**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Medical Technologies Evaluation Programme**

**Artificial intelligence auto-contouring to aid radiotherapy treatment planning: early value assessment**

**Final scope**

April 2023

## Introduction

The topic has been identified by NICE for early value assessment (EVA). The objective of EVA is to identify promising technologies in health and social care where there is greatest need and enable earlier conditional access while informing further evidence generation. The evidence developed will demonstrate if the expected benefits of the technologies are realised and inform a final NICE evaluation and decision on the routine use of the technologies in the NHS.

NICE’s topic selection oversight panel ratified artificial intelligence (AI) auto-contouring to aid radiotherapy treatment planning as potentially suitable for an EVA by the medical technologies evaluation programme (MTEP). Abbreviations are provided in appendix A.

## Description of the technologies

This section describes the properties of the AI auto-contouring technologies based on information provided to NICE by companies and experts, and information available in the public domain. NICE has not carried out an independent evaluation of this description.

### Purpose of the medical technology

External beam radiotherapy uses ionising radiation to kill cancer cells in the treated area. It aims to give a high dose of radiation to cancer cells but as low a dose as possible to nearby healthy cells. Contouring is an important part of the radiotherapy treatment planning process. It involves outlining the target volumes and organs at risk (OAR) to guide radiotherapy so that treatment is effective and radiation toxicity is reduced. AI auto-contouring technologies aim to improve contouring efficiency by automatically contouring the OAR and perhaps the target volumes before radiotherapy. These technologies have been trained using deep learning convolutional neural networks to process images from CT or MRI scans and produce an initial contour. Images and contours are then reviewed by trained healthcare professionals and modified as needed.

Clinical experts advised that they spend a lot of time creating and reviewing manual contours. There is some evidence that AI auto-contouring with healthcare professional review is quicker than manual or atlas-based contouring. It may save costs by reducing healthcare professional time needed to do contouring. It may also improve consistency of contouring between people, standardise processes and improve adherence to international guidelines. Clinical experts considered that AI auto-contouring could result in quicker radiotherapy treatment planning pathways and shorter time to treatment for patients. [The Royal College of Radiologists clinical oncology census report 2021](https://www.rcr.ac.uk/clinical-oncology/rcr-clinical-oncology-census-report-2021) reports immense workforce pressure because of staff shortages and continued effects from the COVID-19 pandemic. Increased efficiency from using AI auto-contouring may increase capacity, allow healthcare professionals to focus on patient-facing tasks and reduce waiting lists. Experts also advised that potential improvements in consistency may lead to more accurate contours and could reduce unwanted variation and outliers. This could reduce toxicity. AI auto-contouring could also increase the complexity of treatment including auto-planning and adaptive approaches which would only be possible once auto-contouring is routinely available.

### Product properties

This scope focuses on AI auto-contouring technologies for radiotherapy treatment planning. For this EVA, NICE will consider technologies that:

* use AI-based algorithms to automatically contour OAR or target volumes as part of initial radiotherapy treatment planning
* are standalone AI auto-contouring software or have AI auto-contouring functionality integrated in treatment planning or radiotherapy platforms
* meet the standards within the digital technology assessment criteria (DTAC), including the criteria to have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC
* are available for use in the NHS.

Technologies for this assessment were identified through NICE topic intelligence, NHS stakeholders and clinical experts, and literature search. In total, 11 AI auto-contouring technologies for radiotherapy treatment planning are included in the scope. The scope of this assessment excludes adaptive radiotherapy systems. Experts advised that these technologies would likely have a different care pathway and should be evaluated separately. The scope also excludes bespoke AI auto-contouring technologies developed in-house by local services using open-source software such as Inner Eye project by Microsoft. The final list of included technologies may be subject to change.

**AI-Rad Companion Organs RT (Siemens Healthineers)**

AI-Rad Companion Organs RT is an AI auto-contouring software that is deployed through the Siemens teamplay digital health platform. It is designed to be used with treatment planning systems and interactive contouring applications. It contours over 60 OAR on CT scans including abdomen, head and neck, pelvis and thorax. It is a CE-marked class IIb medical device under the EU medical devices regulation (MDR).

**ART-Plan (TheraPanacea, Oncology Systems)**

ART-Plan is a standalone AI auto-contouring software trained using international guidelines. Images are automatically sent to ART-Plan for contouring and then to the treatment planning system. ART-Plan contours over 150 OAR and lymph nodes including abdomen, brain, head and neck, thorax and pelvis on CT images and abdomen, brain and male pelvis on MRI. It is a CE-marked class IIb medical device under the EU MDR.

**AutoContour (Radformation)**

AutoContour is a standalone AI auto-contouring software. It has been trained using consensus guidelines and structures are named in line with the American Association of Physicists in Medicine (AAPM) Task Group 263 standardised nomenclatures in radiation oncology. AutoContour is vendor neutral and works with most treatment planning and imaging systems. It has DICOM standalone capability and can also be integrated with Varian Eclipse using the Eclipse Scripting application programming interface (API). Images from the CT or MRI scanner or Eclipse are sent to AutoContour for auto-contouring before being sent to the treatment planning system or back to Eclipse. It contours over 200 structures including OAR and lymph node regions in the chest and abdomen, head and neck, and pelvis on CT images and brain on MRI. It is currently undergoing regulatory approval with a notified body for CE-marking as a class IIa medical device.

**DLCExpert (Mirada Medical)**

DLCExpert is an AI auto-contouring software that is compliant with international consensus guidelines. DLCExpert is deployed on Mirada Medical’s Workflow Box platform, which is a software application designed to perform automated workflows. It is designed to be used with existing treatment planning or image processing software. DLCExpert contours over 160 structures on CT and MRI images, including abdomen, breast, head and neck, prostate and thorax. It is a CE-marked class I medical device under the EU medical devices directive (MDD).

**INTContour (Carina Medical)**

INTContour is a standalone AI auto-contouring software that automatically delineates organs on CT or MRI images. Healthcare professionals can create and use customised models which the company claims can improve accuracy and efficiency. It can also be integrated with Varian Eclipse and RayStation treatment planning systems. It contours over 60 target and OAR structures from abdomen, head and neck, male pelvis and thorax. Regulatory approval for use in the UK is expected in 2023.

**Limbus Contour (Limbus AI, AMG Medtech)**

Limbus Contour is a standalone AI auto-contouring software developed in line with international consensus guidelines. It is locally hosted and can be installed on any existing hardware without the need for a graphics processing unit (GPU) or cloud connection. It is vendor neutral which means DICOM (digital imaging and communications in medicine) files can be sent to the existing treatment planning system or workstation for review and clinical validation. It contours over 160 OAR and target volumes including lymph nodes, abdomen, breast, central nervous system, head and neck, lung, pelvis and prostate on CT images, and central nervous system, gynaecologic and brachy structures on MRI. It is a CE-marked class I medical device under the EU MDD.

**MIM Contour ProtégéAI (MIM Software)**

MIM Contour ProtégéAI is a standalone AI auto-contouring software that automatically contours OAR and sensitive structures from CT or MRI images. Image data is sent from the hospital picture archiving and communication system (PACS) or local planning system to MIM software for contouring before being saved as DICOM RT structures. Healthcare professionals can manually correct contours before sending to treatment planning systems. MIM Contour ProtégéAI is vendor neutral and installation can be customised to service needs. It contours head and neck, thorax, lungs and liver, prostate and abdomen structures from CT images and prostate from MRI. It is a CE-marked class IIa medical device under the EU MDD.

**MRCAT Prostate plus Auto-contouring (Philips)**

MRCAT Prostate plus Auto-contouring is a clinical application integrated in Philips Ingenia system for magnetic resonance imaging in radiation therapy (MR-RT). It provides automatic contours and density information for dose calculations in a repeatable workflow. MRCAT images conform to DICOM standards and can be exported to treatment planning systems. The company said that the system can replace traditional CT-based workflows with an MRI only radiotherapy workflow from imaging and planning to position verification.

**MVision Segmentation Service (MVision AI Oy, Xiel)**

MVision Segmentation Service is a standalone AI auto-contouring software trained to comply with international guidelines using a peer-reviewed process. CT or MRI images from the scanner or treatment planning system are exported to MVision. A structure set is created and contours are added to the original images. These are then sent to the DICOM folder or treatment planning system. It contours over 160 structures including OAR and target volumes in abdomen and thorax, brain, breast, head and neck, and pelvis. It is a CE-marked class I medical device under the EU MDD.

**OSAIRIS (Cambridge University Hospitals NHS Foundation Trust)**

OSAIRIS is an open-source standalone AI auto-contouring software. It is a cloud-based workflow acceleration technology that only activates GPU resources on demand. It has been designed for free use and sharing within the NHS and complies with the NHS Azure Blueprint. It contours up to 26 head and neck and prostate treatment site structures on CT images. Regulatory approval for use in the UK is in progress.

**RayStation (RaySearch)**

RayStation is a radiotherapy external beam and brachytherapy planning system with AI auto-contouring functionality included as part of the standard contouring tools. It uses a high-speed GPU-powered algorithm to automatically contour structures needed for the creation of radiotherapy treatment plans. It integrates deep learning auto-segmentation into the workflow which allows for automation of the radiotherapy treatment planning workflow from data import to data export. It contours over 70 structures on CT images including breast and lymph nodes, head and neck, male pelvis, thorax and abdomen. It is a CE-marked class IIb medical device under the EU MDD.

## Target conditions

The target population for this assessment is people having radiotherapy treatment planning for external beam radiotherapy.

[The National Cancer Registration and Analysis Service and Cancer Research UK’s statistics on chemotherapy, radiotherapy and surgical tumour resections in England](https://www.cancerdata.nhs.uk/treatments) reports that between 2013 and 2019, about 40% of people with cancer had radiotherapy as part of their cancer treatment. [NHS England’s radiotherapy dataset](https://www.cancerdata.nhs.uk/radiotherapy/dashboard) shows that there were 134,419 radiotherapy episodes in England in April 2021 to March 2022 and 1,507,521 attendances. An episode refers to a continuous period of care including all preparation, planning and delivery of radiotherapy, while attendances are the number of times a person attends a radiotherapy department and receives treatment in an episode of care.

The highest number of radiotherapy episodes between April 2021 to March 2022 were reported for:

* Female breast: 35,834 episodes and 285,279 attendances
* Prostate: 24,065 episodes and 355,418 attendances
* Lung: 15,153 episodes and 129,559 attendances
* Head and neck: 7,934 episodes and 187,403 attendances
* Small intestine and colorectal: 6,937 episodes and 83,001 attendances
* Haematology: 6,064 episodes and 45,932 attendances
* Other invasive cancers: 5,694 episodes and 25,743 attendances
* Non-melanoma skin cancer: 5,221 episodes and 54,299 attendances
* Brain and central nervous system: 4,405 episodes and 76,089 attendances
* Gynaecology excluding cervix: 4,397 episodes and 57,286 attendances
* Oesophago-gastric: 3,624 episodes and 42,507 attendances.

Clinical experts advised that AI auto-contouring could be used to aid treatment planning for everyone having external beam radiotherapy. There may be some uses of external beam radiotherapy where contouring is not typically used and AI auto-contouring may not provide any additional benefit. Some experts suggested particular benefit in people with multiple tumour sites or complex OAR such as head and neck squamous cell carcinoma, abdominal or lung tumours, and breast cancer needing lymph node irradiation.

## Care pathway

Contouring in radiotherapy treatment planning is used to outline the target volume and OAR to guide radiotherapy so that treatment is effective and radiation toxicity is reduced. Healthcare professionals most often use manual or atlas-based contouring or model-based segmentation. Manual contouring is the most common contouring method used in standard care. Manual contouring of target regions is usually done by clinical oncologists, while contouring of OAR may also be done by clinical technologists (dosimetrists) or therapeutic radiographers. There are published guidelines for contouring OARs and disease sites from organisations such as [European Society for Radiotherapy and Oncology](https://www.estro.org/Science/Guidelines) and the [Royal College of Radiologists](https://www.rcr.ac.uk/publication/radiotherapy-target-volume-definition-and-peer-review-second-edition-rcr-guidance). Atlas-based contouring and model-based segmentation are not as widely used in standard care. Atlas-based contouring is an automated method that contours new images using models based on historical images of similar patient anatomy. Model-based segmentation is also an automated method that contours images using statistical shape models for different organ structures. Contours regardless of contouring method should be reviewed before being used in treatment planning in line with guidance such as [the Royal College of Radiologists guidance on radiotherapy, target volume definition and peer review](https://www.rcr.ac.uk/publication/radiotherapy-target-volume-definition-and-peer-review-second-edition-rcr-guidance).

***Potential place of AI auto-contouring for radiotherapy treatment planning in the care pathway***

AI auto-contouring would be used as part of standard care radiotherapy treatment planning. Radiotherapy is usually given in hospital on an outpatient basis. AI auto-contouring would be reviewed and edited as needed by trained healthcare professionals, including clinical oncologists, therapeutic radiographers, clinical technologists and medical physicists. All contours should be reviewed and modified as needed before being used in treatment planning.

## Comparator

AI auto-contouring would be used as an alternative to manual or atlas-based contouring or model-based segmentation as part of standard care radiotherapy treatment planning. For some cases, AI auto-contouring may generate contours for structures that are not routinely produced in standard care. In these instances, no contours or no contouring may be an appropriate comparator to consider.

## Scope of the assessment

Table 1 Scope of the assessment

|  |  |
| --- | --- |
| Population | People having radiotherapy treatment planning for external beam radiotherapy |
| Interventions (proposed technologies) | AI auto-contouring technologies for initial treatment planning, namely:* AI-Rad Companion Organs RT (Siemens Healthineers)
* ART-Plan (TheraPanacea, Oncology Systems)
* AutoContour (Radformation)
* DLCExpert (Mirada Medical)
* INTContour (Carina Medical)
* Limbus Contour (Limbus AI, AMG Medtech)
* MIM Contour ProtégéAI (MIM Software)
* MRCAT Prostate plus Auto-contouring (Philips)
* MVision Segmentation Service (MVision AI Oy, Xiel)
* OSAIRIS (Cambridge University Hospitals NHS Foundation Trust)
* RayStation (RaySearch Laboratories AB)
 |
| Comparators | Contouring methods used in standard care to contour OAR and target volumes including lymph nodes. These include:* manual contouring
* atlas-based contouring
* model-based segmentation.

Comparators may also include ‘no contours or no contouring’ for cases where AI auto-contouring may generate contours for structures not routinely contoured in standard care. |
| Healthcare setting | Outpatient settings |
| Outcomes | The outcome measures to consider include:**Accuracy and acceptability*** Clinical acceptability of contours including alignment with national and international guidelines
* Accuracy of contours including quantitative measures of DICE coefficient and qualitative measures
* Degree of contour edits needed before use in radiotherapy treatment planning
* Consistency of contours including interrater reliability
* Impact on radiotherapy treatment planning quality assurance including surrogate, qualitative and quantitative measures such as:
	+ Dose prescription changes
	+ Dose volume distributions
	+ Radiation toxicity
	+ Missing targets
	+ Adherence to international guidelines
* Usability, user experience and satisfaction

**Resource and system impact*** Contouring time including time needed for healthcare professional review and manual edits
* Radiotherapy treatment planning time including time saved and difference in time to start of treatment
* Number of more complex plans produced including number of structures contoured
* Impact on staffing and treatment planning resources, such as changes in skill-mix or healthcare professional grade needed to produce and review contours
* Impact of the system on clinical oncology training (including training of all healthcare professionals contributing to radiotherapy treatment planning)
* Impact on healthcare professional performance and productivity more broadly, such as efficiency, increase in patient-facing tasks and staff wellbeing.
 |
| Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration should include:* Costs of AI auto-contouring software including installation, licence fees, maintenance and update costs for additional libraries or features
* Costs of any associated technology needed to use AI auto-contouring tools excluding capital costs for equipment that is otherwise used in standard care
* Healthcare professional grade and time
* Cost of other resource use such as additional appointments or healthcare professional training
 |
| Time horizon | The time horizon for estimating the clinical and economic value should be sufficiently long to reflect any differences in costs or outcomes. |

## Other issues for consideration

**Population**

* This EVA is focused on people having radiotherapy treatment planning for external beam radiotherapy. This includes cancer treatment in several different regions with different associated OAR and target volumes including lymph nodes that may affect contouring accuracy and efficiency. Subgroups within the population may be considered depending on the available evidence.

**Characteristics of AI auto-contouring**

* AI auto-contouring technologies may differ in their implementation, structures and costs. Some technologies are standalone software while others are integrated in holistic treatment planning or radiotherapy systems. This should be considered in the assessment, including how technologies fit into standard care radiotherapy treatment planning and resource implications for different types of AI auto-contouring technologies.

**Evidence**

* This assessment will look across a range of evidence types including real-world evidence. It will evaluate the clinical equivalence, efficiency and resource consequences of using AI auto-contouring in addition to standard care radiotherapy treatment planning. This will include evaluating whether AI auto-contouring technologies have equal or superior outcomes to manual or atlas-based contouring or model-based segmentation in NHS services for the same disorder.
* The assessment will focus on evidence from use of the technologies with standard training sets. Evidence generated from technologies that have been retrained using local populations will be flagged.

## Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

AI models can contain algorithmic bias depending on the population used in training. Populations used in training datasets may not be representative of patient populations in clinical practice which can cause potential age, gender, disability and ethnic bias. Clinical experts advised that there is a potential for gender bias, for example a lack of representation of the female pelvis and male breast cancer in some training datasets. There is also a potential for disability bias, for example not including people with hip replacements in training datasets. Training datasets may also underrepresent children and young people. This may affect the performance of AI auto-contouring for these populations. AI auto-contouring may perform best with certain CT or MRI sequences or with the person being in a specific position such as supine head-first. Training datasets may not include data on atypical positioning which may make AI auto-contouring less accurate for some people with limited mobility. Clinical experts advised that AI auto-contouring may also not work as well for people with atypical anatomy associated for example with previous medical interventions such as surgery.

Potential risk of bias of a specific technology should be considered when deciding if to use that technology in research or clinical settings. This should form part of a local assessment process before purchase and clinical decision-making. Companies should also provide detailed information on training datasets as part of their product information pack, including guidelines used and demographics such as age range, gender ratios and inclusion of disabilities.

Cancer is considered a disability under the Equality Act 2010. Incidence rates in the UK for all cancers combined are highest in people aged 85 to 89 with more than a third of diagnoses each year being in people aged 75 and older. Age and disability are protected characteristics under the Equality Act 2010.

## Potential implementation issues

When deciding if to use AI auto-contouring technologies, radiation oncology services should consider:

* compliance with GDPR, information governance and cybersecurity standards
* staff acceptability of AI auto-contouring including ease of implementation considering workforce skills and workflows
* education and training needed to use the specific technology
* how automated decision-making fits into local protocols
* bandwidth and server requirements
* monitoring performance, risk assessment and quality assurance.

Experts and stakeholders outlined several considerations for using AI auto-contouring technologies in the NHS. AI auto-contouring technologies should:

* conform to national and international guidelines
* come with detailed information on training datasets used, software optimisation and validation
* be DICOM compatible
* be vendor neutral and able to integrate into current workflows easily and automatically
* include all relevant OAR and targets including additional structures not manually contoured
* be customisable, such as which structures to include, structure names, colours and fit with local protocols.

## Authors

**Dionne Bowie**

Topic Lead

**Bernice Dillon**

Technical Adviser

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# Appendix A Abbreviations

|  |  |
| --- | --- |
| AI | Artificial intelligence |
| API | Application programming interface |
| DICOM | Digital imaging and communications in medicine |
| DTAC | Digital technology assessment criteria |
| EAR | Early value assessment |
| GPU | Graphics processing unit |
| MDD | Medical devices directive |
| MDR | Medical devices regulation |
| MTEP | Medical technologies evaluation programme |
| OAR  | Organs at risk |