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Trustworthy reuse of health data: A transnational perspective

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ABSTRACT

Background: The widespread adoption of electronic health records (EHRs) is accelerating the collection of sensitive clinical data. The availability of these data raises privacy concerns, yet sharing the data is essential for public health, longitudinal patient care, and clinical research.

Method: Following previous work in the United States [1,2], the International Medical Informatics Association convened the 2012 European Summit on Trustworthy Reuse of Health Data. Over 100 delegates representing national governments, academia, patient groups, industry, and the European Commission participated. In all, 21 countries were represented. The agenda was designed to solicit a wide range of perspectives on trustworthy reuse of health data from the participants.

Results and conclusions: Delegates agreed that the "government" should provide oversight, that the reuse should be "fully regulated," and that the patient should be "fully informed." One important reflection was that doing nothing will have negative implications across the European Union (EU). First, continued fragmented parallel non-standards-based developments in multiple sectors entail a substantial duplication of costs and human effort. Second, a failure to work jointly across the stakeholders on common policy frameworks will forego a crucial opportunity to boost key EU markets (pharmaceuticals, health technology and devices, and eHealth solutions) and counter global competition. Finally, and crucially, the lack of harmonized policy across EU nations for trustworthy reuse of health data risks patient safety. The productive dialog, initiated with multiple stakeholders from government, academia, and industry, will have to continue, in order to address the many remaining issues outlined in this white paper.

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1. Background

Healthcare is a data intensive enterprise. Hospitals, pharmacies, laboratories and other healthcare organizations generate clinical data as a by-product of service. The widespread adoption of electronic health records (EHRs) is accelerating the collection of sensitive clinical data. The availability of these data is raising privacy concerns, yet sharing the data is essential for public health, longitudinal patient care, and clinical research. These benefits increase with the scale of the data sharing, and with the variety of health and care environments taking part. Across the European Union (EU), there is vast potential to realize such benefits. However, the EU presents a diversity of cultures, languages, policies, regulations and operational arrangements for data access and collection, which impedes the full promise of health data reuse, not only across borders, but also within the individual countries.

Within individual EU member states, there is a long history of enhanced data collation into population based disease registries. This is often termed "secondary uses" or "reuse" of data for purposes other than direct care of the patient. There currently exists an opportunity to create a common framework allowing the EU and its member states to analyze healthcare data collected in real-world settings.

Individuals and organizations from many segments of the healthcare landscape, including patients, caregivers, clinicians, public health professionals, academics, private research organizations, governments, health insurers, and life science companies all have an interest in understanding what happens to patients while they are under the care of a clinician, on a medication or following surgical intervention, regardless of whether it involves hospital-based, office-based or community-based care. A common framework outlining the methodologies and rules for the trustworthy reuse of these data will facilitate the ability to extract the insights needed from health data across the EU.

In the United States (US), between 2005 and 2008, an effort led by the American Medical Informatics Association and a consortium of healthcare companies, public health organizations, academia and private sector research organizations set forth an initiative to outline a framework for healthcare data stewardship for the US. This framework was explored and refined in meetings convening a host of highly respected experts from the US and Europe [1,2]. National Committee for Vital and Health Statistics (NCVHS), a Health and Human Services (HHS) advisory committee vetted and recommended this framework for the US [3].

Following this experience, the 2012 European Summit on Trustworthy Reuse of Health Data convened by the International Medical Informatics Association was held in Brussels, Belgium on May 14–15, 2012. This white paper reports on the findings of this meeting.

2. Opportunities

For all nations there are benefits, risks and issues of trust involved in reusing health data. Furthermore, nations will need to borrow insight from one another in order to realize the full potential of this reuse. So we begin by examining some motivating opportunities for four groups of globally relevant beneficiaries: 1) individual patients and citizens; 2) public/population health; 3) health scientists and policymakers; and 4) healthcare businesses. The following vignettes illustrate typical issues for these beneficiaries at present and in envisioned futures of optimal trustworthy reuse of health data.

2.1. *Opportunity for individual patients and citizens*

2.1.1. *Status quo*

Mrs. Dardel is a type 2 diabetic, overweight, with high blood pressure, and has just been diagnosed with chronic kidney disease. When she saw the renal physician he seemed most concerned about her blood pressure. The diabetes nurse on the other hand seemed more concerned about her blood sugar. Mrs Dardel's primary care physician asks her to lose weight to control her blood pressure, but she read a website that blamed her weight on the diabetes treatments. She is afraid to exercise in case she has a heart attack, but keeps that fear to herself.

2.1.2. *Potential of future trustworthy reuse*

Mrs. Dardel has an on-line profile, integrating all of her health records in an easy to use and interactive 'avatar like' form. Far from being a passive recipient of clinical records and treatments of old, she is now an active co-producer of her health information – adding regular biomedical measurements (e.g. blood pressure), experiential measurements (e.g. quality of life), and comments. She shares weight and physical activity information with her friends and family to encourage her in achieving a healthy weight and feeling better.

2.2. *Opportunity for public/population health*

2.2.1. *Status quo*

Public Health Physician Dr Arnaud and local health service commissioner Dr Wigertz are examining the literature relating socio-economic status to obesity in order to consider how to target clinical and public health measures for weight control. The literature suggests that obesity is more prevalent in deprived areas. However, a quick analysis of national survey data showed a counterintuitive picture for their region, where women from lower income households tended to have higher body mass index (BMI), yet among men the socio-economic trend in BMI was the other way around. These local policy makers need obesity profiles for localities smaller than those published in national reports, but they find it too difficult to access the relevant data from local sources.

2.2.2. *Potential of future trustworthy reuse*

Drs. Arnaud and Wigertz initiate a local obesity-profiling task based on widely shared templates from other localities. The public health and healthcare teams use the templates to build a comprehensive set of queries and analyses. For the child population they search child health and education records using privacy protecting linkage – the educational records provide more socio-economic detail. For the adult population they have access to complex queries of coded primary care records, which distinguish pre-defined/screening BMI checks

from opportunistic BMI measurement in order to help provide unbiased estimates of being overweight. After the local policies have been implemented the searches used to inform them are reused to help investigate the effects of implementing those policies.

2.3. Opportunity for health scientists and policy makers

2.3.1. Status quo

An international committee of epidemiologists and clinical researchers is convened to address confusion in the literature over the possible effects of diabetes treatments on the risks of developing various cancers. Some papers claim to demonstrate an increased risk from long acting insulin whereas others show no significant effect. There is disagreement over study design, in particular the control of potential confounding by indication and the handling of time-varying exposures. In addition, co-prescription with metformin might mask risks because it may be protective against developing cancer. Meta-analyses have failed to resolve the confusion and policy makers are calling for researchers to share their data and run larger, more definitive studies.

2.3.2. Potential of future trustworthy reuse

The importance of investigating the relation between diabetes treatments and cancer is trending in scientific social networks. Connected researchers quickly self-organize into a small number of global study groups, reusing and enhancing data extraction/cleaning and statistical modeling procedures that deal with time-varying exposures and confounding by indication. Further sub-population analysis with genotyped case-cohorts reveals a set of genetic determinants that might enable more targeted therapy in the future.

2.4. Opportunity for healthcare businesses

2.4.1. Status quo

PharmaCorp has a new therapy that recently received regulatory approval in Europe. While some countries let the drug be prescribed, others require an additional review by national pharmaceutical review organizations. Despite suggestions in one of the medicine's early clinical trials that the medicine is particularly effective in a specific population, the trial did not have enough patients with the finding to show a statistically significant difference. A full blown clinical trial to demonstrate this difference would take many thousands of patients and many years to complete. Due to the fact that there are similar drugs on the market, the national pharmaceutical review committees decline to make the therapy available in several countries. Without those markets, there are insufficient sales to keep the drug on the market. The therapy slips into obscurity.

2.4.2. Potential of future trustworthy reuse

PharmaCorp has a new therapy that recently received regulatory approval in Europe. While some countries let the drug be prescribed, others require an additional review by national pharmaceutical review organizations. Despite suggestions in one of the medicine's early clinical trials that the medicine is particularly effective in a specific population, the trial did not have enough patients with the finding to show a statistically significant difference. Because some countries had already had this medicine on the market, aggregated clinical data is available across many countries that can be studied to test this hypothesis in silico. PharmaCorp is told that to gain full prescribing approval, the company should do an observational study of EHR data to determine if the sub-population theory can be demonstrated in the general population. Because data are available, the study can be performed in several weeks instead of several years. The findings demonstrate that there indeed is a subgroup of patients in whom this medicine is especially effective. The national pharmaceutical review committee allows the drug to come to market because it has this specific efficacy in the study population. The medicine is now broadly available and is targeted precisely to the patients in whom it has the greatest efficacy. The medicine stays on the market, making a substantial difference to the lives of thousands of patients.

3. Methods

A steering committee of representatives from the International Medical Informatics Association (IMIA), health data experts, the European Commission, and the major sponsors from life science and healthcare businesses organized and planned the 2012 European Summit on Trustworthy Reuse of Health Data. At the Summit we adopted a broad definition of health data to include not only data that resides within EHRs, but also data in health registries, personal health records, and even home sensors. The Summit took place in Brussels, Belgium from May 14 to 15, 2012. Over 100 delegates representing national governments, academia, patient groups, industry, and the European Commission participated. In all, 21 countries were represented. The agenda was designed to provide diverse perspectives on trustworthy reuse of health data in the form of keynote speeches and expert panels, and to solicit perspectives from the delegates. The format challenged entrenched viewpoints from the participants given their diverse backgrounds. To capture the essence of the presentations and delegate discussions and mitigate multi-lingual translation issues, an artist was used to graphically capture major discussions during the meeting. The agenda and presenters' slides were collected and made available on the Summit's IMIA website: http://euhealthdata2012.imia.info. Finally, all of the plenary sessions were recorded and posted on Summit's YouTube channel: http://www.youtube.com/user/EUSTRHD.

3.1. Breakout sessions

The breakout sessions were designed to stimulate Summit attendee discussions, surface perspectives, and prioritize seven unique dimensions to be used in a future European Union health data reuse framework.

The Summit delegates were selected for each breakout session to ensure a balance of nationalities and sectors.

A scenario with specific questions was presented to the delegates in the plenary session prior to each of the breakout sessions (see Appendix). A Summit steering committee member facilitated each of the breakout sessions. At the start of each breakout session, a Summit delegate either volunteered or was assigned to be the session's rapporteur. The rapporteur provided a 5-min report of the breakout's discussion, perspective and findings in the next plenary session.

Each of the scenarios and question sets was designed to capture facets associated with health data use (see Appendix). The first scenario referenced a 2011 New England Journal of Medicine article and outlined an instance regarding health data reuse for research into rare diseases. The questions for this scenario required the breakout groups to focus their discussion on "opportunities and trust". The second case described a current example of the monetization of health data by a technology vendor; the breakout groups discussed the influence of governance. The third case portrayed the use of health data for public health surveillance and asked the breakouts to focus on policies that will facilitate reuse of health data.

Then, each of the groups was asked to evaluate the scenario with reference to the seven unique dimensions. These dimensions were presented on a poster in the breakout room and allowed the delegates to present their perspectives on a five-point Likert scale (see Fig. 1).

The groups were instructed to allocate 45 min for open discussion and use the last 15 min to assign preferences for each dimension of the proposed framework. The breakout groups were given the freedom to determine how they wanted to capture the sentiment of the group's perspective for the dimensions. Two out of three of the breakout groups used one or two points on the dimensions to represent their perspectives. While, one of the groups chose to use the sticker dots that were made available to them and allowed each group member to represent their perspective for each of the dimensions. An average value was calculated for each scenario for each dimension for each breakout session. Consensus was considered if the average was less than or equal to two or greater than or equal to four.

4. Results

As intended, the Summit's agenda and format stimulated diverse stakeholder discussions that crossed country borders and stakeholder perspectives.

4.1. *Breakout sessions*

The breakout sessions provided time for the delegates to surface and debate key aspects associated with the three scenarios and question set for reuse of health data.

The discussion was at times heated and some individuals held very strong opinions. A summary general of each breakout session was reported to the entire Summit follows:

Scenario 1: Integration of multiple databases to conduct a retrospective disease specific analysis

- Existing data sets would be difficult to combine and analyze as they have different, often undocumented, structures and qualities.
- Patients should be able to opt in and choose to participate
- Privacy and patient consent regulations, policies, and procedures would need to be re-evaluated.
- The "creation' versus 'reuse" of data would need to be defined and communicated.
- Organizations might need accrediting as trusted third parties for controlling access to these data sets, aggregating disparate data sets, and moving the data to interested parties for evaluation/analysis.

Scenario 2: Collection and re-selling of EHR data by a vendor

- Database size does not reflect quality.
- Patients should be able to opt in to these types of uses of their health data.
- Stewardship of data will be required.
- The intent and purpose for capture of the data needs to be made clear.
- If the data are misused, then it is a crime and laws should be enforced.

Scenario 3: Public health bio-surveillance at a global level

- This is technically possible.
- There are clear benefits from early detection via proactive approaches.
- Systemic change is required to achieve the required global scale.
- The clear societal benefit makes inaction unethical.
- The essential actions are:
  - bringing stakeholders together in a collaborative way;
  - enforcing essential data and information standards;
  - documenting of the context of the data; and
  - deploying easy-to-use systems to access and manipulate the data collaboratively.

Table 1 shows the output from the working groups where there was general consensus. The discussion was rich and varied and a single table oversimplifies sentiment and group preferences. For all three scenarios, the groups agreed that the "government" should provide oversight, that the reuse should be "fully regulated," and that the patient should be "fully informed."

The breakout sessions revealed that much more work needs to be done to build a health data reuse framework for the EU. In the final working session with all of the delegates, specific action items were identified and prioritized as necessary for building the health data reuse framework.

1. *Engage and educate all stakeholders* – due to the public sensitivity related to consent for and transparency of reuse of personal information, the topic of health data reuse requires societal support. Specific actions were to:
   a. publish a white paper to capture the Summit's proceedings;
   b. engage the media as a route to the public;

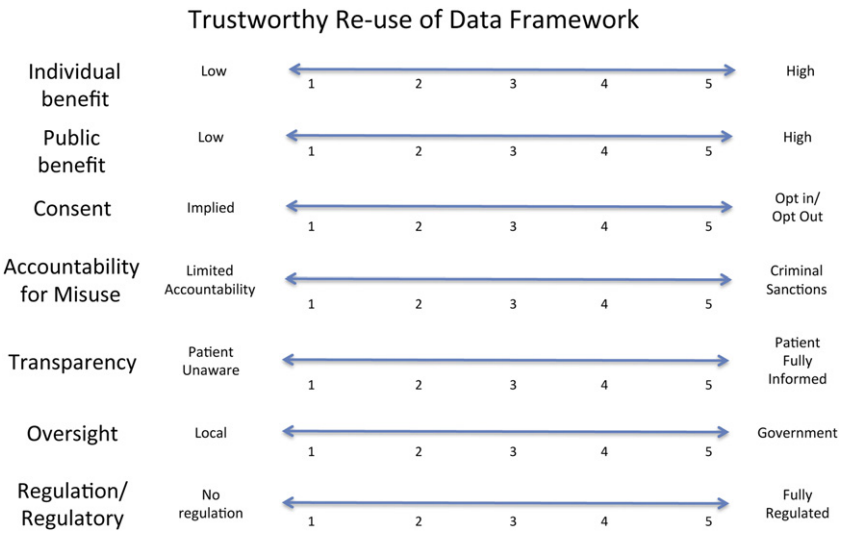

Fig. 1 – Dimensions of a proposed data framework.

Table 1 – Results of breakout sessions.

Attribute	Scenario		
	1	2	3
Individual benefit	No consensus	No consensus	No consensus
Public benefit	High	No consensus	High
Consent	No consensus	Opt in/Opt out	Implied
Accountability for misuse	Criminal sanctions	Criminal sanctions	No consensus
Transparency	Patient fully informed	Patient fully informed	Patient fully informed
Oversight	Government	Government	Government
Regulation/Regulatory	Fully regulated	Fully regulated	Fully regulated

   c. engage with the World Health Organization to integrate the Summit's output with the current drafts of a new eHealth Resolution; and
   d. integrate the Summit's output into ongoing discussions in the Article 29 and related work groups of the European Commission.[1]
2. *Define trust* – continue these types of discussions with diverse stakeholder groups, including the citizens of the EU, to develop a code of conduct and transparency, patient consent process, legal framework, accreditation mechanisms and other aspects.
3. *Develop compelling use cases/scenarios* – outline the true value proposition of the reuse of health data; clearly articulate current applications and uses of health data that are relevant for the EU; include business cases as possible drivers for action.
4. *Build a roadmap* – Provide a vision and action plans of how to move from the current position to a future norm of trustworthy reuse of health data.

5. Discussion

The 2012 European Summit on Trustworthy Reuse of Health Data stimulated a rich discussion. The Summit did not seek speciously simple answers. Our key findings were that the processes of health data reuse need to be transparent with the patient fully informed and that national governments must play a seminal role. These findings highlight a set of open questions that need to be addressed by concerted transnational efforts.

The cornerstone of data sharing and reuse is trust; therefore, the pivotal goal is the implementation of a trustworthy process for handling citizens' and patients' health data. Following the definition of [4], in a trusted relationship, "One party (trustor) is willing to rely on the actions of another party; the situation is directed to the future. In addition, the trustor abandons (full) control over the actions performed by the trustee." As a consequence, a trustworthy system is such that the trustor can "place

[1] As part of Article 8 (privacy), the Article 29 Data Protection Working Party was set up under the Directive 95/46/EC of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

his/her trust and rest assured that the trust will not be betrayed".

A system for data reuse should thus prove its trustworthiness by fulfilling the responsibility of dealing with the data within the limits of a social contract, regulated by policies, between the citizens and the organizations handling such a system.

The European Summit results and findings stem from the notion of trust. These findings can be summarized looking at the main components needed to build a trustworthy system: a technological component, a research component, and an exploitation component.

The technological component of a trustworthy system concerns the design and implementation of IT tools and services able to guarantee data quality and data security, as well as to provide interoperability, adaptability and scalability. Specific projects funded by the EU and by the IMI initiative [5], such as EHR4CR [6,7], are dealing with such challenges, with the perspective of defining use cases, tools, technologies and a business model for data reuse. In particular, the EHR4CR business model includes accreditation and certification plans for EHR systems capable of being integrated within a system for data reuse.

The research component of a trustworthy system deals with the evidence that can be derived from a reuse of data. Such a topic is related to a variety of methodological problems, inherent to the statistical and data processing methods that are needed to derive reliable results [8,9]. Such methodological aspects are intertwined with the technological ones, since the quality of evidence is strictly related to the quality of data. Such quality depends on a variety of crucial issues, including contextual meta-data and semantic interoperability between information systems. Adopting known analytics standards such as the Good Research for Comparative Effectiveness (GRACE) principles in the area of comparative effectiveness [10] is one way of ensuring that the research component of data reuse is held to a recognized high standard.

The exploitation component of a trustworthy system is related to goals of the data reuse, which may include a variety of purposes, from clinical research, epidemiology and surveillance to post-marketing analysis. The purpose of data analysis has implications that belong to the realm of policies and regulations, which are essential aspects for the establishment of trust. The management of informed consent is a central part of this issue. In fact, the current regulations in many EU countries, similar to the US with the HIPAA act, assume the consent (implied or explicit) for use of data is strictly limited to the purpose for which the data were collected [11]. This may seriously limit the scope of data analysis. This theme needs to be reconsidered in the light of the existence of a proper trustworthy system based on an agreement between citizens and health care organizations. However, new policies and regulations related to patients' privacy should be based on a wide consensus at the national and EU level. Specific practical examples of policies for handling data reuse are provided by regional initiatives in Europe, such as in the UK and in Catalonia. ISO/TS 14265:2011 provides a classification of purposes for processing personal health information that can help make policy formulation more granular [12].

As a consequence, the first important conclusion of the Summit is that it is mandatory to involve citizens and patients' organizations in the process of defining a trustworthy system should:

1. help clarify the benefits that data sharing and reuse provide to research, public health, personal health and business; and
2. take into account those issues related to privacy and protection of data that really matter to patients and citizens.

Certainly, the 2012 European Summit has clarified that one of the important components of trust is transparency. Both the technological and policy aspects should thus define clear processes that ensure a transparent management of the data and the capability of keeping track of the scope and purposes of the use of information. A topic that will need careful discussion between the different stakeholders concerns the guarantees provided to citizens. The diversity of cultural background and legal systems in Europe makes such discussion and conciliation of the different views challenging.

The EU eHealth Task force report on Redesigning health in Europe for 2020 [13] has explicitly dealt with the issues of data reuse. In particular, two "levels" of change advocated for eHealth 2020 are dealing with the data: "My data, my decisions" and "Liberate the data". The first level of change clearly states: "individuals are the owners and controllers of their own health data, with the right to make decisions over access to the data and to be informed about how it will be used". Such a radical shift moves the focus from health care organizations to each citizen, who is now the subject (and not the object) of data management. Regulations and policies for data reuse should, therefore, properly take into account this aspect, thus defining proper instruments for data sharing and detailed management of individual agreements. This "level of change" is also connected with a crucial recommendation reported in this document: "Building a new legal basis for health data in Europe". The second "level of change" is on data liberation. Concerning data liberation, the document states: "Governments should ensure that health data is robust (accurate and reliable), gathered in a standard way, anonymized and then made freely available to anyone that can add value to it. This 'open data' approach encourages many entrepreneurs to innovate rather than creating a monopoly or market domination by a few service providers." The "Liberate the data" level of change has been strictly related with a recommendation reported in the same document: "Use the power of data". The data liberation theme was at the very heart of the European Summit, since it is a key topic of the IMIA initiative toward the definition of a trustworthy data reuse system. The commitment of institutions and health professionals toward data liberation is a crucial step that still needs to be performed. However, the two levels ("My data, my decision" and "Liberate the data"), as mentioned above, need careful considerations and wise policy-making when moving from theory to practice. Anonymization, for example, cannot be seen as the solution to the problem of data liberation because in many contexts, complete anonymization is not possible.

One important reflection based on the outcome of the Summit is that doing nothing will have negative

implications across the EU. First, continued fragmented parallel non-standards-based developments in multiple sectors entail a substantial duplication of costs and human effort. Second, a failure to work jointly across the stakeholders on common policy frameworks will forego a crucial opportunity to boost key EU markets (pharmaceuticals, health technology and devices, and eHealth solutions) and counter global competition. Finally, and perhaps most importantly, the lack of harmonized policy across EU nations for trustworthy reuse of health data risks patient safety.

Combining the findings and open issues mentioned above, the road to reach the goal of a trustworthy system for data reuse has been drawn but it still remains long and winding. IMIA will act as an independent convener, able to provide a forum and to foster initiatives to overcome the current difficulties, including disruptive ideas, since "doing nothing is not an option", and the need of providing benefits to all stakeholders involved in data sharing and reuse, from citizens to companies, is urgent.

Summary points

What was known before

- Healthcare is data intensive.
- Availability of data is raising privacy concerns.
- Policy makers, public health officials, scientists, clinicians, citizens, and industry all benefit from the reuse of health data.
- Data transfers between EU countries present challenges from the diversity of cultures, languages, policies, regulations and operational arrangements.

What was learned

- Processes of health data reuse need to be transparent.
- National governments must play a seminal role.
- Trust is the corner stone for data sharing and reuse.
- It is mandatory to involve citizens.

6. Next steps

The Summit highlighted that the benefits outweigh the risks of reuse, but reuse may be blocked when risk predominates the discussion. Future work needs to highlight the challenges of building a framework for trust and on the challenges relating to the negative aspects of potential breaches in the privacy of citizens.

Nations and regions are addressing variants of similar cultural, organizational and technical issues in order to add value through better use of health data. However, in order to realize maximum benefits of this use of data, transnational approaches must be developed. This is not only important for facilitating knowledge sharing, or enabling the mobility of citizens and services (as exemplified by the epSOS project [14]), but also necessary for achieving the critical mass and contextual diversity of data needed for vital research.

The heterogeneity of approaches and solutions is therefore a richness that must be harnessed through interoperable mechanisms. These necessitate some level of harmonization of policies, information standards and infrastructures. Such mechanisms must therefore be promoted at the global level, in order to develop a converging path toward better data sharing and use, while respecting the local needs and sensitivities.

As identified in the final working session during the Summit, next steps to raise awareness and build consensus about these issues include:

- An active dissemination of progress toward a framework for the trustworthy reuse of health data at national, regional and international scientific conferences dealing with medical/health informatics and public health, as well as through the International Medical Informatics Association (IMIA) communication channels to its member societies and regional groups.
- Consultation with stakeholders and experts in order to formalize guidelines and recommendations, and promote knowledge sharing approaches, in line with the tools already developed such as the National eHealth Strategy Toolkit jointly published by the World Health Organization (WHO) and by the International Telecommunications Union (ITU) [15].
- Presentation of these recommendations and their discussion with ministries of health, policy- and law-makers, in particular during the World Health Assembly meeting, and at other regional meetings such as the European Union's eHealth week.
- Integration of these issues in the preparatory work of a renewed WHO eHealth resolution, capitalizing on the momentum initiated in 2005, but adapting it to the current needs and challenges, which include interoperability, trustworthiness and trusted use of health data.

A lot has been achieved in a short period of time. While our initial discussions frequently focused on research, other aspects of health data reuse such as public health and strengthening health systems will be highlighted in future processes. The productive dialog, initiated with multiple stakeholders from government, academia, and industry, will have to continue, in order to address the many remaining issues, and to follow and adjust the dissemination of the program outlined above.

Author contributions

AG, CS, IB, RB, SL, KE, PM, AL, CR were responsible for the study design. AG, CS, IB, RB, SL, KE wrote the initial drafts of the white paper. AL, CR, PM JM and GDM edited and revised the manuscript.

Conflicts of interest statement

SL works for conference sponsor AstraZeneca, AL works for conference sponsor Deloitte MCS, Ltd, CR works for conference sponsor Jansen Pharmaceuticals.

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Appendix.

A.1. Scenario 1

Children with attention deficit-hyperactivity disorder (ADHD) are frequently treated with medications that have simulant effects on the heart. Although these medications are generally thought to be safe, case reports from Canada and the United States included cases of sudden death, heart attacks, and strokes in children under treatment for ADHD. A retrospective analysis of multiple data sources including electronic health records, health registries, and pharmacies provided data for 1,200,438 children ages 2 to 24 was conducted to determine the risk of cardiovascular events for children taking ADHD medications.

A.1.1. Background

This scenario is adapted from an article N Engl J Med Nov 2011. Many believe that large clinical databases are necessary to provide evidence-based recommendations for rare diseases. This scenario also stresses the need for large data sets to analyze rare outcomes in relatively common clinical situations. In contrast to scenario #3, this type of analysis is not real time, involves the integration of multiple data sources that may not share any standards.

Questions for Breakout group

1) Could such a study be conducted across the EU?
2) Will any single European country have enough patients for such a study?
3) What are the barriers to conducting such a study?
4) Should data from EHRs be centralized to facilitate such a study?
5) Who needs to give permission for such a study?
6) Who needs to give consent for such a study?

A.2. Scenario #2

A successful vendor of Electronic Health Records (EHRs) wants to develop new revenue streams while decreasing the costs to physicians of purchasing and maintenance of their EHR. Their idea is to sell the data collected by their EHRs and return some of the revenue as discounts or offsets to the initial purchase price or the ongoing maintenance costs of their EHR. Their plan is to ask the physician or office manager to participate in the program. If permission is granted, they will poll at midnight the EHR (via the Internet) and download an anonymized patient record for each patient seen during the previous day. The data will be aggregated and cleaned at central storage facility. The company will then seek commissioned studies for €50,000 on this dataset, thus avoiding the transfer of data outside the company.

A.2.1. Background

This scenario is actually about an existing company in the United States. The discussion of monetization of data was the most difficult discussion we had in the two previous meeting in the United States. However, every time an item of data is moved from one location to another (e.g. a data transaction) money also moves. The infrastructure providers profit, the software providers profit, and the consumers of the data benefit. While we do not think about improved healthcare as a "profit," poor quality health care costs our society money. This example just makes explicit the monetization of data. Again the discussion will be uncomfortable for some and lively.

Questions for the breakout

1) Should this be allowed?
2) Who needs to give permission to access the EHR?
3) Does the patient need to provide informed consent?
4) Should patients be aware their data is being sold?
5) Should any of the monetary benefit accrue to the patient?
6) How much is patient data worth?

A.3. Scenario #3

There is a new strain of Flu that has surfaced in China. There is growing concerns that it will spread through out Europe given the increase in trade and interaction with all parts of Asia – that coupled with the fact that there are more than 10 flights a day from China to De Gaulle, Heathrow and Frankfurt. The European Commission wants to set up bio-surveillance system that can aggregate all of the chief complaints and other clinical data from every emergency room across Europe, monitoring the information steams for "hot spots".

A.3.1. Background

In contrast to scenario #1 on Monday, this is a massive multinational undertaking (investment.) This scenario poses many technical and logistic problems not addressed in scenario #1. The data needs to be transmitted real-time and up-front standards need to be in place. In the United States such an undertaking has consumed over $250 million and still much work remains.

Questions

- Can this be done (now)?
- What policies would be needed to make this possible?
- What challenges are there concerning multiple languages, systems, and data streams
- Who's going to pay for the system?
- Who governs the use of the collected data for other than public safety?
- Who governs the re-use of the data gathered? Can the data be used for other purposes other than surveillance?

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