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Exploring Statistical Relationships for Risk Assessment and Value Computation of Digital Health Technologies in India

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ABSTRACT

In this research, we explore the statistical models that have contributed to determining the value of digital health technologies (DHTs) in global contexts and demonstrate their critical application using diverse datasets within the Indian context. We highlight the incorporation of several key healthcare analytical approaches, such as propensity score matching to evaluate treatment effects in cardiovascular research, structural equation modeling to examine psychosocial factors contributing to academic burnout among college students, and random survival forest classification methods for identifying genetic markers associated with breast cancer prognosis. We utilize a college-level social burnout survey and a comprehensive Kaggle dataset to show the application of these approaches. This is the first study of its kind to highlight both these datasets and key analytical methods, tools that are underutilized in India, while showing their practical relevance for guiding digital health investments and addressing healthcare challenges in the country. This study draws on several case studies with datasets to present a future perspective, where key statistical methodologies play a central role in improving healthcare productivity and promoting personalized care.

Keywords: Digital Health Technology, Propensity Score Matching, Structural Equation Modeling, Machine Learning.

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INTRODUCTION

Digital Health Technology Overview

In today's rapidly and evolving technological landscape, digital health technologies (DHTs) stand out as symbols of innovation and transformation. These technologies cover a range of tools and applications such as mobile health (mHealth), health information technology (HIT), wearable devices, telehealth and telemedicine, and personalized medicine.[1,2] By leveraging computing platforms, connectivity, software, and sensors, DHTs are transforming the delivery and experience of healthcare services. DHTs are being used, ranging from promoting general well-being to acting as an integral component of medical devices. These technologies are not only utilized in clinical environments but also work in conjunction with multimodal medical products such as devices, drugs, and biologics. One of their most significant contributions is providing healthcare providers with comprehensive, data-driven insights into patient health, while simultaneously empowering patients to take a more active role in managing their own care. The benefits of digital health are substantial, including improvements in medical outcomes and operational efficiencies. Enabled by these innovations, patients can make informed decisions about their health, and providers can facilitate early diagnosis and manage chronic conditions beyond traditional care settings.

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In mid-2023, the digital therapeutics alliance (DTA), the leading international trade organization on digital therapeutics, and its partners outlined key categories of digital health. Their report outlines eight categories, including software used in health systems, tools outside traditional health settings, and patient-focused areas like care support, digital diagnostics, digital therapeutics, wellness, and remote monitoring. Each category highlights the diverse and integrated roles DHTs play in modern healthcare, significantly impacting providers and patients. As we delve deeper into the intricacies of DHTs, it becomes clear that these innovations are not merely shaping the future of healthcare but they are also actively redefining it, offering new paradigms for health management and care in the digital era.[3]

Advanced Statistical Method for DHT Evaluation

Furthermore, DHTs play a key role in enhancing healthcare effectiveness, expanding access, reducing costs, improving quality, and personalizing medical care. The FDA's Center for Devices and Radiological Health (CDRH) is leading efforts to integrate medical devices with consumer-facing technologies, optimism about a future shaped by these innovations. To address complexities of this field, the FDA has focused on several priority areas, including software as a Medical Device (SaMD), Artificial Intelligence and Machine Learning (AI/ML) in SaMD, cybersecurity.[4] This proactive approach ensures a balance between leveraging technological benefits and managing potential emerging risks.

Challenges of DHT Implementation

Despite its promise, DHT also introduces substantial challenges. These technologies handle highly sensitive personal data, making them susceptible to increasingly sophisticated cyber threats. Integrating DHTs with existing healthcare infrastructure (like hospital IT systems) often comprised of legacy systems, can be complex, and may lead to inefficiencies, errors, or data silos. Regulatory challenges also persist, as DHT-related products are governed by diverse laws and standards (e.g., HIPAA in the U.S. and GDPR in Europe), making compliance costly and resource-intensive, particularly for startups and smaller organizations. Furthermore, DHTs risk exacerbating health disparities, as not all populations have equitable access to digital tools or reliable internet connectivity. Traditional healthcare payment systems are often ill-suited to accommodate digital health solutions, potentially hindering their adoption. Without clear reimbursement pathways from insurance providers or public health systems, healthcare providers may hesitate to integrate new technologies into routine practice.[5]

Generating Value of DHT

DHTs are significantly reshaping healthcare by improving operational workflows, enhancing clinical outcomes, and elevating patient engagement.[6,7] For instance, electronic health records (EHRs) minimize administrative burdens, reduce the need for manual record-keeping, and decrease labor costs.[8, 9] Predictive analytics plays a crucial role in optimizing inventory and supply chain management by basing orders on real-time needs, resulting in cost-effective resource utilization.[10] In addition to reducing expenses, DHTs can also generate new revenue streams for healthcare providers through services such as personalized medicine, telemedicine, and lifestyle-focused wellness programs.[11]

Objective

This study presents and analyzes several advanced statistical models that contribute to the evaluation of DHTs in the Indian context. It examines how these models aid in quantifying and optimizing the impact of DHTs on healthcare delivery. Using a series of case studies, the article explores how statistical methodologies enhance healthcare efficiency and support patient-centered strategies. It discusses statistical techniques such as Propensity Score Matching (PSM), for analyzing treatment effects in cardiovascular research, Structural Equation Modeling (SEM) to investigate psychosocial determinants of academic burnout, and Random Survival Forest (RSF) for identifying genetic markers related to breast cancer prognosis. In addition, this research utilizes a rich Kaggle dataset to estimate COVID-19 fatality thresholds, demonstrating the practical utility of these models for public health decision-making. By showcasing these applications, the article advocates for the broader use of these robust statistical models in real-world healthcare scenarios, with a primary emphasis on the India context, highlighting their role in making healthcare more efficient, equitable, and informed by localized data through the lens of digital transformation.

ADVANCED STATISTICAL MODELING IN HEALTHCARE

Propensity Score Matching

Propensity score matching (PSM) assesses treatment effects in healthcare datasets by comparing matched samples to reduce selection bias. This commentary discusses methods to ascertain both relative and absolute treatment effects when employing propensity score matching within competing risk data frameworks. Relative treatment effects are determined using cause-specific hazard models in matched samples, while absolute effects are evaluated by comparing cumulative incidence functions (CIFs) between matched treated and control subjects.[12] The cause-specific hazard model for the k^{th} event type allows one to estimate the association of covariates with the cause-specific hazard function for the k^{th} event type as follows:

$$\lambda_k^{CS}(t) = \lambda_{0k}^{CS}(t)\, exp(\beta X)$$

where $\lambda_{0k}^{CS}(t)$ denotes the baseline cause-specific hazard function for the kth event type, and X denotes a vector of covariates and the subdistribution hazard function for event type k defined as:

$$\lambda sd,k(t)= \lim_{\Delta t \to 0} P(t<T\leq t+ \Delta\, t, D=k|T>t \cup (T<t \cap K=k))$$

where T be the time of the event; D be the event type (e.g., cause of death or failure type); k is the specific event of interest (e.g., death due to cardiovascular disease in a study with multiple causes of death); Δt be a very small time interval, approaching zero. $P(t<T\leq t+\Delta t, D=k)$ be the probability that an event of type k occurs within the small time interval $(t,t+\Delta t]$.

PSM was applied to survival data with competing risks using the EFFECT dataset (10,063 myocardial infarction patients, 5-year follow-up). Monte Carlo simulations assessed empirical Type I error rates of various statistical methods comparing CIFs. Results promote the use of a marginal subdistribution hazard model tailored to accommodate within-pair clustering of outcomes, enhancing the accuracy in testing CIF equality and estimating subdistribution hazard ratios. This approach bridges the gap between theoretical statistical models and practical applications in medical research, providing a robust framework for more precise treatment effect estimation in the presence of competing risks.[13]

Structural Equation Modeling

Stressors may affect the mental and physical health of college students, leading some of them to burnout syndrome. To evaluate this syndrome in syndrome in students at Arizona State University (ASU), a survey was conducted using a previously developed questionnaire, with ordinal variables. A theoretical structural equation modeling (SEM) was proposed, and the estimated model was obtained by applying the partial least squares (PLS) approach (Figure 1). Based on the PLS-SEM path coefficients, the latent construct "behavioral stress" directly affects "distress" and "insecurity" and indirectly affects both "quantitative demands" and "academic burnout".

SEM, particularly the PLS-SEM approach, has been applied effectively to explore the psychosocial factors contributing to academic burnout among ASU students.[14] This advanced statistical technique allows for the simultaneous modeling and analysis of relationships between observed and latent variables, capturing complex interactions within educational and psychosocial data. In the present study, SEM was used to investigate how latent variables like "behavioral stress", "insecurity", and "academic demands" contribute to burnout, utilizing data collected through a comprehensive survey. The findings highlight significant causal pathways, such as the impact of "distress" on "burnout", and the model suggests that increased "insecurity" and "stress" are strongly associated with higher "burnout" levels among students. We can write the structural equations (from Figure 1) of the estimated model as:

Insecurity = f (Behavioral stress); Distress = f (Behavioral stress)

Quantitative demands = f (Insecurity)

Academic burnout = f (Quantitative Demands, Distress)

We can write the structural equations (from Figure 1) of the estimated model as:

$$\textit{Insecurity} = 0.548\,\textit{Behavioral stress};$$

$$\textit{Distress} = 0.655\,\textit{Behavioral stress};$$

$$\textit{Quantitative demands} = 0.625\,\textit{Insecurity};$$

$$\textit{Academic burnout} = 0.360\,\textit{Quantitative demands} + 0.498\,\textit{Distress}.$$

These insights are critical for developing targeted interventions aimed at reducing stress and improving well-being in academic settings, also demonstrating the practical applications of SEM in real-world psychological research.

Classification Methods: Random Forest and Regression Comparison

This study aims to identify key genes associated with mortality progression in breast cancer in patients by utilizing advanced analytical methods to rank influential predictive factors. Leveraging Logistic regression alongside various classification models such as random forest, support vector machine, linear discriminant analysis, and decision tree, the study found random forest to offer superior predictive accuracy.

Specifically, the random survival forest (RSF) method was adapted for right-censored survival data, incorporating strategies like bootstrapped data growth, random feature selection, and deep tree growth. The RSF method employs a unique log-rank splitting approach to enhance the precision of gene selection, utilizing the Nelson-Aalen cumulative hazard estimator expressed as

$$\mathrm{L}\,(x,c) = \frac{D^{\frac{1}{2}}\left(D_j - \sum_{l=1}^{N} I\{x_l \leq c\}\, H^{\wedge}(T_l)\right)}{\left\{\sum_{l=1}^{N} I\{x_l \leq c\}\, H^{\wedge}(T_l)\right\}\left\{D - \sum_{l=1}^{N} I\{x_l \leq c\}\, H^{\wedge}(T_l)\right\}}$$

where $D_j = \sum_{i=1}^{N} d_{i,j}$; $j = 1, 2$ and $D = \sum_{i=1}^{N} d_i$, $H^{\wedge}(t) = \sum_{t_i \leq t} \frac{d_i}{Y_i}$ (Nelson Aalen estimator); $Y_{i,j}$ is the individuals who are at risk (alive) or who had an event (death), and $d_{i,j}$ is the number of events at time t_i in daughter node j, where $j \in \{1, 2\}$.

The data for this analysis was sourced from the NKI breast cancer dataset,[16] comprising 272 patients characterized by 1554 gene attributes, 10 clinical attributes, and 3 general attributes, highlighting significant variables such as chemo, hormonal treatments, and gene expressions. This comprehensive approach underscores the potential of integrating complex statistical methods in medical research to enhance predictive accuracies in breast cancer prognosis.[17]

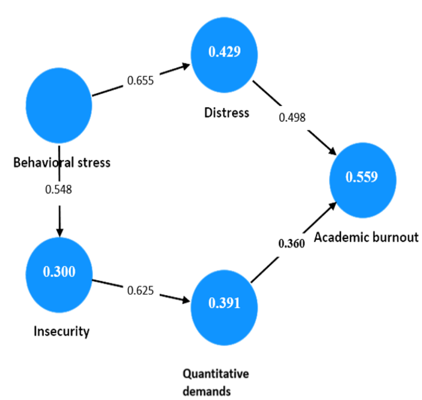

Figure 1: Partial least squares-structural equation modeling estimates, obtained with SmartPLS 3.0 software[15].

Two different survival splitting rules have been implemented by using separate RSF methods and by constructing the rank of risk factors, such as chemo and hormonal treatments, due to breast cancer.

Survival Analysis with Competing Risk

This work explores COVID-19 mortality risk factors using advanced survival analysis techniques that account for competing risks, a significant improvement over traditional methods like the Kaplan-Meier and Cox proportional hazards models. We employ the subdistribution hazard model, which is particularly suited for datasets with competing risks. The model is represented by the equation

$$\gamma_1(t \mid x) = \gamma_{1;0}\left(t\right) exp\left(\eta_1^T x\right)$$

where $\gamma_1(t \mid x)$ denotes the subdistribution hazard for the event of interest depending on the vector of covariates x, $\gamma_{1;0}(t)$ is the baseline subdistribution hazard for an individual with all covariates equalling zero, and η_1 is the vector of regression coefficients.

Analyzing COVID-19 data from Kaggle, which includes 66,000 records with demographic and disease-specific variables, our findings provide a detailed profile of mortality risks based on a dataset with considerable completeness (53.6k valid entries) and some missing data (18.0k). This research underscores the enhanced predictive power and accuracy of survival models in public health studies, particularly in understanding pandemics like COVID-19 under different scenarios. It also illustrates the differential impact of COVID-19 based on gender and age.[18]

Model Validation and Taxonomy of Survival Analysis

This work demonstrates the robust integration and validation of advanced statistical models such as PSM, SEM, and RSF, highlighting their versatility across various medical fields, including cardiology, oncology, and psychological health. PSM was validated through Monte Carlo simulations in the EFFECT Study, confirming its effectiveness in handling competing risks and improving accuracy in cardiovascular treatment assessments. SEM was successfully applied to analyze psychosocial factors influencing academic burnout at Arizona State University, showing significant correlations that facilitate targeted interventions for improving student well-being.[14] Meanwhile, RSF proved superior in identifying genetic markers for breast cancer prognosis, outperforming traditional methods with its precision in handling right-censored data, which underscores its reliability and clinical applicability.

The taxonomy (from Figure 2) of survival analysis provides a structured classification of statistical methods that analyze time until an event of interest occurs.[17] It encompasses the analysis by identifying the role of explanatory variables (covariates), characterizing the type of time-to-event data (survival data), addressing the presence of alternative events that could interfere with the event of interest (competing risks), and extending survival predictions beyond the observed data (extrapolation) and each category encompasses specific methods tailored to handle different aspects of survival analysis[18] This structured framework systematically ensures comprehensive, diverse methodologies and precise application of survival studies.

DISCUSSION

Selected Approaches in Healthcare

Advanced analytical methods applied in real-world healthcare scenarios highlight the transformative potential of statistical models in enhancing medical outcomes and operational efficiency.[19] For instance, the application of these models in analyzing COVID-19 mortality risk factors using a Kaggle dataset provided detailed insights into pandemic management, demonstrating the models' adaptability and precision in public health crises.[20] Furthermore, the incorporation of these models supports healthcare professionals and researchers in making informed decisions, facilitating early detection of diseases, managing chronic conditions more effectively, and tailoring treatments to individual patient needs.[21] The proactive approach of integrating technologies such as Software as a Medical Device (SaMD) and Artificial

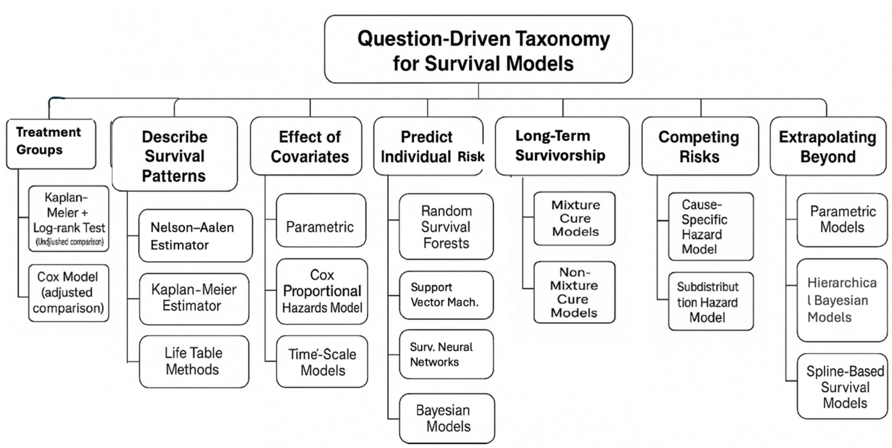

Figure 2: Taxonomy of Survival Analysis.

Intelligence further illustrates the forward-thinking strategies necessary to harness technological benefits while managing potential risks effectively.[10,22]

Key Statistical Methods for Evaluating DHT

Overall, the validation and discussion around these models emphasize their indispensable role in not only advancing medical research but also crafting a responsive and efficient healthcare system capable of addressing both current and emerging health challenges.[23-25] This synthesis of technology and methodology heralds a new era of digital health where innovation meets practical application, ultimately redefining healthcare delivery and patient care in the digital age.[26] Future research should expand the use of advanced statistical models like Propensity Score Matching, Structural Equation Modeling, and Random Survival Forest across various medical fields, integrating these with emerging technologies such as blockchain and AI for enhanced data management and real-time analysis. Efforts should focus on leveraging these models for predictive analytics in public health, enhancing treatment personalization, and developing ethical frameworks for AI applications. Collaborations across disciplines will be crucial to maximize the potential of digital health technologies, ensuring a comprehensive approach to improving healthcare outcomes and operational efficiency.[27]

Additionally, longitudinal studies will help assess the long-term impact of these innovations, supporting continuous improvement in healthcare delivery.

Value Assessment of DHT

The above key statistical methods can generate significant value for DHTs by enhancing the analysis, interpretation, and utilization of these technologies' vast and complex data. They can enhance predictive analytics by enabling early detection of diseases and facilitating personalized medicine. These models can handle complex and high-dimensional data simultaneously and also enhance decision support systems by improving accuracy and reducing uncertainty. Models can help optimize DHTs interventions such as telemedicine, mobile health apps, and remote patient monitoring through adaptive interventions and cost-effectiveness analysis.[1,11] Advanced algorithms can analyze real-time health data streams, offering instant feedback through techniques such as dynamic risk assessment and anomaly detection. By leveraging advanced statistical models, large-scale health data can be used to identify population-level health trends, predict disease outbreaks, and inform the design of effective public health interventions.[28-32]

Evaluating DHTs requires a comprehensive value framework that goes beyond traditional clinical and economic assessments to include humanistic, ethical, societal, and system-level dimensions unique to digital innovations.[33,34] While aligned with conventional evaluation approaches, the clinical value of DHTs includes improved health outcomes, early diagnosis, prevention, treatment adherence, and reduced complications, supported by data from randomized controlled trials (RCTs), electronic health records (EHRs), mobile app logs, and patient-reported outcomes.[35] Similarly, economic value is assessed through cost-effectiveness, quality-adjusted life years (QALYs), and budget impact analyses, using data on intervention costs, healthcare utilization, and productivity metrics.[36]

Beyond clinical and economic impact, DHTs bring added value through their contributions to extended human experience, ethics, and social equity. Humanistic value emphasizes user satisfaction, digital empowerment, usability, and quality of life, elements often captured through surveys, focus groups, and engagement metrics from apps and wearable devices.[37,38] Ethical and societal considerations such as equity in access, digital inclusion, data privacy, and cultural acceptability are critical to DHTs adoption and can be evaluated through demographic analyses, equity audits, and subgroup impact studies.[39,40] Furthermore, DHT-specific factors like implementation readiness, interoperability, and integration into existing health systems must be assessed through system audits, provider feedback, and reviews of digital infrastructure.[41,42]

The estimation of DHTs value depends on integrating diverse data sources through structured methodologies such as health technology assessment (HTA), multi-criteria decision analysis (MCDA), and simulation models.[43,44] Stakeholder preferences captured through tools like discrete choice experiments or Delphi panels can also add context-specific weight to each value element. Relevant national and global datasets play a critical role, including the National Family Health Survey (NFHS),[45] Health Management Information System (HMIS),[46] Ayushman Bharat Digital Mission (ABDM),[47] and Demographic and Health Surveys (DHS). International sources like the Global Burden of Disease (GBD),[48] WHO ICTRP, and GDHI also provide useful benchmarking. Platforms such as DHIS2[49] and OpenMRS,[50] widely adopted in low and middle-income countries (including parts of India), offer real-world evidence from public health programs.[51] Supplementary sources like Google Mobility Reports[52] and ITU connectivity indicators[53] support analysis of behavioral trends and infrastructure readiness. Aligning DHTs evaluations with such multidimensional value frameworks and high-quality datasets ensures informed, equitable, and scalable decision-making in digital health adoption.

Limitations of These Statistical Methods

The efficiency of statistical models is highly reliant on the quality and integrity of the data. In this context, gaps, inconsistencies, and the lack of standardization in data collection can significantly limit the accuracy of predictions produced by the models. The findings deliberated may not be generalizable outside the particular situation or populations studied. For instance, models developed and validated in urban hospital settings may perform poorly in rural or less technologically advanced areas. Advanced statistical models can also be complex to implement correctly. Additionally, integrating new DHTs solutions with existing healthcare infrastructures poses significant challenges, as incompatibility between new and older systems can lead to errors and inefficiencies.[54,55]

Future Work

Future work could focus on developing more robust methods for data collection and management to ensure that the datasets used are comprehensive, accurate, and reflective of diverse populations. Future research can focus on bridging the gap between emerging digital health technologies and existing traditional systems by developing standardized software and promoting integration mechanisms that enhance interoperability. Further studies are required to address ethical dilemmas and regulatory complexities related to DHT, ensuring patient privacy and data protection.[11] Exploring the application of innovative technologies such as the Internet of Things (IoT), blockchain, and artificial intelligence could provide novel routes to optimize healthcare delivery. Moreover, conducting comprehensive assessments of the long-term and implications of these technologies can provide critical insights into their sustained effectiveness and scalability.

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