CONFERENCE HIGHLIGHTS

The launch of the European Institute for innovation through health data

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Abstract: The European Institute for Innovation through Health Data (*i*~HD) has been formed as one of the sustainable entities arising from the Electronic Health Records for Clinical Research (EHR4CR) and SemanticHealthNet projects, in collaboration with other European Commission projects and initiatives. The vision of *i*~HD is to become the European organisation of reference for guiding and catalysing the best, most efficient and trustworthy uses of health data and interoperability, for optimizing health and knowledge discovery. *i*~HD has been established in recognition that there is a need to tackle areas of challenge in the successful scaling up of innovations that rely on high-quality and interoperable health data, to sustain and propagate the results of eHealth research, and to address current-day obstacles to using health data. *i*~HD was launched at an inaugural conference in Paris, in March 2016. This was attended by over 200 European clinicians, healthcare providers and researchers, representatives of the pharma industry, patient associations, health professional associations, the health ICT industry and standards bodies. The event showcased issues and approaches, that are presented in this paper to highlight the activities that *i*~HD intends to pursue as enablers of the better uses of health data, for care and research.

Keywords: electronic health records; clinical research; real world data; information governance; interoperability standards; quality assurance

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1. Introduction

As electronic health record (EHR) systems proliferate across large and small healthcare organisations, such as hospitals and general practices, and providers migrate from paper to electronic systems for routine clinical documentation, there is an increasing wealth of fine-grained health data that can support better quality patient care, health system decision-making and clinical research. For example, 96% of US hospitals now have EHR systems that meet the requirements of the Office of the National Coordinator for Health Information Technology (ONC)[1]. Over 90% of general practitioners in the United Kingdom, Netherlands, Australia, and New Zealand use EHR systems[2].

This fine-grained health data is progressively becoming more and more structured and coded, rather than free text (word processed) letters and reports. This increases the computability of the data, enabling the greater application of smart analytics such as decision support, reminder and alerting systems, care pathway management systems and querying populations of EHRs for public health, academic and industry research and safety monitoring such as pharmacovigilance[3].

Health care systems need to demonstrate that they are cost-effective, are working towards optimising clinical outcomes and patient satisfaction, and are proactive in the monitoring and prevention of patient safety issues including those due to poor care coordination and communication[4]. To illustrate the patient safety challenge, the US Food and Drug Administration (FDA) estimate that medication errors cause around one death every day and injure 1.3 million people annually in the United States[5].

Unmet medical needs, chronic diseases, ageing populations, and the emergence of personalised medicine are amongst the factors contributing to a growing consumer demand for the highest quality of healthcare and accelerated research into effective and safe innovative medicines.

However, pharmaceutical innovation faces numerous R&D challenges causing significant study delays and increased costs. Over the last 12 years, the average cost of conducting clinical trials has increased three-fold. The number of drug development programs has grown by an average of 6% per year from 2002 to 2011. In parallel, clinical research is growing in complexity and labour intensity. This is partly due to the need to conduct large clinical trials that provide definitive evidence of clinical benefits and safety, and to the increasing demand from regulators and payers to generate value-based evidence which requires conducting further studies to assess the "real-word" comparative effectiveness, safety and cost-effectiveness of innovative medicines compared to existing therapies.

The pharma industry is under increasing pressure to contain the growing costs of conducting clinical trials whilst in parallel generating more and more evidence, and to reduce the delays in conducting those trials, which are largely due to challenges in patient recruitment[6]. The main bottlenecks in current clinical research include sub-optimal protocol designs, slow and lengthy patient recruitment, and labour-intensive and time-consuming clinical study conduct. Specific issues include the difficulty in evaluating patient populations and in optimising protocol design, identifying suitable patients for clinical trials, the manual and redundant re-entry of data, the reliability of data sources, and the difficulty in detecting and reporting infrequent adverse events.

Evidence is now emerging of practical and trustworthy ways in which EHRs can be reused for research in order to optimise clinical trial protocols, identify the sites most likely to recruit sufficient patient numbers, and to assist those sites with tracking the patients who meet trial eligibility criteria[7]. There is now also growing evidence that the reuse of EHRs in this way is cost-beneficial to the pharma industry[8].

There are growing opportunities for using health data to engage patients more directly in their own illness self-management and in the collection of data during clinical trials. Innovations such as wearable sensors, smartphone applications, lab on a chip combined with the ubiquity of video communications enable remote clinical consultations, the tracking of physiological parameters and feedback systems to patients to be delivered at a low cost and in ways that are well accepted by patients[9].

Perhaps the most exciting opportunity, attracting multi-million investments from European and US governments and from pharma, is the potential for conducting research directly on large population data sets derived from routinely collected clinical data, known as "Real World Data" and sometimes as "big health data". Apart from traditional epidemiological research, analyses of large population data repositories has the potential to generate evidence for comparative effectiveness studies, biomarker validation, fine-gra-

ined stratification of patients for risks and to optimise treatment outcomes[10].

However, much as there is excitement about the opportunities from scaling up the use of health data, in particular for research, there are concerns about providing confidence to the public that such uses of their data can be undertaken in ways that protect their privacy and respect the confidentiality of the disclosures they have made to health professionals[11].

A second challenge lies in the integration of the data themselves, which originate in multiple electronic health record systems that have different information structures, use different terminology systems and are, of course, often captured in different natural languages. There are interoperability standards published by several international Standards Development Organisations (SDOs) that can help address this heterogeneity, by providing harmonised representations that can be used to communicate data or used to construct a consolidated data repository for analysis. However, uptake of the standards by the vendors of EHR systems is proving slow, due to weak market incentives, and interoperability between these systems remains piecemeal and limited.

2. The European Institute for Innovation through Health Data

The challenges of privacy protection and interoperability are being addressed through many different research and development initiatives, such as those sponsored by the European Commission through its Framework Programmes and Horizon 2020, and also by many national and regional eHealth programmes. However, these solutions themselves often remain in silos, are not propagated or maintained, and therefore fail to combine and scale up to deliver holistic solutions to these problems. In order to address this, at a European level, and arising from some such European projects, a new not for profit European Institute was launched in 2016: the European Institute for Innovation through Health Data (*i*~HD). This institute was created in order to unite efforts to enable better uses of health data for the benefit of learning health systems and clinical research[12]:

- To play a central role in governing and expanding a trustworthy health data driven ecosystem including EHRs and clinical research platforms;
- To promote the adoption of healthcare standards and of data quality, to enable more effective, safer and better integrated healthcare;
- To act as a connector between health care and clinical research standards, that are presently developed in silos and impair the interoperability and pooling of health data for research;
- To promote to society the importance of using health data for research, to improve efficiency through reduced duplications, delays, costs enhance speed and efficiency in clinical studies.

i~HD held its inaugural conference and public launch in March 2016, in Paris. The inaugural conference brought together over 200 experts from across Europe, including health ministries, insurers, the pharma industry, healthcare providers, patient associations, health professional associations, the health ICT industry and standards bodies. The rest of this paper summarises the key initiatives and themes that were presented during that conference, and which indicate the priorities that *i*~HD will address in the coming years.

3. Re-using health data for research: outcomes of the EHR4CR Project

The EHR4CR project (2011–2016) with a budget of +16 million Euro, involved 35 academic and private partners (10 pharmaceutical companies) and was one of the largest of the IMI Public-Private Partnerships in this area (Figure 1). The consortium included 11 hospital sites in France, Germany, Poland, Switzerland and the United Kingdom. It was part-sponsored by the European Commission through the Innovative Medicines Initiative (IMI).

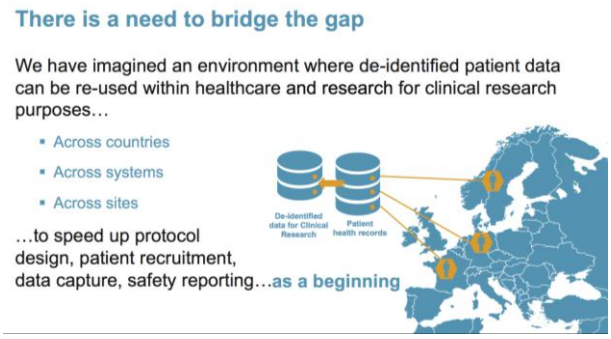

Figure 1. The overall objective of EHR4CR

The coordinator of EHR4CR, Mats Sundgren from AstraZenca, explained to the conference that the project has developed a robust and scalable platform that can utilise de-identified data from hospital EHR systems, in full compliance with the ethical, regulatory and data protection policies and requirements of each

participating country[13]. The EHR4CR platform supports distributed querying to assist in clinical trials feasibility assessment and patient recruitment. The platform can connect securely to the data within multiple hospital EHR systems and clinical data warehouses across Europe, to enable a trial sponsor to predict the number of eligible patients for a candidate clinical trial protocol, to assess its feasibility and to locate the most relevant hospital sites. Applications are offered to connected hospitals to assist them to efficiently identify and contact the patients who may be eligible for particular clinical trials. The EHR4CR solution is compliant with EU legislation and respects the position of hospital and patients towards their health data. Patient level data never leaves the connected hospitals.

This development has required securing acceptance from the patients, the public and the research and health service communities. Therefore, in parallel to the technical developments, senior level decision makers, ethics boards and industry executives and scientists, were consulted to provide strategic insights into the most robust and acceptable technical and procedural approaches that should be taken to ensure privacy protection and compliance with European and national/regional regulations on data protection.

EHR4CR has shown that such a platform has the potential to significantly improve the efficiency of designing and conducting clinical trials, reducing time and costs, reducing administrative burdens, optimising protocol feasibility assessments, accelerating patient recruitment, making study conduct more efficient, enabling the participation of European hospitals in the more clinical trials and thereby potentially increasing research income[14].

The European Institute for Innovation through Health Data arose in part out of the EHR4CR project, to develop and promote best practices in the governance, quality, semantic interoperability and uses of health data, including its reuse for research. An important role of *i*~HD is to provide independent governance oversight of clinical research platforms and their expanding networks of hospitals.

The first EHR4CR service provider, Custodix[15] is now launching its operational platform, InSite[16], for Europe-wide deployment, to be governed by *i*~HD.

An early adopter *Champion Programme (CP)* has been launched as a first step in building a pan-European network of hospitals connected to the InSite Platform. The objectives are to start building a community of hospitals interested in reusing their EHR data for research, to further validate and improve the technology and to refine the business model, creating a win for all stakeholders. It is designed to provide a low-risk entry for all stakeholders into a new business model approach to efficient use of Real World Data. Thus, the programme is a key step in building the EHR4CR envisaged ecosystem of network of hospitals, service providers and pharma users. The CP aims at proving the value of Real World Data for clinical research and the InSite technology on a wide scale.

Brecht Claerhout, the CEO of Custodix, explained that in 2015 the industry partners, Custodix and *i*~HD developed a collaboration model that outlined principles, terms and budgets for the CP. The eight involved industry partners, a.k.a. Industry Champions, are Amgen, AstraZeneca, GlaxoSmithKline, Janssen, Roche, Sanofi (as previous EHR4CR Efpia partners), ICON plc, and Boehringer-Ingelheim. Each industry partner sponsors the connection/setup of three hospitals of preference to the InSite platform. Each sponsoring Industry Champion selects these Champion Hospitals, in full transparency with the other Industry Champions. The programme will also involve governance through the *i*~HD Institute. The budget model for industry partners includes for each Industry Champion to provide in-kind support at various stages of the CP (e.g. to provide the necessary resources to propose validation plans and support their execution) and a fee to become members of the *i*~HD Institute.

The scope of the CP is to have a 15 – 30 Champion Hospitals from different EU countries, giving access to at least 2 million patients. The programme aims at including at least one US hospital to demonstrate the global ambition of the program. The current candidate Champion Hospitals include organisations from Sweden, UK, Poland, Netherlands, Germany, Spain, France, Belgium, Finland, Switzerland and Italy.

The first phase of the CP, through to 2017, will offer opportunities for industry partners to execute the EHR4CR Protocol Feasibility Service, and Patient Identification & Recruitment service across all hospitals connected to the platform, for on-going trials. It will provide business value to participating industry and to hospitals. Industry partners will have access to a new innovative tool for better trial design by optimising clinical protocols through direct responses from updated EHR data. The protocol feasibility testing service will allow fast iterations of inclusion/exclusion criteria, which will reduce costly corrective measures such as protocol amendments, late addition of new trial countries or sites. The established, and

growing, hospital network in place will improve trial success rates and reduce the number of trials failed due to failure to recruit. Champion hospitals will be able to attract more clinical research studies and use the InSite tools to speed up identification of trial candidates and enable in house research and other learning health system analyses.

Through the sponsoring process and transparency within the industry Champion group, Industry Champions will be able to improve their relationship with a growing network of hospitals. The pre-competitive collaboration model brings benefits in allowing industry to jointly validate and improve the InSite platform while working with *i*~HD in refining the rules of engagement for a sustainable ecosystem. Furthermore, this jointly-undertaken initiative removes the need for each individual company to establish their own hospital network.

The intention is to secure a long term relationship with all actors and to further expand this novel ecosystem for supporting clinical research using EHRs in Europe and beyond. The ambition is to grow the network by attracting more hospital sites to join the platform, involve more service providers, and more end-users from both industry and academic centres.

4. Scaling up the use of big health data

The Executive Director of the Innovative Medicines Initiative (IMI) Pierre Meulien, told the audience that IMI is investing over 5 billion Euros in public private research projects[17]. He emphasised its ambition of improving the affordability and speed of access to innovations for patients. The first IMI programme funded 59 projects with a budget of €2 billion. IMI2, recently launched, has a budget of €3.3 billion, with a more ambitious scope. Many of these IMI projects are using electronic health records to speed up clinical trials and using big data to discover how to better target innovative therapies to the particular patients who will respond best to them. The new *Big Data for Better Outcomes* programme, part of IMI2, will also work closely with health care stakeholders to help apply new evidence emerging from big data to improve healthcare systems (Figure 2).

Participants also learned about Europe ś largest "big data" project in health: the *European Medical Information Framework* (EMIF, funded by IMI) from its co-ordinator Bart Vannieuwenhuyse, of Janssen. EMIF is creating an environment that allows for the efficient re-use of existing health data (the EMIF Platform). To ensure immediate applicability, EMIF includes two specific research topics that are helping to guide the development of the Platform: the identification and validation of protective and precipitating factors for conversion to Alzheimer's Disease (EMIF-AD) and predictors of metabolic complications of obesity (EMIF-Metabolic).

The EMIF Platform's primary objective is to facilitate the re-use of healthcare data. Given the variety of data sources that may be useful for research, it will enable identification, assessment and selection of suitable data sources (the EMIF data catalogue, Figure 3).

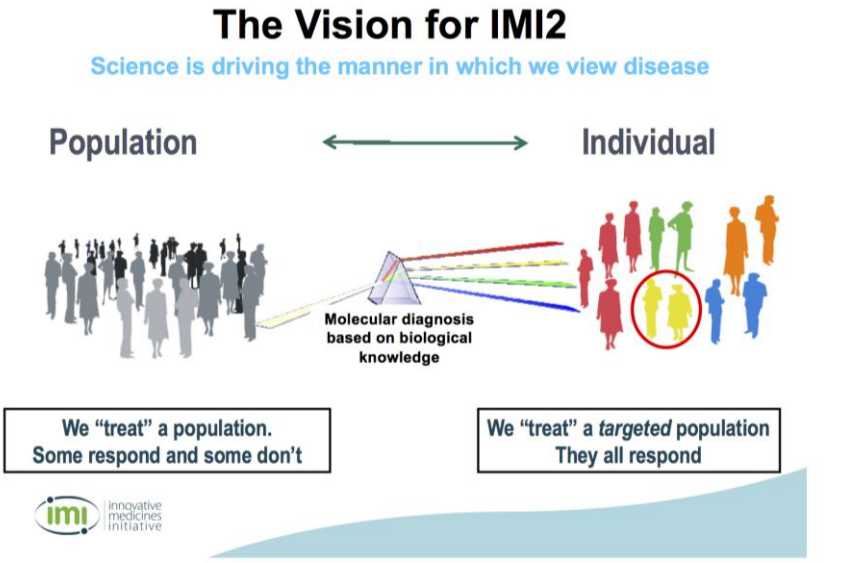

Figure 2. The vision for the IMI2 programme

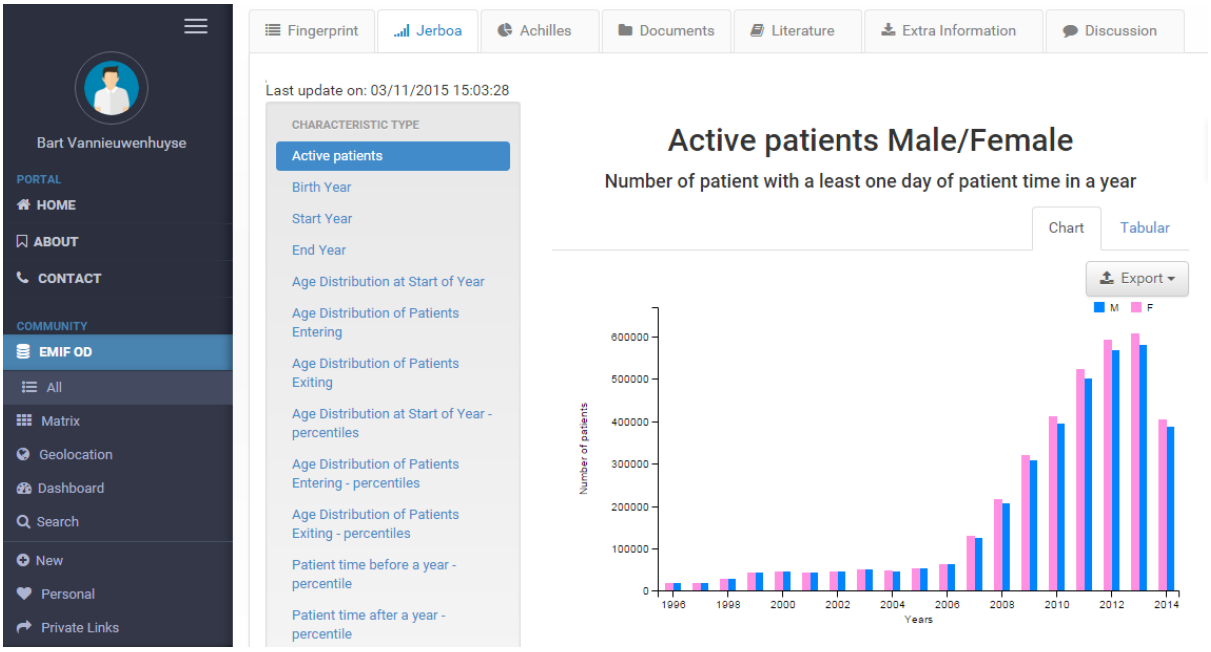

Figure 3. The EMIF Catalogue of research data sources

Because data come from multiple sources and have different formats and content, the Platform harmonises the data according to well established data format and semantic standards to enable answering the research questions. Under a global philosophy of creating data platforms (federation), connecting software (data extraction software) and mechanisms for governance (legal, ethical and privacy) are also included in the work plan. Platform development, including data access, analysis and visualisation is addressed using an agile paradigm in which user requirements gathering and prototype evaluation are iteratively undertaken.

EMIF-AD and EMIF-Metabolic serve as use scenarios and test beds for the Platform. EMIF-AD aims to discover and validate diagnostic markers, prognostic markers and risk factors for AD in non-demented subjects. EMIF-Metabolic aims to identify risk markers for metabolic complications of obesity, by identifying and testing biomarkers in small and medium-sized cohorts followed by testing in large clinical populations with outcome data.

Possible sustainability models for EMIF are being studied in order to ensure adequate post-project continuation of products and services developed.

5. The trustworthy reuse of health data for research

As mentioned earlier, it is vital that the reuse of health data for research is considered trustworthy by society. This naturally means demonstrating compliance with data protection legislation, at a European level and across all European Member States. The new General Data Protection Regulation, replacing the existing European Directive, will place greater obligations on research users and data custodians to have undertaken privacy impact assessments and to have incorporated privacy protection as a fundamental design feature of systems and repositories. However, some Member State variation will remain in the precise rules surrounding, for example, the protection of pseudonymised data. Nevertheless, it will be important for the research community to win public trust by working towards consistent information governance practices and expectations across Europe. This includes societally acceptable codes of good practice for governing the many uses of health data, which reflect state of the art in privacy protection and information security. These are necessary to give confidence and reduce the risk for those providing data for research use e.g. hospitals, GPs, patients, and offer greater confidence and reduced risk for those performing the research, managing the data or sponsoring the research.

i~HD is working to provide several layers of guidance and voluntary codes to support a consistent and trustworthy approach across Europe, including:

- Quality labelling criteria for clinical research platforms and services;
- Codes of Practice for feasibility studies and for remote data access and sharing;

- Standard Operating Rules, that specify requirements for technical safeguards and specified duties;
- Standard Operating Procedures including access controls, incident management, audit & monitoring;
- A staff competence checklist and training resources about data management and privacy protection when using research platforms;
- The formation of an *i*~HD Information Governance Board, providing voluntary oversight.

The information governance framework (Figure 4), building on work led in EHR4CR by Peter Singleton, has been developed as an integrated design of IT controls supported by organisational measures. It is linked with existing codes of practice, such as the IMI Code of Practice on the Secondary Use of Medical Data[18].

Peter explained to the conference that privacy protection is delivered on multiple levels through specific 'privacy by design' requirements: personal data is only processed by original data controller; the Clinical Data Warehouse holds only pseudonymised data; the InSite Platform only handles aggregate data, with additional protections for small-cell data; role-based access controls are implemented to limit access to aggregate data. These controls are supported by extensive audit trails with facilities for pro-active reporting, and are linked with organisational controls (e.g. Operating Procedures) to ensure that there is overall effectiveness of the oversight of data use across the system.

The EHR4CR Core Principles, now being taken forward by *i*~HD, are (in brief):

- Data minimisation
- Data exchange protocols
- Strong information security
- Risk management controls
- Appropriate access control facilities
- Adequate audit trails
- Ensure appropriate use
- Operational effectiveness
- Effective information governance
- Proper training & resourcing
- Clarity of authority
- Effective enforcement
- Legal conformance

The main objectives for these principles are: to build on legal requirements; to act as a basis for building and establishing trust between partners: to provide solid, though flexible foundations for initial operations; to articulate the level of controls to data providers, regulators, patients, and the public at large; to guide further development of standard operating rules and procedures; and to provide a possible governance framework for other EU healthcare projects in the future.

6. The importance of quality in EHR systems

John O'Brien told the conference that reliance of healthcare delivery organisations on well governed and

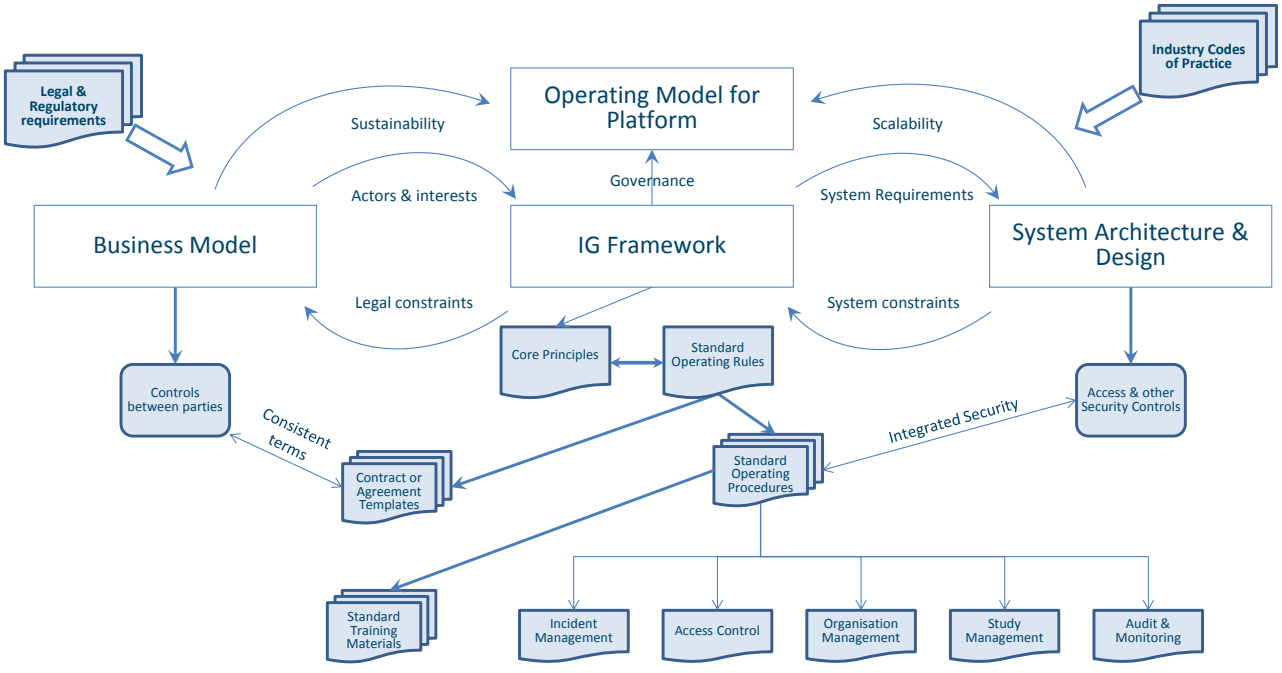

Figure 4. Overview of the *i*~HD information governance framework

quality assured data and information has grown progressively in recent decades and continues to at an ever accelerating rate. At corporate level, data and information are moving from a position of being viewed as a facilitator to one in which it holds core factor of hospital production status. It is increasingly employed as an embedded input in the diagnosis, treatment and care production process. Excellent and successful healthcare delivery has become inherently dependent on reliable data and information. There is a strong emerging example-supported view that where healthcare organisations employ advanced data and information as integrated inputs in the service production process, they enjoy improved patient access, care quality and satisfaction, resource utilisation and efficiency, workforce engagement and functioning and competitive advantage.

As its importance and emergent factor status advances, data and information present a number of challenges at corporate level. These centre primarily around continuity assuring its quality and fully exploiting its ever expanding potential. Focus here has tended to concentrate on EHR's (in their extended patient pathway/multi device/multi use manifestations) and the information workforce.

Other primary health service production factors such as facilities, devices, pharma and health care professionals are governed and operate within a robust assurance environment (e.g. regulatory/professional bodies, standards based certification, mandatory credentialing etc.). EHRs and the information workforce are not similarly governed or assured, notwithstanding their apparent co-input status. Related approaches with respect to EHRs are found mainly in certification and quality labelling initiatives most recently exercised through application of EuroRec (EU) and ONC (US) standards to EHRs or elements thereof, culminating in awarding of compliance seals/certification to product suppliers. Information workforce credentialing has become a central work stream in proceedings of the EU/US Cooperation Forum on eHealth. Progress in both instances has however been slow and delivered limited success – a notable exception being the Belgium experience in EHR certification.

Going forward there is a need to revisit the data and information governance and quality assurance agenda and render it much more directed and demanding. In the case of EHRs, the historic focus has centred on the supplier community. Recent endeavours to coalesce suppliers, funders and users (Healthcare Delivery Organisations) in the context of the eHealth eco-system in this respect are necessary and important developments. It is posited, however, that for long run success, the user community requires to be the prime focus and to assume lead driver status in this realm within the eco-system framework. Users are the prime beneficiaries of essential and well governed and quality assured data and information. This suggests that, at core, there is a concomitant onus on them to demand and drive related status and standards.

User approaches in this respect might include:

- Use of quality labelling standards to assess and where indicated inform adaption of installations;
- Use of quality labelling standards as part of procurement specification and evaluation systems;
- Promotion of development of dedicated data and information education and training programmes – particularly with affiliated Academic Institutions;
- Advocacy and support for creation of appropriate professional bodies for data and information workforce;
- Increased location of trained/qualified data and information personnel in key clinical teams/divisions.

There is also a compelling case for Health System Accreditation bodies to significantly develop their established standards and criteria sets with respect to EHR systems and the information workforce. In the circumstances, it is becoming evident that healthcare delivery organisations need to re-imagine data and information and its consequential governance and quality assurance requirements.

7. EHR system quality labelling and certification

Pascal Coorevits gave a presentation about EuroRec's approach to quality labelling and certification. The European Institute for Health Records (EuroRec, http://www.eurorec.org) holds the largest collection of quality criteria for EHRs in Europe. The EuroRec repository contains more than 1700 validated functional quality criteria for EHR systems. This repository is categorised and indexed, and many of the criteria have been translated in 19 European languages. In addition to the repository, a number of tools and methodologies have been developed for using these criteria for quality labelling and certification of EHRs. The current collection of tools (web-based applica-

tions) consists of (1) Composer (for browsing, selecting etc. the criteria from the repository), (2) Certifier (for creating certification "sets" of selected criteria), (3) Scripter (tool for developing test scripts and test scenarios) and (4) Testing tool (for conducting, reporting and coordinating conformance evaluations) (see Figure 5).

Figure 5. EuroRec's Quality Labelling and Certification Tools

EuroRec's current portfolio of quality labelling and certification services is addressing quality criteria and functionalities of EHRs in care and research settings (re-use of EHR data). A formal collaboration between EuroRec and *i*~HD will be initiated regarding the quality labelling and certification of service providers. Based on international standards and experience through European research projects (EHR Q-TN, HITCH, ANTILOPE), *i*~HD will play the role of the certification body and EuroRec will be the conformity assessment body in this new quality assurance framework (see Figure 6).

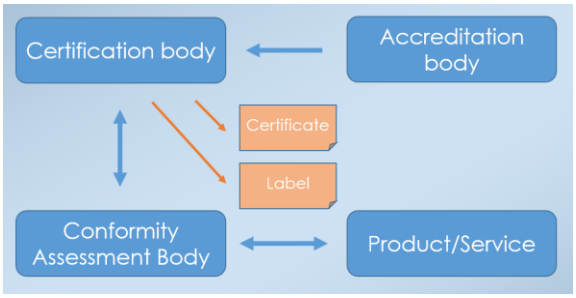

Figure 6. Actors involved in Quality Labelling and Certification

The European Institute for Innovation through Health Data is currently developing a quality labelling and certification program for certification of health research platforms, services and tools. It will develop, together with EuroRec, the quality criteria, test plans and certification processes for research platforms, services and tools which support the re-use of EHR data for clinical research (cf. secondary use of EHRs) to certify conformance to the EHR4CR specifications. In order to develop the quality criteria, specific international relevant standards will be investigated, best practices and criteria will be investigated from relevant European research projects (non-exhaustive list of relevant FP7, H2020 and IMI projects: EHR4CR, EMIF, EURECA, TRANSFORM, INTEGRATE, etc.) and criteria and processes from similar and complementary initiatives will be investigated (e.g. eClinical Forum, ECRIN criteria for clinical trial centres). A first set of candidate criteria will be presented to and discussed within an expert group. Using an iterative process for feedback gathering and by using a formal consensus method the final criteria will be developed. Together with the final criteria, the test methodology will be finalised and the governance framework will be installed. It is aimed that the *i*~HD quality labelling and certification program and services will be launched beginning of Q4 of 2016.

8. High quality interoperable health data for care and research

Collection, storage and analysis of health data has been, is and will be one of the fundamentals to provide efficient healthcare services and its importance is only increasing considering the growing amount of health data collected every day. The situation gets even more complicated because relevant health information does not only come from traditional interviews and medical tests in a hospital or outpatient clinic, but it involves data that patients collect themselves using wearables for tele-monitoring and data that healthy people collect using wide variety of health and well-being apps. In addition, information from other sources such as social platforms or data collected for a non-medical purpose may provide useful insights for better public health policy making. This rather wide variety of data sources is considered in the work of the European Commission in supporting development and implementation of eHealth in the EU.

Terje Peetso[1] told the audience that the European Commission has already put in place several activities to improve EU interoperability in healthcare[19]. First of all, eHealth interoperability is one of the 16 key actions under three pillars of the Digital Single Market Strategy[20] and it is also part of the "EU eGovernment Action Plan 2016-2020 - Accelerating the digital

[1] This section expresses the personal views of the author and in no way constitutes a formal/official position of the European Commission.

transformation of government"[21] that supports Member States in the development of eHealth services that also enable cross-border exchange of patient data and e-prescriptions, based on the guidelines adopted by the eHealth Network[22,23].

Interoperability has a prominent role in the eHealth Action Plan 2012 – 2020[24] in which one of the four areas of actions is dedicated to addressing technical, semantic, legal and organisational issues. As a result, the Commission, with the endorsement of the eHealth Network, proposed the Refined Health Interoperability Framework[25] based on the results of studies, pilots and research projects. In addition, on 28 July 2015 the Commission has adopted the Decision on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement[26].

Furthermore, in other three areas of the Action Plan – "Research and Innovation", "Deployment and uptake" and "International cooperation" – interoperability is addressed directly or indirectly. For example, during the period 2012–2020 research and innovation funding is foreseen from the EU Framework Programme for Research and Innovation Horizon 2020[27]. Indirect effect on achieving interoperability is also expected through increasing awareness of the benefits of eHealth in general as well as from better understanding of the importance of data sharing and cross-border cooperation to achieve better health outcomes. Finally, interoperability is one of the three areas of the Memorandum of Understanding signed by the representatives of the EU and US in 2010 [28].

It is important to underline that in addition to the activities listed above, interoperability is closely linked to many other documents such as the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare[29], the EU Regulation 910/2014 on electronic identification and trust services for electronic transactions in the internal market[30] and the political agreement on the Network and Information Security (NIS) directive[31]. It is also related to actions following the public consultation on the Green Paper on mHealth[32].

A mix of actions, methods and tools support the process towards interoperability through engagement, education, development, testing, deployment, monitoring, knowledge sharing and feedback. All these activities enable healthcare providers to reach the critical mass of empowered users and break the existing silos which together will effectively contribute to accessing personalised medicine.

9. Expert panel on semantic interoperability

Following the talk by Terje, Veli Stroetmann led an expert panel discussion on the challenges of improving semantic interoperability across EHR systems, at a European level. The panel brought together the perspectives of health ministries (Michèle Thonnet, Jeremy Thorp), a clinician (Robert Vander Stichele), a patient (Petra Wilson) and a health insurer (Christoph Rupprecht), and focused on the role decision makers should play in promoting and supporting better learning from health data.

In interoperable and connected systems, data can be used and reused across diverse settings to counter health system fragmentation; in cross-border situations coping with increasing mobility across Europe and in mobile tools to facilitate home care and self-management of chronic disease. Interoperability of eHealth solutions is essential for achieving continuity of care, which is the key to reducing patient risks, avoiding duplication and saving healthcare resources. Interoperability enables not just sharing of information, it reduces clinician as well as patient burden to repeatedly provide data and supports the efficient coordination of multidisciplinary teams to provide seamless, integrated care. From a patient's perspective, the main benefit of interoperability is an end to giving the same information over and over again.

The consistency and comparability of data brings data use a step forward from improving patient care to facilitating public health management and clinical research. All these factors are crucial to achieve a preventive, predictive, personalized, people-centred and participative health system.

To successfully implement interoperability and to achieve these goals, we still have to overcome many challenges. Data governance and access conditions have to be carefully planned to provide trust to patients; and the benefits of internal secondary use of interoperable data should be made clear to encourage clinicians' adoption. Physicians need to able to use the clinical data they collected in their records and registers for their own research, internal audit, and keep control of the research uses of these data by third parties.

Many health ICT solutions exist that accommodate the needs of various stakeholders but lack connectivity, patient orientation, and most importantly fail to effectively support communication and cooperation between different stakeholders in the healthcare system. Standards are available but many proprietary systems

and solutions are still not aligned with interoperability standards, which are limiting the possibilities for further development. User support needs much improvement in terms of human interface, natural language processing and granular reference terminologies which allow interoperability and at the same time matching diverse needs of specialty classifications.

Current ICT use in health has shown great results in capturing and structuring health information, yet the work to link these systems to care pathways and business processes in order to achieve continuity of care is still in its infancy. Strict machine processes of ICT are sometimes not flexible to accommodate all of the human workflow. The heterogeneous interest of various stakeholders makes it difficult to implement and modernize ICT fitting diverse needs to achieve interoperability.

Another limitation lies on how the ICT services are planned and deployed. Existing governance structures are not able to produce regulations and legal frameworks which fit the current development. Using a pharmaceutical dominated model to prove Return on Investment makes it difficult for ICT in health to show its cost-effectiveness and consequently impede investment.

One major problem is that standards are often costly and difficult to access which hinder the adoption by small-sized vendors and organizations. Standards dissemination needs to allow wider and easier adoption among all levels of stakeholder. Standards adoption is a continuous path as there will always be new standard developments. More effective strategies which include training and ongoing support of adoption have to be considered. Input of clinicians and patients has to become more strongly a part of standards development. Cooperation and collaboration among standard bodies and vendors can save resources and avoid iteration and duplication when developing standards.

The decision making power to help scaling up interoperability resides in public authorities, insurers and the health industry, whereas clinicians and patients are in a passive position. Public authorities have to focus on regulations which could leverage unachieved efforts and unmet needs, and promote trust and credibility among stakeholders. The number of clinicians who are willing to drive the process of interoperability is limited and, thus, should be supported, trained and coached. Scientific officers of European scientific associations should also be targeted to speed up the process of adoption of standards in clinical guidelines, research, decision support systems and registries. Ultimately, patient demand has to be educated and nurtured by patient associations.

The audience were informed that *i*~HD is playing a growing role in the development and quality labelling of interoperability specifications, bringing together clinical and research domain experts, with patients, to help ensure that future standards will support patient care, learning health systems and clinical research.

10. Interoperability as a driver of co-creation of health and wellness

Petra Wilson told the audience that Europe is ageing and our dependency ratio is heading towards less than 2:1 - that means there will be fewer than two working age people (15-65) for every person over 65 years old. The issues this raises are manifold, encompassing questions about working in older age, youth unemployment, rise in chronic conditions, cost of care, and many more. Technical interoperability in health and wellness technology will certainly not solve all the problems, but it can help address a key issue: how can we empower and enable patients to be more actively engaged in evaluating their actions to promote health and wellness.

The engagement of the end consumer in the development of a good or service may be defined as having two aspects: co-production and co-creation. Co-production is often described as the involvement of the user in the design of a product, which has arguably has been the case in healthcare for many years with the use of the controlled trial in drug development. The term co-creation is often used to describe the continuous engagement of the user in service use to create on-going value for the user and others [33]. Co-creation sees the role of patients extending beyond being passive health care recipients, or even active participants in their own care, to involvement in innovation and value creation in health care — from being “users and choosers” to becoming “makers and shapers” of services[34]. Co-creation in healthcare is complex and is slowly evolving through the input of many disciplines including sociology, psychology, management science and many more. Here we are interested in exploring the role of health informatics can play in adding to the on-going endeavours to ensure that patients can become co-creators of not only their own health, but of evolving healthcare systems.

The emergence of wearable and implanted devices for continuous monitoring, ambient data collection tools such as pedometers, social media records of mood and situation, geo-location devices and many other new technologies, offer an opportunity for the patient to engage directly in the co-creation of their own health and the development of health systems (Figure 7). They offer the potential to collect real-time, personal and contextual data to help patients and clinicians understand the impact of a medication, situation, mood, exercise or other external factors on health.

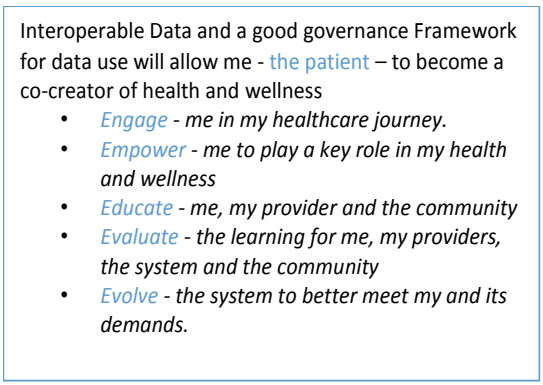

Figure 7. The five E's – characteristics of co-creation of health

The key to unlocking that potential, to igniting the engine that will drive real change in healthcare, is the extent to which the data can be shared and re-used. To ensure that we can use the many new technologies that allow for better data collection in a truly co-creative way, we need to ensure that they can be reliably collected, safely processed, shared, used and reused. While this a huge ask, two key components to addressing it are within our grasp: interoperability of health information systems and health information governance frameworks.

These two components demand that SDOs must develop good standards and profiles, which law makers must devise new concepts of data custodianship and that policy makers must shape the policies which ensure that the standards are used and the governance frameworks are user-friendly. These are of course huge tasks, but ones that we are equipped to tackle, and indeed must tackle if we want to ensure that our health systems evolve to be co-created through the active engagement of patients, empowered to share their data so that systems can be continuously evaluated to drive an evolution towards a sustainable healthcare system that values the promotion wellness rather than the rectification of harm.

11. How to speak to politicians to engage countries in the fight for prevention of brain disorders

Mary Baker, MBE, gave the afternoon keynote talk about the societal challenge of an ageing society, the growing challenge of multiple chronic diseases and the need to accelerate research into innovative treatments. Drawing on her long experience working for professional societies and charities in neurological disease, Mary pointed out that brain research in Europe is a rapidly evolving field. The complexity of understanding brain function and brain diseases brings responsibilities as well as opportunities for the neuroscience community for the benefit of society. Despite these major challenges and all the efforts of the scientific community in Europe, we are still struggling against the discrepancy, still present in Europe, between the huge societal impact of brain diseases on the one hand, and the modest financial and time resources allocated for brain research, teaching and the care of brain diseases on the other. There is no way to escape from the fact that brain disorders are a major public health problem in Europe and the rest of the world. An analysis of the health economic studies of brain diseases in Europe, published by the European Brain Council in 2011, led to an estimate of €798 billion for the total cost of brain disease in Europe in 2010. This burden is bound to grow. Addressing these large costs requires intensified research, both basic and clinical, and the creation of novel solutions. Future generations deserve nothing less.

We must work with the policy makers. We must also understand the policies and the active outlines presented by the various directorates of the Commission and work to use the aspirations of each Presidential term of each Country to benefit society.

The combination of ageing populations and lower economic growth is leading policy makers to question the sustainability of European healthcare expenditure. At the same time as seeking to increase 'cost-effectiveness', however, we must also strengthen our focus on the outcomes our health systems deliver - for the patient, the economy, and society.

Society needs to be much more committed to promoting wellness and accelerating the discovery and testing of innovative treatments. Our ageing society is accumulating long-term conditions, and we need to be much more proactive in prevention and early detection. Health data are vital to improving our understanding of disease and the impact on the lives and wellbeing of

patients. Society needs to better trust the security measures that can nowadays be applied to protect privacy, and to recognise the balance in proportionality between safeguarding health data and putting health data to good use.

Conclusion

i~HD has been established as a European not for profit body, registered in Belgium through Royal Assent. It is governed by its member stakeholders, public and private, through an elected Board and officers. It is being financed by a mixture of membership subscriptions, and will in the future add income from fees from providing services such as certification and accreditation, specific project grants and other income from education, training and expert advisory roles.

i~HD will continue to work on the development of best practices to promote a trustworthy ecosystem for reusing health data for research, and the adoption of standards for high quality and interoperable health data. *i*~HD will also be working with patient associations to understand their views on societally acceptable ways to scale up learning from health data, and how such learning can also ensure patient involvement and empowerment.

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No conflict of interest was reported by the authors.

Author contributions

All authors were speakers at the conference. Dipak Kalra and Georges De Moor were also responsible for the scientific organisation and content of the conference.

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