Medical Informatics Initiative

Supporting Project – Central Office of the National Steering Committee

Data Sharing Working Group – Uniform Use and Access Policy Key Issues Paper

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Preface

A key objective of the German Federal Ministry of Education and Research's Medical Informatics Initiative (BMBF MII) is to create uniform, underlying conditions for uniform, nationwide data access and data sharing. To achieve this objective, in addition to technical harmonization, it is necessary first and foremost to establish uniform, organizationally and legally assured underlying conditions for data access and data use. For this reason, the Data Sharing Working Group focused on the fundamental principles of data sharing and developed the following key issues for a uniform use and access policy. In addition to the provisions of this key issues paper, compliance with data privacy and protection regulations (at the state, country, and EU level), provisions of hospital law, guidelines from medical profession legislation, patent and copyright laws, and potentially other aspects of the legislative environment governing the protection of patients who receive care (German Civil Code (*BGB*)) or participate in studies (German Pharmaceutical Law (*AMG*), German Medical Devices Act (*MPG*)) is also required.

The Medical Informatics Initiative (MII) will be sponsoring efforts by consortia, made up of at least two health care locations associated with a university and possibly other partners, to specify and establish data integration centers for improved data access and data sharing, which generally will constitute a location-based compilation of data and allow for cross-consortia use. The following key issues for a use and access policy are presented based on the assumption that the distribution of data integration centers and associated use & access committees that are involved in the data sharing decision-making process will be determined within a consortium and will be designed so as to be transparent for external researchers and partners.

These key issues for a uniform use and access policy are initially focused on making data documented in connection with routine patient care available for secondary purposes. Furthermore, it will also be the mission of the DICs to be established in connection with the Medical Informatics Initiative to make primary data collected in a research context (from studies, registers, cohorts, etc.) available for research and patient care purposes in a uniformly processed and integrated format. The key issues in this paper have not fully captured the underlying conditions necessary for re-use of primary data from research and will need to be augmented in a later version.

It is important to note that the purpose of this key issues paper is to provide guidance. It does not result in any automatic, legal obligation independent of review and confirmation of all of the required steps by the organizational and legal committees of the data producers or, respectively, the participating consortia and their partners.

This key issues paper is also intended to draw attention to the inspiration provided by international activities relating to the topic of data sharing. Reference is made in particular to the FAIR Initiative in this regard[1].

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[1] Wilkinson MD (2016) The FAIR Guiding Principles for scientific data management and stewardship, http://www.nature.com/articles/sdata201618 (retrieved March 24, 2017).

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1. Definitions

a) Use & Access Committee

Each consortium is to establish one or more use & access committees (UAC) and stipulate their responsibility for the data integration centers (DICs). These UACs will perform reviews of the suitability and subject matter of requests to use data, consulting local experts in the fields of data privacy and protection, ethics commissions, and legal departments in the process. They will make a decision regarding whether to approve use, whereby the consent of the data producer is to be obtained. Each UAC is to establish for itself a use and access policy and/or rules of procedure governing the details.

b) Data User

This is the role of individuals or institutions that avail themselves of the services provided in connection with the Medical Informatics Initiative in order to locate and to use data. These individuals or institutions may be part of the same consortium to which the data query is addressed (intra-consortial) or to a different consortium (inter-consortial) or they may exist outside of one of the participating consortia (external) (see the definition of "consumer" in the OAIS[2]).

c) Data Producer

This is the role of individuals or institutions that make data available for data sharing (see the definition of "producer" in the OAIS[2]).

d) Request to Use Data

Requests lay out the subject matter constituting the rationale for and the formal procedures of a project involving the use of data.

e) Coordination and Registry Office

The Coordination and Registry Office is a central and neutral institution within the monitoring body that handles coordination and administrative tasks. It accepts requests to use data from external partners and turns these over to the relevant UACs or data integration center transfer offices. It maintains a central registry of all data sharing projects and an index of local use and access policies and rules of procedure.

f) Transfer Office

The transfer office is one of the roles of a DIC. It is responsible for the technical and, as applicable, administrative implementation of data sharing.

g) Data Use Agreement

The data use agreement governs all of the legal and administrative aspects for the partners participating in a project involving data sharing; its content relates to the joint request by the partners participating in a project involving the use of data.

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[2] CCSDS Reference Model for an Open Archival Information System (OAIS). Recommended Practice. Magenta Book. 2012. Consultative Committee for Space Data Systems: Recommendation for Space Data System Practices, CCSDS 650.0-M-2, http://public.ccsds.org/pubs/650x0m2.pdf (retrieved: 2017-03-24).

2. Purpose

This use and access policy is intended to create a transparent and efficient foundation for uniform national data access and data sharing for medical care and research purposes[3], whereby the interests of the researchers and institutions participating in the research project and the interests of the institutions providing data and their employees as well as the interests of patients and subjects are to be balanced against one another[4].

3. Basis and Purpose of Use

The basis for data sharing is the informed consent – structured so as to be as broad as possible – of the patient, or other legislative basis for purposes of medical care and research[3]. A request process is required for the access and use of data. In addition to the participating consortia and their locations, a request can be filed by any public or private institution for the specified purposes. By filing a request, the requester is obligated to comply with the fundamental legal, ethical, and scientific conditions and standards.

4. Roles of the Local UACs and Data Integration Centers

a) A UAC is to be formed at every MII location that has a data integration center.

b) This UAC will be in charge of deliberating on the content and formalities of the data use requests submitted. It will make a decision regarding data use in compliance with the respective applicable use and access policy and rules of procedure. Data use can mean that data is turned over, or it can also mean that access will be granted to locally stored data for distributed analysis processes.

c) Each location is to stipulate in its use and access policy how the data release guarantor's role is to be arranged (e.g., use cases PIs, department managers, hospital directors).

d) In the case of comprehensibly accessible data use from several locations, one UAC should take over as the lead committee. It will then share the results of its deliberations with the other UACs involved so that those UACs can use the results for their decisions.

e) Each local UAC will take on an oversight role and can request reports on the status of the data release, data processing, and publication of the project it is monitoring at any time.

f) The relevant data integration centers are to provide the data users filing requests with access to the data in compliance with the use and access policy and rules of procedure.

g) Each data integration center is to develop an archiving plan for released data for purposes of ensuring that analyses can be reconstructed.

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[3] "Medical research" refers to any type of medical research, in particular illness-oriented research, patient-oriented research, basic research, biomedical research, systems medicine research, and health services research.
[4] With regard to the objectives of the German Federal Ministry of Education and Research's Medical Informatics Initiative (BMBF MII) see also the Mission Paper dated December 22, 2016

h) The data transfer offices of the data integration centers are to assist the Central Project Register of the Central Coordination and Registry Office by providing regular reports and updates for all of the data use requests processed (transparency requirement) via a project portal to be constructed.

5. Central Coordination and Registry Office

a) A Central Coordination and Registry Office of the Medical Informatics Initiative (CCR^{MII}) is to be created to support access for use of data by external users (see above) and for the transparency of all uses of data.

b) Requests to use data submitted via the CCR^{MII} are to be forwarded by the CCR^{MII}, after a review to ensure that the formal requirements have been met, to the UACs of the consortia for their review of the subject matter and suitability. Their decision regarding data use for the intended research is then conveyed to the CCR^{MII} and registered. The CCR^{MII} then forwards the decision to the requester.

c) The consortia are to ensure that requests for which a decision has been made are processed and are to establish the conditions necessary for doing so.

d) The consortia and locations are to declare their commitment to supporting the purpose of the policy (Section 2). However, whether data is made available depends on a decision made voluntarily by the individual institutions, and they are free to decide against doing so in any given case (opt-out). As part of this process, corresponding rules in line with the objective of the funding program and which take into consideration the interests of the parties providing data are to be implemented and made transparent. If a decision is made against turning data over, reasons are to be provided.

e) The CCR^{MII} is to maintain a public register that documents all of the approved and, as applicable, denied uses of data from all of the DICs of the MII. It is to report annually on the status of registration.

f) The CCR^{MII} is to set up an independent, central arbitration board. The makeup, responsibilities, and rules of procedure of the arbitration board are to be laid down during the first year of the Medical Informatics Initiative's setup phase.

g) In light of the setup work to be performed by the MII, the goal is to have an option for use of data by external users starting in 2020.

6. Central Project Register

The CCR^{MII} will maintain a project register with records of all requests to use data for projects involving data sharing and the results of such requests (intra-consortial, inter-consortial, and external), which will serve to satisfy the transparency requirement for data use. The register will also contain information on the progress of the approval process for the project involving data sharing. Key information from the register about data sharing will be made available to the public. No payment will be required to access this information. The register will be subject to quality assurance measures to ensure the validity of the information found there. It will be able to be searched electronically. Rules of procedure to be adopted by the National Steering Committee will set out the procedures in more detail.

7. Simultaneously Turning Over Data Where Research Objectives Overlap Heavily

Where similar research projects overlap heavily, during the request process, the relevant use & access committee should work toward cooperation between the requesting project partners, taking into consideration the interests of all of the participants.

8. Patents and Other Intellectual Property Rights

The data user may not apply for any patents or other intellectual property rights related to or underpinned by the data turned over by the data producer without express written consent. The institutions providing data are to be stakeholders in all patents or other intellectual property rights arising from data made available. The nature and scope of the interest held is to be laid down in a contractual agreement with individually negotiated clauses.

9. Publications

a) Publications on the results of the data use are to be pursued.

b) Publication projects, their nature, scope, and rules for assigning authorship are to be described in a publication plan in the project request.

c) The institutions providing data are to be informed of all intended publications that are based on the data made available. A note must be added to any publications based in whole or in part on the data turned over by the data producer stating that the data was made available by the institutions providing the data. Those individuals involved who generated or processed the data on behalf of the institutions turning the data over are to be identified in an appropriate fashion. In all other respects, the version of the Guidelines on Good Scientific Practice published by the German Research Foundation (DFG) valid at the time apply to all publications.

10. Rules for Using Data

a) **Underlying conditions for data sharing**
   Data are to be turned over exclusively in accordance with statutory guidelines or the guidelines set out in the consent forms signed by the data subjects and presented to the data users. When data is disclosed for research projects, appropriate security precautions are to be taken to ensure the privacy of the participants and the confidentiality of the data (e.g., anonymization, pseudoanonymization).

   The project partners must take technical and organizational measures that adequately safeguard the data turned over by the data producer against unauthorized access and loss; such measures must comply with the statutory guidelines, particularly those governing data protection. In particular, the recipient may not make any attempt at re-identification and must immediately notify the institution turning over the data of any suspicion of violation of data protection regulations (e.g., in the event re-identification is possible or might be possible) or other irregularities during the processing of data.

b) **Adherence to the request, approval, and responsibility**
   The data turned over by the data producer are to be used exclusively for the requested and approved use and only within the time period for which the request was made and approved.

Stipulations and conditions contained in the approval are to be complied with. A new request must be filed for any other (intended) use of the data above and beyond that requested – even use of data that may be necessary beyond the originally requested time period. The requester is responsible for the use of the data and must document what other associates had access to the data; the requester must have those associates affirm their compliance with the use and access policy in writing.

c) Prohibition on disclosure
The copying and disclosure of data material to third parties above and beyond the requested and approved use is barred. If third parties would like to use data, a new or revised request to use data must be filed.

d) Obligation to delete
The data user must delete the data provided once the period of use specified in the project request has ended. The obligation to store project data in the case of publications can be satisfied by the DICs. In such cases, the DICs are to ensure that the project data, including the results, are available to the project for later inspection of the data and follow-up analyses (see recommendation 6.1 of the Guidelines on Good Epidemiological Practice published by the German Society for Epidemiology (DGEpi)). This shall not have any effect on the Rules of Good Scientific Practice or other legal provisions. The deletion is to be confirmed to the relevant transfer office in writing.

e) Sanctions for breaches
In the event of breaches of the use and access policy or of the data use agreements for the specific project, the approval granted to the project partner for use of data can be withdrawn in whole or in part.

11. Rules for the Request Process

a) Data will be turned over only after a request is filed. A request process is to be implemented for this purpose. The request is to contain the following information:
- Principal investigator
- Contracting party
- Other participants (e.g., cooperation partners)
- Project title
- Project objective
- Project description
- Scientific background
- Intended time period
- Work schedule
- Details of the data required (use of the metadata index)
- Publication plan
- Information on feasibility
- Additional positive evaluation by an ethics committee, if applicable

b) When a request is filed, the consortia are to ensure that potential project partners are presented with the option of a feasibility review of their research project. A process is to be set up for this purpose to report back to the requester the number of potential patients and study subjects within the limits of the options allowed under data privacy and protection law.

12. Data Use Agreement

a) A data use agreement must be signed in order for data to be turned over after approval is granted. By signing this agreement, the project leader and project partner are committing themselves in writing to compliance with the conditions and stipulations for use.

b) In particular, the data use agreement is to specify:

    i. The project start and end dates

    ii. The data to be provided for the research project

    iii. Provisions governing patents and other intellectual property rights as per Section 6, rules for using data as per Section 8, the obligation to file reports and provide information as per Section 9, and the reporting of results as per Section 10

    iv. The latest date for deletion of any data turned over by the data producer

13. Obligation to File Reports and Provide Information

Within one year of the project's end, the project partner must send to the DIC or, respectively, UAC issuing the data a final report in written and electronic form. The UAC is to forward this to the Central Coordination and Registry Office. Where data is used to author a scientific publication, submission of the publication manuscript will suffice.

14. Reporting Results

As a general rule, results and data derived from research projects that are relevant for further use by the DICs are to be sent to the DICs involved in suitable electronic form once the research project has been concluded. Further details are to be governed by the use agreements.

15. Liability and Responsibility

The institution responsible for data collection and processing

1. provides no guarantee above and beyond the quality level defined in its QM system (or expanded via supplemental, project-specific SOPs) for the correctness and suitability of the data for the requested and approved purpose.

2. assumes no liability for losses of any kind arising due to the work with the project data.

The foregoing limitations of liability do not apply in the event of willful misconduct or gross negligence. Except for incidents of intentional breach of contract (obligations), the institutions collecting data assume no liability for indirect loss. The foregoing limitations of liability also apply with respect to the statutory liability of the institutions responsible for data collection and to the personal liability of its legal representatives, employees, and independent parties assisting with or subordinates assigned to render performance.

The data user is responsible and liable for the handling of all data transmitted. The project partner is liable for all losses of any kind caused by the project partner during the use of the data materials, in particular any such losses as arise due to the unauthorized use of or disclosure of data and/or results.

Abbreviations

AG	"Arbeitsgruppe" (Working Group, WG)
AMG	"Arzneimittelgesetz" – German Pharmaceutical Law
BGB	"Bürgerliches Gesetzbuch" – German Civil Code
BMBF	"Bundesministerium für Bildung und Forschung" – The Federal Ministry of Education and Research (www.bmbf.de)
CCSDS	Consultative Committee for Space Data Systems (https://public.ccsds.org)
DFG	"Deutsche Forschungsgemeinschaft" – German Research Foundation (www.dfg.de)
DGEpi	"Deutsche Gesellschaft für Epidemiologie e. V." – German Society for Epidemiology (http://dgepi.de)
DIC	Data Integration Center in the Federal Ministry of Education and Research's Medical Informatics Initiative funding plan
ISO	International Organization for Standardization (www.iso.org)
MI	Medical Informatics
MPG	"Medizinproduktegesetz" – German Medical Devices Act
NSC	National Steering Committee of the Federal Ministry of Education and Research's Medical Informatics Initiative
OAIS	Open Archival Information System: Reference model and ISO standard for archival systems
UAC	Use & Access Committee
CCR[MII]	Central Coordination and Registry Office of the Medical Informatics Initiative