



RIKSREVISIONEN  
*The Swedish National Audit Office*

RiR 2007:23 Summary

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Government response to medical  
negligence reports

# Summary

SNAO has examined whether the Government, the National Board of Health and Welfare and the Medical Liability Commission (HSAN) are doing what is required of them with regard to the handling of reports of medical negligence. HSAN's remit is to investigate, following the report, whether medical or healthcare staff are responsible for neglecting their professional duties. The National Board of Health and Welfare is the national supervisory authority for medical and health care.

SNAO's assessment is that HSAN has in the formal sense fulfilled its undertaking under the Law (1998:531) on the Medical and Health Care Professions (LYHS). SNAO's audit has not included assessing the quality of decisions made from a legal perspective. In addition to HSAN's undertaking under LYHS, SNAO has audited the way in which HSAN handles the process surrounding medical negligence reports and has observed the following failings.

## **The Government should have been informed earlier of the problem caused by applying the present system**

Prior to the formation of HSAN, the Standing Committee on Social Questions assumed that great demands should not be made of the individual patient with regard to the formulation of the content of the medical negligence report (SoU 1979/80:16). Many patients are unable to meet the requirements on reporting medical negligence that are imposed by the system. A fifth of patients have difficulties in identifying the person the negligence report is aimed at. According to HSAN, it is unable to help these patients in any way, even if in some cases it is probable that disciplinary action should be taken. The problem has existed since 1994, when the requirement was introduced to cite a particular person as responsible for the negligence. HSAN should have informed the Government earlier of this problem. It was not until 2006 that HSAN wrote to the Government describing the practical difficulties of applying the present system of reporting medical negligence.

## **Information concerning what it means to be a party to a medical negligence case is absent from HSAN's information material**

The requirements that must be satisfied when reporting medical negligence are high. It is only the professional medical or healthcare staff who can be reported and only the medical or health care that has been reported that can be investigated by HSAN. The person who reports the negligence becomes a party to the case, and the person who is cited becomes the opponent. HSAN neither can nor should help one party rather than the other. This means that the person reporting the negligence cannot expect HSAN to do its own investigation to establish fault and liability if the report is incorrect. HSAN

does however request supplementary information from the parties. Information concerning the patient's position as party to the case and how far HSAN's investigation can go is absent from the report form and from HSAN's website. A greater understanding of what it means to be a party to a medical negligence case would cause patients to be more careful in their own inquiries before reporting the case. If HSAN provided clearer information, it is likely that fewer incorrect reports would be made to HSAN, and also the large number of supplementary documents the agency has to deal with would also probably be reduced.

### **HSAN should have referred more mistakenly submitted cases**

One fifth of those reporting medical negligence addressed their reports to the wrong instance. The other instances are principally the local patient advice and liaison service, the Patient Insurance service and the National Board of Health and Welfare. This proportion is underestimated, as many people take up a number of matters in a single report of negligence. If the results are added up to the total number of negligence reports that HSAN deals with, it means that slightly more than 800 reports are sent to the wrong instance. HSAN has referred slightly more than 100 of these to the correct instance.

### **The National Board of Health and Welfare has no national picture of medical negligence reports**

Lex Maria is a legal provision according to which medical and healthcare providers in Sweden have an obligation to report to the National Board of Health and Welfare if, in connection with medical or health care, a patient suffers or is exposed to the risk of suffering serious injury or illness. The job of the National Board is then to investigate and to make decisions concerning the case. The purpose of the Lex Maria rule is to investigate the incident in order to take various steps to prevent any repetition. Another purpose is, through the investigation, to make the patient concerned aware of what has occurred. SNAO's audit shows that the National Board has done no follow-up of the extent to which patients or their families are given the opportunity to describe the incident in the Lex Maria reports. SNAO has collated information from the National Board and found that in approximately 40 per cent of the Lex Maria reports there is no information from the health system about patients having the opportunity to submit their version of events.

The National Board of Health and Welfare has a particular responsibility for knowledge development and knowledge dissemination in medical and health care. The National Board has, as part of its duty to give knowledge feedback to the healthcare system, failed to use the information on medical injuries that exists in patient reports, that is to say the reports that HSAN and the local patient advice and liaison services disseminate to the agency. The National Board uses only the Lex Maria cases in its work to give knowledge feedback on medical injuries to the healthcare system. Inasmuch as it does not use the medical negligence reports submitted by patients, there is a

danger that knowledge is being lost which could be important for the preventive work.

In 2004, the National Board ceased to compile national data on the activities of the patient advice and liaison services. As a result, neither the agency itself, the healthcare system, the Government or the Riksdag (Parliament) has a complete picture of the complaints that patients have submitted to the patient advice and liaison services.

## **The Government should be aware of the risk of treating medical and healthcare personnel unequally**

SNAO has drawn attention to the fact that the previous government gave the National Board of Health and Welfare a very great deal of scope to influence its working methods as regards the system for reporting medical negligence. The direction this has taken has been a move from an individual-focused approach to a more system-focused approach. According to the system-focused approach, faults and errors are the results of failings in the healthcare's organisation, rules and working methods rather than the mistakes and failings of individuals. Against this background, the National Board of Health and Welfare has in increasingly fewer cases considered that there is cause to report medical and healthcare personnel to HSAN for disciplinary action.

In SNAO's opinion, there is a danger that medical and healthcare personnel are in some cases not being reported to HSAN despite the fact that they can be liable for something which according to HSAN may have given rise to disciplinary action. SNAO considers that the Government left the agencies to deal with matters which, during the 1990s, were the subject of Swedish Government Official Reports (SOU), political discussion and decision-making.

### **Recommendations**

SNAO has submitted the following recommendations:

- SNAO recommends that the Government should work to ensure that the opportunities are improved for patients to have their case considered by HSAN. The Government should therefore consider proposing that the Riksdag soften the requirement in LYHS, whereby the patient is obliged to identify the person who was responsible for the negligence that is being reported.
- SNAO proposes that HSAN be given greater responsibility for investigating the question of who was responsible for the negligence, among other things by making investigations in the healthcare system, based on the patient's report, into the identity of the person responsible.
- Within the framework of the current legislation, HSAN should refer all mistakenly received cases to the correct instance.
- HSAN should inform potential claimants, in its information material to patients and on its website, of what the role of party to a medical negligence case involves.

In order to safeguard against failings in the follow-up of medical negligence cases and to improve the work to prevent medical injuries,

SNAO makes the following recommendations:

- SNAO considers that the National Board of Health and Welfare should ensure that patients are given the opportunity to give their version of events in Lex Maria reports.
- The National Board of Health and Welfare should give knowledge feedback on medical negligence cases to the health service on the basis of patients' reports to HSAN and to the local patient and liaison services.

To ensure equal treatment of medical and healthcare personnel, SNAO makes the following recommendation to the Government:

- The Government should give a supplementary directive to the ongoing investigation into patient safety and supervision, etc. (Dir 2007:57) in order to draw attention to the consequences implied by the National Board of Health and Welfare's change of practice with regard to the Lex Maria cases that are sent to HSAN. As a result of this changed practice, medical and healthcare personnel risk being treated unequally depending on whether they have been reported to the National Board of Health and Welfare or to HSAN.