Project report

Croatian Island Telemedicine System Project: Public Health and Technical Evaluation

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Preface

The questions we address in this report are based on dialogue between the Norwegian and Croatian partners in the project. The Norwegian partners have been visiting Croatia three times, once in 2005 and twice in 2006, and the Croatian partners visited Norway in autumn 2006. In 2005 the Norwegian partners met Croatian partners in Zagreb. In June 2006 the Norwegian project members gave a presentation at the 3rd Croatian & International Congress on Telemedicine and e-Health in Hvar of some cases and experiences in Norway. The Croatian partners visited NCT in October 2006 where members of the staff at NCT and the University Hospital of North Norway presented different telemedicine projects. The last meeting took place in Croatia in December 2006. We visited Split, the islands of Hvar and Brac, and Zagreb. These meetings have represented an opportunity to discuss the focus and the content of this report. This discussion has been followed up by e-mail correspondence in January 2007. In the report are also included issues that the Norwegian partners consider to be of interest for the implementation of telemedicine in Croatia.

The purpose of this report is to analyze and describe some challenges to implementation of telemedicine services and how we have tried to solve these challenges in Norway. The content that is presented here is based on Norwegian as well as international experiences. The report is not a comprehensive recollection of telemedicine applications or telemedicine services. A presentation of telemedicine applications in Norway was given to our Croatian partners when they visited the Norwegian Centre for Telemedicine in 2006.

The report is written by Vedad Hadziavdic, Frank Larsen and Leif Erik Nohr, all members of the staff at the Norwegian Centre for Telemedicine. The report is structured in three parts, and each part is written by one of the three authors. The content of the different parts reflects the educational backgrounds of the authors. In part one, Hadziavdic looks at technological issues and telecommunications approaches, in part two, Larsen discusses organizational barriers to implementation of telemedicine and in part three, Nohr considers regulations and legal issues.

The first part of the report addresses technological issues that have been discussed. During the initiation of the project, the partners agreed to address certain technological issues outlined in the project contract. The agreement was reached based on the needs and wishes of the Croatian side and the relevant experience and knowledge of the Norwegian side. Some of the issues (Teleradiology) where extensively presented and discussed with the head of the Teleradiology Department in Tromsø during Croatian delegation's visit to Tromsø. However, during this and subsequent meetings, new issues emerged and Mr. Mladen Novosel added a comprehensive description of an envisioned fully automated telemedical center, that he wished to discuss. The partners agreed that these issues should be examined and this has affected content of the final report. On the issues where NST has had experience and knowledge, specific technical issues have been added. On the issues where NST has done pilot tests but not the full technical implementation, NTS's engineers have expressed their opinions and these have been reported. Many of the issues raised in Mr. Novosel's document, however, were outside the scope of NST's experience and knowledge. Some of the issues have not been tried out anywhere in the world, to the best of our knowledge.

The second part of the report looks at the process of implementation of telemedicine. Telemedicine is not just a technology; it's also a way of working. When we try to implement telemedicine we also have to consider the organizational arrangements and the health care workers. The chapter begins with a definition of telemedicine. There are different definitions and we will apply a broad concept of telemedicine that includes a variety of actors, technologies and services. The main theme in this part is about barriers and facilitators to implementation of telemedicine. First we report from a study of GPs experiences with telemedicine. Training, remuneration and changes to routines are considered to be important factors. Next, a national framework for implementation of telemedicine is presented. But our main concern in this chapter is to outline some principle we should apply when we try to implement telemedicine. Teleconsultation is one the most frequently used telemedicine techniques and in the last section we describe some factors that have to be considered when we want to extract the maximum benefit from a teleconsultation.

The third part of the report deals with a number of legal issues in telemedicine and eHealth. Legal issues have been discussed within the project both at the meeting and conference in Hvar and during the meetings we had in Tromso. Prior to this report, we have received a number of quite specific questions and problems regarding eHealth/telemedicine and law. The chapter on legal issues is for the most part based on these questions and in it we try to address these highly relevant issues and to answer the questions. In order to provide insight and background to some essentials of the Norwegian legal system, the report also contains an English translation of the Norwegian Health Personnel Act.

Tromsø, March 2007

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1. Part one: Relevant technological issues in the Croatian telemedical project

The purpose of this report is to transfer knowledge and experience from Norwegian telemedical services and research projects for the benefit of the Croatian authorities in their effort to build up telemedical applications. The content of this technological contribution is based on meetings, email correspondence and discussions between the Croatian and Norwegian project participants, needs expressed by the Croatian delegates and the restrictions based on the services that the Norwegian Centre for Telemedicine (NST) has implemented or done research related to. In addition, several issues that the Norwegian participants found relevant for the proposed services where included. Director of the Croatian Centre for Telemedicine (CCR), Mr. Mladen Novosel, has provided a description of the technical requirements that CCR would like to see in a future fully automated centre for dispatching and coordinating telemedical services in Croatia. Views of the Norwegian participants on this vision will be especially addressed throughout this document.

1.1 Infrastructure, responsibilities and workload division

The infrastructure, responsibilities, support and maintenance of the telemedical services in Norway is a module-based enterprise. As opposed to current plans of the Croatian authorities and the Croatian Centre for Telemedicine (CCR), where most of the responsibilities and the authority are centralized under the umbrella of the CCR, technical and organizational requirements of telemedical services in Norway are distributed to different companies/institutions.

Norwegian Health Network Inc. (NHN), which is a closed network for electronic communication and cooperation within the health and care sector in Norway, is a company owned by regional health authorities, where each of the five health region has en equal share in the company. The company has a board of directors and a user council. User council consists of ten members appointed by network user institutions and their assignment is to advise the company on services and content that is needed by the users. The company has 32 employees from technical staff, economical advisors to communication advisors. The main reason why the network provision is separated into a single company is that it is the best way to make sure that the Norwegian health care sector has a communication network that is adjusted to the needs of the medical professionals, that may very from all other sectors in the society with regard to both security, stability and reliability. The only other sector that may have comparable requirements is military. In addition, coordinating logistics leads to lesser expenses than if each region or hospital would have to get their own network services on the free marked.

As mentioned, the main purpose of the NHN is to provide infrastructure for secure and effective communication among units in the Norwegian health care system. However, there is a close collaboration between the NST, NHN, and users. This allows for both task specialization, so that the quality of services is at the highest possible level, and a close collaboration between users to developers so that the content of the network is adjusted to user's needs. An example, which will be further elaborated later, is the administration system for video conferencing. The media processing system is owned, administered, and

maintained by the Norwegian Health Network, and it is situated on their premises. NST has, however, an access to the user interface and functionalities of the system.

In addition there, each health care region has its own IT-division that is responsible for many of the technical services that can be relevant for telemedical applications. They cover different tasks ranging from support to development and some technical solutions that have been developed by regional IT-divisions, like the first solution for message exchanges based on X.400 through mailboxes in 1997, was later transferred to companies that were able to ensure constant development and upgrades (in this case Well Diagnostics).

Well Diagnostics is a spin-off company from research and development at the NST and is the biggest provider of software for medical multimedia handling, system integration and secure communication on the Norwegian marked. The company has established important relationships with several leading electronic patient record (EPS) companies, research institutes, hospitals, laboratories and nursing homes that are very important for the further development of electronic communication within the health care sector for the purpose of improvement of telemedical services. Later, some of the NSTs experiences with its products and their specifications will be provided.

NST on its part is responsible for the design, implementation and testing of solutions that are more on the research and concept-testing side. Not on the maintenance, support, or implementation in the health care system side. NST has a counselling role and not the decision-maker role, which is somewhat different from the model chosen by the Croatian authorities for the Croatian Center for Telemedicine. NSTs software development strategies in the last years, as ever more specialized companies emerged on the market, has been to bridge the gaps between technologies instead of making everything from the scratch.

Comments on the Telemedicine Virtual Hospital (TVH) project initiated by the Croatian Telemedicine Centre:
In our opinion, the scope the project is too big and it incorporates too many of the solutions that are highly specialized, complicated to both maintain and integrate with other solutions. In Norway, many of the functionalities and tasks that are incorporated in the envisioned TVH, are handled by specialized companies or IT-divisions with several dozens of employees, as portrayed above. These institutions and companies have worked together for many years to bridge differences and technical communication problems, and at the same time upgrade the software and add new features as the users' needs expanded. The envisioned software for a fully automated TVH includes technical specifications that require communication between hardware and software from several vendors and our experience is that it is extremely difficult to make this work on a large scale with too many features and functionalities.
The maintenance and upgrades of such a system, as each vendor comes with updates and added features, would mount up to a task that would require too much time and too many employees to handle on a centralized bases.

On the other hand, for CCT to do the implementation itself, it would require too many employees and probably not be economically sound. Our recommendation is to divide the current needs of the Croatia health authorities in modules and to solve them one by one, aiming for integration in the long run. Each module in itself will certainly be challenging enough. An example is a project that NST is currently involved where a medication card for each patient is distributed to nurses in the field, who visit patients for check-ups. The system includes a portable unit that communicates with the patient's electronic patient record at the

hospital in order to provide relevant information for the medication dosage. The implementation requires a collaborative development between a secure communication software vendor, electronic patient record vendor and NST developers. Even though the project participants have years of experience in collaboration on similar projects, the business models of different companies, protection of closed source software and opening of limited access through specially designed modules, has taken more than a year to resolve one single issue. This happened also despite the fact that all three companies are Norwegian and familiar with each others routines.

In the rest of this section, some questions that may have not been answered in the comment above will be specifically addressed:

1. It seems to us that procurement of such software would be justified only if positive experience from other countries proves it. Considering this, could you please tell us, regarding this topic, your experience and knowledge about the situation in Norway, but also in other countries for which you happen to have notion about

   We are not aware of the existence of such as system and we certainly do not have it in Norway.

2. Please give us a reply / opinion whether such software is generally necessary;

   The project represents an ideal integration of all necessary solution in a virtual hospital that we hope will emerge in the future. We do not think that it is realistic at this point in time nor is it necessary.

3. Do you think that at the present state of development of telemedicine in Croatia such an acquisition would be justified or are there some other priorities to which activities and resources in Croatia should be directed for improvement of the implementation of telemedicine;

   We do not think that any country that we are aware of, at this point in the implementation of the telemedical services, has enough workload, acceptance or integration of services to justify investment in such a system.

4. Is there any ethical dilemma on the use of such software considering the fact that it would serve for tracking and storage of all information on patients, which would be interchanged between the medical doctors (we assume that confidentiality of data should stay untouched in this case as well as it is in the “classical” specialist examination/check-up)?

   Such software would not comply with the Norwegian law that implies very strict regulations on exchange and storage of patient information. We do not see any likely changes in that in the near future.

1.2 Videoconferencing

Videoconferencing is probably the most famous telemedical service even though it is not necessarily the most used one. However, it has been used for many years for several purposes and CCT has already installed several units that have been successfully used on several locations. Here we will point out the most important technology related learnings we have made in our research projects and services that have been implemented.

1.2.1 Video conference management

Here is some information about NST's experience in managing video conferences in medical applications:

1) The systems mainly used within the Norwegian health network are Tandberg videoconference (VC) endpoints. The administration system, (Media processing system (MPS)) is also a Tandberg system. http://www.tandberg.net/products/tandberg_mps_800.jsp

NST does not own the media processing system (it is owned by Norwegian Health Network), but our engineers have access to the user interface and functionalities of the system. This unit is capable of connecting to multiple units at same time and/or has many conferences at the same time. The exact number of units manageable at the same time is scalable. The key numbers for our current use are:

- Max no. of simultaneously telephone calls (IP): 32 (System not used primary for telephone calls)
- Max no. of simultaneously single endpoints connected in conference: 40
- Max no. of conference sessions: 15. (2 or more endpoints can participate in one session)
- ISDN channels: 60. (It typically takes 6 channels to one ISDN VC unit, e.g. a total of 10 ISDN VC units can be used simultaneously (most VC units use IP).
- Total bandwidth: 42240 kbps.
- The VC systems can also call directly end-to-end. A direct connection will not affect the quotas mentioned above.

Typically the system is used to connect several VC studios and/or telephone in one conference session. You can book at video conference in advance and you can choose between dial-out and/or dial-in participants. The VC master can monitor the connection status for the participants in near real time and can add or remove studios on-the-fly. Other functionalities of the system are:

- Statistics with several parameters monitored
- Possible to add streaming functionality.
- ISDN gateway.
- Authentication.
- Gatekeeper.
- Software upgrade of endpoints

Other brands of media systems with similar functionality:

- Polycom

- Cisco
- Codian

2) Endpoints. All the VC endpoints in the Norwegian Health Network support H.323 (IP) and/or H.320 (ISDN). There are no restrictions on which brand the endpoints are, but the majority of the endpoints are Tandberg Endpoints on IP. There have been many discussions and trials of using proprietary software on PC (e.g. Skype) for videoconference, but this is not officially used for the following reasons:

- Security and encryption issues.
- Compatibility issues with other systems.
- Stability and third party server is not quality checked.

A few software packages make an ordinary computer H.323 compliant (e.g. Polycom PVX). In lab tests we have performed, this software worked well, but it will still have major disadvantages compared to classical hardware systems:

- You will need to have PC support in addition to VC support.
- Security (a PC can be hacked or get a virus).
- It is difficult to connect extra equipment, (document camera, extra camera, no pan/tilt/zoom camera is standard)

The advantage of PC software H.323 software is of course the costs, which are much lower than for hardware systems.

1.2.2 Service quality

Service quality is not a uniquely defined term. Distributed Management Task Force (DMTF) in the Open Group uses the following definition: “A collection of technologies that allows application and users to request and receive predictable network service levels in terms of bandwidth, jitter, and/or delay.” The last comprehensive study, where all known telemedical services in Norway were examined, tested and evaluated for the technical specifications and quality of services was in 2002. Since then, technology has evolved, protocols have changed and NST has gathered new experiences. However, there is no systematic report on the standards and quality of the services depending on the transmission rates since then. However, based on our current knowledge and experience, we make the following recommendation for all telemedical services:

A stable, connection of 2 mbps is sufficient for all telemedical services that we have experience with on the most modern equipment. It is however a major requirement that the service is stable. We therefore recommend a 2 mbps dedicated connection for each service.

In the rest of this section, we will summarize the most important points from the 2002 report that could still be useful for different services. Recommendations for minimum connection capacity are made on the basis of comparison between face-to-face consultations and the telemedical services and the physicians decided when the quality was good enough for making diagnosis.

- Endoscopy applications (colon) – using protocol H.323 for transmitting video, the minimum of 1 mbps was recommended for successful diagnostic purposes.

- Ultrasound (blood vessels) - using protocol H.323 for transmitting video, the minimum of 768 kbps was recommended for successful diagnostic purposes.
- Ultrasound (heart) - using protocol H.323 for transmitting video, the minimum of 5 mbps was recommended for successful diagnostic purposes.
- Ultrasound (foster diagnostics) - using protocol H.323 for transmitting video, the minimum of 768 kbps was recommended for successful diagnostic purposes. However, at the hospital were the service was installed 3 mbps was used.
- Remote follow-up (dialysis) - using protocol H.323 for transmitting video, the minimum of 384 kbps was recommended.
- Gastroscopy (streaming and real-time) - using protocol H.323 for transmitting video, the minimum of 1.5 mbps was recommended for successful diagnostic purposes.

The minimum connection capacity is given for one-way communication. For the two-ways communication, which is the case in most applications, twice as big capacity was recommended. In addition, the protocol overhead (around 10%) needs to be calculated in for H.323. How big the overhead really is depends on the package size. For most of the specified applications, the capacity is shared between video and sound. In all these cases, it is not know which frame-rate was achieved. Frame-rate indicates how natural the motion will be perceived. It was however reported in the project that the expected satisfactory frame-rate for clinical applications was around 25 frames/sec.

In the end, it should be noted that details like video standard, format, and data rates are not the only factors that influence quality of the service. Colours of the interior, design, choice of the camera etc. can be just as important.

1.2.3 Interior

All the equipment that is used in hospital rooms where patients are diagnosed or treated has to fulfil all the standard electro-medical requirements for hospital equipment. All new installations are required to report to the Norwegian authorities for fire and electrical safety.

Room illumination has proven to be important in videoconferencing. Traditional illumination is usually designed for meetings where the source of light is above the heads of the meeting participants. This has created some problems in medical applications since this kind of illumination created shadows when cameras are used in the room. The result is that the upper parts of the face are better illuminated than the lower part. Observants at the other endpoint will perceive this as dark areas under the eyes and on the lower part of the face. One way of resolving this problem is by the so called indirect illumination where, the light source is directed towards the walls or the ceiling, while only a small portion of the light is radiated directly into the room interior. The normal daily light has not given very good results in our tests, especially if the windows are behind the participants' back. We advise the users to shot out the daily light by thick curtains. It is also not advisable to mix sources of light of different quality, e.g. spot light with normal room light, since this produces unexpected combinations of colours.

Placement of the camera and microphone has to be adapted to the interior design and Placement of the furniture. In special applications, like in an emergency room, there will be need for several cameras and microphones. Even though the videoconferencing equipment is supplied with wide-angle cameras, when the number of people in the room increases to e.g. eight or higher, there will be need to place the camera further away. In that case, a

second camera might be needed to details of interest. Most of the microphones supplied with the videoconferencing equipment have very good quality and our experience suggest that one microphone in the center of the room is sufficient for most of the applications. They are also designed to capture sound in a radial manner. When the number of persons increases up to e.g. eight, there might be a need for the second microphone. However, each microphone should be placed 1-2 meters away from the closes person. On shorter distances, sound distortion has been observed.

Choice of furniture has to be adapted to each special service. In consultation rooms, however, we have had good experience with a pear (drop)-shaped tables where the broad end is placed in the direction of camera. This is the best way to capture participants and there are no objects or persons in the way of the camera.

Blue colour is very often used in many studios. There is however room for modifications here and our experience is that warm colours create the best working conditions. The only strict requirement that should be followed is that the colours should not be too dark. Curtains should not have patterns since it created distractions.

Security aspects of the rooms that are used for medical consultations should be considered. Some of the important issues that the Norwegian data security authorities require to be considered are:

1) Physical restrictions to the studio where the equipment is installed. This will prevent any unauthorized personnel to connect to an ongoing conference.

2) If sensitive information is transmitted during a video conference, access to the room should be restricted and any transparent walls (glass) should be covered.

3) All participants should be made aware of the security issues and the fact that there may be participants in the room other than those visible on the screen.

4) In the case of IP based videoconferencing over PC, one should check if any traces in form of temporary files are left on the computer. In the best case, such temporary storage should be avoided by adjusting the system settings.

1.2.4 Maintenance and support of the system

As with most sorts of technological equipment, maintenance or support problems and needs in use of videoconferencing equipment will arise. These systems are especially vulnerable since they are situated in several physical places. In Norway, experience has shown that technical support personnel is just as important in the daily practice as in the implementation phase. The responsibilities should be clearly defined and personnel that can give on-line support should be available at any time during practice. This can basically make all the difference between physicians that use the equipment and find it valuable and useful and physicians that never use it. E.g. NST has experience with a project where a sophisticated equipment was placed in a gastro-surgical unit. The use of equipment was complicated and technical support was not available at all times. The service was ignored by physicians and closed in the end.

1.3 Security and technological solutions

NST has conducted several evaluations and projects where technological solutions for security requirements where an issue. The software for the communication within the NHN that NST's projects have involved in most cases is Well Communicator. The most important Well Communicator features are:

- it supports standard messaging formats: XML, EDIFACT, and HL7.
- it supports the use of ebXML, PKCS7 encryption, reciet mechanisms and message attachments, public key encryption with X.509 certificates, and S/MIME as exchange format for electronic messaging applications (RSA/3DES/SHA-1).
- it does not set any restrictions on the number of users from a single installation.

Well Communicator has following functionalities that ensure security aspects of information transmission:

1. It is only possible to send messages to recipients that are authorized beforehand.
2. Every recipient has to be registered with a specific encryption requirements.
3. All messages are encrypted correspondingly before transmission.

It exchanges information through a message based, asynchronous, communication channel using SMTP for outgoing messages and POP for incoming messages. This is example of the use of an old-fashioned “mailbox model”, where messages are retrieved from a mailbox into a secure zone. The use of “mailbox” model increases the security since all contacts from the secured zone to the outside world are initialized from the inside. Well Communicator is however not an end-user program. It is assumed that a communication module is installed that can communicate with Well Communicator. More information and technical specifications can be found on the web site of Well Diagnostics Inc.

There are however some security issues that need to be addressed. Password handling is the oldest but still very relevant security problem. The biggest problem in this regards seems to be handling of several different passwords for accessing different layers of the health information system. These passwords usually have different security levels setting different password requirements and having different expiry dates. This leads to users writing down their passwords or getting around the system by sharing log-ons. One of the solutions could be the usage of RSA-tokens as they are used in VPN-solutions. It was successfully tested in one of NST's projects, where all health personnel that had access to laptops used in a services, was given an USB-pen called eToken with a personal certificate or a RSA code generator called RSA SecureID. The authentication was two-factor based: it combines something the user knows (password) and something user has (certificate on an eToken). Certificate on the eToken is encrypted and needs to be decrypted by typing the user password on the computer with USB-pen inserted. RSA SecureID is a code generator that generates a 6-digits code when the user password is entered. This code is then used together user name and password. Once the user is logged on, she will be given access to internal logging pages. Here, Citrix MetaframeXP was used to ensure end-to-end encryption from the laptop computer to the safe zone. One of the observed problems with this solution was that employees would forget their eTokens and then start borrowing from each other in order to get access to the systems. Routines for such cases should therefore be put in place.

An authentication technology solution that is now being made available on most new laptops is the fingerprint reader. It could replace some of the technologies mentioned above. There where however two problems with it: small finger injuries or even called fingers could prevent a successful logging and the Norwegian data security authorities were not willing to approve generation of a database with employees' fingerprints. This method would require some additional licensing/servers for a single sign-on solution.

Yet another solution that has been very useful on laptop PCs is Skanix Illusion from Skanix Inc. Skanix illusion is a program that monitors any changes on the computer where it is installed. When computer is restarted, all changes are set back. This means that all errors introduced by the user (installation of a program, virus, change of settings, etc) are removed at the first reboot.

Thales Trusted Mail Plug-In (TMP) is software that has successfully been tested for improving the security of the communication within the Norwegian health sector. TMP is a plug-in to Microsoft Outlook and is supposed to hinder unwilling sharing of sensitive information through email. TMP monitors several different factors in emails - file extensions, where on the server the file comes from, origin of the content that is pasted into the email etc. Depending on these factors, TMP will automatically label emails as sensitive or non-sensitive and the sensitive email will be allowed to be sent only to users that are authorized in advance.

1.4 Choice of hardware/software vendors

CCT has asked specifically if NST could recommend vendors for certain acquisitions of software or hardware. NST has worked together with several suppliers of hardware and software solutions for telemedical services. Our experience is that the best way to get both hardware and software to meet needs and requirements of users, is to initiate a dialog with several suppliers, express the needs and choose the supplier that give the best support and shows the most willingness to adapt the software to the your needs. The experiences have varied and even though some trends can be drawn, it can not be justified to single out any company as an unwanted partner.

Here are some examples: In some situations, small companies have proven to be more flexible in adapting their software for the special needs of the users than bigger companies. In a contact with a company, when we asked for a Norwegian menu on the equipment, the vendor required that we purchase a certain amount of units if they should invest in translating the menu. This, however, does NOT mean that bigger companies necessarily are less willing to adjust the software to the users' requirements. Many years of personal contact between NST's engineers and Tandberg Inc. has led to a very fruitful cooperation and exchange of ideas, where Tandberg has implemented many of the suggestions that NST has provided to them. The same has happened with Well Diagnostics. These are however relationships that are carefully built over years in order to ensure a successful cooperation between the vendor and users.

Comments on the CCT's plans for acquisition of new equipment and software solutions: Our advice to the Croatian Telemedicine Centre is to engage all interesting vendors in

conversations, describe the needs, both current and future and take the best deal on the marked, based not only on the price but also on the willingness to integrate solutions needed by CTC. The competition is hard in this technological field and many companies are willing to provide extra services in exchange for contracts. There is however no “golden standard” for the choice of the vendor.

One of the questions was directed to Mr. Stig Karoliussen on the matter of pros and cons of different software that we have experience with. The answer complies with the rest of the suggestions that we have made in this section. The equipment is as good as the deal you are able to negotiate with the vendor for your own purposes and applications.

1.5 Additional comments

During meetings with the Croatian colleagues, many interesting and relevant questions were raised. We have tried to answer them to the best of our knowledge. Several interesting questions will however remain unanswered since we do not have any knowledge or experience with the technology in question. Some of the plans of the CCT are highly ambitious and involve technological solutions that we have not tried out. There are however few things that need to be mentioned as a comment to some informal conversations that we have had with the Croatian colleagues. The three most successful telemedical services in Norway are Teleradiology, Telepathology and Teledialysis and Teledermatology.

Teleradiology is become so integrated in the hospitals daily practice that it is simply called radiology – it is the default way of organizing radiological services in a hospital. Details of the system and routines where presented to the Croatian colleagues during their stay in Tromsø.

Telepathology was tested for the first time in the beginning of '90s. A tissue sample was taken under a surgical operation and a pathologist would remotely steer the microscope and make a diagnosis while the surgery was conducted. In this was it was avoided that the patient should be operated on for the second time if the pathological analysis should show that the tissue sample was not benign. Typical setting would involve a video streaming from one of the three possible cameras – microscope, operation table or the personnel. Parallel with this service, an image based service was developed for the same purposes. Both solutions are wide spread today and are used all over Norway. This kind of service belongs to the so called category 1 applications, which require high quality of service and constant availability. The capacity required was 1mbps each way with H.323.

Teledialysis is another application that has been successful. Using Fresenius 4008E/S/H and Gambro AK200S with a PC and a Tandberg conferencing unit has been successfully applied on several locations.

One the fields that certain participants have expressed interest in was Teledermatology. That was one of the oldest services in Norway dating back to 1989 where a video-based service was established between two cities in Northern Norway. Images where taken with a camera (not a dermatoscope) and it was up to specialists to decide which diagnosis could be determined safely. An ongoing project at NST involves follow-ups of children with eczema,

using a digital camera. One of the new projects at NST, which is a research project, involves using pocket dermatoscopes for computer aided diagnostics within a teledermatological service. NST, however, has not done any systematical studies if the usage of standard dermatoscopes in teledermatological services, which is one of the points the Croatian participants has inquired about. We have done some lab tests but no systematic studies that provide reliable results.

Many of the other services have had successful test studies, benefits have been shown and the quality of service determined. They did not spread out in use to such an extent as the previous mentioned ones.

One of the points that were singled out in the proposal for the fully automated virtual hospital was an integrated central that can handle both videoconferencing and IP-telephony. We are aware that the University Hospital in North Norway has such a unit supplied by Ericsson. NST has however now experience with such systems and we do not know how effective the user interface for booking and administration is. We recommend the Croatian colleagues to contact a vendor for more information, e.g. Ericsson.

Another question posed by the Croatian colleagues was if there was a system for keeping the record of all conversations over the phone or video conference during consultation. We do not have such system, mainly because the Norwegian data security authorities strictly forbid such recordings. Even in non-medical applications, users have to give their consent to any recording of the conversations.

2. Part two: Implementing telemedicine

2.1 Introduction

When we try to implement technology there are at least two things that one should be aware of. First, telemedicine is not just technology; it's also about human beings and the organization of work processes. When we implement telemedicine we not only introduce a new technology but also a new way of working. When we try to implement telemedicine we have to consider both the technology and the organizational settings the technology are supposed to fit into. It is the technology in use and not just technology that is our interest. It's the persons who use the technology who through their efforts produces the results.

Second, telemedicine is about communication with other carers and patients across distances. And very often the communication crosses organizational borders. That means that there are two or more actors who have to do something.

Now we will look at some factors that actors have to consider when they try to introduce telemedicine. Based on our own experiences from projects and routine services and from studies, Norwegian as well as international, we will specify some factors we have to consider when we try implement telemedicine. We will focus the organizational and the human factors, but the challenges to implement new technology have to be considered in relation to technology and the problems the technology is meant to solve. The challenges vary from services to services and from user groups to user groups.

2.2 What is telemedicine?

There is more than one definition of telemedicine and new definitions have occurred when technology and practice have developed or changed. Definitions of telemedicine have traditionally focused on clinical services. Telehealth is a broader concept focusing not only physicians but also nurses and other healthcare workers, and incorporating administrative services and education. A third concept, telecare, is used to describe use of telemedicine to deliver health services to people in their homes or supervised institutions. The concept e-health has also been introduced. To some this concept is instructive because it focuses the patients and health care workers use of Internet access health information. Some say that the patient will be a more important driver of telemedicine in the future. In the following sections we will have in mind a broad concept of telemedicine.

There is a variety of telemedicine services. We can describe the services according to the technology and the main users. The services use text, data, still images, video and audio. Some examples of these services include:

- Medical consultation
- Treatment (psychiatry)
- Continuing education for doctors, nurses, and other medical personnel
- Training
- Transmittal of prescriptions and doctor's orders

- X-ray, and ultra-sound data transmission
- Medical database access
- Retrieval of medical literature
- Monitoring
- Electronic referrals

Store-and-forward versus real time interactive

In telemedicine different techniques can be used: store-and-forward (asynchronous) and real-time interactive (synchronous). An example of store-and-forward is the use of still images for consultation in dermatology. The participants are separated by time and space. In teledermatology a GP can take a photographic picture and then send it to a specialist at a hospital. The specialist can examine the picture and send an answer later. Real-time interactive is a telemedicine technique that uses video-conferencing technology. Participants are separated only by space, not by time. Video-conferencing technology has been used for different purposes: teleconsultation, meetings, training, education etc. The store-and-forward techniques are easier to organize than the real-time interactive technique because the partners don't have to communicate in real time.

2.3 Barriers and facilitators

Researchers have reported a lot from studies of communication between GPs and hospital. Both store-and-forward and real time interactive techniques have been used for a range of services. Here we present some findings from a study in northern Norway.

A study that examined the conditions for the use of telemedicine between general practitioners and hospitals were conducted in 2002. The services offered were in the branches of dermatology, cardiology (heart sound monitoring of infants), ear, nose and throat, and plastic surgery. The intention was to investigate more thoroughly the possible barriers and facilitators which GPs encounter in the implementation of telemedicine in N-orthern Norway.

The interviews showed that GPs saw advantages of the services in general and saw clear benefits for the patients. For the GPs, the advantages are shorter response times, the opportunity to learn, especially for those who qualified recently, and the possibility of teamwork. For patients, telemedicine means that they can avoid the journey to the hospital and save time. However, the extent to which GPs were using the services was limited, although some GPs used them fairly frequently. The most widely used service was dermatology. The differences in use cannot be explained only by the number of patients who were candidates for telemedicine services.

The interviews with the GPs revealed positive attitudes to telemedicine services, but the use of the services remained limited. There were several reasons for why the use of the services remained limited. One was the lack of experience. Telemedicine involves the introduction of a new kind of technology. The GPs did not find the technology very difficult to use, except for ENT; rather, they felt that they needed to practice more often. The number of patients who are candidates for telemedicine could be one of the reasons limiting opportunities to practice, but even in dermatology, where the number of patients was fairly high, the GPs

expressed a need for more practice. Although they found the training programmes to be good, the GPs expressed a need for more follow-up as they started to use the technology. The other main barrier to the use of telemedicine services in general was the lack of remuneration.

The study indicates that the use of telemedicine services is a product of many factors. Some of these are strategic factors that we can do something about, such as training, remuneration and changes to the routines.

2.4 National framework for the implementation of telemedicine

The absence of a national policy can act as brake to progress of telemedicine services. The health care sector in western countries can metaphorically speaking be described as a patchwork. There are a lot of different institutions and telemedicine is a technique that very often crosses institutional borders. Government can play a crucial role as drivers of telemedicine because national governments are institutions that, to some degree at least, can coordinate activities of public institutions or make cooperation easier. In Norway the following factors have been vital to the implementation of telemedicine:

2.4.1 A national health network

A national health network was established in Norway in 2004. Norwegian Health Network Inc. (NHN) is a secured and closed network for electronic communication and interaction in the health and social services in Norway. All public hospitals in Norway, about half of the primary physicians and some private specialists are connected to the health network.

2.4.2 National strategies and action plans

In the last decade the Norwegian government has launched three action plans. The plans define the challenges in the health care sector and how implementing new technology can be an effective measure for improving quality and effectiveness in the health (and social) sector. They describe how contributions of different actors need to be coordinated to pull in the same direction.

Planning can be top-down or bottom-up. A top-down strategy to planning means that the governments sets goals, defines proper actions and enact laws that encourage the use of telemedicine. A bottom-up strategy means that the government issues advice and guidelines. The government avoids specifying the direction; it’s the health care workers and the organizations that initiate the telemedicine projects.

2.4.3 Funding

Financial support is critical to the development of telemedicine services. Telemedicine is still a new way of deliver health care. In this phase it can difficult to demonstrate cost benefits because the system is not completely implemented and there are not enough cases. Funding can also be necessary because of the nature of a telemedicine system, that telemedicine crosses organizational borders. Sometimes cost and benefit is not equally

distributed among the organizations and then all organizations don't have the same incentive to invest money and personal in a telemedicine project.

2.4.4 Remuneration

To demonstrate that a specific telemedicine services is cost effective can not ensure that the partners will start to use the equipment on a routine basis. The lack of financial incentives that recompensed the extra cost for one or more of the partners can be a barrier to the use of telemedicine.

2.5 Facilitators to telemedicine implementation

Implementing telemedicine services can be a complicated task. Some telemedicine services fail to become a routine way of delivering health care, but there are also many successful telemedicine services. It is important that we learn from these telemedicine practices, both failures and the success stories. Implementing telemedicine requires understanding of the health care organizations and the work processes of the health care workers as well as the political and administrative context. Based on our evaluations and practical knowledge we present some principles that should guide the implementation process.

2.5.1 Principle 1: Think chain of actors and actions

The establishing of a sustainable telemedicine system will involve a lot of actors, actors who belongs to different organizations. Telemedicine must be understood as a chain of actors and actions. It is not enough to implement a technology, it's necessary to get the health care personal to use the technology. It's important that every actor in this chain do what they are supposed to perform.

2.5.2 Principle 2: The service provider must play a leading role

Traditionally it's hospitals that provide a telemedicine services. The service provider must play an important role in implementing and maintaining the telemedicine services. The hospitals must build a robust organization that is able to deliver the services to the receivers as intended. A robust organization also means that the actors who call for help must have the opportunity to communicate with the right specialist. When problems occur and they are not able to carry a conference through as planned, the hospitals must inform the receivers. The hospital will also play a crucial role in informing the potential users about the services and how it is organized.

2.5.3 Principle 3: The healthcare workers must own the telemedical system

Technologies also need local advocates and supporters. We sometimes find examples that the technology is installed but no one is ever using the technology. It is not enough that someone from the outside is acknowledging the importance of and is advocating the technology. The support and action of the clinicians are of vital significance. When people feel that they are the owner of the system they will more likely to invest time and energy to explore the possibilities of the telemedicine equipment.

2.5.4 Principle 4: The need for training

The effect of a new technology is often diminished by the lack of skills on the part of the users. Training course can be a useful way to give factual knowledge and the possibilities and restrains of the technology but skills and techniques have to be acquired and accumulated through practical use. Training can also focus on common error situations and how these problems can be solved. People's learning curve is different and it's not unusual that some become super users that help others.

2.5.5 Principle 5: Support

As with technology in general you sometimes find that the telemedicine technology doesn't function optimally or it's failing. Telemedicine technology can be extra vulnerable since telemedicine means communication between two or more sites via an infrastructure. Therefore, there is a need for personnel at that are responsible for running of the equipment and that can give a helping hand when problems occur. The need for support is most important in the beginning, before the primary users know how to handle the equipment. But there will always need for some roles that should be responsible for support and a telephone number for who to call.

2.5.6 Principle 6: Time schedule

The use of telemedicine will normally require the establishing of time schedules. In telemedicine two techniques may be used; asynchronous (store-and-forward) and synchronous (real time). Asynchronous techniques are normally easier to organize because we just need a deadline for the health care workers to send an answer to the request. Synchronous or real time techniques require that one establish that say who shall attend and when the conference will take place.

2.5.7 Principle 7: Structure

A real time technique, for example videoconference technology, differs from face-to-face-meetings. When we meet and communicate via videoconference there is a need to structure or organize the communication process. The need to structure the sessions are relative to the numbers of participants and the problems they have to deal with. Who are the leader of the session or what the "chain of command" is, what the problem is and who own the "problem" or the "situation" could be clarified before we start the session.

2.5.8 Principle 8: Knowledge of each other

That the actors know each other before they start to use telemedicine can make easier to communicate and make a decision. When you know the other actor's skill level you normally feel safer when you give advice. The need to know each other is relative to the situation or type of problem at hand. Trust is also based on knowledge of the procedures, are they well-known or not, and the education of the other actors.

2.5.9 Principle 9: Troubleshooting guide

Even though telemedicine technology has been used for several years now, sometimes you see that things go wrong. There can be problems to connect or a breakdown during the session. The result can be a lack of trust in the telemedicine system so that the health care workers don't want to practice telemedicine. A troubleshooting guide that is placed beside the equipment can be useful. This guide can present solutions to some simple and common problems.

2.5.10 Principle 10: Practice, practice, practice

Education and training programmes is very often not sufficient to make a sustainable telemedicine system. To make it easy or convenient to use the technology health care workers need to practice. When people have been practicing for a while the consultation will be less time consuming and it will also be easier to handle simple problems that frequently occur.

2.6 How to do a videoconsultation

Teleconsultation is one the most frequent example of telemedicine techniques. The image of a teleconsultation is normally of a patient and his or her GP communicating with a specialist at a hospital via a videoconference unit. As we have said before consultation can be undertaken using still images. We will now like to focus videoconsultation because it is more challenging to organize. The question we will try to answer is; how can videoconsultation be organized to extract the maximum benefit from the consultation process?[1]

- *The location of the equipment:* The location of the equipment is more important than we usually think. To have a dedicated room for videoconferencing at a long distance to where the core activities of the institutions are taking place makes it inconvenient for the health care personal to use it. Access to the room to should easy but also be able to be controlled so interruptions don't occur so often. It can be difficult to fulfil both the need for easy access and privacy.

- *Agree upon the purpose of the session:* Is this a consultation, monitoring of the progress of a treatment, second opinion or training

- *Session initiation*: Procedures for how and when a videoconsultation can take place should be specified. Some videoconsultations can be planned and then we need some kind of booking system. Other consultations are urgent, emergency calls, and then we need procedures for who to call and the handling of that specific call.

- *The consultation process:* A videoconsultation should be organized quite similar to an ordinary consultation: The partners are introduced, the partners observe each other, the specialist direct and observe, dialogue between the partners, and a conclusion or diagnosis is reached. The difference is that the specialist must rely on activities undertaken by another

[1] A. C. Norris, Essentials of Telemedicine and Telecare, John Wiley & Sons, Ltd, England, 2002.

person. The communication process then becomes more crucial. Communication should be clear and emphasized and the parties should be avoiding talking over each other.

-*Session closure*: Once the consultation process is ended the specialist should ask the remote health care worker and the patient if they have any questions. Remote health care workers should also be invited to make calls for discussion and further queries after the session.

-*Decide on documentation*: The procedures and the outcome of the videoconsultation should be properly documented.

2.7 Summary

Technology in use: Telemedicine is not just technology; it's also human beings working together to produce a health service.

Reorganization: Telemedicine is a new way of working and very often changes has to be made in two or more organizations.

National framework: The existence of national framework can motivate health organizations to implement telemedicine. Such a framework is important because telemedicine is crossing organizational borders.

Chain of actions: Telemedicine is a chain of actions. If one actor don't do what was planned or expected the service will fail to function.

The service provider: The providers of telemedicine services have to play crucial role in the implementing and routinization process. They must develop a robust organization and communicate the service to potential users.

Organization of teleconsultation: Videoconsultation represents the image of the typical telemedicine service. The session should be organized quite similar to an ordinary consultation. But since the specialist don't meet the patient face to face it is necessary to organize the sessions more thoroughly to compensate for the lack of direct communication with the patient.

3. Part three: Legal Issues in Telemedicine and eHealth

3.1 Introduction

Telemedicine and eHealth is still an area where a lot of legal issues need to be clarified and solved. Solutions and services are still very much in their infancy and the level of integration and implementation varies a lot from country to country. It is probably also fair to say that in most cases, legal issues are not in the forefront when it comes to carrying out eHealth projects or implementing solutions.

Having said that, there is no doubt that the importance of clarifying the legal frameworks and overcoming legal barriers is widely recognised as important. In most countries health care is surrounded by extensive legal frameworks, as is information security issues.

This chapter on legal issues in Telemedicine and eHealth is based on the work we have done on this in Norway, and will for the most part use Norwegian legislation as a basis. We are, however, involved in a number of international projects, and where this is relevant, examples from other countries and legislations will be given.

For more general information on the Norwegian Health Care system – in English, we can recommend the articles and links found on this site:

http://www.helsetilsynet.no/templates/ArticleWithLinks____5522.aspx

3.2 Working with legal issues in telemedicine and eHealth

There is no specific legislation on telemedicine and/or eHealth in Norway. This means that such services must operate within existing legislation. The challenge is then to assess and clarify the legal framework and to find ways of adapting and adjusting both technology and solutions to fit within the framework. In some cases it might also be necessary to point at the need for legislative changes.

At NST we have approached the work on legal issues by focusing at laws and regulations as a *framework* within which telemedicine and eHealth must operate. We have found this approach more fruitful than to see laws as barriers at the outset. But of course, to the extent regulations act as real barriers to presumably good services, it is important to work towards finding ways to overcome and/or removing these barriers.

We would also recommend aiming at establishing a good cooperation with relevant groups, institutions and organisations when working with legal issues in this field. Our experience shows that it is both valuable and strategic to have a good dialogue with e.g. health authorities (at all levels), medical associations, health care managers, doctors, project leaders etc. etc. Such a dialogue is probably necessary in order to identify the actual and

relevant issues to work with and through the cooperation; these parties give feedback to the work on legal issues.

To the extent possible, some work on legal issues should be included in all telemedicine-/eHealth projects. We believe that this will be of great value both for the overall quality of the project in question and for the development of the work on legal issues.

3.3 Issues and questions in the Norwegian-Croatian project

The rest of this part of the report is for the most part based on the questions we have received from our Croatian partners and from Prof. Goldner in particular. We will try to give as comprehensive answers to these questions as possible, and we hope this can be a valuable contribution to further work on implementing and utilising telemedicine and eHealth in Croatia.

3.3.1 Responsibility

***Question:* Which doctor is responsible and for what? How do you resolve problems in practice and have there been any cases before Norwegian courts?**

The term "responsibility" is rather complex and can include at least three situations or aspects:

Responsible practice
Legal and ethical requirements for good, professional practice and conduct. These requirements can be found in formal legislation as well as in many kinds of professional guidelines. In Article 4 of the Norwegian Health Personnel Act2, this aspect of responsibility is expressed like this:

"Health personnel shall conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general". [3]

"Doctor in Charge"
This aspect of responsibility is about the professional duty to take responsibility for the patient and for her/his treatment. In a treatment "setting" where a number of doctors and other health care personnel are involved, it is necessary to make sure that one (or at least only a few) have the overall responsibility and the final decision making power. This is no less important when it comes to providing health care by telemedicine. In this context it is perhaps even a greater risk that this responsibility becomes unclear – leaving the patient in an uncertain situation.

In many (most) cases, it is clear from the situation at hand who the "doctor in charge" is. If this is not the case, it is recommended that this is made clear among the parties. An example: In a videoconference, the specialist clearly states to the other doctor and the patient that she or he get enough information from the videoconference to make a qualified

[2] The Act is attached as an appendix to this report
[3] Unofficial translation. The translation can be found here:
http://odin.dep.no/hod/engelsk/regelverk/p20042245/042051-200005/index-dok000-b-n-a.html

decision on treatment of the patient and consequently take responsibility – becomes the doctor in charge. If the specialist does not think she or he can do this, the doctor sitting with the patient is in charge and is responsible and the consultation is more a second opinion – consultation.

Sanctions

The final aspect deals with the consequences of the first to – being held responsible and being subject to sanctions.

In Norway we have very few cases where health personnel are sued. In the case of misconduct, most cases are settled and decided by a National Patients' Injury Compensation Board. More information on this can be found here http://www.pasientskadenemnda.no/templates/Page.aspx?id=2076 .

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It is in fact difficult to give a more precise answer to these responsibility questions. Responsibility and especially issues concerning good and professional conduct is a so-called legal standard and assessed based on the situation at hand. This is however clearly an important issue in telemedicine and eHealth, and as a consequence the Norwegian Health Ministry issued this "circular letter" which aims at clarifying questions concerning telemedicine and responsibility by interpreting Norwegian legislation. The document is meant to be a guideline for telemedicine users.

The guideline starts out by stating that the legal requirements for responsible practice (as quoted above) are the same in telemedicine as in traditional medicine. A special emphasis is laid on the requirement that all health personnel must practice in accordance with her or his qualifications. Furthermore the duty of documentation (keeping of records) is emphasised.

The guideline lays down one principle that is very important in telemedicine: It clearly states that in terms of responsible and good medical practice, it does not matter how information is transmitted to the doctor. The important issue is whether or not the doctor gets enough and relevant information. It does not matter if the doctor (or any other health care personnel) gets the information by face to face examination of the patient, by email, by videoconference or by any other means. This is actually a quite important statement as we have seen examples of Ministries, Health Boards and Medical Associations taking another approach and making clear statements in the direction that responsible medical practice can only be provided by "traditional" face to face consultations and that all other methods (incl. telemedicine and/or eHealth) are "second-rate" and only suited for general advice and second opinion.

The Norwegian Circular Letter concludes with a summary:

- The use of telemedical services does not alter traditional responsibility requirements
- All health care personnel have a duty to ensure that they make responsible decisions
- A responsible medical assessment must be based on relevant and necessary information
- If the information received is not relevant or sufficient, health personnel in charge of the treatment have a duty to gather more information or to see the patient in person (face to face)
- In a telemedicine setting it is important to clarify the parties' roles and premises.
- It is a duty for health care institutions to establish routines and systems that ensure that the use of telemedicine is responsible towards the patient.

3.3.2 Privacy, confidentiality and data security

***Question:* How to ensure it and what if it is abused?**

Confidentiality and privacy are fundamental issues in health care – in Norway as everywhere else. These issues are heavily secured by law, both in health care legislation and through legislation on information security. Norway, as an EEA member has passed legislation in accordance with the EU-directive on processing of personal data.4 Health information shall be considered sensitive and appropriate security regimes must be in place in order to secure it.

Patient privacy is primarily ensured by strict regulation of confidentiality in the doctor – patient relationship. This legislation applies for as many as 28 different types of authorised health care personnel.[5]

Principles and legislation on confidentiality must of course not be jeopardised or weakened by implementation and use of electronic solutions. This is also one of the most essential questions in telemedicine and law; How to ensure strict legislation on information security and confidentiality and at the same time make it possible – and legal – to utilize the enormous potential of modern information- and communication technology.

On a technological level, information security, including confidentiality and privacy, is ensured by making sure that technical and organisational measures and solutions meet legal requirements. This is both a responsibility for hospital owners and managers (system responsibility) and for each individual health care personnel (professional responsibility). This is a responsibility on all levels of providing health care and in all parts of the treatment process. The duty of confidentiality is part of the duty of responsible practice.

On a technical/technological level, eHealth and telemedicine solutions must meet legal and ethical requirements. This means both that systems must ensure a sufficient level of security in order to meet confidentiality requirements and at the same time provide solutions that makes it possible to add information, use information, share information, etc, according to legal provisions. As this is a very dynamic field, both in terms of technical development, user demands, new possibilities and legal frameworks, the different technical solutions are constantly changing and hopefully improving.

Encryption of data is a keyword, and is required both for storing and transmitting of information. Both end user applications and networks must be encrypted. Norway has a national health network (www.nhn.no) that connects all hospitals and some general practitioners. Traffic through this network is encrypted. In addition all end users are required to have encryption in place as part of their information security regimes.

According to Norwegian legislation it is required for end users to carry out risk assessments in order to ensure security and to make sure that security regimes meet potential risks and treats to the system. This risk assessment shall also include assessment of network-security.

[4] Directive 95/46/EC of The European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
[5] See The Health Personnel Act, article 48

Breach of legal requirements on information security can be a violation of both health legislation and legislation on processing of personal data. For health care personnel it is probably most relevant to be sanctioned according to health legislation. Sanctions can be in the form of administrative sanctions, ranging from being warned to loosing the license.

3.3.4 Payment/reimbursement

Question: Payment of doctors' services in telemedicine – how does it work and who is paid; the doctor providing and/or the doctor asking for a consultation?

Lack of regimes for payment and/or reimbursement of telemedicine services are probably one of the major barriers to grand-scale implementation of such services – in Norway as in many other countries. This is more a political than a legal issue, but obviously with legal implications.

Norway has a system of publicly funded health care. Care is funded through a combination of doctors and institutions getting paid a fixed sum from the health ministry, tariffs for each consultation and payment directly from the patient. Public funding is covering more than 95 % of the total expenses to health care in Norway.

At present, there are a number of tariffs in place for specialists and only within the fields of teledermatology and teleothorhinolaryngolgy. In other cases, payment has to be administered within the traditional/ordinary payment regimes.

There is no direct financial stimulation to increased use of telemedicine services by e.g. special funding for investments in telemedicine equipment. The mentioned tariffs attempt to take into account increased time-consumption related to the use of telemedicine.

To our knowledge it has not been discussed in Norway to make a distinction between urgent and non-urgent consultations as mentioned in your questions.

It is difficult to give general advice on payment and reimbursement regimes. There are many ways to solve these issues and as mentioned, politics is probably more important than law. A good payment regime should take into account extra costs and/or time-consumption referring to the use of telemedicine. How this is done will depend on the health insurance policy in different states.

3.3.5 Licensing

Question: Is there licensing for the provision of telemedicine in Norway or can a person use it without a license? Who gives the license, how and whom?

It is not required – or possible - to have a specific license for practicing telemedicine in Norway. To our knowledge there are very few countries that in fact have such requirements. This means that provision of health care by telemedicine is subject to the same legislation as health care in general. Persons with a valid license as health care personnel can provide care by telemedicine and/or eHealth services, provided that this is done in a responsible manner (see above).

Other medical staff that doctors – usually nurses – do quite frequently use telemedicine equipment especially in services where the patient sees a specialist via telemedicine. For example, the patient meets with a nurse at the local health care centre or at his general practitioner's office and the nurse take pictures or do tests and then transmits the information (by videoconference, email, etc) to the specialist.

Licensing issues is the responsibility of The Norwegian Registration Authority for Health Personnel (SAFH). Their website is available in English here http://www.safh.no/english/index.html and the site contains all relevant information regarding regulations and procedures regarding licensing/authorisation.

3.3.6 Consent issues

Question: Patient's consent – is it required for the use of telemedicine and how is it given (orally or in writing)?

Consent is of course a fundamental basis for treatment – in telemedicine as in all aspects of health care. Accordingly, telemedicine must be based on consent. A more important question is whether or not it is necessary or advisable to ask for specific consent from the patient when using telemedicine or whether it is sufficient to base treatment on presumed consent (i.e.). This is not directly solved by Norwegian legislation and an answer must be based on a more general interpretation of laws and other guidelines.

To the extent that a given (telemedicine) service is new, untraditional and presumably unknown to the patient, she or he should be asked specifically to consent. In the case of telemedicine and/or eHealth solutions being part of a project, it shall in most cases be mandatory to obtain the patient's consent. As the use of telemedicine becomes more routine and part of everyday provision of health care, consent can to a larger extent be presumed.

The need for explicit – expressed – patient consent must also be assessed with relation to the service in question. One would consider consent differently when it comes to implementation of electronic health records or electronic information exchange than one would do with a project where the patient is asked to participate in experimental telecardiology (for example).

It is worth mentioning that Norway, as most countries in the world, follow the Helsinki Convention on research on humans. In the convention it is clearly stated that such research must be based on informed consent and that consent to participate in most cases shall be written.

According to Norwegian legislation, there are no formal requirements for giving consent. This means that consent can be presumed, given orally or given in writing on a consent form or otherwise. But regardless of how consent is given, providing sufficient information is of the essence. We are talking about informed consent, and the patient has a right to get all necessary information about the treatment and procedures, expected outcome, risks, etc. for consent to be valid. It is the responsibility of the health personnel providing the treatment or performing the examination to make sure that the patient is given relevant information and that she or he is giving a valid consent.

There are of course a number of other questions regarding consent that could be discussed (personal competence, consent by proxy, etc) but we believe that it will be to detailed to address them in this report.

3.3.7 Cross border supply of telemedical services

***Question:* Does cross-border provision/supply of telemedical services in Norway require a prior contract between the relevant Norwegian institution and the institution abroad or, even, and inter-state contract?**

Even though we fully realise the huge potential there is in cross border health care by telemedicine, we do not have many examples of such services in Norway, and almost none in routine use. There have been (and still is) some work being done on cross border services in different projects and especially within the field of radiology. One relevant project is “Baltic e-Health”. In this project there has been done some work on the legal aspects of cross border provision of health care services and the report from this work can be found on the project website www.baltic-ehealth.org .

One way of regulating cross-border services is obviously through contracts between participating parties and/or institutions. In the mentioned Baltic project we have tried to write a draft contract for these situations, especially with teleradiology in mind.

Norway has entered a number of bi- and multilateral agreements in the field of health care, but none with direct relevance to cross-border telemedicine services. Maybe the future solution will be a combination of overall, general, state-to-state agreements supplied by more specific contracts.

With regards to transferral of information across country borders, Norway (as part of the EEA) is required to follow EU regulations, especially the above mentioned Directive on processing of personal information. More, and updated information on cross-border transfer of personal data can be found at this site:

http://www.ipr-helpdesk.org/controlador/resources/showDocument?idFicha=0000006542&formato=xml_html&nomFichero=ES_TransferPersonal&idFichero=00&len=en

One particularly difficult issue when it comes to the provision of cross-border services is payment/reimbursement. It is possible that this issue is especially suitable for contractual negotiations and regulations.

3.3.8 Use of different facilities

***Question:* The use of different facilities in telemedicine (email, fax, telephone, etc.) – is it regulated and how do you prevent possible misuse when consultation is provided by fax or phone?**

As mentioned earlier, there is no specific regulation on specific means of communication. The use of email, fax, phone, etc must meet standards and requirements of existing health care legislation. Misuse, will be treated accordingly and can be subject to sanctions from supervising authorities etc.

To our knowledge there are very few examples of actual consultations taking place by fax or phone except for things like renewals of subscriptions and second opinion from doctor to doctor. The latter is quite common, and a there is a standard tariff in use for these consultations.

3.3.9 Liability and insurance

***Question:* Does it exist and how does it function in Norway?**

Norway has a system of publicly funding for health care expenses. More information about the Norwegian system can be found at this website:

http://www.regjeringen.no/en/ministries/hod/Documents/Veiledninger_og_brosjyrer/2000/The-Health-and-Social-Affairs-Sector-in-Norway.html?id=419255

There are relatively few cases concerning health care before Norwegian courts. In very few cases are health care personnel held directly responsible for irresponsible actions. Most malpractice cases are settled by/through Norsk Pasientskadeerstatning (NPE) which *"…is an independent national body set up to process compensation claims from patients who believe they have suffered an injury as a result of treatment under the Norwegian public health service."* More information about this body can be found (also in English) at this website: http://www.npe.no/

3.3.10 Work schedules

***Question:* Who and how establishes the work schedule of the doctors that be consulted? Does the system work non-stop – 24 hrs? What if the consulted doctor does not respond to the request, can the consulted doctor refuse to provide the consultation even when he/she has sufficient data?**

This question is difficult to give a good, general answer to. First of all it is probably not a particularly legal question, second it touches upon the organisational issues which are in fact one of the more difficult in the process of implementing telemedicine and eHealth and third the answers will vary from institution to institution, from department to department and from service to service.

On a general level, Norwegian Health legislation establishes places an overall systems responsibility on hospital owners and managers. This responsibility must include the duty to establish services and regimes that can function also with regards to telemedicine and towards "customers" from other hospitals or from General Practitioners. Some services for example within teleradiology and trauma care works around the clock allowing for smaller hospitals to send images to (typically) the University Hospital, either as part of the process of transferring a patient or for interpretation or second opinion. Other services work within ordinary working hours.

Response time should be included in the overall organisation of a service.

The last question has never been put to test as far as we know, but it is a very good and relevant question. If a (telemedicine) consultation is part of the routine provision of health

care and the received information is sufficient for advice or treatment, it is my opinion that a doctor must have a very good reason to refuse to treat the patient and by doing so probably force the patient to travel in to the hospital.

3.3.11 Response time

***Question:* In what time is the consulted doctor obliged to respond to the request in case of a regular and not emergency consultation?**

Response time is not regulated by law, and we do not know of examples of services where this issue has been regulated by contract or otherwise.

3.3.12 Documentation/recording of data

***Question:* Does Norway provide a system where all the data is being recorded, including all the oral communications between the two doctors, e.g. by phone?**

Documentation is regulated by the Health Personnel Act6 with additional regulations. According to its Article 40, patient records "…shall be kept in accordance with good professional conduct and shall contain relevant and necessary information about the patient and the health care…". Two core words here are "relevant" and "necessary".

As far as we know, there are no systems in place that actually record all the data, nor is this required by law. Accordingly, documentation systems should be made so that they provide solutions and possibilities for different kinds of health professionals in different situations to add information that they consider to be relevant and necessary in the situation in question. As pointed out in the quoted section of article 40, documentation, both the duty to document and content of records, shall be done in accordance with good professional conduct.

In the case of consultations by telephone between two doctors it will fulfil the legal requirements if the consultation is recorded – in writing – electronically or otherwise by the doctors involved.

With regards to telemedicine services, it has been discussed whether or not videoconference consultations (with patients) should be recorded and the recording added to the patient's records. So far it has not been required to do so, but this might change as records become more integrated with electronic communication between hospitals, doctors, general practitioners and patients.

3.3.13 Definitions of telemedicine

***Question:* What is the official definition of telemedicine in Norway?**

There is no official definition of telemedicine in Norway. The term is in fact quite dynamic and constantly changing. One global "trend" is to sort the term telemedicine under the broader term eHealth, where eHealth encompass (almost) all possible solution that involves the use of information- and communication technologies in health care.

[6] English version attached to this report

Telemedicine is in most cases reserved for services that implies more direct treatment of patients at a distance, e.g. telesurgery or teleradiology.

At the Norwegian Centre for Telemedicine we work by a more “open” definition where both e-education, eHealth and telemedicine is included in the term. At our website we have collected some definitions from throughout the world:
http://www.telemed.no/index.php?id=44355

4. Attachment

Act of 2 July 1999 No. 64 relating to Health Personnel etc.

(The Health Personnel Act)
(With amendments made previous to 1 July 2002)

UNOFFICIAL TRANSLATION

Chapter 1. Objective of this Act, its scope and definitions

§ 1 *Objective of this Act*

The objective of this Act is to contribute to safety for patients and quality within the health service as well as trust in both health personnel and the health service.

§ 2 *Scope of this Act*

This Act applies to health personnel and facilities where health care is being provided.

The King stipulates regulations relating to the application of this Act to Svalbard and Jan Mayen and may lay down special provisions out of regard for the local conditions. To the extent determined by the King in regulations, this Act shall apply to persons onboard Norwegian ships engaged in foreign trade, to Norwegian civil aircraft in international traffic and to installations and vessels at work on the Norwegian continental shelf and within Norwegian rescue area.

§ 3 *Definitions*

For the purpose of this Act, the term health personnel shall mean:

1. Personnel with an authorisation pursuant to section 48 or a licence pursuant to section 49,
2. Personnel in the health services or in pharmacies who perform acts as mentioned in the third paragraph,
3. Pupils and students who in training as health personnel perform acts as mentioned in the third paragraph.

The Ministry may in regulations determine that the Act or certain provisions of this Act shall apply to further specified personnel not included under the first paragraph.

The term health care shall mean any act that has a preventive, diagnostic, therapeutic, health-preserving or rehabilitative objective and that is performed by health personnel.

The term health institution shall mean an institution that is governed by the Specialist Health Service Act and the Municipal Health Services Act.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

Chapter 2. Requirements to professional conduct for health personnel

§ 4 *Responsible conduct*

Health personnel shall conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general.

Health personnel shall act in accordance with their professional qualifications, and assistance shall be obtained and patients shall be referred on to others if this is necessary and possible. If the patient's needs so indicate, the profession shall be performed through co-operation and inter-action with other qualified personnel.

Upon co-operation with other health personnel, the medical practitioner and the dentist shall make decisions in matters concerning medicine or dentistry respectively in relation to examinations or treatment of the individual patient.

The Ministry may in regulations determine that certain types of health care shall only be provided by personnel with special qualifications.

§ 5 *Use of assistants*

Health personnel may in their work assign certain tasks to other personnel if it is considered safe to do so based on the nature of the assigned task, the qualification of the assigned personnel and the guidance that is being provided.

Pupils and students shall as a rule only be assigned tasks based on their need for training.

§ 6 *Use of resources*

Health personnel shall ensure that the health care does not mean unnecessary loss of time or unnecessary expenses to patients, health institutions, the National Insurance Scheme or to others.

§ 7 *Emergency health care*

Health personnel shall immediately provide the health care they are capable of when it must be assumed that the health care is of vital importance. Pursuant to the limitations laid down by the Patients Rights Act section 4-9, necessary health care shall be given, even if the patient is incapable of granting his consent thereto, and even if the patients objects to the treatment.

When in doubt as to whether the health care is of vital importance, health personnel shall perform the necessary examinations.

This duty does not apply to the extent that other qualified health personnel undertakes the responsibility to provide health care.

§ 8 *Duty of abstinence*

Health personnel may not consume alcohol or other intoxicating substances during working hours.

Medicinal products that are necessary due to illness are not considered to be intoxicating substances pursuant to the first paragraph. Health personnel using such products shall as soon as possible notify their employer thereof.

The Ministry may in regulations determine that health personnel may be required to provide a breath analyser test, blood test or a similar test upon suspicion of breach of the first paragraph and may give provisions relating to a ban on consumption of intoxicating substances for a fixed period of time prior to going on duty.

§ 9 *Ban relating to the receiving of gifts while acting in a professional capacity*

Health personnel may not on behalf of themselves or on behalf of others accept gifts, commission, service or other benefits that are suitable to affect the services provided by health personnel unduly.

Health personnel may furthermore not accept gifts, commission, services or other benefits from patients, unless the gift etc. is of insignificant value.

The Ministry may in regulations stipulate further provisions relating to what benefits that are included under the first and second paragraph.

§ 10 *Information to patients etc.*

The health care provider shall give information to persons entitled thereto pursuant to the Patients Rights Act section 3-2 to section 3-4. In health institutions information in accordance with the first sentence, shall be given by the person whom the institution designates thereto.

The Ministry may in regulations stipulate further provisions relating to the duty of information.

§ 11 *Requisition of medicinal products for which a prescription is required*

Medical practitioners and dentists only may make a requisition for medicinal products for which a prescription is required. The Ministry may in regulations determine that other health personnel holding an authorisation or licence may be granted a limited right of requisition.

The Ministry may in regulations stipulate further provisions relating to the requisition of medicinal products including provisions relating to the design as well as the filling in of prescriptions and requisition forms. It may also be determined that certain medicinal products shall be exempt wholly or in part from this right.

§ 12 *Examinations in connection with a criminal offence*

A medical practitioner, nurse or medical laboratory technologist shall, upon request from the police, take a blood test or perform similar examinations of persons suspected of a criminal offence while under the influence of alcohol or other intoxicating or narcotic substance when this is in accordance with statutory law and may be performed without danger.

A medical practitioner shall upon request from the prosecuting authority perform a physical examination of suspects in a criminal case when such an examination has been decided pursuant to section 157 of the Criminal Procedure Act. Furthermore a medical practitioner shall upon request from the relevant prison governor perform a physical examination of an inmate in a prison facility when such an examination is decided pursuant to the provisions of the Prison Act section 30 a.

A medical practitioner, nurse or medical laboratory technologist is under no obligation to perform examinations pursuant to the first and second paragraph of:

1. Spouse, registered gay partner, person who lives with the person in question in a relationship resembling that of marriage or a gay partnership, fiancé(e), relatives whom the relevant person descends from or whom descends from him in a direct line, siblings or people who are equally closely related through marriage or partnership. A relationship based on adoption or fostering is considered equal to that of kinship.
2. Person whom the relevant health personnel is providing medical treatment for.

The Ministry may in regulations stipulate further provisions relating to the duty to perform examinations pursuant to this section, including the stipulation of provisions relating to the limitation of this duty and on exemptions.

(The Prison Act was repealed by Act of 18 May 2002 No. 21 relating to Execution of Sentences etc. (The Execution of Sentences Act) which entered into force 1 March 2002. Cf. now the Execution of Sentences Act section 29.)

§ 13 *Marketing*

Marketing of health services shall be responsible, factual and sober.

Upon marketing of facilities providing health care, the first paragraph shall apply correspondingly.

The Ministry may in regulations stipulate further provisions on the marketing of health care, including provisions relating to a ban on certain types of marketing.

§ 14 *Ordering of health personnel to participate in duty rota*

The Ministry may determine that health personnel shall participate in duty rota at their place of residence or their place of work.

The Ministry may stipulate further provisions relating to the implementation etc. of duty rota.

§ 15 *Requirements to medical reports, medical certification etc.*

Anyone who issues medical certification, medical reports etc. shall be careful, precise and objective. A medical report etc. shall be correct, and contain only such information that is necessary for its intended purpose. Health personnel that are disqualified pursuant to the Public Administration Act section 6 shall not issue a medical report, medical certification etc.

Chapter 3. Requirements to the organisation of facilities

§ 16 *Organisation of facilities providing health care and internal control*

Facilities providing health care shall be organised in such a way that health personnel are able to comply with their statutory duties.

The Ministry may in regulations stipulate further provisions on the organisation of facilities providing health care and on internal control.

§ 17 *Information on matters which may endanger patient safety*

Health personnel shall of their own accord provide information to the supervising authorities on matters that may endanger patient safety.

Chapter 4. Special rules in connection with authorisation

§ 18 *Notification of health personnel's practice*

Health personnel holding an authorisation or licence in private practice shall notify the municipality or the regional health enterprise upon opening, taking over or entering a practice governed by this Act. Notification shall also be given upon the termination of practice.

The Ministry may in regulations stipulate further provisions relating to the type of information that shall be provided, when it shall be provided, and how it shall to be registered and passed on to a central register.

(Amended by Act of 15 June 2001 No. 93 (in force 1 Jan. 2002 in accordance with Decree of 14 Dec. 2001 No. 1417).)

§ 19 *Notification to employer of any subsidiary source of income and other engagement in other practice or enterprise*

Health personnel holding an authorisation or licence shall of their own accord inform their employer of any subsidiary sources of income and engagements, ownership

interests etc. in other practice or enterprise, which may come into conflict with the interests of the main employer.

In addition, the employer may demand that health personnel holding an authorisation or licence provide information on any health care practice which the health personnel provide as a self-employed person, for other employers or providers of assignments in Norway or abroad, as well as ownership interests and collaboration etc.

Information relating to the name as well as the nature and extent of their subsidiary source of income or engagement shall be provided.

This provision does not limit the obligation to provide information on subsidiary sources of income pursuant to an agreement or other statutory provisions.

§ 20 *Insurance*

Health personnel with an authorisation or licence running a private practice shall have insurance as security to cover the economic liability to patients that may arise in connection with the performance of their profession.

The Ministry may in regulations stipulate further provisions relating to the obligation to have insurance.

Chapter 5. Duty of confidentiality and the right of disclosure

§ 21 *General rule relating to the duty of confidentiality*

Health personnel shall prevent others from gaining access to or knowledge of information relating to people's health or medical condition or other personal information that they get to know in their capacity as health personnel.

§ 22 *Consent to give information*

The duty of confidentiality pursuant to section 21 is not to prevent information from being made known to the person that the information directly relates to, or to others, to the extent to which the person who is entitled to confidentiality gives his consent thereto.

For persons below 16 years of age, the provisions of the Patients Rights Act section 4-4 and section 3-4 second paragraph, shall apply correspondingly for consent granted in accordance with the first paragraph.

For persons over 16 years of age, who are incapable of considering the question of consent for reasons as mentioned in the Patients Rights Act section 3-3 second paragraph, their next of kin may grant consent pursuant to the first paragraph.

§ 23 *Restrictions in the duty of confidentiality*

The duty of confidentiality pursuant to section 21 is not to prevent:

1. information from being made known to a person who already have previous knowledge of the information,
2. information from being provided when there are no valid interests to indicate secrecy,
3. information from being passed on if the need for protection must be regarded as being adhered to if identifying characteristics have been omitted,
4. information from being passed on if exceptional private or public grounds make it legitimate to pass on the information, or
5. information from being passed on in accordance with rules laid down in or pursuant to law when it has been expressly stated or clearly presumed that the duty of confidentiality shall not apply.

§ 24 *Information after a person's death*

The duty of confidentiality pursuant to section 21 is not to prevent information relating to a deceased person from being passed on if weighty grounds so indicate. Upon assessment of whether information shall be provided, the assumed will of the deceased, the nature of the information, as well as the interests of his next of kin and the interests of society shall be considered.

A person's next of kin is entitled to access into the patient records relating to a deceased person unless special grounds indicate otherwise.

§ 25 *Information to co-operating personnel*

Unless the patient objects thereto, confidential information may be given to co-operating personnel when this is necessary in order to provide responsible health care.

The duty of confidentiality pursuant to section 21 is furthermore not to prevent personnel who are providing assistance with electronic processing of such information, or who is providing servicing or maintenance of equipment, from gaining access to such information, when such assistance is necessary in order to comply with statutory requirements for documentation.

Personnel as mentioned in the first and second paragraph are subject to the same duty of confidentiality as health personnel.

§ 26 *Information to the management of a facility and to administrative systems*

The health care provider may give information to the management of a facility when this is necessary in order to provide health care, or for the purposes of internal control or for the purposes of quality assurance of the service. The information shall in as far as possible be given without identifying characteristics.

The health care provider shall not be prevented by the duty of confidentiality pursuant to section 21 from providing the patient administration of the relevant facility with the patient's birth registration number, information relating to diagnosis, possible needs for assistance, offer of services provided, admittance and release dates as well as relevant administrative data.

The provisions relating to the duty of confidentiality shall apply correspondingly for personnel employed in patient administration.

§ 27 *Disclosure of information when acting as an expert*

The duty of confidentiality pursuant to section 21 is not to prevent health personnel acting as experts from giving information to the person or body that have assigned them as experts, if the information has been received in the process of carrying out this assignment and the information is significant for the assignment.

Anyone acting as an expert shall make the patient aware of the assignment and what it entails.

§ 28 *Information to employers*

The Ministry may stipulate regulations relating to the access to pass on information relating to the medical condition of an employee to his employer to the extent that the information concerns the employee's suitability for a certain type of work or assignment.

§ 29 *Information for other purposes*

The Ministry may determine that information may or shall be provided for use in research, and that the duty of confidentiality pursuant to section 21 shall not prevent this from taking place. To such a decision, conditions may be attached. The provisions relating to the duty of confidentiality pursuant to this Act shall apply correspondingly to anyone who receives this information.

The Ministry may in regulations give further provisions relating to the use of confidential information in research.

The Ministry may in regulations regulate the right of health personnel to release and use confidential information for purposes other than health care when the patient has granted his consent thereto. This applies to purposes such as insurance and credit institutions etc.

Chapter 6. Duty of disclosure etc.

§ 30 *Information to the supervising authority*

Health personnel shall grant the supervising authority access to the premises of the facility and provide all the information which is considered to be necessary in order to carry out supervision of the health personnel's activities. Notwithstanding the duty of confidentiality, the health personnel shall release the documents, sound and picture recordings etc. required by the supervision authority.

§ 31 *Information to emergency units*

Health personnel shall notify the Police or the Fire Services when this is necessary in order to prevent serious injury or damage to person or property.

§ 32 *Information to the social welfare service*

The health care provider shall in his work pay attention to matters which should lead to measures from the social welfare service, and shall by his own accord provide the social welfare service with information on such matters after having obtained the patient's consent thereto, or in so far that the information can be provided notwithstanding the duty of confidentiality pursuant to section 21.

Notwithstanding the duty of confidentiality pursuant to section 21, the health personnel shall provide information to the social welfare service, when there is reason to believe that a pregnant woman is abusing intoxicating substances in such a way that it is highly probable that the child will be born with defects, cf. the Act relating to Social Welfare Services section 6-2a. Upon order from the agencies responsible for the implementation of the Act relating to Social Welfare Services, the health personnel shall also provide such information.

Health institutions shall appoint one person who is responsible for the release of such information.

§ 33 *Information to the children's welfare service*

The health care provider shall in his work pay attention to matters, which could lead to measures from the children's welfare service.

Notwithstanding the duty of confidentiality pursuant to section 21, the health personnel shall of their own accord provide the children's welfare service with information when there is reason to believe that a child is being maltreated in the home or is being subjected to other forms of serious neglect, cf. the Act relating to Children's Welfare Services section 4-10, section 4-11 and section 4-12. The same applies to cases where a child has demonstrated prolonged and severe behavioural problems, cf. the aforementioned Act, section 4-24.

Upon order from the agencies responsible for the implementation of the Act relating to Children's Welfare Services, the health personnel shall also provide such information.

Health institutions shall appoint one person who is responsible for the release of such information.

§ 34 *Information in connection with driver's licences and pilot licences*

Medical practitioners, psychologists or optometrists who find that a patient holding a driver's licence for motor vehicles or a pilot licence for aircraft does not fulfil the necessary medical requirements, shall encourage the patient to hand in his licence. If the patient's medical condition is presumed not to be of a temporal nature, the health personnel as mentioned, shall report this to the public authorities in accordance with further provisions laid down by the Ministry in regulations.

The Ministry may in regulations stipulate further provisions on the implementation of and to supplement the first paragraph, and may also stipulate that the provisions of the first paragraph shall apply correspondingly to patients who serve outside aircraft, if their service is significant to the safety of aviation.

Chapter 7. Notification requirements

§ 35 *Notification of births*

Medical practitioners or midwifes shall notify the National Population Register of births. The notification shall contain information on who the father of the child is pursuant to the provisions of the Children Act sections 3 and 4 or whom the mother has named as the child's father in cases where paternity has not been resolved. The Ministry may in regulations determine that such notifications shall also contain additional information.

If the paternity has not yet been resolved or if the parents are not living together, the notification of birth shall be sent to both the National Population Register and the maintenance enforcement officer.

Notification of birth shall be issued even if the child is stillborn.

Medical practitioners or midwifes shall notify the Medical Birth Registry of deliveries and termination of pregnancies following the twelfth week of pregnancy in accordance with regulations laid down pursuant to the Personal Health Data Filing System Act.

(Amended by Act of 18 May 2001 No. 24 (in force 1 Jan. 2002 in accordance with Decree 18 May 2001 No. 502).)

§ 36 *Notification of deaths*

Medical practitioners shall issue certificates of deaths that they acquire knowledge of in their practice. The Ministry stipulates regulations relating to the certificates.

Medical practitioners who have issued medical certification of death or who have provided health care to a person prior to his death shall provide the municipal medical officer with the necessary information relating to the cause of death.

The municipal medical officer shall pass the information on to the Causes of Death Register.

If there is reason to suspect that a person did not die of natural causes, the medical practitioner shall notify the Police thereof in accordance with regulations laid down by the Ministry.

If investigations have been instigated in order to determine if death occurred by a criminal offence, the medical practitioner shall provide the court with information that is relevant to the case provided the court requests it.

§ 37 *Notification to health registers etc.*

The King may order health personnel holding an authorisation or licence to provide information to personal health data filing systems in accordance with regulations laid down pursuant to the Personal Health Data Filing System Act.

(Amended by Act of 18 May 2001 No. 24 (in force 1 Jan. 2002 in accordance with Decree 18 May 2001 No. 502).)

§ 38 *Notification of severe injury to persons*

Health personnel holding an authorisation or licence shall as soon as possible submit a notification in writing to the county medical officer of severe injury to a patient caused by the rendering of health care, or of injury inflicted upon one patient by another. Notifications of incidents that could have lead to severe injury to persons shall also be submitted.

The notification requirements for health personnel pursuant to the first paragraph do not apply if the health institution is subject to the notification requirements of the Specialist Health Service Act section 3-3.

(Not in Force, see Decree of 1 Dec. 2000 No. 1199.)

Chapter 8. Duty relating to documentation

§ 39 *Duty to keep patient records*

The health care provider shall enter or record information as mentioned in section 40 in a patient record for the individual patient. The duty to keep patient records does not apply to co-operating personnel providing care in accordance with instructions or guidance from other health personnel.

Health institutions shall designate one person with superior responsibility for the individual patient record including making decisions relating to what information is to be entered into the patient record.

The Ministry may in regulations instruct health personnel as mentioned in the first paragraph to keep a separate record that remains with the patient himself (patient's own records).

§ 40 *Requirements to the contents of patient records etc.*

The patient records shall be kept in accordance with good professional conduct and shall contain relevant and necessary information about the patient and the health care, as well as the information that is required in order to comply with the notification requirements or the duty of disclosure laid down in or pursuant to law. The records shall be easy to comprehend for other qualified health personnel.

It shall be evident from the records that has entered the information into the patient records.

The Ministry may in regulations stipulate further provisions relating to the contents of patient records and responsibility for the records pursuant to this provision including provisions relating to storage, transfer, cessation and destruction of patient records.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 41 *Duty to provide patient access to records*

The health care provider shall provide access to the patient records to anyone entitled thereto pursuant to the provisions of the Patients Rights Act section 5-1.

In health institutions the person with superior responsibility for patient records pursuant to section 39 shall make sure that access is provided pursuant to the first paragraph.

§ 42 *Correction of patient records*

Health personnel as mentioned in section 39 shall upon demand from the person whom the information relates to, or of their own accord, correct wrongful, deficient or improper information or comments in patient records. Correction shall be carried out through re-entering the information of the patient records, or by adding a dated correction in the records. Corrections shall not be made by deleting information or comments.

If a demand for correction is refused, the demand for correction and the reasons for its refusal shall be entered into the patient records.

Refusals of demands for correction may be appealed to the county medical officer, who, after obtaining a statement from the Data Inspectorate, determines whether corrections can be made.

The Ministry may in regulations stipulate further provisions relating to correction pursuant to this provision.

§ 43 *Deletion of information in patient records*

Upon demand from the person whom the information in the patient record relates to, or of their own accord, health personnel as mentioned in section 39 shall delete information or comments in the patient record, if this can be done without implications to public interest, if it is not contrary to the provisions in or pursuant the Archives Act sections 9 or 18, and:

1. the information is wrong or misleading and felt to be a burden for the person they relate to or
2. the information clearly is not necessary in order to provide health care for the patient.

If a demand for deletion is refused, the demand for deletion, and the reasons for the refusal shall be entered into the patient records.

Refusals of demands for deletion may be appealed to the county medical officer. A statement must be obtained from the Data Inspectorate. If the county medical officer is of the opinion that deletion may be contrary to the Archives Act sections 9 or 18, a statement shall also be obtained from the National Archives of Norway.

The Ministry may in regulations stipulate further provisions relating to deletion pursuant to this provision.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 44 *Patient records on the wrong person*

Upon demand from the person whom the information relates to, or of their own accord, health personnel as mentioned in section 39, shall delete patient records, or information or comments in patient records that have been recorded on the wrong person, unless public interest indicate that such deletion should not take place. The provisions of section 43 second to fourth paragraph shall apply correspondingly.

§45 *Transfer and release of and access to patient records and information therein*

Unless the patient objects thereto, health personnel as mentioned in section 39 may give the patient record or information therein to others who provide health care pursuant to this Act when this is necessary in order to provide health care in a responsible manner. It shall be evident from the patient record that other health personnel have been given access to the patient records pursuant to the first sentence.

The Ministry may in regulations stipulate further provisions to supplement the first paragraph and may include among them that other health personnel may be given access to patient records, also in cases not included under the first paragraph.

§46 *Electronic patient records*

Patient records may be kept electronically.

The King may in regulations stipulate further provisions relating to the use of electronic patient records, including setting up requirements relating to instruction and measures that shall ensure that any outsiders do not gain knowledge of or access to the records.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 47 *Use of notes on patients and patient records as evidence*

In legal or administrative cases relating to the professional conduct of health personnel, notes recorded in patient records, patient records and patient record material may be required for the purpose of being presented as evidence, either as originals, or as certified photocopies or printouts.

Chapter 9. Conditions relating the granting of authorisation, licence and certificate of completion of specialist training

§ 48 *Authorisation*

Authorisation pursuant to this act is granted to the following categories of health personnel:

a) Emergency Medical Technician *(Ambulansearbeider)*

b) Pharmacy Technician *(Apotektekniker)*

c) Audiologist *(Audiograf)*

d) Medical Laboratory Technologist *(Bioingeniør)*

e) Occupational Therapist *(Ergoterapeut)*

f) Pharmacist *(Farmasøyt)*

g) Chiropodist *(Fotterapeut)*

h) Physiotherapist *(Fysioterapeut)*

i) Medical Secretary *(Helsesekretær)*

j) Auxiliary Nurse *(Hjelpepleier)*

k) Midwife *(Jordmor)*

l) Chiropractor *(Kiropraktor)*

m) Clinical Nutritionist *(Klinisk ernæringsfysiolog)*

n) Medical Practitioner *(Lege)*

o) Care Worker *(Omsorgsarbeider)*

p) Optometrist *(Optiker)*

q) Prosthetist *(Ortpediingeniør)*

r) Orthoptist *(Ortoptist)*

s) Cardiovascular Perfusionist *(Perfusjonist)*

t) Psychologist *(Psykolog)*

u) Radiographer *(Radiograf)*

v) General Nurse *(Sykepleier)*

w) Dental Health Secretary *(Tannhelsesekretær)*

x) Dentist *(Tannlege)*

y) Dental Hygienist *(Tannpleier)*

z) Dental Technician *(Tanntekniker)*

æ) Social Educator *(Vernepleier)*

The right to be granted an authorisation following an application belongs to anyone who:

a. has passed an examination in the relevant subject at a Norwegian university or college or through occupational training at a secondary level,
b. has completed practical training in accordance with regulations laid down by the Ministry,
c. is under 75 years of age and
d. is not considered to be unfit for the profession.

The right to be granted an authorisation following an application also belongs to anyone who:

a. has passed an examination in a foreign country which is recognised as being equally as good as the equivalent Norwegian examination,
b. has passed an examination which is recognised in accordance with agreement on mutual recognition pursuant to section 52, or
c. has otherwise proven to possess the necessary skills.

The Ministry may in the regulations decide that categories of health personnel that are not included under the first paragraph may be granted authorisation following an application. Upon decision, emphasis shall be on the consideration for patient safety, the contents and objective of the relevant education, the extent to which the relevant profession is carried out independently, as well as considerations relating to the harmonisation between Norway and other countries.

The Ministry may in regulations stipulate additional requirements for the granting of authorisation for each individual category of health personnel, including that the requirement shall also apply to those who already have an authorisation or public certification at the time of entry into force of these regulations.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 49 *Licence*

Health personnel, who do not have the right to an authorisation pursuant to section 48, may be granted a licence following an application. A licence may only be granted

to health personnel that are considered to be suited in accordance with the type of licence granted, and the tasks it covers.

A licence may also be granted to health personnel who has passed an examination in a foreign country, which has been recognised in accordance with an agreement on mutual recognition pursuant to section 52.

The licence may be limited in time, to a certain position, to certain types of health care or otherwise.

The Ministry may in regulations stipulate additional requirements related to the granting of a licence and the conditions attached to it, including that the requirements shall also apply to those who already have a licence at the time of entry into force of these regulations.

§ 50 *Border licence*

Publicly employed and authorised health personnel in Sweden and Finland working along the Norwegian border can carry out their work in Norwegian municipalities along the borders without an authorisation or licence pursuant to sections 48 and 49.

§ 51 *Conditions relating to the granting of a certificate of completion of specialist training*

The Ministry may stipulate regulations on the conditions relating to the approval of authorised health personnel as specialists within a limited area in the field of health, including that the requirements shall also apply to those who already have a certificate of completion of specialist training at the time of entry into force of these regulations.

§ 52 *International agreements*

Based on agreements with other countries relating to mutual recognition, authorisation, licence and certificates of completion of specialist training may be granted to aliens.

The Ministry may in regulations stipulate further provisions to supplement the first paragraph, and may among them stipulate special requirements for recognition that are necessary in order to comply with international agreements.

Chapter 10. Granting and expiration of authorisation, licence and certificate of completion of specialist training

§ 53 *Granting of authorisation, licence and certificate of completion of specialist training*

The Norwegian Directorate for Health and Social Welfare grants authorisations, licences and certificates of completion of specialist training subject to further

stipulated remuneration. The Ministry may in regulations instruct the individual educational institution and others with educational responsibility to grant authorisations for education where practical training *(turnustjeneste)*, cf. section 48 second paragraph litra b, is not required. The Directorate may delegate the authority to grant certificates of completion of specialist training to private professional associations.

The Norwegian Directorate for Health and Social Welfare may refuse to grant an applicant authorisation, licence or certificate of completion of specialist training if circumstances exist that would have provided grounds for revocation pursuant to section 57.

A decision pursuant to the preceding paragraph of this provision is an individual decision pursuant to the Public Administration Act.

If there is reason to believe that grounds for revocation exist, the Norwegian Directorate for Health and Social Welfare may order health personnel to undergo examinations as described in section 60.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359), Act 21 Dec. 2001 No. 119 (in force 1 Jan. 2002 in accordance with Decree of 21 Dec. 2001 No. 1524) and Act 28 June 2002 No. 62 (in force 1 July 2002 in accordance with Decree of 28 June 2002 No. 638).)

§ 54 *Expiration of authorisation, licence and certificate of completion of specialist training*

Authorisation, licence and certificate of completion of specialist training expire when the holder turns 75 years of age. The professional title may however still be used.

Health personnel over 75 years of age may however be granted a licence or certificate of completion of specialist training subject to certain conditions, cf. section 49 fourth paragraph and section 51.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

Chapter 11. Reactions etc. to breach of the provisions of this Act

(Heading amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 55 *Request for assessment of possible breach of duty*

A person, who is of the opinion that provisions relating to duties stipulated in or pursuant to this Act have been breached in his disfavour, may request an assessment of the matter from the supervising authority. The patient may act through a representative. The request is to be sent to the county medical officer.

A representative pursuant to the first paragraph is the person who has the authority to lodge a request on behalf of others, or who is competent to grant consent pursuant to the provisions of the Patient Rights Act, chapter 4. A person holding power of attorney, who is not a lawyer, shall present a written authorisation.

The county medical officer shall consider the views put forward in the request, and may also address other matters than those put forward in the request.

If the county medical officer is of the opinion that a reaction should be imposed pursuant to the provisions of chapter 11, the case shall be sent to the Norwegian Board of Health. The third paragraph shall apply correspondingly to the handling of the case by the Norwegian Board of Health.

The supervising authority shall give the person who lodged the request information on the result of the case, as well as a brief presentation of the grounds for this result.

The Ministry may in regulations stipulate further provisions relating to the rules of procedure for the supervising authority, and may stipulate provisions on time limits for the lodging of a request pursuant to this section.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 56*Warning*

The Norwegian Board of Health may give a warning to health personnel who intentionally or negligently contravenes duties stipulated in this Act or provisions pursuant to this Act, if the breach of duty is liable to endanger the safety of the health service or impose a considerable burden on patients.

A warning is an individual decision pursuant to the Public Administration Act.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 57 *Revocation of authorisation, licence or certificate of completion of specialist training*

The Norwegian Board of Health may revoke an authorisation, licence or certificate of completion of specialist training if the holder is unfit to practice his profession in a responsible manner for reasons of severe mental illness, mental or physical impairment, prolonged absence from the profession, use of alcohol or narcotics or substances with a similar effect, a gross lack of professional insight, irresponsible conduct, gross breach of duty pursuant to this Act or provisions stipulated in accordance with this Act, or due to behaviour considered to be incompatible with professional conduct.

Authorisation, licence or certificate of completion of specialist training may be revoked if the holder in spite of a warning fails to comply with statutory requirements.

An authorisation, licence or certificate of completion of specialist training may also be revoked if the conditions stipulated in regulations in accordance with section 48, section 49 or section 51 have not been met.

An authorisation, licence or certificate of completion of specialist training that have been granted on the basis of a similar certificate in another country, may be revoked if the certificate granted in the other country is no longer valid.

Revocation is an individual decision pursuant to the Public Administration Act.

§ 58 *Suspension of authorisation, licence or certificate of completion of specialist training*

If there is reason to believe that the conditions for revocation are present, and the health personnel is considered to be endangering the safety of the health service, the Norwegian Board of Health may suspend authorisation, licence or certificate of completion of specialist training pending a final decision in the case. The suspension may apply for a period of six months and may be extended once for an additional period of six months.

Suspension is an individual decision pursuant to the Public Administration Act.

§ 59 *Limiting of authorisation*

The Norwegian Board of Health may limit the authorisation so that it only applies to the performance of certain activities under certain conditions.

Such limitations may be stipulated in cases where health personnel in spite of the fact that the conditions for revocation are present, are considered to be suited to perform activities within a limited field under supervision and guidance.

A decision relating to the limiting of authorisation is an individual decision pursuant to the Public Administration Act.

§ 60 *Order of examination by experts*

In cases where revocation of authorisation, licence or certificate of specialist training is to be considered, the Norwegian Board of Health may order health personnel to undergo a medical or psychological examination by experts.

The Norwegian Board of Health may suspend authorisation, licence or certificate of completion of specialist training so long as the order given pursuant to the first paragraph is not complied with.

§ 61 *Voluntary renouncement of authorisation, licence or certificate of completion of specialist training*

Health personnel may themselves renounce their authorisation, licence or certificate of completion of specialist training by submitting a written statement to this effect to the county medical officer. The document granting authorisation, licence or

certificate of completion of specialist training shall if possible be handed in at the same time.

§ 62 *New authorisation or licence*

The Norwegian Board of Health may grant health personnel who have lost their authorisation, licence or certificate of completion of specialist training by revocation or voluntary renouncement, a new authorisation, licence or certificate of completion of specialist training if the relevant health personnel is able to prove that he is suited thereto. The new authorisation may be limited pursuant to section 59.

Refusal of an application for a new authorisation or licence is an individual decision pursuant to the Public Administration Act.

§ 63 *Loss of the right to require medicinal products in Group A and B*

If medical practitioners' or dentists' requisition of medicinal products is considered to be irresponsible, the Norwegian Board of Health may revoke the right to require such medicinal products wholly or in part for a period of time, or permanently. The same applies to other health personnel who in regulations laid down pursuant to section 11 have been granted a limited right to require medicinal products.

Health personnel may themselves renounce the right to require medicinal products as mentioned in the first paragraph by submitting a written statement to this effect to the county medical officer. A renouncement is binding for the period of time for which it has been granted.

If the conditions for revocation are still present upon expiry of the time limit pursuant to the first paragraph, the Norwegian Board of Health may make another decision pursuant to the first paragraph.

When medical practitioners or dentists do not themselves have the right to require medicinal products in group A and B, the municipal medical officer, chief consultant or the county dental officer shall require the medicinal products that are necessary for the relevant medical practitioner or dentist in his practice. They may also grant approval to other health personnel to carry out requisitions.

A decision relating to the revocation of the right to require medicinal products is an individual decision pursuant to the Public Administration Act.

§ 64 *Suspension of requisition rights*

If there is reason to believe that the conditions for a revocation of requisition rights are present, and health personnel is considered to be endangering the safety of the health service, the Norwegian Board of Health may suspend the right to require medicinal products as mentioned in section 63, pending a decision in the case, but not exceeding six months. If the health personnel delay the case, the suspension may be extended for an additional period of six months.

A decision relating to the suspension of the right to require medicinal products is an individual decision pursuant to the Public Administration Act.

§ 65 *Reduction of period of loss of requisition rights*

If it is found to be safe to do so, the Norwegian Board of Health may return the rights to health personnel to require medicinal products in group A and B prior to the time when the stipulated period expires.

Refusal of this type of application is an individual decision pursuant to the Public Administration Act.

§ 66 *Information to employers and to other countries*

The Norwegian Board of Health shall notify the employer of warnings, revocations, voluntary renouncement or suspension of authorisations, licences or certificates of completion of specialist training or requisition rights or limiting of authorisation. The term employer also includes any public authority that the relevant health personnel have entered into an agreement with relating to the running of a practice.

If the health personnel run an independent practice with an agreement relating to the running of a practice, the Norwegian Board of Health shall give the relevant public authority advance notice when there are legitimate reasons to suspect that the conditions for the aforementioned measures are present, and the decision will influence the possibilities to comply with the agreement.

Upon revocation, voluntary renouncement and suspension of authorisations, licences, certificates of completion of specialist training, requisition rights or upon limiting of authorisation, the Norwegian Board of Health shall notify the countries that Norway by international law is required to inform.

§ 67 *Punishment*

Anyone who intentionally or by gross negligence contravenes the provisions of this Act, or who aids and abets thereto, shall be punished by fines or a term of imprisonment not exceeding three months.

Public prosecution will be instituted if it is in the public interest or by petition by the Norwegian Board of Health.

Chapter 12. The Norwegian Appeals Board for Health Personnel and the Norwegian Pharmacy Appeals Board

(Heading amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 68 *The Norwegian Appeals Board for Health Personnel and the Pharmacy Appeals Board*

A Norwegian Appeals Board for Health Personnel *(Statens helsepersonellnemnd - HPN)* is established. In cases governed by the Pharmacy Act, the Board shall refer to themselves as the Norwegian Pharmacy Appeals Board *(Apotekklagenemnd - AKN).*

The Norwegian Appeals Board for Health Personnel is the administrative appeals body for decisions pursuant to sections 53, 56-59 and 62-65. The Pharmacy Appeals Board is the administrative appeals body for decisions as stipulated in the Pharmacy Act section 9-1 first paragraph.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 69 *Organisation of the Norwegian Appeals Board for Health Personnel*

The Norwegian Appeals Board for Health Personnel shall be an independent body with high expertise within the fields of health and law that is appointed by the Ministry for three years at a time.

The Norwegian Appeals Board for Health Personnel shall consist of three members of the legal profession, one of whom shall be the head of the Board, as well as three members with a background as health professionals and one lay representative.

The Norwegian Appeals Board for Health Personnel may appoint two experts to assist in each individual case.

The Ministry may in regulations stipulate further provisions relating to the organisation of the Norwegian Appeals Board for Health Personnel.

§ 70 *Executive processing work by the Norwegian Appeals Board for Health Personnel*

The Ministry may in regulations lay down further provisions relating to the executive processing to be carried out by the Norwegian Appeals Board for Health Personnel.

§ 71 *Judicial review*

Decisions by the Norwegian Appeals Board for Health Personnel pursuant to sections 53, 56-59 and 62-65 may be brought before the courts that may review all aspects of the case.

Cases are to be reviewed pursuant to the provisions of the Civil Procedure Act, chapter 30. By order of the court it may be decided that decisions pursuant to the provisions of the first paragraph shall not come into effect pending a final decision in the case, or before a final judgment has been reached.

Notwithstanding these provisions, decisions may be brought before the Parliamentary Ombudsman.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).

§ 72 (Repealed by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

Chapter 13. Miscellaneous provisions

§ 73 *Compensation for loss upon suspension and revocation*

If decisions relating to suspension or revocation prove to be invalid or set aside for other reasons, compensation for loss may be claimed pursuant to the general provisions relating to the statutory provisions relating to damages.

§ 74 *Use of protected title*

Holders of authorisation, licence or certificate of completion of specialist training only are entitled to use such job titles characteristic of the relevant group of health personnel.

No one must unrightfully make use of or announce activities in such a way as if to give the impression that the person concerned has been granted an authorisation, licence or certificate of completion of specialist training.

The Ministry may in regulations give further provisions relating to which titles are protected pursuant to this section.

§ 75 *Entry into force*

This Act shall enter into force at the time determined by the King. The King may determine that certain provisions of this Act shall enter into force at different times.

(The Act entered into force 1 Jan. 2001 with the exception of section 38, in accordance with Decree of 1 Dec. 2000 No. 1190.)

§ 76 *Transitional provisions*

Regulations etc. laid down pursuant to Acts repealed or amended upon entry into force of this Act shall apply to the extent that they are not contrary to this Act or regulations stipulated pursuant to this Act.

Persons who, upon entry into force of this Act, holds an authorisation, public certification as health personnel, licence or certificate of completion of specialist training, shall keep their authorisation, certification, licence or certificate of completion of specialist training pursuant to this Act.

The Ministry may stipulate regulations relating to the implementation of this Act including transitional provisions.

(Amended by Act of 21 Dec. 2000 No. 127 (in force 1 Jan. 2001 in accordance with Decree of 21 Dec. 2000 No. 1359).)

§ 77 *Repeal of and amendments to other Acts*

From the time of entry into force of this Act, the following Acts are repealed:

1) Act of 13 July 1956 relating to physiotherapists etc.

2) Act of 8 January 1960 No. 1 relating to certification of nurses.

3) Act of 11 June 1971 No. 54 relating to orthetists and prosthetics and sale of orthopaedic appliances

4) Act of 23 June 1972 No. 69 relating to certification of psychiatric nurses

5) Act of 9 March 1973 No. 13 relating to certification of psychologists

6) Act of 14 June 1974 No. 47 to relating to certification of health personnel

7) Act of 13 June 1980 No. 42 relating to medical practitioners

8) Act of 13 June 1980 No. 43 relating to dental practitioners

9) Act of 26 April 1985 No. 23 relating to midwifes