AI-Enhanced Personalized Medicine: Machine Learning Approaches for Tailoring Treatment Plans Based on Genetic, Clinical, and Lifestyle Data

By Dr. Hans Müller

Associate Professor of Electrical and Computer Engineering, University of Auckland, New Zealand

1. Introduction to Personalized Medicine

The treatment of patients historically relies on the use of medicines that work best for the larger population but could have variable effects or adverse reactions in some individuals. The release of such drugs has justified the use of a one-size-fits-all approach, where the prescription decision is not individualized based on patient characteristics. A paradigm shift in healthcare is observed when the most effective therapeutic strategies for specific patient populations are designed. The convergence of genetic variation, clinical features, and lifestyle factors provides the biggest promise for increasing therapeutic efficacy and patient safety in recent years. This has encouraged the initiation and provision of data and clinical trial arms to treat the affected populations. The application of AI in analyzing these multilevel data to find the hidden patterns, novel connections, and actionable insights may aid in the prior and custom therapeutic strategy.

This approach of tailoring the therapy to the patient's requirements is known as personalized or precision medicine. The goal of personalized medicine is to find out about the individual's molecular profile, where the causes of the disease originate, and then prescribe the optimal treatment that works best for the patient at the earliest onset. The large-scale economic impact and patient management requirements across the specialized healthcare continuum create an immediate need for personalized medicine. For years, the healthcare industry has been sluggish in leveraging this paradigm for early patient management and shifting the way healthcare is performed, making management beyond the standard of care the domain of a few high-volume centers. It is not difficult to appreciate that another driver is building a generation of therapies. The impact is an increased emphasis on patient selection or suppression by reduced but more directed toxicity. Concomitantly, narrow patient populations with orphan diseases provide the urgency and potential regulatory flexibility to combine assets and clinical protocols in seeking to provide a market advantage and quick revenue generation opportunity.

1.1. Definition and Significance

The term personalized medicine defines an emerging medical model wherein information about an individual patient's genetic, clinical, phenotypic, and other characteristics specific to him or her influences the medical decisions made by a healthcare professional in terms of current and future patient care. Personalized medicine is argued to offer a range of benefits to the healthcare community at both the individual and population levels. This includes providing patients with effective drug therapies and, in doing so, maximizing therapeutic benefits, minimizing the likelihood and severity of adverse reactions, and reducing the need for additional treatments. Beyond the medication pathway, integrating patients' unique biological, clinical, and lifestyle information in care can foster patients' active role and engagement in their healthcare. As a result, patients can have greater satisfaction with their treatment and improved clinical outcomes. In the UK, the significant promise of personalized medicine for improving patients' health and well-being is clearly emphasized in a number of recent high-profile policy papers discussing the future of healthcare.

It has been suggested that healthcare professionals, both primary and secondary care, need to adapt how they operate in response to the rapid developments in biomedical science and patient-centered care. The relevance to clinical practice demands the breakdown of siloed clinical pathways to facilitate integrated, multidisciplinary teams through individual "patient journeys." There is also the need to develop "culturally, contextually, and behaviorally tailored interventions" and novel "ways of delivering treatments and care." With respect to personalized medicine, recent literature has estimated a two hundred to two thousand fold increase in data in patients' records for use in making medical decisions. Machine learning, both supervised and unsupervised, can be harnessed to transform these phenomic and biological data into precise treatments. Moreover, machine learning approaches can predict new disease-associated genes that could be relevant for new drug target identification. In summary, big data offers the chance to transform personalized medicine for the better.

2. Foundations of Machine Learning in Healthcare

Machine learning is revolutionizing medicine by greatly enhancing the diagnostic, prognostic, and therapeutic decision-making processes. Learning algorithms can find patterns in far larger data sets than a human brain can process alone. Due to this capability, machine learning is considered a type of artificial intelligence. Two general paradigms of machine learning have been extensively used in health care: (1) Supervised Learning – used for predictive modeling with the dependent variable being the label that classifiers use to make predictions from input features. (2) Unsupervised Learning – identifies patterns from input features alone and is commonly used for clustering-based classification. There are several types of algorithms that assist healthcare providers in making these types of decisions.

Descriptive models like logistic regression models are used for descriptive modeling of data. Classifiers are used when the data are labeled with classes of interest. Clusterers organize unlabeled data into "natural" structures or classes. Sometimes, these clusters can correspond to classes of a given problem. Association rule learners find relationships between variables of interest. Anomaly detection classifiers flag data instances that are irregular. For example, anomaly detection has been applied to diabetes datasets to predict adverse events. Dimension reduction is a data preprocessing step that projects data from a high-dimensional space to a lower-dimensional one. Machine learning has already been utilized in the areas of personalized treatments, including patient diagnostics, treatment planning, patient monitoring, and support for clinical operations. It offers the two main unique advantages of avoiding irrational exuberance, which can often happen in small studies that usually do not include the entire population, and can help solve interdisciplinary and multidisciplinary issues to further personalize rarely one-size-fits-all treatments.

One of the main requirements of such a patient-tailoring approach is the need for finding patterns in large healthcare databases. These patterns are used to study the possibility of developing treatment tailoring decision-making processes. The availability of big datasets is commonly seen as a hard proposition to avoid. However, not only are large databases increasingly available, but it is also possible to generate data sets from studies or projects. Larger studies normally provide more accurate results, as smaller ones might be subject to sampling noise. Even in the context of the "small big data" from "the midpoint of the pipeline," machine learning studies can be productively performed. There are a number of algorithms that almost always surface, and it should be taken into consideration that different datasets can react distinctively to the same algorithm so that one might just try a few of them to see what works best with each specific dataset. Finally, a conclusion that is brought here is that the pool of patients' data can be seen as a unique source of knowledge, which can be used to increase the treatment-tailoring pipeline performance. Therefore, machine learning is a fundamental midpoint step in the treatment-tailoring pipeline. In summary, machine learning is seen as a way of working as well as communicating, not only why things are predicted to behave in a certain way, but also what can be predicted from those predictions. Solutions cannot be brought from a single endeavor: once a diagnosis is set in place, it will not be enough to just predict the outcome of one approach, but many, helping the clinician forge a plan for the chosen treatment as well as discussing with the patient working hypotheses regarding available options.

2.1. Overview of Machine Learning

To introduce machine learning, we can consider the foundational concepts upon which the technology is built. Consider the pair of terms in "machine learning" together: machines learn. Of course, they cannot learn as humans do, because their workings are principally rooted in algorithms. An algorithm is an organized procedure for solving problems or a step-by-step process for computing things. That little detail is huge; however, machines are being taught or "programmed" to "learn" the steps to the solution themselves.

There are multiple possible paths up this learning cliff. Machine learning can be categorized into a few different categories, which is a function of the type of task: • Supervised Learning: Learning in which humans teach the machines only on the basis of the correct answers. • Unsupervised Learning: The machine is given data—for instance, a polaroid picture of any variety, from landscapes to radiation scattering to the ionization of a helium atom, with the task of categorizing the images into different piles without much help from the outside, possibly even into piles no one knew to look for before the piles emerge. • Reinforcement Learning: In which the machine learns to overcome new challenges by revising an incomplete plan of attack. These are not the only subcategories of machine learning, but they are three important ones. These categories frequently ship with algorithms, or problem-solving flows, to get the job done, whatever that job might be. Oftentimes, machine learning models will take in numerical or categorical features to make predictions. When experimental data has been collected to train models, labeling this decision or condition as its outcome is critical. This can involve using images to "diagnose" diseases or predicting the future health of an individual patient based on their medical images.

3. Integration of Genetic, Clinical, and Lifestyle Data

Personalized medicine focuses on tailoring an individual’s treatment based on the unique constellation of genetic, clinical, and lifestyle factors related to their disease. Personalized medicine can result in more successful therapies, reduce unnecessary interventions, and be more cost-effective. In healthcare, many genetically informative data and environmental factors are collected. These include genetic tests, clinical biomarkers, patient history, and electronic health records. More recently, these can also include patient-generated data, such as mobile health data, geospatial information, and other environmental exposures. Even though each data type captures unique health information, no single dataset encompasses all relevant dimensions of health. At the same time, the challenge exists to integrate all of these data in a way that could lead to more effective diagnoses and treatment plans targeting a person's variable state of wellness or disease.

The large variety of information types available in healthcare serves different purposes. Often, clinicians focus on diagnosis using a single data type or cluster of tests of similar functional type, yet this may be a crude classification. Subtyping patients with a larger, more multi-domain set of factors may help to identify relevant clinical clusters. Technological advancements facilitate the integration of many domains of data for analyses. For example, in healthcare, there is a move to biobanks and data warehouses holding genotypic, phenotypic, and longitudinal patient information. Health information requires interoperable systems that can securely link a patient’s holistic health profile to information generated from population-level public health data, research, and economic measures. In such systems, many datasets are likely to be monitored for quality, such as protocols for data acquisition, data processing, and data linkages. In this way, researchers are better informed on whether individual data analyses are appropriate for a given question for personalized medicine. This integration is important for personalized or precision medicine, which relies on interdisciplinary and innovative systems to support fully informed decision-making. Currently, there are a few limitations both to integrating these data and maximizing information from these resulting joined-data analyses that must be addressed. These limitations are addressed in the discussion below.

3.1. Data Sources and Collection

To integrate genetic, clinical, and lifestyle information sources into a data set for informing personalized medicine approaches, various data collection sources exist. For personalized pharmaceutics, identifying genomic sequences is the most important predictor out of these three classes of data. DNA sequence data establishes pharmacokinetic information, primarily through drugs' kinetics and dynamics analyses. When these phenotypes are integrated with information from patients' electronic health records, a more holistic health understanding can improve personalized drug efficacy and avoid potential safety problems. In this regard, electronic health records offer detailed and objective patient health assessment information. Furthermore, to create gene-lifestyle interaction models or conduct scientific studies, participants' genetic and clinical data need to be stored. Electronic health records are advantageous because every patient clinic visit is recorded. Also, patient self-reported information such as working hours, occupation, history of liver disease, allergies, dietary habits, etc., is important and difficult to extract from medical records.

Non-invasive smartphones and wearable technologies can be an easily accessible information source for data extraction. Moreover, mobile health apps for monitoring and drug adherence also offer useful patient data collection points. Here, the requirements for artificial intelligence to deliver personalized medicine necessitate creating a broad and diverse source of data using innovative technology to capture daily behaviors and other interactions. However, small data collection points can have fewer subject consent requirements, suggesting these data sources may be less accurate given potentially compromised patient privacy. This is the reasoning behind ensuring the completeness, accuracy, and transparency of data to improve the accuracy of tailoring and personalization of common medical practices. These smaller data collection sources may be used in machine learning applications for determining per-dose drug effects and optimal times of dosing from the combination of patients' lifestyle and genotype data to maximize treatments.

4. Machine Learning Models for Treatment Tailoring

Advancing Medicine: Machine Learning Approaches for Personalizing Medicine

Machine learning and artificial intelligence have gained popularity in generating treatment recommendations for individual patients based on multiple data types. Machine learning algorithms can learn from complex datasets to identify treatments that are most effective for particular subgroups of patients. Although clinical trial study designs for identifying prognostic and predictive markers conventionally rely on regression-type models, machine learning algorithms are beginning to be applied to identify those patients that should or should not be treated. However, the selection of model and corresponding algorithm for making a treatment recommendation should be considered closely. Different algorithms may or may not identify subgroups who should be treated based on differing patient characteristics.

Many machine learning models simultaneously consider multiple features and can identify subgroups of patients with different rates of response or survival to a given failure. Three commonly used algorithms include decision trees, support vector machines, and neural networks. Several studies illustrate the application and benefit of these models applied across a range of diseases, such as oncological and chronic diseases. They offer advantages in not requiring strong distributional assumptions, handling large numbers of covariates, and offering good predictive performance. However, these algorithms can be difficult to interpret, and understanding the consequent treatment decision is challenging. Decision trees, unlike other models, offer some clarity in understanding why a treatment decision is conferred; however, those with greater depth reduce their interpretability. Given that individualized treatment decisions are patient-facing, it is important to strive for an interpretable model that can guide individual patient treatment decisions. Empirical research demonstrates that patients tend to favor a data-driven clinical decision based on their individual predictor profile rather than a physician's intuitive prediction, suggesting that the machine learning model could be useful in shared decision-making. The use of machine learning to generate treatment strategies in practice is still an emerging paradigm. However, as personalized medicine rapidly evolves, there will be a growing need for computerized clinical decision support tools to integrate myriad data in making personalized treatment decisions.

4.1. Supervised Learning Algorithms

A significant amount of research in precision medicine involves developing and applying machine learning approaches to tailor treatment plans. Supervised learning algorithms, which are presented in this subsection, are more commonly used in the medical context.

Supervised Learning Supervised learning involves training a model based on labeled data. The model learns its mappings and relationships using the input feature values of the dataset, and the corresponding output is referred to as a training set. Two common variations of predictions made using supervised learning algorithms are easier to comprehend: generally linear regression (if the output is continuous) and classification (if the output is binary or multi-class classification). The main difference between these and other approaches is the reliance on labeled data to be used as training data.

Types of Supervised Learning Algorithms Depending on the problem and features to be modeled (i.e., the necessitated constraints), different types of statistical and machine learning methods are utilized. Some of the most widely used techniques in healthcare contexts are as follows: 1. Linear Regression 2. Logistic Regression 3. Decision Trees 4. Ensemble Methods 5. Neural Networks

Practical Applications In clinical settings, supervised learning algorithms can predict various patient outcomes, such as mortality, length of stay, diagnosis, test results, and others. For example, a supervised learning model predicts patient response to psychotherapy for major depressive disorder.

Challenges Using a regression analysis also introduces statistically significant problems. The reliability and generalizability of the model must be assessed using training and validation datasets. To overcome biases and prevent the model from "memorizing" or fitting the data more than once using the validation set, the model will have to undergo a series of features and their associated coefficients to refine and improve performance. Premature convergence is caused in between. Sometimes, based on training data, it is difficult to unambiguously capture whether the model is memorizing or learning from the extracted data. By adjusting and calibrating the model, one can escape disparity.

In some situations, regularization techniques such as L1, L2, and AUC are used to limit high feature weights, avoid overfitting, and make the model's performance less reliant on a specific subset of patients. The regularization term is added to the cost function, which increases with the feature weights.

Application Use Case Using a supervised learning model, a clinical decision to adopt a particular treatment strategy is made based on a pre-treatment modifiable risk factor. To estimate the number of enrollments expected in each stage, individualized treatment effects expressed in an average causal effect are used. After using the logistic regression model to categorize the PD-L1 status of the strata section individuals to either high or low, ATE will differ based on whether the first-line ICI or whatever controller's treatment has been received. For people who received initial ICI, CRT was given because stratum individuals got a large ATE. The most controllers received by individuals in stratum individuals will be given CRT with low ATE.

5. Challenges and Ethical Considerations in AI-Enhanced Personalized Medicine

Technical Challenges. As with the implementation of every AI-based tool for medical purposes, certain technical challenges must be addressed. First, bias in the data with which the AI algorithms are trained must be abolished. Moreover, the "black box" aspect of AI can be particularly problematic in personalized medicine, where decisions can affect individual lives. As AI applications in personalized medicine are more concerned with accuracy rather than speed, AI trustworthiness in this context matters more. Furthermore, large repository databases holding genetic, clinical, and lifestyle data that are crucial to refining personalized therapies should be highly secure. A number of issues are associated with a "digital divide" and there is a risk of medical AI algorithms being "exacerbators of disparities" in terms of which groups of people they are effective for. Given the possible negative impacts on the health care of a given population if an AI-driven treatment plan is implemented, the design and data procurement for the clinical trial, and the AI model validation need to be as unbiased as possible. One strategy to limit the impact of an AI treatment plan exacerbating disparities is to develop fair AI algorithms. An AI algorithm is said to be "fair" if it provides similar results to different population groups in proportion to the true positive rates. Another important factor is related to data. While increased data collection can improve AI efficacy, this should not be conducted at the cost of privacy. Because treating providers will also have access to the massive amounts of sensitive data from these curated repositories that fuel AI, it is critical that they are maintained in a highly secure manner. Ethical considerations. Very similar to AI ethics in general, patient privacy is one of the major ethical barriers to the application of AI in personalized medicine. Patients' consent is also a major consideration, with AI needing to wait for patients' consent to store and use their genomic data. Patients may also need to give consent for the results of AI-improved treatment plans to be shared with them. Finally, information security of the collected data must also be a large concern due to data storage of large amounts of very sensitive patient information, further raising data security level requirements. It is evident that worldwide directives covering advances in personalized medicine are necessary to ensure global use and benefit. Moreover, there are legal and regulatory hurdles that need to be crossed before AI can be used in the area of personalized medicine. Modern laws and regulations, including those used by healthcare providers, should be revisited to include AI living inside medical devices. AI in personalized medicine currently tends to be "off the shelf" rather than designed according to specific problems and challenges. Clinicians must also be ready for the consequences of involving AI in decision-making, primarily in how they interact with patients. Over nearly the last two decades, it has been found that every disabled person they asked designed the robot with a "kill switch" and that disabled people preferred a human caregiver over a robot. They suggested adding a "hard" kill switch to DNA-aware AI programs. More recently, with regard to robots and autonomy, some physically or mentally disabled individuals preferred to have a robot with autonomy but a reliable way to set arbitration rules. Setting rules should reduce the problems associated with uncertainty. Finally, AI is the result of people's decisions and as such needs to be implemented according to ethical guidelines. In the context of cloud-based services, it has been suggested that all parties involved in personalized medical AIs should subscribe to an ethical checklist for medical AI developed using funds from government agencies and corporate interests.

5.1. Data Privacy and Security

The processing of large volumes of personal and medical data presents an increased risk to privacy and security. The average total cost of a data breach was significant. Data breaches, either caused by accidental or intentional incidents, can lead to data corruption and extortion, loss of market value, fines, and litigation, negatively affecting the future healthcare industry. To protect patients' data, several methods such as encryption, authorization, and access control are used. Data should be encrypted to be unreadable to unauthorized individuals or entities. Healthcare access control should only grant appropriate access rights to authorized users. Before users log in to the system, they should be authorized by two-factor authentication. Besides, regulations and guidance were enacted to enforce medical data privacy protection. Technologies such as instant encryption were also developed to protect the data of genomics patients.

In the United States, the Health Insurance Portability and Accountability Act was enacted in 1996 to provide the legal framework for maintaining data privacy, including health and clinical data privacy. The General Data Protection Regulation provides the legal baseline for handling personal and sensitive data safely across the EU countries. Although it does not specifically mention the obligations related to AI or machine learning, it applies to the processing of health data of European patients, which means that European regulations and data handling best practices will apply to the use of patient information. In today's data-driven clinical practice, patient consent is essential to share data with different stakeholders such as healthcare providers, researchers, insurance companies, government entities, commercial companies, and others. Whenever patients allow their data to be used for certain purposes, it is essential to define the types of data to be used and the period of time for using this data. If a data recipient or data processor would like to use the data for additional purposes, they have to seek patient consent to do so. A legitimate basis for sharing patient medical data can include patient consent; the necessity to transfer patients' data for medical reasons in a veterinary surgery situation; the need to save someone's life if the patient is unable to make a freely expressed personal choice; the safeguarding of public health reasons; or the administration of justice.

6. Conclusion

In conclusion, AI and machine learning provide important tools that are driving the concept of personalized medicine deeper and further. Disease prevention, diagnosis, and treatment expanded exponentially in recent years, leading to safer and more effective solutions. By combining genetics, clinical data, lifestyle, and different types of patient-related information, it is feasible to design treatment plans tailored to the patient. There are many challenges that need to be solved, for example the integration of multi-omics data, methods to personalize decision making and ethical and privacy-related issues. Also, frequent patient evaluations both in the clinical areas and hospitals are important, as well as evaluation of human needs. The number of ethical and practical issues is increasing at the same time. Integrating methods for patient characterizations, subsets clustering, and drug- or therapy-pathways discovery is still a daunting task. Research and testing directly in the clinics are urgently needed.

Future personalization in medicine will be mainly focused on a few areas. First, machine-learning methods, especially deep learning networks, are gaining in popularity and more readily available, providing a very effective approach for personalization of many patients' treatments in the new few years. Future AI techniques also can have the potential to add personalization of treatment to an entirely different level of accuracy and possibility to assist with human characteristic biases. Near-to-market new AI technologies include those capable to find subpopulations, suggest new clinical trials, and propose patients for specific novel treatment group testing.

In the year of 2022, machine learning is still rapidly evolving, and can quickly bring a novel possibility for treatment personalization that we are not currently aware at this moment. With so many coming machine learning innovations, the health care community not only data scientists but also clinical, IT, and especially ethicists needs to remain updated and ready for this potential. In particular, future clinicians and patients should learn and understand the possibility and limitation of personalized medicine. New therapies and treatments would require restructured pharmaceutical organization to design therapies fitting smaller markets yet being profitable. In addition, current IP system that rewards drug or therapy innovation as a whole irrespective of subsets may also need to be reviewed. Comprehensive integration among medical professionals, data scientists, ethicists, and institutional regulators are therefore called for on a global scale.

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