



Human Brain Project

**Citizen's view on data protection and privacy in research projects
Portugal**

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EXECUTIVE SUMMARY

This report summarizes the results of the citizens meeting on data protection and privacy in research projects held in Lisbon at the Centro Cultural de Belém, on the 6th February 2016. The meeting was attended by 33 participants (17 women and 16 men), selected to reflect as much as possible the demographic diversity in Portugal based on the Census 2011. Participants debated and answered a set of 19 predefined questions relating to the topic under discussion, subsequently they interviewed each other and finally came up with a list of pressing issues and recommendations.

From the analysis of the outcomes of each of these activities it emerges that the majority of the participants agrees on sharing anonymous personal data for medical research. However, they express great concern about the possible misuse of the data. Not all participants consider anonymisation a safe mechanism of data protection, but for most of them the common good that might derive from medical research should prevail over individual interest. Usually, the idea of common good is associated to public and non-profit organizations. Many citizens would feel more comfortable in sharing their data if they received detailed and clear information on how it is used, for what purposes and by whom. Feedback on research outcomes is considered a form of compensation for sharing data, while the possibility of citizens being able to track their personal data is seen as an important component of data protection. Although, there was no consensus on the best type of consent, citizens agreed that consent is an important instrument for taking free and informed decisions, and some participants expressed the view that they should be asked for informed consent even when data is anonymised.

Citizens recommended the establishment of an independent organization with the function of regulating and controlling collection, access and use of data. They suggested that data protection should be regulated by an international legal framework, and that there should be more and clearer information about the use of personal data in scientific research.



1 INTRODUCTION

In February 2016, the Human Brain Project (HBP) hosted citizen meetings in Austria, Bulgaria, Poland, Portugal, the Netherlands and Sweden. The HBP citizen meetings were set up to provide the public with an opportunity to reflect on issues related to privacy and data protection in research projects, and to provide their ideas and opinions directly to the researchers and managers of the HBP. The present report is one of 6 country reports detailing the result of the national meetings. The results of all six citizen meetings will be collected in a main report and delivered to the researchers and managers of the HBP project. The reports will also be made publically available.

The report first gives a brief overview of the context of Portugal, before proceeding to the results.

1.1 PORTUGAL

The aim of this report is to analyze citizen's perception of data protection and privacy issues in research project. The goal is to provide HBP researchers and management with input they can use to plan the design of data collection and processing procedures in the HBP. We will begin with providing some basic information about Portugal.

Portugal is on the western side of the Iberian Peninsula and is the westernmost country of mainland Europe. In addition to continental Portugal, the country includes the archipelagos of Azores and Madeira, which are autonomous regions of the country. Considering the Census of 2011 the country had a population of 10,562,178 (52% female, 48% male)¹. It is a semi-presidential representative democratic republic. Its capital and largest city is Lisbon and the official language is the Portuguese.

In 2015 Portugal's estimated nominal Gross Domestic Product (GDP) was of the order of 197.510 billion USD (total) and 18,983 USD (per capita). In the same year, the estimated Purchasing Power Parity GDP was of 288.553 billion USD (total) and 27,734 USD (per capita).² In the second quarter of 2015, the services sector contributed with 76.7% of Gross Value-added (GVA) and employed 67.8% of the population. Industry, construction, energy and water represented 21.1% of GVA with 24.2% of employment, while agriculture, forestry and fishing generated only 2.2% of GVA with 8.0% of employment. In the last decade Portuguese economy has been characterized by the diversification of services and a significant change in the specialization of its industry, with a substancial growth of electronics, energy, pharmaceutical industry, ICT and telecommunication sector.³ Within the services sector, tourism plays a relevant role, accounting for nearly 15% of the total

¹ National Institute of Statistics.

http://censos.ine.pt/xportal/xmain?xpgid=censos2011_apresentacao&xpid=CENSOS

² International Monetary Found, December 2015.

³ <http://www.portugalglobal.pt/EN/Biblioteca/Documents/PortugalFichaPaisIngles.pdf>



Portuguese exports of goods and services, and showing a steady growth (+12.4% between 2013- 2014, + 12.2% between the first half of 2015 and the same period of 2014).⁴

According to the Organisation for Economic Co-operation and Development's (OECD) Main Science and Technology Indicators (MSTI), in 2011 Portugal's Gross Domestic Expenditure on Research and Development (GERD) was 1.46% of GDP, with 45.11% of Research and Development (R&D) expenditure financed by government, 44.72% by industry, 7.48% by other domestic sources, and 6.03% by sources abroad. 47.39% of R&D funding was performed by the business enterprise sector, 36.39% by the higher education sector, 7.38% by the government sector and 8.84% by the private non-profit sector.⁵

In 2008, according to the European Observatory on Health Systems and Policies, 65.7% of the total health expenditure was covered by public funding and 34.4% by private funding (non-profit institutions, voluntary health insurance, out-of-pocket payments and minor other sources), with out-of-pocket payments accounting for 83.4% of private expenditure.⁶ In Portugal the Ministry of Health coordinates all health care provision and financing of public health care delivery system,⁷ which consists of a network of public and private providers, each of them connected to the Ministry of Health in its own way, with different agreements with respect to their financing flows. In 2014 the total expenditure on health was 9% of the GDP.⁸

Similar to other Member States of the European Union (EU), Portugal's legislation about personal data and data protection is based on the European Directive 95/46/EC (currently under revision) and on European recommendations. According to Portuguese law, medical data belongs to the data subject, and as medical data processors, all health system units must guarantee data confidentiality, grant the safety of databases storage systems, control data access and ensure professional code of conduct by professionals with access to personal data. Health units must prevent illegal data access by third parties by implementing protection measures envisaged by the law, and health information can be used only according to the terms specified by the written consent of the data subjects or their representative. If anonymised, health data can be provided to third parties for scientific research.⁹

The Portuguese data protection authority, Comissão Nacional de Proteção de Dados (CNPd, National Data Protection Commission), has the mandate to supervise and monitor the

⁴ <http://www.portugalglobal.pt/EN/Biblioteca/Documents/PortugalFichaPaisIngles.pdf>

⁵ OECD MSTI database, 2011 figures. See http://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB

⁶ http://www.euro.who.int/__data/assets/pdf_file/0019/150463/e95712.pdf. In 2007 the total expenditure on health was 9.4% of the GDP and public payments covered 69.8% of total expenditure.

⁷ http://www.euro.who.int/__data/assets/pdf_file/0019/150463/e95712.pdf

⁸ National Institute of Statistics | Portdata, February 2016,

<http://www.pordata.pt/Portugal/Despesa+corrente+em+cuidados+de+sa%C3%BAde+em+percentagem+do+PIB-610>.

⁹ Law 12/2005, 26th January, Personal genetic information and health information.



compliance with data protection laws and regulations at the national level and to collaborate with international bodies to guarantee trans-border data protection. The CNDP is an independent body formed by seven elements. The president and two members are elected by Parliament; one member of each is designated by the Government, Superior Council of Magistracy and Superior Council of the Attorney General. Among its functions the CNDP has the authority to approve, investigate and examine the gathering and use of citizens' data, and in case of non-compliance or misconduct it can publicly penalise data processors, order the elimination or destruction of data, and cancel, temporarily or indefinitely, processing of data. Whenever an organization, institution or company wishes to collect and process citizens' data, they must request permission stating the purposes for which the data will be collected and providing specific information about the context of the data collection. Under extraordinary conditions, the CNDP can authorize the use of personal data for purposes different from those used for collection, as well as data linkage and international data sharing. It has also the mission to promote and evaluate codes of conduct, foster dissemination of information about data protection, and ensure the citizens' right to access, rectify, update and in some cases eliminate their data from databases.



2 RESULTS FROM THE QUESTIONNAIRE

On the 6th February 2016 a citizens meeting on data protection and privacy in research projects was held in Lisbon at the Centro Cultural de Belém. On the day of the meeting 33 Portuguese citizens debated and answered a set of 19 predefined questions relating to the topic under discussion, they interviewed each other and finally came up with pressing issues and recommendations. The participants were selected to reflect as much as possible the demographic diversity in Portugal based on a reference sample previously built on the basis of 2011 Census by the national team¹⁰ working for the activity *European wide views on Sustainable Consumption*¹¹ under the PACITA European project¹².

The variables considered for the participant's selection were gender, age and education (Table 1). Relatively to the different age groups, the presence of citizens illustrates what initially was projected by the reference sample, with the exception of the group younger than 30, which was underrepresented. It was at the level of education that the biggest deviation from the reference sample was observed as there was an overrepresentation of participants with a high educational level. Considering 2011 Census and a sample of 33 participants, 21 participants of low educational level (ISCED 1-2)¹³ should have been present instead there were 3 citizens. In contrast, there were 16 participants with a high educational level (ISCED 5-8) instead of 5 citizens, and 14 participants with an intermediate educational level (ISCED 3-4) were present instead of 7 citizens. Regarding gender, the composition of the participants' group matched the reference sample, with 17 women and 16 men. A total of 11 participants worked in health care, ICT, science or in the government/public sectors, 10 were retired, and 7 were unemployed.¹⁴ Only two citizens were students. Two participants were members of patients associations, the Support Association for Patients with Depression and Bipolar Disorder and Portuguese Association of Bariatric Patients, but only the participant of the latter was an active member.

¹⁰ Almeida, M., Castro, L., Freitas, C., Durão, E., Relatório Nacional Consulta Pública sobre Consumo Sustentável, Lisbon 2015:<http://www.itqb.unl.pt/science-and-society/pacita/Relatorio%20Nacional%20Consulta%20Publica%20sobre%20Consumo%20Sustentavel.pdf>

¹¹ European Policy Report: <http://www.pacitaproject.eu/wp-content/uploads/2015/02/EWViews-Report-Final-WEB.pdf>

¹² <http://www.pacitaproject.eu/>

¹³ Educational levels as defined by the International Standard Classification of Education (ISCED). See <http://www.uis.unesco.org/Education/Documents/isced-2011-en.pdf>

¹⁴ In the enrolment form, 9 rather than 7 participants indicated that they were unemployed.



| Educational level | Gender | Age (years) | | | | |
|--|--------|-------------|-------|-------|-------------|-------|
| | | 18-29 | 30-39 | 40-59 | 60 or older | total |
| Low educational level (ISCED 1-2) | Men | 0 | 0 | 0 | 0 | 0 |
| | Women | 0 | 0 | 1 | 2 | 3 |
| Intermediate educational level (ISCED 3-4) | Men | 0 | 3 | 3 | 3 | 9 |
| | Women | 0 | 2 | 2 | 1 | 5 |
| High educational level (ISCED 5-8) | Men | 1 | 1 | 3 | 2 | 7 |
| | Women | 2 | 1 | 5 | 1 | 9 |
| Total | | 3 | 7 | 14 | 9 | 33 |

Table 1: Characterization of citizens according to gender, age and educational level.

2.1 VIEWS ON THE MEANING OF PRIVACY

The results obtained in the questionnaire indicate that 45% (corresponding to 15 participants) choose to define privacy as “My ability to choose what information about me is shared with third parties”, while 30% (10) consider it “Transparency in how information about me is being used”.¹⁵ Regarding what the participants consider to be private data, 64% (21) answered the addition of all the options provided which included health status, political and religious views and activities.¹⁶ About the compromise between privacy protection and research the opinions are divided with 36% (12) of respondents answering that high levels of protection should be required only for some types of data; 24% (8) consider research to be more important than privacy protection; 15% (5) do not feel that their personal data needs specific protection, and only 6% (2) of participants answer that the protection of privacy is more important than research.¹⁷

2.2 VIEWS ON DATA PROTECTION

Considering the issue of data protection, more specifically, how personal data should be protected, 30% (10) of participants answer that “data should be anonymised, and an ethics committee should also review if the protection is adequate”, whereas 18% (4) would like to be asked for informed consent every time researchers would like to use their data, even if the data has been anonymised. In contrast, none of the participants chose the options considering broad consent or data not needing to be protected.¹⁸ Focusing on anonymisation as a possible tool for protecting personal data, 24% (8) of the participants answered that it is not an

¹⁵ Corresponding to question 6.

¹⁶ Corresponding to question 15.

¹⁷ Corresponding to question 9.

¹⁸ Corresponding to question 7.



adequate protection of personal data, while 18% (6) agreed that it is, and 21% (7) was not sure.¹⁹

2.3 VIEWS ON DATA COLLECTION AND DATA USE

The issue of data collection was featured in the question of who should legitimately collect personal information, with 39% (13) of participants opting for “Public institutions for research purposes” (48% if we consider also the answers of the 3 citizens who selected more than one option). On the other hand, none of the participants opt for the options according to which “business for profit purposes” or “industry to develop non-health services” could collect personal data of individuals. Note that this was the question with the highest percentage (12%) of participants wishing not to answer.²⁰

Considering whom should be able to have access and use personal data, 58% of participants (19) chose “both public organisations as well as private industry can use my data for research, but they should be strictly controlled for living up to the latest anonymisation standards and an ethics committee should review all procedures”. In contrast, 18% (6) opted for “only publically funded organisations and institutions may use my data for research, but they should be strictly controlled for living up to the latest anonymisation standards and an ethics committee should review all procedures.”²¹

Regarding participants’ main concerns on the use of their data for research, it appears most of them, 73% (24) are worried that their data might be used for personal or financial gains instead of scientific progress.²² To answer the question on how the data may be used, 18% (6) of participants chose more than one option. If the multiple choices are taken in to account, the options most voted were “if my data is anonymised it may be used for anything researchers deem appropriate” with 36%, followed by “if my data is anonymised it may be used for any research project that I have agreed to have it used for” with 27%. Only one participant opted for “My data does not need to be anonymised and can be used as researchers wish to use it.”²³ By taking into account the consequences of data being shared, 64% (21) of participants consider that others (e.g. family) could potentially be affected by the use of their data.²⁴

2.4 VIEWS ON INFORMATION ABOUT DATA ACCESS

Considering the issue of availability of information about the use of individuals’ personal data, 82% (27) of participants indicate that they do not feel informed enough about who has

¹⁹ Corresponding to question 16.

²⁰ Corresponding to question 17.

²¹ Corresponding to question 8.

²² Corresponding to question 12.

²³ Corresponding to question 18.

²⁴ Corresponding to question 13.



access to their data and in what it is being used for,²⁵ furthermore 94% (31) of participants do not know where they can obtain more information about the use of their data in research projects.²⁶ The need for more information seems to be one of the main reasons that led participants to join the meeting with 49% (16) answering that they thought that joining the HBP meeting was a good occasion to learn more about data protection and privacy issues.²⁷

When participants were questioned about the qualifications scientists should have to be able to process personal data more than one option was selected and with opinions divided. 27% expect scientists to keep them update about their research, while 18% expect that their data will not be used for any other research that was not agreed to, and another 18% expect to be informed if scientists find information about possible illness(es).²⁸ (confirm the results, differences on the data obtained from us and DBT)

2.5 VIEWS ON THE BACKGROUND MATERIAL AND QUESTIONNAIRE

Concerning the background material, 70% of participants (23) found that the information booklet gave a good overview of issues related to data protection and privacy in research.²⁹ However, one participant commented that “there was a lack on definition of concepts” and that “the context was presented, but all the possible users of patient medical and clinical data were not identified”.

Regarding the questionnaire, 67% of participants (22) considered that the questions matched well with the information booklet, although there was 6% (2) who found it too hard (in fact, one of these participants did not answer the majority of questions). Some (2) commented that certain questions could have different answers and others (2) found questions to be unclear or not well framed.³⁰

²⁵ Corresponding to question 10.

²⁶ Corresponding to question 11.

²⁷ Corresponding to question 4.

²⁸ Corresponding to question 14.

²⁹ Corresponding to question 5.

³⁰ Corresponding to question 19.



3 THEMES FROM THE GROUP INTERVIEWS

3.1 THE MEANING OF PRIVACY

In general the participants at the Lisbon meeting did not discuss directly the meaning of privacy. However, in the question list of one of the tables for the group interviews there was a question regarding the concept of privacy. The answer of one of the groups to this question was twofold³¹ as it was suggested that privacy could have a negative and positive definition. The negative definition considers privacy as protection of personal data, avoiding its exposure and limiting its accessibility. While, the positive definition associates privacy to the possibility of always being informed about where and for which purposes personal data is used. One participant specified: *“It is impossible to keep our data private. We should at least know where it ends up and have the possibility to track it down.”* On a similar line, in another group, one participant stated: *“I think that citizens should always be able to have access to their data. I must know how my data is being used at any time, to know what image they are giving of me and to be able to correct them.”*

3.1.1 What is personal data

During the discussion and group interviews participants did not address directly the concept of “personal data” or exact identification of what should be considered as “personal data”. However, one of the groups put forward a question to find out what was the opinion of participants on personal data. One of the answers to this question suggests that maybe the concept of personal data is not as clear, one participant stated “ [one can make] a *distinction between personal data and data that can be used for something, for instance medical research.*” It was also mentioned that *“there is a fine border between what I consider to be personal and what do I want to share for medical research”*.

Despite the possible uncertainty regarding the concept of personal data, by analysing the notes and audio recordings of the participant discussions it was inferred that protection of personal data is considered to be essential for participants. It is also worth noticing that in the questionnaire 64% of participants answered with the most comprehensive option (including leisure activities, political and religious views, health status and friends) to the question on what they consider about themselves to be private.³²

3.1.2 Reflections on consequences of misuse, who is affected/how

The citizens present at the meeting did not discuss the possible consequences of data misuse, even though they expressed awareness and concern about it. In the discussion of the most pressing issues and proposal of recommendations,³³ all groups expressed concern about the

³¹ The other group with this question in their list did not answer discussing instead whether it should be possible to access medical data using citizens ID number.

³² Question 15. See Section 2.1.

³³ See Section 4.



possible misuse of their data. It can be speculated that since the issue of privacy and data protection is seldom treated by the Portuguese media, and information about this topic is very limited,³⁴ citizens are not completely aware of the direct possible consequences of data misuse, and how they might be affected.

3.2 PROTECTION OF PERSONAL DATA

All groups discussed the issue of personal data protection and data anonymity, for example, one participant stated: *“as a rule, all data should be protected by anonymisation and could be made public only with the authorization of the data subject.”*

In general, citizens seemed concerned with the possibility of their data being traded and used for purposes they had not agreed on. Many expressed mistrust in the ability of institutions to keep data protected, as it was observed that *“[personal data] is easily accessible through new technologies.”* Another participant stated: *“As soon as we provide our personal data, it is stored somewhere and it could be stolen. From the moment we make our data available, we run the risk that it is used for purposes which are different [from those we had agreed on].”*

One group expressed the idea that although data protection is described and understood as a technological problem, the real issue is ethical and dependent on the code of professional conduct. Technological protection can always be breached, and if those who have legal access to databases do not behave ethically, technological protection is not useful. One group considered data protection to be related with citizens giving authorization for data use and being able to control their use, although participants admitted not having control on their data, more specifically, on the data that are shared.

3.2.1 Views on anonymisation

From the analysis of the discussions and interviews it results that, in general, citizens agree that data should be anonymised since anonymization is seen as an important mechanism for data protection (e.g. from commercial interests or data being transferred). However, when faced with the question of whether they feel protected when data are anonymised one group answered negatively. In another group a participant remarked that it is always possible to identify an individual by combining different sets of data. The participants seem to consider that anonymization techniques do not ensure total protection.

It was also suggested that research participants should be given the opportunity to decide which data about themselves they are willing to share or keep private. One example is of a citizen that stated: *“Depending on the kind of disease I have, I might wish or not to have my data anonymised. Actually, I might wish not to share my data at all. For instance, if I had AIDS and hypertension, I might wish to share my data on hypertension, but not on AIDS,*

³⁴ Questions 10 and 11. See Section 2.4.



independently of anonymisation. Preliminary information is fundamental. To know what kind of research will be done with my data.” Another citizen stated that although data should be anonymised the option of providing data not anonymised should be agreed by citizens on case to case basis.

3.2.2 Perspectives on consent

During the interviews citizens did not explicitly introduced questions or discuss the issue of consent and different types of consent, but along the debate participants referred to the need of them being able to provide authorisation for their data to be used and the relevance of having an informed consent. However, in the following debate over the most pressing problems and related recommendations they defended contrasting positions on whether informed consent should be required when data is anonymised.

3.3 ACCESS AND USE OF PERSONAL DATA IN RESEARCH PROJECTS

In general participants considered their data to be important for medical research and said they were willing to share it since the common good should prevail over the individual interest. However, most of them stressed the importance of keeping data anonymous and preventing data misuses. There were some participants ready to give up some of their privacy for the interest of research but this was not a widespread view.

Several citizens highlighted the importance of receiving adequate information about the institutions that use their data and the type of research being conducted, so that they can decide if they are willing to share their personal data. One participant claimed: *“The citizen has to say how and until which point his data can be used. It might be used for this but not for that. The citizen should have the possibility to choose which information he wants to share and which one he wants to keep private.”*

3.3.1 Attitudes towards the use of private data

“Information” on the nature of the research projects and their outcomes, and “choice” on whether to provide one’s personal information were frequent words in the answers to questions regarding the use of personal data, as can be seen in the following quotes: *“It is fundamental to have information about how the data will be used and about the entity that will use it.”* – *“I think I’d be willing to donate my data for medical investigation if I knew what the objectives of the research are and if in the end I was informed about its outcomes.”*

Participants expressed concern about the lack of guaranties that data will not be used for other proposes beyond research and one observed that *“(…) who does what? Who controls what? Who keeps this data, what will it be used, there should be more transparency in relation to all possible uses [of data]. There is no guarantee that the databases do not escape (?) For purposes that were not foreseen.”* Therefore, different groups discussed the need for a tight



control of the institutions/entities that collect and use data as well of the ones that have access to the data. Views on who should be in charge of such control, however, diverge. For some it should be a public institution, for others it should be a private non-profit organisation, in order to ensure its independence from political pressures. Participants agreed that it should be an organization that has no political or financial interests in the data that it is supposed to protect.

3.3.2 Perspectives on consent

For the majority of participants informed consent is perceived as an important instrument for the protection and control of personal data. However, they expressed frustration with the language used in medical consent forms (e.g. informed consent for diagnostic procedures) and pointed out that both the quality and extent of information provided is poor. It was referred that the lack of clear information hinders the possibility to take genuinely informed decisions.

Considering the type of consent on the use of personal data in research projects, there was not a consensus among participants on whether it would be better an informed, dynamic or broad consent, as each one of these options had its supporters. For one participant *“Broad consent is the best option. We give the authorization for different types of research. If we are aware that it is done for improving, for a global benefit then we give the authorization for all the researches, we are open to that.”* But according to another citizen *“people must be informed as the studies proceed, even if this might makes the operability of research more difficult. I think they should always ask me for consent.”* Note that although during the debate and in the final recommendations some citizens seemed to be in favour of broad consent, in the questionnaire none of the participants chose broad consent as an adequate form of data protection.³⁵

3.3.3 Who may have access to personal data

In general, the participants consider that medical doctors, researchers and scientists could access their data, if they work for institutions certified by the State, supported by ethical committees and supervised by external auditors who should ensure that data protection norms are enforced. Some citizens maintained that only public institutions should access the data, however it seemed to prevail the position that, as long as data is used for medical research, and thus for the common good, then both public and private entities could be granted access. Usually, the idea of common good was associated to public and the non-profit organizations.³⁶

There was a widespread concern about the ethical accountability of institutions (both public and private) that access and use citizens’ data. To tackled this issue was suggested the creation of ethical committees and independent agencies for data protection assessment and supervision. One group pointed out the issue that data protection is a complex and difficult

³⁵ Corresponding to question 7. See Section 2.2.

³⁶ This is consistent with answers to Question 17. See Section 2.3.



matter because data is stored in digital clouds, has monetary value and can be legally accessed by different entities: *“Nowadays with digital clouds, which are private, it is very difficult to know what happens with our data, it can always be decoded. It is sensitive information, it has economical value. From the moment this data can be converted into money, many questions arise. Sensitive information should not be stored in the clouds. It is very difficult to guarantee [data] security, especially when there are several entities involved, because everything is up to the ethics of each organization.”*



4. RECOMMENDATION

OVERVIEW ON THE ISSUES AND RECOMMENDATION FOR EACH TABLE

| Table 1 (blue) | |
|--|--|
| Pressing issue | Recommendation |
| Need of supervision and control of all institutions collecting and handling citizens' data. | Existence of an ethical and independent organization that works as a supervisor and regulator. It should include representatives from non-profit civil society organizations. The organisation will “ensure that data is used for the good of humanity”. |
| Education and training of those who collect, handle and use citizens' data is not a guarantee of data protection. | Creation of a mechanism that eliminates data not necessary for scientific research (name, address, parentage), without possibility of retrieval. |
| Lack of information about the relevance of personal data for scientific research; and need to encourage citizens to donate their data. | Both public and private entities should be able to use citizens' data for research. However, the research should have a positive impact on the cost and benefits of health care for society. |
| Need of a legal framework. | International and transversal regulations supported by international institutions such as the United Nations (UN) and World Health Organization (WHO). |



| Table 2 (yellow) | |
|--|---|
| Pressing issue | Recommendation |
| Harmonization of European rules and norms. | There should be harmonization of European rules and norms on data protection and privacy in research projects. |
| Supervision of data use. | All institutions that have access to citizens' data (collection and use) should be monitored. The supervision should be carried out by an external and independent organization. |
| Definition of rules for the protection of data and privacy in research projects. | Rules for data and privacy protection in research projects should be defined by a large group of actors and stakeholders: citizens, scientists, medical doctors, jurists, and ethicists. |
| Informed consent versus dynamic consent. | There should be a gradual transition from informed consent to dynamic consent. Although the main issue with dynamic consent is on how to involve people who do not have access to the Internet or are not able or willing to use it. |
| Citizen's compensation for having contributed with their data for scientific research. | Citizens should be informed about the results of the research studies on which their data was used. A monetary compensation could take place if the results of the research generate profits. However this type of compensation was considered to be too complex to put in place. |



| Table 3 (green) | |
|------------------------|---|
| Pressing issue | Recommendation |
| Anonymisation. | Reliable procedures for anonymization of medical data should be ensured. European legislation should support harmonisation on data anonymization in the EU Member States. |
| Consent. | On the issue of consent views were divided between broad and informed consent. On the issues of informed consent on anonymised data there were two different views: <ul style="list-style-type: none">– anonymised data can be used in scientific research without informed consent;– even for anonymised data citizens should provide informed consent for data to be used. |
| Data collection. | On the issue of data collection opinions diverge between two points: <ul style="list-style-type: none">– data can be collected in databases and used by researchers as long as anonymization is consistent;– further analysis of the issue will be required, as databases can be used for other purposes different from those considered initially. |
| Legal framework. | A European referendum, to survey the opinion of citizens, should be conducted on the development of a legal framework on issues of data protection and privacy in research. The legal framework should include mechanisms to monitor the protection and use of data stored in medical databases (e.g. legal consequences for misuse of data). |



| Table 4 (white) | |
|---|---|
| Pressing issue | Recommendation |
| Information on the institution collecting data. | Citizens should be provided with information regarding the institution collecting data including the type of institution, the purposes for collecting data, and the general and specific aims of the research. This information will support citizens on the decision to share or not their data. |
| Financial compensations to citizens for sharing their data. | Citizens should be financially compensated or by others means when sharing their medical data. |
| Consent. | Consent should be informed and clear. Citizens should be informed on the option of having support from an independent person when receiving information regarding consent. |
| Supervision of data use. | Establishment of an organization that ensures compliance with anonymization standards. The organization should be non-political, non-partisan and autonomous from external influence. |



| Pressing issue | Recommendation |
|---|--|
| Data protection, security and guarantees to the data donor. | To improve and enhance transparency on the legislation related to data protection providing clear legal consequences for data misuse. Definition of a European framework to be adopted by all Member States. |
| Data access in case of a crisis. | In the specific case of a crisis the common good should prevail over the personal interest. However, the access to databases should be controlled by the State. The institutions or researchers who are given access to the database can use the data only in relation to very specific problems. That is, the access to databases must be well defined and limited. On this basis it will be decided which data can be accessed by researchers. |
| Storage and protection of citizens' data. | Public organizations should be responsible for storing and protecting citizens' data and providing information on third parties with given access to medical data. Citizens should have information on the aims and type of research that data will be used. |
| Financial compensation. | There should be no financial compensation for data donors, except in the cases of risk for the data donor. In this context the possibility of a financial compensation for data donors should be taken into consideration. |
| Donor's consent on data access. | Data donors should always be informed on the use of their data. |



| Table 6 (orange) | |
|---|---|
| Pressing issue | Recommendation |
| Misuse of data. | To fight situations of data misuse there should be heavy penalties, with suspension of activities when applicable and right to compensation by the affected party. There should be a declaration of interest that specifies when, for what purposes and by whom data are used and analysed. |
| Regulation of organizations and data users. | A code of conduct for data users, similar to those of other professions, should be established with clear guidelines and penalties in case they are not thoroughly complied. |
| Information to data donors on the use of their data | Information about the development of research studies should be provided to citizens whose data is used in research. Citizens should have access to their data and be able to withdraw it at any time if it is being used for research not covered by consent. |
| Guarantees about data use. | To establish a system that ensures that data is used for scientific research and progress in health, and not to provide a profile of citizens to private institutions, in particular profit driven organizations (insurance, banks, financial groups, etc.). |

SIMILARITIES ON THE ISSUES AND RECOMMENDATIONS BY THE DIFFERENT GROUPS

By analysing the discussion of the most pressing issues and recommendations of the citizens present in the Lisbon meeting (divided in six groups), five issues stood out: (1) regulation and control of data use, (2) definition of an international legal framework for data protection and privacy in research projects, (3) consent, (4) information about the nature and aims of the organizations that can access and use data, and (5) data donors compensation.

- 1) All groups expressed concern about the possible misuse of data and emphasized the need to create a system of regulation and control of organizations and individuals that collect and use data. For most of the groups, such control should be carried out by an independent organization while one group recommended that organizations and data users should follow and respect a professional code of conduct. Furthermore, three



groups suggested the legal establishment of penalties for organizations and individuals which have misuse data.

- 2) Four groups considered essential the existence of a legal framework that regulates data protection and privacy in research projects, and it was also specified the need for harmonization of European rules. One group also suggested the organization of a referendum to find out the opinion of the European citizens about data protection and privacy in research projects. One group suggested that the legal framework should be defined at the international level by the UN/WHO.
- 3) Four groups identified consent as a pressing issue, although, their specific concerns and recommendations were diverse. Two groups discussed what would be the best type of consent: one considered the possibility of a gradual transition from informed consent to dynamic consent, while the other suggested the option of broad consent. On the other hand one group stated that consent form should be written in a simple and clear language, and information from an independent party should be provided to data donors. While another group specified the importance of consent as an essential condition for the use of data, with citizens always informed on how their data is being used. One group considered the issue of informed consent on anonymised data and two opposing positions were present: those who considered that even for anonymised data informed consent should be provided and those that anonymised data can be used by researchers without informed consent.
- 4) Three groups explicitly addressed the issue of having information on the nature and aims of the organizations that collect, access and use data, on the research for which data will be used and on the development and results of the research studies. All groups agreed that citizens should receive clear information that should support citizens on the decision to provide or withdraw the use of their data in research projects.
- 5) Three groups dealt with the issue of compensation for citizens whose data is used for scientific research. One group agreed that compensation should be given by providing information to citizens on the results of the research; another group suggested that there should be financial or then other type of compensation (not specified). Another group expressed that there should not be a financial compensation, unless it exists some real risk for the data donor.



5. CONCLUSIONS

In the Lisbon citizens meeting on data protection and privacy in research projects one of the main issues of discussion was related to whom can access data and how personal data should be protected. Participants expressed great concern about the possible misuse of data, especially about the possibility of data being used for personal or financial gain instead of scientific progress. The great majority of participants agreed with the view that personal data needs to be protected and organisations, both public and private, which collect, access and use data must be controlled and supervised by an independent body above political and financial interests. Citizens agreed on the need of international regulations on data protection and privacy.

A widely shared opinion was of medical doctors, researchers and scientists being able to access personal data on the condition of working for institutions certified by the State and under the supervision of ethical committees and external controllers who ensure that data protection norms, including anonymization, are enforced. Not all participants consider anonymization a safe mechanism for data protection, but for most of them the common good that could derive from medical research should prevail over the individual interest. In general the idea of common good was associated with public and non-profit organizations.

Information was another topic of debate. The majority of participants agreed that there is a lack of information on how, for what purposes and by whom personal data is used. Many citizens would feel more comfortable in sharing their data if they received detailed and clear information on how it is used and by whom. Most of participants would also like to be informed about the results of the research on which their data has been used, and such feedback is considered a form of compensation for sharing data. Consistent and clear information on citizen's data and the possibility to track it down was considered an important component of data protection.

Finally, on the issue of consent, although there was no consensus on the best form of consent, citizens agreed that it is an important instrument for protecting their right to take free and informed decisions on the use of their data. Participants also considered the issue of consent regarding anonymised data with some considering important to give consent even for anonymised data.

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6. ANNEXES

Please provide us with the filled in questionnaires.