1) Introduction and scope

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 trials; 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. 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 m-health 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 as part of 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 citizens' participation.
Scope of the Opinion

The Opinion explores the transformations that citizens' 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 One of the 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, m-health, 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 Two of the Opinion sets out the ethical implications of the paradigm shift (or set of shifts) identified in Chapter One. 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 Three of the 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 citizens' 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 Four of the Opinion puts forward a set of recommendations, aimed at EU and national level policymakers, industry and other stakeholders, which aim to maximising the benefits and minimise the harms associated with new health technologies and citizen participation in health policy, research and practice.
2) **Key Ethical Reflections**

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 forum 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 personalised 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 unpinning 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 re-frame 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 inter-personal 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 draws 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 health care, 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 hand 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 re-framing 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 re-balancing 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 personalised 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 re-defining 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:
3) **Recommendations**

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 re-calibrating 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 relation 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 citizens 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 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 recognized 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 to set up 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 to take the necessary enforcement action when required.

Provision of care

- The EGE recommends that the introduction of remote medicine programmes (with reference to mHealth, eHealth, 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 health care 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 rigor– 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 by 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 pro-active 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 health care priorities and allocation of resources.

- The EGE underscores the importance that patients have easy access to their health records, as enshrined in the Oviedo Convention on Human Rights and Biomedicine, and are 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 for new technologies to deepen 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.