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Abstract: This document is a consolidated catalogue of requirements for the Electronic Health Care Record (EHCR) and Electronic Health Care Record Architecture (EHCRA), gleaned largely from work done in the EU Framework III and IV programmes and CEN, but also including input from other sources including world-wide standardisation initiatives. The document brings together the relevant work done into a classified inventory of requirements to inform the on-going standardisation process as well as act as a guide to future implementation of EHCRA-based systems. It is meant as a contribution both to understanding of the standard and to the work that is being considered to improve the standard. Major features include the classification into issues affecting the Health Care Record, the EHCR, EHCR processing, EHCR interchange and the sharing of health care information and EHCR systems. The principal information sources are described briefly. It is offered as documentation that is complementary to the four documents of the ENV 13606 Parts I-IV produced by CEN Pts 26,27,28,29. The requirements identified and classified in this deliverable are referenced in other deliverables.

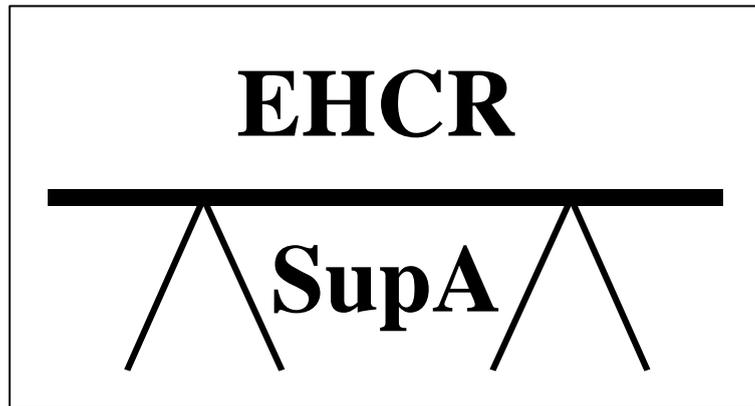
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The Electronic Health Care Record Support Action



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1 Introduction

The purpose of this deliverable is to provide a consolidated classification of the requirements for the Electronic Health Care Record (EHCR) and EHCR architecture (EHCRA). These requirements apply to the EHCR (in terms of quality, shareability etc) **and** they provide (part of) the specification that must be met by any EHCR Architecture.

It is neither possible nor appropriate to divorce requirements for the *electronic* healthcare record from requirements for the healthcare record *per se*. However, the latter have been well documented and are dealt with here only in overview. It is important to appreciate that *electronic* records must also adhere to all the requirements necessary to foster good quality, sharable records of care.

It is recognised that the requirements expressed here will not necessarily conform exactly to the requirements that a particular prospective purchaser of an EHCR system might list. The intention is, rather, to create a comprehensive set of requirements that cover the necessary features to support the requirements of all such purchasers, in a form amenable to guiding the design of the generic EHCR Architecture.

The requirements for electronic records are sub divided by overall topics such as responsibility, comprehensiveness, expressiveness and faithfulness and then further subdivided into specific requirements such as boundaries and definitions, preservation of context and so on. Each sub topic is summarised and specific requirements listed in tabular form.

The material for this document has come from many sources including relevant projects from the EU's framework III and IV programmes and from CEN. Further detail on information sources is given in References, section 2.

The document also covers record processing, interchange and sharing of EHCR data insofar as they impinge upon the EHCRA.

Requirements for EHCR systems are outside the remit of this deliverable. However, a short section is devoted to some of the key requirements for quality systems that will be based on a standard EHCR Architecture.

The numbered requirements of this deliverable will be used as references in later deliverables.

2 Information Sources

The major information sources are listed here in alphabetical order

2.1 CEN (TC 251)

CEN TC251 is the Technical Committee (www.cen251.org) of the European Standards Organisation with responsibility to develop standards that enable compatibility and interoperability between independent systems in healthcare. The European standardisation programme provides an important channel to use the results of the R&D programme in health telematics, conducted by DGXIII.

The following documents were produced in July, 1999:

CEN Technical Report "Health informatics - The Domain Model: Electronic healthcare record communication"

prENV 13606-1: “Health informatics – Electronic healthcare record communication - Part 1: Extended Architecture”

prENV 13606-2: “Health informatics – Electronic healthcare record communication - Part 2: Domain Termlist”

prENV 13606-3: “Health informatics – Electronic healthcare record communication - Part 3: Distribution Rules”

prENV 13606-4: “Health informatics – Electronic healthcare record communication - Part 4: Messages for the Exchange of Information”

2.2 GEHR

The Good European Healthcare Record (GEHR) project under the 3rd Framework EU Telematics programme, developed a comprehensive and widely applicable common data structure for using and sharing electronic healthcare records within Europe.

GEHR brought together a large, clinically centred but multi-professional project team. Its members came from industrial, healthcare and academic backgrounds and from diverse countries of Europe. It produced an Information Model providing the minimum specification for the structure and content of information held at a site and an exchange format specification for how information can thereby be exchanged between heterogeneous sites.

2.3 I4C

This project aimed to create a “multimedia-based computer patient record for cardiology” as well as a workstation. A description of the necessary data required for the Cardiology Patient Record (CPR) was produced from an amalgamation of the data items present in the records supplied.

Work primarily built upon the Open Record for Care (ORCA) Model developed at Erasmus University, Rotterdam. Other models used were those for handling electrocardiograms (as defined by INSERM U121 in Lyon) and for handling cardiac catheterisation data (designed by Medizinische Hochschule, Hannover).

The CPR was designed to facilitate direct patient care, quality assurance of care, management support, research, education and training. An aim was to allow data to be exchangeable between all systems.

2.4 Nivemes

The NIVEMES project aimed to create an international network of Health Service providers that would offer, in integrated fashion, Telemedicine – Teleconsultation services to remote, isolated places and at sea for both routine and emergency situations.

NIVEMES is based on ATKOSoft A_MedLine[®] software suite technology and utilises a powerful Multimedia Health Record. The project is was sponsored by the International Transport workers Federation.

2.5 Nucleus

The mission of the NUCLEUS project was to develop and implement an integrated multimedia electronic patient record and its customisation environment, on the basis of the concepts of RICHE.

The NUCLEUS project has been carried out in concertation with several other AIM projects (like SHINE, Trilogy, GALEN, and others) and with several CEN TC251 activities (like WG1, PT 010 and PT 011). The NUCLEUS consortium has played an active role in achieving cross-programme

concertation in AIM on healthcare records (PL 1) and on telemedicine applications framework aspects (PL 6).

2.6 Prestige

The Prestige environment deals with the clinical guidelines management. Clinical guidelines and protocols have been shown to be effective in improving the healthcare process in terms of quality, efficiency and outcome. The purpose of Prestige is to use information technology to assist in the generation, dissemination and routine application of guidelines and protocols. The technology used to support these guidelines includes architectures for multimedia patient records which allows all healthcare professionals involved in the care of a patient to have access to information about this patient. As such it has to handle all data that are useful to protocol management. This include elements like protocols of course, but also care-plans, diagnosis, actions refined in examination, investigation, prescription intervention and so on. ^{PR-SS}

2.7 RICHE

The RICHE project had defined a framework for open patient-based healthcare information systems. One of the concepts of the RICHE architecture is a means of co-ordinating the various steps related to a healthcare process. This co-ordination is provided by the Act Management System. The RICHE Reference Architecture is patient and clinical focused ^{RI-SS}

2.8 SPRI

The purpose of SPRI is, within the area related to information systems in healthcare and medical care, to provide recommendations for the structure of the information of healthcare in Sweden.

The recommendations agree, insofar as it is possible, with European proposals for standards, but also connect to and be adapted to Swedish needs and experiences.

The RAM is primarily based on the results that have emerged from the work within CEN/TC251 concerning common European standards in healthcare.

It is intended to be the basis for information systems in healthcare and medical cares that are to enable such co-operation

2.9 STAR

The approach of this project is to extend the concept of the NUCLEUS co-operative environment and shared record, from within an Healthcare Organisation towards all healthcare within a region, in addition to the SHINE telematics services and thereby enabling the provision of seamless care to the population. ^{ST-SS}

2.10 Synapses

Synapses is a three year project within the fourth Health Telematics R&TD framework of the European Commission. It aims to support the improvement of patient care by enabling healthcare professionals to access clinical record information more readily at their computer workstations.

The Synapses project sets out to solve the problems of sharing data between autonomous information systems through the development of middleware server systems. The project methodology draws together and builds on the extensive work and results in the field of Telematics, IT and Telecommunications, and CEN TC/251. Synapses servers will be built and prototyped in a variety of test sites across Europe, in order to test the applicability of a generic server specification to a range of different legacy healthcare record systems.

The main objectives were:

- To specify a generic and open means for combining healthcare records or dossiers consistently, simply, comprehensibly and securely, to enable the sharing of data between different information systems in different places.
- To produce aids and guidelines that can be used in the migration from legacy healthcare systems, as an evolution strategy for a region or Member State, or as an exploitation plan for a healthcare site or commercial company.

The specification and the guidelines will be placed in the public domain.

3 The Health Care Record

3.1 The Role of the Health Care Record

The foundations of the relationship between a clinician and a patient are the delivery of clinical care to the highest standard and the respect for patient autonomy. This inevitably leads to the conclusion that the right to informed consent and the right to confidentiality are also moral principles of the highest importance. ^{GR-8}

The following primary uses of Patient Records can be identified

- Patient Care Delivery (Patient): Documents services received, constitutes proofs of identity, self-managed care, verify billing.
- Patient Care Delivery (Provider): Foster continuity of care (i.e. serve as communication tool), describe disease and causes (i.e. support diagnostic work, support decision making about diagnosis and treatment of patients, assess and manage risk for individual patients, facilitate care in accordance with clinical practice guidelines, document patient risk factors, assess and document patient expectation and patient satisfaction, generate care plans, determine preventive advice or health maintenance information, remind clinicians, Support nursing care, documents services provided (e.g. drugs and therapies).
- Patient Care Management: document case mix in institutions and practices, analyse severity of illness, formulate practice guidelines, manage risk, characterise the use of services, provide the basis for utilisation review, perform quality assurance.
- Patient Care Support: allocate resources, analyse trends and develop forecasts, assess workload, communicate between departments.
- Billing and Reimbursement: document services for payments, bill for services, submit insurance claims, adjudicate insurance claims, determine disabilities (e.g. workmen's compensations), manage costs, report costs.

The following secondary uses of Patient Records can be identified:

- Education: document health care professional experience, prepare conferences and presentations, teach health care professions.
- Regulation: serve as evidence in litigation, foster post-marketing surveillance, assess compliance with standard of care, accredit professionals and hospitals, compare health care organisations.
- Research: develop new products, conduct clinical research, assess technology, study patient outcomes, study effectiveness and cost-effectiveness of patient care, identify population at risk, develop registries and databases, assess the cost-effectiveness of record systems.
- Policy: allocate resources, monitor public health.
- Industry: conduct research and development, plan marketing strategy. ^{C-ENV-SD}

A common European health record would be immensely beneficial to many health-related activities including research and epidemiology, health care economics, and many businesses such as pharmaceuticals or health insurance. ^{GR-5}

The healthcare record should be able to

- form the basis of a historical account
- record preventative measures
- support communication
- remind clinicians about anticipated health problems and planned actions

- identify deviations from expected trends
- provide a legal account
- support clinical research
- enhance efficiency of health professionals
- support continuing professional assessment
- support medical education
- accommodate decision support
- access medical knowledge bases
- assist with audit
- accommodate future developments ^{GR-19}

Many ethical issues arise from the purposes of the EHCR and these may be made explicit, and assigned to a hierarchy which will itself aid the resolution between competing ethical imperatives:

- The primary purpose of the EHCR is to benefit the patient by providing a record of care which supports present and future care by the same or other clinicians. ^{GR-8}
- The secondary purpose is to provide a medico-legal record of the care provided and hence support and demonstrate the competence of clinicians. ^{GR-8}
- Tertiary purposes must be legitimate (involve consent) and can never be allowed to compromise the primary or secondary purpose. Examples of tertiary purposes are the generation of data for health service management or public health programmes. ^{GR-8}

When electronic health care records are used, patient information must be at least as accessible as today. ^{SY-1A-N} In addition, computerised records should support developments in health-professional education, in particular self-directed and problem based learning. ^{GR-9}

3.1.1 The Role of the Clinical Record in Education

Computerised records should be viewed as a rich resource for analysis and study by students ^{GR-4}. This means that computerised healthcare records should be accessible to students at an early stage in their education ^{GR-9} and should support developments in health-professional education, in particular self-directed and problem based learning ^{GR-9}.

The relationship between data quality and patient care should be obvious, encouraging students to take responsibility for patient data ^{GR-9}. As all healthcare professionals learn by apprenticeship, it is of fundamental importance that students feel actively involved in patient care, and responsible, by making some of their observations in the 'real' notes ^{GR-9}. Clinicians, epidemiologists and medical educators will need to design activities that encourage students to use records as a learning resource ^{GR-4}, with easy access to statistical support tools ^{GR-4}, and retaining for example the nursing main chart and the nursing care plans as basic concepts. ^{SY-1A-N}

3.2 Clinical Competence and the Health Care Record

The EHCR should enable and reflect the competence of the clinician that creates it. The specific components of competence include:

- the consistent ability to select and perform tasks employing intellectual, psycho-motor and interpersonal skills:
 - to deliver curative and rehabilitative care
 - to promote health
 - to organise preventive activities
 - to plan, organise and evaluate health education activities
 - to collaborate with other agents of community development
 - to participate in research
 - to manage his or her services /resources

Del 1.4

- to train other members of the health care team
- to participate in and sometimes to lead the health care team
- to engage in self directed learning
- to engage in self evaluation and quality assurance
- the consistent demonstration of appropriate moral and personality attributes:
 - honesty
 - self awareness
 - empathy
 - respect for patient autonomy
 - confidentiality ^{GR-19}

Some components of clinical competence are closely related to the role of clinicians in the societies in which they practice. The healthcare record must not impose the values of one society on the clinical practice of another, although it should promote ways of learning about different styles of clinical practice ^{GR-19}. Clinicians need the ability to modify the record by explaining, reinterpreting and commenting on their actions without altering their initial record. ^{GR-19}

The medical profession and the public have a right to expect that when a competent clinician uses the EHCR, its structure will allow a fair assessment of patient care in its widest sense. ^{GR-19}

3.3 The Healthcare record

Health care and medical care are given the general responsibility for the health of the population. To be able to fulfill this task, healthcare has various resources ^{SP-1}. A healthcare record is a repository of information regarding the health of a subject of care (ENV12265) ^{SY-1A-Tech}. It is also a functional unit that all healthcare professionals know, and know how to relate to. It is used to establish the principles for the information they need and use, the information they may have access to (nursing chart, medical notes etc.), how to organise information, how to search for information, etc. ^{SY-1A-Tech}. It may be regarded as a familiar ‘user interface’ to patient information, and defines the information content as well as commonly used combinations of information. It also defines the information context. ^{SY-1A-Tech}

The moral justification for the creation, storage and processing of health records derives from the fact that they are instrumental for the protection of life and health ^{GR-8}. Records may be defined according to organisation (one in each organisational unit), profession (medical record, nursing record, lab data record), etc. ^{SY-1A-Tech}. A personal health document could represent for the patient an integration of his health history. Without a portable health document, this health history has to be rebuilt by the general practitioner by interviewing the patient (who does not always remember exactly) or, worse, by prescribing (repeat) diagnostic examinations. This is the only way to make the information circulate among medical personnel ^{C-ENV-SD}

‘The record’ should remain a user concept ^{SY-1A-Tech} to which both national and international laws and regulations relate. Rights and responsibilities are defined according to it, etc ^{SY-1A-Tech}. Fixed principles for structures and presentation may greatly improve the usability of and accessibility to the information. ^{SY-1A-Tech}

The cooperation in the HC sector aims at managing the collaboration between HCPs through a act life-cycle with regard of performer-resquester roles, irrespective of the workstation location. ^{ST-SS}
Reliability of patient data is of the utmost importance. ^{I-1}

Reduction in the current duplication of information which occurs because the different professions keep separate notes is needed.

“Typed documents are more commonly seen as shared medical information, and clinicians tend to feel a greater sense of peer appraisal through their letters. The quality of such letters probably represents the author better than their note keeping. They are therefore more likely to reflect accurately a clinical summary and the thought processes of the doctor.” ^{GR-4,C-ENV-SD}

Health care and medical care are increasingly focusing on the patient in the process of care. Different resources in healthcare and medical care will cooperate in the treatment of the patient. In that context, information about the condition of the patient and the process of care are of great importance ^{SP-1}. Focus should be on the primary processes of healthcare production. ^{NU-SS} In a distant future, one may imagine that a patient has only one (virtual or physical) record. However, in the foreseeable future, more than one record may exist. ^{SY-1A-Tech}

The term 'healthcare record' is used throughout, as it does not imply that the use of the record is confined to doctors. It does however imply that the discussion is confined to that part of the record created by clinicians, with specific reference to administrative information where relevant. ^{GR-8}

3.4 Independence from Health Systems Environments

The need for the adoption of a common Information Model and a Common Communications Profile is recognised to allow data to be exchanged freely and to ensure interoperability ^{DC-1}.

One of the biggest benefits of an Information System is a frame of references for all the developments undertaken inside an organisation. The dictionary concept is a warranty for a less expensive, consistent, integrated transfer or porting of the information. The portability aspect of the dictionary itself should not be neglected. At least three dictionaries are needed:-

- the *data dictionary* describes the users' file and the data stored in the Information System as well as the algorithms associated with the data;
- the *elementary procedures dictionary* describes the logical concatenation of the data linked to an event, also the associated algorithms;
- the *super-procedures dictionary* describes the elementary procedures' chaining needed to record an event and its algorithms. ^{GR-5}

Software Independence involves the process of being compatible with all existing software and also with evolving software. That means that failures or inadequacies in any one software application should not affect others ^{GR-5}. This would mean having a common standard Architecture for communication of data across software applications in a widely accepted and standard way ^{GR-5}. As a result of specialisation in health care, the medical information pertaining to a specific patient is often scattered over several documents and information systems. ^{I-1} In a distributed environment, it must be possible to turn a large, heterogeneous and distributed set of EHCR components into a seemingly integrated and homogeneous record. ^{NU-SS} The substance of the (healthcare) activity is basically stable, but it may change in its details from time to another due to new and/or changed methods and technologies. The way in which work is organised will, on the other hand, always change, for many reasons, one being the need to adapt to changes in the substance of the activity at a detailed level ^{SP-1}.

Ideally, the medical record includes all available patient data, irrespective of its source and provides medical professionals with meaningful views on these data ^{I-1}

4 The Electronic Health Care Record (EHCR)

4.1 Responsibility of the EHCR

The EHCR must be capable of being at least a full replacement of the paper record^{I-10}. As such, it is important that it preserves security, integrity and robustness of the information it contains,^{NU-SS} and still fulfils the two major roles of the traditional medical record - supporting the care of the patient and providing retrospective evidence of competent care.^{GR-8}

The EHCR must be a legally acceptable document, admissible as evidence in legal proceedings, as well as guaranteeing the validity of prescriptions and other orders^{GR-8}

The information model for EHCRs must be general enough to represent patient data for all specialties with the requirement that there is:

- No unnecessary redundancy,
- Optimised unambiguous representations of medical concepts
- A proper reflection of chronology
- The possibility of representing evolving insight^{I-10}

The record should, where possible, support moral and ethical behaviour in the clinical setting.
GR-4,GR-8

The EHCRA should allow a system to be designed to enable the user (the clinician) to customise knowledge and the way that care is administered to suit local and individual practice, whilst allowing all authorised users access to the same base of information about the patient - to create a truly shared patient record.^{NU-SS}

In order to encourage take up, the architecture proposed for the EHCR should be clear and unambiguous, **simple and quick to learn** for those who need to use it.^{C-ENV-SD}

The EHCR should be structured in a way that preserves the original meaning of the information^{GR-4}. Grouping of data is a major aspect of the context and presentation of the health record. It is essential to preserve the structure and context of the data.^{GR-5}

Prohibitive levels of standardisation should be replaced by configuration and customisation facilities. Hence, only a few basic concepts (universal by nature) need to be standardised.^{NU-SS} One of the previously prohibitive types of standardisation is that of specifying the professional activities when delivering patient care, and the associated patient record components.^{NU-SS}

The models developed should be *generic*. Care should be taken to avoid the use of terms or concepts which are specific to some particular clinical practice e.g. *episode*.^{NU-SS}

Rules for entering, amending, deleting, commenting etc. must be clear and consistent.^{SY-1A-Tech} Explicit rules must exist for the reorganisation of EHCR information^{SY-1A-Tech}. Reorganisation according to additional principles (time, activity, problem, document, diagnosis), should only be allowed if data can be safely extracted from its original context. Rules must be defined to allow this^{SY-1A-Tech}.

Explicit rules must exist for the reuse of information^{SY-1A-Tech}. This implies a set of security rules, and restrictions regarding the removal of data from its original context^{SY-1A-Tech}

There is an identified need to adopt current and emerging International standards.^{DC-1} Strong data standards are available for medical images and signals, laboratory data and drug data.^{DC-1} Compatibility with specific medical message syntaxes is required e.g. ACR/NEMA, SCP-ECG, and EUCLIDES with conversion tools to permit integration^{DC-1} Optimal choices for the adoption of major international communications standards in the medical field need to be made^{DC-1}

The need for the adoption of a common Information Model and a Common Communications Profile is recognised to allow data to be exchanged freely and to ensure interoperability.^{C-ENV-SD}

It must be possible to specify the mechanism for upgrading from one published version of the architecture to another.^{DR-1}

RER1	The EHCR should be structured in a way that preserves the original meaning of the information
RER2	The EHCRA must preserve the structure and context of the data
RER3	The EHCRA should be generic and not the standardisation of a particular model of health care
RER4	The standard must include clear and consistent rules for: Entering, amending, deleting, commenting; Re-organising information in the form of "views"; Extracting information; Re-using information
RER5	The EHCRA should allow for compatibility with existing international standards wherever possible and appropriate
RER6	The standard must provide a common Information Model and a common Communications Profile
RER7	The standard must allow for the specification of a mechanism for upgrading from one published version of the architecture to another
RER8	The EHCRA must preserve security, integrity and robustness of the information
RER9	The EHCR must be a legally acceptable document
RER10	The EHCRA should ensure there is no unnecessary redundancy
RER11	The EHCRA should provide for optimised unambiguous representations of concepts
RER12	The EHCR should correctly reflect chronology
RER13	The EHCRA should be clear and unambiguous

4.2 Subject of healthcare

The subject of the EHCR will usually be an individual but there will be occasions e.g. in social work, where the subject is a group e.g. a family.

SLH1	The EHCRA must cater for the situation where the subject of the EHCR is a group rather than an individual
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4.2.1 Identification of the Patient's Record

Special attention should be given to the identification of patients, and of the associated EHCRs.^{NU-SS} The system should provide direct access to the patient's record where appropriate, by such identifiers as radiology number and hospital unit number. All further searches of patient data should make use of a subset of these data items: Surname, forename(s), sex, date of birth and address.

The record must cope with international forms of name. For example, the system may need to try matching with the surname and forename interchanged to allow for Asian names entered incorrectly.
C-ENV-SD

EHCRA-based systems should have the ability to confirm the existence or not of a record for a patient.^{ST-SS}

There should be the ability to assign, compare and associate unique patient Ids and Patient Ids at the local organisation.^{ST-SS} Patients may be known under different ID-numbers. It must be possible to associate more than one such number with a patient with reference to the institution/department where each number is in use.^{I-10} If one patient can be identified in more than one way, these different identities should be capable of being linked together in order to always provide a comprehensive view of the patient's medical record data.^{SP-1}

Patient Characteristic is a generic term which covers anything that might be thought to describe a patient, be that date of birth and other basic demographics, medical conditions or vital signs.^{NU-SS}

IDP1	The EHCRA must cater for the recording of all appropriate identification attributes including local identifiers
IDP2	The EHCRA must allow for international person name conventions
IDP3	It must be possible to associate more than one such number with a patient with reference to the institution/department where each number is in use
IDP4	If one patient can be identified in more than one way, these different identities should be capable of being linked together

4.3 Comprehensiveness

The EHCR must contain or reference all information thought to be clinically relevant to the care of a patient^{GR-19}. The data stored in the EHCR must be adequate, relevant and not excessive in relation to the purposes for which it is collected, which must themselves be specified, explicit and legitimate. A patient would then have grounds for requesting the removal of data deemed to be outside these limits^{GR-8}. Informal notes of clinicians about patients, which they would not wish them to see, must be hand-written, and absolutely private. In no circumstances should such notes be entered on the computer^{GR-8}

The electronic record must contain at least all parts of today's paper-based records.^{SY-1A-N}

In clinical practice, physicians do not record everything that occurred, but only those data that they consider relevant at the time of recording. Relevance is subjective but, regrettably, insight only comes after a series of events have taken place, and not beforehand. Fortunately, experienced physicians are able to identify events sufficiently early that might be relevant for future patient care. However, if persons other than the physician who entered the data will use the patient data at a later stage, then at data entry the physician should be encouraged to enter complete data and the system may assist in checking the consistency and reliability of data^{I-1}

The record must be ordered around a realistic support of the processes of clinical care.^{GR-19}

Observations involve a wide variety of types of data. The electronic healthcare record will need to cope with all of these. This will include a range of multimedia^{I-1, GR-4}, simple textual entries and narrative comments^{GR-19}, as well as catering for more structured entries involving coded information.

Specialist centres and research projects may require the documentation of extra information which cannot be predicted in advance.^{GR-19} In addition, the different clinical situations in which the record (or parts of it) may be used must be taken into account. For example, the patient-held record in obstetrics, child health, chronic disease, involves the doctor recording care in a record which is carried by the patient.^{C-ENV-SD}

The EHCRA will have to consider aspects such as videoconferencing and Smart Cards.^{NI} The model will also need to reflect the reality of distributed EHCRs and EHCR systems.^{DR-1}

Health records must contain psychological, social and family information.^{GR-4}

The electronic record must recognise that medical data has:

- complexity
- levels of certainty and precision
- severity
- diversity of data types^{GR-4}

The record must be capable of containing information on:

Healthcare processes, Activities, Medical problem, Healthcare requests, Healthcare characteristics, Resources, Users and Authorisation^{SP-1}

Medical notes often contain sketches and diagrams done by doctors because they are a clearer and quicker way of recording information.^{C-ENV-SD, GR-19} Clinicians must be able to record information in the form of drawings and diagrams^{GR-4}

The use of symbolic diagrams and stylised symbols to convey concepts must be allowed.^{GR-19}

Apparently simple elements of healthcare information can at times require quite complex recording structures, which may vary depending upon the institution and with time.^{GR-19}

Activities may be part of agreed, planned, current, accomplished as well as reviewed healthcare processes. The healthcare processes can be aggregated, and in this way form for instance contacts and periods of care.^{SP-1}

The record should cope with opinions, diagnoses, instructions, suggestions etc.^{NI} The EHCR should allow for the storing of reviews, care plans, hypotheses and conclusions.^{RI-SS}

Ideally, the EHCR should contain all data on the patient history, physical examination, diagnostic test, and therapeutic interventions to support patient care.^{I-1}

Interpretations are the result of reasoning on the basis of available observations.^{I-1} Decisions may include the request for further investigation, treatment or discharge.^{I-1}

It is extremely important for diagnoses that the physician can:

- Assign a diagnosis name
- Assign a status to that diagnosis (considered, confirmed, rejected, cured etc.)
- Assign a time-stamp to the specified status

It is important that the physician can characterise each event with his own description. This can facilitate consultation of the record later by providing clues as to what happened during the contact.^{I-1}
¹⁰ A patient visit may produce a variety of data^{I-10} and clinicians must continue to be able to use a rich and varied vocabulary^{GR-4}

CHV1	The EHCR must contain or reference all information thought to be clinically relevant to the care of a patient
CHV2	The data stored in the EHCR must be adequate, relevant and not excessive in relation to the purposes for which it is collected, which must themselves be specified, explicit and legitimate
CHV3	The EHCR must be capable of containing all parts of today's paper-based records
CHV4	The EHCR should cope with opinions, diagnoses, instructions, suggestions
CHV5	The EHCR should allow for the storing of reviews, care plans, hypotheses and conclusions
CHV6	The EHCR should allow for the recording of all data on the patient history, physical examination, diagnostic test, and therapeutic interventions to support patient care
CHV7	The EHCR should allow for the recording of interpretations, observations, decisions request for further investigation, treatment or discharge
CHV8	The EHCR should place no restriction on the clinical vocabulary used within it
CHV9	The EHCR should allow a physician to record: a diagnosis name, a status to that diagnosis (considered, confirmed, rejected, cured etc.) and a time-stamp to the specified status
CHV10	The EHCRA must continue to allow clinicians to use a rich and varied vocabulary
CHV11	The EHCR must be able to contain psychological, social and family information
CHV12	The EHCR must be capable of containing information on: Healthcare processes, Activities, Medical problem, Healthcare requests, Healthcare characteristics, Resources, Users and Authorisation
CHV13	The EHCRA standard should consider the effect on the EHCR of aspects such as videoconferencing and Smart Cards and distributed EHCRs

4.4 Expressiveness

Presentational views on EHCR data, for patient care, decision support, scientific data analysis or for quality assessment of care, require patient data to be highly structured and unambiguous. It is extremely difficult to fulfil these requirements with narrative (textual) data.^{I-1}

While at times, or in some locations there may be an overwhelming need to have a healthcare record with rigid protocols, decision support and management plans, other clinicians will require expressive narrative to convey their findings^{GR-19}. This being the case, the EHCR must allow the clinician to express information, ideas and justification for actions fully and without restriction,^{GR-8} and a record should be able to contain any kind of information a user chooses to enter^{SY-1A-Tech}. This should include the identification of different problems, the recording of the reasons why an intervention is done^{I-1} and links between actions and patient problems reflecting the physician's insight^{I-1}. In addition, Health Care providers should be able to register the characteristics and protocols of their primary processes, and the templates, according to which they want their professional activities to be documented in the EHCR.^{NU-SS}

EXV1	There should be no restrictions on the type of data that can be entered into the EHCR
EXV2	The EHCR should support the use of protocols, decision support and management plans
EXV3	The EHCR should support the identification of problems and the recording of a clinician's reasoning
EXV4	The EHCR should support the recording of links between data

4.5 Faithfulness

The healthcare record should be structured in a way that preserves the meaning of the information when it was originally written, so that it can be understood if read by another person elsewhere. ^{GR-19}. There should be no loss of accuracy if an electronic record is used instead of pen and paper for textual data. ^{GR-19}

Completeness and integrity of the record data is important ^{N1}. A key characteristic of the health record is that it should be a faithful¹ record of what was observed ^{GR-5}. Rector and colleagues identify three aspects of faithfulness²:

- Faithfulness to the clinicians observations of the patient;
- Faithfulness to the decision making process;
- Faithfulness to the clinical dialogue ^{GR-19}.

Users will have to be able and willing to enter data accurately, and mechanisms for patients to check accuracy must be established ^{GR-8}. It must also be apparent when the electronic version and when the paper version is the main ‘media’ for the information ^{SY-1A-N}. In the case of data being inaccurate, control of contents should reside with the patient ^{GR-8}.

There is a duty to notify others in receipt of inaccurate data which can be ‘hidden’ by creating ‘versions’ restricted rights. Corrections must be made as signed and dated additions to the corrected information, which clearly state which information is invalidated, who did it and why ^{SY-1A-N}. The sense and meaning of the record must be maintained and the reason for the amendment recorded. If accuracy is disputed, the data should be annotated with the patient’s opinion ^{GR-8}. Invalidated information must never be deleted (except where there is a legal requirement to do so). The user must be clearly informed that invalidated information exists, but not necessarily forced to review it. ^{SY-1A-N} Patient data or actions, once collected, must not be changed retrospectively, as this would have severe legal implications. ^{I-1}

The health record has to be faithful to the meaning of the original source of the information. ^{GR-5}

FHL1	The EHCR should be structured in a way that preserves the meaning of the information when it was originally written
FHL2	The EHCR should be a faithful record of what was observed
FHL3	The EHCR has to be faithful to the meaning of the original source of the information
FHL4	Invalidated information must never be deleted ³
FHL5	Patient data or actions, once collected, must not be changed retrospectively

4.6 Specific Requirements of the EHCR

4.6.1 Single Record of Care

The ethical and legal demand is for a single logical record of care ^{GR-4} for each patient, with no ambiguity about the recording made at a particular contact ^{GR-8}

Thus, each EHCR has a single, logical subject of the record – the subject of care ^{DR-1} (See also Subject of healthcare). The EHCR of a patient may refer to other people who are themselves subjects

¹ "Faithful" here is used in the sense of being accurate and sufficiently complete.

² Rector A, Nowlan W, Kay S. 1991 Methods of Information in Medicine 30:p176-86

³ National laws in certain countries may demand that data be completely erased in certain specific situations. In these cases, this requirement cannot be met.

of care on the same or other systems, e.g. the patient's mother. This does not alter that fact that there is only one subject of care for that patient's record.

A patient may have more than one actual record, and thus, the details of the logical subject of care may be composed of information from a variety of record sources^{DR-1}. Patient information may also be found in other 'feeder' systems, like laboratory systems, ADT systems, etc., outside the boundaries of a specific record. This may be both clinical and demographic information.^{SY-1A-Tech}

The information may be found in other systems for several reasons, including temporary storage before it is included in the record, etc.^{SY-1A-Tech}

The record of care of a patient may begin with records concerning the foetus and may continue to include entries about and beyond the patient's death^{DR-1}. Although ante-natal information may well exist in the EHCR of the patient's mother, the patient's EHCR may begin in its own right prior to birth.

SHR1	There should be a single logical record of care for each subject
SHR2	Each EHCR applies to an identified subject of care
SHR3	Details of the subject of the EHCR may be built from different information sources
SHR4	The EHCR should allow for pre-birth and post-death entries

4.6.2 Boundaries and Definitions

It is important that the scope of the EHCR, as with all definitions, is clearly defined^{SY-1A-Tech} in order that this is absolutely clear to all parties what is and what is not the health care record^{GR-8}. The term EHCR is used when referring to the health record created and stored on computer. It is the equivalent to the computerised patient record (or CPR) in the American literature^{GR-8}.

One way to define the boundary of the record is that it contains "all recordings made by a responsible clinician regarding the care of the patient". Thus information does not form part of the EHCR until a HealthCare agent has taken responsibility for that information and committed it to the record.^{GR-8}

It may be debated as to whether the record should specifically accommodate different persons' 'views' of the information^{DR-1}. The definition of the boundary above would suggest that the 'view' only exists in the record if a healthcare agent takes responsibility for its inclusion regardless of whether it would be 'sensible' to include it. This alone, then, is not sufficient definition.

The following gives a more rigorous definition^{DC-1}:

Information is part of the EHCR of a subject if, and only if, the following conditions are met:

- (I) The information is believed relevant to the health care of that subject by health care person(s) who are in a position to take responsibility for it
- (II) Appropriate health care person(s) have taken responsibility for the inclusion of the information in this EHCR

Information could become part of the EHCR if any of the following conditions are met:

- (I) The information is directly related to the health care of the subject
- (II) A clinical decision, inference or other act may – at any time - be taken based upon it
- (III) Non-inclusion of the information could detriment the care of the subject
- (IV) It is non-clinical (administrative) information associated with the characteristics (physical, social etc) of the subject or related (directly or indirectly) to the care of that subject

BND1	Boundaries must exist to define what is/is not regarded as part of an EHCR
BND2	Information is part of an EHCR of a subject if, and only if: (i) The information is believed relevant to the health care of that subject by health care agent(s) who are in a position to take responsibility for it (ii) An appropriate health care person(s) have taken responsibility for the inclusion of the information in this EHCR

4.6.3 Administrative Information

Patient identification, location and demographics are topics that are highly susceptible to differences of approach by different healthcare organisations, especially when they are viewed in the context of the whole of Europe. Practices are also likely to change over time. It is important to be flexible in representing such information. ^{NU-SS}

Appointments made need not be part of the EHCR. ^{I-10}

Patients can have more than one name (eg maiden name, married name) and a number of characteristics not limited to the basic demographics (date of birth, sex, etc.) all of which should be classifiable. ^{NU-SS}

Places and/or systems may identify patients using local identifiers and any variety of additional attributes from surname to date of birth to biographical information. It should be possible to use whatever properties are deemed appropriate at the time to identify and verify the correct patient record. ^{DR-1}

ADM1	The EHCR must support the recording (and classifying for identification purposes) of patient identification, location and demographics data
ADM2	The EHCR must support the recording of more than one name for a patient (e.g. maiden name, married name)
ADM3	The EHCR must support the suitable recording and use of any properties deemed appropriate in identifying and verifying the correct record

4.6.4 Organisation of the record

It must be possible to organise the information in sections similar to today's paper record. The organisation may be model-driven. ^{NU-SS}

Health records must accommodate both highly structured methods of recording information and very informal methods of recording information. ^{GR-4} For an EHCR to have benefits, data in that record need, at least to a certain degree, to be structured and coded. ^{I-1}

The current practice is that each department decides the content and organisation of Patient Records, tailoring them according to its specific requirements. A department is not really isolated, patients move from one department to another, therefore the patient record must be somehow interrelated. ^{C-ENV-SD}

In the same way as healthcare processes are broken down into activities, they may be aggregated to larger wholes. This can be done in several steps, and in that way e. g. healthcare contacts/healthcare instances and healthcare episodes/healthcare chains respectively can be formed. ^{SP-1}

It is important that test results are presented to the physician in a transparent unambiguous fashion. The physician should always be aware of which lab provided the results.^{I-10}

Sometimes the order of multiple values matters (e.g. the order of names in a full name, or values in a vital signs sequence) and sometimes it does not. The record should be able to cope with multiple values and ordering.^{DR-1}

The content of the different parts must be defined according to today's systems and ways of handling information.^{SY-1A-N}

Information may be divided into four categories:

- Personal Data – e.g. Demographics, Insurance details
- Special Characteristics – e.g. blood group, allergies, other emergency data
- Histories of the Patient – e.g. inherited history, personal history, special history
- Medical Events – all important transactions of a patient with the system that should be recorded e.g. Diagnoses, Drug Prescriptions^{NI-ML}

The partitioning of data into categories (such as medications, symptoms, test results, demographics) gives structure to a patient record. Categories are characterised by the procedure by which the patient data were acquired and are source-oriented views on the patient and the data contained in the record.^{I-1}

All entries, section headings, contents etc. need to be unambiguously interpretable, including after exchange.

ORG1	The EHCRA must cater for structured and coded data.
ORG2	The EHCRA must allow the lab that provided the results to be identified in the EHCR
ORG3	The EHCR should be able to contain multiple values and ordering of entries
ORG4	Information in the EHCR should be able to be divided into sections or categories

4.6.5 Links

To make the process of care more transparent, and to be able to use the data for multiple purposes, semantics need to be added to patient data in an EHCR.^{I-1} The EHCR depends on knowledge. This knowledge comes in two main groups: classification information and semantic links between elements of information. Both can be dealt with in a unified model.^{NU-SS}

The EHCRA should support the definition of links between the components in the record,^{I-1} as well as between EHCRA.^{C-ENV-SD}

4.6.5.1 Intra-Record Links

When utilising patient data (e.g. for medical auditing) it is important to have insight into how the data in the record are interrelated. These relationships are not self-evident; the temporal order will only tell part of the story.^{I-1}

The EHCRA must represent the many functional and logical links which exist across all data for a patient^{DC-1} These 'Semantic Links'^{ST-SS} need to be typed using information from a terminology service or knowledge-base.^{NU-SS} Links should be entered and processed in a controlled way.^{SP-1}

The result of an incoming laboratory test may be related to a request that was made during an earlier patient visit^{GR-19}, and a prescription may pertain to a patient problem that was defined previously.

Other examples of semantic links would be that pain (a patient characteristic type) indicates administer pain relief (a class of Act), or administration of pain relief results in absence of pain.^{NU-SS}

LNK1	The EHCRA must represent typed semantic links which exist between data in an EHCR
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4.6.5.2 Inter-Record Links

Individual patients' EHCRs should be linkable to other patient's EHCRs. Examples of such links include genetic or household links.^{C-ENV-SD}

There should be classifiable relationships between patients (e.g. different types of family relationship, contact relationship, epidemiological relationship).^{NU-SS}

LNK2	The EHCRA must represent typed semantic links which exist between EHCRs
LNK3	There should be classifiable relationships between Patients

4.6.6 Preservation of Context

Interpretation of information in a record may depend on its information context^{SY-1A-Tech} Preservation of this context may be essential for correct interpretation.^{SY-1A-Tech} This implies that an information element should have a defined original context in the record, and so that it is clear in which part of the record each element originated. An information element in a record must know that it is a part of a record, and in which part of the record it belongs.^{SY-1A-Tech}

PCX1	The EHCRA must maintain the original context of all elements of the record
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4.6.7 Observations recorded by Students

If students are given access rights to an EHCR system, they should be clearly identified by the system as being students, in order that it is clearly visible to subsequent viewers of the record that the observations were recorded by a student.^{GR-9}

Student notes have different properties from other entries: they are excluded from analyses and are not transmitted to external institutions.^{GR-9}

It should be possible for a qualified professional to validate a student's entry, document that they agree with the student's notes and change the status of the student's notes to that of qualified professional. The student's notes would then have the same appearance as the 'live' record, be included in analyses and be transmitted to external healthcare organisations.^{GR-9}

STD1	Student interactions with the EHCR must be identifiable as such
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4.6.8 Language

In the European and International community, language is an important aspect of information.^{GR-5} Internationality implies support for local languages.^{NI} The record must be able to cope with information recorded in different languages, whether this be individual entries or complete sections of the record.^{DR-1}

The EHCR should be independent of national language. ^{GR-5} Language independence should include not only national language but also medical language and coding systems for medical language - associated codes are nothing more than additional languages. ^{GR-5}

To permit language independence, much of the contents of the EHCR need to be coded. Over time, the EHCR may come to contain a mixture of different national languages, nomenclatures and indeed coding systems. ^{GR-5}

There will be a number of elements of the health record that need to permit translation, and hence require coding. These include: the structure of the record i.e. headings, field names etc. the contents of the record i.e. values, morbidities, prescriptions, terms and their codes etc. ^{GR-5}

It may be necessary from time to time to translate information provided as free text, into a language other than that of original recording, for viewing or other purposes ^{GR-5}. Free text entries require information regarding the language in which they were written.

It is thought to be unsafe to translate more than once from the original language as this compounds possible errors of interpretation that may be introduced during the translation process. It is just as important to identify what does not translate as what does. The suggested rule is that any term is translated only once from its original language. ^{GR-5} This will require the ability to be able to tell from the EHCR whether information has been translated from the original.

This list of supported languages will need to be extended as new countries join the EC. Extending language independence to complex character languages such as Japanese and Chinese is a much greater problem and should be borne in mind when designing the architecture. ^{GR-5}

LNG1	The EHCR must cater for information recorded in different languages, whether this be individual entries or complete sections of the record
LNG2	It must be possible to identify in the EHCR the existence and reliability of any translation.
LNG3	The EHCR should indicate wherever information has been translated from its original language
LNG4	The EHCRA should consider the future diversity of languages in which entries may be recorded and presented

4.6.9 Free Text

Free text plays an important role in the health record to supplement entries taken from dictionaries, lists, and coding systems for none of these is likely ever to be totally comprehensive. ^{GR-9}

There are two methods to bridge the gap between the need for the structured health record and the users unstructured preference. These are coded input or natural language processing (NLP). ^{GR-5} (See also Language above)

FTX1	It must be possible to include free text entries in the EHCR
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4.6.10 Numerical and Quantifiable Data

Many medical data have numeric values (e.g. weight, serum cholesterol), and it is particularly in such data that the notion of precision becomes important. ^{GR-19}

Record entries will include a variety of quantified data, such as heights, weights, blood pressure and dosages which may be expressed as values with appropriate units or perhaps as percentages ^{DR-1}

Values of entries may be expressed as ranges of values (approximate or accurate). These may be one-sided (such as “more than 3”) and may be exterior ranges (e.g. “ ≤ 3 and > 5 ”) ^{GR-19}

Quantities may be recorded on an instrument, whose characteristics may effect the interpretation of the value (e.g. non-standard or faulty scales). It may be necessary to record certain characteristics of the instrument, for example the accuracy of the values it produces. This may be expressed as a range e.g. 10 mg +/- 0.5 ^{GR-19}

The record should be able to hold values of the form “x of n per y of d” ^{GR-19}

NQD1	EHCR entries should be allowed with numerical values which may include units
NQD2	The expression of precision of numerical values in the EHCR should be catered for
NQD3	The EHCR should allow the recording of various forms of ranges of quantities
NQD4	The EHCRA should consider the recording of information relating to the instrument from which values were obtained
NQD5	The EHCR should be able to hold values of the form “x of n per y of d”
NQD6	The EHCR should allow for numerical values expressed as percentages

4.6.11 Multimedia and Externally Referenced Data

The record will include multimedia aspects including images and sketches. ^{NI}

Medical notes often contain sketches and diagrams done by doctors because they are a clearer and quicker way of recording information. A drawing contains less ambiguity. Many clinicians like to explain things to patients using sketches, because it helps establish a common language, helps convey spatial relationships of organs.

There is a wide variety of drawings in use. They are fairly standard in their style and in the way information is depicted. Drawings are sometimes the only record of transaction between a doctor and a patient and must be therefore stored securely and be transferable." ^{C-ENV-SD}

Clinical drawings should be incorporated into the data structure in such a way that the information they contain can be submitted to analyses comparable to those allowed for numeric or coded values ^{GR-4}

The special nature of drawings as being, sometimes, the only observation made requires special attention to the patency of the record. ^{C-ENV-SD} The special nature of drawings as being, sometimes, the only observation made requires special attention to the patency of the record ^{DC-1}

Incorporation into the record of material produced by various popular graphics packages may also be needed ^{DC-1}

There must be a guaranteed link provided between any externally held data and the other clinical and administrative data with which they are closely associated. The management of local external storage must keep relevant sections of data together when export/import of data is being carried out. ^{C-ENV-SD}

The record must be able to contain data elements of an 'external reference' type which point to storage elements that are appropriate for containing data of any type not suitable for incorporating directly in the record ^{DC-1}. References in the record may be to the locations of permanently stored external data and/or to local copies of permanent data kept for convenience ^{DC-1}. Certain types of 'bulky data' have been identified, but the EHCRA must allow other types to be added as needs

develop^{DC-1}. If local external data are deleted, associated references in the record must be suitably modified^{DC-1}

The management of local external storage must keep relevant sections of data together when export/import of data is being carried out^{DC-1}

Many test results are now in image form (X-rays, ultrasound etc.).^{GR-19} ECGs and EEGs are expressed as analogue data, usually stored graphically^{GR-19} It should be possible to include laboratory data, ECG recordings, images and drawings in the electronic record.^{GR-19} The record should take into account the inclusion of information from medical devices such as cardiographs, tomographs, medical film scanners etc. and the possibility of registering the corresponding data directly on to the system.^{NI-ML} Standard protocols for e.g. ECGs should be usable.^{NI-ML}

The record must be able to cope with sequences of similar measurements such as in vital signs monitoring.^{CM-1} Bio-signals in the record may need to allow for some form of compression.^{NI-ML} A range of volumes and rates applies to bulky data, which must be accommodated both by messaging and transmission systems and by storage systems^{DC-1} Data compression to approved standards will be required for the transmission and storage of bulky data. A general requirement for compactness of all data exists to permit storing large amounts of clinical data over time^{DC-1}

The range of methods for conveying information is not static and will evolve as medicine itself progresses. The EHCRA must provide for the full range of multi-media data types to be incorporated within the record.^{GR-19}

Different ways of handling multi-media data in the record e.g. the use of MIME must be catered for.^{DR-1}

MXR1	The EHCR must be able to contain data elements of an 'external reference' type which point to storage elements that are appropriate for containing data of any type not suitable for incorporating directly in the record
MXR2	The EHCR will need to include multimedia aspects
MXR3	The EHCR should take into account the inclusion of information from medical devices
MXR4	The management of local external storage must keep relevant sections of data together when export/import of data is being carried out
MXR5	If local external data are deleted, associated references in the EHCR must be suitably modified
MXR6	Data compression to approved standards will be required for the transmission and storage of bulky data
MXR7	The EHCRA must provide for the full range of multi-media data types to be incorporated within the EHCR

4.6.12 Problems

The electronic record must allow the recording of a list of problems^{C-ENV-SD} There may also be specific handling of information concerning that problem or problems that are the origin of one or several healthcare processes. This information can be used to group healthcare characteristics in relation to the different problems of the patient.^{SP-1}

A patient may have different concurrent problems.^{I-1}

PBM1	The EHCR must be able to contain Problem Lists
PBM2	The EHCR must be able to reflect that a patient may have concurrent problems

4.6.13 Events

To preserve accountability there are events apart from the provision of clinical care which should be recorded in the EHCR. Access to records by patients or the reasons for not allowing access are examples.^{GR-8}

Events can be characterised by the fact that the information about each one:

- Can be regarded as having been discovered at one moment
- Has been provided by the same source
- Was entered or stored in the EHCR at one moment^{I-10}

For legal purposes and for a proper interpretation of its context, the following information must be known for each event:

- The patient to which it pertains
- The type of event (first visit, follow-up visit, specific test)
- The moment of entry
- The moment when the information of the event became available
- The person who entered the event
- The source of the information covered by the event
- The department involved in the event
- The specialty involved in the event^{I-10}

EVT1	The EHCR needs to be able to contain Events apart from the provision of clinical care
EVT2	An Event can be regarded as having been discovered at one moment
EVT3	Specific information about each event in the EHCR must include: <ul style="list-style-type: none"> • The type of event (first visit, follow-up visit, specific test) • The moment when the information of the event became available • The source of the information covered by the event • The department and specialty involved in the event

4.6.14 Acts

Any provision of care to a patient may be termed an Act. Acts may aim to provide diagnosis, treatment, survey, synthesis.^{RI-SS} Acts are related to a patient and requested by a health care professional (the requester) to health care providers.^{RI-SS}

Acts follow a life-cycle : they may be established, validated, requested by one team, accepted, scheduled, started, provisionally reported, completed by another team. They may also be cancelled, refused, suspended, abandoned.^{RI-SS} Acts may be also part of a protocol or a guideline.^{RI-SS}

Throughout the life cycle, when new information is generated or when a change of act status occurs, acts and their contents may be referenced in the EHCR.^{RI-SS}

An act should include standard attributes related to its status.^{RI-SS} For example, for a requested act, the patient identification, the act identification, the characteristics of the request (requester, requesting unit), and the desired conditions for the performance of the act.^{RI-SS}

It should be possible to represent acts, their structure, state, authorisation and class.^{ST-SS}

There should be the ability to record the status of an act.^{ST-SS} There should be the ability to record the authorisation of an act^{ST-SS}. There should be the ability to manage change to information associated with an act^{ST-SS}

The EHCRA should provide for the association of one or more components of the EHCR with each change of status (event) in the life cycle of actual acts.^{NU-SS}

The identity of the person who asked for the performance of a Medical Action for a patient should always be recorded.^{NI-ML}

ACT1	The EHCR must be able to contain information about Acts including their structure, status, authorisation and class
ACT2	When new information is generated or when a change of act status occurs, acts and their contents may be referenced in the EHCR
ACT3	The EHCRA should provide for the association of one or more components of the EHCR with each change of status (event) in the life cycle of actual acts.
ACT4	The identity of the person who asked for the performance of a Medical Action for a patient should always be recorded in the EHCR

4.6.15 Requests and Results

Requests for investigations need to be recorded in the health record^{DC-1} and the record should support the following characteristics for lab tests:

- The type of test
- The moment the sample was taken
- The moment the sample was examined
- The test result itself and the reference values
- Optional comments on the test^{I-10}

It must be possible to relate all results of investigations to the requests registered and identified in the Health Record. The identification of requests and of the ensuing results must include identification of the requester^{DC-1}

It will be necessary to cope with variable numbers of reports for a particular test data acquisition and a hierarchical numbering system is recommended for tying together multiple results for a request^{DC-1}. Data sets appropriate to the test will include items for recording all necessary attributes of the request (including necessary clinical accompanying data), using standards like ACR/NEMA and EUCLIDES where available^{DC-1}

The achieving of the incorporation of test results into the EHCR will require that the transfer of the data or of references to them must be able to proceed in an automated way, but with appropriate control by the user of entries of received.^{DC-1}

RQR1	The EHCR should support the following characteristics for lab tests: <ul style="list-style-type: none"> • The type of test • The moment the sample was taken • The moment the sample was examined • The test result itself and the reference values • Optional comments on the test
RQR2	It must be possible to relate all results of investigations to the requests registered and identified in the EHCR
RQR3	The identification of requests and of the ensuing results must include identification of the requester
RQR4	The EHCRA must cope with variable numbers of reports for a particular test data acquisition

4.6.16 Prescriptions and Drug Administration

There must be the ability to store drug information in the EHCR. ^{GR-19} Many patient records support the specification of drug prescriptions but do not easily support the recording of actual drug intake by the patient. Both functions need to be supported by the EHCR. ^{I-10}

Prescribing and drug administration records need to be differentiated, and the attributes of the prescription as a key document initiating a chain of events must be included in the record, and the necessary protocols for protecting the record in the context of computerised prescribing observed. ^{DC-1}

Drug selection can be on the basis of Anatomic Characteristics, Therapeutic Characteristics, Clinical Characteristics, Pharmaceutical Characteristics, Active Substance or Commercial Name ^{NI-ML} A different brand name may be used for the same medical substance in different countries. ^{C-ENV-SD}

The prescription is not an isolated communication of instructions between the doctor and the pharmacist who is expected to dispense the drug, or others directly involved with the care of the patient. It increasingly involves health administrators, epidemiologists and other medical professionals who wish to have access to the anonymised information for their own purpose. ^{GR-19}

PDA1	Prescribing and drug administration entries in the EHCR need to be differentiated
PDA2	The attributes of the prescription as a key document initiating a chain of events must be included
PDA3	Access and distribution rights applied to prescriptions should consider the range of healthcare agents involved

4.6.17 References to Non-Patients and Places

Identifying and demographic data should be available about persons that are involved in the healthcare of the subject. ^{SP-1} Demographic data may be based on a population directory. ^{SP-1}

Patients can have more than one Location and there can be more than one Patient in the same Location. ^{NU-SS}

When referring to people and places in the record, the question arises as to how much (or how little) information is needed about each of these. For example, if the record refers to a clinician taking legal responsibility for an entry, is it necessary for the record to contain his/her name, registration details, profession, address, contact numbers etc.? If, for example, a contact number (012 3456 789, say) for an Helathcare Person is recorded, this implies that *a* contact number for that person *at the moment of recording*, was 012 3456 789. Numbers change: for example the inclusion of the digit '1' in UK numbers, or when the HCP moves office or address. The question arises as to whether at any point in the future, this knowledge would be useful or be of legal necessity. On the other hand, if it were known whether the number were still valid, the information would at least be useful during this time.

A similar case can be made for addresses. If contact information is stored in the record, it should be possible to cater for e.g. contact number 'only available at ...' and electronic addresses where not standard email or where further information is needed – e.g. extra passwords etc. If addresses are stored in the record, how should these best be represented? The format varies from country to country. Some useful information may be gained by studying how other organisations such as electricity boards, banks, insurance etc. deal with addresses ^{DR-1}

NPP1	The EHCRA should cater for identification and demographic information about persons related to the care of the subject
NPP2	The EHCRA should cater for appropriate identification of locations including the relationship to the subject of care
NPP3	Where appropriate, the EHCRA should allow for a wide range of contact information

4.6.18 Alerts , Triggers and Decision Support

The EHCRA must be able to cope with alerts and triggers and linkage to knowledge/decision support tools.^{DR-1}

ATD1	The EHCRA must be able to cope with alerts and triggers
ATD2	THE EHCRA must be able to cope with linkage to knowledge/decision support tools

4.6.19 Derived Data

The record must be able to cope with data derived from other data by formulae e.g. Body Mass Index^{DR-1}

DRV1	The EHCRA must be able to cope with data derived from other data by formulae
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4.6.20 Dates, Times and Chronology in the record

Chronology is an important aspect of medical recording because it is crucial for a proper interpretation of medical information and for decision-making.^{I-1}

Time-stamping of patient data and physicians' decisions and interventions is essential.^{I-1} Dates and times should be able to reflect the time zones in which the information was recorded and sub-second precision.^{DR-1} Time may be expressed in absolute terms ("July 4th 1996, 06:00 p.m."), as a relative expression ("one month after") or as a duration ("lasted 10 seconds").^{I-1}

Interpretations vary over time. The items to be recorded should serve dynamic explanation.^{I-1} If, for example, an opinion later changes, the EHCR should allow for the new insight to be recorded. Therefore, all data related to an event should allow for three time stamps:

- The moment the data are acquired and entered^{NI-ML}
- The moment the physician obtained his insight
- The moment his insight became applicable.^{I-1}

An EHCR standard should cover the effect of legacy data that does not indicate the time or date correctly as it may result in EHCR information being out of order.^{DR-1}

DTC1	Dates and times in the EHCR should be able to reflect the time zones in which the information was recorded and sub-second precision
DTC2	Time-stamping of EHCR data is essential
DTC3	Time may be expressed in absolute terms as a relative expression or as a duration
DTC4	All data related to an event should allow for five possible time stamps: <ul style="list-style-type: none"> • The moment the data were entered and committed to the EHCR • The moment the data were acquired • The moment the event took place • The moment the physician obtained his insight • The moment his insight became applicable.

DTC5	The EHCRA must provide for legacy data that do not have date and time stamps
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4.6.21 Sources and providers of information

Input into the EHCR may be by an authorised person or electronically. ^{C-ENV-SD}

The source of the record should be recorded. This may require identification of the system, machine, network, building, Health Care Facility etc. ^{DR-1}

It should be noted that information in the record may have arisen from a person or an electronic tool. ^{DR-1}

SCP1	The EHCRA should support EHCR Information that may have arisen from a person or from an electronic tool
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4.6.22 Normal and Physical Ranges

The EHCRA should consider the representation of normal and physical reference ranges.

In considering this issue, the effect of a value flagged as ‘out of range’ should be taken into account. Systems could prevent the value from being entered (but this is probably not a good idea) or give an explicit warning. Should the EHCR include the fact that a value was out of normal range?

Normal range can depend on the country, specialty, context etc., so the range would need to be stored in the EHCR, too. What is considered a normal range can change within the health care organisation over time which will reflect upon the manner in which such reference ranges are modelled. If normal ranges are not in the EHCR at all, and a decision was taken based on the system saying the value was out of normal range, there would be no record of it. ^{DR-1}

Similar issues need to be addressed for physical ranges. ^{DR-1}

NPR1	The EHCR should support the recording of the normal reference range as defined at the time that a particular result was entered into the record
NPR2	The EHCR should support recording of the context of a normal range e.g. the clinical context, specialty etc.
NPR3	The EHCR should support the recording of the physical range as defined at the time that a particular result was entered into the record

4.6.23 Comments in the record

It must be possible to register comments upon all kinds of information, and where appropriate, to define explicitly a specific comment’s required attention-level. ^{SY-1A-N} Multi-media comments are not in widespread use now, but their future use should be considered. ^{DR-1}

CMR1	The EHCR should support recording of comments to all kinds of information
CMR2	The EHCR should allow recording of levels of emphasis on comments
CMR3	The EHCRA should support future inclusion of different types of comments, such as multi-media comments, that are not currently in widespread use.

4.6.24 Certainty

Data of all types when recorded carry with them degrees of uncertainty. This relates to all information, but especially to clinical findings and interpretations. ^{GR-19}

Use of language in describing uncertainties is often ambiguous, and Bryant and Norman⁴ have demonstrated the wide disagreement about the meaning of common terms, such as 'probably'.^{GR-19}

CTP1	The EHCRA should support EHCR Entries that carry with them degrees of certainty
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4.6.25 Severity

The assessment of severity or risk in a situation is often as important as the recording of findings and may be the sole basis for management decisions.^{GR-19}

SVY1	The EHCRA should allow for the recording of severity
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4.6.26 Terminology and Knowledge

There is a need to represent concepts expressed as classes of objects and semantic relationships.^{NU-SS} The requirement is for a single code per relevant concept.^{GR-5} The system would need in addition rules to govern the combinations of these codes to ensure that they made sense.^{GR-5}

The record architecture must accommodate the current growth towards the systematisation of medical knowledge.^{GR-19} There are many classification systems used in medicine, and a shared healthcare record must allow use of any one or all of these systems.^{GR-4} For example, coding of diagnoses^{I-10} or drugs^{NI-ML} should be according to internationally accepted coding schemes

The national language, nomenclature, and coding system must be recorded for each concept used.^{DC-1} In many cases one term has more than one meaning which differs according to the context.^{GR-5}

The EHCRA should incorporate a translation convention to mark the degree of faithfulness of the health record after translation.^{GR-5} The EHCRA should permit translation only as a single step away from the original language.^{GR-5}

The development of an EHCRA needs to support the recording and communication of data derived from term sets, but avoiding the pitfalls of many current classification systems.^{GR-19}

Computerised records must offer not just terms but structures that allow for the various uses and combinations which reflect the many approaches and specialities in health care.^{GR-4}

Different codification schemes may be used between sites.^{NI} The use of internationally accepted codifications simplify language independence and should be maximised.^{NI} There are emerging international codes for coding systems. The EHCRA needs to be able to store the reference for the original coding systems using the Health care Coding-scheme Designator (HCD) which, under CEN, is responsible for the Registration of coding systems used in health care. HCD is a six character code which unambiguously identifies each registered coding scheme.^{GR-5}

Translating to the nearest term will not guarantee that the original author's concept and meaning is accurately expressed. The same is true of coding systems.^{GR-5}

There are two extremes available for coding the contents at input. The first is to create a code for every possible entry. This would result in a huge coding system and impossible development and

⁴ Bryant G. D., Norman GR. (1980) New England Journal of Medicine, 302;411

maintenance. On the other hand a separate code for every single word in the contents would be difficult to translate as frequently the same word has different meanings according to the context and domain in which it is used. Neither extreme is satisfactory. ^{GR-5}

The record should be able to handle negation e.g. that a symptom was not present. It should also be able to handle simple logical expressions e.g. that the diagnosis was that the patient had either X or Y. ^{DR-1}

Where coded data has been used in the record, the user should be able to see at least one presentation of the textual form of the data at any time that it is needed. ^{DR-1}

It may be appropriate and/or necessary to provide recommended coding schemes for certain features in the record. ^{DR-1}

The EHCRA must be able to cope with ranges of terms E.g. -, trace, +, ++, +++, ++++ or low, medium, high. ^{DR-1}

Knowledge must be able to be expressed in the EHCR ^{RI-SS}

Within Health record entries there are many short hand abbreviations such as “SOB” (shortness of breath). Some terms such as “acute myocardial infarction” have become standardised in their usage and are increasingly being drawn from term sets. ^{GR-19}

TKW1	Concepts should be represented in the EHCRA by a single code
TKW2	Where the EHCRA allows for combinations of codes, combinatorial rules must be defined
TKW3	The EHCRA must allow for any and all coding schemes to be represented
TKW4	The national language, nomenclature and coding scheme must be available in the record for each concept code used
TKW5	Where terms in the EHCR have been translated, a means of indicating the faithfulness of the translation should be provided
TKW6	The EHCRA must be capable of representing coding schemes by means of the CEN HCD
TKW7	It must be possible to store the negation of a term in the EHCR
TKW8	Where coded data has been used in the EHCR, at least one textual presentation of the term must be available at the time it is needed
TKW9	The EHCRA must be able to represent ranges of terms
TKW10	It must be possible to express knowledge in the EHCR
TKW11	The EHCRA should allow for the recording of coded recognised abbreviations

4.6.26.1 Synonyms

There are many synonyms in use in doctors' notes and the availability of these is necessary to make any system acceptable to individual users. ^{GR-19, C-ENV-SD}

Synonyms are widely used, sometimes to act as an indicator of the term a patient has initiated, and sometimes to reflect the expression that has been used in explanation to the patient. Other synonyms will reflect the personal vocabulary of the clinician or the speciality. ^{C-ENV-SD}

Synonyms are an important part of nomenclatures. For each synonym there is also a preferred term. Some prefer all synonyms to be converted to the preferred term when entered into the record whilst others prefer the synonym to be stored since the record is then faithful to the original data. The EHCRA should allow both options..^{GR-5}

The EHCRA should incorporate storage of preferred terms and synonyms in the original language.^{GR-5}

SYN1	The EHCRA should allow for the recording of preferred terms and synonyms where desired
SYN2	The EHCRA should incorporate storage of preferred terms and synonyms in the original language

4.6.27 Other Forms of Data

Questionnaires must be accommodated in the record in some way, whether it is the whole questionnaire or just the answers.^{DR-1}

Lists, tables and graphs may need to be represented in the record^{DR-1}

Protocols of care need to be represented and/or referenced in the record.^{DR-1, PR-SS}

OFD1	The standard should consider the representation of (or reference to) questionnaires (in whole or part) in the EHCR
OFD2	The standard EHCRA should consider the representation of lists, tables and graphs in the EHCR
OFD3	The standard should consider the representation of (or reference to) protocols of care in the EHCR

5 Electronic Health Care Record Processing

5.1 General

There are many uses to which EHCRs may be put. All of these should be enabled by the adoption of a good quality standardised EHCR. The introduction of an EHCRA standard should lead to improved quality of EHCR information. This in turn should enable a wide variety of electronic processing of data to take place which was hitherto difficult or impractical.

Use of a standard EHCR by a well-designed system, should allow many repetitive processes to be automated, e.g. prescription orders, billings and reporting and general routine administrative tasks..^{C-ENV-SD}

It should be feasible to access decision support tools and bibliographic databases directly.^{C-ENV-SD}

To make data entry flexible in both scope and detail, it should be supported by terminology and knowledge-base systems. These can, for example, suggest which concepts can be used in what contexts.^{I-10}

It must be possible to perform both analyses within an individual patient's file and on a population of patients for epidemiological purposes. The request language for this should be easy to use^{GR-4}

Systems should be able to offer support for improved follow up of the patient and clearer prescription processing.^{C-ENV-SD}

Basic manipulation functions systems should be able to offer might include:

- a function supporting an overview of the available material
- a function allowing to select and display individual documents^{C-ENV-SD}

The information model will allow for flexibility of presentation including customisable and simultaneous views of the same data.

Each profession within a certain shared process has a unique approach and different needs. The EHCRA should facilitate the building of systems which can be customised to the users' individual needs without compromising the underlying information.

It should be possible to present information in a familiar way for the users. The record system must be able to adapt to different specialities' and different departments' tradition for recording and presenting information, including problem oriented records and "fixed / flexible form" records.^{C-ENV-SD}

It must be easy for the user to be sure that she has seen all information in the system regarding a patient

It must be possible to produce reports based on the information.

Information stored in EHCRs must be in a form which renders it amenable to automated processing. This may include activities such as indexing, selective retrieval, transmission, display, storage, analysis and manipulation.^{C-ENV-SD}

- The users must be allowed to modify the ways in which record contents are displayed.^{C-ENV-SD}
- EHCRA-based systems should include a mechanism to make the information available to other applications (quality assurance, utilisation review, claims processing, expert systems and knowledge resources). This should include provision for alias patient identification where desired.

- re-use of information (referrals, discharge letters..)

An interested user must be provided with the possibility to automate individual working tasks and processes - beyond the normally provided measures - without having to learn a conventional programming language. ^{C-ENV-SD}

The EHCRA should enable the performing of time critical tasks, when they are necessary. ^{C-ENV-SD}
Automatic translation facilities might be provided to allow the EHCR to be read in different languages. ^{C-ENV-SD}

EHCRA-based systems should be able to interact with educational software so the latter is seen as relevant and supportive. ^{C-ENV-SD}

In order to make an electronic record a practical proposition there needs to be alternative methods for data entry to the conventional keyboard. ^{C-ENV-SD}

The ability to analyse data at the time of consultation ^{C-ENV-SD} will be facilitated. Clinicians work in consultation under pressure of time. Locating a single piece of information during consultation can sometimes be frustratingly difficult. ^{C-ENV-SD} Two key desirable consequences of adopting a standardised EHCR, are rapidity of information access and saving time.

If a clinician has just used a set of notes, they can expect to have almost immediate access to them for re-checking.

An exchangeable EHCR will provide support for the shared care process ^{C-ENV-SD}

Links, suitably described in the EHCR will allow connectivity with hospital administrative systems and in particular data concerned with the management of available free beds, charging and billing, cost evaluation, study of cost by disease, study of DRG, communication with bio-signal and laboratory results management software for access to laboratory results, X-rays, functional tests and EKGs. ^{C-ENV-SD}

The computerisation of the clinical information is worthwhile only when aimed at improving efficiency in clinical data analysis and activity planning” ^{C-ENV-SD}

EHCRA are only one of the information repository in the complex dynamic flow in the ward. The added value should result in improving efficiency in daily activity, by giving real time suggestion for actions to perform. ^{C-ENV-SD}

The exact structure of entries could be defined in different ways. To solve this problem a frame of reference ('dictionary' or 'template') can be adopted. These would also need to be exchangeable and comparable. ^{GR-5}

A range of features and/or tools will be needed to support the improved quality of information. Tools useful for self-training and which may assist with the selection of treatment options can be developed. ^{C-ENV-SD} Printed reports will contain, in addition to the report narrative, other items of data held on the system relating to the patient and the request. ^{C-ENV-SD} Facilities can be provided to monitor the 'process' dimension of the data. ^{C-ENV-SD}

The use of the EHCR in a multi-user environment requires a degree of control over data entry to allow concurrency. Once incorporated in the record, all data should be easily viewed, and available for a variety of functions. ^{C-ENV-SD}

Information which appears in more than one part of the record (medical chart, medical record or nursing record) must automatically be updated if the content is changed at one of the places.

The legal issues raised by translating EHCRs must be addressed. ^{GR-5}

A number of common services can be identified to cater for:

- Patient identification and demographic information about persons treated in healthcare
- The healthcare process - activities related to different conditions and the joining of these to larger entities
- Treatment characteristics - descriptions of the patient's conditions, health state and treatment
- Organisation - resources in healthcare and medical care and the joining of these to organisational structures from different perspectives.
- Terms and concepts - definitions of concepts in healthcare and medical care and how these concepts can be stated as terms.
- Authorisation - the definition of users of the information system and rules for the access of these users to stored information. ^{SP-1}

There may also be specific handling of information concerning that problem or problems that are the origin of one or several healthcare processes. This information can be used to group healthcare characteristics in relation to the different problems of the patient. ^{SP-1}

Health care professionals should be able to monitor the progress of the actions of care undertaken, in a comprehensive way ^{RI-SS}

There should be the ability to associate and retrieve contact data about a patient.

There should be the ability to retrieve the complete data available for a patient given appropriate identification, whether on the local system or externally. ^{ST-SS}

There should be the ability to create, update and delete views and links. ^{ST-SS} and the ability to use queries to return matching information, acts, links etc. on the patient. ^{ST-SS}

From a practical point of view, the query formalism used to search in the patient record must be able to combine queries to the patient database and queries to the knowledge-based model and to shift from one to the other. Moreover, since retrieval of information in the patient database proceeds from both direct query and navigation, the query language must be able to combine direct access with powerful navigational facilities ^{NU-SS}

It should be possible to have views and filters on the information in the record. ^{NI}

Studies have shown that ambiguous descriptions and missing data may hinder proper interpretation. ^{I-1}

To make the process of care more transparent, and to be able to use the data for multiple purposes, semantics need to be added to patient data in an EHCR. ^{I-1}

Medical data should not be unjustly used for purposes other than for which they were collected, without the provider of the data knowing this. To accomplish this, legal/scientific, technical, software and hardware measures are required. ^{I-1}

Data in the EHCR should support:

- Quality assessment of care
- Management
- Research and education^{I-1}

Audit trails must be possible. ^{NI} Chronological displays of information of given categories must be provided. ^{SY-1A-N}

Display of requested, but not completed, activities must be possible. ^{SY-1A-N}

The different purposes for which patient data should be suitable, requires a general approach to the documentation of the data, involving a knowledge model that defines which data and expressions are allowed, and operational instantiations of that knowledge, that represent the actual patient data. ^{I-1}

All information in the record should behave in the same way / according to the same principles ^{SY-1A-Tech}

GEP1	The EHCR should facilitate decision support and the use of bibliographic databases
GEP2	There should be a standard method for querying the EHCR, which enables efficient data analysis
GEP3	The EHCRA should support entries acquired by a variety of means
GEP4	The EHCRA should facilitate the use of exchangeable clinical and entry templates
GEP5	It must be possible for information which appears in more than one part of the EHCR automatically to be updated everywhere if it is changed in any part
GEP6	Information stored in EHCRs must be in a form which renders it amenable to automated processing
GEP7	The EHCRA should allow for appropriate recording of attributes for patient identification
GEP8	The EHCRA should permit recording of descriptions of the patients' conditions, health state and treatment
GEP9	The EHCRA should improve provision of audit trails
GEP10	The EHCRA must consider the inclusion or otherwise of requested, but not completed, activities.

5.2 Terminology and Knowledge-base Services

In order to facilitate a common understanding of terms used in shared EHCRs, terminology services and knowledge-base systems will need to be developed to accompany systems based on the EHCRA.

It will be important to establish the level of detail which represents a relevant concept and any rules for combinations of simple codes. ^{GR-5}

It will be an important feature if there is to be any hope of consistent use of terms across the Community, to provide any definitions for terms. ^{GR-5}

Semantic Links in the record (see Links) need to be typed. This type should be a part of the classification of knowledge, thus allowing the knowledge management tools to control the semantic links in the record. ^{NU-SS}

Conceptual entities may belong to a common data sets which may be shared by the Health Care Organisation, or may be specific to an application. ^{RI-SS} For these types and their substance to be equivalent and known to all systems and their users that manage instances of similar phenomena, it is essential that they be described in a term catalogue or coding scheme service. ^{SP-1} Concepts in healthcare may be defined by being divided into different domains, by having each concept being

subdivided into its smallest components and by means of having interrelationships, logical as well as ontological, between concepts in the catalogue defined^{SP-1} Descriptions as well as instances of healthcare characteristics, problems, healthcare requisitions and also activities and healthcare processes can be described by such a catalogue service.^{SP-1}

The use of local objects and the associated terminology augments the risk of inconsistency. The consideration of domain knowledge helps master this risk by preserving the coherence and integrity of the exchanged information.^{RI-SS}

The Knowledge-based approach should support the modelling of personal objects structures and interrelations.^{RI-SS} It should be possible for core concepts to be refined and aggregated in order to describe the health care professional user's personal domain of applicability of the data sets they use.^{RI-SS}

Relationships between concepts need to cater for semantic links and to reflect the different dependencies from one taxonomy to another^{RI-SS}

A customised semantic model of the medical and organisation information is required. This semantic model can enable the integration of knowledge within the HIS, the federation of legacy systems, the modelisation of user objects. It supports the customisation needs, protocol management, encoding and nomenclature management.^{RI-SS}

Patient characteristic types should be related together through classification systems.^{NU-SS}

TKS1	EHCRA based systems must support interoperability with Terminology Services and Knowledge-base Services to support the use of coded concepts in a standard EHCR
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5.3 Use by Different Professionals

Each professional group looking after a patient will wish to have a "view" of the patient's record which enables them to read just their own notes in a meaningful way. However they will at times wish to consult notes made by another professional group^{GR-4}

The record may be used by many interested parties. These include:

- the patients themselves and their appointed carers
- the clinician, in preventive or anticipatory care roles
- groups of clinicians working in primary or secondary care
- paramedical colleagues working with the patient
- clinicians and clerical or research staff for clinical audit, personal or department quality assurance
- hospital managers and health care purchasers (health authorities or insurers) for quality assurance
- health care planners at hospital, practice, district region or national level
- legal advisors for the patient or clinician
- clinical researchers
- medical students and medical teachers
- commercial product developers for market research (e.g. pharmaceutical industry)
- insurance companies for determining payment, or assessing risk
- politicians and health economists (and journalists!)^{GR-19}

Research on medical records should have informed consent as the guiding principle. Research without consent is only possible if there is no chance of breaching confidentiality. This purpose must then be explicitly expressed to patients having notes at that Healthcare Organisation (HCO), with the mechanism for getting ethical approval for that research. The design and purpose of the research should be available to patients, and the results made available through the HCO. ^{GR-8}

There must be a standard process for anonymising personal health information. ^{GR-9}

It should be possible to provide services allowing to use customised views, for users and groups of users when consulting the medical record. ^{RI-SS} The user should be able to create individual "views" or filters through which patient information can be accessed, thus allowing meaningful, coherent access to information created by many different Health Care Professionals. ^{NU-SS}

PUP1	The EHCRA must cater for the recording of use, as appropriate by any interested party
PUP2	The standard must facilitate the anonymisation of data for research purposes

5.4 Evolution

The practice of medicine is evolving in many areas at a rapid rate. Attitudes to record keeping can change dramatically in a short time, and innovations may lead to totally new data being recorded in a few centres. Adaptability is a major requirement of any computerised healthcare record. ^{GR-19} The meaning of information can vary over time. ^{GR-5} The healthcare record must be capable of evolution as society develops and defines some aspects of the common core of practice. ^{GR-4} There are three key areas of change; in time, place and clinical perspective ^{GR-19}

Potentially all data sets in use in the EC Health Care domain will need to be incorporated. An open structure is needed to allow for evolving data sets. ^{DC-1} The mapping of codes from one scheme to another will become increasingly important as information is more frequently shared.. ^{DC-1}

Message types will undoubtedly increase and support must be provided to expand them. ^{DC-1}

EVN1	The EHCRA based systems must allow for the future evolution of data sets, message types, clinical practice and technology.
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5.5 Access

The electronic records must be accessible anywhere use of such records can be expected. ^{SY-1A-N}

A 'borderless' health record will rely on trust and recognition of others' work practices. At present, for example, in the United Kingdom a patient has full access to their medical record. In Spain, this is not the case. It is clearly important that information recorded in Spain under one working practice is not accessed by the patient when in the United Kingdom. ^{GR-8}

The expression of consent extends to who does and does not have access to their medical records. ^{GR-8}

Member states are able to legislate that the right of access to medical data may be exercised only through a medical practitioner. This right is not available in all countries. In some countries there is only partial access. The UK legislation does not allow access to health care records made before November 1991. In Belgium the patient only has access to the 'objective data', not the 'subjective' or written memory of the clinician. ^{GR-8}

Patients should be denied access to the content of their Record if evidence exists that access will cause serious harm to themselves or others. Such harm should not be thought of subjectively but objectively. Clinicians who argue for restricted access should be accountable for recording their evidence and reasons, which should largely be based on the principle of patient competence.^{GR-8}

The record must be ordered around requirements for access to information^{GR-19} Information given to the clinician ‘in confidence’ (i.e. should not be shared with the patient) should not be entered into the record if the patient has access to that record.^{GR-8}

The record must be accessible to patients and be presentable in a form which avoids unnecessary jargon^{GR-19}

Confidentiality and the question of who has access to the record must be defined^{GR-19}

It is essential that only authorised personnel have access to medical record data.^{SP-1} A person from the staff is authorised to take part of a certain patients medical record data based upon the fact that this person participates in the care of the patient.^{I-10} What data from the patient's medical record that this person has access to depends directly or indirectly upon what activities that this person takes part in, or is going to take part in.^{SP-1}

Those human resources that need access to the information system are defined as users. This definition of user is made on the basis of a number of user roles, and it describes the ways in which specific users are permitted to use the information system and also what medical record data are to be made available.^{SP-1} Any user, with sufficient confidentiality rights, may access the EHCR and consult its content.^{RI-SS} Users could be designated as of a particular group (e.g. Pathologists) reflecting patterns of access.^{NI-ML} If a user normally relies upon a Personal Identification Number (PIN), there will be situations when the patient is unable to provide this (e.g. due to a heart attack).^{NI-ML}

All data stored for a particular Patient should be accessible.^{NU-SS}

Medical data can be categorised into permanent (e.g. one's genetic profile) and variable data (e.g. a blood pressure). Permanent patient data have the interest of many parties and should be extremely well protected in EHCR systems. In Europe, there may be more sensitivity towards improper use of patient data than elsewhere.^{I-1}

Privacy implies several issues. For instance, it means the right to be ‘left alone’ but it also signifies that everyone is entitled to decide for himself how, when and to what degree others may dispose of his medical data.^{I-1}

PGA1	Standard EHCRs, being portable, must facilitate appropriate adherence to laws, regulations and guidelines of the countries and societies in which they are created and used
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5.5.1 Availability

The EHCRA environment must provide an accessible and available record to authorised users whilst providing adequate protection against unauthorised access.^{DC-1} Further processing of data should be enabled through being able to access the appropriate parts of the data^{DC-1}

Electronic signing of entries and changes should be enabled to permit audit of the stored data ^{DC-1}
 Communications infrastructures must provide the clinician with confidence that all or some patient data can be accessed reliably and easily as required. Security services at least to the level of X.400 will be required. ^{DC-1}

Medical records are required for future purposes, and may be required to be held for as long as 30 years. If used for research purposes in the United States the records may have to be held for 75 years. ^{GR-8}

Digital data may be encrypted, and require ‘keys’ to unlock it. To the degree that the EHCR may require software which has become obsolete, may require hardware that is no longer available, or may have ‘keys’ which have been forgotten (e.g. pin numbers), then durability is much more of an issue in the present climate of lack of standards. ^{GR-8}

PAV1	Electronic signing of entries and changes should be enabled by the EHCRA
PAV2	The EHCRA environment must provide an accessible and available record to authorised users

5.5.2 Transparency

When information has been restricted, the patient should be informed of this fact. It should further be made clear to the patient who should be contacted if and when the patient wishes to challenge this decision. ^{GR-8}. A user should know of and have access to all data to which they are entitled ^{GR-8}

Once incorporated in the record, all data must be easily viewed and available for a variety of functions ^{DC-1}. All acts and their professional contents related to a particular Patient may be stored across several databases. All information related to a specific Patient should be accessible, regardless of where this is physically stored. ^{NU-SS}

5.5.3 Access by clinicians

Once a patient has consented to a clinician making an entry into their record, all clinicians involved in the patient’s care in that particular Health Care Organisation (HCO) should have appropriate access to it. This is of major importance, as the alternatives have been said to be unworkable and potentially dangerous. It is difficult for a clinician can accept the responsibility for care and recording care without knowing they have access to the complete record of care ^{GR-8}. If HCOs wish to differentiate between clinicians, the only moral and safe alternative is to have separate records with communication via ‘reports’ ^{GR-8}. Patients must know which professionals have ‘clinical’ status in the HCO and consequent access to the EHCR. ^{GR-8}

The authorisation functions assume that all medical record data have been classified in terms of authorisation beforehand, but the healthcare provider who is in charge of a certain amount of medical record data will, in agreement with the patient, make the final decision on what authorisation is required for the medical record data at hand. ^{SP-1}

When retrieving medical record data, the authorisation functions will dynamically check the requested medical record data. This check is based on the access privileges that the person was given when he or she assumed the role as user of the information system. On the basis of these privileges, and on the basis of considerations based on relations between different medical record data, it is determined what medical record data will be made accessible at each occasion. ^{SP-1}

A physician also has a responsibility to safeguard patient data, and should ensure that the data are well protected. ^{I-1}

The use of Health Cards by patients and professionals should be considered ^{NI-ML}.

PAC1	The distribution rules of the EHCRA should allow for dynamic checks of access authorisation should be carried out when any data is retrieved
PAC2	The EHCRA should take account of the security implications of the use of Health Cards

5.5.4 Access by non-clinicians

Non-clinicians have no duty to make recordings in the EHCR except in the administrative section, and therefore require no access to the record on grounds of accountability^{GR-8}. Complete denial of access should be available to patients.^{GR-8}

The conditions that apply for non-clinicians to access a record must be public and available to the patients at the time of record creation. If there is an interaction with the patient, which initiates access, the non-clinician should ask for the patient's consent at the time.^{GR-8}

The notion of more or less sensitive personal health information should be rejected on the grounds that it is the patients that determine 'sensitivity' and not the information^{GR-8}

PAN1	An EHCRA based system should require patient consent for non-clinician access to personal health data. This may need to be reflected by the EHCRA
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5.5.5 Access by researchers

Researchers gaining access to the detailed contents of a patient's record must always be with the consent of the patient, the clinician, the controller and an ethical committee.^{GR-8}

Relevant professional and or educational qualifications pertaining to access for those who are not involved in patient's clinical care but rather for research purposes must be public.^{GR-8}

PAR1	An EHCRA based system should require patient, physician and ethical consent for research access to personal health data. This may need to be reflected by the EHCRA
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5.5.6 Access by technologists

The technologist has no duty of care involving active EHCRA except when there are problems involving a live system. All development must be on a dummy medical record system.^{GR-8}. Technologists should not normally have access to the EHCR, although if there are technical problems this will clearly be necessary. Access to the patient's records must be in the presence of the controller and with the consent of a clinician. Test records on the live system, which are not included in analysis, should be available.^{GR-8}

Technologists will need to be educated in confidentiality rules. The total access time of technologists to patient records should be logged by the controller and reported annually.^{GR-8}

PAT1	EHCRA based systems should only allow access to technologists with specific clinical authorisation. This may need to be reflected by the EHCRA
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5.5.7 Access by students

Students should be able to experience using a 'live' medical record system safely. If given access rights to the electronic medical record system, they should be clearly identified by the system as being students. This is done so that it is clearly visible to subsequent viewers of the record that the observations were recorded by a student^{GR-9}. Clinical students will need to learn to record their findings on the live system.^{GR-9}

It would be very helpful to be able to identify patients followed by particular students during their training.^{GR-9}

Student notes have different properties from other entries: they are excluded from analyses and are not transmitted to external institutions. ^{GR-9}

It should be possible for a qualified professional to validate a student's entry, document that they agree with the student's notes and change the status of the student's notes to that of qualified professional. The student's notes would then have the same appearance as the 'live' record, be included in analyses and be transmitted to external ^{GR-9}

It would be very helpful to be able to identify patients followed by particular students during their training. ^{GR-9}

The use of EHCRs by students demands anonymising of records. ^{GR-9}

PAS1	The EHCRA should reflect the fact that student data are excluded from analyses and are not transmitted to external institutions
PAS2	The EHCRA should allow a qualified professional to validate a student's entry, document that they agree with the student's notes and change the status of the student's notes to that of qualified professional.

5.5.8 Access by legal professionals and other third parties

Copying the EHCR to third parties that have a legal or other legitimate interest in the record should involve written consent by the patient and a clear undertaking by that third party to use it for specified purposes. The Commission of European Communities directive gives guidance on when disclosure of personal information may be made without consent. ^{GR-8}

PAO1	The EHCRA distribution rules may need to reflect access by the patient
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5.5.9 Confidentiality

The right to confidentiality has always been taken seriously by the medical profession. However, there is a crucial qualification stating that breaches of confidence can be morally justified in some situations provided that they are in the interests of the patients and/or the public. In fact, the situations where breaches of confidence can be justified morally in the competent patient's best interest are few and far between. They primarily concern life-threatening emergencies where clinicians need information from relatives when for one reason or another they cannot get it from patients. ^{GR-8}

Issues of Data Confidentiality in Data Exchange must be addressed. Providing protection of data from unauthorised disclosure during communications is essential as is the preserving of data integrity during transmission and detecting any modification, insertion and deletion. ^{C-ENV-SD} Non-repudiation in Data Exchange is also vital and a proof of the origin or of the delivery of data must be provided. ^{C-ENV-SD}

Acceptable breaches of confidence in the interest of the public bring us closer to many current debates about the management of, say, HIV/AIDS patients. In most European countries clinicians have either the moral discretion or the obligation to breach confidence in the face of such harm. ^{GR-8}

In all of these situations, the rights of the public to protection from harm - including the rights of insurers - are deemed to trump the rights of the patient. There no longer appears to be much disagreement within the profession about this ^{GR-8} In light of the potential ease of others accessing and transmitting the whole or partial contents of such records, the potential for abuse is great ^{GR-8}

In weighing up the balance between the rights and duties of clinicians, it is important to ground it in as much of a partnership-in-care with patients as is practically possible. As regards health records, this entails providing patients with control over and access to their records to a degree that is consistent with their safety. ^{GR-8}

Confidentiality is a legal principle, protected by legislation and common law. Yet this principle is not at all clear when considering the movement of information among professionals caring for a patient.

GR-8

The legal phrase, ‘qualified privilege’, describes the protection from libel or defamation for people who have a duty to pass information on to others who have a duty to receive it. This covers doctors or nurses who may be involved in a case conference, making a referral, or giving a reference. Most countries have legislation covering such disclosure to non-health professionals including legal professionals, and clinicians’ professional bodies have codes of conduct. GR-8

Adequate safeguards need to be established to ensure privacy, confidentiality, and data protection.

For instance, there may need to be methods of stripping records of personal identifiers. GR-9

There has been much debate in various countries about confidentiality, e.g. if a piece of info about a patient ‘leaks’, how did it happen? Did someone read it from the system when the screen was left unattended? Did someone gain unauthorised access? Who has seen the record? DR-1

The issue of who has seen the record was previously thought (e.g. in GEHR) to be irrelevant, but it seems increasingly likely to be important. The standard should address how this is catered for and whether it is part of the EHCR.

The key issues can be summarised as GR-8:

1. The limits of patients' control of the creation, movement and processing of the health record.
2. The limits of the control of access to the contents of the health care record by patients and clinicians and others.
3. The establishment of individual accountability through the EHCR as a physical record of the contact between clinician and patient, and to avert potential negligent use of the health record.
4. The appropriate patterns of security enforcement and organisation. Audit thereof for protection of individual privacy, including professional guidelines for appropriate 'whistle blowing'.
5. The creation of educational processes which inform both patients and health professionals about their rights and duties.
6. The role of regulation in the development of the EHCR.

The ‘Public interest’ argument and issues of potential abuse by the state can be summarised:

- People rarely consider the consequences of not respecting confidentiality. People’s health data is already available to others by requesting medical reports from clinicians and bypassing this is difficult to justify. We assert that access to the record by the state should be under judicial control. The following may be deemed appropriate reasons for state intervention: subversive activity, criminal activity, for the purposes of public health, for political reasons or for evaluation of individuals.
- All access to health care records must be made via the judiciary, and never directly by the state. Legislation should ensure this state of affairs.
- There is much speculation about the use of pin numbers by patients to control access to their record. The ‘smart card’ will need sophisticated access control, but EHCRs at a HCO should be available to the clinicians providing care without the explicit consent of the patient. Layers of access within the record controlled by such devices may be unacceptable. The primary aim must be to improve clinical care.
- The clinician may be a broker in many of the dealings the patient has with other organisations. All such activity should take place under strict professional codes and legislation, and require the written consent of the patient.
- There is a particular aspect of justice which is not usually considered in health care, but is relevant in the context of the development of an EHCR. That is justice as the “fair distribution of benefits and burdens”; those who benefit the most from an innovation carry

a fair burden of the risk. The controller is given the primary responsibility for the EHCR, and works with the administrators and clinicians to ensure the rights of individuals are protected. We believe that the role of controller and clinician should not involve the same person.

- Legislation designed to make people accountable for the records (with a consequent risk of litigation) must ensure that there are real benefits accrued by those individuals from using the EHCR. Failure to do so will result in a sudden halt in the development.

It is of the utmost importance that in all (future) EHCR systems the proper measures are taken to protect the privacy of patients and to protect the data.¹⁻¹ Medical confidentiality must also be protected.^{NI-ML}

CFY1	Issues of Data Confidentiality in Data Exchange must be addressed
CFY2	The EHCRA data exchanges must provide a proof of the origin or of the delivery of data
CFY3	The EHCRA must provide features to permit systems to grant access to secured information in emergency situations.
CFY4	The possibility of logging who has 'seen' information on screen must be addressed by the standard
CFY5	The EHCRA must enable adherence to rules, regulations and laws governing confidentiality

5.6 Security of the record

It is important to emphasise that security must be a major requirement and is often the foremost concern in most patients' minds when the subject of EHCRA arises.^{GR-19} It is of great importance to protect the data, to guard the privacy of patients, and to protect the professional interests of health-care professionals.¹⁻¹ An important part of the EHCRA therefore concerns the management of authorisation and secrecy in the handling of healthcare data.^{SP-1}

The security requirements for the medical applications could be expressed as a combination of the following aspects:

- confidentiality: prevention of unauthorised disclosure of information
- integrity: prevention of the unauthorised modification of information
- availability: prevention of the unauthorised withholding of information or resources.^{C-ENV-SD}

Data Protection requires the following security functions for multimedia medical information:

- Identification and Authentication: determining and controlling user access permission to resources
- Access Control: preventing users and processes gain access to information or resources that they are not authorised to access^{C-ENV-SD}

Any EHCR which is even more widely accessible on a network will need to have a greater degree of security protecting access.^{GR-19}

A very sophisticated audit trail will need to be kept, and it may be that the record will need to be partitioned to tailor access to individual rights.^{GR-19}

To assist in the security of EHCR information, the following issues should be taken into account.

Authentication and credentials will be necessary.^{NI} There must be a watertight method to identify the author of the record (electronic signature).^{GR-19}

It must be possible to update the record but it must be impossible to alter or erase previous entries completely.^{GR-19, SY-1A-N}

If the record is to be used by a large number of professionals for different purposes it must be possible to withhold certain information from general viewing.^{GR-19}

There should be an agreed set of information associated with every entry including definition of ownership of the information and who is permitted to view it.^{GR-19}

Records should be created, processed and managed in ways that optimally guarantee the confidentiality of their contents and the legitimate control of patients over them. The record must be secure, yet accessible to patients.^{GR-8}

Whether or not records are indelible, it will be possible to falsify records by entering a false Date/Time in a computer clock for example. This must be guarded against as far as is possible.^{GR-8}

Encryption algorithms should be considered.^{NI-ML}

Alteration by accident or purpose of the stored information should be avoided.^{NI-ML}

SCY1	The EHCRA must include features relating to confidentiality, integrity and availability
SCY2	The EHCRA must enable secure identification, authorisation and access control
SCY3	It must be possible to attach access rights to sections of the EHCR
SCY4	There must be a watertight method to identify the author of the record (electronic signature)
SCY5	If the EHCR is to be used by a large number of professionals for different purposes it must be possible to withhold certain information from general viewing
SCY6	There should be an agreed set of information associated with every entry including definition of ownership of the information and who is permitted to view it
SCY7	Measures to guard against falsification of date and times should be considered

5.7 Healthcare Agent

Communication support for co-operative decision making in therapy is a typical problem of co-operative case handling between two institutions performing health care on the same patient, where one institution acts as the referring institution being initially in charge of treating the case, and the other one acting as the referred institution contributing to this treatment by performing a specific limited task for the referring institutions^{C-ENV-SD}. "Today, patients are hospitalised more often for nursing surveillance and nursing care than for medical care. In inpatient units, the nurse, not the physician, is the primary integrator and co-ordinator of information and often the primary deliverer and monitor of care"^{C-ENV-SD}

"Representative Individual Users of Patient Records are:

- Patient Care Delivery (Providers): Dentists, Dieticians, Laboratory technicians, Nurses, Occupational therapist, Pharmacists, Rehabilitation therapists, Physicians, Physician assistants, Psychologists, Radiology technicians, Social workers.
- Patient Care Delivery (Consumers): Patients, Families.
- Patient Care Management and Support: Administrators, Financial Managers and Accountants, Quality Assurance Managers, Records Professionals, Risk Managers, Unit Clerk, Utilisation Review Managers.
- Patient Care Reimbursement: Benefit Managers, Insurers (public or private), Accreditors, Government Policy makers and legislators, Health care researchers and clinical investigators."^{C-ENV-SD}

An *Agent* has a responsibility for a *Patient*, and this responsibility should be able to be classified.^{NU-SS} Agents should be defined^{ST-SS} Inter-subject relationships should be defined^{ST-SS} In terms of law, institutions, as well as natural persons are legal or artificial persons^{I-10}

All people referred to in the record should, if possible, be uniquely identifiable. Additional checks (e.g. photo) may be desirable.^{DR-1}

Medical record data are managed in an information system. All staff that will use the information system are defined by the system as users. When a person is working with the information system, the person acts in a defined user role. One person can on one occasion act only in one role, but may, however, act in different user roles at various points of time^{SP-1}

All organisation units are described and joined to form organisational structures of different kinds^{SP-1}. The description of units and resources is made on the basis of a number of predefined types of units and resources respectively^{SP-1}. There is also the key concept of the Agent, who is responsible for the patient and for Actual Acts^{NU-SS}. All staff are described on an individual level in a staff directory. On the basis of the staff directory, human resources are created by associating individual staff to one or several units^{SP-1}. In the same way, non-human resources are linked to units on the basis of specific directories^{SP-1}

HCA1	All people referred to in the EHCR should be uniquely identifiable
HCA2	The roles and responsibilities of agents should be definable in the EHCR
HCA3	Institutions as well as people are legal HCAs

5.7.1 Author Responsibility

It is widely recognised that every entry in the record must be attributed to an author. What is displayed in the record should be a true account of events as recorded by the author.^{GR-19}

If changes need to be made, it must be possible to step through and account for those changes individually within a rigorous audit trail.^{GR-19}

The responsible clinician, the only category of person entitled to make an entry in the health care record, must remain accountable both for the quality of that record as well as the care that has been documented.^{GR-8} It is important that individuals are clearly identified – possibly with digital signature^{GR-8}

Research involving automatic processing demands that at some previous time a person entered appropriate data. This person must be qualified (and able) to have added the information to the record, and must have wanted to add the information. These two prerequisites may be frequently overlooked.^{GR-8}

There is an absolute requirement that each ‘transaction’ within the record is attributed to a responsible clinician.^{GR-8} The responsible clinician making a recording must accept that he or she is then accountable for the care given.^{GR-8}

Administrators are responsible for the physical safety of the system and data, and the software that runs it^{GR-8} The administrator is responsible for nominating a controller for the system containing EHCRs.^{GR-8}

Third parties must respect the confidentiality of data even if anonymous. The purpose for which the access is allowed and the time frame must be explicit. Third parties must have ethical approval for access to the data. Processing undertaken by the third party should not threaten confidentiality of any party, and should be declared as the basis for access, preferably in a contract. The processing should also be validated, and the results checked with the HCO supplying the data, before action is taken.^{GR-8}

The responsibility for a HCO’s records will be with the controller, as will the educational requirements of staff members.^{GR-8}

Information can only be regarded as part of a record if it is entered according to explicit rules.^{SY-1A-Tech} This implies that a set of principles and rules shall exist, defining both which users are allowed to

enter information, and which criteria to be used. ^{SY-1A-Tech} These may include predefined rules allowing automatic inclusion of all data from one or more feeder systems, rules requiring automatic assignment of a specific status (temporary/ not signed) to automatic included data, rules requiring explicit consent before data from feeder systems are regarded as part of a record, etc. Such rules may be predefined and modifiable, and may include a request for explicit consent. ^{SY-1A-Tech} In some instances/countries, only the information entered as a result of an explicit action by an end user is regarded as part of the legal record. ^{SY-1A-Tech}

HAR1	Every entry in the record must be attributed to an author
HAR2	The EHCRA should enable accounting for individual changes in the EHCR
HAR3	The EHCRA must ensure that individuals are clearly identified – possibly with digital signature
HAR4	There is an absolute requirement that each contribution to the record is attributed to a responsible healthcare Agent.
HAR5	The EHCRA should consider identification of the Agent responsible for the EHCR at the HCO
HAR6	The standard should address rules requiring explicit consent before data from feeder systems are regarded as part of a record
HAR7	The purpose for which the access is allowed and the time frame must be explicit.
HAR8	Third parties must have ethical approval for access to the data.

5.7.2 Accountability to Patient and Profession

The medical record must enable and reflect clinical competence ^{GR-4} and every entry in the record must be attributable to an author ^{GR-4}

Health records must be comprehensible to the non-medical reader e.g.: patient, lawyer, audit department ^{GR-4} and the rationale for clinical decisions must be apparent from the health record (what was done and why) ^{GR-4} A clinician (an agent or health care professional) is responsible for a patient for some period of time. ^{NU-SS}

Computerised patient records must ensure privacy, confidentiality and data protection ^{GR-4} Patient data must never be lost. ^{GR-4} The responsible clinician making a recording must be clearly and unambiguously identifiable. This responsibility may be individual or shared, depending on the system of delegated authority which is in place. The data set required to identify a responsible clinician will be determined elsewhere. ^{GR-8}

A subsidiary role of the EHCR is its function as a legal document, which establishes the accountability of the clinician. ^{GR-8} Liability is being bound by or responsible for conformance to specific standards. Not to adhere to such standards invites a potential claim for civil or criminal negligence. It is necessary for the EHCR to specify the accountability of the clinician. In the case of system failure with harm resulting to a patient, or data accessed without authorisation, the controller will be liable. Processing data without consent will involve liability, as will failure to fulfil the other responsibilities of controller as specified in future legislation. There is an increasing recognition of the potential for liability of designers and operators of decision support systems. ^{GR-8} For any piece of information it must be possible to identify the source and the time of registration. ^{SY-1A-N} Much of the information included in medical record data consists of highly confidential data. This means that there must be very strict requirements for authorization ^{SP-1} Only one person at the time must be allowed to change information in a given record. ^{SY-1A-N}

APP1	The responsible Healthcare Agent making a recording must be clearly and unambiguously identifiable
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APP2	It is necessary for the EHCR to specify the accountability of the Healthcare Agent
APP3	Any piece of information in the EHCR must make its source and the time of registration identifiable
APP4	Only one person at a time must be allowed to change information in a given EHCR

5.7.3 The role of controller

Every Health Care Organisation (HCO) will need to nominate a *controller* responsible for the processing. Thus the Commission of European Communities Directive defines a *controller* as “any natural or legal person, public authority, agency or other body who processes personal data or causes it to be processed, and who decides what is the purpose and objective of the processing, which personal data are to be processed, which operations are to be performed upon them and which third parties are to have access to them”.

The controller is given responsibility for ensuring these conditions apply is therefore accountable for their legal application.^{GR-8} The security and accuracy of the data and the ‘correctness’ of processing are the prime responsibility of controllers.^{GR-8}

The accuracy of the data held in a health record is the responsibility of the controller. The duty of the controller must, for reasons of confidentiality and accountability, be exercised through a responsible clinician. Establishing the accuracy should normally involve consultation with the patient, but may require consultation with other clinicians at times.^{GR-8}

Personal data must be:

- a) “processed fairly and lawfully;
- b) collected for specified, explicit and legitimate purposes and used in a way compatible with those proposes;
- c) adequate, relevant and not excessive in relation to the purposes for which they are processed;
- d) accurate and, where necessary, kept up to date; every step must be taken to ensure that data which are inaccurate or incomplete having regard to the purposes for which they were collected are erased or rectified;
- e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes in view; Member states may lay down appropriate safeguards for personal data stored for historical, statistical or scientific use.”^{GR-8}

In the case of data being inaccurate, control of contents should reside with the patient.^{GR-8}

CLR1	The EHCRA should address the inclusion of the identification of controllers
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6 EHCR Interchange and the Sharing of Healthcare Information

The EHCR is a "means of communication between physicians" ^{C-ENV-SD} Physicians within an institution must be able to share information in their records ^{I-10}

The record must allow cross-linkage of data and possibly links to data in other records or record fragments. If one end of such a link is transmitted, it must be possible to know that the link exists, when it was established and where the other end of the link can be found. Should the other end of the link be transferred later, even if the link has been subsequently refuted, it should be possible to identify it as such. ^{DR-1}

Authentication in Data Exchange provides confidence that an entity is not attempting a masquerade and that the source of data is the claimed peer entity, only at times during communication. ^{C-ENV-SD} Access control in Data Exchange provides protection against unauthorised use of resources accessible via open systems. ^{C-ENV-SD} Data Confidentiality in Data Exchange is necessary to provide protection of data from unauthorised disclosure during communications. ^{C-ENV-SD} Data Integrity in Data Exchange is necessary to preserve data integrity during transmission and detecting any modification, insertion and deletion. ^{C-ENV-SD} Non-repudiation in Data Exchange is also necessary to provide a proof of the origin or of the delivery of data. ^{C-ENV-SD}

The health record architecture must facilitate communication between agencies ^{GR-4} The architecture must facilitate record storage on different sites and the standard provide a common interchange format between heterogeneous systems. ^{GR-19} It must take account of the wider needs for communication of the record, which must traverse all aspects of the health care services, and cross regional and national boundaries. ^{GR-19}

Different modes of data exchange will be required to meet local requirements ^{DC-1} Data will need to be extracted from the record for use for epidemiological purposes ^{DR-1} A range of volumes and rates applies to bulky data, which must be accommodated both by messaging and transmission systems and by storage systems. ^{C-ENV-SD}

The sharing of records/data implies that an agreement or 'contract' has been established setting out the terms under which such records are shared or made available. ^{SY-1A-Tech}

The medical record should be integrated and shared. ^{RI-SS} It should be possible to transfer healthcare information between information systems, even though these are handling the information according to different data structures. ^{RI-SS} Other healthcare providers should be able to have access to and utilise the act and template specifications owned by another. ^{NU-SS} Patient data should be exchangeable between providers on the same level and between different levels. ^{I-1}

Unjustified exchange of data should be subjected to well-defined rules and regulations and inappropriate or indiscriminate transfer of data should be prohibited. ^{I-1} The controller must establish that records are only transferred with the patient's and clinician's consent, that the HCO requesting the record is authorised to do so, and that the communication is safe in terms of errors and confidentiality. Only the necessary information (parts of the EHCR) should be transferred. ^{GR-8} The EHCR must offer the possibility for data exchange with existing systems within and outside the health care institution ^{I-10}

EIS1	If one end of a link is transmitted, it must be possible to know that the link exists, when it was established and where the other end of the link can be found
EIS2	Should the other end of the link be transferred later, even if the link has been subsequently refuted, it should be possible to identify it as such
EIS3	A range of volumes and rates applies to bulky data, which must be accommodated by messaging and transmission systems and by storage systems
EIS4	The standard must provide a common interchange format between heterogeneous systems
EIS5	The EHCRA must enable use of different modes of data exchange to meet local requirements
EIS6	The sharing of records/data implies that an agreement or 'contract' has been established setting out the terms under which such records are shared or made available.
EIS7	Only the necessary information (parts of the EHCR) should be transferred.

6.1 Data received from other systems

Facilities are required to receive, view, vet, and accept data received via messaging systems. Special conditions may apply, for example, to the indelibility of attribution of results to a laboratory, or to externally held data being the only detailed observation available which will need to be accommodated in the Architecture and supporting tools. ^{DC-1}

The ability to interchange drug data must also be a feature of the Health Record standard. ^{GR-19}

Exchange of records in whole or in part, merging of records and incorporation of record components originating from other records may occur. ^{SY-1A-Tech} After the transfer of data the contents of the information as well as its context should remain. ^{SP-1}

DRS1	Facilities are required to receive, view, vet, and accept data received via messaging systems
DRS2	The EHCRA must enable the interchange of drug data
DRS3	The EHCRA must preserve the contents of the EHCR information as well as its context on transfer

6.1.1 Legacy Data

It must be possible to convert all the old paper-based information into an electronic form. ^{SY-1A-N}

A question arises as to the effect of legacy data that does not indicate the time, date or context correctly as it must not be allowed to compromise the integrity of data in the EHCR (see Dates, Times and Chronology in the record). ^{DR-1}

LGY1	It must be possible to convert all the old paper-based information into an electronic form
LGY2	It must be possible to incorporate legacy data (from paper or other sources) into the EHCR

6.2 Locating merged information within the record

A major perceived benefit of computerisation is the ability to have many different views of the same data, allowing different professionals use of the same information, and reducing the need to enter similar data many times in the record. ^{GR-19}

There will be many EHCRs each containing a mixture of recordings made at that HCO and reports of care at other HCOs. There may be partial or complete copies of the records of other HCOs forming part of the record. The ability to cope with this situation is critical, maintaining a single logical record. ^{GR-8}

Each entry in the health care record may need to be uniquely identifiable within and across systems and places ^{DR-1} Information may appear in more than one record and in more than one part of a record and overall data integrity must be maintained ^{SY-1A-Tech}

LMI1	The standard should provide guidance in order that EHCRA-based systems have the ability to cope with incomplete or partial records from elsewhere, maintaining a single (merged) logical record
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6.3 Function and Communication of the Record

Medical data should be structured in such a way that it is transferable between different systems. ^{GR-4} It must be possible to communicate with other information systems either in administration or ancillary support outside the building in which the computerised medical record is being accessed ^{GR-4} While the record is a repository for evidence of communication, it is not a means of communication except for continuing care. There is a duty to communicate by means other than the record, by 'reports'. ^{GR-8}

There should be the ability to use asynchronous messaging where systems are not immediately available on-line. ^{ST-SS}

It should be possible to control the distribution of data spread over the HIS by referencing acts done by any element of organisation ^{ST-SS}

FCR1	EHCR data must be transferable between systems
FCR2	The standard should address the communication with other information systems
FCR3	The standard should address the ability to use synchronous and asynchronous messaging

6.4 Movement in place

Some components of clinical competence are closely related to the role of physicians in the societies in which they practice. The medical record must not impose the values of one society on the clinical practice of another, although it should promote ways of learning about different styles of clinical practice ^{GR-4}

Movement is an operation on the record, and has at least three attributes to describe it: type ('Move' or 'copy'), extent ('complete' or 'partial') and conformance ('conformant' or 'non-conformant'). ^{GR-8} 'Move' (as opposed to copy) of a record is the only situation where an EHCR can be deleted. Deletion of EHCRA must be controlled by law and therefore 'moving' must also involve a legal process. The transfer of the EHCR may be to an HCO, which works to standards that are similar to that of the originator of the record, or to a HCO which has differing standards. A 'move' of this nature poses a potential threat to the patient and clinician. Such transfers are non-conformant. ^{GR-8} The essence of the problem is establishing standards which enable conformant transfers to be made with confidence. This demands regulation of security and codes of practice. There is certainly a requirement for patients to have control over movement of the record. There should be professional penalty and legal redress if transfer is not sanctioned by the patient. Transferring part of the medical record must be covered by the same rules as transferring the complete record. ^{GR-8}

The movement of information is a separate issue from the movement of the record. A 'report' in the form of a letter, or electronic message allows movement of information without movement of the record. This is the accepted method of communication at present. The clinician and patient must decide if the transfer of information is conformant, and if not, the patient must give explicit consent. ^{GR-8}

Specific legislation should exist to give patients control over reports to other third parties who are not involved in the care of the patient (e.g. insurance companies, employers etc.). It must be said that patients cannot have it both ways. If the control of flow of information is restricted on the grounds of privacy, the standards and efficiency of clinical care will suffer ^{GR-8} The controller - who by definition has control of processing - is expected to notify the patient before processing takes place and ensure that an up to date list of processing functions is available to the patient ^{GR-8} The patient should consent to movements and processing of the record. At times this may not be possible due to inability to communicate or lack of competence. Clinicians and controllers will be accountable for decisions taken at such times if consent is not given. The rights of parents to control movement of the records of their children are established as important carers or next of kin. Judgement of competency should be made on the basis of reduced consciousness, or in line with accepted psychiatric practice. ^{GR-8}

It is important to record the basis for a decision to 'copy' or 'move' an EHCR to another HCO and the consent of patient or next of kin ^{GR-8}

MIP1	The EHCRA should reflect the fact that patients should have control over movement (and processing) of the record. The rights of parents to control movement of the records of their children are established as important carers or next of kin
MIP2	Where patient consent is not possible, health care professionals and controllers will be accountable for decisions taken.
MIP3	Transferring part of the medical record must be covered by the same rules as transferring the complete record
MIP4	It is important to record the basis for a decision to 'copy' or 'move' an EHCR to another HCO and the consent of patient or next of kin
MIP5	The EHCRA must not impose the values of one society on the clinical practice of another

6.5 Portability

The challenge is to allow the sharing of data, resources, and services independently of the system architecture, the platforms, the networks and the data format. ^{GR-5}

Storage media are continuously in evolution and affect portability e.g. when reading archived data. There are two main categories of problem - physical portability of the data over time and compatibility of the storage media. Physical portability means that the problem is a data transfer problem, not an interpretation problem. ^{GR-5}

Physical Portability concerns the lifetime of the information supports and implies either that technical evolutions do not affect the hardware or data must be ported to the new media at least once or the un-archiving tools remain available. ^{GR-5}

Support for storage media must thus evolve at the same time as the media themselves. ^{GR-5}

The need for communication between heterogeneous machines shows the necessity to use a common data format to allow the use of information across networks. ^{GR-5}

There is an ever increasing need to exchange documents. Requirements are that it be done easily, quickly, and with security and reliability. ^{GR-5}

Suppressing the use of paper -The goals are to minimise the costs of data entry, to improve the quality of technical documentation, to manage its maintenance and to stimulate industry to use electronic data integration. ^{GR-5}

The EHCR architecture must be such that it can be easily imported or exported by any application software/ programs. ^{GR-5}

There should be filters to interface /translate between application software programs and the EHCR architecture. ^{GR-5}

For these types and their substance to be equivalent and known to all systems and their users that manage instances of similar phenomena, it is essential that they be described in a term catalogue. The purpose of this term catalogue is to declare concepts used in healthcare, based on a concept catalogue.^{SP-1}

In the same way as types are described in the concept and term catalogue, the values that may occur as instances of a certain type are also described.^{SP-1}

7 Electronic Health Care Record Systems

Health Information Systems (HIS) based on the EHCRA must be simple and quick to learn to use and to master in the normal course of work.

All activities that physicians now perform with paper records, should be capable of being carried out using electronic records. ^{SY-1A-N} In particular, a Physician must be able to record all data that results from a contact with a patient in a fashion that is tailored to his/her specific domain. ^{I-10} The record system must recognise in a fast and secure way that a user has finished using the system. ^{C-ENV-SD}

All such HIS should be rigorously tested to ensure all users are able to record all information they would want to record. This will necessarily include the ensuring of conformance to the EHCRA.

To make data entry flexible in both scope and detail, it should be supported on the HIS by knowledge about which concepts can be described in what contexts. ^{I-10} This will require HIS to have access to suitable terminology services and knowledge base systems.

There are many synonyms in use in doctors' notes and the availability of these is necessary to make any system acceptable to individual users. ^{GR-19}

There are many desirable functions of a good quality EHCRA-based HIS. Basic manipulation functions of a system may, for instance, include:

- a function supporting an overview of the available material
- a function allowing to select and display individual documents ^{C-ENV-SD}

The HIS should offer functionality to output and exchange extracted information. ^{C-ENV-SD} The system must have an alert display function. ^{SY-1A-N} Context dependent help facilities must be accessible within the system. ^{SY-1A-N}

The use of Electronic Health Records in a multi-user environment requires a degree of control over data entry and access rights to allow concurrency ^{DC-1} Mobile terminals may be required to give access to the Health Record in certain situations. ^{DC-1}

Computerised patient record systems include two key requirements. First patient and provider privacy must be protected. Second, data and software must be safeguarded against tampering and unintentional destruction. These requirements demand both system and data security measures. ^{GR-19}

Medical records should be available at the point of clinical need. Care must be taken to ensure that access to a computer is not inadvertently also made difficult. Clinicians will, for example, need to take a useable record with them on home visits. ^{GR-19}

Introduction of an electronic record system should enable - but not require, major organisational changes. ^{SY-1A-N}

The system's basic structure must enable implementation of local solutions needed in different hospital wards and departments. ^{SY-1A-N}

Information that appears in more than one part (i.e. in a document or part of a document) must be automatically updated if the content is changed in all parts simultaneously. ^{SY-1A-N} The system must visualise the occurrence of updating to all users accessing a specific part of the record during the updating process. ^{SY-1A-N}

The record system must however enable adaptation to different specialities' and different departments' and hospitals' tradition for recording and presenting information. ^{SY-1A-N} It must be

adaptable to different ways of organising the record, including problem oriented records and "fixed / flexible form" records.^{SY-1A-N}

A basic understanding of a record system should be obtainable within 15 minutes of instruction.^{SY-1A-N}

Logon, logoff, and access to any specific chart should be fast^{SY-1A-N}

Medical record data are managed in an information system. All staff that will use the information system are defined by the system as users. When a person is working with the information system, the person acts in a defined user role. One person can on one occasion act only in one role, but may, however, act in different user roles at various points of time^{SP-1}

In effect, the insufficient semantic expressiveness of traditional design (relational-based) approaches makes them unable to manage metadata and complex information referring to domain dependant knowledge.^{RI-SS} A modern HIS requires an effective methodological support for the design of open, partitioned, friendly architecture for the management of personal, sharable, complex objects.^{RI-SS} Aggregation and navigation facilities (which, in turn, can be fully configured and customised) should be facilitated in order to assist in the appropriately personalised utilisation of the record by the respective healthcare providers.^{NU-SS}

Information systems in health care are generally used on four levels:

- The region (country, state or province)
- The health-care institution (the hospital or an organisation of health-care providers)
- The clinical department, the outpatient clinic or the primary care practice
- On a personal level i.e. that of the physician, nurse and patient.^{I-1}

ESY1	All activities that physicians now perform with paper records, should be capable of being carried out using electronic records
ESY2	The EHCRA standard should offer guidelines with respect to output and exchange of extracted information.

7.1 Data Capture and Entry

Systems will need to provide a variety of efficient and effective means for capturing data^{SY-1A-N}, including all those currently used in relation to paper records^{I-10}, as well as others for which electronic media is necessary.

Drawings are seen as one “quick” way of recording information.^{GR-19} Medical notes often contain sketches and diagrams done by doctors because they are a clearer and quicker way of recording information. A drawing contains less ambiguity. Many clinicians like to explain things to patients using sketches, because it helps establish a common language, helps convey spatial relationships of organs. There is a wide variety of drawings in use. They are fairly standard in their style and in the way information is depicted. Drawings are sometimes the only record of transaction between a doctor and a patient and must be therefore stored securely and be transferable.^{C-ENV-SD}

HIS should also be able to cope with forms-driven data entry, natural-language entry and structured data entry.^{I-1} Facilities will be required in HIS to derive data for the Health record from externally held reference databases,^{C-ENV-SD} and there will need to be alternative methods for data entry to the conventional keyboard and mouse methods.^{GR-19}

Data reliability and completeness during data entry, is an important aspect to be incorporated into new EHCRA based systems. ^{I-1}

The results of investigations, while they may be frequently processed by software, should be vetted by an appropriately authorised healthcare agent, if necessary, prior to their being entered into the electronic record. ^{GR-4, GR-19} All entries in the record require human authorisation – and hence legal responsibility – for their inclusion, even if they have been provided or input by electronic means. ^{C-ENV-SD}

Structured data entry for narratives or specific procedures should be promoted but not enforced^{I-10}
 The record system must be able to record necessary graphics and images (e.g. temperature, heart rate, BP). ^{SY-1A-N}

The amount of time required to capture good quality data has to be kept to a minimum: “The greatest stumbling block to successful operation of a computer stored medical record is devising a means of accurate, efficient, and economical data entry” ^{C-ENV-SD} HIS should try to keep the time for data input to an acceptable minimum, or there is a danger that the EHCRA standard may not be widely used. ^{C-ENV-SD}

DCE1	The EHCRA must cater for the entry of information by a variety of means
DCE2	All entries in the record require human authorisation

7.2 Data Presentation and Output

The electronic record must present the clinical problems at least as easily and quickly as is possible with today's paper based record. ^{SY-1A-N}

Information must be presentable in a format familiar to the users. ^{SY-1A-N}

The record system must be able to present necessary graphics and images (e.g. temperature, heart rate, BP). ^{SY-1A-N}

Printout of any piece of information (accessible to the user) must be possible at any time. ^{SY-1A-N}
 It must be possible to choose new ways of presenting information (colours, graphs, icons etc.). ^{SY-1A-N}
 Arranging and displaying commonly used combinations of information must be quick and easy. ^{SY-1A-N}
^N The information overview must be at least as good as in today's manual system. ^{SY-1A-N} It must be quick and easy to make paper copies from any selection of the medical record. ^{SY-1A-N} It must be easy for the user to be sure that he/she has seen all information in the system regarding a specific patient. ^{SY-1A-N} Display surfaces, where appropriate, should be sufficient to show a full X-ray image in a size comparable to the conventional X-ray film format. ^{C-ENV-SD}

It must be possible to present information in the context it was recorded, and in ways similar to today's manual system. ^{SY-1A-N}

DPO1	The EHCRA standard should address the status of graphics and other alternative representations of data that exists in the EHCR
DPO2	The ECHRA standard may need to address rights or rules for the output and/or presentation of information in the EHCR
DPO3	It may be necessary to convey through the EHCR, the nature of devices on which information is presented where this may affect the clinical interpretation

7.3 System Access

The system should have a built in facility for prohibiting unauthorised access to information according to existing (national) rules and laws. ^{SY-1A-N}

Inappropriate use of the information system should be detected. ^{SP-1} The ways in which a user accesses the components of the information system and medical record data are controlled by a set of authorisation functions. ^{SP-1}

The system must contain mechanisms that automatically recognise when a user has finished using the system, and from then on perform a temporary shut-down of that user's access. ^{SY-1A-N}

The system must allow violation of "normal" access regulations in emergency situations. Such violations must be explicitly notified by the system itself to enable subsequent inquiries. ^{SY-1A-N}, ^{SP-1}

Management of the rights and roles of HCPs will be needed. ^{ST-SS} There should be the ability to confirm authorisation ^{ST-SS} and the entry of non-authorised personnel (Administrative or Medical) to the system should be avoided. ^{NI-ML}

SYA1	The distribution, access and authorisation rights attached to categories of potential information users will need to be shared through the medium of the EHCR
SYA2	EHCRA based systems should allow for the need for access to secured information in emergency situations.

7.4 Quality Assurance

Systems should be written efficiently and should take into account appropriate computing techniques ^{C-ENV-SD}, and health informatics principles. EHCRA based systems should be built to accepted software engineering and software maintenance standards in order to allow evolution as technology, clinical and EHCR requirements evolve.

System software and associated hardware should follow standards on Health and Safety, ergonomics and Human-Computer Interaction.

Design and implementation may be overly simplified in an effort to proceed quickly and with apparent efficiency. Security should be an integral part of the system design. ^{GR-8}

The motivation of designers to provide efficient, safe and transparent systems for EHCRA must be high and sustained. Abuse at the design stage could cause immense problems. A designer's 'ego' may become intertwined with the system she or he is designing, thus becoming threatened by changes to the system. Designers have a duty to ensure that their practices are thorough and appropriately motivated. ^{GR-8}

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