

Review

## Advancing model-based systems engineering in biomedical and aerospace research: A comprehensive review and future directions

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### Abstract

Model-Based Systems Engineering (MBSE) represents a modern methodology for developing complex systems using models, prioritizing alignment with customer preferences through comprehensive systems based modeling. Using PRISMA guidelines, data was gathered from peer-reviewed journals, systematic reviews, case studies, and computational studies from databases such as PubMed and Google Scholar, from the past 24 years. The study provides a comprehensive view of the current state of MBSE applications in healthcare and engineering addressing the practical challenges they face, offering strategic suggestions to improve future outcomes. This research introduces the Dynamic Risk Management Framework (DRMF), designed to leverage real-time data and predictive analytics to bolster system reliability and performance. The reviewed articles illuminate the essential role of MBSE in creating sophisticated systems and emphasize the need for improved modeling language integration, standardized processes, and increased interoperability. Further studies are required to validate its effectiveness and overcome its current limitations. As an emergent discipline within systems engineering, MBSE holds significant promise for future development, positioning itself as a critical tool for optimizing diverse fields of application. Further investigations are essential to validate MBSE's effectiveness and address its existing limitations.

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## Keywords

Systems Engineering, Biomedical, Biosensors, Artificial Intelligence, Machine Learning, Systems Modelling, Model-based Systems Engineering, Dynamic Risk Management Framework

## 1. Introduction

Systems engineering describes the development of systems of independent engineers working alongside one another throughout steps of modeling, simulation, testing, etc. [1]. For several years now, this process has solely revolved around document-based applications, argued to have well-defined benefits, as there continues to be a research and literature gap on other approaches. In other words, in the past, the true yield of the benefits of model-based systems engineering (MBSE) was unclear. Now, studies suggest the probable expectation of MBSE to detail the ‘life-cycle’ of systems’ developments and implement multi-domain designs, especially constructive in industry projects [2][3]. However, researchers hoping to transition to MBSE methodologies still face hurdles in achieving a full shift. Challenges lie in the lack of information on MBSE’s successes and the inconsistent result of MBSE’s application in real industry scenarios, creating uncertainties in professional usage, which will be discussed in depth later in this paper. Without persistent and steady results throughout all tests, uncertainties still lie in the professional usage of MBSE [4]. Resultantly, several critical areas within MBSE need further research to realize its full potential in cutting-edge fields like healthcare, engineering, artificial intelligence, and machine learning.

Current research on MBSE has shown that it is effective in enhancing system integration, communication, and project management. For example, studies have shown significant advancements in healthcare systems through MBSE applications, leading to improved patient satisfaction, and operational efficiencies [5]. Likewise, MBSE has played a crucial role in aerospace engineering projects to improve system design and its lifecycle management [6]. However, the integration of AI/ML within MBSE frameworks and its broader application across diverse industries remain underdeveloped [7]. Although preliminary research suggests that integrating MBSE with AI/ML can improve predictive maintenance and real-time analytics [7], there is a lack of comprehensive studies on detailing best practices for integration methodologies. Moreover, the application of MBSE in healthcare, especially in rural and low-resource environments, has not been explored extensively [5]. This review is important to address these gaps and provide a comprehensive understanding of MBSE’s potential and limitations. While previous systematic reviews have focused on specific aspects of MBSE, our review provides a more holistic view.

In healthcare, MBSE has mainly been implemented in well-equipped urban environments. These studies have shown significant improvements in system efficiencies and patient care [5]. However, the rural healthcare systems, which are more challenged by factors such as lack of specialized facilities and care, and financial constraints, have not received sufficient attention in MBSE research [5]. Tailoring MBSE frameworks to these particular issues could greatly improve healthcare delivery and emergency preparedness in underserved areas. On the other hand, in engineering, especially in aerospace, MBSE has been used to manage the complexities of system integration and lifecycle management [6][8][9]. Projects like NASA’s MBSE Pathfinder have shown that detailed system models can improve understanding and integration of complex systems [8]. Nevertheless, the potential of AI/ML to further advance these capabilities by offering real-time data analysis and predictive maintenance has not been tapped into yet [7]. The integration of AI/ML with MBSE can help aerospace systems to adapt to changing conditions and requirements, predict failures, and optimize operations in real-time [7]. Many case studies show the possibilities and existing gaps in the application of MBSE across various industries [6][10][9][5]. For example, an AI-based MBSE approach used in developing a hypothetical supersonic transport aircraft showed improved iterative development and early validation processes [9]. However, this study also revealed some limitations concerning the integration of AI/ML technologies into the current MBSE frameworks in terms of scalability and interoperability [9]. In healthcare, the applications of MBSE in a rural telemedicine system showed significant improvements in resource management and patient care coordination [5]. Yet, it also pointed out limitations related to data management and the need for continuous updating of models to reflect real-world conditions accurately [5]. These case studies highlight the need for further research to create a more extensive framework that can support the integration of AI/ML with MBSE [7]. Further research in these areas will enable the broader adoption of AI/ML-based MBSE across various industries by providing valuable insight into scalable and interoperable solutions. This research will contribute to the ongoing academic conversation and practical applications, driving innovation and improving outcomes in healthcare, engineering, AI/ML, and beyond.

It is crucial to address the above gaps to further advance the

field of MBSE and to achieve the best results in its application across different sectors. To illustrate, by tailoring MBSE applications to the specific challenges of rural healthcare, significant improvements in healthcare delivery and emergency preparedness can be achieved. And by integrating AI/ML with MBSE, we can revolutionize system design and operation by providing real-time optimization and predictive maintenance capabilities. This study focuses on these application’s limitations, specifically throughout industries of healthcare, engineering, AI, and ML, providing improvements and solutions in the form of concepts and frameworks. Thus, this study will employ existing literature studying both MBSE’s applications and limitations, articulating what is

specifically required to address the raging uncertainties.

2. Systematic Review

2.1. Review of Existing Research

For the encompassing review of the existing literature discussing the applications and limitations of Model-Based Systems Engineering (MBSE), a systematic approach was taken. This study followed the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines in conducting the literature search and review.

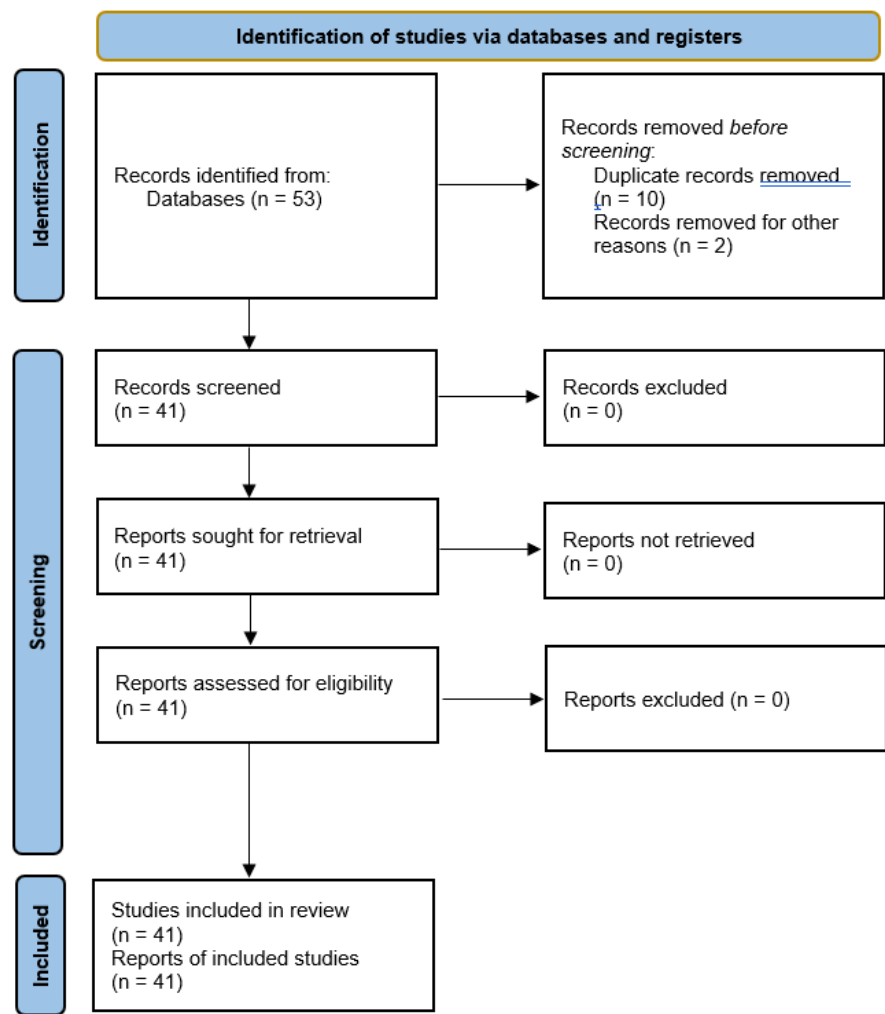


Figure 1. Systematic review selection process.

Study	Field	Methodology	Key Findings	Limitations
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Systems Engineering Challenges and MBSE Opportunities for Automotive System Design [11]	Engineering	Systematic Review	MBSE methodologies can assist during the testing phase, to confirm if the design meets specific requirements. Furthermore, it can develop enterprise-wide model-based engineering (MBE) capability, connecting with other sources. MBSE methodology also specifically caters to feature modeling. Overall, multiple applications of MBSE in the automotive field were found.	However, each application comes with its challenges, and their solutions have not been addressed. For example, establishing enterprise-wide MBSE processes to develop MBE capability introduces many obstacles, including the amount of investment needed for resources, finding interfaces for the integrated data system, and developing propositions to prevent defects in the design.
Model Based System Engineering (MBSE) and design assurance process in the context of mitigation of design errors during the development of highly integrated and complex aerospace systems [12]	Engineering	Case Report Study	In the programs and missions observed in this study, all design errors and resulting accidents were caused by the incorrect application of the correct methods or the correct application of the incorrect methods. In other words, each error could have been avoided if MBSE methodologies were in use. MBSE techniques allow for the analysis, testing, and evaluation of complex systems, easily locating dire errors.	While in theory, MBSE methodology would be able to solve these issues in design error, it is still unclear how this technology would integrate with current design assurance processes. In addition, in this study, further research must be done on the fragility of the MBSE methodology that could lead to design errors.
Model-Based Systems Engineering Applied to Trade-Off Analysis of Wireless Power Transfer Technologies for Implanted Biomedical Microdevices [13]	Engineering / Healthcare	Analytical / Computational Study	The combination of MBSE and other methodologies was found to be the best technique to decide Acoustic Power Transfer (APT) technology as the most suitable option for the implanted biomedical microdevices. The MBSE methodology was able to identify the system level at which the trade-off should be applied. In addition, MBSE was found to be efficient even in designs of sizes of millimeters.	Present technologies, such as MBSE methodologies, do not have the greatest range of variation. So, in the scenario of finding the best implant size of the biomedical microdevice, the MBSE technology is unable to display the full scope of each variation, making the results slightly inaccurate. For the technology to be truly accurate, expensive, strict mechanisms are needed, being ultimately impractical.
MBSE to Support Engineering of Trustworthy AI-Based Critical Systems [14]	AI	Case Study	MBSE was applied to this program in order to establish consistent guidelines and a corresponding 'tooled workbench'. MBSE methodology adapted to the ARCADIA / Cappella perspectives, with this study focusing on the operational analysis, or the analysis of the engineering methods that a	Tools of MBSE methodologies, such as ARCADIA and Cappella, were found unable to match perfectly with the specific Viewpoints of an individual project, so changes must be made, furthering the operational analysis process. Further research must also be performed on how the established MBSE guidelines carry over to other sections of the ARCADIA / Cappella perspectives.

			Trustworthiness environment would support. Ultimately, MBSE enabled the construction of a complex, multi-level AI system.	
A First Step towards AI for MBSE: Generating a Part of SysML Models from Text Using AI [15]	AI / ML	Experimental Study	An AI4MBSE approach was determined plausible, as the NER-trained model was able to automatically generate SysML entries. This allows for a transition into <i>enhancing</i> the NER models to generate more elements of SysML.	This study acknowledges the significant investment necessary for an MBSE approach, because of human and technology capital. The transition from other methodologies to MBSE can also be challenging on its own. SysML itself requires consistent involvement.
Recommendations for the Model-Based Systems Engineering Modeling Process Based on the SysML Model and Domain Knowledge [7]	ML	Analytical / Computational Study	Adoption of MBSE is still limited because of the availability of skilled workers and the lack of ‘informatization’. In this study, SysML was utilized to <i>provide</i> training data for future recommendations of modeling by MBSE, also addressing previous issues such as a lack of modeling efficiency, accuracy, and reliability.	Other obstacles, such as the refusal of integration of MBSE in traditional companies and the challenges of uniting efficient AI systems with MBSE methodologies are mentioned, but not addressed by the SysML generation solution.

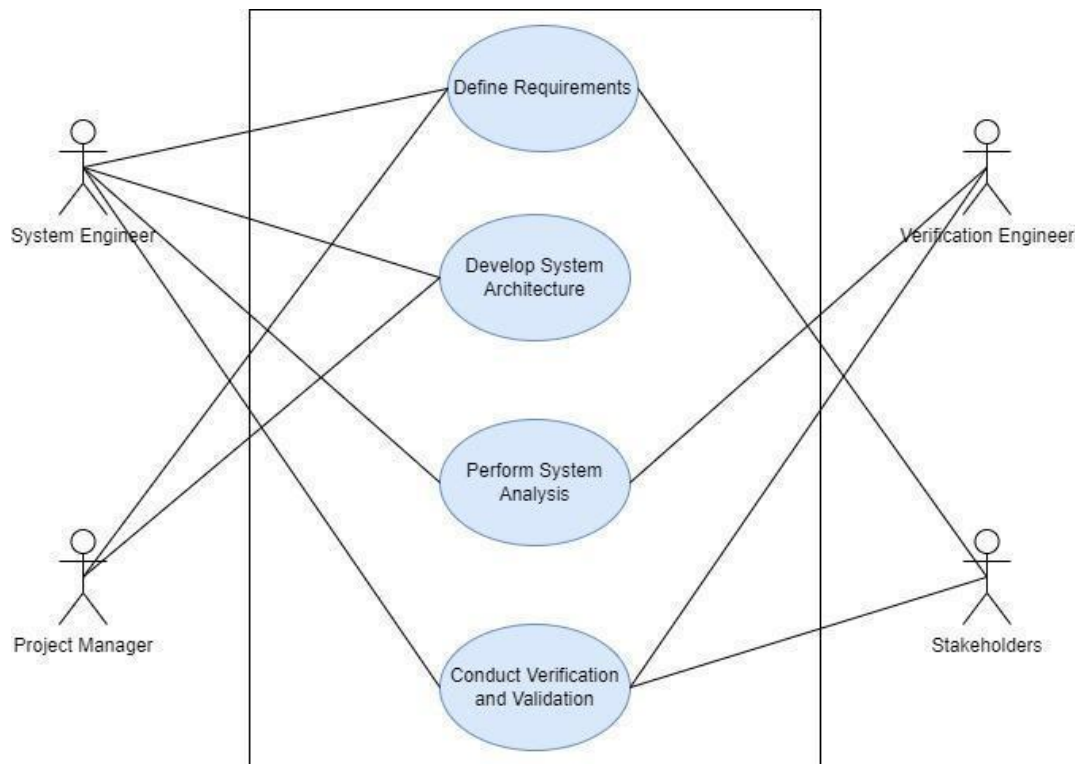
**Table 1.** Systematic review selection process.

Various methodologies of completed and published papers from the past 24 years from databases such as PubMed, Google Scholar, ResearchGate, etc. were included (figure 1). However, opinion pieces, editorials, and non-research articles were excluded. After related papers were found, their abstracts and methodologies were screened based on previously decided eligibility criteria, an example being relatedness to the study’s research topic. With this screening process, multiple applications of MBSE across multiple fields were found, but its limitations were addressed as well (table 1).

## 2.2. Model Based Systems Engineering

In recent years, with a rapid increase in digital modeling, there has been an implementation of MBSE in various industries. MBSE is a methodology that highlights a model-centric design instead of the traditional document-centric design. It supports the requirement for design, analysis, verification, and validation necessary in the development of complex systems. MBSE consists of three key concepts: the

model (a simplified representation of a complex system), systems thinking (viewing a system as part of a larger interconnected system), and systems engineering (a multi-skilled approach that makes sure that all requirements are met throughout development). MBSE also covers four systems-engineering domains: requirements/capabilities, behavior, architecture/structure, and verification/validation. These key areas of focus need to be addressed throughout the system during the system development life cycle and are defined within the model using modeling languages like SysML or UML. Modeling utilizes four instruments: language (the common terminology for transparent communication), structure (well-structured models for simplicity and consistency), argumentation (the justification of design decisions), and presentation (the visualization of abstract ideas for better comprehension). These four domains are implemented in the three key concepts of MBSE. When adopting MBSE, organizations must consider the architectural frameworks to guide



**Figure 2.** The different actors and their interactions with an MBSE system in an engineering project.

modeling activities, requiring support for its stakeholders, processes, environment, and information flows when delivering complex systems [16]. With a single modeling language, MBSE fosters collaboration amongst several stakeholders and improves communication, among other benefits. This makes it possible to identify and fix design issues early on, improving system performance and quality [17][19]. MBSE facilitates decision-making by offering a holistic system picture and assisting engineers in investigating design options and forecasting effects [20]. All things considered, MBSE promotes more economical and successful system development.

The creation, architecture, and administration of complex systems have seen a significant transition from document-based approaches to MBSE, which has had a significant influence on the engineering, machine learning, healthcare, and artificial intelligence sectors. The following table lists significant historical turning points and advancements in MBSE, illustrating the field's evolution and the contributions made by important technologies and research throughout the years.

The integration of digital twins, AI, and IoT with MBSE is the most recent major advancement; it greatly enhanced

MBSE's potential. IoT makes real-time data gathering and analysis from linked devices possible, yielding valuable insights that can enhance system functionality and design [26]. Engineers can trigger and predict system behavior under different conditions using digital twins, which are virtual representations of real systems that help create more precise and systematic designs [27]. By offering data analytics, predictive maintenance, and optimization algorithms, AI further augments the capabilities of MBSE, enhancing decision-making processes and system performance [28]. By implementing these contemporary technologies, downtime and operating expenses are decreased through constant monitoring and repair [29]. These technologies will advance further, and complex system performances will be enhanced by their combination with MBSE.

By using automated tools and simulations to make sure systems satisfy specifications, verification and automated validation in MBSE have enhanced system development. Early design problem discovery is made possible by methods like model checking and simulation-based testing, which significantly lowers the chance of expensive mistakes [30] [17]. Digital models speed up and increase the accuracy of verification by enabling in-depth simulations. Furthermore,



Time Period	Key Development	Description	Source
1960s-1970s	Early CAD Tools	Introduction of early computer-aided design tools that improved precision and efficiency in engineering designs.	[21]
1980s-1990s	Introduction of UML	Standardization of the Unified Modeling Language (UML), providing a united method for system design	[21]
1990s	Development of SysML	Addition of the Systems Modeling Language (SysML), providing a method for broader engineering applications.	[22]
Early 2000s	Formalization of MBSE	Model-based approaches are being used, and complex systems are replacing traditional systems.	[23]
2000s-2010s	Industry Adoption of MBSE	Widespread use of MBSE, which enhances system lifecycle management, in defense, aerospace, and other industries.	[24]
2020s	Integration of Digital Twins and AI	Artificial intelligence and digital twins are used for real-time system optimization and simulation.	[25]

**Table 2.** Historical development of modeling tools.

MBSE's continuous verification facilitates regular maintenance and updates, guaranteeing that systems continue to meet changing standards and needs. With a clear understanding of MBSE's definitions and principles, we will now explore the benefits and applications this methodology offers across different fields.

## 2.3. MBSE in Healthcare

### 2.3.1. Diabetes Mellitus

Healthcare costs rapidly increase year by year while coverage and offered services decrease, posing an unprecedented challenge for healthcare systems globally. The major issues that governments, healthcare providers, payers, and consumers face are cost and quality, access to care, technology, an aging population, and, as focused on in this paper, chronic diseases such as heart disease, stroke, cancer, mental illness, and diabetes. These have significant implications for healthcare costs. Changes in healthcare technology will be rapid and even disruptive as the adoption of new digital health information technologies (HIT), such as electronic medical records (EMRs), is transforming the way physicians, patients, and other stakeholders interact. Health IT systems, a focal point for the paper being discussed, are complex systems and possibly systems of systems and must be treated as such; as in taking a “holistic and integrative systems view”, made harder by the difference in capabilities of all human participants in healthcare systems [31]. This challenge is addressed using a specific class of healthcare management systems (HCMS), as a vital first step towards the

systematic application of modern MBSE methodologies, frameworks, and tools for the design, construction, operation, and maintenance of such systems. This paper selected, as a focus application, the modeling and management of Diabetes Mellitus (or Diabetes 2) due to its high and even growing prevalence worldwide. It goes on to describe a methodology and a framework that uses recent developments in MBSE and its tools, to establish a conceptual architecture for such an HCMS for Diabetes 2 that is scalable, expandable, linkable, capable of learning, easy to use, can operate in a distributed collaborative manner, and can provide quantitative answers to “what-if” questions such as “what is the most effective treatment”. Furthermore, it focuses on a crucial component of such an HCMS, which is a reasoning engine, to prove the massive potential that modern MBSE methods have for real-life applications [31].

They developed a model for diabetes progression as a Controlled Hidden Markov Chain (CHMC), with three states for diabetes mellitus (healthy, pre-diabetic, and diabetic) and gave it a variety of possible inputs such as time, an estimate of disease state, the sum of all costs (such as the cost of tests and intervention), the behavioral characteristics of the patient, and the interconnection and transition between all attainable values. Three methods for tradeoff analysis were subsequently developed and applied. One of the methods, entitled the Evaluation by Monte Carlo simulation (EMCS), conducted a comprehensive and straightforward generation of all possible sample paths for any number of patients. Using a set procedure, the EMCS computed Pareto points that concisely describe the relative value of treatments and tests in relation to the overall healthcare quality throughout a patient's medical

history [31].

The EMCS proved to be both scalable and improvable when more powerful machines were used. Nevertheless, the authors of this paper were more interested in “superior efficiency” and as such they developed and evaluated two other methods, called Fully Observable and Fully Observable Multi-criteria Optimization (FOMCO), that took slightly different inputs but achieved similar tradeoff analysis as the EMCS method while taking far less computational time than the aforementioned method. Conclusively, the Reasoning Engine design can provide answers to many problems that may be faced in healthcare management, evaluate a patient’s behavior, find the best tests and interventions, and more, hence proving the real-world value of MBSE tools [31].

### 2.3.2. Rural Healthcare System Disaster Planning

Effective disaster response planning is essential for emergency preparedness, but rural communities often lack the necessary resources and tools. The authors hypothesize that this gap could be filled by MBSE through the application of system modeling to help improve preparation for disasters. The basis of this paper is to help eliminate the lack of research into MBSE’s application in rural healthcare systems (which often have few resources, limited access to specialized care, and transport issues to contend with) and does so by reviewing and evaluating dozens of studies based on the use of MBSE and SysML in the healthcare systems of rural communities, especially in the case of natural disasters. Rural communities have to rely on healthcare facilities that often face financial and staffing limitations, risk of closure, and delayed or limited access to external resources/funding. MBSE can be used to improve readiness for disasters through computer simulations and thereby help rural communities optimize their resources and plan effectively.

This scoping review uses PRISMA methodology and a variety of sources with few limiting terms (such as the location of a rural community or the year a research paper was published). Some of the studies that were hence reviewed were limited by available data for model parameters (particularly in the studies based around COVID-19) while some studies appeared not to have any model or simulation limitations. Additionally, the authors of this paper did not do a quality assessment of the studies reviewed which may have resulted in the use of low-quality studies that compromised the quality of this scoping review; the lack of inclusion of all available sources (e.g. Google Scholar) due to their being such

a large volume of search results; the use of publications in the English language only; and the possibility that there was a publication bias and selective reporting within the studies included.

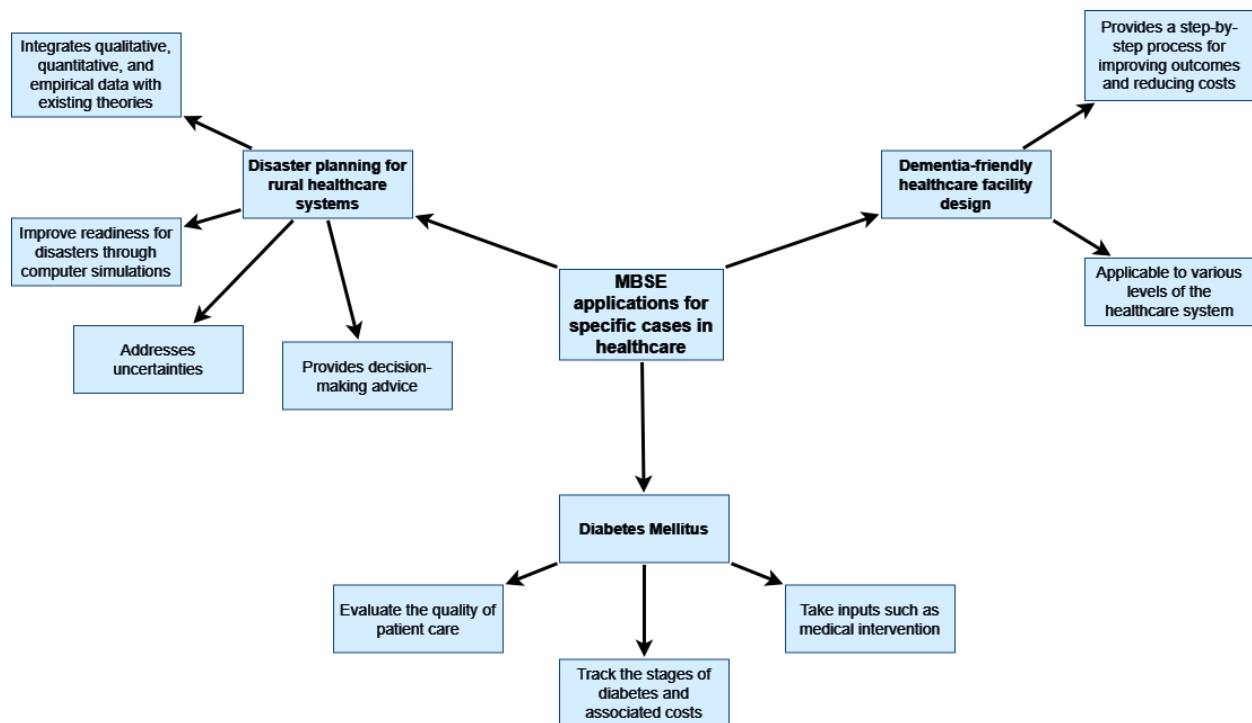
Computer simulation is a particularly ideal solution for developing disaster research as it considers disasters from a systems point-of-view, addresses uncertainties in the inputs, and provides decision-making support. Amongst its many uses, it can also integrate qualitative, quantitative, and empirical data with existing interdisciplinary theories. The authors of this review determined that there is a clear need to expand the applications of MBSE to support rural communities and their preparedness for natural disasters as well as expand the definition of healthcare systems beyond hospitals to better serve rural healthcare needs [5].

### 2.3.3. Framework for Healthcare Facility Design

This paper aimed to develop a framework for implementing dementia-friendly designs that address the limitations of existing assessment tools (such as a lack of adaptation, focus on target users, and a comprehensive development base and well-organized classification of AVs (Architectural Variables) and HCOs (Health and Care Outcomes)) by taking into consideration the complex interactions between AVs and HCOs and applying a systems engineering approach. The authors state that “Systems engineering, particularly the MBSE approach, is well-suited for healthcare design due to the complex nature of the healthcare sector.” MBSE entails comprehending the elements that impact health outcomes, identifying their relationships, and revising designs, processes, or policies accordingly to improve outcomes and reduce costs. Subsequently, the study explored the application of the MBSE approach in healthcare facility design, highlighting its potential to overcome the challenges and complexities entailed in developing an assessment framework for dementia-friendly designs. The authors reviewed 105 Evidence-Based Design (EBD) studies and thereby extracted 396 interactions between AVs and HCOs which were then systematically organized and visualized through the use of MBSE principles, the ARCADIA method, and Capella as a modeling tool [32].

Ultimately, their findings demonstrated that MBSE can have a remarkable impact in two key areas. Firstly, MBSE’s role as a common language and framework for dementia-friendly design is crucial due to the proven advantages it offers (such as providing a logical and computational engine for





**Figure 3.** MBSE Applications in specific healthcare case studies.

web-based software that architects and EBD researchers can use), and secondly, MBSE has high potential as a tool for evidence-based healthcare design as it takes a holistic approach that is essential due to the complex nature of healthcare design while also increasing the efficiency of the assessment process. Furthermore, applying MBSE to healthcare design can enhance the design process and improve health outcomes. In addition, this study was faced with limitations such as a need for the assessment framework to be further developed, assessed, and refined and the necessity for additional research into MBSE. The authors then go on to propose using other modeling tools for future studies [32].

## 2.4. Applications in Engineering

The FUELEAP (Fostering Ultra-Efficient, Low-Emitting Aviation Power) project at NASA Langley Research Center is a prime example of MBSE's application in aerospace engineering. MBSE was employed to enhance communication, documentation, and project management throughout the project lifecycle. SysML (Systems Modeling Language) was used to create detailed models of system requirements and architectures. This enables better understanding and integration of complex aerospace systems. The project demonstrated significant improvements in the efficiency and accuracy of system design and development processes [33].

Another application is the MBSE Pathfinder project. This project aimed to evaluate the benefits of MBSE across

multiple NASA spaceflight systems. This project focused on optimizing rocket engine design and testing. Engineers used SysML to develop integrated models that linked system requirements with design elements, resulting in considerable time savings (50%) and improved accuracy in testing and verification processes. The MBSE Pathfinder project was able to prove the advantages of a digital framework for SE (systems engineering) and emphasized the importance of early and continuous model validation [8].

The integration of Agile methodologies with MBSE was explored in the development of a hypothetical supersonic transport aircraft. This Agile MBSE approach sped up iterative development and early validation processes. By combining the Object-Oriented Systems Engineering Method (OOSEM) with SysML, the project team was able to dynamically adjust designs based on continuous feedback and evolving requirements. This method significantly improved the adaptability and responsiveness of the engineering team, while also developing more efficient and effective design processes [8].

In systems requirements management, MBSE was used to ensure comprehensive traceability and verification of requirements throughout the system lifecycle. Detailed requirement diagrams and traceability matrices were created using SysML to link requirements to specific system components and design elements. This improved the accuracy and completeness of requirements while also providing better communication among stakeholders and streamlining the verification process [9].

The MBSE Infusion and Modernization Initiative (MIAMI) at NASA is an effort to integrate MBSE across multiple projects and programs. MIAMI focuses on improving the SE workforce, increasing efficiency, improving decision-making processes through digital modeling techniques, etc. Examples from MIAMI include the development of reusable modeling templates and automated document generation processes, leading to significant time savings and improved consistency in project documentation [8].

The practical benefits of MBSE in aerospace engineering and general engineering are numerous. As mentioned above, these include improved communication and collaboration among project teams, improved traceability and verification of requirements, more efficient management of complex systems, and better accuracy of system design and development processes. For example, the use of SysML models in the FUELEAP project allowed for better integration of subsystems and early identification of potential issues. This reduces the likelihood of rework and delays, which can be costly [33]. Similarly, the MBSE Pathfinder project shows how digital models could be reused across different stages of the project lifecycle, from concept design to testing and validation, to save time and ensure consistency and accuracy [8].

One challenge is the complexity of creating and maintaining detailed system models. This requires specialized training and expertise, which can hinder the widespread adoption of MBSE. Engineers and project managers also need to be proficient in SysML and other MBSE tools to effectively develop and manage system models [9][8]. Another challenge is the integration of different MBSE tools and ensuring their interoperability. Different projects and organizations may use various tools and modeling languages, making it difficult to share and integrate models across platforms. Standardization of MBSE tools and techniques is crucial to improving interoperability and seamless collaboration among project teams. Managing/updating large quantities of data in MBSE frameworks can be very resource-intensive. As system models are becoming more complex, their accuracy must be maintained, which will require significant effort. Data management strategies and automated tools (discussed later) are needed to handle the continuous flow of information and to ensure that models remain up-to-date [8][7][37][9].

## 2.5. Applications in Generative AI and Machine Learning

Generative AI and Machine Learning have transformed several industries by allowing machines to complete tasks that demand creativity and decision-making abilities. Nonetheless, the complex nature of creating and overseeing AI systems requires strong engineering practices. Throughout the

system's life cycle, MBSE makes use of models to support system design and analysis.

Several tools facilitate the integration of MBSE and AI/ML: (a) SysML: A modeling language used for complex system analysis, design, and verification. In order to include AI and ML models into system designs, it offers a standardized method for designing system architecture and behavior. (b) MATLAB/Simulink: Software platforms providing analysis and simulation capabilities commonly used in scientific and engineering applications. They aid in the creation and evaluation of AI algorithms as well as their incorporation into MBSE-based system models. (c) IBM Rational Rhapsody: System and software engineering procedures are integrated with MBSE practices through IBM Rational Rhapsody. It makes it easier to integrate AI and ML features into system designs by enabling the visualization, specification, and design of complex systems. (d) MagicDraw with Cameo Simulation Toolkit: Tools to simulate SysML models using MagicDraw and Cameo Simulation Toolkit: These tools help validate and verify system behavior. By allowing engineers to test AI-driven features inside of system models, they can guarantee dependable and strong performance.

Because of their complexity and resource requirements, developing sophisticated system models in MBSE for incorporating AI/ML presents difficulties. Iterative validation, computational resources, and professional labor are needed to provide realistic representations of AI functionalities. Maintaining these models takes a lot of work and calls for regular upgrades to keep up with changing needs and advances in technology. Advanced modeling techniques and strategic resource management are essential for maximizing system performance and flexibility in dynamic contexts [39]. Because of their complexity and resource requirements, developing sophisticated system models in MBSE for incorporating AI/ML presents difficulties. Iterative validation, computational resources, and professional labor are needed to provide realistic representations of AI functionalities. Maintaining these models takes a lot of work and calls for regular upgrades to keep up with changing needs and advances in technology. Advanced modeling techniques and strategic resource management are essential for maximizing system performance and flexibility in dynamic contexts [37].

## 2.6. Systems Modelling

According to Friedenthal and Burkhart (2003), the Systems Modeling Language (SysML) is a visual modeling language with versatile applications that facilitates the description, analysis, design, verification, and validation of intricate systems. The Unified Modeling Language (UML) has an extension called SysML that is designed with systems engineers' needs in mind. It offers a standardized method for modeling systems, which can comprise information,

processes, people, hardware, software, and facilities. Systems engineers can integrate these models with a variety of engineering studies since it offers a graphical notation and semantic foundation for modeling system requirements, behavior, structure, and parametric equations [23]. By bridging the semantic divide between systems engineering and software engineering, the use of SysML has made the transition considerably easier [38].

Model-Based Systems Engineering (MBSE) is a formalized technique that stresses the creation and utilization of systems models as an essential component of the systems engineering process [38]. One of the main drivers of MBSE is SysML. To enable the creation of complex systems over their entire lifecycle, MBSE blends the three fundamental ideas of modeling, systems thinking, and systems engineering (table 3). The general-purpose graphical modeling language known as SysML, or the Systems Modeling Language, has emerged

as a vital resource in the field of Model-Based Systems Engineering (MBSE). SysML is a standardized method for describing, analyzing, designing, and verifying large systems that may comprise hardware, software, data, people, processes, and facilities. It was created as an extension of the Unified Modeling Language (UML) [39].

SysML's primary attributes, which render it highly appropriate for MBSE, encompass its capacity to represent system prerequisites, conduct, configuration, and parametric equations. This enhances the overall quality and performance of the system by enabling systems engineers to incorporate a wide range of technical evaluations into a comprehensive model [22]. Furthermore, the reuse of UML 2.0 concepts in SysML facilitates a smoother transition and collaboration between systems engineering and software engineering disciplines [38].

Tool	Healthcare Application	Engineering Application	AI Application
Cameo Systems Modeler	Modeling and simulation of medical devices, including requirements management, behavior analysis, and structural design.	Aerospace system design, including requirements traceability, interface management, and trade-off analysis.	Developing trustworthy AI-based critical systems, using SysML to establish consistent guidelines and a corresponding 'tooled workbench'.
Rhapsody	Designing and validating complex healthcare systems, such as hospital information management and medical imaging workflows.	Automotive system design, including feature modeling, testing, and enterprise-wide model-based engineering capabilities.	Generating SysML models from text using AI techniques to enhance MBSE processes.
Enterprise Architect	Modeling and integrating biomedical devices and implants, including wireless power transfer analysis and optimization.	Addressing design errors in highly integrated and complex aerospace systems through MBSE methodologies.	Providing training data for future MBSE modeling recommendations to improve efficiency, accuracy, and reliability.

**Table 3.** Types of SysML tools and their use cases in healthcare, engineering, and AI systems.

A general-purpose graphical modeling language for complex system specification, analysis, design, and verification is called Systems Modeling Language, or SysML. It is closely related to the Model-Based Systems Engineering (MBSE) methodology, which stresses the application of models at every stage of the lifecycle of system development. A wider range of diagrams and structures appropriate for systems engineering, such as requirements, behavior, structure, and parametric models, are made available by SysML, an extension of the Unified Modeling Language (UML).

Behavioral simulation, tradeoff analysis, requirements management, and system architecture modeling are just a few of the features that SysML tools offer and that can be utilized

in MBSE. SysML, for instance, can be used to model medical systems and equipment in the healthcare industry, guaranteeing that requirements are recorded, design choices are supported, and the system as a whole is validated. In engineering, SysML helps with the modeling of complex systems, such those seen in automotive and aerospace products, making it possible to identify design problems early on and promoting cross-disciplinary team collaboration. In the field of artificial intelligence, SysML can be used to model the elements and algorithms of AI-based systems, assisting in guaranteeing their reliability and compliance with system-level specifications.

Although each of the three SysML tools has advantages, Cameo Systems Modeler is particularly noteworthy for being

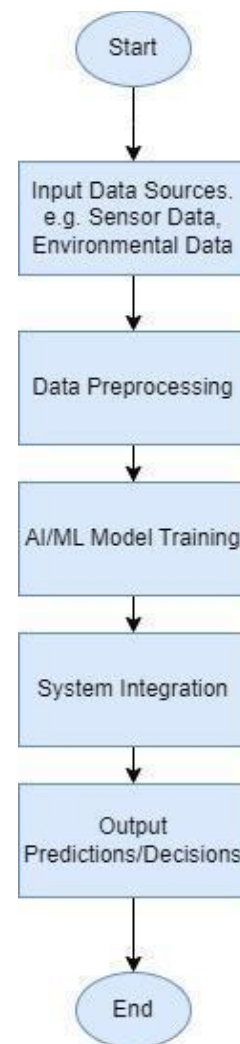
a complete package that works well with the MBSE procedure. It is a top option for businesses wishing to implement a model-based approach to systems engineering because of its extensive modeling capabilities and close interface with other engineering tools and environments [40].

### 2.7. Advancement Efforts

Although it is quite advanced, MBSE was found to face several limitations, from scalability issues in integrating numerous models in large-scale systems to incomplete standardization and interoperability across engineering domains [41]. Improving model integration frameworks is essential when it comes to models within a complex system working seamlessly. By refining interfaces and standardizing data exchange, frameworks can use various methodologies, allowing different models to communicate and operate efficiently. Organizations can improve their integration frameworks to achieve better consistency, accuracy in simulations, and effective system designs. Then, interoperability standards must be enhanced, which can enable diverse systems and components to work smoothly by creating different or updating protocols, guidelines, and specifications to make sure that different systems are exchanging information and operating in conformity. By developing universally accepted standards that can address new emerging technologies, industries can reduce integration costs and promote innovation. Additionally, improved standards can enable scalability for a more flexible system design and solution to industry problems. These capabilities are extensively covered in the AI and ML section, describing complex simulation and machine learning techniques that increase the effectiveness of MBSE.

By applying complicated algorithms in integrated systems to determine the optimal configuration and tactics, organizations can benefit from highly efficient operations, lower costs, and increased system performance. As a result, the systems are stronger and more equipped to manage rising demand. MBSE has highlighted a number of notable developments in the healthcare sector. Telemedicine platforms and data analytics work by connecting patients to healthcare practitioners virtually for follow-ups, tests, and consultations. These platforms prioritize telecommunications. Patients in remote or rural areas can benefit from telemedicine by saving time and money on travel expenses by connecting with patients via smartphone apps or conference platforms. The COVID-19 pandemic is one pivotal instance where there has been a sudden interest in the utilization of virtual care. Another notable development is personalized medicine, which is a revolutionary approach that allows medical treatment to adapt to the individual characteristics of each patient. However, Personalized and Telemedicine can be costly at times for the companies themselves as there is a need to cater

to individual patients, it requires complex implementation and often poses privacy risks. But, Personalized medicine can provide precise, yet effective, treatment by considering the genes, environment, and lifestyle of each patient, accessing the genetic, phenotypic, and psychosocial ‘footprint’ to customize medical treatment and care. The consequences can be mitigated through technological economies of scale lowering costs, improved data security measures, and as an alternative, data analytics which refers to a method of interpreting and analyzing health information by methodically using statistical variables. Analyzing massive data sets reveals patterns and trends that can support clinical decision-making.



**Figure 4.** Data flow diagram showing the flow of information within an MBSE framework integrated with AI/ML systems.

By employing machine learning to deliver data-driven insights, enhance patient outcomes, and support public health management, it can also be utilized in disease surveillance, patient management, and resource allocation.

Future implementations in MBSE can substantially



improve the efficiency of MBSE in engineering and AI/ML to address the challenge of complexity and training requirements, and comprehensive training programs for engineers and project managers are essential. These programs should focus on building expertise in MBSE tools and methodologies. In addition, with tool integration for wider acceptance, in other words, where tools will seamlessly combine MBSE with AI/ML development platforms, establishing industry standards for applying MBSE in AI/ML can help ensure consistent integration of continuous learning and adaptation mechanism models in order to stay up-to-date with fast developments in AI/ML technologies. Although Using AI/ML can be complex and often pose high costs with continuous maintenance. To alleviate these issues, organizations can use a scalable AI/ML framework, invest in training programs and ensure high-quality data collection.

A new proposed concept is the Dynamic Risk Management Framework in MBSE: A new, innovative concept proposed in this paper is the Dynamic Risk Management Framework (DRMF) for MBSE. This framework aims to combine real-time data and predictive analytics to continuously assess and manage risks throughout the system life cycle. Incorporating DRMF into SysML models will allow engineering teams to carefully identify and mitigate potential issues, providing overall greater system reliability and performance. Although DRMF poses similar issues to using AI/ML in MBSE, the use of DRMF can lead to better, more resilient, and more adaptable systems, which will be capable of responding to changing conditions and requirements which certainly poses more benefits than losses.

### 3. Conclusion

For a system engineer to be versatile, they must be flexible. In this century, multidisciplinary systems have a lot of promise, but there are technological and cultural barriers that need to be overcome. Some limitations of MBSE include the need for improved modeling language integration and methodologies, which need additional study.

Basically, MBSE is essential for creating sophisticated systems in fields like medicine and engineering. It needs to evolve through standardizing processes, improving usability, and facilitating communication between cognitive scientists and system designers. The future of MBSE looks to be bright, according to advice from experts. Establishing metrics and value models, promoting modeling tool interoperability, and developing MBSE best practices and certifications seem to be very close to implementation. In the coming decades, organizations will need to adopt this model-based methodology to handle complexity, enhance cooperation, and

foster innovation. Experts have recommended developing metrics and value models, advocating interoperability among modeling tools.

These sorts of models will be extremely important in the upcoming decades in handling complexity, enhancing collaboration, or igniting innovation as companies and industries begin to adopt them. MBSE is vital for advanced systems in medicine and engineering, with standardized processes and improved usability. Further validation studies are needed. Standardizing MBSE languages, tools, and frameworks is crucial for overcoming communication barriers and integrating into diverse engineering disciplines and simulation software, ensuring transformative impacts. Embracing MBSE empowers engineers and organizations to navigate challenges effectively, fostering agility, scalability, and innovation essential for engineering competitiveness.

### Conflicts of Interest

The authors declare no competing financial interests or conflicts of interest.

### Author Contributions

S.V., K.D. Conceptualization. A.M., O.M., P.K., S.A.B., V.T. Visualization, Writing – Original Draft, Writing – Review & Editing.

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