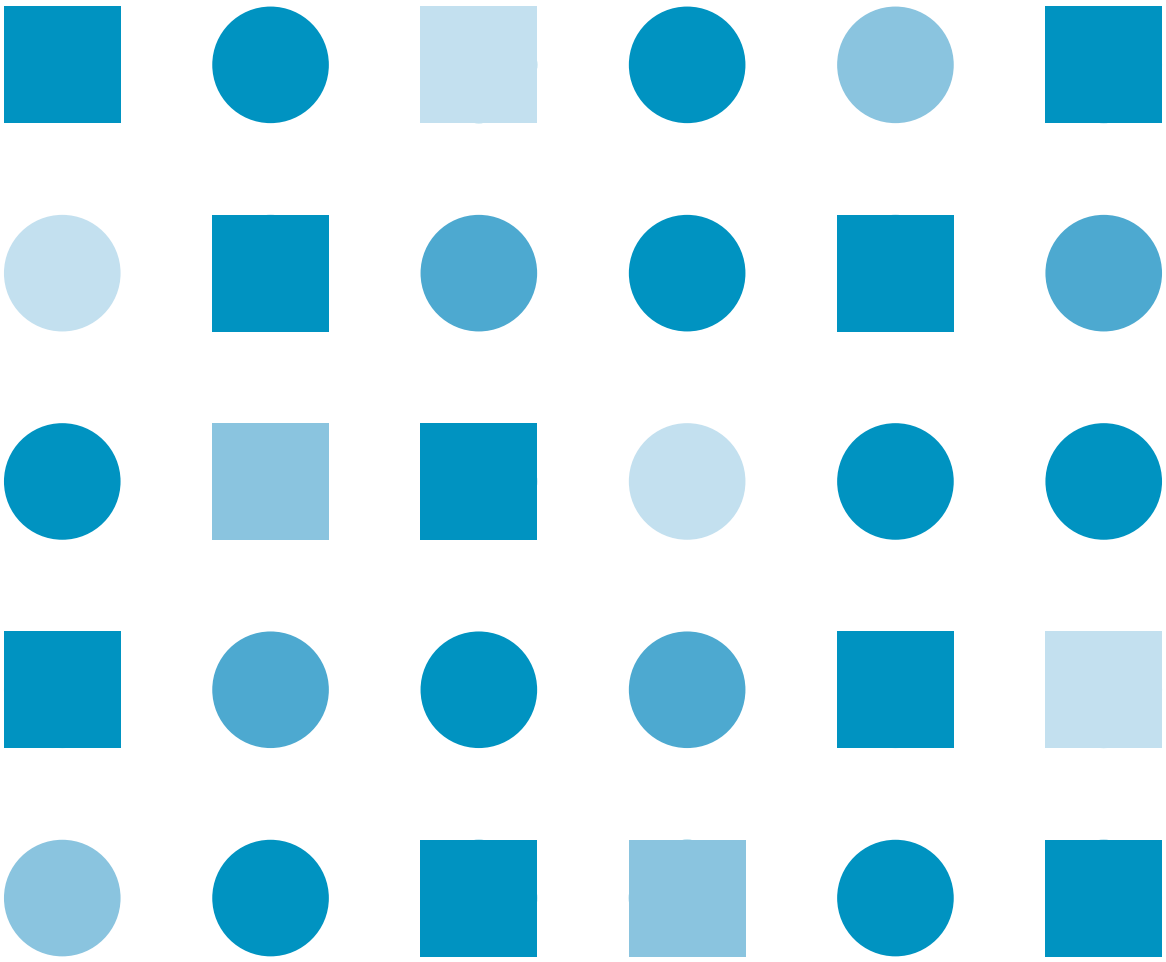
Recommendations for the development and operation of health-related registries



Issued by:
ANQ, FMH, H+, SAMS, University Medicine Switzerland
July 2016, version 1.0

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Fundamentals

Preamble

The following recommendations for health-related registries have been prepared by the organisations ANQ, FMH, H+, SAMS and University Medicine Switzerland. The recommendations represent minimum standards for the development and operation of health-related registries, i.e. systematic collections of health-related personal data. When implementing the recommendations, consideration should also be given to the specific aims, scope and field of application of the registry.

Target groups and aims of the recommendations

These recommendations are addressed primarily to the managers responsible for registries, their staff and the participants involved. They are also addressed to the management of hospitals and other service providers, to health and accident insurers, and to political institutions involved in planning.

For existing and future registries, the recommendations provide a basis for assessing quality and ensuring that:

- health-related registries are appropriately structured so that they can fulfil their function;
- protection of privacy rights is assured for the persons whose health-related data is recorded;
- appropriate guidance is available for agencies providing funding for registry organisations;
- registry managers and staff have the necessary scientific and technical expertise;
- the human and financial resources required for this purpose are made available;
- data is collected, recorded and used in accordance with clearly defined criteria;
- the quality of data is assured and documented;
- further use of data for research and quality assurance is appropriately regulated.

Background

Patients, health policymakers and service providers have a legitimate interest in high-quality – and at the same time affordable – healthcare. Here, health-related registries have an important role to play. They are a key element of quality assurance, contribute to the transparency and comparability of medical services, provide a basis for clinical and epidemiological research, and deliver essential data for health policy and planning. They are becoming increasingly important not only because of the spread of chronic diseases but also in the light of recent developments such as personalised medicine, big data, self-tracking (quantified self technologies), e-health, etc.

A large number of registries exist[1], and their functions and aims vary according to the field of application (and the legal foundations).[2] For the purposes of the following recommendations, a *health-related registry* is defined as a systematic collection of health-related personal data, gathered in accordance with specified criteria.[3]

The development and operation of a registry frequently requires substantial investments of time, organisational effort and financial resources. The value of the data collected can be undermined by incomplete and/or inconsistent data registration, barriers to data access, lack of expertise on the part of registry operators and staff, inadequate resources, etc. Registries can only fulfil their function if their financing is assured. In addition, the operators must have appropriate infrastructure and procedures, an adequate organisation, the requisite expertise in registry development, management and use, and the necessary human and financial resources.

Legal aspects

Managers and staff are primarily bound by the legal framework applicable for the registry in question (cantonal and federal data protection legislation, Federal Statistics Act, Health Insurance Act, Therapeutic Products Act, Epidemics Act, Human Research Act, Cancer Registry Act, Electronic Patient Record Act, etc.).

The present recommendations have no legal force and are thus not legally binding. The aim is that funding bodies, operators and participants should agree to adopt these recommendations for registry development and operation.

1 Cf. for example: www.fmh.ch/saqm/_service/forum_medizinische_register.cfm
2 Cf. the DDQ paper: Medizinische Register: Wo liegt der Schlüssel zum Erfolg? / Registres médicaux: où se trouve la clé du succès? *SÄZ / BMS* 2012;93:35: 1253 ff.
3 Various definitions are used in the literature. The definition used here is based on the paper cited in footnote 2. Cohort studies can also be regarded as registries if they are conducted in accordance with these recommendations.

Recommandations

The following recommendations are applicable for health-related registries, as defined in Section 1.2. When implementing these recommendations, it is essential to take into account the specific aims, scope and field of application of the health-related registry. They are designed for the evaluation of registries that are planned, under development or already operating and are therefore formulated in general terms. The relevance of individual recommendations may vary depending on the aims and function of the registry.

1 Preparatory work at the planning stage

	Criterion	Comments*
1.1	The need for the registry and the benefits are specified for all parties, including patients.	The reasons why the registry is needed are clearly explained (e.g. disease incidence/prevalence data, indication quality, qualitative comparison of institutions as a control instrument for authorities, etc.).
		Reasons are given to explain why a registry is required for the thematic area in question and why there are no alternative solutions (e.g. studies).
		A detailed account is given of the direct, or at least indirect, benefits for service providers or third parties (e.g. federal/cantonal authorities) and for patients.
		The cost-benefit ratio is balanced and is clearly presented.
1.2	The legal framework is clarified.	The contractual and/or legal basis is documented.
		The relevant legal framework – cantonal and federal data protection legislation, Federal Statistics Act, Health Insurance Act (KVG), Therapeutic Products Act, Epidemics Act, Human Research Act, Cancer Registry Act, Electronic Patient Record Act, etc. – is clarified in advance.
		The relevant approvals (e.g. ethics committee, data protection) are available when data collection begins.
1.3	Integration of the registry is defined.	Before a new registry is established, linkage to existing national/international registries and/or registry consortia is to be examined and initiated, unless there are reasons not to do so. (For existing registries, see also: www.fmh.ch/saqm/_service/forum_medizinische_register.cfm)
		The nature of the registry – regional, national or international – is declared.
		If participation is obligatory, the commissioning body is specified.
		To avoid duplication, investigations concerning existing data are carried out in advance.

* The comments are to be understood as offering guidance. The points listed by way of example illustrate how each of the criteria can be met.

	Criterion	Comments
1.4	The context and any competing interests are transparently disclosed.	The context in which the registry initiators and commissioning body (e.g. authority, service provider, NGO or professional association) act is transparently disclosed, together with any conflicts of interest.
1.5	Development and longer-term funding are assured, a financial plan is available.	A detailed financial plan is available.
		The financing of the registry is clearly and transparently presented, and the funding bodies are identified.
		The costing takes into account initial development of the registry, including infrastructure, database, user training costs, etc., and longer-term maintenance, including periodic evaluations and additional analyses.
		Responsibility for financing of the registry is defined by the commissioning body and the operators, and is adapted to the aims and purposes of the registry, i.e. – costs/financing of KVG-related elements must be separately quantifiable. This makes it possible to meet the requirement for separate statement of chargeable costs and for differentiation of costs for research, etc.; – if registry participation is mandated by the state or through existing contracts, it needs to be defined how data collection is to be financed for registries with a legal framework other than the KVG (Epidemics Act, Cancer Registry Act, etc.); – for modular structures (e.g. obligatory or voluntary components), the financing of individual modules is transparently presented.
		Detailed estimates are available of the time required for data collection [4] and data processing – both for registry participants and for operators.
		Costs are presented for the preparation of accompanying documentation, such as user/data regulations, evaluation plans, periodic reporting and publications, as well as data validation costs.
		Resources are defined for (if necessary) multilingual development (programming, product databases, manuals, etc.) and for operation with multilingual support.

4 The term “data collection” covers the entire process from patient data collection to the availability of data which has undergone cleansing and plausibility checking.

2 Registry design

	Criterion	Comments
2.1	The aims and functions are clearly defined, and the questions to be pursued are formulated.	The aims and associated functions of the registry are clearly defined, as well as the questions to be pursued.
		Conditions and the framework for participation (optional or obligatory) are defined.
		The type and scope of data collection (full or partial) is defined and justified.
		The lifetime of the registry is defined (limited or unlimited period).
2.2	The organisation of the registry is clearly described in a plan/regulation.	A plan is available, describing the organisation and the key elements and functions of the registry.
		All the actors concerned are involved in the development of the registry, and their roles and responsibilities are defined and documented.
		The commissioning body and registry manager are specified in the plan, as well as the roles and responsibilities of other actors involved.
		Whenever possible, the structure of the registry should be modular (modules for different uses).

3 Expertise required for registry management

	Criterion	Comments
3.1	The managers' expertise matches the aims of the registry.	The expertise of registry managers matches the aims of the registry. Registry operators have the types of expertise listed below.
		It is shown in what form institutionalised exchanges take place between clinicians, statisticians and software operators/developers.
3.2	Scientific expertise is assured (methodology, clinical expertise in the relevant area).	The body responsible for management of the registry ensures that the requisite scientific expertise and experience in the relevant area is available.
		The expertise required for data analysis, interpretation and reporting is available.
3.3	Technical expertise is available (registry development, processes, logistics, database quality and security).	The body responsible for management of the registry ensures that persons with the requisite expertise in scientific methodology, statistics, processes and IT are available and fully involved in project organisation.
		Experience in the management of large and complex datasets is available.

4 Data protection and data ownership

	Criterion	Comments
4.1	Data regulations are available, covering the following points:	
a)	Protection of privacy: description of data anonymisation/coding processes and informed consent, as well as the right to inspect data, management of revocation of consent and data storage.	Though this list is not exhaustive and not applicable for all registries, the following points are to be checked:
		The documentation system used is compatible with the legal provisions.
		The need for the patient's written consent has been examined.
		The patient information sheet and declaration of informed consent (verbal or written) are available, in line with current standards and compliant with legal requirements.
		Regulations exist for the management of data in the absence of informed consent.
		A clear description is given of the need and of the processes for coding and/or anonymisation of personal data.
		Should the need arise, patient identification or re-identification is possible.
		Donors' right to inspect data is assured.
		The management of revocation of the data donor's consent is regulated.
		Data storage is regulated.
b)	Data access/data ownership/ inspection and access rights/further use of data by third parties.	All data sources (e.g. administrative/official data, different departments, forms, analytical instruments) are identified and responsibility for data collection is defined.
		Inspection and access rights are explicitly defined and are specified in a cooperation agreement between the actors concerned and/or in the data regulations.
		The registry operator has access to the raw data with the smallest possible number of designated persons.
		Data ownership, transfer and use of data by third parties are defined.
		The conditions for use of data for research purposes are specified, and the necessary processes for reviewing requests and transmitting data to research leaders are defined.
		For all the above-mentioned aspects of data protection, the necessary provisions are described in plans/regulations and accessible to all persons involved in the registry.

5 Data collection and data use

	Criterion	Comments
5.1	The data variables to be collected are clearly defined and adapted to the aims.	Data collection is adapted to the defined aims (as short as possible and as extensive as necessary).
		The data variables to be collected are scientifically valid, clinically relevant and accurately describe the outcome (e.g. quality indicator).
		Important demographic variables are specified.
		The inclusion and exclusion criteria are defined for the study population.
		The necessary clinical/anamnestic variables are specified.
		Important procedural variables are specified (e.g. type of intervention and important details influencing the outcome).
		Risk variables influencing the outcome are identified (for risk adjustment).
		The greatest possible harmonisation of variables is sought, based on existing nomenclatures with consolidated definitions.
		The number and type of data collection instruments used (assessment instruments, questionnaires, etc.) are clearly shown and are adapted to the aims pursued.
		The data collection instruments are valid und reliable; reference is made to the relevant literature.
5.2	Technical structures are adequate and capable of development.	If possible, established ICT platforms, interfaces and software solutions are used, allowing for future connection to e-health and permitting research.
		The interfaces required for efficient and, if possible, fully automated registry participation are available.
		A modular registry structure (minimum dataset, health, accident and other social-insurance-related modules, research modules, etc.) is implemented as far as possible. This is necessary for different financing streams and permits targeted participation. It also allows registry participation to be appropriately integrated into local or regional research or other quality assurance programmes, and redundancy due to changes of system or media is avoided.
		The software used permits flexible expansion beyond the core dataset, either in the form of permanent additional modules for interested participants or temporary additional modules for studies.
		The registry portal offers additional functions, which permit autonomous use of data by participants or provide anonymised and limited access to the data pool.
		The registry software has administrative functions, user-friendly data input, and graduated role and profile assignment, as well as data sharing options.
		The registry software has central remote administration, including functions to support participants in their activities.
		If a registry includes additional components such as follow-up investigations or patient-completed questionnaires, planning and administration functions are available to facilitate management and overviews.

	Criterion	Comments
5.3	Linkage to administrative/official data or the option of integration into hospital information systems (interoperability) is assured.	Whenever possible, technical and definitional linkage to administrative/official data (MedStat) or the option of integration into hospital information systems is assured. This basis promotes standardised data collection across different specialties, improves data quality, simplifies quality assurance and relieves the burden on service providers' human resources. Duplication in data collection is avoided or reduced to a minimum.
5.4	A data flow diagram is available, clearly describing data collection[5], transmission and processing.	The collection, management, transmission and transfer of data (e.g. from hospitals to the registry operator), as well as data processing, is specified in a data flow diagram. The data flow diagram is a component of the registry documentation and is accessible to all persons involved in the registry.
5.5	An evaluation plan is available, precisely describing data analysis and the reporting of results.	How data is to be evaluated in accordance with the aims of the registry is defined in advance. In an evaluation plan, the processes of data preparation and analysis are described clearly and in detail. The following topics are covered in detail: descriptive analyses; risk adjustment method; presentation of the results of data analysis; types of report and reporting for different target groups (online, paper, etc.), intervals (annual, half-yearly) and the addressees; authors or publishing institution/organisation. The evaluation plan is accessible to all persons involved in the registry.
5.6	A publication plan is available, precisely describing the requirements, content and form of publication, as well as target groups.	The publication of registry data and associated indicators is defined in a publication plan, specifying the form of publication (anonymised, coded or transparent), presentation, timing, medium, etc. As far as possible, registry operators, data suppliers and users are involved in the process of developing the publication plan. The (initial) publication rights, target groups and goals of publication are defined. The publication plan is accessible to all persons involved in the registry.
5.7	Further use of data for research is supported.	The framework for the transfer of data to third parties for research purposes is defined. Data sharing under specified conditions in the interests of open science is highly recommended.

5 The term "data collection" covers the entire process from patient data collection to the availability of data which has undergone cleansing and plausibility checking.

6 Quality assurance

	Criterion	Comments
6.1	A validation plan is available, including periodic review procedures, to ensure data quality.	The validation plan specifies measures to enable quality assurance of registry operations and ensure a high level of data quality. This includes details of measures within the data collection process and measures for retrospective assessment of data quality (e.g. programme, content and criteria for assessment procedures or monitoring visits, etc.).
		The scope and priorities of validation are based on the aims and functions of the registry in question.
6.2	The registry's aims and functions are periodically evaluated for their appropriateness.	It is explained how, at specified intervals, the aims and functions of the registry are to be periodically evaluated with regard to appropriateness and the attainment of goals.

7 Change of purpose and dissolution

	Criterion	Comments
7.1	Processes for a change of purpose are defined.	In the event of a change of purpose of the registry (e.g. new control purposes on the part of authorities), the interaction between the registry, the additional users and other actors is to be newly defined.
		In the event of a merger with another registry, or changes in the purpose of the registry, processes are defined for data transfer/deletion/destruction.
7.2	Processes for dissolution of the registry are defined.	In the event of dissolution of the registry, processes are defined for data storage times and/or data deletion/destruction.

Checklist for review

1 Preparatory work at the planning stage

1.1	The need for the registry and the benefits are specified for all parties, including patients.
1.2	The legal framework is clarified.
1.3	Integration of the registry is defined.
1.4	The context and any competing interests are transparently disclosed.
1.5	Development and longer-term funding are assured, a financial plan is available.

2 Registry design

2.1	The aims and functions are clearly defined, and the questions to be pursued are formulated.
2.2	The organisation of the registry is clearly described in a plan/regulation.

3 Expertise required for registry management

3.1	The managers' expertise matches the aims of the registry.
3.2	Scientific expertise is assured (methodology, clinical expertise in the relevant area).
3.3	Technical expertise is available (registry development, processes, logistics, database quality and security).

4 Data protection and data ownership

4.1	Data regulations are available, covering the following points:	
	a)	Protection of privacy: description of data anonymisation / coding processes and informed consent, as well as the right to inspect data, management of revocation of consent and data storage.
	b)	Data access / data ownership / inspection and access rights / further use of data by third parties.

5 Data collection and data use

5.1	The data variables to be collected are clearly defined and adapted to the aims.
5.2	Technical structures are adequate and capable of development.
5.3	Linkage to administrative/official data or the option of integration into hospital information systems (interoperability) is assured.
5.4	A data flow diagram is available, clearly describing data collection, transmission and processing.
5.5	An evaluation plan is available, precisely describing data analysis and the reporting of results.
5.6	A publication plan is available, precisely describing the requirements, content and form of publication, as well as target groups.
5.7	Further use of data for research is supported.

6 Quality assurance

6.1	A validation plan is available, including periodic review procedures, to ensure data quality.
6.2	The registry's aims and functions are periodically evaluated for their appropriateness.

7 Change of purpose and dissolution

7.1	Processes for a change of purpose are defined.
7.2	Processes for dissolution of the registry are defined.

Information on the preparation of the recommendations

Consultation procedure

The recommendations for the development and operation of health-related registries were circulated for consultation between 22 October 2015 and 10 January 2016. The following organisations/authorities were invited to comment:

all the medical organisations represented in the governing body of the FMH,
hospitals and clinics,
cantonal authorities,
medical faculties, santésuisse (health insurers), MTK and curafutura,
registry operators listed in the Medical Registries Forum.

Approval

The recommendations were approved on the following dates by the issuing bodies' executive committees:

ANQ	30 June 2016
FMH	23 June 2016
H+	9 June 2016
SAMS	30 June 2016
unimedsuisse	3 June 2016

Evaluation

The recommendations will be periodically evaluated and, if necessary, revised by the issuing bodies ANQ, FMH, H+, SAMS and unimedsuisse.

The recommendations are available on the issuing bodies' websites.

The checklist is available as a PDF file and as an Excel file.

Publication details

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Layout
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