i-SART: A Prototype AI-based Tool to Enhance Patient Safety in Radiotherapy

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Abstract In the complex field of radiotherapy (RT), ensuring patient safety is crucial. Risk management is a valuable tool for aiding RT departments in achieving this goal by systematically addressing hazards in their systems. Disseminating information about potential failures has been recognized as paramount to improving patient safety globally. This paper presents i-SART, a novel web application that aims to facilitate proactive risk management and share knowledge about potential failure modes (FMs) in a timely and efficient way. Based on the Failure Modes and Effects Analysis (FMEA) methodology, i-SART features a database of 419 FMs. The innovation lies in the integration of AI techniques that engage RT professionals in an interactive learning process by generating discussions about potential failures and safety measures. The web application is a work in progress and will be released soon for user evaluation. We anticipate i-SART to effectively promote proactive learning in FMs, enhance patient safety, and pave the way for advanced AI-based risk management in RT.

1 Introduction

In the ever-evolving landscape of radiotherapy (RT), where precision is paramount, ensuring patient safety is crucial. The meticulous approach required in RT demands a comprehensive strategy to mitigate potential risks and enhance the overall safety in the patient pathway.

In RT, stringent safety standards and robust measures govern the use of radiation. Although accidents are rare, errors may occur at various stages, occasionally compromising clinical outcomes. The International Commission on Radiological Protection (ICRP) underscores the potential risks, especially those associated with new technologies [1].

To minimize the risk of failures and prevent unintended exposure, the implementation of risk management in RT has been regulated in many countries [2, 3], utilizing both reactive and proactive methodologies. Reactive risk management employs Incident Learning Systems (ILS) to collect and analyze adverse events, errors, or near misses. Notable international and national ILS, such as SAFRON (SAFety in Radiation Oncology) [4], ROSEIS (Radiation Oncology Safety Education and Information System) [5], and RO-ILS (Radiation Oncology-Incident Learning System) [6], provide valuable insights about incidents to the RT community. Proactive risk management involves the implementation of systematic methods that assist organizations in managing their weaknesses by identifying and addressing potential failures before they occur [7].

Approaches used in RT include Failure Mode and Effects Analysis (FMEA) and its variations, such as Failure Mode and Effects Criticality Analysis (FMECA) and Healthcare Failure Mode and Effects Analysis (HFMEA), as well as other methods like Fault Tree Analysis (FTA) [7], Hazard and Operability Analysis (HAZOP) [8] and the Systems Theoretic Accident Model and Process (STAMP) [9, 10]. Although many departments have successfully implemented proactive risk management, others face challenges due to limited knowledge of assessment methodologies and a lack of resources. Moreover, proactive risk management involves forward-thinking, focusing on identifying and preventing potential hazards before they manifest, which is particularly challenging especially when implementing new technologies or techniques. The World Health Organization's (WHO) Global Action Plan for Patient Safety (2021-2030) [11] emphasizes the proactive identification and mitigation of risks in healthcare, aiming to enhance patient safety. It calls for the dissemination of such knowledge, yet the vast majority of knowledge about potential risks is not disseminated and remains compartmentalized within the departments. While national and international ILS provide learning about incidents post-occurrence, there is no similar platform that promotes proactive knowledge before potential failures turn into errors.

Our research aims to bridge this gap by developing a web application, the i-SART, an Intelligent Safety Assistant in RT that facilitates proactive risk management and enhances patient safety awareness. Central to this effort is a database that gathers a large number of potential failure modes (FMs) defined as the ways or modes a process or system can fail. Innovative to our approach is the integration of AI techniques that engage RT professionals in an interactive learning process about FMs and safety measures. The advantage of i-SART is that knowledge about potential failures can be disseminated in a timely and efficient way, worldwide. We envision i-SART as a free-to-access tool for all RT users fostering collaboration and future improvements. This is a collaborative effort between the Faculty of Biomedical Sciences of the University of West Attica and the Faculty of Computer Sciences of Vrije Universiteit Amsterdam and is a work in progress.

2 Materials and Methods

Design of i-SART

The design of i-SART was based on FMEA methodology, selected for its ability to yield both qualitative and quantitative results. In an FMEA process study, a dedicated team identifies FMs, along with their causes and effects. The team assesses the FMs in terms of their likelihood of occurrence (O), lack of detectability (D), and potential severity (S). This evaluation aids in prioritizing FMs for implementing risk mitigation strategies.

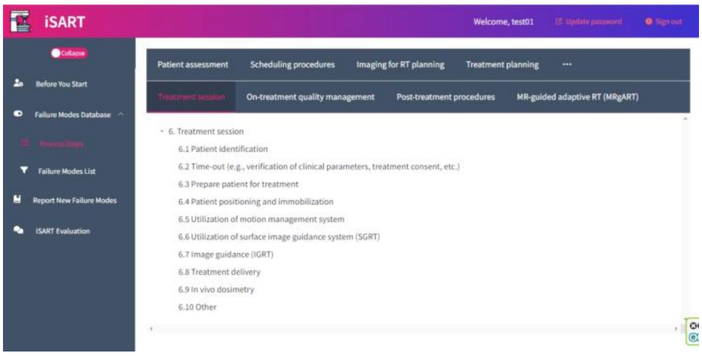
I-SART used the seminal report of the American Association of Physics in Medicine (AAPM), the AAPM TG100

[12], as a benchmark. This report was developed as a proactive risk management FMEA-based methodology specific to RT.

Initially, we created a process map that depicts chronologically the sub-processes and their steps within the main RT process. The i-SART process map includes 8 sup-process and 61 steps.

1. Patient Assessment / Initial Consultation (13 steps).
2. Scheduling procedures (4 steps).
3. Imaging for RT planning (14 steps).
4. Treatment planning (TP) (10 steps).
5. Pre-treatment QA procedures (3 steps).
6. Treatment session (10 steps) (Fig. 1).
7. On-treatment quality management (4 steps).
8. Post-treatment procedures & Follow-up (3 steps).

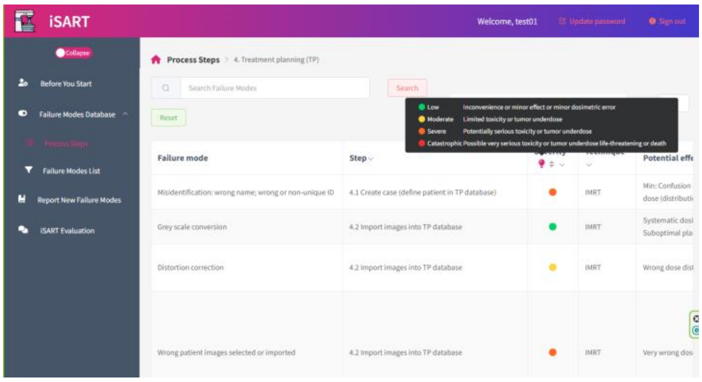
Additionally, the specific procedure of the advanced technology/technique MR-guided adaptive RT (MRgART) was separately mapped in 12 steps.



6. Treatment session
- 6.1 Patient identification
- 6.2 Time-out (e.g., verification of clinical parameters, treatment consent, etc.)
- 6.3 Prepare patient for treatment
- 6.4 Patient positioning and immobilization
- 6.5 Utilization of motion management system
- 6.6 Utilization of surface image guidance system (SGRT)
- 6.7 Image guidance (IGRT)
- 6.8 Treatment delivery
- 6.9 In vivo dosimetry
- 6.10 Other

Figure 1: Sample of i-SART interface showing the steps in the treatment session sub-process.

At each step, the collected FMs (as described in the results section), their severity, causes and effects, and mitigation strategies were stored in the database. To ensure a harmonized severity (S) across all selected FMEA studies, we created a modified scale in the form of traffic lights for ease of visualization (Fig. 2).



🟢 Low Inconvenience or minor effect or minor dosimetric error
🟡 Moderate Limited toxicity or tumor underdose
🟠 Severe Potentially serious toxicity or tumor underdose
🔴 Catastrophic Possible very serious toxicity or tumor underdose life-threatening or death

Failure mode	Step			Potential effe
Misidentification: wrong name; wrong or non-unique ID	4.1 Create case (define patient in TP database)	🟠	IMRT	Min: Confusion dose (distributi
Grey scale conversion	4.2 Import images into TP database	🟢	IMRT	Systematic dosi Suboptimal pla
Distortion correction	4.2 Import images into TP database	🟡	IMRT	Wrong dose dist
Wrong patient images selected or imported	4.2 Import images into TP database	🟠	IMRT	Very wrong dos

Figure 2: Sample failure modes within the treatment planning sub-process, indicating their severity using a traffic light format.

Data collection

Our research included a sample of FMEA studies that met our eligibility criteria: diversity in external photon beam RT techniques, country representation, studies conducted in English, and the provision of sufficient data to align with our design's objective of offering comprehensive information on FMs.

Technical Description i-SART

Technically, i-SART is a cloud-hosted web application with two user roles: administrator and user, each having distinct interfaces and data accesses. The administrator, who is an RT expert, manages the system and the application database.

The back-end of the web application was developed using Python 3.9 and the Django REST framework. Secure information transfer between client and server was ensured through JSON Web Token authentication. A relational database MySQL, was chosen for persistent storage of user and FM information.

The user interface of i-SART was created using Vue.js, a JavaScript based framework. FM search, filtering, and sorting functions are available. There is also an option for the user to insert in the database a new FM validated by the i-SART administrator. The administrator can also monitor statistics on FMs in various charts. Additionally, all users can evaluate the tool and provide comments and suggestions for improvement. The general workflow of i-SART is shown in Fig. 3.

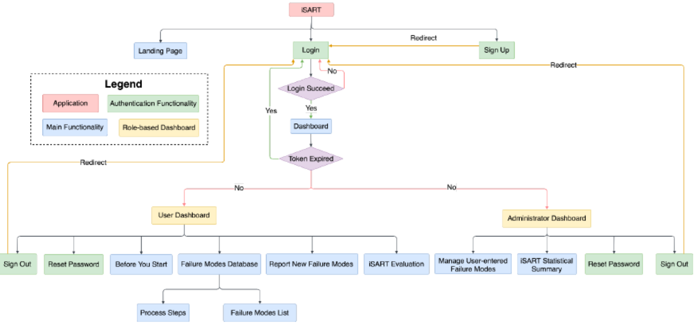


Figure 3: The general workflow of i-SART.

Experimental work on synthetic FMs

To augment the database for potential future use in machine learning, we experimented with the possibility of generating synthetic (artificial) FMs using Generative AI (GenAI) techniques such as Hidden Markov Models, ChatGPT-3, and Generative Adversarial Network (GAN) [13]. Specifically, for GAN, we employed the seqGAN model [14] with a total of 2,305 records extracted from our FMs database and incident data from SAFRON [4] (Fig. 4).

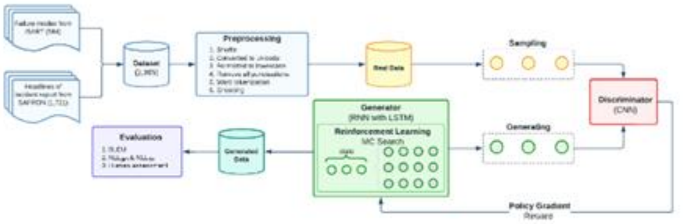


Figure 4: The architecture of the GAN-based synthetic FMs generation experiment.

Current work

We are currently working on integrating an AI tool, specifically a chatbot, into i-SART. This addition aims to elevate user interaction by generating engaging discussions about FMs. Users will have the opportunity to seek insights, clarification, and practical solutions based on white papers, seminal reports, and relevant literature, all within the i-SART. This feature not only promotes proactive learning but also serves as a valuable resource for users seeking timely and context-specific information.

3 Results

Initially, a total of 728 FMs were gathered from 10 FMEA articles and reports. The seminal AAPM TG100 report [12], which provides potential FMs in Intensity Modulated Radiotherapy (IMRT), served as the foundational source, Complementing this, seven articles were included that explored FMs in: RT process [15], 3D Conformal RT [16], lung Volumetric Modulated Arc Therapy (VMAT) [17], Surface Guided deep inspiration breath -hold (DIBH) breast RT [18], Stereotactic Radiosurgery/Radiotherapy [19] and MR guided adaptive RT [20, 21]. Additionally, data from two unpublished reports from the UK investigating breast VMAT and lung Stereotactic Body Radiation Therapy (SBRT) were incorporated.

To identify duplicate FMs across the articles and reports, we utilized a semi-automated approach, initially employing AI-based Natural Language Processing (NLP) algorithms. Results were subsequently manually reviewed by researchers to confirm duplications. We also merged common-ground FMs that included supplementary information while excluding ambiguous or insufficiently detailed FMs from our database. The total number of FMs in i-SART is currently 419 as illustrated in Fig. 5.

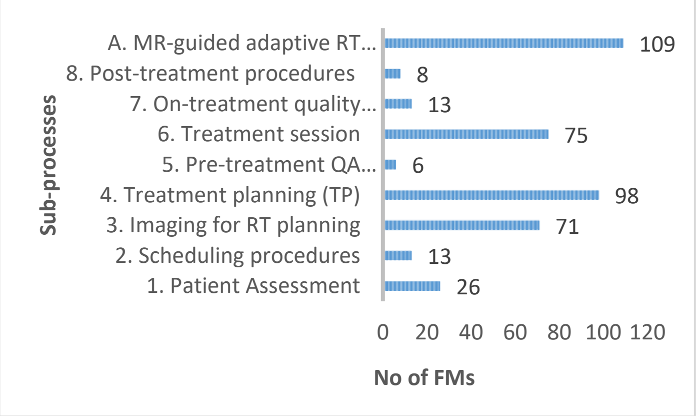


Figure 5: Number of FMs per sub-processes from 1 to 8. MR-guided Adaptive RT is indicated by the letter A.

Our experiments with GenAI to augment the FM database resulted in very few interesting and sensible new FMs, most probably due to the small size of the training dataset, which will hopefully increase, as i-SART will gain more users. The results were not incorporated into the database. However, these explorations lay the groundwork for potential future work.

We will soon release the application for user evaluation to assess its effectiveness and identify areas for improvement. We anticipate that users will contribute new FMs to enhance the database, fostering continuous growth and knowledge exchange.

4 Discussion

Proactive risk assessment within RT has garnered recognition as an essential tool for preventing incidents and errors. While national and international ILS offer valuable insights into lessons learned from past events, there is a noticeable gap in proactive learning on potential risks. Our research aimed to bridge this gap through the development of i-SART, an intelligent Safety Assistant in RT.

Built upon the FMEA and AAPM TG-100, i-SART takes a systematic approach to create a large database of potential FMs in RT process. The integration of an AI chatbot will further enhance user engagement by generating discussions about FMs and safety measures. Additionally, the tool provides a platform for users to contribute new FMs, promoting continuous knowledge exchange. It may also become useful for RT vendors by offering insights into potential risks based on real-world practice. Furthermore, i-SART has the potential to complement free–access ILS, contributing to an overarching approach to risk management for the wider RT community.

Acknowledging its limitations, i-SART currently does not encompass all existing techniques and technologies in RT, focusing on the most widely used ones. Due to the limited number of studies used, generalizations cannot be made, and the tool cannot be considered as a 'one-size-fits-all.' It is indicative and informative, prompting reflection on the user’s practice while aiding in the identification and mitigation of potential risks promoting proactive learning.

Looking ahead, we anticipate i-SART to drive further innovations in integrating AI techniques and providing a substantial dataset for machine learning applications, FMs predictions and synthetic FMs generation while also encompassing other proactive risk management methodologies.

5 Conclusion

In this paper, a prototype of i-SART is presented, which is a web application designed to promote proactive learning in patient safety in RT. By integrating AI capabilities and employing the FMEA methodology, i-SART provides a dynamic platform for proactive risk management. We anticipate i-SART to enhance patient safety awareness and facilitate valuable knowledge exchange, particularly crucial as new techniques and technologies continually emerge. Envisioning the continuous evolution of i-SART, our hope is i-SART to become an essential safety assistant in the hands of every RT professional.

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