Title	IMPROVE SAFETY, QUALITY, AND EFFICIENCY IN RADIOTHERAPY WITH AUTOMATED HIT SYSTEM
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1 Abstract

Purpose: To develop and evaluate software tools and algorithms that automatically detect potential errors and issues in radiation therapy (RT) patients' data and documents. The goals are to reduce human errors and improve patient safety and work efficiency.

Scope: Patients' data and documents covered by this study are the structural data extractable from the clinical computer systems and database servers, and the documents could be analyzed by computer programs. These data and documents are normally checked by medical physicists manually in the clinical quality assurance workflow.

Methods: Prototype software tools were developed for detecting simple errors and inconsistencies based on pre-defined error detection rules. They are further enhanced, automated, and evaluated in clinical settings. Novel error detection algorithms, including multiple machine learning-based algorithms, were developed to detect advanced errors that are not supported by rule-based error detection.

Results: This study found that it was practical to develop and implement the automated and semi-automated electronic chart check software tools for modern RT departments. They are effective in error detection and could be useful for improving patient safety and work efficiency.

Key Words: Radiation therapy, patient safety, quality assurance, machine learning, health informatics, error detection, chart checking.

2 Purpose

The purpose of this research project was to develop, evaluate, and clinically deploy a suit of health information software tools and algorithms to automatically and semi-automatically verify patient data and documents in radiation therapy departments. The purposes of the software tools and algorithms are to significantly reduce human errors, improve patient safety as well as treatment quality and work efficiency, and reduce the overall cost of care for cancer patients receiving radiation therapy.

The three objectives are:

1. To further automate our prototype EcCk (Electronic Chart Check) physics chart check tool and to integrate it with other physics quality assurance tools we have developed.
2. To increase the error detection coverage in EcCk by developing novel algorithms and methods for detecting previously unsupported advanced errors.
3. To measure the clinical impacts and dissemination.

3 Scope

3.1 Background

High risks associated with radiation treatments are related to the high severities of the potential errors and the complexities of the treatment systems, the treatment modalities, and the clinical workflow. In many aspects, radiotherapy (RT) treatments are as complex as surgeries, times up to 40+ fractions, across a period of months. Patient safety in radiation therapy (RT), as a paramount issue, has been widely recognized by national and international organizations, including IAEA, ICRP, NRC, WHO, ASTRO, and AAPM. RT errors were ranked as the #1 and #2 health technology hazards by ECRI in 2011 and 2012. The reported errors in the literature were about 2% per patient, believed to be a small percentage of total errors. Major incidences were rare but had caused very serious consequences, including death. At our RT department, the severe, high-risk, and mid-low-risk errors in both treatments and quality control (QC) steps are 0.55%, 6%, and 53% per patient, respectively, according to the reported clinical events. Not only efficiency and safety are affected; these errors also affect clinical outcomes and treatment qualities.

Figure 1 shows a simplified, but already complex, clinical workflow in a RT department, with multiple groups of professionals involved and potential errors in each single step.

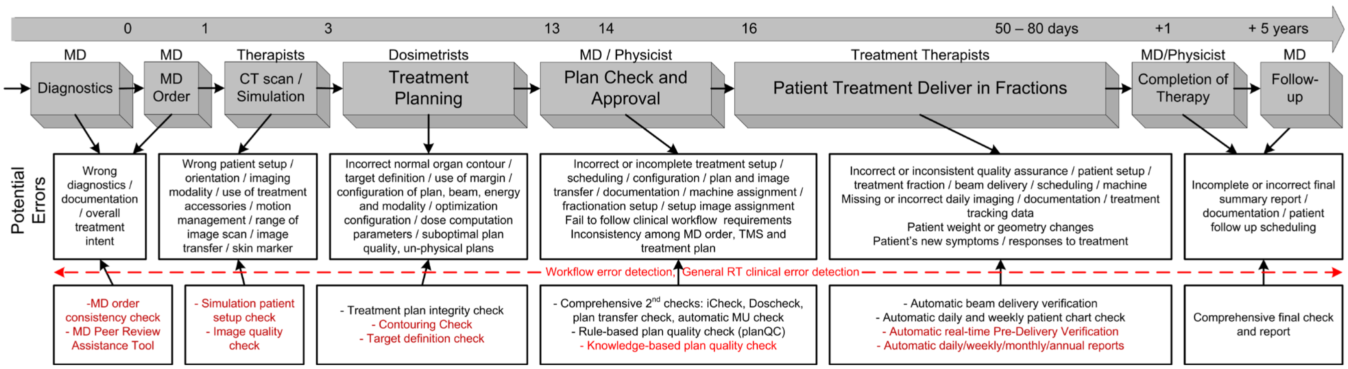

Figure 1: A simplified RT clinical workflow. The middle row contains a partial list of potential errors. The bottom row contains the checks. The items in black text are already in clinical use, and the items in red text are to be implemented. Scales of the comprehensive checks are much greater than other checks.

Treatment quality is another major concern due to significant variations in quality control stemming from demanding and complex clinical workflows and the competition for the limited human and clinical resources. Accounting for ~50% of total human workload together, both safety and quality control have been improving due to workflow improvements according to the lessons learned from previous incidents and following published recommendations and guidelines. However, a significant gap persists between what is possible and what is typically realized in clinical practice. Fast-advancing new technologies and treatment modalities, which offer better options for tumor targeting and normal tissue sparing, demand much more safety and quality interventions that are often not sustainable or systematically resulting in under- or substandard utilization of these technologies.

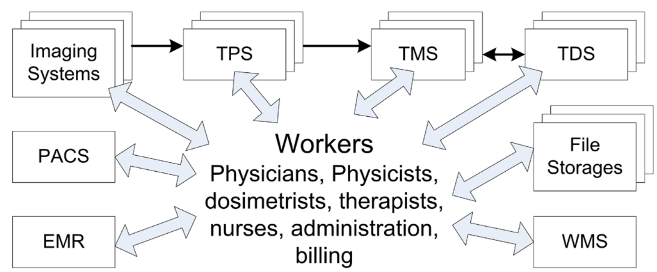

Figure 2: Computer systems in modern RT departments. TPS = Treatment Planning System. TMS = Treatment Management System. TDS = Treatment Delivery System. WMS = Workflow Management System. EMR = Electronic Medical Record. PACS = Picture Archiving and Communication System.

AAPM, ICRP, and ASTRO have published many recommendations to cover almost every aspect of RT workflow with the intent of ensuring patient safety, quality of care, and error prevention. Current error prevention and quality control measures in RT basically rely on human workers to follow the rigorous clinical workflows and to verify operation of the machines, the treatment data in computers, and the output by other workers. Though it is the standard of care, the current approach is fundamentally dependent on staffing, expertise, and alertness of human workers. A significant and proven problem with this approach is that it is naturally <u>inefficient</u> to use humans to check low-probability problems by computers and other humans. It is <u>ineffective</u> because many problems frequently go undetected. It is <u>inconsistent</u> because human workers have different levels of expertise and different understandings of the work performed and of elements required for quality and safe treatments. It is <u>very costly</u> by accounting for approximately 50% of workers' effort in RT. Ultimately, it is <u>unsustainable</u> with the recent advanced technologies, including IMRT (Intensity-Modulated Radiation Therapy), IGRT (Image-Guided Radiation Therapy), and SBRT (Stereotactic Body Radiation Therapy), because thousands more parameters and images need to be processed and checked than with previous 3DCRT (3D Conformal Radiation Therapy) methods.

On the other hand, in the past 10 years, RT departments have evolved from paper-based to completely computer-based and paperless treatment management. As shown in Figure 2, dedicated Treatment Planning Systems (TPS) are universally used. Dedicated Treatment Management Systems (TMS) are now managing all aspects of the patient RT treatments, including patients' electronic medical records (EMR). Treatment delivery machines (TDS) have also become very sophisticated with onboard CT (Computed Tomography) scanners, controlled by multiple computers and fully integrated with TMS. There are also dedicated Workflow Management Systems (WMS) and Picture Archiving and Communication Systems (PACS) to store patient image data. Not yet expert systems, these computer systems have been designed only to serve, record, and track data (and documents) in electronic format and to retrofit the traditional workflow. They have indeed provided the foundation for a paradigm change to expert systems that can be created to manage and ensure the safety and quality using electronic data stored in these existing computer systems. As outlined above, the traditional way (relying on humans to check data in the computers) has many deficiencies and is ready for improvement.

3.2 Context

The goals of this study are to develop, implementation, and evaluate the patient chart check tools and algorithms for automatic detection of errors, inconsistencies, and issues in the patient charts. This study was designed to cover the cancer patients who received external beam radiation therapy treatments in the departments of radiation oncology.

3.3 Settings

Modern radiation oncology departments that are equipped with the industrial standard treatment management systems (ARIA by Varian Medical System, or MOSAIQ by Elekta), treatment planning systems (Eclipse by Varian Medical System, Pinnacle by Philips). This study has been conducted mainly at the Department of Radiation Oncology, Washington University School of Medicine, the affiliated Barnes Jewish Hospital, and satellite hospitals under BJC (Barnes Jewish Hospital Care).

3.4 Participants

The target users of the to-be-developed automated patient chart check tools and algorithms are the medical physicists and the radiation therapy dosimetrists (the treatment planners). Therefore, the participants of this study are the medical physicists and the dosimetrists, not the actual patients.

3.5 Incidence and prevalence

The focus of this study is to automatically detect errors, inconsistencies, and potential issues in the patients' charts using software tools and novel algorithms. There are many types of potential errors during radiation therapy treatments. Some errors are very severe but very rare, for example, treating a wrong patient and treatment of the patient with a wrong treatment plan. Other errors happen frequently but are associated with minimal risks, for example, an incorrect dose rate chosen for the treatment beam.

Inconsistencies are referring to the situations that same piece of data or information appears inconsistent at different places. Inconsistencies in the patients' charts could also take many different forms. They are commonly caused by a piece of data that was updated at some places or in some documents but not updated at other places or in other documents. They are not necessarily errors, because not all the inconsistent values will drive the patient treatment for the next step. However, the inconsistent data or documents raise questions and cause confusion about which values are the final and correct ones.

Issues are like inconsistencies but refer to the discrepancies between the data in the patient chart and the common requirement of clinical practice or clinical workflow. For example, patient treatment documents should be ready to go 1 day prior to patient's first treatment fraction, because delayed document preparation and approval could cause other delays in the downstream.

At our RT department, the severe, high-risk, and mid-low-risk errors in both treatments and quality control (QC) steps are 0.55%, 6%, and 53% per patient, respectively, according to the reported clinical events. There is no quantitative estimation about the inconsistencies and the issues, because they happen too often to be recorded. A rough estimation among a small number of patients indicated that the inconsistencies and issues happen at >200% per patient.

Quality of care often has completely different definitions in various healthcare fields. In RT, quality can be defined as minimized variation in standard care delivery. In this study, we will further limit the definition as the correct and efficient completion of the safety and quality check tasks and the minimization of errors, both of which were shown to correlate to the treatment outcomes.

4 Methods

4.1 Introduction

In this study, we developed an intelligent computer system, EcCk (Electronic Chart Checking). Its purpose is to automatically check and analyze patient data in clinical computer systems and to report any safety risks and quality issues by detecting errors, inconsistencies, and variations based on medical knowledge and clinical workflow requirements. The clinical goals are to improve the accuracy, efficiency, and consistency in error detection and quality control and indirectly to improve the treatment qualities and clinical outcomes.

Not all errors, inconsistencies, and potential tissues are detectable in the patient's chart. Estimated according to the reported clinical events, our EcCk prototype tools could only detect ~40% of clinical errors at the beginning of this R01 grant. The specific aim 2 of this grant was designed to expand the automated chart checking coverage to detect new and advanced errors/issues that were not supported previously. However, the expanded error detection coverage is still limited within the errors and issues that are detectable in patients' data and documents that are directly accessible from the clinical computer systems. The items checked by EcCk software tools are listed in the Table 1.

Table 1: The list of items checked by the EcCk software tools and novel algorithms developed in this R01 grant. These items are supported according to the most important and frequent errors observed by the previously reported events and FMEA studies.

Data	What is checked?
Basic	Patient name and ID, consistent prescription names among TMS, TPS, and WMS.
Prescription	Treatment prescriptions consistent among TMS, TPS, WMS, and Approved.
Patient setup	Patient setup configured and approved in TMS. Consistent among TMS, plan, and simulation.
Treatment plan	All beams, control points parameters, beam name and identifier, machine, tolerance table, isocenter, weight point, MU (Monitor Unit) calculation, and additional configuration in TMS.
Treatment calendar	Treatment fractions configured and scheduled. Consistent with prescription. Treatment beams assigned into fractions according to the treatment prescription.
Image guidance	Uses of setup beams, beam orientation, and field size; setup of reference images and parameters; schedule per treatment sites and machines
Patient documents	Required documents completed correctly per treatment sites and modalities. Approved. Consistent with the treatment plan. Required QA completed. Result acceptable.

4.2 Specific aims and methods

4.2.1 SA1 – Automate and enhance the automatic chart checking software tools

The goal of SA1 was to enhance and automate the automatic chart checking software tools and algorithms, deploy and test them clinically, and evaluate the implementation and efficiency. For SA1, we have completed the following tasks:

- Patient master database was developed to facilitate automation.
- EcCk was enhanced to generate the plots and check multiple treatment record trends: couch table positions and SSD daily or weekly measurements.
- Weekly chart checking was automated, then improved to support ARIA [30], Viewray, and proton treatments and to integrate the Automatic dynamic MLC log QA results.
- Automatic weekly chart check programs were developed for UCLA cancer center and tested [30]. Most modules of weekly chart check programs of EcCk for MOSAIQ have been re-designed and re-developed to support ARIA.
- A set of client/server programs [34] was developed to seamlessly extract Eclipse plan, dose, and

structures data so to allow remote access of Eclipse planning data.

- ECCK was improved to integrate ADQ, iCheck, Chart Check Assignment, and dynalog QA tools.
- Viewray-specific EcCk programs were developed to support the new MRI-LINAC radiation therapy treatment modality [9, 18, 21].
- A new feature was developed in EcCk to generate an electronic dashboard for new patients. This web-based electronic and auto-updating dashboard allows automated detection of clinical workflow issues (incorrect or late status of each clinical workflow steps, missing required documentations, etc.). This work is helping reduce the occurrences of workflow errors and communication issues, to avoid unnecessary patient delays and to avoid rushed (potentially unsafe) finishing of clinical work items.
- A stand-alone program was developed to semi-automatically and randomly assign patient weekly chart check tasks to individual medical physicists and to track the weekly chart checking status [22].
- Automatic and manual checklists were developed per treatment modality and disease sites.
- The testing datasets were developed.

4.2.2 SA2 – Develop novel algorithms and methods to improve error detection coverage

The goal of SA2 was to expand the automatic chart checking coverage by developing novel rules and novel algorithms to check the patient's data, documents and images that were previously not supported. Within the scope of SA2:

- We symmetrically analyzed the RT plan parameters per treatment disease site and treatment modalities for all the treatment plans of the past 8 years [29]. The goal was to understand the common treatment plan data statistics (e.g., MU/cGy ratio, numbers of beams and segments) to quantitatively define the common sense-based rules to guide manual or automatic checks. Two methods (Median absolute deviation, Error-leveling) were developed to generate error statistical data automatically.
- A novel method was developed to quickly compute the 3D fluence volume [4] of the patients' specific treatment plans so as to automate and expediate the patients' specific quality assurance.
- Workflow error detections were implemented as an electronic and auto-updating new patient whiteboard for tracking patient treatment preparation workflow steps and detecting delays.
- A novel algorithm was developed to automatically enhance the X-ray image contrast [33].
- A novel machine learning algorithm was developed to automatically detect and confirm the patient treatment site, orientation in the daily treatment setup X-ray images [31].
- EcCk was expended to check patient daily 2D-2D setup images [32].
- An algorithm was developed, given a new treatment plan, to predict treatment delivery time for Viewray MR-IGRT patients [2]. This algorithm was necessary for patient treatment scheduling and was useful as an indicator to assess the treatment plan complexity.
- The prototype APDV (Automatic Pre-Delivery Verification) program [37] was developed to automatically check the integrity and accuracy of the treatment plan parameter just prior to radiation treatment delivery.
- A machine learning algorithm was developed to automatically detect potential errors in the prescription order data [13]. The algorithm used the Bayesian models (probabilistic graphic model) to the potential errors as the statistical outliers.
- A knowledge-based method was developed to capture the data variable dependencies as the trained decision trees used the trained tree to detect irregular data variable combinations [51]. In this way, the potential prescription errors, as the irregular prescriptions, could be identified.
- A knowledge-based error detection method (association rule) was developed to detect treatment prescription errors, patient setup errors, and treatment plan errors [53, 60]. Compared with two previously developed machine learning error detection methods (Bayesian network method [13] and the isolated forest method [51]), the association rule method is capable 1) of automatically

mining the clinical and physics knowledge from the clinical dataset in formats that are readable and understandable to human users, 2) presenting the detected error in ways that are understandable to human users, 3) integrating with manually defined error detection rules, and 4) naturally supporting missing values in the clinical data to detect errors (also missing values).

- A new stand-alone program has been developed based on EcCk programs to automatically generate a web-based report of patient treatment data changes in the treatment management system. This daily report is generated automatically every early morning and is used clinically by the treatment machine therapists to verify the patient treatment plan data and to identify unintended or incorrect changes in the treatment plan data.
- A novel image noise reduction algorithm was developed to maximize the image noise reduction while preserving the image features [6]. This algorithm was developed to improve the accuracy of automated checks of patient daily treatment image guidance.
- A novel algorithm was developed to correct MRI image intensity inhomogeneity [36]. This work is to improve the accuracy of automated verification of patient daily treatment image guidance.
- A novel and practical method [4] was developed to quantitatively assess the risks and robustness of RT plans for the most critical organs (spinal cord, brainstem, optic chiasm, optic nerves) using geometrical transform of the official clinical treatment plan dose volumes (per radiation beam).
- A method was developed to assess RT plan quality based on historical knowledge and the sum of weighted distance (SWD, the weighted distance from the organs-at-risk to the treatment target).
- A generic patient documentation processing procedure was developed.
- A prototype of automated verification of patient treatment image guidance was developed based on the previously developed automated image contrast enhancement, automated treatment site identification using machine learning.
- An artificial neural network machine learning method [14] was developed to predict the RT plan dose distribution then compute the plan quality so as to predict the optimal tumor target radiation coverage, given the contours of the tumor target and the normal organs. In this way, the treatment plan quality could be predicted prior to the time that the treatment plan is prepared, and the quality of the already prepared treatment plan could be quality assured against the previous similar cases.
- The same artificial neural network was applied to compare and evaluate the treatment plan qualities between the older and new MRI-RT machines [16].
- A novel method was developed by the PI to quality check the image fusion used by RT treatment planning based on automatic detection of landmark pairs in the image pairs [9].
- A novel deep-learning method [12] was developed to automatically detect large number of landmark pairs in the lung CT images so as to estimate lung tumor motion and quality check the motion management for lung cancer patients.
- A novel deep-learning method [11] was developed to automatically segment the normal organs in the abdominal MR images for abdominal and pancreas cancer patients receiving the MRI-guided RT. The purpose is 1) to speed up organ segmentation so to minimize the patient total treatment time and 2) to ensure the manual organ segmentation.
- A novel hierarchical procedure was developed to automatically segment the whole skeleton [5] in patients' CT images. The purpose was to enable automated verification and patient daily 3D-3D image guidance and to allow automated verification of 3D image fusion based on bony structures.

4.2.3 Support new sites, new radiation therapy treatment machine and clinical software system vendors, and new treatment systems

The goal was to expand the automatic chart checking efforts from the main hospital to smaller-scale satellite hospitals and to cover additional and new clinical software vendors and new radiation therapy treatment machines and treatment planning systems. Within the scope of SA3:

- The EcCk system was enhanced to support the satellite hospitals by integrating the multiple database systems used by each satellite hospital.

- Algorithms were developed to process patient documents in Microsoft word files in docx format to support automated checks of patient documents and to support different patients' documentation formats from different hospitals.
- Algorithms were developed to process patient documents in PDF format using OCR to support checks of patient treatment plan documents for UCLA.
- A software tool, a chart checking timer, was developed with clinical database integration to support quantitative measurement of improvements of working efficiency by using the automated chart check programs. The tool was then used to compare the medical physicist work efficiency between using and not using the semi-automated chart checking tools.
- New EcCk rules were developed to support the new collaboration site – Provision Proton Center at Knoxville, TN, for proton treatments, and for UCLA.
- The treatment management system was updated from MOSIAQ to ARIA in cloud at the PI's department. The EcCk system was updated to support the new ARIA in cloud.
- Most of the EcCk prototype features and functions, implemented and tested in MATLAB, have been ported to the new ARIA and Eclipse API and re-implemented into C# to obtain better user interface and tighter integration with ARIA and Eclipse.

4.3 Data Sources/Collection

Patient's data and documents analyzed for error detection were directly obtained from the clinical computer systems–treatment management systems ARIA and MOSAIQ, treatment management systems PINNACLE and ECLIPSE, and WUSTL in-house radiation oncology workflow management system DosBoard. Data collection and analysis were performed as per institutional IRB approval.

The queried and analyzed patient data and documents are patient ID (ID only, no other PHI), patient treatment planning data, prescription (site name, PTV name, total dose, number of fraction, dose per fraction), radiation beam parameters (beam MU, gantry, collimator, field sizes, MLC leaf positions, number of segments, number of beams, energy, machine, beam type, bolus, wedge), patient setup parameters (orientation, accessory devices), data in the department MD order database, patient setup parameters (patient orientation, use of treatment accessories), PTV (name, margin, sequential or concurrent boost), daily setup beam requirements (schedule of daily and weekly cone beam CT, 2D portal images), treatment plan PDF document, treatment schedule, treatment history records (dates, treatment machine and beam parameters, manual overrides), quality assurance document (status of pass or fail, and dates), chart checking history (who and when), and flags of data approval and overrides (who, when, and what are approved and overridden).

4.4 Interventions

This study is a retrospective patient chart checking tool development study. During this study, patients' data, documents, and images were retrospectively analyzed after the patients' treatments have been concluded for supporting the software tool development tasks. The errors found during the retrospective analysis were not be used back to support patient clinical treatment decision and did not affect or change the patient treatment plan and treatment course.

Results of this study, for example, the rules to automatically check the patients' chart, were latterly implemented in the clinical physics software tools that were used in the clinical workflow as secondary physics tools.

4.5 Measures

The results of software tool implementations were measured on whether the designed features and functions were implemented correctly and complementation, for example, whether the previously independent multiple software programs were integrated into a single EcCk packages as designed in SA1, and whether EcCk automation was implemented to carry out the patient chart checking tasks automatically or semi-automatically, as designed.

The results of the developed novel error detection algorithms were measured qualitatively and scientifically. For example, the error detection sensitivity and specificity of the Bayesian network-based error detection algorithm (Chang and Yang, Development and validation of a Bayesian network method to detect external beam radiation therapy physician order errors, International Journal of Radiation Oncology*Biology*Physics, 2019) were quantitatively evaluated on both true and simulation errors. Similarity, other novel algorithms developed by R01 were also quantitively evaluated but in their own different ways.

4.6 Limitations

Not all errors in the radiation treatment patient treatments could be detected automatically. The scope of automated error detection is limited by a few important factors:

- Limited by the accessibility of the patients' chart and data. Patients' data and documents within the radiation oncology department computer systems are relatively accessible, because the radiation oncology departments are very well computerized. Additional patient data, for example, the patients' chemotherapy treatment schedule and treatment prescription, are available not in the RO computer systems but in the hospital EMR system. Inaccessibility to such critical patient prescription and schedule data limits the accuracy for detecting radiation therapy prescription errors, because RT and chemotherapy prescriptions are often interdependent.
- Limited by the readability of patients' data and documents. Patient's data and documents are often unreadable, for example, the optic scanned PDF documents. Many readable data and documents are not structured, and the data elements could be reliably read then processed by current computer programs and algorithms.
- Limited by the intelligence of the software implementation and the error detection algorithms. The simple errors, for example, the inconsistencies of a same data elements at different data tables in the database, could be easily detected based on pre-defined rules. The advanced errors, for example, the inconsistencies of the treatment prescription of a patient, compared to the previous similar patients' prescriptions, are much more difficult to detect due to the variety and diversity of the errors and could be detected by simple rules.

Not all radiation therapy (RT) treatment planning systems (TPS) are supported. This study only supports the Varian Eclipse TPS and Phillips PINNACLE TPS, because the PI's department has only these two TPS systems. Though these two major systems cover >90% of all RO departments, newer and specialized TPS systems (e.g., TomoTherapy, RaySearch, CyberKnife) are not supported. However, the principle of the automated chart checking software tools and the error detection algorithms are all applicable to the uncovered TPS systems.

Not all RT treatment modalities are supported. This study focuses on external beam treatments, which accounts for >80% of all RT cancer patients. Other RT treatment modalities (e.g., brachytherapy, GammKnife, TomoTherapy, proton therapy, and radiopharmaceuticals) are not currently supported. However, the principle of the automated chart checking software tools and the error detection algorithms are very applicable to the supported RT treatment modalities.

5 Results

5.1 Principal Findings

- It is practical to develop and implement the automated and semi-automated electronic chart check software tools for the modern radiation oncology departments.
- The chart checking software tools can effectively detect simple errors, inconsistencies, and issues based on pre-defined rules.
- The automated electronic chart check software tools and algorithms are evidently useful in the clinical workflow in the RO departments. They could indirectly improve the work efficiencies by the medical physicists and radiation therapy dosimetrist. They might be useful to indirectly reduce the overall cost of patient care by improving the worker's efficiency.
- The software tools, based on data, documentation and image processing algorithms, and pre-defined common rules could be adapted to support different clinical computer and database systems and combinations and to support radiation oncology of large or smaller scales.

- Novel machine learning algorithms could be developed and applied for detecting advanced errors after the machine learning models are trained using a relatively large amount of patient data. Such machine learning-based algorithms are powerful for processing high-dimensional data (e.g., the image data) that the conventional rule-based error detection algorithms cannot handle.

5.2 Outcomes

Outcomes of this R01 are 1) the implemented and enhanced patients' chart checking tools that were prototyped and then clinically deployed (please see the specific accomplishments in 4.2.1 to 4.2.3), 2) the novel image and data processing algorithms to detect certain types of advanced errors that could not be detected based on simple rules, and 3) common applicable tools and procedures for processing data and document.

5.3 Discussion

Clinical computation infrastructures keep changing. At the PI's department, the treatment management system, which was the main source of patient data and documents, was updated from MOSAIQ to the cloud-based ARIA. All data tables and documents were changed accordingly. The clinical workflow was also changed significantly. The EcCk prototype had to be updated to support the new database and documents. Many previously implemented EcCk rules and features were not applicable anymore. However, the principle, the pre-defined rules (not the implementation of the rules), and the novel machine learning algorithms, data/image/document processing algorithm were still very applicable.

Our EcCk tools do very well for detecting simple errors/inconsistencies/issues based on pre-defined rules. However, detecting errors based on manually defined rules is limited. First, the rules are depended on the clinical workflow and department-specific requirements; therefore, they are not always applicable to different institutions, because the clinical workflows are very heterogeneous across the nation. To support different institutions, the rules need to be reviewed, revised, and then re-implemented in the software tools. We developed the rule specifications. Our rules were defined in XML files and therefore could easily modified to support new institutions. However, the PI had to be involved to transcribe the department-specific workflow requirements into the rules definition in the XML configuration files. In the future, it may be possible to modify the clinical workflow to allow more automated patient chart checking. In fact, many clinical workflow steps need to be upgraded to suit the updated clinical computer systems and the increasing integration of patient data and documents in electronic formats.

It is still difficult to automatically check the patients' documents. Both the Microsoft word file format and PDF file format are commonly used in the clinic, and either format is suitable for automated documentation processing, data extraction, and data checking. In the future, the clinical Word documents should be redesigned so that the files can be easily converted and parsed by computer programs. PDF files are generated by different clinical computers from different vendors to be the read-only patient records. In the future work, vendors should consider inclusion of the patients' data elements and data dictionaries in the PDF file header, so that the data could be readily processed by other computer programs to extract and check the embedded data elements. Machine learning and deep learning methods could also be useful for extracting information from patients' documents.

The whole healthcare industry is moving toward the machine learning and AI direction. Machine learning approaches are very suitable for detecting the advanced errors that were currently impossible for rule-based checks to detect, for example, to automatically evaluate the patients' plan quality against the population average of similar cases. In years 4 and 5, we have been working extensively on developing knowledge-based novel algorithms, including machine learning and deep-learning algorithms, to detect advanced errors and issues, for example, organ labeling issues and plan quality issues. Even though we had successfully published papers for the new machine learning error detection algorithms, our results were rather sporadic and were only enough to cover a few advanced errors, for example, prescription errors. In the future, a more complete study is required to systematically investigate using machine learning methods for detecting advanced errors in RT. A unified machine learning solution might be required to integrate the conventional machine learning methods (e.g., Bayesian network, decision trees, association rules) and deep-learning methods (suitable for processing large amount of data and image data) so that the error detection results could be comprehensive and human understandable.

5.4 Conclusions

A software package and novel error detection algorithms were developed in this study to check errors in radiation therapy patients' charts automatically and comprehensively. These software programs and algorithms were clinically tested and evaluated at larger and smaller RT departments. They could automatically detect ~60% of clinical errors, assist in manual error detection of the remaining 40% errors, and potentially prevent the most severe errors in real time. They could significantly improve patient safety and quality control, especially at smaller RT departments with fewer human experts.

5.5 Significance and implications

The significance of this study is to demonstrate that automated patient chart check software tools can be developed and clinically deployed to aid human workers for automatic detection of potential errors, important inconsistencies, and potential issues. This study has also demonstrated that such computerized chart checking approach could be adopted by different RT departments of large or small scales. Computer software tools are suitable and effective for error detection, because most patients' data, documents, and images are always in the computer systems. In comparison, human workers might not be well suited for the repetitive error detection tasks.

The main implication of the automated error detection software tools is to improve patient safety via improving the error detection accuracy and efficiency and, therefore, reducing the errors passing through the quality assurance steps in the clinical workflow. The secondary implication is the potential for improving RT workers' efficiency and the potential of reducing overall cost of patient care because of the improved RT worker efficiency.

This study does not imply that the human RT workers could be entirely released from the manual error detection/quality assurance tasks, though. In fact, this study has confirmed the computerized error detection is suitable for detecting simple errors, for example, the inconsistencies of the same data element at different places of the database. The advanced errors that require human workers to comprehensively apply the clinical knowledge and to connect many different components of the patient's data and clinical considerations are very difficult to automatically detect. Therefore, the computerized error detection should be applied to help human workers on the simple tasks and allow the human workers to focus on advanced tasks.

6 List of Publications and Products

6.1 Bibliography of Published Works

6.1.1 Peer-reviewed journal manuscripts published and directly supported by this R01

1. Deshan Yang*, H. Omar Wooten, Olga Green, Harold H. Li, Shi Liu, Xiaoling Li, Vivian Rodriguez, Sasa Mutic, Rojano Kashani, *A software tool to automatically assure and report daily treatment deliveries by a Cobalt-60 radiation therapy device*, Journal of Applied Clinical Medical Physics, 17(3), May 2016, page 492-501, https://doi.org/10.1120/jacmp.v17i3.6001
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6.1.2 Peer-reviewed journal manuscripts, contributed by this R01

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28. Wang, Yuhe; Mazur, Thomas; Park, Justin; Yang, Deshan; Mutic, Sasa; Li, H Harold, *Development of a fast Monte Carlo dose calculation system for online adaptive radiation therapy quality assurance*, accepted by Phys. Med. Biol., 04/2017

6.2 Conference abstracts

The main topics of the studies supported by this R01 grant are patient safety, software tool development, quality assurance, and clinical error detection. Many results were shared to the medical physics and radiation oncology audiences in the national annual conferences. A large number of oral presentations and conference abstracts was generated, as listed below by years and by conference meetings.

6.2.1 AAPM (American Association of Physics in Medicine) 2015 annual meeting

29. Shi Liu, Jingnan Mao, Harold Li, Sasa Mutic, Deshan Yang, *A Retrospective Statistical Analysis of Consistencies in Treatment Plan Parameters by the Treatment Site and Modality*, oral presentation
30. Xiao Chang, Deshan Yang, *An Automated Physics Weekly Chart Checking System Supporting ARIA*, snap oral presentation
31. Xiao Chang, Deshan Yang, *Automatic Recognition of Patient Treatment Site in Portal Images Using Machine Learning*, electronic campus poster discussion
32. Jianfeng Qiu, Deshan Yang, *Automatically Detect Patient Treatment Position and Orientation in KV Portal Images*
33. Jianfeng Qiu, Harold Li, Tiezhi Zhang, Fangfang Ma, Deshan Yang, *Automatic Image Contrast*

Enhancement Based On Automatic Parameter Optimization for Radiation Therapy Setup Verification

34. Deshan Yang, Yu Wu, Guangrong He, Xiao Chang, Lindsey Olsen, Sasa Mutic, *Comprehensive Plan Integrity and Quality Check by Accessing Eclipse Planning Data Remotely Via a Novel Eclipse-API Client-Server Interface*
35. Shi Liu, Harold Omar Wooten, Yu Wu, Deshan Yang, *Prediction of the ViewRay Radiotherapy Treatment Time for Clinical Logistics*

6.2.2 AAPM (American Association of Physics in Medicine) 2016 annual meeting

36. Deshan Yang*, H Gach , H Li , S Mutic, *An Effective Homomorphic Unsharp Mask Filtering Method to Correct Intensity Inhomogeneity in Daily Treatment MR Images*, oral presentation
37. S Liu, Y Wu , X Chang , H Li , Deshan Yang*, *Automatic Pre-Delivery Verification Using Statistical Analysis of Consistencies in Treatment Plan Parameters by the Treatment Site and Modality*, oral presentation
38. X Chang, T Mazur , Deshan Yang*, *Treatment Site and View Recognition in X-Ray Images with Hierarchical Multiclass Recognition Models*, oral presentation
39. X Chang, A Kalet, S Liu, Deshan Yang*, *A Unified Machine-Learning Based Probabilistic Model for Automated Anomaly Detection in the Treatment Plan Data*, oral presentation
40. Rapeepan Maitree, G Guzman , A Chundury , M Roach , Deshan Yang*, *Maximal Noise Reduction Filter with Anatomical Structures Preservation*, snap oral presentation
41. S Liu, T Mazur, H Li, O Green, B Sun, S Mutic, Deshan Yang*, *A Correlation Study On 3D Fluence-Based QA and 2D Dose Measurement-Based QA*
42. Rapeepan Maitree, A Curcuru, H Gach, Deshan Yang*, *An Approach to Estimate Noise in Patient Image by Computing the Minimal Difference in Neighborhoods*

6.2.3 AAPM MRV Chapter meeting 2016 spring

43. Deshan Yang, *a method to compute and apply 3D fluence for VMAT treatment delivery Verification*, oral presentation
44. Xiao Chang, Deshan Yang, *Radiotherapy plan anomaly detection with machine learning methods*, oral presentation

6.2.4 AAPM (American Association of Physics in Medicine) 2017 annual meeting

45. Shi Liu, Thomas Mazur, Yabo Fu, Harold Li, Sasa Mutic, Deshan Yang*, *A Method to Evaluate Dosimetric Effects on Organs-At-Risk for Treatment Delivery Systematic Uncertainties*, oral presentation
46. Shi Liu, Yabo Fu, Thomas Mazur, Harold Li, Deshan Yang*, *Knowledge-Based Automatic Pre-Delivery Plan Verification Using Isolation Forest*, oral presentation
47. Xiao Chang, Harold Li, Alan Kalet, Deshan Yang*, *A Method to Detect Radiation Therapy Physician Order Errors Using Bayesian Networks*, oral presentation
48. Yabo Fu, Shi Liu, H. Harold Li, Deshan Yang*, *Adaptive Direction-Dependent Regularization for CT Abdomen Deformable Image Registration*, oral presentation
49. Yabo Fu, Shi Liu, H. Harold Li, Deshan Yang*, *Hierarchical Atlas-Based Segmentation of the Human Skeleton in CT Images*, oral presentation
50. Deshan Yang*, Yabo Fu, Harold Li, Ye Duan, *A Method to Automatically and Accurately Generate Large Number of Ground Truth Landmark Points to Verify Deformable Image Registration on Abdominal 4DCT Images*
51. Xiao Chang, Harold Li, Deshan Yang, *Learning Knowledge of Radiation Therapy Treatment Plans Using Decision Tree*

6.2.5 ASTRO (American Society for Radiation Oncology) 2017 annual meeting

52. Xiao Chang, Harold Li, Alan Kalet, **Deshan Yang***, *Detect external beam radiation therapy physician order errors using machine learning*, **oral presentation**

6.2.6 AAPM 2018 Conference

53. Xiao Chang, H. Harold Li, Yabo Fu, Baozhou Sun, Deshan Yang*, A Method to Detect Errors in Radiation Therapy Physician Orders Using Association Rules, oral presentation.

54. Deshan Yang, Yabo Fu, Xiao Chang, H. Harold Li, A Method to Improve Landmark Pair Positional Accuracy for Image Registration Verification, snap oral presentation.
55. Yabo Fu, H. Harold Li, Deshan Yang*, A Preliminary Study on Convolutional Neural Networks for 4D-CT Lung Deformable Image Registration, oral presentation.
56. Dao Lam, Thomas Dvergsten, Tianyu Zhao, Deshan Yang, Sasa Mutic, Baozhou Sun, A Stacking Method for Predicting Patient QA Passing Rates Using Machine Learning, oral presentation.
57. Yabo Fu, Thomas Mazur, Shi Liu, Xiao Chang, Yonggang Lu, H. Harold Li, Parag Parikh, Deshan Yang*, Automatic Segmentation of Multiple Organs from ViewRay MR Images Using Deep Densely Connected CNN for MRI Guided Adaptive Radiotherapy, oral presentation.
58. S Liu, P Dubrowski , Y Fu , Deshan Yang, Y Yang , A Yu, Improving Patient Positioning Reproducibility During Head and Neck Re-Simulation for Re-Treatment Using a Surface Mapping System.
59. Deshan Yang, Experimental and Computational Dosimetry for MRgRT - Online Adaptive MRgRT Dosimetry and Dose Accumulation, oral presentation.

6.2.7 ASTRO 2018 Conference

60. Xiao Chang, Harold Li, Yabo Fu, Deshan Yang*, Knowledge-Based Error Detection in External Beam Physician Orders Using Association Rules, oral presentation

6.2.8 AAPM 2019 Conference

61. Yabo Fu, Xue Wu, Harold Li, Deshan Yang*, Accurate Landmark Pairs Detection for 4DCT Lung Deformable Image Registration Verification, oral presentation
62. Xue Wu, Allan Thomas, Jeffrey Williamson, Deshan Yang*, Deformable Registration of Uterus and Upper Vagina Wall Using Gaussian Mixture Model (GMM) Plus Finite Element Model (FEM) and Dose Gradient-Based Evaluation for Supporting GYN HDR Brachytherapy Dose, oral presentation
63. Allan Thomas, Yonggang Lu, Parag Parikh, Deshan Yang*, Evaluation of Surface-Based DIR Accuracy Using Digital Phantom Simulations and a Customized Physical Phantom for MR-Guided Plan Adaptation, oral presentation
64. Yabo Fu, Harold Li, Deshan Yang*, High Quality Digitally Reconstructed Radiographs Generation From Low Resolution CT Images Using Super Resolution CNN, oral presentation
65. Deshan Yang*, Yabo Fu, Xue Wu, Harold Li, Improve Deformable Imaging Registration Accuracy Using Pulmonary Vascular Extraction for Lung CT Images, oral presentation
66. Allan Thomas, Yabo Fu, Parag Parikh, Deshan Yang*, *Plan Metric and 3D Dose Prediction for Improved Online Adaptive Decisions in MR-Guided Radiation Therapy*, oral presentation

6.3 Electronic Resources

None

6.4 Products

- EcCk– the main physics chart checking tool. It is our main platform for developing, testing and evaluating new chart checking functions and new algorithms. As a product, it supports automatic and semi-automatic new start check, weekly checks and other automated chart checking features, and serves a central hub to access all other physics quality assurance software tools and workflow tools.
- VRART – the Viewray-specific version of EcCk. It was designed for checking Viewray MRI-RT treatment plans that are very different from the conventional RT plans prepared by the common Eclipse or PINNACLE TPS systems. This tool is critical for expediting physics quality assurance efforts in the online, MRI-guided treatment adaptation sessions [9]. This tool was officially licensed to Viewray, Inc., and then was supplied by Viewray to all other Viewray installation sites.
- Software library to access and process data from Pinnacle TPS server (copyrighted)
- Quality assurance and plan veto software tool (copyrighted)