Summary

Patient safety – is there adequate central government provision for high level patient safety? (RiR 2015:12)

SWEDISH NATIONAL AUDIT OFFICE

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Audit background

The Swedish National Audit Office has audited whether central government has made adequate provision for care providers to promote a high level of patient safety. A high level of patient safety is a fundamental requirement under the Health and Medical Services Act. Yet every year there are a number of healthcare-related injuries, which entail great human suffering and significant costs to society. Measurements show that a healthcare-related injury, that is an avoidable injury, occurred in just over 8 per cent of all care episodes. The additional cost of these injuries, solely in the form of extra days of care, is estimated to be between SEK 6.9 and 8.5 billion per year.

Reasons: Despite a number of initiatives in the area of patient safety, problems still remain. Surveys of healthcare-related injuries indicate that the number of serious injuries has fallen since 2008, while less serious injuries remain at essentially the same level. Almost one in ten patients still suffer healthcare-related injuries. The audit ambition was to seek explanations for identified patient safety problems for both central government and care providers.

Purpose: The purpose of the audit was to audit, on the basis of deficiencies and problems in the area of patient safety, whether central government has made adequate provision for care providers to promote a high level of patient safety. The Government, the Health and Social Care Inspectorate and the National Board of Health and Welfare were audited.

Implementation: The audit is based on interviews with representatives of the Ministry of Health and Social Affairs, the Swedish Association of Local Authorities and Regions, the National Board of Health and Welfare and the Health and Social Care Inspectorate, as well as representatives of different function levels in nine county councils and regions. Moreover, a number of document studies were made as well as an overall examination of research literature in patient safety aimed at identifying central conditions for achieving long-term patient safety. A reference group of researchers and experts on patient safety were co-opted to the audit to discuss conditions for a high-level of patient safety.

Finally the higher education institutions' educational programmes for medicine were analysed to audit the existence and scope of courses in patient safety, and the reference material was supplemented by questions to the medical programme directors at the country's seven higher education institutions.

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Audit findings

The Swedish NAO compared identified central conditions for a high level of patient safety with the current patient safety work methods of care providers' and central government. Based on this, the Swedish NAO considers that central government has not made adequate provision for care providers to promote a high level of patient safety.

Through the Patient Safety Act the Government has provided a good foundation for promoting a high level of patient safety. At the same time the legislation assumes that the actors – both care providers and central government – that are to carry out the work have progressed relatively far in their approach to patient safety. The Swedish NAO considers, however, that the county councils are not currently capable of full compliance with the purpose and requirements of the Patient Safety Act. This applies in particular to the learning and capability of working preventively. Nor have the central government agencies responsible for supervision, regulations and support managed to live up to the ambitions of the Act. The Government's governance of the agencies has not been adequate in these respects.

After analysing the Swedish patient safety system the Swedish NAO draws the following conclusions.

Management's responsibility for patient safety

An important factor for a high level of patient safety is that the care providers' organisational culture is developed. For patient safety to have an impact there must be an understanding of the need and significance of active and systematic patient safety work. This applies throughout the organisation – from the most senior management right to the care services.

The Swedish NAO's opinion is that the management has a great responsibility for patient safety and that the safety culture must be developed. A sound safety culture means in practice that the healthcare staff are afforded the conditions and tools to deal with unexpected care situations without serious incidents occurring. It is the responsibility of the management that these conditions are in place.

Deficiencies in the care providers' learning and preventive work

The audit shows that there are deficiencies in the learning of the care providers. In light of healthcare-related injuries that have occurred, care providers have a responsibility to take measures and spread knowledge as well as to work preventively to increase patient safety. At present the dissemination of lessons learned in the organisation is deficient and there is seldom any follow-up of measures taken.

When learning is not effective it is difficult to work preventively. The preventive work is limited at present, which applies for example to risk analysis. An important component of the conditions for a high level of patient safety is also professional development and continuing training of

healthcare staff. The audit shows that these components are often given low priority in the care services due to lack of time. The contribution of patients and their relatives in preventive work promotes patient safety but this area is not developed by the care providers.

Competence and organisation in healthcare is crucial for a high level of patient safety

The competence and opportunities of continuing training of healthcare staff are crucial to a high level of patient safety. This assumes a high level of awareness and sound knowledge of patient safety in the management of the healthcare services. At present responsibility for continuing training is divided between the care provider and the individual employee, and in practice it is the care provider that determines the extent to which healthcare staff can participate in continuing training. Unlike many other EU Member States, there are no requirements concerning the content and scope of continuing training of Swedish healthcare staff. Nor is there any systematic testing of the knowledge of licensed healthcare and medical staff. This means that it is up to each care provider to offer healthcare staff continuing training, while there are no detailed requirements regarding the content or scope of this training. This may imply risks for patient safety.

An important part of patient safety work concerns how care services are organised. It is a matter of having the right person in the right place, as well as having functioning teamwork with different professions. Staffing shortages affect patient safety; there are problems regarding both understaffing and difficulties in recruiting nurses and doctors. High staff turnover and temporary agency staff impose particular requirements of the care provider to ensure continuity and healthcare staff with adequate knowledge.

Inadequate support to care providers in application of the regulatory framework

The Patient Safety Act has meant increased requirements of care providers to create functioning patient safety work. However, care providers need help in applying the regulatory framework to fulfil the intentions of the Patient Safety Act. Central government has not provided adequate support here. For example, there are currently no adequate definitions of certain central concepts and no guidance as to how the Act should be applied regarding participation of patients in patient safety work. The Swedish NAO considers that there is scope through regulations to describe in more detail how patient safety work should be conducted, thus clarifying how the legislation should be interpreted.

Moreover the National Board of Health and Welfare's support for care providers' management systems is limited. The Swedish NAO's audit shows that the National Board of Health and Welfare can do more in its normative role in patient safety work. It is now more than four years since the Patient Safety Act came into force but as yet there is no revised regulation for lex Maria cases. This creates uncertainty among care providers.

Deficient central government supervision

The Swedish NAO's audit shows that there are deficiencies in supervision. Several of these can be traced to the earlier supervisory activities before the Health and Social Care Inspectorate was established on 1 June 2013. Thus the problems are known by both the Government and the Health and Social Care Inspectorate. Despite this, the Swedish NAO's audit shows that several important conditions for effective operative supervision are not in place. The Health and Social Care Inspectorate does not have a fully developed case management system and the agency has not fully provided the conditions for uniform and effective case management for the operative supervision. To date the Health and Social Care Inspectorate has had no fundamental structure for following up consistency in complaint cases; only one follow up has been made.

The Health and Social Care Inspectorate's processing times for individuals' complaints is increasing on an annual basis, despite one of the reasons for a new supervisory agency being to streamline processing. At the same time the number of open complaint files has decreased since spring 2014.

Self-initiated supervisory activities are limited. According to several of the county councils interviewed, supervisory visits have decreased. To the extent the Health and Social Care Inspectorate's case officers visit health care services it is regarded as positive by the care providers and as a good way to pass on knowledge and draw attention to patient safety issues.

External supervision reporting has been given priority by the Health and Social Care Inspectorate. However, the supervisory findings are reported to care providers mainly at an aggregated level of knowledge, which makes it difficult for care providers to learn from incidents that took place in other care providers' activities. Moreover reporting has mainly been at management level and not at the level where care services are delivered.

The Health and Social Care Inspectorate is charged with cooperating with other supervisory agencies. To date this has been limited. Common supervisory activities may lead to better impact through the supervisory agencies concerned being able to give more coordinated attention to care providers on aspects of high relevance for patient safety.

The Swedish NAO emphasises, however, that the potential of supervision to promote patient safety is affected by the ability of care providers to assimilate the knowledge. The audit shows that there are currently deficiencies in care providers' learning that affect the impact that supervision may have on the practical delivery of care.

The Swedish NAO further points out that there is reason for supervisory activities to draw attention to the serious care incident in Mid Staffordshire, England. The incident was due to a series of different factors. An important observation is, however, that the information, above all from patients and relatives, could not be dealt with effectively. The supervisory agencies did not point out the problems in their inspections and did not cooperate interactively. Consequently two

conclusions can be drawn. One is that patients and relatives are an important source of information. However, there must be a recipient able to process the information systematically. The second conclusion is that supervisory agencies must have correctly focused and operative oversight. The conditions for such oversight must therefore be prioritised and in place at the agency responsible.

Patient safety issues are not made visible in medical training programmes

The Swedish NAO considers that the contents of higher education health and medical care programmes are of significance for long-term patient safety work. This applies to all health and medical programmes, however in the audit only the content of the programme for medicine was examined. The parts of the course on patient safety based on recent patient safety research are, however, very limited in the medical programme. To a great extent the higher education institutions offer lectures, often non-compulsory, in the latter part of the programme. Some programme directors for the medical programme at the higher education institutions consider that patient safety is involved in all clinical courses in the same way as communication and ethics, for example. However, structured course components in health and medical care programmes based on recent patient safety research assume another approach than solely clinical aspects or regulatory issues.

The Government has not provided sufficient governance to the agencies

The Government has initiated the Patient Safety Act as well as patient safety agreements, which have contributed to building up a structure for patient safety work in county councils. In the opinion of the Swedish NAO, however, the Government's measures have not been adequate in terms of steering and following up the work of responsible agencies in supporting care providers. It should have been clear that the raised level of ambition that the Act entails regarding the responsibility of county councils assumed equally well thought out efforts in terms of supervision, standard setting and support.

The aim of the Government in setting up a new supervisory agency was to improve efficiency and strengthen oversight. The audit shows that several important conditions have not been fully met as regards supervision of health and medical care services, which in combination hamper effective and efficient oversight. The Swedish NAO therefore considers that the Government's governance has been inadequate in this respect. Attention should also be drawn to the fact that the care providers' learning is weak, which makes it more difficult to achieve the ambitions of the Patient Safety Act of effective and efficient oversight.

The Swedish NAO has noted the Health and Social Care Inspectorate's wish to create greater scope for self-initiated supervision by limiting the Inspectorate's obligation to investigate individual complaints. It is certainly important that the Health and Social Care Inspectorate starts up its important self-initiated supervision and increases the agency's contacts and cooperation with

the care providers. However, this important issue should not be linked to the question of how independent processing of comments and complaints from patients and relatives is organised.

In its interim report the Complaints Inquiry proposes that care providers should handle complaints from patients and relatives with support from the patients' advisory committees where patients and relatives were not treated as they would wish. The Health and Social Care Inspectorate's obligation to investigate should be restricted to situations where there is a special need have an independent and formal review of an incident. This should only apply to cases where incidents in care services have had or risk having serious consequences for the patient.

The Inquiry's proposals are based on the care provider being the body that can best process patients' complaints. At the same time the Inquiry shows that the care providers' treatment of complaints received via the patients' advisory committees differs very widely. It is relatively common that the care provider's picture of what happened is different and that it is the word of the patient against that of the care provider; only in exceptional cases does the care provider attempt to explain why things could have gone wrong or why the patient could perceive the situation as he or she does. The Swedish NAO's audit also shows that there are variations between care providers. The Swedish NAO therefore considers that there is a risk that patients feel that their complaints are not treated in a correct way if the care provider is to be responsible for handling complaints.

The Swedish National Audit Office's recommendations

On the basis of the audit findings and conclusions the Swedish National Audit Office makes the following recommendations to the Government.

- Ensure that the right conditions exist for effective and efficient supervision.
- Ensure that the National Board of Health and Welfare is a support for care providers in application of the regulatory framework for patient safety.
- Instruct the National Board of Health and Welfare to be responsible for long-term national steering and coordination of patient safety work.
- Implement in-depth investigations of care incidents that are important as matters of principle.
- State the importance of patient safety knowledge in the system of qualifications in the Higher Education Ordinance.