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Application of Lifetime Electronic Health Records *Are we ready yet?*

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Abstract

Integrated care concepts can help to diminish demographic challenges. Therefore, the use of eHealth solutions is recognised as an efficient approach. Lifetime electronic health records (LEHRs) are expected to increase continuity, effectiveness, efficiency and thus quality of the care process. With respect to these benefits, an overarching implementation of LEHRs is desirable but non-existent. Hence, the aim of the article is to analyse the current LEHR implementation readiness of EU member states to derive implications for further LEHR research and development. Therefore, a case study on Denmark, Germany and Italy was conducted. The analysis shows that all countries fulfil the technical requirements but Denmark has great experiences and willingness to implement advanced eHealth measures like LEHRs. First Italian pilot projects are quite promising as well. The article paves the way for LEHR implementation and therewith for integrated care.

Keywords: Electronic Health Record, Personal Health Record, Implementation, Requirements, Integrated Care

1 Introduction

The health care systems in Europe are faced with challenging transition processes due to demographic change, which leads to skilled worker shortage and an increasing number of multi-morbid patients (Harper, 2010). Given these challenging circumstances, integrated care can improve and ensure the quality of care (Lerum & Frich, 2012). An IT-based solution is a feasible approach to reduce the bottleneck of human resources and budgets (Iakovidis, 1998). Since the sketched changes are a Europe-wide challenge, the question raises whether there will be Europe-wide solutions. Anyway, EU's policy aims at spreading IT-based systems in health care by means of electronic health records (EHRs) all across Europe by the end of the decade (Kierkegaard, 2011). The progress in information and communication technologies (ICT) and eHealth solutions offer various options to meet the change and enable integration and networking (Dixon, 2007). A much higher level of integrated care all

along an individual's lifetime is possible. Lifetime EHRs (LEHRs) are seen as a tool to support this vision.

An LEHR is a "lifelong electronic collection, storage and provision of all health related information about its owner, allowing integrated care and functioning as a data basis to improve the quality of health care on the individual and societal level" (Gand, Richter, & Esswein, 2015). They shall be used across institutions and sectors in health care and include not only medical information, but also information on alternative treatments, lifestyle etc. LEHRs differ from EHRs, because these typically do not cover the whole lifespan and represent a provider-based view. LEHRs also differ from personal health records, since the information is primarily collected, managed and used by the owning individual alone (Caligtan & Dykes, 2011; Tang et al., 2006; Waegemann, 2002). The vision of LEHRs is expressed by a number of synonyms such as EHRs for integrated care (International Organization for Standardization, 2005), lifelong personal health records (Barbarito et al., 2015), lifelong integrated EHRs (Katehakis et al., 2007) or lifelong virtual EHRs (van der Linden et al., 2009).

LEHRs are expected to reduce information asymmetries by empowering the individual, increase continuity, quality, patient safety, effectiveness and efficiency along the care process and thus reduce costs as well as redundant work (Chaudhry et al., 2006; Katehakis et al., 2007; Tang et al., 2006). However, an area-wide implementation of (L)EHRs in Europe is not known so far. There are regional initiatives but no overarching approach. The interoperability of different solutions is not given. Nonetheless, the need for large-scale sharing of medical data has been expressed (Stroetmann et al., 2011).

Research on LEHRs is rare so far, whereas EHRs are studied in more detail (Caligtan & Dykes, 2011; Häyrynen, Saranto, & Nykänen, 2008; Kukafka et al., 2007). The main LEHR characteristic (lifetime validity) raises specific research questions, such as on sustainability and data retention. Various organisational approaches for LEHR delivery have been analysed with respect to ethical and legal issues. The establishment of Independent Health Record Banks has been proposed for sustaining LEHRs, because neither the consumers nor the care providers seem to be capable of providing the compilation and a sustainable storage (Shabo, 2006, 2010). With regard to technological infrastructure, a federated architecture was argued to be best fitting (Tsiknakis, Katehakis, & Orphanoudakis, 2004) and a service-oriented architecture for LEHR delivery was demonstrated being appropriate as well (Katehakis et al., 2007).

The divergence between recognised benefits and yet non-application of LEHRs makes advancement of LEHR implementation worth pursuing. Since a "one-size-fits-all" approach is not recommended in eHealth (Currie & Seddon, 2014), the analysis of country specifics is necessary. Therefore, the article aims at qualitatively assessing the current state of implementation readiness of EU member states by a case study deriving implications for further LEHR research and development. The method and country selection are described in section 2. In section 3, the criteria used for the assessment of LEHR implementation readiness are presented and demonstrated. The results are summarised in section 4. The paper closes with a discussion on open issues in section 5.

2 Method

The case study is conducted for a sample of EU members demonstrating LEHR implementation readiness criteria with real countries' data and to handle the multitude of aspects by reducing real world's complexity (Yin, 2014). The countries were selected based on an even geographical distribution and the results of the cross-national eHealth analysis by Currie & Seddon (2014). This quantitative study assessed EU countries on two dimensions (ICT penetration and availability; eHealth access and

usage) and identified four distinct groupings with declining dimension values: frontrunners, followers, leapfroggers and laggards (Currie & Seddon, 2014). Denmark (frontrunner), Germany (follower) and Italy (leapfrogger) were chosen as they are geographically close centrally in Europe but also represent north, middle and south European countries. At first view, the categorisation supports the assumption of Italy being not ready for the introduction of LEHRs yet. However, the vision of LEHRs has already been regionally implemented (Barbarito et al., 2015). This makes an analysis even more interesting, because it allows the assessment of the chances for countrywide dissemination.

The information for the assessment was collected through desk research. An argumentative-deductive approach in terms of a literature analysis (Palvia et al., 2003) has been conducted.

3 Case study

3.1 Assessment criteria for LEHR readiness

Numerous articles already analysed non-functional requirements for (L)EHR systems, such as data security and integrity, authenticity, availability, portability, performance and efficiency, maintainability, reliability, and usability (Fernández-Alemán et al., 2013; Hoerbst & Ammenwerth, 2010; Iakovidis, 1998; van der Linden et al., 2009). As the present article focuses on implementation preconditions on country-level, such system-specifics are not of primary interest. The case study uses the partly adapted assessment criteria for LEHR readiness as proposed by Gand et al. (2015). They consider not only IT-based indicators (such as Currie & Seddon, 2014) but also socio-economic ones. The criteria are described in Table 1.

Criterion	Description
Culture	Culture is a question of overarching societal willingness and awareness . A faster and more extensive communication across the borders of distinct health care providers and the collection of data from every necessary or available source should be considered as reasonable and thus be practiced whilst sensitising for potential risks.
Regulation & Governmental Commitment	Regulations regarding the functioning of an LEHR system ensure the use of common standards and long-term interoperability. The documentation systems should be compliant with data protection laws without hampering necessary data exchange. Documentations should stand up in court (auditability) not only having informative character. Only authorised and auditable data accesses with health care related intentions are acceptable. Avoiding misuse by alert regulatory is recommended. Privacy aspects and informational self-determination are of high importance due to the intimacy of the collected data. Focussing on the rights (informed consent) and needs of the citizens is highly important. Positive regulation should accompany with governmental commitment promoting the advantageousness of LEHRs.
Incentives	Measurable incentives and benefits are important to change the long-term behaviour and therefore the acceptance of new approaches like an LEHR. Health care providers and consumers have to use ICT in their daily routines. This might be incentivised by the provision of explicit (monetary) benefits (or fines) or by laying down usage rules.
Compliance	Care process related regulations like continuous quality assurances and system evaluations are necessary to enable compliant integrated health care . LEHRs should be integrated in clinical practice and protocols (and in individuals' daily routines). Decision support systems are a way to ensure consistent care by accessing an overarching database storing process and consumer related information.
ICT Infra-	A basic ICT infrastructure (i.e. ICT penetration and availability) is necessary to

structure	implement LEHRs on the technical level. The focus lays on the existence of connectivity options between different health care providers and citizens and complementing infrastructure for authentication etc.
Standards	Open and universal standards, common data models/formats, terminology and the consistent use of those are necessary prerequisites for interoperability , authentication, data security, long-term retention and hence to exchange health data across several health care institutions and sectors. These also ensure the trust in the system's capabilities and therefore acceptance.

Table 1: Assessment criteria for LEHR readiness (Gand et al., 2015)

The criteria show, that the government can establish the basic preconditions for successful LEHR implementation.

3.2 Country assessment

The application of the criteria is demonstrated by assessing the present situation in Germany, Denmark and Italy. Possible reasons for differences regarding eHealth implementation will be examined.

3.2.1 Culture

In Denmark there is the aspiration to become a highly IT-based society putting health care on a digital basis. This is based on deep-rooted openness for new technologies all across the society which in turn leads to a fruitful basis for the implementation and adoption of new eHealth solutions (Kierkegaard, 2013; Protti & Johansen, 2010; Currie & Seddon, 2014).

In contrast, a definite separation between German health care providers leads to inflexible, not very permeable borders between different sectors. Huge differences between the professional cultures of different occupation groups further hinder interdisciplinary and cross-sectoral cooperation. A rather low willingness to change structures and realise innovative care concepts is present (Amelung & Janus, 2005; Degeling, Maxwell, Kennedy, & Coyle, 2003). Moreover, Germany has a large population and a highly developed well performing health care system. But this comes along with a higher level of conservatism and difficulties managing large-scale eHealth systems on the national level (Currie & Seddon, 2014; Stroetmann et al., 2011). In contrast, initial studies show, that there might be a majority of citizens having a positive attitude regarding the implementation of overarching EHRs. However, concerns regarding privacy and data protection, uncertainties about the concrete features and accompanying risks are also highly relevant issues (Hoerbst et al., 2010).

Despite the plan of the Italian government to push forward innovative eHealth concepts (Barbarito et al., 2015), the information exchange between different health care providers in the regions is not fully satisfying (Bonacina, Marceglia, & Pincirol, 2011). A way to raise quite narrow adoption and user interests might be the integration of features allowing interpersonal cooperation and exchange focussing on user empowerment (Cabitza, Simone, & De Michelis, 2015; Comandé, Nocco, & Peigné, 2015).

3.2.2 Regulation & Governmental Commitment

The Danish government has the goal to spread integrated care concepts and mutually useful patient-carer interactions by means of eHealth solutions. Therefore, MedCom, an institution to coordinate eHealth actions, was founded in 1994 (Deutsch, Duftschmid, & Dorda, 2010) showing a strong commitment to eHealth advantageousness. Denmark also takes an exemplary role in designing an overall legal framework for sustainable eHealth solutions considering important aspects like privacy, confidentiality, liability and data protection (Stroetmann et al., 2011). The

government aspires a high degree of patient independency and empowerment (Kierkegaard, 2013). The use of EHRs is mandatory and they are well accepted by the physicians (Protti & Johansen, 2010).

The German government promotes integrated care projects (see § 140a ff. German Social Act Five), but the main focus lays on integration on the indication level until now (Schreyögg, Weinbrenner, & Busse, 2006). This leaves room for higher levels of integration. Because informational self-determination is ranked as a constitutional fundamental right, Germany has strong data protection laws. These can hamper cross-sectoral data exchange and integrated care approaches (Amelung & Janus, 2005; Menzel, 2006). A project to implement an electronic health card ought to promote integrated solutions, but demonstrated eHealth to be a tough act to follow in Germany: the project was controversially discussed and delayed for many years; the range of functions is still limited (Engemann, 2013).

The Italian law on privacy and security is also quite a hurdle for innovative overarching eHealth solutions. Here, special effort for clarification and introduction of regional implementation guidelines are a precondition for the application of those. Another issue is the split of responsibility in the Italian legislative structure: initiatives of the central level pushing innovative eHealth concepts (the broad implementation of the “Fascicolo Sanitario Elettronico” as an overarching EHR) are highly desirable. But the regional responsibilities for the real implementation of those laws in health care hamper an overarching implementation (Barbarito et al., 2015).

3.2.3 Incentives

Considering the high Danish governmental (and societal) commitment, there seems to be low need for incentives to use eHealth. Nonetheless, there were some helps to boost these especially at the beginning of MedCom’s work (e.g. data consultants, peer influence and collegial pressure, funding by the ministry and physicians’ education seminars). This led to a high rate of eHealth use by practitioners even before the mandatory phase begun (Protti & Johansen, 2010).

The German social security laws primarily offer incentives based on cost reductions for patients (e.g. for taking preventive actions) and health care providers (e.g. no-name drug prescriptions allowing the cheapest medication). Sustainable behavioural change is not a major goal (Schmidt, Gerber, & Stock, 2009). Latest legislative measures include incentives (and sanctions) for a dissemination of eHealth solutions and the implementation of a uniform infrastructure for telematics and interconnections in health care (*Draft of a law for secure digital communications and applications in health care*, 2015).

In Italy, incentives for the practitioners (presumably no experts for IT or documentation) to get them use new eHealth solutions are also a quite new issue. Incentive payment schemes are regionally implemented to overcome this. Other prospective ideas are special educations and training programmes. Furthermore, mandatory goals for the specific use of eHealth solution shall play an important role, too (Barbarito et al., 2015; Comandé et al., 2015).

3.2.4 Compliance

The use of EHRs in Denmark is mandatory and these are well accepted in general, which in turn leads to a highly compliant use. Nevertheless, there are still frictions in the physicians’ work due to eHealth usage. Acceptance problems and technical shortcomings might have been undervalued. But the authorities permanently observe these considerations, so improvements are planned (Grosen, 2009; Kierkegaard, 2013; Protti & Johansen, 2010).

The increasing publication of highly evidence-based medical guidelines is a way to obtain compliance within the health care process. But the voluntary usage, and insufficient linkage to practical implementation in clinical practice guidelines are open issues. This enforces the argument for mandatory regulations establishing a higher rate of integrated care (Kopp, 2011; Perleth, Jakubowski, & Busse, 2000).

In Italy, the necessity to develop or use established interoperability guidelines has also been recognised as relevant. Where introduced, they (together with mandatory goals) had a positive impact on the adoption of newly designed eHealth solutions (Barbarito et al., 2015). In contrary, the absence of guidelines and process management is the suboptimal standard. Educational efforts are also necessary to get systems adopted. The effort to design new workflows that integrate and adapt existing standards, clinical and administrative processes and practitioners' work was inadequately considered so far and resulted in a lacking diffusion (Barbarito et al., 2015; Bonacina et al., 2011).

3.2.5 ICT Infrastructure

On the technical level, Denmark is highly competitive. The disciplines of health care and informatics work very closely together, there is broad internet access and usage almost across the whole country (Currie & Seddon, 2014). The use of EHRs is mandatory since 2004 (Kierkegaard, 2013; Protti & Johansen, 2010). There are also several national and regional strategies to reach the IT-related goals. These result in a multitude of distinct health information exchange and storage initiatives, platforms and portals covering the majority of clinical relevant processes (Kierkegaard, 2013).

Although Germany performs less well on eHealth indicators (usage and access), it has a mature health infrastructure, an excellent medical technology sector and performs well on ICT indicators (Currie & Seddon, 2014; European Commission, 2010).. So, it is assumed that technical preconditions are fulfilled.

The individuals' usage of the Internet seeking health-related information is much more common in Germany and Denmark (usage rate: about 50 %) than in Italy (ca. 30 %). The rate of households with internet access is also much lower: about 90 % in Denmark and Germany compared to ca. 70 % in Italy (Eurostat, 2014). So, the technological preconditions need to be improved for a broad implementation of LEHRs. Again, heterogeneous healthcare information systems are an observable obstacle for overarching eHealth solutions in different hospitals and organisations. Missing interoperability as well as inadequate ways to represent the complex and uncertain clinical processes can be observed (Bonacina et al., 2011). But there are regional initiatives (e.g. in Lombardy region) to expand the capabilities of the infrastructure for accessing, storing and managing health data. The vast amount of unstructured and noisy (partly irrelevant) data may also lead to further ICT needs (e.g. for Big data analyses) that were not fully operationalized yet (Barbarito et al., 2015).

3.2.6 Standards

In Denmark, commonly used frameworks and communication standards for eHealth solutions were developed or made compulsory (Kierkegaard, 2013). Nonetheless, due to fragmented responsibilities for health care providers within the Danish administration there is a multitude of partly incompatible health record systems leading to frictions in data exchange. There are commonly used and compulsory procedures, but not a single one all over the country. Partly, these circumstances diminish the advantages of the eHealth solutions and lead to suboptimal situations when it comes to inter-institutional or unscheduled treatments. Structural reforms shall lead to improvements (Grosen, 2009; Kierkegaard, 2013).

In Germany, overarching electronic exchange and integration of health-related data are not common. Standards are mainly used for data exchange within a single

institution. There is no common usage of standards for inner-sectoral or cross-sectoral exchange. This strongly limits a quick implementation of LEHRs (Klar & Pelikan, 2009).

For Italian hospitals, a special strategy is necessary allowing integration of different systems by adopting HL7 standard. The idea was to design a special middle-layer infrastructure that builds an interface for all connected health service providers and the definition of interoperability specifications. Shortcomings in the HL7 standard, hampering the regional implementation of new solutions were also recognised. Suggested changes for this standard shall help to overcome this (Barbarito et al., 2012, 2015). In general, there are no commonly accepted terms or ontologies supporting or even allowing clinical communication on a conceptually integrated level (Bonacina et al., 2011).

4 Summary

The results of the case study are summarised in Figure 1. Overall, Denmark shows a lead regarding readiness for LEHR implementation. The broad experience with EHR usage and the problems that came along with it have to be considered for LEHR implementation and support the proposed assessment criteria. In contrary, Germany is only partly ready to implement an LEHR yet. The country's considerable capabilities have only lead to first important steps. Especially the regulation criterion might currently be excessively fulfilled, what makes it an obstacle rather than an enabler for higher integration. Italy overall is partly ready. Progressive initiatives like in the Lombardy region (Barbarito et al., 2015) may be predestined for further analyses and functioning as a starting point for dissemination activities to other regions.

Country \ Criterion	Culture	Regulation & Gov. Commitment	Incentives	Compliance	ICT Infrastructure	Standards
Denmark	●	●	●	◐	●	◐
Germany	○	◐	◐	◐	●	◐
Italy	◐	◐	◐	◐	◐	◐

Explanation	● extensively fulfilled	◐ partly fulfilled	○ insufficiently fulfilled
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Figure 1: Summarised country assessment of the case study

One limiting factor of the present case study is the non-existence of real, broad LEHR implementations by now. However, the great experiences in Denmark with eHealth solutions, the LEHR-like pilot projects in Italy and the highly developed health care systems in the analysed countries provide a good basis for conjecturing positive future developments towards LEHR realisations. Still, smaller populations accompanying with greater willingness to change (like in Denmark or Lombardy) seem to be an advantage to successfully implement new eHealth solutions (Currie & Seddon, 2014; Kierkegaard, 2013; Stroetmann et al., 2011).

5 Discussion and Conclusion

In summary, the article contributes to the research field of eHealth by showing prerequisites for the implementation of advanced concepts like LEHRs and by exemplarily demonstrating whether those are given or not. Hurdles causing the disuse are touched on but shall be further analysed. Together with the findings of the present study, implications and measures for a successful implementation of LEHRs can be derived.

The case study revealed great potentials for Denmark whereas Germany showed hindering conditions, which need to be adjusted. Italy takes a medium position with first piloting regions. To the authors' mind, a uniform, Europe-wide LEHR solution is not desirable. Country-specific (considering the respective health care systems) but

interoperable solutions should be aimed at. Furthermore, it is essential to intensify research on possible LEHR implementation solutions as well as on the societal acceptance of such. Already proposed solutions need to be evaluated with respect to country-individual conditions. Furthermore, the indicators of the adapted assessment criteria for LEHR implementation readiness should be further developed, to improve their applicability.

For the practice, the present study can function as starting point for the assessment of own solutions and comparison through the criteria with country readiness and therefore helping to successfully design and spread concrete LEHR implementations.

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