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EPIDEMIOLOGY
AND PUBLIC HEALTH

MY DNA, EVERYBODY'S BUSINESS?

QUALITATIVE ANALYSIS OF THE BELGIAN CITIZEN FORUM ON THE USE OF GENOMIC INFORMATION

WHO WE ARE

SCIENSANO can count on more than 700 staff members who commit themselves, day after day, to achieving our motto: Healthy all life long. As our name suggests, science and health are central to our mission. Sciensano's strength and uniqueness lie within the holistic and multidisciplinary approach to health. More particularly we focus on the close and indissoluble interconnection between human and animal health and their environment (the "One health" concept). By combining different research perspectives within this framework, Sciensano contributes in a unique way to everybody's health.

For this, Sciensano builds on the more than 100 years of scientific expertise of the former Veterinary and Agrochemical Research Centre (CODA-CERVA) and the ex-Scientific Institute of Public Health (WIV-ISP).

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Authors

Chloé Mayeur
•
Wannes Van Hoof
•

Chloe Mayeur · T+32 2 642 55 73 · chloe.mayeur@sciensano.be
Wannes Van Hoof · T+32 2 642 56 97 · wannes.vanhoof@sciensano.be

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EXECUTIVE SUMMARY

Rapid advances in personalized medicine and genomic technologies increase the number and diversity of situations where citizens have to make complex and personal choices about the use of their genomic information. Additionally, successful deployment of the genome for preventive and medical purposes requires the development of large representative datasets including health and environmental information of the individuals over a life-course period. In short, the genomic revolution is everybody's business. Therefore, Sciensano and the King Baudouin Foundation (KBF) organized a Belgian citizen forum in 2018-2019 on the ethical, legal and societal implications (ELSI) surrounding the use of genomic information in healthcare. The goal is to allow 32 citizens to look at the place of the genome in society and formulate recommendations for the Minister of Public Health and all stakeholders of this field.

The statement "My DNA is my property because it is the most intimate part of an individual" is an important takeaway from the citizen forum. Based on this statement, citizens require autonomy in decision-making related to the use of their genomic information and consider that it is society's responsibility to provide citizens with the rights of individual control, transparency, and traceability in the uses of this information. Citizens must use these rights responsibly to protect their privacy.

The citizen panel strongly believes that "Individuals are more than their genome and should not be prisoners of it". To this end, protection against any form of discrimination, categorization, and rejection of individuals based on their genetic makeup must be established.

The citizens assert that there are many societal responsibilities to protect citizens from downsides and promote upsides from the use of genomic information: the precautionary principle should guide the way in the development of a framework for genomics. Within a well-developed framework that inspires trust around the use of genomic data, solidarity and reciprocity are core values that citizens support in the context of genomic data sharing.

Citizens identify a range of individual responsibilities in decision making in genomics and accept that societal nudges might be required to balance personal interests and the common good.

This citizen forum shows that citizens can make meaningful contributions to a complex field like ELSI in genomics. Continued citizen involvement of the public in the governance of genomic information in society is vital. It ensures that societal norms and values guide the technology and not the other way around.

1. INTRODUCTION

Rapid advances in personalized medicine and genomic technologies increase the number and diversity of situations where citizens have to make complex and personal choices about the use of their genomic information. DNA testing raises new questions and issues from conception (e.g. prenatal and neonatal screening) to adulthood (e.g. genealogy, carrier screening, precision medicine). Additionally, successful deployment of the genome for preventive and medical purposes requires the development of a large representative dataset including health and environmental information of the individuals over a life-course period. In short, the genomic revolution is everybody's business.

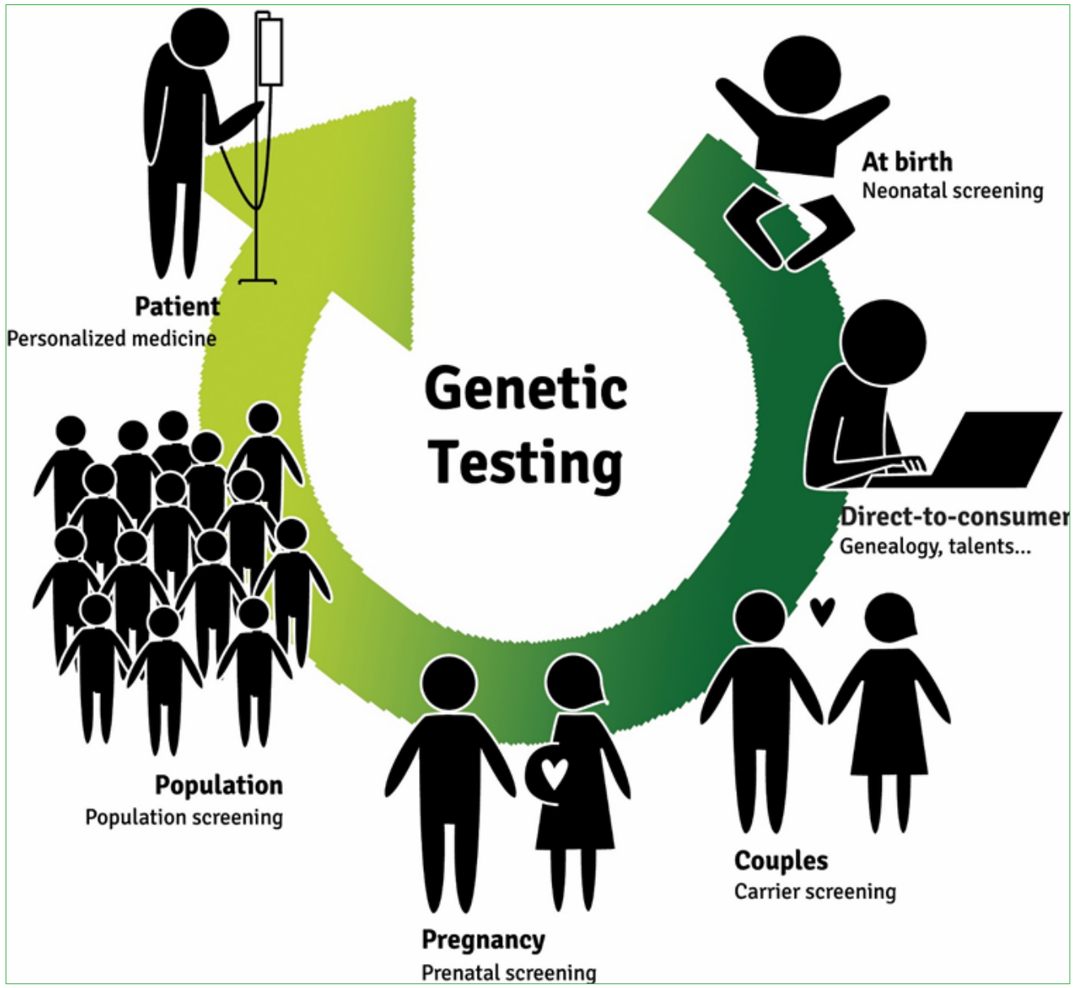
Therefore, Sciensano and the King Baudouin Foundation (KBF) organized a Belgian citizen forum on the ethical, legal and societal implications (ELSI) surrounding the use of genomic information in healthcare. The goal was to allow a group of citizens to look at the place of the genome in society and formulate recommendations for the future. We took this initiative at the request of the Minister of Public Health, who came to listen to the citizens' recommendations in person at the end of the project. Two reports already exist on this project. The first describes the narratives of the citizens and stays close to their original recommendations (KBF & Sciensano, 2019a). The second describes the whole process of the citizen forum as a policy-making initiative, starting from the issue framing workshop with experts, through the three weekends of citizen deliberation and ending with a stakeholder workshop (KBF & Sciensano, 2019b). In this report, we will present the qualitative analysis of the discussions that took place over the three weekends of the citizen forum and present conclusions and recommendations for the future regarding the use of genomic information in society.

The citizen forum is in line with the growing body of public deliberation initiatives in health care. Traditionally, these projects aim to bring together citizens to produce concrete policy outputs on sensitive issues in health care such as biobanking, reimbursement, end-of-life care, abortion, priority setting, drug development and more (Abelson et al., 2013). These subjects have many ELSI that may be prone to profound disagreements. Deliberative approaches aim to create 'safe liminal spaces' where laypeople, stakeholders, policymakers and experts alike can engage in well-informed, constructive discussions (De Rynck & Steyaert, 2019). These discussions may not always lead to a new consensus, but should always facilitate better mutual understanding, pinpoint remaining areas of tension and highlight opportunities for improvements on current practices.

In genomics, public involvement is often limited to questioning stakeholders, mostly in the form of surveys and interview studies involving patients, professionals and research participants (e.g. Dheensa et al., 2019; Middleton et al., 2016; Van Hoof & Moens, 2019). Some studies have attempted to describe attitudes towards genomics in the general public (Middleton et al., 2018; Milne et al., 2019). While these studies may be very informative, they remain descriptive and leave a lot of room for interpretation concerning translation to policies and regulations.

Recently, several countries have decided to tackle the issue of developing a policy framework for genomics hand in hand with citizens using deliberative processes. In France, the public was consulted as part of the review of the French law on bioethics. This initiative included the organization of 271 events where the law on bioethics was discussed with stakeholders and citizens, input from experts and professional organizations and a citizen forum with a specific interest in genomics (CCNE, 2018). Genomics England reported on their public engagement efforts regarding genomics that citizens call for a new social contract in health care (Ipsos MORI, 2019). Within the horizon 2020 program, a 'stakeholder involved ethics' project (SIENNA) was launched with genomics as one of the core subjects (Rodrigues et al., 2018). These initiatives show that there is an international interest to give direction to the evolution of genomic technologies based on societal norms and values.

1.1 A LIFE CYLCE PERSPECTIVE



From conception to adulthood, we now have access to genomic technologies and to the information our genomes provide to personalize and inform precise approaches for optimizing our health and for combating disease (Rehm 2017). Why is personalized medicine important? Because we all have a unique genome – four to five million genetic variants per individual – that responds differently to treatments. Hence, a personalized approach to screening, diagnosis, and treatment could be beneficial for everyone. All over the world, national genomic medicine initiatives are driving transformative change under real-life conditions, while simultaneously addressing barriers to implementation and gathering evidence for wider adoption (Stark et al., 2019).

1.1.1 Neonatal Screening

Since the sixties, a blood sample is taken from all newborns in many countries, to detect possible congenital diseases that may be managed at an early stage of childhood. These neonatal screening programs are without a doubt in the best interest of newborns: lives are saved, and disease burden and morbidity alleviated. However, neonatal screening still raises a lot of ethical challenges. Sénécal and colleagues

(2018) give several examples: which criteria should govern whether or not to include a disease in the list of screened conditions? What should be the consent procedure and/or the notification process to parents? Should we screen the DNA of newborns?

Concerning genomic screening for newborns, the consensus so far was that it should be limited to targeted analysis and identification of gene variants conferring a high risk of preventable or treatable conditions, for which treatment has to start in the newborn period or early childhood (Howard et al., 2015). However, the advances in whole-genome sequencing may put pressure on these limitations. In Belgium, cystic fibrosis is the first genetic disease added on the list in 2019, opening the door to genetic screening of newborns.

1.1.2 Direct-to-Consumer Testing

Direct-to-consumer tests (DTC) are genetic tests that consumers can buy directly online, without the intervention of healthcare practitioners. It is now possible to send a DNA sample through an online service and receive your test results from a company on the other side of the world. Since our genome does not only contain information about our health, DTC goes beyond the medical field with genealogical testing, talent screening, attempts to measure partners' genetic compatibility for dating, dietary advice, personalized fitness advice, precision cosmetics and more.

The academic consensus is that we must remain cautious with these tests because they are not always reliable. Moreover, our phenotype results from the complex combination of environmental and genetic factors. DTC can also reveal secondary results about predisposition to diseases (e.g. Alzheimer, Parkinson) without providing medical support or interpretation. Misunderstanding of results could expose people to inappropriate lifestyle or health measures. This is one of the reasons why some countries, like Germany, impose legal restrictions on DTC (Kalokairinou, et al. 2018). In Belgium, no specific law regulates DTC testing (Superior Health Council, 2012).

1.1.3 Carrier Screening

Nowadays, thanks to carrier screening, couples who want to have children can check if their future baby would be at risk of developing serious diseases. Indeed, even healthy couples have a one-in-four chance to give birth to a child with a serious inherited condition, if both partners carry the same defective gene. Couples in that situation face several options: having children and dealing with their potential illness, in vitro fertilization with embryo selection, pregnancy with prenatal screening potentially followed by abortion, adopting or not having children (Rehm, 2017).

In Belgium, only commercial companies offer carrier screening before pregnancy since it is not part of the healthcare system. Yet, the Superior Health Council (2017) advised a pilot program to prepare a widespread implementation of carrier screening within the Belgian population.

1.1.4 Prenatal Screening

During pregnancy, the doctor can take a blood sample from the mother to check if the fetus does not present any chromosomal abnormality, like Down syndrome. This is called non-invasive prenatal testing (NIPT). Compared to traditional methods, this test presents the advantage of being more precise and less invasive. Currently, recommendations are not to expand NIPT-based screening to include other disorders (Dondorp et al., 2015). However, this may change as the technology develops.

Belgium is a frontrunner in noninvasive prenatal screening: it is considered standard practice and fully reimbursed.

1.1.5 Population Screening

In general, population screening is based on population risk, not individual risk. However, not every 30, 40 or 50 year old in the population has the same risk of disease. Genomics allows for a more personalized approach to screening. For example, several large trials are underway to investigate whether personalized breast cancer screening is more effective than traditional screening methods (Román et al., 2019).

In the future, whole genome screening may become even cheaper and the question may arise whether it is beneficial to sequence the genome of the entire population. Previous recommendations stressed that whole-genome sequencing requires a justification, stemming from a clear medical need (van El et al., 2013). However, advances in genomic technologies may put pressure on this position. In Belgium, the Superior Health Council has launched a working group about genetic screening in healthy populations.

1.1.6 Personalized Medicine

According to some, genomics marked a turning point in the history of medicine (e.g. Rehm, 2017). From traditional medicine based on the model 'general symptom-diagnostic-treatment', we moved to personalized medicine based on prevention and targeted diagnostics and treatment. Personalized medicine, powered by genomics, promises to improve the population health and reduce public health spending in the long term.

Particularly important medical progress has been made in the field of cancer. In Belgium, a specific strategy was developed to implement next-generation sequencing technologies in oncology (Van Valckenborgh et al., 2018).

2. METHODS

2.1 THE CITIZEN FORUM AS METHOD

A citizen forum, also described as a deliberative forum, is an internationally approved method where a small group of selected citizens, generally consisting of 16 to 32 individuals, debate and reflect in-depth on complex and controversial societal issues (Mansbridge et al., 2012; Steyaert & Vandensande 2007). During an extended period - three weekends in this case - open discussions are organized, fostering critical attitudes and both individual and collective reflection. The final aim is to produce political recommendations, to inform decision-makers of fundamental needs and values expressed by well-informed citizens.

A team of facilitators, translators, and resource persons with different expertise related to the topic, help the citizen panel formulate balanced and well-informed opinions. An advisory committee supervises the quality of the informative background material and helps in the selection of resource persons who come to inform and challenge citizens. On top of that, two researchers from the Catholic University of Leuven assess the quality of the process. They go on to publish their conclusions in a separate report (Marien & Felicetti, 2019). Throughout the citizen forum, we are paying particular attention to transparency: the citizens receive detailed summary reports after each weekend, their advice and criticisms are taken into account on both methodology and content level, and they review and approve the final report before publication (KBF & Sciensano, 2019a).

2.2 RECRUITMENT AND PARTICIPANTS' PROFILE

A citizen forum is a qualitative method, requiring personal attention for each participant, significant commitment from the participants and in-depth facilitation and analysis from the organizers. To be able to guarantee high-quality outcomes, the goal is not to constitute a panel that represents the entire Belgian population. The aim is to form the most diverse citizen panel possible based on age, gender, socioeconomic and professional background, to generate rich discussions among participants.

With the help of about ten field-based organizations and the Bpact online panel, 492 citizens respond to the initial call to participate in the citizen forum. Candidates receive an online questionnaire with socio-demographic questions, questions about their motivation to be part of this project, and questions about their knowledge of the topic. People with a serious genetic disease and professionals in the field of genomics – doctors, researchers, or experts - are excluded. Participants mention three main motivations to be part of the citizen forum: the participatory nature of the project, personal or family reasons, and interest in the topic.

After the first phase of recruitment, 160 citizens remain. Among them, the KBF and Indiville select 32 citizens, according to specific criteria, such as age, gender, language, level of education, work and family situation (see table 1). Only three participants work in a field connected to healthcare: one works as an intercultural mediator in health, one is a collaborator in a medical administration, and the last one has gone through an internship in medical imaging as part of his master's degree in physics. Three participants could not come to the last weekend for several reasons (illness, new job, unknown reason).

Table 1. The citizen panel (n=32)

Criteria of selection	Number of participants per criterion
Gender	
Men	16
Women	16
Language	
Dutch	16
French	16
Age	
18-25	5
26-45	12
46-65	15
Work situation	
Employee	11
Public servant	3
Self-employed	2
Pensioner	4
Work incapacity/disability	1
Voluntary housewife/house husband	3
Jobseeker	4
Student	4
Level of education	
Primary education	2
Technical education	1
Vocational education	1
Secondary education	8
Artistic education	1
Higher education	19
Family situation	
Alone	7
Cohabitation with spouse/children/parents	23
Community housing (student housing, nursing home, institution, ...)	2
With children	20
Without children	12
Connection to the health sector	
Is or was professionally active	3
No professional connection	29

2.3 THREE WEEKENDS

During three weekends, the citizen panel debates and reflects on the ethical, legal and societal issues surrounding the use of genomic information, with the final aim of producing and presenting policy recommendations to the Belgian Minister of Public Health.

2.3.1 Before the Weekends: Issue Framing Workshop and First Meeting Session

The citizen forum starts with an issue framing workshop, where we ask more than 50 Belgian and international experts and policymakers to frame and identify the main ethical, legal, and societal issues that should be discussed during the forum (KBF & Sciensano; 2018a). The results of this workshop would inspire the questions we will ask the participants.

Before the citizen forum begins, participants meet each other and the organizing team at an evening session on 28 June 2018. This first meeting allows participants to have a brief introduction to the project. They also receive an information booklet.

This booklet gives an overview of the main ELSI in genomics through nine real-life practical case studies, which illustrate how genomics might influence our lives, and entails complex individual and collective choices (KBF & Sciensano, 2018b). The nine case studies are:

1) Personalizing cancer treatment through DNA testing and genomic data sharing.
2) Informing the family in case DNA testing reveals a higher risk to develop an inherited condition.
3) Carrier screening for couples who desire to have children.
4) Prenatal screening.
5) Neonatal screening.
6) How to deal with secondary findings and the doctor's role.
7) Direct-to-consumer testing and dealing with uncertainty.
8) Managing databanks and data sharing.
9) Non-medical screening (talent and behavior) and potential uses by insurances, employers, and legislators.

2.3.2 Weekend 1 (15-16 September, Antwerp)

The first weekend aims at familiarizing citizens with the topic, understanding which issues are at stake, and identifying the first set of values and opinions that emerge intuitively.

To give participants an active role in the process, they get to choose several case studies from the booklet to discuss during the weekend as a starting point. They choose case studies 2, 3, 8, and 9. Facilitators use role-play and the journalism method to launch the debate and to stimulate participants' critical thinking (KBF & Sciensano, 2019a). Those methods require participants to listen carefully to each other, to consider issues from various angles, and to ask themselves as many questions as possible. Those exercises lead to the creation of a mind map, which summarizes the main themes and their related issues and values identified by the participants (Annex 1). At the end of the first weekend. The citizens identify what types of resource persons they want to meet during the second weekend, and the questions they will ask them.

2.3.3 Weekend 2 (20-21 October, Charleroi)

The second weekend aims at exploring remaining case studies, answering citizens' questions, calling opinions of the first weekend into question and developing a framework of values.

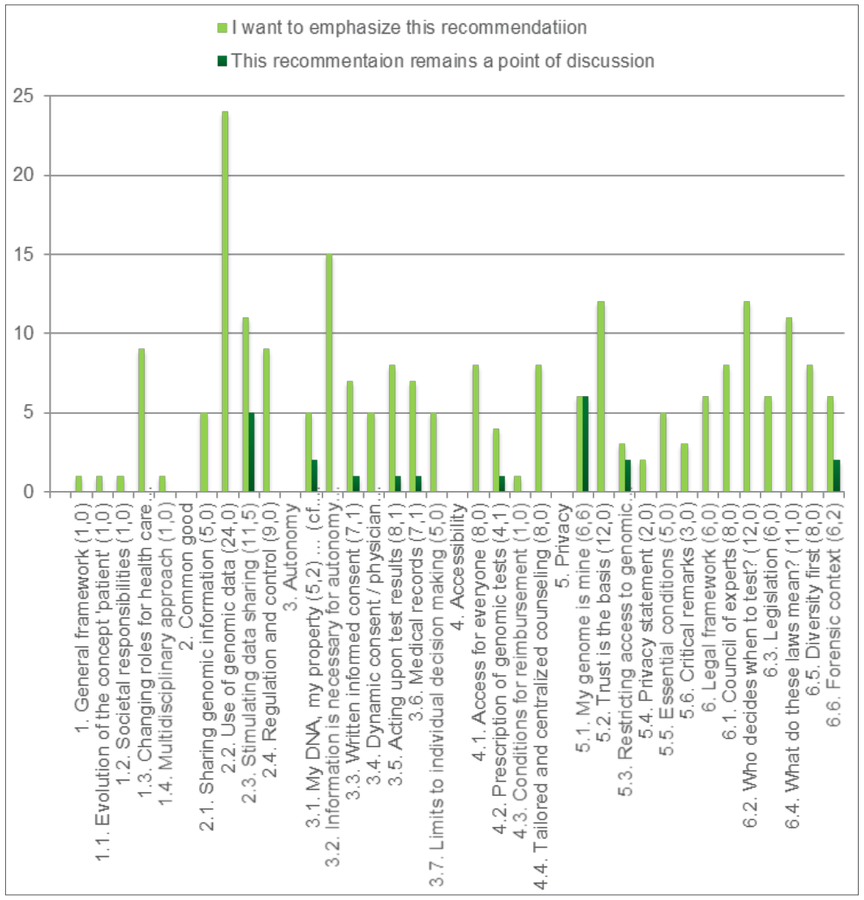
Fourteen resource persons with different expertise (law, genetics, biobank, ethics, patient associations, etc.) are invited to answer citizens' questions, to support and to challenge the discussion amongst participants (KBF & Sciensano, 2019a). The goal is not to transform citizens in genomic experts – they already are experts in their own experience – but to provide them with the basic knowledge they lack to understand all aspects of the debate.

Through various methods (defense speech, 'fishbowl', mood board, etc.), citizens are asked to argue in-depth about every opinion, to create links between themes and ideas, and to select the main themes that will constitute their final recommendations (Steyaert & Vandensande, 2007).

2.3.4 Weekend 3 (30 November-01-02 December, Brussels)

The last weekend aims at writing and presenting final recommendations to the Ministry of Public Health. Facilitators work with templates to create the recommendations with citizens. Citizens criticize and improve their recommendations in sub-groups and plenary sessions and are asked to highlight the values behind each theme. Some resource persons with broad areas of expertise are also invited to help with any remaining questions. Once all recommendations are completed, each citizen indicates recommendations they prioritize using white tokens, and recommendations they disagree with using red tokens. Because the goal is not to reach a consensus, disagreements that persist on recommendations are mentioned as well (Table 2 and Annex 2).

Table 2. Remaining disagreements in the citizen panel. See Annex 2 for a full description of the recommendations.



On the last afternoon, the Minister of Public Health visits the forum in person to listen to the citizens' recommendations, with members of the Ministry and some members of the advisory committee (see KBF & Sciensano, 2019a&b for a full description of the composition of the advisory committee). This presentation is followed by a discussion between citizens and members of the Ministry.

2.4 DATA ANALYSIS

All discussions that take place between citizens and experts or amongst citizens themselves during the citizen forum are recorded and transcribed. In all plenary sessions and some subgroup sessions, simultaneous translation is provided so everyone could speak their language. Hence, the transcriptions include a mix of Dutch and French data. Data analysis is always performed in a team where all researchers are fluent in both languages and at least one researcher is a native speaker.

The central research question that guides the thematic analysis is: how should we deal with genomic information in society? The data are analyzed using inductive thematic analysis in Nvivo 12 (Braun & Clarke, 2006). This method requires starting with an open coding process. One researcher codes the transcriptions manually, another checks the codes and enters them in Nvivo while a third researcher resolves disparities between interpretations. Special attention is paid to keeping codes close to the original data, which allows themes to emerge naturally. These themes are grouped in bigger themes with careful consideration for interconnectedness by two researchers who are constantly discussing alternative interpretations. A common critique of thematic analysis is that it boils down to a simple counting of statements (e.g. Buetow, 2010). To counter this, we do not give special weight to high-frequency codes,

but to codes from discussions that have a big influence on the flow of the citizen forum and the final recommendations (Annex 2). Additionally, we are vigilant to focus sufficiently on significant disagreements and divergent opinions (Vaismoradi et al., 2013).

2.5 STRENGTHS AND LIMITATIONS OF THE PROJECT

The citizen forum is continuously audited by two independent researchers, who report on various strengths and weaknesses of the process (Marien & Felicetti, 2019), concluding that "the citizen forum under observation enabled for high-quality deliberation. Moreover, the deliberative approach adopted in this project contributes to the recognition that citizens, individually and collectively, can contribute to decisions on complex matters that affect their lives.". They base this conclusion on four main points:

1) The citizen forum is very inclusive. The recruitment process results in a diverse group of participants and the forum enables meaningful discussion between different perspectives.

2) The citizen forum enables participants to arrive at informed considered judgments. Through neutral information provision and the use of resource persons from different backgrounds, the participants improve their understanding of the issues at stake.

3) The participants effectively influence significant elements of the process. The process is open to the input of citizens at all stages. They write and validate the recommendations (Annex 2) and the original report (KBF & Sciensano, 2019a).

4) Internal transparency is very high. The participants are put in a condition to understand and to contribute to the workings of the forum.

It is impossible to claim that every possible perspective in society is represented in a group of 32 citizens. Moreover, only citizens who are interested and engaged participated, because a citizen forum asks a lot of time and energy. Additionally, genomics is a technical subject and despite our efforts to provide comprehensible information and competent resource persons, a lack of knowledge might still inhibit some participants to speak their minds. Despite these difficulties, efforts are continuously made throughout the forum itself and in the analysis afterward to include as many different perspectives as possible.

The informative booklet and information provided by resource persons undoubtedly influence the outcomes of the citizen forum. To mitigate bias as much as possible, the booklet is written in the form of cases, against the background of a life-course perspective, following the idea that it represents choices any individual might encounter regarding genomics during a lifetime. By focusing on cases and choices, we avoid taking a position on issues as much as possible. The resource persons that are invited to the forum are either asked to present all sides of a discussion or when a resource person comes to defend a certain point of view, another expert is invited to defend the opposite position. Both the information booklet and the resource persons are checked and approved by an independent advisory board (KBF & Sciensano, 2019a&b).

The forum is organized in two languages, namely Dutch and French. Even though in all plenary and most group discussions translation is foreseen, this may affect citizens' understanding of the debate and ability to participate. It also makes data analysis more difficult, but this is mitigated by relying on bilingual researchers.

Every phase of the qualitative data analysis is performed by two or three researchers, who are constantly triangulating and auditing each other's work.

3. RESULTS

3.1 ME AND MY GENOME

To understand the values and needs expressed by citizens of the panel, we have to describe the significance they assign to the human genome. A better understanding of how citizens consider the human genome will lead to better insights into the values they attribute to genomic information.

3.1.1 The Genome Is the Most Intimate Part of Individuals

All citizens agree that their genome in a way defines who they are since it is unique to each individual. Citizens compare the genome to a bar code that renders individuals always identifiable, and talk about it as the "internal identity card".

They consider the information we can extract from it to be a part of an individual's "intimacy", i.e. private life. Genomic data warrants protection for two main reasons:

Firstly, because the genome contains a lot of sensitive information about the individual's and their relatives' health (predispositions, inherited conditions, the influence of our environment and lifestyle, etc.) and further intimate insights (personality, talents, behaviors, origins, etc.), the citizens argue that genomic information is more sensitive than information about their health.

> *[DNA] says something fundamental about who I am. It contains more information about me than the result of a blood test does, which only reveals specific diseases. DNA largely defines who we are.*

Secondly, privacy protection is all the more important because citizens fear that the use of their genomic information can be turned against them or their relatives, which makes them vulnerable. In this respect, citizens get the impression of laying themselves bare when sharing their genomic data. This is particularly true when the genome reveals weaknesses in health (e.g. diseases) or personality traits (e.g. low tolerance to stress). By privacy, citizens mean all information individuals want to keep confidential because its disclosure could negatively affect their lives – it could lead to rejection, negative judgment or discrimination. For instance, the disclosure of genetic diseases may change the way relatives, an employer or society at large consider and treat you as a person. Consequently, citizens consider privacy protection to be one of the key principles of this debate, to protect the individual and their relatives' wellbeing.

3.1.2 Fundamental Tension: The Genome as the Individual's Property versus Common Good

Though all citizens recognize the human genome as the most intimate part of an individual, they disagree on whether it should be framed within the concept of individual property or the common good. This tension constitutes one of the biggest conflicts of values among citizens since the conceptualization of the human genome determines the support of how genomic information should be used in society.

Those who view the genome within the framework of individual property argue that the individual is the right person to decide what can be done with their genomic information.

> *DNA is my property; it belongs to me mostly because it goes beyond health and a medical record. It is about identification. [...] So I decide what I do with it.*

For some citizens, the main practical implication of this conceptualization of the genome is that one should have the right to make any decision regarding their genome, no matter the consequences. This includes the right to sell their genomic data.

> *Everyone should be allowed to sell their data. We do what we want with our data, like with our organs. However, it does not mean that it is a good thing to do.*

Conversely, the majority sets limits on the individual's autonomy and warns against the risks of harm if an individual is allowed to do what they want with their genomic information. These citizens argue that being the owner of something does not mean that the individual is free to do as they please, but that they are responsible for it and the possible consequences for themselves and others. These citizens think that legally permitting individuals to sell their genomic data to third parties will create a society focused on individual interests, instead of a culture of giving.

> *It is important to ensure that everyone remains the owner of their genome, but they should also develop a sense of common good. Even if my genome remains my property, it is still of interest to others. For this reason, we want to support a culture of giving, instead of a culture of marketing.*

Some citizens question the idea that the individual is the owner of their genomic information even further and argue that the genome is a common good. They argue that all individuals inherit their genes from their ancestors and pass them on to their children. Hence, the genome contains sensitive information about relatives, giving individuals the responsibility to consider their relatives in decisions about the use of their genomic information.

Additionally, these citizens point out that each individual shares 99.9% of their genome with the rest of humanity. In their eyes, the human genome binds us together. As a result, each individual has a moral responsibility to use their genomic information in a way that serves the general interest. For example, sharing genomic data for scientific research that enriches medical knowledge to improve the population's health.

> *I feel that if I do the test for medical or other reasons, my results should be accessible to everybody, at a minimum to help my family situation [...] or to support scientific progress. Thus, access for all. We must acknowledge that we are all connected, we are all Homo sapiens unless I am mistaken, we are part of the same big family. Therefore, it should be used for all, and not kept for oneself.*

Those citizens favor altruism and solidarity over individualism. A small minority even speaks about selfishness if the individual does not act in the general interest.

To sum it up, the citizen forum presents arguments for both a communal and a private conception of the genome. All genomes share a common basis of 99.9%, but at the same time, the genome is the most intimate part of an individual because of its uniqueness. In the end, all participants but one agree with the statement "My DNA is my property" and all support the idea that there is a common interest in enhancing the knowledge about the human genome in all its variants. Consequently, society should give rights to individuals on their genomic information, but individuals should act responsibly and may have some legal and societal duties in return. Fundamental disagreement remains about the practical implications of these values.

3.1.3 I Am More than my Genome

Citizens are convinced that they are more than their genetic makeup. The genome does not tell the whole story about individuals since humans are socially, culturally, emotionally, and psychologically complex. Moreover, an individual's identity and health are determined by education, environment, and lifestyle as well. Therefore, citizens want to be treated and considered as human beings, not as the sum of their genomic data. Citizens fear being reduced to the information their genome may reveal.

> *We are more than our genome [...] There is a risk that people say 'I have received my DNA screening results, so I am like this, this and this'. No, we are much more than that.*

Citizens fear that the knowledge of their genome, by themselves or by others, reduces their freedom and choices in life. They refuse to believe in a deterministic conception of genomics. This is why citizens ardently defend that individuals should not be prisoners of their genetic makeup and that DNA cannot be used as a quality label of individuals. This must be true in all spheres of society, from the workplace to a bank or insurance firm and in private life. For instance, employers should not have access to DNA test results of employees to redirect their careers according to their stress tolerance or their 'inherited talents'. In short, individuals should have the right to an open future, whatever their genes may reveal.

Another consequence of the citizens' statement "I am more than my genome" is the need to develop a holistic approach of human beings, in both medical and research contexts. Healthcare practitioners and researchers should treat and study patients in all their complexities, namely as psychological, social, and emotional entities, instead of focusing on biomedical and genetic aspects. According to the citizen panel, a multidisciplinary approach (geneticist, psychologist, doctor, sociologist, etc.) is required in genomics.

3.1.4 The Genome Implies Uncertainty, Doubt, and Fear

3.1.4.1 The Genome Implies Uncertainty

Generally defined as 'the conscious awareness of ignorance' uncertainty is particularly manifest in genomics. Citizens identify different levels of uncertainty in that field.

Often, genomics test results only show probabilities, risks, percentage of predispositions to diseases the individual may or may not develop in the future.

From the information they were given and their interactions with experts, citizens understand very well that genomics is still a young science. Nowadays, scientists do not yet know most genes' significance and how they relate to diseases. During the forum, experts made several contradictory claims or expressed uncertainty about future possibilities. Since the significance of so many genes still needs to be discovered, citizens do not know what kind of results scientists may find in their genome later.

> *Nowadays, genomics is still a mess of sorts. All right, scientists already have read a whole section of the human genome, but they do not know anything about it. If you change this little part, what will actually happen? They don't know. [...] We know a lot about human DNA but actually, we know very little.*

Citizens also point out that nobody can know in advance what information the genome will reveal. A case in point is the issue of secondary findings.

> *Be careful, it is like opening Pandora's' Box. You do not know what will come out.*

3.1.4.2 The Genome Implies Doubts

Citizens underline the fact that genomics brings about new difficult personal choices, which generate doubts and hesitations. This is especially true with the issue as to whether individuals want to learn more about their genetic makeup or not.

One citizen expresses the new existential questioning that genomics raises: "How can I live without knowing when I know that I could know?". This argument follows the same logic as the technological imperative, which requires using new technologies for the reason that they are available. However, the ability to do something – e.g. knowing one's genome thanks to DNA sequencing – does not mean that one should do it or that is it right to do it.

Citizens' perplexity about the choice of knowing their genome or not comes from their awareness of both the benefits and harms that such knowledge could cause. Citizens understand that the knowledge of their genome can change their way of living, both in a positive and a negative sense.

> *The sword of Damocles is hanging over her head. She has had no symptoms in all these years. It costs her dearly [...] you know, the psychological aspect of feeling like it's going to start whenever you don't feel 100%. Actually, she says that she would have rather not known. However, this is easy to say twenty years later because she is not sick; if she had been sick...*

3.1.4.3 The Genome Implies Fears

Citizens express their fear about the many possible misuses of genomic information. They understand that if scientific progress in genomics generates more possibilities, it creates new risks too.

Discrimination and categorization of individuals based on their genetic makeup constitute one of the greatest fears of citizens because it reinforces inequalities in life and reduces individuals' liberty. Citizens argue that people who present a high risk of developing diseases should not be treated differently outside the medical sphere, namely in their social and professional relationships.

Citizens' concerns go beyond the present and include future generations too. Citizens worry about the possible reduction of human diversity through eugenics and genetic manipulation. Citizens oppose programs that aim to systematically eliminate illness and disabilities or to enhance genetic features promoted by our society focused on performance (e.g. intelligence); leading to the standardization of populations in the long term.

> *The right to be yourself must be guaranteed; the right not to correspond to the cult of performance and perfection. This is related to our wish of a world with diversity, and to our fear of a world where everyone is conformed due to genomic manipulation and the like. We want to avoid that kind of world.*

In general, citizens warn against the human tendency to seek constantly to go a step further and to test boundaries of scientific possibilities. Citizens think that "Playing God" and taking the role of nature will inevitably take a wrong turn. Hence, citizens conclude that genomics should always respect human diversity in its many applications.

> *This is the respect of human beings as they are no matter if they are disabled or not [...]. The respect for human life. [...] If we begin to select to that point, we take a role that is not ours, because nature already makes the selection. At a given moment, we may need people who carry this or that feature we considered as a disability, or people who do not have the perfect genome but who resist one specific disease others do not resist. This is how nature has always worked.*

3.2 SOCIETAL RESPONSIBILITY

The citizens see their genome as something very intimate. Any use of genomic information in society, therefore, requires a large degree of trust. This means that citizens believe that several societal responsibilities need to be taken up. Only when these requirements are met and sufficient safeguards are in place, are they willing to partake in societal genomic initiatives.

3.2.1 Precautionary Principle

The citizen panel recognizes the huge potential for good inherent in genomics. 'The common good' is even a separate theme in their final recommendations (see Annex 2). However, if the genome is so powerful, these powers can be used for destructive purposes as well. The citizens fear the abuse of genomic information in many different forms. Because they realize that genomic information can always be used for other purposes than they originally intended and uncertainty about future developments in genomics persist, they demand a clear legal and ethical framework surrounding the use of genomic information. In short, they recommend proceeding with caution, using the precautionary principle to guide the governance of genomic data.

They understand governance in a very broad sense: laws, regulations, recommendations and even societal norms and principles in as far as they are subject to public awareness and nudging. These should all be guided by the precautionary principle.

3.2.1.1 Legal Framework

The most powerful way according to the citizens to exercise precaution is to develop a strict legal framework. The citizens call for comprehensible legislation, so they understand their rights and can claim them when necessary. These laws should serve to protect the private lives of people whose genome is being used. The need for privacy protection is a very strong conviction for all citizens that held up to various challenges, like the comparison to social media:

> *Facilitator: We live in a world where everything is shared on Facebook and the like. Why is this [genomic information] so sensitive? Because as you put it now, privacy protection is an absolute principle. [...]*
>
> *Citizen 1: I think this concerns medical information, it concerns my body at its most intimate part. That's why, for me personally.*
>
> *Citizen 2: There needs to be confidentiality. [...]*
>
> *Facilitator: So what you are saying is that this genomic information is intimate information.*
>
> *Citizen 1: Yes, for me it's my, I mean it's true that we share with everyone on social media. And we are 95% the same, or even more, right, I don't remember. But the part that is left, you know, that is me, my intimate self that belongs to me. And everything medical also, it belongs to me. [...]*
>
> *Citizen 2: Exactly, if we treat it [genomic information] this way, like social media, we would lose authority over something that belongs to us. It is everything, it is even more than our bodies.*
>
> *Citizen 1: If we lose this, we lose everything.*

As the citizen panel believes that these data are even more sensitive and powerful than traditional personal and medical data, they argue for a specific legal status for genomic data. This would allow for better protection and a tailored approach when necessary.

Besides this specific legal status, the ways citizens envisage genomic data protection are through increased individual empowerment and control (1), combined with institutional oversight (2).

1) After their discussions with experts, the citizens are even more convinced that laws on patient rights should serve to increase individual empowerment and control in genomics. Therefore, these laws need to be expanded and amended to better suit the challenges posed by genomics. The citizens remark that this is very similar to the approach of the General Data Protection Regulation (GDPR) imposed by the European Union.

2) From institutional oversight, citizens expect strong oversight on data security and data access in light of privacy protection. Access to third parties (parties other than the treating physician or specific research institution/service provider) should be limited as much as possible. Citizens also expect institutions to protect society from certain utilizations of genomic information, like eugenics, discrimination, and genetic manipulation.

The citizens agree on these general principles, but practical applications are not so easily resolved. Especially regarding commercialization, discussions around a legal framework persist. Some citizens are against any form of commercialization because it would mean using their DNA, i.e. their intimate self, as a means to an end that does not serve the common good, but the good of a company. Others argue that they should have a right to do with their DNA as they please, including selling it. Another argument in favor of commercialization is that involving the private sector might boost scientific advancement. Also regarding the commercialization of DNA testing in the form of DTC testing, the panel remains divided. Their conclusion on the matter is that it is not necessary to prohibit these tests, but our institutions should try to dissuade people from using them.

The citizens are also aware of the potential negative sides of a comprehensive legal framework. Too many restrictive laws and regulations might limit scientific progress and other potential benefits for society. Therefore, citizens support adaptive laws and regulations or a flexible legal framework, without compensation in areas like specificity, applicability, and strictness.

3.2.1.2 Soft Laws and Regulations

The citizens are aware that besides explicit laws and regulations, genomic information is also governed by, for example, medical and research practice. They argue that in all contexts (medical, research, commercial, etc.) the genome should be treated in a multidisciplinary fashion because genomics touches on physical health, mental health, relationships, ethics, etc. Professionals must approach the genome in a tailored way. This obligation should be expressed in the soft laws that regulate their profession.

For example, between a physician and their patient, there should be a specific charter that regulates how specific situations that may occur during genomic testing are handled. This charter is something that can be agreed upon between physicians and patients individually, like informed consent, but preferably it is a more general framework. In this charter, subjects like medical confidentiality, reporting of secondary findings and dealing with relatives after a germline mutation is found, should be treated. It should be clear for every citizen how their genomic information will be handled by a particular professional.

Professional responsibility also includes properly treating genomic data. This includes following the rules imposed by the legal framework, but it goes further than that. For example, concerning research, it means respecting the efforts of citizens and patients who share their data. Someone who agrees to support scientific research should also reap the fruits of scientific progress. This means that research subjects should be notified when results from future research might benefit them or whenever something significant is found out directly about them.

3.2.1.3 Levels and Forms of Government

Concerning practical discussions about the development and sustainability of a legal framework, the citizens have a clear view on the policy level at which genomics should be regulated. They remark that scientific research on genomics and the business of genomics have long surpassed national borders. Therefore, they believe that Belgium should subscribe to international initiatives to regulate the use of genomic information, like the GDPR.

On a national level, the citizens call for a multidisciplinary council of experts, underlining again the specific nature of genomic information. These data should be governed under the auspices of different experts who can adapt the legal framework when necessary and approach the issues surrounding genomics from different backgrounds.

3.2.1.4 Raising Awareness and Nudging

When a firm legal framework is established, the citizen panel realizes that there remain a lot of areas where decisions around genomics are regulated by implicit norms and values, rather than explicit rules. However, when this is the case, society still has a role to play through raising awareness and even nudging in certain cases. For example, regarding the role of society in genomic data sharing, a big point of discussion remains whether an individual should be completely free to decide or society should enforce this in one way or another. One solution that could alleviate this tension for most citizens is to leave the decision to the individual, but to offer incentives for data sharing, to make it the default option or to raise awareness about the importance of data sharing to nudge citizens into acting in support of the common good.

3.2.2 Respect for Autonomy

Respect for autonomy is a very important societal responsibility according to the citizens. Individuals should be empowered to make decisions about their genomic information and these decision should be respected.

> *So yeah, I'm going to talk about autonomy. My DNA is mine, it is my property. So, I can decide on my own whether or not I want a genetic test, what I want to know or not and whether or not I will do something with the results.*

3.2.2.1 Freedom of Choice, Information, and Dissemination

The citizens discuss the importance of having the freedom of choice regarding genomics and identify the most important prerequisite: good information. They stress this in the clinical context, in the form of good informed consent practices, but also concerning society at large, starting with organized education. Expanding the knowledge about genomics in the population is necessary to prepare them for the inevitable time when they have to make decisions about their genome of their children's genome.

Informed consent is a returning subject throughout the citizen forum. It relates strongly to the underlying theme of the potency of genomic data. The citizens understand well that traditional conceptions of informed consent are strongly related to a sense of control. However, they believe that it is impossible to fully retain control in genomics. When someone does a test for one thing, they can get results for something else. They may find out something about their relatives. Future research might always bring additional information to light. Et cetera. All these characteristics of genomic testing and screening undermine the traditional conception of informed consent as an individual's specific approval for medical intervention.

Nevertheless, citizens still emphasize the importance of a good informed consent process. The goal of this process may be slightly different: to inform patients about their rights and the significance of the test. Two important rights citizens highlight in this context are the right to revisit your original decision and the right to remove your data at any point. There is no consensus about whether generic or specific or dynamic or some other form of consent is preferable. However, in principle, informed consent constitutes an important way to respect autonomy and empower patients according to all the citizens.

The citizens identify one more important prerequisite for freedom of choice: transparency. Only when it is clear for which purposes genomic information is used, is it possible to make meaningful decisions as an individual. This transparency can take many forms, ranging from institutional oversight (including information campaigns for citizens and patients) to notifications to every individual whenever their data are being used. However, none of these options may be ideal:

> *But regarding what you were saying, I think it could be possible that at a given moment you would be overloaded with requests to use your data for research. And you may feel like saying f* this. But then it would still be your decision, and you could still say like, I don't want all these requests so want to remove my data. Or you can say I have faith in this and I accept everything.*

3.2.2.2 The Right to Know and Not to Know

Many decisions concerning the genome depend on the situation and the individual. However, all citizens recognize the right not know as an absolute right. Once this decision is made, every professional working in the field of genomics must respect it, even if this means that individuals or relatives will not find out relevant information for their health or well-being. Additionally, knowing or not knowing should not automatically determine your course of life afterward. This goes back to the central underlying theme that citizens do not believe that human beings can be reduced to one thing.

> *Citizen 1: But it depends on our personality as well. If you know, what will you do with it, or not, that depends on your personality.*
>
> *Citizen 2: Unless this leads to obligations, like, now you know so you have to, for example, eat less fat. So many things are possible. In any case, the focus is always on the mind, you know, and less on the feeling in your belly where you just live your life.*
>
> *Citizen 1: Yes, the tension between medicalized society and the right not to know.*

However, when a finding has been made, other rights and duties may supersede the right not to know. Several discussions in the citizen forum juxtapose the professional obligation of physicians and researchers to diagnose and treat disease to individuals' right not to know. Especially in the case of secondary findings and hereditary diseases, a person might cause themselves or their relatives harm by employing their right not to know. The panel agrees that medical confidentiality should be the general rule, but some citizens leave the door open for exceptions in individual cases.

3.2.2.3 Access to Data

The citizen panel agrees on four fundamental rights that need to be respected with regard to access to genomic data.

1) Right to information: An individual has a right to know who is accessing their data, in all transparency.

2) Right to control: An individual has a right to control who is accessing their data, it is ultimately their decision what can and cannot happen to the data (some citizens mention concepts like notifications and blockchain here).

3) Right to reconsider: An individual can reconsider at any time without any detrimental consequences and block access to certain, or all, parties.

4) Right to be forgotten: An individual should be able to claim the removal of their data from any database for future use. For historical purposes, the panel remains divided because this might disturb the integrity of both scientific research and clinical practice.

The overwhelming majority of the citizens believes that all these rights are inferred from one fundamental, underlying right: their claim to a property right over their DNA. What this means in certain contexts differs in discussions amongst citizens, but "I am the owner of my DNA" is one of the most recurring codes in this qualitative analysis. From this core conviction, the citizens build a rights-based narrative, with references to patient rights and human rights, that focuses on privacy protection and individual control regarding genomics.

3.2.2.4 Exceptions to Respect For Autonomy

During the three weekends, respect for autonomy becomes a key value for the citizens, which is rarely if ever questioned explicitly. However, in less explicit terms, the citizens identify several limits to the value of respect for autonomy, most notably regarding privacy protection, the common good, commercialization, and discrimination. When any of these values are at stake, it can be justified to overrule the autonomous choice of an individual. For example:

> *Citizen 1: I think this [DNA] should not be commercialized. It's true that someone can decide to use private services, so they pay but it should not be commercialized after. We, ourselves, if we decide to share, we share.*
>
> *Citizen 2: That's it. We can share for research, because we have the right, but not to sell. You know why, why you can't just sell? Even if it is for use in scientific research?*
>
> *Citizen 1: It just seems immoral to me.*
>
> *Citizen 2: It's like a kidney, you don't commercialize that.*
>
> *Citizen 3: Just like you don't commercialize an organ, you don't commercialize genomic data.*

Moreover, individual autonomy is naturally limited in genomics because sometimes familial information is at stake. Additionally, some citizens feel very strongly that in genomics, some reciprocity might be required. For instance, when a test and treatment are reimbursed in society, the least one can do is help future patients by sharing their data. Or, if one wants to reap the benefits of scientific research, one should allow their data to be used for fundamental research.

Finally, respect for autonomy requires an autonomous agent, with the capacity to make decisions. While citizens do explicitly identify this as an issue for minors and other incapable individuals, they are also conscious of the fact that in genomics, everyone might be an incapable agent. Because genomics is difficult to understand and decisions can be very complex, the citizens highlight the need for high-quality counseling. Especially after talking to experts who did not always know all the answers themselves, or were left speculating about possible future scenarios, the citizens realize that respect for autonomy has its limits.

3.2.3 Equality and No Genetic Discrimination

The final recommendation that almost all citizens vote to be the most important (see Table 2 and Annex 2) is an unequivocal ban on genetic discrimination. They understand genetic discrimination to be treating someone negatively based solely on their genetic makeup. This is the main reason why third parties who

have the power to negatively influence the lives of people – like banks, insurers, employers and even in some cases the government – should be denied access to genomic information.

> *Citizen 1: There is a lot of distrust in this group. We distrust the secondary use of data after a person agreed to share their genome or their genomic data. There was a lot of distrust regarding the proper use after the fact.*
>
> *Citizen 2: We have the feeling that it will escape us and that there is some kind of danger.*

Fear is the keyword to describe the experience of the citizen panel when they think about the possible ways the genome might be used to discriminate against people. Fear in the undetermined sense, which is the worst kind of fear because it is hard to appease. They could point to a lot of different particular ways of discrimination that they were fearful of, but there would always be an additional feeling of danger that remained looming. This is mainly related to the amount of power they attribute to genomic information and the uncertainty about what research will make possible in the future.

The fear of genetic discrimination is also related to the view of the citizens that an individual is more than their genome. 'I do not want to be a prisoner of my genome' is a statement that was made in the first weekend and was repeated like a mantra ever since. Genetic discrimination is exactly the opposite of this: using one characteristic of a person they have no control over and treating them worse because of it.

The core value that supports this position amongst the citizens is equality. This value also inspires the citizens to speak out against eugenics. Centrally organized efforts to improve the gene pool in society go against the idea of fundamental equality. Additionally, citizens argue that human diversity is something to be cherished. Diversity should be seen as something enriching and the reason why humanity continues to evolve, both on a genomic and a cultural level.

3.2.4 Efficiency and Utility

A final societal responsibility that is defined by the citizens is the need to make sure that genomics is used effectively. For instance, reimbursement strategies must delineate between genomic tests following a clear medical or psychological need and tests that merely serve to fulfil a desire or an interest. The citizens recommend that there would be an independent, multidisciplinary Council of Experts that decides which tests and treatments deserve reimbursement. This Council should comprise of geneticists, oncologists, psychologists, ethicists, sociologists, legal experts and any other kind of expert that might meaningfully contribute to the questions surrounding genomics.

3.3 INDIVIDUAL RESPONSIBILITY

The issue of responsibility in the use of genomic information is very complex, in light of the multitude of actors that play a role, such as government, researchers, health practitioners, and commercial actors. Apart from the societal actors we mentioned in the previous chapter, citizens identify another central actor: the individual.

3.3.1 Individual Responsibilities within the Legal Framework

In the ideal society described by the citizen panel, there is a well-thought-out legal framework that provides individuals with rights that will lead to their protection. Particularly the property right over their genome gives them decisional power and control. However, these laws can only serve to protect provided individuals responsibly use their rights. Where the legislator decides to respect the autonomous choices of citizens and patients, these people have a responsibility to make good choices. If every individual were to decide something that undermines the legal framework (e.g. selling their genome, not sharing genomic data for the common good ...), a good legislative framework can lead to bad societal outcomes.

In the same vein, citizens discuss whether the individual's right to use genomic technologies (e.g. prenatal screening, embryo selection, carrier screening) to avoid children who will develop genetic diseases or disabilities might lead to eugenics and reducing human diversity in the long run. The majority supports this individual right as long as it is motivated by medical purposes. Some citizens think that eugenics

can be the cumulative result of individual decisions in the long term, but not a collective program. The minority nuances or disapproves this individual right because it discriminates and categorizes disabled and sick people. These citizens, who favor the child's right to be born whatever their genome might be, point out that it may put social pressure on parents who choose to keep a high-risk baby, or even worst, blame them for it if the child develops the disease later.

In short, as members of a given society, citizens understand that their individual choices all put together constitute the society of tomorrow.

3.3.2 Privacy

The legal protection of confidential data is worth nothing if individuals are not aware of their right to privacy, or act in a way that undermines it.

3.3.2.1 Autonomy and Responsibility to Protect Privacy

Because the genome describes intimate aspects of the individual's identity, citizens declare that the individual is the right person to decide what can be done with their genomic information, including access, sharing, and disclosure of test results to relatives. To ensure this autonomy in privacy protection, citizens request more individual control on data through transparency and traceability in its uses. This individual control also seeks to avoid misuses of data that could weaken individual freedom and the right to an open future. This mechanic would turn privacy protection to a large extent into individual responsibility.

In the opinion of the majority of the panel, if individuals have to protect their privacy it is because it protects their autonomy. The disclosure of genomic information could diminish the range of current and future choices in many fields, like employment, mortgage credit or insurance, leading to what citizens refer to as being prisoners of their genome.

3.3.3 The Right to Know or Not to Know, The Right to an Open Future

According to citizens, individuals are also responsible for their right to know or not to know their genome, which may alter their wellbeing and right to an open future, positively or negatively.

> *When you map your genome, you open a gate. So you open a gate that lets you see something you didn't know before [...] You opened a gate, so you have to deal with the results, whatever they are.*

On the one hand, citizens recognize that genomic testing helps prevent diseases by detecting predispositions and inherited conditions. It may also create new opportunities and boost self-confidence thanks to talent screening. On the other hand, citizens dread the many harms the knowledge of their genome may bring about, such as anxiety, the feeling of being trapped by their genetic makeup, complications with health insurance, potential conflicts with relatives who may carry the inherited condition as well, and so forth. In any case, citizens recognize the psychological impact of DNA testing: one cannot ignore the information in their genome once it is revealed.

Generally speaking, citizens trust the ability of humans to deal with their genomic information and to adapt to issues raised by the knowledge of their genome. This is especially true since citizens refuse to believe in a deterministic conception of genomics and put the responsibility on individuals in the way they make use of this information.

> *There is a danger that 'I'm an alcoholic, sure, but it's not my fault. It's in my DNA so I can't help it.' Well no, that's abusing DNA. You always have to keep in mind you're more than – ok, it may be in there, but I can do something about it.*

This debate on individual responsibility in health raises awareness on the risk that the knowledge of the genome could label and blame people for their risky behavior – "You knew you had this genetic predisposition". Some citizens want society to nudge people into being more responsible by letting them assume the financial consequences of their unhealthy behaviors. In response, several citizens assert that

knowing one's genome should not lead to an obligation to adapt one's behavior. Everyone should have the right to decide autonomously what to do with the test results.

3.3.4 Duties to Others

Genomics implies additional responsibilities towards others since citizens consider the human genome as a common good that binds individuals together. From the present qualitative analysis, it appears that this genetic connection between humans has two main consequences in terms of individual responsibility. First, one cannot act as if they do not share their genes with their family – which raises the issue of informing relatives about test results. Second, individuals must acknowledge that they need each other to improve their health, and more broadly the population's health thanks to genomic data sharing.

3.3.4.1 Informing the Family

The responsibility towards family takes various forms and is illustrated by the statement "my liberty ends where yours begins", but also the difficulty of drawing the line between those liberties.

For several citizens, individuals should prioritize their relatives' wellbeing and health over their liberty in decision-making. This includes the duty of informing relatives in case the test reveals inherited conditions while respecting their right not to know to avoid unnecessary anxiety. Few citizens think that individuals should take relatives into account in the decision-making process before taking the test, because it may negatively impact their lives.

> *Maybe this test will reveal genetic mutations my brothers, sisters and children may carry as well, with all the consequences it may have on them like needing treatments or testing, or whatever. So before getting them into that, perhaps I should ask their opinion, which would influence my decision to take the test or not [...] because I would not make a decision I cannot own later.*

The duty of informing relatives is such decisive for some that they request to allow doctors to break the medical secrecy in case of inherited, life-threatening and curable diseases. Others prefer to enhance individual responsibility and awareness through a patient-doctor discussion before the test about the potential consequences on relatives. One citizen pushes the responsibility towards relatives further by giving individuals the moral duty to test themselves for inherited, life-threatening and curable diseases, especially regarding parental duty towards their children. Other citizens disagree with these extended responsibilities that reduce individual liberty and recognize the individual's right to decide on their own to inform their relatives or not. The discussion remains open.

3.3.4.2 Data Sharing for the Common Good

Some citizens think that autonomy should be reconsidered in light of solidarity, which benefits everyone and tends to be forgotten in this era of individualism.

> *Every person is embedded in society, so I would say if you just want to do whatever, you'll be less free than you are now.*

The citizens specifically recall this idea in the context of the moral responsibility to share genomic data for the common good. Citizens define the common good as scientific research that aims to improve the population's health thought personalized diagnosis, treatment and prevention, and to build a fair society where everyone has an equal opportunity to live healthily.

In general, the majority position can be summarized in one simple sentence: everyone should have the right to decide autonomously, but these decisions are tied to moral responsibilities towards others who may be affected by one's decision.

3.4 PERSONAL INTEREST AND THE COMMON GOOD

Up to this point, our analysis shows that the narrative of the citizens about responsible use of genomic information starts from the societal responsibility to establish a good framework and the individual responsibility to navigate this framework. In practice, however, the societal and individual levels are very interconnected. Here, we will focus on this interconnectedness during the discussions in the citizen forum.

3.4.1 Personal Interest

It is society's responsibility to provide individuals with a well-thought legal framework that establishes their rights – such as autonomy, privacy protection, individual control, and empowerment –, takes precautionary measures to avoid misuses that threaten these rights and oversight that ensures that they are respected. In turn, it is the individual's responsibility to use these rights given to them, to make good decisions in the use of their genomic information, and not to undermine the importance of privacy protection by making one small eroding decision after another. However, an area of tension arises when citizens discuss instances where individuals might make ethically questionable decisions.

The individual's right to sell their genomic information or to give insurers, employers and banks access to it is a case in point. While a minority considers that individuals – as owners of their genome – should have the right to make any decision regarding their genomic information, no matter the consequences, the majority warns against the harm of such conception and sets limits on the individual's autonomy within the legal framework. Citizens who oppose these two individual rights fear that society suffers the consequences of the irresponsibility of some. In their eyes, the commercialization of genomic data will create a society focusing on individual interests, instead of a culture of giving; which is immoral since one makes a profit from data they could freely share for the good of society, namely scientific research. Following the same logic, the majority disapproves of giving third parties access to their genomic information because this could lead to discrimination and socioeconomics inequalities among the population.

Regarding data sharing, individuals have personal interests in it, since the progress of scientific research aims to improve the population's health and to give everyone an equal opportunity to live healthily. However, the fear of losing their privacy makes citizens reluctant to share their data, which explains the importance of trust in all uses of genomic information.

> *On the one hand, we want to do something – and yes, we are social beings – we want to do something for society, partly because it will benefit us. But on the other hand, it is a little controversial, you know, we are all ramped up because hey, this concerns my DNA!*

In short, as members of a given society, citizens understand that their individual choices all put together constitute the society of tomorrow. Hence, it is not always easy to separate individual responsibility from societal responsibility in genomics.

3.4.2 Common Good

The common good is defined by the citizens as scientific research that aims to improve the population's health thought personalized diagnosis, treatment and prevention, and to build a fair society where everyone has an equal opportunity to live healthily.

There is a societal responsibility to promote solidarity for the common good in certain cases. The citizens mention data sharing for quality assurance and the organization of care (e.g. reimbursement) in this regard. Society should also inform the public about the benefits of data sharing to enhance individual responsibility towards the common good. What is more, citizens mention many conditions that society must guarantee for the sharing of genomic data, such as privacy protection and measures against misuses (e.g. discrimination and eugenics), respect of individual rights (control, transparency, and traceability of data uses), and quality control of research.

While the citizens propose an approach in genomics that empowers individuals and respects their autonomy, this does not mean that people should decide whatever suits them best. Every individual still has a responsibility to take the common good into account when they make decisions about their genome

because scientific research will never succeed to improve medicine and the population's health without the willingness of people to share their genomic data. While a certain number of citizens refer to the duty of beneficence and altruism by supporting the donation of their genomic information, others tend to be more supportive of the principle of reciprocity (e.g. link data sharing to reimbursement of the test).

3.4.3 Area of Tension

When does the common good supersede individual interests and vice versa? This question is a hotly debated issue in the citizen forum.

This tension is particularly striking in the three main ways citizens consider data sharing, that balance individual interests – mainly privacy and autonomy – with collective interests – mainly solidarity and the common good:

1) A minority thinks that the government should oblige citizens to share their genomic data for the common good.

2) Society should nudge citizens to participate in the common good by sharing data by default. However, the individual has the right to refuse it.

3) The decision to share or not to share genomic data should be left to individuals themselves, without any societal pressure.

Individual and collective interests are always interconnected and need each other to make society work. This explains the majority position that can be summarized in one simple sentence: everyone should have the right to decide autonomously, but these decisions are tied to moral responsibilities towards others who may be affected by one's decision. In other words, my DNA is everybody's business.

4. DISCUSSION AND RECOMMENDATIONS FOR THE FUTURE

4.1 A COLLABORATIVE APPROACH TO ELSI IN GENOMICS

The citizen forum represents a way to create practical policy output with involvement from citizens, experts, stakeholders and policymakers (KBF & Sciensano, 2019b). This collaborative and deliberative approach offers an alternative to a market-based approach or authoritarian approach where one actor in the field of genomics might determine the entire playbook (Parkinson, 2006; De Rynck & Steyaert, 2019).

4.1.1 A Citizen Forum as one Piece of the Puzzle

Just because the citizen panel voices certain recommendations, it does not follow that this exact recommendation is ideal. It is important to look behind their opinions for their reasoning, where norms and values can be identified. For example, when the panel calls for a multidisciplinary council of experts to govern genomics, this means that they believe that genomic information has special characteristics that warrant specific regulatory interventions. They proceed to formulate a proposal, but they are well aware that it is up to capable legislators, experts, and stakeholders to develop these in the real world.

4.1.2 My DNA Is my Property

'My DNA is my property.' Whether or not this statement is true in a legal, ethical or even philosophical sense, the fact that the entire citizen panel feels this way is an important takeaway from the citizen forum. It is something that policies about the use of genomic information need to take into account. The citizen panel infers from this conviction that they should get a lot of control over the use of genomic information. This control, in turn, enables them to protect their privacy and to autonomously decide about how they want their data to be treated.

This does not mean that citizens believe that individuals should be the only ones making decisions about their genomic data. In some cases, the government can enforce data sharing, for example, to support basic clinical functions. A minority of citizens even support obligatory data sharing in genomics, which they compare to paying taxes. The discussion around the practical implications of the statement remains open, but the basic conviction that my DNA is mine is universally shared.

4.1.3 Solidarity, Reciprocity and the Common Good

The central struggle underlying many themes in the citizen forum is the conception of the genome as the most personal, intimate property and a common good at the same time. All citizens would agree with both conceptions at least to some extent. The higher they value the common good, the more they will emphasize the need for solidarity (in genomic data sharing for example). The more they value their property right, the more they will focus on privacy protection and autonomy. Both conceptions are not mutually exclusive, but it has been impossible to find a universal balance in this citizen forum.

In general, the citizens express strong convictions regarding reciprocity and justice. They propose that genomics must serve to enhance equality in society rather than diminish if. They support a strong claim for data sharing based on reciprocity: when genomic services are reimbursed and they benefit health and wellbeing in society, individuals have a moral responsibility to share their data. While strong disagreements persist on the practical implications of their principles, citizens support a comprehensive societal framework around genomics – guided by the precautionary principle – within which responsible individual decisions about one's genome are supported.

DISCUSSION AND RECOMMENDATIONS FOR THE FUTURE

4.2 RECOMMENDATIONS FOR THE FUTURE AND IMPLICATIONS FOR POLICYMAKERS

- Continued citizen involvement in the governance of genomic information in society is vital. It ensures that societal norms and values guide the technology and not the other way around.
- Dissemination of information about the genome is required for citizens to be able to make informed decisions and meaningfully participate in the debate about ELSI in genomics.
- Citizens can make meaningful contributions to a complex field like ELSI in genomics if only to indicate their preferences and values.
- The benefits of genomics for society and scientific progress in the field are recognized by the citizens as an important common good.
- Genomic data are sensitive data and there are many societal responsibilities to protect citizens from downsides and promote upsides from the use of genomic information: the precautionary principle should guide the way.
- Within a well-developed framework that inspires trust around the use of genomic data, solidarity and reciprocity are core values that citizens support in the context of genomic data sharing.
- Citizens identify a range of individual responsibilities in decision making in genomics and accept that societal nudges might be required to balance personal interests and the common good.

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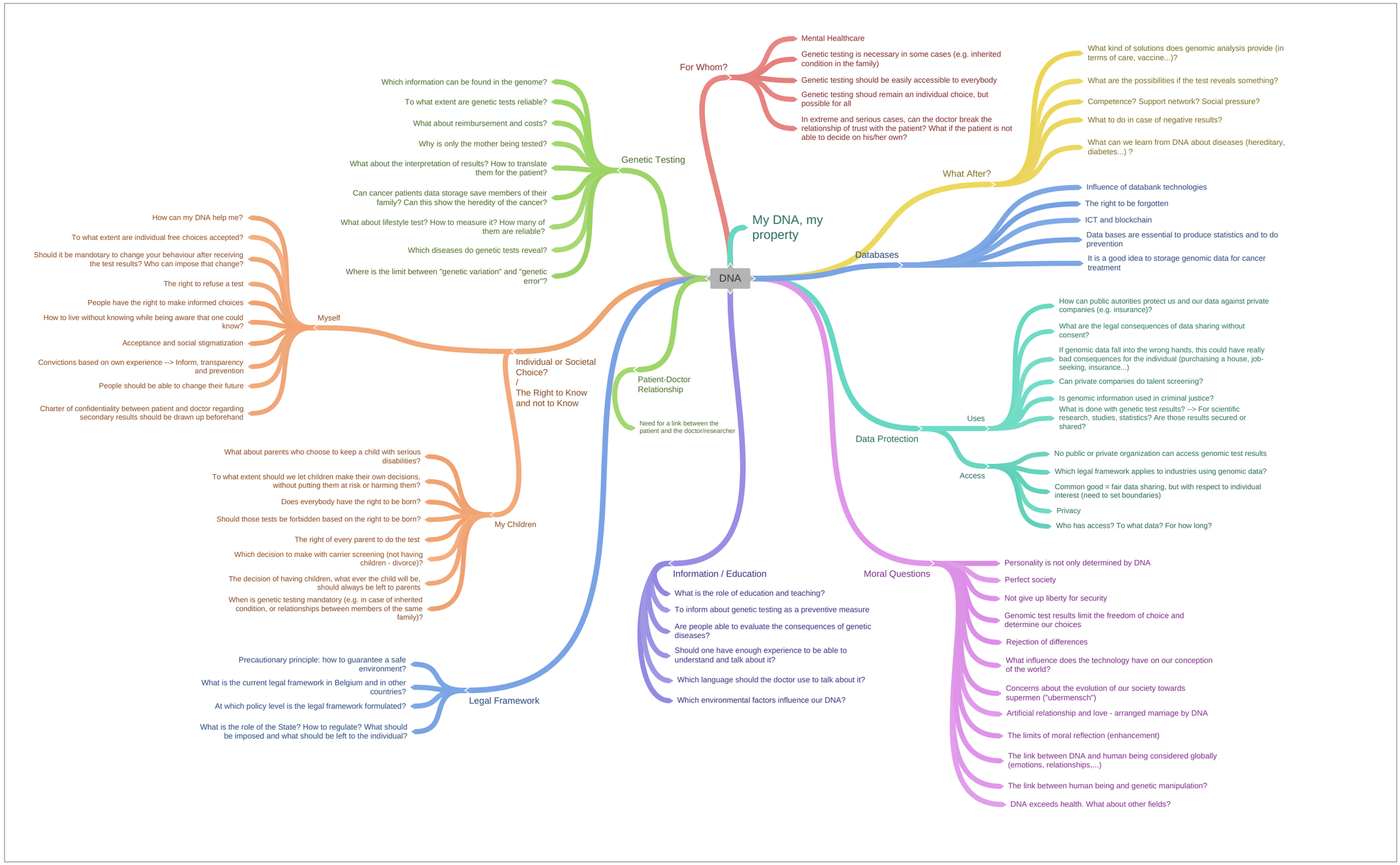
ANNEX 1



ANNEX 1

ANNEX 2

CITIZENS' PRESENTATION

"MY DNA, EVERYBODY'S BUSINESS?"

What do citizens think about the use of genomic information in health care

This citizens report[1] was presented by the participants of the citizen forum "My DNA, a matter that concerns everyone?" to the minister of Health and Social Affairs Maggie De Block on 2 December 2018.

32 citizens participated in the citizen forum. They discussed the use of genomic information in healthcare during three weekends: 15 and 16 September in Antwerp, 20 and 21 October in Charleroi and 30 November, 1 and 2 December in Brussels.

GENERAL CONTEXT

Evolving healthcare in an evolving society

- The traditional healthcare paradigm was focused on the treatment of ill people.
- For some time now, new technologies have entered healthcare, such as big data, health apps and health devices, genomic technologies, etc. Because of these evolutions, we expect great changes in the way we will organize healthcare.
- How will the healthcare system deal with these changes?

The impact of this evolution on the concept of 'patient'

If a genomic analysis shows that someone has an increased risk for a certain condition, is this person, from then on, a patient, a pre-patient, ...?

- All citizens agree that it is important to define the categories of patients and/or pre-patients with clear criteria. This definition should neither be too broad or general nor too limited. Also, the rights and duties of these categories of people should be defined.
  - Some citizens think that once a person calls upon the healthcare system to receive care/ treatment/services, that person becomes a patient.
  - Other citizens think that a person is only a patient at a specific time and in the specific interaction with a healthcare provider. When I visit a cardiologist, I am a patient in a specific relation with this cardiologist but I am not a patient in general.
  - Some citizens think that everyone should be free to decide whether to be considered a patient or not.

The responsibility of society

It is important to consider the responsibilities of society towards these groups of persons/(pre-) patients. What are these responsibilities?

- Recourses for prevention/treatment should be provided to persons with a high genetic risk.

1 The citizens' report was presented to the minister as a PowerPoint file. This file was integrally copied to this document. Only linguistic corrections have been made. This presentation was created by the citizens themselves and validated by every member of the panel, but it does not reflect a pure consensus, nor is every opinion always explicitly mentioned.

  - If we offer a test, we should also offer prevention, care and/or treatment to these persons.
  - Data and information about these persons should, whenever possible, be used for societal wellbeing (by use of research and/or diagnostic tools).
- Who is paying for the prevention or treatment of this group?
  - How should we treat persons who have an increased risk but no symptoms yet?
  - The majority of participants think that society should finance the tests and subsequent treatments. Others suggest that people should pay for this themselves.
  - Is there a need for a "financial paradigm shift" in the new model of healthcare? Is there a need for new ethics? For new responsibilities? For new financing?

Changing roles of healthcare providers

How does the role and work of the clinician change and what will be the impact on the clinician-patient relation?

- When using genomic tests, various experts and healthcare providers must collaborate as a multidisciplinary team. Besides their specialism, every healthcare provider should be able to treat the patient in a good way and to deal with their circumstances. This does not imply that all healthcare providers should be trained coaches but they should have sufficient mastery of these skills.
- In this evolving healthcare with its evolving care relations, we feel a need for new mediating persons and translators. These functions and roles might be described as bridging functions, wellbeing coach, director of care, etc.
- A quite obvious person to take up this bridging function is the general practitioner (GP). The clinical curriculum should pay sufficient attention to ethics and worldview.

Multidisciplinary approach

- Genomic research should be organized using a multidisciplinary approach in which various disciplines collaborate.
- The results of genomic research should not be interpreted merely from a biomedical perspective, but also from a broader societal perspective which emphasizes a "bio-medical-psycho-social" approach.
- Since genomic research reveals new insights on public health and health risks, other researchers besides medical specialists should be involved, such as sociologists, psychologists, epidemiologists, health economists, ethicists, etc.
- A Council of Experts (cf. infra) should translate the results of genomic research into, on the one hand, legal guidelines and actions and, on the other hand, public clinical practice.

THE COMMON GOOD

Sharing genomic information

We want to share our genomic information if it serves the common good

- We define common good primarily as scientific research, conducted according to the rules of art, which enables us
  - To better understand the human species, so we can build an opportunity-loaded and just society that maximally encourages personal development and fulfilment.

- To organize prevention and treatment in a targeted way, so everyone has equal chances to a healthy life.

- It should be ensured that data are only used in this context.

The use of genomic information

We think that the use of genomic information

- Should not be a ground for social, economic and legal discrimination (for instance, access to insurances or jobs).
- Should not be used for the development of war instruments or arms.
- Should not result in the reduction of human diversity or societal diversity, neither on a global level nor on a regional level.

We think that in the use of genomic information, the Human Rights should be respected at all times *(*an excerpt from the charter of Human Rights was added as an attachment*).

Stimulating data sharing

We expect the government and society to maximally encourage citizens to share their data for the common good.

- We do not think that people should be forced to share their data. There are two possibilities:
  - Or I am free to share my data and I am stimulated in this activity by the government.
  - Or it is a moral duty to share my data and hence, my data are automatically shared. Nevertheless, I do have the right to decline this data sharing.
- One participant thinks that, on behalf of the common good, data sharing should be an obligation without any individual and free choice.

Regulation and control

We strongly advocate to regulate and control the sharing and use of genomic information.

We differentiate several possibilities:

- Genomic information should be collected in a European database in the interest of scientific research.
- Belgium commits itself to the avoidance of every possible abuse (controlled on a national level)
- Belgium concludes bilateral agreements with organizations and countries with which data are shared.
- The GDPR is used as a framework for the use of genomic information.
- An international organization is responsible for the good use of genomic data and the control over data sharing and data use.

AUTONOMY

My DNA, my property (cf. privacy)

My DNA is mine; it is my property, so I can decide independently whether I have a genomic test or not, what I would like to know or not, what I do with this information, etc.

- In general, there is a need to raise awareness among the general public about the existence of genetic tests and their possibilities and limitations. People should not be fully informed about these tests but they should pay more attention to the existence of these tests and an interest might be created.
- Raising awareness about genomic tests is important to avoid a trivialization of genomic tests and to make people realize the impact of genetics on their lives and in our current society. People should learn to ask "the right questions" about genetics.

Information as a prerequiqite for autonomy

To guarantee the autonomy of the (tested) individual, it is essential that this person is not only aware of the existence of genomic tests but does also realize the details concerning:

- What this test entails.
- What this test can mean for one's personal life, family and future. When required, this person can be stimulated to already talk about this with their family.
- Possible interventions and treatment
- How, when, by whom and to whom the results of a genetic test will be communicated.
- The costs and potential reimbursement of the test.
- This information should be provided by the clinician (GP, gynecologist, pediatrician, geneticist, etc.) who demands the test. In case of very complex and specific tests, the clinician may rely on a genetic counsellor.
- All information/advice should be provided in laymen's terms, a sufficient amount of time should be spent on this consult and additional information should be used and provided (brochures, decision aids, websites, patient organizations, ...).
- For all of this, clinicians should be educated and informed about when and how to correctly provide information and how to adequately consult people.

Written informed consent

People should be sufficiently informed about and give a formal and written informed consent for genetic and genomic testing.

- People should consent explicitly.
- Before testing, people should receive information about the scope of this test and about the possibility of treatment for the disease risks that can be detected.
  - Similarly, people decide for every test what they do and do not want to know, also concerning secondary findings[2].
- Finally, people decide about what will happen with their data, especially concerning the accessibility and use of these data. To whom may these data be given? Who has access to these data and under which circumstances (e.g. for further scientific research)?

Dynamic consent - dynamic compliance

Knowing that people can change their minds about health issues, people should always be able to recall their decision, whatever it is.

2 During the citizen forum, no difference was made between incidental and secondary findings.

- The clinician should regularly verify whether the agreement is still relevant and whether the participant wants to change their consent - especially at times when results are reported.
  - The majority of the participants think that the clinician should always, without any exception, ask for informed consent.
  - Others, however, think that under specific circumstances the clinician has the right not to respect a person's wish not to know. This right applies to situations where a test reveals a predisposition for a severe yet treatable condition that requires urgent intervention. In this case and when it concerns hereditary conditions, the clinician is also allowed to inform family members for their best interest and wellbeing.
- Some participants think that if people request a test but decide not to know the results or not to act on the results, they should pay for this test themselves.

Acting on test results

People should be free to decide whether and how they act on test results (whether they accept treatment or not), irrespective of the specific results.

- People should not be obliged to follow treatment or to preventively change their behavior. People with a high disease risk cannot be forced to take preventive actions.

Inclusion in the Global Medical File

Genomic data should be included in the Global Medical File.

- To guarantee the quality of the information and to avoid unfounded diagnoses, unjustified reassurance, and abuse, most participants think that genomic data should only be accessed by medical professionals and institutions (hospitals, GPs, specialists, etc.). Only medical institutions can allow access to genetic data.
- Others, however, think that the person concerned should easily have access to their data since they are the only owner of these data.
- Finally, participants think that these data should not be accessible for other actors such as health insurers, etc.

Limits to self-determination

A person's autonomy to decide whether to take a genetic test can be limited under specific circumstances.

- In case of legal coercion (especially for the recognition of parentage), in case of suspicion of a crime, etc.
- When people are no longer able to consent (coma, Alzheimer's disease, etc.).
  - In these cases, it is necessary to take into account people's perspective, if they have previously expressed this in a written document.
  - Otherwise, it is up to the family, the custodians or who is responsible for the person concerned to express their opinion.
  - Otherwise, it is up to the clinician who supervises the person to express their opinion.

ACCESSIBILITY

Accessible for everyone

Genomic tests for medical reasons should be accessible and possible for everyone

- Genomic tests should be accessible for everyone, with or without prescription, if they have a medical reason (including reasons for mental health).
- If (despite the request of a person who thinks they need a genomic test) the treating physician declines the request for a genomic test, it is recommended that this person (as usual) consults another physician for a second opinion. Therefore, this person should receive the prescription for the test, the relevant information, the necessary support and the right to reimbursement.
- The person who requests a test should be able to launch an appeal to a multidisciplinary committee (this could be the same committee that decides on the criteria for reimbursement).
- When someone chooses to do a test on their initiative for medical reasons, this will be possible under the same circumstances (for instance in the same laboratory) as someone who is tested on prescription.

Prescribing a genomic test

Routine genomic tests (NIP-test, heel prick test, etc.) can be prescribed by a GP or by a treating specialist. In case of rarer or more complex tests, the GP or specialist should refer the person to a genetic counsellor.

- This counsellor should:
  - Be specialized in the use of genomic tests.
  - Be able to talk in laymen's terms.
  - Have a multidisciplinary perspective.
  - Use a psychological approach to inform and counsel persons in the most suitable way.
- This counsellor should be easily accessible (easy and quick access) and should be able to spend a considerable amount of time with the person (longer consultations, etc.).

Criteria for reimbursement

When a physician prescribes a genomic test, this test should be reimbursed following the criteria determined by the Board of Experts (cf. recommendation on "legitimacy")

- If a person is tested on their initiative, the test should not be reimbursed. This applies to the test in itself and not to a potential treatment if the test would reveal disease or a higher risk for disease: this follow-up treatment should be reimbursed under all circumstances under the rules applicable.
- Some participants think that a partial reimbursement could be possible when this test would be valuable for research, statistics, etc.
- Other participants suggest that, when a non-prescribed test is followed by treatment, this test may as well be reimbursed.
- There are no arguments for the reimbursement of recreational testing.

Personalized and centralized counselling

From the moment the test results are available, the patient must be counselled by one central person.

- In all cases (routine tests, rare tests or more complex tests), the person who prescribes the test (GP or specialist) receives the results and reports them.
- If a disease is identified, a central contact person should be available to support the patient. In some cases, this should be the GP, in other cases, this should be a genetic counsellor.
- Why the GP?
  - Because he/she knows the patient quite well and has a trust relationship with the patient.
  - To realize this option, a sufficient amount of GPs should be available, so they can spend a sufficient amount of time with every patient. Additionally, these GPs should attend an additional, specialist course.
- Why a genetic counsellor?
  - Some participants think it is more suitable for persons to be supported by a genetic counsellor since this counsellor has specific competences and skills. This is especially useful when the test revealed a genetic illness with a severe impact or when there is a family risk.
- In both cases and if required, both the GP and genetic counsellor can call for the assistance of various specialists or others.

PRIVACY

My genome is mine

My genome is mine, even in a world where everything is (apparently) shared and commercialized. This attitude is important since my genome covers more than my health and vice versa; what defines me, is more than my health and/or the potential illnesses that are discovered in my DNA. My DNA is a way of identifying me and exactly therefore, it should be my choice what happens with this DNA.

- Primarily, it should be my choice what I would like to know about my DNA but it certainly should also be my choice with whom I want to share my DNA and for which purposes.

Trust is the foundation

The confidential use of my genomic data is crucial.

- To share my data, I need to be sure that my trust will not be compromised.
- Great risks arise when my genomic data become available to persons/organizations against my will. The availability of my genomic data can negatively impact my future possibilities or it can infringe on my freedom. Genes should not determine people's future and fate.
- Therefore, it is important to prohibit every way of discrimination based on a person's genomic information.

Prohibiting some from accessing genomic information

The majority of participants want to legally prohibit access to genomic information to those who are in a dominant position (banks, employers, insurers, etc.).

- A minority of participants do not agree because they think this conflicts with the idea of being the owner of one's genomic information.

- In everything I do or want to be, I want to be considered a person and not an aggregate of data.

privacy statement

We expect everyone who uses or has access to our genomic data, to respect our privacy. These persons should be bound by an obligation of confidentiality and they should subscribe to a privacy statement. This must be strictly controlled (see below) and violations must be sanctioned.

essential prerequisites

Some essential prerequisites should be met to be able to choose whether we want to make our data available for various purposes (e.g. research):

- We should be sure that the organization/actor to whom our data are accessible, can be trusted. This should be realized using quality controls and certification (ISO, etc.). Quality controls should, at least, check whether privacy statements and rules regarding transparency are respected. Also, the quality of storage (anonymization, the encryption of data, stress tests of servers, the unique repository on a central server, etc.) should be verified.
- Traceability and transparency: we should be notified of where our data are located and stored, who holds it, who has access to it and who has used/requested data and for which purposes.
- We want to stay informed about the results that are achieved through the use of our genomic data.
- Every time they want to use our data for other purposes than those to which I initially agreed, I should have the opportunity to revoke my permission and opt-out.
- If I – for whatever reason – want to delete my data from the central database, this should be possible at any time, but without undermining the permissions and authorizations that were already given.
- It was suggested to include different categories concerning the use of genomic data in the consent form, so people can indicate to which categories they consent and to which they don't.

Critical remarks

Some citizens expressed some critical remarks regarding the prerequisites that were discussed.

The importance of always being able to let your genomic information be deleted, also for authorizations that were initially given.

The idea that "my genomic information is mine" was contested.

Some citizens suggest the reverse idea, where someone's genomic information can be used for generally accepted applications, except when the person concerned explicitly refuses.

LEGITIMACY

Genomic tests as established and accepted technology and the legal framework of genomic tests

Council of experts

A multidisciplinary and pluralistic Council of Experts (including for instance geneticists, scientists, ethicists, etc.) should decide on a list of criteria grounded on therapeutic utility to justify the use and reimbursement of DNA tests. These criteria should be dynamic and anticipate to scientific progress.

Potential criteria are therapeutic utility (curing a disease, reducing the life-threatening risk, reducing psychological suffering, etc.), increasing quality of life, reliability, etc.

- Genomic science increasingly affects society. In this complexity, the Council of Expert should guarantee fundamental human rights.
- Various ideologies and cultures should be represented in this Council.
- The Council should be in touch with what happens in society and should regularly consult citizens.
- We suggest that there is a need for a clear system: revision of the criteria, accreditation, and control of the laboratories, etc.

Who decides about testing

A reimbursed genomic test in a medical context should be prescribed by a physician who makes sure that the request meets the fixed criteria. When a test is not prescribed by a physician, people can have a genomic test by themselves, for which they also pay themselves. In case of non-reimbursed genomic tests, there should be the possibility to have this test reimbursed by the Council of Experts.

- If people are not allowed to ask for a non-reimbursed test in Belgium, this creates the risk of people buying/using tests abroad which are not verified.
- Also in case of non-reimbursed tests, assistance by a physician is recommended.

legalization

The authorities concerned should adjust legislation in accordance with scientific progress and in deliberation with the Council of Experts. This way, the common good and the protection of vulnerable populations will be guaranteed.

- Genomic tests are associated with various fields of the jurisdiction (health, prevention, wellbeing, ...). Therefore, legalization should be coherent across the different fields and levels of policy in Belgium.
- Belgian jurisdiction should be an example of agreements on a European (EU) and global (e.g. WHO) level.
- Legislation should be able to flexibly react to rapid evolutions in science, and both nationally and internationally.

Legislator, I beg your pardon?

New legislation should be translated into concrete situations and should be explained in laymen's terms to all stakeholders that are involved in genomic testing: citizens, physicians, researchers, lawyers, ...

- It usually is impossible for citizens and patients to estimate the impact of specific laws in healthcare and privacy on their daily life.

- Moreover, they notice that also physicians and researchers find it difficult to be sufficiently informed about new legislations and to correctly estimate their impact.

Diversity is primordial

Reducing the diversity of the human species can never be the purpose of genomic research or genomic tests.

- Nevertheless, it may be an effect of individual decisions. The right to choose is a fundamental Human Right.

The forensic context

The use of genomic tests in a forensic context should always follow the instruction of a lawyer.

Suspects cannot invoke their right to privacy for the verification of their identity.

CONTACT

Chloe Mayeur • T+32 2 642 55 73 • chloe.mayeur@sciensano.be
Wannes Van Hoof • T+32 2 642 56 97 • wannes.vanhoof@sciensano.be

MORE INFORMATION

www.sciensano.be

Sciensano • Rue Juliette Wytsmanstraat 14 • 1050 Brussels• Belgium
T +32 2 642 51 11 • T presse +32 2 642 54 20 • info@sciensano.be • www.sciensano.be

Responsible editor : Christian Léonard, Managing director • Rue Juliette Wytsmanstraat 14 • 1050 Brussels • Belgi