Conceptual Framework for a Centralized Objection Office for Patient Data Use in Research

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Background

The Legal Framework

Recent legislation (GDNG and LKHG MV) has transformed medical research in Germany by facilitating the use of routine clinical data without the need for explicit individual consent. However, this is balanced by the right to object (opt-out) under §50 LKHG MV, which is mandatory and has a low-threshold . Patients must be able to stop the processing of their data immediately and effectively.

State of the Art

Existing frameworks, most notably the Medical Informatics Initiative (MII), have already established robust structures. Data Integration Centers (DIC) and Trusted Third Parties (TTP) effectively manage “broad consent" (opt-in) and project- or study-based data access.

The Operational Gap

Although infrastructures such as the MII's DIC are effective at managing broad consents, they do not fulfil the mandatory requirements of the LKHG MV for real-time, automated objection enforcement. This results in a critical operational gap: the lack of a system to automatically intercept data exports based on a patient's right to object.

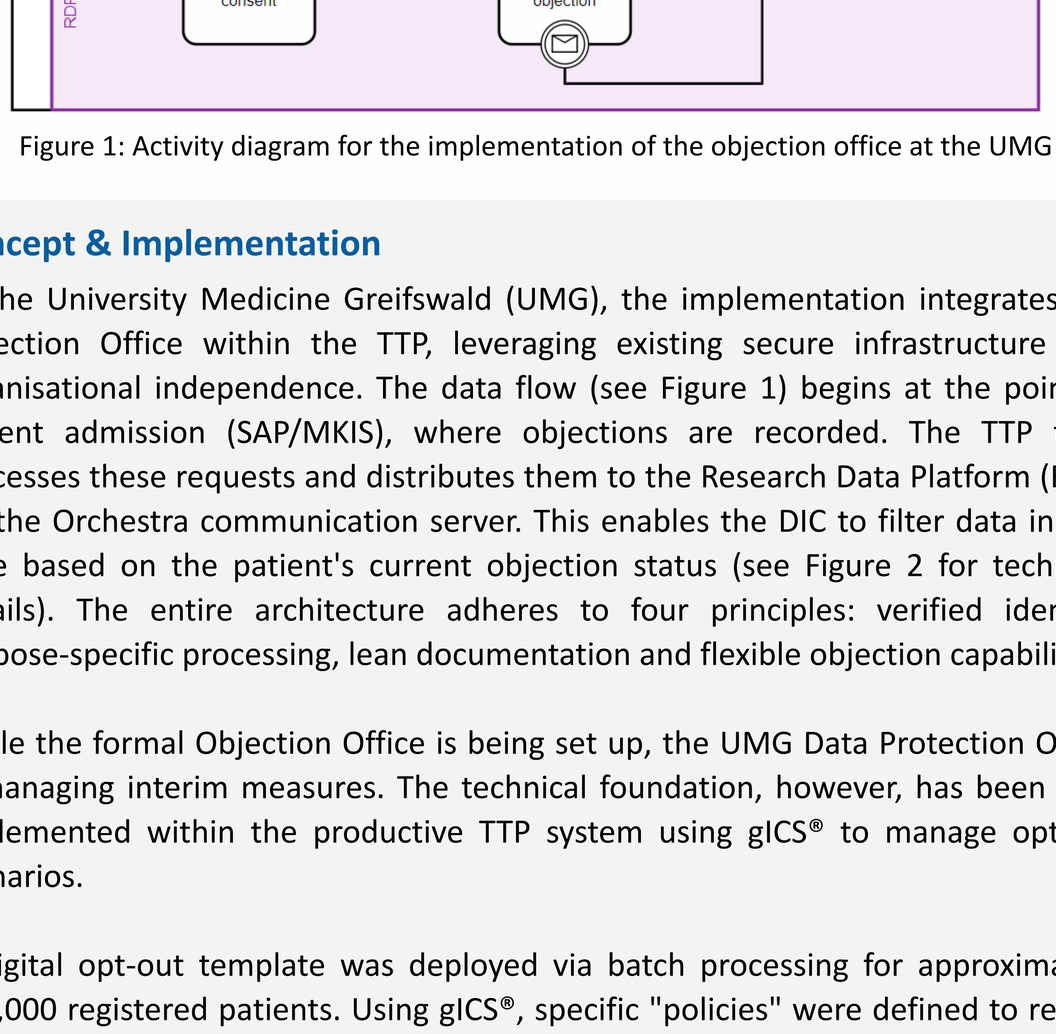

Figure 1: Activity diagram for the implementation of the objection office at the UMG

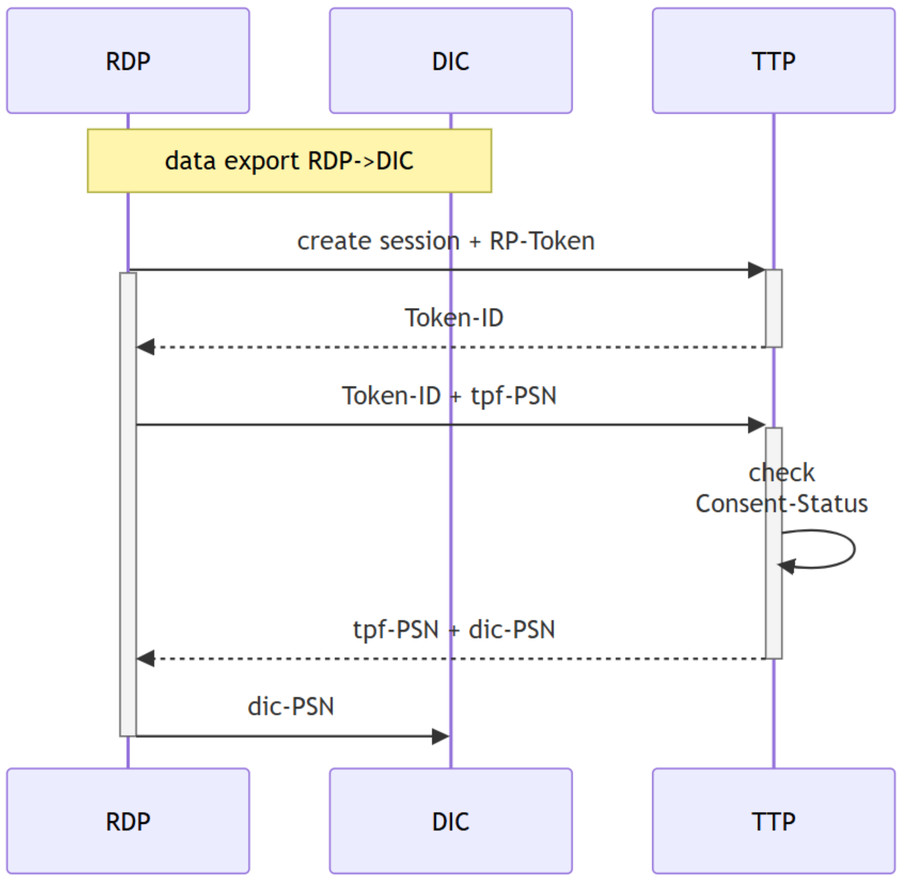

Figure 2: Sequence diagram illustration the process of exporting data to identify patients with and without objections under the LKHG MV

Concept & Implementation

At the University Medicine Greifswald (UMG), the implementation integrates the Objection Office within the TTP, leveraging existing secure infrastructure and organisational independence. The data flow (see Figure 1) begins at the point of patient admission (SAP/MKIS), where objections are recorded. The TTP then processes these requests and distributes them to the Research Data Platform (RDP) via the Orchestra communication server. This enables the DIC to filter data in real time based on the patient's current objection status (see Figure 2 for technical details). The entire architecture adheres to four principles: verified identity, purpose-specific processing, lean documentation and flexible objection capabilities.

While the formal Objection Office is being set up, the UMG Data Protection Office is managing interim measures. The technical foundation, however, has been fully implemented within the productive TTP system using gICS® to manage opt-out scenarios.

A digital opt-out template was deployed via batch processing for approximately 365,000 registered patients. Using gICS®, specific "policies" were defined to reflect the legal requirements of LKHG MV, ensuring that data usage is both purpose-bound and transparent. Consent statuses are made available to other institutions (e.g., DICs) via standardised HL7 FHIR, SOAP or REST APIs.

Discussion & Conclusion

The transition from manual interim solutions to a centralized, automated objection system at UMG demonstrates that legal compliance in health research requires more than legal interpretation - it demands deep technical and organizational integration. While manual processes can ensure basic compliance in the short term, they lack the scalability and auditability required for large-scale research.

The UMG model serves as a practical blueprint for the implementation of the European Health Data Space (EHDS). As Europe moves toward a standardized framework for the secondary use of health data, the UMG's approach proves that a centralized objection office is essential to balance medical innovation with patient autonomy. By leveraging existing MII infrastructures (TTP and DIC), institutions can reduce operational costs and accelerate the adoption of federal (GDNG, GeDIG) and European mandates. Ultimately, automating the "Opt-out" process is not just a technical requirement, but a prerequisite for maintaining patient trust in the digital health ecosystem.

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