

This document is a translation of the original assessment in Swedish by SHK of the response to the recommendation. In case of discrepancies between this translation and the Swedish original text, the Swedish text shall prevail in the interpretation of the assessment.

The National Board of Health and Welfare

SHK's assessment of the National Board of Health and Welfare's response to the recommendations

The Swedish Accident Investigation Authority (SHK) published final report SHK 2023:02 on 20 January 2023, concerning a serious incident involving a delay in care in relation to an indeterminate abnormality of the pancreas.

The report issued a total of five safety recommendations, three of which were addressed to the National Board of Health and Welfare (SHK 2023:02 R3, R4 and R5). On 20 April 2023, the National Board of Health and Welfare submitted its response to SHK's safety recommendations.

The National Board of Health and Welfare was recommended to examine whether the working method now introduced at Uppsala University Hospital—under which the healthcare provider requesting an examination is also responsible for ordering it—could usefully be implemented more widely across the health and medical services and, if appropriate, to work towards such implementation in collaboration with relevant authorities and organisations (R3).

In its response, the National Board of Health and Welfare stated that it has undertaken activities related to the recommendation and examined the possibility of promoting wider implementation of this working method. However, there are certain challenges, including those relating to the regions' responsibility as competent authorities, meaning that it is ultimately the regions that decide whether new working methods can be introduced.

In response to the recommendation, the National Board of Health and Welfare will review published content and discuss the matter with other stakeholders within the National Council for Patient Safety. SHK considers the recommendation to have been addressed and assesses the response as satisfactory (**Closed – satisfactory response**).

The National Board of Health and Welfare was also recommended to clarify, as appropriate, what the regulatory framework provides regarding the sharing of diagnostic images from imaging examinations produced by another healthcare provider, and how this may be done in a manner that ensures information security and patient safety.

In its response, the National Board of Health and Welfare stated that it plans to publish guidance on the regulatory provisions governing healthcare providers' ability to share diagnostic images produced by other healthcare providers, and on how such information may be transferred in a manner that ensures information security and patient safety (R4). SHK considers the recommendation to have been addressed and assesses the response as satisfactory (**Closed – satisfactory response**).

The National Board of Health and Welfare was also recommended to examine whether the application of the regulatory framework governing the use of the National Patient Overview (NPÖ) could be simplified and clarified in order to facilitate good care (R5).

The National Board of Health and Welfare points to several challenges associated with the recommendation, given that information sharing within health and medical services is a much broader issue than NPÖ alone. According to the Board, legislative and regulatory amendments would also be required and, before this could take place, a Government inquiry would be necessary.

In light of this, the National Board of Health and Welfare currently has no planned work that would address the recommendation. However, it notes that work is under way in this area in response to the European Commission's proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM(2022) 197. If the proposal is implemented, it would affect the conditions for the exchange of information within the health and medical services.

In light of the complexity of information sharing within the health and medical services, SHK understands the difficulties involved in addressing this recommendation. The National Board of Health and Welfare's response indicates that examining the matter would ultimately require a review of the regulatory framework for information sharing within the health and medical services as a whole.

There may well be grounds, in the longer term, for examining systemic simplifications and clarifications. However, the recommendation was primarily concerned with the application of the current regulatory framework within the health and medical services. Work to examine the application of the regulatory framework could, for example, have begun by reviewing the use of NPÖ.

As the National Board of Health and Welfare has addressed the matter only at an overall level, SHK considers the recommendation to have been addressed only in part (**Closed – partly satisfactory response**).

Yours sincerely,

Kristina Börjevik Kovaniemi
Chair of the Investigation