BACKGROUND

Several drawbacks of conventional medicine can now find their remedy in the new discoveries and advances in the pharmaceutical field. In recent years, proteomics and genomics have been considered sources of cutting-edge ideas and concepts, which in turn, may become common approaches in individual or population health field. Nowadays, the benefits of progress in pharmaco-genetics become more obvious also in solving problems posed by the inability of conventional medicine for solving problems such as:

• Genetic variations among individuals lead to differences in response to drugs;
• High percentage of lack of efficacy with some medicines;
• High incidence of adverse effects to drugs;
• Evidence-based medicine supports a standardized application of therapy that does not take into account variations of response in individual patients;
• Clinical trials are geared around taking statistical information about the general population of patients and applying it to the individual [1].

CONCEPTS

Personalized medicine1 is the new concept aiming to predict the risk and the treatment of disease on the basis of a person's genetic profile, which would render biologic consideration of race obsolete. But it seems unwise to abandon the practice of recording race when we have barely begun to understand the architecture of the human genome and its implications for new strategies for the identification of gene variants that protect against, or confer susceptibility to, common diseases and modify the effects of drugs [1].

The revolution in medicine related to the concept of "personalized medicine" consists in finding individualized treatment for each patient but also in testing and monitoring its effectiveness. In general terms, personalized medicine is a medical model that emphasizes the systematic use of information about a particular person, in order to select and/or optimize the curative or preventive medical care [2]. Traditionally, personalized medicine used information on family history, social conditions, environment and behavior to determine individualized treatment. But once the human genome was deciphered and multiple possibilities for its analysis to correlate genetic differences between individuals and with different clinical and biological profiles of individuals exist, the personalized medicine term relies greatly on the establishment of a genetic profile of each individual (it is possible by technological advances in areas such as proteomics, genomics, metabolic analysis, genetic testing - textbox 1).

By implementing the concept of personalized medicine, it is expected the patient will be able to know all about the individual's health. Also, by generating genetic maps of individual health and electronic medical records which contains this genetic map (DNA chip), it is presumed that thanks to computer analysis of their health information there will be prerequisites of knowledge or appreciation of: susceptibility to disease; certain behaviors such violence, even criminal; response to certain drugs / therapies etc.

In term of public health, many attempts are linked with the possibility of stratification of individuals according to genetic and metabolic profile so that it could be determined and selected the scheme and even drugs and doses tailored to individual level and for which an individualized treatment determines an effective response. It is about the

1 Specified for the first time in 1998 (as the title of a monograph, "Personalized medicine"), and furthermore found in Medline since 1999 [1]
possibility to personalize the treatment at individual level ("the right medicine for the right patient"), by the individualized diagnosis of a personal profile: differential diagnosis of the disease, genetic predisposition testing and pharmacogenetics.

Textbox 1. Concepts related to personalized medicine

<table>
<thead>
<tr>
<th>GENOMICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genomics is the branch of genetics that studies organisms in terms of their genomes (their full DNA sequences)</td>
</tr>
<tr>
<td>Genomics is a discipline in genetics concerning the study of the genomes of organisms. The field includes intensive efforts to determine the entire DNA sequence of organisms and fine-scale genetic mapping efforts.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROTEOMICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proteomics is the branch of genetics that studies the full set of proteins encoded by a genome; it studies the full set of proteins in a cell type or tissue, and the changes during various conditions, is called proteomics.</td>
</tr>
<tr>
<td>Proteomics is the large-scale study of proteins, particularly their structures and functions. The proteome is the entire complement of proteins, including the modifications made to a particular set of proteins, produced by an organism or system [3].</td>
</tr>
</tbody>
</table>

CURRENT APPROACHES.

In the past 10 years, the term has become one of the favorite topics of the various events in which professionals from different fields related to public health try to shape and determine the role of personalized medicine in improving individual and population health status. In this view, numerous forums, congresses and conferences at national, regional and even international level are and were hosting vast spaces for exposes and debates on this topic.

National context

In Romania, the concerns in recent years demonstrate a growing interest of scientific community, researchers, health care providers and drug manufacturers. Although few in number, the articles and other communications on this topic are designed to inform and raise awareness on the new concepts appearing in the world, and to draw attention to the benefits and problems resulting from the development of this segment. The subject is included in the agenda of scientific events (eg. “Academician Nicolae Cajal” Symposium ) and discussed in scientific articles. Also, implementation of this concept is a target proposed by some drug companies, in order to offer and join both the enlargement of activity’s spectrum and consumers’ needs (e.g.: Pegasys therapy for patients with chronic hepatitis C virus genotype 2 or 3).

International context

In the international context, the concerns on personalized medicine are much more obvious and advanced. Several initiatives and conferences (i.e. legislative action "and Personalized Genomic Medicine", initiated by Barack Obama, the group "Personalized Medicine Coalition "International Conference dedicated to personalized medicine, Haifa, 10th- 11th October 2010 - Appendix 4, Public Health Forum Gastein 2010, etc.) are devoted to medicine personalized, and putting into practice this concept became a current and feasible reality for some developed countries such as USA.

The concept is perceived also as a challenge for Health-care Policy in the European context. The concerns are related to aspects such as: Patient's Hopes & Concerns, Patient Rights, Opportunities & Challenges, Cost of Medicine, etc.

Opportunities & challenges of the personalized medicine at European level

Personalized medicine is a new concept enrolled in the current trend of scientific progress, which derives from the need for valuing scientific discoveries to their full capacity, and that creates a new framework in terms of prompt and individualized diagnosis and treatment to the patient.

Although the concept is rather less discussed and applied in clinic, the current interest on the European level is to develop this sector and implement the concept in clinical practice.

The novelty of this concept leads to a precautionous position of the researchers and even policy makers, but at the same time, to an active one towards a large applicability of the concept; the position of the policy makers is reflected through the concern and interest shown by European organizations having decision-making power at high level .

Thus, the Directorate General of Public Health of European Commission has established, until now,
four rounds of meetings as workshops; by this it created a framework for experts and stakeholders, and thus supported the EC approach in the attempting to promote a new vision for the new decade (2020) that includes personalized medicine as one of the common topics at EU level.

The current approach in this field includes the concern in defining and identifying the opportunities and challenges induced by applying a perspective which is centered on implementation of the personalized medicine into clinical practice.

Even if, the benefits of personalized medicine in terms of efficacy are already proved for some technologies, a lot of intermediate actions must be taken into account to implement and translate the theoretical concept into the current clinical practice.

One of the most recent events such “The 2010 Gastein Workshop (textbox 2) on Personalized medicine” stresses the need of collaboration for action in this field and suggests actions/movements towards aspects such as [3]:

- Research and development;
- Patient involvement;
- Equality and ethical aspects;
- Health care professionals training (professional and ethical aspects);
- Health care systems changed perspectives;
- Legal framework;
- Value of personalised medicine (social, economic, ethical and political aspects) [5].

Value of Personalised Medicine
- Social, Economic, Ethical and Political aspects.

Socially, it obviously appears that the basic issue deriving from a personalized medicine approach of the patient treatment it is represented by the possible stratification of the population into small groups. In this context, it is obvious that the same problems existing for rare diseases could act for such small groups and they are linked with: availability of treatment, affordability to treatment, possible isolation of groups and even stigma, discrimination etc.

Culturality is another aspect that could represent one of the barriers in implementing this concept. It is expected that once the added value of implementation of personalized medicine is demonstrated, the rhythm of implementation and even the acceptance for changes in old behaviors to not be equally sustained by all cultures.

Most of the ethical aspects of personalized medicine are based on pharmacogenetics, genetic screening and impact on healthcare. Also, it is expected that problems linked with insurance to appear as insurance companies may increase their premiums based on the susceptibility data. In this regard, the intervention of the Government must be promptly introduced in order to assure people that all of them will benefit on the long term.

Understanding the social effects of genomics requires an analysis of the ways in which genetic information and a genetic approach to disease affect people individually, within their families and communities, and in their social and working lives. This information will lead to measures for the prevention of stigmatization and discrimination of different populations on ethnic grounds [1].

Economically, a lot of uncertainties are already discussed. It is about of the global cost and individual cost of implementing this concept.

A special attention on financial aspects of personalized medicine could be pay for other important aspects:
How profitable would be usage of personalized medicine for pharmaceutical companies; and how affordable would be for healthcare providers [1].

Being a new stream in the field of public health, the future approaches must be focused on research, economic and impact evaluation of each diagnosis and treatment. We have to put in balance the costs and the benefits of applying personalized medicine at large scale. What benefits (in terms of curability, adverse side effects, money, quality of life etc) and what costs involves such approach? Research will be the necessary support to argue and stay at the basis of decision-making process regarding the application of the new medical procedures.

This requires a high representation and involvement of the HTA (Health Technologies Assessment) experts and institutions with experience in evaluation and comparison of different medical procedures. Even if, for most of the new procedures, the efficacy was demonstrated for selective persons, the approach must be completed by making obvious the economic added value of these procedures [5].

Politically speaking, there are two pillars for discussion:

- on one hand, the evidence shows that Europe is ready to explore and develop personalized medicine domain, accordingly with two important principles of European health systems: health equity and universal access, avoiding throwing out innovation too early based on lack of data at the onset and must to continue in this line;
- EU member states must aim to ensure that personalized medicine contributes to the improvement of population health effectively and efficiently with clear and robust evidence of patient value, and a time frame to develop the data to prove it, by a good collaboration between health professionals and policy makers [5].

Prospects and Limitations of Genetic Testing

Although expectations consecutively to human genome decoding are high, caution is required in the application of methods for which there is no solid scientific evidence regarding the potential beneficiaries and potential adverse events that may occur. The largest reserves are in terms of value of genetic testing in predicting disease.

Nowadays, genomics has a low impact in many therapies, due to the lack of some proper systems for decision based on evidence. One of the obstacles in implementing these tests in clinical units is represented by the lack of multicenter clinical trials arguing genomic tests’ usefulness [6].

Both supporters and protesters of genetic testing consider necessary to continue studying in this field, as long as the prediction of disease involves many factors and the general opinion which was suggested in the 2009 Goldstein Conference is to turn more sharply toward the study of rare variants.

The rapid progress being made through meta-analyses suggests that many more common variants conferring a risk of disease will be identified in the next several years, leading to increasing stability of individual risk estimates. Once risk estimates are more stable, the usefulness of genetic screening will need to be considered for each disease, and recommendations will be for twenty-first century medicine what the x-rays were for twentieth century clinical practice [5].

CONCLUSIONS

As a new approach, personalized medicine must demonstrates, by scientific arguments, that it serves to fulfill the scope of public health in general: preventing disease, prolonging life, and promoting health. The entire society must be engaged and entire population must benefit from results of this effort.

The first echoes are high resounding and policy makers are already sensitized to potential of personalized medicine. As a prerequisite, research must support and stay at the basis of a good understanding of disease mechanism and then, based on these scientific evidence, specific scientific advice must be produced and provided in this field, at European and international level. The efforts must be common and concentrated in many countries, the best solution being represented by establishing and developing networks, partnerships or collaborative structures at European and international level. The effort must be common to all target groups and stakeholders and society and scientific community must be involved.

References

2. CHEN J.Y., XU H., SHI P., CULBERTSON A., MESLIN E.M.; Ethics and Privacy Considerations for Systems Biology Applications in Predictive and Personalized Medicine; Chapter 1; DOI: 10.4018/978-1-60960-491-2.ch001; http://www.igi-global.com/viewTitle.aspx?titleid=52309&sender=e6b21262-3fca-499c-8e37-3f2f2cf1d0be
3. ABHILASH M.; Applications Of Proteomics. The Internet Journal of Genomics and Proteomics. 2009 Volume 4 Number 1