

The evolution of clinical decision support

From obscurity to relevance

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Contents

Introduction

The progression of CDS over time 3

The multifaceted role of CDS

CDS are only as good as their utilization 5

CDS comes in all shapes and sizes 6

CDS as digital applications for precise care along a patient pathway 7

The dynamic use of CDS in clinical practice

Diagnosis and treatment for precise complex disease management 8

The overutilization of medical imaging orders 9

Leveraging AI for efficient image interpretation and workload decrease 10

CDS for outcomes-based therapies in non-small cell lung cancer

Lung cancer screening early detection 11

CDS for radiotherapy in early-stage non-small cell lung cancer

Consult, simulation, planning, radiation treatment, and follow-up 12

Summary

The future of CDS appears promising 14

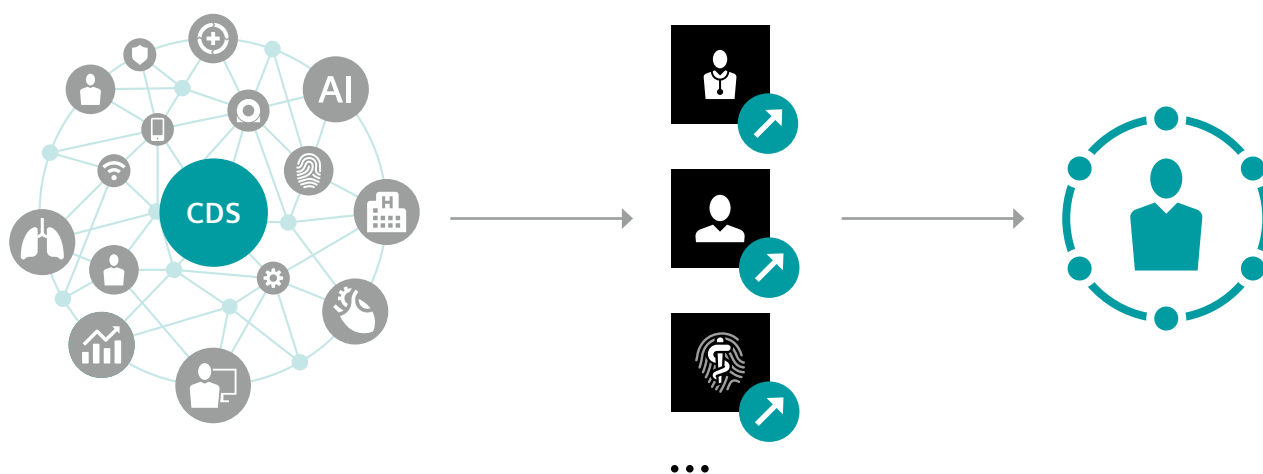
Introduction

The progression of CDS over time

Clinical Decision Support (CDS) and its applications, first introduced in the 1980s, have since undergone rapid progression in their adoption and use in clinical practice. CDS applications are designed to assist clinicians in complex decision-making and can be applied through computerized clinical workflows as well as electronic medical records (EMRs) with advanced capabilities [1]. The objective of CDS is to improve healthcare delivery through the enhancement of medical decisions based on clinical knowledge, patient data, and other related health information [2]. The rising complexities of chronic disease management, coupled with the

accelerated growth of healthcare big data, has contributed to the need for CDS adoption.

And while fragmented health systems have only served to further amplify the issue of accelerated big data, this expansion has presented both a challenge and an opportunity: the challenge is in how to leverage the impact of growing clinical data in routine care; and the opportunity is in how to amass the data in a useful and actionable format that ensures connectedness across patient care delivery.



Stakeholders across the continuum of care may face challenges ranging from:

- Unwarranted clinical practice variations [3]
- Adoption of health information technology (HIT) [4] to
- Physician burnout [5]

Each of these mentioned challenges, if left unresolved, could put a strain on the overall treatment and management of patients. Addressing these areas could create opportunities to optimize the patient journey along a care pathway where:



Patients feel empowered being front and center in the decision-making process of their care,



Physicians are confident in the adoption and use of digital applications to enhance the overall treatment of patients while maintaining standards of care, and



Healthcare leaders are better positioned to run health systems where interoperability and integration of data ensures improved quality and patient experience.

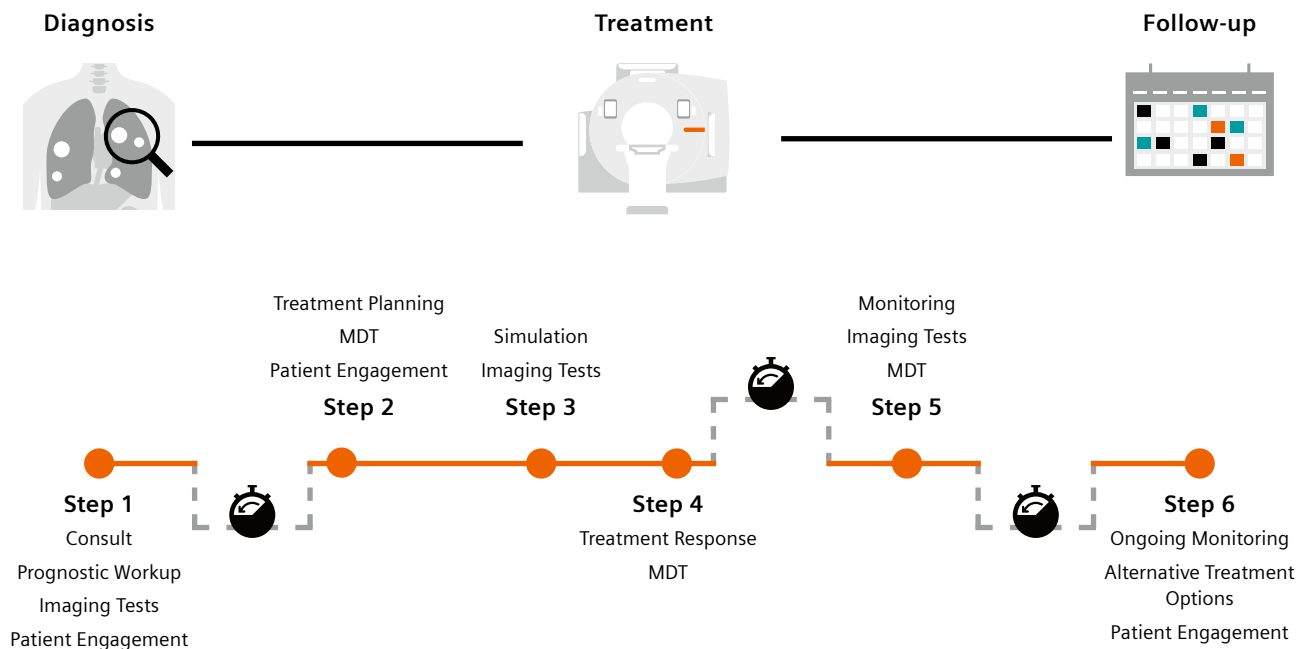
Incorporating CDS into clinical routine could support navigating through the often-complex web of decision-making for clinicians.

The multifaceted role of CDS

CDS are only as good as their utilization

The potential value gained from utilization of CDS in enhancing clinical workflows and providing support for informed decision-making at the point of care can be impacted by the frequency of their use and clinical utility. Consider for example the care pathway for patients with complex diseases, where the patient journey may be filled with many starts and stops, from initial prognostic workup to diagnosis, treatment, and follow-up.

A disconnected care pathway can contribute to misdiagnosis, over-treatment, unnecessary image ordering, and unwarranted variations. The continuously evolving standards of care and challenges with data impede the ability to scale in clinical use; therefore, the ability to effectively implement these accepted standards can help accelerate the use of CDS while at the same time improve the overall quality of care [6].

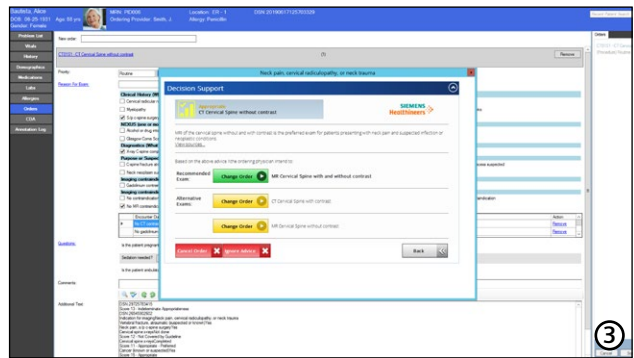
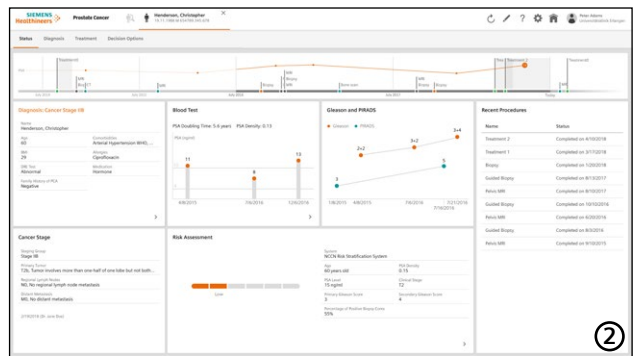
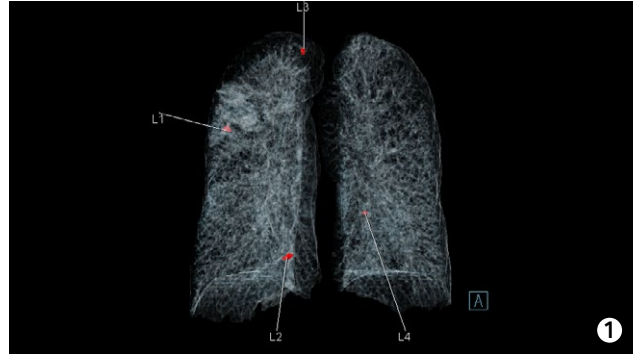


CDS comes in all shapes and sizes

CDS applications used at the point of care can range from uncomplex to more advanced in functionality, complexity, and intelligence. Some examples include:

- CDS providing diagnosis and treatment recommendations at the point of care ①
- CDS for image analysis and interpretation using Artificial Intelligence (AI) techniques ②
- CDS for image ordering decision support based on defined appropriate use criteria ③

A well-designed CDS application has the potential to standardize care by incorporating evidence-based guidelines that impact treatment decisions and use relevant data and AI – when needed – to enable personalized care delivery for favorable patient outcomes.



CDS as digital applications for precise care along a patient pathway

Clinical decision support applications are designed not to replace clinician judgment, but to support decision-makers during diagnosis, treatment, and follow-up of patients for more personalized and precise care. Personalized care driven by precision medicine (PM) – also known as *personalized medicine* – is an innovative approach in tailoring disease prevention and treatment. The objective of PM is to position clinicians to efficiently and accurately make informed decisions on the proper course of action for any given patient. The achievement of this requires digital applications that are not only compatible with clinical workflows but also able to streamline the biological complexities surrounding disease management [7].

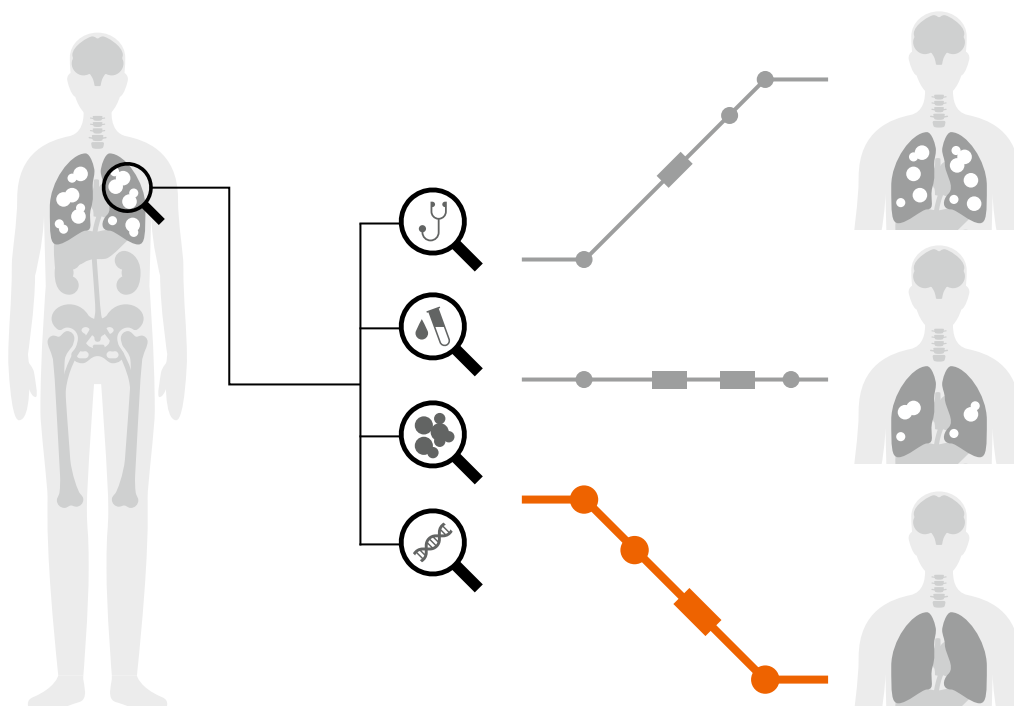
Precision medicine is about getting it right the first time – through the right diagnosis and targeting the right treatment to the right patient at the right time.

On the heels of precision medicine is also the idea of *precision imaging*, which encompasses image ordering and image analysis.

There is an increased focus on the central role of medical imaging in diagnosis and treatment driven by the demand from an aging population and growing prevalence of chronic diseases. The selection of appropriate imaging tests and the analysis of results using advanced AI techniques are influential key drivers in enabling timely and accurate diagnosis to help drive appropriate treatment and follow-up along a care pathway. The variations and use cases of CDS in clinical settings are numerous and can range from guideline-driven decision support to advanced CDS that incorporate AI techniques.

These could include:

- Evidence-based decision support for complex disease management
- Guideline-driven decision support for appropriate image ordering
- Advanced decision support for image reading and interpretation



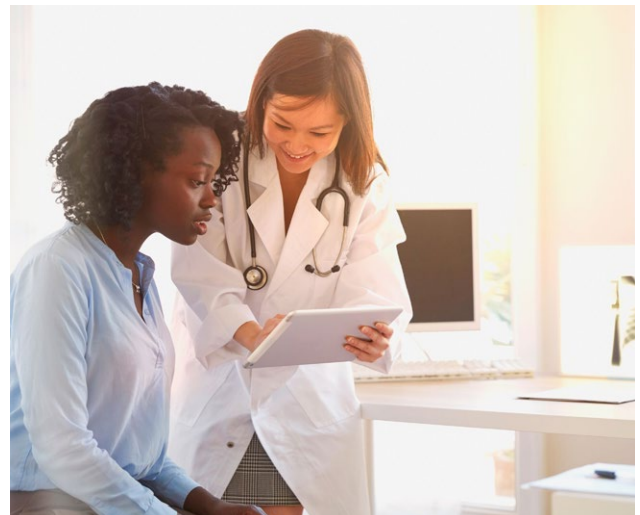
The dynamic use of CDS in clinical practice

According to the U.S Centers for Medicare & Medicaid Services (CMS), clinical decision support is not designed to replace clinical judgment, but instead to offer information supporting care team members in managing complex and expanding patient data for more informed, timely, and quality-based decision-making [8].

Diagnosis and treatment for precise complex disease management

The employing of CDS in complex disease management such as cancer care has shown promise in improving clinical, operational, and financial value. Unwarranted variations in care is an area that continues to influence outcomes associated with overtreatment and lack of adherence to guidelines [9]. CDS applications that utilize evidence-based guidelines in combination with AI techniques are designed to ensure personalized and standardized care leading to optimal outcomes. The amount

of data associated with complex disease management cases is enormous; therefore, the ability for a CDS application to leverage relevant information from multiple data source systems, for precise diagnosis and treatment decisions, is imperative. A multifaceted CDS application could have the ability to integrate relevant data – imaging, clinical, pathology, genomics – together with AI learning functionalities and risk models for predictive analysis and recommended treatment pathways [10].



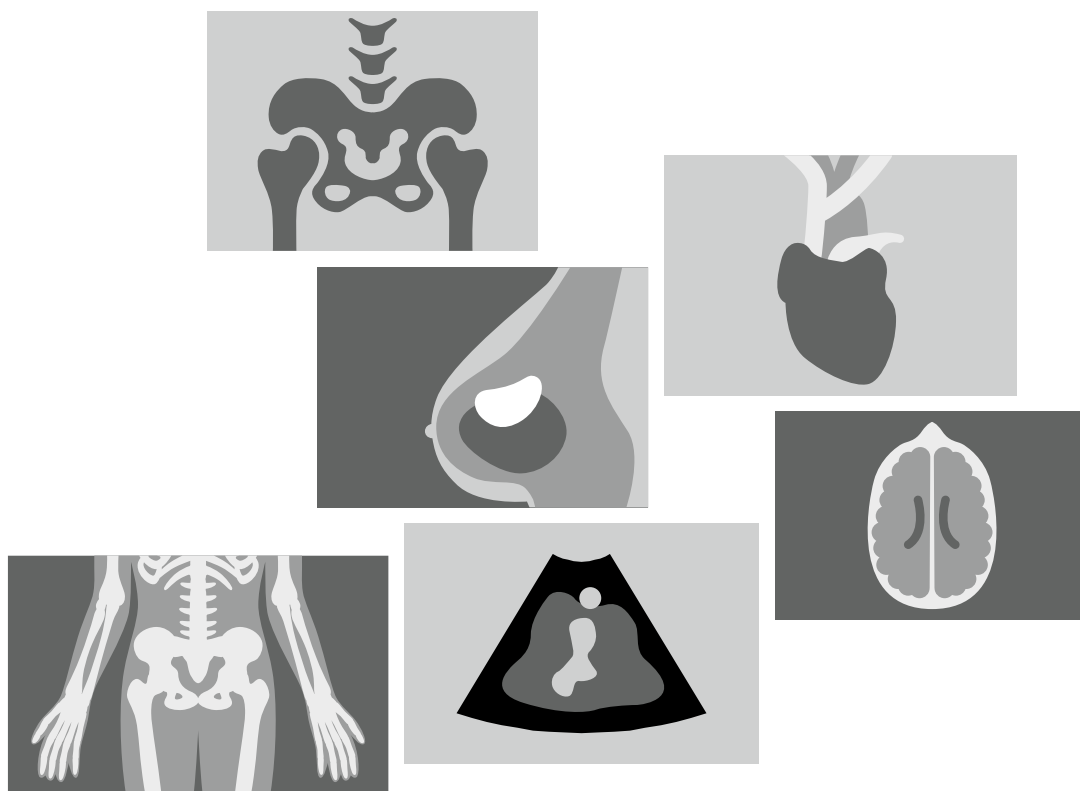
The overutilization of medical imaging orders

Delays in diagnosis or overtreatment of chronic disease patients has brought about a valid concern regarding the appropriate use of advanced imaging studies. A study of more than 135 million imaging exams conducted by researchers at Kaiser Permanente, UC Davis, and UC San Francisco looked at the rates of imaging scans including CT and MRI across several integrated healthcare systems. The results showed a continued upward trajectory throughout the duration of research [11]. Additionally, CMS has indicated that up to 26% of all imaging orders are done incorrectly when placed without evidence-based standards [12].

The inappropriate use of advanced imaging not only impacts patient care by causing delays in treatment and potentially exposing patients to unnecessary radiation, it also leads to the misuse of valuable resources and generates unnecessary cost. The rising cost of care is a major challenge across healthcare delivery systems.

A recent study conducted by the Journal of the American Medical Association revealed that the United States spends twice as much on healthcare as any other high-income country in the world, with higher utilization of imaging technology serving as a key driver [13].

To circumvent these issues, federal regulations and mandates now require the use of imaging CDS in clinical practice. In the United States, for example, the Protecting Access to Medicare Act (PAMA) mandate will require clinicians and diagnosticians to consult appropriate use criteria (AUC) using an electronic CDS application in the ordering of advanced imaging exams. Employing such an application helps to manage and determine the necessity for imaging – acting as an assistant in the selection of the most appropriate imaging based on a patient's unique clinical condition – while factoring in local standards of care and current evidence-based guideline recommendations [14].



Leveraging AI for efficient image interpretation and workload decrease

Diagnostic imaging plays a central role in disease management from prognostic workup to diagnosis, treatment, monitoring, and follow-up. At each step, imaging, along with other clinical results, is used to determine the next-best course of action. Imaging helps to map out the phenotypic profile of a patient throughout the course of the disease [15]. Being able to quickly detect critical findings for patients who are chronically ill requires a highly efficient radiology image analysis workflow for faster turnaround times. Using AI solutions in the imaging interpretation and reporting process often leads to an improvement in workflow efficiencies and, for junior radiologists, an increase in interpretation confidence [16]. Some studies have shown that cognitive factors contribute to diagnostic errors in 75% of cases [17].

Utilization of AI solutions has the potential to significantly reduce the likelihood of diagnostic errors. For example, medical imaging-based AI can be utilized to reduce the time spent determining the diameter of the thoracic aorta by automatically measuring coronary artery calcification volumes and helping to identify osteoporosis, all from a single CT scan of the chest [18–21].

Additional studies have shown that on average, a radiologist needs to interpret an image every 3–4 seconds in an 8-hour day to keep up with workload demands. In such constrained conditions where visual perception and decision-making are key, errors are unavoidable. Having a seamlessly integrated AI component embedded in the imaging workflow would reduce errors, increase efficiency, and achieve image interpretation objectives. Such a process would be conducted with the least amount of efforts by providing automated prescreened images with segmentation and detection for the radiologist to review.

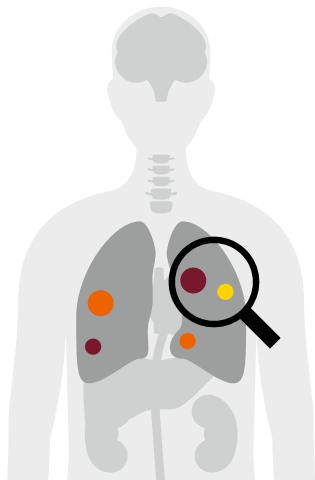


CDS for outcomes-based therapies in non-small cell lung cancer

Lung cancer screening early detection

Lung cancer is the leading cause of cancer-related deaths in the world, with small cell lung cancer (SCLC) making up approximately 15% of cases and non-small cell lung cancer (NSCLC) accounting for roughly 85% of remaining cases. NSCLC identified at an early stage has a favorable prognosis, with 5-year survival rates of 70–90% for stage I with small localized tumors [22].

The combined 5-year survival for lung cancer in general remains at a low 18% because most patients are already at an advanced disease state at the time of diagnosis. However, for patients with early-stage disease, the 5-year survival is as high as 80%, emphasizing the importance of early detection screening [23]. Connected CDS applications could streamline the screening process supporting a more tailored prognostic workup where a patient's historical context is considered in the decision-making process. For example, consider a case where a patient has ongoing comorbidities such as chronic obstructive pulmonary disease (COPD) or diabetes; this would be relevant information to have at the point of care and would shape a screening and treatment process tailored exactly to that patient.



CDS for radiotherapy in early-stage non-small cell lung cancer

Consult, simulation, planning, radiation treatment, and follow-up

CDS can support in the initial consult between the radiation oncologist and a patient who plans to undergo radiotherapy and wants to discuss the expectations and outcomes with their clinician. Having an application with longitudinal patient history, imaging, and pathology results and recommended next steps supports a holistic consultation process and enables more precise diagnostic

and treatment planning. To plan for a simulation, the radiation oncologist consults a decision support application which considers the patient's indications and decides on the appropriate imaging exams, thus minimizing unnecessary exposure to radiation and the need for repeat testing.

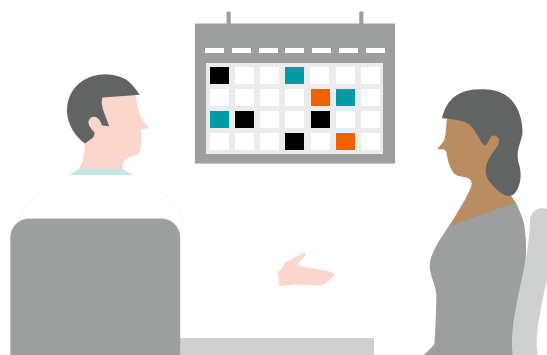
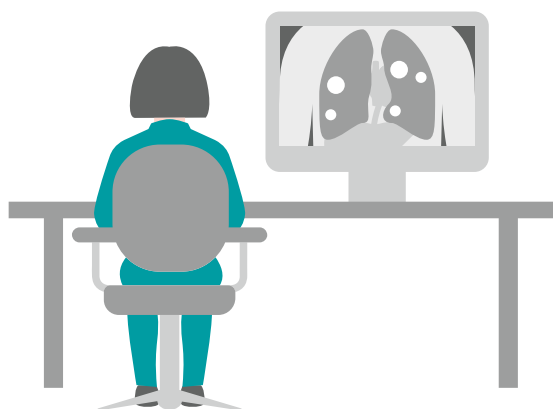
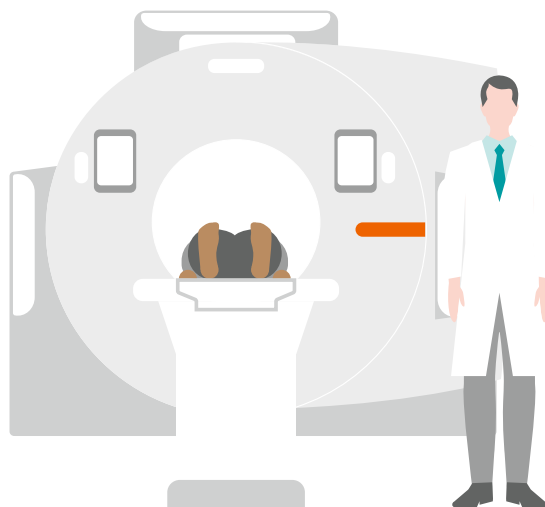


Radiation treatment planning can be automated by segmenting targeted tumors for radiation dose optimization. Organs that surround targeted tumors are at risk of potential damage during the radiation therapy. AI can help with radiation therapy planning, especially in the contouring of organs at risk (OARs), which, when performed manually, is a time-consuming process flagged with inter-clinician variability [24]. Automating the contouring process using AI solutions can potentially speed up the process and improve the consistency of the contouring.

Additionally, assessing response to treatment by monitoring over time is essential for evaluating the success of radiation therapy. AI could augment these assessments, thereby improving accuracy and speed. Developing a customized treatment plan and monitoring of treatment

results can be achieved through a CDS supporting multi-disciplinary team planning, where all clinical experts can come together and decide on a tailored treatment approach with patient preferences incorporated to drive optimal outcomes.

Clinical decision support has the power to connect patients to past decisions and history, which can be retrieved within or across different institutions. The impact of decision support applications is to efficiently enable further investigation into prior related decisions by aiding a clinician's expert opinion, thereby decreasing the effort required to reach a decision. When more time is dedicated to reviewing the actual recommended clinical decision provided by a CDS application, this could lead to a likely improvement in cost, efficiency, and overall outcomes of care [25].



Summary

The future of CDS appears promising

In today's healthcare landscape, CDS applications are being positioned as game changers for decision-making at the point of care. Healthcare is evolving, and so is the process of how care is delivered, with an increased reliance on adequate digital applications necessary to streamline the workflow for frontline care teams. There is an increasing demand for both delivery of high-value care and digitalizing the connectedness of care across various platforms to improve and optimize the patient journey.

Technology can serve as a conduit in enabling ongoing clinical decision support, facilitating access to care, and keeping record of outcomes for assessing treatment benefits [26].

For example, the novel COVID-19 pandemic shed light on the gaps in care delivery across hospital systems, presenting a need for more agile and remote capabilities. Additionally, the expected continued demand for telehealth access post-pandemic could present opportunities for digital technologies to support the growing pressures on clinicians by providing patients with more efficient and rapid care delivery.

The future of CDS appears promising as the need for decision support continues to increase in line with global population demands, pandemic preparedness, exponential rise of big data, interoperability, and advancement of AI. We are in the midst of a paradigm shift where healthcare is moving toward digital transformation and implementing sustainable systems which enable optimal care delivery, now and in the future.

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The statements by Siemens Healthineers' customers described herein are based on results that were achieved in the customer's unique setting. Because there is no "typical" hospital or laboratory and many variables exist (e.g., hospital size, samples mix, case mix, level of IT and/or automation adoption) there can be no guarantee that other customers will achieve the same results.

Siemens Healthineers Headquarters

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com