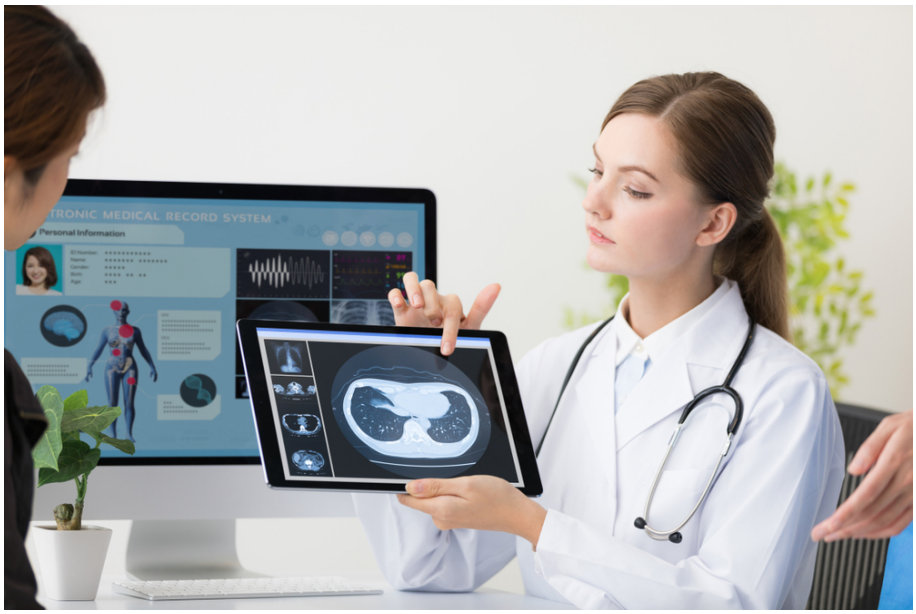
IN-DEPTH ANALYSIS

Requested by the ENVI committee

European Parliament

Digitalisation and Big Data: Implications for the health sector



Policy Department for Economic, Scientific and Quality of Life Policies
Author: Prof. Stefania BOCCIA, Dr Roberta PASTORINO, Dr Luca GIRALDI, Università Cattolica del Sacro Cuore, Italy, Ms Kimberley VAN DEN BERGEN, ECORYS Netherlands B.V., The Netherlands

Directorate-General for Internal Policies
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DIRECTORATE GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC AND QUALITY OF LIFE POLICIES

WORKSHOP

Digitalisation and Big Data: Implications for the health sector

European Parliament, Brussels

Brussels, 19 June 2018

PROCEEDINGS

Abstract

This report summarises the presentations and discussions of the Workshop on "Digitalisation and Big Data: Implications for the health sector", held on 19 June 2018 at the European Parliament. The aims of the workshop were to analyse the implications of digitalisation and Big Data for the health sector. The workshop was hosted by Ms Soledad Cabezón Ruiz (MEP) and Mr Alojz Peterle (MEP).

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CONTRIBUTING EXPERTS
Prof. Tito Poli, University of Parma – Azienda Ospedaliero Universitaria di Parma, Parma, Italy.
Dr Albert Mercadal Playà, Head of EMEIA Big Data and Analytics Center of Excellence, Fujitsu, Madrid, Spain.
Dr Lydia Makaroff, Director of the European cancer patients' coalition
Mr David Supple, Expert in GDPR compliance Zissou Projects ltd, London, United Kingdom.
Dr Levente Kiss, Senior assistant professor, Institute of Physiology, Semmelweis University of Medicine, Budapest, Hungary.
Prof. Jesús M Hernández Rivas, HARMONY Alliance Coordinator, Institute of Biomedical Research of Salamanca, Spain.

AUTHOR(S)
Prof. Stefania Boccia, Università Cattolica del Sacro Cuore, Rome, Italy
Dr Roberta Pastorino, Università Cattolica del Sacro Cuore, Rome, Italy
Dr Luca Giraldi, Università Cattolica del Sacro Cuore, Rome, Italy
Ms Kimberley van den Bergen, ECORYS Netherlands B.V., Rotterdam, The Netherlands

RESPONSIBLE ADMINISTRATOR
Miklós László GYÖRFFI

EDITORIAL ASSISTANT
Eva ASPLUND

LINGUISTIC VERSIONS
Original: EN

ABOUT THE EDITOR
To contact the Policy Department or to subscribe to its newsletter please write to:
Policy Department Economic, Scientific and Quality of Life Policies, European Parliament
B-1047 Brussels
E-mail: Poldep-Economy-Science@ep.europa.eu

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CONTENTS

LIST OF ABBREVIATIONS

CoE	Centre of Excellence
CISO	Chief Information Security Officers
COO	Chief Operating Officer
DG	Directorate General
DPO	Data Protection Officer
EASyM	European Association of Systems Medicine
EBM	Evidence Based Medicine
EC	European Commission
EHR	Electronic Health Records
EMEIA	Europe, Middle East, India and Africa
ENVI	Committee on Environment, Public Health and Food Safety
EU	European Union
FSCS	Financial Service Compensation Scheme
GDPR	General Data Protection Regulation
IECSCYL-IBSAL	Instituto de Estudios de Ciencias de la Salud de Castilla y León-Instituto de Investigación Biomédica de Salamanca
ICT	Information and communications technology
MCU	Molecular Cytogenetics Unit
MEP	Member of European Parliament
MS	Member States Evidence Based Medicine
UK	United Kingdom

EXECUTIVE SUMMARY

The workshop on “Digitalisation and Big Data: Implications for the Health sector" was organised by the Policy Department A Economic & Scientific Policy for the Committee on the Environment, Public Health and Food Safety (ENVI) Working Group Health of the European Parliament. It took place at the European Parliament, Room A3G3 of the Altiero Spinelli Building and was hosted by Ms Soledad Cabezón Ruiz (MEP) and Mr Alojz Peterle (MEP).
The aim of the workshop was to analyse the implications, opportunities and issues of digitalisation and Big Data for the health sector. The workshop was organised in six topics presented by six different speakers. The topics were discussed in two panels. The first panel addressed the topic of the potential use and sources of Big Data in healthcare and their potential challenges, by focusing on the potential for Big Data from a European health care system point of view, and the cultural and technical challenges related to the use of Big Data and electronic health records. The second panel was on digitalisation and Big Data in practice, including the management of legal and regulatory aspects, training and education actions, as well as the need of multidisciplinary partnerships to effectively tackle the challenges and the opportunities of using Big Data for health. Two question and answer sessions were opened after each panel.

In the first panel, the first topic was presented by Prof. Tito Poli (Maxillofacial Surgery Unit, Università degli Studi di Parma – Azienda Ospedaliero Universitaria di Parma). He discussed the clinical and cultural challenges ahead for the efficient use of Big Data in healthcare. He also focused on the comparison between Evidence Based Medicine and Big Data analytics, showing some issues related to Big Data analysis form the medical point of view. In the second topic Dr Albert Mercadal Playà (Head of EMEIA Big Data and Analytics Center of Excellence, Fujitsu) focused on technical challenges related to the management of electronic health records, in relation to data analysis and computing infrastructures, data quality, acquisition, curation and visualisation. He presented a solution provided by Fujitsu to support the decisions of medical doctors and managers. The third topic was presented by Dr Lydia Makaroff (Director of the European Cancer Patient Coalition), who discussed the innovation process in Europe and provided information on European health care systems. She then reported on some example of the benefits that Big Data Analysis can provide in the field of rare diseases and in genomic analyses.
The first round of questions and answers highlighted the issues of the use of hidden algorithms in Big Data analysis, the importance of involving citizen when interpreting the results of the analyses that include their personal data and the issue of informed consent.

The second panel was opened by Dr David Supple, who is an expert in GDPR compliance (Zissou Projects ltd). His presentation focused on the General Data Protection Regulation (GDPR) and its legal and regulatory aspects, including privacy protection and data sharing policies. Training and education were addressed by Dr. Levente Kiss (Senior assistant professor, Institute of Physiology, Semmelweis University of Medicine, Budapest, Hungary). Dr Kiss showed the importance of having health care professionals and clinical researchers trained in the field of information technologies, and provided examples of how automated Big Data analysis can improve student performances. Last presentation was held by Prof. Jesús M Hernandez Rivas (HARMONY Alliance Coordinator), who provided an example of Big Data established within the HARMONY project he coordinates. He showed the characteristics, the goals and the opportunities that this big platform can provide in the field of haematological diseases.

The second round of questions and answers focused on the importance of data security and data protection.

LEGAL AND POLICY BACKGROUND

Big Data in the health sector can be defined as "encompassing high volume, high diversity biological, clinical, environmental, and lifestyle information collected from single individuals to large cohorts, in relation to their health and wellness status, at one or several time points"[1].

Digitalisation and the use of Big Data is not new in the healthcare field. Medical diagnosis from imaging data in medicine and quantifying lifestyle data in the fitness industry are already widely used applications. Big Data can be used to describe the disease process and provide diagnostic answers. It can be predictive and/or prescriptive. The use of Big Data and digitalisation leads to new perspectives on, among other things: the prevention of disease, the improvement in diagnosis and therapy, the enhancement of patient's outcomes, improved patient satisfaction, and the optimisation of the use of resources in health.

The last two decades have seen an explosion in Big Data throughout the health-care value chain, as well as the advent of new platforms, tools, and methodologies in storing, structuring, and analysing such data[2]. Important developments include the use of genomic data in drug discovery, the sharing of clinical-trial data, the use of electronic healthcare records (EHRs), and the increased availability of data from mHealth applications, patient registries, and social media. The concept of data fusion is gaining further significance since, in addition to the collection of individual data elements, the fusing together of heterogeneous data coming from different sources is also increasing.

The potential of Big Data in improving health is enormous. Digital technologies can empower patients, support public health policies, provide more integrated healthcare, and reduce healthcare costs. The use of Big Data may prompt the assessment of effectiveness of health interventions and personalised medicine. Moreover, the opportunities of digitalisation are tremendous; the digitalisation of medicine allows for worldwide comparisons of disease progression and treatment responses. Whole-genome sequencing allows for searching and comparing human genomes.

Big Data technologies can derive value from large datasets in ways that were previously impossible. However, these technologies also require a considerate balance of opportunities and challenges. Management of Big Data and digitalisation might be challenging, because of the personal nature of the information enclosed and therefore poses new challenges for privacy and data security. The use of Big Data research methods often raises complex ethical issues which intersect with technology, social sciences, and law. Thereby, the use of Big Data may have implications for policy and for international legal frameworks. Research in this theme ranges from the theoretical and technical implications of cloud computing, anonymisation, privacy and cyber security to the legal and social dimensions of data.

The new Data Protection Regulation (GDPR) tries to balance patients' privacy while ensuring that patients' data can be shared for healthcare and research purposes[3]. In addition to data protection challenges, other issues arise, for example, related to data infrastructure, because the European health systems and databases are diverse and fragmented. At the same time,

[1] Bartha Maria Knoppers and Adrian Mark Thorogood. Ethics and Big Data in health. Current Opinion in Systems Biology. Volume 4, August 2017, Pages 53-57.

[2] Szlezak, N., et al. The role of Big Data and advanced analytics in drug discovery, development, and commercialization. Nature, 2014. 95(5): p. 492-5.

[3] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance).

the opportunities for using Big Data require legal and political measures in the area of digital health and care regarding patients' rights, personal data protection, data-access, as well as the facilitation of interaction between patients and health care providers. The policies established to govern Big Data in health care are therefore considering the importance of protecting the health data of individuals.

PROCEEDINGS OF THE WORKSHOP

1.1. Welcome and opening – Mr Alojz Peterle, MEP, ENVI Committee

Mr Alojz Peterle, MEP, opened the workshop by thanking the audience and all the speakers. He introduced the topic of the workshop stating that digital health has already provided many opportunities to solve the problems of health care services and continued to explain how the use of digital technologies is increasing in medical training and education for patients and other health care consumers.

Mr Peterle mentioned the challenges which European Health Care Systems face regarding the sustainability of health care delivery. Concerning the role of the new technologies, he expressed the necessity to focus healthcare on patients and their families. He concluded his introduction stating that artificial intelligence, machine learning and Big Data will probably have a stronger role in the near future.

He also emphasised that it is the MEPs responsibility to ensure that the position of the European Union, as work leader in health and technology.

1.2. Part 1: Digitalisation and Big Data in practice: management of HER, the legal aspects and training

1.2.1. Introduction

Prof. Stefania Boccia, Università Cattolica del Sacro Cuore.

Prof. Stefania Boccia thanked Mr Peterle and introduced the first panel, “The potential use and sources of Big Data in healthcare and their potential challenges”. She explained that the panel will be on three different topics that will be discussed by three different speakers. She also mentioned that it was planned to have Mr Dennis Horgan, Executive Director of the European Alliance for Personalised Medicine, speaking at the first session, but unfortunately he could not be present. Dr Lydia Makaroff replaced Mr Dennis Horgan.

Prof. Boccia introduced the first topic, “Clinical and cultural challenges ahead for the efficient use of Big Data in healthcare”, and introduced the speaker Prof. Tito Poli as the coordinator of the Horizon 2020 “BD2Decide” project that focuses on identification of innovative prognostic model for head and neck cancer patient management and stratification.

She then continued to the second topic which was about the technical challenges related to the management of electronic health records, specifically on the interoperability of electronic health records. This topic was presented by Dr Albert Mercadal Playà, Head of EMEIA Big Data and Analytics Center of Excellence, who is leading several projects on data science and Big Data technologies.

Finally, she introduced the third topic that was regarding the potential of Big Data for European health care systems, and she talked about the significant challenges that health systems are facing, and the necessity for more effective and efficient approaches in prevention, diagnoses and treatment. She introduced the speaker Dr Lydia Makaroff that spoke on behalf of Mr Denis Horgan. Dr Makaroff is the director of the European cancer

patients' coalition, and has over ten years of experience in non-communicable disease research and policy development.

1.2.2. Clinical and cultural challenges ahead for the efficient use of Big Data in healthcare – Prof. Tito Poli

Prof. Tito Poli, University of Parma – Azienda Ospedaliero Universitaria di Parma, Parma, Italy.

Prof. Tito Poli addressed three main points in his presentation: the first point he mentioned was regarding clinical and cultural challenges for efficient use of Big Data; the second point he reflected on was about being ready for a quantum leap offered by Big Data; and his third point referred to the proposal of a European shared guideline to govern digitalisation and Big Data.

Regarding the first main point, he compared two approaches used to produce scientific evidence that are Evidence Based Medicine (EBM) and Big Data Analytics. While EBM is hypothesis driven, Big Data Analytics is data-driven. Big Data Analytics starts with the collection of big amounts of data and moves directly to knowledge, using algorithms called "black boxes". These different approaches represent two different cultures in which EBM emphasizes the empirical evidence and the methodological rigor, while Big Data analytics underlines the used algorithms. Problems resulting from the use of "black-box" algorithms include mainly the risk of the lack of awareness about the use of an incorrect algorithm, and the inscrutability of multiple algorithms.

Despite these criticisms, Prof. Poli acknowledged the ability of Big Data analytics to provide more precise and detailed individual risk estimates and concluded his presentation stating that the two approaches are not excluding each other, since they can assist each other, for example, through the use of hybrid algorithms. He stated that measures need to be implemented to better manage Big Data. These measures include: specific training for physicians, the need of implementing the information technology architecture in hospital and the need of improving data security and data protection.

Moving to the other two points, Prof. Poli stated that we are potentially ready for a quantum leap in Big Data analytics; however, in order to achieve this quantum leap, an improvement in the management of the digitalisation process in healthcare and clear and shared guidelines are needed. He concluded his presentation with a proposal for the establishment of a pan-European standardisation framework for in silico models methodologies applied in personalised medicine.

1.2.3. Technical challenges related to the management of electronic health records – Albert Mercadal Playà

Dr Albert Mercadal Playà, Head of EMEIA Big Data and Analytics Center of Excellence, Fujitsu.

Dr Albert Mercadal Playà introduced three main challenges regarding electronic health records (EHR). The first challenge concerns the limited capabilities which EHR have to help doctors and managers to perform data analysis and to predict future events. The second challenge is related to the difficulty of comparing different groups of patients, and the third regards the difficulties that technologies have when analysing unstructured data such as EHR.

He then presented a solution called Hikari (light in Japanese) provided by Fujitsu, together with other institutions. Hikari allows doctors and managers to investigate the state of a service, hospital, or region, and to make comparison between them. This solution is not intended to change the decisions of the doctors and managers, but rather to provide support

in order to assist them in making better decisions. Hikari is a modular solution and includes health risk analysis assessment models to help doctors in predicting risk behaviours, the length of stay in the hospital, a model that extracts relevant information from the EHR, medical notes and imaging.

Dr Playà listed the strengths of Hikari including the possibility for the doctors to perform advanced search and cohorts' analytics, without the aid of a data specialist. In addition, he mentioned the use of machine learning to predict health risk and future patients' behaviours. A further asset represents a biomedical knowledge graph created by building EHR data from more than 0.6 million patients that can be adapted to different countries; and finally, the capacity to process heterogeneous structured and non-structured data.

He concluded his presentation by showing a case-study that Fujitsu had at the San Carlos Clinical Hospital in Madrid, where they used Hikari to solve three challenges. The first one was about helping Clinical Documentation Specialist in making decisions about the patient treatment and getting reimbursement from the health care providers: in using Hikari, they were able to automatically extract the ICD10 codes from the medical records, speeding up the entire process and allowing the professionals to decide which was the best treatment and the related cost. The second challenge was predicting the risk of mental health illness: with Hikari they were able to achieve an accuracy higher than 75%. The last challenge is ongoing and regards the use of machine learnings to predict the length of stay in the hospital.

1.2.4 European Health Care Systems and the potential for Big Data – Dr Lydia Makaroff

Dr Lydia Makaroff, Director of the European Cancer Patient Coalition.

Dr Lydia Makaroff commenced her presentation providing a definition of the term "innovation" as the translational knowledge and insight to value which was intended as the value to patients, as well as value to society. According to her presentation, all the money invested in innovation should return to the society in terms of value.

Dr Makaroff summarised the situation in Europe: a very slow innovation performance and a strong decline in Europe's comparative advantages in terms of education, research broadband infrastructure and ICT training. She therefore highlighted the main challenge from a European point of view: the choices Europe has to make to perform better innovation.

She changed the subject to science evolution and the opportunities of personalised medicine in terms of treatment at the right time. She continued by pointing out the time-lag of health care systems compared to personalised medicine.

Dr Makaroff then provided two examples of the opportunities that a European Health Care System can provide in terms of Big Data. The first example was the European Reference Network, a network that includes 26 countries and can provide valuable information about rare diseases. The second example was a voluntary joint declaration for linking existing and future genomics databanks that was made by several European countries in order to reach a large cohort of 1 million sequenced genomes. She also focussed on the details of this declaration listing the political commitments for the members.

1.2.5 First round of Questions and Answers

The first round of questions and answers was opened by MEP Mr Peterle.

Q: Mr Peterle (MEP) asked concerning the level of acceptance that "black-box" algorithms has in the community of medical doctors, as they can limit the role of the doctor to just an observer.

A: Prof. Poli answered the question through talking about his personal experience. From his point of view, Big Data is a very good opportunity since it can show things that traditional evidence based medicine cannot, but it needs to be governed. He provided an example, regarding head and neck cancer patient's stratification, in which the best way is combining the two approaches, traditional evidence based medicine and Big Data analytics.

Q: Mr Peterle (MEP): was asked whether in the case of an accident, who would be responsible between the medical doctor and the algorithm.

A: Prof. Poli said that the final responsibility lays always with the physician, since the algorithm is just a tool and the final decision is taken by the physician.

Q: Mr Jerome Boehm from European Commission asked whether the tools developed by Fujitsu could be used for research purposes in order to collect and process data coming from different sources of EHR, not only for helping doctors, but also for improving research.

A: Dr Playà stated that it is completely possible to use the system developed by Fujitsu for researcher purposes. He said that the system is built by researchers themselves and that the system is already being used by researchers. He concluded saying that they are working in what he think is the key challenge for the industry, that is to reduce the difficulties that doctors and researcher have in understanding how they can take advantage from these technologies.

Q: Mr John Wubbe from Digital Health Europe had a question concerning the involvement of the citizen in sharing or giving access to data.

A: Dr Makaroff answered the question stating that is very important that people who are donating their genetic data to research should be always informed of the results. She emphasised that this is the discussion which needs to be held at the GDPR.

Q: Ms Miroslava Karaboycheva from European Parliamentary Research Service (EPRS) had a question regarding the political commitments of the Declaration of Cooperation "Towards access to 1 million Genomes in the EU by 2022". The question concerns what kind of plan has been put in place to achieve the purpose of better health for citizens and future sustainability of health systems.

A: Dr Makaroff answered that these are actually the questions which need to be answered and noted that there are now expert committees that have been set up to answer these questions.

Q: Mr David Mena from Andalusia Public health System (Spain) asked how to solve the problem of consent to the use of data for secondary purposes.

A: Prof. Poli answered the question providing two examples of how informed consent works in Europe. He said that in Italy, the informed consent for a specific study is needed every time the data of patients want to be used, while in the Netherlands, informed consent may also relate to the use of data for more than one study.

A: Dr Playà added that you must always request the patients for their permission regarding the use of their data, and that the main point is how you ask them.

Q: Prof. Boccia from Catholic University of Rome had a question on how Big Data can contribute in the prevention of the disease, taking data not from patients but from healthy people to improve preventive actions.

A: Dr Makaroff noted that one of the great values of EHR is that it is possible to focus on what is happening in the people's life prior to them becoming ill, for example, looking at the environment or at the genetics of the person through EHR in order to identify new risk factors that are possible to be modified or prevented.

Q: Ms Cabezón (MEP) asked about the possibility of patients to have access to the results.

A: Dr Makaroff stated that patients should always be given access to the results of the data. She also said that patients need to be empowered to have more access to the health data results.

1.3. Part 2: The potential use and sources of Big Data in healthcare and their potential challenges

1.3.1 Introduction

Prof. Stefania Boccia, Università Cattolica del Sacro Cuore.

Prof. Boccia opened the second panel “The potential use and sources of Big Data in healthcare and their potential challenges”, indicating that this panel would also be discussed by three different speakers.

She introduced the first presentation that focused on the legal and regulatory aspects, including privacy protection and data sharing policies and was presented by David Supple, who is an expert of data privacy and cyber security and also a broad member of the European association of system medicine.

Prof. Boccia then introduced the second topic that focused on training and education needs in relation to digitalisation and Big Data in health care: she outlined the need of new education and training program for data and system management, as we currently experience a lack in cross-disciplinarily in education and training. The topic was presented by Dr Levente Kiss who is Senior Assistant Professor at the Institute of Physiology of the Semmelweis University of Medicine, Budapest, Hungary.

Lastly, she introduced the third topic that was about the digitalisation in healthcare and the source of Big Data: the topic focused on the main trends of digitalisation in healthcare and the source of Big Data including telemedicine, mobility and cloud access, artificial intelligence and Big Data. The topic was presented by Prof. Jesús Hernández Rivas who is full Professor at the University of Salamanca. He is currently the coordinator of the Harmony project, a large IMI funded project with the aim to facilitate the use of diverse data sources to deliver results that affect health outcomes or treatments.

1.3.2 Legal and regulatory aspects, including privacy protection and data sharing policies – David Supple

Dr David Supple, Expert in GDPR compliance Zissou Projects ltd.

Dr David Supple commenced his speech talking about the General Data Protection Regulation (GDPR) and its applications. GRPR regards different types of data however the most important focus was placed on sensitive data which is the information that needs to be

protected against unwarranted disclosure. In the last 20 years this data has not been used in the interest of the citizens. GRPD provides new regulatory requirements and allows for the identification of organisations which are not doing the right thing, and does not prohibit the use of data for lawful reasons.

Dr Supple then introduced the key health specific challenges around this topic which involve the level of interest that patients have in a healthier nation, the comparison between interest in their own health and national health in general, and to demonstrate the responsible sharing of their data in order to achieve better health outcomes. To achieve these challenges, he focused on the harm that patients can receive when their data is stolen and used for fraudulent purposes and therefore on the necessity of building a system where patients can trust, since there are thousands of data that are regularly violated.

He continued to talk about the citizens' rights and focused on the consent and the main characteristics that consent should have in order to respect citizens' rights. He ended his speech focussing on the difference that GDPR has compared to the Y2K deadline in terms of continuity and evolution: there will be new emerging privacy and security risks and the GRPD requires an ongoing effort.

1.3.3 Training and education – Dr. Levente Kiss

Dr. Levente Kiss, Senior - Assistant Professor, Institute of Physiology, Semmelweis University of Medicine, Budapest, Hungary.

Dr. Levente Kiss introduced his speech talking about the Semmelweis (that is also the name of his University) reflex, that is, "the rejection of the new in favour of the old". In current context, this refers to the rejection of using artificial intelligence, Big Data and digitalisation in the context of teaching.

Dr Kiss therefore focused on the importance to have adequate health care professionals and clinical researchers that are able to use the latest information technologies in the context of education and training. He gave some examples on what digitalisation can provide in the setting of education and training: e-learning and blended learning (mixture between classroom and self-learning using electronic devices), use of eBooks, gamification in order to motivate students in learning.

He also showed some examples of how automated Big Data analysis can lead to better training and education, for example, using automated grading systems in order to analyse the students' performance, give them feedback and help them in their academic performances. He said the teacher's role is a role at risk of automation, although the risk is lower in comparison to the other roles. This automation should not result in a standardisation of teaching and student performance, but should rather consist in an improvement of the output due to the greater amount of data available.

1.3.4 Digitalisation in health care and sources of Big Data – Prof. Jesús M Hernández Rivas

Prof. Jesús M Hernández Rivas, HARMONY Alliance Coordinator, Institute of Biomedical Research of Salamanca.

Prof. Jesús M Hernández Rivas provided a concrete example of a current use of Big Data. He started talking about an initiative, the Innovative Medicines Initiative (IMI) which is the largest public-private partnership in healthcare, with the aim of using EHR for improve outcomes and safety: a project built within the IMI is the Harmony project that focuses on haematological malignancies that he coordinates.

Within the Harmony projects, they are building a high-quality Big Data platform including molecular and clinical data from patients with haematological diseases in a safe and secure environment. Data will be collected from both private and public sector. The goals are to harmonise the outcome measures and the endpoint at the European level, to speed-up the process of drug development and access and to increase the application of omics data in clinical practice. The project includes 53 organizations form 11 European countries and involves all the stakeholders, from patients to universities, hospitals and industries. A platform to ensure data privacy and data protection, as well as anonymisation was established in the context of Big Data approach, allowing the platform to grow without problems.

He concluded stating that with this project, Big Data represents not the future but rather, the present: the opportunities provided by public health systems allows data sharing and data incorporation that can improve the clinical practice, as well as preserve the patient's privacy.

1.3.5 Second round of Questions and Answers

MEP Ms Cabezón opened the second round of questions and answers.

Q: John Wubbe from Digital Health Europe, made a query in relation to GDPR, and whether it is possible to arrange the reliability when there are large amounts of data and, secondly, how to ensure that this data is not going to have an impact on the quality of life of the citizens.

A: Prof. Rivas: responded to this question by outlining how they secure data in the Harmony project. The solution they provided is the anonymisation i.e. they anonymise the patient data before they come to the platform; moreover, nobody can have direct access to the data. He said that data security is ensured 100% and the possibility to identify the patient from the data is very low.

A: Dr Supple: Dr Supple also responded to the question noting that he does not believe in e-secure computer systems. He then pointed out two issues concerning data anonymisation: firstly, anonymised data is not subjected to GDPR; secondly, with anonymised data, the benefits for the patients is lost, as it does not provide the option to inform the patient regarding important discoveries which concern him. He therefore brought attention to the pseudonymisation that could solve the issue concerning the lost benefit for the patient.

1.4 Conclusions by MEP Ms Soledad Cabezòn

MEP Ms Cabezón concluded the workshop.

MEP Ms Cabezón adjourned the workshop by thanking everybody for their contributions and mentioned that the discussion on digitalisation and Big Data will be continued.

ANNEX I: PROGRAMME

Organised by the Policy Department A
Economic & Scientific Policy for the Committee on the Environment, Public Health and Food Safety (ENVI) Working Group Health

Workshop

Digitalisation and Big Data: Implications for the health sector

Tuesday 19 June 2018 from 10.00 to 12.00
European Parliament, Room A3G3 Altiero Spinelli Building, Brussels

AGENDA

Co-Chairs: Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP)

10:00 – 10:10 Opening and welcome by the co-chairs Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP)

Part 1 – The potential use and sources of Big Data in healthcare and their potential challenges

10:10 – 10:15 **Short introduction of Panel 1**
Prof. Stefania Boccia, Università Cattolica del Sacro Cuore

10:15 – 10:25 **Presentation on clinical and cultural challenges ahead for the efficient use of Big Data in healthcare**
Prof. Tito Poli, Maxillofacial Surgery Unit, Università degli Studi di Parma – Azienda Ospedaliero Universitaria di Parma, Parma, Italy

10:25 – 10:35 **Presentation on technical challenges related to the management of electronic health records**
Dr Albert Mercadal Playà, Head of EMEIA Big Data and Analytics Center of Excellence, Fujitsu, Madrid, Spain

10:35 – 10.45 **Presentation European Health Care Systems and the potential for Big Data**
Dr Lydia Makaroff, Director of the European Cancer Patient Coalition

10:45 – 11:00 Questions & Answers Panel 1

Panel 2 – Digitalisation and Big Data in practice: management of legal aspects, training and multidisciplinary partnerships

11:00 - 11:05 **Short introduction of the Panel 2**
Prof. Stefania Boccia, Università Cattolica del Sacro Cuore

11:05 - 11:15 **Presentation on legal and regulatory aspects, including privacy protection and data sharing policies**
Dr David Supple, Expert in GDPR compliance Zissou Projects ltd, London, United Kingdom

11:15 - 11:25 **Presentation on training and education**
Dr. Levente Kiss, Senior assistant professor, Institute of Physiology, Semmelweis University of Medicine, Budapest, Hungary

11:25 - 11:35 **Presentation on digitalisation in health care and sources of Big Data: a multidisciplinary partnership**
Prof. Jesús M Hernández Rivas, HARMONY Alliance Coordinator, Institute of Biomedical Research of Salamanca, Spain

11:35 - 11:50 Questions & Answers session Panel 2

11:50 – 12:00 Conclusions and closing by the co-chairs Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP)

ANNEX II: SHORT BIOGRAPHIES OF EXPERTS

Prof. Tito Poli

Professor Poli completed his graduation (Medicine and Surgery) and post-degree training (Specialisation Maxillofacial surgery) at the University of Parma. He developed a specific interest for oncological research in the head-neck area and, in particular, in the application of sentinel node biopsy technique in oral carcinomas. Since 2008, his research focused on the identification of prognostic and predictive multifactorial signatures for head and neck cancer and patients' stratification. This research led to the exploitation of advanced computing and new data analytics applied to high-throughput data (Big Data) for "in-silico" modelling aimed at personalised medicine.

The quality of the research carried out to date is attested by the funding of 3 consecutive projects by EU ("Neomark-ICT Enabled Prediction of Cancer Recurrence", FP7; "OraMod- VPH based predictive model for oral cancer reoccurrence in the clinical practice", FP7; "BD2Decide- Big Data and models for personalized Head and Neck Cancer Decision support", Horizon 2020), in which Prof. Poli has held the role of Coordinator.

Dr Albert Mercadal Playà

Albert is responsible for the Advanced Analytics practice, as well as the Centre of Excellence (CoE) in Advanced Analytics & Big Data (based in Madrid) at FUJISTU for Europe, Middle East, India and Africa (EMEIA) Region. In his role, he leads several projects around Data Science and Big Data technologies for various sectors & markets (incl. healthcare) as well as transforming Fujitsu's existing portfolio.

Prior to joining Fujitsu in 2017, Albert worked as Chief Operating Officer (COO) for the Big Data Spanish Start-up Synergic Partners which was acquired by Telefonica Company in 2015. He has acquired 7 years' experience working in the field of Big Data, Artificial Intelligence and Analytics. Albert holds a BCs and MSc degree in Civil Engineering from the Polytechnic University of Catalonia, a Master Degree in Strategic Project Management from IE Business School and Global Management Program from IESE Business School.

Dr Lydia Makaroff

Dr Lydia Makaroff is the Director of the European Cancer Patient Coalition. She has over ten years' international experience in non-communicable disease research and policy development in academia, the pharmaceutical industry, and the non-profit sector. She conducted medical research during her PhD at the Australian National University and as a senior post-doctoral fellow at the University of Washington.

After working in Global Market Access at a pharmaceutical company, she joined the International Diabetes Federation as their Epidemiology and Public Health Manager. She has experience quantifying the impact of non-communicable diseases, monitoring national governments' commitments to health, providing tools to Member Organisations, writing policy papers, and working with the European Institutions to advocate for change.

Dr David Supple

Dr David Supple is an independent data privacy and cyber-security subject matter expert, a Board member of the European Association of Systems Medicine (EASyM) and a Scientific Advisory Board member for ERACoSysMed.

Dr David Supple predominantly works with global financial services companies in areas of evolving risks across IT, Information, Privacy, Cyber and Resilience. David has recently delivered a programme in order to meet the requirements of GDPR for a major transatlantic banking services organisation. His notable appointments also include the Financial Services Compensation Scheme (FSCS) where he was employed as Director of Information Management, Information Security (CISO) and the Data Protection Officer (DPO)

In addition to being a Board member of EASyM for three years, David was the Chair of patients for U-BIOPRED for 6 years, as well as being involved in a wider range of health charity and research initiatives. A speaker at multiple congresses of the European Respiratory Society, David has also just joined the steering committee leading an NIHR funded research project on implementing supported asthma self-management in routine clinical care. David has also been a long-term judge in the PENNA UK Patient Experience Awards.

Dr. Levente Kiss

Levente Kiss is a senior assistant professor at the Department of Physiology at Semmelweis University, Budapest, Hungary. His research interests are mainly focused around the role of gasotransmitters in cardiovascular physiology and pathophysiology with particular attention to hydrogen sulfide. His work has received approx. 1300 citations with an h index of 13. Along with research activities he has a keen interest in improving medical education at Semmelwes and in Hungary. He has been involved in teaching physiology to Hungarian and foreign medical, dental and pharmacy students since 2004 and he is a member of the Hungarian Society of Medical Education and Health Science since 2011. Aside of his duties at the Department of Physiology, he is the appointed director of the Teaching Centre of Semmelweis University.

Prof. Jesús M Hernández Rivas

Professor Jesús María Hernández Rivas is Full Professor in the Department of Medicine of the University of Salamanca and senior staff member of the Dept. of Haematology at the University Hospital in Salamanca. He leads the Research group of Molecular Cytogenetics at the Instituto de Estudios de Ciencias de la Salud de Castilla y León- Instituto de Investigación Biomédica de Salamanca (IECSCYL-IBSAL). Moreover, he heads the Molecular Cytogenetics Unit (MCU) at the Cancer Research Centre (University of Salamanca). MCU is a facility devoted to the molecular cytogenetics and next generation sequencing of cancer patients. More than 100 hospitals in Spain, and occasionally others from the EU, have used the MCU services. He is currently the project coordinator of the HARMONY project, a large IMI2 funded project, which aims to facilitate the use of diverse data sources to deliver results that reflect health outcomes of treatments that are meaningful for patients, clinicians, regulators, researchers, healthcare decision-makers, and others.

This report summarises the presentations and discussions of the Workshop on "Digitalisation and Big Data: implications for the health sector", held on 19 June 2018 at the European Parliament. The aims of the workshop were to analyse the implications of digitalisation and Big Data for the health sector. The workshop was hosted by Ms Soledad Cabezón Ruiz (MEP) and Mr Alojz Peterle (MEP).

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