



Personalized Medicine: A Review

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ABSTRACT

The goal of personalized medicine is to maximize the therapeutic efficacy and to attenuate the threat of drug toxicity for an individual patient. It shows right drug & dose, right patient and at right time administration of a medication. Personalized medicine focuses on individualized drug treatment according to each patient's genetic makeup as well as molecular diagnosis. Genomics have the power to improve the target selectivity of drugs, the selection of volunteers and patients for clinical trials and hence the chance for success of many agents in specific populations and individuals, which is the key promise of personalized medicine. The main aim of this study is to evaluate the personalized medicine about its indications and benefits, its issues and health care implications. Future perspectives as well as actual clinical applications. Personalized medicine promises prediction, prevention and treatment of illness that is targeted to individuals 'needs. Translational genetics and genomics research have led to the development of powerful tools for clinical diagnosis, assessing individual's genomic profile for disease prediction/prevention, high-throughput genome-wide screening for predisposition or protection to complex medical conditions, and development of vaccines and new drugs.

Keywords: Personalized medicine, pharmacogenomics, screening, target therapy.

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INTRODUCTION

Personalized drugs may be a therapeutic strategy targeted to individual patients' or cluster of patients. are often outlined as a mix of progressive molecular identification and ancient strategies, for diagnostic and therapeutic ways exactly tailored to individual patients like case history.¹ within the past years usually sickness diagnosing was supported symptoms which may be indicative of the many diseases. Now a days, diagnosing of some sickness of some sickness has become additional correct as a result of we have a tendency to be able to take a look at for genes familiar to be related to the sickness.² It means making medicines unambiguously within which treatment is tailor-made for a personal patient, however it may mean classifying in people into stratified sub populations that take issue in their status to explicit sickness or in their response to a particular treatment.³

The approach depends on scientific development in our comprehension of however a person's distinctive molecular and genetic profile makes them liable to bound diseases.⁴ According to the EU Parliamentary analysis Service (EPRS 2015), it refers to Associate in Nursinging "emerging - evolving approach to medicine" that uses

scientific insights into the genetic and molecular basis of health and illness brought on by the sequencing of the human order, to guide alternatives in relevance the prediction, prevention, identification and treatment of illness. Therefore, the aim of the personalized medicine is sometimes giving the impression to be the "right treatment for the right person at the right time this new approach to medicine, supported rising technologies and sciences, has changed the apply and consequently the health care system.

The possibility to predict and to intervene before injury, has remodelled the reactive health care system, supported the treatment of diseases, terribly} very "prospective health care" system, cantered on bar and treatment of diseases in relationship with personalized made-to-order personalised} risk. Analysing scientific literature, it's shown that the ideas of "Systems Medicine" and "System Biology" are actually a lot of and a lot of. In fact, the new trend of specific interest is that the supposed "P4 systems medicine".⁵ personalized medication (PM) encompasses a broad and evolving command suggested by a patient distinctive knowledge and biomarkers parole (i.e., clinical, genetic, genomic, and epigenetic/environmental. Thus, PM is committed to survey, monitor and diagnose risk to supply and gift patients with distinct treatments spanning from their molecular and specific outline. Though, PM jargon is evolving and a number of linguistics interpretations exist (e.g., customized, personalised, precision), its main underlying premise is to approach and overhaul medication by victimisation integrative biomarkers (short for biological markers) to treat patients not diseases.⁶



While a lot of data of the patient ordination can beyond any doubt bring several several for patients, this by itself is unlikely to correct the short falls in current medication prescribing, usage and observation (pharmacotherapy). Special efforts area unit necessary to confirm that the medication method is improved in order that a revocable downside don't diminish the scientific and technical advances within the rap which might well be led to. genetic science has the ability to boost the target property of medicine, the choice of volunteers and patients for clinical trials and therefore the possibility for achievement of the many agents in specific populations and people that is that the key promise of personal drugs. customized drugs need to be coupled with customized medicines and their personal administration. therefore, the title of this statement uses the word "delivery" in its two senses: first, the conventional sense of

optimization of drug delivery via formulations and devices; and second, the physical delivery and administration to/by the patient.

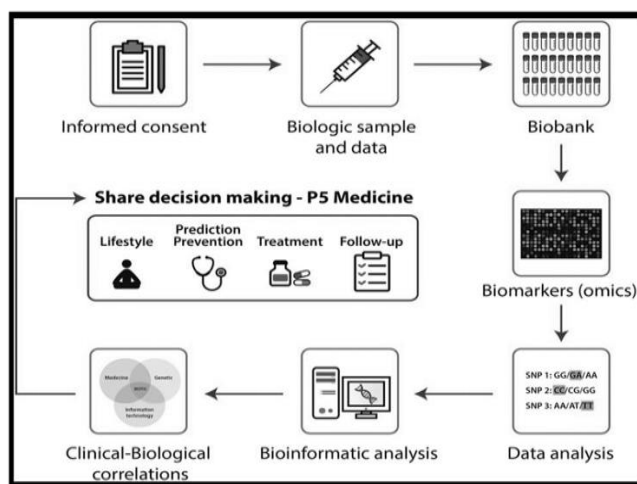


Figure 1: Steps on the road to personalized medicine⁶

As is appreciated, the drug substance though a key a part of the sole think about achieving made out comes. If there are strategic mistakes in approaches to drug style within the last decade, it's been that molecular biological and information processing consultants yet as high through-put screening advocates have maybe generally minimised the very fact that a drug and its target don't seem to be shut neighbours in vivo (as critical in silica) unless the drug will reach the specified sites depleted quantities, while not degradation in to inactive or harmful metabolites, or sequestration by unwanted sites. this is often obvious, and has been for a protracted time, however the "drag ability" of place active therapeutic agent has usually been wanting.⁷

An elusive goal

Biotechnology is leading the means in remodelling the landscape of drugs and therefore the pharmaceutical business. Twenty-five years since the introduction of

recombinant human endocrine, biotechnology has gained momentum in driving innovations in medical specialty. Regenerative drugs and genetic drugs square measure 2 such examples at the forefront of biotechnology. Biotechnology isn't solely a supply of latest drugs, however is additionally a driver for revolutionizing drug development. Advances in biotechnology, technology, and data technology square measure serving to patients to benefit from tailor created therapeutic intervention. The considered application of the product of biotechnology can lower health care value within the long haul and increase productivity within the non-public sector. however personalised drug medical care has long been associated degree elusive goal in medical specialty. the most reasons for this contradiction in terms square measure lack of the requisitions, lack of incentives, economic barriers and maybe even medical and pharmaceutical skilled in atria.⁷

Multiple influences

The advanced of influences on personalised medicines is summarized; clearly there are several typically competitive, pressures. though almost about all drug candidates are evaluated in subjects with one unwellness underneath well controlled trial conditions, patients with a chronic unwellness are additional apt to suffer from one or additional different chronic diseases. a powerful case will so be created for coming up with ways that to supply versatile drug delivery profiles to accommodate disease- disease interaction additionally to minimizing drug-drug interactions. Patients sixty-five years previous or on the far side could also be prescribed a mean of thirteen medication and as several as twenty-eight. The challenge, therefore, is American state wise to plan to plot delivery systems which will permit the de novo assembly of multiple medications straight off before use. This task could also be expedited by increasing the efficiency of the drug itself, and advances in technology.⁷

Application of Personalized Medicine

1. Diagnosing disease earlier in development using optimal surveillance, thereby allowing more effective interventions or treatment options.
2. Avoiding preventable drug related complications and side effects resulting from generic "one size fits all" drug prescribing.
3. By ensuring appropriate drug is used and that the dosing regimen takes into consideration any genetic variants enhance the therapeutic efficacy which may affect metabolism of the drug.
4. If someone is at increased risk of developing a disease, followed by promotion of and support for compliance with available prevention strategies.⁸

Advantages of Personalized Medicine

1. Decreased health care cost.
2. Due to better targeted therapies, there will be higher probability to get desired outcomes.
3. Mainly focus on prevention and prediction of diseases rather than reaction.
4. Probability of negative side effects can be reduced.
5. Disease intervention will be earlier in comparison to the past⁹

The Promise and Hype of Personalized Medicine

This account is, however, not the primary factor the final public would possibly suppose after they hear of 'personalized medicine'. Instead, the most specialize in the personal in customised medicine would possibly generate Associate in Nursing air of undoable guarantees and expectations relating to medicines and coverings fully tailored to each individual person. The commitment nature of medication throughout this field is that the main target for the articles inside the first section of this volume. The authors specialize in however clinical, business and alternative sectors mention customized medication what guarantees area unit made; to whom area unit they made; will they be fulfilled; what drives the creating of promises? however area unit we've got a bent to assess whether or not or not substance, if it exists, is good, dangerous or just necessary therefore on keep the show on the road? These queries area unit exhibit throughout a context inside that a significant gap has emerged between the promise of progress created by business, analysers and politicians on the one hand and conjointly the truth of biomarker-based customised medicine in analysis findings and clinical follow on the alternative. This raises issues with every historical and current clinical importance.

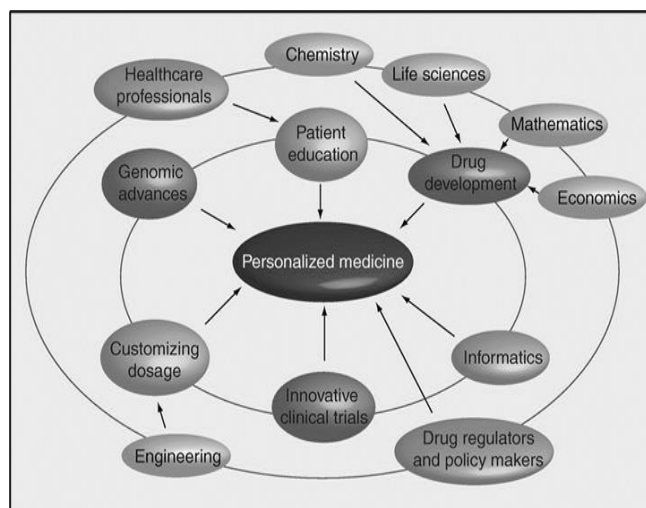


Figure 2: factors, scientific, economic and professional, impinging development and potential of personalized medicine⁵

Key Features of Personalized Medicine³

1. Based on the information above, we define PM as any technology that aims to improve the prevention, diagnosis and treatment of diseases by using patients' individual characteristics to identify the most appropriate care. In terms of treatment.
2. Diagnostic testing is involved: Personalization requires additional information about the patient or the nature of the disease, obtained via diagnostic testing that uses technologies such as molecular diagnostics, gene sequencing (e.g., next generation sequencing) or immunohistology chemistry assays.
3. A range of technologies are incorporated: There are a range of medical technologies that can deliver benefits small molecule, large molecule (biologics), advanced therapy medicinal products (ATMPs).
4. Individualized therapies: These include modified T-cell therapies and gene therapies, which are considered ATMPs.
5. Targeted: Treatments are expected to vary between individuals with the same disease.
6. Targeted therapies: These area unit therapies that act on specific molecular targets related to unwellness. These targets will arise from specific mutations related to the unwellness or they will be protein-expression targets at intervals biological pathways. In medical specialty, for instance, targeted therapies exert antitumor effects through multiple mechanisms: cell proliferation inhibition, necrobiosis induction, metastasis suppression, and immune perform regulation.

Stratified medicine:

Pharmacogenomics, therapy targeted to patient subgroups / disease subtypes

Individualised medicine:

Integration of biomarker and phenotypic data to determine optimal therapy for the individual patient

Individualised healthcare:

Integration of biomarker, phenotypic and environmental data to allow recommendation on interventions to prevent ill health and optimise well being

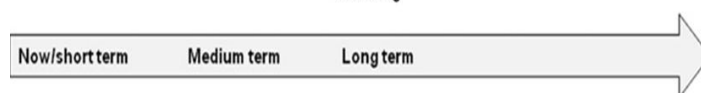


Figure 3: Personalized healthcare: from stratified medicine to Individualized Healthcare¹¹

Benefits of Personalized Medicine³

- Better treatments for patients.
- Delivering benefits to healthcare systems and society.
- More efficient development of novel medicines.

1. Better treatments for patients³

- Reduced adverse events: PM could be targeted at patients who are less likely to have an adverse reaction, reducing safety concerns.
- Improvements in overall survival.
- Improved efficacy: patient more likely to receive a medicine delivering a clinical benefit, and treatment targeted at patients who will respond.

2. Delivering benefits to the healthcare system and to society³

PM has the potential to vary the approach health care professionals and systems determine and manage health issues. this could begin with improved diagnoses and coverings because of higher matching of patients' desires and therapeutic advantages, and may ultimately cause additional economical allocation of health care resources.

Theoretically, these can occur in a number of ways:

Focusing on prevention and prediction of disease

Improving the management of diseases

3. Improving management of diseases

There area unit some studies showing improvement in bar of bound cancers. One example is NSCLC. Patients with advanced NSCLC World Health Organization won't work do not pay into social contribution schemes like insurance funds, pension funds, or treatment funds. The productivity losses double once Associate in nursing used friend becomes a career for the patient with malignant neoplastic disease. traditionally, patients with pathologic process NSCLC received cytotoxic therapy regimens; but, the invention of genetic alterations that drive neoplasm progression in subsets of NSCLC has remodeled the clinical management of this unwellness. Today, new treatments have extended the time before symptoms worsen, delaying the negative physical and emotional consequences related to unwellness progression. Recent developments embrace the power to focus on the PD-1/PD-L1 pathway through the synthesis of organism antibodies.³

The Information Requirement of Personalized Medicine:

'Personalized medicine' isn't precise term. The health profession can show that it's forever experienced personalised medication. Doctors will ponder factors like age, sex associate degreed history in making an identification, and might tailor treatment to the individual patient taking under consideration factors like eco-morbidities and getting to the patient' psychosocial, life vogue and presumably family and economic circumstances. The assortment, method and analysis of data became extra systematic, and typically automated. info is also extra merely mass and mined. It's against this backdrop that the commitment to proof primarily based medication (EBM) as a central dogma of

apply should be understood. EBM is 'the conscientious, explicit, and even-handed use of current best proof in making picks regarding the care of individual patients, this proof being encapsulated inside the pointers, standards, decision support tools thus on that became Associate in Nursing a lot of and a lot of common resource in tending. The randomized controlled trial (RCT) has become the 'gold standard' for generation of best proof in bioscience manufacturing info on the optimum course of action for the 'average patient'. However, even this can be being challenged on account of being conducted on extremely elite and atypical populations mistreatment finish points a lot of suited to doc patients. a lot of atypical the present attentiveness in personalized medication is concerning personalising largely the science {of medication of drugs of medication} It guarantees to maneuver on the far side the generation of proof on the optimum intervention for the 'average patient' towards manufacturing knowledge domain and 'individual evidence' of however best to treat the particular person on the idea that every individual has special feature of their sickness moving medicine faraway from 'one size fits all' towards 'personalized interventions.'¹¹

Biotechnology Innovation organisation (BIO'S) Principles

Any regulatory approval processes and mechanisms for personalized medicine products must be risk-based, transparent and predictable, and must ensure product safety, effectiveness and accuracy.

Elements include: -

- Adoption of personalized medicine products requires refund policies that reflect the worth that those products provide to patients.
- The training and education of healthcare providers should be a priority so that personalized medicine innovations can often implemented into clinical practice.
- Modernized product development and approval pathways for innovative personalized medicine technologies.
- The federal should maintain robust funding for scientific research project to enable new discoveries in personalized medicine.
- Improvements in the healthcare information infrastructure are required so as to support effective implementation of personalized medicine.

Personalized Medicine in Drug Development

Sceptics argue that customized drugs, and consequently biomarkers, don't seem to be a basis or stimulant for consecutive generation of recent medication, contention that the term is simply a completely unique word for basic tools to probe biology It is proven that biomarkers have long been part of good clinical diagnostic and clinical



practice to live biomarkers like, vital sign and serum cholesterol as potential risk factors for cardiovascular diseases. Despite the challenges of accurately defining to accessing relevant emerging technologies, and biomarker science the use and concept of biomarkers have had some recent successes in terms of regulatory approvals biomarkers are crucial to generate safe and efficacious drugs, they are also essential for deciding which patients should receive what treatment and when it appears that reconstruct personalized drugs is thus processes of collaborating between patients and researchers.

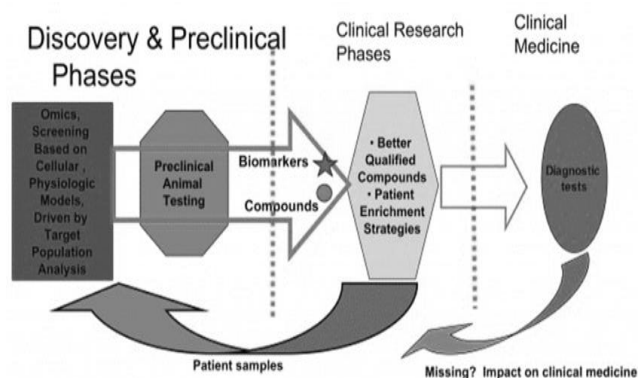


Figure 4: Biomarkers connect discovery and clinical research ¹³

The Potential and Limitation of Personalized Medicine in Primary Care ¹⁴

There are a unit vital implications for medical care, specially for detection of breast, sex gland and body part cancers, bar of anaemia cardiovascular disease, and screening for a sex organ risk a a lot of stunning implication is that the commitment to a customized medication approach through the utilization of genetics to tailor prescriptions to the individual. genetics is that the study of the variation in drug responses between individual because of genetic variations. the topic has existed for many decades with the observation of phenotypes (expressed biological characteristics), like slow acylation of some antihypertensives, differential responses to antitubercular medication. medication exert their action through receptors and enzymes area unit proteins, that area unit recoded for by deoxyribonucleic acid. deoxyribonucleic acid molecular analysis ought to so reveal patient-specific information concerning the receptors and enzymes for a given drug, and consequently the impact of that drug at a private patient level before the patient has taken the drug. The prediction of response to treatment and one by one tailored recommendation on life style and malady prevention: the proper drug, for the proper patients, at the proper dose. disposition to abide by genetics results might not be restricted to a complicated cancer and HIV. There could also be as several as thirty fifth of the anaemia cardiovascular disease population United Nations agency don't answer statins, as measured by changes in initial wall thickness. it's not clear that patients would settle for the label of non-responder while not making an attempt the drug, notably if no various

treatment is obtainable specially for them lipid. The National Health Service (NHS) would volitionally fund statins for those patients with anaemia cardiovascular disease United Nations agency sets counsel they're non-responders. A cost-effectiveness modelling analysis comparison the general public health to the customized medication approach is probably going to the method forward.

CONCLUSION

PM is considered to be an innovation in the healthcare system.¹⁵ The scope of evidence-based medicine in the rapidly changing medical and health practices following the completion of human and other genomes. The new genome-based technologies and bioinformatics tools offer tremendous power for revolution is in the diagnosis. The genome-based evidence, made accessible to clinicians and health professionals, is robust, accurate and individualised or narrowed down to the small patient population teams. The future clinicians and health professionals will required combine with knowledge and skills in applying broad range of genomic based diagnostic and therapeutic tools.¹⁶ Personalized medicine (PM) is a relatively new medical model for classifying, understanding, treating and preventing disease based on data and information on individual biological and environmental differences.¹⁷ The real game of personalized medicine is therefore played on social comparison, proposing criteria of equity and distribution of resources that need to be carefully evaluated Education in PM is critical. So, the challenge will be critical in order to create projects and strategies in agreement to the will of the people and attentive to the needs of patients. It is a challenge tough to win, essential for the optimal course of treatment success: mutual affection and listening the other's point of view between doctors and patients is needed. ⁵

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