ARGOS Policy Brief on Semantic Interoperability

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Abstract. Semantic interoperability is one of the priority themes of the ARGOS Trans-Atlantic 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 US that can be shared and combined.

Experts from both continents have met at three ARGOS workshops during 2010 and 2011 to share understanding of these issues and how they might be tackled collectively from both sides of the Atlantic. This policy brief summarises the problems and the reasons why they are important to tackle, and also why they are so difficult. It outlines the major areas of semantic innovation that exist and that are available to help address this challenge. It proposes a series of next steps that need to be championed on both sides of the Atlantic if further progress is to be made in sharing and analysing electronic health records meaningfully.

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. Wide-scale engagement with professional bodies, globally, is needed to develop these clinical information standards. 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.

There is need to gain greater experience in how semantic resources should be defined, validated, and disseminated, how users (who increasingly will include patients) should be educated to improve the quality and consistency of EHR documentation and to make full use of it. There are urgent needs to scale up the authorship, acceptance, and adoption of clinical information standards, to leverage and harmonise the islands of standardisation optimally, to assure the quality of the artefacts produced, and to organise end-to-end governance of the development and adoption of solutions.

Keywords. Electronic health records, interoperability, knowledge representation

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Introduction

Countries around the globe are increasingly using information and communication technologies (ICT) to improve individual and public health, to strengthen health-care systems, and to address pressing health-care challenges and growing disease burdens in an increasingly borderless world.

The European Commission with European Union Member States and the United States of America have each initiated comprehensive research programmes, eHealth policy initiatives, and strategies to implement eHealth solutions to support their health systems to better meet these challenges. They fully recognise that, in spite of great variations in social models and health-system structures, many of the questions and issues are the same, and that trans-Atlantic cooperation in this field is very beneficial.

The ARGOS Trans-Atlantic Observatory for Meeting Global Health Policy Challenges through ICT Enabled Solutions is an international platform for dialogue and collaboration on health policy issues, to address the multiple issues that surround making this vision a reality.

Semantic interoperability is one of the priority themes of the ARGOS Observatory. This is a globally recognised, difficult challenge that must be addressed if electronic health records are to be of high quality and capable of being shared among heterogeneous systems in such a way that the information in them can be 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 the US that can be shared and combined.

Experts from both continents have met at ARGOS workshops, in March 2010 in Barcelona, in November 2010 in Washington DC and in May 2011 in Budapest.. These meetings have been prefaced by expert briefing papers, and each included a rich mix of short presentations and in-depth discussions, enabling participants to develop mutual understandings of the problem space, priority areas that have been explored, solutions foun d, and problems not yet solved. This policy brief summarises the problems and the reasons why they are important to tackle, and also why they are so difficult. It outlines the major areas of semantic innovation that can be called upon if we are to make progress in addressing this challenge. It proposes a series of next steps that need to be championed on both sides of the Atlantic if further progress is to be made in creating, sharing and analysing electronic health records meaningfully.

1. The need for semantic interoperability

The adoption, use, and interoperability of electronic health records (EHRs) has become a major focus of European and US eHealth policy, strategy, and investment.

Clinicians of all disciplines require access to detailed and complete health records in order to manage the safe and effective delivery of health care. These records need to be linked to salient knowledge and guidance to support point of care decisions, and to be shared in real time within and among care teams across geographical boundaries. These requirements are becoming more important as the focus of health-care delivery shifts progressively from specialist centres to community settings and to the patient's personal environment, and with the increasing recognition that decision support and computerised clinical guidelines can significantly improve the safety and efficiency of

health care. In parallel, the needs of public health and clinical research for analysable data across multiple EHR systems, and across national boundaries, is growing.

There are many clinical, health service, public health, and research drivers for integrated EHRs:

- manage increasingly complex clinical care;
- connect multiple locations of care delivery;
- support team-based care;
- deliver evidence-based health care;
- improve safety through mechanisms that:
  - reduce errors and inequalities;
  - reduce duplication and delay;
- improve cost effectiveness of health services;
- enrich population health management and prevention;
- empower and involve citizens;
- protect patient privacy;
- better inform and exploit biomedical research.

Many of the safety-critical scenarios requiring the computational support of health IT involve knowledge-management failings or gaps in communication. Particular points in the clinical process that are often not currently documented in computable forms and that are not always done well (i.e., in which care steps might be delayed or omitted, or dangers introduced), and for which sufficient knowledge now exists to improve safety, include:

- New medication prescriptions: the safety of prescriptions is often compromised by a lack of comprehensive information on concurrent medication (including purchased drugs) and details of known allergies, in particular since this information might be split across multiple care organisations and health records;
- Reminders and prompts for overdue or overlooked health care actions and interventions;
- Evidence-based care: the use of clinical guidelines and other forms of evidence to determine the optimal management strategy and care pathway for a given patient, particularly for chronic conditions;
- Care transfers: referrals and within-team workflows that ensure communication among care providers of the degree of urgency and the expectations of treating clinicians;
- Care co-ordination: ensuring that a high-level view can be taken of distributed (multi-team) care to protect against duplication, delay, and incompatible interventions.

Getting useful information out of existing paper or electronic systems has proved to be a significant obstacle to date, whether for the support of individual patient care, or for quality and safety monitoring, service planning, or research. Currently, many health-care systems and life-science databases are organised in ways that fulfil the needs of the original designers, but have little chance of bringing benefits to the

community at large. Resources designed to support semantic interoperability in the experimental biology and clinical-trial domains, for example, do not support interoperation with counterpart resources developed in the contexts of health care.

We need to make longitudinal care safer, more patient inclusive, and more evidence based, and to speed up the discovery of new knowledge and its translation from bench to bedside (Figure 1).

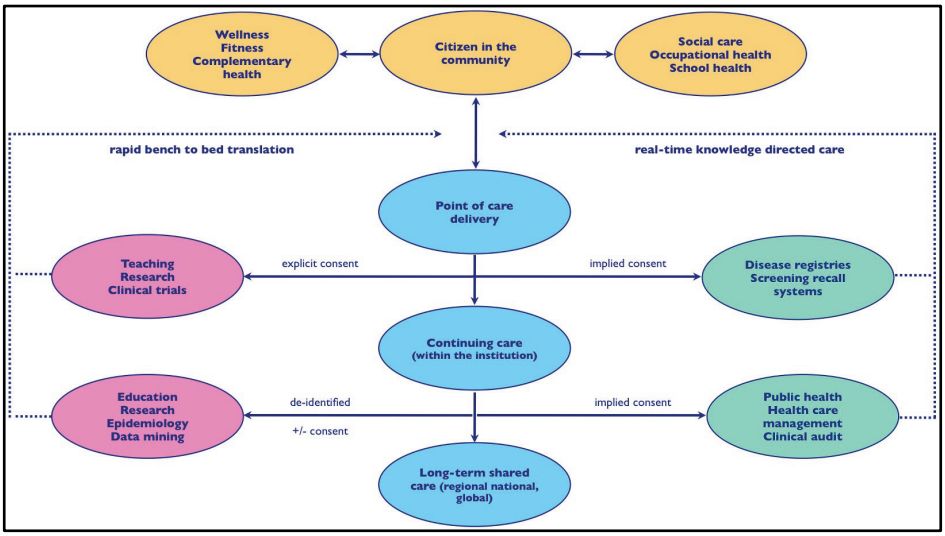

Figure 1. Health information flows that need semantic interoperability support

To meet these challenges, human interpretation of clinical notes and correspondence on paper is no longer adequate. Islands of disconnected electronic information based on ad hoc health-record architectures are no longer acceptable. **We need electronic health record systems and clinical applications that can better support the creation of records that not only are comprehensive and consistent but also are faithful to the perspectives of the patient and clinician. These record systems need to be complemented by decision-support systems, notification and alerting components, and analytic tools that can process integrated health data that are drawn from multiple systems that function interoperably.** A new generation of personalised medicine, underpinned by 'omics sciences and translational research such as the Virtual Physiological Human, needs to integrate EHRs with data from fundamental biomedical research, clinical and public-health research, and clinical trials.

Important progress has been made in this direction, and there are some early successes. We know, for example, that decision-support systems can help prevent serious errors when they have access to comprehensive allergy, diagnosis, and past medication data from the EHR in a processable form, and that, when cross-mapped to data on drugs, their effects, and active ingredients, can offer safety alerts to the prescriber.

To provide this level of interoperability, clinical information within EHRs needs to be formally and consistently represented in order to be understood—not only by humans but also by machines, so that they can be computed and, for example, re-used in target systems whose information model may be different, and be mapped to a wide range of knowledge resources (such as clinical-practice guidelines, eligibility criteria for clinical-trial protocols, and the alerting criteria of surveillance systems).

Achieving such interoperability across the breadth of health and health care is the challenge that needs to be addressed.

2. Progress towards semantic interoperability

The goal of semantic interoperability is to be able to recognise and process semantically equivalent information homogeneously, even if systems are differently structured, using different terminology systems, or using different natural languages. The EU SemanticHEALTH project [1] defined four levels (with two subdivisions) of semantic interoperability:

Level 0: no interoperability at all;

Level 1: technical and syntactical interoperability (i.e., the data can be imported and understood by human readers, but with no computable semantic interoperability);

Level 2: two orthogonal levels of partial semantic interoperability:

- **Level 2a**: unidirectional semantic interoperability (i.e., the data can be processed meaningfully but may require dedicated knowledge management and data transformations in order for it to be used in the receiving system);
- **Level 2b**: bidirectional semantic interoperability of meaningful fragments (i.e., clinical content can be interpreted by the receiver in ways that are equivalent to locally-created information);

Level 3: full semantic interoperability with sharable context (i.e., received data can be combined seamlessly with local data and processed homogeneously).

Level 3 interoperability is quite a high aspiration, although it is the level of interoperability needed to fully realise the benefits of processable EHRs in a distributed (eHealth) environment. It is the end goal of a journey towards realising semantic interoperability. To help make this end state achievable, at least for the clinical data that computers can usefully process, the EU report recommends that unnecessary diversity in the ways that equivalent expressions may be represented should be minimised.

Semantic interoperability requires the adoption of standards, to support accurate and complete clinical documentation that is faithful to the patient's situation, and then for EHR data to be transferred and structurally mapped into a receiving repository in a way that enables the clinical content to be interpreted with a commonly understood meaning. Figure 2 shows the breadth of artefacts that need to be leveraged together in order to gain maximum value from the knowledge within electronic health records, and for which standards are needed.

The development of such clinical information standards requires wide-scale engagement with professional bodies throughout health care, globally.

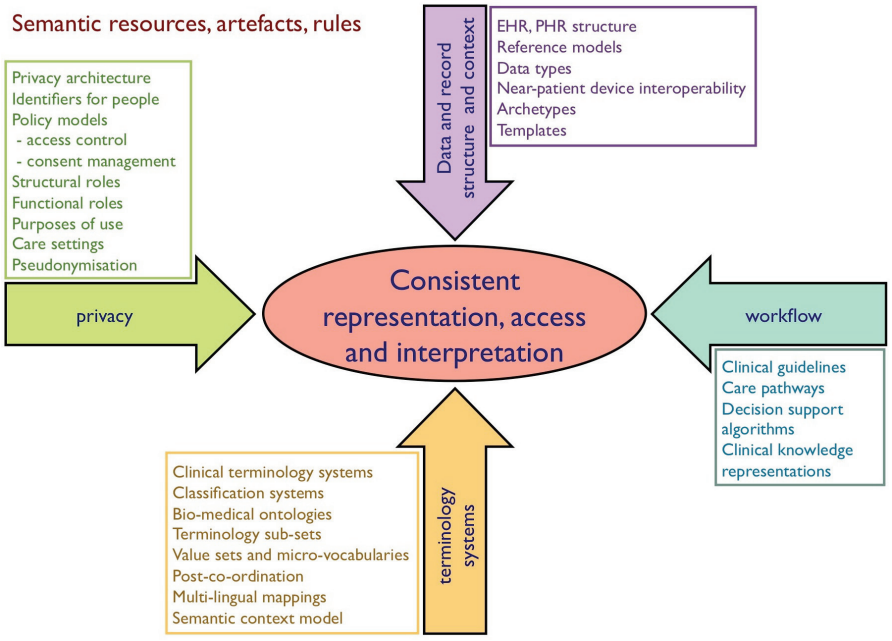

Figure 2. Semantic interoperability resources

For the semantic interoperability of EHRs, the critical focus of attention (for example in many eHealth programmes) should be:

- adopting a generic, standardised model for representing and communicating part or all of a patient's EHR;
- nominating (and possibly translating) a comprehensive clinical reference terminology or terminologies, which, to be effective, should include logically well-structured term definitions;
- developing clinical models (represented using standard data structures) that help to ensure that clinical documentation within EHRs (including the use made of clinical terms) is consistent.

It is of critical importance that these semantic representations enable the creation of records that are as faithful as possible to the patient's situation and to the clinicians' intended meaning.

Together, these elements provide the basis for patient-level information on which other tools such as decision-support systems, clinical-workflow managers, and population analysers can reason.

2.1. EHR reference models

The approach taken internationally on EHR information architecture has been to develop rigorous generic representations (EHR reference models) suitable for specifying all kinds of clinical entries and documents. This kind of model defines the information properties that will be common to all of the entries contained in it, such as a high-level universal hierarchical structure; the dates and times of events; identification of relevant persons and devices; data for management of version integrity

and auditing access; and support for suitable access controls. These models provide important interpretation context such as when and where each clinical encounter or activity took place, by whom data were provided and who entered them, who the subject of the information is (e.g. if not the patient, then perhaps a family member). The globally best-recognised EHR reference models are the ISO EN 13606 Part 1 EHR interoperability reference model, the HL7 Clinical Document Architecture Release 2, and the *open*EHR Reference Model.

Provided that the reference model to be used is known by both sending and receiving information systems, any health record extract exchanged between them will contain all of the structures, names, and medico-legal information required for it to be presented faithfully on receipt, even if the nature of the clinical content has not been agreed in advance.

The main role of the EHR reference model is therefore to support the standardised representation of the care-process context and the clinical documentation context, and to provide the structural framework for clinical models and for data values such as clinical terms and units of measure.

2.2. Clinical terminologies

Clinical knowledge has traditionally been implemented in health care through clinical coding schemes. Such schemes have, at their most basic level, provided nomenclatures, controlled vocabularies, and hierarchical classifications of diseases, aetiologies, and treatments to facilitate the entry and analysis of health-care data. Examples include ICD, ICPC, SNOMED International, LOINC, and Read (versions 1 and 2).

A clinical terminology primarily serves to provide a systematised and controlled vocabulary of clinically relevant phrases that can be used during data entry to offer a more precise and shareable expression than can be obtained by free text alone. Being controlled expressions, the translation of a terminology to another natural language is moderately scalable, permitting EHR data to be interpreted across languages. Different fine-grained (very precise) terms can be cross-mapped to a coarser grained one to permit them to be processed homogeneously, if the mapping is sufficiently precise for a particular purpose. More sophisticated relationships, such as the clinical manifestations of a disease, can also be represented.

SNOMED Clinical Terms (SNOMED-CT), the newest and largest clinical terminology, has the extra property of term post-coordination. This means that basic terms can be combined to compose more complex expressions. For example, a "headache" can be stated to be located in the "frontal region" of the head and "left sided" and "severe" all in a single terminological expression. SNOMED-CT also permits terms to be members of more than one hierarchy, which could allow terms to be positioned, for example, by context of use and by pathological process and by anatomical location.

Both the use of terms across languages and the hierarchical organisation of terms are contributions towards semantic interoperability. However, the translation of a large terminology such as SNOMED-CT into a new language is a significant undertaking, and for some health cultures there are concepts and relationships that are not yet well represented (e.g., as in some Asian cultures). The utility of vast combinatorial possibilities of expression through term post-coordination has been

questioned, and ways of scaling back the space of possible post-coordinated terms through constraint formalisms are being developed.

Other terminologies are used more extensively by the research community, such as those developed by CDISC and by the bio-informatics community, and for EHR data to contribute more directly to research these kinds of standards will need to be harmonised or cross-mapped.

2.3. Clinical models

The need to define and share clinical models — specifying how a multi-part entry should be structured and populated with values, such as a pain symptom or heart sounds or a prescribed drug — is not new, but such definitions have historically been represented in different ways, as paper or electronic forms, templates, tables, spreadsheets, database schemata, and so on. These definitions of how clinical data should be organised have not hitherto easily been shareable. This situation has resulted in different professional communities, even in neighbouring hospitals, adopting different templates for similar care scenarios, making it very hard to compare or analyse the aggregate data.

Clinical models, such as archetypes and Continuity of Care Documents (CCDs), provide a systematic approach to representing the definition of any EHR data structure. The adoption of clinical model standards helps to ensure data quality as well as consistency within EHRs. An archetype is a knowledge artefact that defines how the EHR reference model hierarchy should be organised to represent the data for a specified kind of entry. Archetypes provide representations for clinical data structures; relevant data-value constraints, such as term lists; and a specification of optionality and multiplicity. CCDs, on the other hand, represent an HL7 standard that provides for an XML-based mark-up language for exchange across sites of data that have previously been entered into EHRs. Both archetypes and CCDs can support the inclusion of unstructured text from EHRs to enable readability of the data by humans in addition to processing of the coded data elements by computers. However, the design of both tend to mirror the existing clinical documentation practice within paper and simple electronic systems, and more work is needed to ensure EHRs support good care collaboration between teams including shared care with patients.

By binding the parts of a clinical model to parts of a terminology system (for example, by specifying that the value for a property called “location of fracture” must be a term from a hierarchy of bones in the skeletal system), it should be possible to foster consistency and reliability (correctness) in how EHR data are represented, communicated, and interpreted. However, this is only partially true in practice. Such binding faces a number of difficulties. Record structures and terminology systems have been developed in relative isolation, with very little or no co-operation on their mutual requirements or scope, resulting in overlapping coverage and a clumsy fit. Much work is still needed to re-align these kinds of resource so that they can be used in a harmonised way, including work on the theoretical foundations of an approach that would make it possible.

2.4. Semantics and Ontology

Ontology resources are becoming widely available, often using OWL, the Web Ontology Language developed by the World Wide Web Consortium, and are being used widely in clinical informatics and bio-informatics research. The BioPortal resource of the National Center for Biomedical Ontology (NCBO) in the US, as of this writing, provides access to some 270 different terminology and ontology resources from clinical medicine and the life sciences. Increasingly, standards organizations are converting resources for data encoding, such as controlled terminologies, into formal ontologies that offer machine processable definitions of each term.

Current work on the part of the WHO to migrate the International Classification of Diseases (ICD) from a linear collection of terms to a rich, OWL-based semantic resource is emblematic of the importance that standard representation languages are taking on, and of the trend to migrate simple lexicons to more formal ontologies. Although interoperability among clinical ontologies typically is achieved by term-to-term mappings (as in the mappings between SNOMED-CT and ICD under development by IHTSDO and the WHO), there is increasing interest in developing ontologies that are intended to interoperate from the start. In the life sciences, the OBO Foundry initiative provides a window on both the significant opportunities and the significant challenges associated with this more top–down approach. Instituting a coordinated strategy for development of consistent ontology resources in clinical medicine has the potential to offer an essential contribution to mapping equivalent expressions within EHRs, between different terminologies, between different granularities of expression, and between different natural languages.

Aligning all of clinical practice – and all of legacy data – to a narrow set of clinical models and term lists will not meet the needs of very diverse kinds of professional, care setting and specialty. Thus there will always be a need for ontology to broker between heterogeneous representations of similar kinds of information.

2.5. Decision making and workflow rules

Semantic interoperability of this field is at an earlier stage, with many different formalisms and tools in use. The Arden Syntax, for example, provides one framework for standardizing the procedural component of situation–action rules created for decision support. The Arden Syntax does not offer a direct mechanism to chain rules together to perform complex inference, however. The Arden Syntax also lacks a standard means to link the data dictionaries of installed EHRs to the canonical data referenced in the rules. The challenge ahead is to harmonise high quality representations, systematically to bind rules to clinical models and ontologies, and to enable a semantics-based sharing of rules, protocols, plans, and guidelines.

3. Scaling up semantic interoperability

Semantic interoperability requires significant investment to deliver widespread and dependable access to published and well-maintained collections of coherent and quality-assured semantic resources: **clinical models such as archetypes and**

templates, mapped to EHR interoperability standards and bound to well-specified multi-lingual terminology value sets, indexed and correlated with one another via ontologies, and referenced from modular care-pathway components. Multi-lingual resources are needed to support cross-border care and to enable cross-border aggregation for research and population health management. These resources need to be embedded within EHR systems and within other systems and services that will analyse and interpret EHR data, and both designers and users need to be trained accordingly.

We have limited global experience in developing harmonised libraries of semantic resources of sufficient scale. There is a paucity of experience and best practice in how knowledge bases should be defined in order to balance the importance of evidence based practice with the individuality of each patient; how resources should be validated, and become widely accepted; how systems should be certified for semantic interoperability, how users (who increasingly will include patients) should be educated to improve the quality and consistency of EHR documentation and to make full use of it.

In taking forward this challenging vision, ARGOS semantic interoperability experts have agreed on the importance of engaging the widest possible range of stakeholders, including patients and their care-giver networks, health professionals, health ministries, health services, and public-health bodies, insurers, health IT vendors and standards-development organisations, industry and academic research organisations, and their networks (e.g., CROs). This engagement should focus on identifying priority scenarios for evidence-based and safe shared care, and on supporting communities to define useful and usable clinical information standards. There is a need to promote a culture of sharing records and of trusting shared records, and a culture of re-using record information. We also need to better promote the importance of good quality EHR documentation. Societal engagement is also vital, for example, to communicate the value of semantic interoperability for patient safety, and to emphasise the value of research.

It is recognised that semantic interoperability is complex, and cannot be tackled as a universal solution in a single hit. Initiatives should start with priority areas that leverage existing clinical consensus and accepted evidence—for example with chronic diseases such as heart failure, population health challenges such as childhood obesity, and possibly the Meaningful Use targets. Pilots should provide practical examples and showcases of successful value derived from richly interoperable records, and a source of learning towards larger scale solutions. Despite much historic investment in pilot projects, few strive to formally assess the benefits, and there is little sharing of the lessons learned. Even within such a focused strategy, it should be remembered that not all clinical data need to be processed semantically. Priority should be given to the data that have known computational value (i.e., for which there is knowledge-related exploitation, for example, for care pathway support or patient safety).

Such an approach will be most likely to achieve rapid and cumulative benefits, while placing minimal demands on legacy systems and legacy clinical practices. The mission should be to identify low hanging fruit — care scenarios in which semantic interoperability can bring rapid benefits for the least investment, to help reinforce the value of this interoperability and to justify larger investments.

Patients and care-givers need to be included in any approach to semantic interoperability, to help enable them to become active players in health-care delivery.

Recording the patient's presenting problem (reason for encounter) and linking that clinical problem to disease(s) and diagnoses and to episodes of care is vital and a central place for patient engagement. Self-management of chronic diseases is another. Vocabularies, ontologies, and record structures need to be inclusive of what patients wish to record, recognising however that this ecumenism may add significantly to the interoperability challenge.

Starting with priority areas does not imply that a piecemeal solution will work: Semantic interoperability is a holistic problem, and needs to be addressed through a coherent strategy. The starting points need to be clearly positioned on a roadmap towards richer interoperability. The approaches adopted should be scalable to more complete semantic interoperability as an evolutionary process.

This roadmap needs to recognise and adequately model the complexity of multiple diseases, and to use a learning loop to refine these models on the basis of individual patient experience (i.e. to base next-generation evidence on patient-level outcomes). Personalised medicine, molecular medicine, genomics and the Virtual Physiological Human are all contributions towards the vision of a "digital patient," in which patient-specific information and personalised knowledge are seamlessly interwoven — progressing from semantic interoperability to information-knowledge fusion.

3.1. Opportunities for Trans-Atlantic collaboration

Given the continued US and EU investments in research on semantic interoperability, rapid value can be gained by better coordination between EU and US R&D projects, which often cover different but complementary aspects of the challenge. The ARGOS Observatory has already enriched mutual awareness of relevant experts and their active threads of research. A continuation of ARGOS, and further inter-governmental collaborations, are now essential.

An early focus for collaboration should be to compile a multi-national overview of how certain categories of clinical information (e.g., patient summaries, problem lists, drug lists, recent lab test results, Meaningful Use categories) are represented, and which use cases each category supports in each country. It is important to share experience of success in fostering good practice in clinical documentation. In parallel, it will be important to review the landscape of clinical content standards—the clinical models and terminologies used in different countries' use cases, and to learn how the health data standards are used within various kinds of health IT components. This work would enable comparisons of approaches to representing similar use cases, leading to the possibility of reducing variation between these representations, or at least to making sure that they are harmonised (e.g., mappable). Over the next few years, we should strive to establish a common body of clinical knowledge to underpin semantic resources, and a well-functioning framework for reusing health information.

Research is needed on the criteria that help to determine (1) what parts of, and how much of, a clinical situation is useful to represent in a health record and (2) what parts of, and how much of, a health record is useful to structure/code/make interoperable. There are, however, limits to the extent to which the scientific models of health should dictate health care and health records. There is probably an optimal

extent of semantic interoperability that returns on investments, balances the art and the science, and keeps provision for alternative ways of working and for the discovery of new knowledge (i.e., some aspects of clinical information might be better not to standardise).

The adoption of semantically innovative solutions will need investments in training professionals and those who will make research and management decisions based on interoperable EHR data. Shared development of educational resources provides another opportunity for trans-Atlantic collaboration.

Other areas of cooperation should focus on research contributing to a common body of requirements, on ways of validating semantic interoperability resources clinically and technically, on common conformance criteria for systems and system components, on practical methods for testing interoperability (e.g., for vocabularies and ontologies) and for validating the correctness and consistent usability of solutions (including human factors), and reciprocally on ways of defining and quantifying the risks from poor quality solutions. There would be benefit in a trans-Atlantic collaboratory for practical testing for technical semantic interoperability, human factors affecting correct and consistent use, and end-to-end preservation of meaning when information is exchanged between systems. The future certification of EHR systems and other clinical software needs to include formal testing of interoperability, including semantic interoperability.

Generating interoperable resources requires strengthening the alignment of the various standards development organisations (SDOs) and investing in harmonising the artefacts they produce. This effort must be driven by a sound understanding of the requirements, the level of detailed interoperability that is needed in practical terms, and depends also upon the willingness of each SDO to cede certain areas of scope in favour of standards developed by other SDOs. This is absolutely a global agenda.

Semantic interoperability will probably be achieved only through systems that are driven by knowledge content rather than by what is written in software code. Medicine is a field with an enormous number of niches. There is a need for a much more flexible, knowledge-driven approach than is the case with most existing systems, with no more data lock-in. Investments in redesigning systems to be knowledge driven requires a sufficient body of coherent and readily-deployable, well-maintained resources, in turn requiring knowledge management governance on a global scale.

It is recognised that the largest investors in semantically interoperable information are not necessarily the largest beneficiaries. There is a need to investigate the stake-holder–specific business models and value propositions that would justify investments to incorporate and enhance semantic interoperability within standards, tools, systems, work practices, service-provision models, reimbursement models, education, and research. It is not clear if these business models will be identical across all countries, but collaboration on their investigation, and comparison of the models, will be important. The ability to re-use data is a critical driver for many stakeholders. Such a study needs also to take into account that some business models are changing, such as those of pharma: from disease treatment to disease management to health management.

To build the case for needed investments, it will be essential also to compile evidence of current inefficiencies and the costs incurred through not having interoperability. Headline examples of resulting problems include the duplication of investigations, prolonged and preventable hospital admissions due to treatment complications, and the high (avoidable) costs of clinical-trials recruitment.

Given that the benefits from semantic interoperability arise only once a critical mass of information is in an interoperable form, strategic investments are likely to achieve return in the medium to long term. Progress therefore needs governmental and inter-governmental backing, and appropriate incentives. Trans-Atlantic alignment on incentives might prove challenging, but would be desirable given that the standards and the systems are increasingly being used internationally.

4. Recommended actions

There are urgent needs to scale up the authorship, acceptance, and adoption of clinical information standards, to leverage and harmonise the islands of standardisation optimally, to assure the quality of the artefacts produced, and to organise end-to-end governance of the development and adoption of solutions.

The following are proposed priority activities that ARGOS and its US and EU sponsors need to endorse, to champion, and to support financially:

1. **Develop criteria for assessing the quality of semantic resources** of all kinds. Establish projects to develop good practice in the design and validation of clinical models bound to terminologies and ontologies and guideline-based pathway models. Ensure that these projects are well-grounded and are of practical relevance to the management of clinical conditions of national and international priority (e.g., chronic conditions, such as heart failure, and population health issues, such as childhood obesity).
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. Focus on benefits versus effort.
3. **Develop sustainable approaches** to scaling up resource development across clinical specialties and stakeholders, importantly including patients, and using successful pilots as showcases. Ensure wide-scale clinical engagement during the design and piloting of clinical models, terminologies, and ontologies. Involve other stakeholders who will create or use health data. Ensure that wider health system and future research needs are supported.
4. **Support translations**. Resources need to be multi-lingual to enable cross-border shared care, cross-border health planning, and global scale research. Specifically consider the challenges of supporting multiple levels of clinical jargon for different stakeholders, including patients and care givers. Develop and validate mappings amongst the different terminology systems in use by different communities, where possible drawing on the support of reference ontologies.
5. **Monitor** the evolving capability and potential uses of natural-language technologies, including the reliability of such approaches for population-level and patient-level decision making. Track technology for automatic encoding of free text or diagrammatic data entry.
6. **Conduct a gap analysis** of informatics tools, knowledge representation formalisms, standards, and clinical content that are needed to support this scaling up—including embedding such resources within EHR systems—and

provide formal recommendations to SDOs and to the EU and US on future objectives to be addressed, including the scope and level of detail that is needed and that would be usable.

7. **Collaborate across the EU and US** on common conformance criteria for systems and system components: practical methods for testing interoperability, and validating the correctness and consistent usability of solutions (including human factors).
8. **Invest in dissemination and education efforts** designed to enable clinical and patient/citizen acceptance, creation and use of knowledge-rich EHRs, to create good quality (faithful, accurate) and re-usable information, to better trust and use information from external sources and to take better advantage of semantically interoperable systems and services. Grow capacity in health informatics expertise including in semantic interoperability.
9. **Foster development of business models** to justify strategic investments in this field, including a critical appraisal of the opportunity costs for key stakeholder groups and decision makers, including clinicians, EHR system vendors, health-care provider organisations, health authorities, insurers, researchers, standards developers, and citizen representatives. Find win–wins and relevant incentives.
10. **Strengthen leadership and governance**. Strong leadership within and across all relevant stakeholders will be essential to drive these actions and to oversee benefits realisation. A governance organisation needs to be nominated to support, co-ordinate, and quality manage the future development of semantic interoperability resources for health and to develop an action plan for future research and educational investments.

5. Conclusion

The ARGOS experts believe that there are no important trans-Atlantic differences in the nature of the challenge or approaches to be pursued, and every reason to work together. The collaborative work initiated by ARGOS needs to be sustained.

6. List of contributors

References

[1] Stroetman,V., Kalra,D.,Lewalle,P.,Rector,A., Rodrigues,J., Stroetman,K., Surjan,G., Ustun,B., Virtanen,M., Zanstra,P. (2009), Semantic Interoperability for Better health and Safer Healthcare. The European Commission. ISBN-13: 978-92-79-11139-6. DOI: 10.2759/38514. http://ec.europa.eu/information_society/activities/health/docs/publications/2009/2009semantic-health-report.pdf