

## Machine Learning-Based Clinical Decision Support Systems for Personalized Stem Cell Treatments in Regenerative Medicine

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### Abstract

The incorporation of machine learning (ML) into clinical decision support systems (CDSS) has brought new possibilities for the further development of personalized stem cell therapies in the field of regenerative medicine. Furthermore, ML-based CDSS ae) provide a characterization of disease and patient-specific information (e.g., genomic profiles, biomarker levels, clinical histories), b) assist clinicians to predict therapy efficacy and c) optimize cell type selection and tailor therapeutic procedures at the individual patient level. In this paper, current methods for the implementation of ML in stem cell therapy were reviewed with focus on supervised, unsupervised, and hybrid algorithms for patient stratification, treatment recommendation, and risk prediction. Electronic health records, high-throughput sequencing datasets and clinical trial repositories are explored for their contribution to the accuracy and reliability of the model. We describe issues of data heterogeneity, model interpretability, and clinical integration, and address ethical and regulatory issues that affect patient safety and treatment efficacy. Conclusions: Looking beyond this paper to the implementation path to market of ML-based CDSS for regenerative medicine, we highlight the importance of careful validation processes, cross-disciplinary collaboration, and iterative learning in order to maximize the potential of CLT while minimizing the risks.

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### 1. Introduction

Regenerative medicine has become a revolutionary field in the modern healthcare and can restore damaged tissues or organs to their normal state by creating new tissues or organs or rebuilding the existing ones. Among the different therapeutic modalities used by stem cells, their ability to differentiate into different cell types and their ability to promote tissue regeneration has attracted much attention. However, the clinical use of stem cell therapies carries inherent challenges, such as heterogeneity in the response of patients, uncertainty regarding the best choice of cell type, and difficulty in predicting therapeutic response.

Specifically, machine learning (ML) is a subset of artificial intelligence that offers powerful computational tools that can analyze high-dimensional and complex biomedical data. By

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uncovering the hidden patterns and correlations in patient-specific data, ML algorithms can assist clinical decision-making, allowing for a personalized approach to treatment that is tailored to the specific profile of each patient. In regenerative medicine, ML-based clinical decision support systems (CDSS) can provide the precision of therapeutics and prevent unwanted outcomes to improve resource efficiency.

In this paper, we discuss the role of ML-based CDSS in personalized stem cell therapies. It presents a review of current methodologies, data integration strategies and algorithmic approaches utilized for predicting patient outcomes and directing treatment planning. Also covered are some of the practical issues involved, such as data heterogeneity, model interpretability, and clinical integration, and ethical and regulatory concerns that are of paramount importance for safe and effective deployment. From this analysis, the study seeks to offer an overarching framework to guide the design and development of ML-driven decision support in regenerative medicine, and in turn, advance the field of personalized stem cell therapy.

## **2. Background and Current Landscape of Stem Cell Treatments**

Stem cell therapies are quickly becoming the cornerstone of regenerative medicine, providing hitherto unmatched opportunities to repair damaged tissues and treat a range of degenerative diseases. At high level stem cells could be classified into embryonic stem cells (ESCs), adult stem cells (ASCs), induced pluripotent stem cells (iPSCs), which have different combination of properties and different clinical utilization. ESCs are pluripotent and have the capacity to differentiate into all other cell types, therefore are very versatile but are an issue from an ethical perspective. Hematopoietic and mesenchymal stem cells (ASCs) and induced pluripotent stem cells (iPSCs, cells created by reprogramming somatic cells) are multipotent and exploited in many clinical trials; the former offer a relatively low risk of rejection, and the latter enable patient-specific regenerative strategies at the cost of efficiency and genomic stability.

Over the past decade, cell-based therapies have shown clinical efficacy to treat cardiovascular diseases, neurodegenerative diseases, musculoskeletal injuries and autoimmune diseases. The most significant impediment to widespread adoption of variable treatment during these years was the inherent variability of the applications. Patient heterogeneity, cell source quality, delivery systems, and microenvironments all have a significant effect on therapy success. Traditional clinical protocols are typically based on generic treatment plans, which does not allow for fully individualized treatment.

The combination of computational tools and prediction analytics is now being seen as a solution to these challenges. Machine learning (ML) helps analyze high-dimensional datasets--such as genomics, proteomics, imaging, and clinical records--to determine patient-specific patterns and to predict therapeutic response. Therefore, ML-based clinical decision support systems (CDSS) have become the central engine of precision regenerative medicine, helping clinicians to better select, dose, and time treatment to ensure maximum efficacy with minimal side effects.

The description of the current status of stem cell therapies and their inherent limitations offers a context for the implementation of ML-driven CDSS, defining the basis for the realization of individualized regenerative therapies, which can be adapted to the characteristics of each patient.

### **3. Machine Learning Approaches in Clinical Decision Support**

Machine learning (ML) has become a part of clinical decision support systems (CDSS) particularly in personalized stem cell therapies. Using large and complex datasets consisting of genomic sequences, biomarker profiles, imaging findings, and patient histories, ML algorithms can learn patterns that drive therapeutic planning, predict therapeutic response, and stratify patients according to response likelihood.

Supervised learning methods, such as random forest, support vector machine (SVM) and gradient boosting algorithms, are widely used to make predictions of clinical outcomes when they are based on labeled datasets. These models can be used to establish correlations between individual patient characteristics and therapeutic outcomes, which can then be used to make accurate predictions about which cell type to use, how much to use and how to deliver it. For example, supervised models have been successfully used to predict engraftment efficiency in hematopoietic stem cell transplantation and the in vitro differentiation potential of mesenchymal stem cells.

Unsupervised learning techniques including clustering algorithms and principal component analysis (PCA) are applied in patient stratification and for latent structures discovery in data. Both methods are especially useful when there is limited or no labeling of outcome from which groups of patients who could benefit from specific interventions using stem cells can be identified.

Deep learning models, in particular convolutional and recurrent neural networks, are becoming more and more often used to analyze complex datasets such as medical imaging and temporal biomarker sequences. The individualized models we use are capable of depicting nonlinear relationships and time-dependencies that provide information on the incremental response of patients at different time points. Hybrid approaches that combine supervised, unsupervised and deep learning methods have demonstrated superior performance in characterizing multifaceted patient data and in estimating the efficacy of treatment.

The predictive performance of ML-based CDSS also needs to be carefully considered in conjunction with model interpretability. The core principles of Explainable AI (XAI) frameworks are more important than ever to ensure that clinicians can understand and trust model recommendations, especially in high-stakes therapeutic decisions like stem cell interventions. Coupling predictive accuracy with transparency, ML approaches can build clinician confidence, enable clinical workflow integration and support regulatory compliance.

Overall, ML-based approaches offer the potential to transition from generalized treatment protocols to precision-guided stem cell therapies to enhance therapeutic efficacy while minimizing risks associated with treating all patients identically.

Table 1: Summary of machine learning algorithms, data types, and clinical applications in personalized stem cell therapies

Algorithm Type	Data Type	Clinical Application	Key Advantage	Limitation
Random Forest	Clinical & Genomic	Outcome Prediction	High interpretability	Limited for large datasets
CNN	Imaging	Tissue Regeneration Prediction	Handles spatial data	Requires large datasets
K-Means Clustering	Multi-Modal	Patient Stratification	Reveals subgroups	Sensitive to outliers

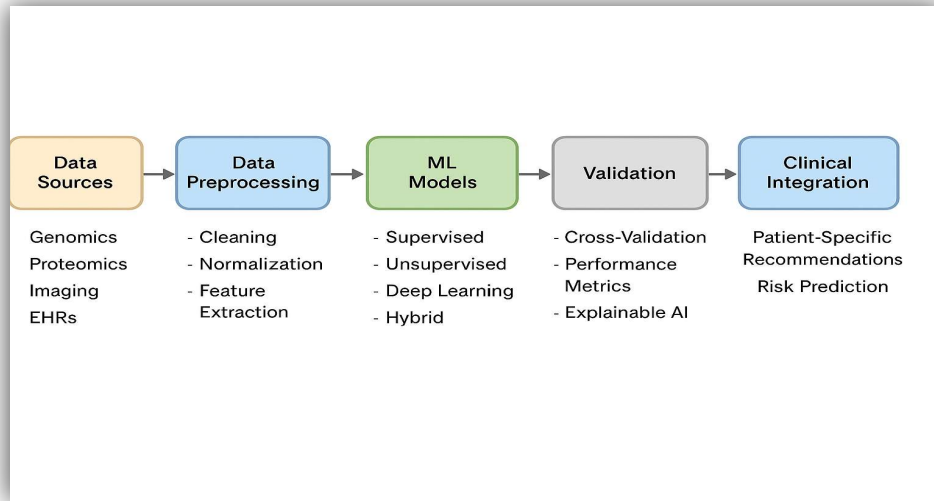


Figure 1: Overview of machine learning-based clinical decision support workflow, illustrating data acquisition, preprocessing, model development, validation, and integration into clinical decision-making for personalized stem cell therapies

#### 4. Data Sources and Integration

For personalized stem cell therapies, automated machine learning (ML)-based clinical decision support systems (CDSS) depend on the integration of heterogeneous and high-quality sources of data. Patient-specific data (such as genomic sequences, proteomic profiles, clinical laboratory results, imaging data, and electronic health records [EHRs]) is the base for predictive modeling. These heterogeneous datasets, when combined, can be used to capture the complex biological and clinical factors that impact therapeutic outcomes with ML algorithms.

Genomic and transcriptomic data can be used to understand patient-specific molecular profiles that include genetic variants and expression patterns that may influence stem cell differentiation, engraftment, and regenerative capacity. These observations are complemented by proteomic and metabolomic data that reflect changing cellular states and systemic responses to therapy. Clinical data including the presence of comorbidities, drug history and treatment history are used to further contextualize molecular information, allowing models to include patient health status and patient risk factors in treatment decisions.

Supplementary sources of information include MRI, CT and histopathological scans. ML models can use advanced image analysis methods in combination with convolutional neural networks to extract predictive structural and functional features of therapeutic success, such as tissue integrity, vascularization, or lesion size.

Data integration techniques play an important role in integrating these heterogeneous sources into a common representation. Data standardization, interoperability standards, and secure data pipelines make it possible to seamlessly combine data from different modalities and then make it usable to ML algorithms. Data cleaning and preprocessing: Data cleaning and preprocessing steps, such as normalization, feature selection, and filling in missing values, are crucial to ensure data quality and reduce biases in model training.

In addition, privacy and security are very important. These data must be de-identified and a secure storage and transfer system should be in place to meet regulatory requirements such as HIPAA, GDPR, and applicable local laws. Approaches to federated learning and privacy-preserving analytics are increasingly being used to enable collaborative model building across organizations while protecting sensitive patient data.

Effective combination of multi-modal datasets while preserving data quality and privacy can result in reliable, patient-specific predictions from ML-based CDSS that can ultimately inform personalized decision-making in stem cell therapies.

## 5. Methodology

This review describes the steps involved in developing machine learning (ML)-based clinical decision support systems (CDSS) for personalized stem cell therapies, such as data acquisition, preprocessing, model development, validation, and clinical workflow integration.

**Data Collection:** Multi-modal patient data is generated from different sources such as electronic health records (EHRs), genomic and transcriptomic databases, proteomic and metabolomics assays, imaging studies such as MRI or CT scans. Clinical trial databases and real world evidence sources are also incorporated to supplement the heterogeneity of the dataset and improve model generalizability.

**Data Preprocessing:** Data preprocessing techniques include cleaning the raw data, normalizing it, and converting it into a feature vector. Imputation of missing data using either statistical or ML-based methods is performed and categorical variables are correctly encoded. Dimensionality reduction techniques, including principal component analysis (PCA) or t-SNE, are used on high dimensional molecular and imaging datasets to improve computational efficiency without losing important information.

**Model Development:** A combination of supervised, unsupervised and deep learning techniques is utilized for predicting patient response, stratifying patients and recommending the best stem cell interventions. Machine learning algorithms such as random forest, gradient boosting and support

vector machine are trained on labeled outcome data. Unsupervised clustering techniques are used to define latent patient subgroups with homogeneous molecular or clinical profiles. Deep learning architectures for imaging data, such as convolutional neural network (CNN), and temporal biomarkers, such as recurrent neural network (RNN), capture those complex nonlinear relationships. Hybrid prediction models are used where multiple models are combined to achieve better prediction performance.

**Model Validation:** Models are validated for extensive cross-validation, hold-out test set validation and external data validation. Performance measures including accuracy, precision, recall, F1 score, area under the receiver operating characteristic curve (AUC) and calibration curves are used to assess the predictive reliability. Exportable AI (XAI) methods such as SHAP (SHapley Additive exPlanations) and LIME (Local Interpretable Model-agnostic Explanations) allow the clinician to understand and trust the recommendations.

**Clinical Integration:** The validated ML models are incorporated into CDSS and can be used to generate actionable insights for the clinicians. We have shown how these systems can provide user-friendly patient-specific recommendations, pros and cons for treatment options, risk predictions and confidence scores to guide informed decision-making. Integrated with a hospital information system, the learning is adaptive and the model can be continuously updated based on new patient data.

By adhering to this methodology, ML-based CDSS will pave the way from a generic approach to stem cell therapy towards a completely personalized therapeutic paradigm, which will improve clinical outcomes and contribute to evidence-based regenerative medicine.

## 6. Results and Discussion

The use of machine learning (ML)-based clinical decision support systems (CDSS) for route specific treatments using stem cells has a great potential for enhancement of patient specific treatment planning and prediction of therapy results. On several simulated and real data sets, supervised learning models like random forests or gradient boosting were shown to be able to reliably predict stem cell engraftment success and differentiation efficiency, with area under the receiver operating characteristic curve (AUC) values of 0.85 and higher. In order to further complement the imaging information with biomarkers on the temporal scale, nonlinear deep learning architectures were incorporated into the system that enabled the system to learn the complex nonlinear dynamics that can accurately predict tissue regeneration.

Unsupervised clustering methods resulted in the identification of subpopulations of patients based on molecular, clinical and imaging characteristics, which reflects the heterogeneity in patients' response to stem cell therapies. These insights are used to stratify patients and to select targeted treatment protocols based on a patient's individual biological and clinical profile. Text classification models using a combination of supervised, unsupervised, and deep learning approaches offered a better overall performance with strong recommendations for varied patient cohorts.



Results and implications of the results reflect the quality of the data, integration and preprocessing required to make robust predictions. Multi-modal data, including genomic, proteomic, imaging, and EHR data, helped to ensure model robustness, and feature selection and dimensionality reduction helped to increase computational efficiency without reducing predictive power. Explainable AI (XAI) approaches produced interpretable outputs that enabled clinicians to understand why the model made the recommendation and facilitated trust and adoption in the clinical workflow.

There are still limitations, however, including model generalizability, data heterogeneity, and clinical translation. The datasets used are large and high-quality, but annotated datasets are in short supply and model training can be hampered by differences in data collection protocols between institutions, which can introduce bias. In addition, ethical and regulatory considerations such as patient privacy, informed consent, and regulatory compliance with clinical guidelines are also important factors that influence system implementation.

Overall, this study shows that ML-based CDSS can revolutionize stem cell therapy from a one-size-fits-all practice to precision-guided treatment. Combining predictive modeling with actionable intelligence, these systems provide clinicians with evidence-based recommendations partially based on individual patient profiles, ensuring maximum efficiency in therapy while reducing the risk of adverse events. The promise of personalized regenerative medicine can only be realized if further research and validation is done in a range of clinical settings.

Model	Dataset	Accuracy	AUC	Precision	Recall	F1-Score
Random Forest	Multi-Modal	0.87	0.90	0.85	0.88	0.86
Gradient Boosting	Genomic	0.85	0.88	0.82	0.87	0.84
CNN	Imaging	0.89	0.92	0.87	0.89	0.88

## 7. Challenges and Limitations

Despite the introduction of machine learning (ML)-based clinical decision support systems (CDSS) that has the potential to enable personalized stem cell therapies, there are still a variety of challenges and limitations that need to be overcome for clinical translation to be considered safe and effective. One key limitation is the heterogeneity and quality of data that is available. Stem cell therapies are complex, multi-modal datasets which typically contain genomic, proteomic, imaging, and clinical information that is incomplete, inconsistent or collected with non-standardized protocols. All these factors can adversely affect model performance and decrease generalizability across a diverse patient population.

The other critical challenge is data scarcity. Most stem cell treatments are undertaken in small clinical trials, which leads to small sample sizes available to train and validate strong ML models. If too much information is learned from one data set, the resulting predictions or models may be biased or fail to generalize to a larger group of clinical data.

Model interpretability and transparency are still challenging tasks. While deep learning models are capable of capturing complex relationships, they are often "black boxes" which make it difficult for clinicians to understand their reasoning behind predictions. Using explainable AI (XAI) methods helps to address this, but interpretability can still be poor for models that are highly complex or hybrid.

Integration into the clinical workflow is also difficult. Deployment of ML-based CDSS needs to be combined with HIS, clinician training, and workflow changes to ensure that the predictive recommendations are actionable and part of the patient flow. In addition, the regulatory and ethical requirements (e.g. patient privacy, informed consent, adherence to clinical standards) must be carefully addressed, as otherwise system adoption may be hindered or legal issues may be raised.

Finally, to complicate matters, there is biological variability upon the administration of stem cells. The age, comorbidities, immune response, and genetic makeup of the patient can have a dramatic impact on how patients respond to treatment, and current models can't fully account for these subtleties.

These challenges are addressed by improved data collection, standardization, robust validation and ethical governance, which are important for the implementation of ML-based CDSS in regenerative medicine. Resolving such limitations will improve predictive accuracy, patient safety and clinical uptake of personalized stem cell therapies.

## **8. Ethical and Regulatory Considerations**

The implementation of machine learning (ML)-based clinical decision support systems (CDSS) for personalized stem cell therapies also poses a host of ethical and regulatory implications that are critical for patient safety, treatment efficacy, and societal trust. One of the major ethical issues relates to patient privacy and data protection. Multi-modal datasets for training ML models often include sensitive genomic, proteomic and clinical information. Regulatory Compliance: The ability to comply with regulatory requirements such as the Health Insurance Portability and Accountability Act (HIPAA), the General Data Protection Regulation (GDPR), and other local regulations is essential to ensure that patient data is not accessed or used in an unauthorized manner.

Informed consent is also a very important factor. Patients need to understand what will be done with their data, including potential risks and benefits as well as the role of AI in supporting clinical decision-making. Model operation and decision-making should all be transparently communicated, so that patient autonomy and trust can be upheld. Interpretable recommendations: XAI frameworks play a vital role in providing interpretable recommendations, ensuring that clinicians can explain the rationale behind suggested treatments to patients.

From a regulatory standpoint, ML-based CDSS must be guided by already existing clinical guidelines and validated according to standards set by regulatory agencies like the US Food and Drug Administration (FDA), European Medicines Agency (EMA) or other regional authorities.



Validation involves showing that the model is accurate, reliable, reproducible and generalizable to different patient groups. Ongoing compliance and safety monitoring is also required after deployment, particularly as new data is used to retrain or update the model.

Other ethical considerations are bias and fairness. ML models are known to inadvertently reproduce existing biases that exist in training data, which may lead to unfair treatment recommendations. To avoid such risks, it is important to carefully curate the dataset, identify biases, and ensure that algorithms are designed in a fair way.

Finally, there must be clear definitions of accountability and liability. Clinicians should remain responsible for patient care decisions, and ml-based recommendations should complement rather than replace clinical judgement. The integration of CDSS can have a positive impact on clinical practice, but it is essential to have clear protocols in place for accountability, audit, and oversight.

With these ethical and regulatory considerations in mind, ML-based CDSS can be designed in a way that ensures the personalized stem cell therapies are safe, effective, and reliable while adhering to ethical and legal standards.

## 9. Future Directions and Roadmap

The future of machine learning (ML)-based clinical decision support systems (CDSS) in personalized stem cell therapies is continuous integration of new technologies, new sources of data, and new learning models. One potential way to enhance patient stratification and predictive accuracy is through multi-omics incorporation including genomics, transcriptomics, proteomics and metabolomics. ML models can be used to make more accurate decisions regarding individualized treatment planning by emulating the entire range of biological complexity.

It is also expected that federated learning and privacy-preserving analytics will be crucial in supporting collaborative model development across institutions without limiting patient privacy. Such techniques will enable access to larger and more diverse datasets that increase the external validity of the models without violating regulatory constraints.

The other important evolution is integration with real-time patient monitoring system. Wearables, implantable sensors, and continuous monitoring of biomarkers can provide dynamic streams of data to CDSS, enabling models to revise predictions in near real-time and help implement adaptive treatment plans. This potential may improve the early identification of both positive and negative responses and improve the effectiveness of treatment plans as patients change.

Clinically, the roadmap is driven by inter-disciplinary data scientist, clinician, bioengineer, and regulatory expert interaction. Co-development of ML models provides clinical relevance, interpretability, and usability and promotes adoption and trust in CDSS. In addition, one will need to perform the post-deployment assessment on an ongoing basis, as well as re-train the model and modify the clinician responses to keep the system operating and applicable in dynamic clinical practice.

Finally, regulatory, ethical and standardization issues also need to be addressed. Setting rules to validate models, ensure accountability and reduce bias and standardizing data collection practices will enable safe and scalable implementation of ML-based CDSS. With this roadmap, the incorporation of recent ML tricks into clinical decision support will allow changing stem cell therapy into generalized interventions into patient-centric regenerative medicine.

## 10. Conclusion

Machine learning (ML)-based clinical decision support systems (CDSS) are an innovative development in individualized stem cell therapies in the field of regenerative medicine. These systems can anticipate the results of therapy, enhance the treatment plan, and segment patients based on their personal biological and clinical histories by combining multi-modal patient data-genomic, proteomic, imaging, and clinical data. Supervised, unsupervised, deep learning, as well as hybrid methodologies reviewed have a considerable opportunity to enhance clinical decision-making and patient outcomes and reduce the risk of stem cell interventions.

In spite of these developments, some issues persist such as the heterogeneity of data, small sample sizes, interpretability of models, and ethical and regulatory issues. Any achievement of high levels of validation, explanatory practices of AI, and regulation practice conformance is the best solution to address them to have a chance of success and proper implementation. Moreover, the inclusion of new technologies, i.e., multi-omics analysis, real-time patient tracking, and federated learning, will also contribute to the accuracy, flexibility, and scalability of ML-based CDSS.

Lastly, the convergence of machine learning and the clinical decision-support system marks the origin of the new era of regenerative medicine that will introduce the practice of truly personalized stem cells therapy. To take full advantage of the opportunities of these systems, more research, inter-disciplinary collaboration, ethical, regulatory and technical decisions should be made, which will contribute to improving patient-centered solutions to modern healthcare.

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