Interoperability Reviews: ARGOS Trans-Atlantic Observatory Policy Briefs

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Introduction

The **ARGOS eHealth Pilot Project** is a funded collaboration between AMIA and a consortium of European organizations led by the EuroRec Institute. The goal of ARGOS is to support the establishment of a Transatlantic Observatory through which to meet global health policy challenges using ICT-enabled solutions and to develop and promote common methods for responding to global eHealth challenges in the EU and the U.S.

A key output of ARGOS is a set of policy briefs, which are about to be published (August 2011) on key topics of Trans-Atlantic importance for the success of eHealth:

- Semantic interoperability
- Modelling and simulation of human physiology and diseases with a focus on the Virtual Physiological Human
- Policy Needs and Options for a Common Approach towards Measuring Adoption, Usage and Benefits of eHealth
- The current status of Certification of Electronic Records in the US and Europe
- eHealth Informatics Workforce challenges

These policy briefs are summarized below.

- **Policy brief on semantic interoperability**
- **Policy brief on modeling and simulation of human physiology and disease**
- **Policy brief on measuring adoption, usage and benefits of eHealth**
- **Policy brief on Certification of Electronic Health Records in the United States and Europe**
- **Policy brief on eHealth informatics workforce challenges**

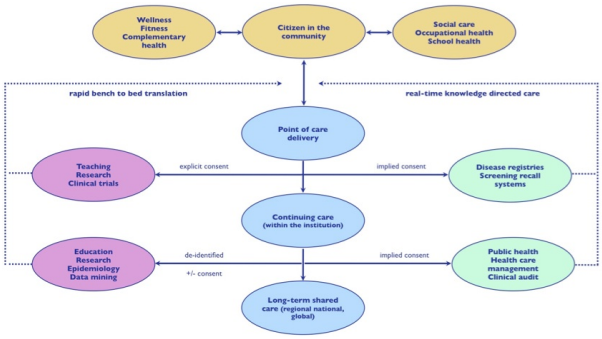
Policy brief on semantic interoperability

Editors: Dipak Kalra, Mark Musen, Barry Smith, Werner Ceusters

Semantic interoperability is one of the priority themes of the ARGOS Transatlantic Observatory. This topic represents a globally recognised challenge that must be addressed if electronic health records are to be shared among heterogeneous systems, and the information in them exploited to the maximum benefit of patients, professionals, health services, research, and industry. Progress in this multi-faceted challenge has been piecemeal, and valuable lessons have been learned, and approaches discovered, in Europe and in the U.S. that can be shared and combined.

Experts from both continents met to explore these challenges at ARGOS workshops, in March 2010 in Barcelona, in November 2010 in Washington, DC, and in May 2011 in Budapest. The ARGOS policy brief on semantic interoperability summarises the problems, the reasons why they are important to tackle and proposes a series of next steps that need to be championed on both sides of the Atlantic.

Semantic interoperability requires the use of standards, not only for EHR data to be transferred and structurally mapped into a receiving repository, but also for the clinical content of the EHR to be interpreted in conformity with the original meanings intended by its authors. Accurate and complete clinical documentation, faithful to the patient's situation, and interoperability between systems, require widespread and dependable access to published and maintained collections of coherent and quality-assured semantic resources, including **models such as archetypes and templates that would (1) provide clinical context, (2) be mapped to interoperability standards for EHR data, (3) be linked to well specified, multi-lingual terminology value sets, and (4) be derived from high quality ontologies.** Wide-scale engagement with professional bodies, globally, is needed to develop these clinical information standards.



Health information flows that need semantic interoperability support

ARGOS has proposed the following key actions that U.S. and EU bodies need to endorse, to champion, and to support financially.

1. Develop criteria for assessing the quality of semantic resources of all kinds.
2. Support research efforts on what parts of, and how much of, a health record is useful to structure, to code, and to make interoperable.
3. Develop sustainable approaches to scaling up resource development across clinical specialties and stakeholders, importantly including patients, and using successful pilots as showcases.
4. Support translations between languages to enable cross-border shared care, cross-border health planning, and global scale research.
5. Monitor the evolving capability and potential uses of natural language technologies for population-level and patient-level decision making.
6. Conduct a gap analysis of informatics tools, knowledge representation formalisms, standards, and clinical content that are needed to support a scaling up of EHR interoperability.
7. Collaborate across the EU and U.S. on common conformance criteria for systems and system components.
8. Invest in dissemination and education efforts designed to enable clinical and patient/citizen acceptance, creation, and use of knowledge-rich EHRs.
9. Foster development of business models to justify strategic investments in this field.
10. Strengthen leadership and governance.

This full policy brief will be published at the end of August 2011 via IOS Press in the series "Studies in Health Technology and Informatics".

Policy brief on modeling and simulation of human physiology and disease

Editors: Marco Viceconti, Andrew Mc Culloch

Life is the result of an intricate systemic interaction between many processes occurring at radically different spatial and temporal scales. Every day, biomedical research and clinical practice produce, worldwide, a huge amount of information on such processes. But this information is highly fragmented, and its integration is largely left to the human actors, who find this more and more difficult as the breath and depth of information available increases exponentially.

The "Virtual Physiological Human" (VPH) involves laboratory and clinical data collections, information databases, models repositories, modeling and information and communication technologies aiming to overcome the fragmentation and the dispersion of the data, information, and knowledge that overall composes what we humans know and understand about life from a scientific and clinical point of view.

These investments in VPH research are largely motivated by the need for integration in healthcare: as all health information becomes digital, the complexity of care increases, and pressure imposes by growing demand and shrinking budgets, the way to achieve the dream of personalized, preventive, and participative medicine at sustainable costs is the integration of all available data, information and knowledge.

There is now a need to coordinate research efforts toward the complete integration of all data, information, and knowledge about human physiology and pathology into a global "VPH cyber-infrastucture" that will produce huge socioeconomic benefits by:

- Enhancing the understanding of diseases, favouring prevention and early diagnosis;
- Accelerating the development pipeline and the assessment of safety and efficacy for innovative drugs and medical devices;
- Assisting the medical professional in coping with the "information overflow" problem; and
- Fostering the development of new healthcare policies that promote a more holistic approach to complex diseases and to the promotion of an active and healthy aging.

This vitally needs Europe and United States to elaborate a joint policy. This Policy Brief explains why the academic, industrial, and clinical stakeholders of the VPH initiative recommend the following actions to European and United States governments:

1. Agree on a common policy to realign all VPH-type research efforts toward the creation of a global VPH Cyber-infrastructure, by ensuring that all repositories of data and models, as well as all the methods and technologies developed during these research projects funded by governmental agencies are mutually interoperable and integrable.
2. Support the establishment and the operations of an International Multi-stakeholder Advisory Group responsible of elaborating a collective vision, as well as the minimum set of standards and the technical guidelines that ensure the interoperability and the integrability of all VPH resources into the global VPH Cyber-infrastructure, according to the vision of the Virtual Physiological Human.

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Policy brief on measuring adoption, usage and benefits of eHealth

Editors: Karl A. Stroetmann, Blackford Middleton

Health policy-makers are challenged by insufficient human and capital capacity to meet demand for services, and to prioritise finite budgets. Demographic change, rising incidence of chronic disease among young and old, and unmet needs for more personalised care are driving the pressure to introduce a new model of health care; a redesigned smart health system.

For eHealth to deliver the expected benefits, it requires, on the one hand, policies to foster actual deployment (including investments, improvement of interoperability, reducing legal and other barriers), and on the other, measures of deployment and the effectiveness of current and future take-up. Micro-level socio-economic evaluations of eHealth systems and solutions can offer significant benefits to health policy decision-makers. These include providing evidence-based information to help decision-makers in eHealth identify the type and scope of benefits for patients, care-givers, healthcare professionals, healthcare provider entities, and other stakeholders to consider when making decisions to invest in eHealth.

A rigorous evaluation framework for identifying and measuring the benefits and costs from eHealth investments and deployment is needed for two reasons:

1. in order to demonstrate the potential, including the points of high-level impact, and
2. in order to analyse incentives structures, and thus identify fields of required policy initiatives and action.

The EU, individual Member States, the United States, OECD, WHO, and industry now realise the urgent need for common approaches toward measuring adoption, usage and benefits of eHealth, thereby optimally contributing toward guiding, controlling and improving policy development and implementation. To advance towar a Trans-Atlantic and global collaboration, the following key strategic foci have been identified:

- Exploit the potential of existing activities
- Identify, analyse, and agree on policy priorities to facilitate moving towards a more standardized approach
- Explore opportunities for developing common methodologies and measures
- Conduct cross-country analyses and benchmarking of policies, achievements and lessons learned
- Support policy analysis through collection of an agreed core set of indicators and a new generation of metrics

Potential priority areas for such work include:

1. Identify common policy needs, ongoing activities, and shareable experience
2. Develop appropriate taxonomy(ies), methodology of data collection (harmonize benefit/measures of ICT adoption, use and impact)
3. Together with OECD, develop modular survey instruments (concepts, measures and tools)
4. Harmonise benefit and cost measures and analysis methods/tools
5. Identify relevance of RoI vs HTA (effectiveness) vs benefit/cost -- socio-economic impact/return (including soft factors for patients/their "willingness to pay")
6. Harmonise measures of ICT adoption, “value” of effective and meaningful use, impact
7. Refine an existing core set of indicators and/or new indicators to measure adoption; modes/purpose of use; critical success factors; outcomes/impacts

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Policy brief on Certification of Electronic Health Records in the United States and Europe

Editors: Georges De Moor, John O’Brien, Doug Fridsma, Carol Bean, Jos Devlies, Pascal Coorevits

Health IT has the potential to make a significant contribution to 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, 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.

Given the increasing complexity of EHR systems requirements and the risk of system deficiencies or failure to meet expectations, there is a need for an assessment process to assure the quality of EHRs in 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 ICT investments are potentially at risk.

Certification, licensing, and accreditation endeavours are now well established and accepted as being essential to quality assurance and improvement advancement. With the increasing investment in, and expanding central role of and dependence on ICT in health, particularly in the core areas of patient diagnosis, treatment and care, there is a growing recognition of the need to quality-assure the content, capacities, capabilities, and performance of related systems as they are applied in the domain.

Certification, licensing and accreditation schemes are necessary because:

- potential for harm may lie in the design of any EHR system (such as failure in design logic, poor or confusing presentation of clinically relevant information), which may be inbuilt deficiencies that are not apparent to the user (healthcare professional);
- clinical information is often distributed over a number of information systems (primary care, secondary care etc.), and as patient data is increasingly shared across these systems providing assurance of their interoperability becomes paramount.

EHR systems must be sufficiently developed, comprehensive and robust to facilitate realisation of anticipated benefits. EHR procurers and end users (e.g. hospital directors and physicians) frequently claim that EHR systems and related product quality, data portability and interoperability are difficult to judge. Certification eliminates this concern for procures/users. Several areas of potential Trans-Atlantic cooperation have been identified.

1. Certification, MU, and the relationship between U.S. and EU efforts

In setting up a certification program for meaningful use, the United States has used both an internationally recognized accreditor for the testing program (NAVLAB) and an internationally recognized accreditor (ANSI) for the certification program. While international certification is not a core component of the meaningful use program, the certification program is structured such that it will not preclude international certification bodies from participation in MU certification by being recognized as certifying or testing organizations.

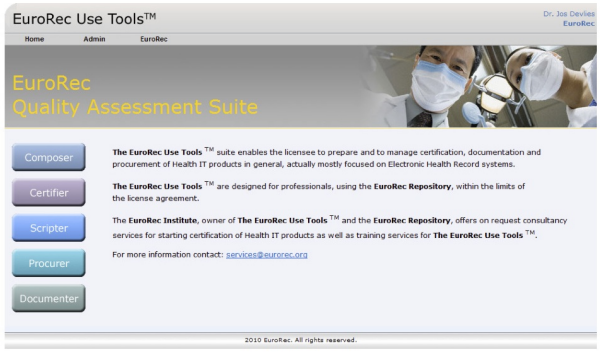
It also may be important to examine the current meaningful use certification program and certification criteria that are being developed within the United States and examine how its scope, granularity, and potential overlap with EU certification programs.

2. Link to international standards organizations

Another area of shared interest is to coordinate efforts across internationally recognized standards organizations. For certification to be successful, we need high quality specifications and testing scripts that can be shared among different certification programs. For example, ISO TC 215, the BRIDG project for clinical research standards and information models, as well as the establishment of a U.S. realm for localization of international standards are all important efforts that we can collectively coordinate within the international standards organizations.

3. Common tools/vocabularies

As we develop standards, implementation specifications, testing approaches, and certification programs, we can share common tools, vocabularies, and other resources to accelerate our shared interoperability goals. The Office of the National Coordinator (ONC) has been supporting the development of model-driven health tools (MDHT) to provide more explicit representations of our information models and certification criteria. Sharing and aligning these tools with our international counterparts can accelerate the development of common internationally recognized standards and certification criteria. It will be important with all of these efforts that the tools are constructed from the beginning with generalizability in mind, so that clinical information models and other resources developed using these tools are consistent across different international programs. Through EuroRec (with approaches ranging from self-assessment to third-party certification depending on the level of confidence needed) and its Seals, the possibility to achieve this for EHR systems has started in the whole of Europe.



EuroRec tools to support the profiling of EHR certification criteria by different countries and care settings in Europe

Finally, three common vocabulary standards (SNOMED, ICD–10, and LOINC) are already being shared across U.S. and EU programs. By leveraging common vocabulary subsets, we can accelerate the development of internationally recognized vocabulary subsets and improve the interoperability in countries with different native languages.

4. Skilled HIT workforce

Further exploration is still needed in this area. Clearly, there are skills to implement and use electronic health records that are generalizable internationally. There also remains additional work to develop quality assessments for electronic health records, users, professionals, and services such as personal health records. It will be important to understand how the development of a skilled workforce and providing quality assessment tools across multiple users and technologies will be needed.

5. Political Considerations

Finally, it is important that we recognize there are political issues that will be critical parts of our success. While we seek to achieve interoperability both nationally and internationally, it is essential that we work diligently to provide consistency in the standards and specifications where applicable, and maintain important differences where that consistency is not required.

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Policy brief on eHealth informatics workforce challenges

Editor: Jean Roberts

There is an increasing demand for informatics human resources from major ehealth developments aimed at supporting more effective health care in many countries. Focus to date has been on the standards required to describe ehealth applications and solutions; with sporadic attention to the workforce necessary to deliver them. There are challenges to ensuring that the ehealth informatics staff involved in production and operation of such ehealth systems are ‘fit to practice’ professionals and their competences can be clearly defined. There are currently different levels of understanding, quantification and definition of the existing and projected workforce requirements across Europe and in the United States. This paper highlights some of the issues to be considered across Europe in moving towards a situation where the limitations to appropriately skilled staff being deployed wherever necessary are reduced, and free mobility of the workforce can be enabled.

This full policy brief will be published at the end of August 2011 via IOS Press in the series "Studies in Health Technology and Informatics."

This project is funded by the European Union within the framework of the Pilot Project on Transatlantic Methods for Handling Global Challenges in the European Union and the United States. The general objective of the Pilot Project, created through a European Parliament initiative, is to promote mutual understanding and learning among EU and US policy researchers and policymakers on a number of challenges with a global dimension.