

AEMH intern 99 / 019

# **AEMH Statement on Legal applications of telemedicine.**

#### I Introduction.

The AEMH plenary meeting in Porto 1998 decided to constitute 7 working groups in different medical subjects. Norway was responsible to coordinate the working group "Legal applications of telemedicine".

In January the Norwegian Association of Senior Hospital Physicians, Of, sent a plan of action to the AEMH secretariat. We asked dr. Lies, dr. Bitenc and dr. Theuvenet, if it was possible for any of them to join the group and come to Norway 5. – 6th of May.

Dr. Bitenc had the possibility to join the group together with dr. Hysing and legal adviser Signe Gerd Blindheim to meet representatives from the telemedicine center in Norway.

To the discussion in the meeting in May we had invited dr. Harald Sunde, general practioner in a small town in the north of Norway called Kirkenes. Once a week he is practicing telemedicine in a consulting room at the hospital in Kirkenes communicating with a specialist in dermatology in the University Hospital in Tromsø.

The Norwegian telemedicine center is also located at the University Hospital in Tromsø.

The leader of the center, Steinar Pedersen, is an ENT specialist. He has been working with telemedicine for years and is recognized internationally as an authorithy on the subject.

He is also the president in the International Society for Telemedicine.

Dr. Pedersen was communicating with us in Oslo on a TV-screen from his studio in Tromsø.

We also invited Leif Nohr who is a legal adviser at the telemedicine center.

On the basis of this report the working group hope that we will get an interesting discussion at the Plenary meeting in Verona. We are also hoping that if the delegates have any comments and questions to this report they will mail it to the following e-mail address: <a href="mailto:signe.gerd.blindheim@legeforeningen.no">signe.gerd.blindheim@legeforeningen.no</a> even before the meeting in Verona, so that adjustments can be made.

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Based on the discussion at the Plenary meeting the group will work out the final report. Legal applications of telemedicine will to a certain extent depend on the legislation in each country. There are, however, certain basic questions and principles for medical doctors in most European countries. The group has tried to concentrate on these basic questions and principles.

## II Definitions and development of telemedicine.

Telemedicine can be described as the use of medical information exchanged from one site to another via electronic communication for the health and education of the patient or health care provider and for the purpose of improving patient care.

The EU-commission has following definition from a programme called *Advanced Informatics in Medicine*.

"Examination, control and administration of patients and training of patients and health personnel by available systems of patient information, not depending on where medical experts or patients are located."

In telemedicine interventions, diagnostic and treatment decisions and recommendations are based on data, documents and other information transmitted through telecommunication systems.

Telemedicine should not be regarded as a new medical discipline, but different systems of communication in order to obtain a better use of medical resources, also in remote areas.

Telemedicine started in the 1960s as mere telephone communication to provide patients in rural areas with medical care. Today telemedicine still encompasses health specialists assisting patients in remote areas by telephone, but the range of telemedicine projects has grown exponentially with the use of interactive video and computer networking. Unfortunately the legal and regulartory environment has not kept pace with this growth. Application of telemedicine has extended into a lot of different medical areas, like radiology,

pathology, dermatology, cardiology, ENT and psychiatry.

# III Telemedicine - International perspective.

Internationally telemedicine services are increasing. Most industrial countries have made heavy investments in experimental telemedicine. In countries where systems of

public health are dominating, financing usually is through public budgets. In countries where most of the health services are financed by private capital, private companies do the financing.

It seems like radiology is the telemedicine service with the greatest increase in volume. In USA, Canada, Australia, Israel and Western Europe including the Nordic countries telemedicine systems has been developing most quickly.

In principle telemedicine has no natural geographical limits. The Internet-technology makes it possible today to establish international working groups specialised in complicated diagnostics of patients with infrequent medical conditions.

Different countries, among them USA and Israel, are working in a global perspective to make health services in telemedicine available for the general public – if they want to pay for the service. WHO is also using systems of telemedicine.

Organising of medical knowledge gives possibilities for different countries both according to improvement of quality and standardizing of medical treatment. Cooperation by telemedicine in education can improve the quality and efficiency of the education.

The technological development together with lowering of prices on systems of telecommunication, can even make it possible to transfer the concepts of telemedicine to developing countries, making these countries more able to take care of their own patients.

# IV Routine services in telemedicine to day.

**Videoconferences.** Can be used for all kinds of meetings where visualizing is needed for education, diagnostics and treatment.

**Teleteaching**. Used for decentralized teaching.

**Telemedicine used as a method for ENT consultations.** The results of this type of examinations are for most of the ENT diseases as well as ordinary ENT examinations.

**Telepathology for biopsies** is regarded a secure medical method levelled as traditional pathology. This service is useful for hospitals without a special department of pathology, and to maintain second opinion on biopsies.

**Telecardiology** with echo-Doppler pictures of the heart is used today as a routine service. The patient is examined in his local hospital while the examination of the heart is transmitted by videoconference system to the specialist in a larger hospital. The

cardiologist controls the examination, possible irregularities and plans for treatment. The results of this type of treatment shows that for several types of heart problems it is possible to ensure the patients examination by centrally located specialist even if they stay at their local hospital.

Telecardiology is also used for second opinion, supervision and education. Small hospitals often have medical equipment not in use, because of lack of a cardiologist. By supervision by videoconference the doctors at the small hospitals can be able to use the equipment themselves.

**Teleradiology** has a great potential as a routine method, both as ordinary treatment and as second opinion. In hospitals with no radiologists or acute ward, it gives the possibility for better services. A consultation in teleradiology can take place in the following way: Hospitals who have a dedicated telemedicine workingstation in their Department of radiology can transmit pictures from this to a coherent working station in the other hospital. If this system is directly connected to the hospitals radiologyinformation systems, it is possible to make the process of external radiologyexaminations similar to the internal treatment in the hospital.

Teledermatology is a routine service today, and the technical quality of pictures is usually estimated to give a qualified basis for diagnostics. This service does not need a lot of medical equipment and in a real improvement for the patient.

## V Areas of development.

The technology of telemedicine is new and still in the stage of innovation. The technology is characterized by testing and questions of competence. It is important that the routine services of telemedicine are not forgotten in the perspective of further development. The technological development is increasing so fast that the need of further development also will be there for well established services today.

We know that both in teledermatology and teleendoscopy connected to ENT examinations there are tests going on how stillpictures can be used as a diagnostic method. If these pictures give a reliable result, pictures can be mailed as enclosed email to a specialist who will look at the pictures on occasion.

Tests have been made with digitized photos of biopsies mailed as enclosed e-mail. The conclusion is that this way of collecting second opinion between pathologists will be acceptable for several pathological diseases.

Patients with retinadiseases caused by diabetes usually need specialist consultation.

There is a test going with fundus camera and digitized transmission of the picture. If the test results turn out to be safe, this examination may turn out to be a routine service.

Telepsychiatry has so far been synonymous with videoconferences and clinical services within psychiatry. Solutions based on Internet as part of the concept of telepsychiatry is increasing and will be focussed as a way of offerening tele-teaching and social security within psychiatric health care.

It is important to test new solutions on established services at the same time as doing research in new areas.

# VI Legal applications of telemedicine.

# A. Can you as a physician deny working with telemedicine system if there is a system established in your hospital department?

Some European countries have agreements between the hospital owner and the unions saying that implementation of new systems can not take place without prior discussion between the owners and the union representatives. It is important to ensure that the technical equipment is of a sufficiently high standard and adequately operational and that the physicians who are going to operate the systems are trained.

Even if the telemedicine system turns out to be accepted in the hospital, and the equipment seems good, the physician should not practice telemedicine, if he feels unsafe about the method for one reason or another.

Like in all other medical treatment the physician will be responsible if he/she fails to meet the standard of skill and knowledge legally expected of a medical practitioner. By using telemedicine the physician even more than ever have to pay attention to ensure that the information is sufficient for safe treatment. The quality of sound and picture must make the physician able to do the diagnoses according to the professional legislation.

The new technology introduced in telemedicine may also increase the doctor's liability because he may be deemed to have responsibility to keep equipment in a reasonable condition. In hospitals the technical staff will probably be responsible for the equipment's condition, but the physician is the one to decide that the equipment works out according to the purpose.

The group's opinion is that there should be a registration system for telemedicine equipment, ensuring an optimal quality. There is a certain risk that for instance hospital budgets will make the owners ask for low-price systems, which may not have the adequate quality.

# **B.** Authorisation - competence

Physicians practicing telemedicine, must be authorized to practice medicine in the country in which they are located and must be competent in the field they are practising it.

It is, however, expected that telecommunication in the future increasingly involves the practice of medicine across international boundaries, which creates questions about new ways of licensing medical professionals. For instance, must a physician also be licensed in the country

where the telecommunication consultation takes place? The working group has discussed the possibility for a system of international accreditation, made by an intergovernmental association, for instance WHO.

In the meantime, the physicians who communicate with physicians in foreign countries have to take the responsibility for using advices from foreign medical consultants. The patient can hardly do any action for damages if the advices turn out to be useless and if the foreign physician is not a part of an established health care system in his country. Developing of international accreditation systems and other international communication systems can change the legal views.

#### C. Advice or referal.

#### Medical advice.

One of the main legal questions concerning telemedicine is, whether the physician asks another physician for advice or whether the telecommunication is a referal. It is very important that this is agreed either between the communicating physicians or as an organised system for instance between a GP and a hospital specialist, or between two specialists in different hospital levels. The agreements should be written down as a part of the institutions or the physicians routine for quality management, and will be very important when responsibility is at stake.

A physician asking for another physicians's advice remains responsible for treatment and other decisions and recommendations given to the patient.

As far as we know the major application of telemedicine is the situation in which the treating doctor seeks another doctor's opinion and advice at the request of or with the permission of the patient.

Legally this situation can be compared to other ways of colleagual discussions and asking for advice in order to give the patient the optimal treatment. Documentation in the patients records what have been done is important if there is a question whether the doctor has acted in accordance with the professional legislation or not – also in practising telemedicine.

The communicating physicians should both do their medical records as a documentation to show that they have acted in the most professional way according to their medical skills.

#### Referal.

The principle of referal is that the specialist or the hospital referred to has the responsibility when the patient is referred either from a GP to a specialist or from a hospital to another hospital.

Dr. Harald Sunde gave us an example how the referal system works out in Kirkenes, a small town in Finnmark county in Norway. In Norway the counties are responsible for the specialist health services to the population. The GP's in Kirkenes do not have technical equipment in their offices. When they give a referal to a specialist in for instance dermatology there is not a dermatologist in the hospital in Kirkenes, so usually the patient has either to travel to the University hospital in Tromsø, which is far away or to wait about six months to see the specialist when he visits the hospital in Kirkenes. Norway has a great lack of specialists in rural areas.

Finnmark county has a telemedicine studio at the hospital in Kirkenes. Once a week dr. Sunde who is not a dermatologist, but a GP, communicates with the dermatologist in Tromsø about a patient who is present in the studio in Kirkenes. This is part of the county's referal system. The responsibility in organizing the referal system belongs to the county and of course to the specialist in the hospital in Tromsø. He/she has to ask to see the referred patients if he means that the information is not sufficient.

The group finds it very important that the doctor who is responsible for diagnosis and treatment by telemedicine always must have the possibility to ordinary consultations if there is any doubt.

Telemedicine has economical advantages as less travel expenditures for the patients and less absence from work. Economical reasons must, however, never prevent the specialist to see his patient if necessary. The group also discussed if telemedicine is an alternative to a referal only when the methods matches 100 percent to ordinary consultations.

It seems difficult to give a plain answer to the question. It will probably depend on the alternatives, how long you have to wait for the treatment, the relationship between the physician and his patient and the professional relationship between the GP and the specialist or between a specialist in a local hospital and a specialist in a university hospital.

### D. Professional secrecy – confidentiality.

The customary privacy and confidentiality of the medical setting is challenged in other ways than with ordinary consultations, because the patient's records and medical history are conveyed not only to the consulting physician, but also, by necessity, to several individuals outside the traditional medical team. The transmission procedure requires technical staff at both ends. In small communities, it is possible that the patient knows the non-medical personnel socially, compounding the sense of loss of privacy.

The physician has both the moral and ethical obligation to hold treatment information confidential. The laws in the different countries protect such information. When this obligation is breached, the patient usually has legal recourse, unless the patient himself releases such information. A physician is allowed to transfer information to other treating physicians in the presence of or with the consent of the patients.

By organizing telemedicine systems, adequate procedures and standards to protect the patient's medical information must be provided. Storing or transmission methods may be used only where confidentiality and security can be guaranteed.

The physician has to make sure that patient data and other information may only be transmitted to a doctor or other health professionals on the request or with the informed consent (permission) of the patient and to the extent approved by him/her. The data transmitted must be relevant to the problem questioned.

Telemedicine practitioners will be held liable for breaches of security and any unauthorized access. The legal issue will not be, whether electronic patient information systems can provide airtight security, but whether such systems can provide privacy protection equal to or better than paper record systems. Newer technologies can actually be more secure. These networks are digital, multiplexed and are often more difficult to manipulate. Medical records groups throughout the world are working with information security specialists to develop standards for security and privacy of electronic patient records.

How far away is the European Health Card?

# E. Patients rights.

The patients informed consent of different aspects by telemedicine consultation and treatment are basic according patients rights. The patient must always have the right to choose a traditional consultation, even if he has to wait for months to see a specialist.

So far in Finmark county in Norway only 4% of the total health services are by telemedicine.

91% of the patients are either very satisfied or satisfied according to inquiries.

Groups of patients are difficult to diagnose by telemedicine: small children, old patients

and patients speaking other languages. Small lesions can be difficult to study since the close up cameras are not always good enough. For these groups ordinary consultations are recommended.

## F. Malpractise.

There are, as far as we know, no precedent decisions involving telemedicine malpractice claims in the court. Therefore the legal extent of a medical practioner's liability remains unclear. Even if this should seem like good news it has something to do with a low number of cases having been brought to court compared with conventional medical malpractice cases.

The reasons can be that licensure and other barriers have prevented physicians from engaging in widespread use of telemedicine. Potential telemedicine participants are reluctant to enter the field without knowing in advance the extent of their liability, i. e. risks of exposure to additional liability may outweigh the benefits of telemedicine.

To prevent malpractise claims in the future the group believe that physicians participating in telemedicine should have agreements of medical responsibility, thoroughness in documentation, a professional relationship to the patient, and deny working with telemedicine systems if there is any risk for professional malpractise according to diagnostics, treatment, accepted confidentiality and medical equipment.

## VII The discussion at the Plenary meeting.

The group has two basic questions:

- \* Is telemedicine in the interest of the medical profession?
- \* Is telemedicine in the interest of the patient?

By having these questions in mind, we hope we can discuss this report point by point.

# VIII Evaluation of the AEMH working group.

The group thinks this way of working is interesting. If you are going to be a participant in a group your union has to pay for it, as far as there is no budget for working groups in the AEMH. That means that to meet across the borders you must have the economic possibilities.

That also means that some persons are excluded from the groups for economical reasons. We have to have that in mind in the further work.

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