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Landscape of Oncology-Specific, FDA-Approved, Artificial Intelligence and Machine Learning-Enabled Medical Devices

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context issues. Many of these same policies are now being applied across Canada to address access to cancer services during the COVID-19 pandemic.

Conclusion: A 20-year case study of the Ontario RT access crisis in the 1990s, and the post-crisis periods, offer many useful learnings that can be applied to current policy challenges in access to care due to the ongoing pandemic.

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Self-Reported COVID-19 Infections and Social Mixing Behavior at Oncology Meetings

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Purpose/Objective(s): The COVID-19 pandemic largely suspended conventional in-person scientific meetings because of the risk of disease spread. In the era of vaccination and social distancing practices, meetings have slowly begun to return to in-person formats. We surveyed attendees and potential attendees of two United States oncology meetings to identify rates of mixing behavior and the subsequent rate of self-reported COVID-19 infection.

Materials/Methods: We collected reported social mixing behavior and COVID-19 positivity of actual and potential in-person oncology meeting attendees of the American Society of Clinical Oncology (ASCO) Quality Care Symposium in Boston, Massachusetts on September 24-25, 2021, and the American Society for Radiation Oncology (ASTRO) Annual Meeting in Chicago, Illinois on October 24-27, 2021 via survey. Participants were identified through publicly available meeting materials and targeted via email when possible. Recruitment was also conducted through Twitter and a radiation oncology newsletter, as well as an anonymous link made available to emailed recruits, with sharing encouraged. In-person respondents to the later ASTRO survey who had attended the ASCO meeting were excluded from the analysis. Statistical significance was determined using Fisher's exact test for rates of COVID-19 positivity and the chi-squared statistic for differences in group characteristics, with a cutoff for statistical significance $p<0.05$.

Results: Response rates from attendees with publicly available emails were 27.4% for the ASCO meeting and 14.3% for the ASTRO meeting. The ASCO survey produced 94 responses, with 48 responding as in-person attendees. The ASTRO survey produced 370 responses, with 267 responding as in-person attendees. Across both meetings, 3 of 308 (1.0%) of in-person attendees versus 2 of 141 (1.4%) of non-attendees tested positive for COVID-19 ($p=0.65$). Among in-person attendees, there were similar low COVID-19 positivity rates among those spending more (>20) vs less (≤20) hours attending live sessions (2.2% vs 0%, $p=0.25$) and between those who went to indoor social events vs those who did not during the meeting periods (0.8% vs 1.9%, $p=0.44$). Attendees largely felt that they would feel comfortable attending additional in-person meetings after experiencing the ASCO (87.5%) or ASTRO (91.9%) meetings and that mask compliance was good or excellent at the ASCO (100%) and ASTRO (94.6%) meetings.

Conclusion: This study indicates that in-person meetings do not seem to be contributing to high rates of new COVID-19 infections in the setting of mask mandates, vaccine mandates, and decreased room capacity allowances. The rate of self-reported COVID-19 infection of both in-person attendees and non-attendees was very low and the meetings were successful at creating an environment where participants felt safe. These findings support the possibility of a path forward for at least partially in-person conferences as new variants emerge and COVID-19 becomes endemic.

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Landscape of Oncology-Specific, FDA-Approved, Artificial Intelligence and Machine Learning-Enabled Medical Devices

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Purpose/Objective(s): 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.

Results: 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.

Conclusion: 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.

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