- **1995: Development inspection program on human tissue**
  It was also felt necessary to get an eye to the quality on human tissue and organs that are used in medicine. The inspectorate gets from time to time signals of quality defects or suspected transports of products from human origin all over the world, but is unaware of the extent of the activities, the trade and the use. The inspection of the blood banks are also used to make an inventory of the human tissue issue.

4. Main problems

Self-sufficiency and voluntary unpaid donations
In the field of blood transfusion, as in that of transplantation, supply shortages confront us with the dilemma of having to choose between two undesirable, unethical solutions: remunerate donors to guarantee supplies or deprive patients of vital treatment. Last year NL had to import paid donation plasma to provide sufficient anti-Rh(D)-immunoglobulin .

Availability versus quality
In the years between 1988 and 1994 the implementation of the new legislation and guidelines on quality sometimes caused serious troubles in the availability of blood products. The plasma fractionation plant and the blood bank seemed to have practised for a long time the policy that quality standards can be overruled by availability problems.

(Non-)compliance
It appeared to be a major task to convert medical practice in blood banking into modern quality management. For instance the GMP-rule that the person who is responsible for the batch release can not be the same as the person responsible for the preparation, or subordinate to that person, was until recently violated.

Variations
Until now there are blood banks who practice that legislation or official standard of the Steering Committee on Blood Transfusion can be interpreted in a personnel way. They are confusing clinical freedom in patient treatment by the haematologist and the responsibilities in the quality management of a blood bank as it is.

Ombudsman: complaints of haemophiliacs
The Haemophilic Patients Society complained to the Ombudsman about the way the Government had realized its responsibilities in preventing them from getting AIDS. A main issue was the lack of speed in the implementation of the rules about heat-treatment of factor VIII. The Dutch blood world at that time was presumably governed as a medical profession: aiming at consensus, giving recommenda-tions, being respectful to other opinions.
The Ombudsman judged that the government should have given more pressure to enforce the implementation of heat-treatment.

Product liability
The plasma fractionation plant has full liability for its blood products. They nowadays have to consider their suppliers of plasma (the blood banks) as providers from the point of view of liability. Some blood banks do not realize the consequences of non-compliance to the rules in collecting plasma for the central production facility.

Optimal versus maximal safety
The risk of a transmission of a virus (HBV, HCV, H1V, HTLV) is in the western world less then 1 out of 100.000, sometimes less then 1.000.000.
There is political pressure from society to increase viral safety to the maximum. It costs lots of money. Is it cost-effective to do more on this issue?
I can give you no answer. In forthcoming September the Dutch Steering Committee on Blood Transfusion will organize a meeting on this subject with scientific people, practitioners, health assurance companies, liability assurance companies, politicians.

International disagreement on safety issues
The CJD-case is an exempla of this point. The FDA requires batches of blood products to be recalled. The EU/CPMP does not recommend that measure. The discussion within the EU is nevertheless going on, mainly because of political reasons.
Better epidemiological methods are needed to come to an answer to these questions.
As a basis for this type of studies all blood products should be subject to tracing and tracking procedures from the donor to the acceptor.

Viral safety versus immunological safety
The viral safety has increased considerably. On the other hand the immunological problems are the same as some decades ago. Recently some delicate publications asked attention for the issue of immunological reactions. That problem can not only be solved by better donor selection but also, and more efficient, by proper and restricted use of blood products. That implicates further post-graduate education of the practitioners.

E. Certification and supervision in health Care

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the Netherlands

This is a presentation on four items:

- the Dutch Council for Accreditation;
- accreditation in and outside Europe;
- ISO 9000 certification;
- my view about the government and certification.

1. The Dutch Council for Accreditation

The Dutch Council for Accreditation was a merger between three well-known bodies in Holland. The bodies were dealing with calibration, certification and with the accreditation of laboratories. I realize that in your world, the word accreditation is different from how we use it world-wide. We use it as a formal recognition of an authoritative body that tells that a body is competent and is working conform international standards. This merger was last year September, so RVA is a very young company. RVC is the oldest part.
Why was the RVC established? We had and still have all kinds of certificates. There was e.g. a certificate for candles which were blessed by a minister and telling in the small prints that when you have a wish, you light this candle and the wish will be fulfilled. This kind of certificate is still in practise in the Netherlands and I am sure that also in your countries you have this kind of certificates too. Another one is the one I got from my American friend. He invited me to his home and showed me a brick which was a brick he told of the Berlin wall. I asked him: how can you be sure? He showed me a certificate and I asked: "How can you believe this certificate". He said that was very easy, because there is a stamp on it. Then I asked: "How can you believe this stamp". "No problem, it is original." He believed this. I told him that in the Netherlands we don't believe these kind of things so we created at that time, 15 years ago, the RVC (one of the members of the merge from last year) and we told the folks in the Netherlands: "Take care, when there is a certificate or mark it must be accredited by the RVC. Then you can believe it".

The council for Accreditation is dealing with the accreditation of certification models, inspection bodies, and last but not least direct accreditation of personnel. We also know the certification of personnel but in the environmental field we are obliged by the government to accredit direct personnel.

When you look at the structure of RVC (RVA) we have a system to harmonize the approaches of the certification bodies. All parties concerned are registered in the board. To harmonize different approaches we normally co-ordinate these kind of groups of people. A better approach is one committee of experts, as we call it, in which all

represented. Last year we set up an institute for the hospitals for the health care with some financial support of the Minister.

To become an accredited certification body we check if it is an independent third party. Independent means independent from all the stakeholders. We check this with people from the field, for example, we sometimes ask government civil servants to join our team which audit the certification body. They must be reliable. That means that at least it must have an appeal procedure. And last but not least it must be acceptable to all parties. That means that all parties concerned are involved in drafting the certification principals.

The certification is seen as a third party. The supplier or a hospital or a school is the first party. And the consumer, purchaser, patient is the second party. The third party must be independent.

2. Accreditation in and outside Europe

The second part of my speech, is the accreditation in and outside Europe. Accreditation started in the Netherlands and is now spread all over Europe. All the European countries have now a council for accreditation. This required an European approach and so we founded the European Accreditation of Certification (EAC). EAC is a European federation of accreditation bodies. EAC has several working groups; the most important is dealing with Peer Reviews. Visiting each other and looking if we are working on the same level. Harmonizing our approaches. This Peer Review is based on four important things: we look at the documentation of the accreditation body, we have an office visit and check the implementation of the procedures, we witness an assessment and last but not least we draft a report in which we give a recommendation. Let me give an example. The Netherlands were visited one year ago by the Germans, by Norway and people from Sweden. We now know criteria, world-wide criteria, ISO guide 61, which you have to meet before you can join the MLA. The MLA is a multilateral agreement. At this moment eight countries have signed the MLA. Finland, Germany, Holland, Italy, Norway, Sweden, Switzerland and the UK. This means that we accept each others accreditations and each others certificates. Before the end of this year, beginning next year, France, Denmark and Austria will join the MLA and in the middle of next year we think that all the other European countries are a member of the multilateral agreement. That means that we have a real European system.

World-wide we have established the international accreditation form (IAF). Four years ago we started in Houston to found the international accreditation form. Like EAC another body was created which is PAC (Pacific Accreditation Council). These are the countries around the Pacific.

To finish this part: we are very eager to restrict the supervision on a world wide level. Who has to pay it? The consumer (patients) and insurance companies.

In the end we will have a world accreditation system with MLA's, between the EAC, the PAC and others. One-stop accreditation and certification is our objective. A certificate that can be used as a world certificate, also accepted in other countries, that is our aim.

3. ISO 9000 certification

The third item is the ISO 9000 certification. Certification I normally split up in certification of products (including services) and quality systems. You can see the product of a hospital as a service. Most times you can bring services under quality assurance systems. I will not dwell a long time on the word quality; for us quality is fitness for use. Fitness for the use of a product, fitness for the use of your service. You can split up quality in: the quality of the service product and the quality of the process. How do you make this service/product and how have you structured your service. ISO 9000 is focusing on these two items. The message of ISO 9000 is if you have organized your process and structure in the right way, the way ISO 9000 is telling you, then your product or service will meet the expectations of your purchasers, patients. It is no guarantee, but you have a high chance that it will. You can split up ISO 9000 in ISO 9001, 9002 and 9003 and ISO 9004. ISO 9004 is focused on the policy and continuity of your business, of the hospital. ISO 9001 and 9002 are talking about demands and needs, for example, from patients or the requirements of purchasers. ISO 9004 is very important for hospitals. It is dealing with the theoretical background you need before you can reach the requirements laid down in the ISO 9001, 9002 and 9003. Let us look closer at this from your point of view. For hospitals you need targets, you have to manage your personnel, you have to organize your hospital, you have to look at the responsibilities, at the motivation. The demands: you must organize your intake, you have to do diagnosis, your organization, your treatment, discharge of the patients. This is the secondary process. ISO 9000 is not telling you how, but what you must organize. At last, the 9004 is dealing with improvement: plan-do-check-act, the Demling cycle. ISO 9004 tells how to improve your services and processes. These are industrial standards, but maybe you can also use these in health care. I was very happy to see the first draft of the committee in Holland which is looking at ISO 9000 and the organization and the important things of the health care. The primary process is, intake, treatment, care and after care evaluation. The other things are research and development, documents, personnel, visual environment and equipment. And the third part is services. As you can see the cyclical processes are very important. That is more or less the plan-do-check-and-act circle. Do it on an ever higher level; then you are improving your system.

4. Certification.

The principal of certification for quality management systems, ISO 9000, is the quality management system assessment by the third party, including always surveillance visits. Essential for certification are an initial visit and surveillance visits. For products also type tests and product surveillance are included. For services you can include looking at the contents of the service. By mystery man or mystery patients, you can see if the service is in line with what you expect. In the Netherlands we are drafting a certification system with elements of the ISO 9000 and elements of the content of the service. Next year we hope to have a scheme on which certification bodies can work when they go to hospitals.

In the Netherlands, we as RVA are seeing that also in other departments of the government, the surveillance of the government is handed over to certification bodies. The government will only do inspections. Inspections are restricted to incidental problems.

APPENDIX I

LIST OF PARTICIPANTS

EUROPEAN PLATFORM SUPERVISORY ORGANIZATION HEALTH CARE
EPSO

12, 13, and 14 June
Noordwijk, the Netherlands

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APPENDIX II

SHEETS

the Netherlands

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Presentation
sheets

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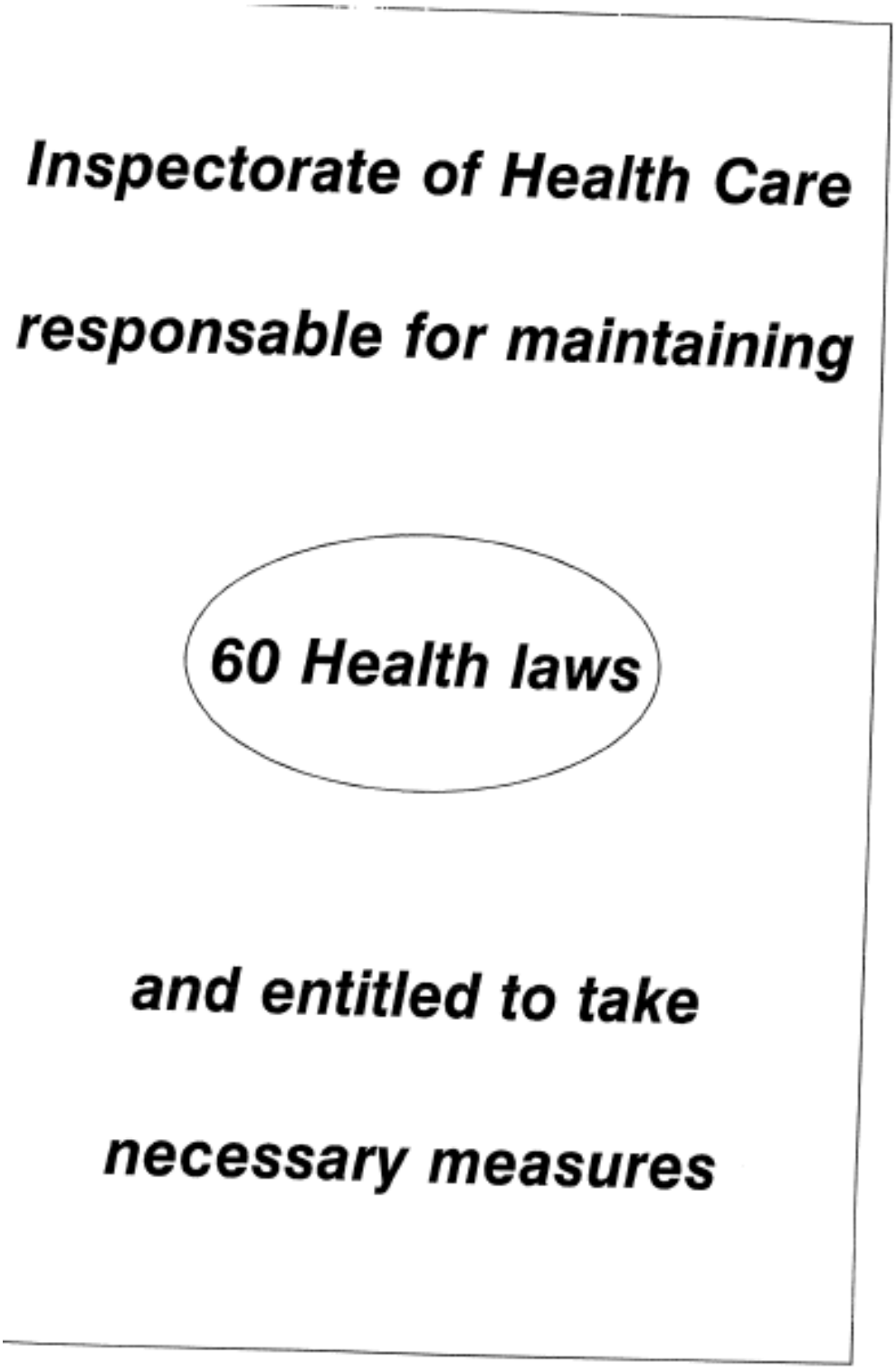
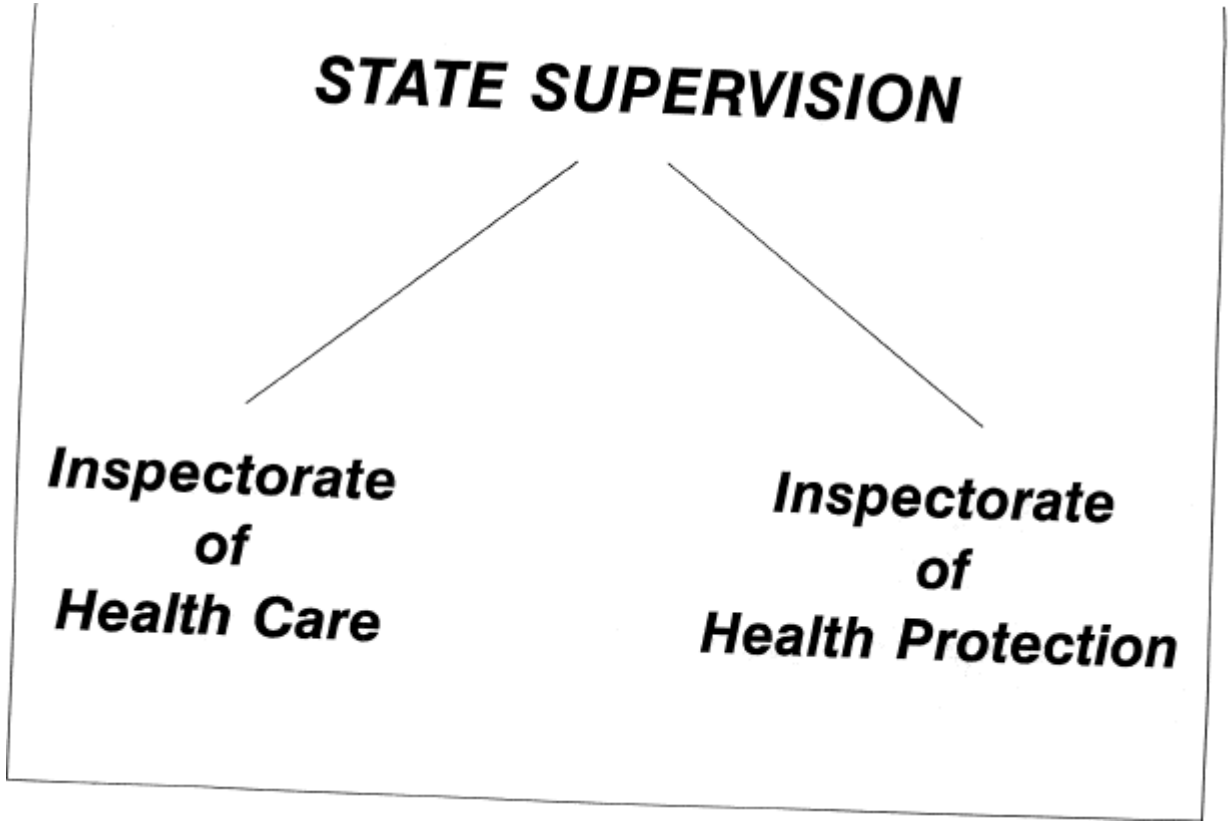
the Netherlands


Inspectorate of Health Care
responsable for maintaining
60 Health laws
and entitled to take
necessary measures

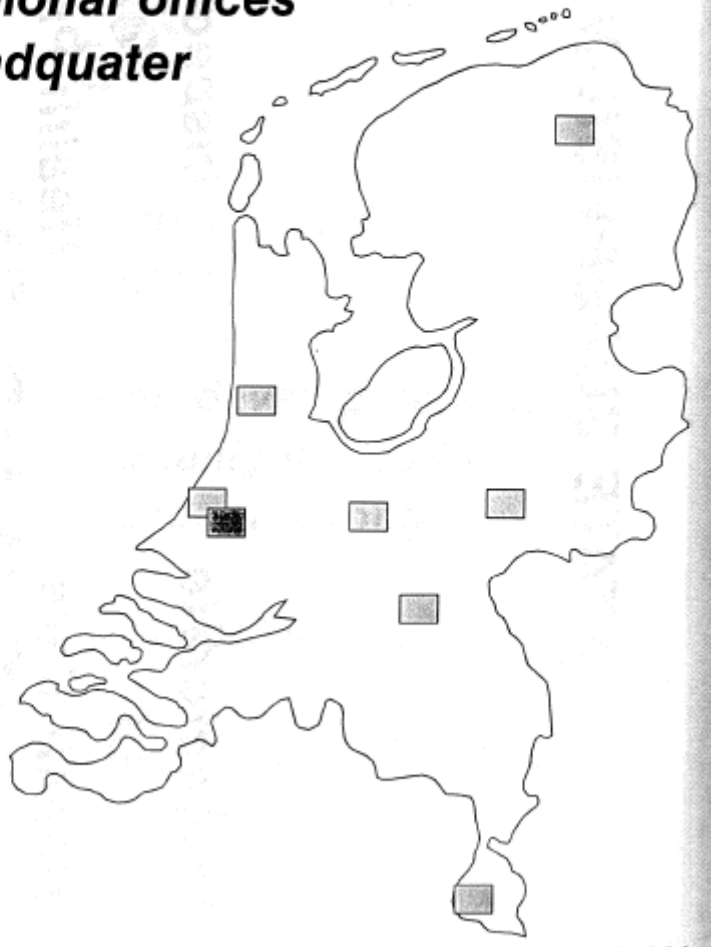
96_127


Inspectorate
Core Business
Supervision
- quality of delivered care
- on development of quality in health care organisations
- on lacking persons
- on the Health State of the population
96_128


STATE SUPERVISION
Inspectorate of Health Care
Inspectorate of Health Protection

Inspectorate of Health Care

Number of stafmembers 320
7 Regional offices
1 Headquater



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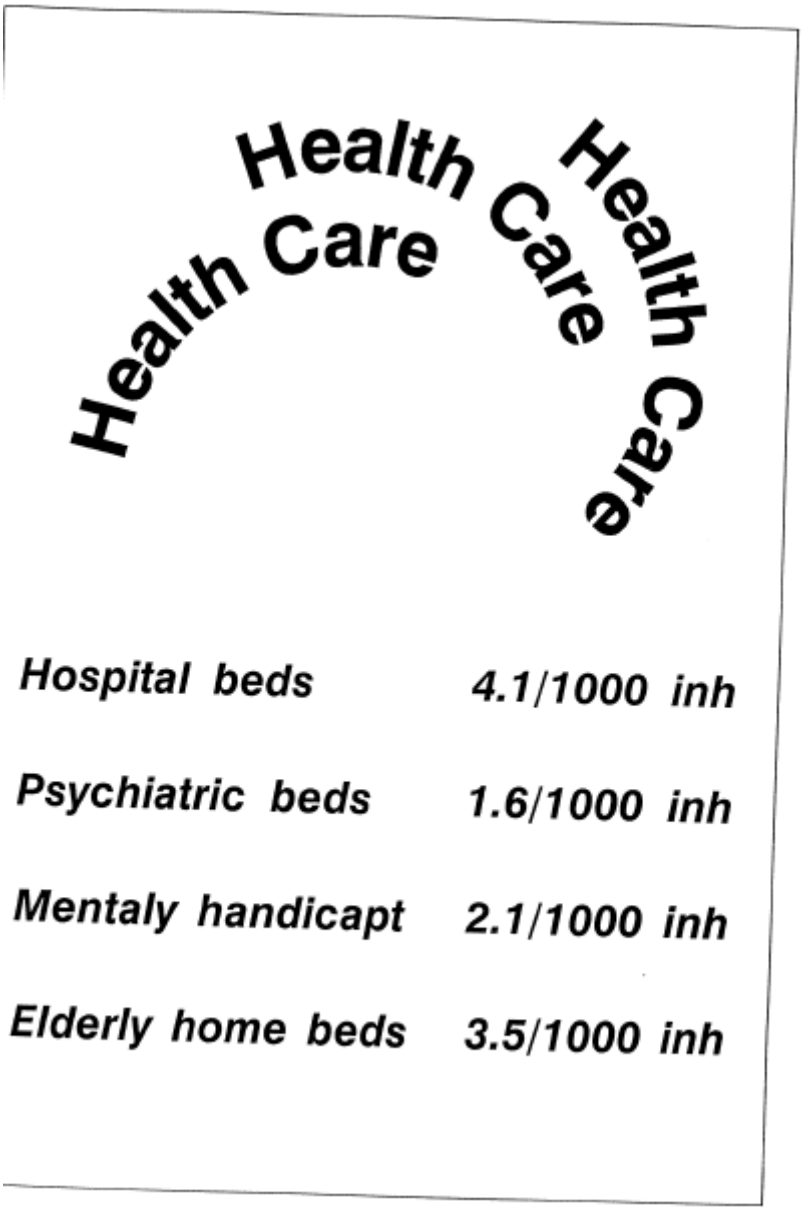
Health Care
Health Care
Health Care
Hospital beds 4.1/1000 inh
Psychiatric beds 1.6/1000 inh
Mentaly handicapt 2.1/1000 inh
Elderly home beds 3.5/1000 inh

96_131

Denmark

Soren Quist

Presentation
sheets

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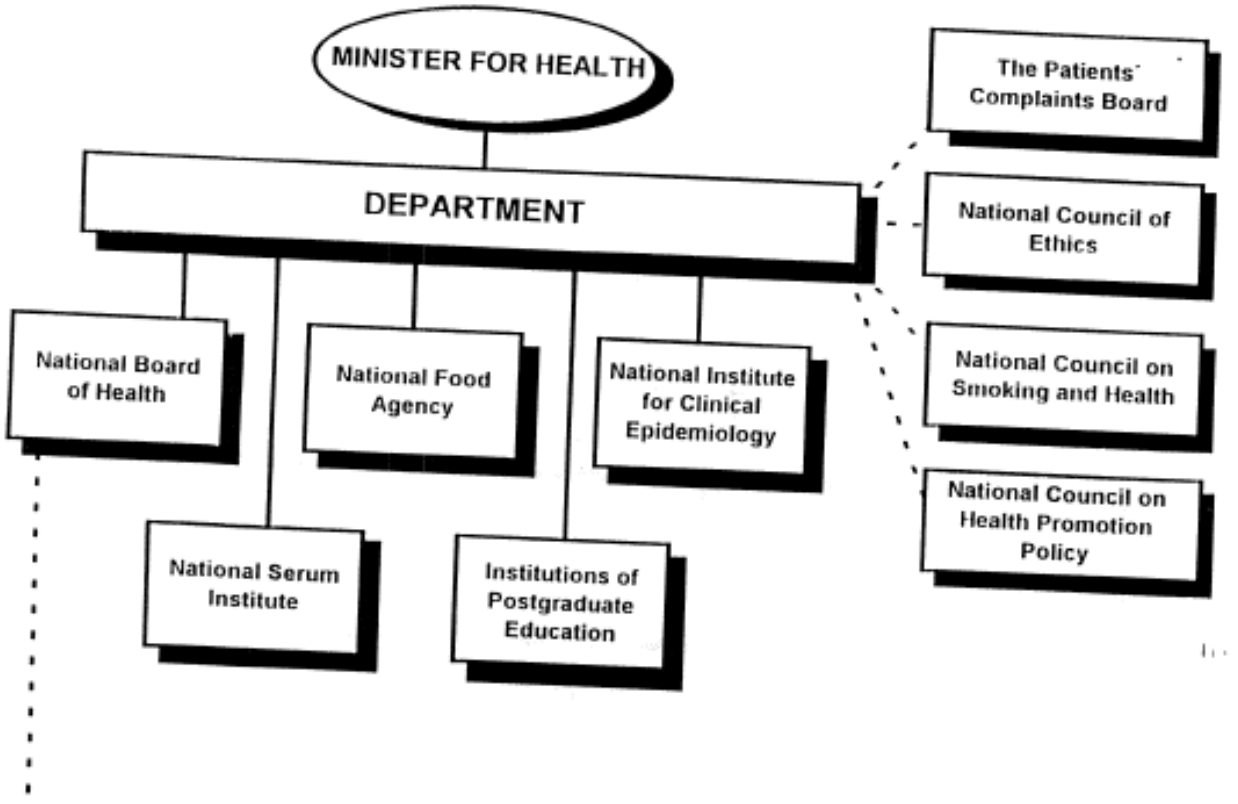
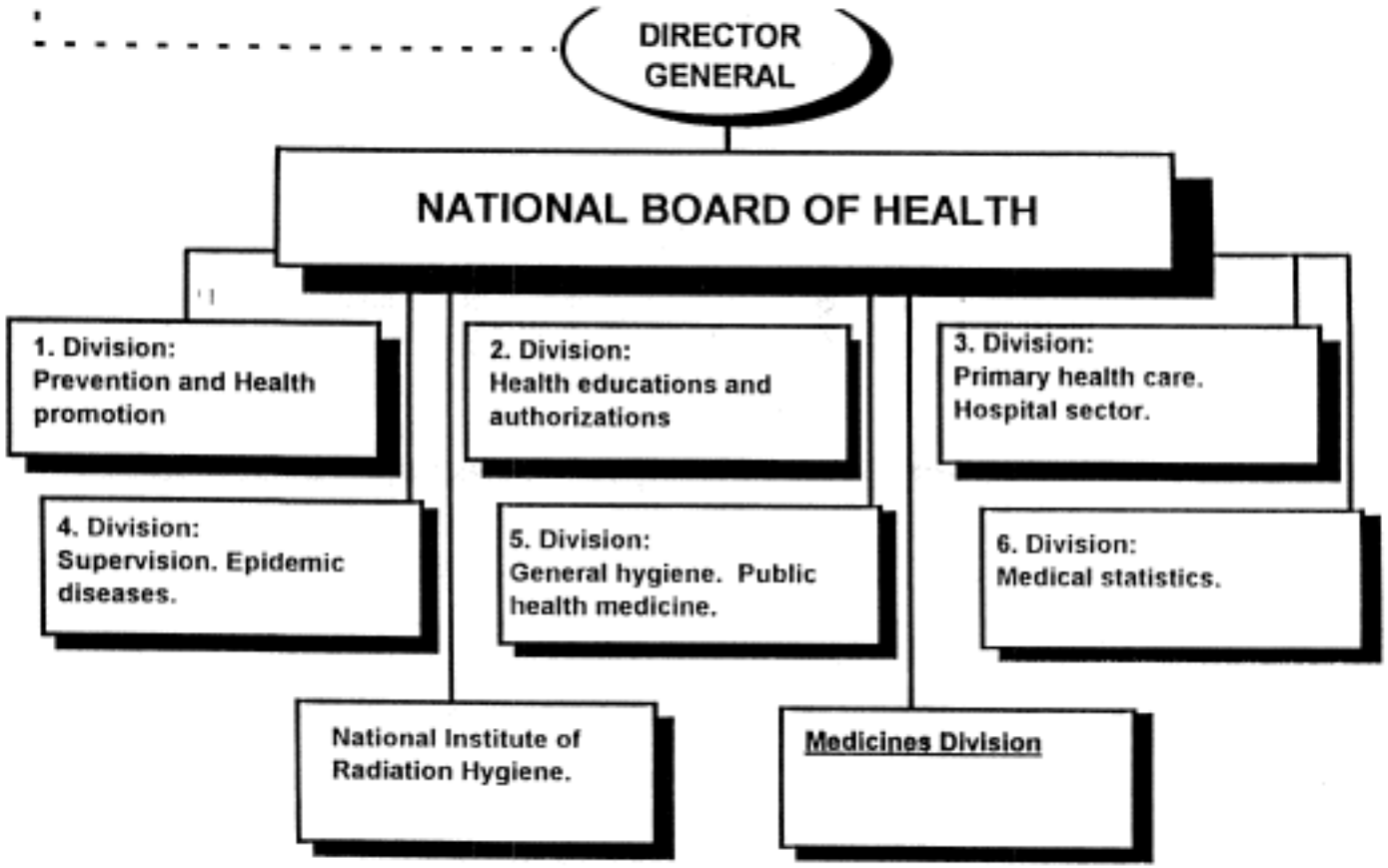

MINISTER FOR HEALTH
DEPARTMENT
National Board of Health
National Food Agency
National Institute for Clinical Epidemiology
National Serum Institute
Institutions of Postgraduate Education
The Patients' Complaints Board
National Council of Ethics
National Council on Smoking and Health
National Council on Health Promotion Policy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2. Division: Health educations and authorizations
3. Division: Primary health care. Hospital sector.
4. Division: Supervision. Epidemic diseases.
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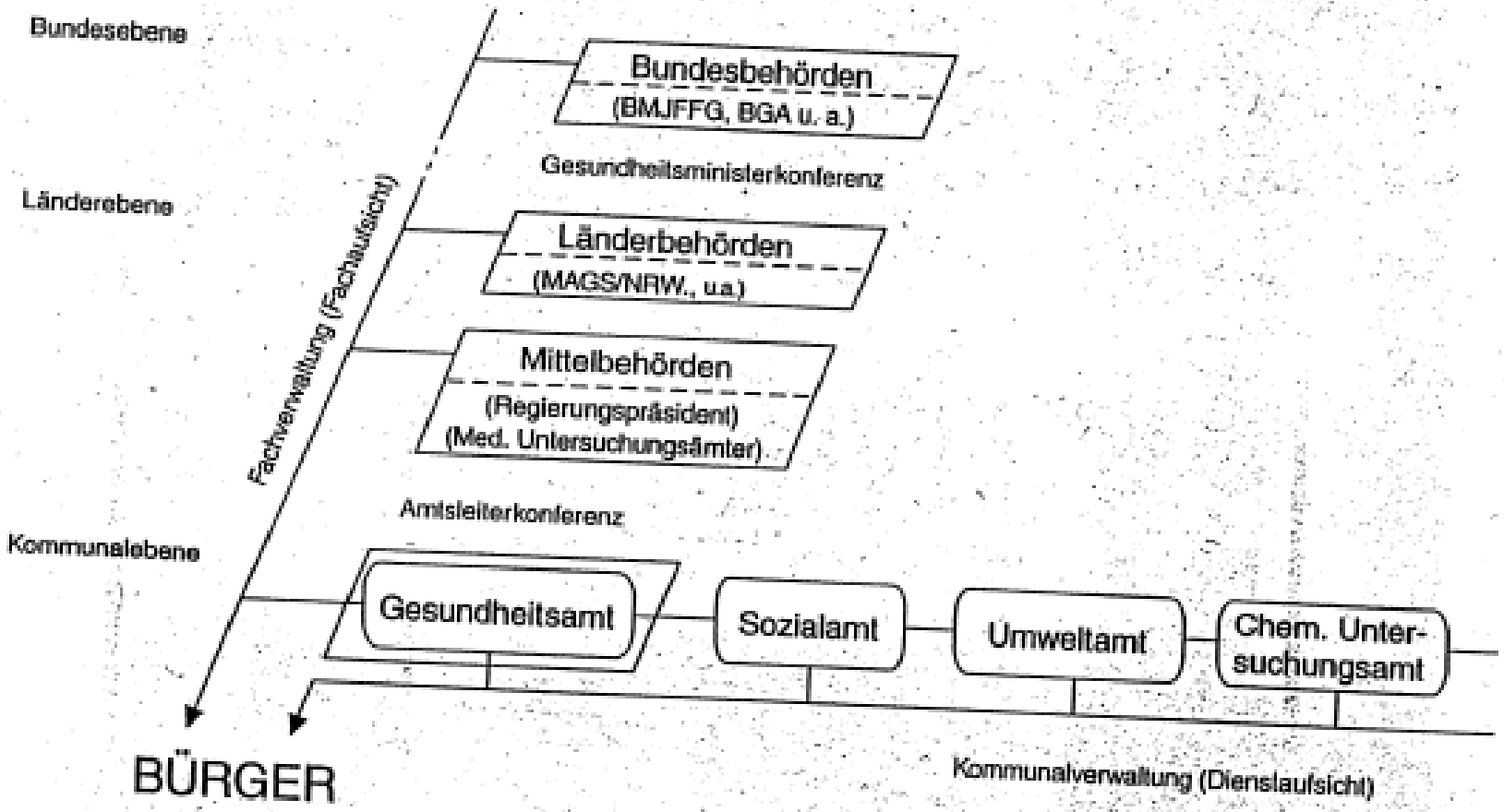

Abbildung 1: Einbindung des kommunalen Gesundheitsamtes in die vertikale und horizontale Verwaltungsstruktur.

Aufbau u. Funktion d. Öff. Gesundheitsdienstes

Abb. 2: Organisationsschema eines großen Gesundheitsamtes (> 200 000 Einwohner) (Organigramm Modellgesundheitsamt Marburg-Biedenkopf aus: Das Modellgesundheitsamt Marburg-Biedenkopf – Abschlußbericht – Schriftenreihe des BMJFFG; Band 80, Verlag W. Kohlhammer, Stuttgart 1982).

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sheets

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THE NATIONAL BOARD OF MEDICOLEGAL AFFAIRS

SUBJECT TO THE MINISTRY OF SOCIAL AFFAIRS AND HEALTH

DUTIES IN THE FIELD OF MEDICOLEGAL AFFAIRS, WHICH PREVIOUSLY FELL WITHIN THE COMPETENCE OF THE **NATIONAL BOARD OF HEALTH** (1650 s - 1991)

NATIONAL BOARD OF SOCIAL AFFAIRS AND HEALTH (1991-1992)

NATIONAL BOARD OF MEDICOLEGAL AFFAIRS (1992 -)

SOME TARGETS:

-IMPROVING THE EVALUATION AND QUALIFICATIONS OF FOREIGN HEALTH CARE PROFESSIONALS ARRIVING IN FINLAND

-DEVELOPING THE SUPERVISION OF HEALTH CARE PROFESSIONALS

PRINCIPAL TASKS:

-LICENSING, REGISTRATION, AND SUPERVISION, DISCIPLINARY MEASURES, RESTRICTION AND DISBARMENT FROM PRACTICING THE PROFESSION

-MATTERS OF FORENSIC PSYCHIATRY

-SOME MATTERS RELATED TO ABORTIONS, STERILIZATIONS AND CASTRATIONS

-QUESTIONS RELATED TO INQUEST ON CAUSES OF DEATH

-RENDERING OPINIONS TO COURTS

-STATUTORY PERMISSIONS PRESCRIBED IN THE ACT ON THE REMOVAL OF HUMAN ORGANS AND TISSUES FOR MEDICAL USE.

NUMBER OF PRACTISING HEALTH CARE PROFESSIONALS IN FINLAND

MEDICAL DOCTORS	14 385
DENTAL PRACTITIONERS	4 751
NURSES RESPONSIBLE FOR GENERAL CARE, MIDWIVES, AND 30 OTHER LICENCED OR REGISTRATED HEALTH CARE PROFESSIONS	ABOUT 200 000

Supervision of the practice of the medical profession

Complaints	*1993*	*1994*
Number of complaints lodged	229	225
Number of complaints transferred to Provincial Boards	189	149

Number of complaints settled at TEO	40	53
Consequences of TEO decisions have been admonitions	5	1

Other types of supervision

Cases settled by the end of the term	136	169
Cases pending at the end of the term	94	84
New cases lodged	98	136

Consequences

– reminder of duty to exercise proper care	8	9
– admonition	21	20
– serious admonition	16	16
– restriction of the right to practice the medical profession	17	13
- disbarment from practicing the medical profession	14	8
– written warning	4	3
– restitution of rights	1	2
Total	*81*	*71*

Certificates on the practice of a profession

Total	*135* *262*

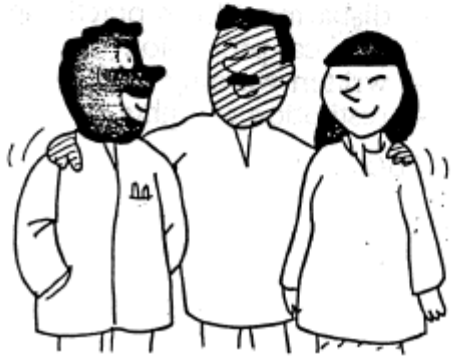
Licenses or authorizations granted to foreign nationals

	1993	1994
Medical doctors	324	317
Dental practitioners	8	11
Head dispensers	3	2
Pharmacists	3	3
Dental technicians	1	2
Opticians	-	1
Trained masseurs	4	1
Total	*343*	*337*

Licences to practice the medical profession in Finland granted to foreign doctors

I Licence to serve as a hospital doctor in Finland	131	91 *
II Licence to serve as a hospital or health centre doctor in Finland	24	14
III Licence to serve as a doctor in Finland	104	99
Total	*259*	*204*

* including 49 new licences



MEDICAL DOCTORS IN FINLAND AND 14 OTHER CURRENT EU MEMBER STATES (31.12.1993)

QUALIFIED IN FINLAND BUT LIVING IN EU MEMBER STATES	FINLAND	THE 14 EU MEMBER STATES
Living in Finland but qualified in the 14 EU Member States		
Finland		306
14 current EU countries	75	

FINLAND LOST 231 MDs

MEDICAL DOCTORS IN THE FINLAND-SWEDEN-DENMARK-NORWAY-ICELAND AREA 31.12.1993

QUALIFIED IN FINLAND BUT LIVING IN	FINLAND	SWEDEN	DENMARK	NORWAY	ICELAND
living in Finland but qualified in					
Finland		172	8	13	0
Sweden	55				
Denmark	2				
Norway	0				
Iceland	0				

MEDICAL DOCTORS IN FINLAND AND IN THE FORMER EAST-EUROPEAN CONTRIES (Estonia, Latvia, Lithuania, Poland, Czeck Rebublic, Hungary, Bulgaria, Rumania, The Ukraine and Russia) 31.12.1993

QUALIFIED IN FINLAND BUT LIVING IN THE FORMER EAST-EUROPEAN COUNTRIES	IN FINLAND	IN THE FORMER EAST-EUROPEAN COUNTRIES
Living in Finland but qualified in the former East-European Countries		
Finland		2
The former East-European countries	137	

Finland won 135 MDs

IN THE GERMANY-UNITED KINGDOM-BELGIUM-DENMARK-GREECE AREA BY VIRTUE OF DOCTOR'S DIRECTIVE REREGISTRATED MEDICAL DOCTORS QUALIFIED IN OTHER EU MEMBER STATES (IN) AND IN THE SAME AREA QUALIFIED DOCTORS MOVED ELSEWHERE WITHIN THE EU (OUT).

YEAR	GERMANY		UNITED KINGDOM		BELGIUM		DENMARK		GREECE	
	IN	OUT	IN	OUT	IN	OUT	IN	OUT	IN	OUT
1977	245	69	451(366)	117	19	97	11	16		
1978	272	64	470(365)	134	22	97	12	20		
1979	381	65	415(290)	108	20	135	7	27		
1980	357*	66	400(266)	130	24	111	6	32		
1981	478*	137	546(362)	93	14	123	6	36	129	241
1982	515*	112	629(364)	69	13	158	6	27	246	204
1983	1018	132	567(240)	80	19	234*	9	35	402	509*
1984	989*	124	302*	74	36	198*	7	28*	346	244*
1985		127	332*		31		12		367	
1986		168	445(59)		67		6		332	
1987		309	995(289)		102		14		290	
1988		541	1309(311) ! 414		129		16		316	
1989		371	1184(253) ! 277		137		11		-	
1990		222	1020(206)		153		14		256	
1991		254	956(202)		*		10		205	
1992										
1993		315	1157(167)		149		24		*	
1994										
1995										

*) Uncertain or failing statistics
In brackets in Ireland qualified doctors reregistrated in UK
! In Germany qualified doctors

After 1987 numerous German MDs were registrated in UK.
Irish MDs seem to be registrated regularly in UK, but very few in UK qualified MDs are registrated in Ireland.

Sweden

Gunnar Fahlberg

Presentation
sheets

Gunnar Fahlberg
Socialstyrelsen
S-10630 Stockholm
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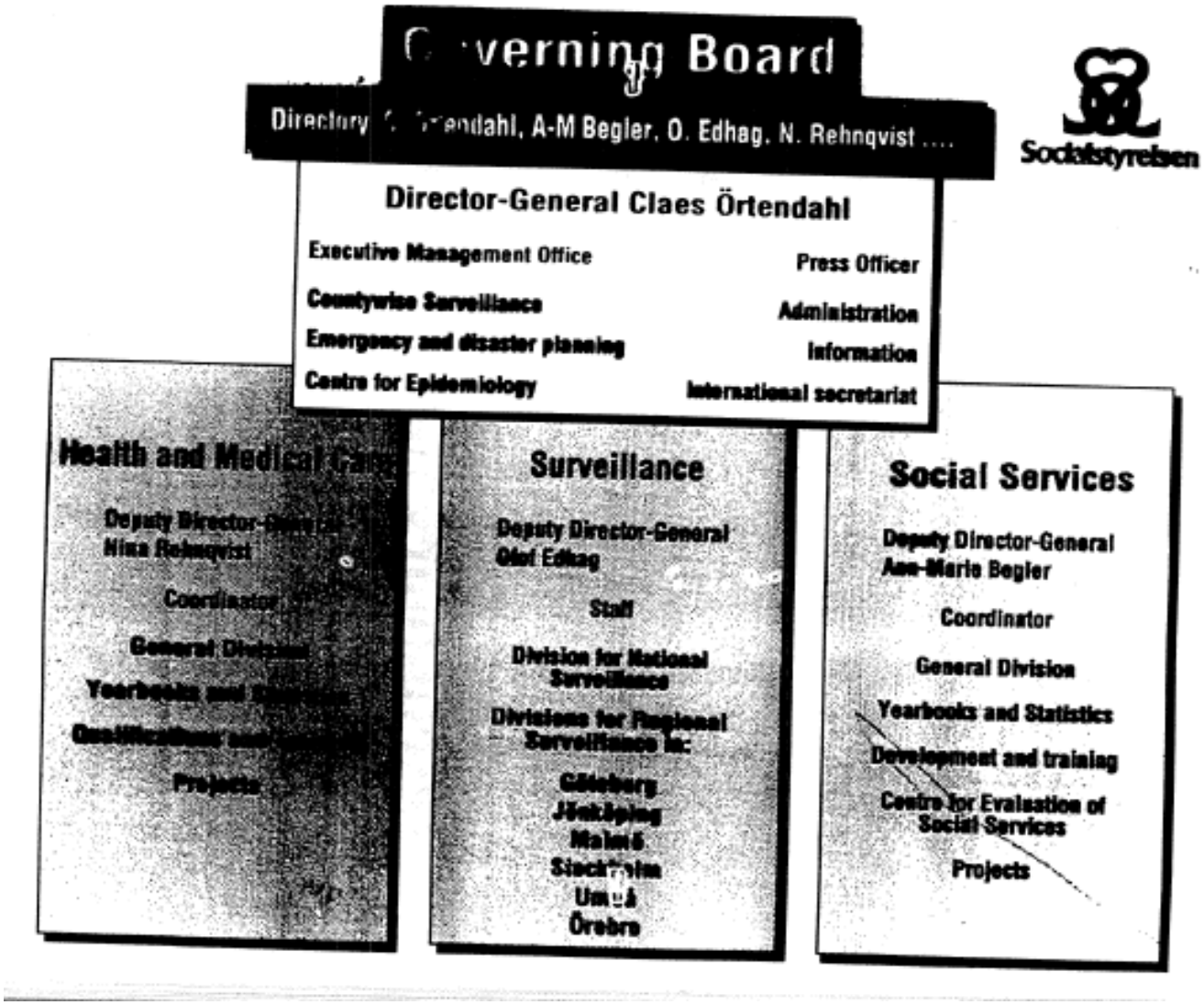
Governing Board
Director-General Claes Örtendahl
Executive Management Office
Countywise Surveillance
Emergency and disaster planning
Centre for Epidemiology
Press Officer
Administration
Information
International secretariat
Surveillance
Deputy Director-General
Olof Edhag
Staff
Division for National Surveillance
Social Services
Deputy Director-General
Ann-Marie Begler
Coordinator
General Division
Yearbooks and Statistics
Development and training
Centre for Evaluation of Social Services
Projects
Örebro

Surveillance

Main regulations

- **Health and Medical Services Act (Hälso- och sjukvårdslagen)**

- **Obligations for Medical personnel Act (Åliggandelagen)**

- **Disciplinary punishment Act (Disciplinpåföljdslagen)**

- **Surveillance Act (97.01.01) (Tillsynslagen)**

The main functions of the board

Our chief tasks are:

- Supervision of
  - health, medical and dental care
  - social services and care
  - public health and hygiene
- Active follow-up by county
- National follow-up and evaluation
- Official statistics and annual reports on health and diseases, health and medical services, and social services and care

The Board also has the overall responsibility for planning and supply in the health and medical services, public hygiene and the social services in preparation for crises and war.

Socialstyrelsen

The OVERLAPPING GOALS for all health and medical care are:

- A good health for all the population
- Health and medical care services to all inhabitants on the same conditions

SUBGOALS:

- Security/quality
- Accessability/availability
- Continuity

Every person has however an own responsibility for his health as well as right of self-determination and integrity

Socialstyrelsen

SURVEILLANCE

- Quality and safety
- Cooperation
- Structure of health care
- Leadership
- Legality

Socialstyrelsen

O. Edhag
National Board of
Health and Welfare, 1995

I. INFORMATION

- **Reports from chief doctors (Lex Maria)**
- **Database of adverse events**
- **Active surveillance**
- **National registers**
- **Individual complaints**
- **Object surveillance**
- **Unannonced inspections**
- **Epidemiology**

Socialstyrelsen

O. Edhag
National Board of Health and Welfare, 1996

UNANNOUNCED INSPECTIONS

- **Emergency departments – competence, availability**
- **Psychiatric care – extent of compulsary care**
- **Dialysis – safety, competence**
- **Medical care of elderly in nursing homes – quality, availability**
- **Oncology – doctor's continuity**

Socialstyrelsen

O. Edhag
National Board of
Health and Welfare, 1996

HOW TO USE THE RISK DATABASE?

- Impulses to concrete preventive measures
- To stimulate the work with quality improvement
- Stimulus to research and development of the medical procedures
- To make deeper studies of the material possible

No identification of the staff members in the database

Socialstyrelsen

O. Edhag
National Board of Health and Welfare, 1994