international risk governance council

WORKSHOP REPORT

COLLECTION, ACCESS AND USE OF HUMAN GENETIC INFORMATION FOR PRECISION MEDICINES: RISK GOVERNANCE CONSIDERATIONS

Tsinghua University School of Public Policy and Management, Beijing, China
28 – 29 August 2015

Workshop on the collection, access and use of human genetic information for precision medicines: Risk governance considerations

Hosted by Tsinghua University School of Public Policy and Management, Beijing, on 28-29 August 2015

The highlights from the workshop presented in this document represent a summary of some of the considerations discussed at the workshop. Participants were not asked to endorse the content of this report. The responsibility for the final content of this report rests with the International Risk Governance Council.

Background

Precision medicine is an emerging field for disease diagnostic, prevention and treatment, which takes into account individual variability in genes, environment and lifestyle. The sequencing and analysis of individual genomes will become a commodity, paving the way to precision (data-driven) medicine to become a major industry in the future, particularly as the health-maintenance industry increasingly engages in an anti-aging agenda. Precision medicine can identify predisposing genes and risk factors (diagnostic), tailor prevention program (life style, nutrition, drugs), continuously record various bio-parameters by integrated biosensors (watches, glasses, contact lenses, clothes…), and ultimately improve therapeutic treatment (curation), including gene therapies, and regenerative and reproductive medicine. Expectations for precision medicine are high, and industry is embarking massively on this route, together with governmental programmes such as in the US[1], China[2] or the UK[3].

Workshop highlights

On 28-29 August 2015, the School of Public Policy and Management at Tsinghua University, the Program on Emerging Technologies at the Massachusetts Institute of Technology (MIT), the Swiss Federal Institute of Technology (EPFL), and the International Risk Governance Council (IRGC) organised a workshop on the ownership, collection and use of genetic information for precision medicine. The workshop was attended by experts from Europe, the US, China, India and Singapore. A list of participants, the agenda and background readings can be found in appendix.

The workshop aimed to identify broad opportunities in the field of medical applications of genetic research, and associated challenges ranking from scientific and medical uncertainties to challenges to existing business models. Were central in the discussions: **issues of data ownership, collection and use, and the need to establish and develop trust between industry, regulators, public authorities and patients, including for the purpose of sharing relevant and accurate data.**

Gene technologies and their application by industry are developing rapidly, particularly in the US and in China. Yet, *governance* of the new field of genomic for precision medicine is developing more slowly and needs to catch up. The rapid developments in science and technology but also in how cultures and values consider questions of ethics, privacy and data protection, pose challenges to regulators and policymakers. There is no universal understanding of what can be done, what should be allowed, what should be prohibited and what should be protected and shared, beyond general principles[4].

Learnings from the development of internet can be useful in that respect. Analogies between both fields include that: security issues face the challenge of risk internalization, privacy appears to be an essentially contested concept (it is a social construct, a surrogate for other values), and data governance involves both operational and legal options. However, internet is de facto a collaborative endeavor, whereas genetic research and application to precision medicine is not (yet) a field of collaborative work. Rather, the fragmentation of research and industry development is still dominated by questions around issues of Intellectual Property and Patents, and often marked by secrecy. This is reinforced by some national (e.g. China) or regional (e.g. EC) regulations that prevent or restrict sharing of data with other countries. Considering that improvements in precision medicine require very large sets of data of various nature (genetic, health and lifestyle), scientists recommend that

[1] The US **Precision Medicine Initiative**, launched in January 2015 and spearheaded by the National Institutes of Health will involve collection of data on genomes, electronic health records, and physiological measurements from 1 million participants. Update on implementation plans (September 2015) can be found in the "Precision Medicine Initiative (PMI) Working Group Report to the Advisory Committee to the Director, NIH", available online here: http://acd.od.nih.gov/reports/DRAFT-PMI-WG-Report-9-11-2015-508.pdf
Need to add other US important actors and projects?

[2] Large scale multi-disciplinary research will begin in 2016 in China, to support dedicated policies for precision medicine. It is expected that codes of conduct for research trials and involvement of industry will be addressed in these policies.

[3] The UK 10K Genomes initiative (http://www.uk10k.org/)

[4] Such as those of the «Framework for responsible sharing of genomic and health-related data by the «Global Alliance For Genomic And Health» or also the Universal Declaration of Human Genome and Human Rights (UNESCO 1998)

governance regimes allow and encourage the constitution of large data banks (biobanks), for which appropriate governance regimes need to be developed[5]. The question for policymakers, regulators and industry should thus be: how to make this possible (and even encouraged) while preventing misuse (with the term "misuse" to be defined).

This note highlights some key issues and then provides a quick review of opportunities and benefits, risks and uncertainties and governance considerations.

SCIENTIFIC AND TECHNICAL LANDSCAPE

Advances in foundational technologies	Applications to health and medicine
• DNA sequencing – Generating genomic data • Information technology – storing, moving, analysing genomic data • DNA synthesis – building genes • Tools and methods – combining, editing, repurposing genes	• Drug synthesis – Artimisen, opiates … and novel variants on existing drugs • Modifying disease vectors – gene drives... mosquitos, ticks • HUMAN PRECISION MEDICINE › 1.0 Target conventional drugs on genetically defined treatment groups › 2.0 Regenerative medicine – Rejuvenate, replace, regenerate damaged tissue › 3.1 Somatic cell gene therapy (SCGT) – Non-heritable alterations › 3.2 Germline gene therapy (GGT) – Heritable alterations

1. Key issues to be addressed in the development of precision medicine

- **Precision medicine is on its way. It will happen, whatever regulation is put in place to constrain it**. It must be encouraged for the benefits it can bring to both personal (individual) and public health. There should be no conflict between investing in better health with the individual as a target and investing in improving global health in the world. To meet this goal, development of precision medicine must be "governed", and the public needs to engage with it.
- **Precision medicine will succeed if the objectives and concerns of all affected and other important actors are taken into consideration**. What does industry want? What do governments and regulators want? What do medical doctors want? What do patients want? At the same time, current innovations in precision medicine will most probably cause a paradigm shift in health care and powerful actors will emerge and must be identified.
- **The dominant global governance issues in the policy agenda-setting process is not defined by a single player but by powerful actors with established objectives and concerns** that structure the governance debate. For example, the scientific community is currently driven and/or concerned by data access, government and society are motivated by data privacy and security, ELSi committees, by ethical issues, and government/industry, by economic opportunities. We are now in a critical juncture, and it is therefore important to identify the key actors who may take leadership roles and set up the governance agenda[6].
- **Understanding risks and opportunities and their governance options.** We need to identify and share as broadly as possible with the public and patients, with policymakers and regulators, and with industry, what are the main opportunities and benefits, what are the main risks and uncertainties and what are

[5] See large biobanks projects in the US and China mentioned above. For Europe, see the BBMRI-ERIC European-wide biobank network http://bbmri-eric.eu/

[6] See Hanzhi Yu's presentation, about governance

the possible governance options for encouraging research and application while mitigating the risks and resolving the trade-offs (between opportunities and risks and between risk). *Transparency* is needed to establish trust[7], in a field that affect people in their most personal matter.

- **Regulation is the cornerstone in this endeavor.** Regulation is needed to balance privacy and sharing, and this may vary in different contexts, to account for regional and cultural specificities.[8] Work is needed to define the scope and specificities of relevant legislations, but with three clear principles. First, regulation must be developed at the national level, with disposition for international collaboration. Second, it must be co-developed with industry, patients and payers. Third, it must also be flexible to allow adaptation to new knowledge and changing values and perceptions, at least until we have reached a certain level of assurance and trust. New regulations will have to be developed and deal with questions of genetic data ownership, data collection in biobanks, and use of data.
- **Privacy and data protection are central to the creation of trust, to facilitate collaboration between actors and between countries**. The question of IP remains open, for genomic diagnostic tools in particular. For example recent cases in the US may indicate that the legislator is revising its appreciation of the pros and cons of IP protection for genomic technologies.

2. Opportunities and benefits

Such "smart medicine" will bring the benefit of scientific advances to the right person at the right time. It will reduce ineffective treatments and their associated costs, when traditional medicine proceeds by "trials and errors". Performance and cost effectiveness will improve for:

- diagnostic: to diagnose genetic predisposition and help prediction
- prevention: to focus monitoring on those individuals that have a reasonable chance of developing certain health conditions
- curation: to target therapies to how each patient will respond to it

Scientific and technological advancements set the scene for improvements in the development of effective **gene therapies**, which are better targeted than conventional therapies. **Regenerative therapies** can help face the economic challenge that degenerative diseases and aging pose to society.

These opportunities can be seized if society can favorably regulate biobanking, since precision medicine is based on knowledge collected from large data sets, organised in biobanks. As acknowledged by the major US, European and Chinese biobank projects, biobanks must include both genomic data, health records (patients' medical data) and other data related to lifestyle and the environment. Medical use of none medical data is one regulatory challenge; "blank check" consent for use of tissues from biobank is another uncharted legal and social territory, with important cultural differences across countries.

[7] "Public trust is required for the proper functioning of government, and governments must be held to a higher standard for the collection and use of personal data than private actors." Big Data: Seizing Opportunities, Preserving Values, Executive Office of the President, US White House, May 2014

[8] For an overview of "How privacy law affects medical and scientific research", see: http://www.genomicslawreport.com/index.php/2015/09/01/how-privacy-law-affects-medical-and-scientific-research/

3. Risks and uncertainties

Those can be related to (a) personal health, (b) conventional public health systems and (c) inappropriate regulation.

(a) Risks to personal health and individuals

Like for any therapeutic treatments, and as enforced by public health authorities worldwide, treatments from precision medicine must be authorized (licensed) on the basis of their safety, efficacy, lack of negative side effects and cost efficiency. Personalized medicine will probably cause a change in traditional cohort-based clinical trials and shift to adverse-effect monitoring patient by patient ("cohort of one").

Other risks include uncertainty about how individuals react physically, emotionally and mentally when they are informed about their own personal genomic characteristics. Information and education of medical personnel, patients and policymakers alike is much needed. The lack of appropriate education about both genomics and personal medicine, and how to communicate to non-experts, is recognized as a major barrier to evidence-based decisions. In particular, medical genetic counseling has to include probabilities and risk communication, in order to avoid unintended consequences, for example for patients' relatives.

Major uncertainties to individual health are related to safety and the uncertainty of long term consequences, especially when specific genetic traits may be modified for the purpose of obtaining a better or preferred state over certain factors. In the case of germline modification[9] (which is legally forbidden in probably all countries, but may be explored by some researchers), it is impossible to predict the long term consequences.

There is a risk that, in countries where regulation and governance are lagging behind the technology, private sector companies that have sequencing capacity will sell on the market analyses that are not validated for clinical or personal use, yet are authorized by their government. The lack of knowledgeable and powerful panels of scientists and clinicians is a risk that must be addressed. In the extreme case, rogue research, industry or even governments might try what ethicists would describe as "worst-case scenarios", where human enhancement is manipulated in the pursuit of private objectives, self-interest or even eugenism.

(b) Risks to public health systems

Current public health systems are facing "business risks" and will probably have to "adapt or fail". They are somehow affected by public policy declarations that the future is in precision medicine, before having been given time to think how their regulations for authorization, licensing and cost reimbursement can be adapted or revised. The risk of discrimination in access to health care has to be solved.

(c) Inappropriate regulation

The lack of policies and standards, and appropriate ethical legal frameworks is a risk to the development of precision medicine. Public health authorities must be aware that, whatever they decide, industry will develop precision medicine and sell it to patients in needs. Both a lack of- and too strict regulation may deliberately or unintentionally affect negatively patients, industry and society. The risk of over-reaction by a regulatory authority must be avoided. Key points in regulation will be: genomic data ownership, data protection for privacy purposes and data sharing for research purposes, rules and processes for anonymization. Biobanks are at the center of the regulation.

[9] Germline modification involves using genome-editing tools to modify the DNA of human embryos in such a way that the new genetic material is always passed to the progeny.

4. Governance considerations

The advent of precision medicine creates a fundamental transformation of the paradigm of clinical medicine.

Because the field is evolving rapidly, the first consideration is the need to fully **embrace change** (that is: what is being done today and what could be done tomorrow), together with the need to **balance innovation and risk management**.

Beyond that, important questions include:

(a) How to engage with and educate individual and collective decision makers to make good decisions?

The lack of scientific literacy of ethics and regulatory committees need to be fulfilled before final decisions are made about what is allowed. Education in genomics and precision medicine will help people get a sound understanding of the science, to differentiate what is hype and what is good science. The decision making process needs to analyse separately health opportunities and risks from ethical and moral considerations. It will also be useful that education and dialogue help define human enhancement in comparison to "standard" medicine, and thus whether human enhancement should be subject to the same regulation as health.

(b) Who owns the data and their interpretation?

Who owns genomic data: the individual, his family, a public health authority, or the company that performs a test? Who owns the analysis of aggregated data and their interpretation?

Related to this issue is the need to develop international guidelines for benefit sharing with developing countries, as was done in other fields. People in developing countries must also benefit from and access to precision medicine.

(c) How to balance privacy and confidentiality with the need for data sharing?

The question of the right balance between individual rights/health and public concerns/health is highly sensitive and its resolution will be determinant for the future of precision medicine, specifically in national policies and regulations. Decisions about how genetic information may be collected, stored and used, and by whom, will determine how both medicine and research will be able to benefit from the digitalization of health-related data.

Regulators, industry and patients can work together to establish a clear link between personal and public health benefits. If some individuals benefit from early precision medicine, they also, at the same time, contribute to enriching the data bases that are needed to develop precision medicine on a larger scale. The collection and sharing of personal data benefit the whole, which in turns contributes to better individual treatments. Although the debate is ongoing US public opinion on data sharing may be shifting toward openness[10].Sensible plans for data sharing must be encouraged, while guaranteeing stringent privacy protection safeguards, and clear bans to use information against the will of an individual.

There is ongoing discussion about the value and practicalities of subject informed consent and data anonymization in the era of genomic medicine, *where individual informed consent impacts relatives, and where data anonymization is not absolute*.

(d) How to react to obvious and dangerous misuse of data?

In order to develop the necessary trust, there must be criminal penalties for misuse of data[11] .Regulatory authorities should have emergency regulations in place for dealing with serious misuse of data and in general misbehavior on the part of any actor, with regards to fair, ethical and acceptable behaviour. These are similar to contingency planning for crisis management. They are needed to create trust between industry, governments and society.

[10] http://www.nature.com/news/giant-study-poses-dna-data-sharing-dilemma-1.18275
[11] Nuffield Council on Bioethics

(e) How to implement adaptive governance of ownership, collection and use of human genetic information for the purpose of developing precision medicine?

The current development of precision medicine strongly suggests that adaptive governance and regulation will be needed. So called "Adaptive Regulation" addresses the following questions:

- How to make laws today that will be valid in the future, considering for example evolving views about privacy?
- How can the design of policies and regulations accommodate the necessary flexibility, in a way that does not induce too much uncertainty to research, industry and society?
- What are the legal options that are robust to technological change and foster innovation?

5. Recommendation: Adaptive Regulation

Adaptive Regulation is a form of regulation that integrates several elements: determination of an objective and expected achievement, monitoring, planned regular review to provide feedback, adaptation of the regulation to improve performance with regard to the initial objective. This provides the necessary flexibility to adapt to changing scientific knowledge, new technology, changing context conditions including changes in social values and perception of risks and opportunities. This also provides a planning, in order to address the risk of regulatory uncertainty.

Getting regulators comfortable with an adaptive framework with built-in reviews and willingness to be wrong and change course enables to reconcile innovation and risk management.

In the case of precision medicine, the following elements could be included in the monitoring, because they will determine how efficacy, safety and cost-efficiency of precision medicine can be improved and thus encouraged by regulatory bodies:

- Linking genetic data and medical records: what progress is made in how genomic data is aligned with phenotypic data and medical records? How does this generate improvements in therapies?
- Performance and efficacy: How does the efficacy compare with conventional medicine?
- Surveillance of industry and research malpractices, misuse of data: does the number of cases reported to health and regulatory authorities increase or decrease?
- Surveillance of discriminative access to precision medicine (equal access to health), benefit sharing and other principles: Does the number of patients treated with gene therapies increase? Algorithms are increasingly used to make eligibility decisions. Those must be carefully monitored for potential discriminatory outcomes for disadvantaged groups[12].
- Progress towards accountable systems: are automated and continuous auditing systems in place, that are able to detect violations of privacy policies and to punish violators improving? [13]
- In the licencing process, elements that can be adaptive include: the treatment eligible population, the level of constraint on prescribing, the tightness of surveillance, and the price.

We propose that these recommendations are refined and compared with those of established authorities and report such as the Nuffield Council on Bioethics, the Global Alliance for Genomics and Health, or the US Precision Medicine Initiative.

[12] Big Data: Seizing Opportunities, Preserving Values, Executive Office of the President, US White House, May 2014
[13] See note 12, page 42

Appendix: workshop agenda, references and panelists

OWNERSHIP, COLLECTION AND USE OF GENETIC INFORMATION FOR PRECISION MEDICINE

A workshop jointly organised by Tsinghua University,

Massachusetts Institute of Technology (MIT), Swiss Federal Institute of Technology (EPFL), and International Risk Governance Council (IRGC)

with support from Center for Industrial Development and Environmental Governance(CIDEG), Tsinghua University

28-29 August 2015, Tsinghua University, Beijing, P.R. China

PREMISES AND GOALS

In the context of the tremendous enthusiasm for precision medicine in China and elsewhere, the organisers of the workshop wish to discuss governance and regulatory issues related to the development of precision medicine in the world. Are there gaps between research, policy initiatives, regulation and practice that require attention from policymakers and regulators? Can innovative, effective and realistic governance recommendations be developed?

This workshop will thus discuss adaptive risk management in precision medicines with emphasis on issues associated with the collection and uses of genetic data for medical purposes.

- Applications treated will include variants of precision medicine, from targeting traditional therapeutics on genetically defined treatment groups to revolutionary gene therapies and regenerative medicines.
- Effective access to and utilization of genotypic data, in combination with phenotypic data and health records, is central to the development of all variants of precision medicine. Yet problems of data access and analysis are too often treated in isolation from drug development, licensing and use.
- This workshop will bring together developers of precision medicines, experts on the regulation of benefits and risks of pharmaceuticals, and specialists in intellectual property rights, patient consent, and cybersecurity and data protection.

The workshop is directed at the following goals:

- **Goal 1**: To identify risk governance and regulatory issues in the development of precision medicines, with attention to the role of genomic data in providing evidence on the safety, efficacy and effectiveness of novel therapeutics under conditions of uncertainty.
- **Goal 2**: To describe and assess commonalities and differences in how China, India, the US and Europe have regulated precision medicines and managed access and use of genomic data, in the context of the high priority assigned to development of precision medicines by China, India and OECD nations.
- **Goal 3**: To identify potential national and international policy initiatives and to specify associated academic research agendas with the end of fostering more effective adaptive regulation of benefits and risks of precision medicines and genomic data access and use.

AGENDA

Chair: Prof. XUE Lan

WELCOME, INTRODUCTIONS AND OVERVIEW

9:00-9:30 FRIDAY 28 AUGUST

- XUE Lan, School of Policy and Management, Tsinghua University
- Kenneth OYE, Center for Biomedical Innovation and Program on Emerging Technologies, MIT
- Gerard ESCHER, EPFL
- Marie-Valentine FLORIN, IRGC

SESSION 1: SCIENTIFIC AND TECHNICAL LANDSCAPE

9:30-12:00 FRIDAY 28 AUGUST

Goal: To identify risk and benefit governance issues in the development of precision medicines, with attention to the role of genomic data in providing evidence on the safety, efficacy and effectiveness of novel therapeutics under conditions of uncertainty.

Themes and Questions: This session will provide a technical foundation for discussion of variants of precision medicines and genomic data, with attention to the current state of the art and to future developments.

- What is the current state of the art of precision targeting of conventional therapeutics, of gene therapies and of regenerative medicines?
- How is genomic data currently being collected, curated, stored and analysed for drug development and regulatory purposes?
- How is genomic data currently being aligned with phenotypic data and medical records for these purposes?
- Over the next decade, how will the state of the art on precision medicines, including gene therapies and regenerative medicines be likely to change?
- How will economic and business incentives for data collection and management and the development of precision medicines change?
- How do answers to the questions above differ for China, India, the US and the EU?

Panelists:

- Jacques FELLAY, EPFL School of Life Sciences and Swiss Institute of Bioinformatics
- Jeremy LIM, Oliver Wyman, Singapore
- Kenneth A. OYE, Center for Biomedical Innovation and Program on Emerging Technologies, MIT
- Saturn Tian, Geneis BioTech
- Bart C. WEIMER, Population Health and Reproduction, University of California Davis, BGI @ UC Davis
- ZENG Changqing, Laboratory of Genomic & Precision Medicine, Chinese Academy of Sciences

SESSION 2: ECONOMIC AND REGULATORY LANDSCAPE

13:00-16:00 FRIDAY 28 AUGUST

Session chair: Kenneth OYE, Center for Biomedical Innovation and Program on Emerging Technologies, MIT

Goal: To describe and assess commonalities and differences in how China, India, the US and Europe have regulated precision medicines and access to and use of genomic data, in the context of the role of development of precision medicines as a strategic priority within China, India and OECD nations.

Themes and Questions: This session will review legislative principles, regulatory frameworks and informal norms that affect the development of precision medicines and the collection, access and use of human genetic information. Briefings and discussion will focus on Chinese, Indian, US and EU differences and similarities on:

Part 1 Licensing and Ethical Issues

- Regulatory frameworks for licensing of precision medicines, gene therapies and regenerative medicines
- Formal rules and informal norms governing subject consent to uses of data
- Ethical challenges to human germline modification and other applications

Panelists:

- DONG Xiao (Marissa), Jun He Law Office
- GUO Zhaozhen, BGI-IRB
- Krishna RAVI SRINIVAS, Research Information System (RIS) for Developing Countries, New Delhi
- LI Yingjie, Zhongyou Biotechnology Institute
- Sirpa SOINI, National Institute for Health and Welfare, Helsinki
- ZENG Xiaofan, BGI-IRB

Part 2 Access and Utilization of human genetic data

- Data standardization and curation
- Intellectual property rights and data ownership
- Data protection, privacy and security

Panelists:

- Arti RAI, Duke University School of Law
- Daniel WEITZNER, CSAIL Decentralized Information Group, MIT
- QI Ming, School of Medicine and Watson genomics institute, Zhejiang University
- YU Hanzhi, School of Public Policy and Management, Tsinghua University

SESSION 3: FUTURE POLICY INITIATIVES AND RESEARCH NEEDS

09:00-12:00 SATURDAY 29 AUGUST

Goal: To identify emerging short falls in potential national and international policy initiatives and to specify associated academic research agendas, with the end of fostering more effective adaptive regulation of benefits and risks of precision medicines and genomic data access and use.

Themes and Questions: This session will focus on assessing the implications of regulatory differences and on recommending regulatory reforms and research agendas.

- How will existing cross-national and interregional differences in the regulation of precision medicines and in the regulation of access to and uses of genetic information affect the location and pace of development of precision medicines? Are the rules of the game transparent to researchers, industry and patients?
- Are regulatory differences likely to persist or converge? Will differences provide distinct national competitive advantages? Conversely, will differences limit data sharing and collaboration to the detriment of technical advance? Are there common principles for regulation of genomic data and precision medicines that could serve as a core for international cooperation?
- How might planned adaptive regulations be designed to deal with changing scientific developments, evolving understandings of risks and benefits, and shifting norms/values on appropriate uses of genomic data and applications of precision medicines? What provisions for regulatory revision may be identified? What research priorities might be identified to reduce critical policy relevant sources of uncertainty? What sources of support for and opposition to an adaptive regulatory approach may be anticipated?

Panelists:

- CHEN Tao, Thermo-Fisher Scientific China
- David GU, Shanghai Quanment High Tec Company
- Gerard ESCHER, EPFL Lausanne
- Kenneth OYE, Center for Biomedical Innovation and Program on Emerging Technologies, MIT
- Kevin WALMSLEY, GU David, Shanghai Quanment High Tec Company
- QI Ming, School of Medicine and Watson genomics institute, Zhejiang University
- XUE Lan, School of Policy and Management, Tsinghua University
- ZENG Changqing, Laboratory of Genomic & Precision Medicine, Chinese Academy of Sciences

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International Risk Governance Council

International Risk Governance Council
c/o École Polytechnique Fédérale de Lausanne (EPFL)
CM 1 517
Case Postale 99
CH-1015 Lausanne
Switzerland

Tel +41 21 693 82 90
info@irgc.org

www.irgc.org