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Research Article

Personalized and Precision Medicine (PPM) as a Unique Healthcare Model to Secure the Human Healthcare and Biosafety: Optimizing the Upgraded Model through The View of Public Health

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Abstract

Policy formation in the field of individual health promotion and protection is one of the priority tasks of national healthcare systems. Canonical health care is becoming increasingly unaffordable in most of the countries, yet it remains ineffective in preventing or effectively treating chronic diseases. The medicine of the XXI century is *Personalized & Precision Medicine (PPM),* by protecting and preserving human health throughout the life. In this regard, an upgraded model of healthcare service, which includes the philosophy, principles and armamentarium of PPM and aimed at identifying the disorder at its early (subclinical) stage, is being created and set up.

PPM focuses on predictive and preventive measures that contribute to the development of individualized strategies for managing a healthy lifestyle that stabilize morbidity rates and can help to improve the working capacity of the population. To achieve the goals of value-based healthcare and the implementation of the PPM concept, it is necessary to combine the assets of the newest advances in basic science, design-driven translational applications with clinical medicine, followed by the introduction and promotion of new generation's translational applications.

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Introduction

Over the course of history, healthcare and thus healthcare philosophy have been focused predominantly on efforts to probe the already diseased individual by focusing down on a type of disorder (***nosology***) rather than on health or so-called pre-illness conditions. Much less effort has been placed on keeping individuals from developing disorders in the first place. PPM is expected to transform this situation giving healthcare professionals of tomorrow much more reliable control over morbidity, mortality and disabling rates, and significantly optimize the cost and efficacy of treatment for those who have fallen ill and already diseased, or are still persons-at-risk. PPM is a name for the grand new paradigm in healthcare management being based first on prevention, pre-clinical detection of the illness, and delivery of drugs to target tissues with exceptional levels of precision [Bilkey GA, Burns BL, Coles EP, Mahede T, Baynam G, Nowak KJ. Optimizing Precision Medicine for Public Health. Front Public Health. 2019 Mar 7;7:42. doi: 10.3389/fpubh.2019.00042; Ashley EA. The precision medicine initiative: a new national effort. JAMA. (2015) 313:2119–20; Weeramanthri TS, Dawkins HJS, Baynam G, Bellgard M, Gudes O, Semmens JB. Editorial: precision public health. Front Public Health. (2018) 6:121. 10.3389/fpubh.2018.00121; Martin-Sanchez F, Lázaro M, López-Otín C, Andreu AL, Cigudosa JC, Garcia-Barbero M. Personalized Precision Medicine for Health Care Professionals: Development of a Competency Framework. JMIR Med Educ. 2023 Feb 7;9:e43656; Alvarez, M.J.R. (2022). Precision Public Health Perspectives. In: Hasanzad, M. (eds) Precision Medicine in Clinical Practice. Springer, Singapore. https://doi.org/10.1007/978-981-19-5082-7_7; Traversi, D.; Pulliero, A.; Izzotti, A.; Franchitti, E.; Iacoviello, L.; Gianfagna, F.; Gialluisi, A.; Izzi, B.; Agodi, A.; Barchitta, M.; et al. Precision Medicine and Public Health: New Challenges for Effective and Sustainable Health. J. Pers. Med. 2021, 11, 135. https://doi.org/10.3390/jpm11020135……..].

The Grand Challenge of Advanced Healthcare Model

Development trends of fundamentally new type of practical health care (personalized medicine) dictate new healthcare requirements. As regard scientific platform, by bringing together post-genome sciences and advanced technological platforms, such as *Bioinformatics* and *Artificial Intelligence (AI)*, in one strong unit, translational medicine (TraMed) is the main resource for creation, introduction and promotion of the new generation's translational applications. In this sense, the primary driving force behind PPM is clearly the basic and translational science. To really understand PPM, we would have to understand the various fields of translational applications that provide the tools to exploit and practice PPM, its different OMICS-rooted tools and genomics tools, in particular! ***(Fig. 1)***.

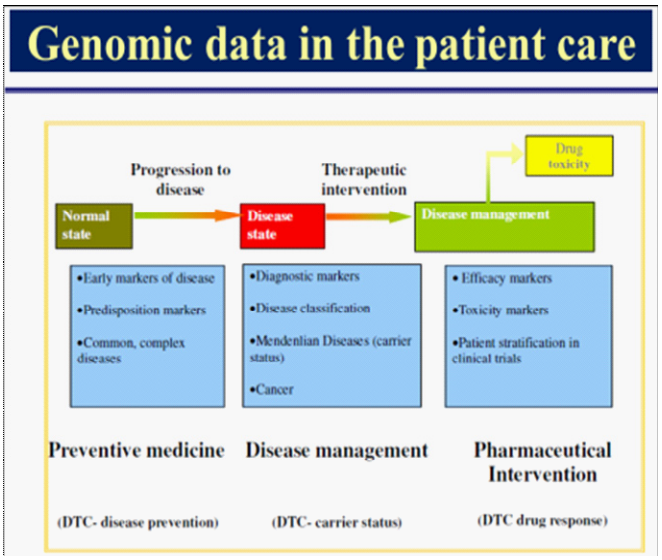
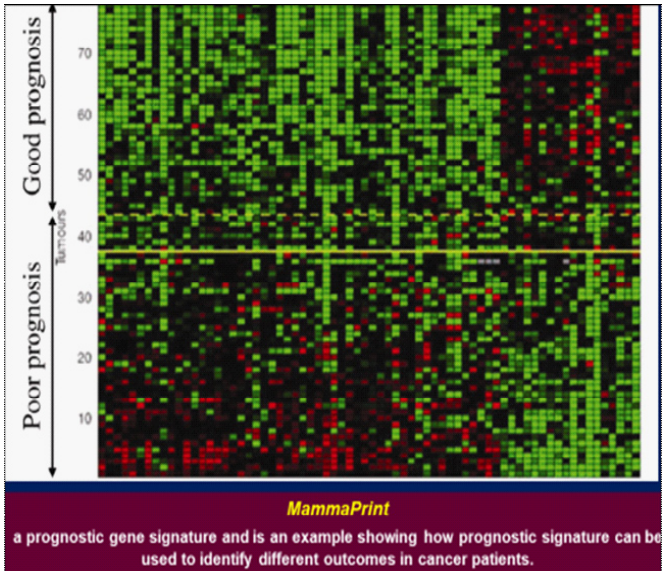


Figure 1. *Value of genomics in patient care*

So, Genomics is considered to be a set of the unique (predominantly, *predictive, prognostic and safety) biomarkers (Fig. 2 A,B)* and thus the molecular tools to probe genome for its quality and now even be tested.



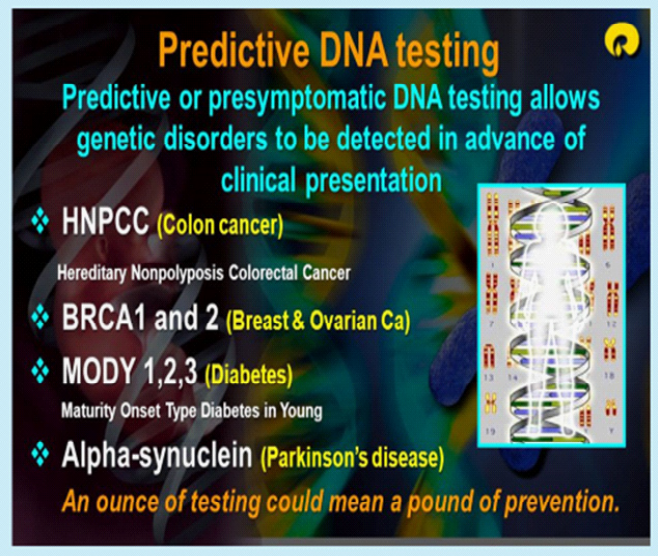


Figure 2. *A-Mamma Print testing; B- Predictive DNA testing*

Advances in the development of genetic tests and biomarker-driven and profile-guided targeted therapies provide the potential to transform medicine and create unprecedented ability for detection, prevention, and treatment of diseases. Therapy approaches based on genetic variants and specific biomarkers have been increasing over the last few decades in association with the increasing availability and affordability of genomic sequencing technology.

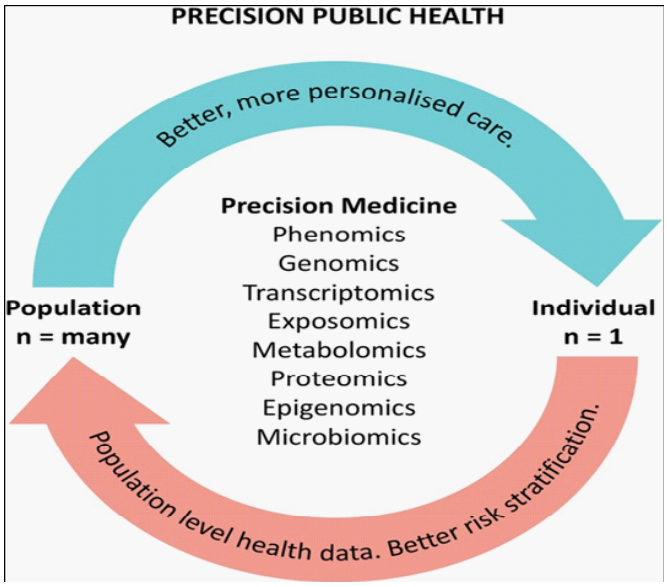


Figure 3. *The PPM-guided OMICS-driven public health cycle*

As the above-mentioned testing and profiling are dependent on the presence of specific biomarkers, they are therefore reliant on companion genetic tests and theranostic [……..]. In this context, there has been growing interest in and advocacy for PPM-related and OMICS-dictated approaches towards optimizing the implementation of PPM-based resources into public health initiatives and daily clinical practice *(Fig. 3).*

The cycle illustrates the benefits of PPM-guided approaches to improving patient care and population health.

A highly functioning PPM-based system will deliver benefits from technologies such as better collective understanding of phenomics, genomics, and other "OMICS-" (such as proteomics, metabolomics, and exposomics) to enable more precise care for individuals. Crucially, our understanding of individual pathologies and biological pathways will also unlock data and knowledge for our population, allowing this approach.

From: Bilkey GA, Burns BL, Coles EP, Mahede T, Baynam G, Nowak KJ. Optimizing Precision Medicine for Public Health. Front Public Health. 2019 Mar 7;7:42.

The development of high-throughput OMICS technologies represents an unmissable opportunity for evidence-based prevention of adverse effects on human health and have important implications for the prevention of chronic diseases, because they can be used to assess the health status during the whole course of life (including the pre-illness states). An effective population health gain is possible if OMICS tools are implemented for each person after a preliminary assessment of effectiveness in the medium to long term. In the future, disease prevention and preventive treatment should be formulated at the individual level according to genomic features. However, a current major challenge is a lack or scarcity of scientific evidence, as well as a lack of ethical, legal, and social regulations.

The production, integration, and use of OMICS-rooted information in healthcare require significant changes in the way such care is organized and provided to individuals. This is also evident in relation to any kinds of pandemics. Therefore, new health policies and specific programs on the OMICS sciences integrated with IT resources will be needed to respond to the needs of citizens and all health stakeholders.

OMICS-rooted knowledge and OMICS-technologies in a tandem with IT-related algorithms and applied tools are transforming the way healthcare can be delivered through greater understanding of the pre-early (subclinical) disease detection and therapeutics. Responsible decision-making in the climate of escalating healthcare costs is required to ensure that PPM can be properly tested on a scale to determine if this approach will lead to better patient outcomes. Additionally, traditional decision-making paradigms must be agile to the PPM-guided approach to ensure knowledge and discovery can be translated effectively and efficiently for better patient care. Subsequently, decision-makers must determine if the goals of PPM can be met by equitably harnessing precision medicine approaches such that the right healthcare is delivered to the right population, at the right time, and in the right place [……].

A broader example of the PPM-guided public health approach, which bridges PPM and public health, is the discovery of overlap in understanding of birth defects, cancer, and rare diseases, such that previously distinct disciplines now intersect. While individuals with such conditions were PPM-related roots allows better stratification of risk (e.g., the risk of an individual with a rare disease going on to develop cancer), new surveillance pathways, and new therapeutic options for identified patients. Better understanding of the pathogenesis of diseases within these three areas translates to better, more precise healthcare for patients and persons-at-risk with birth defects, cancer, and rare diseases. This new knowledge can be utilized to aggregate populations, better targeting health initiatives and fulfilling the PPM-related public health paradigm. Not only are there intersections for birth defects, rare diseases, and cancer, there is also an opportunity to identify more targeted prevention and surveillance based on more accurate knowledge of disease risk profiles.

Biomarkers as the «Diamonds» for the Development and Implementation of PPM

As well as know, PPM provides procedures for disease prediction and for the prediction of consequences and complications. It should be noted that these arrangements are more suitable in healthy persons than in patients with a disease manifestation. In this regard, the biomarker-based analysis is intended as a first step towards a more personalized and precision treatment and clinical utility.

A biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, disease processes, or biological responses to a therapeutic intervention. Biomarkers can be used to reduce uncertainty and guide clinical care.

Among a scope of genomic testing we would stress:

(i) ***carrier testing*** (being offered to individuals who have a family history of a genetic disorder and to people in certain ethnic groups with an increased risk of specific genetic conditions);

(ii) ***cancer predisposition testing*** provides information about an individual's risk of getting certain types of cancer;

(iii) ***newborn testing*** (to identify genetic disorders that can be treated early in life and other disorders including monogenic and orphan diseases: *the causal gene is known for more than 3,500 monogenic and orphan diseases*);

(iv) ***prenatal testing (NIPT)*** (aiming to detect changes in a fetus's genes or chromosomes before birth to secure the national biosafety);

(v) ***pharmacogenomics-related testing*** is aimed at tailoring drug therapy at a dosage that is most appropriate for an individual patient, with the potential benefits of increasing the clinical efficacy and individualized safety [……] ***(Fig. 4).***

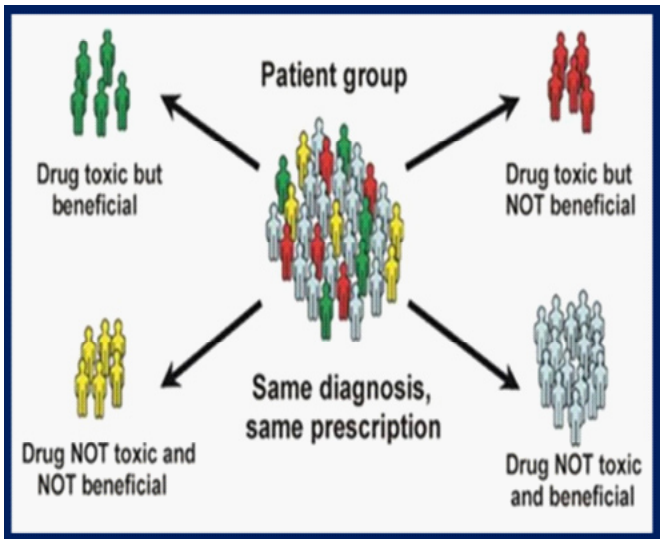


Figure 4. *The alternatives of the pharmacogenomics-related testing*

Pharmacogenomics testing can be used to predict and to target medicines to good responders or to identify whether an individual has an increased risk of a specific adverse drug reaction from a particular medicine.

Pharmacogenomics makes individualized medication more attainable by combining a patient's genetic information with information about how specific medications are broken down in the body, allowing healthcare professionals to tailor medical treatment to the individual characteristics of each patient. This trend toward PPM represents a substantial shift in daily clinical practice from what worked for a "typical" patient to what now works for each "individual" patient and even for a person-at-risk. When healthcare professionals are equipped with insight into their patients' genetic makeup, they are able to optimize clinical outcomes and reduce adverse drug reactions. We do believe that pharmacogenomics testing can improve medication-related outcomes across the continuum of care in all health-system practice settings [……].

And, finally, ***low risk general wellness tests*** being offered for purposes the FDA considers general wellness (e.g., tests that predict athletic ability or provide information about a child's ability in certain sports).

OMICs Resources and Technologies in Daily Clinical Practice

The unique outcome of the integration of the genomic testing, clinical diagnostic studies and translational research is ***Genetic passport*** [……]. ***(****Fig. 5).*

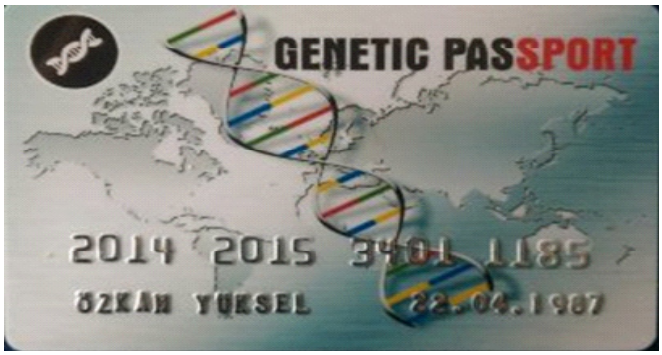


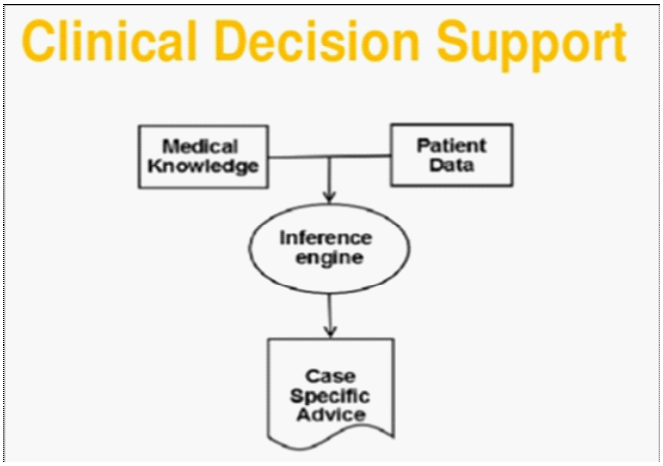
Figure 5. *Genetic passport of future*

The landscape of genomic testing has changed considerably with the emergence of ***direct-to-consumer (DTC) genomic testing (Fig. 6)*** to secure genetic risk prediction tools for a wide array of common diseases and thus the national health stability.

Figure 6. *Direct-to-consumer (DTC) genomic testing*

DTC testing being marketed directly to consumers without the involvement of a health care provider is expanding the number of people who are able to get genetic testing of their DNA. DTC tests are intended to provide information on an individual's genetic risk for certain medical diseases or conditions. The latter may help an individual (including persons-at-risk) make decisions about the health state, lifestyle choices and can inform discussions with a health care provider [……].

Improved patient (or persons-at-risk) outcomes with the application of the above-mentioned biomarker tests must consider not only increased survival or quality of life, but also improved ***clinical decision support (CDS) & making (Fig.7 A, B, C)*** leading to the avoidance of unnecessary therapy or toxicity captured within the rapid learning system.



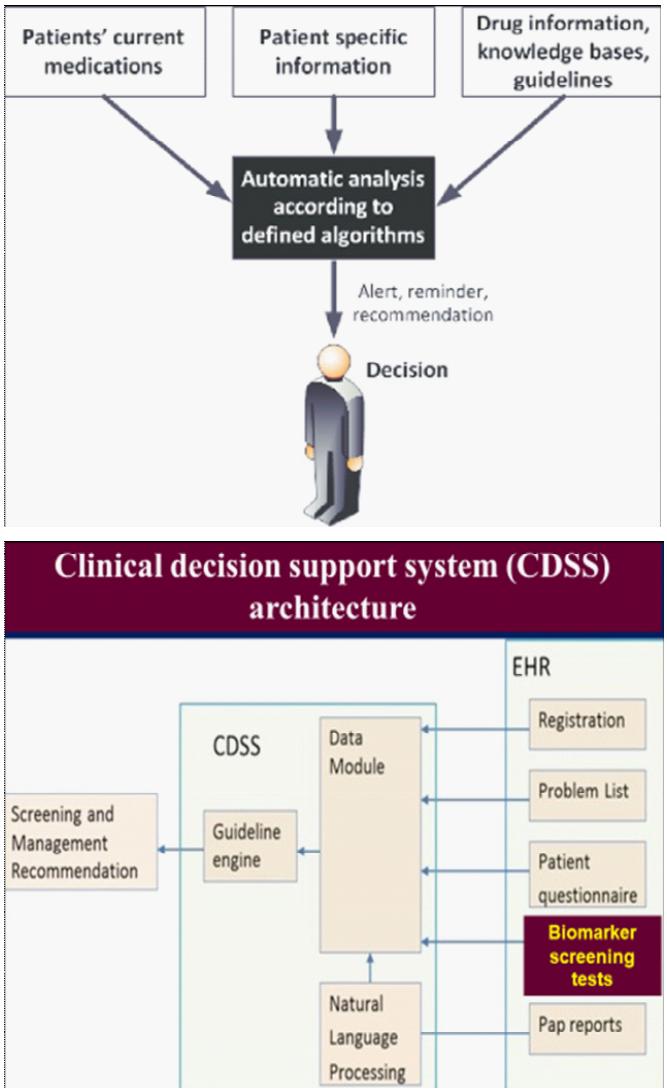


Figure 7. *A,B,C Clinical decision support (CDS) & making*

The CDS architecture takes advantage of EHR, data mining techniques, clinical databases, domain expert knowledge bases, available technologies and standards to provide decision-making support for healthcare professionals. The architecture will work extremely well in distributed EHR environments in which each hospital has its own set of distributed knowledge bases, which is specialized in a specific domain (i.e., oncology), and the model achieves cooperation, integration and interoperability between these knowledge bases. In this connection, CDSSs have been hailed for their potential to reduce medical errors and increase health care quality and efficiency, as well as been widely promoted for improving clinical outcomes, referring to the practice of medicine based on the best available scientific evidence. In this context, public health policy and decision-making must adapt to PPM-guided and driven frontier of healthcare delivery to ensure that the broad public health goals of reducing healthcare disparities and improving the health of populations are achieved, through effective and equitable allocation of healthcare funds [Bilkey GA, Burns BL, Coles EP, Mahede T, Baynam G, Nowak KJ. Optimizing Precision Medicine for Public Health. Front Public Health. 2019 Mar 7;7:42. doi: 10.3389/fpubh.2019.00042; ……].

Individual Health Management Under the Aegis of PPM

Opportunities exist at every stage of disease initiation and progression to develop a ***Personalized Health Plan (PHP)*** addressing lifestyle, risk modification and disease management, and later, ***Personalized Health Management & Wellness Program (PHM&WP)*** [……] ***(Fig. 8).***

Figure 8. *Personalized Health Management & Wellness Program (PHM&WP)*

So, a combination of genomic and phenome-related biomarkers ***(Fig. 9)*** is becoming of great significance to be applied in PPM and need to be translated into the daily practice to predict risks of the disease chronification and thus of disabling [……].

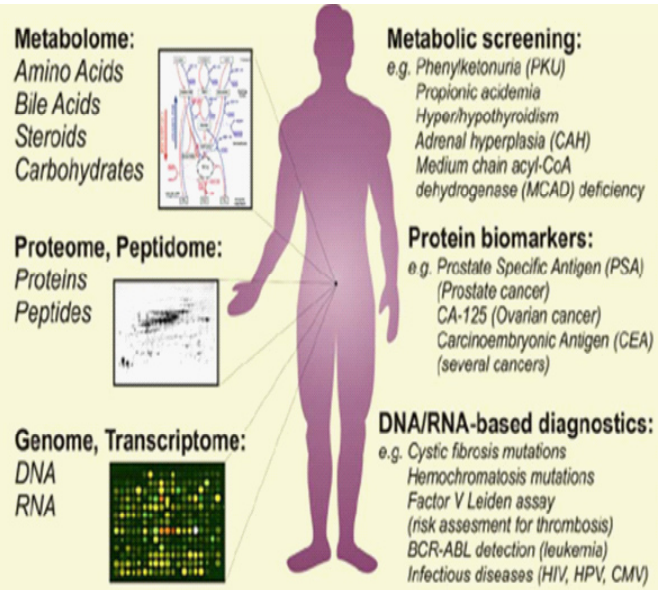


Figure 9. *Combination of genomic and phenome-related biomarkers*

Meanwhile, biomedical science advances and innovations in the related subareas need to be integrated into PPM-based practice, both at the clinical trial stage and in routine care. For instance, advances in biomedical informatics and IT technologies brought on and suiting the goal by applying mathematical modeling to secure constructing and maintaining unified biobanks and databanks necessary for personal health monitoring, for instance, by the increasing availability of electronic medical records (EMRs), electronic patient registry (EPR, telemedicine and mHealth tools and cloudy technologies have allowed for the proliferation of data-centric tools and inter-hospital network communications armamentarium, especially in the context of ***personalized & precision healthcare (PPH)*** [……]**.** As a result, a patient or a person-at-risk becomes a data carrier ***(Fig. 10).***

And you might understand that bioinformatics, artificial intelligence (AI), machine learning (ML) and biostatistics will be crucial in translating those data into useful applications, leading to improved diagnosis, prediction, prognostication and treatment. So, our viewpoint would support the contributions of translational applications in developing a preventive and personalized treatment approach to manage chronic diseases and to thus monitor the patients and persons-at-risk to secure the positive outcome and their health finally [……]..

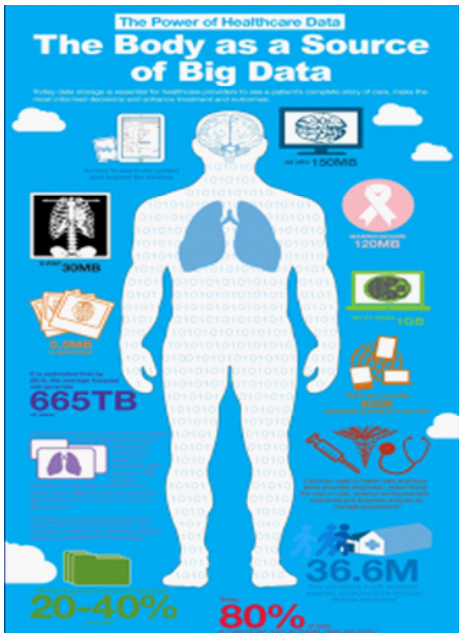
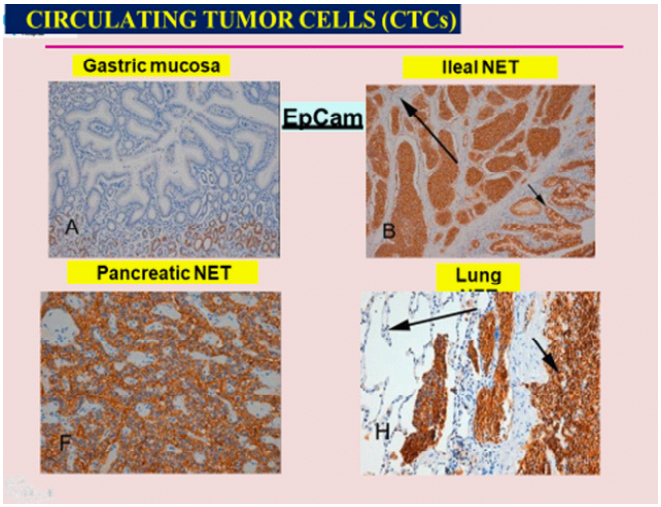


Figure 10. *The human body as a Source of Big Data*

Phenomenal Targeted Approaches to Therapy and Wellness

A greater understanding of the underlying biological mechanisms of many diseases is enabling researchers to pursue new targeted approaches to fighting them. Greater precision will also come *via* increasingly sophisticated medical images, analyzed by advanced algorithms. The application of ***molecular imaging*** to diagnosis and treatment choice in cancer is a particularly telling example, replacing random biopsies with an accurate picture of the pattern of lesions in an individual's tumor and/or metastatic cells [……]..



The unique examples of the latest applications to illustrate subclinical and predictive risks as applicable to tumor progression are ***CIRCULATING TUMOR CELLS (CTCs)*** [……]. ***(Fig. 11A,B)***

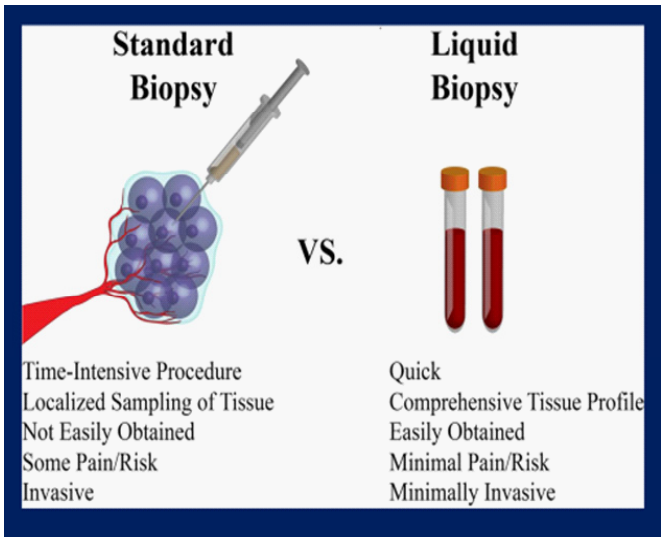


Figure 11. *A- CIRCULATING TUMOR CELLS (CTCs); B- To draw a comparison between Standard Biopsy and Liquid Biopsy*

The latter as biomarkers and molecular tools of the latest generation are able to control the latent stages of cancer progression and thus to monitor the patients and cancer progression at any stages.

From the early stages of discovery through biomedical innovations, drug development and the delivery of targeted therapies to patients, it is important that public policies create an environment that provides incentives for accelerated innovation and ensures patient access to these important treatments. For instance, the molecular profile of an individual patient and their disease influences the effect of a medicine; and biomarker diagnostics help to target the right medicine to the right patient. So, across a variety of therapeutic areas, an increasing number of treatments are becoming ***personalized (Fig. 12A,B)*** being based on principles of precision biomarker-based targeting whilst getting the treatment ***targeted*** [……].

Moreover, the development of the upgraded philosophy to manage the biomarkers (including ***predictive biomarker classifiers***) can be subjective, but pivotal trials should test hypotheses about the effectiveness of a new ***BIOMARKER-TARGET-DRUG trio*** in subsets defined in a completely pre-specified manner by a predictive classifier and should not contain any subjective components [……]

As you might see from the above-mentioned, PPM has drastically changed and is keeping on changing the landscape of healthcare. In reality, PPM is the new revolution in medicine which is dramatically modifying the traditional paradigm in medicine with huge consequences for health care systems. And putting PPM-tools in a public health perspective requires an apprehension of the current and future public health challenges.

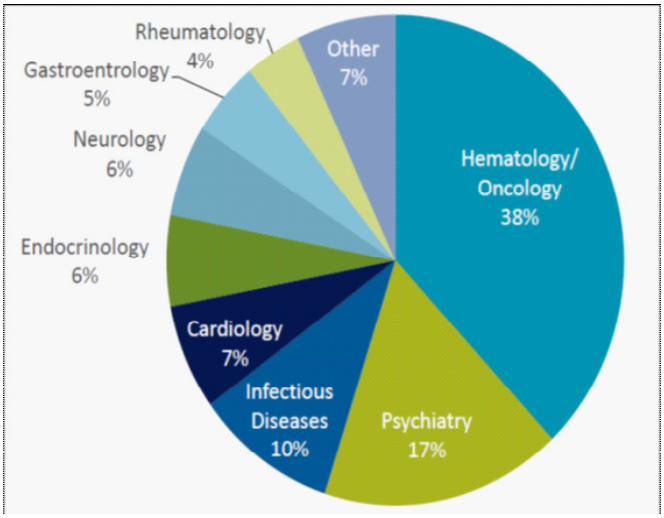


Figure 12. *A, B«Must-have» Key to Secure the Human Healthcare -Targeted Therapy*

Philosophy of Newest and Up-Dated Public Health

Due to our experience, a symbiotic relationship between public health and PPM may exist. And this approach will

be possible only with the integration of data across levels of influence and analytic wisdom in using those data toward better identification of disease and lifestyle risks. In this sense, all healthcare professionals of the future should be educated to deliver ***patient-centric care (Fig. 13)*** as members of interdisciplinary teams, emphasizing evidence-based practice, quality improvement approaches and bioinformatics.

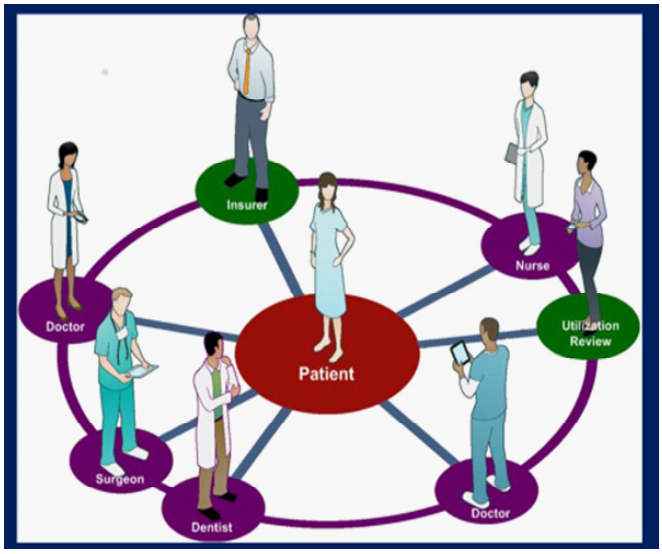


Figure 13. *Patient-centric care*

And thus greater collaboration between clinician and patient (or person-at-risk) would replace the traditional clinician-dominated dialogue with more effective patient-clinician partnerships. So, the current model "physician-patient" would have to be gradually displaced by a "medical advisor-healthy persons-at-risk" model. And biological and medical data from individuals can be analyzed with environmental data to determine the drivers of health and well-being. This approach mentioned should be based on postulates which will change the incarnate culture and social mentality!

Today, a new buzzword has crept into the health sciences lexicon: ***PPM-based public health***. More accurate methods for measuring disease, pathogens, exposures, behaviors, and susceptibility could allow better assessment of population health and development of policies and targeted programs for preventing disease and managing disorders at the personalized level whilst operating with precision tools and datasets. The initial drive toward PPM-based public health is occurring, but much more work lies ahead to develop a robust evidentiary foundation for use [Naumova, E.N. Precision public health: is it all about the data?. J Public Health Pol 43, 481–486 (2022). https://doi.org/10.1057/s41271-022-00367-5; ……].

Health care has changed since the decline in mortality caused by chronic diseases, with a direct impact on the cost of public health and individual health care. We must now transition from traditional reactive medicine based on symptoms, diagnosis and treatment to a system that targets the disease before it occurs and, if it cannot be avoided, treats the disease in a personalized manner.

PPM and PPM-based Public Health call jointly for a transdisciplinary approach to support safe and effective deployment of the new enabling diagnostic, predictive, preventive, prophylactic, therapeutic and rehabilitative technologies not to treat but to get cured!!! So, health policy being based on PPM-based Public Health concept can be the first resource to help us use PPM therapies in a sustainable manner in healthcare systems to secure the public health being the best one.

In modernizing public health by developing surveillance systems and compiling environmental risk data repositories and nutritional dashboards, we must ensure high data quality and data usability in the short and long terms. It means that agencies responsible for data collection must establish strategies for ensuring data security, credibility, and longevity [……].

You might see that a unique opportunity arises for unusual and, even extraordinary, strategic partnerships between governments, regulatory, academic, healthcare and business sectors. And for public health professionals, the work environment contains the systems for public health policy programming, interventions, monitoring, and assessments [……].

The emergence of PPM in practice will depend on the interplay between several stakeholders. So, partnership working is identified as a key prerequisite in taking action on the social determinants of health, because this requires comprehensive action by a range of stakeholders working in a concerted and sustained way to address the issues. Action is essential to develop an understanding and appreciation of the social determinants of health and the social gradient and to engage these sectors and professions to meet the demands of the new agenda.

For doctors, PPM poses major medical education and clinical practice challenges. Biopharma, Biotech and medical insurance companies are already building PPM and PPM-based Public Health model into their research and development strategies. Payers themselves are probably the most skeptical at this point, fearing, with some justification, ever-escalating prices. But they too will embrace the new era if they are offered solutions that combine targeting diagnostics, targeted therapies and tracking digital tools. The result will be fewer occasions on which they pay for ineffective treatment and indeed the potential for fewer treatment episodes, as a result of more targeted prevention [……].

The core functions of national and local government need to be strengthened, especially in relation to comprehensive understanding of the causes of the causes of inequities in health, participatory governance that engages and empowers individuals and communities and that adopt new roles in creating the conditions in which power is shared and health and well-being are co-produced with citizens and communities. It means concerted action by the range of individuals, agencies and all levels of government that can affect the social determinants of health, fostering whole-system approaches to addressing inequities in health.

PPM-guided Public Health calls for understanding of the value of cooperation and teamwork. The real hurdle in assembling data from multiple sources is the multiplicity of terms, units, naming conventions, and varying formats for recording time and locations. Working together, we can streamline and enforce systematic and uniform terminology and create built-in translators and glossaries as essential parts of public health data enterprises. By offering information on data completeness, reporting gaps, and limitations, we could build better recommendations for future steps and strive for precision on every occasion. Honestly, partnership needs to be based on co-production of health and well-being in a delivery model that shifts the balance of power towards local people and communities and away from professionals and formal institutions. Evidence from implementation suggests that the above approach frees up local policymakers, citizens and communities to tailor specific solutions to local problems. Achieving the synergy needed to sustain progress requires coherence of strategy, policy and delivery across the whole system consistent with the values and principles of social justice [……].

Communication challenges in PPM-guided public health require more research on public engagement approaches to guide communication best practices and communication frames in these areas. Some of these challenges such as engaging communities in population-based biobanks are already underway.

In addition, the traditional interaction with genetic testing and counseling is changing. Patients continue to be the main targets of genetic testing, including NGS, in various clinical fields. Yet in addition, the public increasingly encounters genomic testing and screening not as patients or as individuals with a family history that makes them candidates for testing, but as specifically targeted groups such as parents of newborns, biobank donors, and users of population screening. Public communication about this will benefit from earlier education for children, students, and young people in a systematic manner. And thus PPM-guided public health will benefit from developing new communicative frames that embody the uncertainty of research and balance privacy and discrimination concerns with mutual benefit [……].

Roughly, nearly two-thirds of individuals believe payers should cover PPM-based tests and treatments because they deliver more value to patients than conventional treatments and may help control overall health care spending ***(Fig. 14).***

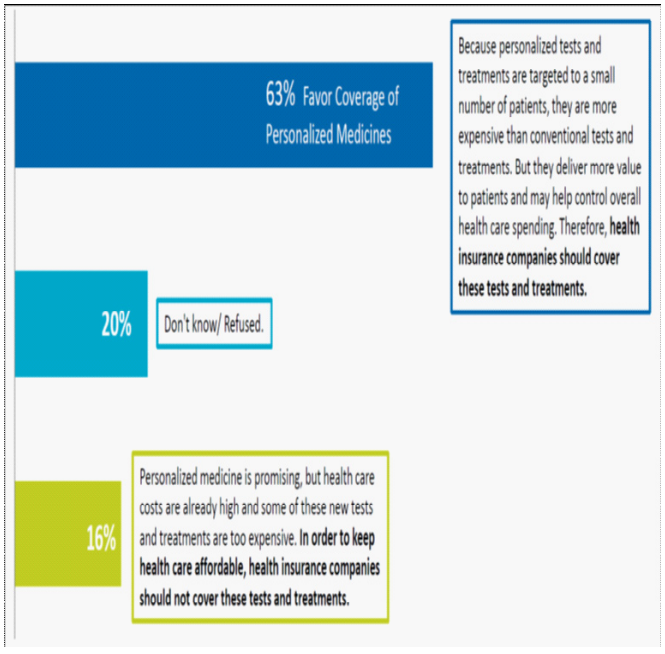


Figure 14. *Value of PPM-based tests and treatments*

Conclusion

Thus, the main task of PPM is to extend healthy life and increase the size of working-age population, with simultaneous and timely detection of pathological changes in the body, and targeted measures aimed at preventing diseases. Implementation of PPM requires a lot before the current model "physician-patient" could be gradually displaced by a new model "medical advisor-healthy person-at-risk". This is the reason for developing global scientific, clinical, social, and educational projects in the area of PPM to elicit the content of the new branch. Since PPM represents a paradigm shift and a new reality for the health care system in the planet, with training being fundamental for its full implementation and application in clinical practice. In this sense, health care professionals face educational challenges related to the acquisition of competencies to perform their professional practice optimally and efficiently in this new environment. The definition of competencies for health care professionals provides a clear guide on the level of knowledge, skills, and attitudes required to adequately carry out their professional practice. In this context, this acquisition of competencies by health care professionals can be defined as a dynamic and longitudinal process by which they use knowledge, skills, attitudes, and good judgment associated with their profession to develop it effectively in all situations corresponding to their field of practice [……].

PPM and precision public health are emerging fields that use genomics and other related OMICS tools, as well as lots of datasets and, finally, Big Data technologies to provide more targeted interventions at the individual, community and population levels. Technological advancements permit the collection and merging of large heterogeneous datasets from different sources, from genome sequences to social media posts or from electronic health records to wearables. Additionally, complex algorithms supported by high-performance computing allow one to transform these large datasets into knowledge. Despite such progress, many barriers still exist against achieving PPM and PPM-guided public health interventions for the benefit of the individual and the population [……]..

Meanwhile, PPM can be thought of as delivering the right intervention to the right individual at the right time, while precision public health can be simply viewed as delivering the right intervention to the right population at the right time. PPM-guided public health is deeply rooted in addressing health disparities and is "about using the best available data to target more effectively and efficiently interventions of all kinds to those most in need." So, to fully harvest the unique potential of PPM and PPM-based Public Health, new generations of new precision diagnostic, predictive, prognostic, preventive, prophylactic, therapeutic, rehabilitative and digital products will need to be matched with new thinking and new practice on the part of all the participants in the healthcare system. In this connection, the healthcare providers, public policy sector, and consumer industries will be required to develop new and creative models and products. And, no doubt, next generations will speak about the XXI century as a time, when medicine became preventive and personalized, and its outcomes – predictive and guarantied.

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