Proceedings

Third International Meeting

3rd - 4th June 1999
Stavanger, Norway

European Platform for Supervisory Organizations for Health Care

EPSO

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Contents

Preface

With pleasure I present you the Proceedings of the third International Meeting of the European Platform for Supervisory Organizations (EPSO) held on 3rd and 4th June, 1999 in Stavanger, Norway.

The first meeting was organized in 1996 as an initiative of the Dutch Inspectorate for Health Care. The aim was to establish an European network for all those officials who have the duty to supervise and monitor the quality of health care in their country. The outcomes of these meetings are definitely showing the need of such a network.

The meeting in Stavanger had a very tragic end with the sudden death of Jitze Verhoeff of the Dutch Inspectorate of Health Care. He was the founder of EPSO and the leading person in promoting the network. As will be possible to see when reading this report he had a strong belief on the importance of EPSO and showed to us all an optimistic view on the future of the network. We will continue our activities in compliance with his stimulating ideas.

It has been proven to be essential that the supervisory bodies for health care in the member states of the European Union and the states connected by the EEA Agreement share their experiences.

The next meeting of EPSO is planned in October 2000.

This report is compiled by Mrs Bep Liedorp at the Dutch Inspectorate. I am very grateful to her for taking care of this important part of the work connected to this meeting. I am sure this report will be stimulating and interesting for all participants of EPSO, including those who were not able to attend.

Geir Sverre Braut
Chief County Medical Officer

Rogaland County Medical Office
Stavanger, Norway

I Introduction

In Europe a growing amount of cross-border activity is rapidly developing and this also concerns medical affairs. Another important issue is the development of quality systems in health care. This may also imply consequences for cross-border health care as well as for supervision. General criteria for the operation of bodies performing inspection (CEN/CEN-ELEC 45005) may also have consequences for inspection methods of health care inspectorates in the EC countries.

It is essential for the different health care inspectors or other officials concerned with state supervision on health care to have adequate communication channels (a network) with their colleagues within Europe.

The European Platform for Supervisory Organizations (EPSO) can facilitate the opportunity to develop, evaluate and exchange valid methods in inspectorate supervision and the development of a network between the participating European countries.

The first EPSO meeting was held on 13th and 14th June, 1996 and was organized by the Dutch Inspectorate for Health Care in Noordwijk, the Netherlands. The second meeting was held in Lisbon, Portugal on 13th and 14th November, 1997. The representatives from the countries who were not able to attend but interested in the results received the proceedings of the meeting.

In the Stavanger, Norway the third EPSO meeting took place on 3rd and 4th June, 1999. Our host made it possible to proceed the initiative for continuing the discussions and ideas on the above-mentioned subjects. The participating countries of the third EPSO meeting in Stavanger, namely, Belgium, Denmark, Finland, France, the Netherlands, Norway, Portugal, Sweden and the United Kingdom, shared the view that an international network on supervision and inspectorate functions, especially from the point of view of state responsibility, is essential.

To make EPSO more accessible it should be considered that European countries that are not a member state of the EU should also have the opportunity to take part in the meeting.

II Summary

During the third EPSO meeting held in Norway the wish and the necessity for the prolongation of the discussions initiated during the former meetings was evident. It is clear that the manner in which health care supervision is organized in the different EU countries varies. But through this informal network of supervisory organizations topics are discussed which form a basis for exchanging experiences and trends related to supervisory activities.

Prof. T. Aven of the Stavanger University College presented a description of risk analysis using a classical and an alternative approach. Risk analysis can be seen as a tool for expressing and communicating about uncertainty. From a point of view as supervising organizations, risk analysis can be used as an instrument. By collecting sufficient data and performing screenings a manner can be found to look for indicators for the level of quality of health care.

A presentation is given by Ms U. Fryksmark of Sweden regarding the annual nationally based surprise inspections and the procedure followed. The different options for inspections by the countries present are discussed. Experiences are compared and the question arises if surprise inspections are an effective measure.
Ms Dr. H. de Nutte from Belgium illustrates in her presentation the treatment of complaints by explaining the present and a future model which implicates that creating a new law on quality means that a supervisory organization achieves a new position with new responsibilities and instruments.
Mr. P. Jarvinen describes the tasks of the National Authority for Medicolegal Affairs in Finland concerning the sanctions which can be taken against a professional when inappropriate health care has been provided. A trend in the supervisory organizations is revalidation.
Mr. J. Hansen of Denmark gives a presentation of the grading of deviations of complaints handled by the National Board of Health and the Patients Complaint Board.

The government of the United Kingdom is creating a new Commission for Health Improvement. It will complement the introduction of clinical governance arrangements. Ms J. Cornwall of the Department of Health in the UK describes the working procedure of this new commission which is an elaborate framework for managing the quality of care.
When discussing quality and its evaluation in health care services it is important that it is kept in mind the proposed objectives of the main international organizations regarding this subject. Ms. A.B. Marques from Portugal presents a framework of systematized and generalized concrete measures for quality in health care.

Mr. J. Verhoeff from the Netherlands emphasizes the importance of the EPSO meetings and the international perspectives which are linked with each other. Another matter is the discussion on the difficulties which are met in these perspectives. Mr. G.S. Braut of Norway confirmed the need for co-operation between supervisory organizations.

A procedure for an audit and the observations from an audit performed at the air ambulance service at Rogaland County Hospital in Stavanger in March 1999 are given by J. Vesseur of the Netherlands and Mr. G.S. Braut.

During the open session Ms N. Mackowiak of France tells about the sanitary safety plan in the north of France and Mr. G.S. Braut describes in brief the challenges to be met in future health care.

III Proceedings

During the meeting it has become evident that the way in which health care supervision is organized varies in the different EU countries. According to the different topics on the agenda it is quite possible that the meetings should be open to more than one person per country. The platform should have as members state supervisory organizations and experts involved in state supervision. EPSO should facilitate all kinds of international developments and provide an international context for supervision in the different countries.

As the core of sound professional standards are belonging to a network of care providers this can be a topic of discussion in the forthcoming EPSO meeting. Also the internationalization of the health care, the cross-boarder care, is an important subject for further investigation. Proposed is to appoint an investigation regarding this subject on the next agenda.

The following proposals were made concerning the continuation of the EPSO meetig:

- the draft proceedings of the third meeting will be forwarded to the participants for comments
- when comments have been incorporated the final proceedings will be forwarded
- the representative of Belgium will look at the possibility of organizing the next EPSO meeting
- the fourth EPSO meeting is planned in October 2000
- attempts will be made to broaden the EPSO network
- the subject of special training courses for inspectors was briefly discussed and it was found relevant to discuss this matter further in the forthcoming meeting
- topics for discussion next meeting are the investigation of the different health care systems in the European Union and the definition of professional standards
- contacts will be established between participating countries before the following meeting to ensure the topics of discussion will be worked out in more detail.
- the Dutch Inspectorate for Health Care provides the secretariat for five years (1996-2000).

IV Opening

Anne Alvik
Director General of Health
Norwegian Board of Health

It is a pleasure for me as Director-General of the Norwegian Board of Health to welcome you to Norway to this third EPSO meeting. I am glad to see that also participants from outside this Nordic network have found the way to Stavanger. We have a network in the Nordic countries for discussing common challenges and problems related to supervisory activities. Nowadays it is important to go beyond traditional borders to take part in a broader set of experiences when planning further development and routine work within our organization and agencies. Therefore, I especially welcome the participants from Portugal, Belgium, France, Great Britain and the Netherlands. I will also use this opportunity to thank the Dutch authorities headed by J. Verhoeff for your continuing efforts to develop the European Platform for Supervisory Organizations.

Even if the European Platform for Supervisory Organizations is an informal network of institutions with similar tasks in different European countries, I believe the role of the network should not be underestimated. A modern supervisory institution must not only relate to the conditions in its own country, but look into how similar tasks are carried out in other countries; especially countries belonging to the same culture which will give very relevant comparisons.

A central requirement in modern theory of quality improvement is to compare ones own practice and results to those of other institutions with similar tasks in order to reveal possibilities for further development. As we in our roles as supervisory organizations require routines for continuous improvement from the providers of health care, I believe we are obliged to set the same standards for ourselves. Such standards have to be developed formally and informally in dialogue with other professionals in the same area. EPSO may serve as an instrument for such a dialogue.

For the Norwegian authorities this kind of informal European network is of special interest as we are not members of the European Community although we have a status of formal association to the Union. With this in mind we appreciate the co-operation within this network and also being responsible for this meeting.

The programme these two days will focus upon various central parts of supervisory work. We will start with a short theoretical introduction to risk theory. We think that modern risk theory may be an area of interest for further development regarding prioritisation of the scarce resources available supervisory activities. After this introduction we will discuss how we select our tasks, a focus on our activities. It is important for supervisory organisations to be aware of our methods of selection. This may be one of the areas where the public and the politicians may raise criticism against us, as we are public institutions or agencies with a higher degree of organizational and professional autonomy than usual for public offices.

Handling of complaints is one of the traditional tasks for supervisory institutions. Even if this task has been allocated to other institutions in many countries it remains a central tool and task for many of us.

How to deal with professional standards remains a central topic for all supervisory organizations, and here I think we have a lot of differences represented in the present selection of countries, which differences are very important to explore further. The last topic will be a discussion on the future co-operation between the organizations represented here and hopefully other nations as well.

Tomorrow will start with a case describing the Norwegian way of doing it seen with Dutch eyes. It is based on a visit to Stavanger from the Dutch inspectorate in March this year. Also methods of handling deviations and non-conformities will be discussed tomorrow.

I am not able to be with you tomorrow, but I am glad to be here and take part in the discussions today. I am sure the discussions will give us all food for thought and I hope that the possibilities for informal contacts during these days will give additional value to the meeting.

V Risk assessment – beyond the evaluation of complaints

The theory of risk

Professor Terje Aven
Stavanger University College

A risk analysis is supposed to be a tool for dealing with uncertainties. A tool for expressing and communicating uncertainty. The analysis does not create uncertainty, but gives knowledge about the uncertainties related to whether certain events occur or not, how large the damages could be, etc.

The trend now is functional requirements which specify what to achieve, rather than the solution required. Risk analysis is a key element in such a functional system as a risk analysis identifies and categorises risk and thus provides decision support concerning choice of arrangement and measures.

There are two possible platforms for risk analysis. The classical approach, which is the dominant framework in line with natural science; and the alternative way by means of expressing probabilities.

Classical approach

- It is assumed that there exists an underlying unknown risk which is a property of the activity, and this risk is estimated in the risk analysis. Uncertainty is related to the accuracy of the estimators compared to the true risk.

  This basis has the disadvantage that the estimates could be extremely poor, the uncertainties of the estimates are usually very large, and as a consequence the analyses do not give a message as clear as desired. It is possible of course to focus on 'best estimates' and ignore the uncertainties, but this is not satisfactory as long as the framework considered is one where risk is an objective quantity and this quantity is the one we would like to say something about. If the analysis does not provide information about this true risk, the analysis is incomplete.

Alternative approach

- Risk is a way of expressing uncertainty. For example, we do not know the number of fatalities the next year due to accidents, and we use probabilities to express this uncertainty. There does not exist any true underlying risk. This basis is called the ***'alternative'*** basis and reveals that a risk is a way of expressing uncertainty.

  The execution of a risk analysis in which risk expresses uncertainty is based on the following principles:

  1. Focus is placed on observable quantities, for instance, quantities that are unknown at the time of the analysis but will be known (with sufficient accuracy) in the future under the assumption the analysis is based on.
  2. The observable quantities are predicted.
  3. Uncertainty related to the observable quantities and the predictions is expressed by means of probabilities.

Classical versus alternative

Most risk analysts today are unfamiliar with the alternative approach to risk analysis, they adopt the classical approach to risk analysis in which risk analysis is a tool for estimating the true underlying risk associated with the activity. Risk is considered to be a property of the activity being analysed and the analysis provides estimates of this risk.

The differences between these platforms for risk analysis are related to the way risk is expressed, the meaning of uncertainty, what is the source for uncertainty, how the results are communicated etc. Adopting the classical approach it would be a goal to come as close as possible to the true risk. A good analysis produces accurate estimates compared to the true, objective risk. However, in practice we cannot know how close the estimates are, since the true values are unknown. Consequently, we have to deal with uncertainty of the estimates. We cannot measure this uncertainty, but it will be large, as a result of weaknesses in models and limited access to good experience data.

In summary:

- A classical risk is based on a risk analysis producing subjective estimates of an objective but unknown risk (future).
- An alternative risk is a based on a risk analysis assessing the uncertainty related to the value of future observable and objective quantities (now).

Discussion

A main point of discussion is what is an acceptable risk factor. In the health care field it is very difficult to find an acceptable risk level and when defining these levels the attitude towards risk must be taken into account. Decisions have to be taken and it is essential that you have a tool for decision support. It is better to use a risk analysis as a tool for comparison instead of focusing on the acceptance of risk.

Most of us would like to have a clear answer. Many risk analysis's accommodate the risk estimate as it were the true risk. Uncertainty is extremely difficult to discuss in a public arena. When talking about uncertainty, it is evident, that the medical profession in the course of time has always been determined to present itself as capable of managing uncertainty. On the other hand there is a growing pressure from patients to be well informed and requesting to know what the options are in a risk analysis. If the profession is on the side of the patients, a form of uncertainty can be ruled out. But health professionals are not trained in this.

From a point of view as supervising organizations, we can use risk analysis to supervise. By collecting sufficient data and performing screenings a manner can be found to look for indicators for bad quality of health care. Of importance is to have an instrument and to know where the risks are.

Both the classical as the alternative approaches of making a risk analysis depend on knowledge and experience, reflected in a systematic way. When using the alternative approach be more explicit in your qualitative thinking and evaluation. It is essential in this approach to collect data. It is dangerous practice to use old data. Use common sense. Try to give a subjective estimate and let the public have the truth. It is an opinion; a factor of risk communication.

How do supervisory organizations select their objects?

Ms Fryksmark
Socialstyrelsen, T-avdeln
Sweden

The National Board of Health and Welfare in Sweden is organized into the Head Office including two main divisions and central administration in Stockholm and six regional supervision units in Goteborg, Jonkoping, Malmo, Stockholm, Umea and Orebro. The Board is managed by the Director-General.
The two main divisions are Health and Medical Services and Social Welfare. The central administration includes units for administration, information and press relations. The six regional supervision units are responsible for the primary medical supervision in their respective regions, assuring quality and safety of Swedish medical care.

The main task of my department is supervision consists of:

- Supervised (surprise) inspections at the same time in all regions (5%)
- Calamities (45%)
- Complaint handling
- Initiatives (indicated during surprise inspections)

The purpose of these surprise inspections is to get a good picture of a specific problem in the health care system. The basis is always the safety of the patients. We have a continuous discussion and every month we have a meeting with the head supervision in Stockholm, discussing the surprise inspections. Different topics are discussed whereby also the point of view of the law is incorporated. Our main task is to prevent injuries and to eliminate risks in health care. But we are also dependent of the course followed by politics. These two factors are taken into consideration when we prepare these inspections.

After we have selected a topic we decide on the design of the inspections. We have to manage the inspection in one day or several days or nights depending on the destination. When formulating the questionnaires for the inspections an expert is called in. The main aim is keeping the questionnaire brief. The forms are filled in completely before they leave the hospital. Usually some 20 to 35 surprise inspections take place in each region. Only the inspections to private practititions are announced as we do not want that patients have to wait. Usually two people from the unit, a doctor (or nurse) and a lawyer participate in a visit. The inspection time varies from two hours to half a day/night, depending on the institute visited. The overall attitude towards the inspections is that we are welcome.

One of the six regional units is responsible for the organization of these inspections. A report is made of the results. The head of the hospital is informed the day after the inspection of the results. The decisions made in the report are public; not the questionnaire. A final aspect of the inspection is the press conference.

If we run across a situation which is not correct, we try to come up with a solution. When we have discovered a severe problem it is categorized under "initiatives" and we do a new surprise inspection.

The aim is to offer support, not only criticism. The inspections are well prepared with relevant chosen topics. The press and the politicians are interested in the results.

Discussion

The different options for inspections in the countries present are discussed. Experiences are compared and the question arises if this is an effective measure for inspections.

An option for surprise inspections in the Netherlands could be, for example, institutions for mentally disabled patients, because this group has the most disability to hide their shortcomings. The respective legislation plays a role. Decisions for making surprise inspections has to do with the final decision in the legislation. Using this instrument means that the government takes a final responsibility. In the Netherlands the final responsibility is led to the institutions, only in the field of the mentally ill the inspectorate takes the responsibility.

In Belgium there are mainly federal inspections with as main purpose the medical activity, medical permits in emergency units etc.

In Denmark the county medical officer can do surprise inspections. On national level inspections are made in co-operation with the institutions.

France has a national directive. This implies that all the audits of the establishments are accessible. Inspections are performed as a result of a complaint or care problem and the duration of an inspection can be up to two days per institution.

In the United Kingdom only the Mental health act gives the opportunity to inspect institutions where patients are detained besides their will.

Mostly private practitioners are subject to surprise inspections in Finland. The policy is not to perform surprise inspections in institutions.

Norwegian law states that a public draft report of an inspection has to be published if a newspaper requests it. The results of an inspection are located on the website of the inspectorate. In Norway surprise inspections are not a normal procedure, only by casualties.

The practice and the potentials of complaints

Ms Dr. Hilde de Nutte
Ministry of Flemish Community
Brussels
Belgium

Internal treatment of complaints

Most institutions have a system for dealing with complaints. A motive for such a procedure can be ethical considerations in the dependency relationship between the patient and his care provider. In that framework the patient is entitled to a serious response when he complains. It can lead to a rich source for improving quality measures. It can also avoid legal procedures and it gives a positive image of the hospital.

External treatment of complaints

- **History**

In the 1980's and 1990's Belgium was transformed from a unitary state to a federal state structure with three communities, the Flemish, French and German speaking communities. Also three regions: the Flemish, the Brussels and the Walloon region. The three communities and regions form the federal state of Belgium. That is characterised by the transfer of responsibilities from the federal authorities to the regions. For the health care the federal authorities have kept a lot of responsibilities. So the basic rules about programming, financing and recognition of hospital remain federal. The communities implement them. At this moment we are in the middle of a process of change. For that reason in the next paragraphs the present and future model is explained. However, the status of these models is not yet finalized.

- **Present model**

Important is that first complaints are discussed among the parties involved. Quite some hospitals have procedure for complaint handling. When one does not manage to solve the problem, they can go to the authorities. In that case the complaint is examined by the regional inspector. If it is a medical fault the patient is referred to the physicians association. If the inspector handles the complaint it involves a visit on the spot and deliberation with the parties concerned. Immediately afterwards a written conclusion is formulated and recommendations are given to parties involved.

- **Future model**

Up to 1997 there were no explicit rules about treatment of complaints. In1997 the Government of Flanders Act for nursing home facilities was announced . This act implies that every institution is obliged to develop a full quality policy based on two items:

- justified care by taking into account: efficiency, effectiveness, continuity and social acceptability of care, and
- respectively dealing with and treating the patients by taking the following elements into account: social contacts, personal reception, appropriate reference of the individual requesting aid, protection of the personal life and the right to self determination, information and participation of the patient and mediation and treatment of complaints.

The quality act laid down says that the policy must be given shape by two items:
- a quality manual and
- a quality plan in which three compulsory themes and two free themes must be developed.

The three compulsory themes are already defined:
- reception
- medical distribution
- hospital infections

There are two indicators developed for the reception theme:
- satisfaction of the patient concerning the quality of reception; this is achieved by an inquiry among patients.
- time difference between appointment and care provision.

Each of these indicators must execute at 0 measuring and lay down a goal. Formulation takes place in the form of a level to be attained by a date, for instance by the end of 2000 to reduce the waiting time to ten minutes. With this indicator an annual report of the results must be given form in a quality manual and also in a quality plan. These data are processed into general outlines for Flanders. They can also be used by the authorities as possible warning lights on the occasion of which certain facilities or certain institutions may be encouraged to analyse deviating results. It is not the aim to compare the facilities with each other or to impose a certain system of quality in the facilities. The overall figures will be published and the institutions can see where there position is. The report gives an overall framework for developing such a system and if possible they can use own initiatives for their quality manual. The importance is self testing. The initial version of these quality manuals must be handed in at the end of September 1999.

As from January 1st 2001 the quality management will be requirement for recognition. This implies that external testing will be necessary. In the present inspection method procedures and the structures are inspected if they meet certain fixed explicit or implicit standards. This no longer fully corresponds to the quality act philosophy. The Health Care Administration of the Flemish community has started to reflect on how the inspection task could be carried out in the future. It has developed an integration visit model, testing and rendering advice that is multi-disciplinary. Such models will be developed in a progressive manner starting with the quality act requirements so conceived that the quality model can integrate in the visiting model. Other aspects like hygiene, finance and management can be added later. Testing of the quality system is a systematic test carried out once in the three or five years. The advise formulated on the occasion requires a continuous follow-up, mainly monitoring data. In the end a procedure will be available for intermediate examination when a complaint arises or new standards are introduced. It is important when dealing with complaints to focus more on the system than the individual care providers.

Discussion

Creating a new law on quality means that an inspectorate achieves a new position with new responsibilities and new instruments. A very important role for the inspectorate is a combination of inspector/advisor, not a controller. By means of collecting data on quality systems one can also be an advisor for the minister. Essential is that an inspectorate knows if the institution has a quality system and is using this appropriately, focusing on effectiveness and efficiency. The quality systems are specifically for institutions. One must be aware of the danger of a growing gap concerning the quality of an individual care providers.

In the Netherlands we have a Complaints Act that says that complaints are best managed where they develop. A consequence of the that act is that the Inspectorates do not have a good overall picture anymore where the problems take place in order to advice and implement better health care. This act does state that the health care providers (institutions) should supply an annual Complaint Report.
Regarding the Quality Act in the Netherlands there are some sections in health care that use ISO norms to check quality, but also there are several hospitals that have there own quality instrument called PACE. The Quality Act says that the institutions have to create a quality system, but the essentials of the quality system is up to the institutions themselves.

Standardized instruments based on the quality paragraph in the legislation are used in Sweden. When inspecting, the National Board makes use of documents which nearly follow the ISO standard.

France has a national agency with professional consensus.

The core discussion is how to trade the roles in the inspectorate side with the advisory side.

Legislation/routing of complaints

P. Jarvinen
National Authority for Medicolegal Affairs
Helsinki
Finland

The National Authority for Medicolegal Affairs is subordinate to the Ministry of Social Affairs and Health. Its task is to see to the appropriateness of citizens' health care services by monitoring the activities of health care professionals. The Authority can sanction a professional by issuing him with a written warning. It has also precautionary measures at its disposal: it can restrict a person's right to practise the profession, or entirely revoke the right to practise.

Legislation

Following a long, almost 20 year debate, the "Law on Patient's Rights" was passed in the Finnish Parliament in 1993. It was the first patient law in Europe. It is stated in the law that there must be good quality but not said how to give this form. Patients should be well informed and patient has right for self-determination. The law was incorporated so that the normal court of law could be avoided.

A patient who is not satisfied with the health care or medical care and related treatment received has the right to complain to the director of the health care unit in question or individual care provider. If, once the complaint has been dealt with, it becomes obvious that the care or treatment may cause liability for patient injury specified in the Patient Injury Law, the patient shall be advised as to how the matter can be initiated through a competent authority or organ.

Complaints in the field of health care are addressed to the National Authority of Medicolegal Affairs, the health care unit in question, the Department of Health and Social Affairs in the relevant provincial departments (there are 5 provincial departments in Finland and they are controlling the health care systems themselves) You can also complain to the Ministry of Health and Social Affairs, the Minister concerned and the Parliamentary Ombudsman, among others. In principle the official to whom the complaint is addressed is the one responsible for investigating it. If the same complaint has been sent to several officials the main principle is that the lowest ranking expert official receiving the complaint is the one to investigate and decide on it.

Since 1980 the National Authority has transferred complaints relating to medical care systems to the Provincial Departments of Health and Social Affairs for investigation. The National Authority only deals with cases related to individual care providers. When a procedure has been set in motion the National Authority investigates in its capacity as an expert organ primarily with help of its permanent experts (approximately 250 permanent specialists represent expertise in the various fields of medicine).

As a result of its review measures, the National Authority may state that:
- the matter does not require further measures on the part of the National Authority,
- draw attention to some procedure or action which was at fault, or
- remind a person of procedures to be followed in similar situations in future.

The punishments at the discretion of the National Authority are:
- verbal and written warnings
- guidelines or regulations to be followed by the person in question in the practice of his profession in future
- ordering practitioners of the medical and dental professions to take part in updating training.

Special attention is paid to patient safety, the equality of citizens and good service to consumers of the health services.

The National Authority may further:
- limit rights of the doctor/dentist to practice his/her profession or
- declare that the person in question has lost his/her right to practice (loss of licence)

The right of certain other professionals to practice may also be revoked.

The importance of solving the patients' complaints locally, wherever possible, has been emphasized for a long time. By establishing this new complaint procedure we hope to be able to reduce the amount of complaints to the central government. Finland has had since 1987 a universal non-fault patient insurance. Depending on the nature of the matter there is the possibility to press criminal charges against a health care professional to claim damages in a civil process or to claim damages from personal injury under the Treatment Injury Act from the Finnish Patient Insurance Centre.

Discussion

The National Board of Health in Denmark cannot withdraw or restrict practise of individual care providers, but we can do it on a voluntary basis. But if the person in question does not agree we have to go to court.

In Norway it is the National Board of Health that makes the restrictions and it will also be in the future according to new legislation becoming into force next year. But then there will be a committee to whom the individual care providers can complain to if they do not agree on the sentence.

In Finland the ministry carries out systematical supervision systems and develops quality systems.

Revalidation is a new trend in the medical field. The GMC in the United Kingdom is bringing in a new system for revalidation every five years. In the Netherlands also. Norway only the general practitioners take part in revalidation. In Belgium the general practitioners and physicians have to follow a medical pilot every four years but can go on practising. In France the system of revalidation has not been implemented.

Plenary colloquium

- **Trends in the supervising organizations**

One of the trends on individual level is revalidation. The other trend is instituting national/federal systems on how to make restrictions on practise.
It is not clear how uniform trends are organized on systematic levels in Europe. One point is to combine supervision and advisory activities. On the other hand one pursues more supervision and clear authorized audit activities. This implies that supervision is a part of the governmental system and advice should be obtained by the care provider himself. Objective is to try combine these issues in the same institutions being aware of the different norms in these roles.
One should also recognize different levels of advice, the difference between non-confirmative and confirmative remarks. An advice can be compulsory or superficial. For an inspectorate it is essential to have instruments to force the care providers to change their actions. Non-conformity in our setting means a non-fulfilment of legal requirements.
Another point is to what extent do supervising organizations have sanctions? Some supervising organizations nowadays prefer to give more attention to the institutions, while others are creating more distance from the care field. But there is no common trend. This is relevant to ones own supervising system.
The ultimate goal is to improve health care for patients. The question arises in the discussion: how effective are you as a supervisor? A supervisor has both a control and advising function, but no sanctions. It is a discussion about health care systems. Are inspections the same as supervising, or the same as an audit or a visitation? You can recognize different levels. The duties and possibilities are laid down in legislation.

- **Laws and ISO standards**

ISO standards are international standardized meanings. But the problem is that when comparing the ISO meanings to the contents of the law is it not always easy to find a combination of ISO-standards within the content of the law. Each country has their own legislation and interpretation. Although each law gives the inspectorates a special role, there are different definitions for inspection in different positions for different purposes. This divergence also manifests itself by the limitations in using ISO instruments; essential is to develop tools for describing a particular law. This is a very interesting topic for international meetings.

- **Power**

The power of the supervising organizations depends on the possibility to enforce the implementations of their conclusions and advice. This is an issue the inspectorates should be aware of, even if one has legal profound tools. This power issue has substantial impact for one's own quality system. In the European Union the inspectorates of pharmaceuticals are visiting each other and testing each others quality system.
Power always produces unattended effects. To avoid side effects of supervision the inspectorates need professional self-evaluation. Another option to avoid these side effects is evaluation of the quality systems by the field-actors themselves.

We see that requirements (legal, professional) lead to a process and/or outcome. Most of the supervisory activities focus on the requirements. The question is should the supervisory organizations focus more on the process or should they just be content with
the self-evaluation of the professional organizations.
The core of sound professional standards are belonging to a network of colleagues. Therefore, this matter of professional standards can be a topic of discussion in a coming EPSO meeting.

VI Supervision of quality and professional and institutional standards

Commission for Health Improvement

Ms J. Cornwell
Department of Health
England

The government is creating a new Commission for Health Improvement. It will complement the introduction of clinical governance arrangements. The Commission will not replace mainstream National Health Service (NHS) performance assessment and management, but will complement and reinforce these processes.
The governments white paper on the quality agenda is now going through parliament. It is an elaborate framework for managing the quality of care. The government is providing new tools to ensure that quality of clinical care and to meet the real needs of patients. The National Institute for Clinical Excellence (NICE) will ensure authoritative national guidance is available for all health professionals on the clinical and cost effectiveness of the latest drugs and technologies. The National Service Frameworks (NSF) will lay down the care that different groups of patients should expect. Projects are started for cancer and for coronary heart disease, mental health services and will be followed by a programme for older people. In the future a programme for work will be started for diabetes. NHS organizations will be obliged to take on responsibility for clinical governance – making sure standards are met.
There will be guidelines for the service and also there will be published guidelines how to provide care for patients. The two together bring together guidelines for health service. The department takes the initiatives and the guidelines will be published by the ministry.
In this new process design clinical governance takes a leading role. Until last year the management was responsible for financial management, clinical care was for the divisions. Now the government says that if you are responsible for running health care organisation, you are also responsible for the quality of care. That is the mechanism to drive the change in primary care groups. In support of that process you have the existing procedures, such as self regulation, clinical staff keeping up to date and patient and public involvement. From April 2000, clinical governance arrangements will be monitored by the Commission for Health Improvement. Every year the government will do a national patient and user survey.

The core functions of the CHI are:

- To provide leadership on clinical governance.
- To conduct routine reviews every 4 years to see if clinical governance arrangements are working.
- To undertake a programme of service reviews to monitor national implementation of National Service Frameworks, and review progress locally on implementation of these frameworks and NICE guidance. In two to three years after changes have been implemented, the Commission will measure the standards.

- Troubleshooting, an entirely new issue. The Commission will have the capacity to investigate and if necessary intervene in serious or persistent clinical problems.
- Helping with inquiries. In the future the Commission shall increasingly take on responsibility for overseeing and assisting with external incident inquires. Lessons to be learned are which methods to use to help run inquires more efficiently and effectively.

One of the principals, as far possible, is working through other organizations rather than working by yourselves. The Commission will need to develop effective working relationships. The teams to do the work will be multi-professsional, but the patient's voice as well will be represented. Judgements will be based on measures of process and outcome.

The key themes early in the life of the new Commission will be :
- style
- working methods.
- relations with other bodies
- relationship with regional offices.

Style
The Commission will be very rigorous but it will be developmental in its approach. It shall try to find a balance between analytical and professional judgement. The staff composition will be looked into (employ own staff / or hire?) and what kind of relationships the staff has with the Trusts, the Commission and the bodies who they investigate.

Working methods
Risk assessment shall be looked into before starting and after implementation. Preparatory work is very important, but the Commission will wish to avoid burdening NHS services unnecessarily.

Relationships with other bodies
NHS organizations feel overburdened by audit, inspection and review. CHI will talk to most of the organizations and look at the evidence they use in their reviews. It will aim to achieve a common evidence base for assessments.
In time, the rewards will be great. It will reduce the burden of inspection and reduce costs. The development of the standards of care is done by NICE or the professionals themselves.

Relationship with regional offices
The implementing of the actions plans that come out of CHI's reviews will be done by the Regional Offices. They are multi-professional. There are eight regions in England.
The Commission for Health Improvement has a interest in:
- service development / good practice
- will provide clinical risk assessment
- follow-up local actions plans
- early warning of severe problems
- effective inquiries

The Commission will hand back the implementation of action plans, following its reviews, to the Regional Offices of the NHS Executive. If a professional does not follow the standards it will be reported to their own professional body. If an organization does not take any action they will be summoned by the minister
Coming steps

- Primary Legislation - houses of parliament by July this year
- Appointments in the Commission in October/November this year.

Framework for quality in health care

Ms A.B. Marques
Inspeccao-Geral Da Saude
Portugal

When discussing quality and its evaluation in health care services it is important that we keep in mind the proposed objectives of the main international organizations in this regard.

- The World Health Organization identifies a high degree of professional excellence, efficient use of resources, minimum risk for the sick, users satisfaction and obtaining health-related results as components of quality health care.
- For Europe the World Health Organization states that in 2000 all member states should have created and developed continuous improvement systems for quality in health care and development and appropriate use of technology in health care.
- Also the European council recommends that all member states should create and promote policies and structures to support the development and setting up of quality improvement systems.

With regard to Portugal it can be noticed that in the last years efforts have been made to progress towards a framework of properly systematized and generalized concrete measures for quality in health care. In November 1995 the current Government incorporated in its guidelines that the guarantee of quality in health care should be provided and also its respective evaluation. One of the measures in this regard provided for the creation of legislation in order to guarantee quality in the provision of health care services.

Quality therefore became one of the priorities within the policies of the Ministry of Health, constituting the creation and development of the System of Health Care Quality. This system uses, amongst others, the European Foundation for Quality Management's self-evaluation model for quality as a reference point. This identifies nine essential areas grouped into two broad categories:

- the means - relating to the structure and manner in which the activities are organized, including: leadership, policy and strategy, human and physical resource management processes;
- the results - relating to the organisation's capacity to perform, namely: satisfaction of citizens and professionals, impact and results.

In order to implement the System of Health Care Quality, the Institute of Health Care Quality (IHQ) was created in April of this year by Council Order. The IHQ shall define and develop standards, strategies and procedures for continuous improvement of quality of the provision of health care, namely:

- to promote the investigation into and development of methods, instruments and programs for the continuous improvement in the quality of health care
- to promote the development of methodologies for quality certification for the units providing health care services to allow them to become accredited
- to promote a framework of continuous professional research and training
- to provide technical support to health institutions and professionals.

Another pillar of the system of Health Care Quality will be the creation of the National Council of Health Care Quality this year. This institute will function as a body for consultation by the Ministry of Health regarding quality, being responsible for drawing up national recommendations for the development of the system.
Also the National Certification Commission will be created this year, which will have responsibility for the certification of specific quality systems.
The Health Technology Evaluation Agency will be created in 2000 which shall have as task to evaluate the clinical, social, ethical and economical impact of technology and procedures in health care.

The most relevant components in the development and setting up of a system of quality are:

- charter of quality, to be drawn up by all units providing health care.
- quality guarantee processes to be established systematically for the various levels
- organizational quality (MoniQuor HC), an instrument for the evaluation and monitoring of the organizational quality of health centres
- management quality (QUAL and MANA) an instrument for the evaluation of the quality of health care management
- clinical guidelines (containing therapy recommendations), technical guidelines, directives and local protocols
- accessibility improvement program
- management of long-term illness
- users satisfaction
- licensing
- certification of health units

Hospital nowadays should adopt practices included within the reference framework, entitled the Portuguese System of Quality in Health, using the above-mentioned measures.
In terms of health centres, numerous quality guarantee programs have already been applied. In respect of health centres special note should be given to the evaluation program from the point of view of the patients concerning the quality of health care and which will allow health centres and even countries to be compared in the future in this specific area.

In respect of the activity of the Inspectorate General for Health, specifically in terms of quality evaluation in health establishments, there are still no quality evaluation measures of the strictly technical aspects of the health care. But in respect of organizational aspects, the IGH has by inspection and audit service, been checking on the quality of the various health care units integrated with the National Health Service. In respect of management audits performed in hospitals, the level of attention given in the respective health care unit concerning ex- and internal quality is checked. Also for specific inspections performed in hospitals and health centres, there is already more direct action on aspects of quality.

Lastly it should be pointed out that the IGH has special responsibility with regard to complaints from the users of all health establishments that come within the NHS. This accompaniment allows the IGH to be aware of the most problematical areas of each establishment and, thus, can take effective measures.

The final reports of the audits and inspections are always sent to the establishments in question and to the regional health administration, as well as to the ministerial office and the central services possessing technical orientation skills.

VII The need for co-operation between supervisory organizations (why and how)

Fields in health care coming together internationally

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The Netherlands

An important topic of this session is to bring in mind the reason for EPSO and to realise what can be helpful in our decision making to take part in these conferences. Of importance is what is happening around us in the health care field and where are international perspectives coming together. On the other hand a certain profession is required to inspect and supervise this field. It is very useful to have international contacts and exchange views about methods and instruments in an international group. Another aspect is the difficulties we meet in these international perspectives.

The fields in health care which are coming together internationally are:

- **The oldest fields are the pharmaceuticals and the medical technology.** Medical technology is from a more recent date. Because of a very strong economical aspect, the inspectorate for the pharmaceutics and especially the pharmaceutical industry are working internationally already for many years. They are trying to incorporate by doing visitations. For instance when there is a firm in US, two or three countries from Europe go to the US and inspect the pharmaceutical plant and take an European decision. Just the same when a plant in France is going to make a certain medicine or a certain medical technology then the French inspect and it goes on the European market. For that reason it is very important that to know each others system for inspecting and therefore there is a very open system in this field. Two fields, the pharmaceutical and the medical technology which is in perspective of the law and legislation, are developing in the same way.

- **The third interesting field is the migrating professionals.** When a doctor goes to another country to practise, it is maybe because a disciplinary law has written him out as a doctor in his practising country. It is then very interesting to have the possibility of a contact in other countries to avoid this and to stop the professional future of this person. In that case it is not only important to know each others legislation but also important how the disciplinary law is working in other countries. Three years ago in Amsterdam, we had a discussion on this topic concerning the norms and values in medical practice. In a network of inspectorates it must be possible to contact each other and exchange information of what is happening and what are the values to take into account.

- **A fourth point of interest is what is happening in the mental health care.** Especially by the intervention by the council of Europe and European court in Luxembourg many patients in mental health care are asking for certain human

rights. The courts are given lines of what is acceptable and not acceptable. We see in all countries these decisions are influencing the practice of mental health care. From that point of view you can see the coming together of the legislation of the rights of mentally ill people and the mentally handicapped.

- **The next interesting point is that of the organ trade, the institution of Eurotransplant.** I refer to a letter sent recently by our Minister to our parliament. The Minister says that she has made agreements with Germany, Austria, Belgium, Luxembourg, and the Netherlands, about the Eurotransplant, an international organisation. It is a very important development because we want to use a market as big as possible to make it achievable for everybody to attain organs. Important to be active in is that there must be norms for safety and quality. There must be a transparency and objectivity in the allocation procedures, there must be a clear and controllable medical criteria for transplantation and a good control system for the waiting list. In facts these are all points for the inspection. In the heart of the medical practice, you see a development which makes it important that in each country there is possibility of controlling and making appointments.

- **Also an interesting item is the transborder health care.** In many countries there is always the problem that people try to get health care from abroad. When trying to get medical health care from abroad we have the problem that the insurance says we only pay for good quality and who says that the institute abroad can guarantee good quality.

- **As last, but one of the eldest, is the infection disease management.** That is a part of the health care so international that the European commission realises that an EU policy on diseases is necessary. Within 5 years a lot of the national policies will be replaced by international policy in Europe in this field. It is quite evident that when it is international there must be supervision from the different countries which can stand for real international standards and for international practice.

These are all fields developing themselves in an international context without our concern or activity and for that reason we must talk together about the problems involved in this area.

The fact that our profession inspects, asks for certain developments. Today, for instance, we had a very interesting lecture about risk analysis. It is a very important aspect in our institutions. The development of indicators is a difficult issue. In Lisbon we have also talked about it. To develop indicators asks for an international scientific research program. Everyone knows it is only possible to monitor some indicators; it is not possible to monitor all indicators that you have in mind. For that reason an international context is very helpful.

The whole discussion of choosing the inspectorate objects. Of course, the law plays an important role in this. But you have to bring it in relation to risk analysis and also in relation to the indicator problem and that makes it possible to choose for certain objects.

The development of instruments for the inspectorates. You have to be active in a new legislation when you are used to operate as a control service (as you do in certain way in pharmaceuticals, in mental health care protection) which leads to a quality law. We have this development in Belgium, the Netherlands, Sweden and Norway. This implies that you have to look at the institutes with a certain distance; another instrument for looking to other indicators. That is a new challenge we have to meet.

It is very good to have our orientations on the values we use to mirror the institutions we are inspecting. Because legislation never gives a complete set of norms, we always have to chose at certain moments what is important and what is the norm and value we shall use.

Also special attention to the difficulties we meet in international perspective . We are all working in different health care systems. In the world there are around 180 health care systems. Each system is quite dependent on its own historical development. Of course, we can exchange information and see how it works. But everyone returns to their own legislation and traditional relations and it is very difficult to bring forward the next step in the development. Furthermore it is very difficult to realise from what responsibility the other one is speaking. There are all different relations and responsibilities in our countries.

We have to realise that our formal position, in fact our power, is highly defined by laws, by legislation. Not, for instance, defined by a market mechanism. It is the law that gives certain very clear patterns of relations we have to respect in looking at our own situation. When talking about other systems, in fact, in certain way we try to evaluate these new insides into ones own system and evaluate what one should do and can do.

These are the main points which we have to take in account when, in Europe, we are going to talk about items of inspectorate and supervisions.

Need for co-operation

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Norway

The need for co-operation may be argued by the fact that supervision is a profession in itself. Furthermore, the profession has something to do with continuous development for efficient en effective methods for supervision and so can initiate and stimulate research in the field of supervisory activities. In literature there is very little written on supervisory methods . There is much research to be done in this area. Not only more research on processes but also more continuous evaluation of one's own methods used.

The first main point which says something about need for co-operation is keeping EPSO, for example, a living network. It is necessary to be able to design our own future. No doubt that every supervisory organization, nationally based, will be influenced by international impulses.

The next point may be sketched out by opening closed doors; so well as for the public as for ourselves. Being able to contact persons working on seem themes. It enhances carrying out legitimate ways of health care systems and health care professionals. Therefore, the second point for co-operation is securing legitimation of supervisory services.

There is a globalization tendency, not only of traditional trade but also of exchange of services and therefore we need standards for co-operation also on supervisory activities. If we manage to make those standards as a set of professional agreements then we could to some extent avoid having them pressed upon us. If one can make professional standards acceptable for the supervisory organizations and acceptable for the public there would be no need for making a lot of directives on sketching out how that should be done. These kind of standards should partly focus on procedures, but not for the least on themes, for instance, contagious diseases. Not only the procedures but also the methods should be elaborated in that kind of common standards. The motivation is that we do not only have to adjust or adhere to international standards originally designed for production industry.

The last item is the role of the public or the governmental supervision systems. For instance, how do we co-operate or even compete with private audit organizations. To have a clear and international agreed basis as possible would be wise in this area.

This question is how should this co-operation be done? In order to achieve this it is essential to promote this on an informal network basis. If we can gain the same value by keeping it informal then it is a surplus value for us as supervisory organizations. Interesting is to think about aiming at the probability of an European Conference on supervisory methods in the coming future to open this arena to more participants than is possible to cater and accommodate in a meeting like this one.

VIII Methods of audit - observations from Norway

Procedure for an audit

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• Introduction

In March 1999 two Dutch inspectors accompanied Norwegian inspectors in Stavanger at several inspections audits. They compared the way of auditing by the Norwegian inspectors with the way of auditing in the Netherlands. In this contribution attention is given to the general aspects of auditing. At the end there are some remarks about the differences between Norway and the Netherlands.

• The aim

Firstly, of importance is to bring in mind what your aim is when performing an audit. There are 4 W's to keep in mind: why, who, when and where and also how often shall you perform an audit. Your aim is that you want to know about quality, report about it, and amongst whom (quality makers/professionals). These are aspects to realise before starting an audit. It is following the route of quality, looking for casualties, and investigating. There are two main categories for an audit:

1. a systematic evaluation of the quality of care
2. or an audit can be done in case of casualty.

• Criteria

The next aspect is which criteria do you follow. The most important criteria to follow are legal requirements. We have to look for the legal aspects and are the professional institutions following them. But there are also important standards and guidelines. The standards are developed by the professional care providers themselves. When the standards are broadly accepted they get the character of a law and we inspect this issue.

• Methods

The methods you choose when you want to audit are divided in qualitative and quantitative. It depends on the aim you choose. When performing an audit in case of problems you can choose for a qualitative method.
Very important is to be aware of how you gather and implement the data. You can choose for a validated instrument in general and administrate your findings, using a structured and/or semi-structured written questionnaire.
A good audit is a description of your observations in a qualitative or quantitative way. Regarding, for example, legal requirements (non conformity), guidelines formulated by the professionals themselves and you shall have to supply conclusions. In your recommendations you can give a neutral remark, show your criticism or in more severe cases give a warning. A non-conformity (Norway) is defined as lack of fulfilment of legal requirements; a remark is defined as an observation that is not covered by the definition of a non-conformity, but which is regarded to be an area for improvement. As supervisory organisation we can ask the institutions to adjust to the given advice and we can give an order now. In the Dutch Law Quality of Care the professional institutions have to follow that order

by law. When a dangerous situation exists we can immediately take action by law. A part of the follow up is to see what the institutions do with the recommendations. It is important to control what you advise.

- **Aggregation of data**

When you have as aim improving the quality of care in general an audit is a good opportunity to implement this aim. Of importance is collecting data in a structured way and comparing the data with each other. By performing an audit and aggregating your data you can, among others, collect policy information for the department of health care and for the organisations of professionals. It is important when we talk about waiting lists, pressure of work, lack of facilities, etc.

In the audits conducted by the Norwegian and the Dutch inspectors in Stavanger in the March 1999 the philosophy is the same: to control and improve the quality of care. The responsibility for the quality itself is given to the providers of health care. In this way the inspectorates can check if the health care providers give attention to (the conditions for) delivering health care of good quality. Sanctions to correct the providers if they do not deliver health care of good quality are given by the different laws. The manner in which the two countries manage is different due to organizational and historical aspects.

Differences between the Norwegian and Dutch audit methods have been seen in the use of structured audit methods. In the Netherlands the inspectors are, more than the Norwegian inspectors, able to use specific instruments when auditing for example a hospital, a general practitioner, or a dentist. By the systemic use of an instrument it is easier to combine the data. In this way the audit results can also be used as policy instruments for policy makers in the governmental department or for the boards of the professional organizations.
Another important aspect of using structured methods and instruments is the validity and reliability of the audits. The results of the audits of the same kind performed at organizations can be managed the same and the results are comparable.

Audit of medical service at air ambulance, Stavanger

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During the EPSO meeting in Lisbon, Portugal in November 1997 a point of discussion was the possibility for exchange of inspectors between countries to learn about each other's inspection techniques. From 8th March till 12th March, 1999 the first exchange of inspectors took place in Stavanger. Two Dutch inspectors of the Inspectorate of Health Care of the Netherlands visited the inspectors of Fylkeslege i Rogaland in Stavanger to exchange information concerning the work of the inspectorates.

- **Audit of medical service at air ambulance, Stavanger**

On 9th March, 1999 an audit was performed at the medical service of the air ambulance at Rogaland County Hospital. The audit was performed as a part of the scheduled audit activities at the Rogaland County Medical Office this year. The aim was to evaluate to which extent the audited service attended to legal requirements by means of their own system for internal control. The audit focused upon:

- the system for internal control
- adherence to sound professional standards
- provision of immediate care
- patient's records

The audit was performed by evaluation of documents, interviews, inspections and verifications of fulfilment of specific requirements.

- **Procedure followed**

In January 1999 the hospital was informed by letter that a system audit will be performed coming March. The documentation received beforehand on request from the hospital was used for the preparation of the audit. The documentation consisted of procedures related to qualitative aspects of the medical service. At the start of the audit an introductory meeting took place between the auditors (3 persons) and the leadership team of the hospital and the responsible persons of the air team. The interviews took place with employees at different levels of the organization. The interviews followed a special list of subjects, especially formulated for this audit. The subjects are related to the different articles from the different acts. After the interviews the questions were verified. All participants were asked the same questions to establish if there were any discrepancies in the answers. In the closing meeting the results were reported directly in a superficial manner. It was possible to discuss some of the results of the audit. The inspectors announced that a formal report with observations and remarks shall be sent to the hospital for comments and a final report will be made up. If there should be non-conformities (not present in this audit) it shall be stated and registered. A follow-up is a consequence of non-conformity.

Discussion

It is pronounced that if every local office has to formulate their own questionnaire it can be an obstacle when trying to achieve standardized data. Inter-inspector variation is a handicap.
When a quantitative audit is performed on a national-wide basis, the questionnaires can be supplied to the local offices where comparison can take place. The audits can be carried out in a qualitative manner locally. Combining the two sort of audits is very powerful.
Professionals are inclined to improve their quality of care when they are aware that other colleagues are also doing so. When centralizing an audit then there is the possibility for comparison of professionals.
A query is if one should ask exactly the same level of quality for each community. There is discussion on 'planned differences'. Perhaps the inspectorate functions, the levels, could be different in different parts of the country. A possibility is to relate more to the processes behind the guidelines.

Another possibility is that the institutions make audit procedures themselves. They use a visitation procedure, auditing each other. The institutions are also developing a PACE instrument, some use ISO instruments. It is essential to be aware of what the field is doing when making an instrument for auditing.

The norms used in an audit of the inspectorate are partly derived from legislation and partly from the professionals. There is still a small group of care providers where there are no norms available. A matter of discussions is if the inspectorate should make their own norms when there are no norms provided when auditing by this group. It can be that the policy of the institutions is defined by the norms of social expectations. The question arises if the inspectorate is authorized to make norms. A possibility is to use the disciplinary board to create norms when there are non. Another type of norm that can be established requires quantitative data (constant continuous improvement). Local expectations instead of technical quality. A basis for future audits could be local expectations.

One last remark is if there has been an investigation what the risk is if no audits are done? There are no hard facts. But an important factor is to take the risk analysis into account when making a capacity for audits and inspections.

IX Grading of deviations, reactions at different levels

Gradings for quality of actions

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In Denmark regulation of heath professionals conduct is done by individual laws for each profession. All of these laws use the same terms to regulate conduct and misconduct. We use the term for health care professionals that they are bound to show care and conscientiousness in their work. There is no limitation of what a health care provider may do in the sense of the law as long as he does it with care and conscientiousness. The definition of care and conscientiousness is defined by the National Board of Health and the Patients Complaint Board.

Each doctor/patient contact is characterized with a countless number of actions possible to take. Only a few of those possible actions represent the right choice; all the other actions are in some degree inferior to those right actions.
The gradings for quality of actions taken by doctors/patients are:

- best choice - exactly right in that particular situation
- within reason - room for differences / opinion - regulated by professionals themselves
- less suitable - but has not yet reached point of misconduct in a legal sense - regulated by the regional state medical officers in the form of written statement to the health professional or a personal talk
- lack of care and conscientiousness - actual misconduct - represents borderline between acceptable and unacceptable on a legal matter - regulated by the national Board of Health and Patient Complaints Board
- severe lack of care and conscientiousness - obtained by checking the counterpart as less suitable - regulated by National Board of Health and Patient Complaint Board - regulated with disciplinary actions
- gross negligence - regulated by the individual professional laws - only judged by court - results in fine or imprisonment, full withdrawal of the right to practice - about 7% of the cases are reopened - the patient complaints board has to give the case to the state prosecutor in order to establish a gross negligence.

The Patients Complaint Board is the only authority who can critisize on a disciplinary level. If the National Board of Health finds that something should be critisized we have to send the matter to the patient complaints board to be evaluated and to receive a verdict. The board consists of 5 persons: a chairman (judge), two representatives for the profession, one person pointed out by the county and one person pointed out by the patient groups. It is not solely decision-based on a health issue. The norm for the board to accept a complaint is professional conduct. Of the 2,500 complaints about 2,000 are handled. The board agrees on about 20% of the complaints with the patient.

In Denmark the National Board of Health has a data base over all the decisions made by partly ourselves, the Patient Complaints Board and another authority called the Patient Insurance. The Patients Insurance allows patients to get a

compensation. They also have about 2,000 cases each year. The data is also incorporated in data base of the National Board of Health. In this manner the Nabional Board of Health partly performs its supervising function, the data base is a major source of information.

Discussion

Denmark and the Netherlands are the only countries who have legislation for negligence caused by nurses (Denmark since 1936 and the Netherlands since 1996). Expected is that in the next few years more disciplinary measures will be taken against nurses. Also this will be the case in Norway in the coming years when the new legislation is incorporated with requirements for professional standards also for nurses.

Finland has the possibility to make their own decisions and appeal to a superior court. In the Netherlands one can bring the cases before a medical or professional court. There can arise a problem that both courts are in action; in this way it is possible that the professional court overrules the medical court and vice versa. The United Kingdom has two routes for complaint handling: the regional health authority and the general medical council. The General Medical Council will comment and exercise a sanction. They will pronounce a negligence, but it is not set up quite as formerly.

The Patients Complaint Board evaluates each case individually with medical experts.
In Denmark the reactions from the Patients Complaint Board cannot be overruled by any another authority. So if the care providers are not satisfied with the decision they can only sue the Patients Complaint Board.

It is difficult to prove if someone died because of malfunction of a doctor. The public prosecutor has a problem to prove the relation of the doctor and the death of the patient. The only manner to prosecute the doctor is when there is a strong one/one relation. In the disciplinary court there is a more standard way of acting. The professional has to act like the other professionals do. The court is not interested if the patient dies, but does the doctor do what he has to do.

The Patient Complaint Board and the National Board of Health solely judge the action, not the outcome of the action. On the other hand the court has the tendency to look at the outcome. That is a conflict between the two courts.

In Denmark we are introducing a system aimed at supervision of systems. It implies that the National Board of Health has the right not to send the complaint to the Patients Complaint Board. In milder cases, for example, we would like to, in co-operation with the patients, work in this manner. This procedure has not yet been yet decided upon.

The General Medical Council in the United Kingdom has introduced into its criteria for good medical practice a duty of care for the patients which includes reporting on your colleagues if their competence is not of a good standard. If you fail to report you yourself are giving severe lack of care.

On the contrary the Danish Medical Organisation, has a internal rule which says you cannot report on colleagues but have to take this up with him.

In the past in the UK the system had a single disciplinary action. The chief medical officer has now convened a group who are looking at the gradation of actions to be taken. The responsibilities of the care providers need more clarification.

In Denmark we have just introduced a new law which will take effect by the 1st of July It is demanding that private hospital and clinics should have a professional doctor responsible for medical activity.

When discussing the gradation of deviations it is important to be aware of, for example, the probabilistic review of risk. We can state that either something happens or does not happen, for example the patient lives or dies. That is what the lawyers are occupied with in criminal law. The other point is what is the action in itself. This may be to do something or not to do something. What is interesting for us as supervisory organization. The action of taking no action in a situation that was leading to death, introducing a probabilistic way of risk analysis into the supervisory reactions. Not only the traditional law-way of thinking should be taken into account, but also thinking about the probabilistic side is a argument for having a kind of gradation on the reactions.

When a professional fits in the category of, for example, 100% less suitable, it can be expressed as a dysfunctioning. A general problem in supervision is how to obtain adequate information about the dysfunctioning of professionals.
It is important to improve the overall quality of care and not concentrate only of the dysfunctioning professionals.

X Open session

French Health Administration

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In France there are about 140,000 medical doctors for 56 million people. In the region Nord–Pas De Calais, situated in the north, near Belgium, 80 health-establishments (medicine, surgery and obstetric) are available for about 4 million people.
There are three status's for health establishment:

- public,
- private and
- private with public concession.

Every year, the Health-minister, after discussion with the Parliament, decides upon the national programme:

- Public hospitals (and private with public concession) have a global budget for the year and have to justify the use for the coming year; there is still (since 1996) a reallocation between richer and poorer regions.
- Private clinics are paid for every service, approved within the limits with medical-unions.

The French administration is very centralized :

- national level : ministry with several directions
- regional level with 2 different directions :
  - regional direction for Social Affairs, which depends on the minister by the 1st minister representative
  - hospitalisation Regional Agency, which depends directly on the Health-minister
- departemental level, which takes orders from all the levels.

In this configuration, there is a kind of liberty in the field of inspection: each region has to devise a plan to verify if all is done in hospitals and clinics to preserve safety and security. This directive complies a special context :

- currents affairs before the court summoning administration, and evolution of administration's responsibility
- acceptable risk by the people is smaller day after day.

Sanitary safety plan in the region Nord–Pas De Calais: test for a global approach

A work-group, consisting of doctors, chemists, engineers and administrative servants, had a mission in our region to elaborate the plan. The objective was to find the best way to control sanitary safety in health establishments, as well as public as private. After discussion, we have chosen for a global approach instead of a specific approach by themes.

Inspecting in a global approach implies to take care of health care, of course, but also of premises care, staff care, food care and so on. We think that risks are not only added but also potentialized.

We choose the establishments with :
- priority risks help, such as :
  - surgery, anaesthetic or emergency activities because of the frequency of critical situations
  - obstetric because of the zero acceptable risk by the population
- complaints
- equitable repatriation between lands and status.

We use the same inspection referential. It makes no difference what kind of establishment. This referential mentions:
- rules
- recommendations and professional consensus

The inspection team consists of 5.2 inspectors: 2 doctors, 1 chemist, 1 engineer, 1 administrative servant. There is one inspection every month.
At the end of the inspection, we give our first report to the direction of establishment : manager and doctor. We are allowed to announce short-time deadlines, follow-up inspections or complementary inspections : our regional manager follows systematically our report.

The results of this global approach are:
- strength :
  - well identified risks
  - responsibilization of the establishments
  - good reactivity from authorities
- weaknesses:
  - cost of inspector's availability
  - evolution towards national agencies and regulation
- a fundamental question:
  - where is the border between safety and quality?

Investigation on different health care systems in the European Union

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Previously in this meeting a topic of discussion was the internationalization of our health care, the cross-boarder care. About one year ago I inquired about the possibility of an investigation describing the different health care systems in the European Union.
It is very instructive for our supervisory organizations concerning both the quality legislation with regard to health care provisions available in cross-boarder health care as well as the means of access to such health provisions. Within ten years it will be an important subject for our insurers. I would propose that this subject be appointed to the agenda of the next EPSO meeting.