Decision-Making Model Transparency for SaMD Machine Learning Algorithms

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Abstract

The purpose of this research is to explore the theoretical decision-making framework of software as a medical device (SaMD) and autonomous clinical decision support in healthcare. Artificial Intelligence (AI) machine learning algorithms have the ability to efficiently evaluate complex datasets to make predictions, however despite the advantages, there are unique challenges in the application to actual clinical problems, including algorithm usage, algorithmic bias, data transparency, and clinical understanding of the machine learning tools. Limited extant research exists on AI-SaMD decision-making transparency, with prior research focusing primarily on the regulatory frameworks of SaMD and AI. Changes in AI and robotic process automation have the potential to radically disrupt and change current organizational healthcare structures. Due to increased chronic disease, aging population, inequality, and environmental factors, there is a desire to improve the accuracy and speed of diagnosis. Different decision-making machine learning lenses can lead to variations in healthcare effectiveness and the ability to support decision-making and machine learning. In prior studies comparing human and AI diagnosis performance, deep learning algorithms demonstrated accuracy equivalent to clinicians. However, due to limited studies reviewing AI performance in a real environment, there is still a high degree of uncertainty in the usage of AI. This research analyzes SaMD literature and develops a theoretical model based on a review of healthcare SaMD decision-making machine learning lenses, in order to develop new theoretical concepts, healthcare industry insights, and recommendations.

Keywords: Software as a Medical Device, SaMD, Decision-Making, Artificial Intelligence, Machine Learning, Clinical Decision Support

1. INTRODUCTION AND IMPORTANCE

Artificial Intelligence (AI) is a method to follow human intelligence and encompasses various learning areas including machine learning (ML), representation learning, deep learning, and natural language processing (NLP) capabilities. The goal of AI in healthcare is to assist decision-making such as diagnosis, risk prediction, medical error reduction, image analysis, and improved productivity. AI has the ability to assist humans in providing healthcare, however despite their advances, their implementation is still limited. Current implementations are complex and issues include data sharing, data integration, regulatory framework compliance, and transparency (He, Baxter, Xu, Xu, Zhou, & Zhang, 2019).

Decision Model Transparency

Data transparency and AI algorithms transparency is a major concern and transparency may be difficult due to algorithmic complexity or company protection of proprietary methods. Accuracy of predictions relies on correctly labeled input data for training input data that should be transparent. Transparency also applies to human understanding of the algorithm, such as how the AI method reached a decision to justify and verify a diagnosis, treatment, or outcome. Often AI algorithms are considered opaque or unknown which may lead to algorithm bias based on race, gender, or other factors. Transparency allows review and analysis of any potential bias, and could ultimately help solve healthcare disparities based on known biases (He et al., 2019).

AI systems used in healthcare are flawed due to the inherent bias contained within these systems (Ngiam and Khor, 2019). The AI bias in healthcare may include any systematic error in the experimental design, sampling, algorithm selection, knowledge capture, reliability and depth of information, expert knowledge, or analysis of the study. While often unintentional, this bias includes information and selection bias. Decision support systems used in healthcare, therefore require additional validation of reliability and validity under a theoretically informed model framework (Gurupur & Wan, 2020).

Originality of Approach

Decision-making is a critical organizational function; however, it is often a complex and ambiguous process. Despite efforts to develop decision models to address business uncertainty, additional research is required on the decision-making process and factors (Nooraie, 2012). Identifying the factors that influence decision-making is an important part of understanding the decisions that are made and resulting outcomes (Ejimabo, 2015). Decision-making is found in clinical literature, however the success of these decisions in improving healthcare outcomes is not conclusive. The research aims and approach is to identify a given set of decision-making characteristics that lead to the best decision-making behavior, ultimately leading to improved healthcare outcomes, with research reviewed specific to the SaMD application subset. Extant research on AI-Software as a Medical Device (SaMD) has focused on regulatory frameworks or clinical applications and uses. The original approach in this research is to review the literature and theoretical foundations to develop a transparent and theoretically informed model framework of decision-making for achieving successful AI-SaMD healthcare outcomes.

2. LITERATURE REVIEW

Artificial Intelligence

Increasing amounts of data and new artificial intelligence (AI) brought to market in the last few years are expected to be a disruptive force in the healthcare industry within the next decade (Manye, 2017; Woodside, 2018). Healthcare spending on AI technology is projected to exceed $34 billion by 2025, a significant increase from $2 billion in 2019. AI is being used to address increasing healthcare costs along with population shifts and workplace shortages. AI can also be utilized for automating repetitive tasks and act as an assistant to healthcare professionals (Maney, 2017; Pifer, 2019a). AI through robotic process automation has the ability to computerize simpler tasks, with over one-third of healthcare job activities able to be automated (Chui, Manyika, & Miremadi, 2016).

In addition to process automation, AI can be applied to other healthcare opportunities such as surgeries and patient mobility. Several medical centers have begun using robotic surgical systems, with the explanation that the robotics are not intended to replace surgeons but rather to improve their abilities through high-definition 3-D images and smaller incisions made with robotic arms that allow a greater range of motion than the human wrist. The US Food and Drug Administration (FDA) has approved over 30 AI algorithms for healthcare, and range from bone image fracture detection to CT scan stroke identification, with radiology analysis the most common area of application. However, there is a lack of specialists to review all the images, with low-middle income countries having the greatest need. AI can be leveraged as a tool to augment clinicians in their decision support and decision-making. In prior studies comparing human and AI diagnosis performance between 2012-2019, deep learning algorithms were 87% accurate compared with 86% accurate for clinicians, albeit with limited implementations (Pifer, 2019b).

Machine Learning and Software as a Medical Device

AI is the broader field of emulating human abilities, while machine learning is concerned with a focused area of AI that trains a machine on how to learn through pattern recognition and the ability of a computer to learn from data and adapt to complete tasks (SAS, 2020). Medical device manufacturers are utilizing AI and machine learning technologies to gather insights from generated data. AI and machine learning as part of SaMD have the ability to optimize performance in real-time to improve health care outcomes (FDA, 2020b). The FDA and International Medical Device Regulators Forum (IMDRF) have developed a new category of AI-based technology separate from more traditional medical devices, known as Software as a Medical Device (SaMD) (He et al., 2019).

SaMD is software used for medical purposes and software used on its own (i.e. that is not within the hardware of a medical device - software in a medical device) that can be used to diagnose or treat and prevent disease. SaMD can be integrated and utilized across various technology products and platforms, including Commercial of the Shelf (COTS) and virtual networks (FDA, 2020; Heier, 2020). Applications of SaMD include screenings, diagnosis, monitoring, alerting, population health management, and digital therapeutics, with the ability to improve health outcomes through data collection accuracy and timeliness (Heier, 2020). For example, researchers have used SaMD in determining undiagnosed sleep disordered breathing (Hilmisson, Sveinsdottir, Lange, & Magnusdottir, 2019).

To ensure patient safety, global regulators have sought to develop a common framework and guiding principles for SaMD. The International Medical Device Regulators Forum (IMDRF) is a global volunteer working group that is developing the guidelines and evaluation of SaMD (FDA, 2020a). IMDRF has developed definitions and a common regulatory framework for SaMD (He et al., 2019). The FDA's traditional medical device regulation was developed with AI or machine learning technologies in mind, and the FDA is reviewing regulatory frameworks to allow learning and adaptability while ensuring the safety and effectiveness of SaMD. In the current proposed framework, a premarket review plan would include the anticipated SaMD modification, controlled algorithm changes protocol methodology and risks, transparency, and performance monitoring (FDA, 2020b).

3. METHODOLOGY

The research methodology follows a metatriangulation design, which is a qualitative theory-building process that allows researchers to better understand and describe the underlying extant theory, gain insights into paradigms, and develop stronger theoretical foundations for understanding phenomenon. The theory-building process includes three steps of 1) groundwork, 2) analysis, and 3) theory development (Jasperson, Carte, Saunders, Butler, Croes, & Zheng, 2002; Saunders, Carte, Jasperson, & Butler 2003).

Groundwork

During the groundwork step of the metatriangulation process, the area of interest, lenses, and document samples are collected. The metatheoretical document sample in this study includes a set of de-duplicated journal articles. The process of article selection was based on a PRISMA chart as shown in Figure 1 (Samadbeik, Yaaghobi, Bastani, Abhari, Rezaee, & Garavand, 2018). These journal articles are selected through an EBSCO search for keywords "SaMD" and "Software as a Medical Device". The initial search yielded 670 total results. The results are further refined to full text, peer-reviewed academic journal articles, with a topic area of healthcare SaMD, and classified with the subject area of healthcare, resulting in 6 remaining articles. Of note, SAMD is a commonly used acronym across varying industries including terms such as Security Assistance Management Directive (SAMD), Solid Assisted Melt Disintegration (SAMD), Students as Multimedia Designers (SAMD), among many others. The individual documents are cataloged, cleaned, and converted to a standard format for analysis preparation.

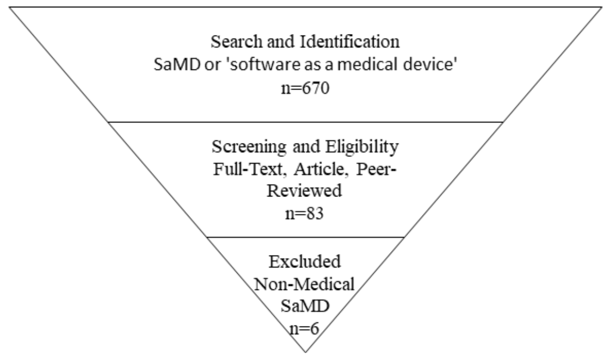

Figure 1: **Article Selection**

Analysis

During the analysis step, the document sample is coded according to the lense and the information-intensive data is further dissected to construct paradigms. The relationship between decision-making and SaMD in healthcare is explored using a set of decision lenses. These decision-making machine learning lenses include the three general decision theories of positive, normative, and behavioral. The data is then deconstructed further to confirm document coding and extract additional insights or patterns. Table 1 displays a summary of the SaMD document sample including the primary study area of focus and primary decision lense coding. In a study on sleep disordered breathing, an FDA approved SaMD was used to analyze sleep data including sleep duration, sleep quality, heart rate variability (HRV), and electrocardiogram derived respiration (EDR) (Hilmisson et al., 2019). Another study developed a decision support grading system software for brain trauma and other conditions, using a mobile device application (Kubben, 2017). McCarthy and Lawford (2015) reviewed cases studies of SaMD and the regulatory environment. These applications included radiotherapy software to calculate ionizing radiation dosage, planning software to assist with the treatment of occlusive vascular disease, and various apps to track exercise, blood pressure, and pulse rates. Many of these apps record data, though make no diagnostic calculations or recommendations (McCarthy & Lawford, 2015). Moshi, Parsons, Tooher, & Merlin (2019) reviewed mobile medical application regulation in Australia compared with IMDRF international standards, and found information security and misinformation were not generally addressed in case and policy documentation, and recommended guidelines be updated to address potential harm from misinformation (Moshi et al., 2019). Stern and Price (2019) discuss challenges with the safety and effectiveness of ML and SaMD. ML predictions and recommendations may lack generalizability in cases of predictive and causal relationships. The improvement of learning in a new task beyond the training for the initial task remains challenging, along with algorithmic biases through training datasets and data collection (Stern & Price, 2019).

Table 1: Analysis of SaMD Document Sample According to Decision Lense

Authors	Study Area Focus	Decision Lense
He et al., 2019	Regulatory Framework	Normative
Hilmisson et al., 2019	Sleep Disordered Breathing	Descriptive
Kubben, 2017	Neurosurgery	Descriptive
Mcarthy and Lawford, 2015	Regulatory Framework	Descriptive and Normative
Moshi et al., 2019	Regulatory Framework	Descriptive and Normative
Stern and Price, 2020	Regulatory Framework	Descriptive and Normative

Theory Development
During the theory development step, perspectives are explored that can account for the paradigms and review of the theory output. A theoretical artifact is introduced based on a review of the decision support lenses, in order to develop concepts and insights following groundwork and analysis.

4. THEORETICAL DEVELOPMENT DISCUSSION AND FINDINGS

Decision-Making Factors and Influences
Individual decision-making is of critical interest to researchers throughout a variety of disciplines, and decision-making is concerned with a concept of rational choice as a descriptive and prescriptive paradigm, choosing the alternative with the highest utility or value. However, many decisions occur under uncertainty, requiring risk probabilities, and individuals display a status quo bias in which they do nothing or use a prior decision. In maintaining the status quo often transition costs are considered in which switching carries higher perceived risk uncertainty or potential value, as individuals often weigh losses greater than gains in decision-making known as loss aversion (Samuelson & Zeckhauser, 1988). Individual perceptions and subjective information can be altered by pre-established risk-taking attitudes, prejudices, beliefs, attitudes, or values, causing ineffective decisions (Kukreia, 2018). Cognitive abilities and biases, perceived outcomes, age, socioeconomic status, and past experience may also influence decision-making (Dietrich, 2010). The ability to communicate and interpret the data with business is an important capability of analytic specialists, and more experience can lead to more accurate and timely decision-making (Janssen, van der Voort, & Wahyudi, 2017). In a review of studies that examined patient decision-making with regard to chronic kidney disease (CKD), many influences to decision-making exist including opinions of family members or providers, other patient experiences, provider interactions, provider trust, perceive family burden, personal well-being, quality of life, among others (Murray, Brunier, Chung, Craig, Mills, Thomas, & Stacey, 2009). In a study of ambulance nurses in emergency care, experience, information, personal security, and environmental factors were found to influence decision-making. Environmental factors such as time of day, season, and weather were significant as nurses preferred working during the day and in better weather conditions (Gunnarsson & Warren Stomberg, 2009).

Organizational policies that penalize or reward risk can influence decision-making. Time constraints may affect a review of alternatives and increase the cost of gathering additional information. Social and cultural norms can also influence decision-making, and decision-making styles may vary by organization or location, such as individualistic decision-making vs. collective decision-making (Kukreia, 2018). In addition, organizational size, resource availability, information systems, politics, communication, social responsibility, and ideology may influence decision-making (Ejimabo, 2015; Nooraie, 2012). Organizations with clear communication of vision and goals can assist with the coordination of decision-making in goal setting (Valaitis, Meagher-Stewart, Martin-Misener, Wong, MacDonald, & O'Mara, 2018). The decision-making process consists of four stages intelligence, design, choice, and implementation. During the first stage of intelligence, the decision-maker formulates the problem or opportunity, and data is collected. In the design stage models and solutions are evaluated through collected data. In the choice stage, the optimal solution is chosen from the set of alternatives. The final stage is the implementation, where the outcomes may or may not be successful, if unsuccessful decision-makers may return to an earlier stage to reevaluate solutions (Markovic, 2018). Data and associated quality, when combined from a variety of sources, integrated, cleaned, translated, and transferred, can influence decision-making. The velocity and veracity of big data generate challenges for decision-making, with incomplete, noisy, or inconsistent data (Janssen et al., 2017). Accurate information can affect the quality of the decision, along with individual constraints that limit the quantity of information able to be processed (Kukreia, 2018). Governance mechanisms are required for the collection and processing of data to ensure quality or understand context and limitations (Janssen et al., 2017).

Decision-Making Theoretical Lense

SaMD is further examined through the decision-making machine learning lense. Decision-making theory is a broad topic and used to model human decision-making. Decision-making has gained adoption through decision support and artificial intelligence systems. Decision theory is utilized to model decision-making with the underlying assumptions of the decision-maker being logical, rational, and fully informed. Computerized decision support systems are used to assist human decision-making (Hansson, 1994; Shah, 2008; Woodside & Amiri, 2015). Decision theory utilizes positive or descriptive and normative or prescriptive approaches. While decision theory may be used as both a normative and positive theory, it is generally normative but has the unique capability of being descriptive and prescriptive within its applications (Shah, 2008).

Positive theory includes single decision items typically within short-term operational areas, normative theory includes alternative decision scenarios typically within managerial areas. Behavioral theory includes both positive and normative theories based on individual perception and bounded rationality, typically within organizational management (Bell, Raiffa, & Tversk, 1988; Shah, 2008; Woodside, 2018). Following the three decision-making theories, there are three types of analytics, descriptive for past trends, predictive for future trends, and prescriptive which integrates both descriptive and predictive analytics for recommending the best decision (Bertolucci, 2013). Distinguishing between positive and normative decisions may prove useful with communication between viewpoints, and reconcile disagreements through learning if the disagreement is formed from normative or positive views; if normative underlying theory and evidence would be unable to reconcile, whereas if positive additional research may address the gap. A positive theory or statement relates to what is without indicating agreement or disagreement and can be true or false. A normative theory or statement is a prescriptive method about what should be, indicating a judgment of agreement or disagreement. There is generally a limited capability to prove or disprove a normative theory or statement. Researchers often do not wish to focus solely on positive or normative theories, instead, they seek to generate normative theories, and identify a method to achieve through positivist approaches (Hansson, 1994; Schenk, 1997; Shah, 2008).

Many decisions may not be easily categorized as only positive or normative, but instead contain a variety of assumptions and biases. Decisions often contain both positive and normative statements for developing policy, to determine the objectives or normative component, and method to achieve the objectives or positive component. Decisions often contain both positive and normative statements for developing policy, to determine the objectives or normative component, and method to achieve the objectives or positive component. For example, a decision that adopting a new healthcare law would be bad for the organization contains assumptions about how to determine if a law is good or bad, or the normative component, and beliefs about the organizational effects of the law or the positive component (Schenk, 1997). Also considered is prospect theory, which attempts non-normative theory within decision-making. The optimal choice could be determined through pairwise comparison methods or weighted values. This may also be referred to as relational vs. numerical methods. This is primarily regulated to actual system implementation and programmatic creation of algorithms to assist decision-makers. The process allows decision-makers to eliminate events of low probability and accept events of high probability with certainty. Prospect theory seeks to explain the decision problem results fully in non-normative ways (Hansson, 1994). There are also bounded rationality considerations in human behavior, where people may not always act rationally. In order to improve models, one may limit the utility functions, factor in information costs, and have multi-valued utility functions. There are often constraints on information for decision-makers, in terms of gathering, storing, processing, analyzing, and deciding. This creates important questions, such as what is important to know, and what type of decision-making is most valuable given a set of influences and constraints (Rubinstein, 1998; McCubbins & Thies, 1996).

SaMD Theoretical Model

The SaMD theoretical research model is modeled after a neural network for decision-making and machine learning. A neural network is a class of non-linear regression and statistical methodologies that have been applied to several applications in healthcare such as fraud and abuse, health screenings, infections, clinical staff, and heart failure detection. Neural networks use biological systems as metaphors for the development of computer systems, and the human brain is seen as a large scale modular neural network. (Boers & Kuiper, 1992; Klimberg & McCullough, 2013; Woodside, 2018). The model consists of an input layer, hidden layer, and output layer as part of a neural network. A typical setup is applied via a multilayered network, in which there is an input, output, and hidden layer(s) between. Each input node is connected to every node in the subsequent layer, along with a connection weight that is adjusted during training. Neural networks are able to identify patterns in input data and form rules previously unknown. As common with human decision-making, data is submitted as input to the neural network, and the output is received, with the hidden layer algorithmic process not easily understood and subject to weighted influences (Klimberg & McCullough, 2013).

Given a set of decision-making factors and influence characteristics, the theoretical model identifies and displays the decision-making process which ultimately leads to healthcare outcomes. The input layer consists of factors that may influence the type of decision-making that occurs. Decisions can be influenced by a variety of factors, and these are categorized into 1) Individual, 2) Organizational, 3) Social/Environmental, and 4) Information. The first construct, individual factors consist of cognitive abilities and biases, perceived outcomes, age, socioeconomic status, and experience. The second is organizational factors and includes size, teamwork, management characteristics, and industry. The third is social/environmental factors, which consist of the physical environment including weather, and social factors and norms including ethical choices and social responsibility. In other words, to what level will a decision be based on social factors vs. success factors, this can be a combination of the individual and firm-level. The fourth is information and associated constraints. This includes information that is available to the decision-maker(s), as well as limitations to that information, such as cost, time, location, etc. These factors all play a role in determining the optimal decision strategy for selection.

The hidden layer contains the three general theories of decision-making, positive, normative, and behavioral. Positive or descriptive theory involves potential solutions that can be decided and how humans make those decisions. Typically, positive decisions involve short-term decision-making in an efficient and effective manner. Typically, these problems are quantitative in nature, have a higher degree of certainty, and require a timely result. Normative or prescriptive theory reviews alternative solutions that will yield the greatest organizational benefit. Normative theory also includes ethical considerations and guidelines for the solutions. Normative theory describes the planned behavior of a decision-maker, and typically involve long-term decision-making in an uncertain environment. Behavioral theory reviews how individuals may address these uncertainties combining both positive and prescriptive theories and includes bounded rationality. Typically, these decisions are made by managers who act as an intermediary between operational and institutional managers to ensure organizational success (Shah, 2008). In current non-transparent implementations, the hidden layer consists of the decision theories: positive, normative, and behavioral. It also includes weighted combinations of these decisions as interactions. These decisions are influenced by the input factors which can lead to non-transparent decision-making biases.

The output layer consists of healthcare outcomes. This generally comprises the firm meeting a set of healthcare quality goals. Goals may include any number of items; for SaMD they can include clinical goals and infrastructure goals such as wellness, system availability, and data quality. The model should be developed as part of the SaMD decision support system on a localized level. In other words, the system will learn for a given set of inputs and outputs, the best decision method. This will be repeated for each decision, and the results compared with a control and fed through the system as part of a result repository. In this fashion, a knowledge database will be created for reference as further decisions are made and the system learns. The results could also be validated with outside experts and research study reviews. The accuracy would then

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be calculated to determine how the system can improve decision-making.

5. SUMMARY AND CONCLUSIONS

Management Implications

The current challenges of SaMD include the development of innovative products that align with patient safety and regulatory compliance frameworks (Heier, 2020). Ethical guidelines can clarify acceptable behavior, and allow ethical decision-making processes to include trust, fairness, and transparency. A stepped process is recommended for decision-making including 1) problem identification, 2) potential issues identification, 3) ethical guideline review, 4) law and regulation review, 5) consultation, 6) potential actions, 7) consequences of actions, 8) best action decision (Ejimabo, 2015). In addressing trust, Blockchain is projected to emerge as a foundation of trust for FDA regulated SaMD, allowing consumers the tools and methods to govern access, utilize, and monetize their data (Matthew, Porto, Ribitzky, Ramonat, Broedl, Clauson, Ricotta, Cenaj, & Ngo, 2020).

For SaMD machine learning algorithms is important to factor in risk and uncertainty in decision-making, as many individual decisions are flawed due to overconfidence in estimates. In addition, decisions may suffer from the quantity of available information and cognitive biases. To help address these biases, blinded decisions can be used to eliminate the influence of stereotypes or irrelevant factors, checklists can be used to reduce errors based on memory, and predetermination of factors for consistency of algorithms (Soll, Milkman, & Payne, 2015). Practical decision analysis involves prescriptive decision-making or what should be done and uses tools, methods, and software to improve decision-making (Shah, 2008). Positive decision-making can be used for operational technology-driven decisions such as evidence-based medicine. Behavioral decision-making can be used for patient-driven managerial driven decisions. Normative can be used for clinically driven long-term driven decisions.

Algorithmic Learning

Individuals utilize mental models for reasoning, responding to the environment, changes in technology, understanding phenomena, making inferences, and defining problems. There are two mental models used for learning: 1) mental-model maintenance which incorporates new information into existing mental models for reinforcement, and 2) mental-model building which modifies existing mental models based on new information (Vandenbosch & Higgins, 1995; Woodside, 2010). Knowledge is generated from a set of intellectual assets that have been developed from experience and learning. Knowledge is often thought of in terms of data and information, however is communicated through an individual which may personalize or reinterpret the data and information. Cognitive elements of mental models include beliefs, paradigms, viewpoints, and schemas that help an individual understand the world (Nonaka, 1994).

6. CONTRIBUTIONS AND FUTURE DIRECTIONS

This research supports a theoretically informed decision-making model that can be used to ensure the reliability and validity of SaMD machine learning in healthcare. Additional recommendations include a transdisciplinary approach to mitigate bias in healthcare systems (Gurupur & Wan, 2020). Making the right decisions can depend on the individual, organizational team quality, environment, stakeholders, and ethical or legal commitments. A reliance on positive, normative, and behavioral decision-making is important to ensure organizational success and maximize efficiency and effectiveness (Shah, 2008).

This manuscript fosters interdisciplinary discussion through blending health science, data analytics, computer science, and decision information science research disciplines. Future directions may include the development visual foundations, and development of a clinical instrument to measure the characteristics, decision-making behavior, and success of SaMD. This would be a longitudinal study to identify whether short-term or long-term healthcare outcomes were met utilizing SaMD. Ideally, there would be significance generated in terms of which decision-making behavior allowed for a greater completion of set goals. This would allow for model hypotheses to be tested in positive form. From this, we can gather the types of decision-making behavior that would best be suited to clinical applications of SaMD.

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