

Guide to health informatics — Results of healthcare service procedures — Delivery to end-users —

Part 1: General guidance and recommendations

ICS 01.140.30; 11.020

Confirmed November 2008

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee IST/35, Health informatics, upon which the following bodies were represented:

- AMS Consulting
- Association of Anaesthetists of Great Britain and Eire
- Conference of Royal Colleges Information Group
- British Computer Society — Health Informatics Group
- British Computer Society — Nursing Specialist Group
- British Institute of Radiology
- British Medical Association
- British Nuclear Medicine Society
- BUPA
- CAT Ltd.
- Department of Health Information Policy Unit
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- Intellect
- Nine Tiles Information Handling Ltd.
- Royal College of Radiologists
- Royal Pharmaceutical Society of Great Britain
- Society for Computing and Technology in Anaesthesia
- University of Salford Health Informatics Research Environment

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 29 May 2003

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The following BSI references relate to work on this British Standard:
Committee reference IST/35
Draft for comment 02/653352 DC

Amendments issued since publication

Amd. No.	Date	Comments

ISBN 0 580 41569 4

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Foreword

This part of BS 8421 has been prepared under the direction of Technical Committee IST/35.

This part of BS 8421 is the first of a multi-part series covering the use of standards and recommendations to assist in meeting the health informatics needs of producers and users for ensuring that the results of healthcare service procedures such as imaging and related data are available within the context of an emerging health record. It is therefore relevant whether these producers and users are individuals, healthcare providers or other stakeholders such as professional bodies.

This part of BS 8421 applies BS ISO/IEC 10746 to the domains of the producers and users of the results of healthcare service procedures.

It is anticipated that parts covering medical imaging and anaesthesia will be produced in the near future. Parts dealing with the results of other types of healthcare service procedure will be produced in due course.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 47 and a back cover.

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Introduction

The smooth implementation of ICT systems to provide safe and secure use of the results of healthcare procedures depends on an understanding by a number of stakeholders of the nature and the varied use of results such as digital images and waveforms that are exchanged in electronic form. These stakeholders include clinicians working in hospital and community, medical device operators (e.g. radiographers and technicians), ICT professionals, medical device system manufacturers, image display and processing system manufacturers and health information management systems manufacturers. This part of BS 8421 is therefore intended mainly to be of use to:

- procurers of systems incorporating health informatics standards;
- implementers of such systems;
- suppliers of such systems.

It is relevant whether these procurers, implementers and suppliers are individuals, healthcare providers or other stakeholders such as professional or trade bodies.

This part of BS 8421 is concerned with the interoperability of systems for the delivery and presentation of the results of healthcare service procedures to end-users. In addressing these issues the purpose of this part of BS 8421 is to:

- provide the basis for subsequent parts of BS 8421 to enable the safe implementation of multimedia reports within the clinical process;
- introduce and use a common set of readily shared terms that can be used by members of different professions when discussing implementations;
- examine the nature of healthcare service procedure reports as delivered and presented using traditional methods;
- inform stakeholders regarding the nature of digital versions of the results of healthcare service procedures;
- review methods for the presentation of electronic healthcare service reports using mixed media facilities and comment upon the suitability of existing and emerging standards and specifications;
- introduce the principles underlying open distributed processing in information systems and their relevance to defining the requirements for delivery of results;
- recommend how to obtain interoperability of systems in healthcare by the creation and use of standard profiles (defined subsets of standards) that are needed to support the performance of carefully defined tasks related to the use of the results of healthcare service procedures.

This part of BS 8421 draws on BS ISO/IEC 10746 to introduce the principles underlying open distributed processing as applicable to achieving interoperable systems in healthcare.

1 Scope

This part of BS 8421 gives general guidance, within health informatics, on the application of standards, specifications and recommendations to the domains of the producers and users of the results of healthcare service procedures.

It describes the communication of the results of healthcare service procedures into the remainder of the healthcare arena in the context of patient records as a whole.

It also reviews presentation of results using health informatics standards and other more general information technology standards relevant to the communication of results from healthcare service departments to end-users.

This part of BS 8421 uses BS ISO/IEC 10746 to provide a framework for understanding the communication of results from healthcare service departments to end-users for the purposes of producing system specifications for interoperability.

Recommendations are made for the use of healthcare standards profiles for the results of healthcare procedures.

NOTE Although this part of BS 8421 is focussed on the communication of results from healthcare service departments to end-users and is not intended to provide guidance for analogous communication in other contexts, some aspects of the guidance could prove to be applicable in those contexts.

2 Terms, definitions and abbreviations

2.1 Terms and definitions

For the purposes of this part of BS 8421, the following terms and definitions apply.

2.1.1

abstraction

process of suppressing irrelevant detail to establish a simplified model, or the result of that process
[BS ISO/IEC 10746-2:1996]

2.1.2

application

specialization of system for the processing of data using software

2.1.3

architecture (of a system)

set of rules to define the structure of a system and the interrelationships between its parts
[extrapolated from BS ISO/IEC 10746-2:1996]

2.1.4

clinical document

record of clinical observations and services¹⁾

NOTE The following characteristics are needed for a record to be regarded as a clinical document:

- a) persistence: it continues to exist in an unaltered state, for a time period defined by local and regulatory requirements;
- b) stewardship: it is maintained by a person or organization entrusted with its care;
- c) potential for authentication: it is an assemblage of information that is intended to be legally authenticated;
- d) wholeness: authentication of it applies to the whole and does not apply to portions of the document without the full context of the document;
- e) human readability: it is human-readable.

2.1.5

compound healthcare service procedure product

set of healthcare service procedure products that have been combined into a single document in physical or electronic form

¹⁾ As defined by the HL7 Structured Documents Technical Committee.

2.1.6**data**

representation forms of information dealt with by information systems and users thereof
[BS ISO/IEC 10746-2:1996]

2.1.7**digital image**

image created from a set of numerical values

2.1.8**discharge report**

healthcare procedure product in which a medical practitioner summarizes (usually for the benefit of a general practitioner) an episode of investigations, therapy and recommended management relating to a patient under their care

NOTE This report may, but does not have to, include, reference or abstract from healthcare procedure products from prime or healthcare service departments.

2.1.9**distributed processing**

information processing in which discrete components may be located in different places, and where communication between components can suffer delay or can fail
[BS ISO/IEC 10746-2:1996]

2.1.10**entity**

any concrete or abstract thing of interest

[BS ISO/IEC 10746-2:1996]

NOTE While in general the word “entity” can be used to refer to anything, in the context of modelling it is reserved to refer to things in the universe of discourse being modelled.

2.1.11**healthcare**

general activity directed at a population or an individual with the objective of maintaining health, restoring health, treating disease or injury, preventing sequels, or making a diagnosis

2.1.12**healthcare department**

part of the healthcare infrastructure able to accept requests for healthcare procedures

NOTE This term is used in this part of BS 8421 to include, for example, general surgery, and also to refer to the service providing a necessary supporting function, such as anaesthesia with respect to surgery.

2.1.13**healthcare multimedia report**

healthcare service procedure report which might be presented using more than one medium

[CR 14300]

NOTE A healthcare application that can present multimedia data presents a healthcare multimedia report. Such an application is usually also able to present monomedia data.

2.1.14**healthcare procedure**

systematic activity directed at, or performed on, an individual with the objective of delivering healthcare

NOTE This general term is used in this part of BS 8421 to include, for example, surgical, medical and (healthcare) service procedures.

2.1.15**healthcare procedure product**

entity produced during the process of performing a healthcare procedure

NOTE A healthcare procedure product may be in physical or electronic form.

2.1.16

healthcare service department

healthcare department able to accept requests for healthcare service procedures

NOTE This is not taken to refer to the provider of a prime therapeutic service such as surgery, but to the provider of a necessary supporting function, e.g. anaesthesia with respect to surgery.

2.1.17

healthcare service procedure

systematic activity provided by a healthcare service department at the request of a healthcare department with the objective of delivering healthcare

2.1.18

healthcare service procedure data

data relating to a healthcare service procedure

NOTE 1 Examples of healthcare service procedure data include patient ID, request ID and healthcare service procedure product ID.

NOTE 2 Healthcare service procedure data may be in physical or electronic form, and is distinct from any healthcare service procedure product with which it might be associated.

2.1.19

healthcare service procedure product

entity produced during the process of performing a healthcare service procedure

NOTE A healthcare service procedure product may be in physical or electronic form, and is associated with one or more items of healthcare service procedure data.

2.1.20

healthcare service procedure report

healthcare service procedure product in the form of text describing a healthcare service procedure that references other healthcare service procedure products, or in the form of a compound healthcare service procedure product, one or more components of which are in the form of text

NOTE This healthcare service procedure report may be in physical or electronic form.

2.1.21

healthcare service procedure request

order, made by an identifiable person, for one or more healthcare service procedures to be performed for a specified patient

NOTE 1 This request may be in physical or electronic form.

NOTE 2 This request is commonly referred to as an “order”.

2.1.22

interoperability

state that exists when one application entity can accept data from another and perform an intended task in an appropriate and satisfactory manner (as judged by the users of the communicating systems) without the need for extra operator intervention

[formalized from CR 14300]

NOTE 1 Interoperability can be expected only with respect to a specific task and between two known application entities.

NOTE 2 Interoperability of systems can be achieved only when clear definitions have been created of the tasks that are to be performed by those systems.

2.1.23

medical device

device, apparatus, or system used to prevent, measure, diagnose, or treat disease in humans, and which does not normally enter metabolic pathways

NOTE A medical device as used in this part of BS 8421 may, but need not, be a medical device in the terms of the European Medical Devices Directive, 93/42/EEC [1].

2.1.24**modelling**

activity to identify:

- a) elements of the universe of discourse;
- b) one or more pertinent levels of abstraction

[extrapolated from BS ISO/IEC 10746-2:1996]

NOTE The elements of the universe of discourse are entities and propositions.

2.1.25**multimedia healthcare service procedure report**

structured report that includes either procedure product data and associated rendering details in electronic form, or pointers allowing access to these data as stored in files

2.1.26**object**

model of an entity

[BS ISO/IEC 10746-2:1996]

2.1.27**ODP standard**

reference model of open distributed processing and any standard that is designed to conform to it, directly or indirectly

[extrapolated from BS ISO/IEC 10746-2:1996]

2.1.28**ODP system**

system that conforms to the requirements of ODP standards

[BS ISO/IEC 10746-2:1996]

2.1.29**open distributed processing**

distributed processing designed to conform to ODP standards

[BS ISO/IEC 10746-2:1996]

2.1.30**proposition**

observable fact or state of affairs involving one or more entities, of which it is possible to assert or deny that it holds for those entities

[BS ISO/IEC 10746-2:1996]

2.1.31**rendering**

conversion, as specified by an appropriate algorithm, of an array of numerical values (array data) that provide a meaningful visible image

2.1.32**report**

entity (generally a clinical document) produced in response to an order (see **2.1.21**)

NOTE A report may be in physical or electronic form.

2.1.33**scenario**

formal description of the process items performed to accomplish a particular function

NOTE In the context of this part of BS 8421, a process item is an entity produced in the carrying out of a healthcare service procedure request (**2.1.21**). It may be in physical or electronic form.

2.1.34**structured healthcare service procedure report**

data structure that can carry the essential content of a text healthcare service procedure report

NOTE 1 A structured healthcare service procedure report may include electronic references (pointers) to procedure products as well as verbal references to them.

NOTE 2 Parts of the structured healthcare service procedure report content are recorded in the form of codes that represent the findings and conclusions of the report.

2.1.35**vector**

one-dimensional array of integer or floating-point numbers

NOTE A vector can, for example, be obtained by calculation from a time series of digital image and “region of interest” data, or by direct measurement.

2.1.36**viewpoint (on a system)**

form of abstraction achieved using a selected set of architectural concepts and structuring rules, in order to focus on particular concerns within a system

[BS ISO/IEC 10746-2:1996]

2.1.37**vital sign**

clinical information relating to life-critical physiological indicators that can be measured by, or derived from, apparatus connected to a recipient of healthcare

2.2 Abbreviations

For the purposes of this part of BS 8421, the following abbreviations apply.

ASCII	American Standard Code for Information Interchange [BS Z 7]
BIIF	Basic Image Interchange Format
CCS	Common Coordinate System
CEN	Comité Européen de Normalisation (European Committee for Standardization)
CEN/TC 251	Comité Européen de Normalisation (European Committee for Standardization), Technical Committee No. 251, Health informatics
DICOM	Digital Imaging and Communications in Medicine
EHR	Electronic Health Record
EHCR	Electronic Healthcare Record (see the Note to 4.2.1)
EPR	Electronic Patient Record
ESDR	Electronic Service Department Record
EWOS	European Workshop on Open Systems
HCMR	HealthCare Multimedia Report
HTTP	Hyper-Text Transport Protocol
ICT	Information and Computing Technology
ICS	Implementation Conformance Statement
ICRS	Integrated Clinical Record Service
IEC	International Electrotechnical Commission
IOD	Information Object Definition
ISO	International Standards Organization
JFIF	JPEG File Interchange Format
JPEG	Joint Pictures Expert Group
MPEG	Moving Pictures Expert Group
ODP	Open Distributed Processing
OID	Object Identifier [ISO/IEC 9834-3]
OSI	Open Systems Interconnection from OSI Basic Reference Model (OSI/RM)

PAL	Phase Alternation Lines (625 lines) TV system
PPR	Patient Personal Record
RM-ODP	Reference Model of Open Distributed Processing
RTSP	Real Time Streaming Protocol
SAR	Synthetic Aperture Radar
SMIL	Synchronized Multimedia Integration Language
UID	Unique Identifier [ISO/IEC 9834-1]
UML	Unified Modeling Language
URL	Universal Resource Locator
W3C	World Wide Web Consortium
XML	Extensible Markup Language

3 Principles

3.1 General

For ICT systems to function safely and securely in healthcare there has to be an understanding by a number of stakeholders of the nature and the varied use of digital representations of information that are exchanged in electronic form.

Traditionally, the clinical information exchanged in British healthcare has been between prime healthcare departments and healthcare service departments. As electronic communication becomes increasingly used, other aspects of the generalized information infrastructure shown in Figure 1 are involved. The service process record and the healthcare process record are the areas with which this part of BS 8421 is chiefly concerned.

NOTE Figure 1 is based upon the model of the healthcare information infrastructure proposed in a CEN/TC 251 short strategic study entitled *Health information infrastructure* [2].

Healthcare service procedure reports presented using electronic facilities are expected to enable improved communication, when compared with commonly used existing methods, of the information obtained by healthcare service departments to those who request their services, thus leading to improved quality of healthcare.

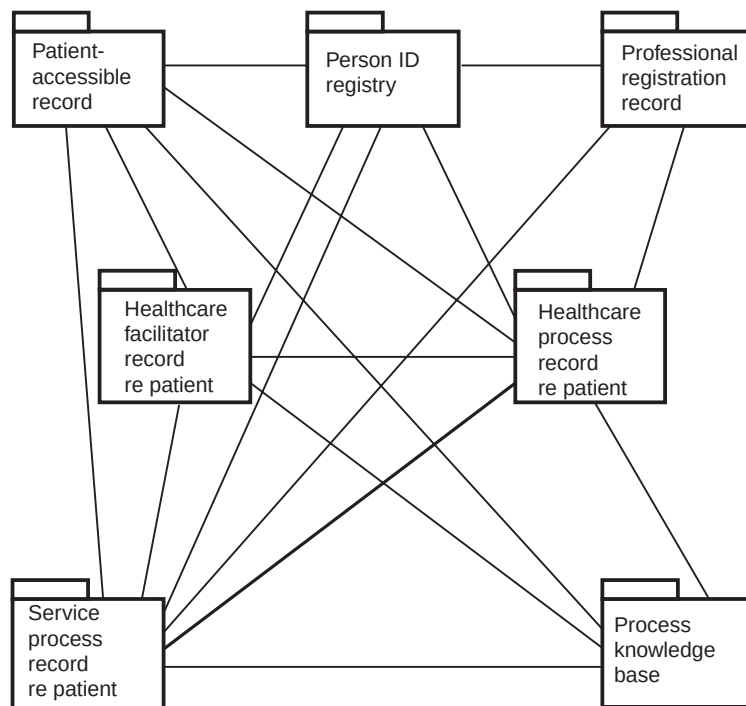


Figure 1 — Healthcare information infrastructure

3.2 Interoperability

Successful implementation of information technology in healthcare needs interoperability (2.1.22).

Interoperability can only be:

- expected of one or more specific tasks;
- within the expectations of the users of the two communicating systems.

The interoperability and usability of systems that can access data representing the results of one or more healthcare procedures depends on the following criteria being met:

a) specifications that need:

- 1) understanding and description of the healthcare tasks to be performed (work involving healthcare domain professionals);
- 2) understanding and description of the data needed to perform each task (work involving healthcare domain professionals);
- 3) identification of appropriate standard data element sub-sets to exchange the data (work involving information and communications healthcare domain professionals);
- 4) implementation of appropriate means of data communication (work involving information and communications professionals);

b) understanding by professionals in the different disciplines involved of certain key aspects of the nature of the working methods and data structures used in other domains so that informed decisions can be jointly made regarding the implementation of information and communications technology solutions;

c) a common terminology that is readily shared by relevant stakeholders;

d) an understanding of the role of professional end users in the task of selection and development of standard solutions.

The implications for the content of data recorded in electronic form can then be determined and included in message and stored standard data structures. The design of messages puts significant constraint on the internal data structures used by applications, since the relevant parts of the message data structures have to map to the internal data structures used by the different applications that can perform a given task.

4 Healthcare records

4.1 General

Information is one of the most important resources held by a healthcare institution. The quality of patient care depends on the quality and accessibility of the information held in relevant records. Records also enable quality management of the institutions themselves, both in monitoring day-to-day performance and in planning future developments – an aspect of their value that is equally applicable whatever the care domain.

Patient records in hardcopy format are often inaccessible because of their size and the fact that they can be scattered around the country in different institutions. These problems can be overcome using electronic storage of records only if appropriate facilities are provided for recording the structure of sets of relevant data so that healthcare professionals can conveniently access them.

The healthcare record can be regarded as a continuum in which some information is more relevant at some times than at others. Although it is convenient “shorthand” to describe large subsets of the continuum as the service department record, the patient record and the healthcare record, these terms primarily indicate the domain in which the information is first used and most commonly held (i.e. the domain of the identified person responsible for the security of the subset of the stored data). The designation is not an indicator of its relevance to the performing of specific healthcare tasks. In particular, it cannot be assumed that the data held in a data subset named for a given domain can provide all the data needed by healthcare professionals performing tasks within that domain, although it might provide all that is needed by many of them.

4.2 Healthcare record domains

4.2.1 *Primary care domain*

Primary care records in the United Kingdom are the working record used within the primary care domain and are regarded as the lifetime records of the healthcare supplied to a person, including records of preventive measures (such as vaccination) as well as overviews of episodes of illness.

NOTE This type of record has been referred to in most NHS documents as the “electronic health record” (EHR), and since mid-2002 as one element of the Integrated Clinical Record Service (ICRS). In the rest of the EU, “electronic healthcare record” (EHCR) is more often used. This record is sometimes referred to as the “primary healthcare record” and is usually kept by, or behalf of, the patient’s general practitioner.

In some healthcare service models the patient’s lifetime record is a full personal health record (PHR), and in others it is one of many primary care records at a given moment. If rapid, legitimate access to appropriate patient health information is required at the point of need then the EHR/PHR is most obvious navigational hub, although this also poses the most challenges in terms of concurrency management.

4.2.2 *Secondary care domain*

The working record used within the secondary care domain can normally be regarded as the patient’s secondary care record (i.e. hospital notes), known in the NHS as the “electronic patient record” (EPR). However, in some models of health provision and in certain situations, the secondary care domain may be a virtual domain that in physical terms is indistinguishable from the healthcare service department domain.

4.2.3 *Healthcare service department domain*

Conventionally in the United Kingdom, this is a sub-domain of secondary care; however, with consolidation of resources, healthcare service departments are increasingly moving towards an independent status that until recently was more commonly seen in Europe or the United States of America.

The record is usually managed by a department, such as an imaging department, able to undertake healthcare service procedures requested by the primary or secondary care domains.

In some situations, the healthcare service department domain may be a virtual domain that in physical terms is indistinguishable from the secondary care domain. The functions are usually differentiated by the passing of a report on a healthcare service procedure to another specialist within the same secondary care department.

The working record used within the healthcare service department domain is generally regarded as the patient’s service department record (i.e. departmental notes); it is increasingly common to describe the electronic instance of this as the “electronic service department record” (ESDR).

4.2.4 Patient personal domain

An alternative form of record is now being offered to patients by a number of Internet companies. These patient personal records (PPRs) are sometimes confusingly termed “personal healthcare records”, and enable patients to control what information is kept and decide what parts to make available to healthcare professionals and others on a world-wide basis. Currently there are no standards for the regulation of these facilities or the format for the storage of the content. The information is generally held for them on an Internet site, using material supplied by healthcare providers.

4.2.5 Management domain

The management domain contains administrative material and material needed for statistical purposes. Audit material can also be needed. Healthcare service department results are not usually communicated at present, although with increasing availability the likelihood is that needs for transfer of high level information for planning and public health tracking will increase.

4.3 Clinical data domains

Data communication is illustrated for the three clinical domains identified in Figure 2. The healthcare provider domains are arranged in a hierarchy. When a diagnostic healthcare service procedure is requested (for example by a secondary care healthcare professional) and performed by a healthcare service department, a considerable amount of data is stored in the ESDR. In the case of an imaging procedure, this includes details such as the medical device settings used when the data was acquired and the identifier of the technologist who performed the data acquisition, as well as the acquired and processed data.

When the healthcare service procedure report is written, all of this data has to be available to the reporting clinician. However, when the report is made available to the recipient in the secondary care (EPR) domain, only an appropriate subset of the data that has been stored in the ESDR is made available.

The ESDR box is drawn deeper than that of the EPR to demonstrate that it contains information of a more detailed nature. A different subset may be made available to the patient. For example, a single image is often given to the patient following antenatal ultrasound imaging procedures. The EPR box is shown as wider and shallower than the ESDR box to demonstrate that the EPR contains a greater quantity of less detailed information about the patient. In other words, a process of abstraction takes place when data is accessed at a higher level. When the patient leaves the secondary care domain a discharge “document” (that is itself an abstract of the content of the EPR) is made available to the primary care domain.

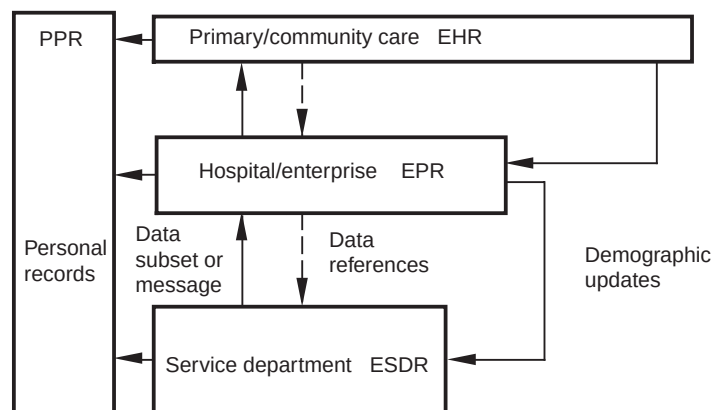


Figure 2 — Clinical record domains

5 Healthcare service departments and healthcare service procedures

Healthcare service departments are a specialization of healthcare departments, and are focussed on the delivery to professionals in primary and secondary care domains of technically specialized services such as biochemical testing, imaging and anaesthesia.

NOTE It is not unreasonable to include services aimed at therapy, such as physiotherapy and radiotherapy, within the grouping healthcare service department. However, because these are often more interactively associated with the general therapeutic regime of a patient they are not dealt with in this part of BS 8421. Similarly, facilities dedicated to the carrying out of routine health checks, such as some occupational health screening clinics, might reasonably be considered to be healthcare service departments but are not considered in detail here.

Healthcare service procedures may (according to the departmental origins) be classified under the following headings:

- a) investigative:
 - 1) continuous data acquisition over an extended period or periods of time (e.g. patient monitoring or microbiology);
 - 2) snapshot information (X-ray or biochemical test);
- b) facilitating.

In general, a diagnostic healthcare service procedure is performed in response to a healthcare service procedure request (or “order”) and the results are commonly presented in the form of a textual healthcare service procedure report that sometimes references or includes a subset of the source information (e.g. images or waveforms).

CEN Report CR 14300 presents scenarios that illustrate needs for different data items to be covered in multimedia reporting. These include:

- free text;
- numerical values;
- data in tabular form;
- uniquely identifiable numeric measurement data;
- medical images;
- trend plots and other x, y co-ordinate diagrams;
- waveforms, biosignals, raw measurements and accumulated data;
- anatomical images;
- artificially generated images such as brain maps and their time synchronization to the EEG;
- digital video and audio and their time synchronization, e.g. to the EEG;
- results of combination of images obtained by multimodality studies.

6 Access to healthcare information

6.1 General

6.1.1 Overview

A major part of the primary and secondary care records held for a patient comprises the results of healthcare services, of which imagery and related data form a large and important part of the records stored within healthcare service departments. Healthcare service procedure results can be conveyed to the primary or secondary care requester as:

- healthcare service procedure report only;
- healthcare service procedure report and accompanying data;
- data only.

Situations requiring access to healthcare service procedure data include those:

- when a healthcare service procedure report has not yet been produced (e.g. emergencies);
- when data is needed to implement treatment (e.g. orthopaedics, intensive care, cardiology);
- during discussion in clinical meetings and education sessions;
- supporting either a clinician's or a patient's confidence in a report;
- retrospectively reviewing a patient's healthcare.

Appropriate access can be provided by sending out copies to be stored locally within user domains, or by making accessible the original copy held by the healthcare service department.

6.1.2 Mechanisms for providing results

Current mechanisms commonly used for providing radiology results illustrate the difficulties that can be encountered. Typically, radiology results are provided in hardcopy form, including sending a text healthcare service procedure report in the post and returning a film packet to the patient's ward with the patient. Results are sometimes needed for reference or medico-legal reasons and are currently accessed by various methods including telephone enquiries, "pulling" film packets for outpatients and selective viewing of previous images "from the packet". This example from radiological imaging practice is generally applicable to other areas such as pathology departments, cardiology, anaesthetics and critical care, although in some instances these are not yet so advanced in their electronic storage of the source data.

Some drawbacks experienced with existing systems include:

- a) sending out material:
 - 1) textual healthcare service procedure report in the post – delays, loss in transit, wrong destination, possibly seen by the wrong person;
 - 2) film packet to ward with patient – department record might then be incomplete and the film not available for healthcare service procedure reporting;
- b) reference:
 - 1) telephone enquires – delays, not available out of hours;
 - 2) pulling packets for outpatients – time-consuming and films not then available in the department;
 - 3) selective viewing from the packet – time-wasting due to lack of structure;
 - 4) readily available information about what is available from within the institution or from other institutions is often not known;
 - 5) often only the healthcare service procedure report or only the images are available;
 - 6) extensive searching for information is time-consuming.