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How will Artificial Intelligence Impact Medical Imaging in 2020? RSNA 2019 Round-up

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The IHS Markit (IHSM) Healthcare Technology team recently attended the annual Radiological Society of North America (RSNA) 2019 meeting in Chicago in December. The general buzz around artificial intelligence (AI) was still very prominent at the show, with vendors showcasing AI integrated software algorithms that promise to reap the rewards to those that invest.

Common opinion at RSNA 2019

The pathway to success is becoming much clearer with the 'if you build it, they will come' mantra becoming a bigger reality than anticipated at the beginning of the last decade. Initial fears of radiologist replacement have been turned into excitement and optimism of what the future may bring.

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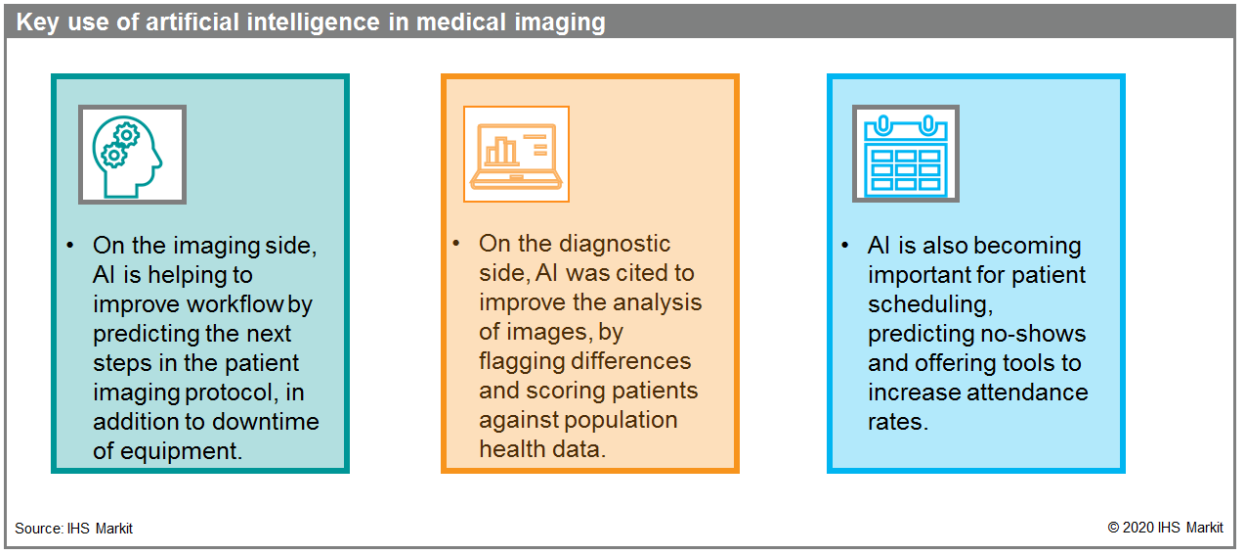

It was also very clear that medical imaging vendors have taken heed of the initial push-back from radiologists and are developing solutions that are ready to help them in their role, to improve the quality of care provision. The message was loud and clear that the solutions need to be that, and not create further challenges to their workflow.

What was new at RSNA 2019

The AI showcase pavilion highlighted not only the increasing plethora of algorithm vendors, but also the creeping presence of computing technology vendors such as Amazon Web Services and IBM Watson in addition to new-timer Google Health. The use of patient data is fast becoming the biggest talking point across healthcare; the invention of electronic health records and increasing collection of data has driven the use of machine learning algorithms. Using their deep-rooted knowledge of data science, these vendors are poised to develop and connect healthcare providers to solutions to their needs.

The increasing use of data also highlighted the need for patient data safety, ensuring data that is stored, is kept safe and not at risk of cybersecurity hacking. Adam Davidson discusses the application of big data to ultrasound in his article *'Big data in ultrasound is not all sunshine and rainbows'*, highlighting the major

upside along with the associated cybersecurity risks. This hot topic has become core in the imaging market, so much so that there will be a dedicated showcase on data storage and security at RSNA 2020.

Key product launches at RSNA

On the 12th September 2019, GE Healthcare made history after it announced 510(k) clearance from the Food and Drug Administration (FDA) of the Critical Care Suite. The Critical Care Suite was built in collaboration with UC San Francisco (UCSF) and uses GE Healthcare's Edison platform. The Critical Care Suite was the first of its kind in the industry having artificial intelligence (AI) embedded algorithms on the mobile X-ray device, to scan X-ray images and more accurately detect the deadly condition pneumothorax.

A number of imaging companies also highlighted their AI-based software product launches at RSNA 2019.

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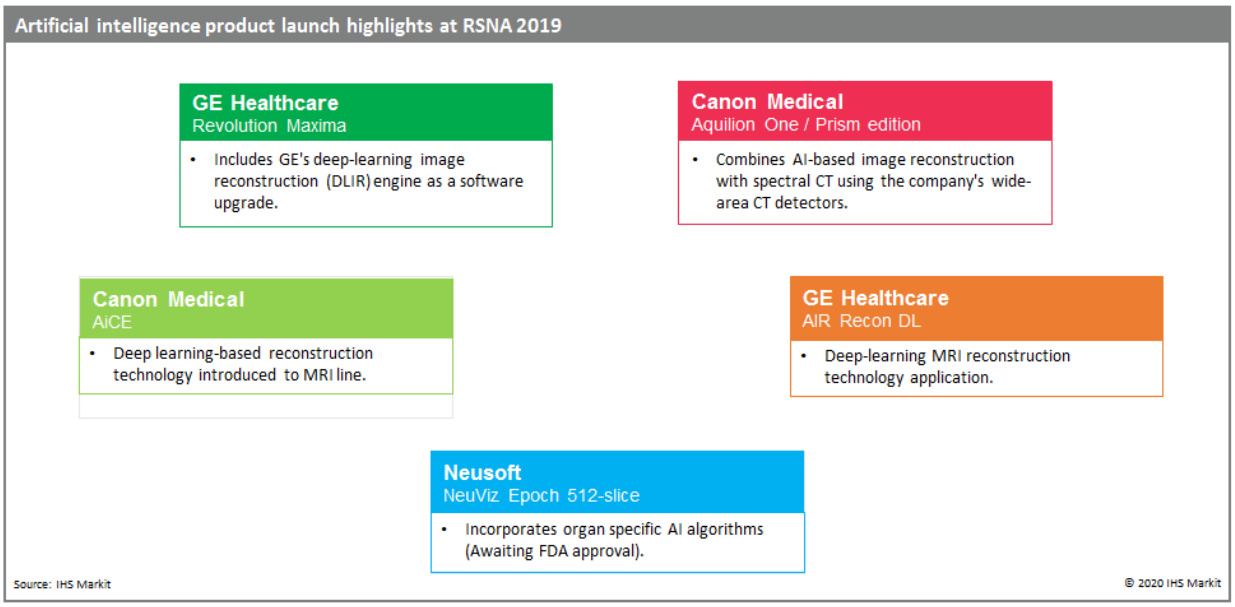

Several companies also demoed their 'in-development' products, including:

Philip Healthcare - IntelliSpace AI workflow suite

Enables health care providers to integrate AI applications into the imaging workflow.

Siemens Healthineers – AI Rad Companion – Brain & Prostrate MR

Brain MR - Segments, calculate volume compares against standard data and produces a report – if there are differences a flag is sent to the user.

Prostrate MR – segments, marks lesions of interest and is sent to PACS. A biopsy can then be performed under MR guidance.

Both Brain MR and Prostrate MR are awaiting FDA and CE regulatory approval.

Google Health focuses in on medical imaging

New to RSNA this year, Google Health showcased their product offering to aid organizations to transition to the cloud. At the show, Google Health demonstrated solutions that enable de-identification of data in DICOM images and HIPAA-supported deployments. Their cloud-based platform has enabled Change

Healthcare to host its enterprise Imaging Network, which offers imaging archive and viewer and AI-powered analytics.

Following on from their appearance at RSNA, Google Health exploded into the news with the claim that their AI-based algorithm, that was jointly designed with the Imperial College in London, outperformed six radiologists in reading mammograms. Google Health claimed the model was then evaluated on a separate de-identified data set of more than 25,000 women in the United Kingdom and over 3,000 women in the United States. In this evaluation, the system produced a 5.7 percent reduction of false positives in the United States, and a 1.2 percent reduction in the United Kingdom. It produced a 9.4 percent reduction in false negatives in the United States, and a 2.7 percent reduction in the United Kingdom.

How has AI in imaging changed from 2018 vs 2019

It is clear that initial fear is turning into excitement. Radiologists are starting to embrace the opportunities that artificial intelligence brings. AI is being used in a wider number of applications across more imaging modalities.

Over the last two years, IHSM Healthcare Technology researched more than 288 vendors and 363 machines to provide a taxonomy of the ecosystem supporting machine learning with diagnostic applications. As part of its research, IHSM Technology identified 15% of machine learning algorithms had regulatory approval (FDA, CE, MFDS, CFDA) in 2018. In 2019, this increased to 28%. Of the 363 machines profiled, 16.5% were for chest and lung applications and 18.2% were for neurology applications.

Reimbursement continues to be a sticking point and a hot topic when discussing the return on investment of implementing AI solutions; there is no reimbursement for AI in the United States. Pricing models vary significantly across vendors, from fee-per-study, analytics-as-a-service, to annual subscriptions. There is unlikely to be more money given and reimbursement will be a game-changer for the future.

Can deep learning be a reality?

The industry has no singular definition concerning what an algorithm is and is not, and oversight for these applications is dependent on their intended use and level of risk to the user. IHSM Technology defines deep learning as, establishing neural networks that allows a computer to continuously train itself to improve its performance of tasks.

By this definition deep learning software continuously learns and trains itself based on 'real-world' experience.

The FDA is currently discussing the regulatory approval process for continuously learning and adaptive algorithms, that may provide a different output in comparison to the output initially cleared for a given set of inputs. It has called for feedback on its proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD). The framework proposed for discussion categorizes SaMD based on its intended use based on two factors:

1) Significance of information provided by the SaMD to the healthcare decision

2) State of healthcare situation or condition

The framework then further proposes that vendors are expected to evaluate the modifications to an approved algorithm based on risk to patients as outlined in the software modifications guidance.

The software modifications guidance uses a risk-based approach and expects a manufacturer to perform a risk assessment and evaluate that the risks are reasonably mitigated. Depending on the type of

modification, the current software modifications guidance results in either 1) submission of a new 510(k) for premarket review or 2) documentation of the modification and the analysis in the risk management and 510(k) files.

On the 22nd January 2020, the FDA announced that as of the 22nd February 2020 it will reclassify medical image analyzers applied to mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection, from class III devices (regulated under product code MYN), into class II (special controls). Medical image analyzers are intended to highlight portions of an image that may reveal abnormalities during interpretation of patient radiology images by the clinician. FDA is also identifying the special controls necessary to provide a reasonable assurance of safety and effectiveness of the device type.

This is expected to streamline the classification process of a new device (in this case a CADe device software including AI algorithms used to 'aid' diagnosis). Section 510(m) of the FD&C Act provides that the FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The special controls will need to be followed which includes design verification and validation in addition to appropriate labelling. The reclassification is subject to premarket notification.

This is a clear step in the right direction to help improve the approval process for algorithms used in medical imaging. IHSM Technology will continue to review the guidance provided by the FDA following on from the review of the feedback they receive.

2020 outlook for AI in imaging

2020 started with Google Health's claim to improved efficacy of its algorithm compared to the trained-human. IHSM Technology expects clinical evaluations of the benefit of using AI enabled solutions to increase through the course of year.

Several 'in-development' AI solutions were showcased at RSNA, with more expected to be approved at the upcoming European Society of Radiology (ECR) show, further expanding the number of clinical applications for AI solutions.

Larger data sets will be used to train algorithms resulting in next generation solutions. Despite the more streamlined approval process for CADe software applications, the FDA is likely to tighten controls for deep learning algorithms, offering the much-needed support to ensure patient safety.

Furthermore, with increasing claim to improve economic value, evaluations will be necessary to identify if AI is in fact improving cost efficiency.

IHS Markit Healthcare Technology will continue to track this market qualitatively as part of its research across the medical imaging and healthcare software markets.

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