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ABSTRACT

Ethics

ETHICS, LAWAND POLICYMAKING IN GOVERNING BIOBANKS—THE TIME FOR *ETHIOMICS*

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Modern medical ethics in general, and specifically in regard to genetics, traditionally revolved around individuals and their care providers. Common well-deliberated issues stemming from this perspective include consent to testing and treatment; the right to receive information and the correlative duty of others to maintain confidentiality; or the duty to warn family members of genetic risks. Indeed, genetics is powerfully and widely perceived as a most private, individually-related object—"my personal future diary". Therefore, lacking an individual's consent, a researcher may not conduct research on individual's body or genes. Are these autonomy-driven concepts ("respect for person") rightly applicable to biobanks and population genomics?

In biobanking for population genomics, each individual's contribution means very little, the aggregate is essential. Collective data, shared and relevant to participants as well as non-participants is the new theme to be examined. Thus, it can be argued that the traditional focus on individual rights fails to address this new 'public' subject of research and its interests.

Devising the rights of the population to be considered along with individual's rights must strike a desirable balance between the goals of improving the health of the community and protecting human dignity and human rights. This quest, which follows the transition from genetics to genomics, from proteins to proteomics, should transform traditional, individually centered ethics to what I term *ethiomics.* Some aspects of ethiomics will be discussed, with a special emphasis on the need for creating means for group engagement.

ETHICS IN PREDICTIVE, PREVENTIVE AND PERSONALISED MEDICINE

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Predictive, preventive and personalised medicine is gradually expressing its potential to be accepted by all healthcare institutions, healthcare professionals, politicians, as well as the general public.

Correct and plausible predictions, active and early prevention, and personalised attitude will undoubtedly bring a higher quality of life to the patient and potentially great economical advantages for the entire society. As the concept evolves, it gets more and more evident that from the social and economical point of view it is the only way for the future sustainable healthcare. The patient's rights, however, should guarantee that any preventive actions arising of the predictions are not forced upon the patient or any individual in "pre-patient" condition. The patient's rights should also guarantee that the patient's data cannot be analysed and consequently, the prediction cannot be made, without either prior written consent or any other form of active approval that is manageable with the current information technology.

If informed about the predictive diagnosis, the patient must always be told that the particular prediction is based upon

the latest knowledge available and that this may be refined, or even changed, when new knowledge or data is available and entered into the system. In this way, the patient becomes more involved, motivated and interested in targeted preventive actions that, in turn, may in many cases lead to less stress, better long-term outcomes and better quality of everyday-life even in situations which, otherwise, will be difficult to cope with.

Legislatively and technically, the patient should be guaranteed permission to view his/her own medical records and to check who else, if anyone, has access to his/her medical records, what changes are been made, if any, who authorises access and for what purpose, as well as another possible data logged.

The ethical aspect of predictive, preventive and personalised medicine, of course, must be supported and guaranteed by (a) implementing relevant new legislation, which must be clear and effective enough to eliminate any possibility of misusing the entire concept, and by (b) a regular healthcare education of the public and the professionals. The legislation must pay attention primarily to the health of an individual person, keeping it at the spotlight of the healthcare, instead of favouring public health. As a result we can expect that the overall population statistics, the public health, will improve. No discrimination on the basis of prediction must be allowed under related legislation.

ETHICAL ASPECTS OF PERSONALIZED MEDICINE

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Most of the ethical aspects of personalized medicine are connected with the pharmacogenetics, genetic screening and impact on healthcare. The pharmacogenetics raises following ethical problems:

- the issues of ensuring equality in medical care,
- when genetics predicts patients less likely to benefit from the available pharmacotherapy
- the right to deny an available treatment to specific patient population depending on the information derived from pharmacogenetic studies.

There is a number of serious questions, ranging from consent and confidentiality of the genetic information yielded from the tests to whether the tests should be available over the counter or through the Internet.

There are concerns that pharmacogenetics may cause inequality in healthcare. The ability to sequence an individual's entire genome will enable production of high amount of detailed genetic information, all known genetic predispositions will be available. The ethical issues concerning the access to and use of genetic information will arise.

The development of two technology platforms, namely biobanks and large health records systems are shifting the paradigm in bioethics thinking. Biobanks are important resources in pharmacogenomics in which individual samples may be studied to establish genotype-phenotype relationships between genetic genetic variation, gene expresion, and disease susceptibility or drug response. Biobanks implicate both clinical and research ethics issues in new ways.

Despite general public support for genetic studies including the use of stored tissues to test and designe new medicines, there still remains distrust of efforts to commercialize the results of the genomic research.

There will be several ethical issues for physicians who have to be able to discuss the latest biomarker studies and their implications for the disease management.

On the other side, personalized medicine proposes the new paradigm to limit the rising healthcare costs. If we will be able to make a better use of the accumulating knowledge to chose the optimal approach tailored to an individual, we will be able to save money of ineffective therapies and adverse events. Personalized medicine will bring together the efforts by pharmaceuticals, healthcare provides, patients, insurance companies, researchers and policy makers. Well treated ethical issues should allow for benefits by all parties involved.