Local Approval Processes in a Federated and Distributed Research Infrastructure - Lessons Learned from the AKTIN-Project

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Abstract. The AKTIN-Emergency Department Registry is a federated and distributed health data network which uses a two-step process for local approval of received data queries and result transmission. For currently establishing distributed research infrastructures, we present our lessons learned from 5 years of established operations.

Keywords. information networks, distributed systems, health services research, data sharing, routinely collected health data, electronic health records, AKTIN

1.   Introduction

The AKTIN-Emergency Department (ED) Registry [1,2] is a federated and distributed research infrastructure providing access to standardized ED routine documentation [3]. Data collected during clinical routine are automatically stored in local data warehouses (DWH) of the participating institutions and can be queried using the central AKTIN Broker. When querying data from the local DWHs, each ED is responsible to review query requests for compliance with local ethical, legal and organizational requirements. The responsibility to review data requests is typically delegated. The responsible person needs all the information required to check conformity of the request. To allow for an informed decision, a data approval process was established. The AKTIN infrastructure has been in operation since 2017. As of Dec 8th, 2022, 48 participating clinics are connected. The objective of this work is to present the lessons learned from 5 years of operation.

The data approval process is integrated into the graphical user interface of the DWH. It is implemented as a two-step process (approval of data request and transmission of results to the AKTIN Broker) in a web application. The user receives a cover letter describing the purpose and content of the request. The user can check the cover letter using the attached metadata and technical syntax. Without the user's consent, a request cannot be executed, and the results cannot be transferred to the Broker. The user has the option to review the results before they are transmitted. For convenience, the user has the option to give a revocable consent of automatic approval or rejection of repeating requests.

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2. Methods

We used descriptive statistics to describe the transmitted status changes of all requests stored on the AKTIN Broker and submitted between May 1st 2020 and Dec 7th 2022. Frequencies and percentages of approval, rejection and failure states as well as mean, median and interquartile range of the review time were calculated. We gathered insights from our operational experience and feedback from ED correspondents.

3. Results

During the 31-month period, a total of 470 data requests were sent, resulting in 10,787 interactions with the release process. In 80.5% (n=8680) of the interactions, the request was approved and the results transmitted, in 1.3% (n=141) the request was rejected, in 0.4% (n=44) the request failed during processing or result transmission and in 17.8% (n=1922) the request remained unassessed. 82.2% (n=7138) of all approval and 32.6% (n=46) of all rejection interactions occurred with automatic consent. The mean processing time between receiving a request and non-automatic approval was 19.29±37.42 days, median was 5.04 (IQR = 0.86-21.29) days. Non-automatic rejection took 44.79±53.33 days on average, median was 26.29 (IQR = 15-41.04) days. There was no known incident where a request was approved by mistake. In individual cases, questions of understanding were asked about the approval process.

4. Discussion and Conclusion

Fulfilling its purpose, the local approval process in the AKTIN registry was used extensively and without adverse events. The majority of requests were approved. We attribute the unevaluated interactions to the high workload within the institutions. It was helpful to track ongoing requests and notify correspondents of pending assessments. Automated email notifications were rarely reacted to. A median of 5 days to assess and approve a request is relatively quick, given the high-stress environment of EDs. The large IQR regarding the processing time of a request reflects a core group of hospitals that assess the requests promptly and reliably. As only timestamps are recorded, there is no information on the actual time spent on the assessment. The high proportion of automated approvals suggests a general trust in the procedure.

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