Enabling Access to Clinical Care Data for Health Services Research – Recent Developments in Applied Medical Informatics in Germany

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In the course of an unscheduled need to replace its hospital information system (HIS; German: KAS) the University Medicine Greifswald (UMG) initiated the KAS+ project. A novel integrated IT infrastructure will connect patient care ("KAS") and research (the "Plus"). By this, patient care data will be made available for research purposes, and conduct of research projects, e.g. clinical studies, will be supported. The architecture also allows to construct and implement dynamic clinical processes.

The goal is to improve research opportunities and personalization of care simultaneously based on a fully integrated management of clinical data.

(1) Data Privacy Protection
Challenge: According to German as well as EU regulations research use of a patient's medical data must be specifically consented. Identifying data (name, address,...) have to be separated and particularly protected.
Solution: Data privacy requirements are met by a technically and organizationally independent Trusted Third Party (TTP). The TTP provides tools for identity, consent, and pseudonym management. (www.mosaic-greifswald.de)

(2) Synchronization of metadata
Challenge: Most conventional KAS Components do not store medical metadata according to the guidelines of good epidemiological practice (GEP). In others, metadata are part of the core implementation and thus hard to extract.
Solution: A central metadata repository (MDR) holds all metadata of the multitude of heterogeneous clinical data sources. Manufacturers of all components of the IT infrastructure supply their own metadata for the MDR in a compatible digital format.

(3) Provision of research data
Challenge: The previous hospital IT infrastructure was built on a multitude of systems many of which are not interoperable, some where not even connected. Moreover, neither methods nor formats of documentation were compatible.
Solution: Medical data from all data sources are transformed by the data integration platform (orchestra by x-tention). To provide adequate data privacy protection, data are cached in a "Privacy Protection & Interface Layer" (PPIL) until a consent is issued. Upon consent, these are pseudonymized and transferred to the research platform.

The UMG’s KAS+ architecture allowing for an optimal integration of components with existing systems that defines an approach for similar infrastructure projects.

The KAS+ project is a strategic partnership of the university hospital, health care researchers, and IT-industry providing the platforms for patient care (MCC by Meierhofer AG), and research (CentraXX by Kairos GmbH).