

European Quality Labelling and Certification of Electronic Health Record systems (EHRs)

Introduction

Healthcare is a global marketplace in which the majority of developed countries are facing many of the same issues of aging populations, increasing complexity and costs of medical treatments, governmental pressures to improve patient safety and contain the rate of cost increases, and a reducing work force. In Europe this is exacerbated by an increasingly mobile population encouraged by the expansion of the European Community.

ICT has the potential to make a significant contribution to the better management of healthcare provision, to more efficient and cost effective use of resources and in areas such as better patient safety and clinical decision support for evidence based treatments. The problem today is that much of the European healthcare ICT industry is fragmented and largely national due in large measure to cultural, language, governmental policies, and the national variations in healthcare funding

The case for Quality Labelling and Standards

More and more Healthcare organisations are faced with a proliferation of ICT software products. As the healthcare providers struggle to introduce more functional systems in support of clinical activities so the issue of interoperability becomes one of paramount importance. Gone are the days when interfacing was a pain that had to be endured. Now, with the ever present need to create solutions that support patients across the care continuum, semantic interoperability is coming to the fore of ICT implementations at local, regional, national, and even international levels.

Without an agreed set of minimum standards and functional criteria to underpin the introduction of robust, sustainable EHRs such major ICT investments are potentially at risk. Given a set of standards and functional criteria around which suppliers and their healthcare customers can collaborate openly, then the introduction of effective EHR solutions across international boundaries becomes a reality. This has been a feature of smaller systems for General Practitioners in various European member states for some time. Now, through the EuroRec QREC initiative, the possibility to achieve this for EHR systems is in sight.

The EC already has a strategy to encourage the development of a strong European ICT market with successful globally respected suppliers within it. As seen in other industries when standards and quality labelling are introduced, manufacturers respond positively to the challenge. In turn this leads to market expansion, increased user acceptability and satisfaction. The days of proprietary ICT technologies and solutions are past, once seen as providing competitive advantage, and now viewed as limiting to both suppliers and their customers.

A European healthcare ICT market, in which standards for quality labelling and certification of basic functionality and semantic interoperability are a feature, will be one that encourages a vibrant and innovative supplier environment.

Benefits to healthcare organisations as purchasers of EHR systems

One of the main reasons for quality labelling and certification of EHRs across Europe is to provide a more secure purchasing environment for the customers of the EHR supplier industry. Quality labelling and certification offers many advantages to the purchasers of EHR systems of which the following are prime examples

- **Choosing a certified EHR product will give you greater confidence that it will perform all of the basic functions you require and has the potential to significantly improve the success of your implementation as systems that are certified will have:**
 - System functions/facilities that reflect local & international best practice
 - Approved Functional profiles for
 - Clinical, administrative, research data access, output and utilisation
 - Interoperability with other systems
 - Systems and data Security
 - Communications
 - Systems, data and information architecture
 - Validated functional criteria designed to ensure optimal information/workflow support
- **A key requirement to support quality outcomes is that an EHR functions as specified and the availability of quality assured products improves prospects in this area**

- **There is growing evidence that suggests significant benefits from investment in quality assured EHRs, arising from improvements in the quality and safety of healthcare services and also the possibility of cost savings. Purchasing a certified EHR product has the potential to improve patient care and service processes by facilitating:**
 - Data/systems interchange and interoperability to support shared knowledge networks thereby improving patient experience and diagnosis/treatment/care outcomes
 - Development of standard work processes based on agreed best practice functional criteria leading to improved workforce productivity and business performance

- **The quality and suitability of EHR products may be difficult for you as a purchaser to assess that the product is robust enough to deliver what you expect. The inventory of resources which underpins the certification process contains defined standards for functional criteria, data and communications architecture, interoperability and security which will assist you in specifying EHR requirements, what an EHR product is expected to provide and how it will meet your needs.**
 - It will support a process/mechanism to check/confirm
 - Specifications accurately reflect your needs
 - Quality of systems specification relative to best practice
 - The proposed system meets specifications
 - Provide assurance that the best system was chosen
 - Enable the potential assessment of:
 - The proposed system supplier capabilities to implement the system
 - The Impact and potential of your organisation to cope with the implementation
 - How to minimise your risk of failure

- **Quality labelling/certification of EHRs has potential to significantly reduce your investment and associated risks by:**
 - Specifying expectations/content of EHRs
 - Specifying interoperability requirements of EHR systems
 - Specifying deployment standards
 - Educating vendors/users on requirements of successful EHRs
 - Driving performance standards convergence
 - Certifying compliance with expectations, content, interoperability, deployment and standards requirements for specific EHRs

- **Companies supplying systems who have undergone the certification process will have demonstrated that they have:**
 - A robust and proven product and solution portfolio
 - Ensured their EHR systems are of demonstrably good quality
 - Commitment/responsibility - providing system support
 - Skills in technology delivery support and innovation
 - Understanding of healthcare service delivery issues
 - Experience and reputation in the healthcare sector

- **The QREC quality labelling and certification system provides an independent, unbiased, professional and trustworthy quality assurance mechanism, It supports risk assessment and analysis, and provides a benchmark to support and evaluate value for money (VFM) initiatives.**

- **Certification of EHR products can lead to an improved market confidence with larger volumes and lower marketing and development costs to vendors thus leading to the potential for lower ownership costs over the lifetime of the EHR. The tendering process can be both simplified and the costs reduced for the purchaser and supplier communities. It will also be more transparent and improved by:**
 - Having best practice validated for systems assessment methodology
 - Potential time reduction through speedier short listing and evaluation
 - Utilising standard criteria and certified product suppliers

Benefits to the supplier industry

With the introduction of Europe -wide quality labelling and certification standards and criteria for EHRs, subsequently adapted for each country's needs, the supplier industry can expect numerous benefits to emerge that are fundamental to securing the wider adoption of known quality labelling and certification standards and criteria. It is important that both purchasers and providers of EHR systems see real and significant benefits in this process and for the suppliers these include:

- **More efficient product development and extended product life cycles against known market requirements.**
 - A more certain climate for investment offering improved RoI in product development
 - Interoperability becomes more a defined task and thus designing and implementing software for this becomes more manageable
- **Certification of EHR products can lead to improved market confidence with larger volumes and lower marketing costs for suppliers. The tendering process can be simplified and become more transparent. The time and costs involved can be reduced for the purchasers and suppliers.**
- **A liberated market in which previously locally developed and locally marketed products have the potential to appeal to a Europe -wide audience**
 - The creation of a more 'level playing field' across Europe becomes a possibility
- **Industry co-operation can be greatly improved by convergence towards known standards and criteria to the betterment of those healthcare organisations served. The quality and professionalism of the delivered product and service will be enhanced over to-day's level and thus the industry enjoys an enhanced reputation.**
- **Suppliers have more opportunity to 'mix and match' their solutions stimulating a market in which both purchasers and suppliers have wider choice**
- **Quality labelling will greatly support the development of National based programmes for EHR rather than**

central governments/ executive agencies becoming too prescriptive and thus reducing supplier choice and options

If the purchasers of EHR enjoy real benefits from software that is more open and functions to minimum standards and criteria, the supplier industry will see a more rapid growth in the market and enjoy improved financial performance.

Overall the introduction of an accreditation process, much as has started elsewhere, e.g. in the US through the CCHIT process, will have a unifying effect within the industry and across the market with purchasers.

A Valuable resource for purchasers and suppliers

- **For both purchasers and suppliers, participation in and utilisation of the certification process will also provide access to:**
 - Trustworthy resources that contribute to producing or validating high quality and more interoperable EHRs.
 - Criteria on which quality labelling and certification is based, and which also indicate the fine-grained requirements that must be met by “good” systems;
 - Guidance materials that explain the way in which accreditation works, and how tests may be performed;
 - Knowledge artefacts such as archetypes, as a trusted (quality-assured) source of specifications that may be downloaded and applied to EHR systems (e.g. in the design of templates and forms);
 - Guidance materials on how good knowledge artefacts can be designed
 - References and pointers to published work that underpins the criteria (such as standards to which conformance is required) or to externally-produced knowledge resources (such as published terminologies and code sets)
 - References and pointers to “trustworthy” software meeting suitable quality criteria (e.g. open source components, implementable technical specifications such as XML schemas and other EHR-related documentation)

If the end users enjoy real benefits from software that is more open and functions to minimum standards, the supplier industry will see a more rapid growth in the market and enjoy improved financial performance.