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Personalized medicine: time for one person one medicine

Prithvirajsinh Parmar¹, Himan Patel^{1*}, Ashvin Mishra², Miteshkumar Malaviya³, Keyur Parmar⁴

¹Babaria institute of Pharmacy, Vadodara, Gujarat, 391240, India

²Sigma institute of Pharmacy, Vadodara, Gujarat, 390019, India

³Shree Dhanvntary Pharmacy Collage, Kim, Gujarat, 394110, India

⁴Faculty of Pharmacy, The Maharaja Sayajirao University, Vadodara, 390001, India

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Abstract

It's becoming clearer that medicine is not one-size-fits-all. The problem with traditional or present way of medical treatment is that they are created for and tested on large group of people. The medicines are prescribed so broadly that they don't work for everyone. Some medicines work very well for certain individual and some not. Medicine was performed in ancient times primarily on the signs and symptoms displayed by the patient and was purely based on the individual experience of the practitioner, thus the term intuition medicine. Nowadays, medicine is based on the evidence produced by scientific research, including clinical trials, which is designated as evidence-based medicine. In future, medication are going to be practiced consistent with algorithms which will take into consideration the patient's characteristics, like genetics, epigenetic and lifestyle, forming personalized medication. Doctors recommend drugs that are most likely to succeed for you based on knowledge about you – your genetics, lifestyle, and environment – in addition the symptoms of your illness. Health care has transmuted since the decline in mortality caused by infectious diseases as well as chronic and non-contagious diseases, with a direct impact on the cost of public health and individual health care. The evolution of medicine has increase the life expectancy of humans. Personalized medicine is the modern way of thinking about medicines. In this review we will discuss how personalized medicine will transform healthcare, how Artificial intelligence and PM working together towards better healthcare, personalized medicine in pharmaceutical industry, its vision for the future and application in various diseases.

Keywords: Personalized medicine, Precision medicine, Artificial intelligence in Pharmaceutical industry, Genomics, PM in healthcare.

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*Corresponding Author

Himan Patel

Email: patelhiman4510@gmail.com

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Introduction

Personalized medicine is the tailoring of medical treatments to the individual characteristics of each patient [1]. Building on our knowledge of how a person's specific molecular biology and genetic code predisposes them to different diseases, and our ability to

develop personalized treatment programs that offer more tailored treatments with the hope of better healthcare [1]. This approach differs from the doctor's common practice of diagnosing trial and error: The doctor recognizes a possible health care situation based on symptoms, develops a prescription plan based on general data such as age and weight, and proceeds to adjust the treatment until it is successful. Personalized medicine is a great opportunity to take a "one-size-fits-all" approach to diagnosis, drug therapy and prevention and turn it into an individualized approach. We are all the same, of course, but we are different too. The idea of applying medication in a way that ignores these differences cannot be truer than going to a shoe store

and purchasing any old pair of shoes without checking the size. Since genomics gives us a window into our differences in a very precise molecular way, it helps us to make individual predictions about disease risk, which can help someone select a prevention plan that is right for them; genomics is playing a critical role in personalized medicine's advancement. In certain cases, it also allows for the selection of right drug at right time.

Our experience with this medication has been confusing number of pills, side effects, instructions, and one-size-fits-all dosing, which we don't always follow. This comes at a significant cost to us in terms of time, resources, and health. In our now exponential, linked, data-driven era, we believe we can and must do more with healthcare. Many medications only help 1 in every 4 to 1 in every 23 people who take them. That's awesome if you're one of them, but what about the rest of us? What if we could re-imagine ways to make it easier for you to take your medicine? To find the doses and combinations that are perfect for you?

Since genomics gives us a window into our differences in a very precise molecular way, it helps us to make individual predictions about disease risk, which can help someone select a prevention plan that is right for them; genomics is playing a major role in the emergence of personalized medicine [2]. The purpose of this paper is to provide an analysis of the future of the pharmaceutical industry disruption brought by personalized medicine. Still lots of work to do here, but maybe the biggest revolution in healthcare is not too far away.

History

Much research has emerged over the last six decades suggesting that a significant portion of drug response variability is genetically determined, with age, diet, health status, environmental exposure, epigenetic factors, and concurrent therapy all contributing [3]. To achieve individual drug therapy with a relatively predictable outcome, different patterns of drug reaction must be taken into account across geographically and ethnically diverse populations. These findings of highly variable drug reaction, which started in the early 1950s, spawned a new scientific discipline known as pharmacogenomics, which combines genetics, biochemistry, and pharmacology [4]. The newer field of pharmacogenomics was born out of advances in molecular medicine, which aims to explain all of the molecular underpinnings of drug response. Personalized medicine is the name given to the

commercialization of this research application. The benefits are yet to be understood for the average patient, but PM will eventually impact the entire environment of our health-care system. The speed of discovery, product creation, and clinical acceptance of PM has accelerated since the human genome was mapped in 2003. PM is a preventive, organized, and validated systemic model for efficient health care. PM works better with a network of electronic health records that connect clinical and molecular data to make it easier for patients and doctors to make the best care decisions possible. To compensate for genetic susceptibilities, PM involves patients in lifestyle decisions and active health maintenance.

PM in transforming healthcare

Medical and healthcare has largely been a reactive profession throughout history. Still today, we must normally wait until illnesses have manifested before attempting to treat or cure them. And, since we don't completely understand the genetic and environmental factors that contribute to major diseases like cancer, Alzheimer's, and diabetes, our attempts to treat them are often imprecise, inconsistent, and unsuccessful. Since it is focused on each patient's special genetic profile, personalized medicine is beginning to transcend conventional medicine's limitations. Personalized medicine has the ability to revolutionize healthcare focus from reactive to constructive. Doctors are better able to predict which medications would function best for particular conditions, which benefits patients. By approving new clinical methods and changing the understanding of medicine in the healthcare system, PM has the ability to enhance drug selection and tailored treatment, minimize adverse effects, increase patient compliance, shift the focus of medicine from response to prevention, and increase cost efficiency, and increase patient trust post-marketing [5].

What role does personalized medicine play in the COVID-19 treatment?

One field where the personalized medicine initiative is currently being used is to aid in the battle against the ongoing global corona virus pandemic. AI and the automated patient model are now being used by scientists to classify COVID-19 high-risk genes. Other studies are looking at whether drugs designed for other diseases can be repurposed to treat corona virus. These drugs may be used to develop new clinical strategies to improve the survival rate of COVID-19 patients that develop complications such as sepsis. Data-driven

observations aid in the isolation and identification of related and underlying disorders, as well as the linkage of such conditions to complications in patients with serious COVID-19 reactions.

Vision for the future

We will see improved health outcomes as we make it possible for physicians to develop a more customized treatment for each particular patient based on their genomic profile. In future big amount of genomic data of patient will be available, by keeping track of the data produced by this new PM approach to patient care. We can gain a comprehensive understanding of preventive drugs, and can be used to guide best practices across a wide range of therapeutic indications and continue to bring patient success stories [3].

Medicine is going to become an information science. The entire health-care system requires a degree of information processing that extends beyond the simple digital transformation of medical and genomic data. In 12 years or so, we may have enormous amount of data on each individual. The real challenge will be to IT (Information technology) hardware or software that can reduce that to real hypotheses about that individual patient [6]. The implementation of Personalized Medicines will result in more affordable and effective healthcare, access to novel biomedical methods, and better reliability over one's own health and genomic data by individuals, as well as economic growth in the healthcare sector [7].

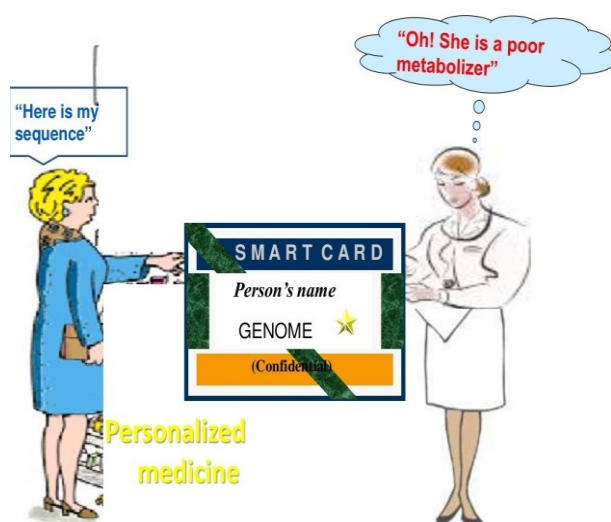


Fig 01: Future of PM in healthcare

Personalized Medicine in Pharmaceutical industry

Manufacturing has undergone a digital revolution, resulting in smart factories and supply chains in the pharmaceutical industry 2.0. In high-value manufacturing industries, industry is gaining momentum. This viewpoint paper looks at what this technology-driven vision can give the biopharmaceutical industry, specifically cell and gene therapies [8].

It was primarily influenced by a number of technological developments: First, computer chips, sensors, and transmitters are becoming increasingly less costly, allowing them to be integrated into a growing number of machines and products. Second, wireless networking allows almost all to be connected to the internet, blurring the line between the digital and physical worlds and allowing machines and products to interact directly and autonomously [8]. These technologies, when combined, allow the development of self-organizing systems that collect and share data on a massive scale and make decisions on their own. Add in other technical advancements like cloud computing, big data analytics, which allows for the real-time handling and analysis of vast volumes of data, and artificial intelligence, which allows machines to learn and adapt, and you have a potent combination that has the potential to change and advance pharmaceutical industry processes.

Doctors may use genomics to determine a person's DNA form and treat them accordingly. Pharmaceutical companies will use this information to develop improved drugs, expanding the amount of marketable compounds by identifying who the target patient is and anticipating a new compound concept for each patient based on genetic data. Pharmaceutical companies can take less time to develop new drugs if profit margins are higher. Productivity has improved as an outcome of newer platforms for gene mapping. In 1998, the community's total sequencing production was about 200 Mb, but by January 2003, the DOE Joint Genome Institute had sequenced 1.5 billion bases in a single month [9].

After years of anticipation, governments all over the world have finally gotten their hands on personalized medicine. In 2015, the US president announced the Precision Medicine Initiative. Over the last few decades, the pharmaceutical industry has seen a decline in research and development, as well as increased market

pressures and a significant erosion of operating margins. In the field of precision medicine surveyed over 100 Pharmaceutical industry leaders from a variety of roles around the world. The findings show that executives are well-versed in the subject, with 92 percent identifying precision medicine as an opportunity and 84 percent having a corporate agenda. Despite both external and internal obstacles, few businesses have been able to begin capitalizing on the potential of precision medicine. Although pharmacogenomics technologies promise enhanced advancement in upstream fundamental biological science, such as the discovery of disease-causing genes and novel drug targets, therapeutic products designed with pharmacogenomics guidance for specifically identified patient subpopulations can also trigger industry concern. The fixed costs of research, development, and testing are the primary costs of drug manufacturing. However, since targeted treatments favor a smaller population, the market is essentially fragmented. As a result, their future revenue sources are smaller, with less revenue to spread the fixed costs around. However, an improvement in the sustainability of such targeted therapies, resulting in longer market availability for personalized drugs relative to blockbuster drugs, could theoretically offset these low potential revenues and sales [10,11].

Artificial intelligence in Personalized medicine

Artificial intelligence in Personalized medicine is a revolutionary new approach advancing healthcare and wellness, knowledge, to improve the quality of life for all over a lifespan. The major concept of personalized medicine is to provide healthcare that is individually designed based on a person's lifestyle, genes, and environment. With the advances in genetics, artificial intelligence and the growing availability of health data, present an opportunity to make precise personalized patient care a clinical reality in the modern world.

It is like Baseball. No two Baseball deliveries, players, or patients are exactly similar. No two diseases or games are exactly the same. To win the Baseball game every ball, every delivery needs unique delivery. Personalized medicine is quite similar to it. In the healthcare no two diseases are same, so the treatments for that will be different and unique for every individual person. AI gives the advantage to measure at once the transcription of all the genetic profile of the individual in an organism. The amount of data that doctors need to examine is enormous. Analyze and finding some combination of genetic profile whose expression levels

distinguish the groups of patients is a daunting task for an individual human, but it is relatively natural one for machines to comply with AI [12].

In the modern world of computers, AI and smart healthcare monitoring devices we can easily collect and store this information very easily. What if your labs can go from the center lab to your phone, your home, to even inside individual's bodies to measure drug levels or other varieties of data? And yes, now we're in the modern era of genomics science. You can start to understand your genomic profile - how your genes impact whether you need low dose, high dose, or maybe a different type of combine drugs. Let's imagine if your doctor or your chemist had this information integrated into their workflow database, augmented with AI, to understand, to leverage that information of the 22,000 or more approved drugs, which drug would be the right combination and dose and for you.

AI in personalized is very important part of artificial intelligence in healthcare. AI is already a big part of IT industry. It will bring together advances in health care such as biomedical data sciences, imaging, and genomics, mobile health, environmental sciences, social engagement, networking and communication to make, therapeutics, diagnostics, and proactive, more individualized, predictive, and precise therapy in near future. On the other side availability of big data and machine learning already involve in pharmaceutical R&D in broad way to discover and develop new drugs. These big data info are probably going to get from better and more refined observing health monitoring gadgets which can utilize to assemble information to seed and key off for the improvement of more reliable predictions.

Personalized medicine has the potential to fulfill the qualifications to upgrade health outcomes by reducing drug-development costs, treatment costs and time. This PM breakthrough in the medical healthcare system can only be possible with the fair participation of customers and patients in trial-based research trials, innovators and marketers developing smart technology and exploring genomic data, and doctors understanding the condition at the molecular level, regulators by guiding providers and consumers and support necessary revolutions in PM regulation and policy, researchers by encouraging target-based drug discovery and conducting groundbreaking experiments to discover new discoveries at the genetic basis of disease, and the IT sector by providing innovative methods to capture, interpret, and protect patient data, big money

stakeholders and leaders by experimenting with new creative market ideas, goal counselling, experimental diagnostics methods, and other customized care protocols [13,14].

Applications of PM in various disease

1. Personalized medicine in Lung cancer

Although systemic treatment for lung cancer is limited, targeted disease treatment is becoming more common, and many more drugs and synthesis, such as monoclonal antibodies (mAbs) and tyrosine kinase inhibitors, are being developed and approved (TKIs). These work against the epidermal growth factor receptor (EGFR) and have a response rate of more than 70% [3]. Further research has found that targeted drugs exacerbate the disease more than cytotoxic drugs, and that these drugs are more expensive than standard drugs [15]. Non-small cell lung cancer (NSCLC) is the most common form of lung cancer, and these cells have uncontrollable cell proliferation. Positron emission tomography (PET) and radioactively branded medications are two approaches to personalized medicine for cancer treatment. Standard assessments of blood samples, urine, and other samples were used to evaluate metabolite concentrations and pharmacokinetics [16].

PET is a form of imaging technique that uses gamma rays to generate three-dimensional (3D) images as a personalised medicine [17]. PET has the benefit of being able to target the diseased site using radio-labeled medications, which will aid in the development of tailored drugs for treatment as a personalised medication. The pharmacokinetics (PK) of targeted drugs were investigated, allowing for the development of new medicines as well as the prediction of radiolabeled drug binding to tumours. Immuno-PET is a type of imaging device that is primarily used to treat antigens. MABs have been studied as a potential agent in Immuno-PET, and mAbs have been labelled with radionucleoids such as ^{89}Zr [18].

2. Personalized medicine in Metastatic Melanoma

New targeted therapies and immunotherapy, which use a patient's immune system to attack cancer cells, are the survival rates. Melanoma that has spread to other parts of the body is a dangerous cancer with a 5-year survival rate of just 15-20 percent.

A mutation in the BRAF gene was discovered to be present in 50 percent of all melanomas in 2002. This mutation causes cancer cell to overproduce and spread.

As a result of this research, three new targeted drugs have been developed and approved by the FDA, which are improving overall survival rates when compared to chemotherapy. Three experimental immunotherapies are now altering the landscape of care. These drugs work by inhibiting proteins that stop the immune system from destroying cancer cells [19,20].

3. Personalized Medicine in Chronic Leukemia

Chronic myelogenous leukemia (CML) has been transformed from a lethal disease to one in which patients live close to normal lives thanks to a new wave of molecularly targeted therapies. The first in this emerging class of targeted therapies was imatinib. Imatinib is a drug that targets abnormal proteins on the surface of cancer cells that signal them to divide. These signals are blocked by imatinib.

As more drugs in this class have been licensed, survival rates have increased significantly, and CML patients are now living lives that are similar to average [21].

This drug really increases lifespan for people who were facing almost certain death. That's the poster child for personalized medicine said by Michael Snyder, PhD, Stanford University.

4. Personalized Medicine in Cystic Fibrosis

Cystic fibrosis is a severe genetic disease caused by mutations in a gene that codes for a protein called CFTR, which controls the body's salt and water absorption and secretion. Ivacaftor works by targeting one of several faulty CFTR proteins in patients, resulting in important and long-term improvements in lung function [22,23].

Author's perspective

Preventive Medicines is a future trend related to personalized medicine. It is expected that, sooner or later, every inanimate object will be able to analyze and recognize your genetic code --including that vending machine in your workplace or office, which may or may

not advise you to skip the chocolate or Vanilla today, so that you can skip diabetes tomorrow.

Personalized Medicine faces many challenges such as changing the clinical profession and practice to the extent that some futurist figure algorithms and machines learning and AI could replace the vast majority of the jobs specialist doctors and physician do today. At last, an effective execution of personalized medication will save numerous lives in the future.

Many medicines don't work for those who are prescribed them. The top 10 grossing drugs in the US in 2015, they only benefit 1 in 23 to 1 in 4 people who take them. And worse about this drug is, when sometimes drugs don't work, can still cause different side effects. Take aspirin - about 1 in 4 of people who take aspirin to minimize the risk of cardiovascular disease. These drugs are unknowingly aspirin resistant and still have the risks of GI bleeds that kill 1000s people every year. ADR (adverse drug reaction) like these that are causes death, by some estimates the number its 4th leading cause of death in the US only [24].

42% of new medicines in the pipeline have the capability to be personalized drugs. In the cancer 73% drugs have the potential to be personalized medicines. Over the 5 years the expected increase in PM investment is 33%.

Conclusion

The theory of Personalize medicine is still in early phase. However, there is an increasingly expanding area of healthcare where a practitioner can select medication based on a patient's genetic makeup, significantly reducing adverse side effects and ensuring better health outcomes. Through the use of the personalized medications approach, each person will receive their full genomic profile details on the day of their birth to put into an individual healthcare record, which has the potential to have a positive impact on healthcare system in the future. Based on patient exposure to multiple diseases, this genomic data will allow clinicians and doctors to adopt more reliable and efficient healthcare approaches. Only the firms that have invested in pharmacogenomics and PM will have more advantage to survive in modern Pharmaceutical market in future. Custom-design diagnosis and treatments will be offered to individual patients by matching their genetic profile to large knowledge-bases. In future the detection and evaluation of disease at each stage will be performing by different diagnostic tools. This also will be an opportunity for new players to enter in Pharmaceutical market by giving innovative ideas in PM. The

pharmaceutical market will move from a mass market to a market of many specialized products in the future.

References

1. Kishorbhai VT, Malaviya, M. . Overview of an ovarian cancer and its treatment aspects. *International Journal of Pharmaceutical and Biological Science Archive*. 2021;9(2):24-30.
2. Hamburg MA, Collins FS. The Path to Personalized Medicine. *New England Journal of Medicine*. 2010;363(4):301-4.
3. Vogenberg FR, Isaacson Barash C, Pursel M. Personalized medicine: part 1: evolution and development into theranostics. *P & T : a peer-reviewed journal for formulary management*. 2010;35(10):560-76.
4. Mancinelli L, Cronin M, Sadée W. Pharmacogenomics: the promise of personalized medicine. *AAPS PharmSci*. 2000;2(1):E4-E.
5. Mathur S, Sutton J. Personalized medicine could transform healthcare (Review). *Biomed Rep*. 2017;7(1):3-5.
6. Rose N. Personalized Medicine: Promises, Problems and Perils of a New Paradigm for Healthcare. *Procedia - Social and Behavioral Sciences*. 2013;77:341-52.
7. Vicente AM, Ballensiefen W, Jönsson J-I. How personalised medicine will transform healthcare by 2030: the ICPeMed vision. *Journal of Translational Medicine*. 2020;18(1):180.
8. Javaid M, Haleem A. Industry 4.0 applications in medical field: A brief review. *Current Medicine Research and Practice*. 2019;9(3):102-9.
9. Ayers A. Personalized Medicine – Future Impact, Pharma Industry Perspective. *J Biomol Tech*. 2010;21(3 Suppl):S5-S.
10. Molyneux D, Nantulya V. Public-private partnerships in blindness prevention: Reaching beyond the eye. *Eye (London, England)*. 2005;19:1050-6.
11. Bhatt P, Narvekar P, Lalani R, Chougule MB, Pathak Y, Sutariya V. An in vitro Assessment of Thermo-Reversible Gel Formulation Containing Sunitinib Nanoparticles for Neovascular Age-Related Macular Degeneration. *AAPS PharmSciTech*. 2019;20(7):281.

12. Uddin M, Wang Y, Woodbury-Smith M. Artificial intelligence for precision medicine in neurodevelopmental disorders. *npj Digital Medicine*. 2019;2(1):112.
13. Jigar Vyas HP, Himan Patel. . Comparative Study of Etoricoxib Loaded Solid Dispersion and Beta-cyclodextrin Complexes for improvement of Dissolution Profile, *Research Journal of Pharmaceutical Dosage Forms and Technology*. 2020;12(2):63-7.
14. Mathur S, Sutton J. Personalized medicine could transform healthcare. *Biomed Rep*. 2017;7(1):3-5.
15. Varnäs K, Varrone A, Farde L. Modeling of PET data in CNS drug discovery and development. *Journal of pharmacokinetics and pharmacodynamics*. 2013;40(3):267-79.
16. Patil S, Lalani R, Bhatt P, Vhora I, Patel V, Patel H, et al. Hydroxyethyl substituted linear polyethylenimine for safe and efficient delivery of siRNA therapeutics. *RSC Advances*. 2018;8(62):35461-73.
17. van Tinteren H, Hoekstra OS, Smit EF, van den Bergh JHAM, Schreurs AJM, Stallaert RALM, et al. Effectiveness of positron emission tomography in the preoperative assessment of patients with suspected non-small-cell lung cancer: the PLUS multicentre randomised trial. *Lancet*. 2002;359(9315):1388-93.
18. van Dongen GA, Poot AJ, Vugts DJ. PET imaging with radiolabeled antibodies and tyrosine kinase inhibitors: immuno-PET and TKI-PET. *Tumour biology : the journal of the International Society for Oncodevelopmental Biology and Medicine*. 2012;33(3):607-15.
19. Malaviya M, Shiroya M. Systemic gene delivery using lipid envelope systems and its potential in overcoming challenges. *International Journal of Pharmaceutics and Drug Analysis*. 2021;9(1):46-55.
20. Vanpariya F, Shiroya M, Malaviya M. Emulgel: A Review. *International Journal of Science and Research (IJSR)*. 2021;10:847.
21. Bhatt P, Lalani R, Mashru R, Misra A. Abstract 2065: Anti-FSHR antibody Fab' fragment conjugated immunoliposomes loaded with cyclodextrin-paclitaxel complex for improved in vitro efficacy on ovarian cancer cells. *Cancer research*. 2016;76(14 Supplement):2065.
22. Ramsey BW, Davies J, McElvaney NG, Tullis E, Bell SC, Dřevínek P, et al. A CFTR Potentiator in Patients with Cystic Fibrosis and the G551D Mutation. *New England Journal of Medicine*. 2011;365(18):1663-72.
23. Narvekar P, Bhatt P, Fnu G, Sutariya V. Axitinib-Loaded Poly(Lactic-Co-Glycolic Acid) Nanoparticles for Age-Related Macular Degeneration: Formulation Development and In Vitro Characterization. *ASSAY and Drug Development Technologies*. 2019;17(4):167-77.
24. Bhatt P, Patel D, Patel A, Patel A, Nagarsheth A. Oral Controlled Release Systems: Current Strategies and Challenges. In: Misra A, Shahiwala A, editors. *Novel Drug Delivery Technologies: Innovative Strategies for Drug Re-positioning*. Singapore: Springer Singapore; 2019. p. 73-120.