Interventions on Clinical Utility

A Methodological Framework for Integrating Artificial Intelligence Agents in Medical Device Design

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ABSTRACT

An artificial intelligent (AI) agent uses sensors to perceive and actuators to act upon its task environment. The sensor module provides the perception of the task environment. The actuator module facilitates the agent's performing actions in the task environment. This research extends the function of a medical device by embedding an AI agent in the medical device during the design process. The research methodology utilizes a generic AI agent with fundamental learning capability and an initial knowledge base. The ability to learn enables the generic AI agent to operate in the initially unknown task environment. After sufficient interactions with the task environment, the agent becomes more competent than its initial knowledge base. The clinical applications are demonstrated through the use of the AI-enabled medical device in surgical training and performance evaluation.

Keywords: AI-enabled Healthcare, Artificial Intelligence, Artificial Intelligent Agents, Design Process, Learning, Medical Device

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INTRODUCTION

The role of artificial intelligence (AI) is increasing in all areas of life and work. The engineering, sciences, and technology disciplines focus on possibly incorporating AI in product design and improving the efficacy of processes and services[1]. Health systems are primary in achieving and maintaining societal health and economic growth. According to the World Health Organization (WHO), health systems are "the ensemble of all public and private institutions and resources, mandated to improve, maintain or restore health, and they encompass "personal and population services, as well as activities to influence the policies and actions in other sectors to address the social, environmental and economic determinants of health"[1]. A medical device is a major component of a health system. It plays a significant role in enabling healthcare to leverage the use of AI technologies to improve the quality of health[2].

A medical device, according to the Food and Drug Administration (FDA), refers to "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is" … "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals …"[2]. This research aims to outline embedding AI technologies inside a medical device to transform the traditional health system into an AI-enabled health system.

AI refers to the to the study of artificial intelligent agents[3]. An artificial intelligence agent receives precepts using sensors from its environment and acts upon using actuators. Precisely, this is a generic form of an embedded system. Therefore, this research study considers these artificial intelligent agents as embedded software or software robots. This research uses a typical software robot with initial domain knowledge and the ability to learn through interaction with the task environment. The primary contribution of this research work is in the form of a framework proposed to design the AI-enabled medical device.

A design process's input is needed, and the output is a solution. In other words, a design is a solution. This definition applies to the medical device design process as well. The input of the design process is the specifications, and the output is in the form of approved design documents. Several recent resources in the literature have mentioned the medical device design and development process [4,5,6,7,8,9,10].

METHODOLOGY

Figure-1 shows a typical detailed design process adopted[4]. The design process is the central component of the medical device design and development process. This research study extends the design process to embed the artificial intelligent agent in the device design. The extended process produces the design of AI-enabled medical devices. It is an important milestone towards an AI-enabled health system. The implementations of the proposed framework presented in this research include applications in surgical training and performance evaluation.

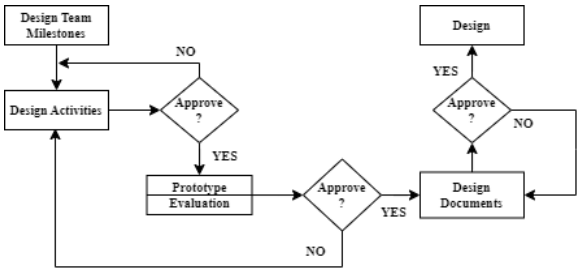

Fig.1 Typical detailed design procedure[4]

The integration of AI in the medical device market is a recent achievement. The FDA product classification website returned two approved devices in search of artificial intelligence; see Fig. 2.

The medical device with code QYV display the slide image and objects of interest from cytology and uses AI-based algorithms to perform detection and/or characterization of cells of clinical importance. The medical device with code QJU uses a trainable AI algorithm to assist users in optimizing image acquisition.

Fig. 2 Results of search "Artificial Intelligence" at the FDA product classification database

The medical devices QYV and QJU use AI algorithms to assist users with better and optimal results. AI is in the form of an assistant that may be trainable using domain data through operator action. Furthermore, the AI algorithm as a software application assists the user in both medical devices. The focused tasks include the detection of objects, classification of cells, and image optimization for clinical significance. These medical devices equipped with AI algorithms are essential for AI-enabled health systems.

In this study, agents are called artificial intelligent agents or software robots. These are AI algorithms used in FDA-approved medical devices with product codes QYV and QJU (Fig. 2)

A software artificial intelligence agent (software robot) acts like a sophisticated function in a programming language. It accepts inputs in various forms. These include data files, real-time network packets, and a variety of human inputs, for example, generated from keyboard, mouse, touchscreen, voice, gesture, etc., as sensory inputs. It acts on the task environment by writing files, sending network packets, and displaying. This study refers to an AI algorithm as a software robot. It has initial domain knowledge and learning ability and is called a base agent. Domain knowledge refers to knowledge specific to the medical specialty, as already described

above, in the case of FDA-approved medical devices. The healthcare system is a complex task environment; one solution or artificial intelligent agent cannot assist physicians.

Authors[11] described the potential uses of AI to interpret electrocardiogram (ECG) and disease classification. They used the notion of AI as a computer model with the ability to make decisions and improve its performance with experience. They anticipated the increasing role of AI in ECG in the future. The computer model they referred to was a machine/deep learning (ML/DL) convolutional neural network (CNN). The ECG data sources included implantable and wearable medical devices. These AI-enabled ECG medical devices perform real-time ECG monitoring to detect and classify cardiac rhythm. Another research uses ML and DL methods to detect cardiovascular diseases in ECG images[12].

Research[13] presented AI-enabled ECG and reported initial results from the medical device. They used the MIT-BIH Arrhythmia Database[14] to train AI models. The prediction was based on a refined logistic regression model. The design of a three-lead ECG machine was implemented and demonstrated through initial results. The limitation of their approach was that the embedded model (agent) acted correctly. The task environment was considered wholly known a priori and entirely predictable. However, this study focuses on the base agent, as defined earlier in this section.

Most medical device design and development research work in the literature review did not mention the insights of the design process[15,16,17,18,19,20]. Furthermore, the considerations of including AI algorithms in the design process of the product development life cycle were rarely outlined. This research study considers the waterfall software development lifecycle for the extension of the typical design process in Fig.1 to formulate the proposed framework.

Verification and validation are two critical aspects of software testing. The verification is related to the device's technical specifications. The validation is associated with the user requirements. The evaluation of medical devices is accomplished according to some standards. It often includes mechanical testing, physical evaluation, and clinical evaluation. In this study, the assessment of the AI-enabled medical device design prototype was proposed through standard methods that evaluate the performance of AI algorithms. A simulation environment is well-suited for verification, and the desired user acceptance level is achieved through a review process for the device design validation.

Proposed Framework

The first step is to update the design team milestones to include AI in the medical device design. The second step is to update the list of design activities to incorporate the base agent in the design. The base agent has initial domain knowledge and can learn through interactions with the task environment (experience). The third step is to embed the base agent inside the medical device design prototype, and the fourth step is to evaluate the performance, verify compliance with the technical specifications, and validate the user requirements. In the fifth stage, the design is finalized.

The base agent (BA) with the initial domain knowledge (iKB) and the ability to learn (A2L) is mathematically represented as follows.

$$\mathbf{BA \equiv Function\ (iKB,\ A2L)} \quad \mathbf{(1)}$$

After sufficient interactions (Is) with the task environment (TE), the base agent uses A2L and updates the iKB to a working knowledge base (WKB) and keeps on updating. A copy of the iKB is stored inside the WKB to ensure backwards compatibility. The operation of the knowledge base update is represented in the form of a BA transformation to the operational artificial intelligence agent (oAIA) as follows:

$$\mathbf{oAIA \leftarrow BA(WKB \leftarrow iKB,\ A2L)} \quad \mathbf{(2)}$$

The medical device design (MDD) was equipped with the BA at the startup and achieved a level specified in (2). The MDD is mathematically represented as a prototype (P) as follows.

$$\mathbf{MDD \equiv P\ (oAIA \leftarrow\ BA)} \quad \mathbf{(3)}$$

Consider an MDD that has passed (p) or failed (f) the evaluation (E). It is represented as follows.

$$\mathbf{MDD\ (p \mid f) \leftarrow E\ (v\ \&\ v,\ c)} \quad \mathbf{(4)}$$

Where v & v ≡ verification and validation, and c ≡ clinical evaluation. The approved final medical device design (MDDfin) is then represented as an MDD that has passed evaluation E. It is represented mathematically as follows.

$$\mathbf{MDDfin \equiv MDD(p)} \quad \mathbf{(5)}$$

The mathematical formulation (1) – (5), developed above, is incorporated in the typical detailed design procedure of Fig. 1 as a graphical representation of the proposed framework for AI-enabled medical device design using AI intelligent agents (Fig.3) The new process is evolved with specified steps in it, and described as follows.

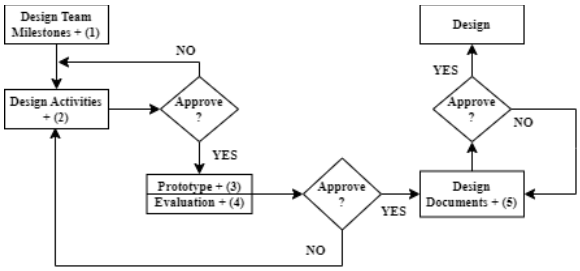

Fig-3. Proposed Framework

The design team milestones include (1) as the first step. The milestones include incorporating the base agent with an appropriate timeline and assigning resources, including domain experts, to ensure the initial knowledge base and learning abilities. The second step is to update the list of design activities to incorporate the base agent in the design. The activity description includes the criteria on which sufficient interactions are defined for the implantation of (2). In the third step, the prototype incorporates (3); in the fourth step, the evaluation (4) is accomplished on the design prototype. In the fifth step, a design that has passed the assessment (5) may be approved for implementation. At this point, an approved design has the AI technology embedded for the implementation team.

Results

This section extends the earlier works[13, 21] utilizing the proposed framework in Fig. 3. Research[13] designed an AI-based electrocardiography (ECG) machine for early detection of dysrhythmia. Their design implemented an AI model trained from the MIT-BIH Arrhythmia Database[14], freely available at PhysioNet.org[22]. Their AI-enabled ECG machine implemented a regression model in the form of a .pkl (dot pickle) file. This file is generated through the pickle Python module. The algorithm has three stages: Date preprocessing, feature extraction, and classification. The implementation looks like QYV, See Fig. 2, and may be converted to QJU in a future version.

Authors[21] proposed an artificial intelligence agent to assist cardiac surgeons in performing or evaluating interventions. Their proposed architecture included an agent capable of thinking critically and solving problems as an assistant. From (2), the BA learned critical thinking (CT) and problem-solving (PS), as follows:

$$\mathbf{oAIA\{CT, PS\} \leftarrow BA(WKB \leftarrow iKB, A2L)} \quad (6)$$

The (6) replaces (2) in the proposed framework, See Fig. 3. The recent related works[23,24,25] in the research literature focused on several important areas and have great potential to incorporate the proposed framework in this research.

DISCUSSION

The proposed framework represents a significant advancement in bridging the gap between theoretical AI capabilities and practical medical device implementation. By conceptualizing AI algorithms as "base agents" with initial domain knowledge and learning abilities, the framework provides a structured approach that goes beyond traditional static implementations. This is particularly evident in the mathematical formulation where the base agent (BA) transforms into an operational artificial intelligence agent (oAIA) through sufficient interactions with the task environment. The framework's strength lies in its systematic integration of AI verification and validation processes within established medical device design protocols, addressing a critical gap identified in current literature where AI integration considerations are rarely outlined in product development lifecycles.

However, the framework's practical implementation faces several challenges that warrant further investigation. While the authors demonstrate applications in ECG analysis and surgical training, the scalability of the base agent concept across diverse medical specialties remains unclear. The assumption that sufficient interactions with the task environment will consistently lead to improved performance may not hold across all medical domains, particularly those with rare conditions or limited training data. Additionally, the framework's reliance on the waterfall software development lifecycle may not be optimal for AI systems that benefit from iterative development and continuous learning. Future research should focus on developing domain-specific adaptation strategies and exploring more agile development approaches that can better accommodate the dynamic nature of AI learning systems in clinical environments.

CONCLUSION

This research work proposed a framework that equips a medical device to leverage the advancements in AI technology for health system transformation from traditional, standard settings to AI-enabled health services. The embedding of

artificial intelligent agents with initial domain knowledge and the ability to learn has been demonstrated through clinical applications. The proposed framework ensures the design of a medical device is AI-enabled. It is a significant step towards AI-enabled health systems. In the future, the proposed framework is fine-tuned to produce a design that inherently complies with a given standard.

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Author Contributions
All authors contributed equally.

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Conflict of Interests
None.

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