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On Appropriate Evaluation Methodologies in the Context of Using Both Accident and Health Record Data

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Abstract. Accident and emergency informatics has become a new approach to accident research in the era of digitization, where it has become realistic to integrate data recorded at accident sites with data in electronic health records of patients. This chapter deals with the question on whether the existing and well-established evaluation methodologies used in accident-centered research as well as in patient-centered research within clinical medicine are sufficient and should also be used for such integrated data or whether they have to be modified or extended. Based on the Gaus-Muche-Nomenclature on studies in clinical medicine, it will be outlined which types of studies are appropriate here. In addition to observational studies and registers, controlled trials using randomization are also be regarded as an important approach for gaining new knowledge. In order to appropriately access data from health records and from accidents, standards for representing and communicating data for such studies will be of importance. Another criterion is referential integrity. Here and with respect to accidents the International Standard Accident Number (ISAN) may be of importance.

Keywords. accident research, injury research, electronic health records, health information systems, study design, data analysis, accident informatics, emergency informatics, medical informatics

1. Introduction

1.1. On the Relevance of Accident Research

Accident research remains an important topic for health coverage and health care worldwide. E.g. “Road injuries killed 1.4 million people in 2016” and are still among the 10 leading causes of death in the world [1].

Traditional accident research is based on individual accidents having occurred in reality ([2], p. 1). As outlined in [3] evaluation methodologies there focus on “In-Depth-Analyzes of accident statistics and accident analyzes. Special focus is placed on research on the basis of … data collections at the sites of the accidents …, which are characterized by extensive documentations of the sites of the accidents, of the vehicles as well as of the injuries …”.

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1.2. Accident and Emergency Informatics: A New Approach to Accident Research in the Era of Digitization

In the era of digitization, it has become realistic to integrate data recorded at accident sites with data in electronic health records of persons being involved in such accidents [4]-[6]. It is assumed that including both data sources, i.e. accident and health record data, will lead to better support and curation.

Although not in the focus here, it has to be mentioned that such opportunities in the era of digitization can be regarded as part of an even more comprehensive development, transforming and, hopefully, improving health care. In addition to traditional health care settings like hospitals, medical offices and nursing homes, we can now much better include personal living environments like homes or vehicles in health care processes (e.g. [7]-[14]).

Based on these now existing opportunities of using both accident and health record data, a novel discipline was formed, called accident and emergency informatics [15]. This "trans-disciplinary science of systematic collecting and managing medical data (e.g., electronic health records) as well as sensor data from the human environment (e.g., acceleration sensors in the vehicle)" [15] aims at integrating such data of accident sites with health records data of persons being involved in such accidents. Research in this discipline has started. International collaboration has been established at IMIA, the International Medical Informatics Association, where in 2018 a Working Group on Accident and Emergency Informatics was formed [16].

1.3. Question and Objective

In this new situation, where it has become realistic to integrate data recorded at accident sites with data in health records, we have to raise the question on whether the existing and well-established evaluation methodologies used in accident-centered research as well as in patient-centered research within clinical medicine are sufficient and should also be used for such integrated data or whether they have to be modified or extended.

The objective of this chapter is to outline, which types of research questions are asked in this context, which types of study may fit in order to provide answers, and what deserves special consideration in the context of information system architectures and infrastructures in order to be able to combine such data.

1.4. References and Approach

As reference for evaluation methodologies in traditional accident research, the reader is referred to [2] and to the proceedings of the Expert Symposia on Accident Research Conferences (e.g. [3]). As reference for evaluation methodologies in clinical medicine the reader is referred to textbooks in medical statistics / biostatistics, such as [17], [18], and [19].

Please note that, as mentioned in the beginning, traditional accident research is based on recording and analyzing individual accidents, including modeling and simulation of accidents. Empirically analyzing patient data in the context of health care is usually done in empirical studies, where sets of patients are included.

In the following, this will be introduced in some more detail. Section 2, highlighting a specific evaluation approach in clinical medicine, is strongly based on parts of two manuscripts in German language [20] and [21]. In particular, in [21] further details as

well as examples for studies can be found. In section 3 proposals will be made on applying and, to some extent, extending evaluation methodologies of clinical medicine. This will be done with respect to considering data from health information systems (based on [22], [23]) and from accidents ([2], [3]), taking into account the visions and activities proposed in accidents [4]-[6] and in [15], [16]. Section 4 will be used for briefly discussing the contents of the previous sections of this chapter, which will close with a call for research on accident and emergency informatics evaluation methodologies in section 5.

2. Evaluation Methodologies in Clinical Medicine

2.1. Introduction

In patient-centered and health-care-oriented 'clinical medicine', the approach to assess health care has developed considerably over the past decades. This has led to specific evaluation methodologies, which can today be assigned to the field of (bio-) medical biometry or (bio-) medical statistics. Evaluation in clinical medicine is focused on humans, especially on patients.

As a medical informatician with close ties to medical statistics, the author would like to use therapy research as an example to describe an important, if not currently, the most important evaluation approach in clinical medicine. This is particularly so because this could and should also play an important role in accident and emergency informatics.

In order to explain this in more detail, this section will report on clinical medicine, on therapy research, and on evaluation methods in therapy research. Their significance for the evaluation in the context of accident and emergency informatics, and there in particular when including accident as well as health record data, will be outlined in the next section.

Let us first of all recall that in clinical medicine, empirical evaluation approaches play an important role due to the complexity of the human being. The reason therefore, which is still valid today, is a quite simple one ([19], p. 5, translated from German): "Every human being is unique ... Therefore, we cannot expect that diagnostic procedures will always provide correct results and that therapies will always work in the same way".

2.2. Controlled Clinical Trials as Gold Standard for Assessing Therapies

In the 20th century, clinical research based on empirical approaches gained further importance. The reason was that because of the mentioned uniqueness of patients, a purely subjective assessment based on the diagnostic or therapeutic outcomes of one patient or of few patients was viewed critically and classified as unscientific. In Germany, such empirical approaches were and still are closely associated with Paul Martini (1932-1959) and his methodology for clinical medicine [24]. It is not without reason that the first article in the journal 'Methods of Information in Medicine', the oldest journal devoted to information in biomedicine and health care [25], was written by Paul Martini and dealt with the "methodology of therapeutic assessment" [26]. In his statement "The basic rule for every therapeutic-clinical trial must involve a comparison of therapeutic approaches" an important finding is summarized: Due to the complexity of the human being, knowledge about how health care can be shaped in the best possible way and, in particular, which therapeutic measures are best suited for patients, can best be gained by a fair comparison of several therapies.

In the second half of the 20th century, therapy research based on such fair comparisons was established by means of controlled clinical trials, which contributed significantly to progress in medicine and in health care as we know it today. The basic prerequisite for fair comparison is so-called structural equality: With the exception of therapies under investigation, all other characteristics of patients that could influence the success of therapies, whether known or unknown, should be distributed as equal as possible in the respective therapy groups [27]. Randomization, the strictly random allocation of patients to therapies, resulted for good reasons in being the best method for this fair comparison. Systematic study design, formal analysis methods (especially statistical hypothesis testing) and computer-based data analysis systems contributed to this progress.

In this context and with a special emphasis on scientific developments in Germany, reference should be made to the textbook on medical statistics by Herbert Immich, published in 1974 [28], to the "memorandum on the planning and conduct of controlled clinical trials" [29], written under the leadership of Hans Joachim Jesdinsky in 1978 [29], and to the book on therapeutic studies published in 1981 under the leadership of Norbert Victor [30].

The essay by Karl Überla on "therapeutic studies: indication, knowledge and challenge", contained in [30], further explains this matter: "The essential component of empirical knowledge acquisition is the repetition of the same events under the same conditions" as well as "In biological comparison, the events do not occur with the same regularity as the rising of the sun. ... Therapeutic studies are the attempt to deal rationally with this variability, which leaves one helpless." ([31], p. 10, translated from German).

In a recently published article on the "development of clinical studies from Paul Martini to the present" Martin Schumacher wrote about this development: "Over the last 40 years randomized clinical trials have become the 'gold standard' in clinical therapy research worldwide and also in Germany." ([32], translated from German).

Ultimately, the aim of these evaluation approaches was to make decisions on a scientific basis in clinical medicine, despite the uniqueness of each individual ([19], p. 5), for the benefit of the patient. Criteria for this scientific basis, including reproducibility, are further discussed in [33], where also additional literature on this topic can also be found there.

2.3. A Nomenclature for Study Types

A scheme for the various study types in clinical medicine based on three criteria, as proposed by Gaus and Muche in [19], is shown in Figure 1. This scheme will be denoted here as the Gaus-Muche-Nomenclature on studies. It describes studies by indices on three axes. Controlled clinical trials are indexed there under diagnostic or therapeutic interventions as intervention studies assessing therapies.

2.4. Ethics and Admission Procedures for Studies in Clinical Medicine

Strict ethical criteria, for which the Declaration of Helsinki [34] forms an important basis, apply to the design, conduct and analysis of such studies, which are experiments on humans, especially in clinical trials.

Before such studies are conducted, ethics committees established for this purpose must approve their study plans. In the case of studies with medications, clinical trials must first have successfully completed phases I (pharmacokinetics, dose-response relationship) and II (tolerability, principal efficacy) before proof of efficacy can be tested in

a larger number of patients in phase III controlled clinical trials [19]. Only after approval of phase III, medications will be admitted in Germany and in many other countries. Phase IV studies, after admission, then serve, among others, for drug monitoring.

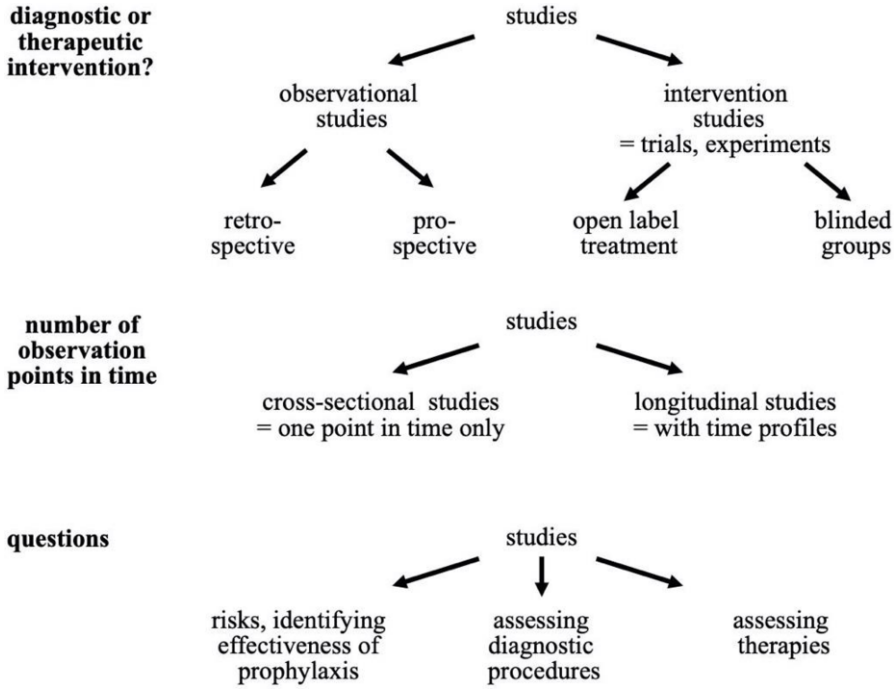

Figure 1. The Gaus-Muche Nomenclature for Studies: Indexing of clinical studies is based on three criteria or axis ([19], p. 38, translated from German). Controlled clinical trials are indexed there at 'diagnostic or therapeutic intervention?' as 'intervention studies' and, at 'questions', as 'assessing therapies'.

Authorities established for this purpose are., e.g., the Federal Institute for Drugs and Medical Devices (BfArM) in Germany and the European Medicines Agency (EMA) in the European Union.

3. Evaluation Methodologies in Accident and Emergency Informatics

3.1. Introduction

Also when discussing appropriate evaluation methodologies in the context of accident and emergency informatics and there in particular when both accident and health record data shall be used, we should first ask, which research questions have to be treated. In addition, in finding answers to such questions by empiric investigations, the use of studies with appropriately planning, conducting and analysis of them, will remain to be a scientific standard. The Gaus-Muche Nomenclature on studies, presented in figure 1, may be of help here.

3.2. Types of Questions and Respective Study Types

Identifying risks in the health of persons as well as preventing risks – i.e. the first index in the question-axis, the third axis of the Gaus-Muche-Nomenclature – is certainly given in accident research. The same holds for assessing therapies, where the term therapy might better be replaced by broader terms, such as activities or procedures.

When patient data are involved, we can assume for the second axis of the Gaus-Muche-Nomenclature that there will usually be several observations in time, in particular when long-term effects of accidents on patients are regarded.

In the first axis, it is suggested to differentiate on whether the intention is to treat questions of prevention or assessment primarily in recording data and in finding correlations. Then observational studies, usually longitudinal ones, are appropriate. Such empirical research may be done in dedicated studies or in registers (see e.g. [27], pp. 71-72).

Being aware that for causal relationships we can hardly find answers through observational studies, the concept of intervention studies, in particular through randomized trials, is also here the most appropriate study type. The reasons are the same as outlined in section 2. The research questions may, however, vary. In accident and emergency informatics questions may, e.g., be on whether a certain treatment of patients after an accident is better than another one, or on whether autonomous vehicles will lead to more risks for humans than vehicles being driven by humans themselves.

3.3. Patient-centered or Accident-centered Studies?

Another question which has to be raised here is on whether such studies should be centered on (a certain group of) accidents or on (a certain group of) humans, respectively patients. As an author coming from medical informatics with, as mentioned, close ties to medical statistics, my first reaction was that also such studies have to center on humans / patients. As accidents are, fortunately, rare events, accident-centered studies may however also be an option.

3.4. On the Use of Data from Health Information Systems for Such Studies

In the context of accident and emergency informatics and in particular when both accident and health record data shall be used, then, of course, using data from health information systems should be considered. An extensive introduction to health information systems, their architectures and their information management strategies can be found in [23]. Here, only some aspects with respect to evaluation methods can briefly be touched.

The most important data sources of health records can be found in hospitals, in medical practices and, maybe, in inpatient or outpatient nursing institutions. In such institutions these data can now often be found in electronic patient records. This eases the access to and the use of such data compared to former times, when records have primarily been paper-based. Data of patients in the mentioned settings are mostly routine data, being primarily recorded and used for patient care. As mentioned in [6] accessing and using these data would most probably improve our understanding of injury events, in particular of long-term effects, and facilitate identification of targets for prevention.

With respect to information system architectures, the efforts in using such data is strongly correlated with the use of standards in representing and communicating such data. If internationally available standards are used (see e.g. [6])), then accessing these data is easier. Existing national infrastructures for patient data are also helpful as well as

so-called eHealth strategies, which usually include such standards (e.g. [35], [36]). Finally, referential integrity, here with respect to patients, is of importance (details in [6], p. 145).

Unfortunately, until today, information processing within health care institutions (e.g. in hospitals) is much better implemented than patient-centered information processing beyond single institutions [37], [38], [39]. Insofar, including such data is clearly possible, and much better possible than in the past. However, efforts in accessing and using these data can still be significantly improved.

For using such data in studies we also have to ask for their data quality and how they were recorded. As mentioned, such date is primarily documented for being used in patient care, and so for patient-oriented (casuistic) data analysis (details e.g. in [27], pp. 75-78). When this data will also be used in studies, among others observational equivalence must be given, too. Observational equivalence means that for each patient, data are recorded in a standardized way. Only then multiple usability of such data is possible. Details on this can be found in [27].

3.5. How to Include Data from Accidents?

From the viewpoint of medical statistics, accident data can be treated similar like diagnostic or therapeutic units, e.g. like lab data. Insofar and with respect to evaluation methodologies nothing additional has to be considered here.

The complexity of including data from accidents is mainly at a technical level. Also, here like with clinical data, it is helpful if existing international standards for representing and for analyzing data are used. As combining accident and health record data is still new, standards in both fields – accident research and clinical medicine – will differ, which will produce more workload for jointly analyzing these data.

Like for data from health information systems, another challenge also will be referential integrity of data from accidents, also comprising referential integrity of human beings, involved there. In this context, the International Standard Accident Number (ISAN), proposed in [5], may play an important role in achieving this integrity.

4. Discussion

In the age of digitization, combining accident and health record data should be encouraged as it can be assumed that with both types of data, better knowledge can be gained for prevention of accidents as well as for diagnosis and treatment of patients after accidents.

Section 2 described how empirical research in clinical medicine is done. Evaluation methodologies are based on studies, with controlled trials as ‘gold standard’.

The author strongly recommends that this evaluation approach also be applied to research questions in accident and emergency informatics. Both observational studies / registers as well as intervention studies seem to be appropriate. However, as causal relationships can best be found empirically through fair interventions also here controlled trials, using randomization are regarded as an important approach for gaining new knowledge.

Let me finally recall that, as mentioned in section 1.2, accident and emergency informatics and its evaluation methodologies may also be considered as being part of another and broader context. Health care is a continuous process in the life of humans. In

the era of digitization, in addition to specialized settings like hospitals, medical offices and nursing homes, such care can also be done in further settings, may it be at homes or in vehicles, and may it be during work or in leisure times. This development is supported, among others, by the now existing health-enabling technologies. In addition, the mentioned references [7]-[14] in 1.2, further examples can be found in [41]-[43]. As oulined in section 2.4 for clinical studies, also here considering ethical constraints is of considerable relevance [44].

5. A Call for Research on Appropriate Evaluation Methodologies in the Context of Using both Accident and Health Record Data

As we are still at the start of combining such data, as visions of linking event data recorder with electronic health records, as suggested in [4], are still visions, and having in mind that in the era of digitization such combinations are possible and should be investigated for the sake of good patient care, a call for research on appropriate evaluation methodologies is proposed.

The author is convinced that the evaluation methodologies from medical statistics form a good basis for empirical research in accident and emergency informatics. He is particularly convinced that study designs like the ones, mention in figure 1, with respective methodologies on how to collect and how to analyze data, should be used as a starting point.

References

[1] World Health Organization. The top 10 causes of death. https://www.who.int/en/news-room/fact-sheets/detail/the-top-10-causes-of-death. Last access: September 30, 2020.

[2] Johannsen H. Unfallmechanik und Unfallrekonstruktion [Accident Mechanics and Accident Reconstruction], 3rd ed. Wiesbaden: Springer Fachmedien; 2013. German.

[3] Bundesanstalt für Straßenwesen, editor. 7th International Conference ESAR "Expert Symposium on Accident Research. Bremen: Schünemann; 2017.

[4] Deserno T. Linking Event Data Recorder with Electronic Health Records – An Option Towards Vision Zero? Proceedings of the 8th International Conference ESAR "Expert Symposium on Accident Research. April 18-19, 2018, Hannover, Germany. To appear.

[5] Le HP, Hackel S, Guenther A, Goldschmidt R, Daoud M, Deserno TM. International Standard Accident Number: A Master Case Index Linking Accident & Emergency with Medical Data. Stud Health Technol Inform. 2019; 258: 120-124.

[6] Al-Shorbaji N, Haux R, Krishnamurthy R, Marschollek M, Mattfeld DC, Bartolomeos K, Reynolds TA. Road Traffic Related Injury Research and Informatics. New Opportunities for Biomedical and Health Informatics as a Contribution to the United Nations' Sustainable Development Goals? Methods Inf Med. 2015; 54: 474-476.

[7] Deserno. Transforming Smart Vehicles and Smart Homes into Private Diagnostic Spaces. In: Proceedings of the 2020 2nd Asia Pacific Information Technology Conference (APIT 2020), 165–171. New York: Association for Computing Machinery; 2020.

[8] Haux R, Hein A, Kolb G, Künemund H, Eichelberg M, Appell JE, Appelrath HJ, Bartsch C, Bauer JM, Becker M, Bente P, Bitzer J, Boll S, Büsching F, Dasenbrock L, Deparade R, Depner D, Elbers K, Fachinger U, Felber J, Feldwieser F, Forberg A, Gietzelt M, Goetze S, Gövercin M, Helmer A, Herzke T, Hesselmann T, Heuten W, Huber R, Hülsken-Giesler M, Jacobs G, Kalbe E, Kerling A, Klingeberg T, Költzsch Y, Lammel-Polchau C, Ludwig W, Marschollek M, Martens B, Meis M, Meyer EM, Meyer J, Meyer zu Schwabedissen H, Moritz N, Müller H, Nebel W, Neyer FJ, Okken PK, Rahe J, Remmers H, Rölker-Denker L, Schilling M, Schöpke B, Schröder J, Schulze GC, Schulze M, Siltmann S, Song B, Spehr J, Steen EE, Steinhagen-Thiessen E, Tanschus NM, Tegtbur U, Thiel A, Thoben W, van Hengel P, Wabnik S, Wegel S, Wilken O, Winkelbach S, Wist T, Wolf KH, Wolf L, Zokoll-van der Laan M;

Lower Saxony Research Network GAL. Information and Communication Technologies for Promoting and Sustaining Quality of Life, Health and Self-sufficiency in Ageing Societies – Outcomes of the Lower Saxony Research Network Design of Environments for Ageing (GAL). Inform Health Soc Care. 2014; 39: 166-187.
[9] Haux R, Koch S, Lovell NH, Marschollek M, Nakashima N, Wolf KH. Health- Enabling and Ambient Assistive Technologies: Past, Present, Future. Yearb Med Inform. 2016: S76-91.
[10] Marschollek M, Becker M, Bauer JM, Bente P, Dasenbrock L, Elbers K, Hein A, Kolb G, Künemund H, Lammel-Polchau C, Meis M, Meyer zu Schwabedissen H, Remmers H, Schulze M, Steen EE, Thoben W, Wang J, Wolf KH, Haux R. Multimodal Activity Monitoring for Home Rehabilitation of Geriatric Fracture Patients – Feasibility and Acceptance of Sensor Systems in the GAL-NATARS study. Inform Health Soc Care. 2014; 39: 262-271.
[11] Mielke C, Voss T, Haux R. Residence as a Diagnostic and Therapeutic Area - A Smart Home Approach. Stud Health Technol Inform. 2017; 238: 92-95.
[12] Wang J, Bauer J, Becker M, Bente P, Dasenbrock L, Elbers K, Hein A, Kohlmann M, Kolb G, Lammel-Polchau C, Marschollek M, Meis M, Remmers H, zu Schwabedissen HM, Schulze M, Steen EE, Haux R, Wolf KH. A novel approach for discovering human behavior patterns using unsupervised methods. Z Gerontol Geriatr. 2014; 47: 648-660.
[13] Wang J, Warnecke JM, Deserno TM. The Vehicle as a Diagnostic Space: Efficient Placement of Accelerometers for Respiration Monitoring During Driving. Stud Health Technol Inform. 2019; 258: 206-210.
[14] Wang J, Warnecke JM, Haghi M, Deserno TM. Unobtrusive Health Monitoring in Private Spaces: The Smart Vehicle. Sensors. 2020; 20: 2442.
[15] Peter L. Reichertz Institute for Medical Informatics. Accident & Emergency Informatics. https://plri.de/en/forschung/methodenorientierte-forschung/aei. Last access: September 30, 2020.
[16] International Medical Informatics Association (IMIA). Working Group Accident & Emergency Informatics (IMIA A&EI WG). https://imia-medinfo.org/wp/accident-emergency-informatics-working-group/. Last access: September 30, 2020.
[17] Van Belle G, Fisher LD, Heagerty PJ, Lumley T. Biostatistics: A Methodology for the Health Sciences, 2nd edition. Hoboken, NJ: Wiley; 2004.
[18] Rosner B. Fundamentals of Biostatistics, 8th edition. Boston, MA: Cengage Learning; 2015.
[19] Gaus W, Muche R. Medizinische Statistik [Medical Statistics]. Stuttgart: Schattauer; 2013. German.
[20] Haux. R. Informationstechnische Aspekte neuer Lebensweisen und Versorgungsformen bei älteren Menschen im Zeitalter der Digitalisierung. Expertise zum Achten Altersbericht der Bundesregierung. [Information technology aspects of new ways of living and forms of care for the elderly in the age of digitization. Expertise on the Eighth Ageing Report of the (German) Federal Government]. In: Hagen C, Endter C, Berner F, editors. Berlin: Deutsches Zentrum für Altersfragen; 2020. German.
[21] Haux R, Karafyllis NC Methodisch-technische Aspekte der Evaluation erweiterten Zusammenwirkens. [Methodological and Technical Aspects of the Evaluation of Extended Collaboration.] In: Haux R, Gahl K, Jipp M, Kruse R, Richter O, editors. Zusammenwirken von natürlicher und künstlicher Intelligenz. [Collaboration of Natural and Artificial Intelligence.]. Wiesbaden: Springer VS; 2020. German.
[22] Haux R, Howe J, Marschollek M, Plischke M, Wolf KH. Health-enabling Technologies for Pervasive Health Care: on Services and ICT Architecture Paradigms. Inform Health Soc Care. 2008; 33: 77–89.
[23] Winter A, Haux R, Ammenwerth E, Brigl B, Hellrung N, Jahn F. Health Information Systems – Architectures and Strategies. London: Springer; 2011.
[24] Martini P. Methodenlehre der Therapeutischen Untersuchung [Methodology of Therapeutic Assessment]. Berlin: Springer; 1932. German.
[25] McCray AT, Gefeller O, Aronsky D, Leong TY, Sarkar IN, Bergemann D, Lindberg DA, van Bemmel JH, Haux R. The Birth and Evolution of a Discipline Devoted to Information in Biomedicine and Health Care. As Reflected in its Longest Running Journal. Methods Inf Med. 2011; 50: 491-507.
[26] Martini, P. Grundätzliches zur therapeutisch-klinischen Versuchsplanung [Principles of Controlled Clinical Trials]. Methods Inf Med. 1962; 1: 1-5. German with English abstract.
[27] Leiner F, Gaus W, Haux R, Knaup P. Medical Data Management. New York: Springer; 2002.
[28] Immich H. Medizinische Statistik [Medical Statistics]. Stuttgart: Schattauer; 1974. German.
[29] Jesdinsky HJ (Hrsg.). Memorandum zur Planung und Durchführung kontrollierter klinischer Studien [Memorandum on the Planning and Conduct of Controlled Clinical Trials]. Stuttgart: Schattauer; 1978. German.
[30] Victor N, Dudeck J, Broszio EP, editors. Therapiestudien [Therapeutic Studies]. Berlin: Springer; 1981. German.
[31] Überla KK. Therapiestudien: Indikation, Erkenntniswert und Herausforderung [Therapeutic Studies: Indication, Epistemological Value and Challenge]. In [30], 7-21. German.
[32] Schumacher M. (2016). Entwicklung klinischer Studien von Paul Martini bis heute [Development of Clinical Trials from Paul Martini to Date]. Drug Research, 2016; 66: 5-7. German.

[33] Haux R. Kriterien für gute medizinische Forschung [Criteria for Good Medical Research]. In: Eich W, Bauer AW, Haux R, Herzog W, Rüegg, JC, editors. Wissenschaftlichkeit in der Medizin [Good Scientific Practise in Medicine], Part IV, 181-201. Frankfurt/M.: VAS; 2003. German.
[34] World Medical Association (WMA). Declaration of Helsinki – ethical principles for medical research involving human subjects. Adopted 1964, last amendment 2013. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/. Last access: September 30, 2020.
[35] de Assis Moura L Jr. Embracing Strategies for eHealth. Yearb Med Inform. 2015; 10: 1.
[36] Al-Shorbaji N. The World Health Assembly Resolutions on eHealth: eHealth in Support of Universal Health Coverage. Methods Inf Med. 2013; 52: 463-6.
[37] Turner AM, Taylor JO, Hartzler AL, Osterhage KP, Bosold AL, Painter IS, Demiris G. Personal Health Information Management Among Healthy Older Adults: Varying Needs and Approaches. J Am Med Inform Assoc. 2020. Epub ahead of print.
[38] Warren LR, Clarke J, Arora S, Darzi A. Improving Data Sharing Between Acute Hospitals in England: An Overview of Health Record System Distribution and Retrospective Observational Analysis of Inter-hospital Transitions of Care. BMJ Open. 2019; 9: e031637.
[39] Haux R, Ammenwerth E, Koch S, Lehmann CU, Park HA, Saranto K, Wong CP. A Brief Survey on Six Basic and Reduced eHealth Indicators in Seven Countries in 2017. Appl Clin Inform. 2018; 9: 704-713.
[40] Ammenwerth E, Duftschmid G, Al-Hamdan Z, Bawadi H, Cheung NT, Goldfarb G, Gülkesen KH, Harel N, Kimura M, Kirca O, Kondoh H, Koch S, Lewy H, Mize D, Palojoki S, Park HA, Pearce C, Bernaldo de Quirós FG, Saranto K, Seidel C, Vimarlund V, Were MC, Westbrook J, Wong CP, Haux R, Lehmann CU. International Comparison of Six Basic eHealth Indicators Across 14 Countries: An eHealth Benchmarking Study. Methods Inf Med. 2020; 59. To appear.
[41] Choi YK, Lazar A, Demiris G, Thompson HJ. Emerging Smart Home Technologies to Facilitate Engaging With Aging. J Gerontol Nurs. 2019; 45: 41-48.
[42] Demiris G, Washington K, Ulrich CM, Popescu M, Oliver DP. Innovative Tools to Support Family Caregivers of Persons with Cancer: The Role of Information Technology. Semin Oncol Nurs. 2019; 35: 384-388.
[43] Musiat P, Yang Y, Maeder A, Bidargaddi N. A Digital Infrastructure for Storing & Sharing Internet of Things, Wearables and App-Based Research Study Data. Stud Health Technol Inform. 2020; 268: 87-96.
[44] Ulrich CM, Demiris G, Kennedy R, Rothwell E. The Ethics of Sensor Technology Use in Clinical Research. Nurs Outlook. 2020. Epub ahead of print.