Linking, analysis and use of biological and health data
National Bioethics Commission of México

1. As part of the efforts to foster bioethical criteria in health affairs, Mexico´s National Bioethics Commission (CONBIOETICA) participates in local and overseas activities to promote ethical and legal tools of data protection and to enforce the current guidelines in this area.

2. We consider health data protection is essential to preserve human dignity and to prevent discrimination and stigmatization against both individuals and communities. Hence, CONBIOETICA has included health data protection as a main issue of its agenda.

3. We are aware that current realities of ours countries require effective legal and ethical guidelines. Consequently, CONBIOETICA is pleased to participate with Nuffield Council on Bioethics in this consultation.

Background

4. In Mexico the right to personal data protection is contemplated in our Constitution since 2007. Nonetheless the Federal Law of Transparency and Access to Public and Governmental Information (LFTAIPG) issued in 2002, which is mandatory for the public sector. The Federal Law of Personal Data in Possession of Individuals is addressed to the private sector with access to this kind of information. Both are the main legal instrument on this matter.

5. The Federal Institute of Access to Public and Governmental Information and Data Protection (IFAI) is the authority in charge of the surveillance of the suitable accomplishment of the Law on this particular aspect. Recently, IFAI has become into a constitutional independent organization able to supervise the respect of democratic principles of transparency and personal data protection.

6. Additionally, health data are protected by guidelines that, without the binding character of laws, are guides for behavior for those engaged in the safeguard of this information. Among these guidelines we may find the General Letter of Patient´s Rights, which was issued by the National Commission of Medical Arbitration (CONAMED), and the Health Personnel Code of Conduct, issued by the Federal Secretary of Health. The aforementioned establishes valuable ethical standards, such as those which instruct a deep respect to

professional secrecy, avoiding contemptuous comments about the personal life of patients, as well as the public mention of medical and social issues related to them. Also, the Health Personnel Bioethical Code, which establishes that all people -not only doctors- that have access to clinical records, are responsible for the confidentiality of the information contained in them.

7. In Mexico, health data are considered by law as sensitive information. The Mexican legal framework defines sensitive data as those that could affect the most intimate sphere of the owners, or those that could cause discrimination or serious risk for them. In particular, law considers sensitive information such as racial or ethnic origin, present or future health status, genetic information, religious, philosophical and moral beliefs, union membership, political views, and sexual preferences.[1]

8. Although health information in Mexico is protected using the general legal framework of data protection, sanitary law specifies some particular rules mainly regarding of confidentiality. Particularly, there is a special focus on topics like organ transplantation, genetic information, human research subjects, patients with mental disabilities and clinical records.

9. Despite Mexican sanitary regulation and ethics criteria are each time more and more detailed, there are some aspects of health data protection that are controversial. The main problems regarding basically on how properly balance principles of confidentiality, privacy and professional secrecy. Some examples can be found in areas such genomics, health research, biobanks and health insurances. This has shown that health information requires special necessities of regulation.

10. As a general principle, personal data treatment is limited by owner´s consent except as stated in law. Some of the exceptional circumstances are:

- If the information is on public records of open access.
- If there is a requirement of judicial, administrative or sanitary authorities.
- If there is some illness that has to be epidemiologically monitored.
- If the treatment of sensitive data are necessary for medical assistance and there are no options for the owner to give his consent.

11. Last exception has been pointed as an extremely general rule. For that reason, some experts consider health data treatment do not have adequate restrictions to properly

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[1] Federal Law of Personal Data in Possession of Individuals, article 3, V.

ensuring privacy and confidentiality. This also points the problem to find the balance between individual and collective well-being.

14. CONBIOETICA considers the lack of specific criteria about appropriate treatment of biomedical data should be covered by bioethical reflection in order to promote the respect of human dignity. The role of bioethics is essential to achieve not only an adequate legal framework, but also to generate awareness about the responsibility of each person who is in charge of health data protection.

Consultation questions

1. Do biomedical data have special significance?

Q. Is it useful (or even possible) to define biomedical data as a distinct class of data? If it is, what are the practical and ethical implications of different ways of defining this class?

> R. We believe that biological data could be considered as a distinct class mainly because it possible usage and interpretation that could be given to it in the future is still unknown. For this fact we consider is necessary prevent some unethical implications may arise.

Q. What factors contribute to the belief that personal biomedical data deserve special protection? Does the sensitivity of biomedical data depend entirely on context or do biomedical data have special attributes that make them intrinsically more sensitive than other kinds of data?

> R. As we stated before, is the fact that the probable usage of these kinds of data is still unknown. We believe health data need a special protection since that information is related with people´s privacy. Also, this kind of data reveals certain aspects that could produce discrimination to the owners of the data, his family or his community.

Q. How are changes in the scope of the data in use providing meaningful insights into individual biological variation and health?

> R. The changes in the scope of the data in use to provide helpful information into individual biological variation, health but also disease, are critical in taking into account the protection and privacy of the individuals from which the data was collected.

Q. Do some sub-sets of biomedical data (such as genomic data sets) present particular ethical challenges or offer ethically important benefits?

R. We believe the prospective of development of the field of genomics represents at this time a great hope but also an ethical concern. However, if certain principles are taken into account and specific measures are included, genomic data and other types of biological information may be for individual and collective gain.

Q. To what extent should genomic data sets be regarded as belonging to one individual and to what extent should other interests (e.g. of family members sharing genomic sequences) be recognised? What implications might this have for consent to collection of such data, for feedback concerning the data and for its broader use?

R. We believe that at this point in time it is for the individual to decide. Individual genomic data are considered by Mexican legal framework as a property of each person.

2. What are the new privacy issues?

Q. Do new information technologies and 'big data' science raise privacy issues that are new in kind or in scale?

R. We believe new privacy issues by new information technologies are new in kind, but not in scale, since all the privacy issues form old and new technologies should be considered at the same scale.

Q. What are the implications for individual anonymity of linking data across large numbers of databases?

R. We think that the individual anonymity implications could be significant. However, there are several considerations and actions that could be used to ensure that the anonymity of individuals would be safeguarded.

Q. What is the 'public interest' in biomedical data? What benefits do we want to obtain? In what circumstances might the public interest take precedence over individual and minority group interests?

R. The public interest in biomedical data should be centered mainly in the common benefits that could arise from it. However, it is important to do so in such a matter that it will not diminish or severely harm individual and minority group interest, particularly form vulnerable populations.

Q. What are the actual harms we should seek to avoid in using biomedical data (e.g. discrimination, stigmatisation)? What evidence is there of these harms having occurred?

> R. Besides using biomedical data for discrimination or stigmatization as is previously mentioned, we believe that it should be avoided the use of such data for corporative gain, instead of a general social benefit.

Q. In what ways does it matter if people's data are used in ways of which they are unaware but that will never affect them?

> R. It matters because it affects their autonomy and the basic principle that they need to decided what could be done with their information. Furthermore, the individuals have to decide by themselves what can affect them or not, especially take into account that these data could be used in the future.

Q. How are applications of computer-based technology (e.g. social networking, image sharing, etc.) affecting concepts of privacy, identity and social relatedness? How related behavioral norms are influenced (e.g. willingness to share and publish data)?

> R. It is clear that computer-based technology applications are affecting the concepts of privacy, identity and social relatedness. For instance, knowing the people that we are interacting with is no longer necessary, the veracity of the information shared cannot be trusted, and people are becoming prone to interact with machines instead of people.

Q. Would it be helpful to treat biomedical data as 'property'?

> R. We believe that it should be treated as property of the individual from which it was collected.

3. What is the impact of developments in data science and information technology?

Q. To what extent and in what ways has the availability of biomedical data and new techniques for analyzing them affected the way in which biomedical research is designed and funded? Is there any evidence that these factors have affected (or are likely to affect) research priorities?

> R. It is inevitable that when a new technology develops and with it a great potential to redefine the way in which heath and disease are perceived, it comes with many changes that include priorities and with it funding an opportunities, the key aspect to

consider in such scenario, is not to diminish other research priorities that should be attended at a local, regional and global context.

Q. What are the main interests and incentives driving advances in data science and technology that can be applied to biomedical data? What are the main barriers to development and innovation?

R. From a Bioethical point of view, as with other aspects of science, the main interest and incentive should be to generate knowledge that would be useful to better the conditions of humans and other living creatures in the planet. The main barrier are the great opportunities for economic gain that implies, these creates an environment where development and innovation is carried out exclusively if an economical profit is foreseen, and excludes or limits other areas of development.

Q. Does 'big data' need a more precise definition or is it a useful concept in the life sciences even if loosely defined? Has enthusiasm for 'big data' led to over-inflated expectations on the part of governments, researchers and/or the general public?

R. We believe the concept "big data" should be expanded and explained.

Q. What are the significant developments in the linking or use of biomedical data, including any we have not mentioned, to which we should pay attention in our deliberations?

R. Possible, to make emphasize that the use of biomedical data should be for a collective benefit.

4. What are the opportunities for, and the impacts of, the use of linked biomedical data in research?

Q. What are the hopes and expectations associated with data use for biomedical, public health and life sciences research? What are the main concerns or fears?

R. The main hopes and expectations are a better and faster way to diagnose, treat, and prevent diseases. The main concerns and fears are that the implementation of these technologies will generate new means of segregation and discrimination.

Q. To what extent do the kinds of collaborations required for data-driven research (e.g. international or multi-centre collaborations) generate new ethical and social issues and questions to those in other forms of research?

R. The extent of cooperation required for data driven research generate new ethical and social dilemmas, regarding privacy and confidentiality, but also associated with intellectual rights and property of the data, and the interpretations of it.

Q. Should researchers be required to allow others to access data they have collected for further research?

R. Only if the individual from whom the data was collected agreed, and an ethics committee has approved such request for a valid protocol.

Q. What sorts of concerns are raised when research is carried out by a commercial firm?

R. It generates several conflicts of interest, and there is the risk that scientific knowledge will become a corporate mean, instead of public benefit.

5. What are the opportunities for, and the impacts of, data linking in medical practice?

Q. What are the main hopes and expectations for medical practice associated with increased use of linked electronic data? What are the main concerns or fears?

R. The main hopes and expectations are a better and faster way to diagnose, treat, and prevent diseases. The main concerns and fears are that the implementation of these technologies will generate new means of segregation and discrimination.

Q. What can be said about public expectations about the use of health care data, in terms of appropriate use, information and control? To what extent would members of the public expect health care data to be shared with other agencies or bodies?

R. We believe that the public expects that health care data will be treated with absolute confidentiality. This information cannot be shared with other agencies or bodies except as stated in law.

Q. Is there potential for privacy controls to hide secrets, such as abuse, or to disadvantage people in unintended ways (by preventing best treatment, perhaps)?

R. We believe not, if these privacy controls are set up properly, and each case is analyzed carefully, to detect exceptions.

Q. Are there particular issues raised by 'risk-profiling' where individuals at high-risk (e.g. of type 2 diabetes) are identified and approached for specific interventions? What might make the difference between this being intrusive and it being supportive?

> R. It depends on the needs and expectations of each individual and in the matter that he/she decided its data should be use.

Q. What are the implications of episodes of treatment across different care providers being used routinely as research data? How might this affect the ethical basis of the doctor-patient relationship?

> R. If the doctor properly explains to the patient these circumstances and obtains a valid consent from him, there should be no ethical affectation.

Q. To what extent does the possibility that biomedical data can contribute to a research base to advance the effective treatment of others create a moral obligation to allow them to be used in this way? What might limit this obligation? How should we regard (and provide for) those who refuse to allow their data to be used?

> R. There should be no obligation, and we have to regard and provide for those who refuse to allow their data to be use, in the best of our abilities. Participation should be on the basis of mutual acceptance.

6. What are the opportunities for, and the impacts of, using biomedical data outside biomedical research and health care?

Q. What are the main hopes and expectations associated with the wider use of biomedical data (outside biomedical research and clinical practice)? What are the main concerns or fears?

> R. Outside biomedical research and clinical practice we do not see any hopes and expectations. However, the main concerns still remain confidentiality, and the possibility for discrimination.

Q. What factors are relevant to determining the legitimate scope of further uses of biomedical data? For example, should it be restricted to a 'compatible purpose' (and, if so, how might this be defined)? To uses that are in the 'public interest'? To use only by public authorities (and those providing public services under contract)? To non-commercial or non-profit uses/users?

R. Again, we believe that at this moment the legitimate uses of biomedical data should be restricted to biomedical research and clinical practice.

Q. What are the ethical implications of using predictive analytic tools with biomedical data outside health care and research (e.g. in recruitment or workforce management)?

R. The ethical implications of using predictive analytic tools with biomedical data outside health care and research relate to the violation of confidentiality, privacy, protection of vulnerable populations, and avoiding segregation and discrimination.

Q. Should individuals be able to profit from the use of their biomedical data (e.g. by selling access to the data to commercial companies)?

R. We believe that individuals should not be able to make financial gains from the use of their biomedical data.

7. What legal and governance mechanisms might support the ethical linking of biomedical data?

Q. What ethical principles should inform the governance of biomedical data? For example, should the principle of 'respect for persons' be given primacy here? How might this relate to principles such as solidarity and tolerance?

R. The ethical principles that we believe should inform the governance of biomedical data are: Autonomy and consent, Nonmaleficence, Respect of Privacy, Confidentiality, Non Discrimination, Intellectual Property and Social Beneficence.

Data protection is considered in Mexico as a fundamental right. Hence it is mandatory for all government institutions to promote, respect, protect and guarantee that Human Right.
On the other hand –as all Human Right– data protection could be restricted when is necessary to preserve collective well-being or when an authority require the information.

Q. Does the use of linked biomedical data require distinctive governance arrangements compared to the use of other personal data?

R. We believe that at this point in time the use of linked biomedical data does require distinctive governance arrangements because its novelty and improper handling in the past.

As we mention above, we consider necessary to build certain rules for the treatment of biomedical data. The legal framework and the ethical analysis need to take into account the challenges mainly regarding health care and research. To achieve this goal, in our opinion, a multidisciplinary analysis that reflects the complexity involved in biomedical data protection is required.

Q. Are the current principles of consent – including the principle that consent can be withdrawn – still 'fit for purpose' in relation to the linking of biomedical data?

R. We believe that the principle of consent it's relevant and fits the purpose in relation to the linking of biomedical data, at several levels, for example consent of the individual that donated the sample, and consent form the researchers and physicians that collected the sample and the clinical data associated with it.

Q. What level of continuing involvement is it reasonable to expect individuals to have in how their data are used after they have been collected?

R. We believe individuals should give their consent for the use of data (present and future) at the time this information is collected, through the informed consent. However, an ethics committee should approve further usage of the data, after it has validated the proper treatment that it will be given.

Q. Should there be an opt-in or an opt-out system for people to decide whether to allow their personal medical data to be used for public benefit?

R. Yes. We consider that aspect as an approach to respect the autonomy of each person.

Q. Under what conditions ought individuals to be content to delegate authorization of the use of health and biological data about them?

R. We believe that the delegate authorization conditions should have the same treatment as any delegation that it is carried out in an informed consent for participating in a research project or for accepting medical treatment.

Q. What role should public engagement and democratic processes play in the determination of governance measures? In what circumstances, if any, might the outcome of democratic procedures mandate overriding individual interests?

R. We believe that the only circumstance in which the outcome of democratic procedures mandate overriding individual interests is to prevent further our gather harm.

Q. What inconsistencies exist in current ethical guidance and governance structures relating to biomedical data?

R. We believe that the main inconsistency relates that most researchers and data collectors think that once the data has been collected it belongs to them.

We consider there are not proper rules for biomedical data treatment. The framework is extremely general to consider the special requirements of health care research and the use of new technologies. Furthermore, it is not clear enough the limits of principles such as informed consent, privacy and confidentiality.

Additionally, professionals of health issues do not know their obligations related with data treatment. This aspect heightens possibilities for an unnecessary damage of the owners of data, and also of their communities.

Q. What examples are there of innovative initiatives that promote privacy while encouraging participation?

R. We don't have any

Mexico's National Bioethics Commission is strongly committed to improve ethical standards regarding health data protection in our country. To collaborate with the Nuffield Council on Bioethics is another step forward to promote the measures necessary to guarantee the defense of human rights related with this matter all around the Globe.

Dr. Manuel H Ruiz de Chávez
President of the Council of Mexico's National Bioethics Commission

Working group: Manuel H Ruiz de Chávez, Simón Kawa Karasik, Ricardo Jiménez Aguado, Sandra Lizbeth Carrizosa Guzmán, Raúl Jiménez Piña, José Manuel Lozoya Pacheco and María de los Ángeles Marina Adame Gayoso.