Electronic Health Records

A Systematic Review on Quality Requirements

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Summary
Objectives: Since the first concepts for electronic health records (EHRs) in the 1990s, the content, structure, and technology of such records were frequently changed and adapted. The basic idea to support and enhance health care stayed the same over time. To reach these goals, it is crucial that EHRs themselves adhere to rigid quality requirements. The present review aims at describing the currently available, mainly non-functional, quality requirements with regard to electronic health records.
Methods: A combined approach – systematic literature analysis and expert interviews – was used. The literature analysis as well as the expert interviews included sources/experts from different domains such as standards and norms, scientific literature and guidelines, and best practice. The expert interviews were performed by using problem-centric qualitative computer-assisted telephone interviews (CATIs) or face-to-face interviews. All of the data that was obtained was analyzed using qualitative content analysis techniques.
Results: In total, more than 1200 requirements were identified of which 203 requirements were also mentioned during the expert interviews. The requirements are organized according to the ISO 9126 and the eEurope 2002 criteria. Categories with the highest number of requirements found include global requirements, (general) functional requirements and data security. The number of non-functional requirements found is by contrast lower.
Conclusion: The manuscript gives comprehensive insight into the currently available, primarily non-functional, EHR requirements. To our knowledge, there are no other publications that have holistically reported on this topic. The requirements identified can be used in different ways, e.g. the conceptual design, the development of EHR systems, as a starting point for further refinement or as a basis for the development of specific sets of requirements.

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1. Introduction

Since the dawn of the concept of an inter-organizational, comprehensive, patient-centered health record in the 1990s in the US, the different concepts of such a record (e.g. computer-based patient record or the CCR – continuity of care record) were always driven by the idea to support health care and to maintain, respectively improve, its quality [1]. Despite the fact that the basic idea remained the same, the specific elements contained or the name that was given to these concepts frequently changed over time [2].

Currently, the term electronic health record (EHR) is widely used. It describes the concept of a comprehensive, cross-institutional, and longitudinal collection of a patient's health and healthcare data. It, therefore, includes data that is not only particularly relevant to a subject's medical treatment but also to a subject's health in general. The patient is regarded as an active partner in his/her treatment by accessing, adding, and managing health-related data, thereby supporting care [3]. All further explanations refer to this definition of an electronic health record.

Regardless of the claim to improve quality and support health care, new challenges arose over time that will need to be addressed by modern EHRs. Just to mention two of these: Cost has more than ever become a critical factor in healthcare and, therefore, also has a strong influence on the development of EHRs (see e.g. [4]). Another issue with regard to EHRs is the need for cross-border interoperability on a technical, but also semantic, level. Due to a number of developments, e.g. the free movement of people, goods, services, and capital within the EU or the higher and better availability of mass transport, mobility in a professional and also private way of people is constantly increasing.

Therefore, the development and implementation of EHRs faces a highly competitive environment with heterogeneous requirements from various domains involving different stakeholders.

Table 1 Initial list of criteria used for the coding of requirements (criteria taken from the eEurope 2002 are bold and all other criteria are from the ISO 9126)

• **Transparency and Honesty**	• Usability and **Accessibility**
• Functionality	– Understandability
– Suitability	– Learnability
– **Accountability**	– Operability
– **Authority**	– Attractiveness
– Accuracy (**Updating of Information**)	– Usability compliance
– Interoperability	• Maintainability
– Security, **Privacy and Data Protection**	– Analyzability
– Functionality compliance	– Changeability
• Reliability	– Stability
– Maturity	– Testability
– Fault tolerance	– Maintainability compliance
– Recoverability	• Portability
– Reliability compliance	– oAdaptability
• Efficiency	– Installability
– Time behavior	– Co-existence
– Resource utilization	– Replaceability
– Efficiency compliance	– Portability compliance

1.1 EHRs – Quality and Requirements

Keeping in mind that one of the primary targets of EHRs is to foster the quality of healthcare and support all stakeholders in the process of healthcare, it is crucial that EHRs themselves adhere to rigid systems of quality assurance and management. Such systems must be implemented along the whole life cycle [5] of EHRs reaching from the design to the operation to the maintenance.

The basis for systems that support and foster the quality of EHRs is – apart from the methodological, structural, and organizational aspects – the collection and definition of EHR-specific requirements. These requirements are of a different nature and origin such as functional/non-functional, legal, organizational, etc. The heterogeneity renders an inter-organizational or even cross-country selection and coordination of such requirements difficult.

Regardless of the specific selection of requirements in a certain context, it is necessary as a first step to be aware of scientifically and/or practically proven and relevant requirements for EHRs.

1.2 Objective and Definitions

The current review aims at the presentation of potential, primarily non-functional (quality) requirements with regard to EHRs based on a comprehensive literature analysis and on expert interviews. Functional requirements are only covered as far as the general functions of an EHR are concerned. The focus on non-functional and general functional requirements was drawn, as the number of potential EHR functionalities is huge. It would be very difficult to define a precise scope for the current review, as this would again depend on a definition of a functional range for EHRs. Another reason for the omission of specific functional requirements is that requirements for such functions are strongly influenced by clinical needs.

Functional requirements which are not covered by the review are, e.g., require-

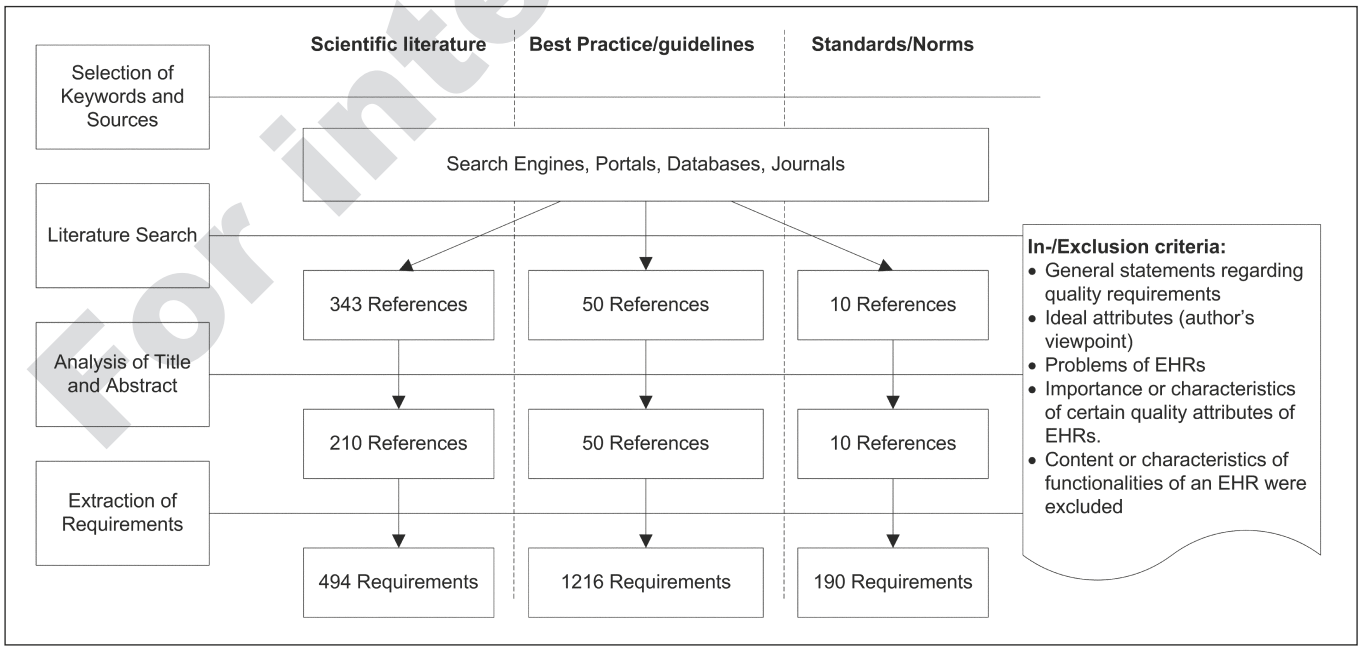

Fig. 1 Short summary of the literature analysis

ments regarding the content of medication lists or requirements that concern order entry. General functional requirements are, e.g., print functionalities, functionalities that concern the display of information or other functionalities such as user authentification.

Quality is hereby defined as the degree to which a set of inherent characteristics fulfills the requirements [6]. Requirements are defined according to IEEE as a condition or capability that must (should) be met or possessed by a system or system component in order to satisfy a contract, standard, specification, or other formally imposed documents [7].

The term quality requirement is intentionally used to denote that the requirements collected and presented in this work are partially rather broad and often concern more than one attribute/characteristic of EHRs.

The following section presents an overview of the methods used to collect and analyze the quality requirements for EHRs and explains the context in which the review was conducted.

Before the methods and results are explained, it is important to note that the manuscript does not aim to present a comprehensive collection of quality requirements in terms of an optimal selection of requirements for EHRs *nor* does the manuscript aim at weighting, rating, or evaluating requirements collected and presented. A selection or rating is regarded as a different task by the authors as this has to be done in accordance with specific quality aims and with regard to a specific context.

Table 2 Comparison of the domains from the literature analysis and expert interviews

Expert Interviews	Literature Analysis
(Legislation and politics)	(Legislation)
Standardization	Norms and standards
Industry, health care providers, and special interest groups	Guidelines and best practice
Science	Scientific literature
Data protection and security	–

Table 3 Total number of experts interviewed for each domain

Domain	No. of Experts
Legislation	1
Standardization	3
Health providers	4
Politics	2
Data protection and security	2
Science	8
Industry	6
Special interest groups	3
Total no. of experts	**29**

2. Methods

In 2007, an extensive research project was initiated with the aim to develop the foundations for the transnational quality certification of electronic health record (EHR) services. The project aimed at developing a fully structured and easily searchable repository of quality requirements, a meta-

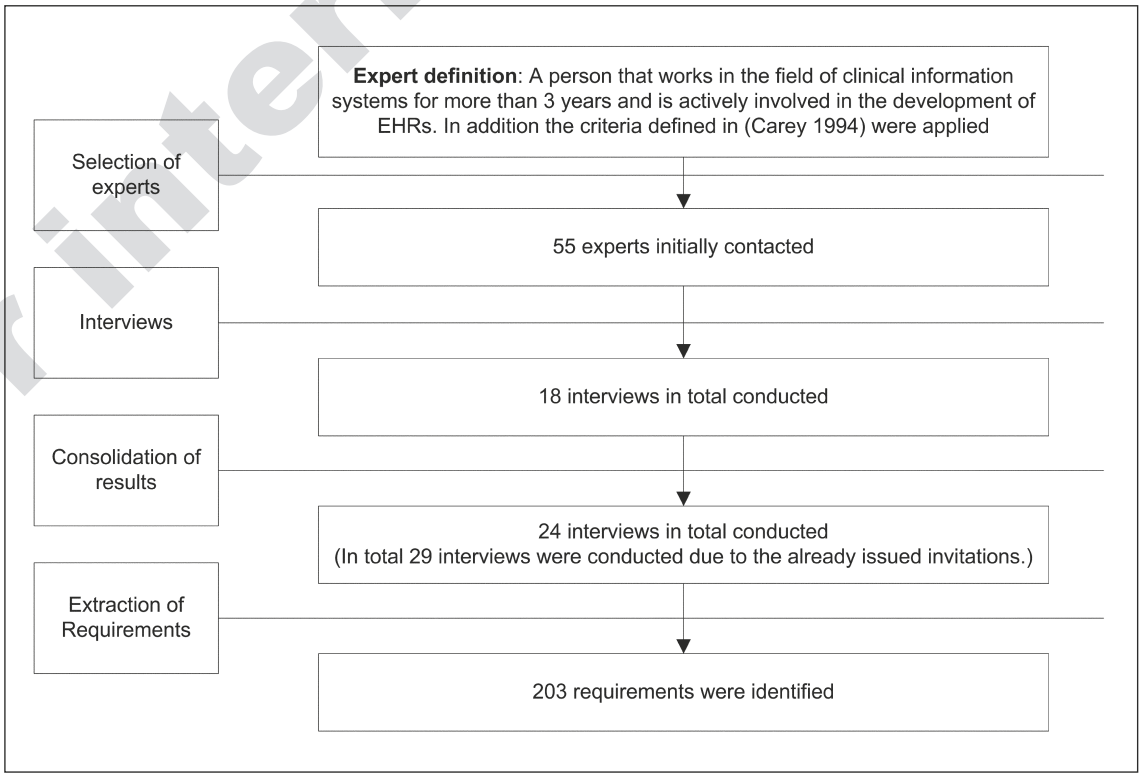

Fig. 2 Short summary of the expert interviews

Table 4 Data security requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Data Security			
Requirements	**References**	**Exp.**	**Cert.**
Security must be guaranteed on different levels within the system [4, 22–34] which includes data security in general [3, 23, 35–39], communication and transport security [3, 23, 31, 33, 40–44] (E) and secure storage [33, 35, 40].	[3–4, 22–44]	3	N
The system should provide a login procedure requiring at least username and password.	[29–30, 44–50]	1	Y
Different security services [43, 51] must be implemented and security policies [32, 49, 52–54] must be explicitly defined.	[32, 43, 49, 51–54]	–	N
The system should make use of a Public Key Infrastructure [46, 48, 55–56] and use attribute certificate based security [56–57].	[46, 48, 55–57]	–	N
It should be possible to see who, why, under what circumstances data was accessed.	[3, 25, 41, 58–59]	–	Y
The system should offer privilege [42, 56] (E and C), user [42, 60–61] and role management [42] (E and C).	[42, 56, 60–61]	3	P
Policies must be sticky when data is transferred.	[32, 35, 58]	–	N
All security measures must be standardized.	[32, 62–63]	–	N
Application security should be maintained.	[42–44]	–	N
Firewalls should be used.	[33, 48]	–	N
There should be the possibility to see who authorized access.	[58, 64]	–	N
A timeout function should be implemented.	[45]	–	Y
After a number of grace logins, the user has to wait a configurable amount of time before another login attempt is possible.	–	1	Y
The system should have a function to change the password.	–	–	Y
The system should support single-sign on.	–	2	Y

model to structure and formally represent EHR services, respectively their requirements/attributes, and a process model for the actual quality certification of services.

Part of the establishment of the requirements repository was an in-depth analysis of the existing literature – which is the basis for this manuscript – with regard to the quality of EHRs. In addition to the literature analysis, expert interviews with European experts were conducted in order to guarantee a comprehensive collection of requirements. This combined approach was chosen in order to complement the mainly "historical" data gathered from the literature with current information on quality from experts.

The following paragraphs describe the literature analysis as well as the expert interviews with regard to their structure and content. This is followed by a description of the process of the development of the requirements from the various sources.

2.1 Literature Analysis

The literature analysis aimed at gathering and analyzing relevant documents in order to deduce *non-functional and general functional* quality requirements for EHR services. To achieve maximum coverage of the existing literature, documents were retrieved from different sources according to the approach of data triangulation as described by Denzin [8]. For the present study, the following sources were included: norms/standards, guidelines/best practice, and scientific literature. Documents that were assigned to norms and standards are descriptions or other documents that represent a consensus agreement between the majority of the stakeholders involved in a certain topic and that are accredited by an international standardization organization. Guidelines and best practice include all documents that were not scientifically published or that are not an accredited standard. This includes all sources that are widely accepted by a certain community or, e.g., by government agencies, which are used to implement EHRs and that are referred to in scientific publications.

The literature analysis was carried out in the first half of 2008. It is divided into data collection, processing, and analysis (see e.g. [9]).

2.1.1 Data Collection

Regardless of the source used for data collection, the search was driven by the use of selected terms – initially taken from the MeSH terms – that can be related to the topic as well as additional terms that were elaborated with experts in the field of EHRs. These terms were further expanded by the terms found during the collection process. The following terms (including verbs where applicable) and combinations (A and B) were used:

A {Assessment (Assess), Certification (Certify), Evaluation (Evaluate), Quality, Requirements, Requirements Engineering, and Usability}
B {EHR, Electronic Health Record, Electronic Medical Record, EMR, Electronic Patient Record, EPR, Medical Software, and Health Information}

The collection of data was limited to documents that were published between 1998 and 2008 and that were originally written in the English or German languages or where an English or German translation was available at the point of collection.

To retrieve *standards and norms*, major standardization organizations were queried including the American National Standards Institute (ANSI) [10], the American Society for Testing and Material (ASTM)[11], the European Committee for Standardization (CEN) [12] and the International Standardization Organization

Table 5 Integrity requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Integrity			
Requirements	**References**	**Exp.**	**Cert.**
All data should electronically be signed [4, 33, 40, 43–44, 55, 61–62, 65–67] (E) and encryption should be implemented [2, 4, 44, 48, 61, 66, 68] for messages [40, 69–70], transfer [38, 50, 62] and storage [33, 38, 41, 44, 50, 71–72] (E) of data.	[2, 4, 33, 38, 40–41, 43–44, 48, 50, 55, 61–62, 65–72]	4	Y
The integrity of all data collected, recorded, processed, stored and communicated should be ensured at all time.	[2, 4, 23, 27, 30–31, 35, 40, 50, 57, 59, 61, 73–74]	–	Y
The system should implement audit trails and logs [2, 25, 41–42, 47, 58, 61, 75] for the change [50], deletion [25] and transfer of data [53, 76] as well as for system interactions [4].	[2, 4, 25, 41–42, 47, 50, 53, 58, 61, 75–76]	–	Y
IP-Sec [44] and TLS/SSL [33, 43, 46, 56, 77–78] (E) should be used for transmission of data.	[33, 43–44, 46, 56, 77–78]	2	Y
The system should indicate when data is modified.	[3, 25, 41, 58–59]	–	N
The system should offer the possibility to validate data.	[33, 65, 76, 79]	–	Y
The system should verify/check data entered.	[28, 49, 80]	–	N
Modification of patient data should be avoided.	[62, 81]	–	N
The integrity of data should be maintained during communication.	[23, 55]	–	N
Changes to a document should be possible without altering the original [25, 76], therefore each version of a document should uniquely and persistently be identified (C).	[25, 76]	–	Y
The system should offer the possibility to verify information offered.	[49–50]	–	N
The system should record what data has been accessed.	[76]	–	Y
The system should acknowledge/verify success or failure of data transmission.	[47]	–	N
An audit record should include date and time, the entity or system component, type of events, and the user identity.	[76]	–	Y
Audit logs should not be changed after recording.	–	–	Y
The system should enable authorized users to view/access audit log records.	–	–	Y

(ISO) [13]. *Guidelines and best practice* documents were primarily retrieved by using Internet search engines including Google, Altavista, Lycos, Yahoo, and MetaGer.

The search for *scientific publications* included online literature databases as well as online and paper-based journals and books. The following databases were queried: PubMed, EBSCO, IEEExplore, Tylor and Francis, ACM digital library, and Citeseer. In addition, Internet search engines were used (see Guidelines and best practice).

2.1.2 Data Processing and Analysis

The references that were retrieved were analyzed by two independent coders. At first, references were judged regarding their

Table 6 Authenticity requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Authenticity			
Requirements	**References**	**Exp.**	**Cert.**
The system should authenticate all actors involved (e.g. users, systems, principals) [2, 4, 22–23, 25, 35, 40, 42–43, 51–53, 56, 60–61, 71, 75] using a token [44–45, 50, 68] or biometric data [44, 57–58].	[2, 4, 22–23, 25, 35, 40, 42–45, 50–53, 56–58, 60–61, 68, 71, 75]	3	N
Each actor should unambiguously and persistently be identified.	[4, 24–25, 35–36, 41–43, 58, 61, 67, 82]	3	Y
The system should implement a non-repudiation/accountability framework.	[2, 25, 31, 40, 44, 48, 55, 61]	-	N
The system should provide information on who composed information or parts of it (author).	[59, 64–65, 83–84]	3	N
Authenticity of data should be assured.	[22, 35, 50, 55]	2	N
The identity and role of the communication partner must be approved.	[76]	–	Y

Availability			
Requirements	**References**	**Exp.**	**Cert.**
Availability of data/information should be ensured.	[4, 23, 27, 29, 47, 50–51, 57, 61, 85–86]	1	N
The system should support archiving of data.	[47, 76]	–	Y
The readability of archived data should be preserved.	[55]	–	N
Deleted data should not be available in the system (e.g. display, export, …)		–	Y

Table 7 Availability requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

title and abstract in order to be included in further analysis. This judgment was based on a number of predefined in-/exclusion criteria that were also used for the second step, the extraction of text passages from selected documents. The inclusion criteria comprised:

- general statements regarding the quality requirements, ideal attributes (author's viewpoint), and problems of EHRs;
- statements that refer to the importance or characteristics of certain quality attributes of EHRs.
- Statements or sources that refer to the content or characteristics of specific functionalities of an EHR were excluded.

The extraction of content was based on a structured and summative qualitative content analysis as described in Mayring [14] and Bortz [15], which combined a deductive and an inductive approach in order to derive categories. An aggregated version of the ISO 9126 [16] and eEurope 2002 [17] criteria was used as an initial system of categories for the categorization of statements, which was successively expanded during the process of analysis (see ▶Table 1 for the criteria initially used for coding). Depending on the different domains three to four cycles were necessary to derive a consistent and categorized list of requirements for a specific domain such as scientific literature. Each cycle was terminated by a revision of the list of requirements which primarily included the summary of paraphrases with similar content, the summary of paraphrases that focus on different aspects of a certain subject and the establishment of new requirements from paraphrases.

2.1.3 Literature Analysis – Brief Summary

In total, more than 10,000 references to *scientific papers* were initially retrieved from different sources as the search was intentionally designed to be very broad. After eliminating the duplicates, 343 documents were selected from the resulting list based on the title of which another 80 proved ineligible for analysis by going through their abstracts. Another 53 documents were omitted after analyzing their content. At the end, 494 requirements were extracted from these documents. An additional 1216 requirements (50 sources) were extracted from *guidelines and best practice*. The high number of extracted requirements is because this document category included requirements from already existing certification approaches such as CCHIT and EuroRec. The extraction of requirements with regard to *standards and norms* was in general difficult, as the number of available free standards is small. Nevertheless, 190 requirements were taken from existing standards and norms. ▶Figure 1 summarizes the process and steps for the literature analysis.

2.2 Expert Interviews

According to the literature analysis, the expert survey aimed at retrieving quality requirements for EHRs by questioning experts from different domains. The domains were chosen in accordance with the domains contained in the literature analysis. The interviews also included, apart from questions with regard to specific requirements, questions concerning the quality certification of EHRs. The results to these more general questions are not a part of the current manuscript but have been published in [18]. ▶Table 2 provides an overview of the domains from which experts were invited and compares them to the domains of the literature analysis.

The interviews were conducted in the middle of 2008 based on a problem-centric qualitative approach. Again, the methods are described by data collection, data processing, and analysis.

2.2.1 Data Collection

To select an *appropriate number of experts*, a combination of selective and theoretical sampling was applied as described in [19] and [20]. This approach implies that the number of experts is extended during data collection if there is no convergence reached with regard to the results obtained. This approach reduces the disadvantages of selective sampling such as the dependence of the quality of the results on previous knowledge.

In order to allow the selection of *experts*, *in-/exclusion criteria* were defined. Someone was regarded as an expert if he/she fulfilled the following criteria: A person who works in the field of clinical information systems for more than three years and who is actively involved in the development (design/implementation) of EHRs. In addition, general criteria were applied to the selection of experts as been defined in Carey et al. [21]. These included, e.g., the demand for the selection of individuals that have the time for an interrogation or which are willing to participate voluntarily, etc.

The interview guidelines were structured according to six topics: meta-data, introduction and definitions; general requirements regarding the quality certification of EHRs; specific areas for the quality certification of EHRs; existing certification approaches; other sources relevant to the certification of EHRs and specific quality requirements regarding EHRs. As has been previously stated, only the last

topic is relevant to this manuscript.

Before experts were invited to participate, interview guidelines were tested in order to avoid any ambiguities or misunderstanding. The interviews were then performed using computer-assisted telephone interviews (CATIs) or face-to-face interviews depending on the preferences of the experts. It should also be noted that experts were not provided with the results from the literature analysis before the interviews in order to not influence their responses.

2.2.2 Data Processing and Analysis

The raw data that was obtained from the interviews was transcribed using summative selective protocols (see e.g. [15]). These protocols were then used for further analysis and the definition of requirements. For details on the analysis, please see 2.1.2 "Data Processing and Analysis" as the same methods have been used.

2.2.3 Expert Interviews – Brief Summary

Initially, 55 experts were selected as matching the criteria defined and were initially contacted by mail. Thirteen responses were retrieved of which nine were positive. Writing a second and third e-mail yielded another 16 positive responses. During the study, another four experts were recruited at different workshops and scientific congresses.

After conducting 14 interviews, the number of diverging answers was already quite low with regard to the questions. Finally, after 18 interviews, no fundamentally new answers were observed. In order to confirm the results gathered from the 18 interviews, another six interviews were conducted, which also did not yield fundamentally new ideas. In total, 29 interviews were performed, which is due to the fact of the already issued invitations for interviews. ▶Table 3 provides an overview of the experts interviewed for each domain.

After processing and analyzing the data captured through the interviews, 203 requirements could be identified. ▶Figure 2 summarizes the process and steps for the literature analysis.

Table 8 Confidentiality requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Confidentiality			
Requirements	**References**	**Exp.**	**Cert.**
The system should maintain confidentiality.	[3–4, 24–31, 39, 41, 50–51, 57, 59, 61, 66, 85, 87]	3	N
The system should implement an authorization [35–36, 42–43, 57, 61, 75, 81, 87–88] and access control [23, 29, 33, 41, 43–44, 55, 57, 60–61, 87].	[23, 29, 33, 35–36, 41–44, 55, 57, 60–61, 75, 81, 87–88]	3	Y
The patient should control access to his data [25, 33, 38, 61, 71, 76, 87, 89] (E) this includes who has access [23, 25, 34, 36, 38, 90], how data can be accessed [34, 90], what can be accessed [3, 23, 34, 36, 90–91] and who has access with whom [3, 34, 90].	[3, 23, 25, 33–34, 36, 38, 61, 71, 76, 87, 89–91]	8	N
Access control should be role-based.	[33, 42, 57, 72, 78, 87, 89]	–	N
Access control lists should be used.	[25, 56, 61]	–	N
The access control must be able to deal with exceptional conditions.	[25, 87]	–	Y
Responsibilities should be defined.	[25, 66]	–	N
The patient should see who has access to his data	[3, 64]	–	N
Confidentiality breaches within an organization should be avoided.	[23, 30]	–	N
Data integration should not create unauthorized disclosure of information.	[25, 75]	–	N
Data should be removed without possibility of recreation, the medium should be obfuscated	[35, 50]	2	N
An information access policy should be stated	[34, 60]	–	N
The system should be able to define time and location based access rights.	[76]	–	Y
The patient should be able to designate someone else to control his data.	[3]	2	Y
The system should distinguish different levels of confidentiality for data.	[76]	–	Y
The degree of confidentiality should be based on the content.	–	–	Y
The system should offer the possibility to de-identify data	–	–	Y
The system should offer the possibility to designate specific data as confidential or blinded, this data should only be available for authorized users.	–	–	Y

2.3 Requirements Consolidation

The literature analysis as well as the expert interviews yielded requirements that are unique for each domain but, in total, still may contain duplicates and/or contradictions. The last step in the process of establishing a repository of quality requirements is the consolidation phase. This phase includes the standardization of the wording of the requirements, the actual consolidation of the requirements from the different source domains, and the handling of contradictory requirements.

In order to be able to merge statements from the different domains, it was neces-

Table 9 Data protection requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Data Protection / Privacy			
Requirements	**References**	**Exp.**	**Cert.**
Privacy should be protected.	[3, 23, 25–26, 29–31, 34, 38, 41, 43, 55, 57, 66, 82, 89, 92–93]	2	N
A privacy policy should be stated.	[30, 32, 35, 49, 53–54, 60, 63]	–	N
The user should be informed about what his data is used for.	[3, 35, 60]	2	N
Access to information should be based on the need to know principle.	[23, 87]	–	N
Confidentiality breaches within an organization should be avoided.	[23, 30]	–	N
There should be the possibility to contest/-dispute (change, correct, delete) information included.	[34]	–	Y

Table 10 Portability requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Portability			
Requirements	**References**	**Exp.**	**Cert.**
The system should ensure backward compatibility.	[26, 76, 94]	–	N
The system should ensure portability.	[50–51]	–	N

Table 11 Performance and efficiency requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Performance and Efficiency			
Requirements	**References**	**Exp.**	**Cert.**
Access to data should be fast.	[23–24, 29, 82]	–	N
The system should respond to any user input with acceptable performance.	[85, 95–98]	1	N
Data transmission and retrieval should be fast and adequate.	[4, 24, 83]	–	N
Network speed should be fast and adequate.	[24, 83, 99]	–	N
The system should be scalable.	[51, 63]	–	N
Records should instantly be updated.	[100]	–	Y

sary to standardize the wording of the requirements and to separate the requirements from their intended importance/weight. This is necessary, as the requirements are in the majority of cases a combined statement regarding a specific subject and its importance as well as its value to the author(s). All judgments such as "must be implemented" or "is absolutely necessary" were eliminated and substituted with the word "should". The weight of a requirement is regarded as an external function that should not be a part of a requirement.

By merging the different lists of requirements, no contradictions or other problems such as opposing requirements were identified.

3. Results

Due to the large number of requirements that were identified, not all of them can be discussed in the present paper. In order to provide a representative sample of the identified requirements, a selection of requirements will be made that includes all the requirements that were at least stated in two or more sources. Therefore, it is possible that important requirements that were only mentioned in one source are not stated in this manuscript.

It is also important to note that only sources are referred to a certain requirement that have explicitly stated the requirement or where there was no ambiguity in assigning certain parts of the source text to a requirement. As far as was avoidable, no assumptions with regard to the specific meaning of certain terms or concepts were made when assigning sources or source-statements to a requirement (e.g. "Does privilege management include user management?"), as the original intention of the author of the source is irreproducible in the context of this analysis.

Upon request, a full list of all the requirements identified can be obtained by the authors.

The results are presented according to the criteria of the ISO9126 and eEurope 2002, which were already used for the categorization of requirements during the process of analysis. Minor adjustments were made to these criteria in order to better fit the data and create reasonable groups of requirements. Some of the requirements refer to more than one category but are – due to space limitations – only listed once.

The results are presented in tables which contain the requirements, references to the sources of the requirements, a column "Exp." that marks requirements which were stated by experts and a column "Cert." that marks requirements that are referenced by the EuroRec Repository *and* that are a part of the CCHIT certification 2008. The col-

umn "Exp." thereby contains the number of experts that have stated a certain requirement whereas column "Cert." has two values, either "yes" or "no". If only parts of a requirement were stated by experts or within a certification approach these parts are marked with "E" for experts or "C" for certification.

The following sections present some basic information for each group of requirements.

3.1 Data Security

Data security is by far the most comprehensive group of requirements and contains 380 requirements in total that are assigned to the main category and four sub-categories, which are confidentiality, integrity, availability, and authenticity. Confidentiality is hereby understood as the degree that data is protected from unauthorized and unintentional disclosure by the system. Integrity is defined as the degree that data is protected from unauthorized and unintentional changes by the system. Availability contains requirements that refer to the degree that the system is capable of providing data at a given point of time under the given conditions. Authenticity refers to the capability of a system to precisely determine the origin of data.

The most prominent requirements by the number of sources identified for this category are the implementation of audit trails and logs, the signature of data, the authentication and identification of all the involved actors, an authorization and access control, and the demand for the control of data by patients. The requirements with regard to data security are shown in ▶Tables 4–8.

3.2 Privacy and Data Protection

Data protection combines different requirements with regard to the protection of personal data from misuse by third parties. As data protection is, in many cases, strongly related to data security, many requiremtents are already covered by data security. Therefore, the data protection category only contains 44 requirements. Another reason for the small number of requirements may be the fact that these requirements are often dependent on national legislation. ▶Table 9 provides an overview of selected privacy requirements.

Table 12 Maintainability requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Maintainability			
Requirements	**References**	**Exp.**	**Cert.**
The system should provide documentation.	[2, 28, 39]	1	N
All workflows that are support by the system should be documented.	[42]	–	N

Table 13 Reliability requirements (abbreviations: Exp. = Nno. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = Yes)

Reliability			
Requirements	**References**	**Exp.**	**Cert.**
The system should support archiving of data.	[47, 76]	–	Y
The system should be reliable.	[96, 97]	–	N
The system should support error recovery.	[101, 102]	1	N
The system should be protected from technical break down.	[92, 103]	–	N
The system should enable to restore application data from a backup.		–	Y

3.3 Portability, Performance/ Efficiency, Maintainability, and Reliability

Portability contains requirements that refer to the ability of a system to be transferred to a different environment. In total, eight requirements were identified for this group (see also ▶Table 10). Performance/efficiency describes the ability of a system to achieve an adequate performance with the given resources. Fifteen requirements were identified, whereas six requirements are shown in ▶Table 11. Maintainability describes the degree that a system or parts of a system can be changed subsequently. This category contains 29 requirements and is described in ▶Table 12. ▶Table 13 contains requirements with regard to reliability (total of 69 requirements), which is defined as the ability of a system to provide a certain performance under given preconditions over a certain time.

As these four categories/groups are of a universal nature, there are not many requirements that could be identified from EHR-specific publications belonging to these four categories. In addition, the identified requirements are universal and not specific to EHR systems.

3.4 Usability

Usability is understood according to the ISO 9241 as the effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environments. In total, 146 requirements were identified that could be assigned to the usability category. Although one has to note that the majority of the requirements identified here are assigned to more than one category. This is because the majority of the requirements often have an influence on the usability of a system. Strictly speaking about usability, the number of requirements identified is lower. It should also be noted that some of the requirements presented in this category are not mutually exclusive.

Most important requirements with regard to the number of sources are that the

Table 14 Usability requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Usability			
Requirements	**References**	**Exp.**	**Cert.**
The system should be user friendly.	[4, 24, 51, 91, 95–97, 101, 104–105]	2	N
The system should be accessible for all kinds of users.	[22–24, 28, 34, 59, 88]	3	N
The system should be easy to understand.	[83, 85, 98, 105–106]	3	N
Navigation should be easy.	[75, 84, 91, 105, 107]	–	N
Information should be understandable (for the intended audience).	[3, 36–37, 47, 71]	2	N
The system should be easy to use.	[33, 47, 102–104]	2	N
Data entry should be convenient.	[22–23, 103, 108]	–	N
Alerts should be user specific.	[33, 67, 79, 105]	–	N
The user interface design should meet the users´ needs and preferences.	[4, 83–84, 104]	–	N
The user interface should be customizable.	[4, 39, 75, 91]	3	Y
The system should be self describing.	[96, 102, 104]	–	N
The user interface should follow the logic of the users.	[71, 104, 109]	2	N
There should be a search engine for data.	[25, 83, 110]	4	N
Data entry should be suitable for the data entered.	[28, 59, 64]	–	N
Data should be collected in space close to the original source of data as soon as data is available.	[66, 80]	–	N
The system should offer the possibility to present content in different ways.	[76, 79]	1	Y
Data entry should support free text.	[39, 64]	–	N
The interface should be user friendly.	[53, 111]	–	N
The system should help users to avoid errors.	[101, 104]	–	N
The user interface should be consistent (including high level consistency).	[23, 101]	2	Y
The system should offer data entry templates for clinical data.	[26]	–	Y
Data entry templates should be customizable.	-	–	Y

system should be user-friendly, accessible for all kinds of users, easy to use and understand and that information is understandable for the intended audience. These requirements and others that were stated by more than one source are listed in ▶Table 14.

3.5 Content

In total, 209 requirements were assigned to the content category, which contains elements that state the general or specific requirements with regard to content (data and information) of a system. Similar to the usability category, the majority of the requirements are assigned to several other categories although more than one-third of the requirements are solely assigned to the content category. The requirements of the content category are also strongly influenced by the requirements from the domain of medical information/data on the Internet.

Requirements that were mentioned the most include that the data format/structure is standardized and that information offered is complete and comprehensive, accurate/unambiguous and is linked to other relevant sources. See ▶Table 15 for a list of selected requirements.

3.6 Interoperability

In the context of this manuscript, interoperability is basically understood as the ability of a system to interact with one or more other systems. What was observed during the analysis of the source documents is the fact that interoperability requirements are often stated for specific purposes, in a specific context, and often related to specific functionalities. As the present study aims at describing the universal requirements related to EHRs and does not focus on the specific functions of an EHR, ▶Table 16 only provides an overview of the standards that were mentioned in the source documents. It would also not be feasible to provide the whole context for the interoperability requirements observed and, therefore, the authors decided to not state the requirements.

3.10 Global Requirements

Due to the high level of abstraction of many observed requirements, it was often difficult to make a distinction between the assignment of requirements to a specific category, e.g. data security or to the category of global requirements. For example, the requirement that the system should be secure belongs to the category data security in consideration of its content but is also relevant for the category global requirements as it makes a statement on the global characteristic of the system. Therefore, only one-third of the requirements in this

Table 15 Content requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = yes)

Contents			
Requirements	**References**	**Exp.**	**Cert.**
Information offered should be accurate/unambiguous.	[23, 25, 36, 47, 59, 64, 68, 76, 80, 86, 91, 112]	3	N
The data format/structure should be standardized.	[4, 23, 25, 29, 38–39, 66, 100, 113–115]	3	N
Information offered should be linked to other relevant sources.	[4, 31, 33, 47, 49, 68, 84, 90, 116]	1	N
Information offered should be complete and comprehensive.	[23, 25, 36, 47, 59, 80, 86, 117]	2	N
Metainformation should be available for data [83, 102] including when care took place [38, 59], the clinical setting [59] and the qualification of the author [38, 54, 83–84].	[38, 54, 59, 83–84, 102]	4	N
The information/data offered should be of high quality.	[31, 66, 91, 103, 112]	2	N
Information offered should be up-to-date.	[23, 25, 28, 37, 83]	3	N
Information offered should only cover relevant material/information for the intended users	[23, 25, 66, 84, 112]	2	N
Information/data sets should be standardized.	[29, 52, 66, 118]	2	N
Dependent documents should be linked.	[50–51, 59, 76]	1	N
References to the source of information offered should be stated.	[83–84, 119]	2	N
The date of creation of information should be stated	[59, 84, 119]	1	N
The system should provide information on who committed data (source of information).	[25, 59, 64]	3	Y
The system should support multimedia content.	[23, 50, 51]	–	N
Information offered should be consistent.	[28, 47]	–	N
The data of last uplate/change of information should be stated.	[40, 84]	1	N
Information offered should be authorized / accredited.	[23, 120]	3	N
Data that is expired should be removed.	[35, 47]	–	N
The system should set minimal data set standards.	[25, 64]	–	Y
Each data element should precisely and consistently be defined.	[80, 102]	–	N
The system should offer the possibility to map objects in information to concepts (e.g. a terminology).	[76, 111]	–	N
Information offered should be adequate for the intended audience.	[28, 83]	4	N
The system should offer the possibility to transform data to other formats.	[72, 121]	–	N
There should be the possibility to assign a degree of importance to a document.	[76]	–	Y
The system should be able to deal with multiple formats.	[59]	–	Y
The system should offer the possibility to comment an information/document by an authorized user	[76]	–	Y
Patient-entered data should be distinguishable from other data.	-	1	Y
Each version of a document should uniquely and persistently be identified.	-	–	Y
Each record has a date of creation.	-	–	Y

category exclusively belong to it. The selected global requirements are listed in ▶Table 17.

3.11 General Functionalities

The general functionalities category is defined as the ability of a system to provide functions that serve as support for context-specific functions. In total, 376 requirements were collected regarding these functions. ▶Table 18 provides a list of these requirements.

Standards and Other Normative Documents		
Standards	**References**	**Exp.**
HL7	[2, 26, 29, 38, 39, 43, 46, 53, 59, 67, 72, 77, 114, 115, 118, 121–128]	2
XML	[29, 33, 38, 48, 53, 56, 72, 94, 96, 102, 115, 121, 125, 128–130]	2
ICD10	[22, 29, 33, 111, 113, 114, 128, 131, 132]	1
LOINC	[29, 67, 102, 111, 114, 128, 129, 132, 133]	–
DICOM	[26, 38, 53, 67, 76, 115, 121, 126]	1
CDA	[33, 65, 72, 115, 125, 127, 134]	1
HL7 RIM	[26, 33, 43, 95, 115, 118, 128]	–
CEN 13606	[43, 56, 59, 77, 126]	1
MeSH	[29, 39, 53, 83, 111]	1
EDIFACT	[59, 126, 135]	–
UMLS	[33, 111, 114, 132]	1
SNOMED	[39, 53, 102, 132]	1
IHE profiles	[115, 118, 126, 134]	7
SNOMED CT	[111, 128, 129]	–
RxNorm	[102, 111]	–
DICOM SR	[115, 134]	–
SNOMED RT	[23, 114]	–
MML	[134]	–

Table 16 Standards and other normative documents which are referenced in the source documents (abbreviations: Exp. = no. of experts that stated a requirement)

4. Discussion

In order to guarantee a high level of quality with regard to the functions offered and the processes supported by EHRs, it seems necessary to define a rigid set of functional and non-functional requirements. These requirements should be primarily based on a sound analysis of requirements imposed by potential users, processes, and functions to be supported and of basic parameters such as the organizational embedding or regulatory issues.

Although this fundamental claim has been true since the dawn of EHRs and is certainly not limited to EHRs, it has gained special importance recently as more and more of the concepts that were developed in a scientific environment at first as prototypes etc. are transferred into live working environments, such as hospitals or medical practices.

4.1 Summary of the Results

In total, 1191 unique requirements were discovered in this study and were assigned to 59 categories and sub-categories. The number of requirements assigned to each category and the relative percentage with regard to all the category entries are listed in ▶Table 19.

The categories that have the most requirements assigned are global requirements, functions, and data security. Obviously non-functional categories such as portability, performance, or maintainability have only a few requirements assigned.

4.2 Review – Boundaries and Focus

So far, several efforts have been made to develop guidelines, standards, and quality certifications that are directed towards the standardization of attributes that are related to EHRs. In general, these approaches differ in terms of the type of problem that they address and with regard to the content/requirements that they impose. What is common to many of them is that they are based on the analysis of experiences from e.g. projects and/or the interrogation of professionals/experts. There are prominent examples such as the IHE (Integrating the Healthcare Enterprise) [136], which develops integration profiles for specific use cases to foster information exchange between different healthcare providers. The development of these profiles is mainly based on a continuous process including experts defining profiles and feedback from industry in order to improve the existing profiles. The same is true for the quality certification offered by CCHIT [137] in the US and EuroRec [138] in Europe. The requirements contained in these EHR-specific quality certifications are predominantly taken from the experience reports of similar projects, best practice, standards, and from extensive expert interrogations or public comments.

What has not been done so far – to the knowledge of the authors – is a comprehensive and structured analysis of the available scientific literature with regard to the quality requirements of EHRs as has been conducted by this study.

As has already been stated in Chapter 1.2 "Objectives and Definitions", the main aim of the study is to determine the non-functional requirements. Functional requirements are only covered to the extent that these requirements refer to the general, supportive functions of an EHR system (e.g. audit functions, print functions, login, etc.). Other comparable papers often focus solely on the functional aspects of EHRs. They primarily define the requirements for certain potential EHR functions (e.g. medication lists or drug interaction alerts) or functional domains such as eMedication. The minority of these papers addresses the non-functional requirements of EHRs in a structured and comprehensive way.

4.3 Review Limitations

The quality requirements were acquired through a qualitative content analysis on

the available literature, which was collected through a comprehensive and structured search of online literature databases, journals, and by using general-purpose search engines. Although the analysis was conducted by two coders and all the involved processes were standardized and defined, a qualitative approach always involves some subjectivity. The selection of literature, respectively the selection of the corresponding keywords and ex-/inclusion criteria of literature and, therefore, the quality – the validity and completeness – of the results finally depend on the people involved.

Apart from the thorough planning of the study, we tried to tackle this problem in two different ways. First, we applied the technique of data triangulation, involving data from different sources/domains in order to achieve a higher diversification of our source documents and, secondly, we tried to confirm and enrich the results from the literature analysis by conducting interviews with selected experts. Both means were directed towards increasing the completeness and validity of our results.

The quality of EHRs is dependent on a holistic view of quality. The current study and its results are focused on non-functional, and only partly on functional, requirements. In order to achieve such a holistic view of quality, it would be necessary to align the current results with the results from other studies and papers that focused on the functional requirements for EHRs.

The limited availability of standards and their high cost has also influenced the results of the current analysis as the number of standards used for the review was restricted to freely available and major EHR standards which were available to the authors. This is due to the fact that standardization organizations were not willing to offer standards without charge and that there were not sufficient funds for the purchase of the standards concerned.

With regard to the expert interviews it has to be acknowledged that the number of experts interviewed for each domain was not evenly spread which may have influenced the results from the expert interviews.

Table 17 Global requirements (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; N = no; Y = Yes)

Global Requirements			
Requirements	**References**	**Exp.**	**Cert.**
The system should follow an object/component oriented paradigm.	[23, 42, 46, 51, 56, 71, 118]	–	N
The applicable laws should be followed.	[25, 31, 62, 66, 76, 86, 89]	–	Y
The system should be based on internet technology.	[23, 32, 33, 45, 47]	–	N
Contact persons should be assigned.	[49, 80, 84, 119]	1	N
The system should obey the HIPAA.	[48, 50, 62, 118]	–	Y
Training on the system should be offered.	[4, 40, 85]	1	N
The system should be platform-independent.	[29, 63, 96]	1	N
The system should be based on a distributed architecture.	[42, 51]	–	N
The system should be based on reference models.	[42, 51]	–	N
A statement of purpose should be defined.	[51, 84]	–	N
A legal policy should be stated.	[36, 39]	–	N
Responsibilities/accountability should be defined.	[36, 62]	–	N
All applicable rules and policies should be stated.	[30, 51]	–	N
The system should support concurrent/simultaneous use.	[50, 79]	–	Y
The system should thoroughly be tested.	[2, 99]	1	N
The system should allow remote access.	[63, 79]	–	N
Support should be available.	[99]	1	N

4.4 Potential Benefits and Use of the Results

The requirements collected by this study make an important contribution to the establishment of a comprehensive view on the quality of EHRs by raising awareness especially for the non-functional requirements of EHR systems.

Table 18 Requirements regarding general functions (abbreviations: Exp. = no. of experts that stated a requirement; Cert. = criteria stated by the EuroRec Repository and by CCHIT 08; P = partially; N = no; Y = yes)

General Functionalities			
Requirements	**References**	**Exp.**	**Cert.**
The system should offer possibilities to summarize information.	[64, 71, 75, 76, 100]	2	N
The system should offer data export/extraction functions.	[47, 59, 71, 76, 111]	–	Y
The system should offer data import functions.	[59, 71, 76, 99, 111]	–	N
The system should offer the possibility to define reminders.	[79, 105]	–	N
The patient should have the possibility to add self-reported health information.	[67, 76]	–	N
A dictionary for terms should be available.	[4, 102]	–	N
The system should offer print functions.	[47, 49]	–	N

Table 19 Number of requirements assigned to main categories (some requirements are assigned to more than one category; therefore n = 1657)

Main Categories	No. of Req.	
	Total	%
Global requirements	377	22.75%
Functions (general)	376	22.69%
Data security	314	18.95%
Content	209	12.61%
Usability	146	8.81%
Interoperability	77	4.65%
Reliability	62	3.74%
Privacy and data protection	44	2.66%
Maintainability	29	1.75%
Performance/efficiency	15	0.91%
Portability	8	0.48%

The study contributes to the existing collections of requirements by adding new or confirming existing requirements from a scientific perspective. The current study is – to the knowledge of the authors – the first comprehensive and EHR-specific approach to the collection of quality requirements that are stated in scientific publications. In addition, the collection of non-functional requirements was, up to now, extensively neglected.

Another potential field of use for the requirements is the quality certification of EHRs. This would obviously require the selection of the relevant requirements and a further evaluation with regard to tangible problems. EuroRec is working towards the establishment of an EHR quality certification and proves itself to be the de-facto European quality certification body for EHRs. EuroRec is/was involved in several European projects that are dedicated to quality certification such as Q-Rec [138], EHR-Q TN [139], and HITCH [140]. The authors are, therefore, in close collaboration with EuroRec to incorporate the findings of this study into the further development of the EuroRec approach.

In order to use the results for the development of high-quality EHRs the requirements may function as a basic indicator of potential problems or fields of problems that have to be considered before, during and after the development of an EHR. Although the requirements cannot directly be applied to a specific EHR project, without selection and further specification of the requirements. A description of how the requirements can be applied to an EHR or parts of an EHR can be found in [141].

5. Conclusion

High-quality EHR systems are a prerequisite to meeting the various demands and promises that are expected from the implementation of the concept of an EHR and to avoid or at least minimize any potential problems. Such high-quality systems involve – among other things – knowledge about the current and future requirements. The repository of requirements that was developed in the present study provides an opportunity for all actors who are involved in the conceptual design or the development of EHR systems to access a proven set of requirements in order to be used as a starting point for further refinement or as a basis for the development of specific sets of requirements.

In general it is important for the future development of EHRs that they are based on a proven and rigid set of quality requirements which deal with EHRs as a whole, including functional as well as non-functional requirements.

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