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Workflow and Clinical Decision Support for Radiation Oncology

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1. Introduction

Radiation oncology involves a complex set of processes and accompanying workflow to evaluate, plan, deliver, and monitor patient treatments. The workflow includes a mixture of process steps requiring clinical decisions at many points, quality assurance checks along the way, on-line and off-line evaluations, and careful patient monitoring. Computerized decision support is a vital component to a number of these processes, providing computational services and evaluation tools for decision alternatives.

In this chapter an overview of the current processes and decisions typically required for radiation oncology patient management will be presented. A description of recent "Lean Thinking" approaches to improve efficiencies in these processes with the primary goal to improve patient care and staff satisfaction will be presented. Finally we present future treatment scenarios that may lead to improved treatments and discuss resulting new requirements for the management and clinical decision support in radiation oncology.

2. Radiation oncology

Radiation oncology is one of the major treatment techniques for the management of malignant tumors (cancer). Radiation therapy is typically used to treat deep-seated, well-localized (focal) regions where high-energy radiation can be concentrated. The radiation used causes ionization within the tissue exposed and this ionization leads to DNA single and double strand breaks which can destroy a cell's ability to undergo mitosis (grow). Concentrating the radiation at target areas and reducing the volume irradiated outside of the target provides the therapeutic advantages that radiation oncology uses to treat cancer.

Decisions regarding treatment of a patient's cancer typically begins with a referral based on diagnostic evidence. Within larger institution, this decision is made within the context of a tumor review board (organized by disease site) at which the patient's case is presented, reviewed, and choices of treatment (including not only radiation but other treatment options including surgery and chemotherapy) are discussed. The various treatment options have their own advantages and disadvantages. It is not unusual for radiation treatments to be preceded by surgery to remove easily extracted parts of a tumor. Nor is it unusual for radiation therapy to be combined with chemotherapy that can treat regions where tumor cells are more disseminated (spread out). In the review board setting, a patient's case is usually screened for possible inclusion into a clinical trial if appropriate.

Patients who are referred to radiation oncology can expect an initial evaluation exam (consult) followed by general decisions about an appropriate treatment course with the possibility of accepting the option of participating in a clinical trial.

2.1 Simulation and contouring

Assuming the treatment decisions includes external beam radiation therapy, as is most often the case, the patient will be scheduled for "simulation" involving a series of steps including design of custom immobilization to insure stable and reproducible positioning of the patient (typically treated on a flat couch) followed by acquisition of volumetric imaging studies that are used to precisely define target volumes, to be treated, and critical neighboring anatomy, to be avoided.

Often a patient will have multiple imaging studies requested including computerized tomography (CT), magnetic resonance imaging (MRI), and/or positron emission tomography (PET - Nuclear Medicince (NM)) used to build the patient model (Fig. 1).(Kessler 2006)

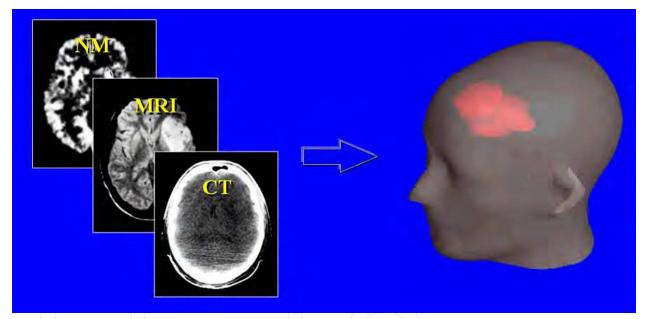


Fig. 1. Multiple modality volumetric images are often used to build a geometrical model of the patient

These studies often provide complementary information that can be useful for radiation treatment planning. The different imaging studies require different equipment, different personnel, different imaging procedures or protocols and have separate scheduling demands. Once imaging studies are completed, additional steps are needed for the cases with multiple imaging studies in that they need to be geometrically registered to each other so that the derived information can be consolidated into a self-consistent picture of the patient. Although the image registration process uses automated techniques, there is still a need to visually inspect the results to insure that they are consistent with expectations (i.e. registrations are not always perfect.)

Throughout these various workflow steps, there are variety of points where there are clinically-based decisions to be made and ultimately, it is the responsible physician who

needs to approve the overall results prior to the next step of treatment planning (designing beam arrangements).

Following image acquisition and registration, the next steps are to generate volumetric definitions of the target and surrounding anatomical features. In some cases these regions can be generated via automated segmentation algorithms. Automated segmentation is often based on trying to identify connected edges which are closely matched to the underlying image data based on absolute image values and image value gradients. Difficulties with this approach occur when the neighboring tissues vary significantly around the periphery of the desired region. The use of standard anatomical models provides some promise for automating segmentation of more of the anatomical features; but a fundamental problem is that cancer by its nature tends to create abnormal distortions which are difficult to account for.

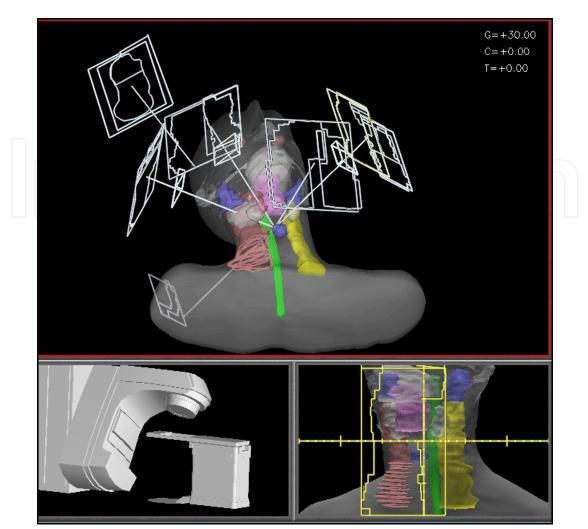
Some manually delineated drawing and editing is still the norm for completing the identification of key volumes. Part of the reason is the failure of even the most robust segmentation algorithms to achieve reasonable segmentation for many cases. In addition, manual volume segmentation is needed to define regions such as the clinical target volume (CTV) which includes not only the contrast enhanced regions visible on cross-sectional imaging (the gross target volume (GTV)) but also includes suspected tumor burden at a microscopic level (not detectable with current imaging techniques) at the periphery of the GTV. Once the CTV is defined, then this volume is typically further expanded to generate a planning target volume (PTV) which accounts for setup and motion uncertainties.

Efforts towards adding computer-assisted support to aid in the process of defining the CTV have been undertaken by a number of researchers. A recent effort by Kalet, et al. 2009(Kalet, Mejino et al. 2009), uses content from a large scale anatomy ontology (Foundational Model of Anatomy(FMA)) to look at identifying and mapping the lymphatic system close to the region of a given tumor. The lymphatic system is a preferred avenue for cancer cells to spread and the primary terminating lymph nodes closes to the tumor are candidates for inclusion in the volume to be treated. Unfortunately, from this study, the completeness and consistency of the FMA knowledge model was found to be an issue. Nevertheless, this study points to techniques that can be employed (in the future) to further assist clinicians.

2.2 Treatment planning

The most prevalent type of radiation therapy is the use of external beam treatments involving the design of a number of directed external beams of high-energy x-rays or particles. Typically a treatment involves radiation exposures delivered sequentially from a pre-defined set of directions all of which are aimed at the target but are otherwise separated to reduce radiation to non-involved tissue. Computer graphics play an important component in the treatment planning design. A beam's eye view (BEV) graphics is shown in Figure 2 showing the view of the anatomy from the perspective of the radiation source (in the head of the gantry). The BEV graphics assists in the shaping to the target and avoidance of normal critical structures. (McShan, Fraass et al. 1990)

Estimation of the expected radiation dose (absorbed energy) requires extensive computer calculations on a volumetric grid. The next step in planning is to then evaluate those results. Figure 3 and 4 provide examples of some of the graphical presentations used for dose evaluation. (Kessler, Ten Haken et al. 1994)



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Fig. 2. External beam design for neck (parotid) treatment. Lower left is treatment machine model position for one of the treatment fields. Lower right shows the beam's eye view projection of target and field shaping.

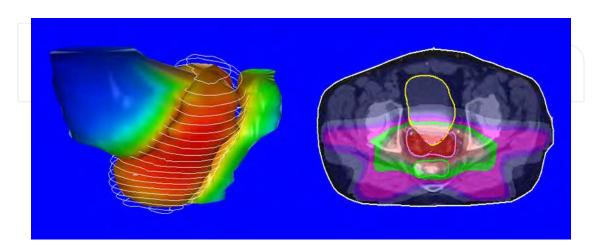


Fig. 3. Dose evaluation graphics for conformal prostate. Left image shows bladder and rectum with color wash representation of dose along with isodose contours surrounding the prostate target volume. Right image shows color wash dose overlaying a single axial slice.

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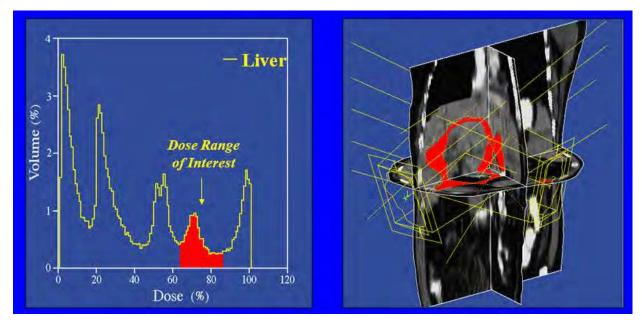


Fig. 4. Dose volume histogram analysis (with dose range highlighted)

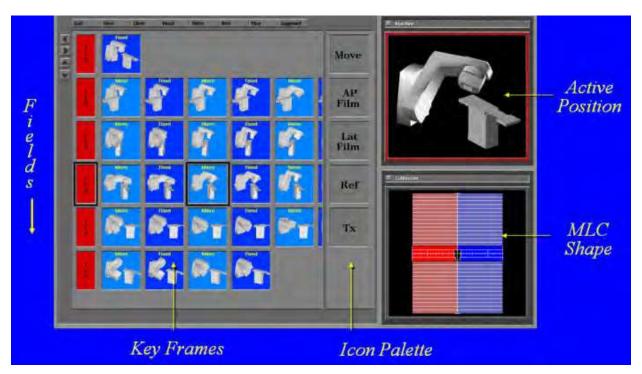
Evaluating the achieved planned dose distribution is a key decision step resulting in physician approval prior to treatment. Despite upfront specification of various treatment planning goals, numerous factors and trade-offs are involved that are not easily quantified or assessed requiring the physician to use his or her judgment and experience by reviewing the dose distributions and the relative shapes of dose volume curves. Ideally, of course, this would not be the case since a decision rejecting the proposed plan can require significant rework based on new previously unstated "goals".

Computer assisted treatment planning is often an iterative process with the dosimetrist responsible for the treatment planning making changes interactively to the beam design to improve the resulting dose distribution. With modern intensity modulation delivery techniques, computerized optimization can be used to design "optimal" treatments based on analytical planning goals. In practice, though, the planning is not fully optimized and there are numerous steps and decisions involved in setting up beam arrangements and even iterating on priorities and goal requirements to achieve an acceptable treatment plan.

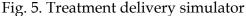
2.3 Treatment delivery

Once a treatment plan is approved, then the next steps in the process require that the data be transferred from the treatment planning system to the treatment machine. In some cases where new or particularly complicated treatments are being proposed, it is necessary to interject quality assurance steps where the treatment plan is delivered to a test phantom with dose measurement devices. The measured data then needs to be analyzed and compared to dose estimations from the treatment planning system (calculated using the same geometry) and the comparison approved prior to treatment.

Another step in treatment preparation can be treatment delivery simulation. As treatment machines become more sophisticated and treatment planning becomes more clever, it is possible to design a plan requiring complicated motions. There are issues of not having the machine collide with itself or worse with the patient (as shown in Figure 5). A delivery simulation step can facilitate the sequence of delivery and interject non-treatment "moves" as necessary for safety.(Kessler, McShan et al. 1995)



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Individual radiation therapy treatments themselves also require several workflow steps. Radiation patients are frequently treated on an out-patient basis which means they need to show up on schedule and the radiation therapist needs to be notified to prep the patient. For the treatment, the patient is placed on the treatment table using the same immobilization device created during simulation. The patient is moved to the approximate treatment position using laser guided adjustments. Typically orthogonal portal images (diagnostic x-rays) or cone-beam CT volumes are taken to assess the patient position against a computer generated version using the planning CT volumes. Generally small adjustments to the patient position are made automatically. Alternatively, small markers implanted directly in the tumor can be used to provide more direct positioning information. (Often tumors themselves are not detectable from typical planar x-ray imaging.)

The actual treatments then involve moving the treatment machine (gantry) to the starting beam angle and then proceeding through the succeeding beams usually without manual interruption. Typical treatment times range from 5-10 minutes for simple cases to over 30 minutes for more complex treatments.

Typically radiation treatments are delivered in fractions (a fraction being one complete delivery of all beams) and fractions are repeated for 30 or more days, usually treated 5-6 times per week. Because of the repeated treatment sessions, there are number of factors which affect the quality of the treatment. Because the patient's setup is repeated for each fraction, there are unavoidable geometrical errors. These are usually inconsequential since the targeted PTV accounts for this possibility. Normal respiratory and cardiac motions also affect the actual dose delivered. For some patients, respiratory gating is used to reduce these effects.

While these issues can generally be managed, the patient can lose weight over the weeks of treatment, their tumor may progress or shrink, and any number of other changes may affect the treatment given. In these circumstances, the patient's situation needs to be reassessed and parts of the entire simulation, planning processes are repeated (as illustrated in Fig. 6) to define a new treatment design suitable for the balance of the desired treatment.

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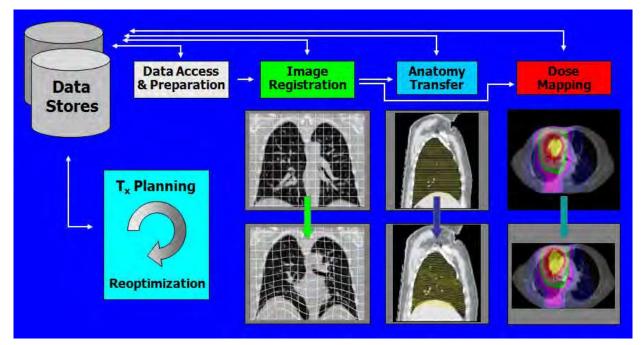


Fig. 6. Treatment modifications typically require new imaging, deformable registration, and propagation of dose which will be used in designing the balance of the treatment.

3. Lean thinking process improvements

The various processes involved in acquiring and preparing data needed for planning and the associated approvals prior to treatment involves a team of people including the attending physician, residents, nursing staff, clerical staff, dosimetrist who do the bulk of the treatment plan design work, physicist for expertise on radiation accuracy and safety, and radiation therapist who control the actual treatment delivery processes. For such a complex intertwining of personnel and processes, it is unavoidable to have inefficiencies that most often arise due to incomplete data or underspecified requirements leading to extra reworking steps. At the University of Michigan, our department has adopted "Lean Thinking" (Womack and Jones 2003) as a consistent approach to quality and process improvement. We have applied the principles and tools of Lean Thinking, especially value as defined by the customer, value stream mapping of our processes, and then with the desire to have one piece flow (i.e. no waiting) make improvements to the workflow processes associated with delivering care to our patients.

Using the lean approach, teams of representatives from our various personnel groups have been formed to first outline the current state value stream map (CS VSM) for selected parts of our processes. (Rother and Shick 2003)A CS VSM is a detailed flowchart that reveals all the actions and processes required to deliver a service to a customer (example in Figure 7).

The CS VSM allows the identification of points in our process where there are large wait times. This activity is then followed by the creation of a future state value stream map (FS VSM) based on the elimination (or minimization) of these no value wastes. Our use of lean techniques has resulted in demonstrable improvements in the management of our patients in our department improving the timeliness of treatments and improving staff efficiencies.(Kim, Hayman et al. 2007)

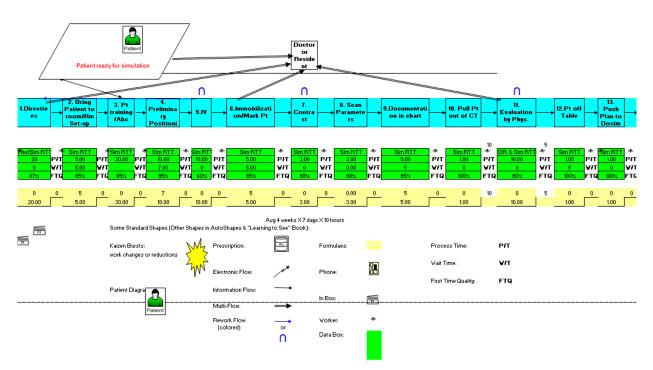


Fig. 7. Partial current State value stream map

Among the improvements in process efficiencies has been the development of planning directives where details about the data required for planning a patient's treatment are itemized. These directives are distinguished by body site, tumor type, and protocol. The directives specify what image acquisitions are needed and specify the subsequent use of this data to delineate anatomical and targeted regions. The directives also specify desired planning goals including treatment type and dose constraints for critical structures and desired target doses to be achieved. As these are generally competing requirements, a prioritization of these goals is also specified. An example directive is shown in Figure 8. To date, these directives have been implemented on paper as a set of guidelines. The physician will make patient specific changes to these guidelines before signing off on a patient's directive. These treatment plan directives describe a standard path for each type of case in the belief that standard work leads to fewer quality problems, less rework, better attention to patient needs, more effective communication, and more efficient use of

resources. The standard planning patterns represent a clinical consensus for each type of case. The directives lead to better-documented decisions and instructions, and more easily allow specification of non-standard instructions.

4. Future workflow

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Surprisingly much of the Lean Thinking improvements have not, to date, required additional technology beyond a bit of paper (directives) and consensus building to understand the processes flow and when they don't. Nevertheless, it is expected that more technology will be introduced in a world that is already extensively technology based. Complex computerized machines are used for imaging, planning and delivery for radiation therapy. The information that is currently communicated is detailed but not necessarily complete in terms of understanding the overall picture of the process flow.

Workflow and Clinical Decision Support for Radiation Oncology

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Target Goals: PTV(s) PTV(s) +/- 5% Min to 1% of target = 99% of prescription dose or Max +7% or Dose Prescription: Sequential Plans - 2.5/fx, 2.0/fx, 1.8/fx or GTV 70 Gy or Gy GTV 70 Gy/2.0 fx or Gy GTV GTV 70 Gy or Gy CTV1 63 Gy/1.8 fx or Gy GTV 70 Gy/2.0 fx or Gy fx CTV1 60 Gy or Gy CTV2 59 Gy/1.7 fx or Gy fx Other Gy CTV2 59 Gy/1.7 fx or Gy fx Plan Parameters: Beam Energy: 6x 16x 6 MV (IMRT) As planning dictates Density Correction: On or 0 or 0 0 0			
PTV(s) +/- 5% Min to 1% of target = 99% of prescription dose or Dose Prescription: Max +7% or Sequential Plans - 2.5/fx, 2.0/fx, 1.8/fx or Single plan, differentially dosed targets GTV 70 Gy or Gy CTV1 60 Gy or Gy CTV2 50 Gy or Gy Other Gy CTV2 Other Gy Gy fx Plan Parameters: 6 MV (IMRT) As planning dictates Density Correction: On or		Max	<40Gy
Imax +7% or Dose Prescription: Sequential Plans - 2.5/fx, 2.0/fx, 1.8/fx or GTV 70 Gy/2.0fx or GTV 60 Gy or GY CTV1 63 Gy/1.8fx or GY CTV2 59 Gy/1.7fx or GY Other Gy Fx Other Gy Beam Energy: 6x Density Correction: On or		to 1% of target = 99	9% of prescription dose or
Sequential Plans - 2.5/fx, 2.0/fx, 1.8/fx or Single plan, differentially dosed targets GTV 70 Gy or Gy GTV 70 Gy/2.0 fx or Gy CTV1 60 Gy or Gy CTV2 50 Gy or Gy Other Gy Gy fx Plan Parameters: 6x 16x Beam Energy: 6x 16x Density Correction: On or	Max		
GTV 70 Gy or Gy GTV 70 Gy/2.0 fx or Gy fx CTV1 60 Gy or Gy GY CTV1 63 Gy/1.8 fx or Gy fx CTV2 50 Gy or Gy Gy CTV2 59 Gy/1.7 fx or Gy fx Other Gy Other Gy fx Gy fx Plan Parameters: Beam Energy: 6 x 16 x 6 MV (IMRT) As planning dictates Density Correction: On or On or Grupped for the set of			
CTV1 60 Gy or CTV2 Gy Gy Gy CTV1 63 Gy/1.8 fx or CTV2 Gy Sy fx Other Gy CTV2 59 Gy/1.7 fx or Gy Gy fx Plan Parameters: Beam Energy: 6 x 16 x 6 MV (IMRT) As planning dictates Density Correction: On or On or Gy Gy Fx		8/fx or	
CTV2 50 Gy or Gy CTV2 59 Gy/1.7 fx or Gy fx Other Gy Other Gy fx Plan Parameters: Beam Energy: 6x 16x 6 MV (IMRT) As planning dictates Density Correction: On or			
Other Gy fx Plan Parameters: Beam Energy: 6x 16x 6 MV (IMRT) As planning dictates Density Correction: On or On or 0 0			
Beam Energy: Density Correction: On or			
Density Correction: 🔲 On or		_	_
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ix Devices.			
	IX Devices:		land block 🔲 open helds
Considerations: 🔲 Previous tx 🔲 Pacemaker 🗍 Multiple tx sites 🔲 Concurrent chemo	Considerations: Previous tx P	acemaker 🔲 Multi	ple tx sites 🔲 Concurrent chemo

Fig. 8. Treatment planning directive for head and neck treatments

Eliminating paper is currently a big driver to reduce costs and improve process flow in most radiation oncology departments. Current vendor solutions to this problem is to provide databases with a mixture of digital data (images, treatment plan design, radiation dose results, treatment records) as well as document management (digitized images of paper documents). While useful, these do not directly help improve data flow needed to tie together the various processes needed for treatment planning and delivery. Despite the high level of technology used in radiation oncology, there are quite often different vendors for the various components of technology used. Communications from process to process are reduced to using DICOM¹ standards for images, radiotherapy plans, and treatment records communication. Unfortunately even with a standard, often vendors interpretation of the standard are not always consistent. The standards, however, do not include (or is not supported by one or the other vendor) related data needed to establish the context of the data communicated.

¹ Digital Imaging and Communications in Medicine division of NEMA http://medical.nema.org/

For example, from our treatment planning system, we can see that an imaging study is available for a particular patient but without other guidance we sometimes don't know the context of that imaging. A particularly thorny issue is that often multiple imaging series are acquired but one is preferred for any of a number of reasons. This leads to workflow issues when the wrong series is pulled and work is begun or even completed before the error is detected. Eliminating of the planning directive "paper" poses another issue. Simply digitizing the directive completed and signed by the physician does not necessarily lead to more efficient use. What is needed in this case is electronic communication of these directive directions to the various personnel and (electronically) to computerized processes involved in acquiring and preparing patient specific information needed for treatment planning. This also implies that the imaging systems and treatment planning system have defined ways to import the directive information. Unfortunately, standards for directives do not currently exist. However, there commonly are ways to "prime" these systems through specifications of default configuration or template files. The ability to create and invoke data translation services is a key requirement of a computerized workflow solution.

Without paper and charts, it is essential to have a method for reviewing a patient's status, assigning tasks, accepting tasks, completing task. The system needs to provide services for change notification, monitoring, and reporting from the various process tasks. Certainly solutions are being provided (or at least being worked on) by equipment vendors to manage the data and work relevant do the specific vendor equipment related tasks. Unfortunately, as has been mentioned there are variety of equipment being used and rarely is there a single vendor solution. Alternative solutions are, of course, in the works with hospitals gearing up to digitize all of the patient record keeping, scheduling, and task monitoring. It is not clear at this point, though, that the particular needs and quirks of individual radiation oncology departments will be readily addressed by vendor's "one size fits all" solutions.

Towards implementing a more flexible workflow environment, we have undertaken work on using an open-source light-weight workflow and Business Process Management (BPM) Platform (Activiti)² coupled with a number of in-house developed applications to build a workflow system. We are still at the exploration phase, but a small example of what can be anticipated follows.

The small example scenario presented here is that when a course of radiation treatments are completed, it is necessary to notify the physician who then needs to add summary notes for the patient's record. The treatment machine database system (in our case Varian's Aria system³) records the results of the final treatment day, there are, of course, notifications used to start billing processes but no active notification to the physician. The goal of this example project is to add an end of treatment trigger to the Aria database that would then send a message to a workflow engine listener which would (based on workflow model guidance) send a message to the attending physician. Figure 9 shows the graphical process modeling needed to implement this simple workflow. We are implementing a small app to run on a Android cell phone that will receive such messages and allow the physician to view the message and directly dictate notes over their phone.

² Activiti BPM Platform http://www.activiti.org/

³ Varian Medical Systems, Inc. http://www.varian.com/

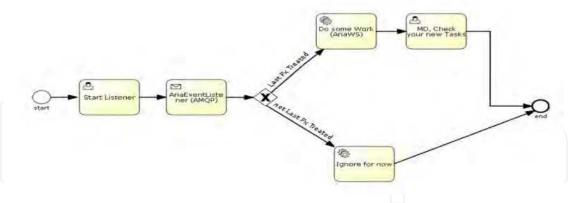


Fig. 9. BPM workflow modeling for signaling end of treatment

5. Future: Adaptive individualized treatments

The rapidly growing understanding of cancer biology and responses to radiation is dramatically impacting the future of cancer treatments. This understanding, for instance, has lead to the introduction of drugs that when combined with radiation can enhance tumor control or reduce normal tissue toxicities. Better understanding of cancer biology has also led to the identification of a number of measurable biomarkers that are indicative or predictive of tumor and normal tissue responses to radiation. The biomarkers may be in the form of lab results or may be from functional imaging techniques. The biomarker information can be used to select between possible sets of planning goals or may be utilized more directly to make patient specific alterations in treatment plans. Furthermore biomarkers, may even provide evidence during the course of treatment suggesting changes to the treatment plan to increase radiation dose to under-responding tumor regions or if well responding, decrease dose to reduce toxicity.

Such adaptive treatment approaches will add additional workflow steps to gather the new biomarker information and then to use that information for planning. In cases when updates of this information are received during a treatment course, then a decision is called for as to whether or not to use that new information to make alterations. That decision may need to be based on an assessment as to the potential gains based on a new treatment design, requiring possibly new imaging and contouring and requiring use of the dose to date propagation techniques illustrated in Figure 6. A decision would, of course, need action levels based on anticipated gains.

Clinical decisions associated with choosing to alter a treatment course, are complex with numerous factors affecting the choice. Evidence provided by biomarkers will have a certain degree of confidence that must be included in those decisions. Also because of the accumulative nature of radiation treatments (dose to date), there is a limit to the amount of alterations that can be effective and that factor also needs to be considered.

Adaptive individualized treatment management seems counter to our earlier described attempts at making the radiation oncology processes lean. It should not be forgotten though that the overall task of treatment plan preparation and design is already centered about conforming to individual patient geometry variations. So, what will be new is adding more biology motivated knowledge to those processes. Fortunately, many of the adaptive tasks can be automated. For instance, contours defined from the original planning scans can be

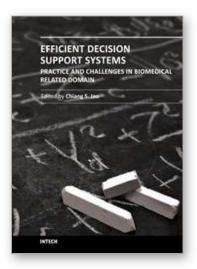
propagated automatically to newer scans based on (deformable) registration and the accumulated doses can be similarly mapped and summed. Treatment beam placements for a new design are likely to follow the original design but will be "tweaked" to achieve the new treatment design. For this support, then the amount of new staff work will be reduce to mainly reviews of the results of the automated process results. It seems clear that computer assisted workflow and decision support will be even more critical in the future to insure that patient management steps are properly scheduled and completed in a timely fashion.

6. Conclusion

This chapter has presented an overview of the workflow and clinical decision needs for radiation oncology. A variety of tasks being carried out by a variety of professional workers are required to plan and manage a patient's course of radiation therapy. Many parts of these tasks require computer assistance for data management, graphical visualization, and calculation services. In terms of overall workflow, a "lean" approach to process mapping and process evaluation has proven valuable towards minimizing wait (waste) times thereby increasing the timeliness of care for the patient. The use of directive instructions has helped in achieving these results by providing physician approved guidelines for various tasks and planning goals needed to develop a proposed treatment. Future workflow and clinical decision support in radiation oncology will need to be robust and flexible to deal with a changing scenario of increasing knowledge about cancer biology and radiation effects and use of evidence-based biomarkers to aid in decision strategies for the management of patient care.

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