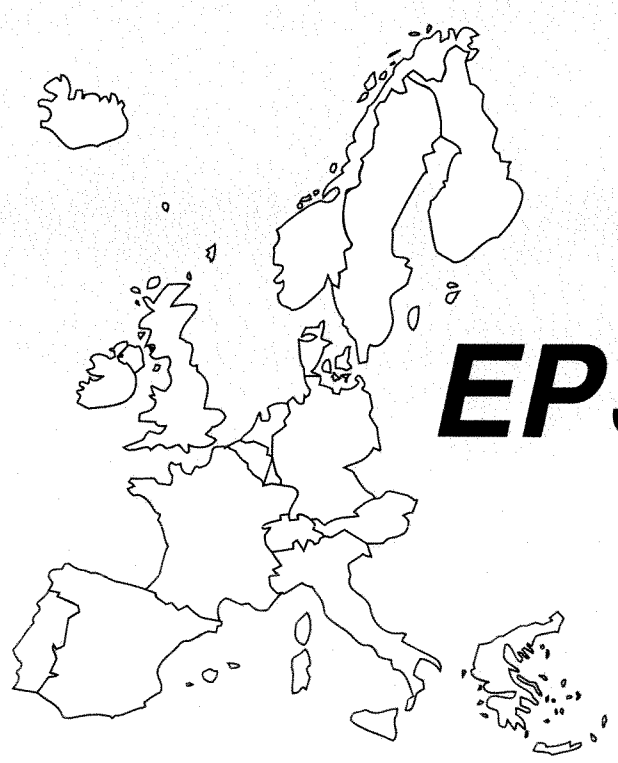
# Proceedings

**Second International Meeting**

**13th-14th November 1997**
**Lisbon, Portugal**

*European Platform for Supervisory Organizations for Health Care*



***EPSO***

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# Preface

It is my pleasure to present the Proceedings of the Second International Meeting of the European Platform for Supervisory Organizations (EPSO) held on 13th - 14th November 1997 in Lisbon, Portugal.

It gives an impression of the presentations held by the attending countries. The main aim of these meetings is setting up a network of key figures in state supervision of health care and an opportunity to develop, evaluate and exchange valid methods in inspectorate supervision.
Special topics were emphasized by different representatives, such as the international context and high degree of standards which have to be achieved for blood products, the main tasks of the pharmaceutical supervision, supervision of hospitals and a presentation concerning infectious diseases and multiresistance.

The next meeting of EPSO will be held in Stavanger, Norway on 3rd and 4th June 1999.

I hope this second report may be of value for all participants of EPSO and also those who were not able to attend but are interested in the developments.

Jitze Verhoeff
Chairman

# I Introduction

The effect of the EC regulations on health care requires international co-operation and communication. General criteria for the operation of bodies performing inspection (CEN/CEN-ELEC 45004) may also have consequences for inspection methods of health care inspectorates in the EC countries.

During last years a growing amount of cross-border activities in Europe in the medical field is rapidly developing. A reason for this development is the flexibility for transfer of medical professionals, blood(products), organs and patients.
Also the development of quality systems in health care is an important issue which may have - and in some aspects already has - consequences for cross-border health care as well as supervision.
Because of these developments 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. In urgent matters this can prevent delay in advising the government about necessary actions to take.

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 meeting on European supervisory organizations health care (EPSO) was organized by the Dutch Inspectorate for Health Care in Noordwijk, the Netherlands on 13th and 14th June 1996. The main aim of this meeting was setting up a network of key figures in state supervision of health care.

On 13th and 14th November 1997 our host, Portugal, has made it possible to proceed in our discussions and ideas on relevant subjects.
The participating countries of the second EPSO meeting in Lisbon, namely Belgium, the Netherlands, Norway, Portugal, Sweden and 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.
Several countries which were not present this year, such as Austria, Denmark, Finland, Ireland and Luxembourg, are highly interested and requested to be kept informed about the results of this meeting. When the next opportunity arises for a meeting they have expressed the wish to participate. The countries Iceland and Switzerland are also interested to participate. 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.
Of importance is the possibility to establish a broader EPSO network. An attempt will be made by Mr. J. Abreu from Portugal to achieve the interest of the countries of Spain, Italy and France in taking part in future discussions. Also with the aid of the colleagues in the pharmaceutical field new contacts shall be put in progress.

## II Summary

The participating countries, Belgium, the Netherlands, Norway, Portugal, Sweden and the United Kingdom presented the position, organization and tasks of their supervising systems.
During these discussions the developments in supervising in the daily practice, the possibility to supervise, the kind of contacts in relation to the field and the problems how to implement the law put forward, formed a major part of the program.

It is clear that the manner in which health care supervision and health promoting functions are organized, varies in the different European countries. Differences exist in the governmental position and the legislation behind the activities performed. In certain ways attention must be given to these developments in legislation and quality of care.

The meeting has provided the opportunity for a broader orientation on the cross border activities in health care.

The presentation on the Portuguese Blood Institute by Dr. A. Conçalves, emphasized the international context and high degree of standards which have to be achieved for blood products. Dr. Conçalves made clear that the Portuguese colleagues are well aware of this responsibility.

Dr. F. Neutel from the Portuguese Inspectorate for Drugs and Pharmacy (INFARMED) gave an explicit presentation on the main tasks of the pharmaceutical supervision. Evident is that activities in relation to pharmacy performed by INFARMED are on standards of international level.

Dr. J. Vesseur, in his presentation on the supervision of hospitals in the Netherlands, explained the main strategy for supervision followed by the Dutch inspectorate. Three sorts of supervision were emphasized, namely, general supervision, thematic supervision and ad hoc supervision. Evident is that there are a lot of developments which show that the health care organizations indeed take measures to guard and improve their quality of care.

In the presentation about infectious diseases and multiresistance, Prof. Dr. J. Torgal from Portugal, explained the connection of the epidemiological aspect of survey and the policy followed when confronted with problems concerning micro-organisms.

Of importance is that an international exchange of information exists regarding two main topics. Firstly, the pharmaceutical network where a good world wide agreement is essential and secondly, aspects and procedures concerning infectious diseases whereby of importance is the benefit of an international surveillance network for communicable diseases. The development of organ donations is a topic which also requires European activities to promote the guarantee of quality.

## III Proceedings

In the future more and more topics will take a prominent place in the border traffic in health care in neighbouring countries whereby a consensus of the quality aspects play an important role.

An item for a follow-up discussion during the next meeting is the supervision of the quality of care. Points of discussion could be: what kind of indicators are used, how are they monitored, the process of health care and the outcome of these indicators.
Also the dysfunctioning of general practitioners is an item for further discussion.

A future challenge can be the sharing of the international experiences in the coming EPSO meeting concerning the daily practice and the stimulation of quality of care.

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

- the draft proceedings of the first meeting will be finalized by the 1st of January 1998
- the draft proceedings of the second meeting will be forwarded to the participants by 1st January 1998
- the representative of Norway will look at the possibility of organizing the next meeting of EPSO
- the third EPSO meeting is planned in May 1999
- attempts will be made to broaden the EPSO network
- topics for discussion next meeting are the supervision of the quality of health care and the dysfunctioning of general practitioners
- possibilities for exchange inspectors between countries will be investigated
- 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

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It is a great pleasure to open the second meeting of EPSO and, also on behalf of the Minister of Health, to welcome you to Lisbon.

Portugal has experienced over the last twenty years an extraordinary development. If you look at our health care expenditure, for example, twenty years ago we were spending around 4% of our gross national product on health care. Now we are close to 8% of our gross national product. This is just an indicator of how quick the development has been over the past years.

An interesting aspect concerning this development, in terms of our financing and managing the health care system, is that today we have the results of these developments, but at the same time we have the remains of the past. Around the late 30's and early 40's, Portugal went through what we can call the social insurance movement which was initiated earlier in the industrial countries of Europe. At that time a network of social clinics was established throughout the country. A distinctive feature of this development in Portugal, compared to more industrialised countries in Europe, was that while in other countries social insurance meant basically to finance existing networks of doctors, in Portugal this meant an effort to establish new clinics which were themselves property of the social insurance. So social insurance was not only a financing mechanism that could finance access to health care to people who were in need of it, but was in southern European countries in general, not only in Portugal, an effort to organize a network of social insurance physicists that could provide the service not available otherwise. Nowadays this feature still influences the way we do things.

Around the late 70's and early 80's we developed a national service system based on our centres and hospitals which were basically public-owned and public-financed. Today, 15 years after, we have a mixture of the past, present and the future. This has an important influence in the difficulties that supervisory bodies have in dealing with the system.
Some professionals are full-time employed with a salary that is manageable. But there are still many colleagues who are still employed in different settings.

We are now entering the third phase of our development of health systems in Portugal. The first being the late 30's/early 40's on the social insurance movement, the second phase in the late 70's/begin 80's, the national service movement, and now we hope we can enter the third phase called modernizing our national system.

I shall describe the main features of this system and what are, of course, the obstacles from the point of view of human resources of performing or misconduct in making a quick transition from a recent past to a different future.
A first important idea is that our health institutions should be full-time institutions. This implies that they should operate morning, afternoon and night and we should provide the possibility to our staff of being full-time staff in our health services. Sometimes that is difficult to do without current legislation. Therefore for this reason there are at this moment under discussion a number of new acts. One of these acts proposes a change on the legal status of our health care institutions. Today there are public institutions that are under the rule and regulations of civil servants. This act proposes that hospitals gradually shall have a public status but will be more close to public enterprises. More flexible management, of both human and technological resources. That is now possible. This will make the management style and the management features of our hospitals quite different with the possibility to create conditions that will reward the employees that are more willing to adopt a full day schedule in our health services. There are also changes in primary care in trying to stimulate on experimental basis a way of performing that facilitates access of patients and general practitioners through good general practice. This experimental scheme again stimulates that general practitioners adopt a full time schedule in the health centres.
In order to be able to enforce this development a few other things need to happen. First of all to make a transition from a philosophy of financing our care with basic substances to a different one based on contracts. We have now five contractual agencies in the country. They started to operate a year ago. The main issue is to initiate a more demanding and evidence based dialog with health care managers in order to discuss what are the expected outcomes and what is expected performance of the financing that is provided to public institutions. Now without that scheme being in full operation, you will realise how difficult it is to adopt a more autonomous form of management and to adopt ways of paying for full-time practice in both hospitals and health centres.

Alongside this attempt to establish the initial phase of contractual agencies there is a new focus on quality of care. We are now defining three levels of quality of care. Everybody has to obtain level one. Levels two and three need to be attained against some benefits in technological resources. This has started quite recently and is an important element to change the system.

During the discussions today you will be given the opportunity to learn more about our system and exchange views and information. I would like to take this opportunity to wish you an interesting and successful conference.

# V Presentations by the participating countries

V.1 Portugal (A. Marques)

V.2 Norway (G.S. Braut)

V.3 United Kingdom (W. Thorne)

V.4 Sweden (G. Fahlberg/C. Tollin)

V.5 The Netherlands (J. Verhoeff)

V.6 Belgium (J. Van Heuverswyn)

## V.1 Portugal

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### 1 Powers and Comptetencies

**1.1** As the Inspector-General for Health stated at the first meeting of EPSO, held from 12th till 14th June, 1996 in Noordwijk, the Netherlands, the Inspectorate-General for Health in Portugal (Inspecçao-Geral da Saúde - IGS) is a central service of the Ministry of Health. Its purpose is to ensure compliance with the law in the health system, aiming to provide well-run, high quality services, safeguard the public interest and defend the legitimate interests and welfare of users.

With the scope of these powers, it is its duty to carry out inspections and management audits on institutions, services and staff in the health system and to exercise disciplinary action and audits with regard to the institutions, services and staff of the National Health Service.

Taking into account the growing number of situations in which the IGS has been called upon to intervene at the level of private institutions outside the health system, the organic law governing the Inspectorate is in the process of being revised, in order to make it possible to carry out inspections on private institutions, in collaboration with the competent services of the Ministry of Health.

In order to facilitate the exercise of its powers, the structure of IGS includes two specific sections: Inspections and Management Audit Service (Serviço de Inspecçao e de Auditoria de Gestao - SIAG) and Disciplinary Action and Audit Service (Serviço de Acçao e Auditoria Disciplinares - SAAD). SIAG works according to an annual activity plan.

**1.2** In terms of the direct exercise of disciplinary powers, in order to investigate any situations which have taken place in National Health Service establishments and have come to its notice, and in order to attribute responsibility, the IGS, in addition to organizing a simple clarification procedure (pre-disciplinary action) may set up investigation procedures (summary investigation, carried out quickly but not exhaustively), enquire procedures (more profound and exhaustive investigation) and disciplinary proceedings (when there is sufficient evidence of a breach of discipline and an identifiable perpetrator).

**1.3** In terms of disciplinary audit, and because the exercise of disciplinary action lies within the powers of those responsible for National Health Service establishments, IGS evaluates how disciplinary action is exercised. It may provide support, propose technical rules and produce guidelines for the correct application of disciplinary legislation.

1.4 The inspection of health system establishments (National Health Service establishments and private establishments linked to the National Health Service by contracts for the provision of given health services) examines all aspects relating to the legality, regularity and quality of how services function, within a preventive and educational perspective. In this area IGS carries out ordinary inspections (essential aspects of the working of a given establishment in its entirety) and subject-specific inspections (the working of various establishments with regard to a specific aspect).

1.5 In the area of management audits of National Health Service establishments, IGS carries out management audits through which it evaluates the activity developed by establishments in terms of economy, efficiency and effectiveness, namely through financial and budget control and monitoring of the implementation of projects or action programmes. This work is also carried out with an essentially preventive and educational perspective in mind.

## 2 IGS Technical Staff

2.1 In order to carry out its activity, in terms of high level technical staff IGS presently has 33 full-time inspectors (28 legal specialists and 5 economists) and one part-time medical advisor.

Given the growing number of situations in which IGS is called upon to act, both because there is an increasing demand for quality and promptness of health care and because users of health establishments are increasingly aware of their rights, the Inspectorate's technical staff has been shown to be insufficient for IGS to respond in useful time. For this reason an increase in staffing levels was recently approved and the Inspectorate is now in the process of recruiting more full-time staff (economists and legal specialists).

2.2 IGS has one doctor who serves as an advisor on a part-time basis. However, there is no engineer, for instance whose specific knowledge and experience would also be useful in certain actions undertaken by IGS. Nonetheless, when it is necessary to use expertise in specific areas, IGS may request technical officers from other services with the Ministry of Health.

In the near future (as soon as the alterations to the organic law have been approved) IGS intends to take on more doctors on a full-time basis (not as full-time members of the inspection staff, but as advisors, on secondment from other services).
In addition, for certain specific actions, the Inspectorate also intends to make use of specialised technical staff in specific areas (engineering, pharmacy, etc.) also on secondment from other public services.

When IGS has to pronounce upon the technical aspects of situations where the suitability of the health care provided is being questioned (which has happened quite often) in addition to a first assessment by the IGS medical advisor, specialist medical expertise is also sought, requested from doctors belonging to the clinical

specialization in question. It should be pointed out that in these situations IGS has the power to ascertain disciplinary responsibility only. Civil and criminal responsibility is a matter for the courts.

## 3 Articulation with other bodies

**3.1** Whereas the essential objective of IGS is to ensure compliance with the law and regulations, it is up to other central services of the Ministry of Health to define the technical rules regarding the organization of health establishments and the provision of health care activities.

In the specific technical areas they supervise, they are also competent to assess the working of establishments and/or the quality of the service provided. In this aspect, their powers may partially coincide with those of IGS. This coincidence or overlapping of powers, when it happens (and it is more virtual than real), is solved by means of articulated action involving both IGS and the central services in question.

This is true above all of the Directorate-General for Health (Dorecçao Geral da Saude - DGS), the Portuguese Blood Institute (Instituo Portgues do Sangue - IPS), the National Institute for Pharmacy and Medication (Instituo Nacional da Farmacia e do Medicamento - INFARMED), the Service for the Prevention and Treatment of Drug Addiction (Serviço de Prevençao e Tratamento da Toxicodependencia - SPTT), the Department of Human Resources for Health (Departamento de Recursos Humanos da Saude - DHRS), the Institute for IT and Financial Management for Health (Instituto de Gestao Informatica e Financeira da Saude - IGIFS) and the Directorate-General for Health Facilities and Equipment (Direcçao-Geral das Instalaçoes a Equipamentos de Saude - DGIES).
For instance, inspections are currently being carried out on hospital pharmacies, and the inspection team includes a technical officer from INFARMED.
Collaboration with DGS is also planned when it comes to the inspection and monitoring of private clinics.

**3.2** There are other bodies external to the Ministry of Health which also have powers to inspect certain aspects of the working of National Health Service establishments, with which the inspectorate's powers virtually overlap. This therefore leads to occasional articulation with those bodies.

Regarding this matter, we may cite above all the Court of Audit (Tribunal de Contas), the Inspectorate-General of the Ministry of Finance (Inspecçao-Geral de Finanças) and the Inspectorate-General for Economic Activities (Inspecçao-Geral das Actividades Económicas). Collaboration with the latter, for instance, extends to inspection of hospital kitchens and refectories.

## 4 Evaluation of Activity Undertaken by IGS

**4.1** Until 1989 IGS acted almost exclusively in the area of disciplinary action. From 1989 onwards, however, IGS gradually widened the scope of its inspection and from 1993 onwards began to carry out management audits.

Since the main concern was, on the one hand, to act above all on a preventive basis and, on the other, to lead the management bodies of health establishments to take full responsibility for the exercise of disciplinary powers, not only has the number of inspection and auditing actions increased, but growing numbers of establishments have been included and the areas covered have diversified.

As examples we may cite inspections on human approach and patient attendance in Health Centres, the speed with which health care is provided in Casualty Units, hospital hygiene (including concern for nosocomal infections and with antibiotics) and hospital waste, the blood transfusion service, dialysis units and human plasma derivatives.

A particular problem in Portugal is the question of medication (promotion/ advertising and prescription/consumption) and the relationship between National Health Service staff and the pharmaceutical industry. For this very reason, IGS is carrying out enquiries and inspections of hospital pharmacies (as mentioned above), together with other inspections in the area of medication.

**4.2** The following tables (3 and 4) give an idea of the activity undertaken by IGS last year:

**Table 3**

IGS/1996

| Disciplinary Action | | Inspection and Management Audit | |
|---|---|---|---|
| Enquiry and investigation procedures | Disciplinary proceedings | Inspections | Audits |
| 193 (a) | 161 (b) | 57 | 12 |

(a) - 80 (= approximately 41%) concerning medical attendance

(b) - 17 (= approximately 10.5%) concerning doctors and medical attendance

**Table 4**

Disciplinary sanctions

IGS/1996

| Written repimand | | Fine | | Suspension or inactivity | | Compulsory retirement or dismissal (a) | | Total |
|---|---|---|---|---|---|---|---|---|
| 5 | 9.6% | 7 | 13.5% | 26 | 50% | 14 | 26.9% | 52 |

(a) - Sanctions applied by the Minister of Health on the recommendation of the Inspector-General for Health.

## V.2 Norway

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### 1 Some facts about the Norwegian society and health care system

Norway has only about 4.4 million inhabitants. At the time the nation has a sound economy, mainly due to incomes from the offshore petroleum-activities. Though there are quite a lot of problems related to the health care systems today, attributed both to resource allocation and resource distribution.

The responsibility for providing health care are divided among the three main political levels of the Norwegian community, the state, the county municipalities ("counties") and the municipalities.

The state is responsible for the legislation (acts, regulations), superior resource-distribution and nation-wide economic welfare schemes; thus governing the main health policies of the nation. In addition the state has established a supervisory system (see below) for health care providers on all levels, including private enterprises and single professionals (e.g. doctors). The state also operates a few specialized clinics, the nation-wide air-ambulance-scheme and some superior public health functions.

The county municipalities, of which there are 19 (Oslo included acting both municipality and county municipality), are responsible by law for the specialized in- and out-patient care. Thus most hospitals are run by the county municipalities. The counties have a very varying amount of inhabitants (from Oslo with about 500.000 to Finnmark with only 75.000). Therefore the county municipalities now are stimulated to collaborate to establish high-cost-services as e.g. radiotherapy for cancer patients.

The municipalities, of which there are 435, are responsible by law for primary health care including public health measures and the health care for the elderly and disabled. The municipalities also have a very varying amount of inhabitants (from Oslo still with about 500.000 to Utsira with only 220 (!)).

It shall also be mentioned that the operators in the petroleum activities have the responsibility for providing primary health care, occupational health services and emergency preparedness on the offshore installations. This is the only industry that is responsible by law providing ordinary clinical services to their employees.

## 2 Trends in health policy by 1997

Norway got a new government by October 1997 based on three political parties in the centre. They seem to continue and enforce the main policies laid down by the Parliament and the former Labour-government. The ongoing revision of major acts will continue, but there probably will be no changes in areas of responsibility for the different political levels mentioned above.

The care for persons with chronic psychiatric diseases will be strengthened and more resources will be given to the municipalities to enable them to take care of patients let out from the psychiatric hospitals. The care for the elderly will be given more resources, e.g. making municipalities able to establish more single-rooms in nursing homes. The cancer-therapy will be given more resources, and the county municipalities are strongly stimulated to cooperate on high-specialized services. There is also established a plan for recruitment of skilled personnel to the health services. The state authorities also work on a plan for stimulating preventive health care.

## 3 Organization of the supervising bodies

The legal fundament for the supervising bodies is the act of 30.3.84 on state supervision of health services. It is focusing on the responsibilities of the health care providers themselves and their obligation to have systems for internal control. The main strategy for the state supervisory agencies is to monitor that the providers themselves have proper systems to evaluate their own services.

The supervising bodies are organized on two levels. Norwegian Board of Health (Norwegian: Statens helsetilsyn), headed by the Director General of Health (Anne Alvik), is responsible for the planning and co-ordination of the state supervisory activities on both levels. In each county there is a county medical office, CMO, (Norwegian: fylkeslege), headed by a chief county medical officer, which is responsible for the operational supervisory activities in that county, directed towards all health care providers (irrespective of ownership).

The supervisory bodies employ about 470 persons by 1997.

The supervisory bodies mainly rely on audits aimed at the health service operators. These audits, usually carried out by the CMOs, are focusing on the systems for quality assurance and delivery of care. Deviations are protocolled when non-conformity with requirements in acts and regulations are observed. If deviations are regarded severe, the Norwegian Board of Health may order to make improvements. The supervisions are carried out according to international standard for audits (ISO 10011-series).

In addition the supervising bodies deal with patient complaints. These are usually focusing on the quality of care delivered in a special case, and may give signals of suboptimal services given by e.g. a hospital or even a private practitioner. In severe cases, the Norwegian Board of Health are in position to withdraw the

permit to practice for e.g. a doctor, a nurse, a dentist or other types of health professionals.

The supervising bodies also to some extent give advice on quality systems in health care and some public health matters. In addition some special medicolegal matters (except forensic tasks) are handled by the supervisory bodies. An example of this may be the evaluation of doctors' certification of fitness to hold a driver's licence.

A current dilemma in practical work is to which extent the supervising bodies shall give advice in addition to carry out supervisions without taking parts of the responsibility from the operators/providers. Another problem is how much the supervising bodies shall be concerned with distribution of health and other public health matters in addition to focusing on the health care systems.

## V.3 United Kingdom

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The last time we met, I explained, that, in the UK we do not have a formal State Inspectorate for our health services, such as that which exists in some other countries. However, the means to monitor quality standards does exist, through professional bodies, independent authorities and within the health service itself through the NHS performance management process. You have circulated an article which recently appeared in the British Medical Journal, and this describes three outcomes of the process of care: clinical outcomes, service or satisfaction outcomes and cost outcomes and stresses the importance of considering whole processes so that all their outcomes can be improved. The article asks whether the UK needs an inspectorate to catalyse work on quality improvement. I would like to describe some of the activity which is already taking place and some initiatives which are planned.

Before I describe to you what we are doing, I should set what follows in context. On 1st May this year we had our first change of government in 18 years. Much work is being undertaken by our new government in the area of NHS organization. We shortly expect the announcement of new plans for the NHS, which will include initiatives on quality. I am unable to describe these to you now, but will be happy to provide information to anyone interested when it is available.

Our new health ministers have outlined their commitment to:

- hold hospitals to account for meeting high standards in the provision of care
- make Health Authorities the guardians of high standards, with a central role in ensuring rising standards of care
- measure success by quality of outcomes, rather than the number of patient "episodes"
- introduce a new NHS Charter, concentrating explicitly on the quality and success of treatment.

The aim in these initiatives is to return to the primary aim of the NHS, to deliver equitable, high quality services to those who need them and to focus on people rather than numbers. The intended focus is what happens to individuals.

We already have a "Patient Charter". This document sets out the standards patients should expect. It has certainly raised the profile of the "consumer" of health services, but it has also - perhaps inevitably - focused attention on indicators which are easy to measure. The Charter is to be revised to focus strongly on quality of care, effectiveness of treatment and quality of information. Obviously the new Charter will have to contain measurable quality standards and the development of these will be a challenging tasks. The Government is

committed to developing the new Charter in full consultation with the public, professional and managers.

But there are some inescapable basics which it will need to address. Who would contest the right of a patient to:

- be treated with respect, dignity and privacy
- have their views listened tot and respected
- be given information in a way they can understand an
- be fully involved in decisions about their care?

The emphasis will be on co-operation and collaboration between all those involved. This will include responsibilities of patients - including the quarter of a million who every year fail to attend for booked operations. As part of this partnership, the Department of Health is working to help ensure that people have the information they need to help them make informed judgements about their own care and that of their families.

**Performance indicators**

Many people feel that the way the performance of the NHS is assessed and managed, has in the past focused too much on activity levels and financial efficiency, and that it has not delivered the right incentives for NHS organizations to focus on the quality of care they provide. So we are also developing a broader-based way of assessing and developing the performance of NHS organisations which can be applied nationally and locally and which captures quality and outcomes as well as activity and financial efficiency - better balancing, in the language of the BMJ article, the service, clinical and financial outcomes of NHS activity. There is something of a cultural change to be effected, and this is a crucial piece of the jigsaw.

Work is underway to develop and pilot a collection of prototype clinical effectiveness indicators. They are being designed to demonstrate how well health services are performing in securing better health outcomes on the basis of sound evidence of clinical effectiveness.

We intend to develop measures of population health outcomes to enable us to monitor comparative improvements in health in different health authorities and among similar population groups in different parts of the country.

I would be interested to hear about indicators and standards which are used by inspectorates and colleagues here and something about the perceived advantages and disadvantages of the various types of inspectorate arrangements.

One of the fundamental requirements for quality improvement is building partnerships across functional, occupational and organizational boundaries. So our work to improve quality will mean building on partnerships at both local and national levels - partnerships among the professions, managers, patients and the public and the Government, and partnership - rather than competition among the different NHS bodies which serve particular populations.

## V.4 Sweden

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The National Board of Health and Welfare is an authority under the Ministry of Health and Social Welfare. The Board has an independent status and we deal under the different laws passed by the Parliament. The Board issues Directions and Official Recommendations which are published in the Code of Statues (SOSFS). The Board can issue Directions and Official Recommendations only for the safety of the patients. The Directions are binding regulations and Official Recommendations contain recommendations on how a Statute may or should be applied, and do not exclude other methods of achieving the objectives stated in the Statute. The Directions and Official Recommendations are directed towards care-providers and executive managers, as well as all health care staff/personnel.

The supervision system for the health medical services and its personnel are based on four different laws or acts:

- Health and Medical Services Act (1982:763)
  The requirements to be met by the health and medical services
- Health and Medical Personnel (Duties) Act (1994:953)
  The duties of the health and medical personnel
- Health and Medical Personnel (Disciplinary Sanctions) Act (1994:954)
- Health and Medical Services (Supervision) Act (1996:786)

The Health and Medical Services Act (1982:763) states the requirements to be meet by the services. The national goals are aimed at assuring the entire population a good health and care on equal terms. Good care means that the services must be of good quality and cater the patient's need of security and treatment, be readily available, be founded on respect for self-determination and privacy of the patient and promote good contacts between the patient and health and medical personnel. Care and treatment shall as far as possible be designed and conducted in consultation with the patient.

The new sections in the Act from 1st January 1997 state that where health and medical services are conducted, there shall be present the staff, facilities and equipment necessary in order for provision of good care to be possible. This section is important for the supervision.
In the new sections the quality assurance is stated. The quality of activities in health and medical services shall be systematically and continuously developed and secured. The Board has issued Directions and Official Recommendations "Quality Improvement Systems for Health Care and Medical Service" SOSFS 1996:24.

In the Health and Medical Personnel (Duties) Act (1994:953) states that a person belonging to health and medical personnel shall do his work in accordance with science and proven experience. A person belonging to the health and medical personnel is personally responsible for the manner in which his or her duties are discharged.

The Health and Medical Personnel (Disciplinary Sanctions) Act (1994:954) deals with disciplinary problems with health and medical personnel, those with authorization (physicians, nurses, dentists, physiotherapists etc.) and those persons assisting the authorized personnel in connection with care, treatment or examination.

In the Health and Medical Services (Supervision) Act (1996:786) the Board's functions are stated. Health and medical services and their personnel shall come under the supervision of the Board. Assignments from health and medical services with regard to sampling, analysis or other investigation forming part of the assessment of a patient's state of health or treatment, without providing health and medical services, shall also come under the supervision of the Board.

The main purpose of supervision by the Board shall be to prevent injuries and eliminate risk in health and medical services. Through its supervision the Board shall support and scrutinize the activity and the measures taken by health and medical personnel. There is a duty to report both from the care-provider, as the staff, if a patient has incurred or has been exposed to risk if incurring serious injury or illness.

A care-provider and its personnel subject to supervision under the Act is obliged to furnish the Board documents, samples and other material relating to the activity and to give the Board such information regarding the activity which is needed for the purposes of its supervision.

The National Board of Health and Welfare has six regional supervisory departments to foster quality and safety within health, medical and dental care. This is done through:

- information
- assessment of individual cases (patient cases, Lex Marias reports, etc.)
- inspections
- supervision of care with individual health and medical services
- supervision of prescription of medicine
- support quality assurance and encourage self-assessment

About 90 persons are working at the regional supervisory departments. In 1996 the six regional supervisory departments did over 700 inspections and supervisory visits. About half of the activities were assessment of individual cases but half of the activities were inspections and visits to support and scrutinize the care-providers quality assurance and self-assessment. In over 140 cases yearly of individual authorized personnel the six regional departments notify the Health and Medical Services Disciplinary Board demanding disciplinary sanction. In a few cases per year the demand is the revocation of authorization.

About 1800 reports per year, according to the Health and Medical Services (Supervision) Act, are dealt with at the six regional supervisory departments around Sweden.

The National Board of Health and Welfare has a database for all reports dealt according to Supervision Act. The database, Riskdatabasen, is accessible for everyone to look for risk in health and medical care.

The regional supervisory departments do unannounced inspections twice a year on the same day all around Sweden; for example the first one we inspected around 60 private surgeons in the first week of October.

## V.5 The Netherlands

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### 1 Some facts about the Dutch health care system

The Netherlands has a surface of 40,000 square kilometres of which 10,000 square kilometres is water. The population is 15 million inhabitants and the age structure is ± 13% older than 65 years. We have a number of 200,000 births a year and the death rate is 130,000. The life expectancy for female is 80 years and for male 74 years, which is in line with the European findings. The family planning is 2 ½ child and that is a growing number.

We have one registered nurse per 100 inhabitants, one GP per 2325 inhabitants and the total number of all doctors is one per 315. The total of the gross national product is 9,4% and that is lowering at this moment. At present it is nearer the 9% and this is inclusive the care for the elderly.
The health care system in the Netherlands is characterised by the fact that we have a number of hospital beds of 4.1 per 1000 inhabitants, which is lowering at this moment. There is a general tendency to keep the people shorter in the hospital, which gives a high burden on the home care in the Netherlands. We have 1.6 psychiatric beds per 1000 inhabitants and 2.1 mentally handicapt which is growing at this moment. The elderly home beds are 3.5 per 1000 inhabitants and in fact we try to lower that number because we are doing our best to keep the elderly in their own surroundings as long as possible with the help of home care.

Our insurance system is a typical private/public insurance mixture. It is characteristic in the manner that nearly all facilities are privatized. Only in view of the preventive activities there is a public responsibility. These are the municipalities which have a preventive task.
About 60% of the population participates in a compulsory insurance fund. Below the income level of *f*62,000 you are obliged to be in this sick fund. The remaining 40% participates in a private insurance. We also have a very interesting law, the AWBZ. It is a law which insures the non-insurable conveniences.

The responsibilities of the central government are firstly to provide the legal titles for the responsibility (who is responsible for what). It also has to take responsibility for the solidarity and the accessibility of health care and for the superintendance c.q. the inspection. Hereby it has a role in the quality of care. In relation to consumer rights the government has an important task. The consumers are the most weak party in health care system, and when they are not actively sustained by the government nothing will happen in relation to the consumer rights.

Our Minister is responsible for all these tasks. For that reason there are two instruments to achieve these goals. One is the Directorate General, which is responsible for the policy assets and secondly, the state inspectorate. The inspectorate is not a state agency, we are a part of the department of the Ministry of Health but by law the inspectorate is able to have their own conclusions and ideas on what is necessary in health care. For reason of this special position the Inspectorate maintains an own contact with the parliament.

## 2 The Dutch inspectorate of Health Care

The inspectorate in the Netherlands has the mission to superintend the public health, the health care and the health care systems as well as on collective as on individual level. Our task is not defined by the place an institution has in the system. It is not influenced by the way it is financed. There is no difference between a public institution or a private institution. They all are submitted to the state inspectorate.
The inspectorate also advises, reports, stimulates and protects the public health and the health of the individual. We advise and report to the Minister and to the field.

The core business of the supervision is to give attention to the quality systems in health care organizations. That is the new development we can see in the whole of Europe. We have some responsibility in relation to the quality of the delivered care. A very interesting item where much attention is given to, is the point of the lacking persons. The monitoring in health care is only monitoring what they are doing, but there is no system that is monitoring what they are not doing. It is the task of our inspectorate to look if there are people not being served by the system. We also look at the health state of the population. These tasks have been presented in two reports at this moment. We have one report on the health state of the population and a report on the quality of the health care system. The last report is a first overview of our health care system which will appear every four years. Attention is paid to the accessibility of our health care system in all aspects, as well as the lacking persons and the waiting lists.

## 3 Quality of health care

There is an important development in thinking about the quality in health care. In our traditional legislation we have had problems with the quality aspects because it was too much input-directed. In our traditional quality, the assurance directed on the input and output aspects, is mostly related to the financing insurance systems. The process of the input is related to the number of beds, the professionals, the organization and the appliances. While the output aims at the care delivery, professional standards, the satisfaction, the state of the art, the complaints/calamities and incidents. For that reason we made a law for all institutions, the Quality Act of Health Care Organizations. This law is not related to the way the institutions are financed, but is related to adequate care. Three important factors to achieve adequate care are patient orientation, effectiveness

and efficiency. The law says that each institution has to take the responsibility for their own quality system. When this law was incorporated the position of the inspectorate became at that moment to see in what way the institutions succeed in creating their quality systems. The law only says "what" to manage but not "how" to manage this. Of course there is the necessity to formulate a norm. The most important thing is that the norm we use as an inspectorate is a norm which has to do with the state of the art and what it used within the circle of the professionals. The patient influence has a prominent place in the development of the norm.

The main problem at this moment is that we have to realize that a quality system on paper is not the same as a working quality system. A working quality system is only a system which increases the probability of giving good care, not an insurance that good care is given. For that reason we must have an interest and here lies something that we have in common as superintendency organizations in health care. What are at this moment the most relevant prospectives to focus on? What is the right information on the quality process and the outcome? Is the system working? It is all about what are the most relevant and valid indicators to achieve in the certain quality perspectives. That is an interesting question for the future.

## V.6 Belgium

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The health care administration position saying that the inspection plays a major role in the external testing of the facilities quality policy was given more foundation by request of the Minister of the Government of Flanders responsible for the health policy.

The argumentation consisted of three elements:
- the nuclear tasks of the administration
- the coherence between quality testing, inspection and recognition
- a comparison of the situation in this field with other trend-seeking countries in Europe.

### 1 Nuclear tasks of the administration

The Welfare, Public Health and Culture Department process plan defines recognition and subsidization to the nuclear tasks of the Department. The Board of Directors reconsidered and redefined the process in this field by taking the coalition agreement policy principles into account; these principles are listed below:

- Flemish administration quality with the following driving forces: subsidiarity, partnership, simplified rules with the appropriate supervision, clearly outlined tasks and a good communication policy.
- Realizing a new public administration type through strategic management in order to have the right social effect by simplified rules, effectiveness, concentrating on clearly outlined fields, good communication and quick decision-making.
- High-quality care an d aid with a larger efficiency, customer-directed to a higher extent, including quality support procedures and structures.

### 2 Coherence between quality testing, inspection and recognition

#### 2.1 Recognition: for which purpose?

Within the Welfare, Public Health and Culture Department, the "recognition" concept stands for various things, ranging from a kind of operating licence through a subsidization condition to a pure quality label.

The Minister stated that "the growing insight into quality concept and quality management will lead to accent shifts in the recognition standards pertaining to

facilities. That is why the Flemish authorities shall focus attention not only on more care structures, but also on care processes and care results, from now on.

The quality policy the facilities conduct shall be reported to the administration responsible for supervision and inspection. The administration shall check the results by means of purposes laid down in advance and possibly recommend adjustments in consultation with the care-providers. An external body - recognized by the authorities - maybe involved in quality testing."

As far as the Health Care Administration is concerned, there is no doubt that recognizing a care facility implies not only quality labelling, but also a subsidization condition and an efficient operation condition for such a facility.

Recognition must be based on a well-founded evaluation of how a facility functions or at least on assessing the potential of a facility to deliver a minimum care quality level.

A new quality Act provides the administration and its inspection services with the possibility of manitoring and judging the processes and results of care in a facility.

This is of vital importance for updating knowledge and experience, among other things yielded by comparing facilities, the administration in general and the inspection in particular.

## 2.2 What is the aim of inspection?

The political consensus on an accessible and feasible health care for any member of society will always result into a very considerable flow of public expenditure and the inherent rules. Such a judicial and financial impact of the authorities on the care sector shall always have to be publicly justified.

As a matter of fact, supervision of or testing facilities will always be involved, not only for controlling the flow of public money to these facilities, but also for checking whether the facilities are worth the public trust and remain so, in other words whether care of an acceptable quality is provided.

"In-spicere" - literally "looking inside" - in facilities remains a unique source of knowledge and information for the administration, enables comparing opinions or positions voiced by the top of a facility - and sent to Brussels orally, in written form or on a floppy disc - to the opinion or experience of the grass-roots level.

Also when we intend to gradually replace the term "inspection" by "supervision" will knowledge of and visits to the field remain vital to assess the strong and weak points of facilities or a network.

Removing the inspection from facilities to the advantage of an external audit system may have negative effects on the policy-preparation, -implementation and -evaluation cycle:

- providing policy-makers with high-quality advice requires a real-life link between the administration and the care facilities and an updated knowledge of the field;

- the image of the administration as a bureaucratic ivory tower without interaction between the inspectors in the field and the policy advisors might negatively affect the official policy credibility.

Inspection is no one-way traffic. Inspection always leads to a mutual data exchange.
Each inspector in a facility is questioned about the trends to be expected in policy-making.
This communication process proves that the administration is customer-friendly.

The inspection's set of instruments - i.e. the legal standards - concentrating too much on the structural elements of care in the past and even today - will gradually be substituted by measuring and evaluating the care results and processes.

Structure indicators will no doubt continue to exist, but in a less detailed form and no longer as exclusive criteria for an inspection.
This evolution is leading to more and more overlapping of the external quality testing and inspection concepts.

**2.3** Is supervision necessary

The "inspection" concept has always been considered and experienced to be an external and discontinuous matter.

On the contrary, the "quality testing" concept has an external as well as an internal component and this process should have a continuous nature.

The quality Act makes the facility itself responsible - first and foremost - for quality testing (internal testing) and quite rightly so. Testing this testing (external testing) may be taken care of by the inspection, assisted by outside organizations or not.

Supervision or external testing of a quality policy is indispensable. One had better avoid problems that might sprout from a too large emphasis of external supervision against the internal monitoring and improvement process.

The quality Act nevertheless emphasized - and quite rightly so - self-testing of and by facilities.

As a matter of fact, there is a certain contradiction between the quality supervision through accreditation approach tending to stress the importance of existing standards and procedures and consequently implying the danger of a fairly conservative top-down attitude on the one hand and the continuous care quality improvement approach (progressive nature) on the other hand.

## 3 Quality policy in Europe

At this point in time, a search is going on for the appropriate inspection rule of the authorities in the quality field, the space left for the facilities themselves and the actions of possible third parties everywhere in Europe and beyond.

Anyhow, a comparison with the approach used in our neighbouring countries is interesting. The EPSO meeting of today is an ideal opportunity to do so. We congratulate you on this initiative.

# VI Presentations on subjects concerning cross-border health care

VI.A The Portuguese Blood Institute (A. Gonçalves)

VI.B The Portuguese inspectorate for Drugs and Pharmacy (INFARMED - F. Neutel)

VI.C Supervision on hospitals in the Netherlands (J. Vesseur)

VI.D Infectious diseases and multiresistance antibiotics (J. Torgal)

## VI.A The Portuguese Blood Institute

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I would like to introduce you the Portuguese Blood Institute, an institution created within the ambit of the Health Ministry, which has tutored competency in the area of transfusion medicine.

Decree-Law 294/90 - as of 21st September
Article 4 - Powers
1. The Portuguese Blood Institute has the following powers
a. To co-ordinate, guide and check, at a national level, activities related to the collection, preparation, conservation, distribution and quality of blood and its components.

The creation of the Portuguese Blood Institute in 1990, has had a propose of organizing the Portuguese National Blood Service aiming essentially:

- first, to render and normalize proceeding and practices since the collection to the administration of blood and its components;
- second, centralize in the three Regional Blood Centres of Lisbon, Coimbra and Porto the blood collection and its processment, entrusting the Blood Hospital Services in the clinical transfusion co-ordination;
- third, to obtain the quality and maximum security applicable in transfusion practice.

In Portugal there are approximately 180 health establishments, public, private and in the military scope, doing transfusions. Some of them in a small percentage, and others employing, it has a high activity.

Portugal has published legislation on the official journal, such as documents related to transfusion - Regulations on Blood Transfusion, and normatives documents as well as recommendations.

Dispatch 19/91 - as of 14th August

- Determination of the blood group in the ABO system.
- Screening of transmissible diseases:
    - Siphilis
    - Ag Hbs
    - Anti-HBc
    - Anti-HCV
    - Alt
    - Anti-HIV 1
    - Anti-HIV 2
    - Anti-HTLV I/II

In such wide universe the IPS has the following inspection activity:

1. For each geographical area of a Regional Board Centre, an expert in transfusion medicine who visits an Hospital Blood Service and with a rigorous and exigent questionnaire inspects the processment of blood, the conditions of the equipment and follow-up the patients therapeutical treatment.
2. External quality control, in which the Blood Services in presence of blood samples sent by the Regional Blood Centres have to perform a group of laboratory tests that identify parameters and requirements to study.
3. Forty-five percent of the Blood Services that I mentioned, nowadays neither collect nor study the blood; the only receive blood from the Regional Blood Centres.
4. Portugal is going to improve Haemovigilance System in the area of blood and its components, starting from 1998, similarly to the traceability study carried out in France, aiming the whole knowledge of transfusion.

## VI.B The Portuguese Inspectorate for Drugs and Pharmacy (INFARMED)

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INFARMED is a public institute granted with administrative and financial autonomy, reporting to the Minister of Health and is thus endowed to follow all the activities related to Pharmacy and Medicines.
The present form was established in 1994 by DL 353/93 of 7th October and succeeded to the former Directorate General of Pharmaceutical Affairs (created in 1984 by DL 103-A/84 of 30th March), due to the need of growth related to increasing activities in medicinal products and cosmetics fields at internal and European levels and to correspond to the public needs.

The main tasks of INFARMED are:

- To collaborate in the general policy of health, namely when related to medicines for human and veterinary use.
- To issue opinions on regulations related to research, production, marketing and use of medicines.
- To guarantee the quality of medicines, guide an d evaluate and inspect the pharmaceutical activity.
- To ensure that relevant information of medicines and health products is made available to health professionals and consumers.
- To guarantee the organisation of the national system of pharmaco vigilance linking with the competent international entities.
- To support studies and research in the field of pharmaceutical sciences.

The Department of Pharmacy and Pharmaceutical Inspection has different tasks and several things to deal with as a supervision body. We have competence to inspect the pharmacies, the pharmaceutical industry and the wholesalers regarding the licensing and supervision of their activities, as well as the products in the market medicinal products (human and veterinary), the cosmetics and the medical devices in the market to ensure their compliance and quality.

According to the area of intervention we have reference documents as in national legislation as well as European harmonized guidelines and international recommendations which is accounted for in our internal SOP's . Also a Quality Manuel is prepared by using the PIC Recommendations on quality system requirements for GMP inspectorates, approved in July 1994. It is not approved a European recommendation for EU/EEA inspection services in the WP of National Inspectorates/EU.

**Medicinal products**

Concerning the conduct and the standards of inspections for medicinal products and manufacturers our experience goes back specially as far as 25 years, when the Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products (Pharmaceutical Inspection Convention - PIC) was established between our partners in the EFTA, using these documents as a reference.

**PIC guide to Good Manufacturing practice for pharmaceutical products and guidelines**

After we became a member of the EEC we adopted the European directives and guidelines for Good Manufacturing Practice (EU/GMP), 1997, for the inspection of manufactures as well as the community procedures on administrative collaboration and harmonization inspections, 1996, that has statements related to the rapid alert system, exchange conduct of inspection, training of inspectors and exchange of information of manufactures and wholesalers distribution authorizations in the framework of administrative collaboration between competent authorities in the EEE.

Thinking of the harmonisation of the conduct of the inspections we have participated in the joint inspection teams with other EM's for training.

We have also been asked by the EMEA to perform joint inspections in third countries during the assessment of an application for a medicinal product submitted by Centralised Procedure, namely USA. We participate also in the Rapid Alert System adopted in the EU as a contact point for transmissions of data related to defective or counterfeit medicinal products.

**Pharmacy supervision**

We have in Portugal about 250 private pharmacies which corresponds to a ratio inhabitants/pharmacy, 4050, less than the European average.

All pharmacies must have through the INFARMED, a valid licence given by the Health Ministry to be in operation and a technical director with the professional title of Pharmacist (a professional licence issued by the Order of Pharmacists for those qualified in Pharmacy or Pharmaceutical Science).

The installations, equipment and documentation have also to comply with national rules stating, namely minimum areas of the number and dedicated rooms, storage condition according to the different medicinal and pharmaceutical products. They also have to have pharmaceutical urgency services outside the normal working period which is rotative and is previously accorded with the regional health authorities.

INFARMED is the competent authority to issue and validate licences and supervises the pharmaceutical exercise in the Pharmacies (L 2125/20/03/65 and DL 48547/28/08/68).

The supervision of these activities are one of the Pharmaceutical Inspection tasks and when necessary, the co-operation of the Health subregions is asked (if they have pharmacists in their staff). Yearly we inspect about 500 pharmacies in a rotative base or to verify complains or for new facilities approval.

To perform these inspections we have standard operation procedures (SOP's) according to the different objectives of the operation and taking into account the

national legislation as well as the recommendations issued by the Order of Pharmacists, the EU Pharmaceutical Committee or international bodies, namely WHO-Good Pharmacy Practice (GPP) in Community and Hospital Pharmacy Settings (WHO/PHARM/DAP/96.1), International Pharmaceutical Federation (FIP), etc.

The professional ethics remain a question for national professional organisation (Order) as it is understood in the subsidiarity principle of the EEC Treaty.

## VI.C Supervision on hospitals in the Netherlands

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One of the tasks of the Dutch inspectorate is the supervision of health care systems, including hospitals. The "somatic" hospitals in Holland are divided in three kinds of hospitals: the academic hospitals of which we have eight in the Netherlands, the general hospitals, about 120 in number and there are the specialised hospitals, for example the rehabilitation centres. We distinguish roughly three manners of supervision. General supervision, thematic supervision and ad hoc supervision. These three methods of supervision, apart from that, also apply for general practitioners, dentists, midwifes, physiotherapists and so on.

### 1 General supervision

On an average of every four/five years we visit, without a special reason, the hospitals for an extensive supervision. The visiting team consists of usually four inspectors. We interview, mostly in separate interviews, the board as the management of the hospital, the doctors and the nurses. Normally it takes two days of interviewing. In the meanwhile we also visit the different departments of a hospital. The interviews do not consist a standard list of yes and no questions. We talk with our interlocutor about a standard list of subjects. A double check is incorporated. Our main interest is which measures do the hospitals take to achieve the highest level of quality of care. What do they do themselves to control the quality of care and what actions are taken when something goes wrong. Roughly we check the quality circle; which quality systems are developed. To control the delivered care you need, for example, the permission of the patients to investigate their medical history. It is also difficult to control because we cannot asses all the often highly specialised treatments, because we don't have the knowledge about it. Another reason to concentrate on the conditions is, that, if the conditions are good, you can assume that the delivered care is also living up to the standards. Complaints of patients also say something about the quality of the delivered care. Since two years there is a special law for complaints in the health care in the Netherlands. All health care providers are obliged to have a regulation to deal with complaints. An installed independent committee judges the complaint. In an annual report, the health care providers have to publish the kind of complaints they were confronted with in the past year and what actions were taken with regard to the judging. So, in a derived way, we as the inspectorate know something about the delivered care.
If the hospitals implement their own quality circles, then the hospitals will have to supervise these themself. In a good working quality circle, we can, as inspectorate, supervise if they indeed have a good supervising system. That our supervision focuses on the supervision of the hospitals carried out by themselves, is due to an appointment which was made between the Dutch government, the providers of health care, the insurers of health care organisations and last but not

least, the organisation of patients. All partners in the Dutch health care system have to work on quality of care from their own point of view. But they should also aim on the implementation of quality systems. The government will facilitate the partners and will control them. That last specific job is ordered to us. The appointment between the health care partners is laid down in the Quality Act of Health Care Organisations. In that law our inspection is the supervising organisation. In accordance with that law the health care organisations have to inform the inspectorate in an annual report of their efforts made to achieve quality of care.

How can you measure quality? Or which items can you ask to know something about their quality circle? We do not require about the results of the health care. In our system we assume that if the efforts of the organization to achieve a high quality are satisfactory, the quality is adequate. The main point is the conditions under which they deliver health care. Thus we inquire and we watch over these conditions. Schematically we distinguish several sorts of conditions. Conditions which have to do with the structure and policy of the organisation. Conditions which have to do with the process of delivering health care and conditions which have to do with the promoting and guarding of the quality of care.

**Concerning the structure of the organization.** We want to know how they arrange their organization and the reasons they have to arrange it in such a manner? What is the position of the medical staff? Is there a nursing staff and, if so, what is their position? Our vision is that if the organization does not have a good structure they cannot manage the care process. Does the hospital have a vision about hospital care? We think that without a vision you cannot formulate hospital health care policy. Without a policy you cannot make plans and you cannot evaluate. The hospital has to formulate their possibilities, because when they don't, there will be a greater chance of casualties. As I said these questions will be asked to the management of the hospitals, the nurses and the doctors. Not only for the management of the hospital should the structure, the vision or the policy be clear, but also for the doctor and the nurse.

**The conditions of the process of delivering care.** Some examples. How do they arrange the different responsibilities of the different health care professionals? Does everyone know what he is allowed to do and also capable to do so? How is the delegation of the care from the day service to the evening service regulated? And how do they transmit the care and the information when someone is changed to an other department? Care processes are clear by standardization, preferably written down in protocols. The quality of the records of the patients has to be watched systematically. What kind of conferences do they organize and with whom do they discuss the situation of the patients? All these conditions say something about the chance that there is a risk for the patient to get the wrong care or that there is a chance of making mistakes.

**The conditions of the efforts to promote and watch quality of care.** Some examples. Do they have a quality policy? Are there special employees for the quality processes? In other words, are there special quality processes. And how do they manage the implementation of quality of care? Does this apply only on

management level. Or is it also a well known concept in the hospital departments, with the co-operation of nurses and doctors? Which activities do they organize to assess the process of delivering care, the process of treating patients. Assessment by the management or by the professionals themselves? How do they learn as much as possible from this. Do they register complications in the treatment of the patients and do they evaluate these complications? How do they organise the schooling and refreshing courses. Do they organise a programme or can everyone choose what he likes, the subject of the schooling or the country where it's given? How do they manage the infection prevention? Is there a structure, consisting of a special committee and a hygienist, with infection prevention protocols. Or must everyone do what one has learned during their study? And how do they manage incidents in the care with disadvantage for the patients or when the patient dies because of a fault?
In Holland every hospital has to have a special committee for accidents. The committee has to analyse incidents and report the investigation to the board of a hospital. The board has to take measures, preventive or corrective. Often there is a problem that one doesn't mention the incident. So what measures does the management undertake to improve the mentioning of incidents?
The general supervision report consists of our impressions, conclusions and on the basis of these our recommendations. We make this report for the hospital. After half a year we visit the hospital again and discuss the recommendations with the board and inquire what action they have taken. We have the possibility to use the measure of a sanction by severe negligence. In the case of a problem doctor, we have the possibility of an investigation and assessment by the Medical Disciplinary Board.

## 2 Thematic supervision

We select a topic, a theme, on the basis of signals and/or incidents or because of trends. For the investigation of the subject we make an instrument that can be used by every inspector in his own region. The headquarter makes a selection of the hospitals which have to be investigated. The investigation results in a report to the hospital, but more important, also in an aggregated report of all the investigated hospitals. This report has a great impact. They are very useful for the policy department of the Ministry of Health Care and for the organisations of hospitals. Examples of themes we investigated are the quality of departments of radiodiagnostics, the policy and management of infusion pumps, the quality of rooms for heartcatheterization, the quality of care in child departments in smaller hospitals, the quality of the activities of the prevention of infection, and so on.

## 3 Ad hoc supervision

This supervision is on the basis of signals, severe complaints, incidents, special reports. Depending on the situation, measures are taken. There is a possibility that we follow the investigation of the own hospital committee and ask for the results of their investigations. Also we can perform an investigation ourselves. Important is that the cause of the incident is detected so measures to prevent repetition can

be made. In case of punishable events we report to the Public Prosecutor or start a procedure for the Medical Disciplinary Board.

Some years ago we have developed these three kinds of supervision. In the meanwhile there is a tendency for more supervision by the hospitals themselves. So the question arises, shall we continue the rather extensive general supervision? There are discussions about some adaptations of our ways to supervise in relation to the recent developments. Maybe you've heard about the Maryland Hospital Quality Indicator Project. Some hospitals in Holland have joined the project in which the hospital defines indicators. Indicators as a quantitative measure that can be used to monitor and evaluate the quality of important governance, management, clinical practice, and support functions that affect patient outcomes. They are tools that can support quality improvement.

Something else is the accreditation or certification of hospitals. There has to be a certification body. We have the Dutch Council for Accreditation and some hospitals or parts of hospitals oriented themselves on a certification on the basis of the ISO 9000 norm. Something completely different is the interest of patients in the quality of hospitals. They are also playing an active part in investigations in that field.
There are a lot of developments which show that the health care organisations indeed take measures to guard and try to improve their quality of care. We are discussing the possibility to perform our supervision on a more distant level. On the other hand, voices in the community ask for an active role of the inspectorate, especially when things go wrong.

## VI.D Infectious diseases and multiresistance antibiotics

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### 1 International Prevention and Control of Infectious Diseases; the role of Public Health Surveillance

#### 1.1 International collaboration in surveillance: why?

Once expected to be eliminated as a public health problem, infectious diseases remain a major source of morbidity in the population. They can often produce distressing systems and complication are again a n important source of mortality.

Despite the decline in the relative importance of communicable diseases as causes of death in developed countries, they do still occur. It is only necessary to recall the small number of children who die each year from meningococcal infection. In developing
countries, communicable diseases are still an important cause of premature death.

The spectrum of infectious diseases is changing rapidly in conjunction with changes in society, technology and the environment.

World-wide, urban migration with overcrowded cities is occurring; international travel and commerce are increasing; food handling, shipping, and processing is changing, together with the diminished effectiveness of public health activities to disease control.
All these points have raised the potential for outbreaks of infectious diseases which do not respect international boundaries.

The emergence of new infectious diseases, for example HIV/AIDS, the Ebola virus, Hantavirus pulmonary syndrome, Legionnaires' disease, Cryptosporidiosis, E. coli 0157 infection, or the resurgence of diseases widely presumed to be under control like plague in India, diphtheria in East Europe, cholera in Latin America, viral haemorragic fever in Zaire, tuberculoses and antibiotic resistant organisms, emphasis the vulnerability of population to events occurring beyond national boundaries.

Changes in antibiotic-resistance patterns and outbreaks of emerging infectious diseases anywhere are now perceived as world-wide threats. It is clear that the problem is global in perspective and needs global public health strategies in response.

#### 1.2 International collaboration in surveillance: benefits

Effective international surveillance co-operation in the control of communicable disease depends on the joining of scientific knowledge with the willingness of