Title: Landscape of oncology-specific, FDA-approved, artificial intelligence and machine learning-enabled medical devices

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Purpose/Objectives:
Machine learning (ML), a type of artificial intelligence (AI) technology that uses a data-driven approach for pattern recognition, has been shown by numerous research studies to be beneficial for tasks across healthcare. In this study, we aim to characterize the commercial availability of oncology-specific AI/ML applications in the clinic by performing a detailed analysis of such devices that were approved/cleared by the US Food and Drug Administration (FDA).

Materials/Methods:
A list of 343 AI/ML-enabled medical devices that were approved or cleared by the FDA up to June 2021 was published by the agency, and this list was used to construct the initial database for our study. The publicly available FDA approval letters for these devices were independently reviewed by two research assistants, and a device was classified as oncology-specific if its primary intended use is related to assisting the diagnosis or treatment of oncologic pathologies. For oncology-specific devices, additional details on device characteristics, FDA regulatory process, and approved indications were obtained. A basic descriptive statistical analysis was performed on the aggregated data.

Result:
Fifty-two (15.2%) of the 343 AI/ML-enabled medical devices were classified as oncology-specific. The growth of the oncologic-specific devices sharply rose since the mid-2010s, with 49 (94.2%) approved in 2016 or after. Fifty (96.2%) devices were cleared by the 510(k) premarket notification pathway, and, except for one class III device, the remaining 51 devices were considered as class II by the FDA. All but one device was considered Software as a Medical Device (SaMD). Thirty-six (69.2%) devices were intended for diagnostic purposes, of which 24 (66.7%), 9 (14.3%), 1 (6.3%), 1 (6.3%), and 1 (6.3%) was for the detection of breast cancer, lung cancer, prostate cancer, thyroid cancer, and bone cancer, respectively. The 16 devices intended for therapeutic purposes were all related to radiotherapy: 15 are for radiation treatment planning (all included organ auto-segmentation as the main function), and 1 is a linear accelerator equipped with AI/ML algorithms.

Conclusions:
Our results showed a rapid increase of oncology-specific, FDA-approved, AI/ML-enabled medical devices since 2016. Further study is needed to assess the impact made by these devices on the delivery of oncology care.