Digital Transformation, COVID-19 and the Post Pandemic World - Artificial Intelligence and Medicine

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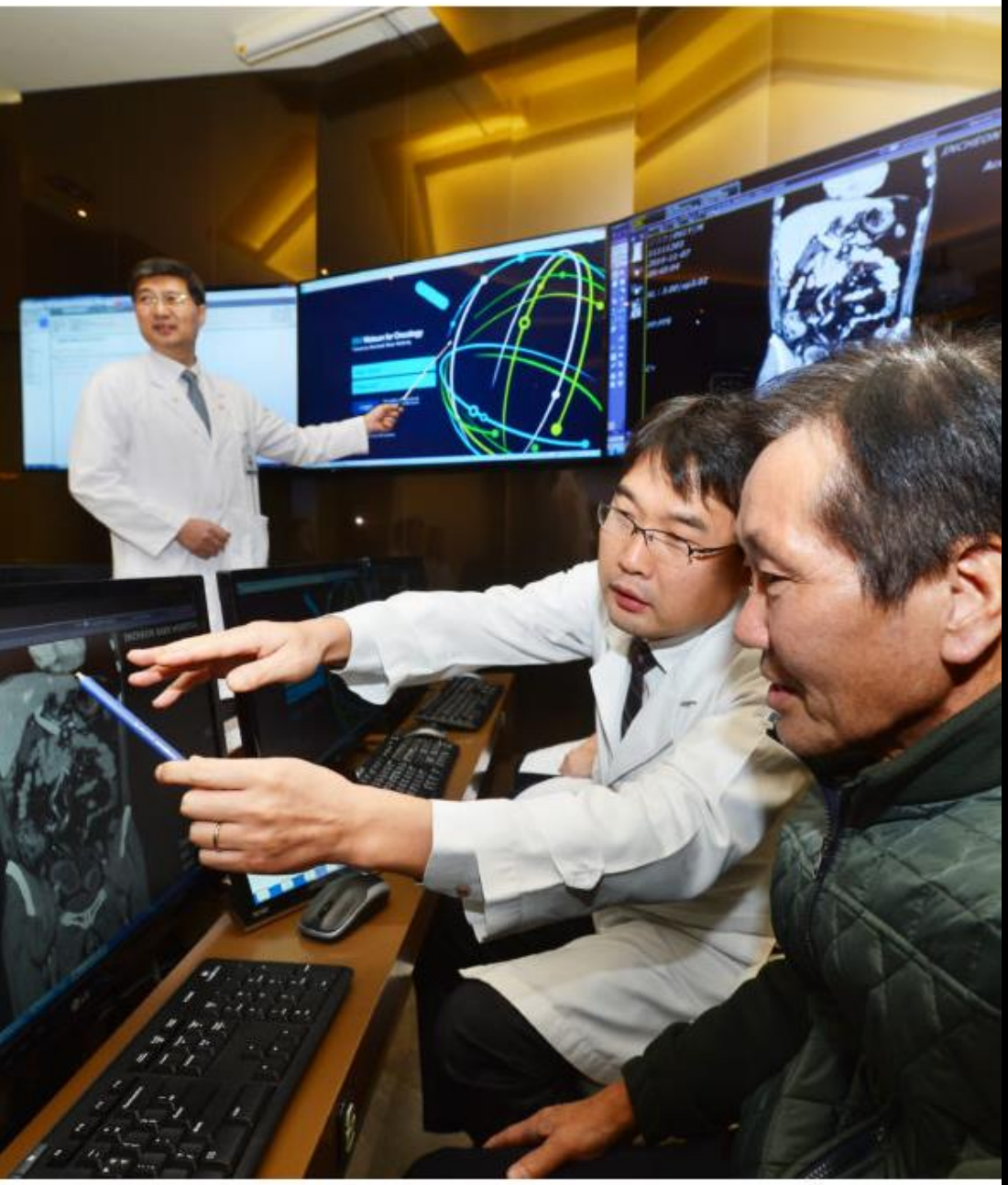
International Academy of CIO
February 25th, 2022



orean to be treated with assistance from Watson for Oncology, reviews his medical information
versity Gil Medical Center

- Source: https://www.statnews.com/2017/09/05/watson-ibm-cancer

MYCIN: A KNOWLEDGE-BASED COMPUTER PROGRAM
APPLIED TO INFECTIOUS DISEASES*

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A rule-based expert system is described which uses artificial intelligence techniques, and a model of the interaction between physicians and human consultants, to attempt to satisfy the demands of a user community that is often reluctant to experiment with computer technology. Experience to date has demonstrated that the program is efficient, relatively easy to use, and reliable in the domain of bacteremia therapy selection. Future work will involve broadening and evaluating the program's expertise in other areas of infectious disease therapy. To that end rules regarding diagnosis and treatment of meningitis have been written and are currently under evaluation.

Introduction

Few potential user populations are as demanding of computer technology as are practicing physicians. This is due to a variety of factors which include the physician's independence as a lone decision maker, the seriousness with which he views actions that may often have life-and-death significance, and the overwhelming time demands which tend to make him impatient with any innovation that breaks up the finely-tuned flow of his daily routine. Yet as medical science has expanded, the individual practitioner has become increasingly less able to manage all the expertise he needs if he is to provide modern medical care. Consultation from subspecialists has therefore become a common and accepted part of practice for those physicians fortunate enough to have easy access to the kinds of expertise they need. Away from large urban or academic centers such consultative advice may be more difficult to obtain, and it is partly for this reason that efforts have been made to develop computer programs with sufficient subspecialty expertise to function in a reliable consultative role.

Despite the medical professions' common reluctance to experiment with clinical computing[1], many consultation programs have failed to emphasize the development of mechanisms for encouraging their use by physicians. In designing the MYCIN program, a clinical consultation system, we have attempted to recognize the need to place the ultimate medical decisions in the hands of the physician. MYCIN includes mechanisms so that the doctor may understand not only the program's advice, but also the basis on which the relevant clinical decisions were reached. Such an understanding is encouraged by allowing the physician to maintain the initiative throughout the consultation, with an ability to request clarification or justification of puzzling points along the way. This process parallels the familiar form of dialog and advice from a human consultant (Fig. 1) and is thereby less threatening than a system which simply submits dogma. MYCIN's area of expertise is the selection of antimicrobial therapy for patients with severe infections. This paper briefly summarizes the MYCIN system and discusses its debt to symbolic reasoning techniques from the field of artificial intelligence.

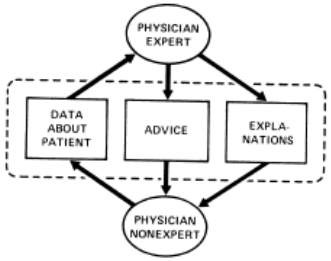

Figure 1 - Diagram summarizing the flow of information between physician and expert in the human consultation process. (Figure reproduced from reference 10).

Artificial Intelligence

Artificial intelligence (AI) is a subfield of computer science in which the emphasis of the research is on symbolic reasoning rather than numerical computations. In many respects the name "artificial intelligence" is unfortunate because it conjures up threatening images of superhuman machines that challenge those capabilities of mankind that have long been thought to be uniquely human. A recent book by a respected computer expert[2] has examined the field in detail and has generated a great deal of discussion not only about what computers could do but should do[3]. Techniques developed by researchers in AI, however, have great potential for application to problems in medical decision making. Since 1970 a small number of researchers, most of whom have had experience rooted in traditional computational approaches to medical decision making, have begun to recognize the need for computer "understanding" of the clinical domain of interest if useful diagnostic tools are to be developed[4]. They point out that capabilities such as heuristic search through large numbers of possible decisions or actions, computational approaches to natural language understanding and generation, and issues of representation for inferential knowledge (all major AI research areas) are central to the problem of giving a computer program a knowledge of medicine at a conceptual level. Such capabilities might allow the program a spectre of creativity and "humaness" that would in turn make it an acceptable tool for physicians. Several recent research projects have therefore begun to examine the use of symbolic reasoning techniques in medical domains [5-8]. An overview of AI and its relationship to medical problem solving is available elsewhere [9].

* This paper was originally prepared for presentation at the Annual Meeting of the Society for Computer Medicine, Las Vegas, Nevada, 10 November 1977.

Artificial Intelligence 59 (1993) 233-240
Elsevier

ARTINT 983

DENDRAL and Meta-DENDRAL: roots of knowledge systems and expert system applications

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During AI's first decade (1956–1966), the task environments in which AI scientists investigated their basic science issues were generally idealized "clean" task environments, such as propositional calculus theorem proving and puzzle solving. After the mid-1960s, a bolder and more applied inclination to choose complex real-world problems as task environments became evident. These efforts were both successful and exciting, in two ways. First, the AI programs were achieving high levels of competence at solving certain problems that human specialists found challenging (the excitement was that our AI techniques were indeed powerful and that we were taking the first steps toward the dream of the very smart machine). Second, these complex real-world task environments were proving to be excellent at stimulating basic science questions for the AI science, in knowledge representation, problem solving, and machine learning. To recognize and illuminate this trend, the *Artificial Intelligence Journal* in 1978 sponsored a special issue on applications of artificial intelligence.

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Source: https://www.wired.com/2012/09/deep-blue-computer-bug/

Source: http://www.cnn.com/2011/TECH/innovation/02/16/jeopardy.watson/index.html

Mastering Chess and Shogi by Self-Play with a General Reinforcement Learning Algorithm

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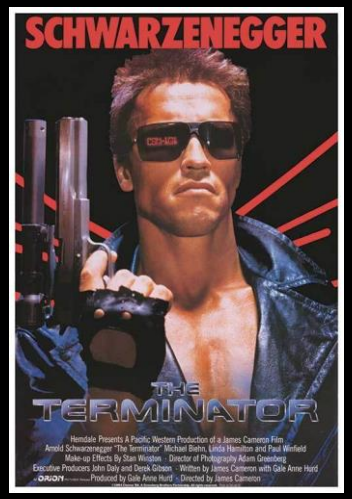
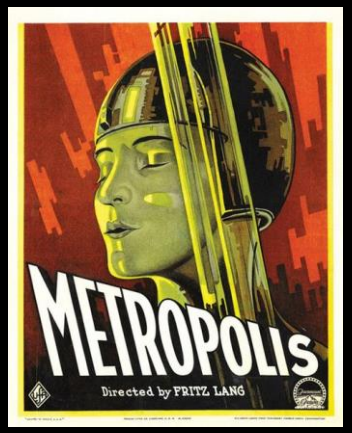
Abstract

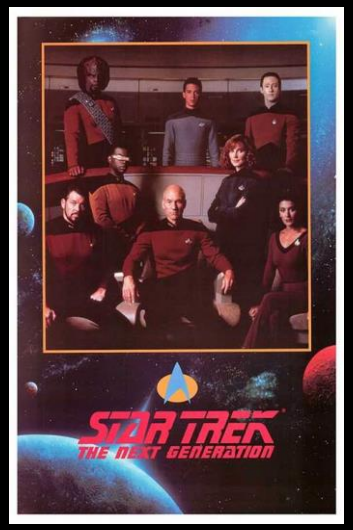
The game of chess is the most widely-studied domain in the history of artificial intelligence. The strongest programs are based on a combination of sophisticated search techniques, domain-specific adaptations, and handcrafted evaluation functions that have been refined by human experts over several decades. In contrast, the *AlphaGo Zero* program recently achieved superhuman performance in the game of Go, by *tabula rasa* reinforcement learning from games of self-play. In this paper, we generalise this approach into a single *AlphaZero* algorithm that can achieve, *tabula rasa*, superhuman performance in many challenging domains. Starting from random play, and given no domain knowledge except the game rules, *AlphaZero* achieved within 24 hours a superhuman level of play in the games of chess and shogi (Japanese chess) as well as Go, and convincingly defeated a world-champion program in each case.

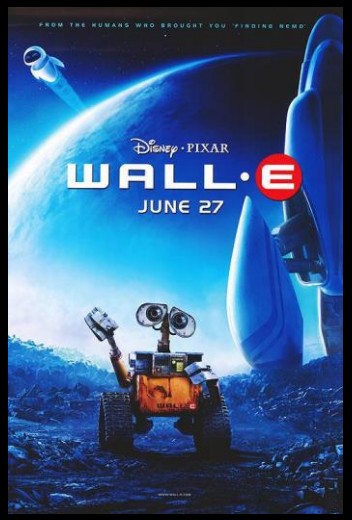
The study of computer chess is as old as computer science itself. Babbage, Turing, Shannon, and von Neumann devised hardware, algorithms and theory to analyse and play the game of chess. Chess subsequently became the grand challenge task for a generation of artificial intelligence researchers, culminating in high-performance computer chess programs that perform at superhuman level (*9, 13*). However, these systems are highly tuned to their domain, and cannot be generalised to other problems without significant human effort.

A long-standing ambition of artificial intelligence has been to create programs that can instead learn for themselves from first principles (*26*). Recently, the *AlphaGo Zero* algorithm achieved superhuman performance in the game of Go, by representing Go knowledge using deep convolutional neural networks (*22, 28*), trained solely by reinforcement learning from games of self-play (*29*). In this paper, we apply a similar but fully generic algorithm, which we









Artificial General Intelligence

Innovations in AI and Medicine / Healthcare

What to expect from AI in oncology

An increasing number of studies suggest that artificial intelligence could revolutionize medicine. In oncology, we are only beginning to fully understand the practical implications.

In the past few years, the terms 'artificial intelligence' (AI) and 'machine learning' (ML) have become common in the news; several important medical advances have been made using these approaches. Some might conclude that we are witnessing a new era in medicine, although others could be confused. What are AI and ML, and how can they affect the practice of medicine? In oncology, the obvious question is how will AI improve the outcomes of patients with cancer? Summaries of studies addressing these questions have already been covered in *Nature Reviews Clinical Oncology*, and will continue to receive the attention they deserve.

In the current issue, Anant Madabhushi and co-authors[1] provide an overview of studies in which AI-based approaches have been applied by pathologists analysing potentially neoplastic tissues. In this Perspective, we learn that researchers have trained computers to distinguish patterns in digitized medical images. Encouraging results have been obtained when the analytical performance of these ML-based approaches is compared with that of expert pathologists. These results alone, however, should not be interpreted as a justification for outsourcing the work of pathologists but rather, as an indication that their workload could be optimized and, importantly, the waiting time for patients to receive a diagnosis can be reduced. Madabhushi et al. also define terms commonly used in AI studies and, thus, we hope that this article will be particularly useful for readers who are less familiar with this field.

Pathology is not the only area in which ML has the potential to improve the outcomes of patients with cancer. Any piece of information that can be translated into patterns, predictable outcomes or pair associations, to mention only a few examples, can be virtually taught to machines. Indeed, AI-based approaches are being used in areas such as radiology and clinical trial design. Another promising use of AI would be the integration of multi-omics data from each individual in order to facilitate the administration of tailored treatments.

In their article, Madabhushi et al. acknowledge the current challenges to implementing approaches using AI in routine clinical settings. Defining standards is one of these challenges: situations exist in which the same clinical question has been addressed in independent institutions with the development of separate ML tools, each one validated in a particular set of samples. Clinicians worldwide need to have the assurance that they can rely on any of those ML approaches when they encounter a similar clinical scenario in their own practice. Collaboration among regulatory bodies, technology developers and clinical staff will be key to define high-quality standards for the use of AI in all relevant areas of clinical oncology.

Another challenge that has already received attention is that of access to care. Eventually, individuals receiving health care at institutions with AI expertise could have better outcomes than those seen in conventional facilities (for example, owing to more timely diagnosis and real-time disease monitoring). Some experts believe that, similarly to other new technologies, the costs associated with using AI will only be high during an initial period and will decrease over time. This expectation is not unreasonable, nonetheless, many medical centres will not be able to afford the initial investment of resources to introduce these tools in their practice. Let's not forget that, in order to implement AI-based tools, institutions will need careful financial planning, but also a critical mass of medical professionals trained in this new approach to medicine. Thus, widespread access to AI-based health care might not happen in the near future.

Finally, some experts are optimistic and believe that, with access to AI, clinicians will have extra time to interact with their patients. Such a shift will only take place if the total duration of patient visits remains the same and AI is not used instead to cover for staff shortages. Importantly, some patients might perceive the adoption of AI by their clinicians as a disruptive element — communication will be key to help them understand the different roles of the human and the machine in their care.

In summary, the practical implications of using AI in routine oncology practice are not yet completely understood. In addition to the challenges discussed, prospective evidence of the potential benefits of using AI in medicine remains limited, thus necessitating further research. The introduction of AI into routine clinical practice is a complex effort that will require multidisciplinary expertise and, more importantly, the input of patients and their families and the cooperation of regulatory bodies.

> "...widespread access to AI-based health care might not happen in the near future..."

1. Bera, K. et al. *Nat. Rev. Clin. Oncol.* https://doi.org/10.1038/s41571-019-0252-y (2019).

U.S. FOOD & DRUG ADMINISTRATION

September 11, 2018

Apple Inc.
% Donna-Bea Tillman
Senior Consultant, Biologics Consulting Group
Biologics Consulting Group, Inc.
1555 King St, Suite 300
Alexandria, Virginia 22314

Re: DEN180044
Trade/Device Name: ECG App
Regulation Number: 21 CFR 870.2345
Regulation Name: Electrocardiograph software for over-the-counter use
Regulatory Class: Class II
Product Code: QDA
Dated: August 13, 2018
Received: August 14, 2018

Dear Donna-Bea Tillman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ECG App, an over-the-counter device under 21 CFR Part 801 Subpart C, with the following indications for use:

> The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer, and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.
>
> The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.
>
> The ECG app is not intended for use by people under 22 years old.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ECG App, and substantially equivalent devices of this generic type, into Class II under the generic name electrocardiograph software for over-the-counter use.

FDA identifies this generic type of device as:

U.S. Food & Drug Administration
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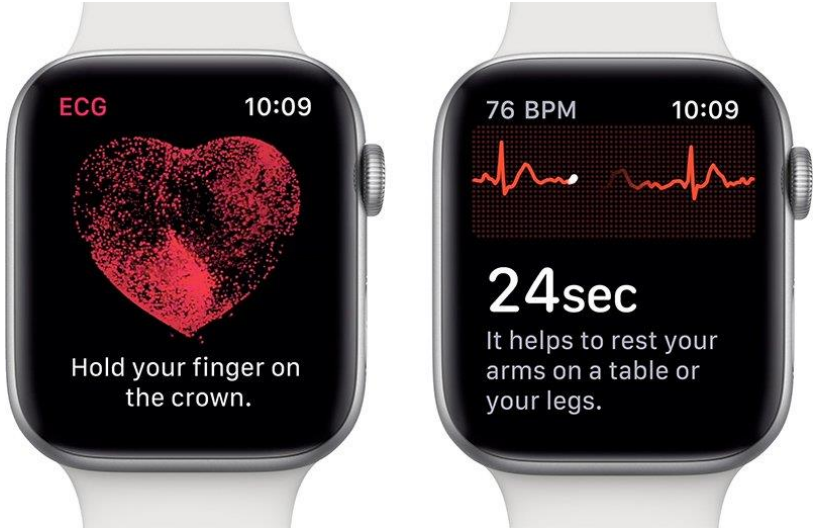

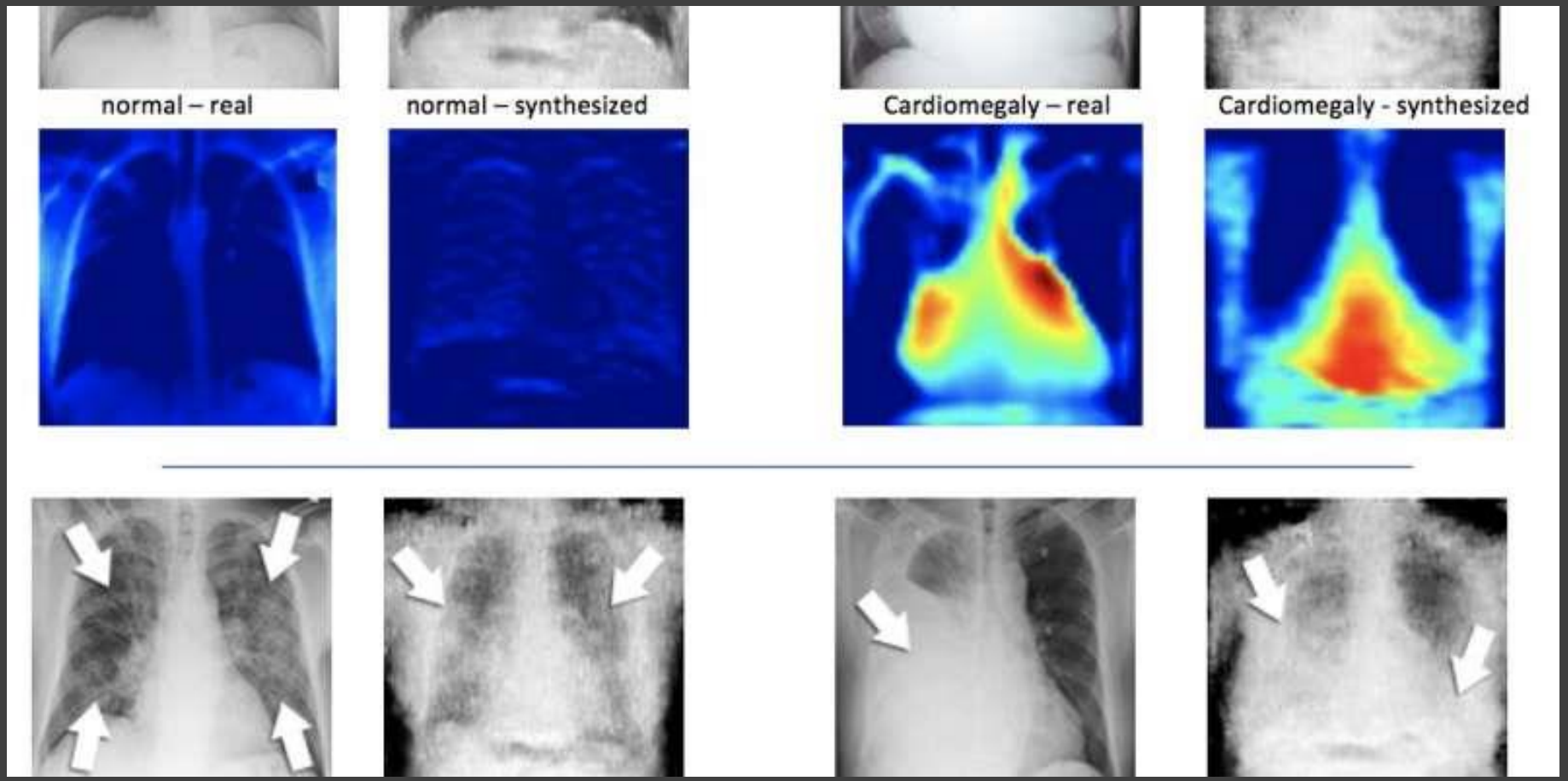

Challenge of Data

- Source: https://phys.org/news/2018-07-artificial-intelligence-x-rays.html

Real Test of “Improving Outcomes for Real Patients”

- Source: https://www.statnews.com/2019/12/18/mayo-clinic-artificial-intelligence-acid-test/

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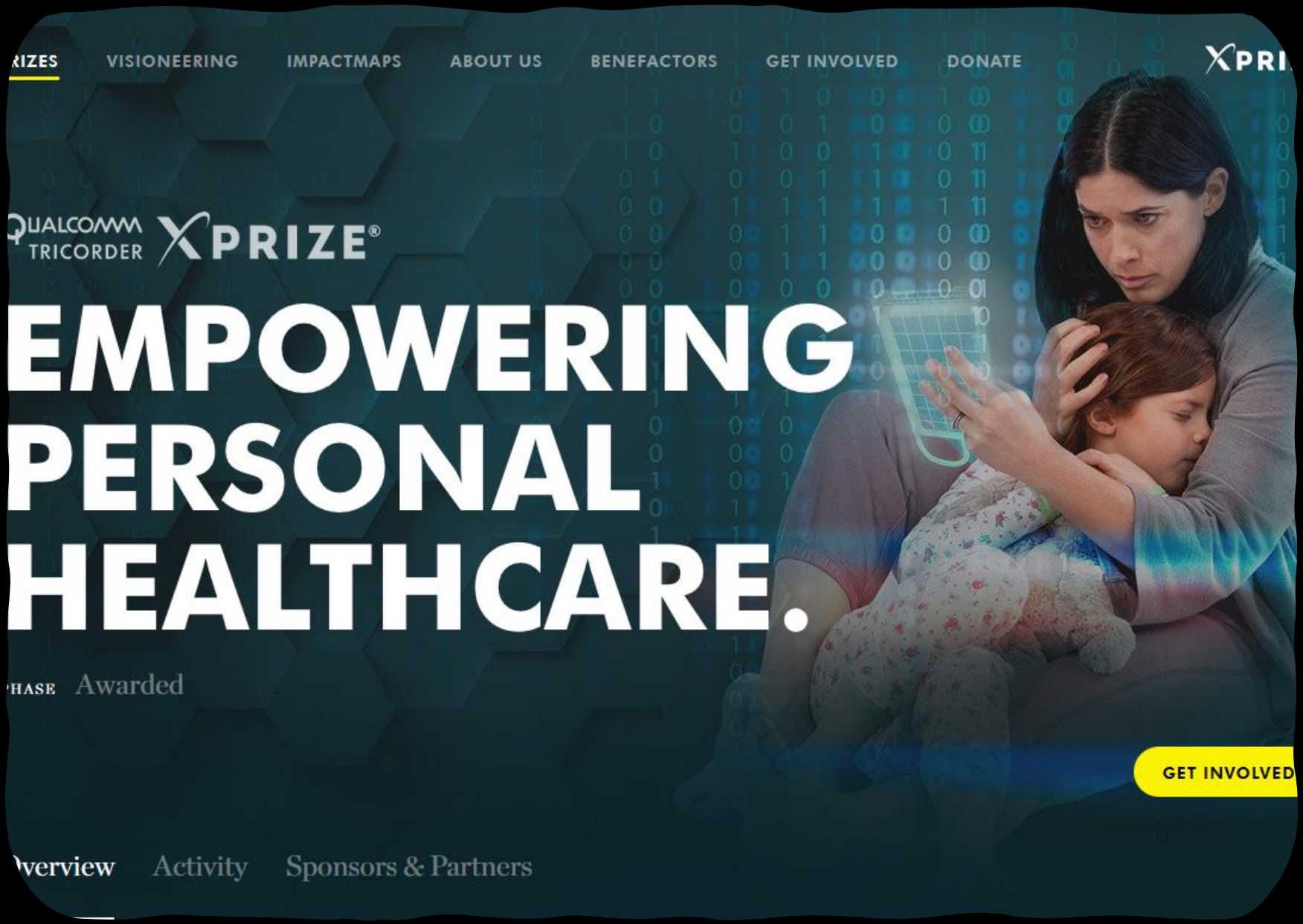
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AI and COVID-19

Artificial intelligence for COVID-19: saviour or saboteur?

As 2020 draws to a close, one thing is certain: the COVID-19 pandemic has had an irreversible effect on the world. The effect on digital health is no exception. The pandemic has forced health-care providers and governments around the world to accelerate the development of artificial intelligence (AI) tools and scale up their use in medicine, even before they are proven to work. An untested AI algorithm has even received emergency authorisation from the US Food and Drug Administration. But will the use of untested AI systems help or hinder patients with COVID-19?

The lax regulatory landscape for COVID-19 AI algorithms has raised substantial concern among medical researchers. A living systematic review published in the BMJ highlights that COVID-19 AI models are poorly reported and trained on small or low quality datasets with high risk of bias. Gary Collins, Professor of Medical Statistics at the University of Oxford and co-author of the BMJ review told *The Lancet Digital Health*, "full and transparent reporting of all key details of the development and evaluation of prediction models for COVID-19 is vital. Failure to report important details not only contributes to research waste, but more importantly can lead to a poorly developed and evaluated model being used that could cause more harm than benefit in clinical decision making."

To support transparent and reproducible reporting, source code and deidentified patient datasets for COVID-19 AI algorithms should be open and accessible to the research community. One such study, published in *The Lancet Digital Health*, reports a new AI COVID-19 screening test, named CURIAL AI, which uses routinely collected clinical data for patients presenting to hospital. In the hope that AI can help keep patients and health-care workers safe, Andrew Soltan and colleagues state that the AI test could allow exclusion of patients who do not have COVID-19 and ensure that patients with COVID-19 receive treatments rapidly. This is one of the largest AI studies to date with clinical data from more than a hundred thousand cases in the UK. Prospective validation of the AI screening test showed accurate and faster results compared with gold standard PCR tests.

However, like other COVID-19 AI models, CURIAL AI requires validation across geographically and ethnically diverse populations to assess its real-world performance. Soltan emphasised that "We also do not yet know if the AI model would generalise to patient cohorts in different countries, where patients may come to hospital with a different spectrum of medical problems."

Even if preliminary models, like CURIAL AI, are proven to accurately diagnose disease in a wide range of populations, do they add clinical value to health-care systems? Last month, X, the Alphabet subsidiary announced that although they were able to develop an AI to identify features of electroencephalography data that might be useful for diagnosing depression and anxiety they found that experts were not convinced of the clinical value of the diagnostic aid. How AI tools for diagnosing health conditions can improve medical care is not always well understood by those developing the AI. Therefore, COVID-19 AI models must be developed in close collaboration with health-care workers, to understand how output of these models could be applied in patient care.

As we enter flu season, AI tools, like CURIAL AI, face an increasingly challenging task to help clinicians differentiate between two respiratory infections with similar symptoms. If AI tools cannot be proven to discern one pneumonia from another, premature use of these technologies could increase misdiagnosis and sabotage clinical care for patients. Mistakes like this, if allowed to scale, will slow future use of potentially life-saving technologies and compromise clinician and patient trust in AI. To assess true accuracy of AI tools for COVID-19, clinical trials are essential to establish how AI can support COVID-19 patients in the real world.

Soltan and colleagues are now planning clinical trials for deploying CURIAL AI within the existing clinical pathways at hospitals in the UK. *The Lancet Digital Health* strongly encourages researchers doing AI intervention-based clinical trials to follow the new extension guidelines SPIRIT-AI and CONSORT-AI. In our previous Editorial, we described the importance of these guidelines to support accurate and transparent evaluation of AI.

AI could be the saviour of the COVID-19 pandemic in the coming year; we just need to prove it.

■ *The Lancet Digital Health*

Artificial intelligence for COVID-19: saviour or saboteur? - Lancet

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Of 300-plus imaging-based AI models for COVID-19 diagnosis, zero suitable for clinical use

Marty Stempniak | *March 15, 2021* | *Artificial Intelligence*

Out of more than 300 published machine learning models for detecting COVID-19 from chest images, zero passed a recent research review, experts detailed Monday in *Nature*.

As the pandemic took hold last year, numerous publications touted the use of AI to help pinpoint the novel coronavirus on X-ray and CT scans. U.K. researchers, however, are casting doubts on these claims amid concerns of "Frankenstein data sets," biases and methodological flaws.

AI and COVID-19 Taxonomy

- Early detection and diagnosis
- Monitoring the treatment
- Contact tracing for individuals
- Projection of cases and mortality
- Development of drugs and vaccines
- Reducing the workload of healthcare workers
- Prevention of disease.

Diabetes & Metabolic Syndrome: Clinical Research & Reviews 14 (2020) 337–339

Contents lists available at ScienceDirect

Diabetes & Metabolic Syndrome: Clinical Research & Reviews

journal homepage: www.elsevier.com/locate/dsx

Artificial Intelligence (AI) applications for COVID-19 pandemic

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ARTICLE INFO

Article history:
Received 6 April 2020
Received in revised form
10 April 2020
Accepted 10 April 2020

Keywords:
Artificial Intelligence (AI)
AI Applications
COVID-19
Coronavirus
Pandemic

ABSTRACT

Background and aims: Healthcare delivery requires the support of new technologies like Artificial Intelligence (AI), Internet of Things (IoT), Big Data and Machine Learning to fight and look ahead against the new diseases. We aim to review the role of AI as a decisive technology to analyze, prepare us for prevention and fight with COVID-19 (Coronavirus) and other pandemics.
Methods: The rapid review of the literature is done on the database of Pubmed, Scopus and Google Scholar using the keyword of COVID-19 or Coronavirus and Artificial Intelligence or AI. Collected the latest information regarding AI for COVID-19, then analyzed the same to identify its possible application for this disease.
Results: We have identified seven significant applications of AI for COVID-19 pandemic. This technology plays an important role to detect the cluster of cases and to predict where this virus will affect in future by collecting and analyzing all previous data.
Conclusions: Healthcare organizations are in an urgent need for decision-making technologies to handle this virus and help them in getting proper suggestions in real-time to avoid its spread. AI works in a proficient way to mimic like human intelligence. It may also play a vital role in understanding and suggesting the development of a vaccine for COVID-19. This result-driven technology is used for proper screening, analyzing, prediction and tracking of current patients and likely future patients. The significant applications are applied to tracks data of confirmed, recovered and death cases.

1. Background

In this worldwide health crisis, the medical industry is looking for new technologies to monitor and controls the spread of COVID-19 (Coronavirus) pandemic. AI is one of such technology which can easily track the spread of this virus, identifies the high-risk patients, and is useful in controlling this infection in real-time. It can also predict mortality risk by adequately analyzing the previous data of the patients. AI can help us to fight this virus by population screening, medical help, notification, and suggestions about the infection control [1–3]. This technology has the potential to improve the planning, treatment and reported outcomes of the COVID-19 patient, being an evidence-based medical tool. Fig. 1 shows the general procedure of AI and non-AI based applications that help general physicians to identify the COVID-19 symptoms.

The above flow diagram informs and compares the flow of minimal non-AI treatment versus AI-based treatment. The above flow diagram explains the involvement of AI in the significant steps of treatment of high accuracy and reduces complexity and time taken. The physician is not only focused on the treatment of the patient, but also the control of disease with the AI application. Major symptoms and test analysis are done with the help of AI with the highest of accuracy. It also shows it reduces the total number of steps taken in the whole process, making more procurable in nature.

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https://scholar.google.co.in/citations?user=2iu3gQIAAAAJ&hl=en (R. Vaishya), https://scholar.google.co.in/citations?user=efjwvvAAAAJ&hl=en (M. Javaid), https://scholar.google.co.in/citations?user=4047-68AAAAJ&hl=en (A. Haleem)

https://doi.org/10.1016/j.dsx.2020.04.012
1871-4021/

2. Main applications of AI in COVID-19 pandemic

1) Early detection and diagnosis of the infection

AI can quickly analyze irregular symptom and other 'red flags'

Prediction Models

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Prediction models for diagnosis and prognosis of covid-19: systematic review and critical appraisal

Laure Wynants,[1,2] Ben Van Calster,[2,3] Gary S Collins,[4,5] Richard D Riley,[6] Georg Heinze,[7] Ewoud Schuit,[8,9] Marc M J Bonten,[8,10] Darren L Dahly,[11,12] Johanna A Damen,[8,9] Thomas P A Debray,[8,9] Valentijn M T de Jong,[8,9] Maarten De Vos,[2,13] Paula Dhiman,[4,5] Maria C Haller,[7,14] Michael O Harhay,[15,16] Liesbet Henckaerts,[17,18] Pauline Heus,[8,9] Michael Kammer,[7,19] Nina Kreuzberger,[20] Anna Lohmann,[21] Kim Luijken,[21] Jie Ma,[5] Glen P Martin,[22] David J McLernon,[23] Constanza L Andaur Navarro,[8,9] Johannes B Reitsma,[8,9] Jamie C Sergeant,[24,25] Chunhu Shi,[26] Nicole Skoetz,[10] Luc J M Smits,[1] Kym I E Snell,[6] Matthew Sperrin,[27] René Spijker,[8,9,28] Ewout W Steyerberg,[3] Toshihiko Takada,[8] Ioanna Tzoulaki,[29,30] Sander M J van Kuijk,[31] Bas C T van Bussel,[1,32] Iwan C C van der Horst,[32] Florien S van Royen,[8] Jan Y Verbakel,[33,34] Christine Wallisch,[7,35,36] Jack Wilkinson,[22] Robert Wolff,[37] Lotty Hooft,[8,9] Karel G M Moons,[8,9] Maarten van Smeden[8]

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Additional material is published online only. To view please visit the journal online.

Cite this as: BMJ 2020;369:m1328 http://dx.doi.org/10.1136/bmj.m1328

Originally accepted: 31 March 2020

Final version accepted: 12 January 2021

ABSTRACT

OBJECTIVE

To review and appraise the validity and usefulness of published and preprint reports of prediction models for diagnosing coronavirus disease 2019 (covid-19) in patients with suspected infection, for prognosis of patients with covid-19, and for detecting people in the general population at increased risk of covid-19 infection or being admitted to hospital with the disease.

DESIGN

Living systematic review and critical appraisal by the COVID-PRECISE (Precise Risk Estimation to optimise covid-19 Care for Infected or Suspected patients in diverse sEttings) group.

DATA SOURCES

PubMed and Embase through Ovid, up to 1 July 2020, supplemented with arXiv, medRxiv, and bioRxiv up to 5 May 2020.

STUDY SELECTION

Studies that developed or validated a multivariable covid-19 related prediction model.

DATA EXTRACTION

At least two authors independently extracted data using the CHARMS (critical appraisal and data extraction for systematic reviews of prediction modelling studies) checklist; risk of bias was assessed using PROBAST (prediction model risk of bias assessment tool).

RESULTS

37 421 titles were screened, and 169 studies describing 232 prediction models were included. The review identified seven models for identifying people at risk in the general population; 118 diagnostic models for detecting covid-19 (75 were based on medical imaging, 10 to diagnose disease severity); and 107 prognostic models for predicting mortality risk, progression to severe disease, intensive care unit admission, ventilation, intubation, or length of hospital stay. The most frequent types of predictors included in the covid-19 prediction models are vital signs, age, comorbidities, and image features. Flu-like symptoms are frequently predictive in diagnostic models, while sex, C reactive protein, and lymphocyte counts are frequent prognostic factors. Reported C index estimates from the strongest form of validation available per model ranged from 0.71 to 0.99 in prediction models for the general population, from 0.65 to more than 0.99 in diagnostic models, and from 0.54 to 0.99 in prognostic models. All models were rated at high or unclear risk of bias, mostly because of non-representative selection of control patients, exclusion of patients who had not experienced the event of interest by the end of the study, high risk of model overfitting, and unclear reporting. Many models did not include a description of the target population (n=27, 12%) or care setting (n=75, 32%), and only 11 (5%) were externally

WHAT IS ALREADY KNOWN ON THIS TOPIC

The sharp recent increase in coronavirus disease 2019 (covid-19) incidence has put a strain on healthcare systems worldwide, an urgent need exists for efficient early detection of covid-19 in the general population, for diagnosis of covid-19 in patients with suspected disease, and for prognosis of covid-19 in patients with confirmed disease

Viral nucleic acid testing and chest computed tomography imaging are standard methods for diagnosing covid-19, but are time consuming

Earlier reports suggest that elderly patients, patients with comorbidities (chronic obstructive pulmonary disease, cardiovascular disease, hypertension), and patients presenting with dyspnoea are vulnerable to more severe morbidity and mortality after infection

WHAT THIS STUDY ADDS

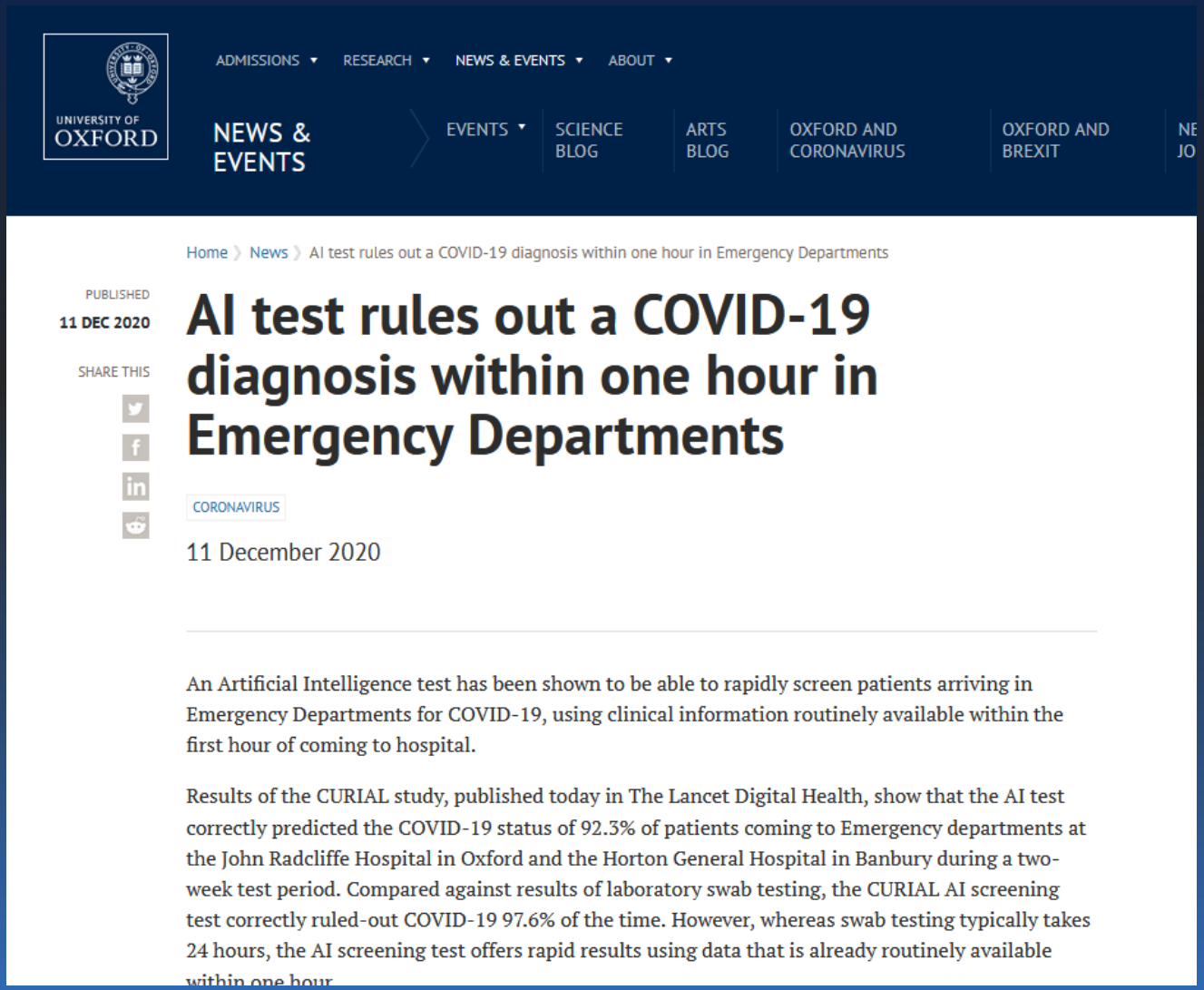
Seven models identified patients at risk in the general population (using proxy outcomes for covid-19)

Thirty three diagnostic models were identified for detecting covid-19, in addition to 75 diagnostic models based on medical images, 10 diagnostic models for severity classification, and 107 prognostic models for predicting, among others, mortality risk, progression to severe disease

Proposed models are poorly reported and at high risk of bias, raising concern that their predictions could be unreliable when applied in daily practice

Two prediction models (one for diagnosis and one for prognosis) were identified as being of higher quality than others and efforts should be made to validate these in other datasets

Early Diagnosis Models



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PUBLISHED
11 DEC 2020

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AI test rules out a COVID-19 diagnosis within one hour in Emergency Departments

CORONAVIRUS

11 December 2020

An Artificial Intelligence test has been shown to be able to rapidly screen patients arriving in Emergency Departments for COVID-19, using clinical information routinely available within the first hour of coming to hospital.

Results of the CURIAL study, published today in The Lancet Digital Health, show that the AI test correctly predicted the COVID-19 status of 92.3% of patients coming to Emergency departments at the John Radcliffe Hospital in Oxford and the Horton General Hospital in Banbury during a two-week test period. Compared against results of laboratory swab testing, the CURIAL AI screening test correctly ruled-out COVID-19 97.6% of the time. However, whereas swab testing typically takes 24 hours, the AI screening test offers rapid results using data that is already routinely available within one hour

Border Testing

AI and Medicine and Regulation

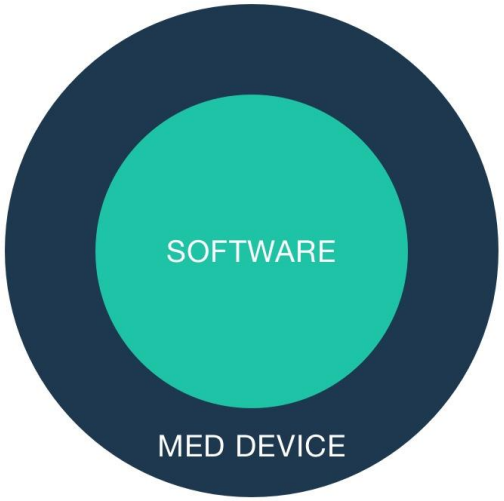
Medical Device Classification

TABLE 1 Classes of Medical Devices

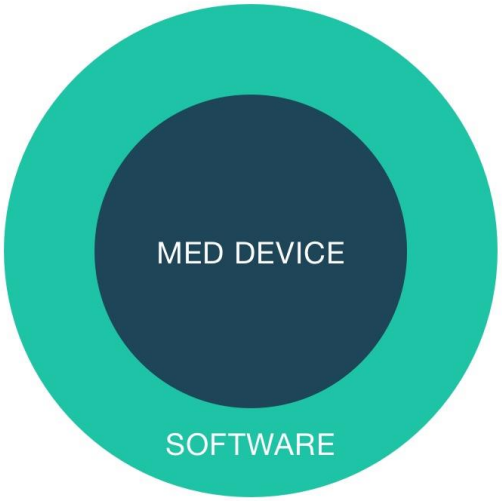
	Risk	Regulatory Pathway	
Class I (e.g., gauze, toothbrushes)	Low risk of illness or injury	75% are exempt from approval	
Class II (e.g., suture, needles)	Moderate risk of illness or injury	The majority will have to go through a PMN application	
Known Class III (e.g., pacemakers, ventilators)	Significant risk of illness or injury	Has a predicate device and may be able to undergo PMN rather than the full PMA process	Does not have a predicate and generally must go through the PMA process device
New devices classified as Class III by default		If low or moderate risk, investigator may petition to have them classified as "de novo" devices, and they may be able to undergo a PMN process rather than full PMA process	

PMA = pre-market approval; PMN = pre-market notification.

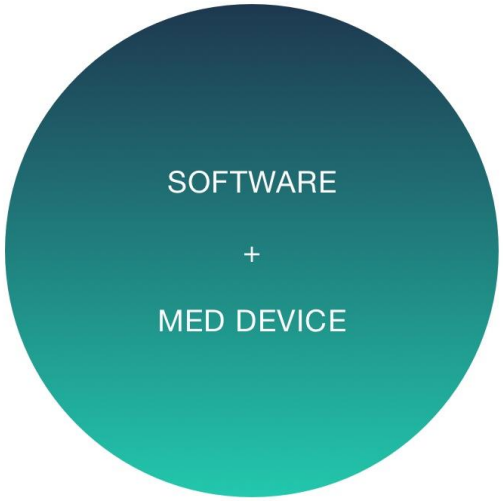
Source: Gail A. Van Norman, Drugs, Devices and the FDA: Part 2



software **in** a medical device



software **supporting** a medical device



software **as** a medical device

SierraLabs

SaMD – FDA and IMDRF Risk Classification

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Digital Health Software Precertification (Pre-Cert) Program

- From premarket evaluation to evaluating company and product
- Periodic to continuous oversight
- Primary manual review and incorporating new tools

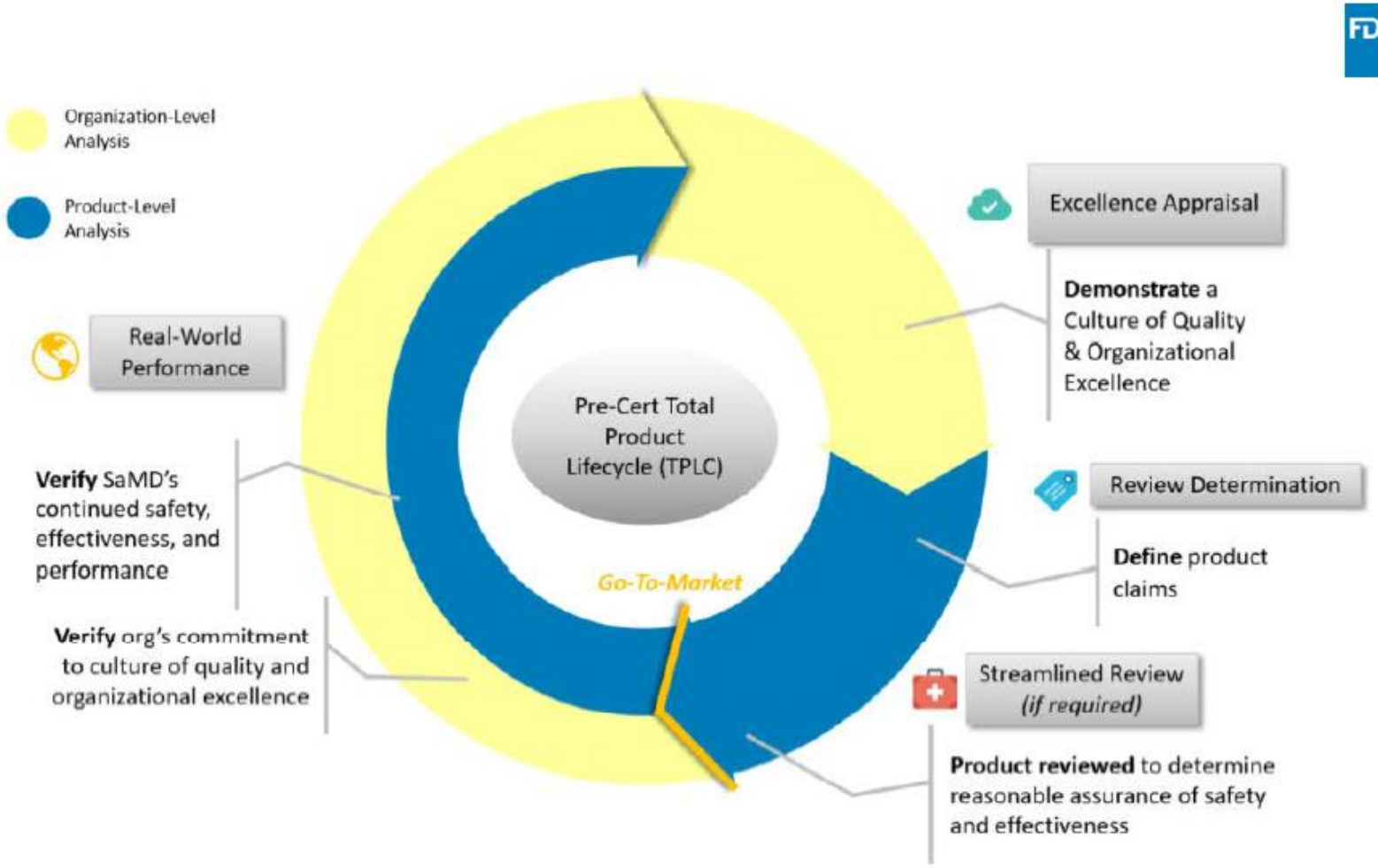
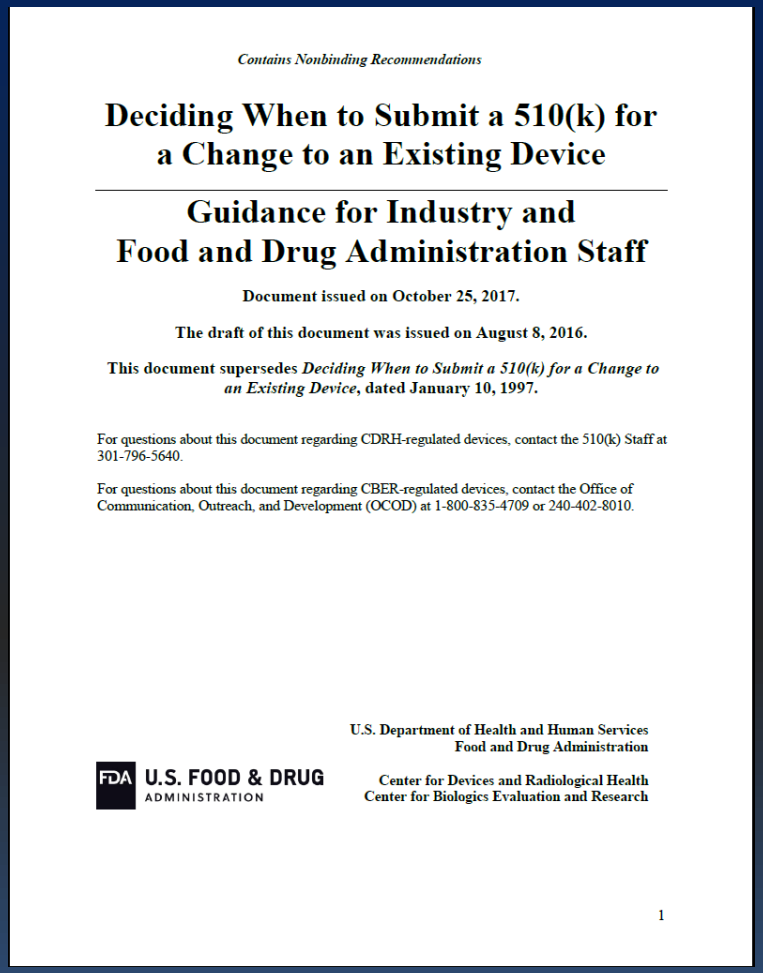


Figure 4. Total Product Lifecycle Approach of the Software Pre-Cert Program



Contains Nonbinding Recommendations

Deciding When to Submit a 510(k) for a Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.

The draft of this document was issued on August 8, 2016.

This document supersedes *Deciding When to Submit a 510(k) for a Change to an Existing Device*, dated January 10, 1997.

For questions about this document regarding CDRH-regulated devices, contact the 510(k) Staff at 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration

FDA U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

1

(3) The device is one that the person currently has in commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture or intended use. The following constitute significant changes or modifications that require a premarket notification.

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source or manufacturing process.

(ii) A major change or modification in the intended use of the device.

IDx

Which patients have diabetic retinopathy?

IDx-DR knows.

You can screen patients for DR during a routine office visit with IDx-DR, rigorously validated with FDA clearance and CE class IIa mark

www.eyediagnosis.net

IDx

IDx-DR: AI-based screening tool for diabetic retinopathy

Identify patients at high risk for vision loss

- Fast and efficient with immediate results
- Easy to use, requiring minimal training
- Validated with FDA clearance and Class IIa mark

An algorithm with the insights of an ophthalmologist

Developed by leading retina specialists, IDx-DR is an automated diabetic retinopathy screening tool that is easily incorporated into your practice.

Trained by doctors for doctors

The IDx-DR software scans retinal images for the same signs of disease that a clinician would, providing results in seconds - no human grader involved.

- Proven to be effective in real-world clinical workflow
- Results in less than a minute
- Clinically validated with high sensitivity and specificity

More information at
info@eyediagnosis.net or
www.eyediagnosis.net

MSL-038-R:B-BC

CE

Viz.ai

Why Viz? Products Resources About Schedule a Demo

THE FUTURE OF AI-POWERED

Intelligent Care Coordination

Viz.ai's mission is to increase access to life saving treatments

What is Intelligent Care Coordination?

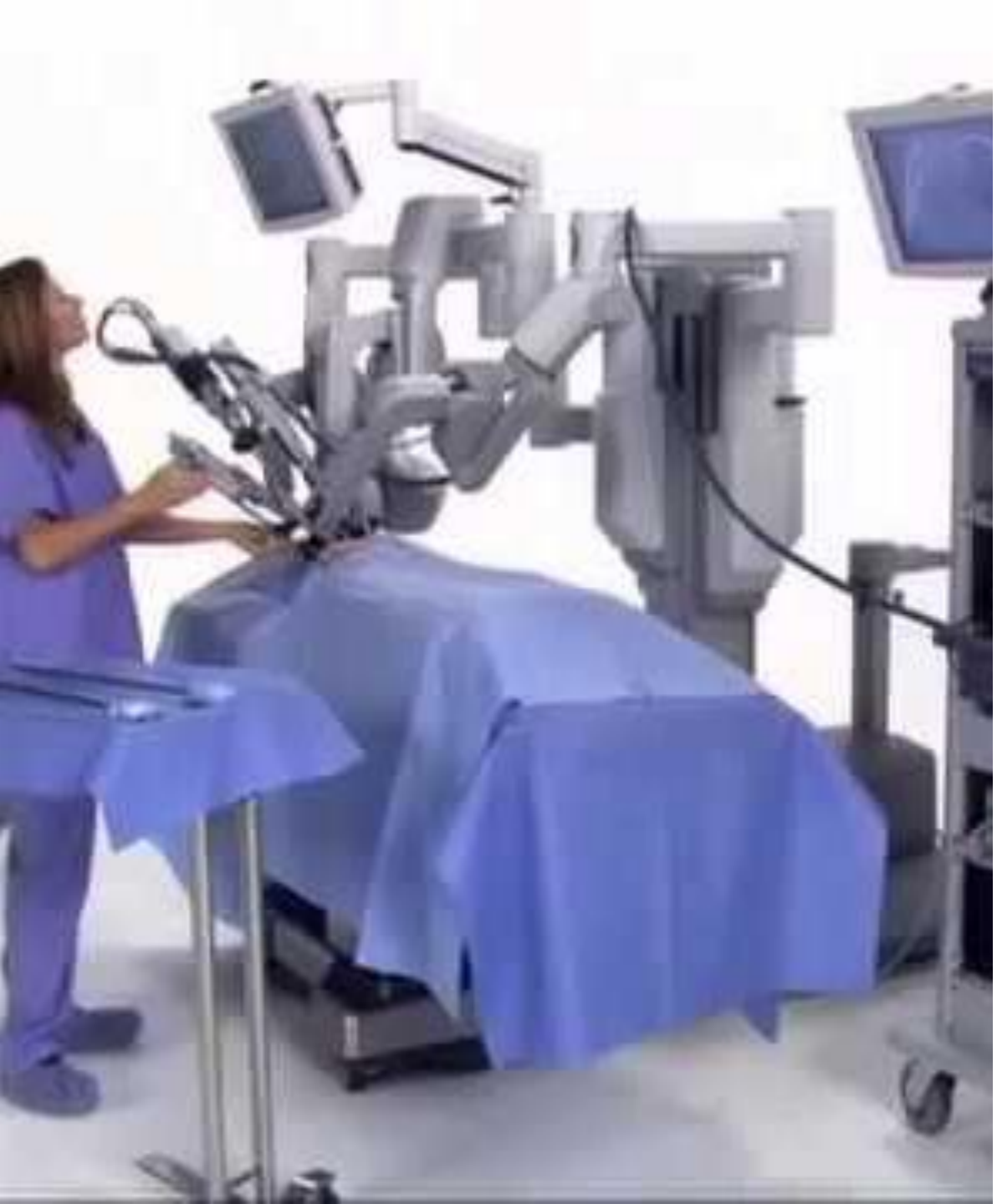
Viz.ai alerts multidisciplinary care teams earlier in the workflow, coordinating care by connecting frontline health care professionals (HCPs) to specialists facilitating efficient communication and coordinating care.

Learn more


Paro

RIBA

Buddy the Robot



da Vinci

SAE **J3016**™ LEVELS OF DRIVING AUTOMATION™

Learn more here: sae.org/standards/content/j3016_202104

	SAE LEVEL 0™	SAE LEVEL 1™	SAE LEVEL 2™	SAE LEVEL 3™	SAE LEVEL 4™	SAE LEVEL 5™
What does the human in the driver's seat have to do?	**You <u>are</u> driving** whenever these driver support features are engaged – even if your feet are off the pedals and you are not steering			**You <u>are not</u> driving** when these automated driving features are engaged – even if you are seated in "the driver's seat"		
	You must constantly supervise these support features; you must steer, brake or accelerate as needed to maintain safety			When the feature requests, you must drive	These automated driving features will not require you to take over driving	
	These are driver support features			**These are automated driving features**		
What do these features do?	These features are limited to providing warnings and momentary assistance	These features provide steering **OR** brake/ acceleration support to the driver	These features provide steering **AND** brake/ acceleration support to the driver	These features can drive the vehicle under limited conditions and will not operate unless all required conditions are met	This feature can drive the vehicle under all conditions	
Example Features	• automatic emergency braking • blind spot warning	• lane centering **OR** • adaptive cruise control	• lane centering **AND** • adaptive cruise control at the	• traffic jam chauffeur	• local driverless taxi • pedals/ steering wheel may or	• same as level 4, but feature can drive everywhere

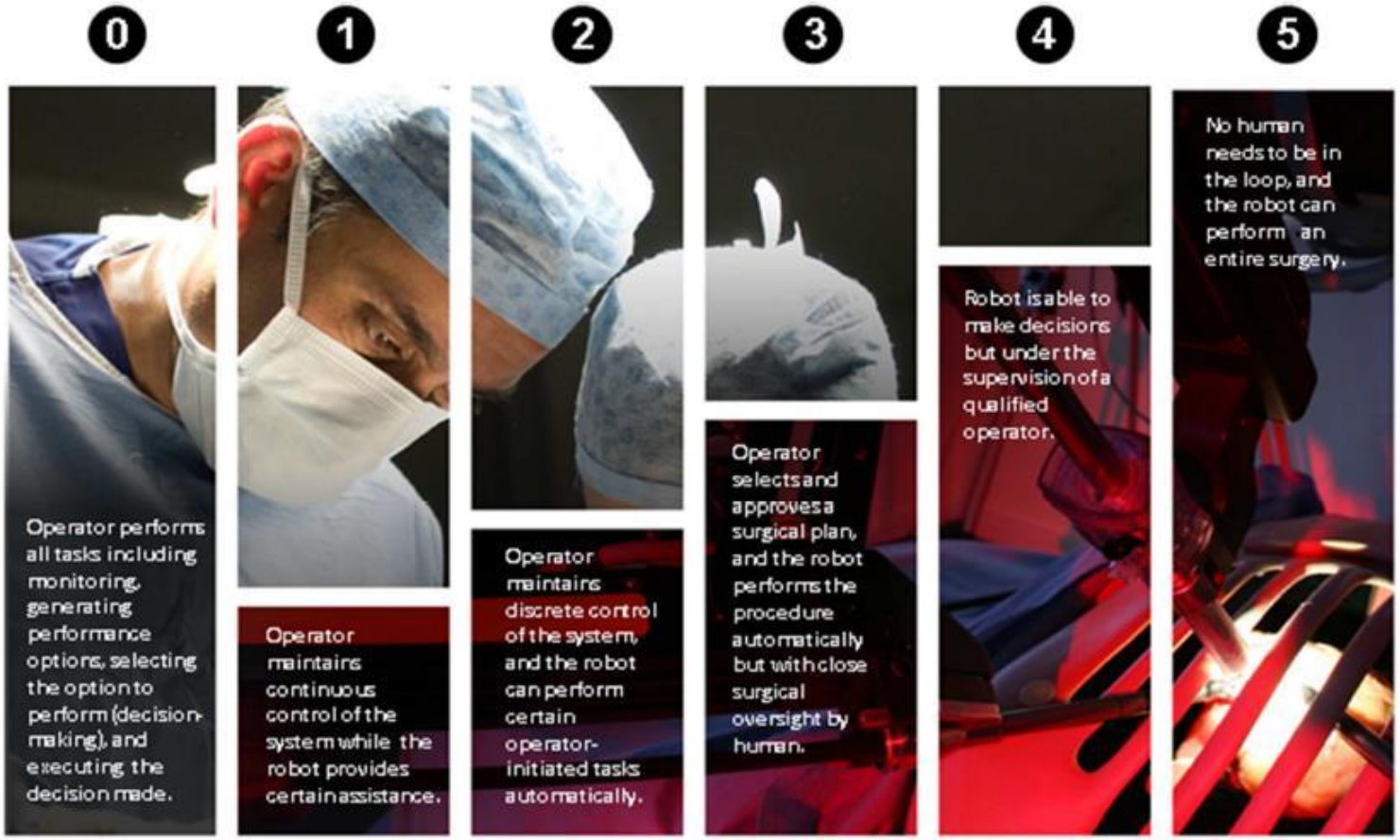


Fig. 1. Different levels of autonomy as mapped to robotic surgery. It is possible that technology may advance faster than regulatory, ethical, and legal frameworks. Risk management during implementation is critical to avoid backlash that would impede progress.

Source: Yang, et al. Science Robotics