RIGSREVISIONEN

Extract from the report to the Public Accounts Committee on Patientombuddet's work with patient safety incidents

November 2015

revision

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1. Introduction and conclusion

1.1. Purpose and conclusion

1. This report concerns Patientombuddet's (national agency for patients' rights and complaints) work to provide a national overview of patient safety incidents.

Incidents and errors that are not caused by the patient's disease and which could have, or did, lead to harm for the patient, are referred to as patient safety incidents. Such incidents may occur during the professional treatment of patients in the healthcare system or in connection with the administration of medicine or provision of instructions on how to use medicine. Examples of patient safety incidents include medical malpractice at hospitals or medication errors occurring in municipal accommodation facilities.

Patientombuddet is an agency under the Ministry of Health with responsibility for the administration of the system for registration of reports on patient safety incidents. The agency analyses the reported data and disseminates knowledge on patient safety incidents. This task was previously handled by the Danish Health and Medicines Authority. With effect from 1 January 2011, this task, along with the processing of patients' complaints and appeals for compensation, was transferred to Patientombuddet and legislation in the area was amended. It appears from the notes to the bill that Patientombuddet should provide a national overview of patient safety incidents based on data from the complaints system and the incidents reporting system. Having access to such a general overview would facilitate effective learning from patient safety incidents that could be converted into improved patient safety. Patientombuddet's work with patient safety incidents is a prerequisite for effective use of the learning potential of the many reports, because it allows Patientombuddet to identify national trends, which the individual municipality or region is not in a position to spot.

In August 2015, the Ministry of Health announced that it intended to change its organization with effect from 1 January 2016; the Health and Medicines Authority will be divided into three agencies, including a new agency for patient safety that will take over the supervisory tasks of the Health and Medicines Authority and the tasks of Patientombuddet.

2. The purpose of the study is to assess whether Patientombuddet – based on the data to which it has access – provides a national overview of patient safety incidents that facilitates effective learning to the benefit of patient safety.

CONCLUSION

It is Rigsrevisionen's overall assessment that Patientombuddet is not providing a national overview of patient safety incidents. At the same time, the Ministry of Health is not sufficiently focused on following up on progress made by Patientombuddet in achieving the target set for the provision of a national reporting system.

The study shows that the functionality of the reporting system used by Patientombuddet does not facilitate easy identification of the most significant national challenges with patient safety incidents. Patientombuddet has to go through the reports manually, which means that only a limited number of the reports are reviewed. A huge potential for learning may therefore be lost, which increases the risk that Patientombuddet does not contribute new knowledge about the area. Moreover, Patientombuddet has only limited knowledge of whether its publications on patient safety incidents are of use to the regions and municipalities in their work with patient safety.

The study shows that the supervisory practice of the National Health and Medicines Authority has included data from the system to address issues concerning patient safety, on a limited basis only. Patientombuddet and the National Health and Medicines Authority are examining the possibilities of using such data in its supervision.

The study shows that the Ministry of Health did not adequately consider how Patientombuddet should solve the task that it took over from the National Health and Medicines Authority in 2011. The ministry did not address that the legal framework conditions would change as a consequence of the amendments to the act, and did not subsequently adjust its expectations in relation to how Patientombuddet should provide a national system for reporting of patient safety incidents. The ministry has not contributed to ensuring that the performance targets defined for Patientombuddet would support the agency in its effort to provide a national system for reporting patient safety incidents.

Rigsrevisionen recommends that:

- Patientombuddet should determine the nature of the functionality and information it requires from the reporting system and reports, respectively, to ensure that the system more effectively contributes to providing a national overview of patient safety incidents.

- The Ministry of Health, Patientombuddet and the National Health and Medicines Authority should determine how the new agency for patient safety should solve the task to ensure that a national overview of patient safety incidents is provided and contributes to improving patient safety.