PhD thesis

Patient complaint cases in general practice

Patient-, general practitioner-, and process factors

in decisions of the Danish Patient Complaints Board

Søren Fryd Birkeland

University of Southern Denmark

Research Unit of General Practice
Institute of Public Health
University of Southern Denmark, Odense

2011

Patient complaint cases in general practice

Patient-, general practitioner-, and process factors

in decisions of the Danish Patient Complaints Board

Søren Fryd Birkeland

University of Southern Denmark

Research Unit of General Practice
Institute of Public Health
University of Southern Denmark, Odense

2011

Content Page

This thesis at a glance

What is already known on this subject?

- The risk of receiving a patient complaint has been suggested to be significantly higher among male medical doctors in general
- Also the risk of being disciplined is considered to be significantly higher among broad groups of male medical doctors
- Senior medical doctors have been shown to be more likely to ever have received a complaint case
- An association has been suggested between lengthy complaint cases and decisions in the complainant's favour
- A substantial proportion of complaint cases have been shown to concern communication issues

What does this study add?

- The increased risk of receiving complaint cases and being disciplined, respectively, among male medical doctors could not be confirmed in the study's general practitioner population
- General practitioners with higher professional seniority were both at increased odds of receiving a complaint case, and when they received one they were also at increased odds of being disciplined
- Generally, case management elongation was associated with increased odds of discipline
- When the complaint was motivated by communication issues in terms of the patient feeling devalued or a request for an explanation, the odds of being disciplined decreased
- Complaint cases based on a wish for placement of responsibility or for review of the general practitioner's competence were associated with increased odds of being disciplined
- If receiving a complaint case where more general practitioners were involved, the odds of being disciplined decreased
- General practitioners with heavier workload had increased odds of receiving a complaint case

PREFACE

This thesis was written as part of the fulfillment of a PhD from the University of Southern Denmark. During the project I was based at the Research Unit of General Practice, Institute of Public Health, and registered under the PhD School of the Faculty of Health Sciences.

The thesis is based on three manuscripts and an overview. The manuscript 'What are the characteristics of general practitioners in complaint cases?' was submitted September 2011. The manuscript 'What types of patient complaint cases against general practitioners are likely to result in disciplinary action?' was submitted October 2011, and the manuscript **'**Process-related factors associated with complaint board's discipline' was submitted December 2011.

I wish to thank many persons, who contributed to the completion of this work: My supervisors Adjunct Professor Jakob Kragstrup (main supervisor), MD, PhD, DMedSci, Associate Professor Niels Damsbo, MD, Professor Mette Hartlev, LLM, PhD, LLD, and Director Peter Bak Mortensen, LLM, for their interest, ideas, criticism and involvement in the project. Thanks are due to René dePont Christensen, Associate Professor, PhD, for advice on statistical analysis and encouragement. I wish to thank Jakob for making my appointment at the Research Unit a reality. All my colleagues have contributed to the interesting environment at the Research Unit for General Practice in Odense. I wish to thank Jesper Rømhild Davidsen, MD, PhD, and Jesper Lykkegaard, MD, GP, for many fruitful discussions in the office. I thank Professors Graeme Laurie, Henriette Roscam Abbing, Anders Halling, and Elisabeth Rynning for valuable briefing about the health care and disciplinary systems in UK, the Netherlands, and Sweden, respectively. I also thank Secretary Ellinor Kruse for personal cheerful support and important help concerning teaching and formalities. Thanks are also due to Secretary Lise Stark for proofreading of manuscripts and comments on the language. Also thanks to the staff at Sundhedsvæsenets Patientklagenævn (now "Patientombuddet") for welcoming me in their department and generously sharing their knowledge and experience.

Thanks are due to my parents who aroused and supported my interest in research, and not least I would like to thank my wife and children for giving me perspective on what really matters in life. I could not have done this without their support and encouragement.

This work was supported financially by the University of Southern Denmark, the PLU Foundation, the Danish Research Foundation for General Practice, the Quality Development Board for General Practice in the County of Southern Denmark, and the Health Insurance Foundation (Helsefonden).

Odense, December 2011. Søren Birkeland

Background

Complaint cases and the general practice profession

Patient complaint cases and the threat of malpractice liability notably influence health care provision. Complaint cases are very exhausting for patients who have had a bad experience with, e.g., their medical doctor, and – not least – for those being brought before a disciplinary board. The professional self-respect is threatened, and particularly in general practice the continuous patient-doctor relationship is at stake; extensive disappointments, frustrations, and incomprehensibility might lie behind and frequently breakdown of patient-doctor communication may be the result. In case the general practitioner (GP) receives a patient complaint, the outcome of the ensuing complaint case progress and the risk of getting disciplined in connection with malpractice liability are of major importance.

The authorities, for their part, spend vast resources on offering means of complaint procedures. In this regard, the authorities seek to properly meet the demands of all the involved parties. Demands are, however, not necessarily appropriately met. Given the high financial and human costs associated with the complaint case process, a continuous attention to complaint cases (including case outcomes) is necessary both to optimize complaint case procedures, preserve and improve the involved parties' legal rights, and ensure health care quality. The latter constitutes the rationale of this PhD study.

General practice, health care quality, and the legal framework

GPs must accept the fact that the development within health sciences is rapid and – at the same time - the standards for proper healthcare are continuously changing. At the same time, there has been a trend away from the traditional paternalistic approach of health care where the quality of

health care was taken for granted. There has been an intensified concern for the patient perspective on health care delivery and simultaneously the regulation of the doctor-patient relationship has increased (see below). The possibilities for patients and their relatives to complain against health professionals including GPs have expanded. Besides, a strong focus is put on the need for quality development in the health care sector. The health professional activities are performed more and more within a legal framework, in which the patient angle is emphasised together with a requirement for weighting and documenting "quality".

Safeguarding health care, professional standards, and the establishment of patient complaints measures

The Danish Act on Health Care introductorily states that "The health care system aims at improving the population's health and prevent and treat illness, distress and impairments of the individual subject" (paragraph 1, Act 913, 13/07/2010, "Sundhedsloven"). The duty of states to safeguard health care in addition to health professional standards is nationally but also internationally acknowledged and has been expressed explicitly in international law. For instance, it is stated in Article 25 (1) of the Universal Declaration of Human Rights (declaration adopted by the United Nations General Assembly in 1948) that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including .....*medical care* and necessary social services, and the right to security in the event of .... sickness, disability, ...". Even though the declaration was not drawn up as a legally binding document (see e.g. Germer, 1996), it has been aimed at defining the meaning of e.g. the concept of "human rights" that is of great importance with regard to e.g. the Charter of the United Nations (Charter of the United Nations and Statute of the International Court of Justice, United

Nations, San Fransisco, 1945). The latter charter is ratified by the member states including Denmark (see Ministerial Order 8, 22/11/1945) and thus implies a binding capacity from a Danish perspective (see e.g. the principles stated in the Vienna Convention on the Law of Treaties, article 14).

In addition the International Covenant on Economic, Social and Cultural Rights (Adopted by the General Assembly of the United Nations on 16 December 1966) was created. The covenant has been ratified by Denmark (see Ministerial Order 5). According to the covenant's article 12, "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and "The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for.... (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness". The comments of the covenant (see General Comment No. 14 (2000)) provide valuable information as to interpretation. For instance, according to the comments, subsection 12, "The right to health in all its forms and at all levels contains the following interrelated and essential elements, the precise application of which will depend on the conditions prevailing in a particular State party: (a) Availability. Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party. The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party's developmental level. They will include, however, the underlying determinants of health, such as .... hospitals, clinics and other health-related buildings, trained medical and professional personnel ...(d) Quality. As well as being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled

medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation". Also, according to subsection 59 the need for judicial mechanism in order to maintain accountability in the provision of health care is acknowledged. Hence, "Any person or group victim of a violation of the right to health should have access to effective judicial or other appropriate remedies at both national and international levels.... All victims of such violations should be entitled to adequate reparation, which may take the form of restitution, compensation, satisfaction or guarantees of non-repetition. National ombudsmen, human rights commissions, consumer forums, patients' rights associations or similar institutions should address violations of the right to health".

From the point of view of health law, the purpose of safeguarding health care *quality* and health care provision *standards* is broadly maintained. An even newer example is constituted by the European bioethics convention (Council of Europe, 1997) which was passed by ratification by the Danish parliament 11 May, 1999 (see Ministerial Order 65, 11/12/2000, "the Oviedo convention", and Motion for a Resolution, adopted by the Danish Parliament, according to 1998/1 BF 5). This convention maintains that appropriate measures shall be taken by the states to provide "equitable access to health care of *appropriate quality*" (article 3) and that "Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and *standards*" (article 4).

The safeguarding of health professional standards might be carried out through different means. As mentioned above, victims of a violation of the right to health might be provided access to effective judicial mechanisms; one approach is by providing a means to *complain* about health care considered unsatisfactory. According to the "Patients' Role"-recommendations and Recommendation (2000)5 of the Committee of Ministers to member states ("On the development

of structures for citizen and patient participation in the decision-making process affecting health care", subsection 15), "..Patients and their organisations should be granted access to adequate mechanisms for enforcement of their rights in individual cases, which could be complemented by *a supervision mechanism by an independent body*. In order to be effective these mechanisms should have a broad range, providing for forms of conciliation and mediation. *Formal complaints procedures* should be straightforward and easily accessible. Financial barriers to equal access to these mechanisms should be removed, either by making access free of charge or by subsidizing people with low incomes who wish to use them". Such recommendations are commonly referred to as "soft law" (see e.g. Hartlev, 2005), which are not legally binding from a traditionally legal dogmatic point of view. Anyhow, they may provide information of relevance about notable and internationally acknowledged legal principles.

It appears that the task of safeguarding *health care*, health care *quality*, health care professional *standards* and appropriate means of *patient complaint procedures* is an internationally acknowledged concern.

Likewise, the issue continues to be of major concern in Danish health regulation. Hence, as it will be described in further details below, the Danish system aims at safeguarding health care quality through means of a number of inter-connected measures, including the claim for authorisation of health professionals, the supervision carried out by the National Board of Health (including the possibility of e.g. authorisation withdrawal), the complaint system, and the system for reporting unintended adverse events. In this regard, not least the complaint system and the supervision carried out by the National Board of Health are closely connected.

*Danish health professionals and the Danish patient complaints system***:** *The authorisation system*

In Denmark, the patient complaints system is closely connected to the authorisation of health professionals. Danish medical doctors are authorised by the Danish National Board of Health. In addition to ensuring the doctor a title protection and the monopoly for specified medical treatment, it follows from the Danish Act on Authorisation of Health Professionals (Act 877, 04/08/2011) paragraph 1 that authorisation serves to "enhance patient safety and promote the quality of health services". Not least, this intention is achieved by requiring medical doctors (and other authorised health professionals) to exercise "diligence" in their professional career. Such a duty has been traditionally found in the Acts of the respective health professions (including the former Act on Medical Doctors, paragraph 6; Act on Medical Doctors, 426, 19/09/1976, see below). Now the duty is stated collectively in the Act on Authorisation of Health Professionals, paragraph 17. This paragraph (Chapter 5, concerning Health Professionals' Duties etc.) states that "In the exercise of health care, an authorised health professional is required to act *carefully and conscientiously*. This requirement also pertains to the use of assistance, the economic prescription of drugs, etc." The duty has been commonly referred to by the authorities as performance within the "norm of generally recognised professional standards". In particular, the latter norm is closely connected to the disciplinary assessments carried out with the patient complaints system (see below).

In addition to the individual duty of authorised health professionals mentioned above, the supervision activity exercised by the authorities exists. This supervision both constitutes a general means, as according to paragraph 213 of the above mentioned Act on Health Care (Act 913), the Danish National Board of Health should "monitor health conditions", but also implies a more individual supervision according to paragraph 215 (a provision formerly placed in the Act

on Central Administration, paragraph 2 and paragraph 4, see e.g. Act 182, 23/06/1932 and Act 397, 10/06/1987). According to the latter provision, "The National Board of Health observes the health care provided by persons within the health care system."

Not less importantly, a legal control with quality in health care has been continuously exercised through means of the previously mentioned access for patients to file a complaint if the quality of a concrete episode of health care, from the patient's point of view, is considered unacceptable.

The patient complaints system

Until 1988: the former complaints system under the Danish National Board of Health

Until 1988, the Danish National Board of Health (Sundhedsstyrelsen) considered complaints about authorised health professionals according to the Act on Central Administration ("Centralstyrelsesloven", see the previous Act on Central Administration, 182, 23/06/1932). Additionally, local health inspectors (or medical health officers, "embedslæger"), on a local basis, assisted the National Board of Health in the supervision of health professionals.

The 1932 Act did not provide much information about the handling of complaints, yet it was stated under the Act on Central Administration that the different categories of health professionals were under the inspectorate of the National Board of Health (see paragraph 4, subsection 1: "The National Health Board inspects that they (authorised health professionals)…. fulfill their duties according to law and, in case of negligence, (the National Board of Health) execute appropriate measures..."). By referring to the duties stated in the respective authorisation laws (see below), the National Board of Health could issue reprimands or warnings for less serious offenses. In more severe cases, the National Board of Health could recommend the

prosecutor to investigate for a criminal offense according to specific provisions in the respective authorisation acts. The National Board of Health could, however, not decide whether a patient should be awarded compensation. Such questions had to be settled by the municipalities, the appointing authorities or the courts. Furthermore, the municipalities and appointing authorities and health care operators had the task to consider complaints and inquiries regarding the level of service, issues concerning the hospital structure etc. This included complaints about whether an employed medical practitioner had demonstrated proper behaviour in connection with providing patient care. Complaints about general practitioners and similar categories of health care professionals concerning e.g. fees, services, and behaviour were filed with relevant local committees according to the Act on Health Insurance, paragraph 23, subsections 2 and 4 ("Sygesikringsloven", see Act 490, 21/07/1986).

As mentioned above, the National Board of Health had the competence to consider disciplinary complaints about health professionals. The term "health professionals" included - first and foremost- those persons authorised by the board according to special legislation (see, e.g., Act on Medical Doctors, 426, 19/09/1976; Act on Dentists, 276, 26/05/1976; Act on Nurses, 66, 27/02/1979; Act on Midwives, 671, 13/12/1978; Act on Occupational therapists and Physiotherapists, 154, 08/05/1968; Act on Clinical Dental Technicians, 100, 14/03/1979; and Act on Podiatrists, 142, 26/04/1972). Moreover the group of health professionals included such persons who directly participated in treatment or care of patients if their education was approved by the public, e.g., nursing assistants and dental hygienists. On the other hand, the term "health professionals" did not include the different groups of people working with health care provision although not approved by the government through means of an authorisation and specific education rules (popularly called "alternative practitioners"); the latter group were not subject to

direct supervision by the National Board of Health but their activity was regulated by the general rules of the Act on Medical Doctors (Chapter VI concerning unqualified practicing, “quackery”). Under certain conditions, unqualified practicing persons were given access to "cure the sick". Within the latter area, however, the National Board of Health could initiate criminal investigation if it was considered necessary.

In many respects, the complaint handling by the National Board of Health was similar to the current case management and constitutes the basics on which subsequent revisions and complaints system constructions have been elaborated. Originally, no specific regulation concerned the procedures, yet the case handling aimed at being in accordance with administrative law principles and e.g. the Act on Public Administration (see Act 572, 19/12/1985). The case handling has been described in, e.g. White Paper 866 (1979). The basic principles were as follows: After the receipt of a complaint and mailing the complainant a confirmation of receipt, the case was briefly summed up by one of the National Board of Health’s appointed medical doctors in collaboration with a legal officer. In this connection it was decided whether it was appropriate to obtain any additional information from the defendant health professional, from the health professional’s employing department, etc., or referral was required to one of the Board’s special advisers. Opinions were obtained in writing from the defendant, and subsequently the case was considered by the appointed medical doctor and the legal officer again and it was decided whether the case should be considered by the Medico-Legal Council (“Retslægerådet”). In case new and significant information was introduced, the matter was conferred to the parties. Subsequently, a proposal for a decision was produced by the legal officer. The proposal typically included the following items: (a) Information about from whom the complaint was received, (b) a short summary of the complaint subject matter, (c) what

opinions had been received by the Board, (d) relevant summaries of the declarations made by experts (including the Medico-Legal Council statement, if any), and (e) a decision with an explanation. The main letter was then sent to the complainant and the involved health professionals received a copy. If a medical doctor got a reprimand, he or she received a specified and separate letter directly from the National Board of Health. Similarly, the local authorities received a copy of the final decisions if the health professional was given a reprimand. If criminal investigation was considered necessary, the case was transferred to the police for prosecution.

From 1988 to 2010: the Danish Patient Complaints Board

The National Board of Health complaint handling had led to growing discontent and distrust of the health care complaint system, which was criticised because of "professional self-judging". It was also claimed that the former system had a lack of involvement of more general (non-health professional) considerations and was not taking legal considerations appropriately into account. Not least, the complaint system was considered to unsatisfactorily accommodate the perspective of the health care users (see e.g. Rasmussen, 1988, and Segest, 1993). The concerns were summed up by the Danish Parliamentary Ombudsman this way: "It might presumably be observed that, in recent times, the public debate has explicated – and possibly promoted – both the weakened confidence with the adequacy of health care provided by medical doctors and doubts about whether the way complaints about health care provided by medical doctors might be considered reassuring. Such a weakened confidence is worrying whether it is founded or unwarranted" (see White Paper 866).

As of January 1988 a revised Act on Central Administration was introduced (Act 397,

10/06/1987), implying the establishment of the "Patient Complaints Board" (Danish: Sundhedsvæsenets Patientklagenævn). From this date onwards, complaints about the professional activities carried out by authorised health professionals should be brought before this tribunal (unless special means of complaining were otherwise prescribed by law; paragraphs 12 and 15).

Now the patient complaint case handling was specifically regulated (according to Act 397, 10/06/1987, chapter 3) and specifications according to the Rules of Procedure, 257, 19/04/1988. The Board was explicitly stated as an autonomous and independent authority (Act 397, paragraph 13, subsection 1). Also, it was stated that it was not possible to complain about the Board's decision to other administrative authorities (paragraph 13, subsection 2), although the complaint case could be reopened if the Board received additional significant information considered likely to have resulted in the Board making another decision (paragraph 16, subsection 3, Rules of Procedure, 257). The complaint had to be filed within 2 years of the point of time when the complainant should be aware of the complaint matter (Act 397, paragraph 22). The Board had, where particular reasons existed, the opportunity to make exemptions from the 2-year limitation period.

In its composition the Patient Complaints Board was characterised by the desire for greater legal insight and decreased medical dominance although in many respects, the case management was essentially as before. The indisputable need for health professional expert assessments in connection with (not least) the case clarification was upheld. Continuously, patients were allowed to complain themselves or be represented by another person (e.g. a patients' association, or a solicitor). The parents could complain on behalf of their children. In

case of a deceased patient, the next of kin (typically the deceased's spouse, parents, or children) complained on behalf of the deceased.

The procedure was as follows: After receiving a complaint from the complainant (e.g. the patient concerned or the patient's relatives) about one (or more) named medical doctors (or other authorised health professionals), the case was clarified by the Board. In this regard, the National Board of Health was heard (paragraph 19, subsection 1). Thus, the National Board of Health incessantly maintained influence on the complaints procedures. All the involved parties received a copy of the complaint and were allowed to receive copies of documents during the case management. The defendant health professional (e.g. general practitioner) could be represented by others (e.g. a solicitor) in the complaint case and was obliged to provide the information which the Board of health considered necessary to clarify the case (paragraph 19, subsection 2). Also other health professionals might be asked in order to clarify the case.

The Board's decision was made by a five-person committee consisting of 2 public representatives, 2 representatives of the health profession concerned (e.g. medical doctors when considering complaints concerning medical doctors) elected by the Minister of Internal Affairs, and a chairperson who was a judge (see paragraphs 16 and 17). The public representatives were drawn from a group of delegates assigned by the previous association of Danish regional municipalities, the Copenhagen Municipality, the Frederiksberg Municipality and the Association of Patient Interest Organizations ("De Samvirkende Invalideorganisationer"). Decisions were made by the majority of votes (Rules of Procedure, 257, paragraph 13).

According to the Rules of Procedure 257 (and afterwards 349 and 631) cases could be completed according to a "simplified" decision process where a proposal for decision was sent to the board members and was concluded if no member opposed it. Furthermore, the possibility

was opened for the chairperson to make the decision alone in those cases giving rise to no doubt (Act 397, paragraph 20). As a prerequisite, such cases should not result in any kind of criticism or disputing conduct with regard to the health professional concerned (as it was afterwards explicitly stated in Rules of Procedure, 885, paragraph 8, subsection 2). The Board was given the competence to criticise the health professional concerned (paragraph 14) or "seek to initiate other sanctions".

Prior to the establishment of the Patient Complaints Board, the proportion of case decisions in favour of the complainant gradually increased from 1980 (just below 10%, see Bill 1986/ 1) to 1986 (23 %). In connection with the establishment of the Patient Complaints Board, parallel to the involvement of laymen in the complaint case decisions, the proportion of cases completed in the complainant's favour ranged from 20-27% (Sundhedsvæsenets Patientklagenævn, statistics, 1997-2007).

The Patient Complaints Board during the study period

The Patient Complaints Board has been continuously revised. Later revisions of the 1987 Act implied e.g. revisions with regard to the Board's sanction remedies (see below). Not less interestingly, however, an early revision in 1993 (Act 503 30/06/1993) implied the involvement of the regional health inspectors in the clarification of the complaint cases (see Rules of Procedure 631, 05/07/1994, paragraph 10). From now onwards, the National Board of Health was not itself obligatorily heard about the concrete cases, yet a new provision was inserted (paragraph 19, subsection 3) stating that "The Complaints Board must keep the National Board of Health informed about its decisions. The National Board of Health can, for inspection purposes, get specified complaint case information". Concurrently, the involvement of the

Medico-Legal Council ("Retslægerådet") decreased from being heard in almost 200 complaint cases in 1997 to 57 in 2007 (Retslægerådet, 1997 and 2007).

A revision in 2003 implied the introduction of an absolute limitation period of 5 years from the health care episode complained about (see Act 428, 10/06/2003). The constrained limitation period was justified by the fact that "it can be exceedingly difficult and protracted to clarify complaint cases of an older age" (Bill 2002/ 1 LSF 223).

In 2007, the regulation of the Complaints Board activity was removed from the Act on Central Administration and included in a new Act on Complaints and Compensation (Act 547, 24/06/2005). According to the preparatory works, the purpose of this revision was to "accommodate the existing regulation with the new (Danish) regional structure and to provide a joint overview for the patients with regard to the opportunities to complain and be awarded compensation in connection with receipt of health care" (see Bill 2004/2 LF 75).

The complaint case analyses of the present PhD study largely concern complaint case handling according to the 2005 version of the Act on Complaints and Compensation (547, 24/06/2005). Mostly, the case handling was unaltered from the latest versions of the Act on Central Administration (see e.g. Act 790, 10/09/2002 and Act 428 10/06/2003). According to Rules of Procedure 885, paragraph 18, it was explicitly stated that the Patient Complaints Board's members were under the Act on Public Administration with regard to claims for impartiality etc. The complaint case handling was continuously financed by the municipalities (Act 547 24/06/2005, paragraph 18) and there was no fee for lodging a complaint.

Firstly, the complaint was received from the patient concerned or relatives about the named authorised health professional(s). Then the case was clarified by the secretariat by help of the health inspectors (Act 547 24/06/2005, paragraph 14); the complaint was sent to the health

inspector in the region where the patient was treated (see above). The health inspector procured information from the people who were affected by the complaint in order to further clarify the contents of the complaint. The health inspector finally summarised the case and sent it to the Board's secretariat, who decided whether the case had been satisfactorily clarified, or if it was considered necessary to ask the Board's relevant health professional experts for an evaluation (see below).

All the involved parties received a copy of the complaint and were allowed to receive copies of documents during the case management. The defendant was asked to produce a statement and provide medical records, X-ray material etc. Also other health professionals might be asked in order to clarify the complaint case. All health professionals being involved in the complaint case had a duty to provide any relevant information, including medical records for the case management.

A proposal was made for decision: typically, in those cases not only concerning patients' formal legal rights, this proposal was based upon evaluations made by the Board's experts. For instance, complaints against nurses were assessed by nurses and complaints about general practitioners were assessed by general practice specialists. The Board's decision was made by a five-person committee consisting of 2 public representatives, 2 representatives of the health profession concerned, and a chairperson who was a judge (see above and paragraph 15, Act 547, 24/06/2005). It should be noted that the health profession representatives in the five-person Board committee should not necessarily be of the same medical specialty as the defendant (and for the most part were not). Thus, ophtalmology (eye-) specialists might very well participate in decisions concerning orthopedic issues. Again, according to paragraph 16, subsection 2, it was stated that the chairperson could make the decision in those cases not giving rise to any doubt; in

2007 almost half of cases (47.2%) were completed this way (Sundhedsvæsenets Patientklagenævn, 2007).

The Patient Complaints Board was given the authority to conclude that a concrete patient complaint provided no basis for criticism of the health professional(s) concerned (Rules of Procedure, 885, paragraph 15), that the case provided a basis for stating that the health professional in one or more specific situations could have acted more appropriately (professional conduct disputed, the "mildest" reaction) or that the case provided a basis for criticism because the health professional had violated the law by not acting "within the norm of generally accepted professional standards" (e.g. by reference to the aforementioned obligation for "carefulness and conscientiousness", Act on Authorisation, paragraph 17). The latter kind of decision implying a criticism of the health professional concerned was the most common "sanction". It was not to be considered whether the patient had received the best possible treatment, yet it was to be clarified whether the health care provision was within the bounds of acceptable health care provision. The Board was also given the authority to decide that the case gave reason to inculcate the health professional to be more careful and conscientious in his or her future work - a critique with injunction (Rules of Procedure, 885, paragraph 15). Finally, the Board was given the competence to bring the health professional concerned for the prosecuting authority. The latter competence has been only rarely used; in 2007, 5 cases were brought to the prosecuting authority (in no case involving a GP).

In the present study, decisions disputing professional conduct and decisions with a criticism are regarded as disciplinary sanctions (a "discipline"). Decisions disputing professional conduct have been included as they indicate the smallest levels of Board's disapprobation. The element of detriment to the defendant and disapprobation are mirrored in the fact that such

decisions could not be concluded by the chairman without involvement of the other Board members (Rules of Procedure, 885, paragraph 8, subsection 2).

The decision (with an explanation) was then sent to the complainant and the involved health professionals. Also, as mentioned above, decisions were sent to the National Board of Health in order to identify areas with a need for e.g. guideline specification in addition to supervising the performance of individual health professionals (see above). Similarly, the local authorities received a copy of the final decisions. In some cases there were, however, deviations from this usual case management, e.g. if criminal investigation was considered and the case was transferred to the police for prosecution. In case a critique with injunction was issued and in case of repeated criticism of a concrete health professional (at least 3 times within 5 years), the name and identification ID of the health professional concerned were made public, for instance on the Board's homepage (see Act 547 24/06/2005, paragraph 17). Also, a selected variety of *anonymous* decisions has been continuously published on the Board's homepage.

So far, it has not been possible to complain about the final decision to other administrative authorities, although the complaint case can be reopened if the Board receives additional significant information considered likely to have resulted in the Board making another decision. Anyhow, Complaints Board decisions may be brought to the Danish Ombudsman (see Patientombuddets Årsberetning, Sundhedsvæsenets Disciplinærnævn, 2011), who may also on his own initiative perform investigations on the Board's case handling in general (see e.g. Folketingets Ombudsmand, 2001).

Ultimately, if unsatisfied with a complaint case decision, the complainant or the defendant may bring the case for the courts. This very rarely happens; hence, in 2007 no

Complaint Board decision was brought to the Danish courts (Sundhedsvæsenets Patientklagenævn, Annual Report, 2007).

From 2011 onwards: the new "Patientombuddet"

The revision of the Danish complaint system has continued after the period under study. Revisions have aimed at enhancing ease of access to the different possibilities of complaining through means of a unified ("enstrenget") structure. From 1 January 2011 onwards, the Danish complaint system consists of the "Disciplinary Board" and "Patientombuddet". The new construction aims at emphasizing the potential for learning from for example reports on unintended adverse events (see APPENDIX 1) and complaint cases. The complaint system as such continues, however, to be separate from the compensation system (see APPENDIX 2).

The case management is mostly unchanged. Some revisions have, however, been implemented (see below). Currently, the Danish complaints system is based upon Act on Complaints and Compensations in the Healthcare System (see Act 706, 25/06/2010) and the Board's activity is regulated by the Rules of Procedure 1447, 15/12/2010.

As a new incentive, patients are offered an opportunity to have a "dialogue" with the regional municipality in order to clarify the course of concrete health care (Act 706, paragraph 1, subsection 3). If the patient is not satisfied with this dialogue he or she may decide to file a complaint against the health professional or the health care unit concerned (according to the Disciplinary Board or Patientombuddet systems).

The Disciplinary Board still decides if health professional performance should be criticized, e.g. with regard to examination, treatment, care, information and consent, preparation of statements, and breaches of confidentiality. As mentioned before, it is considered whether the

health professional in question has acted within the norm of generally accepted professional standards (namely referring to the Act on Authorisation, paragraph 17 concerning "carefulness and conscientiousness"). From 1 January 2011 onwards Patientombuddet's secretariat clarifies the complaint case without case preparation by the regional health inspectors (see above). Continuously, cases are considered by health professional experts when appropriate (Rules of Procedure 1447, paragraph 4, subsection 3). Also the opportunity still exists to bring the case before the Medico-Legal Council and the National Board of Health (paragraph 4, subsection 4). Based upon the case investigation, the Board's secretariat makes a proposal for a case decision. The decision is made by the Board comprising two laymen, two health professionals, and the Board's chairperson who is a judge. In the cases not giving rise to any doubt, the chairperson may make the decision (paragraph 15, subsection 4) although such cases might not result in criticism being issued (Rules of Procedure for the Disciplinary Board 1447, paragraph 5, subsection 2). The Board may decide to impose a sanction. Still, the most commonly used sanctions are criticizing the health professional concerned; the possibility of disputing professional conduct thereby concluding that the health professional in one or more specific situations "could have acted more appropriately" has been omitted. Additional possible sanctions are discipline with injunction, or bringing the health professional concerned before the prosecuting authority. The final decision is sent to the complainant, the health professional, the Danish National Board of Health, and if relevant, other authorities, employers etc. (Rules of Procedure for the Disciplinary Board 1447, paragraph 11). The complaint case decision is made publicly available on the internet with the health professional's name and authorisation identification code if the health professional concerned has been disciplined with injunction, has been repeatedly disciplined, or has been disciplined in connection with serious breaches of the

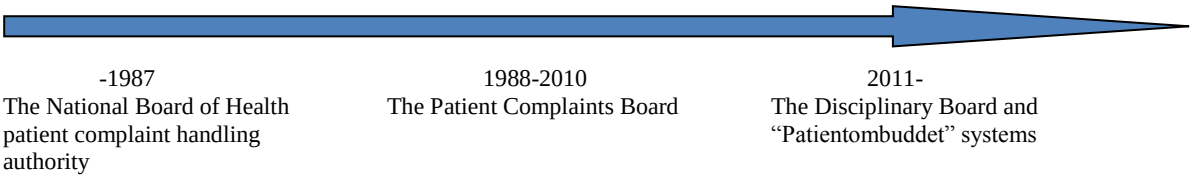
profession rules (Chapter 1, Ministerial Order 1445, 15/12-2010). Still, complaints have to be lodged within 2 years after the time of suspicion of wrong treatment and – in all instances - within five years after the day the treatment occurred (Act 706, paragraph 4).

Still it is not possible to complain about the final decision to other administrative authorities, although the complaint case can be reopened if the Board receives new significant information or if substantial breaches in the complaints handling have been detected (Rules of Procedure for the Disciplinary Board 1447, paragraph 14, subsection 3).

From 1 January 2011, complainants alternatively have the opportunity to file a complaint with the Danish "Patientombuddet" with regard to concrete health care, without intending named health professionals to be disciplined (Act 706, paragraph 1). In those cases, "Patientombuddet" may conclude that the health care provided by a health care unit was criticizable. It is also possible to complain about certain groups of health professionals without an authorisation (see paragraph 2, subsection 2 in Act 706, and Ministerial Order 1448, 15/12/2010, paragraph 1).

Regional public patient advice offices have been established in order to guide people through the different systems (Danish Act number 913 on Health Care, Chapter 11).

Figure 1. Development of the Danish patient complaint system



Complaint cases and quality improvement

The complaint system has ever since its introduction managed an abundant number of complaints from dissatisfied patients and their relatives, including cases involving the

professional work of GPs, where the norms of generally accepted health professional standards has been materialized.

The potential for use of the patient complaints in quality development has been repeatedly maintained. Hence, the Board has stated that it perceives it to be an essential task "to ensure that the wealth of information, which is collected in connection with the Complaints Board proceedings, is processed and made available to others. This allows for using complaint decisions in order to help develop health care quality. If this option is not fulfilled, complaint case handling loses its constructive purpose..." (Sundhedsvæsenets Patientklagenævn, 94/95, page 9). Likewise, in the preparatory work on Act on Complaints and Compensation in the Health Care System (Bill LSF 75, note section 3.1.1, see also Act 547, 24/06/2005 on Complaints and Compensation in the Health Care System) it is stated that "There are two main purposes for the patient complaint system. First, the Board considers whether a health care provider has violated health regulations. The Board thereby helps to ensure that the health professional does not repeat a questionable professional behaviour. Secondly, by informing about the decisions, the Board contributes to the ongoing quality assurance and quality in health care". The goal is thus - at least in theory – a means of individualized prevention as well as a kind of "general prevention" or generalised quality improvement. The risk of receipt of a reprimand (criticism) or, ultimately, losing the authorisation may indeed have a preventive effect. Although the complaint system development may have rendered the possibility of authorisation withdrawal less hypothetical, due not least to legal rights considerations, the revocation of a health professional's authorisation is still difficult and very protracted. In this connection, the possibility of being displayed on the health authorities' homepages as a "negligent" health professional (the "pillory mechanism", see above) may have much more

(unpleasant and) pronounced effects. The latter means of "preventive" effects received, however, no prominent attention in connection with the introduction of the Act. According to White Paper concerning Act 547 (which introduced the pillory mechanism, see 2004/2, BTL 75, remarks, point 2), the purposes for making a health professional's name and authorisation ID publicly available was to add to the "transparent health care sector where also the quality of health care from specific health professionals is displayed" and inform the health care users by providing a basis for exercising the free choice among health care providers. Again the quality of health care provision comes in first line.

Likewise, the quality improvement potential is internationally acknowledged; according to the abovementioned Recommendation (2000)5, subsection 16, "Systematic collection and analysis of patients' complaints should be used to gather information on the quality of health care and as an indication for areas and aspects that need improvement." Correspondingly, an explanatory memorandum contains an Article 16 on the *systematic and collective analysis of complaints*. Pursuant hereto, "Collation and collective processing of complaints provides information on how the system is functioning. They provide a means for the user to express his dissatisfaction, and can be developed as a tool for evaluating the quality of health care…."

Although there is a massive need for identifying problematic health care patterns, the extensive information pertaining to the complaint case decisions has been only very sparsely used in connection with the task of developing quality in general practice. The causes can be many. It might be questioned whether the publication of the rather large case load on the Board's website has the GPs' attention. No formalized education based upon the Complaints Board's practice exists and the production of more general guidelines on the basis of specific complaints themes has been limited. This is perhaps particularly the case where complaints not only concern

carefully controlled patient rights (e.g. right of access to patient files).

Patient complaints represent, however, a readily accessible source of patient perspectives on health care (including general practice) where the quality is perceived unacceptable by the health care user. Simultaneously, the complaint system and the concrete quality evaluation rest on a comprehensive regulatory and administrative basis (the Acts concerning authorisation, and legislation regulating the complaint case management mentioned above). As a consequence, an abundant case law has evolved harbouring in-depth investigation of patient-initiated complaints about concrete health care quality, which can hardly be achieved with a comparable thoroughness in connection with any other health services quality assessment system available (e.g. registration of adverse events). The patient complaints system, furthermore, excels in comparison with other registration systems, because special high-risk areas are continuously "naturally precipitated", with the possibility of further analysis. In this regard, the assessment takes as a departure a patient inquiry and not an "incident" of uncertain significance. All in all this implies a considerable potential for analysis and quality developments. By being far the most common first point of contact between the health care system and its users, general practice might serve a reasonable point of departure.

Danish general practice

The general practice sector in terms of a “family doctor” is a long-lasting institution in Denmark. Nevertheless, it is undergoing a continuous development, as does its institutional settings (see for a comprehensive overview of Danish general practice: Pedersen, Andersen, and Søndergaard, 2012).

Administratively, the provision of health care to the 5.4 million Danish inhabitants is

offered by the 5 regional municipalities. Hence, it explicitly follows from the provision on competence in the Act on Health Care (Act 913, paragraph 74) that the duty of making arrangements for hospital care provision lies with the Danish regional municipalities. Likewise, according to paragraph 54, "the Regional municipality has the responsibility for making arrangements available with practicing health professionals", that is: the regional municipalities are conferred the duty of managing e.g. the regional GP sector. Within the regional municipalities, the structure of general practice, including the number of GPs, is regulated. More than 99% of the Danish inhabitants are listed with a local GP and receive tax financed medical health care (primary and secondary) free of charge.

The average Danish citizen has approximately 7 contacts per year with their GP (daytime clinic consultations, telephone consultations, email consultations, and home visits). The GP serves the patients on his or her list. The number of attached patients amounts to an average of almost 1600 patients per GP.

The education of general practitioners in Denmark has been revised in recent years. Currently, authorisation as a specialist in general practice requires 6 years of (mostly practical) training after medical school (see Ministerial Order 1248, 24/10/2007, paragraph 2). Medical school in Denmark requires 6 years of university studies (see Ministerial Order 814, 29/06/2010, Supplement's point 5.3). Before education as a specialist in general practice, the medical doctor must finish a clinical basic education (1 year, see Ministerial Order 1256, 25/10/2007, paragraphs 2 and 5). After receiving authorisation as a specialist in general practice, there are no requirements for further education or for recertification, yet through allocating funds GPs are encouraged to participate in continuing medical education. Some courses are provided by the Danish authorities, but a considerable amount of continuing education is provided through means

of the pharmaceutical industry's corporate sponsorship.

Danish GPs are self-employed. General practice is paid by the health insurance both per patient on the GP's list and according to the quantity of service provided. Danish general practice has a gatekeeper function in relation to the rest of the health care system. Hence, as mentioned above, the GP is most often the patient's first contact with the health care system. Also, general practice is responsible for cooperating and providing care of listed patients during out-of-hours including weekends. In this regard, local GPs work together in regional out-of-hours centres which are typically located close to local hospital emergency departments. During the out-of-hours services, patients or their relatives can call the GP on duty, get an out-of-hours surgery consultation, or receive a home visit when appropriate. Home visits are carried out by GPs on a rota system. Alternatively, where available, patients may visit the open hospital emergency unit.

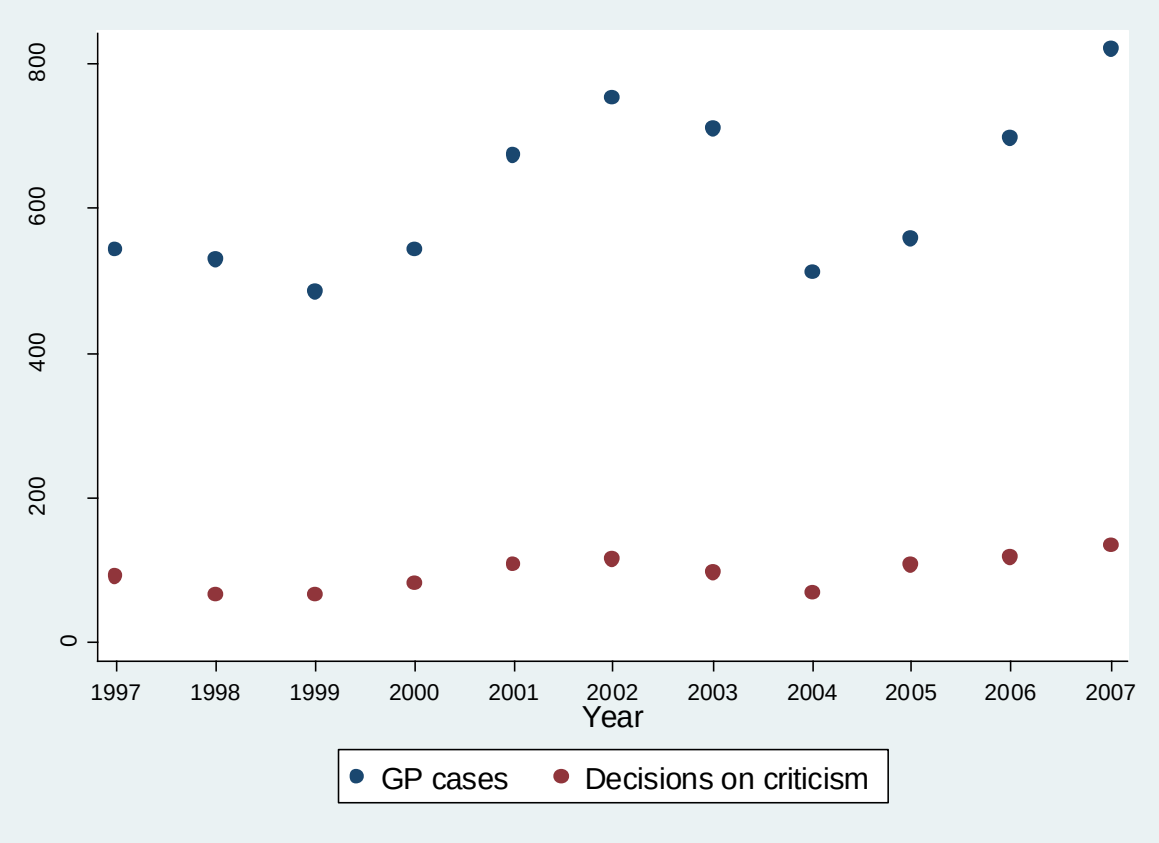
Danish general practices are organised in several different ways. Practices might be organised either as single-handed practices or as partnerships. The single-handed practices might be, e.g., owned by two part-time GPs. A group of single-handed GPs can share premises and staff, but not patients. For the time being, there is a development towards more partnership practices (Larsen, 2010) which might be partially due to the fact that the proportion of female GPs is increasing and that they prefer the working conditions associated with this way of organising general practice. The GP population age profile has continuously increased (DADL, 2007). Concurrently, Danish general practice is confronted with the fact that a large number of GPs are close to the age of retirement and a deficiency of GPs is developing, especially in rural areas with many single-handed practices.

During the last years, Danish general practice activity (number of consultations) has been continuously increasing; for daytime general practice this amounts to a 27% increase from 2000

till 2008 (DADL, 2009). Patients are free to select a new GP (for a minor fee) and previous surveys have suggested that the patients' satisfaction with Danish general practice is rather high (Jensen and Crone, 2008). Anyhow, a small proportion of patient-GP encounters results in complaint cases.

The Patient Complaints Board (now Patientombuddet) keeps descriptive annual statistics on the amount of complaints in the Danish health care sector. During the period 1997-2007 the number of complaint cases against Danish GPs increased slightly (see figure below) yet the total number of GPs being criticized was almost constant (Statistical information: Danish Patient Complaints Board, 1997-2007).

Figure 2. Danish General Practice: number of complaint cases (upper curve) and decisions of criticism (lower curve) during the years 1997-2007



In this respect, it should be mentioned that in 2007 Danish general practice delivered approximately 35 million consultations (DADL, 2009).

In 2007 the total number of patient complaint cases completed by the Patient Complaints Board was 2,387.

A comparative perspective on general practice and disciplinary proceedings

As described above, a special disciplinary tribunal (Complaints Board) has been established and continuously developed in Denmark in order to consider patient complaints about health professionals including medical doctors (e.g. GPs).

A parallel development is seen in surrounding countries. In-depth analyses of Danish patient complaint case patterns in general practice may provide information of international relevance to the extent the settings in Denmark are otherwise comparable to the situation in other countries. Below is given a brief comparative description; comparisons are made with another Scandinavian representative (Sweden), a representative of the European continental law systems (the Netherlands) and a representative of common law (the United Kingdom), respectively. In connection with the depiction of each country, the role of *general practice* in health care provision will be mentioned, followed by remarks on the *legal system* in question and a description of the country's handling of *patient complaints*.

Sweden: Health care in Sweden is similar to the provision of health care in Denmark in the sense that everyone has equal access to health care services and that the system is taxpayer-funded. Contrary to Denmark, however, there is a small fee per visit to the GP surgery. The amount of the fee varies among Swedish regions, but it is typically 150-200 SEK. Swedish general practice plays a central role in Swedish health care, although its organization is slightly different from the Danish model (it varies, however, among Swedish county councils). The great

majority of general practices (health care centers) are owned by county councils and so the GPs and staff are employees. Anyhow, the number of privately owned general practices working under contract is increasing. Patients are registered with a GP but are allowed to change GP. The GP acts as a gatekeeper with regard to referral for specialist treatment. The Swedish health care centers are open weekdays during the day and some are also open in the evening. When the health centre is closed, acute health care provision is available from the local emergency unit which is open 24 hours a day.

The historical basis of Swedish *law*, as is the case for the other Nordic countries, is the continental legal tradition with high dependency on statutory law. Of major importance in Swedish health law is the Patient Safety Act (Lag 2010:659, om patientsäkerhet), which aims to promote "high patient safety in health care". The Patient Safety Act regulates for instance the certification of medical doctors (Chapter 4). It also regulates the obligations of health professionals including the claim for providing a competent and diligent care in accordance with "science and proven experience" (Chapter 6, paragraph 1).

A number of possibilities exist for those dissatisfied with health care (e.g. general practice health care). Local patient boards (Patientnämnd) have the task of supporting and assisting patients in health care and getting appropriate information (Lag 1998:1656, om patientnämndsverksamhet m.m.). Also, the boards should encourage contact between patients and health professionals, and assist patients in contacting the right authority when reporting supposed errors. The local boards have no authority to make any decision on disciplinary action.

According to the Patient Safety Law (Lag 2010:659, om patientsäkerhet), *complaints* about health professionals are centrally handled by the Swedish National Board of Health and Welfare (Socialstyrelsen) (Chapter 7, paragraph 10). Complaints can be filed by anyone, but

should be filed within two years of the event concerned (paragraph 12). The case handling is in writing (Chapter 7, paragraph 17), but if it is considered appropriate from an investigative point of view, oral information is obtained. If the Board becomes aware of healthcare professionals not fulfilling their obligations according to the Patient Safety Act or according to other regulation applicable to health care, the Board shall "take measures for the obligations to be performed" (Chapter 7, paragraph 29). As already mentioned, among the health professional obligations, it follows from Chapter 6, paragraph 1, that healthcare professionals should carry out their work in accordance with "science and proven experience". Additionally, care should as far as possible be planned and performed in agreement with the patient. Not least, patients should be treated with consideration and respect. If there is reasonable suspicion that a specific health professional has committed an offense, for which imprisonment is warranted, the prosecution authority is notified (Chapter 7, paragraph 29).

The National Board of Health and Welfare has no further formal disciplinary sanctions, but according to Chapter 7, paragraph 18, the Board may decide whether an action or omission by any health professional is unlawful or is inappropriate with regard to patient safety. Such a decision requires that both the complainant and the health professional have been heard and have been given the opportunity to comment on the proposal for decision. The decision is in writing and contains the underlying reasons. The decision is sent to the complainant, the health professional and relevant healthcare providers.

If the Board considers that there might be grounds for, e.g., revocation of certification or restriction of prescribing, the "HSAN" (the Medical Responsibility Board) is notified (paragraph 30). According to the Patient Safety Act, Chapter 8 (paragraph 13), HSAN considers questions about probation and revocation of the authorisation. For instance, according to paragraph 1,

HSAN may dictate a probation period if the health professional concerned has demonstrated professional incompetency and poses a danger to patient safety, or has committed a crime that is likely to affect confidence in the health professional. Also the authorisation is withdrawn (paragraph 3) in case of gross incompetence or if the health professional has committed a serious crime. Alternatively, according to paragraph 10, the competence to prescribe e.g. narcotic drugs might be restricted or withdrawn in case of abuse. According to Chapter 9 (paragraph 2), the HSAN comprises a chairman and eight other members. They are appointed by the government for three years. The chairman is a judge and the other members have special insight into the variety of healthcare matters. The HSAN case management is in writing, although, if it is considered appropriate from an investigative point of view, the Board obtains oral information (paragraph 10).

In 2007 (under a somewhat different complaints board structure), 3100 complaint cases were completed, among which approximately one eighth resulted in a discipline (e.g. a warning) (Kammarkollegiets Årsredovisning, HSAN, 2007). An estimated amount of almost one fourth of complaints concerned general practice (Jonsson and Øvretveit, 2008).

The Netherlands. The *general practice* sector and GPs play a central role in Dutch health care. So-called huisartsen ("home doctors") collaborate about providing round the clock primary care and patients cannot consult a hospital specialist without a GP referral. There are, of course, exceptions in case of, e.g., emergency. Almost all GPs work in private practices. Since 2006, health care has been provided by a system of mandatory insurance for the entire population in connection with a risk equalization programme, so that the insured are not penalized for their age

or health status (children under 18 are insured by the government, and assistance is available to those with low incomes).

The Dutch *law* system is mainly based upon the French Code Civil. Written law is the main source of law, though case law constitutes an essential source of law. The Act on Medical Treatment (Wet geneeskundige behandelingsovereenkomst, Stb. 1994, 837) is the major general patients' rights act, while the ordinary *complaint* procedure is regulated in the Act on Complaints by Clients of the Health Care Sector (Wet van 29 mei 1995, houdende regels ter zake van de behandeling van klachten van cliënten van zorgaanbieders op het terrein van de maatschappelijke zorg en gezondheidszorg). According to this Act, general practices are obliged to have a system for patients to file complaints about the behaviour of the practitioner towards the client, which is to be managed within the practice. Under this law, no sanctions can be imposed on the practitioner, nor can financial compensation be awarded to the complainant. The Act has two primary objectives: to restore the relationship between the patient and the healthcare professional (strengthening the position of the patient); to use the outcomes of the complaints procedures to improve the quality of healthcare.

Complaints might, however, also be filed with the Dutch disciplinary tribunals. The Individual Health Care Professions Act (Wet van 11 november 1993, houdende regelen inzake beroepen op het gebied van de individuele gezondheidszorg, 655) regulates the provision of care by professional practitioners and the complaints system also operates according to this act (Section 2, Chapter VII). The objectives of the disciplinary procedures are to improve the quality of professional practice and to protect patients against unprofessional conduct.

Patient complaints are in the first instance dealt with by one of 5 regional disciplinary boards and appeals are dealt with by a central disciplinary board (Section 2, Chapter VII, Article

47). Complaints may originate from patients, family members, or the Health Care Inspectorate concerning medical doctors, nurses, dentists, midwives, etc. The right to submit a written complaint lapses by limitation after 10 years (article 65). The regional disciplinary tribunals each consists of two lawyers and three representatives from the health profession in question (article 55). After a local tribunal verdict, it is possible to file a high appeal at a central disciplinary tribunal (article 56) consisting of 3 lawyers and 2 health professionals.

In connection with the case handling, the preliminary investigations start with a written procedure: complaint and retort. The written procedure may be followed by a verbal exchange of views (optional). This may result in an amicable settlement. If no use is made of the verbal exchange of views or no settlement has been reached, a formal court session takes place. The tribunal can impose a number of different measures, including warning, reprimand, issuing of fines or suspend the health professional concerned for 1 year or cancel the registration of the professional (article 48).

In 2007, the total number of complaints completed by the regional boards was approximately 1300, and by the central board 300. Almost one fourth of complaints concern GPs. The complaint is concluded "founded", resulting in, e.g., warning, in roughly one fifth of complaint cases (Tuchtcolleges voor de Gezondheidszorg, Jaarverslag, 2010).

The United Kingdom. The British healthcare system to a large extent resembles the healthcare systems of other European countries: the healthcare system is publicly funded (National Health Service) providing a comprehensive variety of health services. Most healthcare (including *general practice*-) provisions are free for residents of the United Kingdom and GPs receive their income from the National Health Service; principals and partners in general

practices are self-employed, although they have contractual agreements with the National Health Service. GP care is provided 24 hours a day although GPs can opt not to provide out-of-hours services. Major reforms of the system are currently being considered.

The United Kingdom does not have one single legal system, but constitutes distinct systems of *law* including, e.g., English law. English law differs from e.g. Danish, Swedish, and Dutch law in a number of ways. In countries on the European continent, there will typically be a certain hierarchy among groups of legal sources. Hence, in these countries, a constitutional law will be superior to ordinary laws which in turn are superior to administrative regulation. In English law, judge-made law ("common law") is of major importance. There is no written constitution and, generally, written laws are found in a range of sources, e.g. statutes, regulations, and case law. Common law, otherwise known as case law (or judge-made law), is a very important source of law and this relies on a relatively strict form of precedent through which a line of cases derives its authority. Generally, decisions of appeal courts and the higher courts are binding on future decisions of lower courts. Precedents have the same level of authority as a source of law as statutes.

An example of an important statute in the medico-legal context is the Medical Act 1983, Part V of which sets up the regulation for both the right to practice as a GP and the General Medical Council's authority to investigate a health professional's fitness to practice due to e.g. professional misconduct, deficient professional performance etc. The General Medical Council, as professional regulator, is intended to be independent of both the government as the main healthcare provider and of domination by any single group of interests (e.g. medical doctors). It is for these reasons that a high number of members of the General Medical Council are non-medical lay members.

Patients may raise their concern about GPs (or other medical doctors) through local *complaint* procedures (local resolution) with the local primary care trust (or National Health Service Hospital Trust or the Private Healthcare Body). Complaints should normally be filed within 12 months of the event in question or as soon as the matter has been brought to attention. Appeals can be lodged with the Parliamentary and Health Service Ombudsman. The Health Service Ombudsman is an institution independent of both the National Health Service and the government.

Alternatively, a complaint might be directed to the General Medical Council if one or more medical doctors are suspected of having made serious or repeated errors (e.g. in diagnosis, treatment, or in breaching a patient's confidentiality). The General Medical Council comprises 12 lay persons and 12 medical members. Complaints should normally be filed within 5 years of the event in question, though older cases may be considered if in the public interest for the case to proceed. The General Medical Council initially reviews the complaint, in order to consider whether there are issues to be investigated. If there are grounds for an investigation, the complainant and the defendant doctor are asked to comment on the complaint and present evidence. Then, the complaint case is considered by a medical doctor and a non-medical General Medical Council senior in order to decide if the concerns are serious enough to call the doctor for a hearing. In that case a panel will make a decision at the hearing in order to decide whether the medical doctor is fit to practice. The possible General Medical Council measures comprise issuing a warning or putting restrictions on the doctor's registration. Hence, the medical doctor may only be allowed, e.g., to perform supervised medical work, only provide certain areas of health care practice, or the medical doctor may be required to retrain or be suspended for a period or forever.

Local public advice and complaints advocacy service offices have been established in order to guide people who wish to make a complaint through the different systems. In 2007, the General Medical Council received approximately 5200 enquiries (including patient complaints) about medical doctors. Up to 50% of enquiries concerns general practice (General Medical Council Annual Statistics, 2009). Approximately one fifth of enquiries results in for example a warning. The General Medical Council produces annual reports, providing up-to-date figures and a breakdown of the type of cases that have been heard.

Remarks about the Danish model as seen from an international perspective

The above brief comparative description of general practice and patient complaint systems in selected European countries (Sweden, the Netherlands, and the United Kingdom) points towards a number of common characteristics which also pertains to Denmark: (a) general practice health care provision is a common and important service in the countries studied. Also, although legal systems vary, (b) complaint systems are generally established in order to consider the performance of health professionals including GPs and whether concrete health care is negligent. Complaints may be filed after the complainant has received guidance from a patient information provider, and the complaint itself is handled by a more or less centralized system with an independent status. Also limitation periods for complaints have been introduced in all the countries. The system may - eventually after an expert witness assessment – decide to impose a disciplinary measure (e.g. a warning or reprimand) or take measures in order to, e.g., withdraw the authorisation. There are, however, some differences. Hence, the Danish model including lay-persons in the final decision-making is not universally established. Yet, taking into consideration the fact that the Dutch model has about the same amount of complaint cases completed in favour

of the complainant and the Swedish model having a considerably lower amount of cases resulting in discipline, it cannot be concluded that the participation of laymen is crucial to the amount of complaint cases resulting in a disciplinary action. Anyhow, from the outset, the Danish complaint system concerning health care provision (incl. GPs) should constitute a reasonable model for analyzing patient complaints' patterns.

Previous studies analyzing complaint cases against general practitioners

There is a lack of research concerning the characteristics of general practitioners involved in complaint cases. Some research exists on the risk factors of receiving a disciplinary sanction. Hence, studies involving all medical specialties (Morrison and Wickersham, 1998; Kohatsu et al., 2004; Clay and Conatser, 2003) have shown an increased risk of receiving a disciplinary sanction among male doctors. Studies have also suggested an increased risk of sanctions among senior doctors (Morrison and Wickersham, 1998; Kohatsu et al., 2004), but one contradicting study suggested a decreased risk (Clay and Conatser, 2003). A Norwegian study suggested that male GPs and male patients are associated with complaint cases resulting in discipline. In that small study, 55 out of the 108 cases (51%) concerned the out-of-hours service (Bratland and Hunskar, 2006). Likewise, a previous Norwegian study demonstrated that among the most serious complaints cases against general practitioners (which were investigated and dealt with by the Norwegian Directorate of Health), the majority concerned urgent needs of medical assistance and deputizing service (Stokstad et al., 1993). Likewise, cancer (and related patient deaths) has been revealed to be a prominent issue in studies concerning malpractice litigations (Lydiatt, 2002). Also a subsequent Italian study of malpractice claims coupled patient death and e.g. misdiagnosis of cancer with a high occurrence of malpractice claims (Fileni and Magnavita,

2006).

From a broader perspective, a number of factors might be hypothesized to be associated with complaint cases to arise as well. Thus, studies on patient satisfaction in general practice have suggested that e.g. practice size influences patients' evaluation of the GP (Heje et al., 2010c) and likewise the GP's age may be of significance; thus, studies have suggested that patients rate younger doctors more positively than they rate older doctors (Heje et al., 2007; Heje et al., 2010b). Similarly, patient satisfaction was shown to be associated with the practice's pressure of busyness. Contrary, the degree of urbanicity of the practice's surroundings only had small impact on patients' evaluation of general practices.

The patient ages may also be associated with patients' satisfaction: elderly patients have been shown to be most satisfied with their GP while satisfaction might also be positively influenced by patient gender and the presence of cancer disease and chronic illness (Heje et al., 2010a; Heje et al., 2008). Other factors may come into play. For example, patients' preferences have been previously suggested to be associated with patients' economic status (Jung et al., 2003).

The relationship between these different patterns of patient preferences and patient satisfaction factors and complaint cases is, however, unknown, but if complaint cases are regarded as indicators of "patient non-satisfaction", one would therefore expect patient preferences and patient satisfaction issues to be possibly mirrored in the distribution of complaint cases.

No larger studies investigating the characteristics of complaint cases ending in *discipline* exist, but it seems reasonable that apart from patient factors, not least the motives for complaining (e.g. wish for punitive measures to be imposed, feelings of devaluation and

humiliation, need for explanation), the kind of illness concerned (e.g. urgent vs. non-urgent), and the healthcare settings (daytime care or out-of-hours services) may potentially influence the odds of the complaint being declared justified by the complaints board and resulting in the GP being disciplined. Even though we have no knowledge of whether complaint motives may be predictive of complaint cases resulting in discipline, a substantial proportion of complaint cases have previously been shown to concern the above-mentioned communication issues. Hence, in Bismark et al.'s study (2006), the communication motive was present in about 40% of complaints. In the latter study, however, a correction motive (e.g. wish for review of the health professional's competence) was even more preponderant (50% of complaints).

In advance, one might expect that if the complainant involves a lawyer, if the period of time to be assessed is extended, or more health professionals are complained about, the likelihood of identifying some health professional negligence resulting in discipline would increase. In accordance with the above-mentioned reasons for introducing the absolute limitation period of 5 years, it may also be hypothesized that delayed complaints are less prone to be declared justified. Additionally, it has been claimed that sanctions might be less likely if the case is assessed by a peer expert witness (Lens and van der Wal, 1994). However, we have limited empirical knowledge about the ways in which way such process factors are actually related to the likelihood of cases resulting in discipline. The only study existing on the relation of process factors with decision outcomes is a Japanese analysis of medical malpractice case decisions; in that study, lengthy cases were shown to be associated with decisions in the patients' favour (Hagihara et al., 2003).

Aims

The previous section has provided background information about Danish patient complaints procedures, Danish health care with focus on general practice, and the Danish system as seen from an international perspective. Based on Danish Patient Complaints Board decisions concerning general practice the three substudies of the PhD project aimed to investigate:

- What are the characteristics of general practitioners in complaint cases? – *Study I*
- What types of patient complaint cases against general practitioners are likely to result in disciplinary action? – *Study II*
- Process-related factors associated with complaints board's discipline – *Study III*

As it appears, the approach used is statistical. From a legal point of view, the approach chosen in the three analyses might be regarded as legal sociological (Dahlberg –Larsen, 2002).

Methods

Introduction to the studies

All three studies were cohort studies based on complaints case decisions completed in 2007 from the Danish Patient Complaints Board concerning general practice. The decisions were reviewed by the author of the thesis (SB). In study I, information on GPs involved in complaint cases was merged with Danish National Board of Health register information about all Danish GPs appointed to the health insurance. In study II and study III, complaint cases resulting in discipline were compared to those not doing so with regard to a number of complaint case and complaint process factors.

Statistical analysis

There is limited tradition for using statistical models in analysing health professional disciplinary proceedings. Therefore, a brief description of the analyses used in the present study is given. The following three analyses of the project aimed at analysing statistical associations with receipt of complaint cases and a complaint case discipline (Complaints Board's criticism, or professional conduct disputed), respectively. Such associations were identified by use of multiple logistic regression. In study I, the dependent variable in the model distinguished GPs receiving a complaint case decision from those who did not and GPs disciplined from GPs not being disciplined, respectively. In study II, the dependent variable in the model distinguished GPs being disciplined from GPs not being disciplined. In study III, the dependent variable in the model distinguished compound cases (eventually involving more GPs) resulting in at least one GP being disciplined from compound cases not doing so and GPs being disciplined from GPs not being disciplined, respectively. Odds ratios (ORs, see APPENDIX 3) for cases resulting in

discipline with regard to a variety of characteristics (independent variables) were estimated and p-values less than 0.05 were considered statistically significant. The analyses were undertaken using a computerized statistical package (STATA®).

Ethics

The investigation was approved by the Danish Patient Complaints Board and the Danish Data Protection Agency. According to Danish law, retrospective register studies do not require approval by the regional committee on biomedical scientific ethics (now Act nr 593, 14/06/2011, paragraph14, subsection 2).

Methods, Study I

As mentioned above, a register-based cohort study was carried out in order to compare GPs receiving a decision from the Complaints Board during a one-year period with all other Danish GPs. Hence, the cohort was defined as GPs providing daytime services on 2 January 2006 and identified by means of the General Practitioners' Register of the Danish National Board of Health (Danish National Board of Health, 2011). GPs receiving a complaint were identified manually by reading the files of all GP-related patient complaints finalised by the Danish Patient Complaints Board in 2007.

Complaint cases concerning treatment in general practice and completed by the Complaints Board in 2007 were retrieved from the files of the Board and reviewed. The identity of all GPs receiving a complaint about daytime services was noted together with the Board's decision. In this regard, it was noted whether the health professional concerned had been disciplined (that is: the Board decided to criticise the health professional or dispute professional

conduct by concluding that an alternative health care provision was more appropriate), or not (see page 23).

Information about the characteristics of GPs (2006) was obtained from the General Practitioners' Register of the Danish National Board of Health, the Danish Health Information Database (2010) and the Danish Ministry of Welfare database (2010) and included: GP and practice identification codes, GP gender, professional seniority (years from graduation), and practice size in terms of number of GPs working together in the practice. The practice number of consultations per three months and practice size were used to calculate the GP output per day. The general practice location was described according to three municipality level variables: "socioeconomic index", "senior citizen proportion", and "level of urbanization". The "socioeconomic index" variable is an index referring to relative municipal expenditures and is based upon a number of socioeconomic parameters (e.g. proportions of unemployed citizens aged 25-59, psychiatric patients, low-income groups; Danish Ministry of Welfare Database, 2010). This measure has been commonly used as standard measure for the state and municipalities in Denmark (Danish Ministry of Welfare, 2009). The "senior citizen proportion" variable is defined as the percentage of the municipality population aged +65 years (Danish Ministry of Welfare Database, 2010). Finally, the "level of urbanization" variable refers to the percentage of inhabitants (out of the total number of inhabitants in the municipality as of 1 January) living in towns with at least 200 inhabitants (Danish Ministry of Welfare Database, 2010; more generally, see above about possible complaint case predictors, pages 43-45).

For the main analysis we only included cases involving daytime services, because no national information about GPs providing out-of-hours services is available. Hence, it was not possible to decide what fraction of providers was at odds of receiving an out-of-hours patient complaint. The

dependent variable in the model distinguished those who received a complaints decision or a decision on discipline from those who did not. Odds ratios of receiving a complaints decision or being disciplined with regard to the characteristics (independent variables) mentioned above were estimated.

Methods – Study II

Complaint case decisions concerning GPs completed in 2007 were reviewed. Based on the model described by Bismark and colleagues (Bismark and Dauer, 2006; Bismark, et al., 2010), the complainant motives were categorised in accordance with the patients' expressed wish for: "explanation", "placement of responsibility"; "quality improvement for future patients", "review of the GP's competence"; "economic compensation", "better level of general service"; "professional discipline" and "other sanction". A complaint may have had more than one motive. The above eight motives covered the following four categories: Communication, correction, restoration, and sanction (see Table 3 under results). Additionally, it was noted whether the complaint was due to "feeling devalued" by the GP. Also, information was gathered on patient gender, patient age, and the illness concerned (see above about possible complaint case predictors, pages 43-45). With regard to patient illnesses, ICPC-2 coding was used. A cancer variable was constructed. Also, based on the ICPC-2 codes, a "serious urgent illness" variable was constructed after consensus between the investigators in study II (SB, JK, and ND). Deciding what illnesses to categorise as a "serious urgent illness" might imply difficulties. For example, some medical doctors would categorise pneumonia as a serious urgent illness and others would not. We chose only to consider diagnoses commonly resulting in death if untreated as "serious urgent illness". The diagnoses considered urgent (life-threatening) with regard to the

present sample were A73, D14, D88, D94, K02, K75, K89, K90, K93, N71, N80, P77, W80.

Furthermore, it was registered if the patient concerned, according to case management documentation, had died ("death of patient"). Other independent variables considered to be factors associated with discipline and potential confounders were healthcare settings (daytime care or out-of-hours), GP gender, and professional seniority (years from graduation until event concerned). Information on GPs' professional seniority was gathered through manual look-up in a publicly available list covering Danish medical doctors (Lægeforeningens Vejviser, 2007). Finally, information on the case outcome was noted. Hence, it was noted whether the GP concerned had been disciplined; that is whether the GP had been criticised for concrete health care or his or her professional conduct had been "disputed" by concluding that an alternative health care provision was more appropriate (see about the Patient Complaints Board above, page 23). Typically, in those cases not only concerning patients' formal legal rights, this decision had been based upon evaluations made by the Board's expert witnesses. For instance, complaints against GPs are assessed by GP experts. The Board's decision is made by a five-person committee headed by a chairperson who is a judge (paragraph 15 in the Danish Act on Complaints and Compensations in the Health Care System, DACC). Being disciplined implies that the GP and the complainant receive the decision by letter. Also, the Danish National Board of Health and the health inspectors are informed.

To analyse variables associated with discipline, odds ratios (ORs) were estimated by means of a multiple logistic regression model. The dependent variable in the model distinguished non-disciplined from disciplined cases and the independent variables considered as factors associated with discipline were the above-mentioned complaint characteristics.

Methods – Study III

In this cohort study, all Danish Patient Complaints Board decisions from 2007 involving GPs were analysed with regard to a number of process factors in order to compare decisions on discipline (the GP had received a decision letter where he or she had been criticised or his or her professional performance had been disputed by concluding that an alternative treatment was considered more appropriate, see page 23) with those not resulting in discipline.

By way of introduction, files related to all complaint decisions in 2007 from the Danish Patient Complaints Board concerning general practice were reviewed. Decisions were treated both as compound decisions (in some cases involving more GPs) and as separate decisions against individual GPs. In a compound decision some GPs might have been disciplined and others might not. The following information was obtained: Complaint delay (time from the medical event concerned until filing the complaint), lawyer involvement by the complainant (judicial expertise used to e.g. formulate complaint), the number of GPs involved, and the event duration concerned (duration of healthcare episode concerned). Complaint delay was intended to measure the time span from the health event concerned before filing a complaint. For practical reasons, the time interval from the last date of the healthcare event until registration within the Patient Complaints Board was used. Obviously this time comes after the time of complaining. The time of registration was, however, considered useful because it was unfailingly available in every case and might be considered closely tied to the time of filing the complaint. The involvement of an expert witness and case management duration (from the date of registration of the complaint within the Patient Complaints Board until the date of decision) were included as independent variables. Finally, information was gathered on decision outcome (dichotomized into discipline or no discipline, see above).

Results

Results - Study I

In total, the cohort comprised 3,765 Danish GPs (65% male) included in the Danish National Board of Health Register. The average professional seniority of participating GPs was 25.5 years (range 2.8-56 years). The sample included 1314 single-handed practices, 910 two-man practices and 1541 larger size practices (663 three-man, 416 four-man, 265 five-man, 126 six–man, 35 seven-man, 16 eight-man, and the remaining 20 being larger).

The Board completed the handling of 419 complaints against GPs in 2007, 265 concerned daytime and 154 out-of-hours services. The associations between receiving a complaint case concerning daytime services and GP and practice characteristics are shown in Table 1.

Table 1. Receipt of a complaint case and the association with general practitioner and practice characteristics (Pseudo R^2=0.0095)

		OR	P	95% Confidence Interval	
General practitioner characteristics					
Gender	Female	1			
	Male	0.97	0.82	0.73	1.29
Professional seniority[1]		1.44	0.03	1.04	1.98
GP output per day[2]		1.29	0.01	1.07	1.54
Practice and practice environment characteristics					
Practice size		0.99	0.86	0.91	1.08
Socioeconomic[3] index		1.61	0.16	0.83	3.13
Senior citizen proportion[4]		0.99	0.76	0.93	1.05
Level of urbanization[5]		0.99	0.09	0.97	1.00

[1]Per 20 additional years of professional seniority since graduation

[2]Per 10 additional consultations per day. Average number of basic consultations per day per GP was 22.3consultations/(day*GP)

[3]Socioeconomic index, range 0.42-1.73, see text

[4]Senior citizen proportion: percentage of +65-years old, range 9.4-28.2%

[5]Level of urbanization, percentage of citizens in towns, range 24.5-100%

For daytime services, high professional seniority of the GP was significantly associated with increased odds of being involved in a complaint. An increase in professional seniority of 20 years corresponded to a 44% increase in odds of receiving a complaint within one year. Also, GPs who had higher output per day had higher odds of receiving a complaint decision; thus, an increase of 10 consultations per day resulted in a 29% increase of odds. No statistically significant associations were found for the other characteristics: Gender, practice size, socioeconomic index, senior citizen proportion, or level of urbanization.

The association between disciplinary action and GP and practice characteristics is shown in Table 2.

Table 2. Disciplinary action and association with general practitioner and practice characteristics (Pseudo R^2=0.0121)

		OR	P	95% Confidence Interval	
General practitioner characteristics					
-Gender	Female	1			
	Male	0.97	0.91	0.56	1.67
-Professional seniority		1.85	0.06	0.98	3.49
-GP output per day		1.31	0.11	0.94	1.82
Practice and practice environment characteristics					
-Practice size		0.95	0.58	0.81	1.13
-Socioeconomic index		0.71	0.59	0.21	2.44
-Senior citizen proportion		1.00	0.95	0.90	1.12
-Level of Urbanization		1.01	0.65	0.98	1.03

Among the 265 GPs who received a complaint about daytime services, 71 received a discipline from the Board (53 conclusions on *critique*; *professional conduct disputed* in another 18 cases). None of the characteristics showed statistically significant associations with the odds of

receiving a discipline.

An additional analysis including complaints about the out-of-hours service showed that complaints apparently were more frequent for male GPs, but the relative amount of out-of-hours work performed by male and female GPs was unknown.

Results- study II

The complaint cases (n=428) completed by the Danish Patient Complaints Board in 2007 concerned 571 decisions against individual GPs. Sample characteristics are shown in Table 3.

Table 3. Descriptive statistics: decision outcome, patient and general practitioner characteristics, and complaint motives in complaint cases towards general practitioners (n=571)

		n.	%
Decision outcome: Discipline	No	445	78
	Yes	126	22
Complaint motives			
-Communication		481	84
	Explanation	300	53
	Placement of responsibility	458	80
-Correction		344	60
	Quality improvement for future patients	214	37
	Review of the GP's competence	328	57
-Restoration		162	28
	Economic compensation	124	22
	Better level of general service	113	20
-Sanction		106	19
	Professional disciplinary action	95	17
	Other sanction	96	17
-Feeling devalued	No	491	86
	Yes	80	14
Patient characteristics			
-Patient gender	Female	335	59
	Male	236	41
-Cancer	No	523	92
	Yes	48	8
-Serious urgent illness (see text)	No	479	84
	Yes	92	16
-Death of patient	No	507	89
	Yes	64	11
General practitioner characteristics			
-Healthcare settings	Daytime care	335	59
	Out-of-hours	236	41
-General practitioner gender	Female	170	30
	Male	401	70

In 22% of cases, the GP was disciplined. Among these cases, the GP was criticised in 96 cases (17% of cases) and the professional conduct was disputed in 30 cases (5% of cases). The 96 cases resulting in the GP being criticised included 8 GPs being disciplined with injunction (among whom one was brought before the prosecuting authority; though the charge was dropped). The average patient age was 45.3 years (range 0-91 years) and the average professional seniority of GPs was 22.2 years (range 0-47 years). The motives for complaining most often fell within the categories of Communication and Correction, whilst the "Sanction" motive was encountered much less often. Table 4 (next page) presents the analysis of complaint case variables predictive of Complaints Board discipline. One case was omitted from the analysis because the patient's age was unknown.

When including variables concerning complaint motives, patient gender and patient age, patient serious urgent illness, cancer, death of patient, health care settings (daytime care or out-of-hours), and GP gender and professional seniority in a multiple logistic regression model, odds of being disciplined were halved when the complaint was motivated by "feeling devalued" (OR=0.39, p=0.02) or a request for an "explanation" (OR=0.46, p=0.01). However, when complaints were based on a wish for "placement of responsibility" (OR=2.35, p=0.01) or a request for a "review of the GP's competence" (OR=1.95, p=0.02) the odds of being disciplined doubled, just as in the case with professional seniority: a GP with 20 years more seniority had doubled odds of being disciplined in connection with a complaint case (OR=1.97, p=0.01). No statistical significance of GP gender could be demonstrated.

Table 4. Complaint case characteristics and the association with decisions on discipline (n=570, Pseudo R^2=0.0789)

	Odds Ratio	P	95% CI	
Complaint motives				
Communication				
-Explanation	0.46	0.01	0.26	0.80
-Placement of responsibility	2.35	0.01	1.20	4.59
Correction				
-Quality improvement for future patients	1.34	0.36	0.72	2.50
-Review of the GP's competence	1.95	0.02	1.14	3.35
Restoration				
-Economic compensation	1.45	0.26	0.76	2.75
-Better level of general service	1.22	0.60	0.58	2.54
Sanction				
-Professional disciplinary action	0.60	0.43	0.17	2.14
-Other sanction	0.69	0.57	0.20	2.43
Feeling devalued				
-No	1			
-Yes	0.39	0.02	0.18	0.85
Patient characteristics				
Patient gender				
-Female	1			
-Male	0.91	0.66	0.59	1.40
***Patient age* (per year)**	1.00	0.35	0.99	1.01
Cancer				
-No	1			
-Yes	0.86	0.73	0.37	2.00
Serious urgent illness				
-No	1			
-Yes	1.46	0.20	0.82	2.59
Death of patient				
-No	1			
-Yes	0.69	0.33	0.33	1.45
General practitioner characteristics				
Healthcare settings				
-Daytime care	1			
-Out-of-hours	0.78	0.32	0.48	1.27
General practitioner gender				
-Female	1			
-Male	1.06	0.82	0.65	1.73
Professional seniority	1.97	0.01	1.19	3.26
(per additional 20 years)				

Results - Study III

In 2007, 427 compound decisions were made concerning general practice. Sample characteristics are outlined in Table 5.

Table 5. Descriptive statistics: process factors in compound complaint case decisions towards general practitioners (n=427)

Case process factor		[Range]
Complaint delay, mean	3 months, 18 days	1 day – 47 months, 5 days
Lawyer involvement	20 (5%)	
General practitioners involved, mean	1.33	1-4
Event duration, mean	4 months, 6 days	1 day – 83 months, 5 days
Case management duration, mean	14 months, 7 days	2 months, 3 days – 72 months, 5 days
Expert witness involvement	393 (92%)	

Most cases (n=338, 79%) only involved one GP. In 55 cases (13%), the number of GPs involved was two. In 18 cases (4%), 3 health professionals were involved, and in the remaining 16 cases (4%) 4 GPs were involved. In 45 cases (11%), one or more non-GPs were involved, most frequently hospital doctors, non-hospital specialists (e.g. ear, nose, and throat specialists), and nurses. In 114 cases (27%), one or more GPs were disciplined.

The compound decisions concerned 571 separate litigations against individual GPs. The association between individual GPs being disciplined and process factors is shown in Table 6 (see next page).

Table 6. Process factors associated with being disciplined as a general practitioner (n=571, Pseudo R^2=0.0384)

Discipline		OR	P	95% Confidence Intervals
Complaint initiation				
Complaint delay (months)		0.988	0.521	0.954-1.024
Lawyer involvement	No	1		
	Yes	1.257	0.633	0.491-3.216
Complaint demarcation				
General practitioners involved		0.661	0.000	0.524-0.835
Event duration (months)		0.996	0.675	0.977-1.015
Complaint decision				
Case management duration (months)		1.038	0.010	1.009-1.069
Expert witness involvement	No	1		
	Yes	1.366	0.452	0.606-3.077

When the number of GPs involved in a complaint case increased, the odds of discipline decreased for the individual GP concerned (OR=0.661 per additional GP involved, p<0.001). Conversely, when analysing the association between process factors and discipline in compound decisions (from the complainant point of view), no statistical association could be detected between the number of GPs involved and odds of the compound decision resulting in at least

one of the litigated GPs being disciplined. In both analyses, however, long case management duration was associated with increased odds of discipline. Hence, a six months prolonged case management duration was associated with 26% increased odds of the case resulting in a decision on discipline (p=0.010, 28% in compound decisions, p=0.011). No association could be demonstrated with regard to event duration, complaint delay, expert witness involvement, or complainant's lawyer involvement. Even when taking clustering into account in separate decisions, the association between decision outcome and number of GPs involved and case management duration, respectively, was statistically significant.

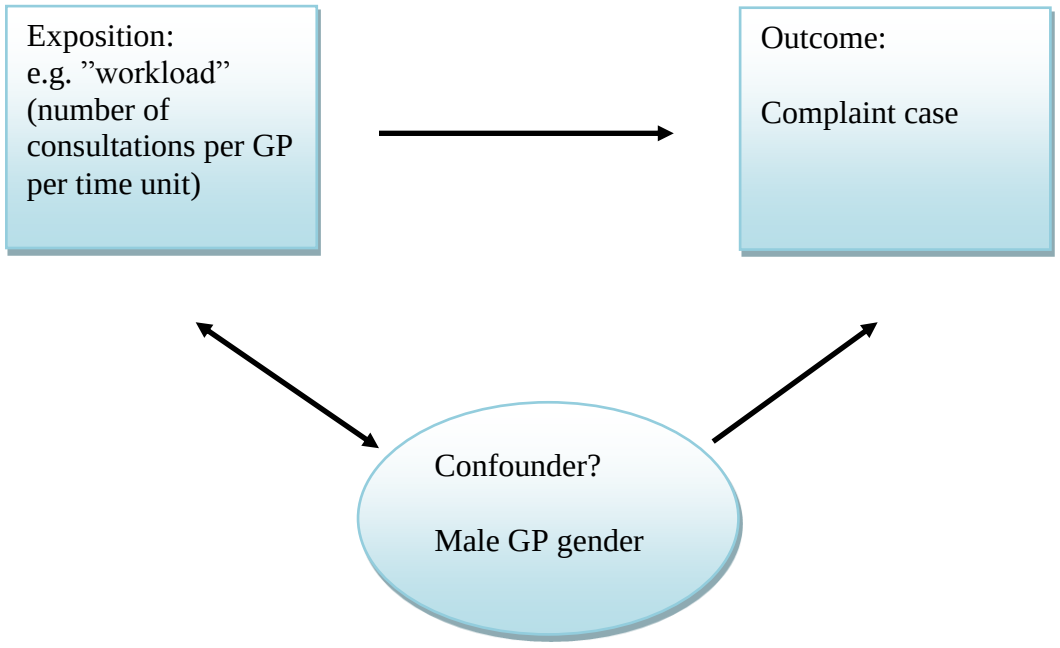
Methodological considerations

The strength of the PhD study is the linkage of complete nationwide administrative register information allowing for an individual level analysis with complete follow-up. Hence the study is not dependent upon information biases and data incompleteness associated with, e.g., questionnaire studies.

Confounding

Confounding is any distortion of a relationship between exposure (e.g. workload in terms of number of consultations per time unit) and outcome (e.g. a complaint case) by an extraneous variable called the confounder which thereby hides or distorts a true effect of the exposure in question.

Figure 3. The role of confounders



The confounder is associated with the exposure in question without being a consequence of it, but is also associated independently with the outcome. The usual way to eliminate confounding is by randomising in an experimental setting. In non-experimental settings where many potential confounders may be present (e.g. gender and age), this approach is not possible. In the present study confounding has been controlled for by using logistic regression models.

In the multiple logistic regression model the different variables (e.g. gender, age, and workload) can be included, at the same time being unconfounded by each other.

Bias

There are two main types of error in epidemiological studies. The one type, random error, reduces towards zero when the study becomes larger, and the second type, bias (or systematic error), tends to remain even when the study size increases towards infinity. When epidemiological studies are interpreted, the possibility of these types of error should be considered because they might otherwise potentially result in an incorrect conclusion by either incorrect accept of a null hypothesis or rejection of a true null hypothesis. Of particular interest in the present study are selection bias (systematic errors in identification of the study population) and information bias (systematic error in the measurement of information on exposure or outcome). The role of random error is discussed under "*The logistic regression models and sample size considerations*".

Selection bias might derive from study participants being systematically erroneously included in the sample. The categorisation of complaint cases had originally been done by the complaints Board's secretariat. According to the secretariat's practice, categorisation within the "general practice" category is done, if the case mostly concerns general practice. This procedure

may of course be subject to some uncertainties. Hence, in total 38 case files were omitted in connection with the case review. Seven case files were excluded as they were actually not primarily completed in 2007, yet they had been considered for reopening in 2007. Some 31 case files were omitted as they did not concern a GP, but e.g. psychiatric specialist treatment. Bearing in mind the aforementioned, there is a possibility that "true" general practice cases might conversely have been misclassified into other health professional categories. Study I implied a coupling of the register-based sample with the complaint case list on Complaints Board decisions from 2007. In this connection, 84 complaint cases originally categorised as pertaining to general practice appeared to involve medical doctors who were not listed in the National Board of Health register concerning those with an appointment to the health insurance. The latter 84 cases were omitted from the analysis and appeared to concern 50 general practice specialists who were not listed in the insurance register and 34 non-specialist medical doctors. Seventeen cases (approximately 20%) resulted in discipline and the remaining 67 did not. A total of 53 concerned the out-of-hours services and the residual 31 did not.

It has previously been mentioned that the Danish complaint system is separate from the compensation system and complainant letters solely expressing a wish for compensation are automatically redirected to the Patient Insurance. Similarly, complaints about the level of service (e.g. long waiting time or bad GP manners) are sent to the regional health authority. When comparing with the situation in other countries, it should therefore be kept in mind that the material only represents complaints about the GP's "professional conduct" as such. Also, the analyses were only taking into account complaint cases completed (decisions) by the Complaints Board. The approximately one fifth of the total number of patient complaints rejected by the Complaints Board has not been taken into consideration. Typical reasons for complaint rejection

are complaints about the level of service (e.g. waiting time) or – as indicated above - claims for compensation without a complaint about a health professional.

Information bias might be considered in study I in connection with calculation of the number of consultations per GP per day ("workload"). In the case of single-handed practices personal number of consultations equals practice number of consultations, although in the present study potential shortcomings may arise as consultations in non-single practices were equally distributed over the partners, no matter what was the actual partner involvement in the practice. For instance, this approach might result in any significance of "workload" being diluted, as perhaps the impact of consultations is due to one partner (the GP concerned) having many more consultations per time unit. In other words, a greater increase in individual number of consultations per day is needed to count at the practice level. This potential shortcoming further implies that, strictly speaking, the analysis is measuring the impact of *working in practices* with high numbers of consultations.

Some single-handed practices may have close cooperation, thus mostly resembling partnerships. Approximately 30% of Danish GPs work in a single-handed practice (all patients are listed with one general practitioner). A total of 61% of GPs work in partnerships and the patients are attached to this partnership and not to an individual GP. The remaining 9% of GPs are organised as "collaborative practices", yet they are formally categorised as single-handed GPs (patients are attached to a specific GP, but the GP cooperates with one or more other GPs, for instance with regard to practice facilities, Maagaard, 2007). In the present study, no special attention is paid to the 9% of GPs organised as collaborative practices.

In addition to complaint decision data, the variables included in study 1 imply two substantially different types: practice level information and municipality level information. It

comes naturally that practice level information provides information more specifically relevant to assessing the impact of the independent variable concerned than does municipality level information; because only register-based municipality-level data on practice location were taken into consideration, the concrete position of the practices concerned, patient ages and socioeconomic information have not been dealt with. Likewise, more complex issues with regard to e.g. differences in patient list compositions have not been taken into consideration. Hence, the use of municipality level data does imply the possibility of "dilution" of effects and only provides a means of "average" information about the general practice surroundings. This might partially quash the analyses of what kind of general practice surroundings impact odds of receipt of complaint cases.

Furthermore, the register-based approach used in Study I gives rise to some considerations regarding measuring population characteristics. Denmark is a small rather homogeneous country with a population of 5.5 million people and a total area of 43 000 km^2. The distances in Denmark are rather small and most people live not far from a provincial town. The method chosen for measuring *urbanization* in Study I has formerly been used for studying Danish general practice characteristics (Olsen et al., 2010). The "*level of urbanization*" refers to the percentage of the number of inhabitants in towns with at least 200 inhabitants of the total number of inhabitants in the municipality as of 1 January (The Danish Ministry of Welfare Database, 2010). Likewise, in Study I the "*senior citizen proportion*"-was defined as the percentage of the municipality population aged +65 years (The Danish Ministry of Welfare Database, 2010). This measure has formerly been used in connection with public health and primary health care research as well (Bowling et al., 2006; Lyngsø et al., 2010). The "*socioeconomic index"* is calculated from a variety of proportions (municipality

level of unemployed aged 20-59 years; 25-49 year-olds without any vocational training; apartments rented out; psychiatric patients diagnosed; families in certain residential accommodation; children in families with limited educational background; singles aged plus 65 years; low-income persons; disabled people outside the labour force; immigrants and their descendants; life years lost; decrease in population size). The sum of weighted criteria is proportioned to the municipality part of the Danish population. Values exceeding 1 suggest a relative increase of municipal expenditures compared to the Danish population, and vice versa (The Danish Ministry of Welfare, 2009). To the author's knowledge, the "socioeconomic index" has not previously been used in research settings, but has been commonly used for public reimbursements.

Register data from 2006 were used in order to best possible reflect the situation where a healthcare event resulted in a complaint case. Thus, we expected lag times with regard to both filing the complaint and Complaints Board case management. The average case management time of all complaint cases is known to be approximately 15 months (Sundhedsvæsenets Patientklagenævn, 2007). However, some of the events might actually have taken place with an unfortunate time relation to the register data.

In Study II, the categorisation of motives for complaining was based on a review and interpretation of complaint letters. Some misclassification may have been introduced by the interpretation. The classification of motives was based on the instrument developed by Bismark et al. (2006). Originally, the instrument was developed in connection with a case study drawn from compensation claims and complaint files in New Zealand in order to investigate the diversity of injured patients' interests (Bismark and Dauer, 2006). One such instrument must, prior to being used for research, in principle be validated systematically, as is

the case in the development of questionnaires. A limited validation has previously been performed. Hence, the instrument was used in a subsequent study from New Zealand (Bismark et al., 2006). In that study, 157 complaint letters were independently reviewed. There is no information available about the number of reviewers, but - using the instrument - a relatively high level of reliability was reached: the coding of the 157 complaint letters "matched" in 83% (131) of cases.

In the present PhD study, however, we did not test reliability of the instrument, nor has the instrument been tested with e.g. translation to Danish and backwards to English. Even though no measure of inter-rater reliability was computed, based on independent ratings of a small test sample by two raters (SB and JK), we judged that the instrument by Bismark could be transferred to the Danish complaint material.

As described in the methods section, the ”serious urgent illness” variable was constructed after consensus between the investigators. Classification of illnesses as “serious urgent illness” might cause difficulties because some medical doctors would categorise e.g. pneumonia as a serious urgent illness and others would not. We aimed at only considering those diagnoses commonly resulting in death if untreated as “serious urgent illness”. With regard to the complaint case diagnoses, this category included the codes A73 (Malaria), D14 (Haematemesis/vomiting blood), D88 (Appendicitis), D94 (Chronic enteritis/ulcerative colitis), K02 (Pressure/tightness of heart), K75 (Acute Myocardial Infarction), K89 (Transient cerebral ischaemia), K90 (Stroke/cerebrovascular accident), K93 (Pulmonary embolism), N71 (Meningitis/encephalitis), N80 (Head injury other), P77 (Suicide/suicide attempt), W80 (Ectopic pregnancy). With regard to emergency cases, Huibers et al. (2011) recently suggested ICPC-2 diagnoses K75 (Acute Myocardial Infarction), K89 (Transient cerebral

ischaemia), K90 (Stroke/cerebrovascular accident), A07 (Coma), N07 (Convulsion/seizure), N88 (Epilepsy), R81 (Pneumonia), D88 (Appendicitis), and U70 (Pyelonephritis/pyelitis) as constituting typical life-threatening health problems. In other words, the concept of serious urgent illness may diverge substantially.

The logistic regression models and sample size considerations

A number of logistic models have been applied in order to identify variables associated with complaint cases and decisions by simultaneously making adjustment for confounding. It appears from the pseudo R^2 measures (denoted in the headings of every table in the results section) that the data in the three substudies only rather incompletely describe the variation in complaint cases and complaint case decisions, respectively. Hence, the R^2 measures seem to leave an abundant space for other factors to (even more substantially) impact the dependent variables. Such other factors might be pertaining to e.g., differences in GPs' communication styles. The describing variables have been chosen from existing evidence about factors being possibly associated with complaint cases and case decisions (see the Background section) and what data have been available.

The question about sample size concerns the number of observations to include in the statistical sample, which is important when the goal is to make inferences about a population from the sample concerned (see above under "*Bias*" and random error). The sample size used might be determined based on the need to have sufficient statistical power. Lack of statistical power to detect meaningful associations is of interest, when a study suggests negative results in terms of "no association" between exposure (e.g. male gender) and outcome (e.g. a complaint case). This problem was relevant especially for studies II and III in which there

were rather few study subjects. In Study III, in particular, the limited number of cases actually involving a lawyer deflates the statistical power. The deflation is reflected in the very broad confidence intervals associated with the multiple logistic regression analysis (OR 95% confidence interval between 0.491-3.216, see Table 6). The deflation of statistical power may also be of importance in relation to the use of expert witnesses, because very few decisions were made without an expert witness. Correspondingly, the multiple logistic regression analysis again revealed a rather broad confidence interval (OR 95% confidence interval between 0.606-3.077, see Table 6).

Discussion

The studies underlying this PhD thesis suggest that GPs with higher professional seniority were both at increased odds of receiving a complaint case, and when they did receive one, they were also at increased odds of being disciplined. Likewise, GPs with a heavier workload were at increased odds of receiving a complaint case. On the other hand, the increased odds of receiving complaint cases and being disciplined, respectively, among male medical doctors, as suggested in previous studies, could not be confirmed in the study's GP population. When the complaint was motivated by communication issues in terms of the patient's feeling of being devalued or a request for an explanation, the odds of being disciplined decreased. Complaint cases based on a wish for placement of responsibility or for review of the GP's competence were associated with increased odds of being disciplined. If receiving a complaint case where more health professionals were involved, the odds of being disciplined decreased. Last but not least, case management elongation was associated with increased odds of discipline.

Discussion – Study I

Only limited literature concerning risk factors of receiving complaint cases in general practice is available. Cunningham et al. (2003) carried out a cross-sectional survey among 1,200 medical doctors in New Zealand. A total of 49% (598) completed the questionnaire and were included. The study comprised a broad range of medical specialties; only 215 participants were GPs, 93 had *never* received a complaint. Among the broad group of medical doctors, those who were more likely to receive a complaint were GPs, male doctors, higher professional seniority doctors, and those with higher postgraduate qualifications. The authors put forward the possible explanation that it is the more experienced doctors who carry the burden of responsibility for

patient care. Contrarily, in the present study, the practice site could not be demonstrated to be of importance: It is remarkable that none of the surrounding variables appeared to influence the odds of a complaint case. This might of course be true and in accordance with the above-mentioned aims of the patient complaint system with regard to "equal accessibility" (see page 12, Council of Europe Recommendation (2000)5, "On the development of structures for citizen and patient participation in the decision-making process affecting health care", subsection 15). In this regard, it could be considered a positive finding that patients equally complain no matter e.g. their socioeconomic background or age. Alternatively, it might be because the surrounding variables chosen are not appropriate or the material is too small. Hence, in regard to socioeconomic index in particular, the confidence interval, although no statistical significance is reached, might point towards higher odds of complaint cases with increased socioeconomic index which would actually suggest a social disparity with regard to complaining.

The significance of high GP output per day suggested in Study I is supported by the findings of Nash et al. (2009). They performed a self-report study among 1,239 Australian GPs. There were 566 respondents (45.7%) and in this group the authors demonstrated that male medical doctors and doctors working more hours per week were predominant among those having had a medico-legal matter.

The findings of Study I suggesting that complaint cases concerning male GPs are particularly preponderant only when including the out-of-hours services confront the common notion that male medical doctors are generally at higher odds of receiving patient complaints. Unfortunately, we do not know what proportion among the GPs listed with the National Board of Health participated in the out-of-hours services and thus were at odds of being involved in an out-of-hours complaint decision; no Danish national statistics about GPs participating in the out-

of-hours services are available. Consequently, it cannot be ruled out if any gender preponderance is due to the gender in itself or results from a skewed job profile, e.g., if male GPs generally perform the scope of work associated with a higher odds of complaints. The out-of-hours service involves a job of high odds with regard to patient complaint cases. In the present study, 37% of all patient complaints pertained to the out-of-hours services, even though no more than approximately one tenth of general practice care pertained to out-of-hours services in 2006 (DADL, 2009). Finally, the findings in study I that no significant association could be demonstrated between being disciplined in connection with a complaint case and GP and practice characteristics confronts previous research findings (Morrison and Wickersham, 1998; Kohatsu et al., 2004; Clay et al., 2003).

Discussion – Study II

Like in the study from New Zealand by Bismark et al. (2006), the results in Study II suggest that most complaints were based on *Communication* and *Correction* motives. Nevertheless, Bismark et al. did not investigate the significance of the complaint motives with regard to case outcome, and the present study is the first to do that.

Recently, feeling deserted or humiliated (in the sense of feeling objectified, insulted, ignored or ridiculed) was suggested to be important when patients lose trust in the doctor-patient relationship (Frederiksen et al., 2009). Similarly, Beckman et al. (1994) previously identified "Devaluing patient and/or family views" as the most important issue in almost one third of malpractice suits. The impact on outcomes has not been investigated before. The results of Study II suggest a decreased likelihood of being disciplined, perhaps because the ones feeling devalued or seeking punitive measures are overwhelmed by resentment and anger. Furthermore,

it has previously been mentioned that even if, according to the Act on complaints and compensations paragraph 2, the disciplinary board considers the health professional performance of authorised health persons, according to the preparatory works, the Board does not consider the ”behavioural attitude” of health professionals. Remarkably, this aspect has been separated from the concept of health professional performance. The findings of the present study might be seen from this point of view; hence, from the study's statistical perspective as well, concluding health professional behavioural attitudes (e.g. bad GP manners) to be doubtful to an extent considered unlawful does not lie within the competence of the disciplinary board. Health professionals' behavioural attitudes may, however, be considered within the regional municipality systems.

Complaints motivated by a wish for “expression of responsibility” or a “review of the GP's competence”, on the other hand, might mirror a relatively high degree of matter-of-factness and possibly to a much higher extent address the core competence of the Board. It corresponds with the competence of the Board as well that complaints partially motivated by a wish for an explanation are associated with decreased odds of discipline. Hence, the new “Patientombuddet” provides the possibility of a regional dialogue (care (Act 706, paragraph 1, subsection 3, see above under *The new “Patientombuddet”*). One of the intentions of the dialogue is, if possible, to clarify the questions on which the patient's complaint might be based and possibly this may, with the consent of the patient, result in the complaint with the Patientombuddet being withdrawn (revision concerning Act on Complaints and Compensation, Bill 2009/1 LSF 130, comments section).

Study I revealed that higher GP professional seniority was predictive of getting a complaint case. Hence, it seems that senior GPs are more likely to receive a complaint case, - and if they do get one their odds of being disciplined are increased. Two previous case-control

studies have demonstrated an association between increased professional seniority and complaint case discipline (Morrison and Wickersham, 1998; Kohatsu et al., 2004), but the findings were contradicted in a third study demonstrating decreased odds (Clay et al., 2003).

The association between professional seniority and discipline may reflect seniority-dependent job contents: senior GPs might be those handling the most complex patient encounters. Anyhow, the study findings could not verify that patient gender, patient age, and serious urgent illness had any impact. Alternatively, the significance of professional seniority might reflect an unspecific *burnout* phenomenon. In favour of this conception speaks a comprehensive European cross-sectional questionnaire survey: this analysis of self-reports demonstrated a positive connection between professional seniority and burnout in terms of "emotional exhaustion" (Soler et al., 2008). The present study could not demonstrate any statistical significance of GP gender.

Discussion – Study III

In general, the association between health disciplinary process factors and decision outcomes has attracted little research attention. The only study existing on the relation of process factors to decision outcomes is a Japanese analysis of medical malpractice case decisions. As in Study III, lengthy cases were shown to be associated with decisions in the patients' favour (Hagihara et al., 2003). The causes of this association might be numerous, but the most likely reason might be that straightforward (short duration) cases typically are those with limited likelihood of negligence, while the cases resulting in discipline may be more complicated, generally requiring a thorough (long-lasting) case management.

Prolonged case management is demanding for all the involved parties in disciplinary

proceedings – not least the defendant. Case management should, however, agree with judicial regulations (e.g. the "reasonable time" requirement according to the European Convention on Human Rights, Article 6). In this regard, it is noticeable that the increased odds of disciplining the defendant with case management prolongation run parallel to case durations up to 6 years.

It has previously been argued that the involvement of lawyers on behalf of patients may increase the possibility of breaches of standards of practice being clarified, because lawyers to a higher extent bring forth written protocols and standards (Moniz, 1992). However, any statistical association with decision outcome could not be verified. The reason might be that a lawyer is only able to contribute little to the examination of the case. As mentioned above, the Board has a duty to independently examine the case and perhaps therefore a lawyer was involved in no more than one out of twenty complaint cases. Hagihara et al. (2003) suggested that only few lawyers have sufficient experience in medical malpractice litigation, and not least in Denmark there is little tradition among lawyers to concentrate their business on health professional disciplinary proceedings.

As described in the Background section of the thesis, the Patient Complaints Board was established among other reasons in order to include non-health professionals in the assessment of patient complaints. With regard to this, the possibility had been put forward that, in connection with complaint case assessments, health professionals might discriminate in favour of their peers. It should be noted that such bias might exist both in connection with the clarification of the case and in connection with the complaint decision-making. In connection with the establishment of the Complaints Board, and the Board committee's composition, lay men and health professionals were equally represented. Anyhow, this equal representation is of little help, if the case clarification and the draft text have been produced by health professionals. However, the belief

that medical doctors typically cover for each other (see, e.g., Scocozza, 2010), could not be confirmed in the analyses. No statistically significant association between fellow professional involvement in the case clarification and the odds of discipline could be demonstrated in Study III. If anything, the relationship appeared to be rather the reverse. This might be due to shortcomings in the analyses (e.g. small sample size), yet it might alternatively suggest that the professional identity of medical doctors is much more complex; wishes about not "stabbing colleagues in the back" might be supplemented by pride about the profession (and not necessarily the health professionals) as such, and e.g. private incentives. Hence, it might likewise be claimed that in the assessment of peers, the individual medical doctor suffers from a "know-it-all" inclination. Likewise, in this regard it should be remembered that it is explicitly stated that the Board's members are under the Act on Public Administration, not least with respect to the claim for impartiality (see above page 17 and Rules of Procedure 885, paragraph 18).

Lens and van der Wal (1994) have highlighted the possible mechanism among health professionals of covering up dysfunction in a so-called "conspiracy of silence" as well. Correspondingly, a Dutch study recently demonstrated that more than one third of "Healthcare Consumer Panel" members had no confidence in the disciplinary proceedings and its independent status (Hout et al., 2009). Anyhow, international guidelines have been issued to ensure expert witness impartiality (Guidelines for the physician expert witness, 1990; Expert witness guidelines for the specialty of emergency medicine, 2010), and another Dutch study actually showed a decreased proportion of complaint cases resulting in discipline after including more lawyers and fewer fellow professionals on the disciplinary board (Hout et al., 2004). Fellow expert witnesses are not appointed in order to cover for their colleagues and, from a statistical point of view, do not appear to do so.

The Board's preparation of the case is, however, highly dependent on the initial demarcation of the complaint case provided by the complainant. From the complainant's point of view, no association could be demonstrated between involving a larger group of GPs in the complaint and the odds of disciplining at least one GP. Some would judge this satisfactory; the opposite result might have suggested an unwarranted element of "fault finding". Though, from the point of view of the GP concerned, the demarcation of the number of GPs involved, contrary to the demarcation with regard to event duration and complaint delay, was not only trivial. Hence, the study suggests that being involved together with other GPs "protects" against discipline. In other words, the instinctive sense of "relief" if realising being litigated in plurality might be substantiated in a statistical counterpart. The mechanisms might be numerous: Firstly, complaints against more health professionals might indicate "shooting from the hip". Alternatively, such litigation might reflect hardly transparent "system matters" or "blurring of responsibility". Other explanations are that the involvement of more health professionals in health care matters – through some kind of "general consensus" - might reduce the odds of malpractice.

As mentioned in the introduction (see under *The new "Patientombuddet"*), from 1 January 2011 complainants have had the opportunity to file a complaint with the Danish "Patientombuddet" with regard to concrete health care without intending named health professionals to be disciplined. In those cases, "Patientombuddet" may conclude that the health care provided by one or more unnamed health care providers was criticisable. The findings of Study III might hint towards that this new initiative, though it offers an alternative means of complaining perhaps less unpleasant for the involved parties, might have a limited impact on future decision outcome patterns.

Conclusions and perspectives

The fundamental right of patients to complain

It is a common principle stated in not least the Danish constitutional law (Grundloven, paragraph 63) that citizens be provided a means of proceeding against the authorities if he or she believes any doing related to the public sector to be wrongful. Additionally, it comes naturally that, in order to prevent e.g. abuse of power, a legal means of "user remonstration" and public monitoring should be ascertained where persons are professionally engaged with working with others. With regard to health care provision, the establishment of a specialised complaints board satisfies these purposes whilst at the same time allowing for a large volume of cases to be assessed within expert settings. Correspondingly, international obligations require patient complaints structures to be arranged; the Council of Europe recommendations have already been mentioned. It appears that these prerequisites are currently offered in connection with the Danish Act on Compensations and Complaints.

The multi-pronged effects of complaint systems

In addition to the safeguarding of patients' legal rights, the establishment of a patient complaint system might serve some other functions. It thus provides a means of influencing the standards of health care from the central level (by e.g. tightening the requirements with regard to journal keeping). This also provides a means of harmonisation of health care provision in diverse geographical areas. Such functions are especially effective when decisions concern general principles and decisions are communicated appropriately to the health care deliverers. The complaint system may serve as a basic means of immediate information source in relation to current topics of concern (e.g. regulation and requirements on cosmetic surgery from sudden

accelerated numbers of complaints on the issue). In connection with the registration of unintended adverse events (see APPENDIX 1), reports may be issued aimed at providing the health care sector with feed-back (e.g. in relation to care of particular critical illnesses).

Furthermore, the existence of a complaints (disciplinary) board might of course be claimed to work as a further incentive for health professionals to "do their best"; a general preventive measure for the broad group of health professionals and an individualised preventive measure for those complained about (and especially those who have been disciplined). As maintained by the Patientombuddet (Patientombuddets Årsberetning, Sundhedsvæsenets Disciplinærnævn, 2011), "there is no doubt that those health professionals receiving a criticism for health care provision will become more attentive in future similar situations". The incentive purpose might be claimed to be of particular importance in Denmark, because there is (practically) no risk of being sued for monetary compensation in connection with stated negligence (see APPENDIX 2).

The Danish National Board of Health continuously uses the complaints decisions for the generalised supervision of the health care sector and may even make national guidelines based upon the decision material. Additionally, the complaint case decisions are used by the Danish National Board of Health in connection with its Supervision activity (Act on Authorisation of Health Professionals, 877, chapter 3, see the Background section). Based upon complaint decisions, the Board of Health may increase its supervision ("skærpet tilsyn") with those health professionals criticised for particular serious matters which may ultimately result in issuing a specified command (e.g. concerning how to behave professionally in regard to abstaining from particular modes of treatment etc., paragraph 7, subsection 2) or revocation of the authorisation (permanently or temporarily, paragraphs 7 and 8, subsections 1). The National Board of Health

may make their decisions (about e.g. specified commands and authorisation revocation) public, for instance on its homepage (see paragraph 13).

It appears that, within the health care area, the assessment of patient complaints is intimately coupled with considering health professional disciplinary responsibility. Even though the health care provider-focused approach might be ingrained in the public debate, this direct coupling is not necessarily innate. As described in the Background section, the new Patientombuddet construction illustrates the issue by allowing complainants to file a complaint concerning the health care provided rather than against one or more named health professionals. The new construction implies a possibility of the Board to conclude that some health care provision was wrongful ("criticisable") without any concrete (that is, named) healthcare professional being blamed. It could be argued that this possibility might in some respects (e.g. from a quality improvement viewpoint) be more powerful than the individualised approach. Hence, the criticism is sustained, yet any "defensive behavioural position" of the receiver - the health professional (-s) concerned - is weakened. In this way, the health care providing unit is allowed to consider the decision from a broader point of view (involving e.g. communication issues among health care workers, communication with patients, and more general perspectives on the standards of health care provisions). Correspondingly, within other areas of the public services, complaint handling does not usually imply the element of individualised disciplinary proceedings; in connection with such case handling there might be more matter-of-fact (and less emotional) response to the content of the case. Anyhow, it remains to be determined how far such new no-name, no-blame constructions (also including e.g. the unintended adverse events report system) parallel to the disciplinary system, perform with regard to improving quality in health care.

Implications of this study

The findings of this PhD project offer insight into some statistical associations between complaint cases and complaint case discipline against GPs, respectively, and a number of measurable GP, complaint case, and process factors. It appears that the mechanisms associated with complaint cases may be complex and that the patient, GP, and process factors included in the models may only partially explain the variation in complaint cases and complaint case decisions.

Anyhow, from Study I it seems that higher professional seniority and increased pressure of business (having more patient encounters per day) increase the GP's odds of being involved in complaint cases: in connection with becoming more senior and delivering more health care provisions per time unit, the risk of the individual GP of being involved in complaint cases intensifies. The findings may have some implications. Hence, all things being equal, in connection with an ageing general practitioner population and an increasing number of health care provisions in general practice, as is currently the situation in Denmark (DADL, 2007 and 2009), an increased number of complaint cases can be expected in the years to come. This in itself will call for consideration of preventive measures - for the sake of patients, their relatives, and (not least) the GPs.

Initiatives should be introduced in order to address the increased occurrence of complaint cases during the out-of-hours services (see Study I). A clarification of the underlying reasons behind the increased amount of complaint cases pertaining to this service is needed and should permit initiatives in order to increase patients' satisfaction with the out-of-hours services and reduce the motivation for complaining. Intensified education initiatives could for example be introduced for those participating in the provision of out-of-hours care. This might improve the

current introductory courses and early supervised out-of-hours duties offered on a regional municipality level. Among additional possible initiatives are making guidelines specified for the out-of-hours services concerning certain patient encounters frequently associated with complaint cases, or regulatory initiatives for example with regard to "time of rest" between providing daytime care and out-of-hours service.

When facing a complaint case, the present study suggests decreased odds of discipline when the complainant is feeling devalued or seeks an explanation, and increased odds when the complaint motives are based on a wish for placement of responsibility or a wish for a review of the GP's competence. In other words, it seems that complaints based on feelings are less likely to result in discipline and vice versa.

Patients on their side might perhaps be even more appropriately informed about the rationale of the disciplinary system and the different ways of complaining (to e.g. the regional municipalities, see also the National Collective Agreeement, Landsoverenskomsten, chapters XIII and XIV), when dissatisfaction mostly concerns the behavioural attitude of the GP (see Study II). This might optimise the possibilities of complaints being handled by the authorities aimed for, and presumably increase patient satisfaction with the complaint system. In this connection it should be noted that while the handling of such complaints typically receives relatively little focus in the public, a substantial proportion of complaints was more or less related to dissatisfaction with the GP behavior.

Correspondingly, relatively many complaints were more or less motivated by a wish for an explanation with regard to the course of treatment. This motivation for complaining was, however, associated with decreased odds of the complaint being declared justified (resulting in a discipline). It might be hypothesised that improving GPs' skills with regard to offering patients

and their relatives appropriate explanations during the course of treatment could possibly decrease the occurrence of “unwarranted” complaints. Contrarily, “Matter-of-fact” complaints (motivated by wish for “placement of responsibility” a “review of the GP’s competence”) resulted in more discipline. Generally, it might be hypothesised that patient advice offices could play an important role when providing advice in the complaint preparation phase; in contrast to “matter-of-fact” complaints, complaints predominantly concerning the behavioural attitude of health professionals or lacking understanding with the course of treatment seem to do less well within the health professional disciplinary system and call for other procedures to be undertaken (e.g. complaining to the regional municipalities).

The odds of being disciplined increase with higher professional seniority. This might call for action being taken with regard to, e.g., education initiatives concerning doctor-patient communication. It might be hypothesised that some complaints arise because shifting standards of health care provision are not appropriately met. The fulfillment of changing demands might be more difficult among the more senior health professionals, and this problem could, due to the broadness of types of health care provision, be a particular concern in general practice. Presumably, a medical doctor's continuing professional development (and "lifelong learning") is paramount to keeping up with advances in health care, including new ways of delivering care within a broad spectrum of issues. Correspondingly, continuing medical education (e.g. mandatory for upholding contract with the health insurance) could possibly help medical doctors both maintaining and developing their knowledge, skills and professional performance in addition to continuously help making reasonable adjustments within the patient-doctor relationship.

The impact of the process factors diverged as seen from the complainant’s and the

defendant's perspective, respectively: statistically significant associations only existed between being litigated in plurality and decreased odds of discipline. Hence, the third study suggests that, a priori, some GPs seem confronted with higher odds of being disciplined when involved in a complaint case. Specific advice arrangements (provided by the public or at least by the Medical Association) might be considered appropriate for the (majority of) GPs being brought to the Board on their own. Hence, basis is provided for the very first "evidence-based" approach to stratifying disciplinary cases into "higher risk" and "lower risk" cases.

Likewise, prolonged case management generally seemed to increase the odds of discipline. Regarding the complaint case handling, future procedural initiatives might take precautionary measures against the fact that some complaint case managements are exceedingly prolonged, yet they frequently result in the GP being disciplined. Thus, specified procedures might be instituted when case handling reaches a certain point of protraction in order to both address human rights "reasonable time" requirements and conserving the preventive functions of the disciplinary system.

Analyses concerning the risk factors for receipt of complaints provide information about particular areas with "patient dissatisfaction", while analyses concerning risk factors for discipline within complaint cases rather focus on areas where the health care provision, from a professional point of view, is considered inadequate. Both perspectives, however, provide information about issues that might be – at least hypothetically - upgraded. Given the human and financial costs associated with patient complaint cases, future studies need to clarify e.g. the function in complaint cases of higher workload, the significance of job contents (not least pertaining to the out-of-hours), structural factors (including general practice organisation), and different patient categories. Additionally, studies should focus on the role of GP-patient

interactions, the impact of GP professional seniority on performance, as well as the variety of judicial mechanisms coming into play in connection with health professional disciplinary proceedings.

SUMMARY IN ENGLISH

This PhD thesis: "Patient complaint cases in general practice. Patient-, general practitioner, and process factors in decisions of the Danish Patient Complaints Board" was performed during my employment at the Research Unit of General Practice, Institute of Public Health, University of Southern Denmark, from 2008-2011. It comprises an overview of three papers, which have been submitted for publication in international peer-reviewed journals.

Background: Healthcare systems commonly give patients the opportunity to file complaints against health professionals including, e.g. GPs. There is, however, limited research concerning complaint cases against GPs and most of the existing studies are based on self-report questionnaires with low response rates. We, therefore, only have limited knowledge about the factors associated with increased odds of receiving a complaint case or being disciplined in connection with a complaint case.

Aims: Based on Danish Patient Complaints Board decisions concerning general practice the PhD project aimed to investigate:

- What are the characteristics of general practitioners in complaint cases? – *Study I*
- What types of patient complaint cases against general practitioners are likely to result in disciplinary action? – *Study II*
- Process-related factors associated with complaints board's discipline – *Study III*

Methods: All three cohort studies were based on complaints case decisions completed in 2007 from the Danish Patient Complaints Board concerning general practice. In Study I, information on involved GPs was merged with Danish National Board of Health register information about all Danish GPs with agreement with the health insurance. In Study II and Study III, complaint cases resulting in discipline were compared to those not doing so with regard to a number of GP, patient, and complaint process factors.

Results: *Study I:* With regard to daytime care, GP professional seniority (measured in terms of years since graduation) predicted higher odds of receiving a patient complaint (OR= 1.44 per 20

years of seniority, p=0.03). GPs who had more consultations per day had higher odds of receiving a complaint case (OR= 1.29 per 10 extra consultations per day, p=0.01). *Study II:* Some 22% of complaint cases resulted in discipline. A total of 41% of complaint cases concerned the out-of-hours services. Cases where the complaint motives were based on a wish for placement of responsibility (OR=2.35, p=0.01), or a wish for a review of the GP's competence (OR=1.95, p=0.02) were associated with increased odds of being disciplined. However, the odds of being disciplined decreased when the complaint was motivated by a feeling of being devalued (OR=0.39, p=0.02) or a request for an explanation (OR=0.46, p=0.01). With regard to patient and GP characteristics, higher GP professional seniority was associated with increased odds of being disciplined (OR=1.97 per 20 additional years of professional seniority, p=0.01). *Study III:* When the number of GPs involved in a complaint case increased, odds of being disciplined significantly decreased (OR=0.66 per additional GP involved, p<0.01). Contrarily, from the complainant point of view, no association could be detected between complaining against a plurality of GPs and the odds of at least one GP being disciplined. From both perspectives, however, longer case management duration was associated with higher odds of discipline (OR=1.04 per additional month, p=0.01). The mean delay from the event concerned until filing a complaint was 4 months and the mean case management duration was 14 months.

Conclusion: The results suggest that GPs with heavier workload are at increased odds of receiving a complaint case. Also, more senior GPs are both at increased odds of receiving complaint cases, and when, eventually, they receive one, they are also at increased odds of being disciplined. When receiving a complaint where more health professionals are involved, the odds of being disciplined decrease. Contrarily, case management elongation seems associated with increased odds of being disciplined. These apparent risk factors, in addition to suggesting potential areas for quality improvement, may indicate areas for future research, e.g. concerning the impact of pressure of business and communication on the patient-doctor relationship, the association between complaint cases and professional seniority, and the legal mechanisms underlying the complaints board decisions on discipline.

DANSK RESUME

Denne ph.d.-afhandling "Patientklagesager i almen praksis. Patient-, praktiserende læge-, og klageprocesfaktorer i klagesagsafgørelser" består af en oversigt og tre artikler, som er indsendt til publikation i internationale tidsskrifter. Arbejdet er udført i forbindelse med min ansættelse ved Forskningsenheden for Almen Praksis, Institut for Sundhedstjenesteforskning, Syddansk Universitet, i perioden 2008-2011.

Baggrund: Det er almindeligt at nationale sundhedsvæsener har indrettet systemer for håndtering af patientklager over sundhedsudøvere, herunder praktiserende læger. Der findes imidlertid kun sparsom forskning omkring klagesagerne i almen praksis, og de eksisterende studier er fortrinsvis udført på spørgeskemamateriale med lave svarprocenter. Der er derfor begrænset viden om, hvilke faktorer som er forbundet med at få en klagesag, eller for at sagen ender med, at lægen får en påtale.

Formål: Formålet med ph.d.-projektet var at belyse:

- Hvad karakteriserer praktiserende læger i patientklagesager? - *Studie I*
- Hvad karakteriserer patientklagesager mod praktiserende læger som resulterer i en påtale?– *Studie II*
- Procesrelaterede faktorer som er associeret med klagenævnsafgørelser med påtale – *Studie III*

Metoder: Alle tre kohortestudier var baseret på alle afgørelser vedrørende alment praktiserende læger fra Sundhedsvæsenets Patientklagenævn i et år (2007). I Studie I blev data vedrørende de indklagede praktiserende læger koblet med landsdækkende registerdata for alle danske praktiserende læger. I Studie II og III blev de klagesager, som resulterede i påtale, sammenlignet med dem, som ikke gjorde, med hensyn til et antal læge-, patient-, og procesfaktorer.

Resultater: *Studie I:* Praktiserende læger med lang erfaring (målt som antal år siden kandidateksamen) havde statistisk øgede odds for at få en patientklagesag vedrørende arbejde i dagtiden (44% øgede odds for at få en klagesag over et år for en 20 år mere senior praktiserende læge, p=0,03). Ligeså havde læger, som havde mange konsultationer per dag, en statistisk øget klageforekomst (OR= 1,29 per 10 ekstra konsultationer per dag, p=0,01). *Studie II:* 22% af klagesagerne resulterede i påtale. 41% af klagesagerne omhandlede vagtlægeydelser. Odds for, at lægen fik en påtale, var øget, hvis klagen var motiveret i et ønske om ansvarsplacering

(OR=2,35, p=0,01), eller et ønske om en vurdering af den praktiserende læges professionelle formåen (OR=1,95, p=0,02). Omvendt var odds nedsat, når klagen var motiveret i, at klager følte sig devalueret af lægen (OR=0,39, p=0,02) eller blot ønskede en forklaring på behandlingsforløbet (OR=0,46, p=0,01). Praktiserende læger med lang erfaring havde øgede odds for en påtale, når de havde fået en klagesag (OR=1,97 per 20 ekstra år, p=0,01). *Studie III:* Hvis flere sundhedspersoner var indklaget i samme klagesag, var odds for at få en påtale, set fra den enkelte involverede praktiserende læges synsvinkel, signifikant mindre (OR=0,66 per ekstra involverede praktiserende læge, p<0,01). For den samlede klagesag var der ingen statistisk signifikant sammenhæng mellem inddragelsen af mere end én praktiserende læge og odds for, at mindst én læge fik en påtale. Fra begge synsvinkler var der statistisk øgede odds for påtale ved lang klagebehandlingstid (OR=1,04 per ekstra måned, p=0,01). Den gennemsnitlige forsinkelse fra klagehændelsen til klage var 4 måneder, og den gennemsnitlige klagesagsvarighed var 14 måneder.

Konklusion: Resultaterne peger på, at "travle" læger har øget forekomst af klagesager. Ligeså synes mere seniore praktiserende læger at få flere klagesager, og når de får en klagesag, er odds for at få en påtale også signifikant forøget. Hvis flere sundhedspersoner er involveret i en klagesag, er odds for at den enkelte får påtale mindre, medens længere klagesagsvarighed omvendt er forbundet med øgede odds for påtale. De forannævnte faktorer indikerer både fokusområder for kvalitetsudviklingsinitiativer og for fremtidige studier. Eksempelvis bør kommende studier belyse betydningen af travlhed og kommunikation i forbindelse med opretholdelsen af læge-patientforholdet, baggrunden for den tilsyneladende sammenhæng mellem klagesager og højere kandidatalder, og det spektrum af juridiske mekanismer, som ligger til grund for tildeling af påtaler.

References

Act on Authorisation of Health Professionals 877, 04/08/2011

Act on Central Administration 182, 23/06/1932

Act on Central Administration 397, 10/06/1987

Act on Central Administration 503, 30/06/1993

Act on Central Administration 790, 10/09/2002

Act on Central Administration 428, 10/06/2003

Act on Clinical Dental Technicians 100, 14/03/1979

Act on Complaints and Compensation 547, 24/06/2005

Act on Complaints and Compensations 706, 25/06/2010

Act on Dentists 276, 26/05/1976

Act on Health Care 913, 13/07/2010 ("Sundhedsloven")

Act on Health Insurance 490, 21/07/1986 ("Sygesikringsloven")

Act on Liability for Damages 885, 20/09/2005 ("Erstatningsansvarsloven")

Act on Medical Doctors, 426 19/09/1976 ("Lægeloven")

Act on Midwives 671, 13/12/1978

Act on Nurses 66, 27/02/1979

Act on Occupational therapists and Physiotherapists 154, 08/05/1968

Act on Patient Safety 429, 10/06/2003

Act on Podiatrists 142, 26/04/1972

Act on Public Administration 572, 19/12/1985

Act on Ethic Assessment of Biomedical Scientific Projects 593, 14/06/2011 ("Lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter")

Beckman HB, Markakis KM, Suchman AL, Frankel RM. The doctor-patient relationship and malpractice. Lessons from plaintiff depositions. Arch Intern Med 1994;154:1365-70.

Bill 1986/ 1 LSF 58, for revision of Act on Central Administration

Bill 2002/ 1 LSF 223, for revision of Act on Central Administration

Bill 2002/1 LSF 224 on the Patient Safety Act

Bill 2004/2 LF 75, for Act on Complaints and Compensation in the Health Care Sector

Bill 2004/2 LSF 75, Proposal for Act on Complaints and Compensation in the Health Care Sector

Bill 2009/1 LSF 130, Proposal for revision of Act on Complaints and Compensation

Bismark M, Dauer EA. Motivations for Medico-Legal Action. Journal of Legal Medicine

2006;27:55-70

Bismark M, Dauer E, Paterson R, Studdert D. Accountability sought by patients following adverse events from medical care: the New Zealand experience. CMAJ 2006;175:889-894

Bowling A., Barber J., Morris R., and Ebrahim S.Do perceptions of neighbourhood environment influence health? Baseline findings from a British survey of aging.J Epidemiol Community Health 2006;60:476-483

Bratland SZ, Hunskar S. [Medico-legal assessments of complaints against general practitioners]. Tidsskr Nor Laegeforen 2006;126:166-169

Charter of the United Nations and Statute of the International Court of Justice, United Nations, San Fransisco, 1945

Clay SW, Conatser RR. Characteristics of physicians disciplined by the State Medical Board of Ohio. J Am Osteopath Assoc 2003;103:81-88

Council of Europe: "the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine", Oviedo, 4.IV.1997. Ratified by the Danish parliament 11 May, 1999, BSV 5

Council of Europe Recommendations: Patients Role-recommendations and Recommendation (2000)5 of the Committee of Ministers to member states. On the development of structures for citizen and patient participation in the decision-making process affecting health care"

Cunningham W, Crump R, Tomlin A. The characteristics of doctors receiving medical complaints: a cross-sectional survey of doctors in New Zealand. N Z Med J 2003;116:1-9

Cunningham W, Wilson H. Complaints, shame and defensive medicine. BMJ Qual Saf

2011;20:449-452

DADL. Aktivitet og økonomi i almen praksis i dagtid og vagttid 2000 til 2008. 6-5-2009

DADL, Praksistælling, Lægeforeningen, 2007

Dahlberg–Larsen J. Retssociologiske indslag i afhandlinger med andet primært sigte. In Juridisk Forskning. Jurist- og Økonomforbundets Forlag, 2002

Danish National Board of Health. The General Practitioner Register 2011. Available from: URL: www.sst.dk

Expert witness guidelines for the specialty of emergency medicine. American College of Emergency Physicians (ACEP). Ann Emerg Med 2010;56:449-450

Folketingets Ombudsmand. Egen drift undersøgelse af 60 sager fra Sundhedsvæsenets Patientklagenævn. J. nr. 1997-3492-980, EDP 2001.807

Fileni A, Magnavita N. A 12-year follow-up study of malpractice claims against radiologists in Italy. Radiol Med 2006 Oct;111(7):1009-1022

Frederiksen H, Kragstrup J, Dehlholm-Lambertsen G. It's all about recognition! Qualitative study of the value of interpersonal continuity in general practice. BMC Family Practice 2009;10:47

General Comment No. 14 (2000). Substantial issues arising in the implementation of the international covenant on economic, social, and cultural rights. The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights)

General Medical Council Annual Statistics, 2009 (http://www.gmc-uk.org)

Germer P. Indledning til Folkeretten. 2. Udgave, Jurist- og Økonomforbundets Forlag, 1996

”Grundloven”, The Danish Constitutional Act, Act 169, 05/06/1953

Guidelines for the physician expert witness. American College of Physicians. Ann Intern Med 1990;113:789

Hagihara A, Nishi M, Abe E, Nobutomo K. The structure of medical malpractice decision-making in Japan. J Law Med 2003;11:162-184

Hartlev M. Fortrolighed i Sundhedsretten – et patientretligt perspektiv. Forlaget Thomson A/S, København, 2005

Heje HN, Vedsted P, Sokolowski I, Olesen F. Doctor and practice characteristics associated with differences in patient evaluations of general practice. BMC Health Serv Res 2007 Apr 3;7:46

Heje HN, Vedsted P, Sokolowski I, Olesen F. Patient characteristics associated with differences in patients' evaluation of their general practitioner. BMC Health Serv Res 2008 Aug 20;8:178

Heje HN, Olesen F, Vedsted P. (a)[Patients' assessment of their general practitioners--the significance of patient characteristics. General results from the DanPEP--part I]. [Article in Danish]. Ugeskr Laeger 2010 Apr 12;172(15):1105-1112

Heje HN, Olesen F, Vedsted P. (b) [Patients' assessment of their general practitioners--the significance of physician gender and age]. [Article in Danish] Ugeskr Laeger. 2010 Apr 12;172(15):1112-1118

Heje HN, Olesen F, Vedsted P. (c) [Patients' assessment of general practitioners.Association with type of practice].[Article in Danish].Ugeskr Laeger 2010 Apr 12;172(15):1119-1126

Hout FA, Cuperus-Bosma JM, de Peuter OR, Hubben JH, van der Wal G. [No improvement of disciplinary jurisprudence since the implementation of the Individual Health Care Professions Act (IHCP Act)]. Ned Tijdschr Geneeskd 2004;148:135-139

Hout E, Friele R, Legemaate J. [The citizen as plaintiff in disciplinary procedures, lack of complaints possibly due to poor knowledge of the disciplinary system for health care]. Ned Tijdschr Geneeskd 2009;153:A548

Huibers LA, Moth G, Bondevik GT, Kersnik J, Huber CA, Christensen MB, Leutgeb R, Casado AM, Remmen R, Wensing M. Diagnostic scope in out-of-hours primary care services in eight European countries: an observational study. BMC Fam Pract 2011 May 13;12:30

International Covenant on Economic, Social and Cultural Rights (Adopted by the General Assembly of the United Nations on 16 December 1966)

Irvine D. A short history of the General Medical Council. Medical Education 2006;40:202-211

Jensen CO, Crone F. Praktiserende Lægers Organisation Praksisundersøgelse. Tekst-rapport, Megafon, November 2008

Johansson A, Lagerstedt K, Asplund K. Mishaps in the management of stroke: A review of 214 complaints to a medical responsibility board. Cerebrovascular Diseases 2004;18:16-21

Jonsson PM, Øvretveit J. Patient claims and complaints data for improving patient safety. Int J Health Care QualAssur 2008;21:60-74

Jung HP, Baerveldt C, Olesen F, Grol R, Wensing M. Patient characteristics as predictors of primary health care preferences: a systematic literature analysis. Health Expect 2003 Jun;6(2):160-181

Kohatsu ND, Gould D, Ross LK, Fox PJ. Characteristics associated with physician discipline: A

case-control study. Arch Intern Med 2004;164:653-658

Lag 1998:1656, om patientnämndsverksamhet m.m. (Swedish Act on Patient Complaints Board Activity)

Landsoverenskomsten, the National Collective Agreement, Regionernes Lønnings- og Takstnævn og Praktiserende Lægers Organisation Af 03-06-1991, senest ændret ved aftale af 21-12-2010

Larsen K. Kompagniskabspraksis vinder stærkt frem. Ugeskr Læger 2010;172:3073

Lens P, van der Wal G. [A study of dysfunction in specialists]. Ned Tijdschr Geneeskd 1994;138:1127-1131

Lydiatt DD. Cancer of the oral cavity and medical malpractice. Laryngoscope 2002 May;112(5):816-819

Lyngsø AM, Backer V, Gottlieb V, Nybo B, Østergaard MS, Frølich A. Early detection of COPD in primary care -The Copenhagen COPD Screening Project.BMC Public Health 2010; 10: 524

Lægeforeningens Vejviser. København: Lægeforeningens forlag; 2007

Martin-Bates C, Agass M, Tulloch A J. General practice workload during normal working hours in training and non-training practices. Brit J Gen Pract 1993;43:413-416

Medical Act 1983 26th July 1983 [with amendments]

Ministerial Order 5, 14/01/1976, Bekendtgørelse af international convention af 16. December 1966 om økonomiske, sociale og kulturelle rettigheder

Ministerial Order 8, 22/11/1945. Bekendtgørelse angående de Forenede Nationers Pagt med tilhørende Status for den Mellemfolkelige Domstol, undertegnet I San Fransisco, 26. Juni, 1945

Ministerial Order 65, 11/12/2000 af Europarådets Konvention af 4. April 1997 om Menneskerettigheder og Biomedicin, Oviedo

Ministerial Order 1248, 24/10/2007 concerning Specialization of Medical Doctors

Ministerial Order 1256, 25/10/2007 concerning Basic Clinical Education of Medical Doctors

Ministerial Order 814, 29/06/2010 concerning University Education

Ministerial Order 1448, 15/12/2010, on Non Authorised Persons within the Health Care Sector under Inspection by the Disciplinary Board

Moniz DM. The legal danger of written protocols and standards of practice. Nurse Pract 1992;17:58-60

Morrison J, Wickersham P. Physicians disciplined by a state medical board. JAMA 1998;279:1889-1893

Maagaard R. Organisation og drift af en almen praksis. I "Almen medicin", 2. udgave, Munksgaard, København, 2007

Nash L, Daly M, Johnson M, Coulston C, Tennant C, van EE, et al. Personality, gender and medico-legal matters in medical practice. Australasias Psychiatry 2009;17:19-24

Olsen KR, Højmark TH., Hansen DG. [Sammenhæng mellem produktivitet, listestørrelse, patient- og praksiskarakteristika I almen praksis] (Danish). Ugeskr Læger 2010;172:1192-1196

Patient Safety Act (Swedish Lag 2010:659, om patientsäkerhet)

Patientforsikringens Årsberetning 2007.Patientforsikringen, København. Available at: http://www.patientforsikringen.dk/da/Udgivelser-og-tal/~/media/Files/Aarsberetninger/aarsberetning07.ashx

Patientombuddets Årsberetning, 2011, Sundhedsvæsenets Disciplinærnævn (see www.patientombuddet.dk)

Patientombuddets Årsberetning, 2011, Dansk Patientsikkerhedsdatabase (see www.patientombuddet.dk)

Pedersen KM, Andersen JS, and Søndergaard J. General practice and primary health care in Denmark. JABFM 2012: 25;34-38

Rasmussen J. Det Iatrogene Ansvar, FADL, Januar, 1988

Retslægerådet. Årsberetninger: Annual Reports 1997 and 2007

Rules of Procedure for the Patients Complaints Board 257, 19/04/1988

Rules of Procedure for the Patients Complaints Board 349, 23/05/1990

Rules of Procedure for the Patients Complaints Board 631, 05/07/1994

Rules of Procedure for the Patients Complaints Board 885, 04/11/2003

Rules of Procedure for the Disciplinary Board 1447, 15/12/2010

Rules of Procedure concerning Disclosure of Decisions 1445, 15/12-2010

Scocozza L. I “Nordjyske”, 22. august 2010: Læger på kanten af loven

Segest E. Patients' complaints: the disciplinary system regarding evaluation of physicians' conduct. Med Sci Law 1993;33:41-46

Soler JK, Yaman H, Esteva M, Dobbs F, Asenova RS, Kati-ç M, et al. Burnout in European family doctors: the EGPRN study. Family Practice 2008;25:245-265

Stolper E, Legemaate J, Dinant GJ. How do disciplinary tribunals evaluate the "gut feelings" of doctors? An analysis of Dutch tribunal decisions, 2000-2008. J Law Med 2010;18:68-75

Stokstad I, Eskerud J, Jordal H, Vigen T. [Complaints about primary care physicians]. Tidsskr. Nor Laegeforen 1993 Mar 10;113(7):863-866

Sundhedsvæsenets Patientklagenævn, Annual report 94/95, Copenhagen: Danish Patient Complaints Board, 1994/1995

Sundhedsvæsenets Patientklagenævn. [Statistical information]. Copenhagen: Danish Patient Complaints Board, 2007

Sundhedsvæsenets Patientklagenævn. [Statistical information]. Copenhagen: Danish Patient Complaints Board, 1997-2006

Sundhedsvæsenets Patientklagenævn. Annual Report [Årsberetning]. Copenhagen: Danish Patient Complaints Board, 2007

The Danish Health Information Database. www.medcom.dk. 2010

The Danish Ministry of Welfare Database. www.noegletal.dk. 2010

The Danish Ministry of Welfare. [Municipal equalization and general subsidies]. Kommunal

udligning og generelle tilskud. 2009

Tuchtcolleges voor de Gezondheidszorg, Jaarverslag, 2010. Annual report of the Health Professionals' Disciplinary Board

Universal Declaration of Human Rights: Declaration adopted by the United Nations General Assembly, 1948

van den Berg M, de Bakker D, Spreeuwenberg P, Westert G, Braspenning J, van der Zee J, et al. Labour intensity of guidelines may have a greater effect on adherence than GPs' workload. BMC Family Practice 2009;10:74

Vienna Convention on the Law of Treaties. Done at Vienna on 23 May 1969. Entered into force on 27 January 1980

Wet geneeskundige behandelingsovereenkomst, Stb. 1994, 837. Dutch Act on Medical Treatment

Wet van 29 mei 1995, houdende regels ter zake van de behandeling van klachten van cliënten van zorgaanbieders op het terrein van de maatschappelijke zorg en gezondheidszorg. Dutch Act on Complaints by Clients of the Health Care Sector

Wet van 11 november 1993, houdende regelen inzake beroepen op het gebied van de individuele gezondheidszorg, 655. Dutch Individual Health Care Professions Act

White Paper 866, 1979 (Betænkning fra det af indenrigsministeriet nedsatte udvalg vedrørende behandling af klager over lægers og andre medicinalpersoners patientbehandling, nr. 866, Januar, 1979)

White Paper 2004/2 BTL 75 (Betænkning afgivet af Sundhedsudvalget den 7. juni 2005, over Forslag til lov om klage- og erstatningsadgang inden for sundhedsvæsenet)

APPENDIX 1 The reporting of unintended adverse events

In connection with the continuing discussions about the patient complaints system and the need for quality improvements and learning from errors in connection with health care provision, the need for a no-name, no-blame system naturally comes into question. On 1 January 2004 the Danish Act on Patient Safety 429, 10/06/2003 became effective. The purpose of the reporting of adverse events is to improve patient safety by preventing other patients being injured by a similar incident (see also Bill 2002/1 LSF 224 on the Patient Safety Act). In this regard preventive measures have been established in order to disseminate information gathered from adverse event registrations both locally, regionally and nationally.

Currently, the reporting of adverse events is regulated in Act on Health Care (Act 913, 13/07/2010), chapter 61 concerning "Patient Safety". Ministerial Orders have been issued for the purpose of comprehensively regulating the system (see Ministerial Order 1, 03/01/2011). According to paragraph 198, subsection 4, an unintended adverse event is "..an event that occurs in connection with health care, including prehospital work, or in connection with the administration of - and information about - drugs. Adverse events include a priori known and unknown events and errors, which are not due to the patient's illness, and are either injurious or could have been injurious, but were averted or otherwise did not occur due to other circumstances".

As introductorily mentioned, the system is a no name no blame system; reporting of adverse events is free of sanctions. Hence, according to paragraph 201 "The reporting person cannot because of his reporting be subjected to disciplinary investigations, any actions by the employer, reactions from the National Board of Health or criminal investigation and criminal penalties by the courts". Information about the reporter is deleted before the report is forwarded

to Patientombuddet.

Healthcare professionals have a duty to report adverse events (se paragraph 198). This duty also concerns staff acting on the responsibilities of health care professionals (e.g. medical secretaries who take blood samples), ambulance staff, pharmacists and pharmacy staff. Patients and their relatives can also report adverse events. Both adverse events that occur in connection with health professions that the health professional is involved in, or becomes aware of (concerning others), must be reported. The reporting must be done as soon as possible, and within 7 days of the point in time when the incident came into the reporter's attention (Ministerial Order 1, paragraph 3).

The duty to report also concerns GPs in those instances associated with infections, injuries from medical equipment, and transfer of patients between different health care sectors (such as when the patient is discharged from hospital to nursing home or should be followed up by the GP; Ministerial Order 1, paragraph 4). There is a duty to report also if any adverse event causes a patient death or permanent loss of functions, and when medical treatment or hospitalisation is needed.

Dependent upon the location of the adverse event, it is reported either to the regional county councils, the municipalities, or private hospitals. After the reporting, the report is analysed. Reports are sent to Patientombuddet (Act 913, paragraph 199). Information about individuals is confidential (paragraph 200). Any contact information provided is deleted before the report is sent to Patientombuddet. Still, it is possible to report anonymously. Knowledge from the reportings is intended to be disseminated nationally in order to contribute to for example changes in treatment, better instructions, and enhanced attention information. In some instances the analysis of adverse events may result in issuing "Warning messages" with regard to e.g.

errors in medical equipments or medications likely to be mixed up with other medications etc.

The number of unintended adverse event reports has increased considerably the last years. During 2011, there were approx. 100,000 reports concerning unintended adverse events to the events database. Approximately 80,000 reports were concluded and about two-thirds of events did not result in any injury, while approximately one in twenty resulted in serious injury or patient death (Patientombuddets Årsberetning, Dansk Patientsikkerhedsdatabase, 2011).

APPENDIX 2 The Danish Patient Compensation System

In Denmark, the health care compensation system is separated from the disciplinary system. In 1992, the first Danish Act on Patient Compensations (367, 06/06/1991) became effective. From then onwards, claims for compensation due to injuries caused by health care were considered by the Patient Insurance Association according to a "no fault" structure; patients did not have to (and mostly were precluded from) going to the courts for seeking compensation pertaining to the provision of health care. There is no fee for patients for filing a claim for compensation with the Patient Insurance Association.

Currently, the system is regulated according to the Danish Act on Complaints and Compensations (1113, 07/11/2011). According to the Danish Act on Complaints and Compensations, both injuries due to health care provided in private hospital, public hospitals, the primary health care sector (general practice, physiotherapists, chiropractors etc.) are covered (i.e. all health care provided by authorised health professionals is covered by the publicly funded compensation scheme) (Chapter 3, paragraph 19).

The Act on Complaints and Compensations explicates a number of prerequisites for awarding compensation (Chapter 3, paragraph 20). Patients are entitled to compensation if injuries have been caused which could have been avoided, taking into consideration that an experienced specialist in the same situation would have acted differently. Likewise, the compensation scheme covers injuries due to failure or malfunction of technical devices etc. Furthermore, injuries which could have been avoided by another equally effective treatment, technique or method are covered, and finally, the compensation scheme covers injuries which are only very rarely and seriously occurring in relation to the illness for which the patient is receiving a treatment (e.g. secondary infections). The injuries must exceed what can be

reasonably expected and should be tolerated. Physical drug injuries are covered when the injury exceeds what might be reasonably expected and should be tolerated (Chapter 4, paragraph 38, paragraph 43). There is a lower limit of compensation claims of DKK 10,000 (DKK 3,000 in case of drug injuries).

Briefly described, the case handling is as following: Any claim for compensation must be filed within 3 years after becoming aware of the injury, yet an absolute limitation period of 10 years applies from the date of injury (paragraph 59). After receipt of the compensation claim from the patient concerned or a relative, the claim is investigated by the Patient Assurance Association. Subsequently, the claim is sent to the health care provider concerned (the hospital, general practice etc. where the injury is claimed to have occurred). The health care provider is asked to write a report and return all relevant material (medical charts etc.). If the patient has received health care at multiple locations, information is gathered from all the involved providers.

The claimant is given the opportunity to submit remarks regarding the case material gathered, before the association's lawyers complete the legal case processing. It is considered whether an injury has occurred and whether there are grounds for awarding compensation. In this regard, the case will typically be evaluated at a meeting with medical doctors where the cases are discussed and a decision is made. In some instances, the medical doctor may request for instance a specialist medical doctor statement. In case the patient is entitled to compensation, the amount of compensation is calculated in accordance with the Danish Act on Liability for Damages (Act 885, 20/09/2005). If the claimant is unsatisfied with the decision, an appeal can be lodged with the Patient Injury Appeals Board, which can increase a compensation award, reduce a compensation award, or revoke a compensation that has been already paid (paragraphs 34 to 37).

Finally, the decisions of the Patient Injury Appeals Board can be brought to court (paragraph 36). The average case management time of the Patient Insurance Association is 8 months from the time of receipt of the claim until a decision is made (Patientforsikringens Årsberetning, 2007).

Compensation awards are covered by the Patient Insurance Association with no regress to the health professionals concerned, unless the health professional has committed a grossly negligent or intended act (paragraph 27, Act on Complaints and Compensations). Danish medical doctors commonly take out private insurance against the risk of regress in connection with e.g. gross negligence and so are not at risk of compensation claims (unless the medical doctor deliberately committed the patient injury concerned).

APPENDIX 3 The concepts of "Odds" and "Odds Ratios"

In the following, the concept of "Odds" and "Odds Ratios" are explained. Suppose that 92 out of 401 male GPs receiving a complaint case are disciplined and 34 of 170 female GPs (see study II):

	Gender		**Total**
Disciplined	Male	Female	
0	309	136	445
1	92	34	126
Total	401	170	571

The probabilities of male GPs being disciplined are

$p = 92/401 = 0.229$, and for not being disciplined: $q = 1 - 0.229 = 0.771$

The probabilities of female GPs being disciplined are

$p = 34/170 = 0.2$ $q = (136/170) = 1 - 0.2 = 0.8$

Then, the odds of being disciplined for male and female GPs are as follows

Odds (male GP) = $p/q = (92/401)/(309/401) = 92/309 = 0.2977$

Odds (female GP) = $(34/170)/(136/170) = 34/136 = 0.25$

That is: the odds for males are 92 to 309, and the odds for females are 34 to 136.

Now, the odds *ratio,* OR, for being disciplined can be calculated as

$$\text{OR} = (34/136)/(92/309) = (34*309)/(136*92) = 0.25/0.2977 = \quad 0.840$$

In other words, the ratio of the odds for females to the odds for males is 0.840 and, hence, the odds for female GPs are about 16% less than the odds for male GPs. The 95% confidence interval of the OR will be from 0.54 to 1.31 (that is: $e^{\ln(0.840)+-1.96*\text{SE}}$, where $\text{SE} = ((1/309) + (1/136) + (1/92) + (1/34))^{-0.5} \sim 0.226$). For the result to be statistically significant, the 95% confidence interval should not overlap 1 (that is: the odds ratios within the confidence interval should all be >1 or <1, the "no difference" point). Hence, though we found OR for female general practitioners to be 0.840 for being disciplined in connection with a complaint case, this apparent decrease is not statistically significant.

Odds Ratios and (Relative) Risks

Odds Ratios and (Relative) Risk (or Risk Ratio, RR) both compare the likelihood of an event between groups.

The Relative Risk compares the *probability* of discipline in each group rather than the *odds*. For females, the probability of discipline is 20% (34/170). For males, the probability is 23% (92/401). Hence, the relative risk of discipline for females is RR=0.87 (0.20/0.23). As mentioned above, the corresponding OR was 0.84. The two measures are quite alike, - which is often the case when the event (here discipline) is relatively uncommon (in this case in about one

fifth). Although there is a small difference, both measurements suggest that females are less likely to be disciplined in connection with a complaint case.

Study I

What are the characteristics of general practitioners in complaint cases?

(Submitted to Scandinavian Journal of Public Health, September 2011)

SØREN BIRKELAND, RENE dePONT CHRISTENSEN, NIELS DAMSBO & JAKOB KRAGSTRUP

Research Unit of General Practice, University of Southern Denmark, Odense, Denmark

Correspondence

Søren Birkeland, Research Unit of General Practice, Institute of Public Health, University of Southern Denmark, J.B. Winsløws Vej 9, DK-5000 Odense C, Denmark. E-mail sbirkeland@health.sdu.dk

Word count: 2068 excluding key points, abstract, tables, reference list

Abstract

Purpose: Limited knowledge exists about factors increasing the risk of general practitioners becoming involved in a complaint case or getting disciplined in connection with a complaint case. The present study aims to identify the general practitioner and practice characteristics associated with complaint cases.

Methods: In a register-based cohort study the Danish Patient Complaints Board's decisions in 2007 concerning general practice were examined. Information on the involved general practitioners was extracted and linked to Danish National register data on all general practitioners. Characteristics of general practitioners receiving a decision and those disciplined were compared with the characteristics of those not receiving a decision and those not being disciplined.

Results: With regard to complaints concerning daytime services, the professional seniority of the general practitioner was positively associated with the risk of receiving a complaint decision during one year (OR= 1.44 per 20 years of seniority, p=0.03). Also, general practitioners with many consultations per day had a higher risk of receiving a decision (OR= 1.29 per 10 extra consultations per day, p=0.01). No significant association could be demonstrated between being disciplined and general practitioner and practice characteristics.

Conclusions: Higher professional seniority and having more consultations per day seemed to be associated with an increased risk of complaints. Studies indicating a higher risk of complaint cases among male general practitioners may suffer from not having adjusted for complaints involving daytime vs out-of-hours services. The possible relationship between professional seniority, rate of consultations, and complaint cases merits further studies to clarify the impact of professional seniority and workload on performance.

Key Words: *General practice, jurisprudence, malpractice, patient complaints, practice, management*

Introduction

Most healthcare systems give patients the opportunity to file complaints, and in a number of countries special patient complaint boards have been organized [1-4]. The systems may differ and in some countries separate systems have been developed for financial compensation of patients. It is, however, a common feature that the complaint boards have the right to impose disciplinary sanctions (most often critique) on the health staff providing the service subject of complaint.

Limited knowledge exists about the characteristic of general practitioners (GPs) involved in complaint cases. We found no studies concerning the predictors of disciplinary sanctions among GPs specifically, but studies involving all medical specialties [5-7] have shown an increased risk of receiving a disciplinary sanction among male doctors. Two studies also suggested an increased risk of sanctions among senior doctors [5,6], but one contradicting study suggested a decreased risk [7].

The aim of the present study based on Danish registers was to analyze the characteristics of GPs receiving a complaint or being disciplined by the complaints board.

Material and methods

Design

A register-based cohort study was designed in order to compare GPs receiving a decision from the complaints board during a one-year period with all other Danish GPs. The cohort was defined as GPs providing daytime services on 2 January 2006 and identified by means of the GP Register of the Danish National Board of Health [8]. GPs receiving a complaint were identified manually by reading the files of all GP-related patient complaints finalized by the Danish Patient Complaints Board in 2007.

Setting

Denmark has a comprehensive healthcare system, which is funded through tax contributions. Danish citizens are entitled to free medical care and can choose their own GP within the municipality. Most citizens choose one of the GPs listed on the municipality's list and it is possible to change GP according to preferences. In 2006, more than 99% of the Danish population was listed with one of 3,765 GPs working in approximately 2,200 local single-handed or partnership practices. GPs provide basic health care including examinations, routine treatment and health care advice and also act as gatekeepers in relation to the secondary healthcare system (practicing specialists and hospitals). GPs are responsible for the care of all registered patients at all hours. The GPs within a region collaborate about the out-of-hours services, where the GPs on call answer emergency calls and make home visits. If dissatisfied with health professionals (e.g. GPs), patients or their relatives can decide to file a written complaint. There is no fee for filing a complaint. A complaints board (until 2010 designated the "Patient Complaints Board", now: "Patientombuddet") handles complaints about professionals who are authorized by the National Board of Health. At the initial stage, the board's secretariat clarifies the issues of the complaint with the assistance of the regional medical health officers ("Embedslæger"). In this connection, the involved health professionals are obliged to provide any information to be used for the clarification of the case. Subsequently, the case is typically evaluated by one of the board's consultants and a proposal is produced for the decision which is finally made by the board. The board is chaired by a judge and in addition comprises two health professionals and two laymen representing the health care users and the hospital owners, respectively. The board may impose disciplinary sanctions. The most commonly used sanction is discipline (reprimand or professional conduct disputed). Additional possible sanctions are discipline with injunction, or

bringing the complaint case for the prosecuting authority. The patient complaint system is unrelated to the compensation system.

Data collection

Complaint cases concerning treatment in general practice and completed by the complaints board in 2007 were retrieved from the files of the board and reviewed. The identity of all GPs receiving a complaint about daytime services was noted together with the board's decision (discipline or no discipline).

Information about the characteristics of GPs (2006) were obtained from the GP Register of the Danish National Board of Health, the Danish Health Information database [9] and the Danish Ministry of Welfare database [10] and included: GP and practice identification codes, GP *gender*, *professional seniority* (years from graduation), and *practice size* in terms of number of GPs working together in the practice. The practice number of consultations per three months and *practice size* were used to calculate the *GP output per day*. The general practice location was described according to three municipality level variables: *socioeconomic index, senior citizen proportion*, and *level of urbanization*. The *socioeconomic index* variable is an index referring to relative municipal expenditures and is based upon a number of socioeconomic parameters (e.g. proportions of unemployed citizens aged 25-59, psychiatric patients, low-income groups) [10]. This measure has been commonly used as standard measure for the state and municipalities in Denmark [11]. The *senior citizen proportion* variable is defined as the percentage of the municipality population aged +65 years [10]. Finally, the *level of urbanization* variable refers to the percentage of the number of inhabitants in towns with at least 200 inhabitants of the total number of inhabitants in the municipality as of 1 January [10].

Analysis

For the main analysis we only included cases involving daytime services, because no national information about GPs providing out-of-hours services is available. Hence, it was not possible to decide what fraction of providers that was at risk of receiving an out-of-hours patient complaint. Data were analyzedby means of logistic regression using STATA®. The dependent variable in the model distinguished those who received a complaints decision or a decision on discipline from those who did not. Odds ratios (ORs) of receiving a complaints decision or being disciplined with regard to the characteristics (independent variables) mentioned above were estimated. A probability level of $p< 0.05$ was considered statistically significant.

Results

In total, the cohort comprised 3,765 Danish GPs (65% male) included in the Danish National Board of Health Register. The average *professional seniority* of participating GPs was 25.5 years (range 2.8-56 years).

The board completed the handling of 419 complaints against GPs in 2007, 265 concerned daytime and 154 out-of-hours services. The associations between receiving a complaints case concerning daytime services and GP and practice characteristics are shown in Table I.

Table I. Receipt of a complaint case and association with general practitioner and practice characteristics

		OR	P	95% Confidence Interval	
General practitioner characteristics					
Gender	Female	1			
	Male	0.97	0.82	0.73	1.29
Professional seniority[1]		1.44	0.03	1.04	1.98
GP output per day[2]		1.29	0.01	1.07	1.54
Practice and practice environment characteristics					
Practice size		0.99	0.86	0.91	1.08
Socioeconomic index		1.61	0.16	0.83	3.13
Senior citizen proportion		0.99	0.76	0.93	1.05
Level of urbanisation		0.99	0.09	0.97	1.00

[1] Per 20 additional years of professional seniority since graduation
[2] Per 10 additional consultations per day. Average number of basic consultations per day per GP was 22.3cons/(day*GP)

For daytime services, high *professional seniority* of the GP was significantly associated with increased odds of being involved in a complaint. An increase in *professional seniority* of 20 years corresponded to a 44% increase in odds of receiving a complaint within one year. Also, GPs who had higher *GP output per day* had higher odds of receiving a complaint decision; thus, an increase of 10 consultations per day resulted in a 29% increase of odds. No statistically significant associations were found for the other characteristics: *Gender, practice size, socioeconomic index, senior citizen proportion, or level of urbanization*.

The association between disciplinary action and GP and practice characteristics is shown

in Table II.

Table II. Disciplinary action and association with general practitioner and practice characteristics

		OR	P	95% Confidence Interval	
General practitioner characteristics					
Gender	Female	1			
	Male	0.97	0.91	0.56	1.67
Professional seniority		1.85	0.06	0.98	3.49
GP output per day		1.31	0.11	0.94	1.82
Practice and practice environment characteristics					
Practice size		0.95	0.58	0.81	1.13
Socioeconomic index		0.71	0.59	0.21	2.44
Senior citizen proportion		1.00	0.95	0.90	1.12
Level of urbanisation		1.01	0.65	0.98	1.03

Among the 265 GPs who received a complaint about daytime services, 71 received a discipline from the board (53 conclusions on critique; professional conduct disputed in another 18 cases). None of the characteristics showed statistically significant associations with the risk of receiving a discipline.

An additional analysis including complaints about the out-of-hours service showed that complaints apparently were more frequent for male GPs, but the relative amount of out-of-hours work performed by male and female GPs was unknown.

Discussion

Summary of main findings

In this cohort study we observed two GP characteristics predictive of being involved in a complaint case: *professional seniority* and *GP output per day*. Only when including the out-of-hours complaint cases without any knowledge about which GPs were at risk of such a complaint case, male GPs appeared to be at increased risk. *Practice size* and environment did not appear to be of significance. No significant association could be demonstrated between being disciplined and GP and practice characteristics.

Strengths and limitations of the study

The analysis was only taking into account complaint cases *completed* by the complaints board. The approximately one fifth of the total number of patient complaints rejected by the complaints board has not been taken into consideration. Typical reasons for complaint rejection are complaints about the level of service (e.g. waiting time) or claims for compensation without a complaint about a health professional. Additionally, only register-based data on practice location were taken into consideration. The concrete position of the practice concerned, patient ages, and socioeconomic information have not been dealt with. Likewise, more complex issues with regard to e.g. differences in patient list compositions have not been taken into consideration.

Register data from 2006 were used in order to best possible reflect the situation when a

health care event resulted in a complaint case. Thus we expected lag times with regard to both filing the complaint and complaints board case management. The average case management time of all complaint cases is known to be approximately 15 months [12]. However, some of the events might actually have taken place with an unfortunate time relation to the register data.

Workload has formerly been measured in terms of an average number of consultations per time unit [13,14]. In case of single-handed practices personal number of consultations equals practice number of consultations. Although in the present study potential shortcomings may arise as consultations in partnership practices were equally distributed across the partners regardless of what was the actual partner involvement in the practice. Hence, it may be argued that strictly speaking the analysis is measuring the impact of working in practices with high numbers of consultations.

Comparison with existing literature

Only limited literature concerning risk factors of receiving complaint cases in general practice is available. Cunningham et al. [15] carried out a cross-sectional survey among 1,200 medical doctors in New Zealand. A total of 49% (598) completed the questionnaire and were included. The study comprised a broad range of medical specialties; only 215 participants were GPs, 93 had *never* received a complaint. Among the broad group of medical doctors, those who were more likely to receive a complaint were GPs, male doctors, higher *professional seniority* doctors, and those with higher postgraduate qualifications. The authors put forward the possible explanation that it is the more experienced doctors who carry the burden of responsibility for patient care. The site of practice was of no importance.

The significance of high *GP output per day* suggested in the present study is supported by the findings of Nash et al. [16]. They performed a self-report study among 1,239 Australian GPs. There were 566 respondents (45.7%) and in this group the authors demonstrated that male medical doctors and doctors working more hours per week were predominant among those having had a medico-legal matter.

The present findings suggesting that complaints cases concerning male GPs are particularly preponderant only when including the out-of-hours services confront the common notion that male medical doctors are generally at a higher risk of receiving patient complaints. Unfortunately, we do not know what proportion among the GPs listed with the National Board of Health participated in the out-of-hours services and thus were at risk of being involved in an out-of-hours complaint decision; no Danish national statistics about GPs participating in the out-of-hours services are available. Consequently, it cannot be ruled out if any *gender* preponderance is due to the gender in itself or results from a skewed job profile, e.g., if male GPs generally perform the scope of work associated with a higher risk of complaints. The out-of-hours service involves a high risk job with regard to patient complaint cases. In the present study, 37% of all patient complaints pertained to the out-of-hours services even though no more than approximately one tenth of general practice care pertained to out-of-hours services in 2006 [17].

The fact that no significant association could be demonstrated between being disciplined in connection with a complaint case and GP and practice characteristics confronts previous research findings [5-7]. Future studies might focus on the impact of controlling for complaint contents including which complaints concern daytime and the out-of-hours services, respectively.

Conclusion

It appears that higher *professional seniority* and having more *GP output per day* increase the GP's risk of being involved in complaint cases. Nevertheless, the study suggests that the mechanisms associated with complaint cases may be complex. Future studies need to clarify what lies behind the increased risk of involvement in complaint cases among GPs of higher *professional seniority* and GPs with higher workload, e.g. the significance of performance and job content factors.

Ethical approval

This study was approved by the Danish Patients' Complaints Board and the Danish Data Protection Agency.

Declaration of Conflicting Interests

The authors have declared no competing interests.

Acknowledgements

This study was supported by the Danish College of General Practitioners, the PLU Foundation, the Region of Southern Denmark, the Research Foundation for General Practice, the Health Insurance Foundation and the Faculty of Health Sciences, University of Southern Denmark. We would like to thank Director Peter Bak Mortensen, Patientombuddet, for providing complaint case decisions for the study. Also thanks to Professor Mette Hartlev for input and ideas. Finally, we wish to thank Secretary Lise Keller Stark for proofreading the manuscript.

References

[1] Irvine D. A short history of the General Medical Council. Medical Education 2006;40:202-11.

[2] Stolper E, Legemaate J, Dinant GJ. How do disciplinary tribunals evaluate the "gut feelings" of doctors? An analysis of Dutch tribunal decisions, 2000-2008. J Law Med 2010;18:68-75.

[3] Johansson A, Lagerstedt K, Asplund K. Mishaps in the management of stroke: A review of 214 complaints to a medical responsibility board. Cerebrovascular Diseases 2004;18:16-21.

[4] Bismark M, Dauer E, Paterson R, Studdert D. Accountability sought by patients following adverse events from medical care: the New Zealand experience. CMAJ 2006;175:889-94.

[5] Morrison J, Wickersham P. Physicians disciplined by a state medical board. JAMA 1998;279:1889-93.

[6] Kohatsu ND, Gould D, Ross LK, Fox PJ. Characteristics associated with physician discipline: A case-control study. Arch Intern Med 2004;164:653-8.

[7] Clay SW, Conatser RR. Characteristics of physicians disciplined by the State Medical Board of Ohio. J Am Osteopath Assoc 2003;103:81-8.

[8] Danish National Board of Health. The General Practitioner Register . www sst dk 2011Available from: URL: www.sst.dk

[9] The Danish Health Information Database. www.medcom.dk. 2010.

[10] The Danish Ministry of Welfare Database. www.noegletal.dk. 2010.

[11] The Danish Ministry of Welfare. [Municipal equalization and general subsidies].

Kommunal udligning og generelle tilskud. 2009.

[12] Sundhedsvæsenets Patientklagenævn. Statistiske oplysninger. København: 2007.

[13] Martin-Bates C, Agass M, Tulloch A J. General practice workload during normal working hours in training and non-training practices. Brit J Gen Pract 1993;43:413-6.

[14] van den Berg M, de Bakker D, Spreeuwenberg P, Westert G, Braspenning J, van der Zee J, et al. Labour intensity of guidelines may have a greater effect on adherence than GPs' workload. BMC Family Practice 2009;10:74.

[15] Cunningham W, Crump R, Tomlin A. The characteristics of doctors receiving medical complaints: a cross-sectional survey of doctors in New Zealand. N Z Med J 2003;116:1-9.

[16] Nash L, Daly M, Johnson M, Coulston C, Tennant C, van EE, et al. Personality, gender and medico-legal matters in medical practice. Australias Psychiatry 2009;17:19-24.

[17] Aktivitet og økonomi i almen praksis i dagtid og vagttid 2000 til 2008. 6-5-2009.

Study II

What types of patient complaint cases against general practitioners are likely to result in disciplinary action?

(Submitted to Scandinavian Journal of Primary Health Care, October 2011)

SØREN BIRKELAND[1], RENE dePONT CHRISTENSEN[1], NIELS DAMSBO[1], & JAKOB KRAGSTRUP[1]

[1]*Research Unit for General Practice, Institute of Public Health, University of Southern Denmark, Odense, Denmark*

Word count: 1785 excluding key points, abstract, tables, reference list, including acknowledgements

Correspondence: Søren Birkeland, Research Unit of General Practice, University of Southern Denmark, JB Winsløws Vej 9A, 5000 Odense C, Denmark. E-mail: sbirkeland@health.sdu.dk

KEY POINTS

This study analyzed patient complaint decisions involving general practitioners completed by the Danish Complaints Board during a one-year period.

- Complaint cases based on a wish for placement of responsibility or a wish for review of the general practitioner's competence were associated with increased odds of being disciplined.
- When the complaint was motivated by the patient's feeling of being devalued or a request for an explanation, odds of being disciplined decreased.
- Higher professional seniority was associated with increased odds of being disciplined.

Abstract

Objective: The risk of being disciplined in connection with a complaint case causes distress to most general practitioners. However, little is known about what types of cases result in disciplinary action being taken. The present study examined what complaint case characteristics were associated with being disciplined. *Material and methods.* The Danish disciplinary board's decisions concerning general practice in 2007 were examined. Information on the motives for complaining, as well as patient and general practitioner characteristics, was extracted and the association with case outcome (disciplinary or no disciplinary action) was analyzed. Variables included complaint motives, patient gender and age, urgency of illness, cancer diagnosis, healthcare settings (daytime or out-of-hours services), and general practitioner gender and professional seniority. *Results.*Cases where the complaint motives were based on a wish for placement of responsibility (OR=2.35, p=0.01), or a wish for a review of the general practitioner's competence (OR=1.95, p=0.02) were associated with increased odds of being disciplined. However, the odds of being disciplined decreased when the complaint was motivated by a feeling of being devalued (OR=0.39, p=0.02) or a request for an explanation (OR=0.46, p=0.01). With regard to patient and general practitioner characteristics, higher general practitioner professional seniority was associated with increased odds of being disciplined (OR=1.97 per 20 additional years of professional seniority, p=0.01). None of the other characteristics were associated with the outcome in the multiple logistic regression model. *Discussion.* Complaint motives and professional seniority were associated with complaint decisions. Further research is needed on the role of general practitioner-patient interactions in complaint cases, the impact of professional seniority on performance, as well as on other potential factors associated with complaint case outcome (e.g. the complaint process itself).

Key Words: *Communication, general practice, ICPC-2, jurisprudence, patient complaints*

The risk of receiving a patient complaint case seriously impacts the work of medical doctors [1]. Professional self-esteem comes into play and in general practice in particular the continuous patient-doctor relationship is at stake. For those general practitioners (GPs) receiving a complaint, the risk of being disciplined may be of major concern.

The characteristics of those complaints most likely to result in disciplinary action have received limited attention in the research literature. A Norwegian study suggested that male GPs and male patients are associated with complaint cases resulting in discipline. In that small study, 55 out of the 108 cases (51%) concerned the out-of-hours service [2]. No larger studies investigating the characteristics of complaint cases ending in discipline exist, but it seems reasonable that apart from patient factors, not least the motives for complaining (e.g. wish for punitive measures to be imposed, feelings of devaluation and humiliation, need for explanation), the kind of illness concerned (e.g. urgent vs. non-urgent), and the healthcare settings (daytime care or out-of-hours services) may potentially influence the odds of the complaint being declared justified by the complaints board and resulting in the GP being disciplined.

This study aims to analyze what characteristics (complaint motives, patients and GPs) are associated with being disciplined in connection with complaint cases against GPs.

Material and methods

Primary health care in Denmark

In 2006, more than 99% of the Danish population was listed with one of 3,765 GPs working in approximately 2,200 single-handed or partnership practices. Danish general practice is based on a contract with the tax-financed Danish National Health Insurance. The GPs act as gatekeepers with respect to the secondary health care system. Patients choose their GP and it is possible to

change GP according to preferences (for a small fee). GPs are responsible for the care at all hours and the GPs in a region collaborate on the out-of-hours service. GPs organize out-of-hours in a rotation system, where they answer emergency calls and make home visits.

The disciplinary system

Primary care users being dissatisfied with their GP may decide to file a written complaint. The Danish health professionals' disciplinary system handles complaints about GPs authorized by the Danish National Board of Health on a non-compensatory basis. At the initial stage, the board's secretariat clarifies the issues of the complaint. Typically, the case is evaluated by one of the board's consultants and a proposal is drawn up before the final decision is made by the board. The board may decide to impose a sanction. The most commonly used sanctions are disciplinary actions (criticism or – until 1 January 2011 – disputing professional conduct). Additional possible sanctions are discipline with injunction, or bringing the health professional concerned for the prosecuting authority.

Methods

Complaint case decisions concerning GPs completed in 2007 were reviewed. Based on the model described by Bismark and colleagues [3,4], the complainant motives were categorized in accordance with the patients' expressed wish for: *explanation*, *placement of responsibility*; *quality improvement for future patients*, *review of the GP's competence*; *economic compensation*, *better level of general service*; *professional discipline* and *other sanction*. A complaint may have more than one motive. The above eight motives covered the following four categories: Communication, correction, restoration, and sanction (Table I).

Additionally, it was noted whether the complaint was due to *feeling devalued* by the GP. Also, information was gathered on *patient gender, patient age,* and *the illness* concerned. With regard to patient illnesses, ICPC-2 coding was used. A *cancer* variable was constructed. Also, based on the ICPC-2 codes, a *serious urgent illness* variable was constructed after consensus between the authors (SB, JK, and ND). Deciding what illnesses to categorize as a *serious urgent illness* might imply difficulties. For example some medical doctors would categorize pneumonia as a serious urgent illness and others would not. We chose only to consider diagnoses commonly resulting in death if untreated as *serious urgent illness*.

Finally, it was registered if the patient concerned, according to case management documentation, had deceased (*death of patient*). Other independent variables considered to be factors associated with discipline and potential confounders were healthcare settings (*daytime care* or *out-of-hours*), *general practitioner gender*, and *professional seniority* (years from graduation until event concerned). Information on GP *professional seniority* was gathered through manual look-up in a publicly available list covering Danish medical doctors [5].

Finally, information on the case outcome (discipline or no discipline) was noted. To analyze variables associated with discipline, odds ratios (ORs) were estimated by means of a multiple logistic regression model. The dependent variable in the model distinguished non-disciplined from disciplined cases and the independent variables considered as factors associated with discipline were the above mentioned complaint characteristics. All analyses were performed using STATA®, release 11.1 (StataCorp, College Station, TX, USA). P-values < 0.05 were considered statistically significant.

Results

The complaint cases (n=428) completed by the Danish Patient Complaints Board in 2007 concerned 571 decisions against individual GPs. Sample characteristics are shown in Table I.

Table I. Characteristics in complaint cases towards general practitioners (n=571)

		N.	%
Disciplined	No	445	78
	Yes	126	22
Complaint motives			
Communication		481	84
	Explanation	300	53
	Placement of responsibility	458	80
Correction		344	60
	Quality improvement for future patients	214	37
	Review of the GP's competence	328	57
Restoration		162	28
	Economic compensation	124	22
	Better level of general service	113	20
Sanction		106	19
	Professional disciplinary action	95	17
	Other sanction	96	17
Feeling devalued	No	491	86
	Yes	80	14
Patient characteristics			
Patient gender	Female	335	59
	Male	236	41
Cancer	No	523	92
	Yes	48	8
Serious urgent illness (see text)	No	479	84
	Yes	92	16
Death of patient	No	507	89
	Yes	64	11
General practitioner characteristics			
Healthcare settings	Daytime care	335	59
	Out-of-hours	236	41
General practitioner gender	Female	170	30
	Male	401	70

In 22% of cases, the GP was disciplined. Among these cases, the GP was criticized in 96 cases (17% of cases) and the professional conduct was disputed in 30 cases (5% of cases). The 96 cases resulting in the GP being criticized included 8 GPs being disciplined with injunction

(among whom one was brought for the prosecuting authority; though the charge was dropped). The average *patient age* was 45.3 years (range 0-91 years) and the average *professional seniority* of GPs was 22.2 years (range 0-47 years). The motives for complaining most often fell within the categories of *Communication* and *Correction*, whilst the *Sanction* motive was encountered much less often. Table II presents the analysis of complaint case variables predictive of complaints board discipline. One case was omitted from the analysis because *patient age* was unknown.

Table II. Complaint case characteristics associated with receiving disciplinary action (n=570)

	Odds Ratio	P	95% CI	
Complaint motives				
Communication				
Explanation	0.46	0.01	0.26	0.80
Placement of responsibility	2.35	0.01	1.20	4.59
Correction				
Quality improvement for future patients	1.34	0.36	0.72	2.50
Review of the GP's competence	1.95	0.02	1.14	3.35
Restoration				
Economic compensation	1.45	0.26	0.76	2.75
Better level of general service	1.22	0.60	0.58	2.54
Sanction				
Professional disciplinary action	0.60	0.43	0.17	2.14
Other sanction	0.69	0.57	0.20	2.43
Feeling devalued				
No	1			
Yes	0.39	0.02	0.18	0.85
Patient characteristics				
Patient gender				
Female	1			
Male	0.91	0.66	0.59	1.40
Patient age (per year)	1.00	0.35	0.99	1.01
Cancer				
No	1			
Yes	0.86	0.73	0.37	2.00
Serious urgent illness				
No	1			
Yes	1.46	0.20	0.82	2.59
Death of patient				
No	1			
Yes	0.69	0.33	0.33	1.45
GP characteristics				
Healthcare settings				
Daytime care	1			
Out-of-hours	0.78	0.32	0.48	1.27
General practitioner gender				
Female	1			
Male	1.06	0.82	0.65	1.73
Professional seniority	1.97	0.01	1.19	3.26
(per additional 20 years)				

When including variables concerning complaint motives, *patient gender* and *patient age*, patient *serious urgent illness*, *cancer*, *death of patient*, health care settings (*daytime care* or *out-*

of-hours), and *general practitioner gender* and *professional seniority* in a multiple logistic regression model, odds of being disciplined were halved when the complaint was motivated by *feeling devalued* (OR=0.39, p=0.02) or a request for an *explanation* (OR=0.46, p=0.01). However, when complaints were based on a wish for *placement of responsibility* (OR=2.35, p=0.01) or a request for a *review of the GP's competence* (OR=1.95, p=0.02) the odds of being disciplined doubled, just as in the case with *professional seniority*: a GP with 20 years more seniority had doubled odds of being disciplined in connection with a complaint case (OR=1.97, p=0.01). No statistical significance of *general practitioner gender* could be demonstrated.

Discussion

The key findings of this study are decreased odds of being discipline when the complaint was motivated by *feeling devalued* or a request for an *explanation.* Increased odds of being disciplined were observed in complaint cases where the complaint was based on a wish for *placement of responsibility* or a wish for a *review of the GP's competence*. Besides, higher *professional seniority* was associated with increased odds of being disciplined.

The present study represents all complaint cases in the country and is based on reliable register data and case files. The Danish complaint system is separate from the compensation system and complainant letters solely expressing a wish for compensation are automatically redirected to the Danish National Insurance. Similarly, complaints about the level of service (e.g. long waiting time or bad GP manners) are sent to the regional health authority. When comparing with the situation in other countries it should therefore be kept in mind that the material only represents complaints about the GP's professional conduct.

The categorization of motives for complaining was based on a review of the complaint letter. Some misclassification may have been introduced by this interpretation, but good agreement was found between observers.

Like in the study from New Zealand by Bismark et al. [4], most complaints were based on *Communication* and *Correction* motives. Bismark et al. did not investigate the significance of the complaint motives with regard to case outcome, and we believe that our study is the first to do that.

Recently, feeling deserted or humiliated (in the sense of feeling objectified, insulted, ignored or ridiculed) was suggested to be important when patients lose trust in the doctor-patient relationship [6]. Similarly, Beckman et al. [7] identified *Devaluing patient and/or family views* as the most important issue in almost one third of malpractice suits. The impact on outcomes has not been investigated before. We found a decreased likelihood of being disciplined, perhaps because the ones feeling devalued or seeking punitive measures are overwhelmed by resentment and anger, whilst complaints motivated by a wish for *expression of responsibility* or a *review of the GP's competence* might mirror a relative high degree of matter-of-factness.

A recent cohort study revealed that higher GP *professional seniority* was predictive of getting a complaint case [8]. Hence, it seems that senior GPs are more likely to receive a complaint case, - and if they get one their odds of being disciplined are increased. Two previous case-control studies have demonstrated an association between increased professional seniority and complaint case discipline [9,10], but the findings were contradicted in a third study demonstrating decreased odds [11].

The association between *professional seniority* and discipline may reflect seniority-dependent job contents: senior GPs might be those handling the most complex patient

encounters. Anyhow, the study findings could not verify that *patient gender*, *patient age*, and *serious urgent illness* had any impact. Alternatively, the significance of *professional seniority* might reflect an unspecific "burnout" phenomenon. In favour of this conception speaks a comprehensive European cross-sectional questionnaire survey: this analysis of self-reports demonstrated a positive connection between professional seniority and burnout in terms of *emotional exhaustion* [12]. The present study could not demonstrate any statistical significance of *general practitioner gender*.

Conclusion and implications

When facing a complaint case, the present study suggests decreased odds of discipline when the complainant is *feeling devalued* or seeks an *explanation* and increased odds when the complaint motives are based on a wish for *placement of responsibility* or a wish for a *review of the GP's competence*. In other words, it seems that complaints based on feelings are less likely to result in discipline and vice versa. Also, the odds of being disciplined increase with higher *professional seniority*. Future studies should focus on the role of GP-patient interactions in complaint cases, the impact of GP *professional seniority* on performance, as well as on other potential factors associated with complaint case outcome, e.g. the impact of the complaint process.

Acknowledgements

The authors wish to thank Secretary Lise Keller Stark for proofreading the manuscript. We would like to thank Director Peter Bak Mortensen, the Danish Patient Complaints Board, for providing complaint case decisions for the study. Also thanks to Professor Mette Hartlev for

input and ideas.

Declaration

This study was supported by The Danish College of General Practitioners: the PLU Foundation, the Region of Southern Denmark, the Research Foundation for General Practice, the Health Insurance Foundation, and the Faculty of Health Sciences, University of Southern Denmark.

Ethical approval

This study was approved by the Danish Patient Complaints Board and the Danish Data Protection Agency.

References

[1] Cunningham W, Wilson H. Complaints, shame and defensive medicine. BMJ Qual Saf 2011;20:449-52.

[2] Bratland SZ, Hunskar S. [Medico-legal assessments of complaints against general practitioners]. Tidsskr Nor Laegeforen 2006;126:166-9.

[3] Bismark M, Dauer EA. Motivations for Medico-Legal Action. Journal of Legal Medicine 2006;27:55-70.

[4] Bismark M, Dauer E, Paterson R, Studdert D. Accountability sought by patients following adverse events from medical care: the New Zealand experience. CMAJ 2006;175:889-94.

[5] Lægeforeningens Vejviser. København: Lægeforeningens forlag; 2007.

[6] Frederiksen H, Kragstrup J, Dehlholm-Lambertsen G. It's all about recognition! Qualitative

study of the value of interpersonal continuity in general practice. BMC Family Practice 2009;10:47.

[7] Beckman HB, Markakis KM, Suchman AL, Frankel RM. The doctor-patient relationship and malpractice. Lessons from plaintiff depositions. Arch Intern Med 1994;154:1365-70.

[8] Birkeland S, Christensen RD, Damsbo N, Kragstrup J. What are the characteristics of general practitioners in complaint cases? Submitted

[9] Morrison J, Wickersham P. Physicians Disciplined by a State Medical Board. JAMA 1998;279:1889-93.

[10] Kohatsu ND, Gould D, Ross LK, Fox PJ. Characteristics associated with physician discipline: A case-control study. Arch Intern Med 2004;164:653-8.

[11] Clay SW, Conatser RR. Characteristics of physicians disciplined by the State Medical Board of Ohio. J Am Osteopath Assoc 2003;103:81-8.

[12] Soler JK, Yaman H, Esteva M, Dobbs F, Asenova RS, Kati-ç M, et al. Burnout in European family doctors: the EGPRN study. Family Practice 2008;25:245-65.

Study III
Process-related factors associated with disciplinary board decisions

(Submitted for publication in BMC Health Services Research, December 2011)

SØREN BIRKELAND, RENE dePONT CHRISTENSEN, NIELS DAMSBO and JAKOB KRAGSTRUP

*Correspondence: sbirkeland@health.sdu.dk

[1] Research Unit for General Practice, Institute of Public Health, University of Southern Denmark, J.B. Winsløws Vej 9, DK-5000 Odense C, Denmark

Word count excluding abstract, acknowledgement, references: 2290 words

Abstract

Background: Most health care systems provide patients with the possibility of filing a complaint about health professionals and in some countries special disciplinary boards have been organized in order to optimize the complaint process. In this regard, the safe-guarding of the legal rights of the involved parties is a crucial concern. Nevertheless, there is limited knowledge about the association between decision outcomes and factors related to the complaint process. Using complaint cases towards general practitioners, the purpose of this study was to identify what process factors are statistically associated with board decisions on disciplinary action as seen from the complainant as well as from the defendant general practitioner's perspective.

Methods: Danish Patient Complaints Board decisions concerning general practitioners completed in 2007 were examined. Information on process factors was extracted from the case files and included complaint initiation (*complaint delay* from the event concerned until filing the complaint and complainant's *lawyer involvement*), complaint demarcation (the number of *general practitioners involved* and *event duration*), and complaint case management (*expert witness involvement* and *case management duration* until a decision was made). Finally, information was gathered on decision outcome (discipline or no discipline). Multiple logistic regression analyses were performed on compound case decisions eventually concerning more litigated general practitioners (as seen from the complainant's perspective) and on separated decisions (as seen from the defendant general practitioner's perspective).

Results: From the general practitioner's perspective, when the number of *general practitioners involved* in a complaint case increased, odds of being disciplined significantly decreased (OR=0.66 per additional general practitioner involved, $p<0.001$). Contrarily, from the complainant point of view, no association could be detected between complaining against a

plurality of general practitioners and the odds of at least one general practitioner being disciplined. From both perspectives, longer *case management duration* was associated with higher odds of discipline (OR=1.04 per additional month, p=0.010). No association could be demonstrated with regard to *complaint delay, lawyer involvement, event duration,* or *expert witness involvement*. There was *lawyer involvement* in 5% of cases and *expert witness involvement* in 92% of cases. The mean *complaint delay* was 3 months and 18 days and the mean *case management duration* was 14 months and 7 days.

Conclusions: Certain complaint process factors might be statistically associated with decision outcomes. However, the impact may be different as seen from the complainant's and the defendant's perspective, respectively. Future studies are merited in order to uncover the judicial mechanisms lying behind.

Key Words: *Case management, general practice, jurisprudence, malpractice, patient complaints*

Background

In most countries, a disciplinary system handles complaints from patients concerning health professionals, including general practitioners (GPs). The disciplinary systems have the difficult task to weigh a variety of considerations when making decisions in concrete complaint cases. These considerations include strict health professional considerations, but also e.g. patient safety interests and professional ethics. The structure of disciplinary systems reflects the judicial safeguarding of these balancing interests. In this regard, the legal rights of the complainants and the involved health professionals persistently play a predominant role.

In Denmark, a complaints board considers patient complaints about named health care professionals who are authorized by the Danish National Board of Health. In January 2011, the board was renamed "the Danish Disciplinary Board" (from "The Danish Patient Complaints Board", DPCB) and some organizational changes were implemented. For the most part the case management is, however, unaltered. The case management is as follows: After receiving a complaint from the patient concerned or relatives about one or more named health professionals, the case is clarified by the secretariat and a proposal is made for a decision. Typically, in those cases not only concerning patients' formal legal rights, the proposal is based upon evaluations made by the board's expert witnesses. For instance, complaints against GPs are assessed by GP experts. The board's decision is made by a five-person committee headed by a chairperson who is a judge **(**§ 15 in the Danish Act on Complaints and Compensations in the Health Care System, DACC).The main disciplinary sanction remedies are either "criticism" or – until 1 January 2011 – "dispute of professional conduct". Other possible, but rare, sanctions comprise issuing a discipline with injunction, or bringing the health professional concerned for the prosecuting authority. In 2007, the DPCB made 2387 decisions and approximately one fifth concerned treatments in general practice [1].

The disciplinary system has been under an ongoing revision in order to optimizethe judicial process. The judicial interests of the parties have been safeguarded by regulations in relation to different process factors (i.e. procedural issues from the medical event concerned until complaint decision). Such process factors considered of importance to the parties include e.g. expert witness involvement and time limits for complaining. Still, **i**t has been continuously debated whether the complaint system pay enough attention to the involved parties' legal rights. In this respect, there are two major perspectives: that of the complainant who complains about one or

more health professionals and that of the individual health professional who receives a complaint.

A priori, one might expect that if the complainant involves a lawyer, if the period of time to be assessed is extended, or more health professionals are complained about, the likelihood of identifying some health professional negligence resulting in discipline should increase. It may also be hypothesized that delayed complaints are less prone to be declared justified and it has been claimed that sanctions are less likely if the case is assessed by a peer expert witness [2]. However, we have limited empirical knowledge as to what extent such process factors are related to the likelihood of cases resulting in discipline. Using decisions against Danish GPs, the objective of this study was to identify process factors statistically associated with decisions on discipline as seen from the complainant as well as from the defendant (GP's) perspective.

Methods

Study database and population

In this cohort study, all Danish disciplinary board decisions from 2007 involving GPs were analyzed with regard to a number of process factors in order to compare decisions on discipline with those not resulting in discipline.

Data collection

Paper files related to all complaint decisions in 2007 from the DPCB concerning general practice were reviewed. Decisions were treated both as compound decisions (in some cases involving more GPs) and as separate decisions against individual GPs. In a compound decision some GPs might have been disciplined and others might not.

The following information was obtained: *Complaint delay* (time from the medical event concerned until filing the complaint), *lawyer involvement* by the complainant (judicial expertise used to e.g. formulate complaint), the number of *general practitioners involved*, and the *event duration* concerned (duration of health care episode concerned). *Complaint delay* was intended to measure the time span from the health event concerned before filing a complaint. For practical reasons, the time interval from the last date of the health care event until registration within the disciplinary board was used. Obviously this time comes after the time of complaining. The time of registration was, however, considered useful because it was unfailingly available in every case and might be considered closely tied with the time of filing the complaint.

The involvement of an *expert witness* and *case management duration* (from the date of registration of the complaint within the disciplinary board until the date of decision) were included as independent variables. Finally, information was gathered on *decision outcome* (dichotomized into "discipline" or "no discipline").

Analysis

Factors associated with discipline were identified by means of a multiple logistic regression model. The dependent variable in the model distinguished decisions on discipline from decisions without discipline. Odds ratios (ORs) for cases resulting in discipline with regard to the characteristics (independent variables) mentioned above were estimated. Analyses were performed on compound decisions eventually involving more GPs and on separate decisions. In compound decisions, outcome was considered as a discipline if at least one of the involved GPs had been disciplined. Additionally, when analyzing the separate decisions, clustering at the case level was taken into account by robust estimation. P-values < 0.05 were considered statistically

significant. The analyses were undertaken using STATA®, release 11.1.

Ethical approval

This study was approved by the DPCB and the Danish Data Protection Agency (Licence: 2008-41-2875). In Denmark, registry-based studies do not by law require ethical approval from the local research ethics committee.

Results

In 2007, 427 compound decisions were made concerning general practice. Sample characteristics are outlined in Table 1.

Table 1. Process factors in compound complaint decisions (n=427)

Case process factor		[Range]
Complaint delay, mean	3 months, 18 days	1 day – 47 months, 5 days
Lawyer involvement	20 (5%)	
General practitioners involved, mean	1.33	1-4
Event duration, mean	4 months, 6 days	1 day – 83 months, 5 days
Case management duration, mean	14 months, 7 days	2 months, 3 days – 72 months, 5 days
Expert witness involvement	393 (92%)	

Most cases (n=338, 79%) only involved one GP. In 55 cases (13%), the number of *general practitioners involved* was two. In 18 cases (4%), 3 health professionals were involved, and in the remaining 16 cases (4%), 4 GPs were involved. In 45 cases (11%), one or more non-GPs

were involved, most frequently hospital doctors, non hospital specialists (e.g. ear, nose, and throat specialists), and nurses. In 114 cases (27%), one or more GPs were disciplined.

The compound decisions concerned 571 separate litigations against individual GPs. The association between individual GPs being disciplined and process factors is shown in Table 2.

Table 2. Process factors associated with being disciplined asa general practitioner (n=571)

Discipline		**OR**	**P**	**95%Confidence Intervals**
Complaintinitiation				
Complaintdelay (months)		0.988	0.521	0.954-1.024
Lawyerinvolvement	No	1		
	Yes	1.257	0.633	0.491-3.216
Complaint demarcation				
General practitioners involved		0.661	0.000	0.524-0.835
Event duration (months)		0.996	0.675	0.977-1.015
Complaint decision				
Case managementduration (months)		1.038	0.010	1.009-1.069
Expert witnessinvolvement	No	1		
	Yes	1.366	0.452	0.606-3.077

When the number of *general practitioners involved* in a complaint case increased, the odds of discipline decreased for the individual GP concerned (OR=0.661 per additional GP involved, $p<0.001$). Conversely, when analyzing the association between process factors and discipline in

compound decisions (from the complainant point of view), no statistical association could be detected between the number of *general practitioners involved* and odds of the compound decision resulting in at least one of the litigated GPs being disciplined. In both analyses, however, long *case management duration* was associated with increased odds of discipline. Hence, a six months prolonged *case management duration* was associated with 26% increased odds of the case resulting in a decision on discipline (p=0.010, 28% in compound decisions, p=0.011). No association could be demonstrated with regard to *event duration, complaint delay, expert witness involvement*, or complainant's *lawyer involvement*. Even when taking clustering into account in separate decisions, the association between decision outcome and number of *general practitioners involved* and *case management duration*, respectively, was statistically significant.

Discussion

The key findings of this study are an association between a rising number of *general practitioners involved* and decreased odds of being disciplined as an individual GP and between longer *case management duration* and increased odds of discipline.

The present study covers all complaint cases in Denmark and is based on register data and case management files, which are likely to be complete and reliable. The Danish complaint system is separate from the compensation system and therefore complaints only seeking compensation (no complaint about professional conduct) are automatically redirected to the Danish National Health Insurance. Complaints about the level of service (e.g. unsatisfactory waiting times) are sent to the regional health authority. When comparing with the situation in

other countries it should, therefore, be kept in mind that the material only concerns complaints about the GP's professional conduct.

The limited number of cases actually involving a lawyer deflates the statistical power. This deflation of statistical power may also be of importance regarding the use of expert witnesses, because very few decisions were made without an expert witness.

In general, the association between health disciplinary process factors and decision outcomes has attracted little research attention. The only study existing on the relation of process factors to decision outcomes is a Japanese analysis of medical malpractice case decisions. As in the present study, lengthy cases were shown to be associated with decisions in the patients' favour [3]. The causes of this association might be numerous, but the most likely reason might be that straightforward (short-duration) cases typically are those with limited likelihood of negligence, while the cases resulting in discipline may be more complicated, generally requiring a thorough (long-lasting) case management.

Prolonged case management is demanding for all the involved parties in disciplinary proceedings – not least the defendant. Case management should, however, agree with judicial regulations (e.g. the "reasonable time" requirement according to the European Convention on Human Rights, Article 6). In this regard, it is noticeable that the increased odds of disciplining the defendant with case management prolongation runs parallel to case durations up to 6 years.

It has previously been argued that the involvement of lawyers on behalf of patients may increase the possibility that breaches of standards of practice are clarified, because lawyers to a higher extent bring forth written protocols and standards [4]. However, the present study could not verify any statistical association with decision outcome. The reason might be that a lawyer is only able to contribute little to the examination of the case. As mentioned above, the disciplinary

board has a duty to independently examine the case and perhaps therefore a lawyer was involved in no more than one out of twenty complaint cases. Hagihara et al. [3] suggested that only few lawyers have sufficient experience in medical malpractice litigation, and not least in Denmark there is little tradition among lawyers to concentrate their business on health professional disciplinary proceedings.

Even though international guidelines have been issued to ensure expert witness impartiality [5,6], Lens and van der Wal have highlighted the possible mechanism among health professionals of covering up dysfunction in a so-called "conspiracy of silence" [2]. Correspondingly, a Dutch study recently demonstrated that more than one third of "Healthcare Consumer Panel" members had no confidence in the disciplinary proceedings and its independent status [7]. Another Dutch study showed, however, a decreased proportion of complaint cases resulting in discipline after including more lawyers and fewer fellow professionals in the disciplinary board [8]. Fellow expert witnesses are not appointed in order to cover their colleagues and, from a statistical point of view, do not appear to do so. The present study could not document any statistically significant association between fellow professional involvement and the odds of discipline.

Anyhow, the disciplinary board's preparation of the case is highly dependent on the initial demarcation of the complaint case provided by the complainant. From the complainant's point of view, no association could be demonstrated between involving a larger group of GPs in the complaint and the odds of disciplining at least one GP. Some would interpret this finding to be satisfactory; the opposite result might have suggested an unwarranted element of "fault finding". Though, from the point of view of the GP concerned, the demarcation of the number of *general practitioners involved*, contrary to the demarcation with regard to *event duration* and

complaint delay was not only trivial. Hence, the study suggests that being involved together with other GPs "protects" against discipline. In other words, the instinctive sense of "relief" if realizing being litigated in plurality might be substantiated in a statistical counterpart. The mechanisms might be numerous: Firstly, complaints against more health professionals might indicate "shooting from the hip". Alternatively, such litigation might reflect hardly transparent "system matters" or "blurring of responsibility". Other explanations are that the involvement of more health professionals in health care matters – through some kind of "general consensus" - might reduce the risk of malpractice.

The Danish disciplinary system continuously implies an opportunity to complain against named health professionals (DACC, § 2). In those cases, the disciplinary board considers whether one or more named health professionals should be disciplined. From 1 January 2011, however, complainants have an alternative opportunity to file a complaint to the Danish "Patientombuddet" with regard to concrete health care without intending named health professionals to be disciplined (DACC, §1). In those cases, "Patientombuddet" may conclude that the health care provided by one or more unnamed health care providers was criticizable. From the present findings, one might be tempted to suggest that this new initiative, though offering additional means of complaining which is perhaps also less unpleasant for the involved parties, might have a limited impact on decision outcome patterns.

Conclusions

The analyses of the present article offer insight into some statistical associations between complaint cases resulting in discipline against health professionals and a number of measurable process factors. The impact of the process factors, however, diverged as seen from the

complainant's and the defendant's perspective, respectively. Hence, statistically significant associations only existed between being litigated in plurality and decreased odds of discipline, and between prolonged case management and increased odds of discipline. Optimal complaint case management is an important goal, because complaint cases are very resource-demanding for the involved parties. Statistical analyses on disciplinary process factors might offer valuable information on issues of key judicial impact, e.g. the association between decision outcomes and process prolongation. Given the high financial and human costs associated with the complaint case process, future studies concerning the mechanisms lying behind the suggested associations should be carried out to optimize the complaint case management, simultaneously preserving the involved parties' legal rights.

List of abbreviations

GP: General practitioner, OR: odds ratio, DPCB: Danish Patient Complaints Board, DACC: the Danish Act on Complaints and Compensations in the Health Care System

Acknowledgements

We wish to thank Secretary Lise Keller Stark for proofreading the manuscript. We would like to thank Director Peter Bak Mortensen, the Danish Patient Complaints Board, for input and providing complaint case decisions for the study. Also thanks to Professor Mette Hartlev for input and ideas. This study was supported by The Danish College of General Practitioners: the PLU Foundation, the Region of Southern Denmark, the Research Foundation for General Practice, the Health Insurance Foundation, and the Faculty of Health Sciences, University of Southern Denmark.

Author details

[1] Research Unit for General Practice, Institute of Public Health, University of Southern Denmark, J.B. Winsløws Vej 9, DK-5000 Odense C, Denmark.

Authors' contributions

The study was conceived by SB, JK, ND, designed by SB, ND, and JK, data analysis was performed by SB and RDC, data interpretation was done primarily by SB, ND, and JK, and drafting the paper was done jointly by SB, ND, and JK with substantial input from RDC. All authors revised the paper and approved the final version.

Competing interests

The authors declare that they have no competing interests

References

1.Sundhedsvæsenets Patientklagenævn. [Statistical information]. Copenhagen: Danish Patient Complaints Board, 2007.

2.Lens P, van der Wal G. [A study of dysfunction in specialists]. *Ned Tijdschr Geneeskd* 1994;138:1127-1131.

3.Hagihara A, Nishi M, Abe E, Nobutomo K. The structure of medical malpractice decision-making in Japan. *J Law Med* 2003;11:162-184.

4.Moniz DM. The legal danger of written protocols and standards of practice. *Nurse Pract* 1992;17:58-60.

5.Guidelines for the physician expert witness. American College of Physicians. *Ann Intern Med* 1990;113:789.

6.Expert witness guidelines for the specialty of emergency medicine. *Ann Emerg Med* 2010;56:449-450.

7.Hout E, Friele R, Legemaate J. [The citizen as plaintiff in disciplinary procedures, lack of complaints possibly due to poor knowledge of the disciplinary system for health care]. *Ned Tijdschr Geneeskd* 2009;153:A548.

8.Hout FA, Cuperus-Bosma JM, de Peuter OR, Hubben JH, van der Wal G. [No improvement of disciplinary jurisprudence since the implementation of the Individual Health Care Professions Act (IHCP Act)]. *Ned Tijdschr Geneeskd 2004*;148:135-139.