European Commission

OPINION NO. 29 OF THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES

The ethical implications of new health technologies and citizen participation

Brussels, 13 October 2015

European Group on
Ethics in Science and
New Technologies
to the European Commission

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Jim Dratwa
Chief Editor

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Opinion No

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OPINION OF THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES TO THE EUROPEAN COMMISSION

The ethical implications of new health technologies and citizen participation No **29** 13/10/2015

Reference: *Request from the President of the European Commission*
Rapporteurs: *Andrzej Górski, Ritva Halila, Laura Palazzani and Marie-Jo Thiel*

THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (EGE),

Having regard to the Treaty on European Union, and in particular Article 6 of the common provisions concerning respect for fundamental rights and Article 11 providing for citizen participation,

Having regard to the Treaty on the functioning of the European Union, and in particular Article 16 concerning the right to the protection of personal data, Article 168 concerning public health, and Article 169 concerning consumer protection,

Having regard to the Charter of Fundamental Rights of the European Union, and in particular Article 1 (Human dignity), Article 3 (Right to the integrity of the person), Article 7 (Respect for private and family life), Article 8 (Protection of personal data), Article 11 (Freedom of expression and information), Article 13 (Freedom of the arts and sciences), Article 21 (Non-discrimination), Article 35 (Right to Healthcare), Article 42 (Right of access to documents) ([1]),

Having regard to the Universal Declaration of Human Rights, in particular Articles 7, 8, 11, 12 and 13, 19, 20, 21, 25 and 27 ([2]),

Having regard to the European Convention of Human Rights (ECHR), in particular Article 5 'Right to liberty and security' and Article 8 'Right to respect for private and family life', Article 10 'right to freedom of expression' and Article 14, 'Prohibition of discrimination' ([3]),

Having regard to the European Social Charter, in particular Article 11 on the right to protection of health ([4]),

Having regard to the International Covenant on Economic, Social and Cultural Rights (ICESCR), in particular Article 15 ([5]),

Having regard to the International Covenant on Civil and Political Rights, in particular Articles 14, 17, 18, 19, 25 and 26 ([6]),

Having regard to the Universal Declaration on Bioethics and Human Rights (2005) ([7]),

([1]) Official Journal C 364 of November 2000, pp. 1-22.

([2]) http://www.un.org/en/universal-declaration-human-rights

([3]) http://www.echr.coe.int/Documents/Convention_ENG.pdf

([4]) http://conventions.coe.int/Treaty/en/Treaties/Html/035.htm

([5]) http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

([6]) http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx

([7]) http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

Having regard to Article 6 of the seventh framework programme of the European Union for research, technological development and demonstration activities (2007-2013), which states that 'All the research activities carried out under the seventh framework programme shall be carried out in compliance with fundamental ethical principles',

Having regard to the Council of Europe Convention on Human Rights and Biomedicine, signed on 4 April 1997 in Oviedo ([8]),

Having regard to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ([9]),

Having regard to Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) ([10]),

Having regard to Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products ([11]),

Having regard to Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market ([12]),

Having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells ([13]),

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare ([14]),

Having regard to Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use ([15]),

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products ([16]),

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([8]) http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm

([9]) OJ L 281.

([10]) OJ L 201.

([11]) OJ L 174/74.

([12]) OJ L 247/21.

([13]) OJ L 102/48.

([14]) OJ L 88/45.

([15]) OJ L 348/74.

([16]) OJ L 18/1.

Having regard to Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 as regards pharmacovigilance of medicinal products for human use, authorisation and supervision of medicinal products for human and veterinary use and on advanced therapy medicinal products ([17]),

Having regard to Regulation (EU) No 536/2014 of the European Parliament and the Council of 16 April 2014 on clinical trials on medicinal products for human use ([18]),

Having regard to the Commission Proposal for a Regulation 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 (General Data Protection Regulation) ([19]),

Having regard to the European Commission White Paper Together for Health: A Strategic Approach for the EU 2008-2013 ([20]),

Having regard to the European Commission Green Paper on mobile Health ('mHealth') ([21]),

Having regard to the European Commission Green Paper on citizen science: citizen science for Europe — towards a better society of empowered citizens and enhanced research ([22]),

Having regard to the Commission Communication of 4 November 2008 entitled 'Telemedicine for the benefit of patients, healthcare systems and society' ([23]),

Having regard to the European Commission guidelines (2012) on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices ([24]),

Having regard to the European Parliament resolution of 14 January 2014 on the eHealth Action Plan 2012-2020 — Innovative healthcare for the 21st century ([25]),

Having regard to the Riga Roadmap 'Investing in Health and Wellbeing for All' adopted in Riga under the auspices of the Latvia Presidency of the Council of the EU on 29-30 June 2015.

Having regard to the Council of Europe Recommendation No R (97) 5 of the Committee of Ministers to Member States on the protection of medical data ([26]),

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([17]) OJ L 348/1.

([18]) OJ L 158/1.

([19]) 2012/0011 (COD).

([20]) COM(2007) 630.

([21]) COM(2014) 219.

([22]) http://ec.europa.eu/digital-agenda/en/news/green-paper-citizen-science-europe-towards-society-empowered-citizens-and-enhanced-research-0

([23]) COM(2008)0689.

([24]) http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf

([25]) 2013/2061(INI).

([26]) Adopted by the Committee of Ministers on 13 February 1997 at the 584th meeting of the Ministers' Deputies (http://www.coe.int/t/dghl/standardsetting/dataprotection/EM/EM_R(97)5_EN.pdf).

Having regard to the WHO Report on ethical considerations for use of unregistered interventions for Ebola viral disease ([27]),

Having regard to the WHO Report 'Health 2020. A European policy framework and strategy for the 21st century (2013)',

Having regard to the World Medical Association (WMA) Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964,

Having regard to the Article 29 Data Protection Working Party, Opinion 02/2013 on apps on smart devices,

Having regard to the Warsaw declaration on the 'appification' of society of the 35th International Conference of Data Protection and Privacy Commissioners held on September 2013,

Having regard to the EGE Opinion (1999) on Ethical issues of healthcare in the information society,

Having regard to EGE Opinion No 20 (2005) on Ethical aspects of ICT implants in the human body,

Having regard to the EGE Roundtable on the Ethics of Citizen Involvement in Health held in Brussels on 22.10.2014,

Having regard to the contributions from the EGE open consultation on the ethical implications of citizen participation and new health technologies,

Having heard the EGE Rapporteurs, Andrzej Górski, Ritva Halila, Laura Palazzani and Marie-Jo Thiel,

HEREBY ADOPTS THE FOLLOWING OPINION:

([27]) WHO/HIS/KER/GHE/14.1.

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European Group on
Ethics in Science and
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OPINION OF THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES TO THE EUROPEAN COMMISSION

The ethical implications of new health technologies and citizen participation

Reference: Request from the President of the European Commission

Rapporteurs: Andrzej Górski
Ritva Halila
Laura Palazzani
Marie-Jo Thiel

Edited by Jim Dratwa
and Joanna Parkin

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Introduction

Recent years have witnessed a wave of innovation in health technologies driven by new medical breakthroughs, novel scientific approaches and the rise of digital health technologies. Pioneering methods of drug development and disease diagnosis, the rise of 'big health data', and new means of providing networked care have led to predictions that European health systems are on the cusp of transformation. While much of the promise held in these technological innovations remains to be fully realised, the rise of new health technologies are accompanied by a profound set of shifts in the way individuals — whether as patients, citizens or consumers — engage with matters of health.

From the consumer who orders a genetic testing kit online to the patient receiving genetically customised medication; from the diabetic monitoring her blood sugar level with a smartphone, to rare-disease patients who mobilise online communities of sufferers to run a DIY clinical trial; individuals and collectives are participating in new and unprecedented ways in the conduct of health research, health policy, and health practice.

The 'participatory turn' in health offers a number of new roles to citizens, whether as experimenters, stakeholders, purveyors of data, research participants, or users. It covers not only the gathering and volunteering of data, and the involvement of non-experts in scientific experimentation and analysis, but also the lobbying efforts of interest groups, public input into research and funding, as well as in the formulation and regulation of policies. Citizen involvement manifests at different stages in the process — from upstream interventions in priority setting, and influencing funding decisions to a more direct downstream involvement of citizens and patients in the use and application of medical knowledge and information. It covers both those active, informed participants who engage from a position of agency as well as those unaware of their contribution.

New ethical complexities of citizen participation in health

The implications of growing citizen involvement in healthcare and health research are complex and potentially transformational. The benefits could be substantial: more informed, empowered patients, taking greater control of their own health, in more effective health systems, driven by medical research that harnesses the power of big data. Certain European governments have already signalled the above-described innovations as a key means to make healthcare more efficient and the solution to preserving European health budgets against a backdrop of population ageing, rationing of care, and rising pressures on the price of drugs, medical devices and services.

Yet the multifaceted nature of participation poses a complex set of new ethical considerations for policymakers, practitioners and participants. Even as trends offer the realisation of greater autonomy on the part of individuals, the potential for empowerment is nuanced by a set of tensions or risks: voluntary involvement can become an obligation to participate; empowerment can be joined by demands that individuals take greater responsibility for their health; and citizen participation in health research can come to resemble instrumentalisation, even exploitation.

Terms such as 'citizen science', which are applied to new phenomena of citizen involvement, embody these inherent ambiguities. 'Citizen science' is often used as a supposedly self-evident notion, with a set of implied positive connotations. But it is an ambiguous expression, with many possible meanings, which need a systematic conceptual reflection in order to move beyond the 'rhetoric', demythologise the expression and understand the diverse meanings with a critical awareness.

As a deeper consequence of these scientific and technological developments and upsurge in citizen participation, the traditional assumptions and institutional arrangements surrounding science (including medicine) have become the object of discussion on a conceptual, social, ethical and juridical level. How does the increasing individualisation and consumerism in healthcare alter principles of solidarity which underpin European health systems? How is the doctor–patient relationship being transformed and where do sources of legitimate, trusted medical authority now lie? As we witness an increasingly dynamic citizen engagement in medical science and research, at which point does willing participation become a manipulation of the notion of consent?

EU policy relevance

Such questions are likely to become increasingly pertinent, not only for national health providers, but also for European policymakers. Precision or 'personalised medicine' has gained growing prominence at EU level

while e-health forms a pillar of the EU's digital agenda; EU funding for research and innovation is channelled towards mHealth start-ups and citizen science-based projects and an EU big data industrial policy is in the offing to exploit the potential presented by growing quantities of health data.

Furthermore, EU and international policy approaches reflect increasing recognition of the importance of participation, in a shift from what might be termed a 'health for all' approach to one of 'all for health.' Indeed, the health dimension of the Europe 2020 strategy has been titled 'Together for Health' and the WHO's European Health 2020 Strategy emphasises political, professional and civil society engagement to improve health within what it calls a 'whole-of-society and whole-of-government approach.'

In recognition of the important shifts underway and their growing EU relevance, the EGE was requested by the President of the European Commission to produce an Opinion on the ethical issues arising from the development of new health technologies and particularly, from the dimension of citizen participation.

Scope of the Opinion

This Opinion explores the transformations that citizen participation in health and medicine induces across different domains together with the resulting ethical implications. Trends and implications of citizen involvement are examined in light of new technologies that have been developed and that are emerging in the domain of health, as well as wider cultural, societal and political shifts, which are transforming the context in which health and healthcare are perceived, organised and delivered.

It does not attempt to give an exhaustive account of health technologies, rather it scrutinises citizen participation via a selection of case studies of scientific and technological innovation, chosen because they embody a broader set of shifts in health and medicine. These shifts include, first, evolving understandings of health and illness and associated changing perceptions of the self and the body; second, changing notions of what it means to be a patient in a modern health context; and third, the increasingly diverse roles performed by citizens/individuals and patients in the production of knowledge and innovation on health.

Chapter 1 of this Opinion examines the principal health technologies which are most central to the shifts outlined above, including data-intensive medicine, omics, 'personalised' medicine as well as so-called 'remote' forms of medicine such as e-health, mHealth, telemedicine and online health resources. The chapter then traces the emergence of the phenomenon of citizen science and citizen participation with specific regard to healthcare and medical research. It critically analyses the diverse meanings and functions of these terms before outlining recent examples of citizen participation in the domain of health.

Chapter 2 of this Opinion sets out the ethical implications of the paradigm shift (or set of shifts) identified in Chapter 1. In unpacking both the promise and potential challenges associated with citizen participation in health, the chapter identifies five sets of considerations: first, the implications of new health technologies and new modes of involvement on perceptions of the 'self', of personhood and of the body in a medical context; second, the implications of potential transformations in the patient–physician relationship; third, the implications of citizen involvement in the research endeavour and the tensions between empowerment, engagement and exploitation; fourth, the implications of new health technologies and citizen involvement on societal understandings, principles and structures governing health; and fifth, implications for notions of solidarity and justice.

Chapter 3 of this Opinion examines the adequacy of current governance arrangements, and identifies new questions and gaps presented by the nexus between new health technologies and new practices of citizen participation. It undertakes, first, an examination of the legal landscape pertaining to participation, charting the rights and protections enshrined in international human rights treaties and jurisprudence which establish the entitlements of citizens to participate in, and enjoy the results of, science and technology. It then identifies potential gaps in the regulatory framework in relation to new health technologies and the suitability of existing oversight mechanisms to cover new practices of knowledge generation and innovation engaging the individual.

Chapter 4 of this Opinion puts forward a set of recommendations, aimed at EU and national-level policymakers, industry and other stakeholders, which aim to maximise the benefits and minimise the harms associated with new health technologies and citizen participation in health policy, research and practice.

Chapter 1 A paradigm shift in health technologies and citizen participation

The rapid development of new health technologies is one aspect of a wider upheaval in medicine and in society more broadly, which is witnessing a transformation of practices, of the way we behave and act on the world and in our understanding and relationship to knowledge, to the status of information and to the way science is elaborated, shared, constructed, renewed, or transformed.

The result is a paradigm shift in health, which is both driving and in turn being shaped by, new technologies, and which consists of at least three fundamental dimensions:

First, are the evolving understandings of health and their associated potential for re-altering perceptions of the self and the body. Innovative and increasingly pervasive means for mapping the human body from technologies which chart an individual's genome (DNA databases, omics) and those which monitor vital signs and biological processes (mHealth) to the spread of health informatics (electronic health records) are producing a gamut of medical information and driving a shift towards a new model of data-intensive medicine. This brings increased diagnostic power but also impacts on the very concept of health, the self, and of the way that individuals understand themselves.

These technologies bridge both the individual and collective. The potential for perceiving one's selfhood through the lens of biological data is particularly acute, given the direct engagement of patients — and citizens more broadly — in producing and analysing this data: not merely bystanders or recipients, but active contributors and participants in the transition to a data-centred understanding of health.

A second fundamental transformation relates to what it means to be a patient in a modern health context, where the dividing line between those who cure and those who are cured can appear increasingly blurred. Together with wider societal shifts, new technologies are protagonists in the destabilisation of traditional structures of power and knowledge underpinning medical practice. Technologies such as telemedicine are moving patient–physician interactions outside of classic clinical settings, while online health resources and mHealth apps are complementing, disrupting or supplanting traditional sources of medical advice, with the advent of the 'expert patient' perhaps the starkest example of the re-allocation of medical authority.

Third, and closely related to the two above-described trends, is the multitude of roles performed by citizens/individuals and patients when engaging with the domain of health, which are increasingly varied, fluid and overlapping. Digital technologies are enabling citizens not only to access new sources of health information, but to contribute data, and even (co) design and (co) lead research experiments. Patients are not only receiving medical care but in turn offering their own experience and advice to fellow sufferers (via virtual, networked communities), the medical establishment and policymakers. While lay persons have long participated in medical (self) experimentation and innovation, the degree of crossover or blurring between roles is new.

1.1. Health technologies

A set of technological innovations, cutting across categories of diagnosis, therapy, treatment and prevention, are at the frontier of the three, above-described transitions in health. The following section presents a snapshot of such technologies via a selection of case studies, chosen for the potential they possess to redefine the relationship between an individual and their health. They represent innovations which, in the words of Andrew Webster, are 'not simply extending the medical repertoire and the instruments available to it but are transforming it.' ([28]). In so doing, they are changing established understandings of illness and disease, and bringing about shifts in shared conceptions of health, medicine and the body.

1.1.1. Omics, 'personalised' medicine and data intensive medicine

Rapid technological developments since the Human Genome Project (HGP) sequenced the first human genome have seen a shift from characterising genomes to developing personalised genomic analysis. In combination with the development of other omics technologies, such advances are enabling the profiling of thousands of molecular components in individuals. The development of complex computational methods to process and model such quantities of new data holds the promise of a more precise, personalised medicine that could transform the treatment and prevention of disease.

([28]) Webster, A. (2002), 'Innovative Health Technologies and the Social: Redefining Health, Medicine and the Body', *Current Sociology*, Vol. 50, pp. 443-457.

Human genome and the new generation sequencing technologies

The goal of the Human Genome Project, initiated in 1990, was to sequence and read the human genome, with an ultimate aim to better understand the function of detected genes ([29]).

Since the publication of the project's first results, the development of new technologies such as new generation sequencing have made whole genome sequencing easier, faster and cheaper ([30]). Today the whole genome sequencing of one individual costs less than EUR 1 000. Genome sequencing produces huge amounts of data that have only partially been analysed ([31]). Rapid development in bioinformatics tools and the significant increase in the capacity and speed of computers have provided new opportunities for data analysis and management.

Recent progress in genomic technology has enabled the analysis of the foetal genome using a small sample of the mother's blood ([32]). This opens the possibility for obtaining information as early as in the first trimester of pregnancy, not only about the sex and possible risks of inherited diseases that the parents may carry, but also may provide a pathway to determine the risks of developing acquired diseases. Genome analyses have become commercially available, often referred to as 'direct-to-consumer' (DTC) testing.

Today an individual can take a sample, send it to a laboratory and receive a genomic analysis, including details of inherited health risks ([33]). Many of these commercially available tests are based on individual variation and risk gene alterations. Tests used by different companies have given variable results, which has raised concerns and caused interventions by public authorities ([34]).

The Personal Genome Project

In 2005, the Personal Genome Project (PGP) was established at Harvard University to shed light on the human genome and the interplay between genetic and environmental factors in influencing individual traits.

The project is based on the principle of public participation and seeks volunteers willing to donate biological samples and personal data to become a public resource, urging 'willing participants to publicly share their personal data for the greater good' ([35]). Participants are asked to input their medical histories alongside their genome sequences. Participation is based upon an 'open consent' framework that purposefully excludes promises about privacy and requires participants to demonstrate comprehension prior to enrolment (in order to enrol, each participant must pass a series of short online tests to ensure that they are providing informed consent.) ([36]). The project initially aimed to collect genomic information from 100 000 members of the public, and has plans to expand into a global network of personal genome projects.

([29]) The Human Genome Project started in 1990, with the full sequence of the human genome published in April 2003. This project revealed that the 3 billion base pair human genome consisted only of 20 500 genes, compared to earlier estimates ranging from 50 000 to 140 000 genes (http://www.genome.gov/12011238); More than 90 % of DNA is non-coding, regulatory or repetitive areas, or of unknown function. Around 0.5 % of sequences differ between healthy individuals — explaining mostly variability in phenotypes, i.e. appearance, hair, eye and skin colour, etc., or they are in repetitive, non-coding regions. Further intensive studies based on the data produced in this project has succeeded in identifying the molecular basis of many rare, inherited diseases and also detecting the so-called risk genes for common diseases such as cancer, diabetes, mental disorders or autoimmune diseases. Cohen, J., 'The Human Genome, a Decade Later: Ten years after scientists finished mapping our DNA, they have many unanswered questions', *MIT Technology Review*, 21 December 2010 (http://www.technologyreview.com/featuredstory/422140/the-human-genome-a-decade-later).

([30]) van Dijk, E. L., Auger, H., Jaszczyszyn, G. and Thermes, C. (2014), Trends in Genetics, 30(9):418-426.

([31]) The whole genome contains about 3 billion base pairs, of which only 3 % codes for RNA. 85 % of clinically significant mutations are in this region, i.e. exons of the genes. Whole-exome sequencing analyses only all coding regions of the human genome. See Rabbani et al., 'The promise of whole-exome sequencing in medical genetics', *Journal of Human Genetics* (2014) 59, 5-15.

([32]) Fan, H. C., Gu, W., Wang, J., Blumenfeld, Y. J., El-Sayed, Y. Y. and Quake, S. R., 'Non-invasive prenatal measurement of the foetal genome', *Nature* 487, 320-324.doi:10.1038/nature11251.

([33]) Su, P., 'Direct-to-Consumer Genetic Testing: A Comprehensive View', *Yale J. Biol Med.* Sep 2013, 86(3): 359-365, published online 20 September 2013.

([34]) For instance, a US enterprise 23andMe had offered health-related genomic information for less than USD 100; however, after a critical letter from the US Food and Drug Administration the company ceased to provide health information to its customer (http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm).

([35]) PGP website (http://www.personalgenomes.org).

([36]) 'Participants in Personal Genome Project Identified by Privacy Experts', *MIT Technology Review*, 1 May 2013.

The PGP is open source and based around the principle of data sharing. All data will be placed within the public domain and made available over the internet so that researchers can test various hypotheses about the relationships among genotype, environment and phenotype.

The project styles itself as an example of 'participatory public research' and puts an emphasis on aspects of participant communication and access to data, as well as the building of a collaborative participatory research community ([37]).

Scientific developments concerning the function of genes have raised expectations for gene editing, including the correcting of gene defects. For example, the CRISPR-Cas9 tool, a technology that allows modification of even germline cells (the reproductive cells which allow genes to be passed from generation to generation) has opened significant new debates within the scientific community including calls for a moratorium ([38]).

Omics

Omics refers to the collective technologies used to explore the functions, relationships, and actions of the various types of molecules that make up the cells of an organism. The above-described development of large-scale DNA sequencing and the subsequent bioinformatic analysis are included under the general term of 'genomics'. The methods for massive analysis of data have advanced in other directions. DNA sequencing can be applied to the cDNA synthesised from RNA extracted from a given tissue producing information of the DNA that is transcribed in it. These data, and those coming from other equivalent approaches such as microchips, for instance, are commonly known as transcriptomics. Massive data analysis of proteins that are present in a given tissue has been termed 'proteomics'. Other types of massive analysis include the identification of metabolites through different chromatographic methods (metabolomics) and some other techniques (the lipidome, the interactome, etc.) that all together have been termed as 'omics'.

One of the challenges of the different methods of massive analysis of biological data is to integrate and to correlate them with observations coming from phenotypic analysis or from methods that analyse genetic variability. This analysis has produced a new discipline known as Systems Biology, which aims to study living systems taking into account their intrinsic complexity, as revealed by omics analysis. Very often the interpretation of this type of massive collection of results requires the construction of models that are based on algorithms. The use and limitations of such approaches has been previously discussed by the EGE. This is especially relevant when they are applied to the study of human health and to human behaviour.

Another promising field of research dealing with the determinants of health and utilising advances in metagenomics and whole genome sequencing is that dealing with the 'microbiome' — the microbes of the human body ([39]). There are at least 10 times as many bacteria as human cells within an individual and new generation techniques have revealed that healthy individuals host thousands of bacterial types, the mouth and gut having the largest diversity. Bacteria residing on the skin and in respiratory areas protect the body against other pathogens; in the large intestine bacteria take part in various processes important for normal body function such as metabolism, energy production from food, immunomodulation contributing to tolerance as well as the fluid balance of the body. The Human Microbiome Project ([40]), spearheaded by the United States' National Institutes of Health, is one of several international efforts designed to take advantage of large-scale, omics analyses to study the microbiome in human health and to provide insights into how the microbiome and human host interact to support health or to trigger disease. Building on the foundation of this research, open access, open source projects such as the

([37]) Ball, M. (2014), 'Harvard Personal Genome Project: lessons from participatory public research', *Genome Medicine*, 6:10 doi:10.1186/gm527.

([38]) See Baltimore, D., Berg, P. et al., 'A prudent path forward for genomic engineering and germline gene modification', *Science*, April 2015, Vol. 348 issue 6230, pp. 36-38; Lanphier, E., Urnov, F. et al., 'Don't edit the human germ line', *Nature*, Vol. 519, 26 March 2015 (Macmillan Publishers), pp. 410-411. A Chinese team run by Huang, J. et al., University of Sun-Yat-sen, Canton, published in *Protein & Cell*, in 18 April 2015, the results of their attempt to modify the genome of human embryos, reigniting the debate over human gene modification.

([39]) A microbiome is 'the ecological community of commensal, symbiotic, and pathogenic microorganisms that literally share our body space — see Lederberg, J. and McCray, A. T., 'Ome Sweet' Omics — a genealogical treasury of words', *Scientist* 2001, 15:8 (http://www.the-scientist.com/?articles.view/articleNo/13313/title/-Ome-Sweet--Omics---A-Genealogical-Treasury-of-Words).

([40]) See the NIH Human Microbiome Project website: (http://commonfund.nih.gov/hmp/overview).

'American Gut Project' have emerged. This project requests a donation of USD 99 to support the project's scientific research in return for a home sampling kit, and an analysis of the bacteria in your sample ([41]).

In order to identify the diversity of risk factors determining the susceptibility of an individual to disease, it is necessary to analyse huge quantities of genomic, lifestyle and environmental data comparing healthy and ill individuals. In doing so, progress in the knowledge achieved from 'omics' and especially genomics research opens the way to more individually tailored personalised medicine and to innovation for new types of tests and therapies. This points the way to new approaches to conducting medical research. Instead of testing many possible therapeutic or diagnostic candidates, new molecules for diagnostics and therapies are created *de novo* in conformity with the molecular profile of the relevant disease. Target groups are also tailored according to the molecular profile, which means that the way new medicines are tested (clinical trials) and also how the medicines will be used in future are likely to change.

Precision/'Personalised medicine'

Precision medicine — also known as personalised, individualised or stratified medicine — the terms are often used interchangeably — aims to deliver the right treatment for the right patient at the right time. By integrating genetic, physiological, behavioural and environmental data, preventative and interventional strategies could be targeted to patients most likely to benefit. The US National Academy of Sciences in their 2011 report 'Towards Precision Medicine' ([42]) drew an analogy between this field of study and Google Maps. In order to help us get from A to B, Google Maps integrates data drawn from a number of diverse sources into a comprehensive set of instructions. Likewise, accessing, integrating and synthesising data from large patient cohorts and healthy populations in order to determine disease/protective mechanism, should lead to more 'precise' health advice, diagnosis and treatment. The success or otherwise of this endeavour is to a large extent dependent on the willingness of citizens to share health and other personal data with scientists and doctors.

The concept of precision medicine is not new but recent advances in genome sequencing, health informatics and wireless/mobile technologies and the convergence of biomedical science and technology has placed a renewed focus on the potential benefits offered by precision medicine.

In 2012 the European Alliance for Personalised Medicine (EAPM) was established with the aim of accelerating the development and delivery of personalised healthcare to European citizens. The EAPM has pointed to the relatively slow uptake of personalised medicine in Europe and has identified low levels of awareness and a lack of involvement of patients in their own healthcare as key barriers to personalised medicine ([43]). The European Science Foundation in their 2012 report on personalised medicine has recommended that healthcare professionals 'work with citizens and patients to define what they need from their relationship with healthcare professionals within the framework of personalised medicine' ([44]). In October 2013, the European Commission published a working document ([45]), detailing the opportunities and challenges for healthcare systems posed by the advent of personalised medicine and committed to monitor developments in the field. During the period 2007-2013 the EU committed EUR 1 billion in funding to research projects underpinning the development of personalised medicine through its seventh framework programme for research ([46]). A budget of EUR 659 million has been allocated for personalised

([41]) Visit the American Gut Project website: (http://humanfoodproject.com/americangut).

([42]) National Research Council, *Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease* (National Academies Press, Washington DC, 2011) available at: http://www.nap.edu/catalog/13284/toward-precision-medicine-building-a-knowledge-network-for-biomedical-research, accessed on 17 September 2015.

([43]) European Alliance for Personalised Medicine, 'Barriers to Access in Personalised Medicine' 2014, http://euapm.eu/pdf/EAPM_Barriers_to_Access_in_Personalised_Medicine.pdf, accessed on 17 September 2015.

([44]) European Science Foundation, 'Personalised Medicine for the European Citizen Towards more precise medicine for the diagnosis, treatment and prevention of disease (iPM)', 2012, p. 50, http://www.esf.org/index.php?eID=tx_nawsecuredl&u=0&g=0&t=1452007758&hash=74aefb48bb7f7a0cd35aac2ec9429a20fa1b87d8&file=fileadmin/be_user/CEO_Unit/Forward_Look/iPM/FL_2012_iPM.pdf,accessed on 17 September 2015.

([45]) Commission Staff Working Document, 'Use of "-omics" technologies in the development of personalised medicine', Brussels, 25.10.2013 SWD(2013) 436 final, http://ec.europa.eu/health/files/latest_news/2013-10_personalised_medicine_en.pdf, accessed on 17 September 2015.

([46]) http://ec.europa.eu/health/human-use/personalised-medicine/index_en.htm, accessed on 17 September 2015.

medicine under the European Commission Horizon 2020 programme, due to launch in 2016 ([47]).

In January of 2015, President Obama announced a USD 215 million research initiative in precision medicine ([48]). The initiative is particularly relevant in the context of citizen science as the entire enterprise hinges on the engagement and collaboration of citizens in open data sharing of their health and personal data. Initially efforts will be directed towards developing customised cancer treatments but the longer-term goal of the research is to generate a cohort of 1 million American citizens to contribute and share their health data, with at least some data coming from existing cohorts ([49]). This may allow the insights gained through precision medicine in the oncology field to be expanded to other spheres of medicine. Data will be derived from analysis of biological material and behavioural data all of which will be linked to an individual's electronic health data. Interestingly, the National Institute for Health (NIH) which is leading on this initiative have committed to engage with individuals, as research partners rather than the more traditional construct of research participants. Data subjects will play an integral role in the cohort's governance through direct representation on committees established to oversee cohort design and data collection, use, management, security, and dissemination. In order to ensure active participant engagement, an ongoing dynamic consent process will also be put in place.

Safeguarding the large amounts of information central to this endeavour will be a significant challenge. In March 2015, the White House convened an inter-agency working group to develop a set of privacy principles ([50]). Recognising that multiple tiers of data access would be required for the optimal use of the data, the group recommended that a robust Data Security Framework should be developed in consultation with experts in data science, security, Health IT, and ethics.

The promise of precision medicine extends beyond treating those who are already ill and includes the capability to identify healthy individuals at increased risk of developing disease, thereby holding out the possibility of instituting preventative measures. Francis Collins of the NIH has stated that this initiative will 'pioneer new models for doing science' and will 'propel our understanding of diseases — their origins and mechanism, and opportunities for prevention and treatment ([51]). The significant investment in precision medicine is not however without its critics. Bayer and Galea ([52]) argue that if the goal is to produce healthier populations, investments in addressing health inequalities rather than in precision medicine should be the priority. It has long been acknowledged that health has been unevenly distributed among social groups and that there is a social gradient of health, i.e. the lower a person's social position, the worse their health ([53]). There are concerns that the focus on precision medicine could signal an opportunity cost for public health measures at the population, rather than the individual level which are required to achieve heath equity.

If there is to be a just and equitable distribution of the potential benefits of precision medicine, those contributing data to build large cohorts of patients and healthy individuals will have to be drawn from diverse backgrounds across the socioeconomic spectrum. There is also the question of if and when therapies do become available will they be cost effective and whether the focus will be placed on treatment or prevention? There are varying opinions on whether precision medicine will in fact result in cost savings to the healthcare systems. On the one hand it is argued that tailored effective treatment with less side effects will result in better health outcomes and overall treatment costs will fall. On the other hand, it is argued that developing treatments for small groups of patients will increase the costs of drugs because developmental costs will be borne by fewer patients taking them. This is reflective of the current debate about the cost of novel therapeutics. If precision medicines become routinely available, this will likely drive a change in reimbursement policies which many argue will mean that such medicines will become more financially viable for both patients and pharmaceutical companies.

([47]) http://europa.eu/rapid/press-release_MEMO-15-5832_en.htm.

([48]) President Obama State of the Union Address, 30 January 2015, https://www.whitehouse.gov/precision-medicine, accessed on 17 September 2015.

([49]) Collins, F. S. and Varmus, H., 'A New Initiative on Precision Medicine', *New Engl. J. Med.,* 2015;372(9):793-795.

([50]) Precision Medicine Initiative: Proposed Privacy and Trust Principles, https://www.whitehouse.govbennedd/sites/default/files/docs/pmi_privacy_and_trust_principles_july_2015.pdf, accessed on 17 September 2015.

([51]) Collins, F. S. and Varmus, H., 'A New Initiative on Precision Medicine', *New Engl. J Med.* 2015, 372(9): p. 795.

([52]) Bayer, R. and Galea, S., 'Public Health in the Precision-Medicine Era', *New Engl. J Med.* 2015, 373(6):499-501.

([53]) Marmot, M., Friel, S., Bell, R. et al., *Lancet* 2008, 372(9650):1661-1669.

If precision medicine is to become part of routine healthcare practice, we will require a workforce that is able to interpret and translate the information it generates into clinical care. There is a current knowledge gap, which will have to be addressed through undergraduate and postgraduate training aimed at increasing data literacy skills.

Precision medicine targeting cystic fibrosis

One of the most successful examples of a precision medicine approach is the use of the drug Ivacaftor, the first of a new class of drugs that target the underlying protein defect in cystic fibrosis. The drug was approved by the US Food and Drug Administration (FDA) in 2012 and is aimed at patients who have a specific gene mutation (G551D CFTR-mutation), approximately 3 % of the cystic fibrosis population. While the patient population that can be helped by the drug is small, the cost of the drug is high: about EUR 275 000 per patient, per year. In July 2015, the FDA approved a combination drug for cystic fibrosis, which contains Ivacaftor and Lumacaftor and targets genetic mutations seen in approximately half of all cystic fibrosis patients. The cost of the new drug is estimated to be USD 259 000 per patient per year.

Data intensive medicine

Big data refers to the massive amount of information collected from different sources (conventional data, molecular and cellular data, imaging, demographic, social and environmental data, etc.). Many branches of science have a long history of dealing with large quantities of data. However, the methods and technologies developed to gather and process data are new. Advances in biology together with development in bioinformatics and computational technologies, give scientists the possibility to generate and analyse large databases, on a scale which was previously impossible. Using these technologies and combining relevant biological, social and/or environmental information, big data may show correlations and interactions of complexities in health and disease that could not be detected before, or at least were far more difficult to study. In many cases it is no longer necessary to first establish a hypothesis and then collect data around it. Data are sent to scientific research centres and health information companies to manage large-scale studies on hundreds of thousands or even millions of individuals in order to stratify disease and measure and correlate different parameters using appropriate algorithms.

Big data brings both new challenges and opportunities linked to the management of large quantities of diverse types of information, the conversion of these data into hypotheses about health and disease and their transformation into usable knowledge. The key challenge centres around transforming biological–social–environmental information into predictive abstract models ('predictive models' and 'actionable models').

The collections of large databases enable scientists to ground their analyses on different aspects of the same phenomenon. In this sense big data can provide a comprehensive and general perspective on a phenomenon in its complexity, without needing to focus on specific or homogeneous details or under controlled conditions.

As explored in the EGE Opinion on the ethical implications of security and surveillance, large amounts of data from disparate sources can be organised and analysed, facilitating the discovery of previously unknown relationships amongst the data ([54]). Datasets can be compared in order to identify common features or trends. Such techniques have been used to identify adverse drug events in the post-approval period to improve patient safety ([55]). The EU–ADR project is a European Commission-funded project which mines clinical data from biomedical databases and electronic healthcare records (EHRs) of over 30 million patients from several European countries for the purposes of the early detection of adverse drug reactions ([56]). It has also been suggested that mining electronic health records has the potential to further medical research as well as clinical care, for instance through monitoring treatment adherence ([57]). Linking genetic data with electronic health records allows for mapping of genotypephenotype correlations. One such study identified genetic variants associated with an increased risk of thromboembolism in patients with breast cancer treated with Tamoxifen ([58]). Recently data mining has also been employed for epidemic surveillance ([59]). Researchers have shown, for example, that 'mining'

([54]) EGE Opinion on the Ethical Implications of Security and Surveillance, 2013.

([55]) Harpaz, R. et al., *Clin. Pharmacol. Ther.* 2012, 91(6):1010-1021.

([56]) Coloma, P. M. et al., *Pharmacoepidemiol Drug Saf.* 2011, 20(1):1-11.

([57]) Jensen, P. B. et al., *Nature Rev. Gen.* 2012, 13:395-405.

([58]) Onitilo, A. et al., *Breast Cancer Res. Treat.* 2009, 115:643-650.

([59]) Kofod-Petersen, A., *Med. J. Aust.* 2012, Mar. 19, 196(5):301.

of Twitter postings can be used to track and predict outbreaks of influenza with approximately 90 % accuracy ([60]). Mayer-Schönberger and Cukier state that 'the correlations may not tell us precisely why something is happening, but they alert us that it is happening. And in many situations this is good enough' ([61]).

Consequently, there has been a shift from knowledge-intensive systems (where experts use a knowledge base to solve complex problems) to data-intensive systems. Large amounts of data are continuously accumulating, e.g. derived from constant monitoring of physiological parameters of individuals (e.g. mHealth), genome analyses, electronic health records and so on. This explosion of information requires tools to obtain a reliable evaluation of change in clinical parameters to preserve high standards of healthcare. In this regard, artificial intelligence may be helpful to achieve this goal: computerised patient records may be analysed by appropriate programs constructed to yield important clinical information or construct algorithms helpful in diagnosis, prognosis and monitoring therapy. This approach may be useful, for example, in intensive care units where monitoring of critically ill patients produces a flood of data while appropriate patient care requires extensive interpretation and a selective assessment of many parameters. Thus, knowledge-based modules are essential tools to determine what is relevant in a given stage of a patient's clinical course ([62]).

This new approach requires a cross-disciplinary interaction of biologists, chemists, physicists, physicians, mathematicians, engineers and computer scientists.

Crowdsourcing clinical trials

How new computational approaches may be successfully applied to analyse large datasets with a clear patient benefit is well illustrated by a recent crowdsourced analysis of clinical trial data to predict amyotrophic lateral sclerosis (ALS) progression. An open access platform was created that contained the merged data from as many ALS clinical trials as possible (> 9 600 patient dataset) and — using a crowdsourcing approach — the solvers were asked to use 3 months of individual patient-level clinical trial information to predict that patient's disease progression over the subsequent 9 months. Thirty-seven unique algorithms were received and two most promising ones were identified. Importantly, the winning algorithms predicted disease progression better than both a baseline model and clinicians using the same data. This approach allows for a substantial reduction in the size of a clinical trial evaluating drug effectiveness and may uncover new clinical parameters relevant for disease progression while shedding new light on the pathophysiology of ALS ([63]).

The rise of mobile and wireless technologies targeting health behaviour (mHealth) has ushered in a new era of health research based on the constant stream of data supplied by users. As mHealth and wider e-health innovation are also allowing individuals to monitor and regulate their health outside of clinical settings, they are further addressed in section 1.1.2. below.

1.1.2. Remote medicine: mHealth, e-health and online health resources

The development of ICT has been revolutionary for citizen involvement in health, providing a set of ICT-based tools which assist prevention, diagnosis, treatment, health monitoring and lifestyle management, as well as new means for linking citizens with medical research. Programs that enable users to analyse genomic sequences are available to anybody using home computers and cloud computing ([64]). Ever larger numbers of people are using mobile phones, watches

([60]) Lampos, V. et al., Proceedings of the 2nd IAPR workshop on cognitive information processing IEEE Press 2010:411-416.

([61]) Mayer-Schönberger, V. and Cukier, K. (2013), Big Data: A Revolution That Will Transform How We Live, Work and Think, London, John Murray Publisher.

([62]) Horn, W., 'Artificial intelligence in medicine on its way from knowledge-intensive to data-intensive systems', *Art. Intel Med.* 2001, 23,5-12. EGE Opinion No 26 on Ethics of Information and Communication Technologies.

([63]) Kuffner, R., Zach, N., Norel, R. et al., 'Crowdsourced analysis of clinical trial data to predict amyotrophic lateral sclerosis progression', *Nature Biotech* 2014, doi 10.1038/nbt 3051, 2015, 33, 51-57.

([64]) Mell, P. and Grance, T., The NIST Definition of Cloud Computing, National Institute of Standards and Technology, 2011 (http://faculty.winthrop.edu/domanm/csci411/Handouts/NIST.pdf).

and radio frequency identification devices (RFID) in health and physical activity monitoring and recording in everyday life and such devices are increasingly used to collect data in research. E-health solutions, through the roll-out of health information networks, electronic health records, telemedicine services and health portals, are providing health authorities with novel means to organise their health delivery systems. The corollary is bringing 'health' outside of the traditional clinical care context and into people's homes and workplaces, integrating the concern for bodily wellbeing into the fabric of individual's everyday lives.

mHealth

The European Commission defines mobile health (mHealth) as covering medical and public health practices supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices and their applications (apps) ([65]). mHealth solutions cover (amongst others) heart rate, blood glucose level, blood pressure, body temperature and brain activities measurements. Some mobile phones have apps where their users can store their personal health data (for instance, the Apple Health App ([66]) and many other examples on Android and IOS platforms ([67])) and apps can be used as communication, information and motivation tools, such as medication reminders or tools offering fitness and dietary recommendations ([68]).

mHealth has been touted as a means to contribute to a more patient-focused healthcare, to support the shift towards prevention and facilitate the delivery of high-quality healthcare by enabling more accurate diagnosis and treatment. Mobile apps can encourage adherence to a healthy lifestyle, resulting in more 'personalised' medication and treatment. Through sensors, medical, physiological, lifestyle, activity and environmental data can be collected, even automatically, and this data can be used for research. Individuals may also receive 'tailored' advice according to the information they provide. In addition, the availability of satellite navigation technologies in mobile devices provides the possibility to improve the safety and autonomy of patients, which in turn may enable a more efficient delivery of health services.

E-health including electronic health records

E-health refers to the application of ICT-based tools and services for prevention, diagnosis, treatment, monitoring and management of health. In its broadest definition, e-health covers a range of functions in the health sector, including mHealth and telemedicine. However, e-health also serves as a common shorthand for a narrower set of tools aimed at data sharing between healthcare providers and between providers and their patients, in particular electronic health records.

E-health is understood to hold the potential to empower patients by providing them with easier access and control over their health information. The storage and transfer of patient records electronically has also been found to lead to fewer clinical errors and improve patient safety and can feed into health research ([69]).

Consequently, while the implementation of ICT in healthcare is a competence of EU Member States, the European Commission has since 2004 been developing targeted policy actions aimed at fostering e-health throughout the EU, citing the economic, efficiency and health benefits of tools such as electronic health records, and their promise to deliver a more 'personalised, citizen-centric healthcare' ([70]).

Although all the EU Member States make use of electronic health records, variations exist in the formats and standards applied, security, quality controls, etc. ([71]). Directive 2011/24/EU on patients' rights in cross-border healthcare calls for Member States to provide, on a voluntary basis, compatible database systems that

([65]) European Commission Green Paper on Mobile Health, April 2014.

([66]) http://www.livescience.com/48132-apple-health-app-explained.html

([67]) http://heavy.com/tech/2013/08/top-best-health-and-fitness-apps-for-android-2013

([68]) European Commission: Green paper on mobile Health ('mHealth'), SWD(2014) 135 final, COM(2014) 219 final. Brussels, 10.4.2014 (http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth).

([69]) Report of the eHealth Stakeholder Group, Patient access to electronic health records, June 2013.

([70]) Commission Communication on an e-health action plan 2012-2020: Innovative healthcare for the 21st century, COM(2012) 736, 06.12.2012; see also Kierkegaard, P., 'Electronic health record: Wiring Europe's healthcare', *Computer Law & Security Review*, Volume 27, Issue 5, September 2011, pp. 503-515.

([71]) Overview of the national laws on electronic health records in the EU Member States (http://ec.europa.eu/health/ehealth/projects/nationallaws_electronichealthrecords_en.htm).

would allow patients to access their own health data, and to facilitate the transfer of patient data between Member States ([72]). However, current implementation of the directive reflects a wide disparity in the level of access currently granted by different Member States to patients wishing to access their health records. For instance, while in Germany a patient may access and even edit their own health records, in many other Member States access by individuals to their own health data is considerably more limited ([73]).

Telemedicine/remote provision of care

Telemedicine is the use of telecommunication and information technologies in order to provide healthcare at a distance ([74]). This can encompass a range of applications covering both consultations, monitoring and treatment between doctor and patients, as well as the soliciting and pooling of expertise between medical professionals. The most common type of telemedicine is specialist consultation within a certain hospital district or national area. Doctors with specific questions concerning the diagnosis or care of a patient may call on consultants located elsewhere to give their expert advice. The remote analysis of imaging data has become part of everyday medical care in Member States today.

Telemedicine has spawned sub-categories such as teleradiology, teledermatology and telepsychiatry and has progressively widened its spectrum with the development of new technologies. It is now possible for instance to carry out distance surgery through the use of robotics and high speed data connections ([75]).

Telemedicine can be of benefit to patients living in remote regions. It saves travelling time for patients, and reduces the time spent in outpatient clinics where individuals are susceptible to spreadable infections.

Telemedicine can also facilitate education and learning and share best practices more easily, as well as imply important efficiency savings. The use of telemedicine has been shown to reduce costs for example, in dermatology consultations ([76]). Remote analysis of imaging data (X-rays, MRI, ultrasonic scans) or specific data (such as cardiovascular surveillance elements) may, however, be beneficial to ensure expert interpretation.

On the other hand telecommunication needs equipment, technical training, and it entails a potential decrease in interaction between healthcare personnel and the patient.

Online health resources

Internet-based resources are becoming increasingly important sources of health advice. According to an EU-wide survey, six out of 10 Europeans now go online when looking for health information (with this figure rising to eight out of 10 among the under-40 population) ([77]).

Online health information appears in a variety of forms. These can include general information websites run by governments or health authorities such as the UK's NHS Choices site in which users respond to questions about their symptoms and receive advice about the appropriate course of action ([78]). They can take the form of sites set up by commercial or private initiatives, such as pharmaceutical companies or special interest sites run by patients groups focusing on particular diseases. Or they can manifest as online forums of an interactive nature, established by individuals or communities of interest to enable users to share symptoms, advice and diagnoses. Social media and internet forums have also proved a popular means of verifying the quality of healthcare, with users reviewing and ranking services and treatments ([79]).

([72]) Directive 2011/24/EU of The European Parliament and of the Council of 9 March 2011on the application of patients' rights in cross-border healthcare (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF).

([73]) Report of the eHealth Stakeholder Group, Patient access to electronic health records, June 2013.

([74]) According to a World Health Organisation (WHO) definition in 1997, telemedicine is a medical act conducted remotely via information and communication technologies.

([75]) Marescaux, J. et al. (2002), 'Transcontinental Robot-Assisted Remote Telesurgery: Feasibility and Potential Applications', *Annals of Surgery*, Vol. 235, No 4, 487-492.

([76]) Pak, H. S., Datta, S. K., Triplett, C. A., Lindquist, J. H., Grambow, S. C. and Whited, J. D., 'Cost minimisation analysis of a store-and-forward teledermatology consult system', *Telemed J. E. Health*, 2009 Mar, 15(2):160-5. doi:10.1089/tmj.2008.0083.

([77]) Flash Eurobarometer 404, European Citizens' Digital Health Literacy, November 2014 (http://ec.europa.eu/public_opinion/flash/fl_404_en.pdf).

([78]) http://www.nhs.uk/aboutNHSChoices/Pages/NHSChoicesintroduction.aspx

([79]) Eurobarometer on quality of healthcare, 2013.

The rising popularity of the internet as a source of medical advice has brought with it the challenge of verifying the accuracy or intelligibility of the information made available. While a majority (90 %) of Europeans polled report that the use of online health information has helped them to improve their knowledge about health-related topics, nevertheless, approximately 40 % do not think that the information they have used came from a trustworthy source ([80]). To remedy the risks associated with inaccurate or misleading information, the European Commission has published quality criteria for websites offering health-related information to citizens ([81]). Several Member States make use of certification or accreditation schemes to help users identify high-quality health information, however misleading information and misinterpretation by lay people of online medical advice remains an enduring challenge ([82]).

Challenges of reliability also affect the use of online pharmacies and the increasing frequency with which people purchase medication over the internet. Medication can be bought from regulated online pharmaceutical suppliers, allowing a convenient and often more cost-effective means to access medication. However studies suggest that over 50 % of medicines purchased from unregulated websites are either falsified, counterfeit or sub-standard ([83]).

The EU's directive on falsified medicines for human use (Directive 2011/62/EU) aims to strengthen the protection of consumers and patients by preventing such medication entering the legal supply chain. To address internet sales, the directive introduces an obligatory logo intended to appear on the websites of legally operating online pharmacies and approved retailers in the EU ([84]).

([80]) Flash Eurobarometer 404, European Citizens' Digital Health Literacy, November 2014 (http://ec.europa.eu/public_opinion/flash/fl_404_en.pdf).

([81]) Commission communication on eEurope 2002: Quality criteria for health-related websites, COM(2002) 667.

([82]) Nuffield Council on Bioethics (2010), 'Medical profiling and online medicine: the ethics of "personalised healthcare" in a consumer age'.

([83]) http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000186.jsp

([84]) Clicking on the logo links to the national regulatory authority websites, where all legally operating online pharmacies and approved retailers in their respective countries will be listed (http://ec.europa.eu/health/human-use/eu-logo/index_en.htm).

Converging practices of health participation

As the uptake of technologies enabling citizen involvement in health become progressively embedded in everyday health contexts, so their various uses steadily converge.

The advent of one technology, such as electronic health records, can find synergies with other tools, such as online pharmacies. This is the case for instance in the United States, where the 'Blue Button' initiative allowing patients to download their health information, including prescription data, is complemented by participating pharmacies offering online tools to allow clients to better manage their prescriptions.

Telemedicine can be mediated through mHealth devices, such as phone apps which offer consultations with qualified physicians, or online platforms such as the Spanish website 'Qbaby' ([85]) which enables parents to open a virtual medical record for their baby, and submit enquiries to a personal paediatrician of their choice. The internet has similarly brought developments in genomics testing within the reach of each and every consumer with websites offering Direct-to-Consumer genetic testing in return for a fee. In return, genome research projects are making use of online tools to find large numbers of volunteer participants.

Many of the above-described technologies serve a dual function of both permitting citizens and patients to take a more active role in the management of their health while 'providing' the raw data that can drive new kinds of health research. Data produced from the use of apps, wearable devices or electronic health records, can be variously collected and used in business ventures as well as scientific studies, such as epidemiological analysis, evaluation of healthcare procedures, pharmacovigilance. Some interactive health websites which allow users to share symptoms and gain advice from fellow sufferers, are simultaneously retaining this crowdsourced data for research purposes. One example is CureTogether, a website which encourages patients to share quantitative information about their medical conditions and symptoms, and which transforms this data into rankings of treatments based on patient-reported effectiveness, with the claim that 'new research discoveries are made based on the patient-contributed data' ([86]).

([85]) https://qbaby.qoolife.com

([86]) http://curetogether.com

1.2. 'Citizen science' and active involvement

While the above-described technological innovations cut across different categories of healthcare (such as research, diagnosis, prevention, therapy), they share a common feature: a greater degree of engagement on the part of the individual in his/her own healthcare and a closer link between the citizen and the advancements of health, knowledge and treatment.

To understand the dynamics at play, the development of these technologies and their implications must be placed in the context of shifts taking place in the production of knowledge and innovation, which have seen the wider public increasingly involved in the research endeavour across a number of roles and functions.

One label associated with this phenomenon is 'citizen science'. In its narrowest interpretation citizen science refers to the increasing propensity for citizens to act as researchers, to effectively supplement the role of scientists in designing, coordinating or carrying out research projects. Yet the term and the phenomena to which it refers are both much broader and more nuanced, and can cover a wide array of participatory actions, including the gathering and volunteering of data, the participation of non-experts in analysis and scientific experimentation, the lobbying efforts of interest groups, public input into research and project funding, as well as in the formulation and regulation of policies. The 'participatory turn', its specific implications in the domain of health and the new roles it offers to citizens as experimenters, stakeholders, and purveyors of data, research participants, partners or even protagonists are in turn closely bound up with the growth of data-intensive science and open science ([87]). These new paradigms in the conduct of science are progressively bringing collaborative networks and dialogue between professional and non-professional participants to the core of the scientific enterprise and as such function as a major driver and enabler of citizen involvement in health.

1.2.1. What is citizen science? Analysis of a new concept

Citizen involvement in health requires interrogating the terms and concepts associated with notions such as 'citizen science' as well as pulling apart the highly diverse actions and forms of participation that are brought together under this label.

A number of typologies have been developed to categorise citizen science — in the sense of citizen involvement ([88]) — that may assist in bringing greater clarity to this discussion. One of the earliest such exercises ([89]) employed the conceptual model of a participation 'ladder', in which the level of citizen agency ranges from full 'citizen control' at the top of the ladder all the way down to 'manipulation'. Intermediary steps include delegated power, through to partnership, placation, consultation, and informing. This approach has been further developed and nuanced ([90]) in five models of citizen involvement: *contractual* projects, where communities ask professional researchers to conduct a specific scientific investigation and report on the results; *contributory* projects, which are generally designed by scientists and for which members of the public primarily contribute data; *collaborative* projects, which are generally designed by scientists and for which members of the public contribute data but also help to refine project design, analyse data, and/or disseminate findings; *co-created* projects, which are designed by scientists and members of the public working together and for which at least some of the public participants are actively involved in most or all aspects of the research process; and *collegial* contributions, where individuals without recognised scientific credentials conduct research independently, with varying degrees of expected recognition by institutionalised science.

However, this is not the only possible classification. Indeed this typology relates to a rather narrow definition of citizen science with a view of citizen involvement in the scientific endeavour restricted primarily to the practical implementation of scientific projects and

([87]) Open Science refers to the movement which aims to transform, open up, and make more accessible science and research through ICT, in order to render science more efficient, transparent, and societally responsive. See *Science as an open enterprise — The Royal Society Science Policy Centre report 02/12*, issued: June 2012, European Commission (http://www.openscience.org/blog/?p=269;http://ec.europa.eu/research/consultations/science-2.0/consultation_en.htm).

([88]) Other expressions used are: crowdsourced science; networked science; civic science; community science.

([89]) Arnstein, S. R. (1969), 'A Ladder of Citizen Participation', *Journal of the American Institute of Planners*, Vol. 35, No 4, July 1969, pp. 216-224.

([90]) Shirk, J. L. et al. (2012), 'Public participation in scientific research: a framework for deliberate design', *Ecology and Society* 17(2): 29.

experimentations (citizens/patients as experimenters in science). It therefore fails to grasp the various forms of citizen engagement 'upstream' in the knowledge- generation process, and the role citizens can play (whether in the form of interested individuals, interest groups, lobbies or other organised civil society stakeholders) in influencing the direction of policy, legislative changes and the programming and prioritisation of research funding.

A complementary typology might therefore focus on locating where in the knowledge-generation process citizen input takes place. Such a typology would determine the degree to which citizens participate upstream as stakeholders: influencing agenda setting for research, defining research priorities and shaping decision-making on funding or generating funding themselves, as well as downstream, by taking into account the degree of citizen involvement in evaluation of outcomes, in accessing results and datasets, and deciding what happens to them.

Taking into account these two axes of citizen involvement (degree of involvement and location of involvement) can be determinant when identifying the ethical dilemmas at stake. It also sheds light on the multiple roles played by citizens in the knowledge-generation process. At first glance, three key roles can be identified: citizens as *producers* of knowledge: 'citizens doing science' (as evidenced by non-experts playing a direct role in health research and experimentation); citizens as *contributors* to the generation of knowledge (e.g. via individuals' — willing or unwitting — contribution of health data; via the role of interest groups in influencing the direction of research programming; and via the participation of patients in the evaluation and assessment of new medicines); citizens as *users* of knowledge (e.g. individuals engaging in online self-diagnosis, using apps to lead a healthier lifestyle and sending data through mobiles).

Embedded within debates on citizen involvement in health are a set of terms, labels and concepts which warrant further reflection, given the inherent associations and meanings they carry with them.

Who are the 'citizens' in 'citizen science'?

The term 'citizen' in this context may not necessarily be synonymous with 'citizenship', yet it does invoke notions of rights, duties and the active participation of individuals as members of a given society (e.g. within the framework of the 'citizenship-as-rights' or 'citizenship-as-participation' models). In parallel, this label can encompass a range of individual or organised actors: stakeholders, lay persons, patients and consumers but also and in counterpoint, organised interest groups, lobbies and corporate bodies. Indeed, this term could prove misleading should it convert the spectrum of societal groups with differing and sometimes conflicting interests, into one homogenous block.

As a prime example, care should be taken when distinguishing between 'citizens' and 'patients' who may, if considered as distinct groups, be seen to be driven by very different sets of motivations ([91]).

Such a patient/citizen dichotomy may however risk obscuring the complexity of the roles at stake. Consider the citizen who happens to be a patient and is active in spaces of public deliberation, or a patient whose citizens' rights and responsibilities must be secured. Taking into account the context-dependent nature of these roles, and how quickly an individual may transition between them (i.e. from the citizen who happens to be a patient and is engaging in health policy deliberations to the patient who suffers and is receiving care), this complexity may be more accurately understood by placing a line of continuity between these two concepts. Such a continuum may also help nuance the traditional framing of the patient as one who suffers and receives care, being therefore intrinsically passive. We may also ask how these classic associations are being disrupted by recent trends to depict patients as clients/consumers: how does the act of labelling the patient as 'consumer' in itself reframe this role and its associated rights and responsibilities? How do we understand the notion of the expert patient? Moreover, at what point does a citizen become a patient?

In addition, the increasing propensity of citizens to engage in 'science' requires an interrogation of this term. Can 'science' be conducted by 'non-scientists'? Who do we mean by scientists when the scientific establishment implies a range of public institutions, private companies and international bodies?

([91]) For instance, while citizens may be wary of putting their data online, patients may be more willing to share their data if they believe it will help solve a chronic disease. One means of overcoming this discrepancy would be to separate out and draw a line between the individual 'citizen' on one side (together with the organised citizens' NGOs and groups which form 'civil society') as distinct from the individual 'patient' (and patient groups representing the organised manifestation of the latter's various interests) on the other.

Value and risks of participation

Care should be taken when using terms such as citizen 'engagement', 'involvement' and 'participation' given the positive associations of these terms with notions of inclusiveness, openness and democratisation. Such labels may function as a form of branding for activities or endeavours where alternative interests (e.g. financial) hold sway. In addition, participation in this context usually comes at a cost for the participants ([92]). An overriding focus on the empowering potential of engagement (while certainly warranting investigation) can draw attention from the double-edged nature of citizen involvement, which carries risks of exploitation, manipulation and control.

The latter warning raises a final inevitable question concerning the rationales that are driving the turn towards citizen involvement and the functions that participation plays. Four conceptual tools familiar to scholars of participatory democracy may provide an entry into this discussion: the rationale of the normative democratic worldview (that participation is essentially the 'right thing to do'): the rationale of output legitimacy (that participation produces more effective outcomes); the rationale of input legitimacy (that the process itself is evaluated more favourably as a result of enabling a range of interests to enter the decision-making procedure); and the rationale of 'buy-in', which implies the fostering of compliance (in a medical context, of following the doctor's orders, taking medication as prescribed, etc. as opposed to 'adherence' which refers rather to a mutual agreement on the prescribed course of action).

These tools should be accompanied by some caveats: first, is the question of whether we can impute a single rationale to organisations which employ participatory methods where multiple, heterogeneous approaches, interests and agendas are at play, and where an institutional mimesis or path-dependency can be the dominant dynamic that drives decision-making. Second, and relatedly, is the question of whether it is really possible to ascribe rationales to individuals as a means to understand individual-level decision-making/actions within organisations. And third, justificatory discourses that are applied to initiatives of citizen involvement may have only a tenuous connection to the processes at play.

([92]) Citizen Participation in Science and Medicine (CPSM) network statement to the European Group on Ethics in Science and New Technologies.

Nevertheless, calls for increased engagement and participation might elicit some key questions: is it a substantive involvement or merely a procedural involvement? Does the call for public engagement respond to a need for greater transparency, public accountability or legitimation? Does it function as a means to manage/govern expectations, hopes and fears or to mediate accountability through shared responsibility?

Such considerations should not to detract from the value brought by participation, but can serve to nuance the so-called 'rhetoric of participation': the assumption that participation brings in itself solution or is an unqualified 'good'.

That is not to deny the multiple benefits of participation. Participants can not only add value for research by providing experimental data, they may also raise new questions and co-create/create (in different possible ways) a new scientific culture. Volunteers acquire new learning and skills, and deeper understanding of the scientific work. As a result of this open, networked and trans-disciplinary scenario, science–society–policy interactions may be improved leading to a more participatory research based on evidence-informed decision-making ([93]).

1.2.2. Recent phenomena of citizen participation in health

Several recent phenomena serve as examples of this new concept, applied to the specific field of health: with reference to citizens as experimenters (patients participating in various degrees in experimentation), as stakeholders (patient expert groups), and as purveyors of data (citizens/patients sending data through ICT, mobiles, digital devices).

Participant-led research

Increasing access to information technologies and use of social networks have enabled citizens to become more active and engaged, in various degrees, as individuals or as communities of individuals in the governance of health and conduct of health research.

([93]) Green paper on Citizen Science for Europe: Towards a society of empowered citizens and enhanced research (http://ec.europa.eu/digital-agenda/en/news/green-paper-citizen-science-europe-towards-society-empowered-citizens-and-enhanced-research-0).

Participant-led research can take the form of self-experimentation, self-surveillance, self-reporting of data, analysis of genomic data, and the design and launch of health research projects including via crowdsourced approaches.

While the phenomenon can take a variety of forms, it is characterised by the active role played by the lay person, with the citizen or patients providing the leading force in the conduct of research projects. These new phenomena stand, to a certain degree, in contrast to the existing infrastructure of research (scientist-driven), although the lines between the two are often blurred.

Patients may self-report the use of off-label pharmaceuticals or experimental drugs; in such cases, individuals may choose themselves the active treatment group and doses, recording and reporting the effects themselves. The outcome of self-reports may then be compiled and analysed, indeed reports are often freely accessible on the net. There are an evolving range of participant-centric initiatives that combine web-based informatics tools with new models of engagement and research collaboration. These emerging initiatives may become approaches to support large-scale and longitudinal research studies.

A growing number of projects can be observed which involve patients wishing to take a more active role in treatment decisions. Whether these are patients with non-curable conditions who want to pilot new medical treatments or dissatisfied research participants who feel that research they have participated in has not been focused enough to patients' needs.

A few of these participant-led research projects are published in scientific journals ([94]). In 2011 *Nature Biotechnology* published a study conducted as a self-experimentation by a group of patients on the effects of lithium on amyotrophic lateral sclerosis (ALS) on the website 'PatientsLikeMe', a platform dedicated to sharing information and disease experiences and using the aggregated data to drive research ([95]). This saw a collaboration between patients as drivers of the research and researchers who provided the data analysis and a confirmation of the hypotheses formulated by the patients in clinical trials.

CureLauncher is a crowd-funded platform designed to help patients to find new treatment options according to their unique condition and to accelerate the research, discovery and development of drugs and devices ([96]). It helps citizens to find the right clinical trials and the treatment, even if not yet experimented or still within the experimentation phase: it is a free resource for patients and healthcare professionals.

There are relevant opportunities emerging from these new phenomena: Data can be collected more rapidly, accelerating the process of discovery and the participation is broader, even global, in the absence of commercial motivation and providing opportunities for people to contribute to science. But ethical challenges arise, given the possible lack of scientific rigour and ethical oversight (see section 2.3).

Experimental care and therapy

In the context of the participant/patients-led research there are also examples of primarily internet-based initiatives for experimental care and therapy.

Experimental care and therapy falls into a number of different categories.

1. The so-called 'compassionate use' of drugs are the use of individual or group treatments for patients affected by serious and often end-stage pathologies, without effective available alternatives of validated therapies, with the aim and hope to bring benefits to the patient's living conditions and quality of life, reducing suffering and also improving research and experimentation. The expression 'compassionate use' refers to feelings of empathy towards seriously ill and

([94]) Frost, J., Okun, S., Vaughan, T., Heywood, J. and Wicks, P., 'Patients-reported outcomes as a source of evidence in off-label prescribing: analysis of data from PatientsLikeMe', *Journal Med. Internet Res.* 2011, 13, e6; Kaye J., Curren, L., Anderson, N., Edwards, K., Fullerton, S. M. et al., 'From patients to partners: participant-centric initiatives in biomedical research', *Nat. Rev. Genet.* 2012, 13, pp. 371-376.

([95]) PatientsLikeMe is a platform for sharing information and disease experiences; it enables patients to connect with patients of the same illness and encourages patients to share data and information. Members (300 000) may choose different privacy settings that may be changed in time: shared data are accessible to third parties, non-shared data not. The website reports aggregated data on symptoms and treatments that may be useful to patients. It is founded on an 'openness philosophy'(https://www.patientslikeme.com).

([96]) http://www.curelauncher.com

incurable patients: it indicates non-validated treatments for personal and single use.

In these circumstances, patients are often ready to try any kind of treatment that would help in their situation; some are even prepared to engage in self-experimentation of new treatments under development or still in the clinical trial phase.

Generally compassionate care is not an alternative to the consolidated paths of pharmacological trial approved in the scientific community, but rather an exception, for particular situations. Its use can raise sensitive questions with regard to scientific assessment, liability, the distribution of resources, and the evaluation of informed consent.

Such experimental treatments need to demonstrate a reasonable scientific basis: data published in international scientific journals, results on animals and preferably results from phase I clinical trials. The prescription requires an evaluation by a panel of experts, in conditions of full transparency, absence of conflicts of interest, publication of the products' composition and the treatment's results, detailed explanation to the patients of the potential dangers, and possible absence of benefits and the drugs' costs.

2. Off-label treatment indicates the use of treatments in a way (as regards indications, modalities of use) that differs from those authorised, with a scientific basis of efficacy and tolerability. It does not oppose traditional standards of experimentation and use of drugs, but allows, exceptionally, under medical control, the use of treatments not yet validated by healthcare regulatory authorities in cases where patients have a serious pathology without validated therapies or with validated therapies which are not effective (as regards therapeutic results with reference to the pathology and to quality of life). Validation is plausible but not concluded, with scientific bases but not yet authorised and licensed.

Investigational drugs can save or extend lives although they have not yet been proven through experimentation to be safe and effective. While new investigational drugs may be effective, they may also have unexpected serious side effects and unforeseen risks.

3. The 'expanded access' to treatments permits patients to have access to investigational drugs and vaccines in situations where no other effective treatment is available and in conditions of emergency, for individual and social health.

The 2014 outbreak of Ebola in Africa is an example. In response to this challenge WHO convened a consultation to consider and address the ethical implications of the use of unregistered treatments (covered by expanded use). The panel, taking into account that in the case of Ebola, not only individual health but also public health was at stake, concluded that it would be acceptable on both ethical and evidential grounds to use unregistered interventions that have shown promising results in the laboratory and animal models but have not yet been evaluated for safety and efficacy in human beings ([97]). It was stipulated that aside from scientific criteria, certain ethical criteria must guide the use of such treatment: transparency, informed consent, freedom of choice, confidentiality, respect for individuals, preservation of dignity, fair distribution and involvement of the community. Furthermore, all scientifically relevant data from this intervention should be collected and shared to establish the safety and efficacy of the interventions. The panel has also identified ethical dilemmas which require more analysis: data gathering vs. promoting optimal care, criteria for prioritising the use of unregistered experimental therapies, and the criteria for determining the distribution of the growing number of investigational interventions unlikely to meet the demand.

This step towards broader use of experimental therapy is paralleled by recent developments and reforms in the USA where the US Food and Drug Administration (FDA) has also expanded access to experimental medicines. In fact, the growth of applications for FDA approval of expanded access has been remarkable in the past years. Some requests are also being made directly to biotech companies by licensed doctors on behalf of their patients. In May 2015, Johnson and Johnson established a panel to work on this topic and make decisions about patients' requests for lifesaving medicine ([98]). Several states in the USA have adopted 'right to try' laws allowing terminally ill patients to access experimental drugs directly from biotech companies without final FDA approval. Evidently, this 'piecemeal

([97]) 'Ethical considerations for use of unregistered interventions for Ebola virus disease', Report of an advisory panel to WHO, World Health Organisation, 2014.

([98]) http://www.jnj.com/news/all/Johnson-Johnson-Announces-NYU-School-of-Medicine-Partnership-to-Evaluate-Compassionate-Use-of-Investigational-Medicines

approach' requires a reform of the FDA expanded access programme. The following suggestions have been put forward: biotechnology companies should have clear and publicly accessible expanded access policies; each patient should know why a request for expanded access is denied; requests for expanded access should be tracked and reported to the FDA; a task force should be established to further improve the expanded access programme.

Similar processes are also being explored in Europe, including under the guise of the so-called 'right to hope'.

These phenomena — compassionate use, off-label treatments, expanded access to treatments — are differentiated practices which nevertheless share similarities: they are all an expression of the way in which both individuals and patient groups exert pressure to speed the pace of research, spearhead new research. The established path of scientific experimentation within evidence-based medicine requires time: the urgency of individual and societal expectations and the possibility to be informed, through ICT, of new possible experimental care and therapy opens the door for new demands.

Patients and their families often search for new ways to experiment care and therapies through web and social networks, in order to directly connect with other patients or groups of patients in the same conditions, but also physicians and scientists in the field. In requesting to self-experiment treatments they reflect a wish to overcome the rigid protocols of research, to open — in specific conditions — new ways of experimentation of treatments, as expression of the right to health, to be cured and cared, to be free in health choices. That requires an ethical reflection of the conditions of compatibility of individual/groups request and the social need of fair distribution of resources (see section 2.5).

As regards the regulatory framework on experimental care and therapy, at international level the Helsinki Declaration, Article 37, allows a non-proven intervention, under medical responsibility and accompanied by an expert opinion, when no other validated effective interventions exist.

Citizen veillance on health

'Citizen veillance on health' is a form of collaboration between citizens and health professionals in creating knowledge, a form of co-collaboration or 'peer-production' of knowledge, generally motivated by personal, combined with shared social goals. 'Citizen veillance' has similarities to both epidemiology and surveillance of public health, but also has specific differences, that qualifies it as a form of 'citizen science'.

A project spearheaded by the Sarroch municipality (Cagliari, Italy) provides a case study of citizen veillance driven primarily by a local community ([99]). In 2006 the Sarroch municipality launched a project of epidemiological investigations with the purpose of using science for policy with the aim of protecting the health of the citizens and the environment. All phases of the project were discussed with the local community in order to raise civic awareness and co-produce knowledge, between citizens and scientists. The citizen-owned Sarroch Bioteca Foundation was established (and subsequently recognised in 2012 as a trusted entity) to gather biological samples donated by citizens to monitor genetic changes as indicators of health. All citizens of the municipality could become members of the project, after registering their commitment (based on informed consent) to be enrolled in specific research.

'Citizen veillance' can serve both as a confrontation with institutions, or often as a way to underline the inefficiency of institutions, in order to compensate for the lack of adequate health protection, and also a lack of adequate legal tools. In this sense 'citizen participatory veillance' becomes a model for the normative implementation of scientific policies in the control of health and institutional implementation. And even more: 'citizen participatory veillance' becomes an assessment and regulation instrument in the public sphere.

The fact that there is a strict connection between collected, monitored and 'veilled' data and health policies (that may also be restrictive as regards freedoms, see infectious diseases), the direct, active and effective involvement, in the sense of participation and collaboration of citizens/scientists in health, is a condition for democratic health choices. Democratising health and health policies may be the real motivation for phenomena of 'citizen participatory veillance' of health and illness: the participation of citizens, patients, and experts–patients (patients that have acquired the skills and expertise on their illnesses) is not a guarantee of

([99]) M. Tallacchini et al. (2014), 'Emerging ICT for Citizens' Veillance', European Commission, JRC Science and Policy Reports.

democratisation ([100]), but a step towards efficacy and social acceptance of veillance and consequent policies.

Expert patients and patient interest groups

Citizens and patients may have knowledge and competences which enhance and complete those of scientists and specialists. In the case of HIV/AIDS, gay communities and patients' organisations have made a significant impact in drug research studies, successfully changed the protocols of clinical trials and managed to modify the name of the disease. Furthermore, groups of patient activists conducted a trial of Pentamidine (used to treat a type of pneumonia) when clinicians refused to do so. Later the drug was approved by the FDA, the first time a medicine has been authorised as a result of community-based experimentation ([101]).

Another example of patient-initiated research was provided by experiments on the use of lithium in patients with ALS. This study paved the way for a subsequent formal clinical trial that confirmed its results that lithium had no effect on the progression of the disease. The outcome has been published by a peer-reviewed biomedical journal ([102]). In this way, patients organisations have become increasingly active in accelerating clinical discovery and assessing the effectiveness of drugs ([103]).

The European Medicine's Agency (EMA), the body responsible for the scientific evaluation of medicines in the EU, provides an example of a regulatory authority which aims to benefit from patient experience and expertise. Patient representatives are members of several EMA scientific committees and patients are involved in regulatory processes. This includes participation in benefit/risk evaluations of medicines, with patients providing their direct perspectives of living with particular diseases and treatment options. The involvement of patients in this way is based on a clear criteria developed by the EMA on when and how to involve patients in the evaluation of medicines ([104]).

1.3. Summarising new opportunities and challenges in health: Prevention, prediction, personalisation, participation and precision

This chapter began by examining the key health technologies which are redefining the relationship between an individual and their health. It then analysed how citizens are becoming increasingly engaged in the production of knowledge and highlighted the new forms of citizen involvement in health driven by the confluence of technological development and changing social behaviours. What are the wider implications of these changes for medicine and healthcare?

According to certain scholars ([105]) the above-described technologies and practices carry the potential to transform healthcare in a number of ways: from a 'reactive' to a 'proactive' approach to medicine, with a growing emphasis on 'preventive' or 'predictive' care, and dealing with disease in a 'personalised' and 'participatory' way. The convergence of new health technologies and new analytical tools of information technologies is held by some to be transforming our current 'reactive model of medicine' (the cure and care of the patient), based on limited data, and 'population-based' statistics and averages to a preventive, predictive, personalised, and participatory medicine.

Such projections are in turn linked to the advocating of so-called 'Systems Medicine'. This term refers to a global approach based on an integrative, interdisciplinary method applied to health and disease, understood in their complexity and encompassing the biological, social and environmental interactions of heterogeneous factors.

The diagnostic possibilities determined by 'omics' and novel biomarkers has raised expectations regarding the capacity of medicine to make an efficient prediction of a person's health condition and consequently

([100]) EGE Opinion on the Ethics of Security and Surveillance Technologies, 2014.

([101]) Bucchi, M. and Neresini, F. (2008), 'Science and public participation' in *The handbook of science and technology studies*, IIIrd edition, eds. Harkett, E. J., Amsterdamska, O. and Lynch, M., the MIT Press, London, pp. 449-471.

([102]) Wicks. P., Vaughan, T. E., Massagli, M. P. and Heywood, J., 'Accelerated clinical discovery using self-reported patient data collected online and a patient-matching algorithm' (2011).

([103]) *Nature Biotechnology* (2011, 29, 411-414).

([104]) Hearing with Dr Noel Wathion, Chief Policy Advisor, EMA. See also: http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000317.jsp&mid=WC0b01ac058003500c

([105]) Hood, L. and Flores, M., 'A personal view on systems medicine and the emergence of proactive P4 medicine: predictive, preventive, personalised and participatory', *New Biotechnology*, March 2012, pp. 1-12.

individualise prevention. The technological possibility to collect and analyse large amounts of data (genomes, bioinformatics) is the condition of the development of precision medicine, as a comprehensive approach to preventing, diagnosing, treating, and monitoring disease in order to anticipate and optimise — through a deeper insight into the disease mechanism — healthcare decisions. Intertwined with 'personalisation', are the expectations and potentials of participation: patients or healthcare consumers are involved passively (as providers of data, through genetic tests and the sequencing of the human genome, donation of biological samples, digital consumers devices, such as health apps, measuring personal information besides biological and environmental data, etc.) and encouraged to actively participate in their own healthcare by following the correct lifestyle and increased awareness of disease (through social networks, virtual communities of patients led by physicians or by themselves, personal monitoring devices, etc.). Crowdsourcing of volunteers might extend and modify the way in which clinical trials are performed in the future.

In contrast to past evolutions in medicine, citizens and patients as consumers may be playing new roles in the realisation of new ways to understand and apply medicine through participation. Networked patients and consumers become actors managing and monitoring their health, while at the same time providing information which promotes scientific advancement. The databases and networks can provide new knowledge on health and disease and be tailored to the condition and circumstances of the single individual. The prospect is for predictive models of health and disease for patients that are actionable — i.e. which provide data that enable them to improve their health. Furthermore, this medicine is beginning to cross the boundaries of the traditional clinical setting, with new digital health devices and systems allowing patients and their family members to manage their health at home.

Potential benefits of this transformation include early and more accurate diagnosis, more selective and effective treatment, reduction of time, costs and failure rate of therapy and clinical trials, the change of focus from disease to wellness, and empowerment of the patient and physicians ([106]).

The acceleration of the transformation raises new societal and cultural challenges, which opens new opportunities, but also new possible challenges, tensions and issues from an ethical perspective.

([106]) Collins, F. S. and Varmus, H., 'A new initiative on precision medicine', *New England Journal of Medicine*, 2015, 30 January.

Chapter 2 Emerging ethical tensions

The promises and potentials of new health technologies and the new avenues for citizen engagement are driving what we described in Chapter 1 as a paradigm shift (or set of shifts) in the way that health and healthcare and perceived, organised and delivered. These shifts bring a number of ethical challenges which are grouped according to the following five sets of considerations:

First, the implications of new health technologies and new modes of involvement on perceptions of the 'self', of personhood and of the body in a medical context (section 2.1). While advances in the field of genetics, diagnostics and health informatics hold immense potential for improved diagnoses and treatments, how can increasingly information-based approaches be reconciled to patients' lived experiences, in other words the day-to-day experience of patients in relation to their own bodies?

Second, the implications of potential transformations in the patient–physician relationship (section 2.2). Are new patterns of participation changing structures of knowledge and power in medical practice? How might such a transformation, together with increasing possibilities for patient–physician interactions to take place outside of traditional clinical settings, impact upon patient empowerment, patient safety and quality of care?

Third, the implications of citizen involvement in the research endeavour (section 2.3). This draws attention to the ambiguity inherent in terms such as 'citizen science' and 'citizen participation', in which notions of empowerment, engagement and exploitation are not always simple to disentangle. It also explores the tensions between citizen involvement on the one hand, versus the quest for scientific integrity on the other.

Fourth, the implications of new health technologies and citizen involvement on societal understandings, principles and structures governing health (section 2.4). This draws attention to the potential for new forms of surveillance, responsibility shifting in the domain of health, and a potential extension of what some have labelled the 'medicalisation' of society.

Fifth, implications for notions of solidarity and justice (section 2.5). How might innovative health technologies make questions of access and inequality increasingly acute? Another important consideration is how an increasingly dynamic engagement of citizens as patients and consumers, could make the arbitration of interests more complex, presenting challenges to the principle of solidarity as an overarching framework for European healthcare systems.

Consideration of these ethical questions will be underpinned by the following ethical principles:

- Human dignity, serving as a basis for requirements of privacy, confidentiality and medical secrecy;
- Autonomy, serving as a basis for requirements of self-determination and participation;
- Beneficence and non-maleficence, serving as a basis for the attempts to weigh anticipated benefits against foreseeable risks;
- Justice, serving as a basis for requirements of equitable distribution of limited resources;
- Solidarity, serving as a basis of the right for everyone to the protection of healthcare, with a special concern for vulnerable groups in society.

2.1. Evolving notions of the self: abstraction versus 'personalisation'?

The developments described in Section 1 may act on concepts of the individual or 'self' — as citizen, consumer, patient, or active participant in preventive, diagnostic, therapeutic or research-oriented health technologies. With the opening of a multitude of new roles for citizens as active participants in all aspects of health, from medical research to the organisation and delivery of healthcare, it is far from clear how they impact the individual's self-concept: on the one hand, most of the technologies presuppose either an information-based approach, transforming the embodied experience of each of us into information that can be transmitted via new technologies, or a biological (physiological) approach that takes the biological dimension of human beings as the crucial target of prevention, diagnosis, or therapy.

On the other hand, however, one can observe the rising interest in health-related social media, which serve as an interactive forum for the narration and communicative sharing of lived experiences: cyberspace welcomes both — life sciences as much as lived experiences. Individuals need both dimensions, the empirical (informational, biological) and the experiential, in order to maintain self-identities, and it does not come as

a surprise that the 'active citizens' strive to integrate their empirical data and their experiential narratives of health and illness into one 'story'.

A possible challenge when it comes to the control of one's well-being is whether, with the rise of a data-intensive medicine, we first rely upon the data we collect, before we correlate them with our 'sense of self'. And even though we share our experiences willingly and often eagerly with others, how they can (still) be part of medical encounters. If the patient becomes more and more active and engaged, it could well be that patients' stories, traditionally part of the doctor–patient relationship, will be more and more transferred to patients' virtual communities (see section 2.2. below).

Advances in the fields of genetics, diagnostics and medical informatics hold immense potential for the delivery and provision of effective healthcare and medical treatments. Yet while measurable and objective variables are important for delivering effective medical treatment, these are not capable of capturing the personal biographies of patients which are equally essential for their medical care ([107]). Whether using genetic testing, new diagnostic techniques such as neuroimaging, digital monitoring devices or mHealth applications, the wealth of 'bio-information' generated by these technologies may feed a progressive understanding of the self which potentially risks becoming detached from social and environmental factors and from the biographical subjectivity of the patient ([108]). This is certainly not integral to the technologies we are examining here, but will very much depend on how these technologies are used in diverse care contexts.

The rise of genetic information

The above questions underlie the increase of genetic knowledge through genome sequencing and genome-wide analysis and the increasing interest in the use of genetic tests which have become faster and cheaper and which open new diagnostic possibilities. The idea that genetic information is a way to gain determinate knowledge of a person's health conditions and susceptibility to illness (the-so called phenomenon of 'geno-centrism') is scientifically and philosophically problematic, as every person is the result of a complex interaction of genes and environment; a person is more than the sum of the parts and non-reducible to them: we 'are' our genes, but also 'beyond' them. Genetic information, while capable of delivering important insights, cannot tell the whole story.

Overcoming the reductionist/determinist genetic paradigm — in both the scientific and philosophical sense — is also important because genetic test results — are subject to a large degree of variability ([109]). The uncertain nature of their results — and the fact that their predictive power relies on a weighing of probabilities, makes it important that patients obtain an official clinical validation of the results and receive medical counselling in order to interpret their implications.

The growth of genetic testing has also brought new ways of living with predictive diagnoses. There is a concrete possibility opened by the availability of diagnostic techniques and monitoring devices, that consumers may become a new class of 'patient' within the world of medicine. They are not 'patients' in the classical sense, as they have no typical symptoms of illness; they are individuals who share genetic predispositions, or whose vital signs manifest abnormalities, who may live in the expectation of the appearance of some sign of disease, organise their lives around visits to the doctor or laboratory tests, and end up feeling ill or even developing psychosomatic symptoms; they are healthy citizens becoming ill and patients anxiously waiting for the predicted probability of symptoms. Linked to this scenario is the challenge of so-called 'incidental findings', unexpected or unsolicited results which emerge from

([107]) Levin, N. (2014), 'Making up "persons" in personalised medicine with metabolomics', *Somatosphere: Science, Medicine and Anthropology* (http://somatosphere.net/2014/02/making-up-persons-in-personalized-medicine-with-metabolomics.html).

([108]) Bio-identity is used in this context to denote a biological-based sense of identification and affiliation, to the exclusion of the social, environmental and biographic aspects of identity formation. The understanding of identity primarily in terms of 'bio-identity' is reductionist in a double sense: reducing several identification categories into one, and reducing the identity of the self to the identification of someone by these categories. For the distinction between 'ipse' and 'idem' (self and sameness) cf. Ricoeur, P., *Oneself as Another*, Chicago 1996.

([109]) The US Government Accountability Office (GAO) performed a retrospective study of results produced by private companies regarding risk prediction for a number of diseases such as hypertension and prostate tumours: separately tested samples gave contradictory results that varied from below-average to average to above-average risk for a single sample. As well as a high error margin, this study also underlined inadequacies in communicating the results as well as the making of false claims regarding the predictive or curative properties of the tests. GAO, 'Direct-To-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices', 22 July 2010 (http://www.gao.gov/products/GAO-10-847T).

tests and which raise important questions concerning how and which results should be returned to patients, taking into account an individuals' desire for such information (right to be informed, right not to be informed).

At the same time, there are important positive implications which result from this increase in medical information and diagnostic power. Knowledge about one's state of health allows to take action to address a problem. Even being informed about a predisposition to a chronic or fatal illness, while on the surface disempowering, can allow individuals to take informed decisions and make important life choices.

Yet the unprecedented power of new health technologies to track, map and classify the body and to define what is normal and abnormal, healthy and unhealthy, holds important consequences for our understanding of — and the link between — the self, health and the body. It opens questions around the potential for post-genomics medicine to move towards a so-called 'systems medicine' which examines the self as an integration of complex interactions among genes, behaviour and the environment ([110]).

The quantification of the self

Questions surrounding the link between the self, health and the body are brought to the fore by the growth in health-related self-monitoring and self-tracking. The transition of complex technologies into the intimacy of people's lives, has allowed these technologies to provide information on the person — regarding both behaviour and biology — in a way that was previously not possible. Individuals can record and monitor specific aspects of their bodies' functioning (e.g. heart rate, metabolism, hormone levels) on a continuous basis, in order to monitor the progress of and maintain health. This has given birth to an organisational movement — the 'Quantified Self' movement — whose members strive for better self-understanding by collecting, quantifying and comparing data about themselves, their way of life, consumption, nutrition, sports, health, aided by the use of connected body sensors such as bracelets, chips, watches, combined with mobile applications ([111]).

How do these technologies influence notions of the self, self-identity and the relationship with the body? Self-monitoring technologies have provided people with extremely effective ways of understanding their bodily processes. From diabetics monitoring blood glucose levels to bipolar patients engaging in mood-tracking, individuals can now gain direct insights into their body's functioning. Do these technologies therefore herald a transition towards individuals reclaiming control over their bodies? May they help broaden the medical gaze beyond the effects of treatment on bodily parameters alone, situating bodies (and effects of medical treatments) within the intricacies of daily lives ([112])? Or are we in fact simply witnessing an extension of the clinical gaze, so that every individual assumes the task of monitoring their 'body-object'? The answer may lie in what precisely is being quantified or measured ([113]). What kinds of information have value, and for whom?

In the CNIL report on this subject, Antoinette Rouvroye notes: 'The phenomenon of the Quantified Self is part of a process not of measurement but of continuous quantification in real-time-contributing to the social production of standards of behaviour, performance and health, highly scalable ... and allowing the possibility to visualise and possibly compare the progress by the users directly connected to the internet through sensors which 'quantify it' ([114]).

For certain observers, the notion of quantified self reflects a continuity of medicalisation trends of the last two centuries, characterised by a tendency to pathologise previously unremarked human conditions, traits and problems. In the case of 'quantified self' movements, medicalisation as driven by the medical profession finds synergies with citizen-driven movements around 'healthism', wellbeing and lifestyle change and

([110]) Kamada, T., 'System biomedicine: a new paradigm in biomedical engineering', *Front med. Biol. Eng.* 1992: 4(1): 1-2.

([111]) http://quantifiedself.com

([112]) Mol, A. and Law, J. (2004), 'Embodied action, enacted bodies: The example of Hypoglycaemia', *Body and Society*, Vol. 10 (2-3), pp. 43-62.

([113]) In his reflection on the quantification of the self movement, Alain Desrosières distinguishes it from the idea of measurement. Quantifying, he writes, is to 'express and give existence in a digital form what was previously expressed in words, not in numbers' while 'the idea of measurement implies that something exists in an already measurable form'. One can thus measure the size and weight of an individual at a particular moment. But the more or less good health does not allow measurement as such. To do so we should establish equivalence agreements. See Desrosières, A., *Pour une sociologie historique de la quantification: l'argument statistique I*, Paris, Presses de l'Ecole des mines, 2008 (329 pages), pp. 10-11.

([114]) CNIL (Commission Nationale de l'Informatique et des Libertés), 'Le corps, nouvel objet connecté. Du quantified self à la M-Santé : les nouveaux territoires de la mise en données du monde', *Cahiers IP, innovation & prospective* N°02, mai 2014, p. 4.

feeds off individuals' drive for self-improvement ([115]). It leads in its own way to the implementation of a health that is no longer a 'state of complete well-being' but a health in position 'meta', always beyond, pulling ahead. The quantified self is based on a voluntary use, but with essentially automated measurements. It collects and circulates a large volume of personal data related to a body, but also ways of life. Most often it is initiated by people themselves, driven by leisure interests, the potential to manage a health condition and/or a promise of mastering one's self.

The digital technologies which enable a 'quantified self' are used by some simply as an amusing gadget, and by others as a highly valued tool for controlling an illness (e.g. diabetes patients measuring their blood glucose levels) or for providing useful insights into bodily states (e.g. women who use fertility apps). But looking beyond these everyday applications, involving the body in its intimacy means legal, ethical, socio-political, economic issues (further explored in section 2.4, and section 3). While the ethical assessment is difficult not only because the notion of quantified self implements heterogeneous practices, but it also uses a variety of tools and applications, the ethical and anthropological risk at stake here is one of fragmentation, of losing the global understanding of an individual's health, which cannot be reduced to parts, measured and quantified.

'Personalisation': the challenge of a patient-centred medicine

'Personalisation' holds the promise of overcoming the above-described fragmentation, in providing a tailored, patient-centred healthcare product. Advances in the technologies driving precision or 'personalised' medicine are making use of ever more refined diagnostic testing, using the analysis of big data to take greater account of patient's genetic and clinical histories to select the best treatments at the most effective doses. Many consider this the future of healthcare: an individually adapted medicine, better targeted, with fewer adverse effects and with potentially important cost savings for national health systems.

However, the very term 'personalisation' in this context is potentially misleading. As J. C. Weber underlines, 'proposed treatments are generally not individualised, but categorised/stratified, they do not vary according to each individual, but according to some categories or sub-types: it is rather a stratified medicine than a personalised medicine. Their implementation in European healthcare systems requires a greater standardisation of the processes involved, from technological validation (which can be easily conceived) to informed consent (which is more difficult to apprehend)' ([116]).

The promise of 'personalisation' does not therefore offer an individual, tailored, nor an entirely person-centred treatment. Even if big data-based developments in 'personalised' medicine are allowing for ever more sophisticated levels of stratification, the 'person' at stake is rather a category, the parameters of which are established via the collection and analysis of large quantities of data. Precision medicine may also raise a degree of ambiguity over how physicians and healthcare professionals will balance data-based diagnoses and treatment options with considerations of the 'experiential' dimensions of a patient's life. Movement in this direction may be underway as new big data technologies begin to recognise the need not just for genetic data but also associated clinical, behavioural, physiological and environmental data. It would nevertheless be important to keep a focus on the contextualisation of a patient's broader social, economic, cultural, or environmental context together with a consideration of a their empirical information.

Such considerations come alongside potentially important ramifications of precision/'personalised' medicine for the solidaristic nature of Europe's health delivery models as further explored in section 2.5.

2.2. Transformation of the doctor–patient relationship: responsibility versus responsibilisation?

The impact of new forms of digital involvement of patients in medicine holds the potential to alter the traditional relationship between patients and health professionals, although the extent and nature of this change is as yet unclear.

([115]) Thiel, M.-J., *La santé augmentée: réaliste ou totalitaire?*, Paris, Ed. Bayard, 2014; Crawford, R., 'Healthism and the medicalisation of everyday life', *Health* Vol. 10, No 4, 401-420 (2006)); Skrabanek, P., 'The Death of Humane Medicine and the Rise of Coercive Healthism', Suffolk (UK): The Social Affairs Unit, 1994; Rose, N., *Powers of Freedom: Reframing Political Thought. Cambridge*, Cambridge University Press, 1999.

([116]) Weber, J.-C., 'Personalised medicine, promises and expectations', Lettre du CEERE (Centre Européen d'Enseignement et de Recherche de l'Université de Strasbourg), No 80, décembre 2014, pp. 2-3.

What is becoming more apparent however, are the ways in which the 'democratisation' of information are making access to medical knowledge no longer the sole preserve of medical professionals. Socio-technical trends have led to a surge in available health data and information, rapidly accessible to an increasingly connected public. While the abilities of individuals to interpret medical information will certainly vary, and physicians continue to be for the vast majority the most important source of medical advice, nevertheless today's citizens are becoming increasingly adept at finding, filtering and interpreting this flow of information as part of their everyday lives: this has been characterised by some as a process of re-appropriating technical expertise by lay agents and part of a wider trend towards social reflexivity ([117]).

As a consequence, the health sector may witness what could be characterised as a new step in the evolving relationship between physicians and their patients. The doctor–patient relationship has already seen an important shift over the last century. The paternalistic and asymmetrical relationship between a doctor and his patient (whereby the patient would describe their symptoms, and the physician provide a diagnosis and issue a set of instructions for treatment) has given way in the last 20 years to a so-called 'partnership approach'. Although the degree to which this has been embraced across healthcare contexts varies substantially, it generally rests on the understanding that both the doctor and the patient share responsibilities; the relationship is consensual, not obligatory; and doctor and patient engage in shared decision-making ([118]). This shift from paternalism to contractualism in the doctor–patient relationship has been an essential part of realising the principle of patient autonomy in modern medical care.

With the rise of new, digital health technologies and availability of online health resources, comes a further possible decrease in the dependence of patients on the 'authority/power' invested in medical expertise. Patients can now research their symptoms and present their physician with their own diagnosis of their illness. They may choose to bypass the doctor altogether, crowdsourcing treatment options or ordering medication from online pharmacies. Patients in some Member States are no longer relying on general practitioners to act as 'gateways' to specialist medical expertise, but instead attempt to diagnose their symptoms and refer themselves directly to the appropriate (or not) specialist.

A parallel trend driven by new health technologies, but with no less important implications for the doctor–patient relationship is the advent of telemedicine and remote care, which no longer obliges a physical interaction between patient and doctor in a clinical setting, facilitating the virtualisation of patient/physician exchanges.

The benefits presented by these developments are potentially considerable. They may see a process of growing self-determination, self-actualisation and empowerment of patients/citizens. The increased technological autonomy can stimulate health awareness, encouraging an improvement in life style (calories and exercise control), motivating citizens/patients to follow medical advice and to participate actively in health issues (e.g. continuously and digitally self-reporting data or symptoms to their physician). Communication between patients and physicians may be improved: it may become faster, easier, better on a quantitative and qualitative level. Those who previously experienced difficult in accessing doctors (e.g. individuals living in remote locations, with limited mobility or mental health problems) could find in telemedicine new possibilities for accessing care. The work of wider health professionals, such as community care providers, could also be significantly facilitated. Digital communication and monitoring devices may, for instance, assist elderly people or end-of-life patients to remain in their homes for longer with the help of digitally connected health visitors, rather than face hospitalisation. There could be subsequent and important efficiency gains and cost reductions for health systems. Indeed, the WHO and the EU have encouraged active participation of patients in decision-making so that the patient can contribute to improving the quality and efficiency of their own care ([119]).

([117]) Giddens, A., (1990), *The Consequences of Modernity*, Polity Press, Cambridge.

([118]) Kaba, R. and Sooriakumaran, P. (2007), The evolution of the doctor-patient relationship, *International Journal of Surgery*, Vol. 5, pp. 57-65; Truog, R. D. (2012), Patients and Doctors — The Evolution of a Relationship, *M.D.N Engl. J. Med.*

([119]) World Health Organisation 2013, Exploring patient participation in reducing healthcare-related safety risks; EU Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections (2009/C 151/01).

However, ethical risks may emerge where technologies cause patients to lose critical contact with medical professionals when it counts. There now exists the possibility, for those who wish to avoid the traditional medical channels, to use new health technologies (health apps, and online resources) as a means to self-diagnose, self-medicate, and self-experiment, without any medical consultation; to buy and use genetic tests and pharmaceuticals online without any counselling, advice, prescription, information, or involvement of physicians. 'Self-patients' means not only digitalisation of the relationship with a physician, but the potential for substitution of the physician (see for instance the health app 'pocket doctor'). While there can be important benefits inherent within these trends, there are also risks of harm associated with inaccurate health information available on the internet, the use of unlicensed medication, and lack of medical oversight relating to mHealth devices and direct-to-consumer diagnostic kits and tests.

An additional, more fundamental question is whether this increasing role in patients' own diagnosis and treatment could ultimately challenge traditional expectations of healthcare. The paradigm shift from paternalism (asymmetrical relationship of physician's authority and patient's vulnerability) and contractualism (symmetrical relationship between physicians and patients, becoming autonomous), risks swinging in the opposite direction towards a 'responsibilisation' of patients, whereby the weight of responsibility falls on the individual to ensure, not only that they are healthy, but that they take proactive measures to monitor, control and interpret their health data and take the appropriate follow-up action (see also section 2.4.). Responsibilisation is not in itself a negative development, indeed a shared sense of responsibility between doctor and patient can be central to ensuring better health outcomes. The challenge is to ensure the right balance, whereby the patient is empowered to exercise their autonomy, while not losing the crucial interpersonal exchange and necessary expert support in interpreting medical information and selecting treatment options.

A number of factors, besides technological progress, provide the backdrop to the evolving relationship between patients and health professionals. On the one hand, economic considerations are likely to influence the decision of certain individuals as to whether to consult a medical professional or resort to alternative (often free) digital health resources. Budgetary considerations on the part of the state can also be factors influencing the roll-out of telemedicine and remote care by decision-makers (see section 2.4.).

But an important additional contextual element of this paradigm shift is the gap between what the citizen expects from medicine and what they receive; what a patient expects from physicians and what they receive. Medical and technological progress has raised expectations significantly around capacity of science to find a cure. Such high expectations may result in dissatisfaction and disillusion when medicine or physicians cannot provide the hoped-for solution ([120]).

This distrust and uncertainty may form at least part of the backdrop to citizen involvement in medicine such as self-diagnosis and sale of medication via the internet, demand for experimental and compassionate therapies, rise of patient groups and the phenomenon of the 'expert patient', even the trend of 'defensive medicine'. An erosion of trust can also explain trends of non-compliance with medical advice that carry significant public health considerations, such as anti-vaccination movements and the threat of antibiotic resistance.

Maintaining and rebuilding trust between patients and medical authorities will be key in the evolving healthcare context. New technologies that support changing modes of patient–physician interaction should be geared towards enhancing the patient–physician relationship and the quality and availability of care provision from healthcare systems.

2.3. Active engagement versus 'passive participation' in health and medical research: consequences for empowerment, exploitation and scientific integrity

Citizen involvement in health and medical research can take many forms and intervene at different stages in the decision-making/knowledge generation/research application process (see section 1.2). Despite these nuances in the notion of participation it is nevertheless helpful to distinguish on a methodological level two simplified models of citizens/patients participation in health: the top-down, 'unwitting' or 'passive' model of participation and the bottom-up, 'active' model. Each model is associated with specific opportunities and advantages as well as bringing its own set of ethical considerations. These tensions centre, in part, around ethical notions of empowerment and autonomy, versus the need to protect individuals from harm.

([120]) Lupton, D. (1994), *Medicine as culture: illness, disease and the body in Western societies*, London: Sage.

The active or 'bottom-up' model of citizen participation in health or medical research is generally community-driven by non-experts or amateurs, who can be either interested citizens, or individuals with a stake in advancing knowledge on a particular medical condition, including 'expert patients'. The passive ('top-down') model is expert driven: scientists and researchers design, lead and oversee the implementation of a project, counting on the participation of citizens/patients to volunteer data or biological samples, partake in trials or engage in narrowly circumscribed analytical tasks.

This first model foresees the active participation of citizens/patients and may open opportunities of advancement of science and of influencing research. By opening up scientific experimentation to new actors it can harness new sources of creativity and energy, and tap into the unique insights of individuals directly affected by health conditions. Such participation serves as a means of empowering patients to become actively involved in learning about and advancing medical knowledge on their condition.

However, the active, bottom-up model has raised concerns surrounding issues of scientific validity, in particular the potential for activities to be carried out without a firm grounding in scientific competence and literacy, scientific methodology or qualified systematic analysis and peer review.

The rise of the 'expert-patient' and the 'expert patient culture' is based on the value of experiential knowledge, not of scientific rigorous training. Moreover, activities which are driven forward by amateurs, outside the institutional frameworks which govern medical research bypass formal mechanisms of ethical oversight.

The bottom-up model of citizen involvement may therefore challenge the principles of evidence-based medicine (EBM) which applies strict criteria for validating medical research (including, inter alia, an appropriately qualified doctor as an investigator). Though EBM is not uncontested, it is generally understood as a process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients and it is presently the gold standard tool for commissioning and provision of healthcare, applied not only in pharmaceutical treatments but also increasingly to surgical interventions, diagnostic tests and medical devices ([121]). Interestingly, it has been recommended that the campaign for real EBM should include sharing decisions with patients and building a strong clinical–patient relationship ([122]). Indeed, there are some initiatives, such as those of the European Medicines Agency, that should be welcomed, which integrate this form of lay expertise into the process of evaluation and regulation (see section 1.2). In addition, citizen participation may have a role in peer review or in a process of 'crowdsourcing ethics review' (e.g. posting a research protocol on an online platform inviting comments) ([123]). In this sense it becomes necessary to define what is science and scientific integrity. Science, in the modern experimental meaning, requires certain criteria and standards to be satisfied; it requires review mechanisms, an empirical proof of the theoretical hypothesis formulated. Experimentation in medicine requires compliance with protocols agreed by the international scientific community.

Does participating outside of the medical/scientific establishment imply a disregard of those standards and mechanisms? Not necessarily: but scientific oversight is important to guarantee the rigour of a project's methodology and the relevance of its results. Are concerns over scientific integrity and evidence-based medicine shared by citizens — do citizens/patients care if a method, process or output does not meet the criteria of science if it is perceived to work? The popularity of homeopathy may serve as one example in this context, as do practices of compassionate use or expanded access to therapies (healthcare based on 'the right to hope' or 'right to try'). Lay non-professional knowledge may contribute to science; the minimal requirement is that it should be validated with the scientific methodology (experimentation, peer review). Examples of non-conventional healing methods ([124]) provide just such examples of lay contributions which remain to be verified by scientific methods.

The 'top-down' model, while fulfilling requirements of scientific method, raises a different set of considerations which centre around the degree of agency of

([121]) Balsey, J. (http://www.medicine.ox.ac.uk).

([122]) Greenhalgh, T., *Brit. Med. J.,* 2014, 348, g3725.

([123]) Crowdsourcing as a participative online activity, on a digital platform, in which individuals, institutions or organisations openly call for voluntarily undertaking a task: it may apply to health, generally it is a call to share data or call for ideas/inventions useful for researchers. It is an increasingly diffused phenomenon. Crowdsourcing is strictly connected to open data: the availability of vast amounts of accessible data helps the diffusion of crowdsourcing. It is a tool for both professional researchers and citizen scientists.

([124]) Also referred to as 'alternative', 'traditional', 'complementary', or 'holistic' medicines.

individuals involved and the delicate dividing line between empowerment and exploitation. The top-down model, in harnessing the data or crowdsourced contributions of large numbers of participants, offers the potential for groundbreaking advances in medicine (see section 1). In addition, it holds important educational potential by enabling individuals to learn about new areas of science and research, with associated advantages for research transparency. Yet with data increasingly becoming a 'tradeable good', narratives that frame citizen involvement as a straightforward partnership between the public and the research community should also be treated with caution ([125]). An example is provided by the case of the direct-to-consumer genome testing company, 23andMe. A commercial company that draws heavily on the participatory rhetoric of citizen science, the company has been criticised for using the genetic data submitted by users to pursue its own profit-making goals. Its policy of transmitting amalgamated data to third parties and its links to Google, have also elicited privacy and surveillance-related fears ([126]).

As one of the core tensions they comprise, citizen involvement initiatives can either subsume or aim to counterbalance the notion of lay people as research 'subjects'. At the extreme of the 'top-down' approach are projects which rely on only a passive participation of citizens — a resource from which data and samples can be extracted but with little access to the outcomes of the study, or control over their data. In the case of data generated via the use of everyday devices (phone apps, wearable body monitoring devices), the risk is to normalise a situation in which everyone is a potential research subject (without the corresponding traditional framework of consent). Controversies surrounding the confidentiality of electronic patient records, legal challenges concerning certain wearables (e.g. the Apple watch), and evidence of the systematic breach of data protection rules by smart phone app providers illustrate the privacy, security and confidentiality concerns regarding citizen involvement and health (further explored in section 3.2).

([125]) Mueller, M., Tippins, D. and Bryan, L., 'The future of citizen science', *Democracy and Education*, Vol. 10, No 1.

([126]) Prainsack, B. (2014), 'Understanding Participation: The "Citizen Science" of Genetics', in Prainsack, B., Werner-Felmayer, G. and Schicktanz, G., (eds) *Genetics as Social Practice*, Farnham: Ashgate; Seife, C., '23andMe Is Terrifying, but Not for the Reasons the FDA Thinks', *Scientific American*, 27 November, 2013.

2.4. Social transformations

New societal drivers in health

Health has very real physical manifestations. But it is also a concept that is constantly being redefined in the context of the economic and social developments around it. The wider political and economic landscape therefore determine how new health technologies will be shaped, taken up and applied. In turn, the apparatus of health, including new health technologies, can act upon and influence modern societies in important ways.

Economic forces, for instance, are playing a key role in driving the take-up of new health technologies. Since many of the devices, apps, and data-generating facilities are new, there is a huge market for these innovations; genome analysis is marketed as a commercial product and certain new health devices have become the latest 'must-have' items (e.g. Fitbit, Apple watch). In a break with traditional health technologies, these are often not aimed at the classic 'patient'. Indeed, some of them may construct a social imagery of the active, capable, autonomous, and affluent consumer of health products, an agent rather than a patient, who willingly collects large amounts of data that companies may or may not use for their own purposes, and research teams may use for scientific trials.

While commercial actors are driving a rapid expansion into the health technology sector ([127]), in parallel public healthcare authorities, eager to reduce the costs of healthcare, often welcome the marketing focus on a healthy lifestyle and the imperative for citizens to take a greater hand in managing their health. Furthermore, efficiency gains offered by technologies like electronic health records; or cost reductions promised by more effective, tailored treatments and preventive approaches to health are being progressively taken up by decision-makers as a solution to containing increasing public health budgets.

([127]) This applies both to big pharmaceutical companies but also to technology firms which have begun within the last decade to identify health as the next important growth market. Giants such as Google, Apple and Samsung have made ventures into health, investing in genomics research, pharmaceuticals, and medical devices. Smaller-scale start-up companies have also proliferated in recent years as health technology entrepreneurs zero in on health as an emerging field of innovation and investment. See Ward, A., 'Technology companies eye health market', *The Financial Times*, 6 March 2015; Stanley, A., 'Tech companies see market opportunity in healthcare innovation', *The Financial Times*, 5 May 2015.

These two distinct set of drivers (commercial and political) are, nevertheless, becoming increasingly difficult to separate as trends lead to a convergence between public and private agendas. This is illustrated by the growing interest among insurers on the role of health monitoring devices to more precisely gauge individual risk.

Monitoring health, measuring risk: a new model of insurance?

New monitoring and tracking technologies may hold the key to more effectively identifying potential health risks before they arise. Among the positive benefits this brings, such a development could also hold important implications for the insurance industry. Until now, the difficulty of predicting who is likely to succumb to illness or misfortune means that the insurance model is broadly based on the principle that individuals pool their risks.

Data monitoring may herald a change in that model, by allowing insurers to price risk more accurately. It also encourages insurers to shift their activities away from simply paying out claims, to intervening in clients' lifestyles. A number of recent developments show that insurers are already beginning to implement schemes to modify their customers' behaviours. For instance, Discovery, a South African health insurer that has expanded to Europe and Asia, has 3 million policyholders who have opted for a scheme whereby they can earn discounts by showing that they are looking after themselves, for example by wearing a device that monitors their fitness or by joining a gym. Oscar, a health insurer in New York, gives all its policyholders a fitness tracker; if they hit a set goal (e.g. walking 10 000 steps in a day) they receive a refund of a dollar. FitBit, the manufacturer of fitness trackers, is now working with a number of insurers and employers who want to keep tabs on their clients and staff ([128]).

More recent advances in technology point to arguably more invasive forms of monitoring. Research is currently underway on bio-monitoring implants that can keep track of how your body is performing internally. Such devices could enable insurers to offer discounts for a range of healthy behaviours, including dietary habits, stress levels and sleep patterns ([129]).

Such developments, as used by the insurance industry, can provide a major incentive for healthy behaviour. However, they also raise questions. Given that many health problems are due to factors beyond an individual's control, how to avoid the risk that clients are penalised or discriminated against, for instance, as a result of their genetic make-up. Insurers may cherry-pick low-risk customers or refuse to cover those predisposed to health problems. This is complicated by the fact that disentangling lifestyle from other causes of disease (e.g. environmental, genetic) is less than straightforward.

In addition, the wider societal implications surrounding such surveillance-like monitoring by private companies must be considered. Customers may feel compelled to participate in the new culture of monitoring and tracking in order to receive the most financially advantageous insurance offers. Despite ostensibly having the freedom to ignore price incentives, financial penalties for non-participation or non-compliance with doctors' orders may act as a subtle form of social control. Participation may begin to appear less voluntary, while good health becomes an obligation that every citizen should strive to fulfil.

Together, these forces are spurring innovation and lend momentum to the long-promised digital revolution in health. Such a transformation could hold immense benefits (see Chapter 1): more efficient ways of monitoring and managing people's medical conditions; a shift towards prevention and early detection ([130]); huge advances in medical research leading to more tailored, accurate treatments; all of which could pave the way to healthier populations and important expenditure savings for national care systems.

Societal shifts in monitoring and managing health

Realising these benefits will, at the same time, require addressing a set of emerging challenges, obstacles and trends on a societal level. One challenge relates to the potential extension of a form of health surveillance

([128]) 'Risk and reward: Data and technology are starting to upend the insurance business', *The Economist*, 14 March 2015.

([129]) Ozimek, A., 'Will body monitoring implants be the future of healthcare', *Forbes*, 3 August 2013.

([130]) Take, for instance, the case of a UK hospital under the National Health System which developed an algorithm to predict which patients were at greatest risk of readmission and was subsequently able to target programmes to address it: community nursing programmes were put in place to educate patients on catheter use after data revealed a high level of urinary infections. Cited in Ward, A., 'Society stands to be winner in race for digital health', *Financial Times*, Wednesday, 17 June 2015.

brought about by new health technologies such as body monitoring devices and implants, the sharing of intimate personal information on health websites or entered into mobile apps. Active care for one's health, and active sharing of health information — for example, by waiving privacy rights or granting companies access to internet fora, which are primarily dedicated to the communication among patients, are not necessarily a sign of sovereignty over the use of one's data. For instance, recent studies have found that nine of the top 20 health-related apps transmit data to tracking companies (FT source) while 80 % of apps are not compliant with data protection rules ([131]).

A second challenge relates to a potential shift in responsibility towards citizens as patients and consumers over the management of their health. There is a degree of ambiguity between positive processes of empowerment implying a new active citizenship, and increased expectations that individuals begin to take upon themselves obligations over their health that were previously the prime responsibility of public health authorities. According to this argumentation, achieving a state of good health becomes not only a goal, but a duty to fulfil and for which each person is accountable, part of a necessity to become more and more autonomous, to leave the passive state for an active participation at all levels. At the extreme end of this scenario, health monitoring and data sharing would become the norm to such an extent that it becomes less the voluntary act of an engaged citizen than a progressively obligatory requirement on individuals. Such an avenue could bring important implications for the core principles that underpin healthcare. It is not beyond imagining in such a context that considerations of lifestyle choices, or judgements as to whether an individual has engaged sufficiently in the management of their own health could begin to erode organising principles such as the pooling of collective risk or equal entitlement to care.

'Medicalisation', 'healthism' and the 'health society'

While the above prospect remains remote in a European context, nevertheless the wider economic and political context sketched above may be compounding changes in how the notion of 'health' is evolving. Certain scholars contend that the rise of digital health technologies and the new forms of participation they engender merely represents an evolution in the medicalisation process that began in the 18th century ([132]), and coincided with the development of modern capitalism, the free market as well as new forms of security and surveillance. Medicalisation is characterised by the extension of the sphere of competence of medicine, with a huge increase of knowledge and data. The diffusion of health information, together with the marketing of health as a 'good' contributes to a new understanding of disorders and symptoms, but also, it may be argued, to the pathologising of normal everyday issues, dysfunctions or psycho-societal problems (such as addiction, obesity, violence, sexual problems, insomnia, and fatigue which are now medically treated). The existence of medical diagnoses and treatments for such conditions have provided immense relief for vast numbers of sufferers who previously were offered few explanations or solutions for their symptoms. Even so, the boundary between individual uniqueness and pathology, between ordinary food and medicine, between health and illness has become blurred. Health has expanded into new areas of life and is arguably becoming integral to the codes, norms and principles which govern everyday life.

Some sociologists have grappled with these trends by referring to the literature within the Foucauldian tradition to understand normalising tendencies around health and medicalisation. In his analysis of modern society, Michel Foucault argues that the body is the target of discrete disciplining practices that seek to regulate its existence. This process of increased medicalisation and control, arises where there is 'a spontaneous and deeply rooted convergence between the demands of political ideology and those of medical technology' ([133]). Following Foucault, Nikolas Rose draws on the notion of 'healthism' as a doctrine that links the 'public objectives for the good health and good order of the social body with the desire of individuals for health and well-being' ([134]). This trend acquires a self-disciplining dynamic: according to Rose, society no longer requires coercion since people wish to be 'healthy' and have internalised the message of healthism without the need for direct state intervention.

In the modern context, such explanations embedded in the paradigm of control and discipline may appear narrow

([131]) Global privacy enforcement network and FT.

([132]) Goubert, J.-P., 'The Medicalisation of French Society at the End of the Ancien Regime', in Stevenson, L. G., *A Celebration of Medical History, London*, 1982, pp.157-172. This author is one of the first to consider the question.

([133]) Foucault, M., *Naissance de la clinique*, ibid., p. 37.

([134]) Rose, N. (1999), *Powers of Freedom: Reframing Political Thought*, Cambridge, Cambridge University Press.

or incomplete without taking into account recent developments such as the growing power of the market as a force in health or the newly established roles accorded to citizens in the health domain, which bring powerful new dynamics to the expansion and evolution of the health concept and the evolution of the 'health society' ([135]).

Scholars argue that such dynamics are extending the accountability for health to all citizens. Their involvement becomes a need, a duty, a way to be autonomous, to take part in the collective deliberation, a way to share responsibility. From an ethical standpoint, this process needs to be considered from the perspective of its societal hazards, such as those associated with the privatisation of risk, the spread of a new kind of health obedience, or even the downgrading of individual rights in pursuit of the collective good ([136]). But it must also be assessed for its beneficial potential: the 'empowerment dimension' that can occasionally lend modern forms of health promotion the character of social movements. Kickbusch contends that in assigning a large role to citizens as social actors across the various domains of health (from public health, personal health, etc.), the modern 'health society' is premised on the principle that social change for health is possible and that systems can be transformed through radical engagement and collective action ([137]). Any ethical assessment of citizen participation in health and its impact upon key ethical principles needs to consider these dimensions in tandem, as part of a nuanced and complex new health landscape.

2.5. Challenges to justice and solidarity

Justice: New forms of inequalities and issues of access

The problem of justice in healthcare is the definition of two elements: who is the subject to be included (or excluded) and what kind/which level of health must be guaranteed (to the subject included). The structural requirements of justice are: guaranteeing equity and avoiding discrimination. Equity should be guaranteed if there is objectivity and not arbitrariness (subjectivity and relativity) in considering human beings and their needs.

New practices of citizen involvement in health are both challenging and reframing the application of these criteria.

Citizens/patients participation in orienting distribution of resources: the case of rare diseases

Orphan diseases which affect relatively small numbers of people can generate little or no direct research investment by industry. The same applies to health issues which could affect much larger numbers of people but in whom there is an uncertain prospect of economic gain, e.g. malaria, or the antibiotics resistance dilemma. Large pharmaceutical companies are focused primarily on diseases that drive their bottom line, meaning in most cases conditions that affect large or affluent population groups. In this context citizen involvement can be a factor in driving research in unprofitable areas such as rare diseases, i.e. acting as counterpoint to market forces.

The Longitude Prize

A striking example of citizen involvement in the allocation of resources is provided by the 'Longitude Prize'. The prize consists of a prestigious grant assigned to projects addressing the most pressing scientific challenge of our times. In 2014 the prize drew on the help of British citizens to decide which scientific problem should form the focus of the award. More than 100 leading scientists identified six major scientific challenges, and the public was invited to vote on which one should be selected for funding. Finally, the British public decided that a project addressing the challenge of antibiotics resistance should receive the award (GBP 10 million). Anyone from amateur scientists to the professional scientific community may submit entries and compete for the award. This example illustrates how citizen involvement in distributing scarce science funds may serve the interests of society and — at least partially — eliminate conflicts of interest.

While citizen involvement opens new avenues for collectivist action and shows potential for rebalancing structural inequalities that have long existed regarding investment in medical research, it also questions the mechanisms of assessment and rationing that public healthcare systems have put in place to distribute health resources. Public decision-making over the allocation of treatment and research resources is not

([135]) Kickbusch, I. (2007), 'Health Governance: the Health Society' in McQueen et al., (eds) *Health and Modernity: The Role of Theory in Health Promotion,* New York, Springer.

([136]) Arendt, H. (1951), *The Origins of Totalitarianism*, New York: Harcourt.

([137]) Kickbusch, I. (2007), 'Health Governance: the Health Society' in McQueen et al., (eds) *Health and Modernity: The Role of Theory in Health Promotion,* New York, Springer.

impervious to media and public campaigning. This presents a particular challenge where certain societal groups or categories of patients and their families (the well-organised, educated, wealthy and articulate) prove particularly adept at leveraging the new digital tools and networks to influence public and media debates in favour of their demands. It also opens a further set of questions around new health technologies, the participation they engender and the digital divide.

New forms of solidarity

Solidarity is perhaps the most important organising principle underpinning healthcare in the European context. Broadly understood as a mutual obligation to assist one another based on a collective commitment to carry costs, it has served to justify a strong involvement of state authorities in public health delivery ([138]).

New questions and challenges surrounding solidarity in healthcare are emerging ([139]), in part linked to increasing financial pressures on public authorities, as well as debates around individual responsibility. There are now signs that changing practices of citizen engagement in health may also be generating new forms of solidarity which diverge from traditional state-centric understandings. Interconnected networks which draw on the possibilities offered by new technologies, are encouraging people to engage in health projects, actions and initiatives, which often reflect strong solidaristic aims. Sharing health data, for instance, is often framed in solidarity terms, such as advancing human knowledge and helping to find cures for disease. Some crowdfunding initiatives also reflect strong solidarity-based objectives.

Such examples of solidarity in the health domain, facilitated by digital interconnectedness, are also emerging at the local level. For example, experiments regarding elderly people who are isolated and unable to take their medication: the prescription is sent to a pharmacy which engages to prepare the order in a short time period (30 minutes) and the person registered in the network passes both the pharmacy and the patient's home, and drops off the medication. The request then disappears from the register. In some networks, this person could be credited with 'solidarity points' ([140]).

Such developments may serve to renew and reinforce the principle of solidarity in a health context, while in parallel presenting a number of new questions: one set of challenges centres around the regulation of these networking communities or structures, which tend to rely on a form of internal or self-regulation. While in some cases such informal governance models may prove sufficient, in others, they may leave participants open to vulnerability ([141]).

Second, is there a tendency for such solidarity movements to substitute for the deficiencies of the state? Initiatives may develop where there is a perceived gap in the social safety net. Alternatively, their success may facilitate or justify the decision to reduce or withdraw certain publicly funded services. They may thus serve both as a symptom and a contributor to a shift in the shared understanding of solidarity, from a state-managed process to one organised and driven by citizens.

Finally, there is an important public interest in forms of solidarity that advance health knowledge and treatments, such as contributing biological data or samples. What is the risk that forms of solidarity which begin life as voluntary expressions of mutual assistance become a new 'obligation' (whether formal, as enshrined in law or informal, in the shape of new societial norms around participation and sharing)? A hypothetical example would be a compulsion to share health data in the service of public health goals, which would put at risk an individual's right to bodily integrity, privacy.

Precision/'Personalised' medicine and implications for justice

Precision medicine could hold the promise of a juster healthcare system. Precision or 'personalised' medicine means 'tailoring' medical treatment decisions to a specific individual's genetic profile and may optimise patient cure and care, by assessing the personal risk and prescribing the treatments with a higher probability of success. According to some proponents, precision medicine may result in cost savings, by avoiding

([138]) Prainsack, B. and Buyx, A. (2011), *Solidarity: Reflections on an emerging concept in bioethics*, London: Nuffield Council on Bioethics.

([139]) 'Justice & solidarity in priority setting in healthcare: Identifying and discussing the ethical and societal issues in resource allocation', Belgian Advisory Committee on Bioethics and the King Baudouin Foundation, June 2013.

([140]) See Giogino, P., *La transition fulgurante. Vers un bouleversement systémique du monde*, Bayard, 2014, p. 114.

([141]) Such has been the case with certain high profile (though non-health related) examples of the informal, sharing economy, for instance the car sharing service Uber, and the online platform for holiday accommodation, Airbnb.

the wasteful 'one-size-fits-all' approach and enabling a more effective cost/benefit analysis ahead of treatment ([142]). Such costs savings could be particularly effective, if precision medicine focuses on prevention, above therapy. Analysis of large datasets (especially in the cancer domain) could offer the possibility to measure the effectiveness of an innovative treatment, tracking its impact over a longer time period, to determine the populations for which a treatment is ineffective, and adjustments for particular patients.

However, currently the transformative benefits of precision medicine are largely speculative. In addition, it must be acknowledged that the targeted approach of precision medicine, which is by nature specific to a small, select group of patients, will inevitably produce interventions that are much more expensive than, for instance, preventive interventions applied broadly across populations ([143]). This has led some experts to sound a note of caution, warning that 'although precision medicine will almost certainly be used in niche applications, if widely implemented, it could be a distraction from low-cost and effective population-wide interventions and policies' ([144]). Precision medicine therefore presents public health policy with a challenge when setting priorities for investment in innovation and when balancing individual demands for expensive, high-tech or personalised treatments with wider social needs for essential/basic forms of healthcare.

A second justice-based challenge presented by precision medicine concerns the potential misuse of genetic information or the risk of 'genetic discrimination' … Thanks to genome-wide analysis, genomics is used to calculate an individual's risk of developing complex diseases. The use of individual genetic information may be the cause of new genetic indirect discrimination and inequitable access to care. From a medical perspective, the use of risk assessment to select patients for additional care is acceptable and justified. But this method may be discriminatory when applied to the general population, in the context of its application across different age and ethnic groups. The efficacy of risk assessing models varies among different age and ethnic groups, with a reduced accuracy for patients under 40 years of age and of specific ethnicities, opening the possibility that some populations are excluded or overlooked.

If new precision medicine genetic technologies have the effect of inequitably excluding individuals, this raises questions around the significant public investment underlying their development. Scientific advances underlying precision medicine genetic-based technologies are the result of an enormous public investment in genomic sciences and research. For this reason it is justified that the citizens expect that these discoveries will translate into services accessible to all.

Access and the digital divide

New health technologies hold immense promise when it comes to tackling long-standing inequalities in access to healthcare. Innovations in the field of telemedicine for instance, are bringing new forms of medical access to patients in remote rural communities from France to India, as well as new forms of training and medical collaboration for health professionals in Africa ([145]). Nevertheless, an enduring 'digital divide' determined by factors such as age, gender, geographical location or socioeconomic status, mean that unequal access to digital technologies as well as highly divergent levels of online literacy persist. This comes alongside additional challenges related to access addressed above.

The growing uptake of new health technologies as part of individuals' everyday healthcare could thus aggravate longstanding health inequalities between different societal groups and across different regions of the world. This would become an additional challenge should potential changes to the roles and responsibilities of patients as a result of new technologies that have been sketched out above, but which are as yet by no means certain, materialise. Any change in expectation that patients should shoulder greater responsibility for their care (e.g. patients taking greater control over their electronic health records, in the form of self-managing check-ups, prescriptions, etc. or presuming a greater reliance on the part of citizens on internet-based health guidance) could potentially privilege an active, informed and connected citizenry. The challenge would consist of reaping the full advantages of these technologies and new modes of engagement while putting the measures in place to ensure as far as possible that their benefits are spread evenly among populations.

([142]) Dzau, V. J. et al. (2015), 'Aligning incentives to fulfil the promise of personalised medicine', *Lancet,* 385, pp. 2118-2119.

([143]) Joyner, M. J. and Paneth, M. (2015), 'Seven questions for personalised medicine', *JAMA*, Published online 22 June 2015, doi:10.1001/jama.2015.7725.

([144]) Coote, J. H. and Joyner, M. J. (2015), 'Is precision medicine the route to a healthy world?', *Lancet*, 385.

([145]) Parizel, E. (2013), 'La telemedicine en questions', *S.E.R.*, Vol.11, pp. 461-472.

Chapter 3 The human rights and regulatory framework

The ethical challenges posed by citizen involvement in health, and by the proliferation of technologies re-fashioning the link between an individual and his/her healthcare, place the adequacy of current governance arrangements into question. An extensive and complex body of law and standards exists to regulate health technologies, developed both at national and supranational level ([146]). The following section does not seek to provide an exhaustive overview of this regulatory landscape, but rather to identify those new questions and gaps presented in particular by the nexus between new health technologies and new practices of citizen participation.

This requires, first, an examination of the legal landscape pertaining to participation: specifically, an exploration of the rights and protections enshrined in international human rights treaties and jurisprudence which establish the entitlements of citizens to participate in, and enjoy the results of, science and technology.

Second, it requires an examination of potential gaps in the regulatory framework in relation to new health technologies and the suitability of existing oversight mechanisms to cover new practices of knowledge generation and innovation engaging the individual.

3.1. A (European) human rights approach to citizens as 'active actors' of their lives and health

This section considers EU Member States' obligations under the European Convention on Human Rights and under the International Covenant on Economic, Social and Cultural Rights, as well as modes of citizen participation in the EU governance framework.

3.1.1. The European Convention on Human Rights and Fundamental Freedoms (ECHR)

The ECHR has been ratified by all Member States of the European Union. Citizen involvement and participation is not mentioned explicitly as a human right in the Convention. However, in line with the idea that the Convention is a living instrument that must be interpreted according to present day conditions by the European Court on Human Rights, its jurisprudence is relevant for some aspects of this Opinion.

(a) Freedom to participate in discussions regarding matters of public health

Article 10 ECHR — the right to freedom of expression.

1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This Article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.

2. The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.'

The European Court of Human Rights (ECrtHR) drew on Article 10 in the case of *Hertel* v *Switzerland*, in which Swiss courts had prohibited the applicant from stating that food prepared in microwave ovens was a danger to health and led to changes in the blood of those consuming it that indicated a pathological disorder and presented a pattern that could be seen as the beginning of a carcinogenic process and from using the image of death in association with microwave ovens. According to the ECrtHR, this prohibition violated Article 10: 'the effect of the prohibition was to censor the applicant's work and substantially to reduce his ability to put forward in public views which have their place in a public debate whose existence cannot be denied. It matters little that his opinion is a minority one and may appear to be devoid of merit since, in a sphere in which it is unlikely that any certainty exists, it would be particularly unreasonable to restrict freedom of expression only to general accepted ideas' ([147]). The (by then still existing European Commission for Human Rights) had concluded that 'freedom of expression is of special importance for

([146]) See for instance Flear, M. et al. (2013), *European Law and New Health Technologies*, Oxford University Press: Oxford.

([147]) *Hertel* v *Switzerland*, 25 August 1998.

free debate on matters of public importance for the community, *such as public health'* (italics added).

(b) Freedom to carry out research

There are obvious similarities and links between the right to freedom of expression and a right to carry out research or seek information. Freedom to carry out research has often been seen as a part of freedom of thought and expression. However the freedom to carry out research is not expressly guaranteed in the ECHR although it might be derived by implication from the right to freedom of expression in Article 10. Also the Explanatory Memorandum to the Charter of Fundamental Rights of the EU describes the right to freedom of scientific research as being 'deduced primarily from the right to freedom of thought and expression'.

(c) The right to have access to information and to public participation in decisions related to (public) health

The ECrtHR remains reluctant to use Article 10 as the basis for a general right of access to information. Since Article 10 expressly imposes on the state a negative duty not to interfere with the freedom to receive and impart information, the Court has been reluctant to recognise that this provision guarantees a general right of access to information, including administrative data and documents (see *Loiseau* v *France* (dec.), no. 46809/99, ECHR 2003-XII (extracts)). It has consistently held that the freedom to receive information prohibits a government from restricting a person from receiving information that others wish or may be willing to impart on him and that this freedom cannot be construed as imposing on a state a positive obligation to disseminate information of its own motion (*Roche* v *the United Kingdom* [GC], No 32555/96, § 172, ECHR 2005-X, with further references). The Government's primary duty is thus not to interfere with communication of information between individuals, be they legal or natural persons.

Complaints concerning a denial of access to information which is of importance for the applicant's personal situation have been generally examined under Article 8 of the Convention which guarantees the right to respect for private and family life:

'1. Everyone has the right to respect for his private and family life, his home and his correspondence.

2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.'

In a number of cases, the court found that the authorities had a positive obligation to disclose to the applicant the relevant data. For example, this was the case where applicants sought access to information about risks to one's health and well-being resulting from environmental pollution (*Guerra and Others* v *Italy*, 19 February 1998), or information which would permit them to assess any risk resulting from their participation in nuclear tests (so called Christmas Island nuclear tests) (*McGinley and Egan* v *the United Kingdom*, 9 June 1998, § 101, Reports of Judgments and Decisions 1998-III), or tests involving exposure to toxic chemicals (so-called Porton Down tests (*Roche* v *the United Kingdom,* 19 October, 2005). The court held, in particular, that a positive obligation arose to provide an 'effective and accessible procedure' enabling the applicants to have access to 'all relevant and appropriate information' (*Roche*, § 162).

'The text of the ECHR does not exactly prompt one to think in terms of environmental risks, so it was genuinely interesting to see the court's crafting of positive obligations from Article 2 (right to life) and 8 (right to respect for private and family life and home)' ([148]).

Article 2 — Right to life

'1. Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.

2. Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than absolutely necessary:

(a) in defence of any person from unlawful violence;

(b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained;

([148]) Murphy, T. and Cuin, G. O., 'Works in progress: new technologies and the European Court of Human Rights', *Human Rights Law Review*, 2010, 637.

(c) in action lawfully taken for the purpose of quelling a riot or insurrection.'

From both articles the ECrtHR has construed a range of positive 'environmental' obligations (the so-called 'greening of human rights'). States must regulate and control hazardous activities (whether public or private) where these are impairing Convention rights or might impair them and they must enforce such regulations. Of particular importance for this Opinion is that states must provide access to information on serious environmental risks (in some instances they may have the duty to inform affected parties) and they must secure both public participation in environmental decision-making and access to justice in environmental cases ([149]). To comply with Article 8, affected individuals must be able to participate in the decision-making process: first, information concerning environmental risks must be available to those who are likely to be affected, and second such individuals must also be able to appeal to the courts, against any decision, act or omission where they consider that their interests or their comments have not been given sufficient weight in the decision-making process' ([150]). In this way the court has assigned a considerable amount of human rights work to the contracting parties.

The court has recently moved towards a broader interpretation of the notion of freedom to receive information and thereby towards the recognition of a right to information (*Társaság a Szabadságjogokért* v *Hungary*, No 37374/05, § 35, 14 April 2009). In contrast to its previous approach, it has found that a refusal of access to documents held by the authorities constituted an interference with the applicants' rights under Article 10 (*Sdružení Jihočeské Matky* v *the Czech Republic* (dec.), No 19101/03, 10 July 2001; *Társaság a Szabadságjogokért*, cited above). Although the public has a right to receive information of general interest, Article 10 does not guarantee an absolute right of access to all official documents (see, for example, *Sdružení Jihočeské Matky*, cited above, where the refusal of access, requested by an environmental association, to technical details of construction of a nuclear power plant was found to be justified by the Court). The Court has further emphasised the importance of the right to receive information also from private individuals and entities.

(d) Right to participate in/benefit from the results of scientific developments without discrimination

Article 14 — Prohibition of discrimination

'The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.'

In an important area of 'new' technologies — medically assisted procreation — the ECrtHR has made it clear that contracting states have no obligation under the ECHR to permit such technologies ([151]). Should they choose to permit them, they have to respect the prohibition of discrimination ([152]).

3.1.2. The International Covenant on Economic, Social and Cultural Rights (ICESCR)

The ICESCR has been ratified by all 28 EU Member States and therefore all are bound by this UN treaty.

The right to participate in/benefit from the results of (medical) scientific research

The ICESCR is the major binding international human rights instrument addressing this issue.

Article 15

'1. The States Parties to the present Covenant recognise the right of everyone:

(a) To take part in cultural life;

(b) To enjoy the benefits of scientific progress and its applications;

([149]) Murphy, T. and Cuin, G. O., 'Works in progress: new technologies and the European Court of Human Rights', *Human Rights Law Review*, 2010, 624.

([150]) Murphy, T. and Cuin, G. O., 'Works in progress: new technologies and the European Court of Human Rights', *Human Rights Law Review*, 2010, 625.

([151]) Murphy, T. and Cuin, G. O., 'Works in progress: new technologies and the European Court of Human Rights', *Human Rights Law Review*, 2010, 621.

([152]) See *S.H. and others* v *Austria; Hristozov and Others* v *Bulgaria; G.N. and Others* v *Italy.*

(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4. The States Parties to the present Covenant recognise the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields.'

Article 15(1)b and c specifies that States Parties, that is the countries that have ratified or acceded to this instrument, 'recognise the right of everyone' both (b) 'to enjoy the benefits of scientific progress and its applications' and (c) 'to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'.

Article 15 ICESCR seeks to ensure that states provide an environment within which the development of science and culture is undertaken for the greater good of society while recognising the need to provide specific incentives for this to happen. Article 15(1) is more specifically concerned with the balance between the individual and collective rights of all individuals to take part in culture and enjoy the fruits of scientific development (subsection b of Article 15(1)) and the rights of individuals and groups making specific contributions to the development of science and culture (subsection c of Article 15(1)).

- 'Article 15(1)b: the right of everyone to enjoy the benefits of scientific progress and its applications.'

According to Chapman ([153]) the right of everyone to enjoy the benefits of scientific progress and its applications has three central components:

- A right of access to beneficial scientific and technological developments;
- A right of choice in determining priorities and making decisions about major scientific and technological developments;
- A right to be protected from possible harmful effects of scientific and technological development, on both individual and collective levels.

See also Article 11 of the Venice Statement on the Right to enjoy the benefits of scientific progress and its applications (2009 — not binding; soft law):

'in the context of Article 15 1(b) ICESCR, enjoyment as "participation" is distinct from enjoyment as actual "sharing" in the benefits of scientific progress and its applications. Participation in scientific progress is valuable in its own right, and while the benefits of science should be shared equitably, neither of these components of the right is a substitute for the other. The right to share in scientific benefits should not be predicated on participation, particularly where there is a direct threat to fundamental rights, most notably the rights to life, health and food.' ([154])

As regards 'Article 15.1(c) ('The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'), the provision recognises intellectual contributions in general without making any special reference to one or other category of existing Intellectual Property rights. Human rights are deemed to be fundamental, inalienable and universal entitlements. In this context, Article 15(1) should be read as putting everyone's right to benefit from the development of science as a human right of more importance than the interests and rights of authors/inventors ([155]).

([153]) Chapman, A. R. (1999), 'A human rights perspective on intellectual property, scientific progress and access to the benefits of science', in *Intellectual Property and Human Rights*, Geneva: World Intellectual Property Organisation, p. 9.

([154]) See for more details Müller, A., Remarks on the Venice Statement on the right to enjoy the benefits of the scientific progress and its applications (Articles 15(1)(b) ICESCR).

([155]) Cullet, P., 'Human rights and intellectual property rights: need for a new perspective', IELRC Working Paper, 2004-4 (http://www.ielrc.org/content/w0404.pdf).

Patient activism

A very interesting example of patient activism in Europe is the involvement of 'the activist patient' in the EU fight against cancer (Europe against Cancer, initiated in 1986). The activist patient in the cancer sphere developed a truly European dimension with the founding of the European Cancer Patients Coalition (ECPC) which 'aims to be the voice' for all cancer patient groups in Europe ([156]).

3.1.3. Citizen participation in the EU governance framework

Principles of participation enshrined in international human rights instruments can also be traced in the governance framework of the European Union, and have been translated into policy mechanisms dealing with health, and science and technologies more broadly.

Participation is enshrined in the legal foundations of the Union, with Article 10.3 TEU providing that 'every citizen shall have the right to participate in the democratic life of the Union. Decisions shall be taken as openly and as closely as possible to the citizen'.

Further, Article 11 TEU states that 'the institutions shall, by appropriate means, give citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of EU action'. It requires the maintenance of an open and transparent dialogue with civil society and obliges the Commission to carry out consultations with stakeholders before key policy action is taken. This is complemented by the addition in the Lisbon Treaty of the European Citizens' Initiative allowing citizens to oblige the EU's executive arm to act upon the presentation of 1 million signatures from the appropriate number of Member States.

Some have pointed to the limits of citizen empowerment in the EU policy context. According to Flear and Vakulenko: 'Although EU law provides a platform for citizen participation, it fails to ensure meaningful empowerment for citizens. There is a failure to specify binding rights to participation, even if there is some attempt to provide the conditions of openness, transparency and accountability that foster participation' ([157]).

On the other hand, there is an increasing tendency for citizens to be referenced in secondary law and soft policy tools surrounding the development of new technologies and health ([158]). A salient example is the approach taken by the European Medicine's Agency towards a progressive policy of patient engagement. This includes the membership of patients' representatives in several EMA scientific committees and patient involvement in regulatory processes, including medicines development and risk/benefit evaluations ([159]).

While the EMA may stand out as pioneering new models of engagement (see section 1.2), the involvement of patients as experts raises a number of ethical considerations (section 2.3).

3.2. Regulating new health technologies: new challenges

To what extent are new practices of knowledge generation and innovation in healthcare covered by existing regulatory frameworks? Are existing mechanisms of regulation and oversight fit for purpose in view of contemporary developments in health and health technologies?

The principles laid down in international law instruments are the reference framework for regulating new technologies: the dignity of the human being, respect for physical integrity, informed and responsible freedom, justice and cooperation. These principles set the broad horizon for regulation, which should if necessary be further clarified in relation to specific technologies.

What may be required to precede emerging health technologies is an innovative 'governance' model for technologies under conditions of uncertainty and unpredictability of progress: a horizon guided by a triangulation of science, ethics and society, capable of grounding the regulation on updated scientific

([156]) Trubek, L., Nance, M. and Hervey, T., 'The construction of healthier Europe: Lessons from the Fight against cancer', *Wisconsin International Law Journal and Legal Studies Research Paper Series Paper n° 1062*, 2008 downloaded from the Social Science Research Network Electronic Paper Collection (http://ssrn.com/abstract=1169363).

([157]) Flear, M. and Vakulenko, A. (2010), 'A Human Rights Perspective on Citizen Participation in the EU's Governance of New Technologies', *Human Rights Law Review*, 10:4, 661-688.

([158]) Flear, M. and Vakulenko, A. (2010), 'A Human Rights Perspective on Citizen Participation in the EU's Governance of New Technologies', *Human Rights Law Review*, 10:4, 661-688.

([159]) http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000317.jsp&mid=WC0b01ac058003500c

consultation, balanced ethical evaluation and social needs. Regulations should draw inspiration from both a careful analysis of the evidence base, as well as the anticipation of possible scenarios, weighing pros and cons, as well as evaluating alternative options, at the scientific, ethical and social levels.

3.2.1. Big health data

One of the most important new regulatory challenges relates to the large-scale collection of data.

Big data in healthcare could be considered a 'big opportunity' when it comes to bringing personal and social benefits. The goals of big data include model-driven patient-specific predictions and simulations and personalised diagnoses and treatments, to allow for advanced searches that can identify homogenous groupings among patients and model similarities; these could be shared between researchers and clinicians to allow for data-intensive diagnoses. The objective is to pool large quantities of data across broader populations in order to identify the most effective services for improving care. But these relevant goals for the advancement of techno-science and public health are also a 'big challenge' to individuals and society.

The transformation of data into new biomedical knowledge is not a simple process. The sheer volume, variety and questionable veracity of data currently impose major challenges to extracting the value expected from big data in healthcare, research and public policy.

The complexity on a quantitative and qualitative level of data collected and aggregated and their use for purposes beyond those for which they were collected, combined with the rapidity of scientific and technological 'convergent' advancement in this field (on a biomedical, genetic, clinical level and at the same time on informational/computational level), is a further complicating factor with regard to regulation.

Challenges are not sufficient reason to limit or even stop the development of the science, but it is evident that new forms of governance and regulation, which could institute a balance between rights to safety, privacy and the right to freedom of responsible research are needed.

The challenge is to regulate the collection, processing and storage of data in a way that guarantees responsible use and promotes the public interest, while safeguarding the fundamental rights and interests of individuals (identity, relationships, health and well-being).

(a) Quality

If the collection of data collected or its analysis is inaccurate or biased, its use for scientific progress is undermined and potentially dangerous for public and individual health (exposing individuals needlessly to risks). Examples of erroneous, miscoded, fragmented, incomplete collections of data, are not uncommon, for various reasons ([160]). There can be biases in the automated processes used for collecting and assessing the data, often due to the algorithms (and their designers) including a lack of human checks in analysis, or lack of training and control of competencies in analysts. Data that comes directly from citizens, who are often unaware of their potential further use for analysis purposes (data coming from direct-to-consumers tests, from mobiles, etc.), can include errors (citizens may provide incorrect data), and lack proper oversight and selection for authenticity.

If data quality in the collection and analysis process is not checked, monitored and ensured, this can generate invalid conclusions, on a scientific and clinical level, with possible negative consequences for individuals and society ([161]).

([160]) E.g. because of the increase in physicians' documentation burden, lack of education and accuracy and/or knowledge of the correct methodology in registering data, lack of updated international classification of diseases or knowledge of them, difficulties in selecting essential and specific information of a patient's history, lack of data harmonisation as regards terminology, etc.

([161]) Eysenbach, 'mHealth and Mobile Medical Apps: a Framework to assess risk and promote safer use', *Journal of Medical Internet Research*, Sep. 2014, 16(9), e210; Buijink, A. W., Visser, B. J. and Marshall, L., 'Medical apps for smartphones: lack of evidence undermines quality and safety', *'Evid. Based Med.'*, 2013 Jun, 18(3), pp. 90-92; Misra, S., Lewis, T. L. and Aungst, T. D., 'Medical application use and the need for further research and assessment in clinical practice: creation and integration of standards for best practice to alleviate poor application design', *JAMA Dermatol.*, 2013 Jun, 149(6), pp. 661-662; Haffey, F., Brady, R. R. and Maxwell, S., 'A comparison of the reliability of smartphone apps for opioid conversion', *Drug Saf.*, 2013 Feb, 36(2), 111-117; Wolf, J. A., Moreau, J. F., Akilov, O., Patton, T., English, J. C., Ho, J. and Ferris, L. K, 'Diagnostic inaccuracy of smartphone applications for melanoma detection', *JAMA Dermatol*, 2013 April, 149(4), pp. 422-426; McCartney, M., 'How do we know whether medical apps work?', *BMJ*, 2013, 346, p. 1811; Husain, I., 'Can healthy people benefit from health apps?', *BMJ*, 2015; 350: h1887 (Published 14 April 2015): 'no evidence indicates that the use of health apps to promote physical activity or dietary change leads to harm, although such absence of evidence isn't necessarily evidence of absence'.

Potential measures to better ensure data quality monitoring have been put forward, including codes of conduct to improve the competences and working practices of operators (including clinicians analysts, engineers, statisticians, bioinformaticians). Proposals include ([162]) 'soft regulation' such as an updated code of practice for clinicians or other professionals involved in collecting health-related data. Others aim to foster inter-disciplinarity between clinicians/researchers and engineers working together to translate and extend their existing and advanced data analysis technology, (including on the one hand the clinically trained human mind), into targeted big data analytical approaches that will achieve clinically effective outputs. Although engineers and clinicians have long collaborated successfully, development work on 'big data healthcare' will require particularly intimate reciprocal understanding by each disciplinary culture of the other. This will require further cultural development in both areas.

Questions of data harmonisation and interoperability of systems also require attention in order to guarantee a positive impact on research and public health (both as research and public policies); public health authorities' initiatives to use data to promote public health should be accompanied by a realistic understanding of challenges in methodologies and practices.

(b) Privacy

Full anonymisation of personal data, while touted as a key means of privacy protection, is very difficult to guarantee and, depending on the data recorded, re-identification is often possible and in some cases can be relatively easily accomplished by combining other data (for example dates of birth, age or location; both DNA and images). Partial anonymisation, also called pseudo-anonymisation, or the replacement of identifiers with a code in order to guarantee the re-identification when necessary or desirable (for example, to give information to individuals when serious illness or specific risks are discovered), entails risks and possible vulnerabilities, including potential access by third parties (employers, insurance companies). Re-identification has to be considered not only as a theoretical risk but also as a practical and real possibility. Consequently, discussion should be deepened at a normative level on how to guarantee transparency at the moment of data collection and find additional measures to prevent identification of individuals, as standardised anonymisation protocols are insufficient in specific contexts ([163]). Given the difficulties of guaranteeing the privacy of a data subject and taking into account that the risk of re-identification is both difficult to quantify and may become greater over time, de-identification might therefore be combined with further controls on the access to and uses of data.

The loss of trust in confidentiality caused by large-scale data disclosures as well as revelations regarding intrusions by government agencies and commercial companies, (including inappropriate data sharing by social media organisations) has also lent weight to calls for new forms of governance as applied to data collection systems. Solutions found at the technical level, such as measures to prevent the identification of subjects and reduce the risk of privacy infringements (privacy-by-design) could offer one means of addressing such concerns.

(c) Informed consent

The adequacy of traditional forms of consent and their applicability to the collection and use of big data have become the focus of attention ([164]). The EGE addressed this topic in its Opinion No 26 on the ethics

([162]) Raghupathil, W. and Raghupathi, V., 'Big data analytics in healthcare: promise and Potential', *Health Information Science and Systems* 2014, 2:3; Hoffman, S. and Podgurski, A., 'Big Bad Data: Law, Public Health, and Biomedical Databases', Case Research Paper Series in Legal Studies Working Paper 2012, 34 October 2012.

([163]) Landau, S., 'Control use of data to protect privacy', *Science*, 30 January 2015, Vol. 347, issue 6221; Parker, M., 'Ethical considerations related to mobile technology use in medical research', *Journal of Mobile Technology in Medicine*, 2012, 1, 3, pp. 50-52; Siòlberman, M. J., Clark, L., 'M-Helath: the union of technology and healthcare regulations', Greenbranch publishing, 2012; Mantovani, E., Quinn, P., Guihen, B., Habbig, A., Hert, P., 'eHealth to mHealth — A Journey Precariously Dependent Upon Apps?', *European Journal of ePractice*, Vol. 20, November 2013; Barton, A. J., 'The regulation of mobile health application', *BMC Medicine*, 2012, pp. 10-46; Cortez, N. G., Cohen, I. G. and Kesselheim, A. S., 'FDA Regulation of Mobile Health Technologies', *The New England Journal Of Medicine*, 2014, 24, pp. 372-379.

([164]) The 'specific' consent invites individuals to agree on specified purpose of research or research directly linked, in a narrow context: users should have control on their data, where they are and how they are used, and for how long; data collected for one purpose not be used for another purpose without user permission; the possibility to correct inaccuracies; protecting security. The 'broad consent' invites people to agree to a general use of data (for research) without specifying details (which kind of research).

of Information and Communication Technologies ([165]). Here we refer only to some specific emerging issues related to big health data.

It would seem that only the broad concept of consent is applicable in the use of big data, which entails asking individuals transparently to consent not only to the immediate purpose for which their data has been collected, but also to unforeseen uses of their data (in so far as new possible uses really are unforeseen) ([166]).

One alternative solution is offered by so-called 'enhanced consent', which aims to enhance privacy, based on the awareness of the personal and social significance of anonymised (individual patient and personal) data for preventive and predictive purposes in healthcare, and for promoting 'data donation' ([167]). This could be combined with 'data inheritance', which is automatically applied after a certain period from the data subject's time of death, unless they have explicitly opted out. 'Enhanced privacy/enhanced consent' could also permit the subject to determine restrictions of consent (e.g. when the study involves an application to which he/she objects in conscience) and should be coupled with the concept of 'personal data portability' where an individual can export or delete his or her data from the system at the end of a relationship with a particular service provider or researcher. The data subject is able specifically to exclude certain data uses whilst allowing data utilisation for the benefit of, for example, healthcare research, alongside maintaining and ensuring that consent can be withdrawn and data completely deleted.

Another method for consent is the 'one-off' consent (narrow or broad), dynamic and flexible, engaging the active participation of the data subjects ([168]). It allows a constant control of data access by individuals, through consent portals. Individuals may check if data are used for private gain/commercial purposes or public good ([169]).

The individual/citizen might decide the level of their engagement. This form of active participation allows participants to shape and influence research using their data. But there is concern about the effective possibility of this kind of service if the data are used and reused for many purposes, as well as questions over how they are to be regulated. Who is responsible to digitally inform the patients/individuals? How is it possible to check that information has been received and understood? How is it possible to monitor these procedures and by whom? Continuing involvement of subjects through 'dynamic' forms of consent can be demanding in practice (for both researchers and data donors).

In a context of greater participation and citizen involvement in science/medicine, concerns also arise where individuals actively participate in research and willingly give their consent to donate data to 'open source' platforms. Online platforms such as 'PatientsLikeMe' report high engagement from patients motivated to donate data to research in new forms of participant-driven research or 'citizen science'. This may be explained as a form of altruistic behaviour, expressed in the willingness to give unlimited permission regarding the use of data in a collaborative or cooperative context. Some criticise this kind of consent data donation, defining it as misinformed naivety and suspecting that the exaltation of an unselfish logic, may be inspired by a hidden desire to stimulate above all the market. Paradoxically solidarity could possibly conceal commercialisation: donors would become free sources of data, exploitable by researchers in both public and private spheres. In this specific field, regulation could require a distinction between not-for-profit research and use of data for commercial purposes.

([165]) EGE Opinion No 26, *The ethics of Information and Communication Technologies*, Brussels, February 2012.

([166]) It requires a 'fully informed' consent (with procedures able to document the real comprehension of it) that refers explicitly to the impossibility to inform on the future possible unforeseen use and reuse of data. It should be explained that certain implications and the scope of consent given when data are collected may become unclear in changing circumstances, especially over long time periods.

([167]) Morley-Fletcher, E., *Big Data Healthcare. An overview of the challenges in data intensive healthcare.* This document constitutes a preparatory draft for the Networking Session on 'Big data and data analytics impact in healthcare' organised by the FP7 integrated project MD-Paedigree, partially funded by the European Commission, for 7 November 2013, as part of the ICT'13 conference in Vilnius.

([168]) See Kaye, J., Whitley, E. A. and Lund, D. et al. (2015), 'Dynamic consent: a patient interface for twenty-first century research networks', *European Journal of Human Genetics,* 23: 141-146; and Bernal, P. (2010), 'Collaborative consent: harnessing the strengths of the Internet for consent in the online environment', *International Review of Law, Computers and Technology* 24(3): 287-97.

([169]) Nuffield Council, The collection, linking, and use of data in biomedical research and healthcare: ethical issues, 2014.

Something specific must be said with reference to genetic data, in the context of genome-wide analysis. In the case of genetic data a genomic sequence may reveal probabilistic information or disease traits or other characteristics in biological relatives. In such cases, there is a conflict between the autonomy expressed through consent by the individual (who gives permission for data access) and the privacy interests of others who may be affected by this permission. This situation is difficult to manage in current data protection mechanisms. Consent, in these cases, should include information on the willingness or unwillingness to receive the results of research, the information about the possibility of 'incidental findings' (unexpectedly revealing results that may be difficult to be known, regarding risks or susceptibility to incurable illnesses), in respect of the subject or his/her relatives.

(d) Restriction of access to data and control of misuse

The difficulties in regulating new forms of consent and in ensuring privacy lend added weight to regulatory questions regarding who is permitted to access data, for what purposes, and over what time period. As neither anonymisation nor consent offer sufficient privacy protections in relation to big data, additional controls on the use of data and above all misuse may be required at a regulatory level. This is particularly important as misuse of data (medical and non-medical) opens possible new forms of stigmatisations and discriminations (e.g. in the misuse of data by insurance companies, or employers).

One proposal put forward to address this issue suggests instituting ethical committees or institutional review boards to control researchers' access to and use of data. Other suggested measures include enhancing the capacities of technologies to control not only collection, but also the use of big data (automated controls and audits) ([170]). There is also discussion on a possible flexible regulation, recognising existing improvements in technology, the need for speedier research, and the importance of balancing pros and cons when it comes to accessing data and evaluating what is the appropriate level of patient/consumer engagement when doing so.

3.2.2. mHealth

In the context of big health data, there are specific concerns related to mHealth ([171]).

(a) Regulatory context of medical and health devices

There is no explicit regulation of mHealth devices and apps at the European level. This field is currently regulated as regards medical data by Recommendation No (97) 5 on the protection of medical data and as regards medical devices by Directive 93/42/EEC concerning medical devices and Directive 98/79/EC on in vitro diagnostic medical devices, and Directive 90/385/EEC on active implantable medical devices. However these regulations are not sufficient in view of the rapid acceleration and take-up of new technologies and devices in mHealth.

Challenges in advance of the launch of the Apple watch, and evidence of the systematic breach of data protection rules by smart phone app providers illustrate the safety, privacy, security and confidentiality concerns regarding citizen involvement and health.

A medical device is defined as: 'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application. Such a device should be intended by the manufacturer for one of a number of defined purposes, one of which is, diagnosis, prevention, monitoring, treatment or alleviation of disease' (Directive 93/42/EEC Article 1, 2).

When an application falls within the scope of the regulatory framework on medical devices it is obliged to comply with the established requirements of safety and performance. However, currently there are no rules in the European regulatory framework to delimit between lifestyle and wellbeing apps and a medical device or in vitro diagnostic medical device.

The rapidity of technological advancement may explain the lack of regulations of mHealth and health apps to

([170]) Landan, S., 'Control use of data to protect privacy', *Science*, 30 January 2015, Vol. 347, issue 6221, pp. 504-506.

([171]) West, D., 'How mobile devices are transforming healthcare', *Issues in Technology Innovation*, No 18, May 2012.

date ([172]). In addition, a strict application and extension of existing regulations to mHealth devices could impose undue obstacles to technological innovation.

In 2012, the European Commission put forward two proposals to update and replace the existing legal framework, one for a regulation on medical devices and the other for a regulation on in vitro diagnostic medical devices. This includes a proposal to introduce a new definition of 'medical device' enlarging the definition referring to 'direct' and 'indirect' medical purposes, which would include products providing information with a 'direct' or an 'indirect' impact on health.

Since January 2012, the Commission's services have issued additional guidance setting out criteria for classification of stand-alone software used in healthcare within the regulatory framework of medical devices ([173]). Medical apps are not designed to operate on one particular device but can function using different operating systems. Given the versatility of operating systems it is difficult to test the medical device with all available accessories, in order to guarantee safety. Even if the designed software is in conformity with the regulations when created, it is difficult to guarantee that it will be in conformity with other smart devices currently available or available in the future.

Apps may in fact function as medical devices (as they are used by customers for diagnostic or therapeutic reasons), but while they are not explicitly subject to the same rules, no assessment of the risk they pose to individuals' health nor specific safety requirements are imposed on app developers before putting apps on the market (it is not yet clear as to the limits of application in this field of the general products safety directive and the directive on liability for defective products apply to manufactured products). There is a need to specify the level of safety to be guaranteed in relation to the kinds of apps (purposes, technology, implications, whether medical or not), safety requirements and the documentary procedures necessary to monitor such standards.

Regulation is not explicit in distinguishing apps for medical purposes (diagnosis, treatment) and apps for lifestyle and wellness with reference to the supervision of a medical doctor or a health professional. Even in the case of so-called 'wellness' apps, recommendations may be warranted as regards seeking the advice of medical practitioners, indicating certified websites with information about certain health conditions or offering medically approved advice related to certain lifestyle behaviours. There is scope (and arguably a need) for regulation to determine criteria and requirements regarding medical supervision (according to the purpose of the app) and the modality of its certification.

The large quantities of data (medical and health data, information personal data, biometric data, social and environmental data) collected and processed by mHealth devices and the ubiquitous continuous communication within the 'mobile ecosystem' (providers, manufacturers, developers, stores, users) raise challenges to privacy ([174]).

Data stored on devices by the user and data collected from different sensors, including location, fall under the scope of the data protection directive (Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, currently under revision and the ePrivacy directive (Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector, as modified by Directive 2009/136/EC). These rules should apply to any apps installed/used by users in the EU, regardless of the location of the app developer or the app store.

One of the core requirements of data protection law is that personal data should be processed fairly. Fairness means among others that the person processing the data (the 'data controller') has made reasonable efforts to guarantee that those to whom the data relate ('data subjects') are aware of who is processing the data and for what purposes. The data protection directive imposes obligations on data controllers and data users: personal data must be collected for specified, explicit

([172]) Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices (MEDDEV 2.1/6 January 2012). These guidelines are, at the moment, the only legal framework for app and software used in healthcare (http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf).

([173]) European Commission, 'Medical Devices Guidance document: Qualification and Classification of stand-alone software', MEDDEV 2.1/6, January 2012.

([174]) The Warsaw Declaration on the 'appification of society' (September, 2013), the Data Protection and Privacy Commissioners meeting, 35th annual international conference, urges legal systems to take into consideration this challenge as central, with reference to the 'actors' involved in mobile devices ecosystem. This recommendation was followed by the Article 29 Working Party on apps (2013), an advisory board on data protection and privacy.

and legitimate purposes, as well as adequate (proportionate), relevant and not excessive in relation to the purposes for which they are collected and/or further processed.

As lifestyle and wellbeing apps can collect general personal data and health data, they should be fully compliant with the relevant provisions of the EU data protection directive ([175]).

(b) Implications for the right to informed consent

The Convention on Human Rights and Biomedicine (Oviedo Convention, 1997) states in its Article 10.1 that everyone has the right to respect for private life in relation to information about his or her health. In a healthcare setting, a healthcare professional would be able to inform and answer patients' questions in an environment of doctor–patient confidentiality. Current apps that collect personal data/medical data rely only on a simple consent at the moment of the app download. This is strictly speaking a violation of the data protection directive which stipulates that collecting health data outside the healthcare environment requires written consent. This is an informatic/informed consent, written on the screen.

The right of users to be informed, to receive information (Article 10 Directive 95/46/EC) means that individuals should be aware of the purpose for which apps are installed and the kind of data that are accessed and processed (also Article 5.3 of the ePrivacy Directive 2002/58/EC affirms that consent is required provided with clear and comprehensive information). Information should include the risks of data breach and leaks (Article 4 ePrivacy Directive 2002/58/EC recognises a duty of notification of data breach). Articles 12 and 13 of Directive 95/46/EC recognise a right to access, rectify, withdraw, delete and object to data processing.

Attention has begun to focus on how to ensure that data collected for the purpose of mHealth services is not further processed for commercial (as well as other) purposes, unless the data subject, duly informed, has specifically and explicitly consented to the processing of his data for those other purposes. According to the principle of purpose limitation, purpose must be specified, explicit and legitimate. ([176]).

The problem is that users are often unaware that they have submitted certain data or, if aware, do not always understand the processing implications. It is not possible for a user to read all the notices required for the large quantity of data collected; sometimes they have little alternative to dissent or change their choice.

A key question is how, if possible, to guarantee to users/consumers a right to be informed and to give their consent, should they wish, to the processing of their data by mHealth devices? This question is particularly pressing in light of the growing secondary use of data (by researchers and commercial companies) and in the context of the high rates of unawareness by users in this regard.

Alongside the EGE's previous reflection on this question in its Opinion on the Ethics of information and communication technologies, other bodies have also considered how to improve mechanisms for consent for apps. One proposed approach is the so-called 'granular consent' put forward in the Warsaw Declaration: 'individuals can finely (specifically) control which personal data processing functions are offered by the app they want to activate'. The consent should be given for each type of data the app intends to access (granular means 'just-in-time disclosures' and 'affirmative express consent'). The patient should give different forms of consent: one consent for the general provisions regarding the app and its functions, and another separate consent for the purpose and means of the processing.

This interpretation is based on paragraph 107 of the Explanatory memorandum of the Recommendation No (97) 5 on the protection of medical data: 'But even in cases where his/her consent is not required — that is, when the collection and processing of medical data follow an obligation under the law or under a contract, are

([175]) Warsaw declaration on the 'appfication' of society, 35th International Conference of Data Protection and Privacy Commissioners, September 2013.

([176]) There is a discussion on the application of e-Privacy Directive 2002/58/EC, as revised by Directive 2009/136/EC consent requirement applies to any information (not limited to personal data, applicable to any information stored on the device). This means that when installing an app, users should be given the choice to accept or refuse tracking technologies on their device. This consent needs to be distinguished from the consent authorising personal data processing. Data controllers can collect consent for both processing operations, either during the installation or before the app starts to collect personal data from the device. Data breach notification duty.

provided for or authorised by law, or when the consent requirement is dispensed with — the recommendation provides that the data subject is entitled to relevant information'. The Article 29 Working Party recently published an opinion 'On apps on smart devices', which deepens and clarifies the legal obligations of each of the subjects involved in the development of apps ([177]). The opinion outlines the need to inform in a clear and unambiguous way data processing to users (the types of data, the purposes, retention periods) prior to the installation of the app.

(c) Profiling of medical and non-medical data

Another key challenge arises from the lack of clear distinction between personal information that can be classed medical data and thus deserves special protection, and non-medical data. mHealth devices gather both medical data but also non-medical data such as personal information, lifestyle data, tracking information, etc.).

Paragraph 38 of the Explanatory memorandum ([178]) of the Recommendation No (97) 5 on the protection of medical data affirms that medical data in this context can also include information relating to general lifestyle: 'The drafters of the recommendation further agreed that under the terms of the recommendation, "medical data" should also include any information — unless it is public knowledge — giving a ready idea of an individual's medical situation, for instance for insurance purposes, such as personal behaviour, sexual lifestyle, general lifestyle, drug abuse, abuse of alcohol and nicotine, and consumption of drugs. This was the reason for including in the definition of medical data the words "manifest and close", that is, having a clear and direct impact on the health situation of the individual'.

Lifestyle information, tracked through apps and devices, can constitute an immense source of sensitive data. Are these data processed as 'medical data' or as 'personal data'?

The abovementioned Explanatory memorandum, states (in paragraph 61) that the processing of the data must be for the purpose of medical treatment: 'In practice, this means that the principles are applicable to the collection or the processing of medical data for the purpose of medical treatment, the assessment of the health situation or the fitness of a person'. According to this interpretation, apps for the purposes of well-being, as a sort of quasi-medical purpose, may also be interpreted as medical data.

(d) Transfer of data

Current EU data protection regulations allow the transmission of data to third parties only with the consent of the user.

Recommendation No (97) 5 on the protection of medical data, Explanatory report, paragraph 143 outlines: 'It is obvious that medical data, one of the categories of sensitive data for which the convention requires special protection, should not be communicated outside the medical context in which they were collected, unless they are made anonymous (in which case the data no longer fall under the definition of personal data)'. Paragraph 195: 'In the second place, the drafters of the recommendation have suggested that communication could take place if the data subject had given consent, and thereby had taken the responsibility in the circumstances envisaged for his/her medical data to be communicated outside his/her national territory to a country where it is impossible to monitor the fate of the data'.

A large proportion of health apps for mobile phones send data (medical and non-medical) externally to third parties without notifying the user ([179]). The complexity of identifying the role of a third party refers to cloud computing providers as they can, according to the specific circumstances, be either data processors or data controllers or both at the same time. The Article 29 Working Party opinion on cloud computing provides guidance on the application of existing data protection rules to cloud providers ([180]).

([177]) Article 29 Data Protection Working Party, Opinion 02/2013 on apps on smart devices, 27 February 2013.

([178]) Council of Europe — Explanatory Memorandum on the Recommendation on the Protection of Medical Data (http://www.coe.int/t/dghl/standardsetting/dataprotection/EM/EM_R(97)5_EN.pdf).

([179]) Mantovani, E., Quinn, P., Guihen, B., Habbig, A. and Hert, P., 'eHealth to mHealth — A Journey Precariously Dependent Upon Apps?', *European Journal of ePractice*, Vol. 20, November 2013.

([180]) Working Party 'Opinion 02/2013 on apps on smart devices', 27 February 2013, WP 'Opinion 05/2012 on Cloud Computing', 01.07.2012.

(e) Liability

Regulations currently do not clearly define or attribute responsibilities to key actors (app manufacturers, developers, operators) with reference to data protection, data breach notification, and data minimisation.

The eCommerce Directive 2000/31/EC on certain legal aspects of information society services, contains information requirements to be provided by service providers. App developers, when they are directly selling apps, are also providing information society services. This means that app traders and developers have to avoid any practices which could mislead a consumer or which could compromise his or her freedom of choice.

Directive 2011/83/EC on consumers' rights applies to the purchase of apps by consumers in the EU (including health apps and lifestyle apps), and aims to ensure a uniform EU-wide level of protection.

3.2.3. Telemedicine

The introduction of telemedicine can impact on the nature of patient–doctor interactions, potentially altering this relationship and the way in which consultations, care and treatment are delivered. Clear guidance about the responsibilities of each party engaged in this interaction, including remotely, should be made available.

The European Commission ([181]) in its communication of 4 November 2008 to the Council and to the European Economic Committee asked the Member States to have examined and adapted their national legislation by the end of 2011, in order to allow wider access to telemedicine services. France for example integrated in its law of 21 July 2009 and then in its decree of 19 October 2010, five acts of telemedicine, and defined the conditions of its implementation.

The European Parliament resolution of 14 January 2014 on the eHealth Action Plan 2012-2020 — Innovative healthcare for the 21st century (2013/2061(INI)) furthermore requested 'the Commission and the Member States to pay particular attention to digital literacy and to technical training in order to ensure that e-health tools, especially telemedicine, are genuinely effective and accessible for the whole population'.

Analysing the various European directives and communications published from 1998 to the end of 2012, as well as legal and regulatory texts published since 2009 in the French Code of Public Health, P. Simon and J. Lucas ([182]) demonstrate that 'European law on the practice of telemedicine is inconsistent and that the European Commission must determine the same legal framework for all Member States of the European Union by 2020. The legal ambiguity between the concepts of e-health and clinical telemedicine is emphasised. Nearly all codes of medical ethics in each European Union Member State specify that clinical medicine cannot be a commercial practice. As a result, in the field of digital health, it is important to distinguish information society services, which can sometimes be a subset of e-health, from healthcare services such as clinical telemedicine.'

3.2.4. Direct to consumer genetic tests

Concerns have been raised regarding the increased availability of genetic susceptibility tests sold direct to consumers. Both governments and private enterprises operating in the sector are being urged to draw up international rules to regulate the market. Policies proposed should also include education of patients to grasp the complexities of the real value of genetic markers; furthermore, they should offer increased protection against possible discrimination (e.g. in employment) of individuals with genetic mutations ([183]).

Although only a few Member States (for instance, Austria and, to some extent, the United Kingdom) have regulated this area, others are proposing the urgent introduction of procedures for self-regulation by companies engaged in direct-to-consumer genetic testing along the lines of the current European guidelines which emphasise the importance of genetic counselling in predictive tests. Others believe that self-regulation may ultimately delay the introduction of legally binding regulations.

([181]) Commission Communication of 4 November 2008 entitled 'Telemedicine for the benefit of patients, healthcare systems and society' (COM(2008)0689).

([182]) Simon, P. and Lucas, J., 'La télémédecine n'est pas du e-commerce mais de la médecine clinique', (Telemedicine is not e-commerce but clinical medicine), doi:10.1016/j.eurtel.2014.01.030 (http://www.eurtelemed.fr/article/876884/la-telemedecine-n-est-pas-du-e-commerce-mais-de-la; consulted 13.02.2015).

([183]) Opinion 18 of the European Group on Ethics, Ethical aspects of genetic testing in the workplace, 2003.

3.3. Further avenues for regulating citizen participation in health

3.3.1. Transparency, clinical trials and drug development

There are close links between transparency and scientific integrity: it is only by sharing research and data that science can be reviewed, verified, tested and, if necessary, improved. Transparency is also critical for underpinning trust: where there is a perceived lack of transparency, science is perceived as being less reliable. The Tamiflu case and the subsequent investigation and findings of the Cochrane Report provide a prime example of this intermeshing of scientific integrity, transparency and trust ([184]).

The question of transparency is at the heart of ongoing debates surrounding access to clinical trials data (as illustrated by recent legal actions brought by US pharmaceutical companies Intermune and AbbVie to block the EMA from releasing data). A new policy on releasing trial data adopted by the EMA and which came into effect on 1 January 2015 aims, according to its Director, to set 'a new standard for transparency in public health and pharmaceutical research and development' by publishing the clinical reports that underpin the decision-making on medicines ([185]).

The secrecy of data in the authorisation procedures for new drugs as well as surrounding the availability of information in the phase following their introduction is ethically questionable. It stands in tension with the right of the citizens to be informed (including of possible negative results), and to have access to documentation, as well as potentially the right to be cured. Patients participating in clinical trials often make a personal sacrifice, exposing themselves to risks associated with the lack of knowledge surrounding the new products they are testing. In the development of its products, the pharmaceutical industry benefits significantly from the support of such participants; without this public contribution the development of drugs would be a great deal more onerous for the pharmaceutical industry. The secrecy of data — especially if asymmetrical, or if negative results have been kept unpublished, will ultimately affect the trust of society vis-à-vis the pharmaceutical industry, science and researchers. In the development of new medicines, publication of negative results cannot benefit the competition, as it is very unlikely that these data can be of any relevance in producing new drugs. It is therefore increasingly difficult to justify that scientific institutions and patients associations do not have access to all toxicological and clinical scientific data concerning drugs, including negative results.

However, transparency is not without limits. Data protection concerns should on occasion act as a counterweight towards transparency in clinical trial data, especially where drug trials on orphan diseases (relying on much smaller numbers of research participants) are concerned. In this regard, it is relevant to note reports that data protection concerns may in the past have been inflated and propagated to serve the interests of those stakeholders wishing to curb initiatives for increased transparency ([186]).

In addition to data protection considerations, commercial concerns can also act as a justifiable limit to transparency. Pharmaceutical companies have argued that disclosing trial data runs the risk of releasing trade secrets. Determining which data from clinical trials can be made public and which data should be redacted goes a long way towards answering this question. However, current definitions of 'commercially confidential information' (CCI) are vague. It remains to be clarified where precisely the burden of proof should lie when establishing CCI (e.g. with industry or regulatory authorities).

Thus, despite recent progress following the adoption of a new clinical trials regulation and EMA policy on releasing trial data, key questions surrounding the correct standards needed to ensure the right levels of transparency in drug development require further reflection. These include how to strike the right balance between open access/transparency imperatives, personal privacy protections and competitiveness, research excellence and innovation.

3.3.2. Regulating self-experimentation and compassionate use

To a certain extent, citizen science currently suffers from a regulatory vacuum. While clinical trials of scientific research are subject to both scientific and ethical

([184]) B. Goldacre, 'What the Tamiflu saga tells us about drug trials and big pharma', *The Guardian*, 10 April 2014.

([185]) European Medicines Agency (2014), 'Press release: Publication of clinical reports — EMA adopts landmark policy to take effect on 1 January 2015', 2 October 2014.

([186]) See leaked memo from EFPIA and PhRMA to patients groups instructing them to express concern about the non-scientific reuse of data.

oversight, research conducted outside institutional settings (such as hospitals, universities, etc.) is usually not subject to the same standards.

Patient-led research can open new paths for scientific advancement, but to be validated, this requires an implementation of regulations and standards covering scientific procedures, such as clinical trials ([187]). This is not only to validate the results but to protect participants from the risk of harm. Regulation is also necessary to prohibit any form of pressure on patients to participate, guaranteeing the right not to participate or to revoke consent without further consequences. Some contend that without adequate public intervention, this leaves the field open to other actors whose motivations go beyond the social good (e.g. profit-driven enterprises).

Another important governance question concerns the lack of ethics reviews covering citizen-led initiatives. Certain scholars have pointed to a trade-off at stake in participant-led projects between ethical oversight and innovation. There may be scope to introduce innovative models of ethical review, such as crowdsourced ethics reviews or the involvement of 'citizen ethicists'. In this regard, depending on the relative risk to participants, different policies have been proposed ranging from no formal ethics review to standard ethics review with a place for crowdsourced review or the input of 'citizen ethicists' ([188]).

This may bring new governance arrangements, applicable to potential new scenarios: e.g. the requirement of scientific oversight (in the statistic design and relevance of research), institution of virtual ethical committees of evaluation of protocols, of virtual informed consent with technical modalities to ascertain real consent.

As regards the 'compassionate use' of drugs for individual patients, Directive 2001/83/CE of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, at Article 5 recognises that a Member State may, in accordance with legislation in force, in order to fulfil special needs, exclude from the provisions of the directive 'medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under his direct personal responsibility'. There is the possibility to authorise temporarily unauthorised pharmaceuticals 'in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm'.

The expression 'compassionate use' is introduced in Article 83 of the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. It defines 'compassionate use' as the use of medical products 'for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life threatening, and who cannot be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 of this regulation or must be undergoing clinical trials'. The conditions for compassionate use are detailed in the 'Guideline on compassionate use of medicinal products, pursuant to Article 83 of Regulation (EC) No 726/2004 EMEA/27170/2006' of the European Agency for the Evaluation of Medicinal Products (EMEA), now the European Medicines Agency (EMA). It requires authorisation and experimentation, admitting their use in specific conditions as exceptional.

While compassionate care (expanded access) programmes permit patients with serious conditions to receive investigational drugs before their formal approval, there are many challenges, including regulatory ones, to its more widespread implementation. Some of the programmes may be financially problematic, as patients may be expected to cover at least some of the manufacturing costs. In addition, they may have only limited effect on the final development and regulatory approval and there may be insurance problems. Some patients believe that they have the right to access drugs at any stage of testing but so far this has not been substantiated by any court decision, although some companies have bowed to patients' pressures. In the USA, 'right to try' laws passed in 20 states as of September 2015 permit manufacturers to provide experimental

([187]) Wicks, P., Vaughan, T. E., Massagli, M. P. and Heywood, J. (2011), 'Accelerated clinical discovery using self-reported patient data collected online and a patient-matching algorithm', *Nature Biotechnology* 29(5): 411-4 (http://www.nature.com/nbt/journal/v29/n5/abs/nbt.1837.html); Wicks, P., Vaughan, T. E., and Heywood, J. (2014), 'Subjects no more: what happens when trial participants realise they hold the power?', *British Medical Journal* 348, g368 (http://www.bmj.com/content/348/bmj.g368).

([188]) Vayena and Tasioulas, 2013.

medicines to patients with untreatable conditions without FDA authorisation and shelter doctors from professional discipline and negligence actions. Their effect is limited as they do not compel manufacturers and insurers to supply and pay for experimental therapies. More precise regulations are needed to foster these programmes. For example, it has been suggested that multicentre ethical review boards focusing specifically on these programmes be established ([189]). Importantly, the regulations governing compassionate care (also referred to as special access programmes or expanded access) vary among European countries (authorising institution, who covers the costs, data collection obligation, informed consent, ethics committee approval). Some experts believe that the programmes should be made conditional on systemic data submission by eligible patients ([190]).

3.3.3. Ownership of data

The growing value (scientific and commercial) associated with data has prompted renewed discussions surrounding data ownership, and the possibility for citizens and patients to benefit from the advantages derivable from their data. International regulations, such as the 1997 European Convention on Human Rights and Biomedicine (and its 2002 additional protocol on biomedical research), have stated that 'the human body and its parts shall not, as such, give rise to financial gain or comparable advantage'. Such an approach may equally be extended to personal data.

However, with changing practices of citizen participation in medical science, and the growth of 'collaborative' and 'participatory' research models, participants are beginning to demand access to results of the research to which they have contributed, either as limited access to the specific group suffering from the disease, or to the wider public.

The right of data subjects 'to be forgotten' implies, de facto, some sort of ownership of data relating to them, and therefore the right to eventually donate data or sell them. It is true, however, that when it comes to data relating to individual subjects, the preferred model for the advancement of scientific research seems to have been not to allow intellectual property (IP) rights deriving from raw datasets, while IP rights should only become attached to the analytic work performed on the data, in the same way as current IP law covers arrangement of facts, but not the facts themselves.

Nevertheless, new questions are opening regarding who owns the results of research. With data now a 'tradable good', are citizens entitled to gain (including financially) from donating their data? Start-up initiatives are beginning to emerge based on just such a model, such as MyHealthBook, a company offering financial incentives in exchange for citizens' health data. The latter raises a number of ethical concerns. Yet, given the considerable wealth generated by pharmaceutical companies from repositories of data derived from individuals (sometimes without their knowledge or consent), should greater reflection not be paid to allowing citizens/patients to share in the advantages of their contributions?

This would entail a significant reconceptualisation of ownership where it pertains to knowledge and research results. For instance, when a pharmaceutical company discovers a new drug, would the data surrounding the production of that medication be considered the sole property of the company concerned or a wider public good (given the shared investment in that innovation: patients who participated in research trials, researchers, education and training systems, etc.)?

There is a strong public interest in the responsible use of data in research to support the development of knowledge and innovation intended to improve the wellbeing of all by enabling advances in healthcare. The implications for ownership is a complex topic in need of extended public debate, and potentially requiring eventual policy attention.

([189]) Darrow, J. J. et al., *New Eng. J. Med.* 2015, 372, 279-86.

([190]) Walker, M. J., Rogers, W. A. and Entwistle, V., *Am. J. Bioethics* 2014, 14, 3-15.

Recommendations

This Opinion set out to explore new trends of participation in health by patients, citizens and consumers. It scrutinised citizen participation via a selection of case studies of scientific and technological innovation, examining the ethical implications of these socio-technical developments before making a critical analysis of the existing regulations and the governance of these phenomena.

The EGE finds that new participatory practices in health are being driven by the confluence of new technologies and social changes in the 21st century. In effect, these practices draw on novel techniques in medical science, reliant on amassing large quantities of volunteer data, which are paving the way for new models of participatory and collaboration-based research. They also stem from the growth of the internet, and mobile devices which are driving new forms of digital networking in health. These trends are by no means confined to the health domain, but form part of wider societal shifts relating to the democratisation of knowledge, the growth of an increasingly informed public, and a greater role claimed by lay citizens in the production of knowledge and innovation.

The result is an increasing diversity of roles available to citizens in health, as research participants or citizen scientists, lobbyists and advocates for particular health causes, or increasingly engaged and connected producers and users of health data and information. Linked to these new participatory practices, and the health technologies which facilitate them, the EGE has identified **three sets of shifts in the way that health and healthcare are perceived, organised and delivered**.

First, the opening of a multitude of new roles for citizens as active participants in various dimensions of health may impact on the way **individuals view their health, their body, and conceptualise illness and disease**. New technologies of participation may offer interactive forums for the narration and communicative sharing of lived experiences. Yet the growth of genetic testing, new diagnostic techniques and digital monitoring devices, and the wealth of bio-information that these tools generate, may feed a progressive understanding of the self whereby health information and data risk becoming detached from social and environmental factors and from the biographical subjectivity of the patient. The EGE recognises that both the empirical (informational, biological) and the experiential (lived experience) are essential components that feed an individuals' understanding of health and illness. Realising the full potential of data intensive medical technologies, such as precision medicine, requires maintaining focus on the broader social, economic, cultural and environmental context of a patient. We also need to be mindful of the ways in which these technologies feed into the production of norms of health, behaviour and performance.

Second, new health technologies, and participatory practices are destabilising traditional structures of power and knowledge which underpin medical practice, **altering what it means to be a patient** in the modern health context. The traditional role of 'patient' as a passive recipient of care appears increasingly incongruous in the face of new associations of the patient as informed partner, client, consumer, expert, or activist. The greater participation of individuals in health is likely to reframe traditional roles of 'doctor' and 'patient', alter how they interact with one another and shift the boundaries between them. Increased technological autonomy can stimulate health-awareness, and motivate individuals to participate actively in health issues, as well as provide new possibilities for accessing care. However, ethical risks may emerge should technologies cause patients to lose critical contact with medical professionals when it counts. The challenge is to ensure an appropriate balance, whereby the patient is empowered to exercise autonomy, while not losing the crucial interpersonal exchange and necessary expert support in interpreting medical information and selecting treatment options. New technologies that support changing modes of patient–physician interaction should be geared towards enhancing the patient–physician relationship and the quality and availability of care provision from healthcare systems.

Third, participatory practices in health are **opening new roles to citizens in the production of medical knowledge and innovation**. The involvement of citizens in the scientific endeavour has brought important innovations in the field of medical science, drawing on the unique perspectives of 'expert patients', of collective intelligence and new avenues opened by big data. It yields educative dividend in the form of knowledge, new skills, new life opportunities and emerging civic awareness, and can invest patients with a greater sense of empowerment over their health. The EGE identifies challenges in integrating the contributions of citizens into the advancement of medical research and in reconciling lay expertise with the rigours of evidence-based

medicine which requires a firm grounding in scientific competence, methodology and review and adherence to standards of ethical oversight. Yet the EGE recognises the valuable contribution that citizens can make to the scientific endeavour and cautions against 'participatory approaches' which disempower, or even exploit, volunteer participants by rendering research subjects a resource from which data and samples may be extracted but with little understanding of the research process, control over their data, or access to outcomes.

On the basis of the shifts identified and explored above, the EGE makes the following **key findings and ethical reflections**:

Balancing autonomy and responsibility: Growing autonomy on the part of citizens and patients in the steering of individual and collective health decisions are a welcome step forward. They not only fulfil requirements for self-determination, self-actualisation and empowerment that are essential for human flourishing, but they also improve health outcomes and the effectiveness of care. A more active engagement on the part of the individual can play an essential part in realising the goal of a patient-centred care. Here, in the spirit of a partnership approach to healthcare, autonomy should come hand in hand with patient responsibility. We should nevertheless be attentive to the ways in which processes of engagement or 'empowerment' are being mediated through external dynamics and drivers, including public healthcare authorities and commercial actors, where interests align to encourage the imperative for citizens to take a greater part in managing their own health. The EGE cautions against any movement towards an 'autonomy in health' which reflect a broader shift of responsibility from state health services to the individual or which transfers the responsibility for risk and the capacity for regulation onto the individual that would ultimately signal a reduction in the standards and quality of healthcare provision.

Disentangling participation: Participation can be an appealing notion, implying as it does inclusivity, openness and democratisation. However, this Opinion cautions against a simple reading of participation as an unalloyed good and reveals the layered meanings contained in terms such as 'citizen science'. Participation can fall short of expectations or produce unwanted outcomes. This takes shape in several ways. Participation may elicit expectations as to greater transparency or accountability, but cannot necessarily provide it. The term 'participatory' may be attributed to services where consent is ambiguous. It can be based on the extraction and sale of personal data, and where it concerns the extraction of profit or labour, act as a veiled form of exploitation.

Weighing up the positive potential of participation for individuals and societies thus centres around a number of axes. The potential for empowerment and enrichment will turn on the degree of voice or agency it accords, access to decision-making and goal setting; or the dividend reaped in terms of education and skills. Minimising the risks of exploitation can depend on the control of ownership of resources accorded to participants, its voluntary or obligatory character and the nature of consent given. Attention should also be given to the nature of the 'participants' themselves who may not always be individual, disinterested citizens, but may encompass a range of organised interests: advocacy groups, lobbies, or corporate actors. Developing a more nuanced understanding of participation in the health domain therefore requires careful consideration of the context in which participation takes place and greater transparency of the goals, functions and outcomes, on the part of both the institutions inviting participation, as well as the participants themselves.

Implications for justice and solidarity: The EGE underscores the importance of an equitable distribution of health resources and the right of everyone, particularly the vulnerable, to health protection. At the same time, it notes that new practices of citizen participation are challenging and reframing the application of justice and solidarity as fundamental organising principles underpinning European health systems.

Citizen involvement can open new avenues for collective action and shows potential for rebalancing structural inequalities that have long existed regarding investment in medical research. However, it can also exacerbate existing imbalances, amplifying the demands of the well-resourced and educated, further widening inequities. Breakthrough advances in medical technologies, such as precision medicine, can likewise present public health policy with challenges when setting priorities for investment. Decisions regarding expensive, high-tech or 'personalised' treatments will need to be carefully balanced with wider social needs for essential/basic forms of healthcare.

New technologies have also opened the way for citizens to engage in health projects, actions and initiatives which reflect strong solidarity-based objectives. These movements are both giving new life to solidarity as a driver of community action and redefining

traditional state-centred solidarity frameworks. The EGE is concerned that these developments change the balance of emphasis as to who should provide solidarity and according to which criteria. We should be mindful of potential shifts in shared understandings of solidarity, from a state-managed process to one organised and driven by citizens.

Based on these considerations, the EGE agrees on the following recommendations in the field of citizen participation and new health technologies:

A. General considerations: changing the way we think about health and about citizen involvement

Reflecting on key notions:

The EGE recommends fostering public debate on entrenched and evolving concepts which underpin our understanding of health and health research and how healthcare is delivered. Reflection should focus on public understandings and potentially contested expectations surrounding the following notions:

- Care, wellbeing and health. How to conceptualise health to better encompass both preventive approaches and holistic/global understandings of health and illness (while addressing medicalisation tendencies)? Attention should be given to societal understandings, principles and structures underpinning health. What is the role of the public health system in regard to debates on benefit sharing and responsibility-shifting in the domain of health?

- Relatedly, this public debate regards the ways in which new forms of participation are recalibrating the balance between individual and collective interests in medical services and medical research. Further, it should open a discussion as to where we, as a society, wish to place the limits on individual interests and where common interest and the public good justify such limitations.

- Being a patient. Perceptions, concepts and practices have changed dramatically over the last decade, leading to tensions extending between passivity and activity, between individual and collective, as well as with regard to evolving understandings of the doctor–patient relationship together with the epistemic and power relations it carries.

Establishing conceptual clarity:

- Given the aforementioned social transformations, it is crucial, when making policy decisions and establishing governance mechanisms, to offer clear definitions and reach a common understanding, on key concepts relevant in the policy sector, such as health, wellbeing, and lifestyle. The EGE thus recommends that the EU institutions in conjunction with Member States endeavour to reach common understandings and definitions on key terms such as 'health', including the demarcation between categories of health, wellbeing, and lifestyle. This is not a detached theoretical pursuit; it has concrete and sorely needed regulatory implications. Indeed such conceptual clarity would in turn support public debate on expectations for public health services as well as support lawmakers when classifying and regulating new health technologies, such as apps which deal explicitly with health, as opposed to other aspects of wellbeing and lifestyle.

- The EGE recommends that the European Commission takes into account the heterogeneous meanings associated with citizen participation when formulating policy proposals, especially when they draw on the concept of 'citizen science'. Attention should be paid to the different dimensions and forms of citizen participation to which the term can apply, the specific value that different forms bring and ethical problems they pose.

Awareness raising and education

- The EGE recommends that training for healthcare professionals addresses the spread of medical knowledge beyond the traditional medical establishment, including the proliferation of online medical information and health apps. Healthcare professionals should be supported in exploring new ways of interacting with patients in light of the availability of alternative sources of health information, including on how to make use of trustworthy health resources while avoiding potential harm from unreliable sources of information. Moreover, with the advent of precision medicine, information management skills, and greater understanding of what precision medicine can and cannot do, will become increasingly important for physicians if patients are to receive maximum benefit. Thus, the EGE recommends that medical curricula integrate training on informatics and advanced statistics, with the aim of increasing data literacy to allow

physicians to interpret and act on results from precision medicine.

- The EGE recommends that the EU institutions and Member States seek to foster public knowledge, awareness and responsibility as well as debate on using trustworthy sources of health information and on making informed choices concerning participation in research and the sharing of health data.

- Online health resources can support citizens to become informed. However, given the difficulties of distinguishing between trustworthy and reliable health websites, the EGE recommends that Member State health authorities support the development of 'certified' health resources with advice that is evaluated by independent/national health authorities. Such recognised sites should also meet EU standards of personal data protection.

- The EGE recommends the furthering of research into the implications of citizen involvement in science and technology as such, and in the health domain in particular.

B. Regulatory recommendations: addressing gaps in the governance of citizen involvement and new health technologies

Digital health products

- The EGE recommends that the European Commission (with the European Parliament and Council, as the case may be) addresses current gaps and loopholes in the regulatory framework concerning digital health products (such as computer software, internet applications, mHealth applications), the safety of which is fully covered neither by the medical devices directive nor by the product safety directive. In addition, the Commission should establish, via measures for rigorous enforcement, greater compliance by all parties with existing legislation and standards.

Data

- Fundamental rights considerations should be integral to EU policy on health data, including big data. This could be delivered, for instance, by including a requirement to obtain individual consent for further processing of health data in the EU regulation on data protection currently under negotiation. In addition, the compatibility safeguard clause which obliges explicit demonstration of compatibility of processing of research data with research purposes, should then be maintained in the regulatory framework.

- As data are deemed to be the new currency of the 21st century, bringing considerable opportunities for economic activity and R & D, and because health data has become both a sensitive and a strategic object of attention, the EGE recommends the EU institutions to clarify the concept of ownership with regard to data. This includes provisions regarding the collection and security of health data. Acknowledging the ongoing debate on the calibration of private ownership of data and the public good, the EGE recommends the setting up of measures in order to protect individuals against the overreach by third parties with regard to health data.

- The EGE recommends a recalibration in the balance between the protection of commercial data relevant to public health and the need for transparency and public access. In this light, it welcomes the provisions on transparency in the new EU regulation on clinical trials. The EGE recommends that the European Commission carefully monitor compliance with the new rules by relevant parties and take the necessary enforcement action when required.

Provision of care

- The EGE recommends that the introduction of remote medicine programmes (with reference to mHealth, e-health, including telemedicine, using remoteness as a tool) maximises the benefits of these technologies and minimises potential harms. Public health providers should carefully assess the implications for quality of care, privacy and impact on budgetary resources before introduction, as well as monitor and evaluate their impact *ex post*. Guiding principles underpinning this assessment should include the following requirements: that telemedicine programmes do not in any way lead to a reduction in the standard of patient care; their introduction should aim to complement rather than substitute face-to-face contact between healthcare professional and patient; their introduction should seek to reduce rather than exacerbate inequalities in access to care. Such assessments should be shared at the European level in order to exchange experience, highlight best practice, verify compliance with patients' rights and to feed eventual reflection on the needs to adapt the legal framework.

- Because certain new diagnostic techniques (e.g. direct-to-consumer and internet-based tests, including genetic tests) are available across borders and cut across different legislative frameworks, the EGE calls on the EU institutions to work together with the Member States to introduce Europe-wide standards and oversight. As the EGE has repeatedly stated, in the case of direct-to-consumer genetic susceptibility tests, these should abide by the following standards:

  — laboratories providing genetic tests must comply with accepted quality standards; privacy and confidentiality of sensitive genetic information should be ensured and security of data guaranteed;

  — information about the purpose and appropriateness of testing must be given before the test is done and avenues for genetic counselling or follow-up advice offered;

  — in accordance with current standards and guidelines, inappropriate testing of minors and other legally incapacitated persons must be prevented unless exceptional circumstances justify such an intervention;

Participation

- The EGE encourages wider and more meaningful participation of citizens in all aspects of the polity. While citizens and patients have long been encouraged to participate in medical research, the EGE welcomes active citizen involvement in health research at different levels, including setting the objectives, goals and structuring of research and policies. It recommends that, when it does occur, the same scientific standards that are required for research — with regard to safety, methodology, ethics and rigour — are preserved.

- New ways of participation require the adjustment of ethical oversight. While ethical oversight can usefully draw upon increasing public involvement, citizen engagement in scientific experiments must be regulated in accordance with the same ethical standards as other forms of research.

- Traditionally, the 'patient' has been a passive spectator in his or her own healthcare. The EGE welcomes and encourages active participation of patients in decision-making so that the individuals can contribute to improving the quality and efficiency of their own care. By vindicating the individuals' right to be informed, to choose and to be heard, patients can play a more proactive role in the design and delivery of healthcare. Patient representatives and advocacy groups have a vital role to play, but it is important that we do not fall into the trap of listening only to the loudest and best-resourced voices. The EGE would also welcome the increased participation of patients and the wider citizenry in discussions about setting healthcare priorities and allocation of resources.

- The EGE underscores the importance of patients having easy access to their health records, as enshrined in the Oviedo Convention on Human Rights and Biomedicine, and being able to interface with their clinical data as proactive users. The EGE recommends that there be a guarantee in every Member State that citizens can obtain copies of their health records, electronic or otherwise, without excessive practical constraint, delay or expense.

Solidarity and justice

- The EGE recognises the new forms of solidarity fostered by citizen participation in health. It urges caution, in noting that solidarity in one context can present an imposition, or signal responsibilisation or commodification in another. The EGE recalls the freedom of individuals to choose not to participate. It notes that commercial pursuits should not masquerade as philanthropic endeavours and recommends transparency also from third parties, to enable citizens to make more informed choices. The EGE underlines the necessity to promote a just solidarity in connection with human rights and the standards enshrined in the EU Charter of Fundamental Rights.

- Precision medicine is a field in its infancy but significant benefits could accrue to European patients and citizens more broadly. It also brings into sharp focus existing questions of distributive justice in healthcare systems that are being currently debated. It is important that funding of this innovative approach to prevention, diagnosis and treatment of disease should not be at the expense of initiatives, which address health inequalities. Further, efforts should be made to ensure that data cohorts are as representative as possible so that any benefits from precision medicine can be shared in a just and equitable manner. The EGE recommends that research

be undertaken at the EU and Member State level on how treatments arising from research in precision medicine will be funded and/or reimbursed through public health systems.

- The EGE draws attention to the position of individuals and groups who cannot or do not wish to engage in new forms of health participation or who have little access to the technologies on which participation relies. The EGE warns of the risk of new technologies deepening pre-existing health inequalities and recommends that where health services are predicated on digital tools, non-ICT-based alternatives be maintained. The EGE calls on the EU to further develop strategies to ensure that those who wish to can make effective use of new forms of health participation and harness the potential of health empowerment.

Recommandations

Le présent avis avait vocation à explorer les nouvelles tendances concernant la participation des patients, des citoyens et des consommateurs en matière de santé. Il a examiné la participation des citoyens à travers une sélection d'études de cas d'innovation scientifique et technologique, évaluant les incidences éthiques de ces développements sociotechniques, avant d'avancer une analyse critique de la réglementation et de la gouvernance actuelle de ces phénomènes.

Le Groupe européen d'éthique des sciences et des nouvelles technologies (GEE) estime que les nouvelles pratiques participatives en matière de santé résultent de la confluence des nouvelles technologies et des changements sociaux survenus au XXIe siècle. En effet, ces pratiques se nourrissent des nouvelles techniques utilisées dans les sciences médicales, basées sur la collecte d'importantes quantités de données fournies par des participants volontaires, qui ouvrent la voie à de nouveaux modèles de recherche participative et collaborative. Elles résultent également du développement de l'internet et des appareils mobiles, qui font naître de nouvelles formes de mise en réseau numérique dans le domaine de la santé. Ces tendances ne se limitent pas seulement au secteur de la santé, mais s'inscrivent dans le cadre de changements sociétaux plus larges qui concernent la démocratisation des connaissances, la part croissante du public averti et le plus grand rôle revendiqué par les simples citoyens dans la production de la connaissance et de l'innovation.

Cela se traduit par une plus grande diversité des rôles accessibles aux citoyens dans le domaine de la santé, en tant que participants à la recherche ou citoyens-chercheurs, lobbyistes et défenseurs de causes particulières liées à la santé, ou en tant que producteurs et utilisateurs, de plus en plus engagés et connectés, des données et informations sur la santé. En lien avec ces nouvelles pratiques participatives, et les technologies de la santé qui les facilitent, le GEE a cerné **trois types de changements dans la façon dont la santé et les soins de santé sont perçus, organisés et dispensés.**

Premièrement, l'accès des citoyens à une multitude de nouveaux rôles en tant que participants actifs dans divers aspects de la santé peut influencer la façon dont les **individus perçoivent leur santé, leur corps, et conceptualisent la maladie et les pathologies.** Les nouvelles technologies de participation peuvent offrir un forum interactif permettant la communication et le partage des expériences vécues. Toutefois, l'essor des tests génétiques, des nouvelles techniques de diagnostic et des dispositifs numériques de surveillance, associé à la richesse des informations biologiques que ces outils génèrent, peut favoriser une compréhension progressive de soi-même, dans laquelle l'information et les données médicales risquent de se dissocier des facteurs sociaux et environnementaux et de la subjectivité du patient liée à ses antécédents. Le GEE reconnaît que la dimension empirique (informations, paramètres biologiques) comme l'expérience vécue sont des composantes essentielles qui favorisent la compréhension de la santé et de la maladie par les individus. Pour pouvoir exploiter pleinement le potentiel des technologies médicales à forte intensité de données, comme la médecine de précision, il est nécessaire de rester centré sur le contexte social, économique, culturel et environnemental d'un patient au sens le plus large. Il faut aussi rester attentif à la façon dont ces technologies participent à la production de normes en matière de santé, de comportement et de performance.

Deuxièmement, les nouvelles technologies de la santé et les pratiques participatives déstabilisent les structures traditionnelles du pouvoir et du savoir qui caractérisent la pratique médicale, **en modifiant ce qu'on entend par «patient»** dans le contexte de la santé moderne. Le rôle traditionnel du patient en tant que bénéficiaire passif de soins semble de plus en plus incongru au regard des nouvelles conceptions du «patient», en tant que partenaire, client, consommateur, expert ou militant informé. La participation accrue des individus dans le domaine de la santé pourrait refaçonner les rôles traditionnels du médecin et du patient, modifier la façon dont ces deux acteurs interagissent l'un avec l'autre et déplacer les frontières entre eux. Une plus grande autonomie technologique peut stimuler la sensibilisation à la santé, inciter les individus à participer activement aux débats sur la santé et fournir de nouvelles possibilités d'accès aux soins. Cependant, des risques éthiques pourraient se poser si ces technologies devaient entraîner une perte de contact entre les patients et le corps médical, dans les moments cruciaux. Le défi consiste à trouver un juste équilibre, pour que le patient puisse exercer son autonomie, sans pour autant être privé de l'échange interpersonnel ni de l'assistance de spécialistes indispensables à l'interprétation des renseignements médicaux et au choix des options de traitement. Les nouvelles technologies qui favorisent l'évolution des modes d'interaction entre patient et médecin devraient être axées sur l'amélioration de la relation médecin-patient et de la qualité et disponibilité des soins dispensés par les systèmes de santé.

Troisièmement, les pratiques participatives en matière de santé **créent de nouveaux rôles pour les citoyens dans la production des connaissances et des innovations médicales.** La participation des citoyens à l'effort scientifique a engendré d'importantes innovations dans le domaine des sciences médicales, exploitant les perspectives uniques du «patient expert», de l'intelligence collective et des nouvelles voies ouvertes par les mégadonnées. Cette participation est source de gains éducatifs sous forme de connaissances, de nouvelles compétences, de nouvelles possibilités de vie et d'une prise de conscience civique, et peut conférer aux patients un plus grand sentiment d'autonomie à l'égard de leur santé. Le GEE perçoit les difficultés que posent l'intégration des contributions des citoyens dans l'avancement de la recherche médicale, la conciliation de l'expertise profane avec la rigueur d'une médecine fondée sur des preuves — qui nécessite une base solide en termes de compétences scientifiques, de méthodologie et d'examen —, ainsi que le respect de normes de surveillance éthique. Cependant, le GEE reconnaît la précieuse contribution que les citoyens peuvent apporter à l'effort scientifique et met en garde contre les «approches participatives» qui déresponsabilisent, ou même exploitent, les participants bénévoles, en faisant des sujets de la recherche une ressource dont on peut extraire des données et des échantillons, mais qui permet peu de compréhension du processus de recherche, peu de contrôle sur les données, ou peu d'accès aux résultats.

Sur la base des changements relevés et analysés ci-dessus, le GEE formule les **principales conclusions et considérations éthiques suivantes.**

Trouver le juste équilibre entre autonomie et responsabilité: une plus grande autonomie de la part des citoyens et des patients dans l'orientation des décisions individuelles et collectives de santé est une avancée dont on peut se réjouir. Cela répond non seulement aux besoins d'autodétermination, de réalisation de soi et d'autonomisation qui sont essentiels pour l'épanouissement personnel, mais améliore également les résultats en matière de santé et l'efficacité des soins. Un engagement plus actif de la part de l'individu peut jouer un rôle essentiel pour atteindre l'objectif de soins centrés sur le patient. Dans ce domaine, dans l'esprit d'un partenariat pour les soins de santé, l'autonomie devrait aller de pair avec la responsabilité du patient. Il faut néanmoins être attentif à la façon dont les processus de participation ou de «responsabilisation» sont influencés par des dynamiques et des facteurs externes, y compris les autorités de santé publique et les acteurs commerciaux, lorsque les intérêts convergent pour encourager la nécessité pour les citoyens de participer davantage à la gestion de leur propre santé. Le GEE met en garde contre une dérive de l'«autonomie en matière de santé» qui correspond à un transfert plus général de la responsabilité des services publics de la santé vers les particuliers ou qui place sur ces derniers la responsabilité du risque et la capacité de réglementation, et qui, en fin de compte, annoncerait une baisse des niveaux et de la qualité des soins de santé dispensés.

Élucider la participation: la participation peut être une notion intéressante, qui implique inclusion, ouverture et démocratisation. Pourtant, le présent avis met en garde contre une vision simpliste de la participation qui la considérerait comme positive à 100 %, et révèle les différentes couches que recèlent des expressions telles que «sciences citoyennes». La participation peut décevoir les attentes ou donner des résultats autres que ceux recherchés. Cela se traduit de différentes façons. La participation peut susciter des attentes quant à une plus grande transparence ou responsabilisation, mais ne permet pas nécessairement d'y répondre. Le terme «participatif» peut désigner des services pour lesquels le consentement est ambigu. Il peut s'appuyer sur l'extraction et la vente de données personnelles et, lorsqu'il s'agit d'un profit ou de travail, constituer une forme déguisée d'exploitation.

L'appréciation du potentiel positif de la participation des individus et des communautés s'articule donc autour de plusieurs axes. Le potentiel d'autonomisation et d'enrichissement variera en fonction du niveau des facultés d'expression et de représentation accordées, ainsi que de l'accès à la prise de décisions et à l'établissement des objectifs, ou des bénéfices récoltés en termes de formation et de compétences. La minimisation des risques d'exploitation peut dépendre du contrôle de la propriété des ressources accordée aux participants, de son caractère volontaire ou obligatoire et de la nature du consentement donné. Il conviendrait également de prêter attention à la nature des «participants» eux-mêmes, terme qui peut ne pas toujours désigner des particuliers désintéressés, mais qui peut englober tout un éventail d'intérêts organisés: des groupes de défense, des groupes de pression, des entreprises. Développer une compréhension plus nuancée de la participation en matière de santé exige donc un examen attentif du contexte dans lequel elle a lieu et une plus grande transparence des objectifs, des fonctions et des résultats, de la part à la fois des institutions invitant à la participation et des participants eux-mêmes.

Conséquences en termes de justice et de solidarité: le GEE souligne l'importance d'une répartition équitable

des ressources de santé et du droit de tout un chacun, en particulier des plus vulnérables, à la protection de la santé. Par ailleurs, il observe que les nouvelles pratiques de participation citoyenne remettent en cause et refaçonnent l'application de la justice et de la solidarité, principes fondamentaux d'organisation sur lesquels reposent les systèmes de santé européens.

La participation des citoyens peut ouvrir de nouvelles voies pour une action collective et contribuer au rééquilibrage des inégalités structurelles qui caractérisent depuis longtemps l'investissement dans la recherche médicale. Cependant, elle peut également accentuer les déséquilibres existants, en amplifiant les exigences des mieux nantis et des plus instruits, augmentant encore les inégalités. Les progrès décisifs réalisés dans les technologies médicales, comme la médecine de précision, peuvent également représenter des défis pour la politique de santé publique, qui doit déterminer les priorités d'investissement. Les décisions concernant des traitements coûteux, sophistiqués ou «personnalisés» devront être soigneusement mises en balance avec des besoins sociaux plus larges concernant des formes fondamentales/élémentaires de soins de santé.

Les nouvelles technologies ont également donné la possibilité aux citoyens de participer à des projets, actions et initiatives en matière de santé qui répondent à des objectifs forts faisant appel à la solidarité. Ces actes d'engagement donnent un nouveau souffle à la solidarité en tant que vecteur de l'action communautaire et redéfinissent les cadres de solidarité traditionnels centrés sur l'État. Le GEE craint que cette évolution ne modifie l'équilibre des priorités, parmi ceux qui doivent assurer la solidarité et les critères qu'il convient d'appliquer. Il importe d'être attentif aux transformations possibles de la conception commune de la solidarité, qui pourrait passer d'un processus géré par l'État à un processus organisé et dirigé par les citoyens.

Partant de ces considérations, le GEE adopte les recommandations suivantes dans le domaine de la participation citoyenne et des nouvelles technologies de la santé:

A. Considérations générales: changer nos conceptions de la santé et de la participation citoyenne

Réflexion sur des notions clés

Le GEE recommande d'encourager le débat public autour des notions — profondément ancrées pour certaines, en pleine évolution pour d'autres — qui sous-tendent notre compréhension de la santé et de la recherche en matière de santé, ainsi que la façon dont les soins de santé sont dispensés. La réflexion devrait se centrer sur les conceptions et les attentes potentiellement opposables du public entourant les notions suivantes:

- Les soins, le bien-être et la santé. Comment conceptualiser la santé pour mieux englober à la fois les approches préventives et les représentations holistiques/globales de la santé et de la maladie (tout en tenant compte des tendances à la médicalisation)? L'attention devrait être accordée aux conceptions, principes et structures sur lesquels repose la santé dans nos sociétés. Quel est le rôle du système de santé publique en ce qui concerne les débats sur le partage des avantages et le transfert de responsabilité dans le domaine de la santé?

- Dans le même ordre d'idées, ce débat public concerne la façon dont les nouvelles formes de participation permettent de réajuster l'équilibre entre l'intérêt individuel et l'intérêt collectif dans les services médicaux et la recherche médicale. En outre, il devrait ouvrir une discussion sur la question de savoir où nous, en tant que société, voulons placer les limites de l'intérêt individuel et dans quelle mesure l'intérêt commun et le bien public justifient de telles limitations.

- Être un patient. Les perceptions, les concepts et les pratiques ont radicalement changé au cours de la dernière décennie, ce qui a engendré des tensions entre la passivité et l'activité, entre l'individuel et le collectif, mais également quant à l'évolution des conceptions de la relation médecin-patient et des rapports épistémiques et de pouvoir qu'elle implique.

Clarifier les concepts

- Compte tenu des transformations sociales susmentionnées, il est essentiel, lors de la prise de décisions politiques et de l'établissement des mécanismes de gouvernance, de donner des définitions claires et de parvenir à une compréhension commune des concepts clés pertinents dans le secteur d'action, tels que la santé, le bien-être et le mode de vie. Le GEE recommande donc que les institutions de l'Union européenne (UE), en collaboration avec les États membres, s'efforcent de parvenir à des conceptions et à des définitions communes de termes clés tels que «santé», notamment en distinguant clairement les catégories que sont la «santé», le «bien-être» et

le «mode de vie». Il ne s'agit pas d'un exercice théorique isolé, mais d'une démarche qui aura des implications réglementaires concrètes et grandement nécessaires. En effet, cette clarté conceptuelle favoriserait le débat public sur les attentes en matière de services de santé publique et aiderait les législateurs à établir une classification et une réglementation des nouvelles technologies de la santé, comme les applications traitant explicitement de la santé, par opposition aux autres aspects que sont le bien-être et le mode de vie.

- Le GEE recommande à la Commission européenne de tenir compte de la variété des significations associées à la participation citoyenne lors de la formulation de propositions politiques, notamment quand elles s'appuient sur la notion de «sciences citoyennes». Il convient de prêter attention aux différentes dimensions et formes de la participation citoyenne que l'expression peut désigner, à la valeur spécifique que ces différentes formes peuvent apporter et aux problèmes éthiques qu'elles posent.

Sensibilisation et éducation

- Le GEE recommande que la formation des professionnels de la santé aborde la question de la diffusion des connaissances médicales au-delà du milieu médical traditionnel, y compris de la multiplication de l'information médicale et des applications de santé en ligne. Les professionnels de la santé devraient être encouragés à chercher de nouvelles façons d'interagir avec les patients compte tenu de la disponibilité d'autres sources d'information sur la santé, y compris en expliquant comment utiliser des ressources de santé dignes de confiance et éviter les préjudices potentiels que peuvent causer des sources d'information peu fiables. En outre, avec l'avènement de la médecine de précision, une importance plus grande devra être accordée par les médecins aux compétences de gestion de l'information et à une meilleure compréhension de ce que la médecine de précision peut et ne peut pas faire pour que les patients puissent tirer un maximum de profit de leur traitement. Par conséquent, le GEE recommande que les cursus médicaux intègrent une formation en informatique et en statistiques avancées, afin de permettre aux médecins, ainsi mieux initiés aux données, d'interpréter les résultats de la médecine de précision et d'agir en conséquence.

- Le GEE recommande que les institutions et les États membres de l'UE s'efforcent de favoriser la connaissance, la sensibilisation et la responsabilité du public ainsi que le débat sur l'utilisation de sources d'information fiables en matière de santé et sur la fixation de choix éclairés concernant la participation à la recherche et au partage des données en matière de santé.

- Les ressources en ligne sur la santé peuvent aider les citoyens à s'informer. Toutefois, étant donné les difficultés rencontrées pour reconnaître les sites consacrés à la santé dignes de confiance sur l'internet, le GEE recommande que les autorités sanitaires des États membres encouragent le développement de ressources de santé «certifiées» contenant des conseils qui seraient évalués par des autorités sanitaires indépendantes/nationales. Ces sites reconnus devraient également répondre aux normes de l'UE en matière de protection des données personnelles.

- Le GEE recommande d'approfondir la recherche sur les incidences de la participation des citoyens dans la science et la technologie en soi, et en particulier dans le domaine de la santé.

B. Recommandations réglementaires: combler les lacunes dans la gouvernance de la participation des citoyens et des nouvelles technologies en matière de santé

Produits de santé numériques

- Le GEE recommande que la Commission européenne (avec le Parlement européen et le Conseil, selon le cas) comble les lacunes et les failles actuelles du cadre réglementaire concernant les produits de santé numériques (tels que les logiciels, les applications internet, les applications de «santé mobile»), dont la sécurité n'est pas pleinement couverte ni par la directive sur les dispositifs médicaux ni par la directive sur la sécurité des produits. En outre, la Commission devrait instaurer, par le biais de mesures d'application rigoureuse, un plus grand respect de la législation et des normes de la part de tous les participants.

Données

- Les considérations relatives aux droits fondamentaux devraient faire partie intégrante de la politique de l'UE sur les données de santé, y compris les mégadonnées. Pour ce faire, il faudrait par exemple inclure, dans le règlement de l'UE sur la protection des données, actuellement en cours de négociation, l'obligation d'obtenir un consentement individuel pour

le traitement ultérieur des données de santé. Il faudrait en outre maintenir dans le cadre réglementaire la clause de sauvegarde en matière de compatibilité, qui impose la démonstration explicite de la compatibilité du traitement des données de la recherche avec les fins de la recherche.

- Sachant que les données sont considérées comme la nouvelle monnaie du XXIe siècle, offrant des possibilités considérables en termes d'activité économique et de R & D, et que les données de santé suscitent aujourd'hui l'attention en tant que biens à la fois sensibles et stratégiques, le GEE recommande aux institutions de l'UE de clarifier le concept de propriété à l'égard des données. Cela passe notamment par des dispositions relatives à la collecte et à la sécurité des données de santé. Reconnaissant le débat en cours sur l'ajustement de la propriété privée des données en regard du bien public, le GEE recommande de mettre en place des mesures visant à protéger les individus et à empêcher les excès par des tiers quant aux données de santé.

- Le GEE recommande un recalibrage de l'équilibre entre la protection des données commerciales présentant un intérêt pour la santé publique et le besoin de transparence et d'accès public. À cet égard, il se félicite des dispositions sur la transparence figurant dans le nouveau règlement de l'UE sur les essais cliniques. Le GEE recommande à la Commission européenne de surveiller scrupuleusement le respect des nouvelles règles par les parties concernées et de prendre les mesures d'exécution qui s'imposent en cas de besoin.

Dispense des soins

- Le GEE recommande que l'introduction de programmes de médecine à distance (en lien avec la santé mobile, la santé en ligne, notamment la télémédecine, utilisant l'éloignement comme outil) maximise les avantages de ces technologies et minimise les préjudices potentiels. Les prestataires de la santé publique devraient soigneusement en évaluer les répercussions sur la qualité des soins, la vie privée et les ressources budgétaires avant leur introduction, et surveiller et évaluer leur impact a posteriori. Les principes directeurs guidant cette évaluation devraient inclure les exigences suivantes: les programmes de télémédecine ne doivent en aucun cas entraîner une réduction du niveau de soins offert aux patients; leur introduction devrait chercher à compléter, et non pas à remplacer, le contact direct entre les professionnels de la santé et le patient; leur introduction devrait chercher à réduire, et non pas à creuser, les inégalités en matière d'accès aux soins. Ces évaluations devraient être partagées à l'échelon européen afin d'échanger les expériences, de mettre en exergue les bonnes pratiques, de vérifier la conformité avec les droits des patients et d'alimenter une éventuelle réflexion sur la nécessité d'adapter le cadre juridique.

- Du fait que certaines nouvelles techniques de diagnostic (par exemple les tests accessibles directement aux consommateurs et par l'internet, y compris les tests génétiques) sont disponibles par-delà les frontières et relèvent de différents cadres législatifs, le GEE invite les institutions de l'UE à collaborer avec les États membres pour introduire des normes et une surveillance dans toute l'Europe. Comme le GEE l'a déclaré à plusieurs reprises, les tests de susceptibilité génétique directement accessibles aux consommateurs devraient respecter les normes suivantes:

  — les laboratoires proposant des tests génétiques doivent se conformer aux normes de qualité reconnues; le respect de la vie privée et la confidentialité des informations génétiques sensibles devraient être assurés et la sécurité des données garantie;

  — des informations sur le but et la pertinence des tests doivent être données avant que le test ne soit effectué, et des pistes de consultation génétique ou de conseils de suivi doivent être proposées;

  — conformément aux normes et lignes directrices en vigueur, les tests inappropriés sur des mineurs et autres personnes frappées d'incapacité juridique doivent être évités, excepté dans les cas où des circonstances exceptionnelles justifient une telle intervention.

Participation

- Le GEE encourage une participation plus large et plus effective des citoyens dans tous les aspects de la communauté. Si les citoyens et les patients sont depuis longtemps encouragés à participer à la recherche médicale, le GEE se réjouit de la participation active de citoyens dans la recherche en matière de santé à différents niveaux, notamment dans la définition des objectifs et de la structure de la recherche et des politiques. Il recommande, dans ce cas, de maintenir les mêmes normes scientifiques que celles qui

s'imposent à la recherche — en termes de sécurité, de méthodologie, d'éthique et de rigueur.

- Les nouveaux modes de participation imposent un ajustement de la surveillance éthique. Si la surveillance éthique peut utilement tirer parti de la mobilisation accrue du public, la participation des citoyens à des expériences scientifiques doit être régie par les mêmes normes éthiques que les autres formes de recherche.

- Jusqu'à présent, le «patient» était un spectateur passif des soins de santé dont il bénéficiait. Le GEE salue et encourage la participation active des patients dans la prise de décisions car ils peuvent ainsi contribuer à améliorer la qualité et l'efficacité des soins qu'ils reçoivent. En revendiquant le droit des individus à être informés, à choisir et à se faire entendre, les patients peuvent davantage intervenir en amont dans la conception et la dispense des soins de santé. Les représentants et les groupes de défense des patients ont un rôle essentiel à jouer, mais il est important de ne pas tomber dans le piège qui consiste à n'écouter que les voix les plus fortes et les mieux dotées. Le GEE serait également favorable à une participation accrue des patients et de la population au sens large dans les discussions concernant l'établissement des priorités en matière de soins de santé et l'affectation des ressources.

- Le GEE souligne l'importance pour les patients de pouvoir facilement accéder à leur dossier médical, comme le prévoit la convention d'Oviedo sur les droits de l'homme et la biomédecine, et de pouvoir interagir avec leurs données cliniques comme des usagers proactifs. Le GEE recommande que chaque État membre garantisse que les citoyens puissent obtenir une copie de leur dossier médical, sous forme électronique ou autre, sans contrainte pratique, délai ou frais excessifs.

Solidarité et justice

- Le GEE reconnaît les nouvelles formes de solidarité encouragées par la participation citoyenne à la santé. Il appelle à la prudence, en relevant que la solidarité peut, dans certains cas, représenter une contrainte ou, dans d'autres, être le signe d'une responsabilisation ou d'une marchandisation. Le GEE rappelle que les individus sont libres de choisir de ne pas participer. Il déplore qu'on puisse faire passer des préoccupations commerciales pour des efforts philanthropiques et recommande la transparence également de la part des tiers, afin de permettre aux citoyens de faire des choix plus éclairés. Le GEE souligne la nécessité de promouvoir une juste solidarité en lien avec les droits de l'homme et les normes consacrées par la charte des droits fondamentaux de l'UE.

- La médecine de précision est un domaine qui n'en est qu'à ses balbutiements, mais qui pourrait présenter de gros avantages pour les patients et, d'une façon plus générale, pour les citoyens européens. Elle met également les pleins feux sur les questions de justice distributive dans les systèmes de santé, qui font actuellement débat. Il est important que le financement de cette approche novatrice de la prévention, du diagnostic et du traitement des maladies ne se fasse pas au détriment des initiatives visant à lutter contre les inégalités en matière de santé. En outre, des efforts devraient être réalisés pour s'assurer que les cohortes de données sont aussi représentatives que possible, de sorte que tous les avantages qu'offre la médecine de précision puissent être partagés de manière juste et équitable. Le GEE recommande que des recherches soient entreprises au niveau de l'Union européenne et des États membres sur la façon dont les traitements issus de la recherche en médecine de précision seront financés et/ou remboursés par les systèmes de santé publique.

- Le GEE attire l'attention sur la situation des personnes et des groupes qui ne peuvent pas ou ne souhaitent pas s'engager dans les nouvelles formes de participation en matière de santé ou qui ont peu accès aux technologies sur lesquelles se fonde cette participation. Le GEE met en garde contre le risque que les nouvelles technologies creusent les inégalités préexistantes en matière de santé et recommande que, lorsque des services de santé reposent sur des outils numériques, des solutions non basées sur les technologies de l'information et de la communication soient maintenues. Le GEE invite l'UE à élaborer de nouvelles stratégies, de façon que ceux qui le souhaitent puissent faire un usage efficace des nouvelles formes de participation en matière de santé et exploiter le potentiel d'autonomisation dans ce domaine.

Empfehlungen

In dieser Stellungnahme wurden zunächst neue Trends der Partizipation von Patienten, Bürgern und Verbrauchern im Gesundheitssektor untersucht. An eine Betrachtung der Bürgerbeteiligung anhand von ausgewählten Fallstudien zu wissenschaftlichen und technologischen Innovationen unter dem Gesichtspunkt der ethischen Auswirkungen dieser soziotechnischen Entwicklungen schloss sich eine kritische Analyse der bestehenden Regelungen sowie des Umgangs mit diesen Phänomenen an.

Nach Auffassung der Europäischen Gruppe für Ethik der Naturwissenschaft und der Neuen Technologien (EGE) hat das Zusammentreffen von neuen Technologien und sozialen Veränderungen im 21. Jahrhundert den Anstoß für neue partizipatorische Verfahren im Gesundheitswesen gegeben. Diese Verfahren stützen sich auf neuartige Techniken in der Medizin, für die große Mengen an Patientendaten erfasst werden müssen und die den Weg für neue Modelle partizipatorischer und partnerschaftlicher Forschung ebnen. Weitere Faktoren, die diese Neuerungen begünstigen, sind die Verbreitung des Internets und mobiler Geräte, die Impulse für neue Formen der digitalen Vernetzung im Gesundheitswesen geben. Diese Entwicklungen beschränken sich keineswegs auf den Gesundheitsbereich, sondern sind Teil umfassenderer gesellschaftlicher Verschiebungen, die in Zusammenhang mit der Demokratisierung des Wissens, der Zunahme einer immer besser informierten Bevölkerung und der Forderung von Laien nach einer stärkeren Einbeziehung in die Entwicklung von Wissen und Innovation stehen.

Das Ergebnis ist eine immer größer werdende Vielfalt der Rollen, die Bürger im Gesundheitsbereich einnehmen können: als Forschungsbeteiligte oder Bürgerwissenschaftler, als Lobbyisten und Interessenvertreter für bestimmte Ziele im Gesundheitsbereich oder als zunehmend engagierte und miteinander verbundene Lieferanten und Nutzer von Gesundheitsdaten und -informationen. Im Zusammenhang mit diesen neuen partizipatorischen Verfahren und den Gesundheitstechnologien, die sie ermöglichen, hat die EGE **drei Verschiebungen festgestellt, die die Art der Wahrnehmung, Organisation und Bereitstellung in Bezug auf Gesundheit und Gesundheitsdienstleistungen betreffen**.

Erstens kann sich die Entstehung einer Vielzahl neuer Rollen für Bürger als aktive Beteiligte an verschiedenen Gesundheitsdimensionen darauf auswirken, wie **die Einzelnen ihre Gesundheit und ihren Körper wahrnehmen und wie sie über Krankheit und Leiden denken**. Neue Partizipationstechnologien können ein interaktives Forum für die Schilderung und Kommunikation von gelebten Erfahrungen bieten. Die steigende Zahl von Gentests, neuen Diagnosetechniken und digitalen Überwachungsgeräten sowie die Fülle von Bioinformationen, die diese Instrumente erzeugen, können ein wachsendes Verständnis des Selbst begünstigen, wobei eine Loslösung der Gesundheitsinformationen und Datenrisiken von sozialen Faktoren, Umweltfaktoren und von der biografischen Subjektivität des Patienten erfolgt. Die EGE ist sich bewusst, dass sowohl die empirischen (informationellen, biologischen) Elemente als auch die (gelebten) Erfahrungen wesentliche Komponenten sind, die das Verständnis des Einzelnen von Gesundheit und Krankheit prägen. Um das volle Potenzial datenintensiver medizinischer Technologien wie der Präzisionsmedizin ausschöpfen zu können, ist es erforderlich, das umfassendere soziale, wirtschaftliche, kulturelle und natürliche Umfeld eines Patienten im Auge zu behalten. Zudem ist zu berücksichtigen, inwiefern diese Technologien die Schaffung von Normen in den Bereichen Gesundheit, Verhalten und Leistung beeinflussen werden.

Zweitens unterwandern neue Gesundheitstechnologien und partizipatorische Verfahren herkömmliche Macht- und Wissensstrukturen, die der medizinischen Praxis zugrunde liegen, und **verändern das Verständnis davon, was es heißt**, im modernen Gesundheitswesen **ein Patient zu sein**. Das herkömmliche Verständnis eines „Patienten" als passivem Empfänger von Gesundheitsleistungen scheint sich immer weniger mit den neuen Vorstellungen des Patienten als informiertem Partner, Kunden, Verbraucher, Experten oder Aktivisten zu decken. Die stärkere Einbindung Einzelner in die Gesundheitsfürsorge dürfte zu einer Neudefinition herkömmlicher Rollen von „Arzt" und „Patient" führen, die Interaktion zwischen diesen beiden verändern und die Grenzen zwischen ihnen verschieben. Eine wachsende technologische Autonomie kann das Gesundheitsbewusstsein fördern, Einzelne motivieren, sich aktiv mit Gesundheitsthemen zu beschäftigen, und neue Möglichkeiten des Zugangs zur Gesundheitsfürsorge schaffen. Wenn die Technologien jedoch dazu führen sollten, dass die Patienten im entscheidenden Fall den unverzichtbaren Kontakt zu den Angehörigen von Gesundheitsberufen nicht mehr haben, könnte dies ethische Risiken hervorrufen. Die Herausforderung besteht darin, ein ausgewogenes Verhältnis sicherzustellen, bei

dem der Patient zu autonomem Handeln befähigt ist, bei der Interpretation medizinischer Informationen und der Wahl der Behandlungsmethoden aber weiterhin den entscheidenden zwischenmenschlichen Austausch und die erforderliche Unterstützung von Experten in Anspruch nimmt. Neue Technologien, die die Veränderung der Interaktion zwischen Patient und Arzt fördern, sollten darauf ausgerichtet sein, das Patient-Arzt-Verhältnis zu stärken und die Qualität und Verfügbarkeit von Gesundheitsleistungen in Gesundheitsversorgungssystemen zu verbessern.

Drittens führen partizipatorische Verfahren im Gesundheitsbereich **zur Entstehung neuer Rollen für Bürger bei der Erzeugung von medizinischem Wissen und von medizinischen Innovationen**. Aus der Einbindung von Bürgern in die wissenschaftliche Tätigkeit sind wichtige Innovationen in der Medizin hervorgegangen, die sich auf die besonderen Perspektiven von „Patienten als Experten", auf kollektive Intelligenz und auf die neuen mit Big Data verbundenen Möglichkeiten stützen. Die Partizipation von Bürgern wirft eine Bildungsdividende in Form von Wissen, neuen Kompetenzen, neuen Lebenschancen und wachsendem zivilgesellschaftlichen Bewusstsein ab und kann bei den Patienten das Gefühl der Eigenverantwortung für ihre Gesundheit stärken. Die EGE zeigt Herausforderungen auf, die mit der Integration der Beiträge von Bürgern in die Förderung der Medizinforschung und mit der Anpassung des Fachwissens von Laien an die strikten Vorgaben faktengestützter Medizin verbunden sind, wofür eine solide Basis an wissenschaftlicher Kompetenz, Methodik und Kontrolle sowie die Einhaltung von Standards für ethische Kontrolle erforderlich sind. Die EGE erkennt jedoch an, dass Bürger einen wertvollen Beitrag zur wissenschaftlichen Tätigkeit leisten können, und möchte vor „partizipatorischen Ansätzen" warnen, die Probanden entmachten oder sogar ausnutzen, indem sie Forschungssubjekte als eine Ressource betrachten, aus der Daten und Proben gewonnen werden können, von denen aber nur wenig Verständnis für den Forschungsprozess erwartet wird und denen nur in geringem Umfang Kontrolle über ihre Daten oder Zugang zu den Ergebnissen gewährt wird.

Ausgehend von den weiter oben beschriebenen und untersuchten Verschiebungen kommt die EGE zu folgenden **wichtigen Erkenntnissen und ethischen Überlegungen**:

Herstellung eines ausgewogenen Gleichgewichts zwischen Autonomie und Verantwortung: Die zunehmende Autonomie von Bürgern und Patienten bei der Steuerung individueller und kollektiver Entscheidungen im Gesundheitsbereich ist als Fortschritt zu begrüßen. Sie entspricht nicht nur den Forderungen nach Selbstbestimmung, Selbstverwirklichung und Befähigung, die wesentliche Elemente des menschlichen Gedeihens sind, sondern verbessert auch die Ergebnisse für die Gesundheit und die Wirksamkeit der Gesundheitsfürsorge. Ein aktiverer Einsatz des Einzelnen kann für die Erreichung des Ziels einer patientenorientierten Gesundheitsfürsorge entscheidend sein. Im Sinne eines partnerschaftlichen Ansatzes für die Gesundheitsfürsorge sollte hierbei die Autonomie des Patienten Hand in Hand mit seiner Verantwortung gehen. Dennoch sollte aufmerksam beobachtet werden, wie die Prozesse der Einbeziehung oder „Befähigung" durch externe Faktoren und Kräfte, z. B. Gesundheitsbehörden und gewerbliche Interessengruppen, beeinflusst werden, wenn es um die Abstimmung von Interessen zur Unterstützung der Forderung geht, dass Bürger die eigene Gesundheit in stärkerem Maße selbst steuern sollten. Die EGE möchte vor Bestrebungen nach einer „Gesundheitsautonomie" warnen, bei der mehr Verantwortung von den staatlichen Gesundheitsdiensten auf den Einzelnen abgewälzt wird oder die Verantwortung für Risiken und die Regulierungsfunktion dem Einzelnen übertragen werden, was letztlich eine Herabsetzung der Standards und der Qualität von Gesundheitsdienstleistungen bedeuten würde.

Entflechtung der Beteiligung: Partizipation kann insofern ein interessanter Ansatz sein, als er Integration, Offenheit und Demokratisierung beinhaltet. Dennoch ist vor einem einfachen Verständnis der Partizipation als uneingeschränkt positiv zu warnen; in der vorliegenden Stellungnahme wird auf die vielschichtige Bedeutung von Begriffen wie „Bürgerwissenschaft" hingewiesen. Die Partizipation kann hinter den mit ihr verknüpften Erwartungen zurückbleiben oder unerwünschte Folgen haben. Hierbei kommen mehrere Möglichkeiten in Betracht. Die Partizipation kann Hoffnungen auf mehr Transparenz oder Rechenschaftspflicht wecken, die sich jedoch nicht unbedingt erfüllen müssen. Der Begriff „partizipatorisch" kann auf Dienstleistungen angewandt werden, die nicht unbedingt Zustimmung finden. Sie können auf der Erfassung und dem Verkauf personenbezogener Daten basieren; bei Vorteilsnahme oder Ausnutzung von Arbeit kann Partizipation eine versteckte Form der Ausbeutung sein.

Bei der Abwägung des positiven Potenzials der Partizipation für Einzelne und für Gesellschaften spielen daher mehrere Aspekte eine Rolle. Die Wirksamkeit der Befähigung und Bereicherung wird sich nach dem

Umfang der gewährten Mitbestimmung oder Mitwirkung, dem Zugang zur Entscheidungsfindung und zur Vereinbarung von Zielen bzw. dem Nutzen für Bildung und Kompetenzen richten. Die Minimierung der Risiken der Ausbeutung kann davon abhängen, inwieweit die Kontrolle über die eigenen Ressourcen auf die Beteiligten übertragen wird, ob dies freiwillig geschieht oder vorgeschrieben wird, und von der Art der erteilten Zustimmung. Ferner sollte darauf geachtet werden, wer die „Beteiligten" selbst sind: Es muss sich nicht immer um einzelne neutrale Bürger handeln; vielmehr kommt ein breites Spektrum organisierter Interessen in Gestalt von Interessenverbänden, Lobbyisten oder wirtschaftlichen Akteuren in Betracht. Voraussetzung für ein differenzierteres Verständnis von Partizipation im Gesundheitswesen sind daher die sorgfältige Prüfung der Bedingungen, unter denen Partizipation stattfindet, und eine größere Transparenz der Ziele, Funktionen und Ergebnisse sowohl aufseiten der Institutionen, die Partizipation ermöglichen, als auch aufseiten der Beteiligten selbst.

Auswirkungen auf Gerechtigkeit und Solidarität: Die EGE unterstreicht die Bedeutung einer ausgewogenen Verteilung von Gesundheitsressourcen und das Recht aller, insbesondere der Schutzbedürftigen, auf Gesundheitsschutz. Gleichzeitig stellt sie fest, dass neue Verfahren der Bürgerbeteiligung eine Herausforderung in Bezug auf die Wahrung von Gerechtigkeit und Solidarität als grundlegende Organisationsprinzipien europäischer Gesundheitssysteme darstellen und eine Neuordnung der aktuellen Rahmenbedingungen nach sich ziehen.

Die Einbindung der Bürger kann neue Wege für kollektives Handeln eröffnen und bietet die Chance, strukturelle Ungleichheiten abzubauen, die bei Investitionen in die medizinische Forschung lange Zeit bestanden haben. Andererseits kann sie aber auch vorhandene Ungleichgewichte verstärken, den Forderungen der gut ausgestatteten und gebildeten Kreise mehr Beachtung schenken und Ungleichheiten weiter verschärfen. Auch bahnbrechende Fortschritte bei den medizinischen Technologien, z. B. der Präzisionsmedizin, können die öffentliche Gesundheitspolitik im Hinblick auf die Festsetzung von Investitionsprioritäten vor schwierige Aufgaben stellen. Entscheidungen über Behandlungen, die mit hohen Kosten oder mit dem Einsatz von Hochtechnologie verbunden sind, oder über „individuelle" Behandlungen bedürfen einer sorgfältigen Abwägung mit dem allgemeineren gesellschaftlichen Bedarf an notwendiger/grundlegender Gesundheitsfürsorge.

Dank neuer Technologien haben Bürger zudem die Möglichkeit, sich an Projekten, Aktionen und Initiativen im Gesundheitsbereich zu beteiligen, die in hohem Maße von Solidarität geprägte Ziele widerspiegeln. Diese Entwicklungen verleihen einerseits der Solidarität als Basis gemeinschaftlichen Handelns neue Impulse und führen andererseits zu einer Neugestaltung herkömmlicher staatlich getragener Solidaritätsrahmen. Die EGE gibt zu bedenken, dass diese Entwicklungen das Gleichgewicht verändern und Auswirkungen darauf haben werden, wer sich solidarisch zeigen sollte und nach welchen Kriterien. Sie ruft daher dazu auf, auf potenzielle Verschiebungen im gemeinsamen Solidaritätsverständnis von einem staatlich kontrollierten Prozess zu einem von Bürgern organisierten und gesteuerten Prozess zu achten.

Auf der Grundlage der vorstehenden Erwägungen einigt sich die EGE auf die nachstehenden Empfehlungen zur Partizipation von Bürgern und zu neuen Gesundheitstechnologien.

A. Allgemeine Erwägungen: Veränderung der Vorstellung von Gesundheit und Bürgerbeteiligung

Nachdenken über Schlüsselbegriffe

Die EGE empfiehlt, eine öffentliche Debatte über fest verwurzelte und in der Entstehung begriffene Vorstellungen zu fördern, die unser Verständnis von Gesundheit und Gesundheitsforschung und von der Art und Weise bestimmen, wie Gesundheitsdienstleistungen erbracht werden. Schwerpunkte dieses Nachdenkprozesses sollten das allgemeine Verständnis und möglicherweise strittige Erwartungen im Zusammenhang mit folgenden Begriffen sein:

- Fürsorge, Wohlbefinden und Gesundheit. Wie soll der Gesundheitsbegriff neu gefasst werden, um sowohl Ansätze der Vorbeugung als auch ein ganzheitliches/umfassendes Verständnis von Gesundheit und Krankheit besser zu integrieren (und gleichzeitig Tendenzen der Medikalisierung zu berücksichtigen)? Hierbei sollten gesellschaftliche Auffassungen, Grundsätze und Strukturen im Gesundheitsbereich sorgfältig beleuchtet werden. Welche Rolle spielt das öffentliche Gesundheitssystem bei Debatten über die Aufteilung von Vorteilen und die Übertragung von Verantwortung im Gesundheitsbereich?

- Diese öffentliche Debatte betrifft somit die Auswirkungen neuer Formen der Partizipation auf das Gleichgewicht zwischen individuellen und kollektiven Interessen bei medizinischen Dienstleistungen und medizinischer Forschung. Zudem sollte sie eine Diskussion darüber einleiten, wo wir als Gesellschaft individuellen Interessen Grenzen setzen möchten und inwiefern gemeinsame Interessen und das Gemeinwohl derartige Beschränkungen rechtfertigen.

- Patient sein. In den vergangenen zehn Jahren haben sich Wahrnehmungen, Konzepte und Verfahren drastisch verändert, was zu Spannungen zwischen Passivität und Aktivität, Individuum und Kollektiv und in Bezug auf in der Entwicklung begriffene Vorstellungen von der Beziehung Arzt-Patient sowie den zugrunde liegenden epistemischen Beziehungen und Machtbeziehungen führt.

Klarstellung von Begriffen

- In Anbetracht der beschriebenen sozialen Veränderungen ist es für politische Entscheidungen und für die Einführung von Regelungsmechanismen von entscheidender Bedeutung, für politikrelevante Schlüsselbegriffe wie Gesundheit, Wohlbefinden und Lebensweise klare Definitionen vorzugeben und zu einem gemeinsamen Verständnis dieser Begriffe zu gelangen. Die EGE empfiehlt daher den Institutionen der EU, sich zusammen mit den Mitgliedstaaten auf gemeinsame Vorstellungen und Definitionen von Schlüsselbegriffen wie „Gesundheit" einschließlich der Abgrenzung zwischen Kategorien von Gesundheit, Wohlbefinden und Lebensweise zu einigen. Es handelt sich hierbei nicht um ein zweckfreies theoretisches Unterfangen, vielmehr hat es konkrete regulatorische Auswirkungen, die dringend notwendig sind. Eine solche Klarstellung der Begriffe würde der öffentlichen Debatte über die Erwartungen an öffentliche Gesundheitsdienste zugutekommen und Gesetzgeber bei der Klassifizierung und Regulierung von neuen Gesundheitstechnologien unterstützen, z. B. von Apps, die speziell Gesundheitsthemen im Gegensatz zu anderen Aspekten des Wohlbefindens und der Lebensweise betreffen.

- Die EGE empfiehlt der Europäischen Kommission, bei der Formulierung von Vorschlägen für politische Strategien insbesondere im Zusammenhang mit dem Begriff „Bürgerwissenschaft" die mit der Bürgerbeteiligung verbundenen heterogenen Bedeutungen zu berücksichtigen. Hierbei sind besonders die verschiedenen Dimensionen und Formen der Bürgerbeteiligung, auf die sich der Begriff beziehen kann, der spezifische Nutzen, den verschiedene Partizipationsformen bringen, und mit ihnen verbundene ethische Probleme zu beachten.

Sensibilisierung und Bildung

- Die EGE empfiehlt, bei der Ausbildung von Fachkräften der Gesundheitsberufe die Verbreitung von medizinischem Fachwissen, unter anderem von medizinischen Online-Informationen und Gesundheitsapps, über die herkömmlichen medizinischen Fachkreise hinaus zu behandeln. In Anbetracht der Verfügbarkeit alternativer Quellen für Gesundheitsinformationen sollten die Fachkräfte bei der Erkundung neuer Möglichkeiten der Interaktion mit Patienten unterstützt werden, wobei auch die Nutzung vertrauenswürdiger Quellen für derartige Informationen und die Verhütung potenziellen Schadens durch unzuverlässige Informationsquellen angesprochen werden sollten. Ferner werden in Anbetracht der aufkommenden Präzisionsmedizin Kompetenzen auf dem Gebiet des Informationsmanagements und ein besseres Verständnis der Möglichkeiten und Grenzen dieser Medizin für Ärzte immer wichtiger, wenn der bestmögliche Nutzen für die Patienten sichergestellt werden soll. Die EGE empfiehlt daher, zur Verbesserung der Fähigkeiten im Umgang mit Daten Informatik und fortgeschrittene Statistik in die Curricula im Fach Medizin einzubeziehen, damit Ärzte die Ergebnisse der Präzisionsmedizin interpretieren und entsprechende Maßnahmen ergreifen können.

- Die EGE empfiehlt den Institutionen und den Mitgliedstaaten der EU, auf die Förderung des Wissens, der Sensibilisierung und der Verantwortung der Bevölkerung sowie auf eine Debatte über die Nutzung vertrauenswürdiger Quellen für Gesundheitsinformationen und über fundierte Entscheidungen über die Partizipation an der Forschung und den Austausch von Gesundheitsdaten hinzuwirken.

- Online-Gesundheitsressourcen können den Bürgern dabei helfen, sich einen Einblick zu verschaffen. In Anbetracht der Schwierigkeit, vertrauenswürdige und zuverlässige Websites zu Gesundheitsthemen zu erkennen, empfiehlt die EGE jedoch, dass die nationalen Gesundheitsbehörden die Entwicklung „zertifizierter" Gesundheitsressourcen mit Ratschlägen fördern sollten, die von

unabhängigen/nationalen Gesundheitsbehörden bewertet werden. Diese anerkannten Websites sollten auch die EU-Standards für den Schutz personenbezogener Daten einhalten.

- Die EGE empfiehlt, Forschungsarbeiten zu den Auswirkungen der Beteiligung von Bürgern an Wissenschaft und Technologie im Allgemeinen und am Gesundheitssektor im Besonderen zu fördern.

B. Empfehlungen zur Regulierung: Lücken im Ordnungsrahmen für Bürgerbeteiligung und neue Gesundheitstechnologien schließen

Digitale Gesundheitsprodukte

- Die EGE empfiehlt der Europäischen Kommission, (ggf. mit dem Europäischen Parlament und dem Rat) derzeit bestehende Lücken und Schlupflöcher im Regulierungsrahmen für digitale Gesundheitsprodukte (z. B. Computer-Software, Internetanwendungen, m-Health-Anwendungen), deren Sicherheit weder durch die Medizinprodukte-Richtlinie noch die Richtlinie über Produktsicherheit vollständig gewährleistet wird, zu schließen. Darüber hinaus sollte die Kommission mittels strikter Durchsetzungsmaßnahmen dafür sorgen, dass die geltenden Rechtsvorschriften und Standards von allen Beteiligten besser eingehalten werden.

Daten

- Grundrechtserwägungen sollten wesentlicher Bestandteil der EU-Politik für Gesundheitsdaten einschließlich Big Data sein. Zu diesem Zweck könnte z. B. eine Bestimmung in die derzeit verhandelte EU-Datenschutzverordnung aufgenommen werden, die die individuelle Zustimmung zur Weiterverarbeitung von Gesundheitsdaten vorsieht. Ferner sollte dann die Klausel zur Sicherstellung der Vereinbarkeit, die zum ausdrücklichen Nachweis der Vereinbarkeit der Verarbeitung von Forschungsdaten mit dem Zweck der Forschung verpflichtet, im Regulierungsrahmen beibehalten werden.

- In Anbetracht der Tatsache, dass Daten als die neue Währung des 21. Jahrhunderts gelten, die beträchtliche Möglichkeiten für Wirtschaftstätigkeit sowie für Forschung und Entwicklung eröffnet, und Gesundheitsdaten sowohl ein sensibler als auch ein strategischer Gegenstand der Aufmerksamkeit geworden sind, empfiehlt die EGE den EU-Institutionen, den Begriff der Inhaberschaft von Daten klarzustellen. Dies beinhaltet Vorschriften für die Sammlung und Sicherheit von Gesundheitsdaten. In Anerkennung der laufenden Debatte über die Abwägung zwischen privater Dateninhaberschaft und dem Gemeinwohl empfiehlt die EGE, Maßnahmen zum Schutz von Einzelpersonen vor dem Übergriff auf Gesundheitsdaten durch Dritte zu ergreifen.

- Die EGE empfiehlt eine Neujustierung des Gleichgewichts zwischen dem Schutz von kommerziellen, für die öffentliche Gesundheit relevanten Daten und der Notwendigkeit, Transparenz und öffentlichen Zugang zu gewährleisten. In diesem Zusammenhang begrüßt sie die Bestimmungen zur Transparenz in der EU-Verordnung zu klinischen Studien.

- Die EGE empfiehlt der Europäischen Kommission, die Einhaltung der neuen Bestimmungen durch relevante Dritte aufmerksam zu überwachen und, wenn nötig, die erforderlichen Maßnahmen zur Durchsetzung zu ergreifen.

Erbringung von Gesundheitsleistungen

- Die EGE empfiehlt, bei der Einführung von Programmen zur Fernmedizin (im Zusammenhang mit m-Health, e-Health einschließlich Telemedizin, Nutzung der Entfernung als Instrument) die Vorteile dieser Technologien zu maximieren und potenzielle Nachteile zu minimieren. Anbieter öffentlicher Gesundheitsdienstleistungen sollten die Auswirkungen auf die Qualität der Gesundheitsfürsorge, die Privatsphäre und die Finanzmittel vor der Einführung sorgfältig prüfen und auch danach beobachten und bewerten. Bei dieser Bewertung sollten als Leitprinzipien unter anderem folgende Forderungen berücksichtigt werden: Telemedizinprogramme führen nicht zur Herabsetzung des Standards der Patientenversorgung; Ziel ihrer Einführung sollte es sein, den persönlichen Kontakt zwischen dem Erbringer von Gesundheitsdienstleistungen und dem Patienten zu ergänzen, anstatt ihn zu ersetzen; ihre Einführung sollte auf die Verringerung von Ungleichheiten beim Zugang zur Gesundheitsfürsorge und nicht auf ihre Verschärfung ausgerichtet sein. Diese Bewertungen sollten auf europäischer Ebene bekannt gemacht werden, um Erfahrungen auszutauschen, bewährte Verfahrensweisen vorzustellen, die Wahrung der Patientenrechte zu überprüfen und eventuelle Überlegungen zur Notwendigkeit einer Anpassung des Rechtsrahmens mitzuteilen.

- Da bestimmte neue Diagnosetechniken (z. B. direkt an den Verbraucher gerichtete und internetgestützte Tests einschließlich Gentests) grenzüberschreitend verfügbar sind und mehrere verschiedene Rechtsrahmen betreffen, ersucht die EGE die EU-Institutionen, zur Einführung europaweiter Standards und europaweiter Kontrolle mit den Mitgliedstaaten zusammenzuarbeiten. Die EGE hat bereits wiederholt erklärt, dass bei direkt an Verbraucher gerichteten genetischen Dispositionstests die folgenden Standards eingehalten werden sollten:
  - Laboratorien, die Gentests durchführen, müssen anerkannte Qualitätsstandards einhalten; Privatsphäre und Vertraulichkeit sensibler genetischer Informationen sollten gewahrt und die Sicherheit der Daten sollte garantiert sein.
  - Informationen über den Zweck und die Eignung der Tests müssen vorab mitgeteilt werden; Möglichkeiten für genetische Beratung oder Anschlussberatung sollten angeboten werden.
  - In Übereinstimmung mit geltenden Standards und Leitlinien ist die Durchführung ungeeigneter Tests an Minderjährigen und anderen geschäftsunfähigen Personen zu verhindern, sofern nicht außergewöhnliche Umstände dies rechtfertigen.

Partizipation

- Die EGE spricht sich für eine breitere und sinnvollere Beteiligung von Bürgern an allen Bereichen des Gemeinwesens aus. Bereits seit Langem werden Bürger und Patienten zur Teilnahme an medizinischen Forschungen ermutigt; die EGE begrüßt die aktive Einbindung von Bürgern auf verschiedenen Ebenen der Gesundheitsforschung einschließlich der Festlegung von Zielen und Vorgaben und der Strukturierung von Forschung und Politiken. Sie empfiehlt, hierbei dieselben wissenschaftlichen Standards für Sicherheit, Methodik, Ethik und Stringenz wie für die Forschungstätigkeit zugrunde zu legen.

- Neue Wege der Partizipation setzen die Anpassung der ethischen Kontrolle voraus. Während die ethische Kontrolle von der zunehmenden Einbeziehung der Öffentlichkeit profitieren kann, ist es erforderlich, für die Bürgerbeteiligung an wissenschaftlichen Versuchen dieselben ethischen Standards aufzustellen wie für andere Forschungsbereiche.

- Bisher war der „Patient" bei seiner Gesundheitsversorgung passiver Zuschauer. Die EGE begrüßt und fördert die aktive Partizipation von Patienten an der Entscheidungsfindung, damit die Einzelnen zur Verbesserung der Qualität und Wirksamkeit der eigenen Gesundheitsversorgung beitragen können. Durch die Wahrnehmung des Rechts der Einzelnen auf Unterrichtung, auf freie Wahl und auf Gehör haben Patienten die Möglichkeit, eine proaktivere Rolle bei der Gestaltung und Erbringung von Gesundheitsdienstleistungen zu übernehmen. Patientenvertreter und Interessengruppen sind von großer Bedeutung, aber es ist wichtig, sich nicht beeinflussen zu lassen und nur die Parteien anzuhören, die sich am lautesten bemerkbar machen und mit den meisten Ressourcen ausgestattet sind. Die EGE würde es zudem begrüßen, wenn Patienten und die Bürgerschaft im weiteren Sinne an Diskussionen über die Festlegung von Prioritäten der Gesundheitsfürsorge und der Mittelzuteilung beteiligt würden.

- Die EGE betont, wie wichtig es ist sicherzustellen, dass Patienten in Einklang mit dem Übereinkommen von Oviedo über Menschenrechte und Biomedizin problemlos Zugang zu ihren Gesundheitsakten haben und als proaktive Nutzer auf ihre klinischen Daten zugreifen können. Die EGE empfiehlt, den Bürgern in allen Mitgliedstaaten zu garantieren, dass sie ohne unzumutbare praktische Hindernisse, Verzögerungen oder Kosten Kopien ihrer Gesundheitsakten in elektronischer oder in sonstiger Form erhalten können.

Solidarität und Gerechtigkeit

- Die EGE erkennt die neuen Formen der Solidarität an, die mit der Bürgerbeteiligung im Gesundheitsbereich einhergehen. Sie mahnt dringend zur Vorsicht und weist darauf hin, dass Solidarität in einem Fall eine Zumutung sein kann und in einem anderen Fall Mitverantwortung oder Kommodifizierung bedeuten kann. Die EGE erinnert an die Freiheit des Einzelnen, sich gegen eine Teilnahme zu entscheiden. Sie stellt fest, dass kommerzielle Interessen nicht unter dem Deckmantel der Menschenfreundlichkeit verfolgt werden sollten, und empfiehlt, dass auch Dritte Transparenz sicherstellen sollten, um die Bürger in die Lage zu versetzen, fundierte Entscheidungen treffen zu können. Die EGE betont die Notwendigkeit, eine gerechte Solidarität in Verbindung mit den Menschenrechten und den in der Charta der Grundrechte der

Europäischen Union verankerten Standards zu fördern.

- Die Präzisionsmedizin steht noch am Anfang ihrer Entwicklung, könnte aber Patienten und Bürgern im weiteren Sinne in Europa deutliche Vorteile bringen. Sie wirft zudem ein Schlaglicht auf gegenwärtig diskutierte Fragen zur Verteilungsgerechtigkeit in Gesundheitsversorgungssystemen. Es ist wichtig, darauf zu achten, dass die Finanzierung dieses innovativen Ansatzes für die Prävention, Diagnose und Behandlung von Krankheiten nicht zulasten von Initiativen zum Abbau von Ungleichheiten im Gesundheitswesen geht. Ferner sollten Anstrengungen unternommen werden, um möglichst repräsentative Datenkohorten sicherzustellen, damit etwaige Vorteile der Präzisionsmedizin in gerechter und ausgewogener Weise allen zugutekommen. Die EGE empfiehlt, auf der Ebene der EU und der Mitgliedstaaten zu untersuchen, wie Behandlungen, die aus der Erforschung der Präzisionsmedizin hervorgehen, im Rahmen öffentlicher Gesundheitssysteme finanziert und/oder erstattet werden.

- Die EGE weist auf die Lage von Einzelpersonen und Gruppen hin, die die neuen Formen der Partizipation im Gesundheitsbereich nicht nutzen können oder möchten oder kaum Zugang zu den Technologien haben, die Voraussetzung für diese Partizipation sind. Die EGE warnt vor dem Risiko, dass die neuen Technologien bereits bestehende Ungleichheiten im Gesundheitsbereich verschärfen könnten, und empfiehlt, in Fällen, in denen digitale Tools erforderlich sind, um Gesundheitsleistungen in Anspruch nehmen zu können, künftig auch Alternativen anzubieten, die ohne den Einsatz von Informations- und Kommunikationstechnologien (IKT) auskommen. Die EGE ersucht die EU, weiterhin Strategien zu entwickeln, um sicherzustellen, dass diejenigen, die dies wünschen, neue Formen der Partizipation im Gesundheitsbereich wirksam nutzen können und das Potenzial der Befähigung im Gesundheitsbereich ausschöpfen können.

The European Group on Ethics in Science and New Technologies

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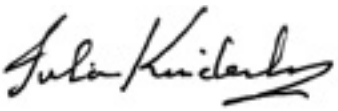

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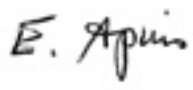

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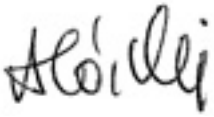

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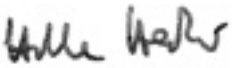

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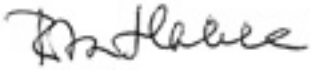

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