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Artificial intelligence and remote patient monitoring in US healthcare market: a literature review

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ABSTRACT

Background: Artificial intelligence (AI) enables remote patient monitoring (RPM) which reduces costs by triaging patients to optimize hospitalization and avoid complications. The FDA regulates AI in medical devices and aims to ensure patient safety, effectiveness, and transparent AI solutions.

Objectives: Identify and summarize FDA approved RPM devices to provide information for the US medical device industry based on previous approvals and the markets' needs.

Methods: We searched publicly available databases on FDA-approved RPM devices. Selection criteria were established to classify a solution as AI. Technical information was analyzed on pre-identified 16 parameters for the qualified solutions.

Results: A total of 47 RPM devices were reviewed, among which 12.8% were classified as a De Novo product and the remaining devices fell under the 510(K) FDA category. The cardiovascular (74%) AI RPM solutions dominated the US market, followed by ECG-based arrhythmia detection algorithms (59.4%), and Hemodynamics and Vital Sign monitoring algorithms (21.9%). The trend observed in the FDA rejected devices was their inability to be classified into clinically relevant categories (Criteria 2 and 3).

Conclusion: The market needs more innovative RPM solutions under the De Novo category, as there are very few. The transparency is low on the technical aspect of AI algorithms. The market needs AI algorithms that can effectively classify patients rather than merely improve device functionality.

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Introduction

Demand for healthcare is rapidly increasing due to the aging population in the USA. As of 2021, approximately 54 million Americans are over the age of 65. This number is expected to increase to 85.7 million by 2050 [1]. Consequently, the healthcare budget is on the rise. In 2020, Medicare spending was around 20% of the total National Health Expenditure. A significant proportion of the expenditure goes to hospitalization [2]. The health system needs care modalities that can increase efficiency and reduce costs. Many such hospitalizations can be avoided through remote patient monitoring (RPM) [3]. RPM involves using connected electronic devices to record personal health and medical data in one location that a provider can review at a different location. Coupled with artificial intelligence (AI), RPM devices help in clinical decision-making by analyzing vital health data points and generating alerts. AI RPM aims for better health outcomes and reduced costs through early detection of adverse health events and prioritizing hospitalization [4]. RPM increases the quality of Medicare, especially continuous RPM because it lowers the chance of further complications and readmission [5].

FDA regulates the sale of medical devices in the US. The regulatory process depends on the classification of AI/Machine Learning (ML) algorithms, as illustrated in the first part of the Supplemental information section of this paper. FDA recognized that AI has the potential to transform healthcare by driving insights from vast amounts of service delivery data. However, concerns loom over patient safety, effectiveness, and quality of care. FDA is developing policies to regulate AI as software for medical devices (SaDM), which will also have implications for RPM. Due to the rapid policy changes, the medical device industry needs information on current AI RPM development and a regulatory perspective. This paper aims to identify the FDA-approved RPM AI solutions in the US market and critically analyze them based on 16

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characteristics. The analysis covered information on market saturation, disease segment, functionality, features, algorithmic performance, and evidence on the quality of the solution which led to a successful approval.

Methods

Framework

From the FDA perspective, we identified the main criteria to qualify a solution as AI RPM (Figure 1).

Databases

We searched the below Databases based on the Figure 1 components and reviewed the FDA approval document.

(1) The Medical Futurist [6]
(2) AI Central [7]
(3) Nature Medicine [8]
(4) U.S. Food and Drug Administration [9],

Criterion 1 focused on the remote use of the solution. Criteria 2 and 3 were essential to qualify as a complete RPM solution. Criterion 3 is important as the prime objective of AI is to handle and classify large data into clinically relevant categories with accuracy. We focused on the functionality and clinical performance of the solution rather than analyzing the technical aspects of the algorithm. From a market access perspective, the functional classification of algorithms is important, but there is limited data available on the statistical aspects of algorithms in existing resources.

If a solution did not follow either criteria 2 or 3, it was only labeled as a potential RPM solution. If a solution missed 2 and 3, it was rejected in the review process. Solutions offering RPM in only hospital settings were rejected, for example, the Holter monitor. RPM devices used by patients or with assistance were qualified for the review.

In this paper, quality control was maintained through double screening. Specifically, one researcher analyzed the solution, and the other verified the information. Only publicly available information was used; therefore, no regulatory or institutional review board approval was needed. A desk review was conducted to extract vital information about the solutions. The literature sources included the FDA decision document, the company's website, published clinical studies, and other electronic articles. We followed the citations of previous studies which were included in this paper. Furthermore, we analyzed the company's website and news briefs for other AI solutions that were not listed in the database. The company's website listed the relevant scientific publication of the device which was useful to extract information on the pre-identified 16 parameters.

As mentioned before, we also searched for recent and relevant news and updates on AI and RPM technology through appropriate search terms on google search and Bing engines. The reasons for successful regulatory approval were interpreted

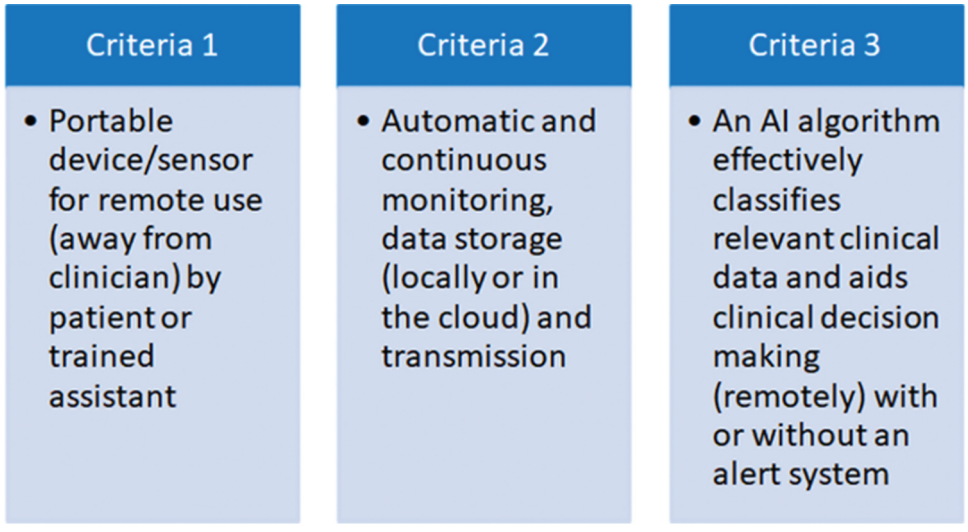

Figure 1. Important criteria to qualify as AI RPM.

from FDA documents accessed from the FDA database [9]. All the collected information about the solutions was sorted into a spreadsheet for further analysis, which is accessible through the Supplementary files.

Results

Database review

The FDA AI database listed 343 approved AI solutions, among which 36 were identified as RPM based on 3 criteria illustrated in Figure 1. Other databases provided 3 unique solutions. The desk review provided 8 other relevant solutions. A total of 47 RPM solutions were reviewed in detail, out of which 12.8% were DeNovo, and the remaining were 510(K). We could not identify any solution under the Pre-Market Authorization (PMA) category. All the solutions were under the class II classification. The cardiovascular (74%) AI RPM solutions dominated the US market (Figure 2).

Table 1 presents the number of identified AI RPM solutions under different systemic and algorithmic categories. Under cardiovascular, ECG-based arrhythmia detection algorithms were the most available in the market (59.4%), followed by Hemodynamics and vital sign monitoring algorithms (21.9%). The De novo approvals were for Hemodynamics & vital sign monitoring ($n = 3$), ECG-based arrhythmia detection (2), and diabetes management ($n = 1$).

On review, 32 solutions fully matched, and 15 partially matched the criteria (Figure 1); therefore, later were classified as potential AI RPM solutions (Table 2). In partially matched, the common missing criterion was the inbuilt AI algorithm for the disease classification. Among all solutions, 47% ($n = 22$) were SaMD. RPM hardware devices for Hemodynamics & VS monitoring were reported interoperable with SaMD.

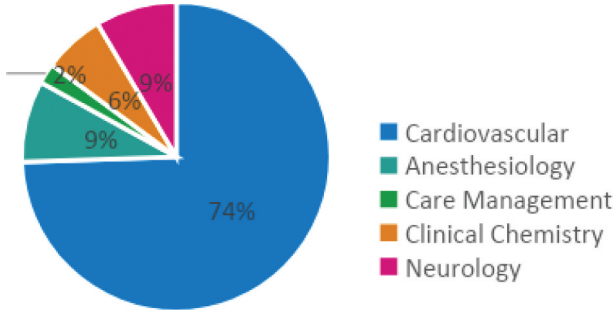

Figure 2. Proportion of RPM solutions under systemic themes.

Discussion

FDA realized the necessity of updating its AI/ML policy. In April 2019, the FDA requested expert and industry feedback and published an action plan in January 2021 [10]. In the action plan, one of the key points was 'building patient-centered approaches via device transparency and other methods.' Through our paper, we tried to review the algorithms and their performance for transparency. Primarily, the technical information over algorithms was not public; the reason may be privacy or intellectual property rights. We observed that AI/ML was not commonly mentioned in the FDA approval documents. The appearance of AI as a term was often on company websites. However, it was difficult to validate if the AI mentioned on company websites corresponds to a particular solution we reviewed from the database.

We applied a standard framework (Figure 1) to identify solutions such as AI RPM. The first selection criteria were related to portability and ease of use. The second criterion was related to continuous remote monitoring (Figure 1), which has been proven to lower the chance of further complications and readmission [5]. The third criterion of having an AI algorithm was the most important. Continuous monitoring produces a large amount of clinical data. Without an AI classification algorithm, it is impossible to analyze the data and can often be a burden for the clinician rather than an aid. The absence of an AI algorithm was the most common reason for rejection. Another study also reported that among 64 AI/ML FDA algorithms, only 29% mentioned any algorithm [11]. AI/ML were also commonly used to enhance device performance by

Table 1. Systemic and algorithmic category of FDA approved AI RPM solutions.

Row Labels	Anesthesiology	Cardiovascular	Care Management	Clinical Chemistry	Neurology	Grand Total (%)
Diabetes management	0	0	1	1	0	2 (6.3)
ECG based arrhythmia detection	0	19	0	0	0	19 (59.4)
EEG based detection	0	0	0	0	2	2 (6.3)
Hemodynamics & VS* monitoring	0	7	0	0	0	7 (21.9)
Sleep monitoring	1	0	0	0	1	2 (6.3)
Grand Total	**1**	**26**	**1**	**1**	**3**	**32**

*Hemodynamics & vital sign monitoring mainly comprised remote monitoring of continuous physiological data such as heart rate, oxygen concentration, respiration rate, etc.

Table 2. Potential RPM AI solutions under different categories.

Row Labels	Anesthesiology	Cardiovascular	Clinical Chemistry	Neurology	Grand Total
			(Figure 1 criteria missing)		
Asthma or COPD management	1 (3)	0	0	0	1
Diabetes management	0	0	2 (3)	0	2
ECG based arrhythmia detection	0	1 (1)	0	0	1
EEG based detection	0	0	0	1	1
Hemodynamics & VS monitoring	0	8 (2 or 3)	0	0	7
Sleep monitoring	2 (3)	0	0	0	2
Grand Total	**3**	**9**	**2**	**1**	**15**

There was only 1 implantable solution for ECG recording, and it was also equipped with a classification algorithm for automatic arrhythmia detection. Approximately 38% of solutions were compatible with apps. None of AI RPM was classified as a life-sustaining solution. The clinical efficacy evidence of the solutions is compiled in the second part of the Supplemental Information section of this paper. We also explained Denovo approvals as case studies for readers to understand the level of performance, evidence, and process for innovative solutions in the third part of the Supplemental Information section of this paper.

suppressing data noise. Therefore, it is important for manufacturers to realize that FDA focuses on AI algorithms that can effectively classify clinical data, as presented in Figure 1.

Our paper is the first which focuses on AI RPM. However, AI application and classification are advanced in image-based technologies. A paper classified AI/ML algorithms in radiology, i.e., computer-aided triage (CADt), detection (CADe), diagnosis (CADx), detection/diagnosis (CADe/x), and acquisition/optimization (CADa/o) [12]. A similar approach is required to classify AI RPM algorithms.

In the context of interoperability and SaMD, we listed the conventional RPM devices which can be coupled with AI. Some examples include digital glucometers, spirometers, EEG, or sleep monitors. The digital stethoscope solution has the potential to be integrated with ECG and vital sign RPM patches for continuous monitoring. The current EEG devices are difficult to use and need further innovation to become portable and user-friendly.

Conclusion

The AI application in RPM is limited compared to imaging. The application of RPM devices is mostly for arrhythmia detection in the cardiovascular segment. Applying AI RPM in hemodynamics and vital sign monitoring provides an excellent opportunity to expand the portfolio. Compared to 510(K), the Denovo applications were few, which should increase by investing in innovative solutions. The interoperability between RPM and SaMD will increase over time. For transparency, FDA AI/ML policy should address interoperability and classification details of AI/ML algorithms in their approval documents.

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Data availability statement

All data generated or analyzed during this study are included in this published article (and its supplementary information files).

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