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The Electronic Health Record

If Electronic Health Record systems are to provide an effective contribution to healthcare across Europe, a set of benchmarks need to be set to ensure quality control and interoperability of systems. This article describes why EuroRec's initiatives are important, considering the present trends where patients need to be put at the centre, clinicians be involved in the design of their applications and healthcare delivery itself be reorganised to become more data driven. EuroRec's aim is to promote development and use of high quality EHR systems. One of its main missions is to support the development of EHR certification.

IT has the potential to make a significant contribution to the better management of healthcare provision. This cannot be achieved without the availability of trustworthy Electronic Health Record systems (EHRs) that provide all necessary clinical information requirements, thus enabling the sharing of timely and up-to-date patients' medical data to support "high quality care" and "continuity of care".

Interoperability and security to protect privacy and confidentiality of patients' data are prime requirements for such EHRs.

The Rationale for Quality Labelling and Certification

Investment in healthcare IT has been comparatively low compared with other sectors. High investment risk for purchasers and low definition of European market requirements for suppliers has contributed to such a situation. This is particularly the case with large-scale investment at regional or national levels. As EHR system requirements become increasingly complex, accompanied by a growing risk of system deficiencies or failure to meet expectations, there is a need for an assessment process to assure the quality of EHRs on the market and to ensure their interoperability with other systems. Without an agreed set of functional criteria to underpin the introduction of robust, sustainable EHRs, major IT investments could potentially be at risk.

Given a set of quality criteria around which suppliers and their healthcare customers can collaborate openly, the introduction of effective EHR solutions across European member state boundaries can become a reality. Several EU member states have already proceeded with EHR systems quality labelling and/or certification, but these differ in scope, in legal framework under which they operate, in policies (legal and financial incentives) and organisation, and perhaps most importantly in the quality criteria used for benchmarking.

Harmonisation, therefore, is a must. Now, through EuroRec and the QRec Specific Support Action (IST-27370-SSA, 2006- 2008), the possibility to achieve this for EHR systems in Europe is in sight.

EuroRec - Its Current Activities and Future Plans

The European Institute for Health Records, dubbed the EuroRec Institute, was formally registered in 2003 as a not for profit organisation. It is organised as a permanent network of National ProRec centres in Europe and provides services to all interested stakeholders: industry (the developers and vendors), healthcare providers, (the buyers), health care authorities and policy makers and patients.

EuroRec's aim is to promote the development and use of high quality EHR systems. One of its main missions – as a de facto recognised European certification body – is to support the development of EHR certification by defining functional and other criteria for testing and assessment. EuroRec is liaising at international level with other bodies such as CEN/BT and TC251, ISO/TC215, WHO, openEHR, HIMSS, CCHIT and many others to follow (e.g. IHE).

The QRec Specific Support Action

By means of the EU FP6 (Sixth Framework Programme) funded project QRec, EuroRec has brought together European experts in the EHR field and is developing formal methods and creating mechanisms for the quality labelling and certification of EHR systems in Europe (starting with primary and acute hospital-care settings; others will follow: e.g. for personal health record systems).

The aim of such an initiative is to also encompass other e-Health software products and services at a later stage (e.g. decision support and other systems that might impact on patient safety). QRec has already provided several deliverables:

Ó The first series of validated, fully indexed and translated quality criteria and functional requirements (over 2,000 in number) for EHR systems

Ó A typology of indexes : business functions (50 in 8 subcategories), care settings (18 in 3 subcategories) and component types (18 in 4 subcategories)

Ó A series of tools (the EuroRec Composer, Certifier, Documenter, Procurer and Scripter) for profiling EHRs (e.g. for national certification processes, for product documentation or for procurement purposes)

Ó Quality assurance of EHR archetypes (i.e. formal sharable models of clinical domain concepts (open EHR/EN 13606 archetypes) for enabling the semantic interoperability in e-Health

Ó A repository of European and International coding systems in use in EHRs, as well as a complete inventory of EHRs related international standards

Ó Test scenarios and proposed certification mechanisms enabling both self-certification (e.g. by the industry) and external certification (e.g. by health care authorities)

Ó EHR tutorials and events.

The Future

EuroRec intends to increase the momentum of its efforts in the years to come.

Its key priorities are to maintain and enrich its central repository of validated criteria, and deepen its involvement in studying quality criteria related to the secondary use of EHRs as potential e-sources - for example in e-Clinical Trials and other e-Research. It also aims to investigate certification of EHRs in other care settings, such as e-homecare and personal health records. Yet another priority area is the validation of clinical archetypes, which provide a useful formalism for reconciling and reusing detailed clinical data specifications across different use cases.

As the barriers between the different types of Electronic Health Record systems and other e-Health related applications whither away, EuroRec intends to broaden its future scope of work to the quality labelling of other types of Health-IT systems, such as Decision Support Systems.

In the near future, EuroRec sees it appropriate to pilot and implement the EHR quality labelling and certification process across Europe, including Eastern Europe. This would be in compliance with the ‘good practice requirements’ it has elaborated. A number of member states (already certifying at national levels) have been seeking to participate more actively in a Europe-wide effort.

These kind of services are highly resource intensive and EuroRec has seen a need to ensure more continuity and followup for its efforts, to give them further traction. It is seeking greater funding for its activities, along the lines of support from the US Department of Health and Human Services to CCHIT, EuroRec’s American counterpart. As a result, EuroRec is exploring avenues to complement its self-supporting activities and EU-project-based revenues with more structural funding mechanisms.

Q-REC at a Glance

Q-REC is developing formal methods and creating a mechanism for the quality labelling and certification of EHR systems in Europe, as well as specifications for EHR procurement.

Its main lines of work are:

EHR Systems Quality Labelling and Certification Development

Ó Producing a State of the Art Report on EHR-Certification Schemas as already implemented in some European countries

Ó Performing a Pan-European Requirements Assay

Ó Proposing a Labelling Terminology and Functional Profiles for EHRs to be certified

Ó Comparing and Harmonising the EHRCertification Procedures at a European level

Ó Drafting Model Certification Guidelines and Procedures

Ó Planning Validation of the Guidelines

Resources for EHR Interoperability:

Ó Register of Conformance Criteria and Guidance Documents for obtaining EHR Certification

Ó Inventory and Guidelines for EHR Archetypes

Ó Registration of Coding Schemes in Europe (as mandated by CEN/TC 251)

Ó Inventory of relevant EHR related standards

Ó Register of XML Schemas and Open Source components for EHRs

Ó Benchmarking Services Manual for Quality Labelling and Certification

Ó Business Plan for new EHR-Certification related Services

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