for Emergency Messaging is described in:

- ETSI TR 102 444: "Emergency Communications (EMTEL); Analysis of the Short Message Service (SMS) and Cell Broadcast Service (CBS) for Emergency Messaging applications; Emergency Messaging; SMS and CBS" [145]. In addition, the following EMTEL deliverables are available.

The following document presents resilience concepts and considers their application within technical systems enabling emergency communications and also considers network preparedness and requirements for specialized systems and capabilities.

- ETSI TR 102 445: "Emergency Communications (EMTEL);Overview of Emergency Communications Network Resilience and Preparedness" [146].

Ongoing work:

- ETSI TR 102 410 (DTR/EMTEL-00003): "Emergency Communications (EMTEL); Requirements for communications between individuals and to authorities whilst emergencies are in progress" [147].
- ETSI TR 102 476 (DTR/EMTEL-00006): "Emergency Communications (EMTEL); Emergency calls and VoIP: possible short and long term solutions and standardization activities" [148].

12.4 Planned EMTEL work

The TC TISPAN Management report for OCG30 informs that "The EC funded STF for Emergency Call and Location Information will start its work in the next few weeks after the EC signature.". It will be relevant to coordinate that work with future ETSI eHealth activities.

12.5 MESA

Project MESA (Mobility for Emergency and Safety Applications) is a partnership project, established by ETSI and the North American based Telecommunications Industry Association (TIA). The project also includes participants from Canada, India, Korea, Australia and Japan, see http://www.projectmesa.org/.

The activities of SC EMTEL include the preparation of ETSI deliverables used to describe requirements for Users, Network Architectures, Network Resilience, Contingency planning, Priority Communications, Priority Access Technologies (e.g. Twisted Pair, Cable/ HFC, Satellite, Radio Frequencies/ fixed and mobile, new solutions) and Network management. MESA will also co-ordinate the setting of authority-to-authority emergency communication requirements and capabilities in order to produce a consistent set of ETSI deliverables and to undertake measures to efficiently continue and stimulate further coordinated EMTEL related work within the ETSI Technical Organization.

The document below describes the user requirements and scenarios that are forming the basis for a functional and technical specification and standards platform that can be installed as either a private system owned by government or a governmental/commercial partnership that provides priority broadband data service to public safety agencies and possibly secondary service to other commercial clients:

- ETSI TS 170 001: "Project MESA; Service Specification Group - Services and Applications; Statement of Requirements (SoR)" [149].

  Many of the requirements listed in TS 170 001 [149] can be assumed to be found when collecting eHealth requirements and would thus form an interesting input document in the eHealth domain.

Another MESA deliverable provides definitions, symbols and abbreviations:

- ETSI TR 170 002: "Project MESA; Service Specification Group - Services and Applications; Definitions, symbols and abbreviations" [150].

The following document represents information in the aim of understanding the often very difficult and dangerous working environments, which the user community is facing, such that Industry can provide the most effective and accurate technical solutions:

- ETSI TR 170 003: "Project MESA; Service Specification Group - Services and Applications; Basic requirements" [151].

The following document describes the overall communication architecture that a Project MESA system operates in:

- ETSI TR 170 012: "Project MESA; Technical Specification Group - System; System Overview" [152].

  The document describes issues and requirements related to networks, sensor, networked devices, connections, and terminals.

The following ongoing work might provide useful input to future eHealth work where data exchange standards could be expected to become very useful:

- ETSI DTS/MESA-SA0070004-1v311: "Project MESA; Service Specification Group - Services and Applications; MayDayML - Emergency Data Exchange Language; Part 1: The Basics" [153].
- ETSI DTS/MESA-SA0070004-2v311: "Project MESA; Service Specification Group - Services and Applications; MayDayML - Emergency Data Exchange Language; Part 2: Alarm Sources; MayDayML01 (Alarm Source vs. Emergency Call Taking)" [154].
- ETSI DTS/MESA-SA0070004-3v311: "Project MESA; Service Specification Group - Services and Applications; MayDayML - Emergency Data Exchange Language; Part 3: Hospital Emergency Sector. Next Status: WG approval (2007-04-01)" [155].
- ETSI DTS/MESA-SA0070004-4v311: "Project MESA; Service Specification Group - Services and Applications; MayDayML - Emergency Data Exchange Language; Part 4: Pre Hospital to Hospital" [156].
- ETSI DTS/MESA-SA0070004-5v311: "Project MESA; Service Specification Group - Services and Applications; MayDayML - Emergency Data Exchange Language; Part 5: First Line Responders. Next Status: WG approval (2007-04-01)" [157].

12.6 Emergency call data transferring

The following 3GPP report examines the issues associated with the transmission of Emergency Call Data from a vehicle to a Public Service Access Point (PSAP):

- ETSI TR 122 967: "Digital cellular telecommunications system (Phase 2+);Universal Mobile Telecommunications System (UMTS);Transferring of emergency call data (3GPP TR 22.967)" [159].

The CALM Handbook [160] provides information on ITS (Intelligent Transport Systems), and is also related to (but not limited to) emergency situations and eCall. The CALM Handbook is edited and updated by The CALM Forum Ltd., working in conjunction with ISO TC-204 and ETSI ERM TG37:

- The CALM handbook, Continuous Air-interface Long and Medium range [160].

  The objective of this handbook is to introduce the reader to the CALM initiative, to explain the need for CALM (Communications, Air-interface, Long and Medium range), to introduce the principles and concepts of CALM, to describe typical services that CALM will support, and to provide pointers to the Standards that underpin the CALM initiative.

12.7 Satellite Emergency Communications

TC SES has created a new working group in June 2006, called Satellite Emergency Communications (SatEC). This group will perform standardization in the area of satellite emergency communications in particular involving broadband services.

12.8 Ongoing 3GPP study on Public Warning System

3GPP is developing a Technical Report which will present the results of the Study on Public Warning System (PWS):

- Draft 3GPP TR 22.968: "3rd Generation Partnership Project; Technical Specification Group Services and System Aspects; Study for requirements for a Public Warning System (PWS) Service (Release 8)" [158].

The intent of this study is to assess the ability of 3GPP specifications to meet requirements identified for PWS. The study considers the following aspects:

- Identify requirements and aspects for PWS.
- Determine existing relevant 3GPP specifications for PWS.

- Perform a Gap Analysis to assess the ability of existing 3GPP specifications to meet the PWS requirements and aspects.

12.9 User Profile

User profiles [162] can be very useful in the Public Safety area as they can store important information and preferences related to a user in an emergency situation, such as:

- profile data to be made available to emergency personnel;
- medical data in profile;
- language preferences;
- other people's contact information in profile (relatives/friends to contact in case the person gets seriously wounded or ill) and their language preferences.

The new STF proposal, currently under development, with the title "Personalization of eHealth systems by using eHealth user profiles (eHealth)", which will bring further benefits to this area.

12.10 Suggested future work

Future work on eHealth would need to be well coordinated with MESA and EMTEL (and coordinated with ISO TC-204). Existing deliverables from SC EMTEL and MESA could be considered as useful input and their future activities should also be coordinated with eHealth activities.

The availability of eHealth related information (e.g. in user profiles) and eHealth services could potentially make possible new and very time critical treatments of people in an emergency situation.

The eCall domain could potentially be enhanced if health related data could be stored in the MSD (minimum set of data). The appropriate bodies are ETSI ERM TG37 and eCall DG (http://www.esafetysupport.org/en/esafety_activities/esafety_working_groups/emergency_call_ecall.htm)

Emergency Service personnel attending incidents are often faced with situations requiring the immediate trauma care of individuals. It is vital in such cases that the actions undertaken by Emergency Service personnel are at a level to relating to life support and within the professional competence of the responder.

When introducing information describing medical conditions great care has to be taken to ensure that the information itself does not deviate the responders' focus from the condition at hand.

At present, technical information provided by network communications systems does not give evidence of the identity of a calling party. Examples of this would be multiple people living at the same address or a car being used by someone other that the registered owner. It is thus not safe to base interventions on information of address, car ownership or communications device used, only.

At present, EMTEL considers that emergency service personnel shall not use such data for identification purposes. Information carried by the victim is of value and is commonly used.

Recommendation 12.10.a: Future work, particularly on emergency response need to be well coordinated with MESA and EMTEL (and coordinated with ISO TC-204).

Recommendation 12.10.b: The availability of eHealth related information (e.g. in user profiles) and eHealth services could potentially make possible new and very time critical treatments of people in an emergency situation. This possibility could be an important area that should be further investigated.

Recommendation 12.10.c: The ongoing work in MESA on MayDayML might provide useful input to future eHealth data exchange standards, and this work should be monitored.

Recommendation 12.10.d: Investigate issues related to enhanced eCall MSD (minimum set of data) and how eHealth user profiles potentially could provide additional information. Because current systems are not necessarily able to provide accurate information as to the individual involved, it is a requirement that examination be given to the avoidance of extended health related data being incorrectly associated with the wrong individual.

13 Usability

13.1 Relevance

The aim of the eHealth action plan [207] stresses the need for user-friendly and interoperable information systems for patients and health professionals across Europe. The eHealth action plan states that the take-up of eHealth systems and services would take place more rapidly were the needs and interests of the user communities (health professionals, patients, and citizens) to be taken on board. In general, these should be better integrated into the development and promotion of e-Health. The equal access of all groups of society to health services is an important goal in the public health policy field. eHealth can offer considerable possibilities for the provision of health services to individuals, groups, and communities. Only through concerted efforts by all stakeholders, can we ensure a successful implementation where all partners benefit.

The ETSI Technical Committee HF has produced a set of deliverables that are thus expected to be very useful in the eHealth area.

13.2 ETSI Technical Committee human factors

The ETSI Technical Committee Human Factors (HF) is the committee responsible for standards and guidelines dealing with ease of use and access to information and communication technology for all.

There is a published technical report on Telecare:

- ETSI TR 102 415: "Human Factors (HF);Telecare services; Issues and recommendations for user aspects" [161].

The scope of the technical report is to address the end user aspects of telecare, with emphasis on the delivery of health and social care services, in and outside of connected (intelligent) homes, with the purpose of ensuring that human factors aspects are duly considered in the current rapid progress towards ICT based delivery of health care services.

The ETSI Guide currently under development by STF299 on "User Experience Guidelines for Telecare Solutions (e-Health)" (http://portal.etsi.org/stfs/STF_HomePages/STF299/STF299.asp) will provide human factors and user experience design guidelines in many aspects in the eHealth domain:

- ETSI 202 487 (DEG/HF-00087): "Human Factors (HF); User experience guidelines; Telecare services (e-Health)" [174].

User profiles can store eHealth related preferences and information and is therefore expected to be very useful for personalization of eHealth services and devices (see more information on future work on user profiles in clause 13.3 on "Future work"):

- ETSI EG 202 325: "Human Factors (HF);User Profile Management" [162].

Language and multicultural issues (e.g. which measurement system is used) can be very essential in eHealth systems. In a "life or death" situation, such as the handling of emergency service communications, the time taken to extract relevant information is critical. Detecting which language to use and then accessing either an operator who can communicate in that language or an appropriate language translation third party service should be provided in the shortest possible time.

To be published very soon:

- ETSI EG 202 421: "Human Factors (HF); Multicultural and language aspects of multimedia communications" [173].

The following report provides an overview of Human Factors deliverables:

- ETSI SR 001 996: "Human Factors (HF); An annotated bibliography of documents dealing with Human Factors and disability" [163].

The following reports provide guidelines for real-time person-to-person communication services:

- ETSI TR 102 535: "Human Factors (HF);Guidelines for real-time person-to-person communication services; Future requirements" [171].
- ETSI TR 102 274: "Human Factors (HF);Guidelines for real-time person-to-person communication services" [172].

The following deliverables are also expected to be useful for eHealth purposes:

- ETSI EG 202 116: "Human Factors (HF); Guidelines for ICT products and services; Design for All" [164].
- ETSI EN 301 462: "Human Factors (HF); Symbols to identify telecommunications facilities for the deaf and hard of hearing people" [165].
- ETSI ES 202 432: "Human Factors (HF); Access symbols for use with video content and ICT devices" [166].
- ETSI TR 102 133: "Human Factors (HF); Access to ICT by young people: issues and guidelines" [167].
- ETSI EG 202 423: "Human Factors (HF); Guidelines for the design and deployment of ICT products and services used by children" [168].
- ETSI TR 102 068: "Human Factors (HF);Requirements for assistive technology devices in ICT" [169].
- ETSI EG 202 132: "Human Factors (HF); User Interfaces; Guidelines for generic user interface elements for mobile terminals and services" [170].

13.3 Future work

Two proposals have been developed, as described below.

13.3.1 Proposal on Personalization and User Profile Management Standardization (e-Inclusion)

One proposal has already been technically accepted by the EC evaluation committee and it is expected that the work will start in 2007, if and when resources will be provided. The results from this work are expected to be very useful in the eHealth domain (among others).

The following two ETSI deliverables are planned to be produced:

- **Deliverable on standardized objects**. The deliverable will be an ETSI Standard (ES) on standardized objects (including settings, values and operations) related to personalization and user profile management, a rule definition language for defining automatic activation of profiles and a common terminology. This deliverable will describe objects related to a range of services and devices with the goal to suit all users' needs including disabled, young and elderly people. The intended readers of this deliverable are service developers and device manufacturers who wish to develop services and devices that can be personalized by their customers, as defined by the user profile management concept described in EG 202 325 [162] "Human Factors (HF); User Profile Management".

- **Deliverable on network and terminal issues**. The deliverable will be a Technical Specification (TS) on issues related to networks, terminals and Smart cards. The intended readers of this deliverable are profile providers, telecom companies and device manufacturers who will implement and provide the underlying infrastructure and architecture of network and devices necessary to achieve the user profile management concept described in EG 202 325 [162] "Human Factors (HF); User Profile Management".

13.3.2 Proposal on Personalization of eHealth systems by using eHealth user profiles (eHealth)

A proposal on eHealth user profiles has been developed and it has been discussed at HF#41 on the 18-22 September 2006. Personalization and effective user profile management will be critical to the uptake of eHealth systems and to achieve eInclusion and eAccessibility. The objective of this proposed action is to provide means to achieve the goal of the new ICT era where eHealth systems can be personalized by the users in order to meet the individual users' requirements and needs, in various situations.

The results from this STF are also expected to become useful for the eCall and ITS (Intelligent Transport Systems) domains as the profiles can store important information and preferences related to a user in an emergency situation. Relevant profile data in the eHealth profile could be made available to emergency personnel such as:

- medical data in profile;
- other people's contact information in profile (relatives/friends to contact in case the person gets seriously injured or ill).

The following ETSI deliverable is suggested to be produced:

- **Personalization of eHealth systems by using eHealth user profiles (eHealth**). The deliverable will be an ETSI Standard (ES) that will define standardized objects (including settings, values and operations) related to personalization of eHealth systems. This deliverable will describe objects related to a range of eHealth services and devices with the goal to suit all users' needs including disabled, young and elderly people. The results from this STF would also be very useful in the eCall and ITS (Intelligent Transport Systems) domain as it can store important information and preferences related to a user in an emergency situation. The intended readers of this deliverable are eHealth service developers and device manufacturers who wish to develop eHealth services and devices that can be personalized by their customers.

14 Security

14.1 Relevance

14.1.1 Overview of security relevance

Within the eHealth context, there is a requirement for an infrastructure in which advanced security enables a high degree of trustworthiness to be achieved. This is important for the legal compliance, user acceptance and for meeting social and ethical challenges which are crucial elements in any eEnvironment. Concepts of communication and application security imply safety, quality and support for privacy.

Security services for eHealth are required to provide:

- auditability and traceability;
- authentication and authorization;
- integrity and confidentiality;
- safety and availability.

Figure 1 summarizes security services, without addressing specific aspects of safety and quality.

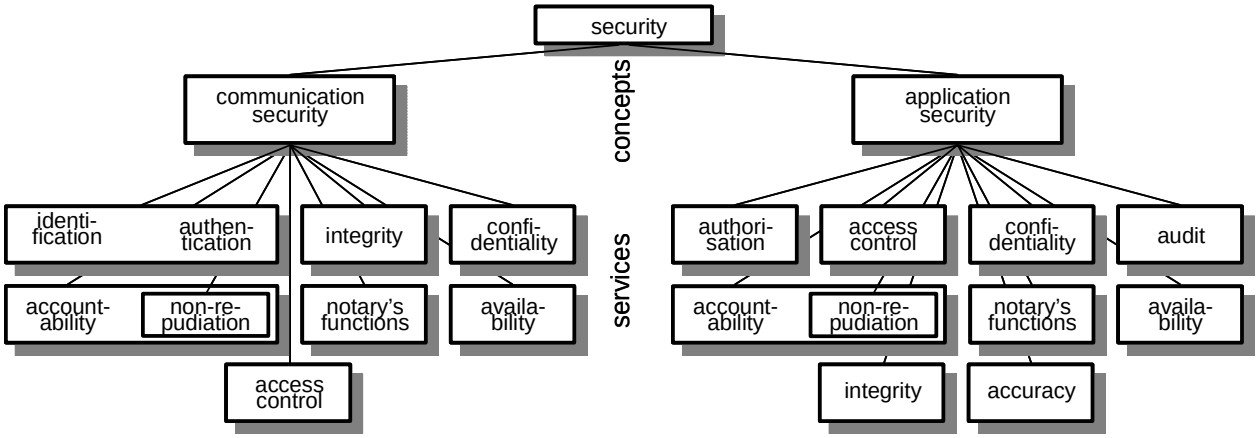

Figure 1: Overview about the relations between concepts, services, mechanisms, algorithms and data for communication and application security services

Early legislation in Germany and other European Countries, supported by further legislation such as Convention 108 of the European Council [216] and the Data Protection Directive (95/46) [217], paralleled by legislation in North America, makes a priority of safety and quality aspects. Thus, services such as accountability, auditability, authenticity and traceability become of primary importance for the assurance of patient protection.

Based on strong mutual authentication of communicating between those principals involved (human users, organizations, systems, devices, applications, components), communication security guarantees integrity, confidentiality, availability, authenticity (regarding author, sender, receiver) including non-repudiation services and without any interception. Communication security services have different requirements between various domains and jurisdictions. Thus, available solutions for providing communication security including standards and publicly available specifications (PAS) can be reused in the healthcare domain.

Application security deals with:

- data availability: guaranteed latency;
- data confidentiality: control of access to data and functionalities;
- data integrity: assurance of error-free transmission and processing of data.

Application security is concerned with authorization of actions, such as access controlled data and functionalities, data availability, confidentiality and accuracy, including:

- authorization to perform certain actions;
- control of access to data and functionalities;
- accountability including non-repudiation services for activities performed;
- auditability and traceability of those actions;
- availability, confidentiality and integrity of the data;
- safety and quality of data and functions in collecting, recording, processing, storing and using corresponding information.

Application security is depending on the underlying policy ruling context and conditions of any recording, processing and use of sensitive personal health information. In that context, policy covers any legal, social, ethical, organizational, psychological, functional and technical implication of the scenarios in question. If one policy aspect changes, the policy changes too, establishing a new policy. Depending on the legal environment and cultural impacts, policies differ between regions (e.g. Europe vs. USA or Asia), countries, states, counties and even single enterprises. Because policies are also depending on the status and the underlying context of a situation, policies in personal care settings and therefore also application security aspects in eHealth are domain specific and highly dynamic.

Communicating and cooperating entities can be grouped according to their properties regarding the underlying policy in its comprehensive view, the environment established or the technology applied (this can also be expressed within the policy), forming domains such as policy domains, environmental domains or technology domains.

14.1.2 Privacy

Because of its social implications, data relating to a user's health condition is most often considered as highly sensitive information. Corresponding to the underlying policies and its sensitivity, recording, processing, storing and use of sensitive personal health data is bound to a specific purpose. This restriction is also valid within a healthcare establishment such as a hospital, which might be one organizational and legal entity, consisting of many different policy domains however.

In most cases, the information will be used by various eHealth services, devices and in the network and the user will need reassurance that this information is stored and applied with due regard to privacy and security. There may also be situations when it will be appropriate or necessary to disclose that information to a human third party. In that context, emergency situations have to be mentioned, but also interests of the community (communicable diseases) or third parties as well as law enforcement activities, which have to be reflected properly.

Summarizing this, some basic principles have been established such as:

- patient's right of confidential use of his information;
- a hospital is a job-sharing institution, but not an informational unit;
- data sovereignty is with the departments;
- inner-organizational disclosure in the context of the treatment contract is restricted to the "need to know" principle;
- protection measures have to be realized according to the state of the art as well as according to the commensurability;
- the appropriate use of data should not be impeded so much by data protection measures;
- technical protection measures should establish a system services controlled by the user.

The EU Data Protection Directive [217] defines beyond the healthcare domain individual privacy rights declaring:

- the Legitimate Purpose Principle (the Finality Principle) saying that the data must be collected for legitimate purposes and not further processed in a way incompatible with the purposes for which they were collected;
- the prohibition underlying the processing of sensitive data with the exemptions:
  - data subject's informed and voluntary consent;
  - medical or health-related purposes and persons covered by professional secrecy or an equivalent obligation;
  - to protect the vital interests of the data subject;
  - further exemptions provided by the Member States;
- with regard to data quality:
  - personal data must be processed fairly and lawfully;
  - personal data must be collected for specified, explicit and legitimate purposes;
  - personal data must be adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed;
  - the data must be accurate and where necessary kept up to date;

- every reasonable step must be taken to ensure that the data which are inaccurate or incomplete, having regard to the purposes for which they were collected or which they are further processed, are erased or rectified;

- personal data must only be kept in a form which permits identification of the data subjects for no longer than is necessary for the purposes for which the data are collected or for which they are further processed.

The EU Data Protection Directive [217] also derives data subjects' rights principles such as:

- the right to be informed;
- the data subject's right of access to data (directly or by a trusted person);
- the right of rectification.

14.2 Range of technical committees

ETSI's standardization activities cover a wide range of security issues, from lawful interception (LI) to algorithms, from electronic signatures to Smart cards, and they relate to every aspect of ICT. In addition, ETSI is working towards the establishment of effective telecommunications systems to protect citizens in an emergency (EMTEL, MESA) and on security issues in Next Generation Networks.

There is also ETSI work on security requirements, in general, security analysis, legal framework needed as well as underlying policies and policy description staff. Also infrastructural services across Europe and between Europe and the USA have been specified. In this context, the ETSI work of the Security Techniques Advisory Group (STAG) or the Security Algorithms Group of Experts (SAGE) (http://portal.etsi.org/sage/sage_tor.asp) is relevant.

14.3 High level documents

ETSI has published a White Paper on Security standards [179]
(see http://www.etsi.org/etsi_radar/whitepaper/home.htm)

ETSI has produced a set of standards and guidelines which show how the Common Criteria as identified in ISO/IEC 15408 [197] can be used effectively within the ETSI standardization process. The documents in this set are:

- ETSI ES 202 382: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Security Design Guide; Method and preformed for defining Protection Profiles" [190].
- ETSI EG 202 387: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Security Design Guide; Method for application of Common Criteria to ETSI deliverables" [183].
- ETSI ES 202 383: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN);Security Design Guide; Method and proforma for defining Security Targets" [189].

Between them, these documents identify how standards fit to the Common Criteria and how developers of standards should prepare their standards with a view to support submission for evaluation of product conforming to the standards. Adoption of Common Criteria objectives in standardization of security countermeasures is also consistent with achieving the objectives and recommendations of the NIS report.

14.4 Ongoing work

14.4.1 TISPAN security standards development

STF292 on "TISPAN security: Standards development in support of the eEurope secure and trusted network environment" (http://portal.etsi.org/stfs/STF_HomePages/STF292/STF292.asp) is currently working in the domain Treat Vulnerability Risk Analysis (eTVRA).

The STF will produce a set of ETSI deliverables currently planned to include:

- Threat analysis for TISPAN (revision of TS 102 165-1 [182]). This document will define the security environment of the NGN, identifying the assets, threats and countermeasures in the NGN. The document will specify the intended protection level for the NGN.
- Countermeasures for TISPAN (revision of TS 102 165-2 [182]). This document will define countermeasures required to provide assured levels of security (under specific threat conditions) for the TISPAN/NGN (Next Generation Network) environment.
- Provision of Protection Profiles (TS 102 165-3 [182]). This document will define how Protection Profiles (one element of the Common Criteria for security assurance and evaluation) are provided in the eEurope trusted network environment.
- ETSI Guide for the application of countermeasures in Service Capabilities (as defined by TS 101 878 [191]). This document will provide best practice guidelines on the achievement of a secure framework for eEurope using the countermeasures and Protection Profiles defined in the documents above.

The ETSI deliverables identified above match those identified in the scope of work as follows:

- Threat analysis for TISPAN (revision of TS 102 165-1 [182]):
  - eEurope secure and trusted infrastructure vulnerability analysis;
  - eEurope security assurance plan.
- Countermeasures for TISPAN (revision of TS 102 165-2 [182]):
  - assured authentication;
  - assured confidentiality of communication;
  - assured integrity of data transfer;
  - assured secure key management and distribution.
- ETSI Guide for the application of countermeasures in Service Capabilities (as defined by TS 101 878 [191]):
  - non-repudiation service building blocks;
  - technical support for implementation of the Privacy Directive (2002/58/EC) [214].

14.4.2 Suggested future work

Recommendation 14.4.2.a: It is required to investigate security issues focused on domain-specific work in the eHealth area. The "business-driven logical view" [204] and technology-driven implementation aspects need to be managed separately.

Recommendation 14.4.2.b: When a radio link is used, the particular requirements for security require to be addressed.

14.5 Roles and access control

14.5.1 Roles

For managing privileges, authorizations, rights and duties including them to access data and functions, there are two ways to assign them to users. The first way is a direct assignment, directly defining the aforementioned properties as attributes of the corresponding users. Because of the huge number of user involved in personal care settings as well as the dynamic nature of entity relationships with changing context and underlying policies, such direct assignment is hardly to maintain. Therefore, an indirect assignment has been established using the concept of roles entities are playing in different relationships and corresponding actions. With this approach, attributes can be assigned to roles and maintained independent of the user management.

14.5.2 Access control

14.5.2.1 Range of roles

There may be a great number of people, with different roles, who need to access various parts of the eHealth system related to the client/care taker. Legitimate access to data and functions (targets) in healthcare settings depends on the roles actors are playing in general and in the context of a specific activity. Therefore, structural and functional roles define access control in health with the structural roles as enabler and functional roles as controller regarding the access to the target. Overcoming the weaknesses of mandatory (MAC) or discretionary access control (DAC) models, role-based access control (RBAC) models have been developed. Especially in the healthcare area, organizational roles and contextual constraints are important.

The basic roles include:

- data owner;
- trusted data observer; and
- non-trusted data observer.

For each role identified in the system, the capabilities of each role with respect to data and operations in the system have to be addressed. Therefore, create, read, write, update and delete rights need to be defined for each role.

NOTE: Any entity may take more than one role in a system and the roles may be restricted by authorization, by time, by location or any other qualifying data.

EXAMPLE: Data records may be created or deleted only from specific users accessing the system from specific terminals.

14.5.2.2 Role based access control

Role-based access control (RBAC) is a concept, described in the ANSI INCITS standard [196], that can be used as a security provider for accessing distributed eHealth components legitimately. The mapping for roles/services is stored in the RBAC service platform.

14.5.2.3 Parameterized access control activities at ETSI

The use of RBAC is being explored in TISPAN and in currently ongoing security STFs. However it is not well documented as RBAC but in more recent work it is referred to as "parameterized access control" where role may be one parameter.

14.5.3 Range of categories

14.5.3.1 Introduction

The various categories of users, including care takers and care givers, that could have differing needs. The following clauses divide users into a small number of generic categories that are distinguished by the way in which eHealth systems are used and managed rather than by any other categorization. The categories in the following sub clauses map well to the categories listed in the ETSI deliverable on user profiles [162]. The eHealth related categories and their roles should be further examined in order to suggest a proper handling of their access control to eHealth systems.

14.5.3.2 Supervision and ownership of responsibility

The supervisory nature of some users applies to client-carer and parent-child types of relationships. We will call this generically a supervisor - supervised user relationship.

As communicating devices become more ubiquitous, their use by some in the population (particularly those with reduced social expectations of responsibility) may need to be supervised or controlled in various ways by their particular parent or carer. The eHealth system needs to be able to provide the potential ability to control or delegate selected elements, activities, or capabilities.

14.5.3.3 Caregiver - Caretaker relationships

The relationships between a caregiver and a caretaker are especially important when each are making use of multiple devices and services, as some of them might be required for the monitoring of health or for alerting when additional aid is required. One complexity in this relationship as well is that, in some cases, the care giver might be the employee of the care recipient or a third party such as a hospital.

14.5.3.4 Formal caregiver - informal caregiver relationships

The relationships between a formal caregiver and an informal caregiver are expected to put some requirements on the eHealth system regarding delegation of the supervision and ownership of responsibility.

14.5.3.5 Parent - child relationships

Initially, the eHealth system of a dependent child (see [163] and [166]) will most likely be used and controlled by the parent or guardian of the child. This child may be allowed to use a restricted set of the system that the parent or guardian has decided as being suitable for used and controlled by the child.

As children develop,, the parent or guardian of the child may selectively allow the child to control increasing parts of their eHealth system. In certain countries there may be legal frameworks that determine when children have the right to control their eHealth system.

14.5.3.6 Manufacturers and service providers

For operational reasons, may also eHealth manufacturers and eHealth service providers be able to view and manage the eHealth system.

14.5.3.7 Suggested future work

Recommendation 14.5.3.7: Various eHealth categories and their roles should be further examined in order to suggest proper management of those roles and handling of their access control to eHealth systems.

14.6 Law enforcement

14.6.1 Accessing health related data

There may be the need for a third party, with appropriate legal approval and documentation, to access a user's health related data without their knowledge. Any such data access may violate the provisions for data protection required in the data privacy directive and should be stated as explicit exceptions. Such exceptions may be stated in the manner of the Data Retention Directive [220].

14.6.2 Suggested future work

Recommendation 14.6.2: Further work on the provision of access to parts of individuals' health related data required for law enforcement purposes would include:

- which parts of the individuals' health related data can be accessed
- in which situations;
- to whom;
- need for nomenclature and multi-lingual controlled vocabulary.

14.7 Identification of people

14.7.1 General relevance

Identification and authentication of any principals including people directly or indirectly involved in citizens' health service or patients' care, respectively, is a crucial part of any eHealth environment. Therefore, identifiers for patients and health professionals as well as tools and infrastructural services for maintaining them have been defined as crucial in all EU documents on future health systems, eHealth Europe, the European eHealth Action Plan [207] but also in the CEN/ISSS eHealth Standardization Focus Group Report [202].

Because health services are a business but also a personal relationship between subject of care and caregiver based on trustworthiness, ethical principles and legal framework, the identification and correct authentication is a basic service to be established. Security services such as authenticity, accountability, traceability, auditability depend on an ID framework. On the other hand, correct identification of people is an essential safety requirement, which becomes even more important in the context of personal health with its highly dynamic, distributed and frequently changing settings. In such environment, traditional authentication mechanisms based on personal relationships and mutual recognition do not work any more. ID failures lead to a huge number of accidents in healthcare resulting in wrong medication, wrong blood transfusion, etc.

While introducing ID services, several important implications have to be considered:

- stability and feasibility of the ID service;
- costs for establishing and maintaining the service;
- user acceptance (including for example cultural aspects and ethical aspects;
- risks of faking ID based on the selected mechanism;
- risk of false positive or false negative verification results.

Authentication of a principal's identity can be provided by:

- knowledge of a secret (e.g. PIN, password);
- token owned by the user (e.g. smart cards, USB sticks) - the legality of the ownership has to be authenticated using, e.g. a PIN;
- properties of the principal (e.g. biometrics such as finger print, iris scan, face analysis, typing or handwriting features, genetic properties).

The aforementioned mechanisms are frequently combined for improving the security level assured. The usability of some of the mechanisms is age-dependent (e.g. biometrics such as fingerprint), some authentication regimes are not feasible (e.g. frequently changing complex passwords in a job environment).

Currently, standardization efforts on biometrics are weakly developed in the SDO community.

In a personal health settings, interoperability has to be provided between any kind of principals involved. Therefore, ID services have to be established and maintained for all those principals including organizations, systems, devices, allocations or components.

14.7.2 Electronic Signatures

14.7.2.1 Relevance

An electronic signature means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication. An advanced electronic signature is uniquely linked to signatory and is capable of identifying the signatory. It needs to be created using means which the signatory users can maintain under their sole control. So an advanced electronic signature is always linked to the data so that any subsequent change of data is detectable. This specific feature of electronic signatures has both a technical and a legal meaning. A digital signature is one form of electronic signature that uses a cryptographic transformation of the data. It ensures integrity, authenticity and accountability of information the signature is bound to.

Electronic signatures are important in a range of usage scenarios and can be very useful combined with other technology such as:

- Electronic health card: The electronic health card will facilitate the verification of the identity of the patient as well as allow for electronic signature and encryption.
- Registered Emails.

14.7.2.2 ETSI TC Electronic Signatures and Infrastructures

Background and current work

The current legislation in most of the European countries - based on the European Electronic Signature Directive [218] and the related and supporting European Electronic Signature Standardization Initiative (EESSI) (http://ec.europa.eu/idabc/en/document/1441/5848) - has defined or at least given an orientation towards electronic signature algorithms that are able to guarantee a certain security level up to 5 years depending on the available key length of, e.g. 1 024 bit or 2 048 bit. This aspect is mirrored in certain regulations with regard to certification service providers and their responsibility in terms of liability.

The ETSI technical committee ESI is active in the Electronic Signatures and Infrastructures area, including the following:

- requirements for Certification Service Providers;
- requirements for certification authorities issuing qualified certificates;
- Certification Authority status and validation.

ESI are active in the area by preparation of reports and other necessary activities, including:

1) developing generic standards, guides and reports relating to electronic signatures and related trust infrastructures to protect electronic transactions and ensure trust and confidence with business partners;
2) liaising with other ETSI bodies in relation to electronic signatures and related trust infrastructures;
3) liaising with bodies external to ETSI in relation to electronic signatures and related trust infrastructures;
4) establishing a continuing work plan in relation to electronic signatures and related trust infrastructures.

More details on current work and links to documents can be found at:
http://portal.etsi.org/fixed/Security/ElectronicSignature.asp.

Planned work

Specialist Task Force STF PZ (TC ESI) on "Electronic Signatures Applied to Registered Emails: formats and policies". The purpose of this STF is to produce two Technical Specifications (TS):

- a TS defining format of the signatures to be applied on registered emails;
- a TS defining the policies of Trusted Service Providers (TSP) applying signatures on registered emails.

Terms of Reference for Specialist Task Force STF QZ (TB TISPAN / WG 7) on "Security and management of identity in the NGN". The deliverable will be an ETSI Guide with title "NGN Security; TVRA and analysis for security of identity in the NGN". It is proposed for approval by OCG#30/Board#59 and it is to be confirmed by TB TISPAN. The scope is to identify the security issues related to identity and to identify means of resolving them. It will carry out a TVRA [180] of identity in the NGN identifying the role of identity, assets related to identity, threats to identity.

14.7.3 Universal Communications Identifier (UCI)

The UCI concept is developed in TC HF. It is currently under further development in TISPAN WG4, STF302 on "Incorporating Universal Communications Identifier (UCI) support into the specification of Next Generation Networks (NGN) " (http://portal.etsi.org/stfs/STF_HomePages/STF302/STF302.asp). The UCI concept described below is based on information in a leaflet on UCI (http://www.eeurope-standards.org/Docs/UCI%20leaflet.pdf).

The Universal Communications Identifier - or UCI - is a new concept for tomorrow's advanced communication networks. It will provide a single identifier for ALL personal communications, replacing the e-mail addresses, mobile numbers and all the other identifiers in use today. It can even remain the same for life, if that is what users want.

The UCI and its supporting network will bring many benefits, in general, and particularly in the eHealth context, as it provides:

- **Trust:** Everybody's UCI label and number will be registered with a "trusted" authority and, under normal circumstances, only the UCI owner will be able to use it. So, when the terminal receives a call or communication from somebody with a UCI, the user can trust that it really is coming from the right person.
- **Stability:** Users do not need to tell everybody when they get new or replacement communications services from a different provider. The UCI always remains the same.
- **Security:** For added security, it will be possible to request positive verification of the source of a communication.
- **Special Requirements:** The additional information field can be used to let communication networks, and people with whom the user communicates, know about any special requirements. For instance, the UCI could specify that a specific user can speak English and German but only read German. Also preferences related to abilities/disabilities can be provided.

A shortlist of ETSI deliverables on UCI:

- ETSI EG 202 067: "Universal Communications Identifier (UCI);System framework" [175].
- ETSI EG 202 249: "Universal Communications Identifier (UCI);Guidelines on the usability of UCI based systems" [176].
- ETSI EG 202 301: "Universal Communications Identifier (UCI);Using UCI to enhance communications for disabled, young and elderly people" [177].

The following UCI document is in drafting Stage:

- ETSI DEG/TISPAN-04004-UCI: "Incorporating Universal Communications Identifier (UCI) support into the specification of Next Generation Networks" [178].

14.7.4 Suggested future work

Recommendation 14.7.4.a: Perform studies to investigate social and psychological implications of certain ID services.

Recommendation 14.7.4.b: Evaluate usability and user acceptance of ID services.

Recommendation 14.7.4.c: Develop Technical Specifications for ID services based on biometrics.

14.8 Identification and tracking of products

14.8.1 Use of Radio Frequency IDentification (RFID)

Radio Frequency IDentification (RFID) is an automated technology used to gather information about a product, place, person or transaction, quickly and easily, eliminating human error. It is an identification and information method for storing and remotely retrieving data using devices called RFID tags or transponders. The RFID tag can be attached to or incorporated into a product, animal, or person and transmitted using radio waves. The data transmitted by the RFID tag may provide identification related information (e.g. location information, details about the product such as ingredients, price, colour etc.). In general, it provides a link to data without the need to make contact with the item, without line of sight or in environments with strong requirements of hygiene that may limit other auto ID technologies (e.g. bar codes and 2D symbols).

A TISPAN technical report overview of RFID has been described in:

- ETSI TR 102 449: "Telecommunications and Internet converged Services and Protocols for Advanced Networking (TISPAN); Overview of Radio Frequency Identification (RFID) Tags in the telecommunications industry" [9].

The TISPAN technical report TR 102 449 [9] provides a list of RFID related standards from ETSI and other standardization organization and describes the potential applications in the telecommunications industry and they area also applicable to the eHealth domain. RFID can be useful in the eHealth domain such as in home health monitoring systems, pharmaceutical tracking or reducing medication errors in hospitals, including:

- product identification and tracking:
  - tracking of equipment type: RFID tags on eHealth equipment could ease tracking and inventory of these items;
  - tracking of individual items: RFID tags could also ease tracking of item serial numbers in the repair processes and other processes (e.g. warranties, asset tracking, etc.).
- package and shipment tracking:
  - for package and shipment tracking, manual entry and/or visual scanning could be eliminated, thus saving work and making records more accurate.

ETSI technical committee ERM is active in the RFID area, see clause 7.1.3 on "RFID in eHealth".

In addition, there ongoing work in 3GPP to standardize miniature machine to machine (M2M) devices based on GSM and UMTS:

- Draft 3GPP TR 22.868: "Technical Report; 3rd Generation Partnership Project; Technical Specification Group Services and System Aspects; Study on Facilitating Machine to Machine Communication in 3GPP Systems; (Release 7)".

The draft technical report 3GPP TR 22.868 lists eHealth specific areas in which M2M is used:

- monitoring vital signs;
- supporting the aged or disabled;
- web Access Telemedicine points;
- remote diagnostics.

14.8.2 Suggested future work

Recommendation 14.8.2: It would be relevant to provide input to 3GPP TR22.868 on eHealth applications for M2M devices.

15 Regulation

15.1 Relevance

The aim of the eHealth action plan [207] is to provide user-friendly and interoperable information systems for patients and health professionals across Europe. The eHealth action plan [207] states major challenges for wider implementation, including (among others): "The lack of standards and accreditation of products, together with different national regulations, have pushed up the cost of development and customization." (see also clause 4.3 on "eHealth action plan"). Regulation issues have already been identified as important at ETSI, as described in the following clauses.

15.2 Emergency telecommunication

EMTEL has identified the need to investigate regulatory issues, which could also be assumed to be an area that would (partly) be relevant to the eHealth domain.

The following Special Report (SR) provides information on European regulatory principles related to emergency communication:

- ETSI SR 002 299: "Emergency Communications; Collection of European Regulatory principles" [144].

The special report identifies the most relevant regulatory principles applicable to Emergency Communications (EMTEL). The intension is to collect more information focused in the relationship between standardization work and EMTEL needs expressed in regulatory documents and update the document in future versions, when appropriate with more and more updated details.

15.3 Currently ongoing work

Work on regulatory issues is currently on going in STF311 on:

- ETSI DSR/OCG-00017: "The consequences on the standardization activities on NGN from the EU ECN&S regulatory view point" [178].

The objective of STF311 (http://portal.etsi.org/STFs/STF_HomePages/STF311/STF311.asp) is to identify:

- the consequences on NGN/IMS standardization from the regulatory view point;
- areas where standardization is needed to achieve public interests objectives and to increase competition.

The STF 311 work is based on the previous work on regulatory aspects, such as the two documents already published in ETSI:

- ETSI SR 002 211 (V1.1.1): "List of standards and/or specifications for electronic communications networks, services and associated facilities and services; in accordance with Article 17 of Directive 2002/21/EC" [192].
- ETSI SR 002 211 (V2.1.2): "Electronic communications networks and services; Candidate list of standards and/or specifications in accordance with Article 17 of Directive 2002/21/EC" [193].

15.4 Suggested future work

It could be relevant to initiate work in the area of European regulatory principles related to eHealth applied to ETSI standardization work.

One example of problems with regulation has been discussed in STF304 on "AT Commands for Assistive Mobile Device Interfaces" (http://portal.etsi.org/stfs/STF_HomePages/STF304/STF304.asp): An AT command for extra high volume control has been considered a good idea by some stakeholders, but there is a problem. It is illegal in some European countries to sell devices that can produce a volume output higher than 100 dB but there are also laws in the same countries saying that people who are hard of hearing should be able to use mobile phones.

ERM_TG30 has a current NWI (New Work Item) investigating the future radio spectrum requirements in the frequency range 406 - 3000MHz for radio communications in the medical field: it is expected that the eventual result of this study will be a Systems Reference Document submitted to the Electronic Communications Committee of the CEPT requesting the allocation of additional spectrum for certain eHealth communications.

Recommendation 15.4: ETSI standardization work in the area of eHealth may require variation in, or new European regulations in related areas.

16 Future e-Health standardization activities

16.1 Summary of the future ETSI eHealth activities

The present document has identified the need for future ETSI work in the eHealth domain. The eHealth domain spans a range of technologies. Therefore, a future ETSI body in the eHealth domain should be a horizontal technical body, responsible for the standardization of eHealth related technology on behalf of all other technical bodies, including both vertical and horizontal technical bodies of ETSI. It will be important to coordinate the ETSI eHealth activities internally and with other standards organization. The need for coordination with eHealth research activities is expected to become increasingly important. The eHealth domain affects a range of stakeholder categories and it will be important to identify these and to coordinate the ETSI eHealth activities with them.

16.2 Relations

16.2.1 Stakeholder involvement

Stakeholder contacts will be important from early stages of the future eHealth activities, and dissemination activities in later stages will also be necessary in order to ensure excellent take-up of the results. Relevant stakeholder groups will therefore be identified and contacts established. There are several national and international stakeholder groups and organizations which would be useful to contact, such as health organizations, user and disability organizations, eHealth system developers and service providers.

The four main categories of stakeholders [174] include:

- Users: including clients, informal carers. These will generate various requirements (also depending on their role, e.g. passive (paralyzed assisted by carer) or active (using the eHealth system themselves);
- Care service providers: including medical and social staff, medical and social service providers (including operators, coordination agents and call centre agents);
- Buyers and procurement;
- Developers and access providers: including eHealth service and equipment suppliers, communication network and infrastructure providers, standardizers.

For further details on the stakeholders categories and their requirements are given in the ETSI report on Telecare services [161].

16.2.2 ETSI technical bodies

The eHealth domain spans a range of technologies. Therefore, a future ETSI body in the eHealth domain could be a horizontal technical body, responsible for the standardization of eHealth related technology on behalf of all other technical bodies, including both vertical and horizontal technical bodies of ETSI.

16.2.3 Standards organizations

Standards are essential for interoperability of communicating systems and integration of information both constituting the concept of eHealth. However many real-world communication architectures, interfaces, transmission protocols and codes are limited to very specific components, applications, manufacturers or domains, resulting in barriers, efforts and costs when exchanging information or even just replacing components. Motivated by this situation, groups of people from different clinical areas worked on standardization of medical data exchange and communication, primarily to improve the situation in their particular professional environments. Hence, the existing established standards are generally based on incompatible concepts reflecting not only the requirements of typical domain-specific applications and conceptual paradigms, but also their development history. However, these originally clinical standards have to be utilized and adopted to make eHealth a reality.

For the reasons mentioned above, the well-established, nevertheless incompatible communication standards in healthcare were developed independently of each other by different organizations. Relevant standardization organizations are either national or international formal standard bodies or organizations of manufacturers and/or users. The system of formal standardization is based on national standard bodies like AFNOR, ANSI, BSI, DIN, etc. These standard bodies with their offices are also responsible for the distribution of finalized standard documents to all interested parties within each country. The European Union has formed the European Standardization Organization CEN as an umbrella organization equipped with legislative capabilities for standardization within Europe. All EU countries participate by formal vote in the process of standards development. The relevant technical committee is TC 251 "Health Informatics". In ISO, TC215 deals with informatics issues in healthcare. Various scientific organizations and manufacturer organizations have a strong interest in standardization. Therefore they formed groups developing standard papers either in order to submit them to formal standard bodies for standardization (like the Point-of-Care Connectivity Industry Consortium did to NCCLS - later renamed to CLSI), or to publish them on their own, partly building organization-specific systems of standards, like DICOM. In the USA, the system of ANSI standardization is generally based on various standard-developing organizations, each of them being responsible for a specific domain. Examples are ASTM, HL7 and IEEE. Further development of standards will be dominated by cross-domain interoperability requirements resulting in close collaboration among the standard-developing organizations.

Following these lines of development, the CEN TC251, ISO TC215 and HL7 Chairs met in October 2006 to further advance shared plans to coordinate and collaborate in delivering global standards that enable interoperable capabilities in the healthcare domain. As explicated in a related agreement report [203], these plans will enhance the contributions of the three standards development organizations (SDOs), strengthen the delivery of standards-based solutions to all customers and support the goal of safe, accessible, quality and effective health service delivery. Recognizing the commitment of ISO TC 215 to serve as a coordinating mechanism and focal point for the collective work of the SDOs, the three SDOs clearly acknowledged that they will be inclusive and open to other international SDOs joining in this growing and evolving harmonization effort.

A small work team has been assigned the task of detailing and continuing the planning process in time to table a full plan for the next ISO TC215 meeting in Montreal, in March 2007. At the meeting, further specific plans will also be tabled for collective harmonization work targeted for delivery in 2008.

For ETSI, this is a perfect scenario to get on board of joint international standardization in the eHealth domain. Given the fields of expertise dominating the SDOs mentioned above, there are numerous areas not covered yet by eHealth-related standardization, regardless of their obvious relevance. However, there are also potential areas of overlap, e.g. with IEEE regarding lower layer issues.

16.2.4 Relation with European Technology Platforms

The relation with European Technology Platforms (ETPs) should be further investigated in the eHealth perspective. With the overall objective to support the development of a European research policy, in particular in orienting FP7 (European Research Area 2007-2013, Lisbon agenda) to better meet the needs of industry, the ETPs are a major policy instrument that aims at:

- providing a framework for stakeholders, led by industry, to define R&D priorities, timeframes and action plans;
- focusing research funding on areas with a high degree of industrial relevance;
- addressing technological challenges which are essential for Europe's competitiveness;

Further information on ETP can be found at http://cordis.europa.eu/technology-platforms/home_en.html.

Annex A:
Technical Standards, Specifications, Reports, Guides

This annex provides information on the various types of ETSI/3GPP deliverables. The information in this annex has been published in [193].

In general all ETSI deliverables are adopted firstly by the group of experts directly working on it and soon after by the responsible TB. The TB approval leads to the publication of the deliverable if it is a TR or a TS or to the submission to the whole ETSI membership approval if it is an ES or EG.

In the case of an EN, the National Standardization Organizations coordinate a per country position determining the approval of the deliverable. If the EN is intended for regulatory purposes special measures may be taken. In the case of SR special rules apply; they are often produced by coordination groups or other ETSI entities, not so often by TBs.

ETSI rules establish how to create, progress, adopt and publish standards according to the applicable regulation (at present the EU Directive 98/34/EC [212]. They are regularly updated by ETSI General Assembly.

Table A.1, excluding earlier types of deliverables, summarizes the main characteristics of ETSI deliverables.

Table A.1: Summary of the main characteristics of ETSI deliverables

Normative	Informative	Adopted by
TS ETSI Technical Specification The *TS* (ETSI Technical Specification) is the preferred deliverable when the document contains normative provisions and short time to 'market', validation and maintenance are essential. A *TS* may later be converted to an *ES* or an *EN*, or be used to publish the contents of a draft *ES* being sent for vote or a draft *EN* being sent for *Public Enquiry* or vote.	**TR** ETSI Technical Report The *TR* (ETSI Technical Report) is the default deliverable when the document contains mainly informative elements.	**Technical Body [TB]**
ES ETSI Standard The *ES* (ETSI Standard) shall be chosen when the document contains normative provisions and it is considered preferable or necessary that the document be submitted to the whole ETSI membership for its approval.	**EG** ETSI Guide The *EG* (ETSI Guide) shall be chosen when the document contains guidance on handling of technical standardization activities in the whole or major parts of the Technical Organization.	**TB + ETSI membership**
EN European Standard (telecommunications series) The *EN* (European Standard (telecommunications series)) is the formal output for standardization at the European level and shall be chosen when the document is intended to meet needs specific to Europe and requires transposition into national standards or when the drafting of the document is required under an EC/EFTA mandate. In a standardization project encompassing drafting of several or many deliverables, only those parts of the project that fulfil the above justification shall become *ENs*; the other parts shall become *TSs*, *TRs* or *ESs*, as pertinent. For emerging technologies, the output shall be directed to *TSs* until the provisions have become 'stable' even if the above justification is fulfilled.		**TB + ETSI full members (European national head of delegations express national votes via NSO)**
	SR ETSI Special Report The *SR* (ETSI Special Report) shall be used for any other kind of document containing information of general ETSI member or public interest. The *SR* is also the appropriate deliverable type for a deliverable with dynamic content generated by a software application on the ETSI web site on the basis of database content.	**Special rules (TB/ Board/ OCG/ ETSI Director General)**

Annex B:
eHealth related work in external standardization organizations

This annex provides input from stakeholders on eHealth related work in other standardization organizations. We cannot guarantee the completeness or correctness of the information in this annex.

B.1 Security, safety and privacy relevant CEN TC 251 standards

Table B.1

Standard/PAS	Title	Remarks
EN 14484:2003	Health informatics - International transfer of personal health data covered by the EU data protection directive - High level security policy	
EN 14485:2003	Health informatics - Guidance for handling personal health data in international applications in the context of the EU data protection directive	
ENV 1387:1996	Medical informatics - Machine readable cards - Health care applications - Cards: General characteristics	
ENV 1867:1997	Medical Informatics - Machine readable cards - Health care applications - Numbering system and registration procedure for issuer identifiers	
ENV 12018:1997	Medical informatics - Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)	
ENV 12251:2000	Health informatics - Secure user identification for health care - Management and security of authentication by passwords	
ENV 12388:1996	Medical Informatics - Algorithm for Digital Signature Services in Health Care	
ENV 12537-1:1997	Medical Informatics - Registration of information objects used for EDI in healthcare - Part 1: The Register	Track: ENQ+FV
ENV 12537-2:1997	Medical Informatics - Registration of information objects used for EDI in healthcare - Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare	Track: ENQ+FV
ENV 12611:1997	Categorial structure of systems of concepts - medical devices	
ENV 12924:1997	Medical Informatics - Security Categorization and Protection for Healthcare Information Systems	
ENV 13606-3:2000	Health informatics - Electronic healthcare record communication - Part 3: Distribution rules	
ENV 13608-1:2000	Health informatics - Security for healthcare communication - Part 1: Concepts and terminology	

Standard/PAS	Title	Remarks
ENV 13608-2:2000	Health informatics - Security for healthcare communication - Part 2: Secure data objects	
ENV 13608-3:2000	Health informatics - Security for healthcare communication - Part 3: Secure data channels	
ENV 13729:2000	Health informatics - Secure user identification - Strong authentication using microprocessor cards	
ENV 13735:2000	Health Informatics - Interoperability of patient connected medical device	
prEN 13729	Health informatics - Secure user identification of healthcare - Strong authentication using microprocessor cards (will replace ENV 13729:2000)	Track: ENQ+FV
prEN ISO 17799	Health informatics - Security management in health care using ISO/IEC 17799	Track: ENQ + FV/VA ISO
CEN TS 15260	Health informatics - Categorization of risks from health informatics products (Acronym: CATRISK)	
prEN 13606-4	Health informatics - Electronic health record communication - Part 4: Security	Track: ENQ+FV
CR 14301:2002	Health informatics - Framework for security protection of healthcare communication	
CR 14302:2002	Health informatics - Framework for security requirements for intermittently connected devices	
CR 13694:1999	Health Informatics - Safety and security related software quality standards for healthcare	
CEN TS WD	Health Informatics - Security requirements for intermittently connected devices	
CEN TS 15260	Health informatics - Categorization of risks from health informatics products	
CER TR 15299	Health Informatics - Safety procedures for identification of patients and related objects	

B.2 Security, safety and privacy relevant ISO TC 215 standards

Table B.2

Standard/PAS	Title	Remarks
ISO 17090-1	Health informatics - Public key infrastructure - Part 1: Framework and overview	
ISO 17090-2	Health informatics - Public key infrastructure - Part 2: Certificate profile	
ISO 17090-3	Health informatics - Public key infrastructure - Part 3: Policy management of certification authority	
ISO DIS 17120	Health informatics - Country identifier mechanism in healthcare	
ISO 20301:2001	Health Informatics - Health cards - general characteristics	
ISO 20302:2001	Health Informatics - Health cards - numbering system and registration procedure for issuer identifiers	
ISO TS 20856	Health informatics - Security management in health using ISO/IEC 17799	
ISO TS 21091	Health informatics - Directory services for security, communications and identification of professionals and patients	

Standard/PAS	Title	Remarks
ISO TS 21298	Health informatics - Functional and structural roles	
ISO TS 22600-1	Health informatics - Privilege management and access control - Part 1: Overview and policy management	
ISO TS 22600-2	Health informatics - Privilege management and access control - Part 2: Formal models	
ISO/TS 22857:2004	Guidelines on data protection to facilitate trans-border flow of personal health information	
ISO DTS 25237	Health informatics - Pseudonymisation practices for the protection of personal health information and health related services	
ISO NWIP TS	Security requirements for archiving and backup - Part 1: Archiving of health records	
ISO TR 21089:2004	Trusted end-to-end information flows	
ISO 21549-1:2004	Health Informatics - Patient health card data - Part 1: General structure	
ISO 21549-2:2004	Health Informatics - Patient health card data - Part 2: Common objects	
ISO 21549-3:2004	Health Informatics - Patient health card data - Part 3: Limited clinical data	
prEN ISO 21549-5	Health informatics - Patient healthcard data - Part 5: Identification data	Track: ENQ+FV (VA ISO Lead)
prEN ISO 21549-6	Health informatics - Patient healthcard data - Part 6: Administrative data	Track: ENQ+FV (VA ISO Lead)
prEN ISO 21549-7	Health Informatics - Patient health card data - Part 7: Electronic prescription	
prEN ISO 21549-8	Health informatics - Patient healthcard data - Part 8: Linkage and reference data	Track: ENQ+FV/VA ISO
prEN-ISO/TS 22600-1	Health informatics - Privilege management and access control - Part 1: Overview and policy management	Track: TCA
prEN-ISO/TS 22600-2	Health informatics - Privilege management and access control - Part 2: Models	Track: TCA
ISO NWD	Health informatics - Audit trails for electronic health records	

B.3 Security, safety and privacy relevant DICOM standards

Table B.3

Standard/PAS	Title	Remarks	
DICOM PS 3.15-2003	Digital Imaging and Communication in Medicine (DICOM) - Part 15: Security Profiles		
DICOM Supplement 31 Affects parts 3, 6, 7, 8, 15	Security Enhancements	Standard	1999
DICOM Supplement 41 Affects parts 2, 5, 6, 15	Security Enhancements 2 - Digital Signatures	Standard	2000
DICOM Supplement 51 Affects parts 3, 4, 6, 10, 11, 12	Media Security	Standard	2000
DICOM Supplement 55 Affects parts 3, 4, 6, 10, 11, 12	Attribute Level Confidentiality	Standard	2001
DICOM Supplement 67 Affects parts 3, 6, 15	Configuration Management	Ballot	
DICOM Supplement 86 Affects parts 3, 16	Digital Signatures for Structured Reports	Work	

History

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