BIOS POLICY BRIEF

How to protect privacy needs when it comes to our genomic data?

07/2019

Highlights

The Joint Action Health Workforce Planning and Forecasting (JA EUHWF) identifies Genomics and precision medicine (Mirnezami et al, 2012) as one of the main drivers shaping health care services for the future, and correspondingly suggests that detailed genetic assessment and treatment skills will be highly important for the workforces involved in assessment, diagnosis and treatment (Fellows and Edwards, 2016).

This policy brief explores the developments in the field of Genomics and Precision Medicine and especially discusses the difficulty of balancing the needs of privacy against the needs of scientific data availability.

Evidence

As it has been noted, "intricate analyses of a patient's genomic data are destined to become an integral part of routine medical practice" (Brazas et al, 2014). In clinical practice, Big Data will improve outcomes for individual patients through personalization of predictions, earlier diagnosis, better treatments, and improved decision support for clinicians in cyclic processes, as well as the development of innovative business models in the field (EC, 2012, 2014).

Despite these projections and early demonstrations of clinical utility, broad translation of genomic medicine into the clinical setting has not yet been seen.

Challenges

The potential of "Big Data" for improving health is enormous, yet at the same time the EU has a wide range of challenges to overcome urgently. Europe is very proud of its cultural diversity; however, exploitation of the data made available through advances in genomic medicine, imaging, and a wide range of mobile health applications or connected devices is hampered by numerous historical, technical, legal, and political barriers. European health systems and databases are diverse and fragmented. There is a lack of harmonization of data formats, processing, analysis, and data transfer, which leads to incompatibilities and lost opportunities. Legal frameworks for data sharing are evolving. Clinicians, researchers, and citizens need improved methods, tools, and training to generate, analyse, and query data effectively. Addressing these barriers will contribute to creating the European Single Market for

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health, which will improve health and healthcare for all Europeans.

Management of medical databases with genomic information

Electronic medical records in some hospitals now hold genomic data for many patients; a massive amount of information that unleashed the potential for targeted research and eases the discovery of key variants, associated with disease or drug treatment, just by delving into the already acquired data. However, health-relevant genetic variants could sometimes become the backdoor to disclose sensitive "private" information.

Numerous databases now exist to curate genomic data derived from clinical trials and other studies. Clinical and scientific use of genomic data is empowered by rendering more of such data publicly accessible and searchable, but in doing so, certain protections for the subjects who have donated their data must be in place. Primarily, this means de-identifying the data, using double blind references so that names and other identifying information about the data is decoupled from the data itself. Recent studies have shown that despite efforts to de-identify data in public genomic databases, researchers could use software to effectively re-identify DNA from those databases.

Balancing the needs of privacy against the needs of scientific availability will become increasingly important as the actual uses of genomic data grow, and relations between genes and phenotypes become better understood. Political responses to concerns about genomic privacy and the misuse of genomic data include the "GINA" Act in the US as well as changes in EU privacy laws. Some of these responses may make it harder to use genomic data for research. A preferable way to move forward would be to design better systems from the ground up, ones that allow ease of use for science and industry, while at the same time warrant greater protections for human subjects.

Currently, genomic data is mainly stored in clouds or in onsite servers where the ability to track who has access to this data, who modifies it and what the data is used for is very limited or sensitive to being hacked. Furthermore, these solutions do not allow easy sharing of the information and have a high cost in infrastructure and maintenance.

Policy Recommendations

The benefits of applying bioinformatics for precision medicine are undisputed, so efforts to expedite these advancements are pressingly needed.

However, with the technological developments for using genomic data, the need of protecting privacy rights emerge.

Ethical and policy considerations of information access, ownership, privacy, and intellectual property need to be regulated, balancing the need for the individual to provide consent for the way in which his/her data is utilized with the need for society to gather and integrate large amounts of data to innovate and serve Personalised Medicine.

It is advisable to make use of cutting-edge technologies, such as block-chain technology to create:

a) secure databases for use in both personal genomics and large-scale science, impenetrable to malicious hacking or other unauthorized uses

b) a global-level infrastructure with supercomputer level computing power for the analysis, visualization and interpretation of genomics data.

Furthermore, legal frameworks for data sharing are evolving. Clinicians, researchers, and citizens need improved methods, tools,

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and training to generate, analyse, and query data effectively. Addressing these barriers will contribute to creating the European Single Market for health, which will improve health and healthcare for all Europeans.

One of the biggest challenges, identified by existing research, is the availability of healthcare professionals that are able to use the latest information technologies developed in the Big Data analytics era (Rozman et al, 2016). Thus, the real challenge is the education of healthcare professionals: healthcare practitioners require the ability to interpret genomic data and make evidence-based decisions from this data.

BioS Project

The BioS: Digital Skills on Computational Biology Project approved in the European Framework of Erasmus+ / Sector Skills Alliances Programme responds to the aforementioned challenges. It aims at advancing the digital skills of European medical doctors through the design, development and delivery of new modular vocational curricula on Computational Biology, as well as transversal skills, straightforwardly responding to the skills needs identified by existing research evidence.

Drawing on the evidence regarding skills needs, the BioS Sector Skills Alliance implements the design and delivery of transnational vocational training content, as well as teaching and training methodologies for the European professional core profile of Medical Doctors, aiming to upgrade their transversal skills as well as their occupation-specific skills in Medical chemistry (biomedical analysis), Medical statistics, Medical interpretation, and Clinical genetics by introducing them to the use of Computational Biology for clinical applications.

The purpose is to provide medical doctors with knowledge, skills and competencies, which will allow them to tackle effectively concurrent challenges in EU healthcare systems, services, and policies, in benefit of the health of EU citizens.

In order to achieve this, the BioS project:

- develops innovative modular curricula that integrate latest advancements in Computational Biology for the Healthcare sector that can be immediately applied by medical doctors in clinical context;
- develops a virtual learning environment aiming to bring together medical doctors, bioinformatic experts, educators and researchers, as well as policymakers across Europe. On this platform, users can exchange experiences and follow virtual lessons;
- delivers BioS training program as a Virtual Open Online Course underpinned by EQAVET;
- provides participants with interactive experience through work-based learning periods.

The Bios training course includes 4 modules, namely: 1) Introduction to Bioinformatics, 2) Computational Statistics for clinical doctors, 3) Commercial personalized genomics services in patient care, 4) Quality Improvement in Healthcare.

The BioS project will reach out directly to approximately 800 medical doctors from 8 EU countries and beyond. The participating end-users represent more than 10.000 healthcare professionals. Additionally, BioS influences other associate partners and stakeholders incl. educational institutions, managers and policy makers from EU countries. The approach is to “train the trainer”, creating a multiplier effect. The virtual learning platform and the educational resources will be available in 8 EU languages (EN, GR, PT, IT, ES, DE, FR, FI) to maximize the pool of possible users.

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The BioS Training Course will start in autumn 2019. The project's current effort focusses on attracting suitable candidates to participate and benefit from the innovative course.

For more information on the BioS Project, please visit our website.

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BioS at a glance

Project Name:
BioS: Digital Skills on Computational Biology

Consortium: Steinbeis University Berlin (SHB), Enios Applications Idiotiki Kefalaiouchiki Etaireia (e-NIOS), OLYMPIC TRAINING AND CONSULTING LTD (OT), Skybridge Partners, Bioinformatics Barcelona Association (BIB), University of Patras (UPAT), European Medical Association (EMA), European Recreation and Health Valley (EUREHVA), BG Klinikum Murnau gGmbH (BGU Murnau), FOR SRL, HiDucator Ltd, EPRALIMA_Vocational School of Alto Lima, C.I.P.R.L. (EPRALIMA), German Oncology Centre (GOC)

Duration: 01.01.2018 – 31.12.2020

Funding Source: EACEA, Erasmus+ / Sector Skills Alliances Programme

Website: https://www.bios-project.eu/