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Radiological Examination Transfer on ATM Integrated Networks

RETAIN

Deliverable D7:

Second Guidelines for TEN-IBC in Medical Imaging

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1 INTRODUCTION

The RETAIN research project (“Radiological Examination Transfer on ATM Integrated Networks”) as part of the “Trans European Networks” initiative of the European Commission examined over a period of two years the usability of modern high-speed wide area networks for telemedical applications in radiology and neurology.

The experimental RETAIN teleradiology conference network used different generations of hard- and software, both on ISDN and ATM networks. The trials – medical advice requests on difficult cases – involved physicians and computer scientists from six sites in four European countries (France, Germany, Portugal, Spain). An in-depth description of the RETAIN trials can be found in [Ret3-5] and [Ret3-6].

The evaluation report of the RETAIN trials is separated into two documents:

- *Deliverable 6: Analysis of the Trials – User and CIG Point of View* describes the analysis of the RETAIN trials including many technical details, drawing conclusions from the practical experiences in “broadband telemedicine”.
- *Deliverable 7: Second Guidelines for TEN-IBC in Medical Imaging* (this document) provides a comprehensible overview over the field of telemedicine/teleradiology and “condenses” the results learned from RETAIN into a set of recommendations (“guidelines”) for implementors and users of telemedical services, especially focused on applications of broadband networks.

1.1 The Increasing Need for Communication in Medicine

The daily medical practice has seen a dramatic evolution over the last twenty years. The progress at the research level and the technological advances have deeply modified patient care from diagnosis to treatment stage. A particular branch of medicine that has largely benefited from the advances made in other scientific fields (physics and computer science) is radiology; the conventional X-ray radiology has not been replaced but completed by several other imaging techniques: computed tomography (CT), magnetic resonance imaging (MRI), ultra-sound (US), echography, etc. The images produced by these new sources yield more information with the possibility to “look into the body” without requiring an invasive surgical act. As a result the medical image has become a key element in patient care; it is not only used for diagnosis purposes anymore but it also helps to prepare a surgical act and/or to control the evolution of the treatment. Another consequence is that the field covered by a radiologist yesterday is now so complex that he must restrict his expertise to a sub-class of his speciality (radio-paediatrics, neuro-radiology etc...). This phenomenon is also increased by the fact that medical knowledge is continuously evolving and it becomes more and more impossible, whatever medical speciality, to follow this evolution in all directions. As an example, the role of the generalist is nowadays to guide his patient towards the adequate specialist (except for classical diseases where treatment is well known). In other terms, the increasing medical knowledge results in the necessity to share it efficiently.

This short introduction aims to point out two important facts that may help to understand some needs in the medical community, even if not yet explicitly expressed:

- The increasing role of the image in the medical process: due to the large amount and diversity of information it provides it is more and more used as a reference when a patient case is under discussion, and
- The necessity for the physician to easily receive complementary expertise from a colleague because of his own keen but narrow expertise. This is a question of communication.

The question arises if modern communications systems and computer technology (often referred to with the term “telematics”) can offer practical solutions to these requirements. A large number of research projects have already carried out work in the field of “health care telematics” in order to answer this question.

1.2 Current Status of Implementation of Telematics in Health

A study on the current status of implementation of telematics in health care in Europe performed by a European research project in 1996 comes to the following conclusion [Telmed1]:

> *As with other telematics sectors, there appears to be a significant mismatch between expectations of what telematics can deliver for health care in Europe and what has actually been achieved. There is little evidence of large-scale co-ordinated strategic development of telematics healthcare systems in Europe. Development has in contrast been fragmented, small scale and primarily driven by experimental and pilot projects underpinned by European Commission R&D Programmes.*

In fact most telemedicine applications existing today are pilot projects paid by some research funds. Integration into daily clinical routine is often insufficient and usually there is also an uncertainty on the data protection and security regulations to be fulfilled. In international projects, an additional uncertainty of the legal aspects is caused by the differing regulations in European countries (e.g. unlike Germany, the use of safe encryption technology is legally very restricted in France). Since most telemedicine projects are paid by research funds, only few studies on financial aspects of telemedicine (e.g. proof of rationalisation effects) are available.

In technical terms, telemedicine applications can often be classified either as expensive "high-tech" projects, operating for instance with TV or satellite transmission technology, or as "low-cost" projects which are limiting themselves to standard equipment and narrowband networks (e.g. ISDN) and offer only limited performance (e.g. significant transmission times or limited image quality). Most of the installed image modalities required for teleradiology are working on analogue media (film), so images must be digitised. This takes time and reduces image quality. Digital image archives (PACS, picture archiving and communications systems) with powerful local networks are still an exception in hospitals today.

Currently there are some signs indicating a change of the situation described above. With the continuously increasing importance of information as an industrial resource, visible for instance in the rapid growth of network services like the "World Wide Web", the necessity to create a communications technology able to match the multi-media "flood of data" is increasing as well. ATM ("asynchronous transfer mode", see section 3.2), a technology for high speed networks, allows to transmit speech, video and data quickly and in high quality over a single connection. This technology will not only be the basis for tomorrow's broadband ISDN, but also offers an excellent infrastructure for telemedical applications, which are by their very nature "multi-media" as well. Moreover the cost pressure in health care and the resulting trends towards concentration, specialisation and outsourcing will require intensified co-operation and communication between clinical institutions. Two additional factors facilitating telemedicine are the increasing use of full digital modalities (e.g. Computed Radiography instead of conventional X-ray) and the increasing acceptance of international standards (MEDICOM/DICOM, EDIFACT, HL7) which make interoperability between devices of different manufacturers possible.

2 REQUIREMENTS OF A TELEMEDICINE SYSTEM

The knowledge transfer during a telemedical conference or consultation involves a combination of formal and informal information: patient and administrative data, images, written diagnoses, etc. are rather formal information sources. Classical transmission techniques for these data are file transfer or telefacsimile. Medical expertise however, consisting of knowledge, experience, opinion, etc., cannot easily be formalised and must be "transmitted" by human communication.

A system allowing physicians to handle patient cases over long distance should therefore integrate human communication with all available "formal" information sources (digital or analogue form) in a natural way.

The basic form of human communication is of course speech, but the importance of non-verbal communication should not be underestimated. Especially in situations where the conference partners do

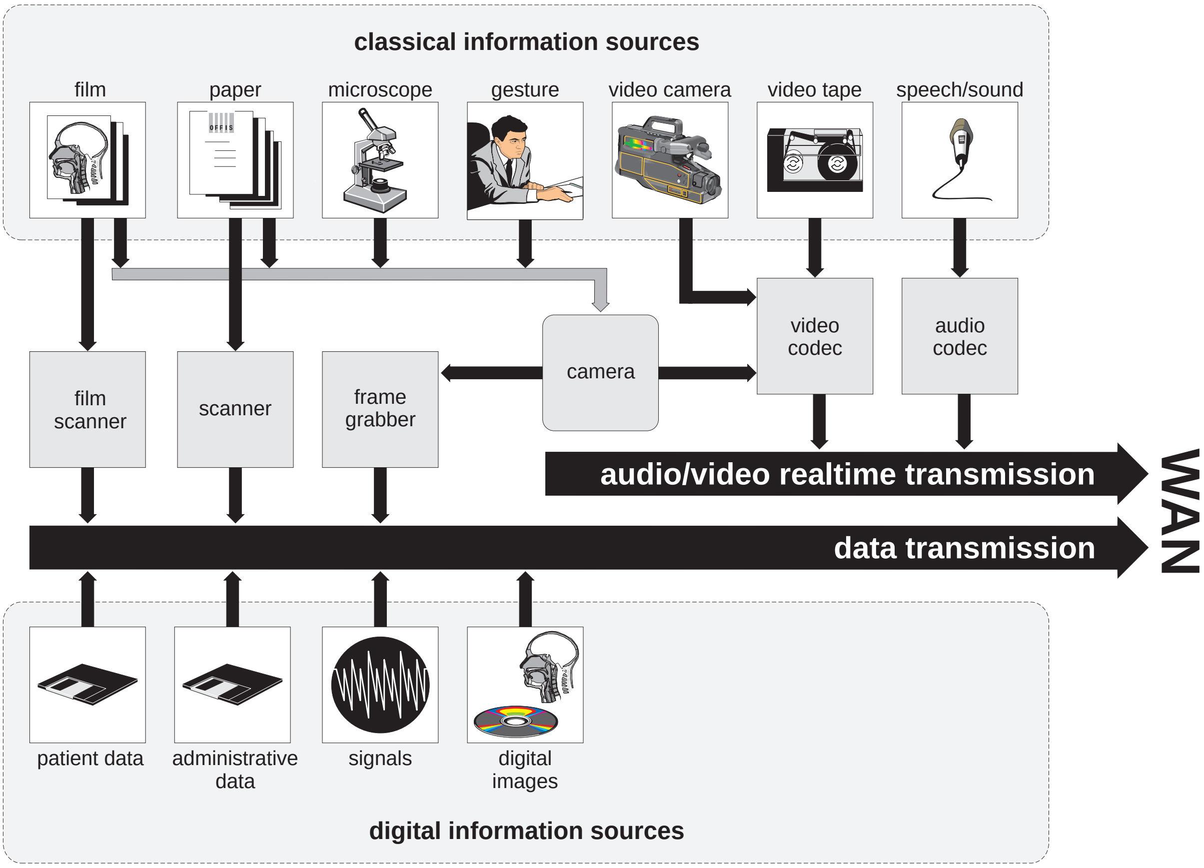

Figure 2-1: Digital acquisition of information sources and resulting data streams

not know each other well or even have to speak a foreign language, seeing the conference partner in addition to hearing him helps to prevent misunderstanding.
The information sources can be separated into “classical” (analogue) and digital information sources. Despite the trend towards digital management of patient related data mentioned above, the majority of information available today will be analogue. Since today’s wide area networks use digital transmission technologies, all information must be transformed into digital data at some point.
Figure 2-1 shows how these information sources can be fed into a digital network, resulting in two data streams: the audio/video stream with strong real-time requirements (low latency, constant bandwidth, low cell/packet loss) and the data stream which is rather “bursty” (variable bandwidth) and does not impose strong restrictions on the real-time characteristics of the network. Functional requirements of the information sources connected with the digitisation process are:

- *Patient and administrative data* are usually managed by a hospital information system or radiology information system (HIS/RIS). The telemedical application should allow the user to download appropriate information from a HIS/RIS server and must therefore be well integrated into the administrative hospital network.
- *Digital images and signals* are created by digital modalities and usually stored in a PACS server (picture archiving and communications system). As for patient and administrative data, an integration of the telemedical application in the PACS network (quick and easy download of images to the telemedicine workstation) is necessary.
  The cooperative discussion and diagnosis on digital images requires more than the transmission of image data: It must be possible to interactively *review* the images. The physicians must be able to cooperatively point to some image details, annotate the images (e.g. encircle a region of interest) and change the window level and width. This requires an application of computer supported cooperative work (CSCW) according to the WYSIWIS principle “what you see is what I see” supporting the special requirements of medical imaging.

- *Images on film* as the most important classical information source must be digitised before they can be transmitted during a telemedical conference. This can be done with a dedicated high resolution film scanner or a camera (mounted over a light table) and a video digitising device. A video digitiser can either be a "frame grabber" that digitises single images (frames) from the video signal or a video codec which encodes the complete video signal. The image quality resulting from this process is determined by the spatial resolution, grey scale depth and linearity of the digitising device. A careful adjustment of the lighting is very important for the result of the digitisation, especially if the resulting data set is limited to 8 bits/pixel. However, unless a high quality film scanner is used, a significant loss of image quality is inevitable.
- *Paper* containing administrative or patient data may be digitised in a way similar to images on film. An additional possibility is the use of telefacsimile in advance to the conference.
- *Microscope, gesture and video:* Visual information is most often recorded with video cameras which can be mounted on a microscope or used as "head and shoulders" camera for visual telephony or a freely usable "handycam", etc. Still images from cameras can be digitised with a frame grabber while motion picture requires the use of video codecs. In general the use of multiple cameras and a video crossbar switch is necessary since multiple video sources must be switched to a single video codec. When narrowband video codecs are used, signal timing is often critical, requiring the use of time base correctors to reconstruct a proper video signal (e.g. for use with VCRs).
- *Speech and sound* are of course recorded by microphones and digitised by audio codecs which are usually integrated with a video codec. However, audio technology is not as simple as it seems. The careful choice of appropriate audio equipment and spatial setup is often critical for the usability of a conference installation, especially when "room installations" with microphones and loudspeakers instead of earphones or handsets are used. Echo cancelling equipment is also often necessary.

Figure 2-1 also indicates that the network technology used for a telemedical application will have to handle both real-time audio/video and "block" data. ATM and ISDN recommend themselves for use in telemedicine because unlike most other transmission protocols (DQDB, FDDI, TCP/IP...) they are well suited for the transmission of real-time data like audio and video. Both technologies offer some degree of scalability: multiple ISDN 64 kBit/s B-channels can be "bonded" (using inverse multiplexers) to provide higher bandwidth and the ATM standards will finally support so-called *variable bit rate (VBR) services* and bandwidth negotiation at connection establishment.

3 NETWORK TECHNOLOGY

A multitude of wide area network protocols exists, for instance ATM, ISDN, DQDB, X.25 and Frame Relay. In addition, some LAN protocols can also be used in metropolitan area networks or campus networks, e.g. FDDI or Ethernet 10BaseFL. However, most of these protocols are not able to transmit real-time information like audio and video in acceptable quality, or transmission of real-time data requires a significant technical effort (e.g. FDDI or DQDB). Therefore, the following discussion will be restricted to ATM and ISDN, which are both able to transport real-time data. See section 3.3 for a discussion on the use of different network technologies in combination with ISDN or ATM.

3.1 ISDN

The development of ISDN (Integrated Services Digital Network) as the digital counterpart to the analogue telephone network already started at the beginning of the 1980s, resulting in a series of ITU-T (telecommunication standardisation sector of the International Telecommunication Union, formerly CCITT) and ETSI (European Telecommunications Standards Institute) recommendations describing the ISDN transmission technologies, interfaces and protocols. ISDN is available for the end user with two different interfaces, the basic rate interface (BRI) and the primary rate interface (PRI). A basic rate interface offers two independent data channels ("B-channels") of 64 kBit/s and a 16 kBit/s control channel ("D-channel") which is used for dialling and status information exchange with the ISDN network. A primary rate interface supports 30 independent B-channels of 64 kBit/s and a 64 kBit/s D-channel (in some countries a B-channel offers only 56 kBit/s and a PRI is limited to 23 B-channels). Each B-channel corresponds to a telephone line and can be used for telephony, fax transmission or data transmission with appropriate equipment. With so-called inverse multiplexers, multiple ISDN B-channels can be "bonded" if more bandwidth than 64 kBit/s is required. Tariffs for ISDN connections are usually identical to telephony tariffs (for one B-channel). This means that bonding multiple B-channels increases the connection costs linearly with the number of channels used.

3.1.1 Audio/Video Transmission over ISDN

The transmission of audio-visual information over ISDN networks is described in ITU-T recommendation H.320 [ITU 93] and most video codecs and boards for ISDN based visual telephony support this standard. H.320 is a composite standard: it refers to other ITU-T recommendations for image compression, audio compression, telematic services, etc. Image compression is performed according to H.261 [ITU 93b], limiting the image resolution to the "common intermediate format" (CIF) with 352x288 pixels. This means that still image resolution is similar to VHS video resolution. H.261 supports still image transmission with quadruple CIF resolution (704x576 pixels which is close to a full PAL frame) as an optional feature. Unfortunately most H.320 codecs supporting still image transmission use proprietary JPEG modules instead which are able to transmit a full resolution frame (PAL, NTSC, SECAM), but are non-standard and in general limited to a single product or vendor. H.320 audio transmission can be either uncompressed PCM audio (recommendation G.711, also used for conventional telephony over ISDN) or compressed (G.722, G.728). Audio compression is important if only two B-channels are used since in this case the compression increases the bandwidth available for the video image significantly. The H.320 recommendation supports bandwidths ranging from 64 kBit/s to 1920 kBit/s, but only 128 kBit/s with G.728 audio ("visual telephone mode b_3") and 384 kBit/s with G.711 audio ("visual telephony mode f_1") are commonly used.

The H.320 approach for video transmission uses a very coarse resolution when the difference between two consecutive frames is large (much movement) and increases the resolution step by step when the frames become similar (little or no movement), up to a maximum of the CIF resolution. This means that the image looks "blurred" if much movement is visible and becomes sharp when there is less movement. The time the image needs to "become sharp" depends mostly on the available bandwidth (the number of B-channels used).

H.320 defines protocols for narrowband data exchange in parallel with the video conference, e.g. for telematic applications like remote control of a camera or a microscope. Support for multipoint video conferencing is also defined as an "optional feature". Codecs supporting multipoint conferencing allow to dial into a so-called multipoint video switch that can be called by multiple codecs and which distributes the incoming signal from one (user selectable) codec to all others.

3.1.2 Data Transmission over ISDN

Several approaches for data transmission over ISDN networks exist, but for TCP/IP as the usual network protocol for telemedical applications, often "serial line IP" (SLIP) or the "point to point protocol" (PPP) are used. Connectivity between different solutions is in general not as trouble-free as it should be, because both SLIP and PPP can be used with a multitude of options, packet header formats, etc. Bandwidth can be increased beyond 64 kBit/s by bonding multiple B-channels. Some ISDN routers also support compression on-the-fly. The upper limit for the available bandwidth is 1920 kBit/s before compression. Additional technical expenditure is necessary to guarantee this as a sustained bandwidth because all B-channels are connected independently and could be switched over different ISDN exchanges, resulting in different latencies for the B-channels. However, solutions for ISDN routers with primary rate interface are available as well as BRI solutions for one or more basic rate interfaces.

3.2 ATM

ATM ("asynchronous transfer mode") is a transmission technology designed for high speed networks. The basic idea of ATM is that data is transmitted by small asynchronous cells, each containing 48

bytes of user data. Unlike connectionless protocols like FDDI or DQDB, ATM is connection oriented which means that a “virtual path” through the network must be set up between two ATM devices before they can exchange data. This connection allows to guarantee certain “quality of service” (QoS) parameters like maximum latency, guaranteed bandwidth and in order delivery of cells, which makes ATM well suited for the transmission of real-time data.
The ATM standards (released as a series of ITU-T recommendations) are not yet complete, although much effort is put into this work by some interest groups like the “ATM Forum”. In general it takes 1-2 years before released features and services of the standard are available in commercial implementations. ATM services not yet released or not yet available on existing wide area networks are for instance the so-called “variable bit rate services” (VBR services) which will allow a user to establish a connection with guaranteed minimum bandwidth and to use additional bandwidth when needed and available, and the “signalling services” allowing a user to “dial” a connection through the network. ATM transmission hardware already exists for bandwidths ranging from 25 Mbit/s to 622 Mbit/s, 2.5 Gbit/s and more are expected.

3.2.1 Audio/Video Transmission over ATM

Unlike ISDN H.320 there is no recommended protocol for the transmission of audio-visual information via ATM. The ATM standards define a process called “ATM adaption layer 1”, describing how real-time data is to be segmented and transmitted by ATM cells. The digitisation and compression of audio/video data is not regulated by the standard, and several incompatible algorithms exist for this task: Motion JPEG, MPEG, MPEG-2, ETSI recommendation 300-174 for the digital transmission of television signals and of course the H.320 family of standards. However, it is expected that MPEG-2, when available in hardware, will become the standard protocol for ATM based video transmission.

3.2.2 Data Transmission over ATM

The transmission of TCP/IP data over ATM is mostly standardised today. The ATM standards define a service called “LAN emulation” which describes how Ethernet or Token Ring frames can be transmitted over an ATM network, allowing to integrate classical LAN based systems with an ATM network. The ATM adaption layer 5 (AAL5) which is used for this purpose is an adaption process designed especially for protocols that ensure error detection and correction on higher levels (e.g. TCP session layer). Alternatively, the Internet standards RFC 1483 [Hein 93] and RFC 1577 [Laub 94] describe a direct implementation of TCP/IP over ATM AAL5 (“classical TCP/IP over ATM”, CLIP). Current ATM boards and drivers often support both LAN emulation and CLIP.

3.3 Migration and Connectivity

Today ISDN based solutions for both audio-visual and data transmission over ISDN are available, affordable and are being used. Since ATM technology clearly has the potential to improve communications by providing faster data transmission as well as better image and sound quality, eventually the question will arise how an existing application can “migrate” from ISDN to ATM technology. Since it is not very probable that ATM technology will be available everywhere in the close future, a mixture of ISDN and ATM will be used and “connectivity” to ISDN services could become a critical factor for the acceptance of broadband based systems and services.
Since the different ATM audio/video transmission techniques are not compatible to ISDN H.320 codecs (of course besides H.320 over ATM), the most straightforward way to connect ISDN and ATM based codecs is an ISDN “dial in point” which simply connects an ISDN and an ATM codec on the analogue side (see [Ret3-6]). Such a simple approach cannot be expected to produce high quality results since two different “lossy” compression algorithms (both introducing image information loss) and two additional analogue/digital conversions are performed. A direct computational approach to “transform” the digital data of one encoding process to another would produce better results but would require hardware implementation and is not available today.
With the spreading of ATM WANs, ISDN routing will often be used as a backup so that mature ATM-ISDN routers can be expected on the market soon. One could imagine commercial providers to

offer ISDN dial-in points for broadband TCP/IP networks (e.g. an ATM based Internet) if a sufficient market exists.
Another migration path from ISDN to ATM could be the use of hybrid networks, e.g. ISDN for real-time data transmission completed by inexpensive broadband data networks, e.g. the commercially available Frame Relay or SMDS ("switched multi-megabit data service") services.

4 IMAGE ACQUISITION

The acquisition of information sources for telemedicine has already been described in chapter 2: Requirements of a Telemedicine System. The discussion in this chapter will mostly add technical details to the basic statements from chapter 2. [ACR 93] separates the processes used for acquisition of medical images into two types:

- *Film digitisation*, which is used for conventional images on film, and
- *Direct capture of images*, which is used when images are directly acquired from digital modalities without processing of conventional film.

Image acquisition should preserve image quality as good as possible. Therefore, a direct capture of images is always preferable to film digitisation. The RETAIN trials have shown that digitising films in high quality is a very time consuming procedure and that the physicians participating in the project generally avoided the use of X-ray films for telemedical consultations when possible (see [Ret3-6] section 3.2).

4.1 Conventional Images on Film

For the digitisation of conventional images on film either a camera or a dedicated film scanner can be used:

- *Camera with tripod and light table:* This is an inexpensive way of digitising films, but the resulting image quality is limited by the resolutions of camera (e.g. 720x576 for PAL) and digitising device (e.g. 352x288 for a H.320 ISDN codec), respectively. It should be noted that the high contrast between dark and light areas on a radiography (e.g. optical densities ranging from 0.2 to 3.0) makes great demands on the capabilities of the camera.
- *Film scanner:* Two types of film scanners exist, CCD (coupled charged devices) based scanners, also called "moving-film scanners" and Laser scanners, also called "fixed-film scanners". Laser scanners offer the best image quality for digitised films, but are also the most expensive scanning device.

The ACR standard for teleradiology [ACR 94] recommends that digitisation systems for small matrix modalities (CT, MRI, ultra-sound, nuclear medicine and digital fluorography) should offer a resolution of 512x512 pixels per image with 8 bits/pixel or better. For large matrix modalities (computed radiography and X-ray), a resolution of 2048x2048 with 12 bits/pixel or better is recommended.
Whereas the recommendations for small matrix modalities can be fulfilled with a camera/light table combination and a frame grabber, the high resolution of large matrix modalities can only be reached with a CCD or laser film scanner.
The usability tests with different image acquisition and transmission techniques and image modalities performed in the second phase of RETAIN (see section 6.1) mostly confirm these recommendations. However, ISDN H.320 transmission of small matrix images, which does not conform to ACR recommendations (spatial resolution only 352x288) was assessed as "very good" for some modalities. [ACR 94] states that

> *There may be less-stringent guidelines for display systems when these display systems are not used to produce the official authenticated written interpretation.*

If images are only digitised for a telemedical "second opinion", this statement can obviously be applied to the digitisation system as well as to the display system (which has weaker requirements in [ACR 94] anyway).

4.2 Digital Modalities

A multitude of digital medical imaging modalities are commonly used in radiology today, including computed tomography (CT), magnetic resonance (MRI), computed radiography, ultra-sound and more. The importance of this sector, which permanently increased in the last 20 years, raised the need for integrated hospital (or radiological) information systems (HIS/RIS). Although the need for a vendor independent image exchange was seen, the available solutions were vendor dependent and did not offer "open" connectivity or image exchange. Image formats commonly used in general purpose image processing, however, were and are not suitable for medical imaging (except IPI-IIF with some limitations). Most general purpose image formats are limited to 8 bits per colour component (e.g. 24 bits/pixel RGB for "true colour"). This offers sufficient colours for human eye's perception, but only 256 shades of grey. Many medical imaging modalities including X-ray, CR and CT, produce monochrome images with 12 to 16 bits/pixel. The human eye is unable to perceive so many shades, but nevertheless the data contains meaningful image information. In order to visualise this image information, medical images are typically displayed using "value of interest (VOI) windowing". This means a section of the available grey range (a window) is expanded to the full grey range of the display device. Different VOI windows are used to visualise different parts of the image ("bone window", "tissue window", etc.). A medical image format must be able to store such VOI windows along with the 12-16 bit/pixel greyscale data. A further demand to a medical image format is the possibility to store (and view) supplementary patient information within the file.

There have been a number of approaches to define a vendor-independent exchange mechanism (mostly file formats) for medical imaging including ACR-NEMA versions 1.0 and 2.0 [NEMA 88], Papyrus (developed by the RACE TELEMED project), Interfile (for nuclear medicine images only), Image Save & Carry (IS&C) and Qsh, but all of them with limited success. This changed in 1994 with the release of the "open" ACR-NEMA standard DICOM ("Digital Imaging and Communications in Medicine") [NEMA 94] which is supported by most equipment manufacturers today and has been adopted as a European pre-standard MEDICOM [CEN 96a].

4.3 DICOM / MEDICOM

The DICOM/MEDICOM standard ("Digital Imaging and Communications in Medicine") [NEMA 94], [CEN 96a] is more than a medical image file format: DICOM defines a model for standardised (vendor-independent) client-server applications for the most common medical imaging related functionalities: Transmission of images, image database services, patient and study management and image printing. These services can be offered by DICOM conformant applications in a LAN or WAN environment with TCP/IP or OSI network protocol. This makes DICOM the protocol of choice for wide-area applications in medical imaging including tele-radiology. DICOM has been criticised for creating a significant network protocol overhead if used on narrowband connections (e.g. one ISDN B-channel only), but currently there is no vendor-independent alternative available.

Whereas DICOM covers the area of network transmission of medical images and accompanying patient data, it does not cover all required aspects of tele-radiology. For instance DICOM defines no services for co-operative image display and manipulation. [CEN 96b, pp. 37-38] puts it this way:

> *It is not uncommon for the results of a study to be passed to a clinician for a second opinion. Typically one or two films showing a set of images will be sent together with relevant technical and clinical material. Such a scheme can be implemented using Medical Informatics techniques. The question arises as to what standards should be used for the exchange of relevant image and descriptive data (...) In the case of thresholdable images DICOM provides a specification for the image data and much of the associated relevant clinical information – but probably not all. The receiving centre may require additional information beyond that sent with the images and means must be provided to respond to queries in this case. Strategies must be developed for grouping relevant image related data in an appropriate way and for duplication where necessary.*

The every-day use of tele-radiological services in a non-experimental scenario will require an integration of the imaging application used for remote image discussion and diagnosis with hospital picture archives (PACS servers) and hospital or departmental information systems (HIS/RIS). This is not a problem with DICOM based PACS since the "DICOM Query/Retrieve Service Class" allows to browse a DICOM archive connected over LAN or WAN and to download images to the tele-radiology application. PACS support for legacy systems is an open question at the moment. Another open question is the necessary level of integration of the tele-radiology applications with administrative hospital information systems (e.g. for reimbursement procedures) or other health care related information systems like lab data or patient bedside monitoring.

4.4 Direct Video Capture

For image acquisition from legacy devices without support for digital image export, "direct video capture" is an alternative to film digitisation. Most digital modalities support an analogue video interface, often in high resolution. Devices exist which allow digitisation from this "documentation interface", avoiding the additional steps of film creation, processing and scanning and, therefore, offering a significantly better image quality.

5 IMAGE COMPRESSION

Digital X-ray images ("computed radiography", CR), large CT or MRI series and particularly "medical movies" (e.g. cardiac ultrasound examinations) require significant space and, in turn, transmission time. For example, in diagnostic cardiology it would be desirable to store approximately 30 seconds of dynamic heart images per patient (i.e. three sections of the heart, and 10 seconds for each section). An uncompressed PAL video (270 MBit/s according to SMPTE 125) would require 1,012 MBytes and a transmission time of 36 hours at 64 kBit/s.
Image compression techniques reduce the amount of image data by computing different, more efficient representations of the image data (e.g. representation in the frequency domain instead of the spatial domain). Two types of compression techniques can be distinguished: *Lossless compression*, which allows to fully reconstruct the original image "bit-by-bit" and *Lossy compression*, which generally yields a better compression ratio, but permanently destroys image information that is usually not important for human perception.

5.1 Lossless Compression

Lossless compression algorithms are able to reconstruct the original data without any loss of information. Several lossless image compression techniques exist. Usually they are based on entropy coding concepts (which are also used for the compression of non-image data). For medical images, the most practical lossless compression is the "lossless JPEG" process [ISO 94]. It is based on forms of Differential Pulse Code Modulation (DPCM) which makes use of the correlation of adjacent pixels. It is based on a sequence of differences between the pixels and their predicted values. These differences are quantified, stored and compressed. In a second stage the redundancy of the remaining information is removed by application of "conventional" entropy coding techniques (variable-length code words, statistical modelling, adaptive coding).
The typical image compression ratio for lossless techniques applied to medical images is approximately 2:1. Considering the significant time required for compression, this seems to be efficient for image transmission over slow network connections (e.g. ISDN) only.

5.2 Lossy (Nonrecoverable) Compression

Lossy compression techniques yield far better compression ratios than lossless compression by removing image information that is not important for human perception. The general problem is to reduce the amount of data to the maximum extent possible while still providing acceptable (or appropriate) image quality, low algorithmic complexity and short compression delay. The best known "lossy" compression algorithm is "baseline JPEG" [ISO 94] which is based on Discrete Cosine Transform

(DCT) coding. Recently some new techniques have been developed which promise to offer better image quality (e.g. less visible artefacts) compared to DCT:

- Vector quantization based on clustering techniques and on constructing code-books which have to be stored
- Discrete Wavelet Transform which is superior to DCT in situations where better spatial resolution at high frequencies than at low frequencies is desirable.
- Iterated function systems (so called fractal coding) which are based on the idea that every image can be segmented and represented by different textures or fractals.

Typical compression ratios for lossy compression applied to medical images range from 5:1 to 15:1, depending on the algorithm and accepted quality loss.
Although lossy compression is able to significantly decrease image transmission times in telemedicine, it should be noted that the compressed and transmitted image is not identical to the original dataset. The differences may be difficult to see, but they are difficult to predict as well. This question is of prime importance when digitally transmitted images are used for diagnostic purposes (especially primary diagnosis) and also related to the question of legal liability. As of today, no common point of view has been achieved on the use of lossy compression in medicine in Europe. [ACR 93] describes the legal situation of the use of lossy compression for telemedicine in the USA as of 1993:

> *A search of recent court opinions and law journals suggest that today no legal standards exist regarding image compression in radiology. The courts generally use a “reasonableness” standard. The standard likely to be fashioned may be: “What would another radiologist in the same or similar circumstances with the same or similar qualifications demand in image quality following compression?”*

DICOM/MEDICOM as the relevant standard for medical image processing (see section 4.3) supports both lossy and lossless image compression according to the JPEG standard [ISO 94], and there is an active working group on compression in the DICOM committee responsible for the development of the standard.

In the RETAIN project, image compression has not been used (except for the implicitly lossy transmission of medical images over the “video channel”, see chapter 6). The high bandwidth available on the ATM network allowed a fast transmission of images in full definition. However, for ISDN telemedicine the use of compression should be considered seriously.

6 IMAGE TRANSMISSION

An adequate image transmission in telemedicine requires that images are sent over the network in *acceptable time* and *acceptable quality*. Furthermore the network must guarantee a certain *quality of service*, e.g. connections should not frequently fail because of network congestion. This chapter describes our experiences on image quality, network protocols, bandwidth and quality of service in telemedicine.

6.1 Suitability of Transmission Techniques for Medical Images

In the third RETAIN phase all images have been digitised and converted to DICOM before transmission. In the second project phase, however, the video codecs were also used to transmit images over the “video channel” which were recorded by a camera with tripod and light table. After the trials, the participating physicians were asked about their assessment of the suitability of the different acquisition and transmission techniques for the available image modalities. Figure 6-1 displays the results of this assessment (more details are displayed in the corresponding figure in [Ret2-9, section 3.2]). The different ratings for one modality show the differing points of view of the physicians. It should also be noted that not all sites used the same digitisation equipment, which accounts for some of the differences (e.g. the poor rating for CT transmission over ATM ETSI video that is technically superior to CT over H.320). However, the ratings show a clear tendency:

- For low-resolution modalities (CT, MRI), video transmission over ISDN H.320 is acceptable. ISDN video is also fine for visual telephony or “tele-teaching”.
- All kinds of motion picture including medical video (e.g. endoscopy) and ultrasound can perfectly be transmitted using broadband video codecs, but not on ISDN.
- The best quality for still images can be reached with digital acquisition and transmission (DICOM). For high resolution modalities, a better display than standard workstation equipment is necessary (e.g. high contrast greyscale monitors).

Application	**H.320**	**ETSI**	**Software**
Network	**ISDN**	**ATM**	**DICOM**
Spatial resolution	360x288	768x576	1024x1024
Contrast resolution (display)	8 Bit (256)	8 Bit (256)	7 Bit (128)
Contrast resolution (manipulation)	-	-	12 Bit
Computed Tomography	++	o	++
Magnetic Resonance	o / ++	+	++
Digital Subtractive Angiography	o / +	+	++
Computed Radiography	--	o	o / +
Digitised X-Ray	--	o	o / +
Ultrasound still image	o	++	++
Microscope still image	-- / +	o	+
Ultrasound video	-- / o	++	--
Medical video	-- / o	++	--
Visual telephony	+	++	--
Lecturer	+	++	--
Group-to-Group video	o	++	--

Figure 6-1: Suitability of transmission techniques for medical image modalities

6.2 Network Protocols for Transmission of Digital Images

One of the most important issues in using broadband networks in medical imaging is the set of suitable network protocol stacks. Today the standardisation efforts for broadband networks mostly concern the layers one and two (physical layer and data link layer) of the OSI basic reference model [ISO 84] with ATM and DQDB protocols being used on the data link layer.

The area of medical imaging was dominated by conventional film for a long time and started its development towards digital storage and network architectures rather late compared to the general IT domain. Efforts toward standards in medical imaging have reached “critical mass” in support by vendors and users only in the beginning of the 1990s. The equipment used before was either standalone or provided connectivity between devices of a single vendor only, using vendor dependent data formats and protocols. There have also been attempts to define specialised medical vendor-independent network architectures. The ACR-NEMA 2.0 standard [NEMA 88] for example defined a protocol stack down to the physical layer, a 50-pin point-to-point interface.

The fast development of information technology in general and especially in networking clearly shows that a specialised “medical” network protocol would detach the medical imaging community from the ongoing IT developments. Even more important, there seems to be no real need for specialised “medical” protocols on the lower network layers (the transport layers 1 to 4), so there is no point in re-inventing the wheel. Recent developments in the medical imaging sector consider this and “build upon” standard network protocol suites. The DICOM standard as the most important standard for medical imaging uses either OSI networks or TCP/IP networks for data transfer. In an OSI environment, DICOM builds its networking services (DIMSE - DICOM Message Service Element) upon the OSI association control service (ISO 8650) and the P-DATA service. In a TCP/IP environment, DICOM defines a “DICOM upper layer service for TCP/IP”, which offers a subset of the OSI presentation and association services so that DICOM applications always use the same low-level network functions independent of the protocol stack. Only on the presentation and association layers DICOM defines specialised medical imaging services with its own “transfer syntaxes” (data encoding rules). The ACR standard for teleradiology [ACR 94], which was published shortly before the official release of the DICOM standard [NEMA 94], recommends that for the transmission of images and patient data:

> *New technology systems should include the current version of the ACR/NEMA image data format standard and the DICOM network standard.*

For other health care related information systems (hospital information systems, radiological information systems) standards like Health Level 7 (HL7) and EDIFACT [ISO 88] are mostly message formats defined on the application oriented layers 5-7 of the OSI reference model and in this way independent of the underlying transport system.

6.3 Bandwidth Demands

In the “First Guidelines” [Ret2-10] we claimed concerning the bandwith required for broadband telemedicine:

> *If all data streams are to be transmitted over a single ATM virtual connection, a VBR (variable bit rate) service with a guaranteed minimum bandwidth seems appropriate. This way sufficient bandwidth for audio/video and CSCW data could be guaranteed as well as a minimum bandwidth for image transfer (e.g. 2 MBit/s for image transfer). Additional available bandwidth (e.g. 8 MBit/s) could be used to decrease transmission times for “bursty” image transfer data traffic. If VBR service is not available, image transfer times can be decreased by switching off the video codec during image data transmission.*

With the additional experience of the RETAIN 3 trials, we have to revise this position slightly. According to [Ret3-6, section 3.1] the estimated average data volume per patient case was 9.3 Mbytes and the largest volume for a single case was 66 MBytes (a CT series with 132 images, fully transmitted for a consultation). The RETAIN teleradiology system allowed either to transmit digital images at 2 Mbit/s or to switch off video (not sound) during image transmission, in this way reaching a bandwidth of 8 Mbit/s for image transmission. Whereas a bandwidth of 8 Mbit/s for image transmission is very pleasant to have – there is almost no perceptible difference to an inhouse transmission of the images over Ethernet (e.g. from a CT scanner to the teleradiology workstation) – it must be questioned if this bandwidth is really necessary. At 2 Mbit/s, the average 9.3 Mbytes require a transmission time of 37 seconds and even the case of 66 MBytes could be transmitted within less than 4.5 minutes, a time that can be used by the physicians to present the case history and previous findings. Therefore, even with image transmission during the conference (e.g. with the physicians waiting at the teleradiology systems), a bandwidth of 2 Mbit/s for image transmission seems to be appropriate for the vast majority of applications.

The audio/video transmission according to the ETSI algorithm ETS 300-174 [ETSI 92] required a constant bandwidth of approximately 8.5 Mbit/s on the ATM network. For commercial ATM video transmission systems, the use of the (similar) MPEG-2 algorithm is expected, which will decrease bandwidth requirements to about 6 Mbit/s. At this bandwidth, a transmission of “medical video” (e.g. ultrasound or endoscopy) will still be possible in good quality.

Besides these bandwidth requirements of a “high-end” system, which makes no compromise on image quality and transmission speed, significantly smaller bandwidths may be acceptable if certain limitations in video quality and transmission time can be accepted. This is of prime importance for users of narrowband networks (e.g. ISDN), even if the narrowband network is only used for a “dial-in facility” to a broadband-based telemedicine network, as practised in RETAIN (see [Ret3-6] section 2.1.4). If no

medical video is to be transmitted, conventional ISDN H.320 video codecs perform well for simple person-to-person visual telephony, at bandwidths of 384 kBit/s or even 128 kBit/s.
For the transmission of digital medical images, significantly lower bandwidths may be acceptable as well if either images can always be transmitted in advance to the conference (e.g. one hour before consultation) or if "lossy" compression is acceptable (see section 5.2). For example, if six ISDN B-channels are used in parallel for image transmission (as used in the RETAIN trials), a lossy compression of 5.3:1 would be sufficient to reach the same transmission times as an ATM based system at 2 Mbit/s. If lossless compression (at a compression ratio of 2:1) was used, the transmission of the average volume (9.3 Mbytes) would take about 1.5 minutes, and the maximum case with 66 Mbytes would require less than 12 minutes – this still seems acceptable for many applications.

6.4 Quality of Service

The characteristics of a telecommunications service are called "Quality of Service", and some network protocols (especially ATM) support a detailed definition of QoS parameters for individual connections. Besides the bandwidth required for telemedical consulation discussed in section 6.3 (which is also a QoS parameter), additional requirements can be derived from the experiences in RETAIN:

- *Latency:* The data transmission for computer supported cooperative work (CSCW, see section 7.2) does not require high bandwidth (in [Ret2-9] we have stated that even 64kBit/s proved to be sufficient). Latency (i.e. the delay each packet sustains during transmission), however, is critical for CSCW data since synchronisation messages influence the user interface "reactivity" on user input. Studies indicate that graphical user interfaces should react within 0.25 seconds on user actions (mouse button clicks etc.). If not, the user perceives the graphical user interface as "slow". This means that a latency of less than 0.1 seconds per unidirectional CSCW synchronisation message should be achieved.
- *Realtime transmission:* Besides low latency, the transmission of real-time information (audio and video) requires a *constant* latency and a guaranteed minimum bit rate. Both ISDN and ATM are well suited for this kind of data transmission.
- *Constant bit rate versus variable bit rate:* The experimental international ATM network "JAMES" (see [Ret3-6] section 2.1) currently offers only "constant bit rate" services (CBR) in form of switched virtual connections (SVC, more or less "virtual leased lines"). Whereas audio and video transmission require only CBR services, the transmission of digital medical images and CSCW discussion produce "bursty" data (i.e. data with a significant variance in bandwidth requirements over time). Although image transmission worked fine with CBR connections when sufficient bandwidth was reserved (see section 6.3), it must be considered as a waste of bandwidth and, consequently, money. Optimum support for bursty data traffic can only be provided by "variable bit rate" (VBR) services which are defined in the ATM standards but not yet supported by the JAMES network.
- *Cell loss:* The RETAIN trials have shown that current TCP/IP implementations are not able to sufficiently manage cell loss in an ATM network. Even a small ATM cell loss leads to a dramatical decrease in transmission speed (see [Ret3-6], section 2.2). Therefore, with current implementations of "TCP/IP over ATM", only ATM connections that guarantee that no cell loss in the network will occur, are usable at all.
- *Connection setup:* In [Ret2-9] we complained about the impractical connection establishment procedures on the "European ATM Pilot", the predecessor to the JAMES network:

  > *A significant restriction even for the limited trials performed in this project were the ATM connection establishment procedures which always took several days. While some processing time for connection establishment requests is acceptable for radiological conferences on a regular basis (e.g. once or twice a week), this is not acceptable for emergency use. In emergency situations where patient transportation or actual treatment planning is to be discussed, it will not be possible to wait several hours or even days for a connection. For this application scenario a quick and simple "dial-through" service will be necessary.*

The reliability of the connection establishment procedures has improved since 1995 (see below), but the procedure is still “connection setup by fax”: Any connection must be requested from the network operators at least a few days in advance. It is not possible to “dial” a connection, although the ATM standards support so-called “signalling services” (see section 3.2) for this purpose. Therefore the conclusion cited above still holds: The procedure might be acceptable for regular (e.g. teleteaching) conferences, but not if quick reaction to the current situation is required.

- *Availability and reliability:* During the 1995 trial period, several times the ATM connection failed to be established at all although it was correctly requested. This situation has definitely improved with the JAMES network, but still misunderstandings between network operators prevented some of our trials (especially the technically complex “multi-point” trials, see [Ret3-6] sections 2.4.2 and 2.4.3) However, these problems are clearly related to the fact that the JAMES network itself is of experimental nature and does not offer commercial services and commercial service quality. More important is the question of availability: Physicians will not rely on a service which more or less often fails because of network congestion or technical problems, especially for emergency use. This also means that sufficient total bandwidth must be available in the network. Frequently “occupied” lines (network congestion) will absolutely discourage their usage for health care.

7 IMAGE REVIEW AND MANIPULATION

According to the “remote consultation” scenario examined in RETAIN, an expert receives medical images and patient related data, forms an opinion on the case and then advises the remote physician on diagnosis or treatment of the case. To fulfil this task, the expert must be able to visualise the medical images and related data adequately and to communicate with the remote physician requesting advice. A multitude of possibilities for communication between expert and physician seeking advice exists (e.g. in a “classical” consultation the expert would prepare a diagnosis and call the requesting physician on the telephone). However, a means of communications suggesting itself if a remote consultation on digital medical images transmitted between computers is being performed, is the use of software for “computer supported cooperative work” (CSCW, see section 7.2). In addition, either audio communication (e.g. telephony) or audio-visual communications (visual telephony) are used for human communication.

7.1 Display Devices

In the RETAIN project, standard “off-the-shelf” workstation colour monitors were used for the visualisation of medical images. As Figure 6-1 shows, the physicians assessed the image quality provided by these monitors as very good for low and medium resolution modalities (CT, MRI, DSA), but only as “good” or “acceptable” for high resolution modalities (X-ray, CR). The ACR standard for teleradiology [ACR 94] recommends that display devices for small matrix modalities should offer spatial resolutions of 512x480 at 256 shades of grey or better – a requirement that can be fulfilled with every workstation today. However, for the visualisation of images from large matrix modalities (X-ray and CR), monitors with a spatial resolution of 2048x2048 with 256 shades of grey or better are recommended. This requirement can only be fulfilled with high-resolution grey scale monitors. [ACR 94] recommends that such monitors should offer a luminance of at least 50 foot-lamberts.

7.2 Computer Supported Cooperative Work

The term “computer supported cooperative work” (CSCW) refers to cooperative human work that makes use of specialised multi-user software allowing to exchange information in form of electronic messages or to work on a common database in a coordinated way.

7.2.1 Synchronous CSCW

Software for *synchronous CSCW* allows spatially remote users to concurrently visualise and manipulate data from a common dataset according to the “what you see is what I see” (WYSIWIS) principle. The distributed application is responsible for keeping the data and the displays on all participating systems synchronous and consistent. A synchronous CSCW application for tele-radiological conferencing must at least enable users to select and view medical images and to interactively change the VOI windowing (see section 4.2). A tele-cursor that allows the users to point to details in the image is also required for discussion. [ACR 94] also recommends the following functionality for image review:

- a magnification function
- the capability of inverting the grey-scale range of the displayed image
- the capability of rotating and flipping the displayed images
- the capability of accurate linear measurements

Desirable additional CSCW functionality includes displaying supplementary patient, study and series related textual information (which must necessarily be available at least at the sender's site) and the possibility to interactively annotate the images in textual and graphical form (e.g. draw a circle around “something” visible on the image). It should be possible to store these “notes” taken during the conference and review them locally later.

Whereas an “import” function allowing the CSCW application to acquire information, especially medical images, from a variety of sources as described in chapter 4, is obviously required, an *“export”* function might be considered a potential danger for data protection because it allows receivers of medical information to copy and redistribute it by means that are out of the control of the sender.

The functionality of a CSCW application can be described in terms of three key features: *Representation* of the data objects and relations between them, *presentation* of the data to the user and *synchronisation* between multiple interactive users. A multitude of approaches for these tasks exists (screen sharing vs. replicated applications, synchronisation on application or communication system level, use of distributed databases vs. data replication in advance to cooperation etc.), but yet there are no accepted standards that would guarantee interoperability between implementations from different vendors and for different platforms. This means that users are still in the unfortunate situation that once a decision for a particular product has been made, all users wishing to participate on the “teleconference network” are tied down to this single product and vendor.

7.2.2 Asynchronous CSCW

In addition to synchronous CSCW, telemedicine can also make use of *asynchronous CSCW*, which can be described as a medical “electronic multi-media message tool” allowing to create case presentations including images, patient related data and explanations (in textual or spoken form) which can be transmitted via e-Mail or similar techniques and reviewed locally (offline) after receipt. In [Ret3-6], the physicians participating in RETAIN stated that such a tool would be a very useful enhancement of the synchronous CSCW software used in the RETAIN trials, allowing the consulted institution to select the appropriate specialist for the case and allowing the consulted expert to prepare for the consultation. Even the sole availability of asynchronous CSCW (no synchronous conferencing) was assessed as a useful tool compared to conventional consultation by the majority of physicians.

If synchronous and asynchronous CSCW are to be combined, it must be possible to use medical “multimedia messages” as a basis for a synchronous case discussion – physicians will most probably not be willing to use two different tools (e.g. different user interfaces) for “online” and “offline” case review. Therefore, an integrated approach will require an appropriate representation of data which allows serialisation of the information (e.g. creation of electronic messages) as well as a synchronised visualisation (WYSIWIS).

Multimedia data models usually describe objects and relationships between objects on a rather high and abstract level. Therefore, it seems only consequent and logical to use the high-level functions for a distributed object communication (e.g. ToolTalk, Distributed Objects, CORBA) which are offered by many operating systems today for synchronous CSCW applications. However, in the framework of the RETAIN trials we have made the experience that communication protocols which operate on a high level of abstraction and consequently require a rather complex protocol stack, may become a problem under certain circumstances when used in wide area network environments (see [Ret3-6] section 2.2.4). Usually wide area networks fulfil only lower requirements on latency, bandwidth and loss of data (e.g. bit error rate) than LANs. Protocol stacks which are not – or poorly – prepared to cope with the limitations of wide area transmission may work perfectly in a LAN environment, but totally fail on wide area networks without any possibility for the software developer to influence the behaviour of the protocol stack. Therefore, it has to be recommended that software developers should select the protocol stack for synchronous CSCW with care and make sure that it remains manageable and controllable.

7.3 Videoconference versus Telephony

In the beginning of the RETAIN project there was a discussion amongst the participating physicians whether visual telephony (instead of conventional telephony) would only be a “nice toy” or a “valuable tool”. Commercial teleradiology systems exist which do not offer a means for visual telephony, so the question arises for which applications visual telephony – which accounts for a significant amount of data and, in turn, transmission costs – is really required. During the RETAIN trials, the video image has been used to transmit:

- The “head and shoulder” image of the conference partners (visual telephony)
- “Windows” between meeting rooms. Often multiple physicians participated in tele-medical conferences on both sides of the connection. In this case the visual telephone system allowed to “look into” the other side's meeting room (video conference)
- Medical images captured by a video camera from film (image acquisition)
- Medical video, e.g. ultrasound examinations or endoscopy video recordings (video transmission)

The importance of *seeing* the conference partner in addition to hearing him (visual telephony) is often underestimated. Non-verbal communication plays an especially important role if the conference partners do not know each other or even speak a foreign language (as practised in RETAIN, where all international consultations were performed in English). The following citation from [Ret2-9] may serve as a typical example for the physicians' reaction after the trials:

> *…it is considered by many physicians that videoconferencing is only a gadget and that the medical problems could be discussed with a simple audio transmission. This is misjudging the importance of the non-verbal… communication. If this is considered to be important, then seeing the image of the conference partner is of paramount importance… It is certain that it is perfectly possible to operate with a telephone handset and no image, but something would be lost.*

Simple point-to-point visual telephony does not require “TV quality” (e.g. MPEG2 or ETSI broadband video), as the physicians' image quality assessments in section 6.1 have confirmed. However, if medical images or medical video recordings have to be transmitted, a high quality video connection is absolutely necessary. Therefore, designers of telemedicine conference systems should carefully consider whether a renunciation of video transmission is possible without a decrease in the quality of human communication between the physicians and, in turn, health care delivery for the patients affected.

8 COSTS AND BENEFITS

Currently the health care systems of most European countries face a similar challenge: An increasingly ageing population, stagnancy of the gross national product and the ever-increasing costs of modern “high-tech medicine” services put an intense economic pressure on the health care systems.
In this situation, a new technology promising to improve health care will not only have to improve the quality or delivery of care in order to be successful (like the introduction of computed tomography in the 1970s which improved quality of care at the expense of increased treatment costs), but will also have to prove its potential to rationalise and cut down costs in the hospitals.
A multitude of telemedicine pilot projects has been and is being carried out in Europe, however, as [Telmed1] points out, mostly in non-commercial settings, e.g. within European R&D programmes. Although virtually all telemedicine pilots claim benefits in health care delivery and most of them also point out possible cost and resource savings by the use of telemedical services, few quantitative in-

formation about costs and benefits of telemedicine is available. The financial benefits most usually claimed in literature on telemedicine (see [Ret3-6] section 7.2 for more details) are:

- *Reduction of transport and travel costs:* Avoidance of unnecessary patient transports and reduction of travel costs for physicians.
- *Reduction of personnel costs:* Diffusion of tasks carried out by higher paid personnel to lower paid personnel.
- *Rationalisation savings:* Reduction of patients' hospitalisation times, avoidance of unnecessary double examinations and a better capacity utilisation of expensive equipment.

In addition to such savings hospitals offering expert advice to remote institutions or requesting second opinions on behalf of their patients may consider “telemedicine” as an additional medical service that is charged to the patient or health care insurance if national health care regulations allow this. Besides these potential purely financial benefits, there are also medical benefits that might motivate health care providers to make use of telemedicine, but which can hardly be quantified (see [Ret3-6] section 1.3 for more details):

- *Improvement of patient care:* State-of-the-art health care by access to up-to-date information; quicker treatment (especially in emergency cases)
- *Improvement of diagnostic and therapy procedures:* Safeguarding of decisions by expert advice, better coordination of patient transports, possibility to “outsource” services rarely used
- *Improvement of skills and know-how:* Diffusion of expert knowledge, acquisition of “interesting” cases (for knowledge centres), continued training by regular teleconferencing.

A quantification of all financial benefits mentioned above will only be possible *after* introduction of telemedical services because most of them cannot easily be predicted and require long-term statistical analysis (e.g. on the reduction of double examinations or patient transports).

Whereas few “hard” figures are available yet on savings realised by a practical, non-experimental use of telemedicine services, the costs for the implementation of such services can be estimated rather easily. In addition to the investment costs (e.g. workstation, video conference equipment, installation of network access) which depend on the available infrastructure in hospitals (e.g. availability of LAN, PACS network, digital modalities, film scanner etc.), a cost evaluation for a telemedical application should quantify regular costs (regular fees for the telecommunications network, maintenance and replacement costs) and usage dependent costs (connection fees, personnel costs, administrative overheads and consultation fees if applicable).

Since the health care sector is no free market in most EU countries, a cost–benefit analysis for a particular application must not only quantify costs and benefits, but also consider which costs are carried by whom (e.g. hospital, health care insurance, government, patient…) and who benefits (in financial terms) from the savings realised by the use of telemedical services. It is a general problem in many health care systems that savings do not benefit the institution responsible for carrying the costs, with the result that services that would save costs on a macro-economic level cannot be realised. Therefore, an introduction of telemedical services may require agreements (e.g. about cost reimbursement) between different institutions in the health care system.

The cost analysis performed for RETAIN [Ret3-6, chapter 7] indicates that the costs for the use of broadband networks (especially ATM) in telemedicine are prohibitive in many European countries today. However, indications exist that communication costs may decrease significantly in the close future (e.g. after the deregulation of the European telecommunications market in 1998) and that ATM may become an attractive alternative to established narrowband network services like ISDN. However, expensive “high-tech” telemedicine systems will be financially viable only if used intensively, and potential users of such services should, therefore, carefully evaluate their real need for communication in advance to the introduction of such systems.

9 ORGANISATIONAL RECOMMENDATIONS

At first glance telemedicine is just "medicine practised at distance". A regular and intensive use of telemedical services will, however, affect the way medical services are delivered to the patient, and this will in turn affect hospital organisation. The structural change visible in many European health care systems today might catalytically accelerate such developments. Therefore, hospital managers would do well to consider organisational aspects *in advance* to the introduction of telemedical services.

9.1 Workflow and Organisational Structure

As [Ret3-6] points out, telemedicine promises to cut down on costs by accelerating diagnostic procedures, improving communication between physicians and, finally, leading to a quicker and better treatment of patients. However, the realisation of these benefits will necessarily involve changes in hospitals' workflow and job outlines:

- Most European health care systems show a trend towards more specialisation, centralised service provision and outsourcing. The possibilities offered by telemedicine may coincide with such trends and may in turn be facilitated by the increased need for efficient communications between physicians and health care institutions "produced" by these structural changes.
- Currently, medical expert advice is mostly given on a voluntary basis besides regular tasks. As the financial analysis in [Ret3-6] indicates, "high-tech" telemedicine (e.g. using broadband networks) will only be viable if used intensively. This means that experts will have to reserve a certain part of their regular work schedule for the provision of medical advice over telemedicine systems, which is clearly a change in physicians' job outlines. Such additional tasks may have to be compensated by additional medical staff, and reimbursement of the resulting costs must be taken into account.
- Telemedicine makes use of a complex technology combining IT with telecommunications. Neither paramedics nor physicians will be able to manage such systems with their current training. Telemedicine could, therefore, produce new job outlines for technicians in hospitals, very much as the position of the "PACS manager" that becomes necessary with the introduction of digital image archives in hospitals.
- If telemedicine leads to decreased hospitalisation times for patients, as sometimes claimed, the introduction of this service is a step towards a streamlined "just in time" medicine. On the long term this will affect the way medical care is delivered to the patient, although it can hardly be predicted where developments might lead to.
- It is sometimes claimed that telemedicine leads to a diffusion of tasks carries out by higher paid personnel to lower paid personnel such as nurses and paramedics. Without a judgement whether such a development would be in the interest of the patient, it would necessarily result in a shift in hospitals' staff structure on the long term.
- Finally, the permanent availability of external expertise might result in changes in the conventional competence hierarchy in which the department leader usually makes the ultimate decisions. The question of professional competence and acceptance by colleagues is a reason why physicians might hesitate to use this technology, as the following section explains in more detail.

9.2 Competence and Personal Communication

An introduction of telemedical services will change the way physicians communicate. In addition to all technical, financial and organisational aspects, the question of user acceptance of telemedical services should be considered. Physicians may feel reluctant to use such services because of the questions of competence and personal communication touched by the introduction of telemedicine:

- Although radiology is a field of medicine where "high-tech" equipment has been used for many years, many radiologists are not used to work with computers. Telemedicine adds the additional complexity of telecommunications to information technology, and many physicians may feel inhibited to use a system they do not fully understand.

- Physicians may be reluctant to request advice from remote experts because they feel that by requesting advice they admit to be incompetent, as [Gass 94] points out. This problem applies especially when the physician requesting advice does not personally know the consulted expert. On the other hand, the consulted expert may feel pressed to make a decision (to prove his expertise) even if it was inappropriate in the given situation. Experience has shown that the threshold of inhibitions is lower when the objective competence of the conversationalists is very different, if the spatial distance is very large or if the consultant is highly qualified.
- Long-term telemedicine projects (e.g. [Gass 94]) have shown that communication between physicians is often oriented towards certain persons (e.g. consulted experts), not institutions. Often even advice requests are only issued by a department leader. Personnel change can, therefore, cut established communication relationships between complete departments or institutions.

10 LEGAL RECOMMENDATIONS

Health care as a sector of prime importance for the society is affected by many government regulations in most European countries. However, the organisation of the health care sector is different in every EU country. This makes it difficult to argue about “legal aspects of telemedicine in Europe” in general. Common points, which can be addressed although, concern the questions of an appropriate protection of patient related data (data protection) and responsibilities with possible legal consequences (liability) for physicians using or providing telemedical services.

10.1 Data Protection

Telemedical consultation involves the transmission of confident patient related data. Although data may be anonymised before transmission to a remote expert (which was considered as an essential feature of a teleradiology system by the physicians involved in the RETAIN trials [Ret3-6]), the case history is most often required by the expert and could be used to identify the patient later. Therefore, precaution must be taken to ensure the confidentiality of patient data when used in telemedicine, as [McCle 95] points out:

> *Picard emphasized the fact that physicians owe a legally enforcable duty of confidentiality to their patients. … It is therefore essential that telemedicine does not detract from this confidentiality in any way. Numerous examples have been raised by many writers and practitioners. For example, there has been some public discussion about confidentiality issues when medical details were sent by fax. Fax machines were often placed in non-secure or open environments to which non-medical staff had access. This kind of failure of confidentiality must be prevented if telemedicine is to succeed in the manner intended.*

Data protection in terms of *security* and *privacy* is only part of the “big picture” of information technology (IT) security, in which EU standards providing a sound basis for the development and implementation of security concepts are currently being developed, as [Baur 96] points out. Along with organisational, educational and technical aspects of IT security, an important part of any security concept for teleradiology is an appropriate software support. Techniques often discussed in this context are:

- *Encryption:* Two types of encryption algorithms are in use today, symmetrical and unsymmetrical encryption. Symmetrical encryption algorithms – a well-known algorithm is the “Data Encryption Standard” (DES) – use the same key for encryption and decryption. Typically, these algorithms are comparatively fast but not as difficult to break as unsymmetrical algorithms. In addition, all symmetrical algorithms share the problem that the encryption key for a set of data must be exchanged between communication partners in a safe way. Unsymmetrical algorithms (also called “public key encryption”) use two keys, a private key and a public key. Data encrypted with the private key can be decrypted with the public key, and vice versa. The public keys are well known to all communication partners. Before transmission, data is encrypted with the public key of the receiver, allowing only him (as the owner of the private key) to decrypt the data. Public key encryption schemes are computationally complex and, therefore, too slow for encryption of large amounts of data. In practise, often hybrid approaches are used in which data is encrypted with symmetrical algorithms, but keys are randomly generated, frequently changed and transmitted in public key encrypted form. It should be noted that application of encryption technology is not allowed or significantly restricted in some EU countries. For instance in France electronic encryption was effectively illegal according to law 90-1170 (dated 29. 12. 1990). This has been changed in 1996, where a new regulation allowed the use of encryption under certain circumstances and restrictions.

- *Digital signature:* Public key encryption can be used to verify that data has been sent by a certain sender and has not been modified during transmission. In its most simple form, data is transmitted twice – one time unencrypted and one time encrypted with the sender's private key. The receiver can decode the second message with the sender's public key and compare it to data transmitted unencrypted. If the data is identical, it must have been sent by the owner of the sender's private key. In practice, only a “fingerprint” of the original data set, created by so-called “secure hash algorithms” is encrypted with the private key and transmitted with the unencrypted data. Of course digital signature can additionally be combined with any form of encryption.
- *Authentication:* Although digital signatures are considered as “trustworthy” today, the private keys involved in public encryption are usually several hundred binary digits long and cannot be remembered by human users. Therefore, private keys are stored on storage media which could possibly be accessed by unauthorised persons. Secure authentication measures attempt to prevent this case, e.g. by using “intelligent” chip-cards containing the private keys in combination with password protection.

Data protection regulations are national law, but the principles of data security and privacy are probably the same everywhere. The German data protection law [BDSG 90] contains an annex describing measures for data protection in general terms. These informal rules, often referred to as the “ten commandments of data protection”, show which areas have to be considered when a security concept for an IT system is developed. The annex states that if personal data is processed automatically, appropriate measures have to been taken…

- to prevent admittance of unauthorised persons to the data processing devices (admittance control)
- to prevent unauthorised reading, copying, manipulation or removal of storage media (storage media control)
- to prevent unauthorised input, perusal, manipulation or erasure of stored personal data (storage control)
- to prevent unauthorised use of data processing devices by means of telecommunications (user control)
- to ensure that persons authorised to use a data processing system can only access data according to their access rights (access control)
- to ensure that it can be determined and examined in which places personal data can be transmitted by means of telecommunications (transmission control)
- to ensure that it can be determined and examined later which personal data has been input by whom and at which time (input control)
- to ensure that personal data that is processed by order can only be processed according to the customer's instructions (order control)
- to prevent unauthorised reading, copying, manipulation or erasure of personal data during transmission or transport of storage media (transport control)
- to form the internal company or authority organisation in a way that meets the special requirements of data protection (organisation control)

10.2 Liability

Although health care legislation differs from country to country, in all countries the physician is responsible to make sure that his treatment of patients is in compliance with the law and the accepted standards and ethics of practice for his profession. A physician may be held liable for failure to comply to these duties. Since telemedicine is a rather new field with many research projects and few "commercial" applications, the question arises in which cases physicians may be held liable for malpractice resulting from inappropriate use of telemedical services. To our knowledge, no liability lawsuit related to telemedicine has been publicised so far, but as [Smit 96] points out, this situation is not very likely to remain:

> *In the current experimental stage of the telemedicine field, many developments may not be safe, either literally or from the viewpoint of legal defence. As the use of telemedicine becomes more widespread, it is almost certainly only a matter of time before some highly publicized telemedical accident occurs, probably with adverse legal and financial consequences. This could create a climate in which telemedicine may be in the best interests of patients or even the only practical mechanism for health care delivery, but clinicians are reluctant to practise telemedicine because they must depend utterly on untrustworthy systems, yet still be totally responsible for the results.*

Since national health care regulations in Europe can be compared as little as national jurisdiction, few recommendations can be given in general terms. However, telemedicine should be treated with the same professionality as any other field of health care. This includes:

- Make sure that telemedicine is applied in compliance with national law and accepted practice of health care professionals.
- Consider which responsibilities are implicitly accepted by requesting or offering remote advice over a telecommunications system.
- If there is uncertainty on the legal position for the use of telemedical services according to national law (which is very likely), or if international telemedical consultation is to be practised, a contractual clarification of mutual rights and duties is to be recommended.

Whereas the first recommendation should require no further explanation, the second and third will be explained on examples. The question whether a specialist may be held liable for incorrect advice given from remote leading to mistreatment of a patient can be answered differently in different countries. In most European countries, the physician actually treating the patient is always responsible for the results, no matter where he has requested advice from. However, as [Brah 95] explains, this is different in the UK (at least in England and Wales):

> *What are the medicolegal implications of teleconsulting? What if the consultant advices 'minor surgery' which the GP carries out under the consultant's televised supervision…and which causes the patient injury? …Telemedicine operated by videoconsultation at which the patient, GP and the specialist can see and consult interactively …is more similar to the normal clinical situation, save that the examination and imaging are, at one remove, assisted by another doctor acting in conjunction with the specialist doctor. …The ultimate responsibility for any treatment decision in hospital will stop with the consultant if he or she took or endorsed it positively or negatively…*

This means that a specialist giving advice to a patient in the UK may be held liable for incorrect advice according to UK law, although the GP is not totally relieved from his responsibility. On the question of liability in international telemedicine, [Brah 95] sets out (again for the UK situation):

> *If, say, a patient residing in England…, as does the GP, was examined in the GP's surgery but was videoconsulting with a specialist practising from… outside the UK…, will the patient be able to bring an action against the consultant… in respect of a consultation that took place in England? It would seem that the consultation was provided to reach the patient in England… and thus arguably took place in England rather than… at the consultant's office. However, it is*

arguable that an action could be brought against the consultant in the different jurisdiction from which the advice was given…

This means that the English patient would have the possibility to bring action against the consulted specialist either according to UK law or according to the jurisdiction under which advice was given, whatever seems to be advantageous. Although the probability of such lawsuits should not be overestimated since the vast majority of telemedical services are and will be performed on a regional or national basis, physicians should make sure that possible uncertainties of this kind are clarified contractually.
Finally, telemedicine is based on telecommunications networks that may or may not be reliable over time. Therefore, users of such services should take appropriate precautions to manage the risk necessarily involved in using such technology, as [Dark 96] points out:

If a service is based on the use of telemedicine, it is important to ensure that the technical specifications are adequate, that the system is sufficiently reliable, and that there are adequate back-up provisions in the case of system failure.

11 REFERENCES

[ACR 93] American College of Radiology, Committee on Research and Technology Assessment: A Guide to Teleradiology Systems, ACR, Reston, 1993

[ACR 94] American College of Radiology, Resolution 21–1994: ACR Standard for Teleradiology, ACR, Reston, 1994

[Baur 96] Baur HJ et al: Aspects of data security and privacy in teleradiology, in: Proceedings CAR '96, Computer Assisted Radiology – Telemedicine/Teleradiology, Elsevier, pp. 525-530, 1996

[BDSG 90] Bundesdatenschutzgesetz (Artikel 1 des Gesetzes zur Fortentwicklung der Datenverarbeitung und des Datenschutzes), BGBl. IS 2954 - 2955, 1990 (in German language)

[Brah 95] Brahams D: The medicolegal implications of teleconsulting in the UK, in: Journal of Telemedicine and Telecare, Vol. 1, pp. 196–201, 1995

[CEN 96a] European Committee for Standardization: Medical Image and Related Data Interchange Format Standards – MEDICOM, CEN/TC 251 prENV 12052 (1996)

[CEN 96b] European Committee for Standardization – Medical Informatics – Medical Imaging and Multi-Media: Report: Medical Imaging Scenario and MEDICOM Model, Draft 1.1, CEN/TC251|WG4, 1996

[Come 91] Comer, Douglas E.: Internetworking with TCP/IP Vol 1: Principles, Protocols and Architecture, 2nd Edition, Prentice-Hall, Englewood Cliffs N.J., 1991

[Dark 96] Darkins, Adam: The management of clinical risk in telemedicine applications, in: Journal of Telemedicine and Telecare, Vol. 2 No. 4, The Royal Society of Medicine Press, London, pp. 179-184 (1996)

[ETSI 92] European Telecommunications Standards Institute: Network Aspects – Digital coding of component television signals for contribution quality applications in the range 34–45 Mbit/s, ETS 300-174 (1992)

[EWOS 93] European Workshop for Open Systems: Profiles for Medical Image Interchange, Report EWOS PT N024, 1993

[Gass 94] Gaßner, Robert: Videokommunikation in der Medizin. Begleitforschung zum Anwendungsprojekt MEDKOM, IZT WerkstattBericht Nr. 15, Berlin 1994 (in German language)

[Hein 93] Heinanen, J: Multiprotocol Encapsulation over ATM Adaption Layer 5, Internet Request for Comment RFC 1483 (1993)

[ISO 84] International Organization for Standardisation: Information Processing Systems - Open Systems Interconnection - Basic Reference Model, ISO 7498:1984

[ISO 88] International Organization for Standardisation: Electronic Data Interchange for Administration, Commerce and Transport (EDIFACT), Application Level Syntax Rules, ISO 9735:1988

[ISO 94] ISO/IEC 10918-1:1994 Information technology -- Digital compression and coding of continuous-tone still images: Requirements and guidelines

[ITU 93] ITU-T Recommendation H.320: Line transmission of non-telephone signals - narrow-band visual telephone systems and terminal equipment, 1993

[ITU 93b] ITU-T Recommendation H.261: Line transmission of non-telephone signals - video codec for audiovisual services at p x 64 kbits, 1993

[Laub 94] Laubach, M: Classical IP and ARP over ATM, Internet Request for Comment RFC 1577 (1994)

[McCle 95] McClelland I, Adamson K, Black ND: Information issues in telemedicine systems, in: Journal of Telemedicine and Telecare, Vol. 1, pp. 7–12, 1995

[NEMA 88] ACR-NEMA 300-1988: Digital Imaging and Communications

[NEMA 94] NEMA Standards Publication PS3.X(1994): Digital Imaging and Communications in Medicine, Parts 1-10

[Pett 96] Pettersen, Sture: Netzwerk für ärztliche Konsultationen, in: Deutsche Telekom – 3. TeleMedizin Symposium, Bonn 1996 (in German language)

[Ret2-9] RETAIN II (TEN-IBC B-2012) Deliverable 9: Analysis of the Trials – User and CIG Point of View, OFFIS, 1995

[Ret2-10] RETAIN II (TEN-IBC B-2012) Deliverable 10: First Guidelines for TEN-IBC in Medical Imaging, OFFIS, 1995

[Ret3-1] RETAIN III (TEN-IBC B-3012) Deliverable 1: Dissemination Actions, CERIUM, 1997

[Ret3-2] RETAIN III (TEN-IBC B-3012) Deliverable 2: Networking Infrastructures, AQL, 1997

[Ret3-3] RETAIN III (TEN-IBC B-3012) Deliverable 3: Terminal Specifications, THOMSON Broadcast Systems, 1996

[Ret3-4] RETAIN III (TEN-IBC B-3012) Deliverable 4: Application Specifications, CERIUM, 1996

[Ret3-5] RETAIN III (TEN-IBC B-3012) Deliverable 5: Description of Trials Performance, CERIUM, 1997

[Ret3-6] RETAIN III (TEN-IBC B-3012) Deliverable 6: Analysis of the Trials – User and CIG Point of View, OFFIS, 1997

[Smit 96] Smith MF: Telemedicine and safety, in: Journal of Telemedicine and Telecare, Vol. 2 Supplement 1, pp. 33–36, 1996

[Telmed1] TELMED Deliverable 1: The Impact of Telematics on the Healthcare Sector – Report on the State of the Art, TI/ECWS/FORMIT, 1996