

SPRING 2020

# ASTRO *news*



## A RETROSPECTIVE ON **SAFETY**

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*A 10-year look back on where we were as a field in 2010 and what we did to improve safety and quality in radiation oncology.*

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*Institutional profiles on quality and safety initiatives.*

### Page 20 **Would you rather have a standard practice or a special practice?**

*A look at why we must standardize error reporting to facilitate local and national learning.*

# TeamBest NEWS UPDATES!

Visit this link to read more: [http://www.teambest.com/news\\_press.html](http://www.teambest.com/news_press.html)



## Best Medical International signs a Memorandum of Understanding with University of Wisconsin Medical Radiation Research Center (UWMRRC) to develop Revolutionary New Carbon Therapy

**PRESS RELEASE (Summary) • January 30, 2020**

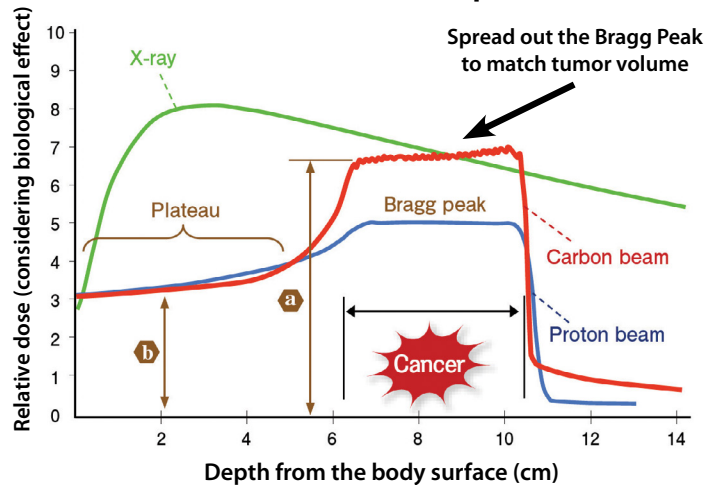
Best Medical International and Best Particle Therapy of TeamBest Companies, have recently entered into a Memorandum of Understanding (MOU) with the University of Wisconsin Medical Radiation Research Center (UWMRRC).

University of Wisconsin and Best Medical are excited about the collaboration, as this brings much needed carbon ion therapy to Midwestern states such as Illinois, Wisconsin, Indiana, etc.

To read the full press release, please visit: [http://www.teambest.com/news\\_press.html](http://www.teambest.com/news_press.html)

For more info about Best Particle Therapy, please visit: [www.bestproton.com](http://www.bestproton.com)

**Peak-to-Plateau ratio of the RBE (a/b) is larger in carbon ion beams than for proton beams.**



Graph courtesy of Hirohiko Tsujii et al., *Radiological Sciences*, 50(7), 4, 2007

## Krishnan Suthanthiran and his TeamBest Companies and Best Cure Foundation wish to congratulate Dr. Dattatreyyudu Nori on his new appointment as the International Director of Apollo Cancer Centers

**PRESS RELEASE (Summary) • January 28, 2020**

Congratulations to Dr. Dattatreyyudu Nori M.D., F.A.C.R., F.A.C.R.O., F.A.S.T.R.O for his new appointment as the International Director of Apollo Cancer Centers in India and South Asia. In his new role, Dr. Nori will oversee the clinical patient care, education and research across the 14 Apollo Cancer centers, including the recently inaugurated proton center. Apollo Health Care System is one of the premier tertiary health care delivery systems and has over 12,000 beds with 1200 oncology beds.

To read the full press release, please visit: [http://www.teambest.com/news\\_press.html](http://www.teambest.com/news_press.html)

For more info about TeamBest and Best Cure Foundation, please visit: [www.teambest.com](http://www.teambest.com) [www.bestcure.md](http://www.bestcure.md)



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# ASTRO news

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## THE TURNING POINT

**TEN YEARS AGO**, The New York Times published an investigative

story about radiation injuries, some of them horrific in scope. In his meticulously researched and reported 6,500-word piece, Walt Bogdanich shed light on technological advances that had allowed radiation oncologists to precisely target cancer, but were fatally undermined by alarming gaps in safety and physics quality assurance protocols, subjecting patients to radiation doses far in excess of what had been prescribed.

Radiation oncology has a long-standing reputation for safety. However, the NY Times report marked an inflection point — the only way to ensure patient well-being and assuage public fears of radiation therapy was to commit to a culture of safety and draw up a blueprint for the steps needed to achieve that. This issue looks at the progress that's been made in the past decade and what more needs to be done.

I vividly recall the time, as I had just been elected to serve on the ASTRO Board. The first Board meeting was in the scenic Napa Valley shortly after the story broke. Needless to say, we saw very little of the beautiful countryside. Tim Williams, the then ASTRO chair, and ASTRO CEO Laura Thevenot showed exemplary leadership at that moment of crisis. In this issue, Tim takes us back to 2010 and details what the discipline did to address the

issue and how ASTRO's six-point Target Safety plan was conceived.


Many institutions have protocols to ensure patient safety. Marisa Kollmeier, Sewit Teckie and Katie Woch Naheedy and colleagues take a closer look at some that have gone “above and beyond” in setting new standards. Suzanne Evans, in a fascinating article on RO-ILS®, discusses common errors of communication, the need for standardization and the potential to develop an “intelligent safety net.” Jean Wright explains that accreditation provides a “framework for ensuring that a practice meets the highest SAQ standards.”

According to the Institute of Medicine, “The biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are not treated as personal failures, but as opportunities to improve the system and prevent harm.” Bhisham Chera and Larry Marks expand on what it means to establish a culture of safety in an organization.

In the nineties, the Blue Book defined the standards for a modern radiation oncology department. However, it hadn't been updated for many years. Inspired by the new emphasis on safety and unprecedented expansion in technology, Anthony Zietman, Jatinder Palta and Mike Steinberg led an intersociety meeting of groups connected with our specialty and achieved the near impossible: a

collaborative document — Safety is No Accident — which quickly became the safety culture handbook for the new era. Todd Pawlicki, Ben Smith, Jim Hayman and Eric Ford led the effort to update this in 2019. As Anthony and Todd state in their article, this sets the bar for safety in radiation oncology.

The Joint Commission is spearheading the concept of high reliability organizations in health care with leadership committed to the goal of zero harm and an organizational safety culture where all staff can speak up about things that would negatively impact the organization. Clearly, we have come a long way. Prospective peer review, clinical quality assurance, establishment of a blame-free environment, and reporting of errors and near misses are becoming part of our work culture.

In the Hippocratic tradition, the patient's well-being has been and should remain the focus of clinical practice. Is it possible to “do no harm” even with the most altruistic of intentions? Probably not. No doubt radiation therapy is increasingly complex and there is an increasing dependence on sophisticated software and hardware tools aiding every step of the process, all of which raise the potential for errors. But, as technology advances, radiation oncology needs to hold on to these hard-won cultural changes and make sure they are further entrenched. Only then can we ensure we do the right thing by our patients. 





## SAFE CARE OF OUR PATIENTS: A SACRED OBLIGATION

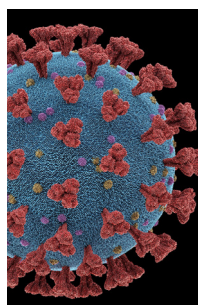
**IT HAS HAPPENED TO ALL OF US.** The call from a therapist, a nurse, a physicist, saying something has just happened in the care of a patient. An error has occurred. We get that sick feeling in the stomach and anxiously wait to hear the details. We devise the appropriate next steps, hang up the phone and try to calm our nerves. We have all been there, and in that moment, would prefer never to receive such a call again.

In reality, we know we want to receive such calls because, while rare, errors in the care of our patients do occasionally occur, and we all are driven to provide the best care possible for our patients. Fortunately, most errors never reach patients and are mitigated during the various phases of planning, quality assurance, chart reviews and other focused tasks. But we know the safe delivery of therapeutic radiation is an inherently complex and high-risk process, and over the years, our field has devised a substantial team-based safety infrastructure to appropriately deliver radiation therapy. In many ways, these efforts have led other parts of medicine.

Indeed, over the past decade, more energy has been given to the science of patient safety, and our field has even more directly prioritized patient safety and quality of care as a central feature. This has included incorporating things like Failure Mode and Effects Analysis (FMEA) to analyze the steps required to see and treat patients from start to finish. It has been reported that routine external beam radiation requires some 270 separate steps. Even if each step is error proof at the 99.9% level, the cumulative total probability of an error would be about 25%. In fact, to prevent an unacceptable cumulative rate of error, we need each step to reach an error-proof rate approaching Six Sigma's (99.99966%). The fact that the observed error rates are much lower than 25% speaks to the measures already in place and to the work by many in our field so that real risk reduction in care has occurred.

But arguably, the two most important evolutions in the last 10 years have been the purposeful development of care teams empowered to report errors and the use of national error reporting (incident learning) systems to share these reports. These two key improvements in safety are, in fact, intimately linked. A "speaking up-speaking out" culture is well known to drive improved performance not only in patient safety and quality, but also in enhancing employee engagement and satisfaction. Moreover, without such a culture, error reporting systems are not populated with data that can both identify trends and mitigate risk. ASTRO's development of the Radiation Oncology-Incident Learning System® (RO-ILS) in partnership with the AAPM was an early and key development in driving an enhanced culture of safety in our field and has continued to be an important tool driving improved care for more than 500 clinics in the United States.

It remains a core mission of the ASTRO Board of Directors to continue this legacy of support for patient safety and quality. We must continue to maintain focus and provide resources for new ideas to emerge and be exchanged through our meetings and our publications and by engaging with stakeholders in industry, government and other professional societies. This is a never-ending process of improvement and without continued focus and attention by ASTRO and all of our members, we risk appearing to step back from our most sacred obligation — the safe care of our patients.



As the situation surrounding COVID-19 evolves, we encourage you to bookmark [www.astro.org/covid19](http://www.astro.org/covid19) for regular updates on changes to ASTRO activities.



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Dr. Alberto Ciarmatori, Medical Physicist,  
Azienda Ospedaliera Ospedali Riuniti Marche Nord Hospital, Pesaro, Italy



Pitch at 0 (chin down)



Pitch at 5 (neutral)



Pitch at 10 (chin up)



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## Updated ASTRO guidance on Supervision Policy

BY BRYAN HULL, JD, MPH, ASTRO ASSISTANT DIRECTOR OF HEALTH POLICY

**ON FRIDAY, NOVEMBER 1, 2019**, the Centers for Medicare and Medicaid Services (CMS) issued the 2020 Hospital Outpatient Prospective Payment System final rule, lowering the supervision level required for hospital-based therapeutic services, including radiation therapy services, from direct to general supervision. After carefully reviewing the rule and clarifying questions with the Agency, the ASTRO Board of Directors approved this updated guidance to help members understand that the supervision changes are more limited than they appear.

**Most notably, direct supervision is still required, and the new general supervision policy does NOT apply when:**

- **Radiation therapy is delivered in a freestanding center;**
- **The work of radiation treatment management is performed;**
- **Brachytherapy (CPT codes 77770-77772), stereotactic radiation therapy (CPT codes 77371-77373) and other services described by CPT codes requiring that the radiation oncologist personally provide the services are performed;**
- **Diagnostic services, such as image guidance, are performed; or**
- **A hospital determines that radiation therapy services require direct supervision.**


“Direct supervision” requires that the physician be immediately available to provide assistance throughout the duration of the procedure. “General supervision” means the procedure is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure.

This ASTRO guidance helps explain that the new supervision policy, which does not apply to freestanding centers delivering radiation therapy, has a limited impact on hospital-based delivery of radiation therapy services, given the patient management requirements

associated with a number of radiation oncology services. It will be important for all hospital-based practices to consider existing supervision requirements in the context of this new policy, in combination with requirements associated with the delivery of radiation therapy.

For instance, the work described by CPT codes 77427, 77431, 77432, 77435 and 77469, radiation treatment management, must be provided personally by the radiation oncologist, who is ultimately responsible for the entirety of patient care. Thus, the weekly management of patients receiving radiation therapy, which involves all technical and medical aspects of managing the patient through a treatment course, is always conducted under the direct supervision of a radiation oncologist, who must continue to independently document their involvement in the process. Additionally, direct supervision associated with the delivery of brachytherapy and stereotactic radiation therapy remains.

It should also be noted that the new supervision policy does not apply to diagnostic services such as image guidance. All hospital outpatient diagnostic tests performed in conjunction with radiation therapy must follow the physician supervision requirements for the individual tests. ASTRO’s supervision guidance specifies those requirements.

In the final rule, CMS states that hospital-based practices may adopt more stringent supervision policies. ASTRO urges members to carefully review supervision policies with hospital administrators and compliance officers. APEX® accreditation standards should be used as a guideline for radiation oncology supervision requirements. ASTRO’s opinion is that a board-certified/board-eligible radiation oncologist is the clinically appropriate physician to supervise radiation treatments; however, this updated document recognizes that some flexibility is necessary for those practices that deliver care to underserved populations who may experience access to care issues. Review the updated guidance at [www.astro.org/PMresources](http://www.astro.org/PMresources). 





## Patient Safety Awareness Week 2020


**PATIENT SAFETY AWARENESS WEEK (PSAW)**, sponsored by the Institute for Healthcare Improvement, takes place each March. It is a time to celebrate the numerous quality and safety initiatives already in place and identify what more can be done to improve patient safety. ASTRO and the radiation oncology community actively participated in a successful 2020 PSAW, which was recognized the week of March 8-14.

New for this year, ASTRO initiated the #SafetyChampion campaign on social media to collect brief videos and short statements from clinicians and practices about their local safety initiatives. Keep a lookout for an upcoming ASTRO Blog post with links to videos and a comprehensive summary of posts.

Radiation oncology clinicians also engaged with colleagues on a *ROhub* discussion thread and with the broader house of medicine on social media with hashtags #PSAW20 and #ROSafety. Additionally,

ASTRO released program reports on the first five years of experience regarding its safety and quality initiatives: RO-ILS, see page 22 and also available at [www.astro.org/roils5yearreport](http://www.astro.org/roils5yearreport), and Accreditation Program for Excellence (APEX®), available at [www.astro.org/apex5yearreport](http://www.astro.org/apex5yearreport).

While PSAW 2020 may be over, ASTRO is still offering an APEX discount of \$1,500 off the total application price for practices that start an APEX application during the month of March. For more information, contact ASTRO staff at [APEXSupport@astro.org](mailto:APEXSupport@astro.org).

Be sure to utilize the momentum from PSAW 2020 to continue these efforts throughout the year. Additionally, seek new ways to promote safety, celebrate local accomplishments and improve safety culture. 



## Best of ASTRO in Istanbul, Turkey

SCIENCE OF TODAY  
HOPE FOR TOMORROW

### TURKEY

ASTRO President Tom Eichler, MD, FASTRO, joins Ugur Selek, MD, FASTRO, of MD Anderson/American Hospital in Istanbul and meeting attendees for their sixth year of Best of ASTRO. During the meeting, Yavuz Anacak, MD, the president of Turkish Society for Radiation Oncology, unveiled a plaque in honor of Dr. Eichler for his presence and support.

Find out more information on the Best of ASTRO Licensing by emailing [education@astro.org](mailto:education@astro.org) or visiting [www.astro.org/BOAlicensing](http://www.astro.org/BOAlicensing).



## *In Memoriam*

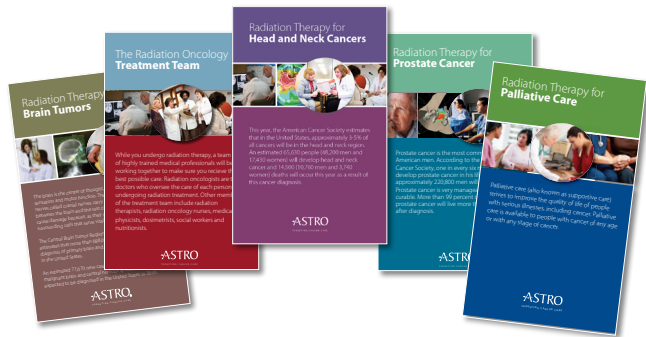
ASTRO has learned that the following members have passed away.  
Our thoughts go out to their family and friends.

- Francisco Alaniz-Camino, MD, Nuevo León, Mexico**
- Hernando Ortiz, MD, San Juan, Puerto Rico**
- James G. Pearson, MD, Edmonton, Alberta, Canada**
- Lawrence Solin, MD, FASTRO, Haverford, Pennsylvania**

The Radiation Oncology Institute (ROI) graciously accepts gifts in memory of or in tribute to individuals. For more information, visit [www.roinstitute.org](http://www.roinstitute.org).








## Patient education offerings update


BY SABIN MOTWANI, MD  
COMMUNICATIONS COMMITTEE CHAIR

**THE COMMUNICATIONS COMMITTEE HAS BEEN HARD AT WORK** these past few months updating and creating new patient education materials. Based on feedback from ASTRO's patient survey, we have been updating and incorporating expanded visual side effects charts into each of the brochures. Newly updated brochures include radiation therapy for brain metastases, breast cancer, head and neck cancer and prostate cancer as well as the treatment team, stereotactic and general RT for cancer.

Additionally, this year we have produced two new videos: Radiation therapy for upper GI cancers and radiation therapy for lower GI cancers. These videos take the viewer through the process of receiving radiation for their cancer and include consults, simulation, treatment, patient testimonials and treatment team interviews. The videos are available to purchase and view at [www.astro.org/patientvideos](http://www.astro.org/patientvideos) and available for patients to watch for free at [www.rtanswers.org](http://www.rtanswers.org).

We plan to complete updates on all the brochures in the collection by the end of 2020. If you have feedback on any of our patient education products, including brochures, videos or the website, please post your comments in the Open Forum on the *ROhub* or contact us at [communications@astro.org](mailto:communications@astro.org). The committee values your feedback and is always looking for ways to improve the resources we create for ASTRO members and patients. 

## IROC-Houston celebrates 50 years of service to the field

**ASTRO IS PLEASED TO RECOGNIZE IROC-HOUSTON** for 50 years of service to the field of radiation oncology. Since 1968, IROC-Houston (formerly the Radiological Physics Center) has supported quality patient care by developing and implementing quality assurance standards that are now in place in clinics across the world, benefitting patients and the field. 

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# TARGET SAFELY

*A 10-year look back on where we were and what we did to improve safety and quality in radiation oncology*

BY TIM R. WILLIAMS, MD, FASTRO

## **ONE OF THE THINGS YOU DO NOT EXPECT TO LEARN**

while serving as the chair of the ASTRO Board is that there are 14 different Pulitzer Prizes for journalism. They include the award for public service, investigative reporting and national reporting, among others. It can be safely assumed that the competition to win an award is fierce, and journalists are always on the lookout for an important story. And so, it came to pass that in 2008 a letter was forwarded to one of the leading investigative reporters in the country, Walt Bogdanich of The New York Times. The letter was from the parents of a patient who had died of radiation injuries as the result of a tragic accident at an oncology program in New York City. Fresh off of winning the Pulitzer Prize for a story on toxic ingredients in medicine imported from China, Mr. Bogdanich's investigative team took note and embarked on a thorough and comprehensive investigation of radiation injuries in both diagnostic radiology and radiation oncology.

Of course, the nature and extent of radiation injuries are quite different between the two specialties — there

being three orders of magnitude difference between the amount of radiation delivered for a diagnostic procedure when compared to a course of therapeutic radiation. It is actually quite difficult to severely injure a patient with a diagnostic dose of radiation (as with injuries from a CT scanner) and there are well over 100 million X-ray-based diagnostic procedures a year performed in the United States. There are over one million courses of therapeutic radiation delivered per year and, as opposed to diagnostic radiology, our treatments can be quite dangerous and are often associated with side effects and possible long-term risks. While it is often said that the first rule of medicine is “do no harm,” there is room in our specialty for another perspective. Sometimes it can be justifiable to place a patient at risk in order to have any meaningful chance to control a malignant tumor. As it was explained to me in my residency, in radiation oncology “the worst complication is a recurrence.” And even as the Bogdanich investigative team was completing its work in 2009, there was a considerable amount of literature devoted to quality and safety in both specialties. Strict

*Continued on following page*

regulations were already in place for isotope-based therapy with the Nuclear Regulatory Commission's 10 CFR Part 35 regulations. There were state-based regulations regarding the credentialing and operation of linear accelerators, registries for treatment errors and advisory boards for radiation protection (I serve on one for the state of Florida), among other efforts.

As it existed at that time, however, the system broke down in the case of the accident referred to in *The New York Times*. The investigative team completed their work in 2009, and the initial article documenting safety issues in radiology and radiation oncology was published in *The New York Times* in January 2010. The tragic story of the misadministration and its aftermath was the centerpiece of the article. ASTRO knew that more articles would follow; we did not know when they were going to be published or their content. ASTRO had not been contacted during the investigative process, nor were we made aware of the publication schedule.

I was chair of the Board of ASTRO at the time, and my first meeting as chair was two weeks after the investigative report was published. As it turned out, in addition to the normal meeting agenda, I had scheduled extra time for strategic planning and open discussion. We ended up ditching the strategic planning and devoted about 15 hours of discussion to quality, safety and what would be our formal response to the investigative report. The Board effort was faultless. We started with a wide-ranging conversation of general concepts of quality and safety in medicine and industry. We learned that, while our specialty was generally quite safe, there were lessons to be learned from the air transport industry, the nuclear power industry and other medical specialties such as anesthesiology. Standardized protocols, anonymous reporting systems for mistakes and errors, patient education and program accreditation emerged as consistent themes other professions have used to improve quality and safety. At the end of the meeting, the Board approved unanimously a six-point Target Safely program for radiation oncology.

That was not the end to the story, of course; rather it was just the beginning. *The New York Times* published more articles over the next couple of months, and

the matter received considerable national attention. Ultimately, we were notified that there would be congressional hearings in Washington. The hearings would allow for more coverage and perhaps more serious questions about the general safety of medical radiation, which could potentially lead to significant changes in regulation. Fortunately for the specialty, and certainly for me, the ASTRO CEO was — and still is — Laura Thevenot, a person quite familiar with the political process. And so, I found myself in Washington, D.C., with a consultant explaining to me the general process of a congressional hearing, including the considerable political theater. I was informed that at any congressional hearing there are basically four types of witnesses. They include the victim, the expert, the good guy and the bad guy. When asked which one of the above I thought I was, I naïvely offered

to the consultant that I should be the expert. Actually, I was going to be the bad guy. I would be the one, under oath, to answer for the transgressions and breakdowns in patient safety. Additionally, there was some possibility that the hearing would be attended by the powerful and mercurial congressman from California, Henry Waxman, who was generally not regarded as a friend of organized medicine.

I would go last. I would be given not one second over three minutes to make my presentation. I was well prepared. As I recall, the presentation took two minutes and


47 seconds. As it turned out after I was finished, there were no incendiary questions or threatening rhetoric. Congressman Waxman did show up but remained silent for the proceedings. The members at the hearing seemed satisfied with our Target Safely program, and we accepted the mandate to make the specialty better.

The crowning achievement of the Target Safely program was the 2012 publication of *Safety is No Accident*, a 52-page document representing the combined effort of 31 authors that became the blueprint for change and improvement in quality and safety, work that continues to this day.

As an epilogue, after the Target Safely program was developed, I sent a handwritten letter to the parents of the patient who had been tragically injured. In it

“ Standardized protocols, anonymous reporting systems for mistakes and errors, patient education and program accreditation emerged as consistent themes other professions have used to improve quality and safety. ”

*Continued on following page*

I offered my sincere condolences for their family's loss and a summary of our efforts in response to the investigation. There are no words in the English language that can offer solace for such a loss. The best that I could offer is redemption, my assurance that as a result of The New York Times investigative reporting and our response to it, the specialty is indeed better than ever and that such an accident should never happen again. 

*Tim R. Williams, MD, FASTRO, is the medical director of the South Florida Proton Therapy Institute in Delray Beach, Florida. He is a past president and chair of ASTRO's Board of Directors and remains active in many of the Society's committees and subcommittees.*

## TARGET SAFELY – Where we are today

ASTRO's six-point plan to improve quality and safety and reduce the chances of medical errors during radiation treatments was released 10 years ago. Here's where we are today:

### POINT 1

#### Event reporting system

In 2014, RO-ILS: Radiation Oncology Incident Learning System® launched as the only medical specialty society-sponsored radiation oncology incident learning system. More than 500 facilities from across the United States have joined RO-ILS to contribute patient safety data to this federally qualified patient safety organization (PSO).

### POINT 2

#### Accreditation

ASTRO's Accreditation Program for Excellence (APEX®) launched in 2015. The APEX Standards for Accreditation were created using various white papers and guidance documents, including Safety is No Accident, and are organized around five pillars: process of care, the radiation oncology team, safety, quality management and patient-centered care. As of publication date, more than 164 facilities have received an APEX determination.

### POINT 3

#### Lifelong learning and maintenance of certification, clinical guidelines

ASTRO continues to be a leader in lifelong learning and self assessment by offering opportunities for CME activities at all meetings and through the ASTRO Academy. ASTRO publishes clinical practice guidelines, practice parameters, consensus documents and white papers. Guidelines are published open-access in *Practical Radiation Oncology*, which launched in 2011.

### POINT 4

#### Patient communications

As a direct initiative of Target Safely, the Communications Committee developed a list of questions for cancer patients to ask their radiation oncologist and care team. The committee also developed a video series, all of which live on RTAnswers.org. And this work continues today. The committee continuously updates patient brochures and creates new videos and presentations to help better present radiation oncology to patients and to help ASTRO members communicate more clearly with their patients.

### POINT 5

#### IHE-RO

Interoperability of radiation treatment and planning systems was identified as a key priority to assist with sharing information electronically and mitigating the likelihood of error. In partnership with the vendor community and AAPM, ASTRO supports the Integrating the Healthcare Enterprise-Radiation Oncology (IHE-RO) initiative which includes Connectathon testing of critical aspects of the radiation oncology process of care.

### POINT 6

#### Advocacy

ASTRO's advocacy has emphasized reassuring policymakers on radiation safety and capitalizing on Target Safely initiatives to make safe radiation therapy even safer. ASTRO launched RO-ILS during a Capitol Hill briefing in June 2014 in partnership with Rep. Frank Pallone (D-N.J.), who had chaired the 2010 House committee hearing scrutinizing radiation therapy safety. ASTRO also successfully advocated for RO-ILS and APEX to satisfy quality and safety requirements as part of Medicare's Quality Payment Program. ASTRO is actively pushing for these programs to be the cornerstone of quality efforts under the Radiation Oncology Alternative Payment Model.





## UTILIZING AUTOMATION TO STREAMLINE THE PLAN CHECK PROCESS

BY MARISA A. KOLLMEIER, MD, AND SEAN L. BERRY, PHD

**RADIATION ONCOLOGY IS A RAPIDLY EVOLVING FIELD** with increasingly complex radiotherapeutic approaches. Additionally, unique and complex hardware and software control systems are used by various team members, including physicians, physicists, radiation therapists and administrative staff. As such, it is essential that radiation oncology practices remain diligent in prioritizing patient safety in processes and procedures.

This is no small task as practices expand to include multiple campuses and face increasing pressure for efficiency, volume and patient satisfaction. Memorial Sloan Kettering Cancer Center has worked to provide our patients with access to novel and advanced treatment approaches that enhance the precision and accuracy of our treatments. With this philosophy, we strive to drive our safety programs to meet this need. Fortunately, developments in the field of computer technology and automation have provided a launch pad for creative and robust programs to enhance our quality and safety programs. One such program is the result of our work to develop and optimize a computer-assisted plan check tool.

Computer-assisted checklists have been used since 2011 in our treatment planning quality assurance (QA) processes to aid in standardization and increase compliance to policies.<sup>1</sup> The physics plan check remains a major site of error detection and, as such, was a clear choice to integrate an automated process. Tedious manual checks of plan parameters can be a challenge when navigating multiple treatment planning and delivery systems,

particularly in a high-volume setting. In addition to determining dosimetric plan quality, the deliverability, adherence to the written directive and preparation of the plan for treatment are all essential elements.

In order to address the needs of maintaining a rigorous plan check prior to treatment delivery and to increase efficiency, we collaborated with software

developers, clinical physicists and departmental leadership at Memorial Sloan Kettering and the University of Michigan to develop an automated plan check tool (PCT) in 2015.<sup>2</sup> At the outset, we identified events related to treatment planning errors/delays to assist in identifying targets (elements) for automation for incorporation into our initial PCT release. The tool was tested using test plans with known errors, and several iterations were required prior to finalizing the tool. That said, the tool was also designed to be

built upon so that new elements could be added as needed, providing tool flexibility. As currently used, the planner runs the PCT, and a second PCT run is performed by the plan checker, supplementing the automated checks with manual checks for items that cannot be, or have not yet been, automated. In our initial report in 2016, in addition to a 60% reduction in plan error/delays, there was an estimated 20% reduction in plan check time.<sup>3</sup> Moreover, the detection and correction of errors earlier in the treatment planning process (and further from the patient) provide more of a buffer to avoid errors/delays reaching the patient. Since our initial work, our PCT increased to include 73 elements. New

“It is essential that radiation oncology practices remain diligent in prioritizing patient safety in processes and procedures.”

*Continued on page 17*





## CREATING A CULTURE OF SAFETY IN A HIGH-VOLUME RADIATION MEDICINE DEPARTMENT

*A 10-year retrospective on Northwell's No-Fly policy*

BY SEWIT TECKIE, MD, AJAY KAPUR, PHD, LOUIS POTTERS, MD, FASTRO

### IT IS WELL RECOGNIZED THAT THE COMPLEXITY

of providing modern radiation therapy requires the integration of sophisticated imaging, treatment planning, electronic medical records and linear accelerator control computers, often from disparate vendors. To achieve success in this process, multiple automated and manual handoffs are required for ever more complex tasks by various members of a multidisciplinary radiation oncology team.

In 2008, our department instituted a detailed quality checklist (QCL)-driven and process-mapped operation. Similar to the concepts presented by Atul Gawande in his Checklist Manifesto,<sup>1</sup> the QCL was a component of a strong “safety-first” environment. We observed that the QCL process failed as a result of being reactive and often an afterthought.

Using approaches developed in manufacturing, we implemented a treatment stopping policy that prohibits treatment initiation without timely completion of planning tasks. We call it the No-Fly (NF) Policy. NF applies interlocks to risk-identified steps in the process of initiating radiation care.

NF allows for timely work but reschedules the treatment start to a later date when high-risk tasks in the planning process are delayed, thus avoiding the “delay-then-rush” culture that is ubiquitous in the field. A typical example of this culture is the rush imposed upon dosimetrists to finish an IMRT plan despite the delay of a physician’s contours. The tradeoff made in NF is that treatment start delays may impact patient satisfaction or coordinated chemo-RT dates. But we as a department came to the conclusion that any other process would allow for workarounds and thereby diminish the intent of decreasing risks.

The NF program has evolved — in two iterations we call NF1 and NF2 — over the past 10 years as we have learned from successes and failures.

### NF1

Three critical developments helped with the implementation of NF1: Six Sigma, prospective peer-review chart rounds and an electronic whiteboard. Six Sigma methodology enabled us to streamline the planning process and set timelines for each planning task so we could measure efficiencies on a task-by-task basis. Peer review is performed prospectively in daily morning department rounds so that all new patients’ contours and prescriptions undergo consensus approval before treatment planning commences (except for emergent cases). The electronic whiteboard is used by all members of the team to track and update the progress of a patient’s radiation process from simulation to start.

Our first iteration of NF1, in 2010, assigned timelines for each step in the treatment planning process. At simulation, patients were given a treatment start date based on these timelines. NF1 mandated that the treatment start date be proactively delayed if there was tardiness in any one high-risk component of the planning process. As a direct result, upwards of 10% of all treatments were delayed due to tardiness in any one or more of the components: contouring, planning, second checking, IMRT QA, MD plan approval, plan uploading and pre-treatment chart check. Not surprisingly, the majority of treatment delays were a result of contouring. NF1 eliminated the concept of rushing to “make up” that tardiness.

NF1 clearly enhanced the safety culture when compared with QCL by reducing risks associated with rushed work. Yet, we discovered that the act of canceling and moving a large fraction of patient starts was stressful for both the patients and the staff. As a result, many patients were not proactively delayed as the policy required, as staff learned how to use workarounds to avoid rescheduling.

*Continued on following page*

# PROCEDURAL DELAY TRENDS

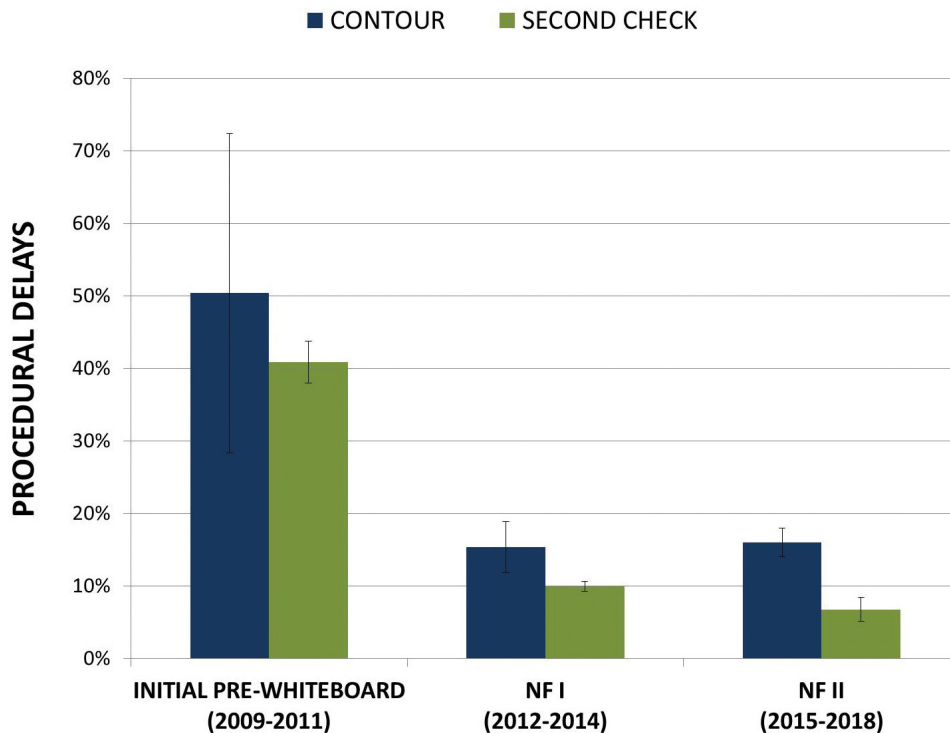


Figure 1: Impact of NF1 - Improvement and stabilization of planning tasks with NF1 and NF2.

## NF2

Through NF1 we learned that the vast majority of proactive treatment delays were related to delayed contour completion and plan modifications. Therefore, we moved the treatment scheduling step downstream in the planning process by linking the MD plan approval step to the new start scheduling. This new process avoided upstream delays such as contouring and planning. This change also allowed for any patient to start treatment early if all the preceding steps were completed on time.

NF2 was successful in significantly decreasing workarounds. Proactive delays decreased to <2% of new starts. But we were unable to shorten the planning process; in fact, the overall time from simulation to start increased by 0.6 days. This longer overall time was a result of the short notice after MD plan review to the potential start date versus the actual date that patients could come to start treatment.

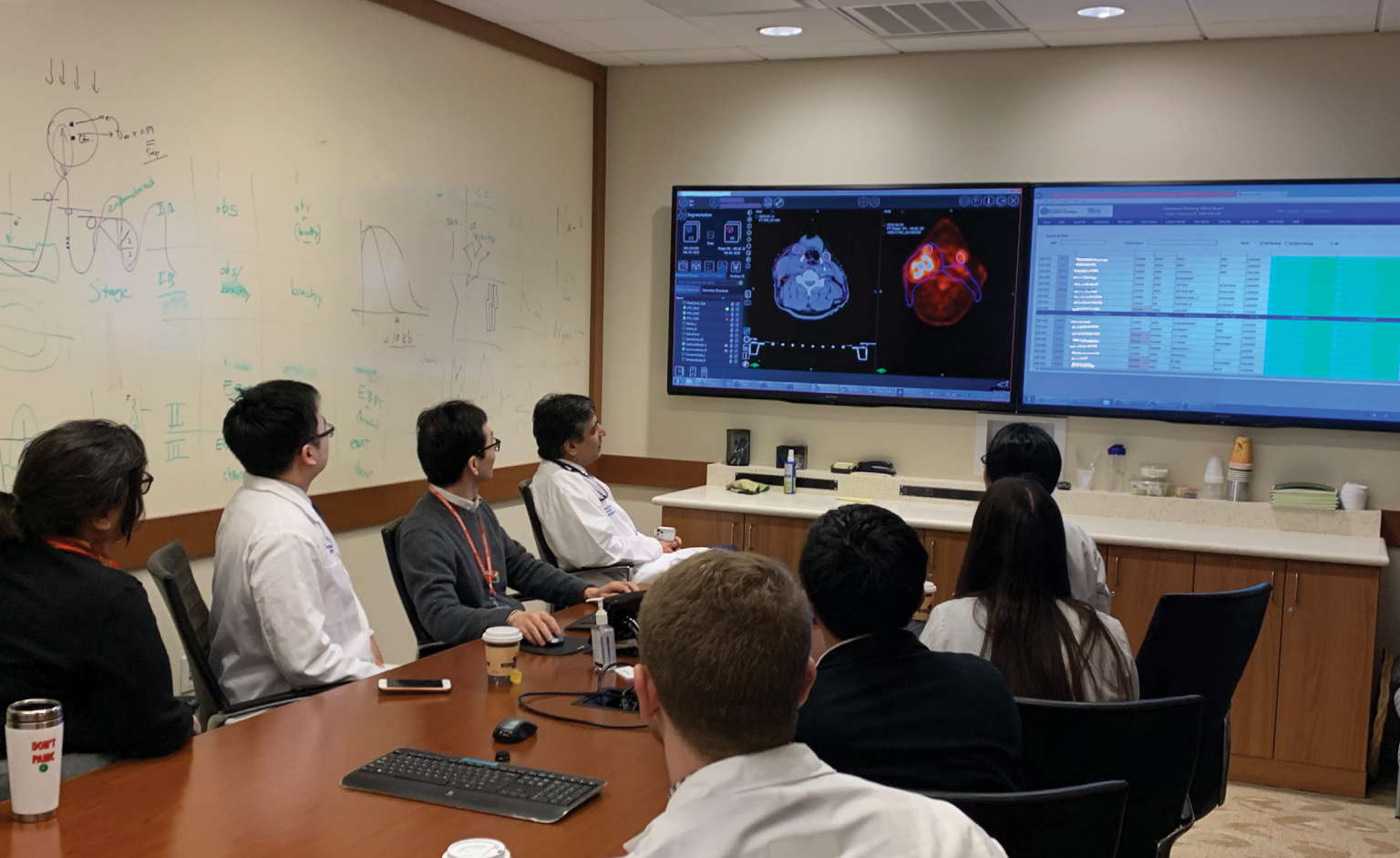
## Next Steps

We have already embarked on changes in the NF2 rules to improve the patient's opportunity for timely treatment starts (NF3). We will monitor how this new change impacts overall time from simulation to treatment start, as well as proactive delays.

## Perspective


Over the past 10 years we have come to appreciate that checklists are fraught with failures and workarounds and that interlocks do work at preventing rushed, potentially unsafe work. We have been able to rollout the NF policy to all of our nine treatment sites across the metropolitan New York region, thus ensuring a Northwell standard of care to all of our patients. This has helped to create a shared vision for all staff and has enhanced their efficiencies by allowing centralized planning.

We have each delivered talks on the No-Fly policies implemented at Northwell. But almost universally we are told that it cannot be implemented at a site for all sorts of reasons. We appreciate the challenge of making No-Fly part of a busy clinical practice.



Radiation medicine physicians, physicists and dosimetrists meet each morning for prospective peer review rounds. They collectively review all new contours, prescriptions and treatment plans. Team members from all departmental sites are encouraged to participate by teleconference. Photo courtesy of Northwell.

While we do not profess to offer the only or best approach to decreasing risk, we have learned over the years that checklists do not have any meaningful impact on rushed work and that workarounds pollute attempts at safety. We have learned that extending even one workaround structurally undermines the efforts of all and breaks the safety culture. And, to that end, we still have room for improvement.

We all manage vulnerable, sick and anxious patients, and the last thing any of us want to do is cancel a new treatment start. At Northwell, we have made safety our culture with the No-Fly policy as our foundation for care. We educate our patients on No-Fly and how it affects their schedule, and we believe we achieve high patient satisfaction metrics not in spite of No-Fly, but perhaps because of it. 

*Sewit Teckie, MD, is an assistant professor of Radiation Medicine at Zucker School of Medicine at Hofstra/Northwell. She is a clinician and outcomes researcher. Connect with Dr. Teckie on Twitter: @TeckieMD.*

*Ajay Kapur, PhD, is a medical physicist and associate professor at Zucker School of Medicine at Hofstra/Northwell with over 25 years of experience in clinical practice, research and education in medical physics.*

*Louis Potters, MD, FASTRO, is the deputy physician-in-chief of the Northwell Health Cancer Institute and professor and chair of the Department of Radiation Medicine, Zucker School of Medicine at Hofstra/Northwell, as well as the Marilyn and Barry Rubenstein chair in Cancer Research.*

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## UNIVERSITY OF MICHIGAN'S FIRST QUALITY SAFETY OFFICER DRIVES DEPARTMENT EFFORTS IN SAFETY AND QUALITY IMPROVEMENT

BY KATIE WOCH NAHEEDY, MS

**IN 2015, I BECAME THE FIRST** quality safety officer in the Department of Radiation Oncology at the University of Michigan. My role is to lead department-wide safety and quality improvement efforts, which include investigation of reported events, development and maintenance of policies and documentation, ensuring department regulatory compliance and educating our department on these efforts. The motivation for creating this role was to have a dedicated point person for all employees when an event occurs, to have routine follow-up after events, to guide improvements made in response to events and to work on supporting department accreditation.

Since starting in this role, our departmental event reporting volume has nearly tripled to approximately 60 events reported per month. Our department reported our first event into RO-ILS: Radiation Oncology Incident Learning System® in early 2014 and, since then, has reported over 1,400 events into RO-ILS. Investigation of these events ranges from a short, focused

conversation with involved individuals to a formal root cause analysis conducted by an interdisciplinary team, including staff, faculty and trainees from all job roles in our department. Event reporting by our employees has led to numerous process improvements to our daily work. For example, our evaluation of the root causes of events that delayed the start of a patient at our treatment units led to two major workflow changes: a standardized

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“By evaluating our processes with respect to accreditation standards, we are able to benchmark and validate our practices in support of delivering safe, high-quality, patient-centered radiation oncology care.”

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therapist pre-treatment checklist<sup>1</sup> and data-driven development of checks for an automated plan check tool.<sup>2</sup> We regularly use staff reported events to adapt these tools as new technology enters our clinic, our department grows and patient care practices evolve. Also, we continue enhancing the tool, both within the University of Michigan enterprise and through a collaboration with colleagues at Memorial Sloan Kettering Cancer Center for automated plan checks.<sup>3</sup>

In 2016-2017, I led our department through our initial APEX® accreditation. This year-long, department-wide effort culminated in our achieving the first APEX accreditation in Michigan and the tenth nationwide. By participating in the accreditation process, we reviewed our charting practices and updated our policy and procedures to ensure compliance with APEX standards. We have used the APEX standards to create

templates in our hospital's electronic medical record (Epic) to standardize documentation of our patient consult and on treatment visit notes. We are now starting the process for reaccreditation in 2021. By evaluating our processes with

respect to accreditation standards, we are able to benchmark and validate our practices in support of delivering safe, high-quality, patient-centered radiation oncology care.

Along with faculty members Jean Moran, Kelly Paradis and Joann Prisciandaro, I provide education to our department on quality and safety in radiation oncology and on our department-specific efforts. Quarterly, we dedicate a department-wide morning conference session



for a “Safety Update,” which summarizes recently reported events of note, any root cause analyses and implemented workflow improvements. We perform an annual network-wide safety culture survey to better understand our safety climate and to identify targets for improvement. This year, we designed a safety poster to highlight and celebrate initiatives within our department to improve patient safety during the prior year. We also celebrated Patient Safety Awareness Week in March with a week of safety-related trivia and prizes. In 2020, I am teaching classes on universal skills that will contribute

to organization-wide efforts across all of Michigan Medicine to become a High Reliability Organization.

I am thankful for this unique opportunity to lead and participate in numerous radiation oncology safety and quality efforts at the University of Michigan. The bottom line is that our patients deserve the safest care possible, and our team focuses on that each day. Success in this position is only possible with support from our department leadership, especially Ted Lawrence, MD, PhD, our department chair; Jim Hayman, MD, MBA, our medical director; Jean Moran, PhD, co-director of the physics

department, and Dawn Johnson, our manager of operations. 

*Katie Woch Naheedy, MS, is the quality safety officer in the Department of Radiation Oncology at the University of Michigan. Her interests are improving the safety, quality and efficiency of radiation therapy planning and delivery.*


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## Continued from UTILIZING AUTOMATION TO STREAMLINE THE PLAN CHECK PROCESS

PCT elements are added from multiple sources, including the PCT development team, planners and plan checkers and the departmental QA committee, upon the review and discussion of events recorded in our institutional incident learning database.

Unique challenges exist in radiation oncology as a technology-driven and multidisciplinary field. Practices benefit from examining their own incident learning systems

to determine the specific patient safety needs and implementing processes that address those needs. Automated computer-based checklists can help streamline the plan check process and reduce errors related to treatment planning. 

*Marisa Kollmeier, MD, is an associate professor at Memorial Sloan Kettering Cancer Center in New York. She currently serves on ASTRO's Multidisciplinary QA Committee and the Code Utilization Committee.*

*Sean Berry, PhD, is an associate professor at Memorial Sloan Kettering Cancer Center in New York. His research and development interests include automation in the treatment planning process to increase safety and efficiency.*

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# SAFETY IS ALL ABOUT CULTURE



BY BHISHAM CHERA, MD, ALISON AMOS, PHD, LUKASZ MAZUR, PHD, AND LAWRENCE MARKS, MD, FASTRO

**TEN YEARS AGO**, several New York Times articles by Walt Bogdanich reminded us that the delivery of radiation can be error prone even with modern-day, sophisticated technologies. These articles shocked and stunned our profession, society and government. These errors published in the Times reawakened the public's fears of radiation. Our profession swiftly and responsibly responded with a multipronged effort from our professional societies, providing guidance and recommendations for many clinical departments to take local action by implementing and revitalizing quality and safety programs. We have seen a tremendous rise in presentations at meetings and publications related to safety, and a patient safety track has been created for the ASTRO Annual Meeting. Indeed, there has been significant activity in the radiation oncology profession since the catalytic Bogdanich articles.

There are many methodologies (Six-Sigma, Lean) and countermeasures (standardization, time outs, checklists, forcing functions, automation) that one can implement, books to read (including ours<sup>1</sup>) and consultants for hire to improve patient safety. The one best approach to improve safety is cultivating a culture of safety. Culture can be conceptualized as why we do what we do. Though a cliché statement, changing culture is hard, and the key requirement to successfully changing culture is active and sustained leadership participation, both at the physician and hospital administrator level. Without the enthusiastic support of physicians and hospital leaders, the safety culture of any clinic will be superficial, at best. A positive patient safety culture directly depends on physicians and hospital administrators being vocal advocates for safety and actively practicing what they preach. At UNC we have improved and sustained a positive safety culture that continues to exceed national benchmarks since 2013 (Figure 1). We think a key reason for our ability to sustain a safety culture is the prioritization of safety by our physicians and leaders. We do our best to walk the talk.

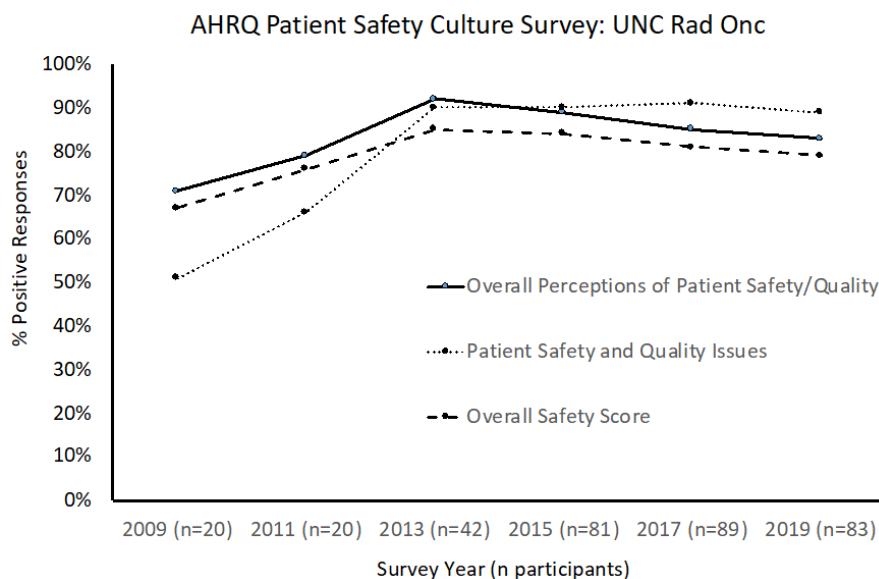
Formal training and education in patient safety for all radiation oncology professionals is also important

for growing and sustaining a safety culture. We must introduce the topic of patient safety early and repeatedly during the training of medical professionals. In our department, all new employees, regardless of rank, are required to complete formal quality and safety training taught by our Division of Healthcare Engineering. Physicians also participate in a safety course given by the UNC Medical School Institute of Healthcare and Quality Improvement entitled Physician Engagement in Quality and Safety. Monthly, we have a departmental quality and safety meeting that is prioritized by giving it the timeslot of one of our daily educational sessions. The main purpose of this meeting is to discuss quality and safety initiatives and issues in the department, and it also serves as a platform for continuous education for patient safety. In addition, we have a daily pre-treatment peer review session where we discuss and critique each others' work — contours, overall plans, for example — and this also promotes our safety culture. Our leadership actively participates in this meeting and they strongly encourage attendance and participation of everyone, including physicians.

We also implemented an event learning system called the “Good Catch” program that is supported by a weekly Quality and Safety review meeting led by physician champion Dr. Chera and attended by most clinical managers. Everyone in the department, from frontline employee to top administrators, is encouraged to submit “good catches.” This weekly review meeting emphasizes the no-blame environment in which good catches are routinely reported and analyzed to drive improvement and learning. The data allow us to better understand how our systems are performing, what the gaps are and where improvement efforts should be spearheaded.

A healthy culture of safety creates and cultivates individual safety mindfulness. Mindfulness, generally speaking, is a practice of heightened awareness, which allows one to be proactive instead of reactive. More specifically, safety mindfulness is about an adherence to evidence-based standard work while maintaining


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**Figure 1:** Patient Safety Culture in the Department of Radiation Oncology at the University of North Carolina, Chapel Hill, NC. Note the improved rates of positive responses and the increasing number of survey participants, over time (rate of response in 2015, 2017 and 2019 was 85-90%).

moment-by-moment appreciation of the potential for latent and active failure pathways. The idea is the awareness of real-time performance, in particular maintaining awareness of risks, and being willing and able to detect, interpret and intervene in abnormal and potentially hazardous situations.

Many radiation oncology professionals believe that they practice safely and reactively respond to patient safety issues as they arise (and may be deemed to have “safety complacency,” an opposite to safety mindfulness). In a healthy safety culture, everyone is thinking and talking about patient safety and is proactively seeing and managing potential patient safety issues. We acknowledge that the multidisciplinary nature of our specialty requires that many diverse individuals need to participate actively to embrace safety mindfulness.

The Bogdanich articles brought about awareness and a concerted response from our profession and, overall, have had a positive impact. Compared to 10 years ago, we believe that patients treated in our clinics are receiving safer radiation treatments, and radiation oncology professionals are increasingly more mindful of patient safety. Changing culture is hard but not impossible. Leadership and education are the way forward. Yes, in the future there will be safety improvements with enhancements in automation and artificial intelligence. However, to improve safety culture, we need to develop people with safety mindfulness. 

*Bhisham Chera, MD, is an associate professor, associate chair and director of Patient Safety and Quality Improvement in the Department of Radiation Oncology at the University of North Carolina School of Medicine.*

*Alison Amos, PhD, is a clinical assistant professor in the Healthcare Engineering Department at the Department of Radiation Oncology in the UNC School of Medicine. She supports implementation and training on creating infrastructure for continuous quality improvement, utilizing Lean-based process improvement and patient safety methodologies.*

*Lukasz Mazur, PhD, is an associate professor and a director of the Healthcare Engineering Department at the Department of Radiation Oncology in the UNC School of Medicine. His practical and academic expertise are in the field of health care quality improvement and patient safety.*

*Lawrence Marks, MD, FASTRO, is the Sidney K. Simon Distinguished Professor of Oncology Research, and professor and chair of the Department of Radiation Oncology at the UNC School of Medicine. His primary interests include breast and lung cancer, normal tissue injury and quality improvement.*

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COMPLIANCE

GUIDELINE

REGULATION

STANDARD

CONDUCT



## WOULD YOU RATHER HAVE A STANDARD PRACTICE OR A SPECIAL PRACTICE?

*RO-ILS demonstrates why we must standardize.*

BY SUZANNE EVANS, MD, MPH

### STANDARDIZATION HAS BECOME INCREASINGLY MORE COMMON

and includes efforts to standardize work outside of direct patient care. For example, RO-ILS: Radiation Oncology Incident Learning System<sup>®</sup> is a national effort to standardize error reporting and facilitate local and national learning. Some practices have abandoned homegrown systems in favor of RO-ILS. True to any change effort, there are early and late adopters of standardization efforts, as well as those who remain skeptical. Skeptics may think that their practice is special and not well suited to standardization.

There remains a struggle in medicine between physicians' desire for autonomy in managing their patients and practice and the provision of high-quality, safe care. We all recognize that there is a great deal of art in what we do, and there are many areas that are "data-free zones," even in oncology. We also recognize that there are true best practices. Most of us feel we have struck the right balance of individualizing our workflow and respecting the "rules," as they are.

It must be recognized that standardization efforts, especially regarding clinical care, come at a time when physician autonomy is, perhaps, at an all-time low. With

the rising demands of electronic medical records, the cumbersome prior authorization process and health care administrators looking at key performance indicators, it seems that everyone wants a say in how we practice as physicians. So it's understandable why we can have an initial aversion to being told which unit of radiation we should be using, how we should write our prescriptions,<sup>1</sup> how we should name our targets and organs at risk,<sup>2</sup> which normal tissues we should contour<sup>3</sup> and even how we should talk about our errors<sup>4</sup> and report them. Have we gone too far in standardization? Can't anything be special or tailored anymore? Certainly, to read the



ROhub forum debate on the use of cGy or Gy as a unit, there are those who argue our field has gone too far.

Let us review, for a moment, the rationale for standardization. To combat medical errors, standard methods of communication (such as SBAR: Situation, Background, Assessment, Recommendation, and both procedural and non-procedural time outs) have been successfully adopted. We also have seen standardization efforts in the form of cancer staging, RECIST criterion for treatment response, pathology synoptic report and others too numerous to mention. Time and time again, adopting standards has led to clearer communication, more complete information and the ability to compare across systems. The efforts by ASTRO and AAPM, as evidenced by the RO-ILS data, have another compelling reason for existence: mitigation against some significant errors that have already happened in clinic.

For instance, one practice reported that a verbal order was given for a prescription of “12 in 2.” The dosimetrist interpreted this as 12 Gy in 2 Gy fractions for six fractions. However, the physician’s intent was 12 Gy in two fractions. Although a written prescription clearly would have been most appropriate, this order would have been clearer as “1200 in 2.” It’s unlikely someone would switch from cGy to Gy in the same sentence; therefore, the “2” would have been better understood to refer to the number of fractions and not the dose per fraction. A similar case occurred when “40.05 in 15” was misheard as “45 in 15.” In another instance — exacerbated by nonstandard ordering of elements — a patient was prescribed 5040 cGy; however, it was not recognized until the first day of treatment that the plan had been generated with 25 cGy per day for 180 fractions. Beyond prescription errors, the RO-ILS data also tells us of an instance where an L4 metastasis was treated, and the cauda equina was not contoured. Upon contouring this structure, it was found to be over tolerance. The RO-ILS data also discusses a case where an incompletely segmented brainstem resulted in an IMRT plan dumping a significant dose in the unsegmented brainstem. This was detected and corrected after two fractions, but it could have been fatal. More examples of events that support the rationale for standardization can be found in RO-ILS aggregate reports.

It is time that we think beyond just how tools like RO-ILS can help us recognize error trends. As Peter

Dunscombe, PhD, used to quip: “An ILS is actually better called an incident teaching system. Whether or not we learn is up to us.”

So how can standardization and RO-ILS help us to truly learn from our accidents? With standardization, there is real opportunity to build intelligent safety nets that can help automate error detection. If we have a library of 300 brainstems segmented in our clinic, can’t our software be trained to recognize when an incompletely segmented brainstem measured several standard deviations in volume below the mean? We can also train software to recognize a “normal”

prescription<sup>5</sup> and alert us when the prescription is unusual for our practice or to notify us when we have not included the expected organs at risk for a given anatomic site. Finally, the adoption of standard naming allows for plan evaluation templates to be used according to the user’s desires and can facilitate peer review and efficient planning.

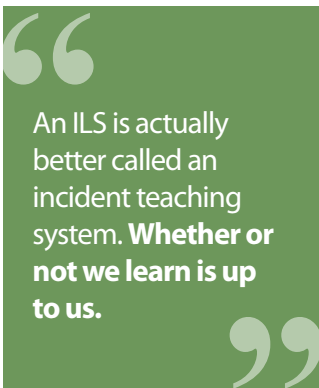
None of these intelligent safety nets are possible without a shared nomenclature and understanding of best practices. Although these tools will take time to be widely available and utilized, standardization is a key to better, more efficient practice. We can’t reap the patient safety benefits of standardization without adoption of these measures. Beginning with utilization of RO-ILS, we can identify where more work needs to be done to either develop standards or improve compliance with existing policies.<sup>6</sup> I, for one, have given up any ideas that I want a special practice. Give me a standard one, and we can get closer to zero harm. Now that’s special.



*Suzanne Evans, MD, MPH, is an associate professor of therapeutic radiology and associate director of the Yale Residency Program. She is a quality and safety expert and serves as vice-chair of the RO-ILS RO-HAC.*

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### RO-ILS Safety Notice

Safety events entered into RO-ILS® and then reported to Clarity PSO are analyzed, triaged and, where warranted, reviewed by members of the Radiation Oncology Healthcare Advisory Council (RO-HAC). In addition to aggregate reports and case studies, RO-HAC may identify an event worthy of escalated status and determine that a Safety Notice is warranted. A RO-ILS Safety Notice communicates findings that may be novel or of higher clinical significance, therefore necessitating prompt review by the radiation oncology community.

RO-HAC determined that a recent event related to stereotactic radiosurgery heterogeneity corrections warranted a Safety Notice because the systematic errors affected multiple patients and were difficult to detect. To read this RO-ILS Safety Notice, visit [www.astro.org/roilssafetynotice](http://www.astro.org/roilssafetynotice).

### RO-ILS releases Program Report: 2014-2019

Nine out of 10 RO-ILS users find the program moderately to very valuable. To learn why, read the First Five Years of Experience report, available at [www.astro.org/roils5yearreport](http://www.astro.org/roils5yearreport).

The report describes the strong state of the program with a focus on accomplishments and programmatic changes initiated during the previous year, including new data elements and a new internal triage mechanism for event review by RO-HAC. The report also highlights the importance of internal event review at the local practice and which enhancements have already been implemented to support this important step in the process.

To learn more about the program and enroll, visit [www.astro.org/roils](http://www.astro.org/roils). Thanks to ASTRO and AAPM sponsorship and the generous support of Varian, AAMD and Sun Nuclear Corporation, there is no cost to participate in RO-ILS.

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# “Safety is No Accident”

## *Setting the bar for safety in radiation oncology*

BY ANTHONY ZIETMAN, MD, FASTRO,  
AND TODD PAWLICKI, PHD, FASTRO

### THE FIRST DECADE OF THE NEW

**MILLENNIUM** was a time of inspired expansion in radiation oncology. Technological advances were appearing at a breathtaking rate, and the promise of more accurate treatment than ever previously thought possible came into clear sight. Physicians, physicists and, ultimately, hospital CEOs were all equally enthusiastic. Not only was the technology good for our patients, but it was fabulous for the health care institution’s bottom line. This was a moment in which financial incentives and good practice seemed to align perfectly, and the market drove us on.

As we rode high on the changes taking place to our specialty there seemed to be no dark cloud on the horizon. In 2009, an investigation involving prostate cancer brachytherapy made it to the front pages of the Philadelphia Inquirer and was even featured in a hotly contested Democratic Senate primary, but that little foretaste of trouble to come seemed to blow over fast. However, in January 2010, the blue skies turned black when an investigative reporter from The New York Times, Walt Bogdanich, released the first in a rapid-fire series of articles on radiation safety.



During this period of exuberant expansion, radiation technology had been installed at institutions that did not have the training, experience or capacity to handle it safely. There was no communication between institutions across the nation; many of the cases were “lawyered up” so that others could not learn from them; and the checklist-based, non-hierarchical culture that characterized the airline industry was not yet prevalent in medicine. It took the power of a free investigative press to show us what, in retrospect, was evidently present.

When the stories began to break, then ASTRO chair Tim Williams, MD, FASTRO, turned the agenda for the Board’s January meeting over to the crisis and developing a positive response to it. Several things were immediately apparent. The old “Blue Book,” last revised in 1991, was insufficient to guide training and staffing requirements in the new era. A modern computer-based accreditation system with safety at its heart was essential, as was a national registry of errors, malfunctions and near misses. A complete culture shift was required in the specialty, akin to the rapid changes that Korean Airlines took in the 1990s to change their reputation from one of the planet’s least safe airlines to one among the safest.

ASTRO quickly convened an intersociety meeting incorporating representatives from ASTRO and 10 other concerned societies including AAPM, ACR and ASRT, to name but a few. Chaired by Anthony Zietman, MD, FASTRO, Jatinder Palta, PhD, FASTRO, and Michael Steinberg, MD, FASTRO, writing groups were formed to make new recommendations regarding the process of care, the radiation oncology team, safety and quality assurance. The final document, aptly named *Safety is No Accident: A Framework for Quality Radiation Oncology and Care*, was published in 2012. It was widely propagated and quickly became the safety culture handbook for the new era. The book’s conclusions were clear and unvarnished. Many of the disasters of the previous decade had been the result of the over-exuberant installation of technology, but that technology demanded minimums of staffing, training and experience. The complexity inherent within advanced technology requires new thinking and new procedures. Quality assurance (QA) and teamwork needed to be integrated into training

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and culture. Safety is No Accident enshrined these evolving values. It provided the foundation for new programs as well as the QA and safety culture that now surrounds all of us from the first day of training onward.

### Incorporating current safety updates and new technologies


In the years following the first publication of Safety is No Accident, radiation oncology experienced many changes, such as the increased use of MR-guided treatments and MR simulation, knowledge-based treatment planning, re-treatments, expanded use of hypofractionation, non-ionizing surface imaging and the increased role of immunotherapy. The RO-ILS® safety initiative was implemented and has matured since 2014, and APEX®, ASTRO's accreditation program, was established. It was generally recognized that achieving the best possible treatment quality and patient safety requires continuous focus from the clinical team.

With these thoughts in mind, an update to Safety is No Accident was initiated in 2017 by ASTRO's Multidisciplinary Quality Assurance Subcommittee and approved by ASTRO's Board of Directors in 2019. The new document covers the same four topics of the first version: the process of care, the radiation oncology team, safety and management and assurance of quality. Updates and clarifications in the 2019 version reflect the most current peer-reviewed safety literature as well as current guidance documents from ASTRO and AAPM, such as Task Group 100 on the application of risk analysis methods.

The roles and responsibilities of the clinical team have been slightly modified to reflect current practice and are summarized in Table 2.1 of the document. The interdisciplinary clinical team is defined as consisting of radiation oncologists, therapists, physicists, dosimetrists and nurses. The safety staffing model proposed in the 2012 version was moved from Chapter 2 to Appendix II of the 2019 version but otherwise remains unchanged. It continues to be a valuable tool for determining safe staffing levels, and its unique approach compliments other existing staffing models.

Recommendations are provided for the appropriate use of an incident learning system — reporting should be met positively, without fear of punitive actions, and employees should have the option to submit information anonymously. Newly added references demonstrate that increased reporting is associated with fewer significant adverse events. The 2019 update uses RO-ILS reports and their subsequent analyses

to emphasize the importance of regular review of workflows, policies and procedures as well as the need to consider radiation oncology as a system. The update points to the need for program accreditation, standardization and the importance of firm process controls for safe practice as well as recommending that concepts of systems engineering should be considered for further improvement of treatment quality and patient safety.

Since 2012, clinicians have used Safety is No Accident as a reference for effective safety practice as well as a teaching tool for residents and staff alike. The updated 2019 version will continue to serve the specialty as one of its key safety documents for years to come. As radiation oncology technologies and processes continue to evolve over time, Safety is No Accident will similarly evolve to help clinicians meet clinical demands while ensuring the safest and best possible treatment for their patients. 

*Anthony Zietman, MD, FASTRO, is a professor of radiation oncology at Harvard Medical School and the Massachusetts General Hospital. He is a former president and chair of ASTRO, the current editor-in-chief of the Red Journal and an ASTRO Gold Medalist.*

*Todd Pawlicki, PhD, FASTRO, is a professor of radiation medicine and applied sciences at UC San Diego School of Medicine. He is currently a member of the ASTRO Board of Directors and the executive editor for physics of the Practical Radiation Oncology journal.*



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## WHY PURSUE ACCREDITATION?

BY JEAN L. WRIGHT, MD

**ALL PRACTICES STRIVE TO PROVIDE SAFE**, high-quality radiation therapy to patients. Yet the increasing demand on systems and providers to meet financial, quality and other benchmarks results in unprecedented strains and exerts pressures that may, at times, compete with one another. For practices considering strengthening or developing a dedicated safety and quality (SAQ) program, the process may seem daunting given the volume and complexity of the various elements of SAQ. Yet the gold standard in evaluating a practice's approach to safe, high-quality treatment remains the stamp of approval from an external body that endorses and validates the practice. This external validation is best achieved through accreditation.

Accreditation programs in radiation oncology provide a framework for ensuring that a practice meets the highest SAQ standards and reflects back to patients, staff and the community that those standards are being achieved. To meet the demand for an accreditation program with an SAQ framework developed and managed exclusively by members of the radiation oncology community, ASTRO created APEX<sup>®</sup> (Accreditation Program for Excellence) through its Target Safety initiative. There are two other accrediting bodies for radiation oncology practices: the American College of Radiation Oncology (ACRO) and the American College of Radiology (ACR). Roughly half of practices in the United States are accredited at the present time. While accreditation is a regulatory requirement in some states and of some organizations, such as Veterans Affairs, many practices voluntarily

pursue accreditation as a means of ensuring the highest quality treatment delivery and communicating that to the community at large.

The APEX accreditation process is built upon five pillars: the process of care, the radiation oncology team, safety, quality management and patient-centered care. Within these pillars are 16 program standards supported by evidence indicators, the metrics by which a practice's compliance with the APEX standards are assessed. Evidence indicators are measured by reviewing medical records and policy and procedure documents and by interviewing team members during a facility visit. The standards, as well as the types of indicators needed to demonstrate that standards are met, are clearly explained in the accreditation guide that is provided at the outset of the accreditation process. The expectation is that practices perform the standards in a consistent manner; yet APEX allows practices to be flexible and creative when demonstrating compliance and supports the development of processes that best suit the practice environment.

The fundamental benefit of pursuing accreditation is that the process itself results in quality improvement in the context of a clear set of goals and standards; accreditation makes safety and quality easy by laying out a defined structure and pathway for performance improvement. Completing the process ensures that established standards are met through uniformity in process, which is the foundation of quality radiation therapy practice. Preparation for accreditation almost

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always requires change in order to achieve this uniformity. Because accreditation addresses all aspects of a practice, it is by nature an interdisciplinary effort that can also serve to inform and elevate the bedrock and often elusive element of safety culture.

There is emerging data that accreditation meaningfully impacts quality outcomes. Accreditation has been shown to be a force to align quality improvement initiatives with regulatory requirements,<sup>1</sup> to quantitatively improve quality metrics in the hospital setting,<sup>2</sup> and feed back into quality initiatives.<sup>3</sup>

In the current environment of expanding demands on providers and practices, accreditation can serve to align priorities, unify processes and elevate the practice in ways both measurable and immeasurable. I personally encourage all practices to pursue accreditation. I am confident that the process will prove rewarding to those who pursue it and will result in meaningful benefits to the patients who receive care in accredited practices. 

*Jean Wright, MD, is an associate professor of radiation oncology and molecular radiation sciences at Johns Hopkins University and serves as the director of the Breast Radiation Oncology Program, as well as the vice-chair for Safety and Quality for the Department of Radiation Oncology. Dr. Wright is also the co-chair of ASTRO's Practice Accreditation Committee.*

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## ASSESSMENT OF KNOWLEDGE RELATED TO PATIENT SAFETY

**IN 1999, THE ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION (ACGME)** and the American Board of Medical Specialties (ABMS), charged with responsibility for developing guidelines for post-graduate medical training and board certification, respectively, jointly promulgated six core competencies they believed represented the essence of skills and knowledge necessary for the high-quality practice of medicine.<sup>1</sup> As with any policy statement based on educational, scientific and clinical standards, there was always an understanding that modifications would be made to the competencies as appropriate.

Following the 1999 publication of the National Academy of Sciences' landmark report *To Err is Human: Building a Safer Health System*,<sup>2</sup> there was considerable concern within organized medicine that the safety issues defined in that report, and the principles for improvement it enumerated, had not filtered down into routine patient care. Some organizations, such as The Joint Commission, met the challenge by establishing patient safety requirements within their mandated standards.<sup>3</sup> It was apparent, however, that ensuring that these cultural and operational changes were adopted throughout the health care system would necessitate greater integration of the issues into graduate medical education and ABMS Member Board certification assessment instruments by direct incorporation of patient safety content into the core competencies.

Such an update to the core competencies was published by the ABMS in January 2014 in its *Standards for the American Board of Medical Specialties Program for Maintenance of Certification*.<sup>4</sup> The new language, which was effective in January 2015, specifically integrated patient safety principles into its program for maintenance of certification (MOC) requirements. In requiring assessment of patient safety

knowledge across the continuum of medical practice, the ABMS acknowledged that many practicing physicians had little indoctrination into the science underlying patient safety concepts and were unaware of the improvements in morbidity and mortality associated with the introduction of proven patient safety initiatives. They also recognized that the elements inherent in patient safety effectively crossed all six of the core competencies.

Although the 2014 ABMS document specifically addressed MOC programming for the 24 Member Boards, there was a clear understanding that the new requirements would also be integrated into graduate medical education training by all ACGME-accredited

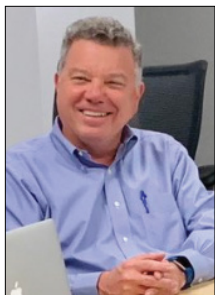
residency and fellowship training programs and into initial certification instruments administered by its Member Boards. Member Boards were allowed significant flexibility in how candidates and diplomates were to be provided with the elemental patient safety knowledge and how assessment tools should be implemented. In 2015, the trustees of the American Board of Radiology

(ABR) determined that, for radiation oncology candidates and diplomates, assessment of knowledge and skills in patient safety would be embedded in its non-clinical skills domains, which included topics such as quality assurance, bioethics, biostatistics, research methodologies and critical literature analysis.

The introduction of non-clinical skills assessment initiated by the ABR was consistent with the actions of the other 23 ABMS Member Boards, but the ABR trustees recognized that the material covered in this domain was vast and, in many instances, subjective. Concerned with a potentially daunting task for candidates and diplomates, the ABR has provided a document that summarizes the material it believes



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## EMPHASIZING SAFETY AND QUALITY IN SCHOLARLY PUBLISHING

BY W. ROBERT LEE, MD, MS, MED, FASTRO

**IT HAS BEEN TWO DECADES** since the Institute of Medicine (now the National Academy of Medicine) published the

influential monograph *To Err is Human: Building a Safer Health System*.<sup>1</sup> The publication laid out recommendations that fell into four categories: 1) Develop knowledge and leadership in patient safety, 2) Identify and learn from errors, 3) Raise safety standards and 4) Create safety systems inside health care organizations. Soon thereafter, the Agency for

Healthcare Research and Quality (AHRQ) would publish the report *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*.<sup>2</sup> The report listed more than 50 patient safety practices that were likely to improve patient safety and specifically described 11

practices that were considered proven to work but were not performed routinely in the nation's hospitals and nursing homes. These early efforts at the beginning of the 21st century continue to shape how patient safety is measured in health centers in the United States and across the world.

Although safety had been central to the discipline of radiation oncology for the last half of the 20th century, patient safety concerns were heightened in the first decade of the 21st century. Rapid developments in and utilization of advanced, sophisticated technologies and well-publicized radiation errors combined to create a crisis of safety within the field.<sup>3</sup> ASTRO, along with other aligned professional organizations, proactively addressed the crisis. The Target Safety campaign was completed, and the monograph *Safety is No Accident* was published.


Coincidentally, the ASTRO Board decided to launch a new ASTRO journal, *Practical Radiation*

*Oncology (PRO)*. It has been my privilege to lead this new journal for the last decade. From its inception, the mission of *PRO* has been to improve the quality of radiation oncology practice. This purpose is met by publishing original articles that focus on patient safety and quality improvement. Indeed, the first article to be published in *PRO* highlighted the many challenges surrounding patient safety in radiation oncology.<sup>4</sup>

This seminal paper is one of the most highly cited in the history of *PRO* and continues to be cited frequently nearly 10 years after publication.

Over the last decade, *PRO* has published nearly 100 papers that focus on quality and patient safety. Many of the papers are in the form of consensus papers and clinical guidelines,<sup>5,6</sup> but several take the form of original articles using incident

learning and other methods to measure quality and safety within and across departments.<sup>7,8</sup> Reviewing the authorlines of these papers highlights the importance of multidisciplinary teamwork to ensure a safety culture. It is gratifying that *PRO* has become the preferred venue of investigators examining safety and quality in the practice of radiation oncology.

Of course, there is more to be done. It is my hope that *PRO* will continue to publish important, practical and timely analyses that emphasize “knowledge with a purpose.” In this way, *PRO* can inform practitioners of radiation oncology and ensure that our patients receive the safe care that they deserve. 

*W. Robert Lee, MD, MS, MED, FASTRO, is a professor with tenure in the Department of Radiation Oncology at the Duke University School of Medicine. He has a busy clinical practice at Duke and the Durham VA Medical Center focusing on caring for men with prostate cancer.*

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“The physician must ... have two special objects in view with regard to disease, namely, to do good or to do no harm.”

– Epidemics, Corpus Hippocraticum

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## Continued from ASSESSMENT OF KNOWLEDGE RELATED TO PATIENT SAFETY

is relevant and minimally essential for its radiation oncology candidates and diplomates to prepare for the qualifying (written) exams in initial certification, under clinical (general and radiation) oncology: The ABR Non-Clinical Skills Syllabus.<sup>5</sup> Topics covered in the patient safety section of the syllabus include communication; the development of a culture of safety; and identification, investigation and prevention of sentinel events by methodologies such as root cause analysis. As with all non-clinical skills items that will be employed in the initial certification clinical qualifying exam, or in the new ABR Online Longitudinal Assessment (ABR OLA) Part 3 MOC assessment instrument, questions will be taken directly from the material or links provided in the syllabus (e.g., the Safety is No Accident monograph).

In developing the patient safety content for its radiation oncology non-clinical skills syllabus and exam items, the ABR has drawn heavily from Safety is No Accident, which was introduced in 2012<sup>6</sup> and updated in 2019.<sup>7</sup> Chapter 3 of the latest document specifically addresses patient safety in the practice of radiation oncology.<sup>7</sup> Although Pronovost et al.,<sup>8</sup> and others, have shown evidence of significant systemic improvement

in errors related to the delivery of medical care, preventable deaths due to medical errors still occur. The ABR is committed to regularly updating content and assessment tools related to patient safety as long as these gaps remain. 

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## HIGHLIGHTS FROM INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY • BIOLOGY • PHYSICS

**November 15, 2019**

### Daily Step Counts: A New Prognostic Factor in Locally Advanced Non-small Cell Lung Cancer?

*Ohri et al.*

This study investigates the usefulness of step count data collected by wearable devices to measure activity as a predictor for hospitalization during radiation therapy and for completing a course of radiation therapy without significant delay. The authors performed a pooled analysis using data from three prospective clinical trials. This study found that baseline physical activity as defined by the authors was a more consistent predictor of hospitalization and completion of radiation therapy treatment than performance status. Activity level was also a statistically significant predictor for progression-free survival and there was a trend suggesting it could also be a predictor for overall survival.

**December 1, 2019**

### Radiation Therapy as a Bridging Strategy for CAR T-cell Therapy With Axicabtagene Ciloleucel in Diffuse Large B-cell Lymphoma

*Sim et al.*

This article reports the use of radiation therapy as a bridge therapy between the collection of T cells and the final administration of axicabtagene ciloleucel (axicel) CAR T therapy. The authors reviewed 12 patients who had failed at least two lines of prior therapy, eight of which presented with bulky disease >10 cm. No significant toxicity related to radiation therapy was identified, and the in-field disease control was effective during the bridging period. The authors acknowledge a short follow-up and small cohort but propose that radiation therapy could be a safe and effective bridging strategy for CAR T therapy. In the same issue, Plastaras et al. provide an accompanying editorial, "[Don't Get Stuck on the Shoulder: Radiation Oncologists Should Get into the CAR with T-Cell Therapies.](#)"

**January 1, 2020**

### The Prevalence and Determinants of Return to Work in Nasopharyngeal Carcinoma Survivors

*So et al.*

-and-

### Return to Work in Survivors of Human Papillomavirus-associated Oropharyngeal Cancer: An Australian Experience

*Zecena Morales et al.*

So and colleagues studied 73 disease-free nasopharyngeal carcinoma (NPC) survivors in Canada who received curative-intent IMRT  $\geq 4$  years earlier. They found while the majority of survivors returned to work (RTW), 31% had reduced work hours since diagnosis by a median of 12 hours a week. The authors call for prospective research to help facilitate RTW for NPC survivors. Zecena Morales and colleagues surveyed 68 patients who completed curative treatment for HPV-associated oropharyngeal cancer (OPC) in Australia  $\geq 4$  months before enrollment. Fifty-eight of 68 participants (85.3%) were working at enrollment; median time to return to work was six months; 45 (77.6%) were in the same role and 35 (60.3%) worked the same number of hours. The authors advocate for attention to symptom management and support from the workplace.

**February 1, 2020**

### Optimizing Whole Brain Radiation Therapy Dose and Fractionation: Results From a Prospective Phase 3 Trial (NCCTG N107C [Alliance]/CEC.3)

*Trifiletti et al.*

One hundred ninety-four patients with brain metastases were randomized to either stereotactic radiosurgery alone or WBRT after surgical resection. Among the 92 patients receiving WBRT, sites predetermined the dose/fractionation that would be used for all patients treated at that site (either 30 Gy in 10 fractions or 37.5 Gy in 15 fractions). While there was no reported radionecrosis, there was a statistically significant increase in the risk of at least one grade  $\geq 3$  adverse event with 37.5 Gy in 15 fractions versus 30 Gy in 10 fractions (54% vs 31%, respectively,  $P = .03$ ). The authors note that hypofractionated regimens remain the current standard of care for patients with brain metastases for whom WBRT is recommended.





## HIGHLIGHTS FROM *PRACTICAL RADIATION ONCOLOGY*

### January-February 2020 Where Society and Medicine Meet: The Identity of Motherhood

*Knoll*

This article tackles the misconceptions about motherhood and the idea that parenthood is the most defining endeavor in a person's life but often penalizes women more. Although the author does not feel that being a mother has affected what she does, studies show that life integration is more difficult for women. She discusses how this pervasive cultural belief led her to try to "hide her motherhood" so as not to appear less committed to her job. The author describes a story from a time during clerkship where a supervisor told her, "You and Jane both did a great job this rotation. But remember that no matter how good a job you do, whenever you walk out that door, everyone is thinking, 'She's going home to her kids.'"

### Definitive and Postoperative Radiation Therapy for Basal and Squamous Cell Cancers of the Skin: Executive Summary of an American Society for Radiation Oncology Clinical Practice Guideline

*Likhacheva et al.*

This new guideline reviews the evidence for the use of definitive and postoperative radiation therapy (RT) in patients with basal cell carcinoma (BCC) and cutaneous squamous cell carcinoma (cSCC). Using a systematic review process, the authors address five key questions including indications for RT in the definitive and postoperative setting for BCC and cSCC, target volumes, treatment planning and the role of systematic therapy in combination with radiation. The guideline recommends definitive RT as the primary treatment for patients with BCC and cSCC who are not surgical candidates, encourages practitioners to enroll patients in prospective trials and to approach care in a multidisciplinary fashion whenever possible. Future research should characterize the role of RT by using prospective registries and clinical trials to assess patient outcomes.

## HIGHLIGHTS FROM *ADVANCES IN RADIATION ONCOLOGY*



### Article in Press

### Combination of a Big Data Analytics Resource System with an Artificial Intelligence Algorithm to Identify Clinically Actionable Radiation Dose Thresholds for Dysphagia in Head and Neck Patients

*Mayo et al.*

The authors of this study developed a method that combined a big data analytics resource system (BDARS) with artificial intelligence (AI) algorithms in order to identify DVH metrics that predicted for dysphagia. The use of the BDARS in combination with AI allowed the authors to analyze a larger range of metrics when compared with manual aggregation methods. The authors found that their results were consistent with previous studies, though more specific. They also note the importance of consistent contouring among clinics as a factor in the utilization of BDARS and AI for potential hypothesis generation in the future.

### The Capital Investment Strategy for Radiotherapy in Ontario: A Framework to Ensure Access to Radiotherapy

*Glicksman et al.*

In this article, the authors document the methods used to develop a capital investment strategy and recommendations to maintain and improve patient access to radiotherapy treatment. A multidisciplinary panel created a list of planning principles for the strategy such as continuing to improve timely access to care for cancer patients; ensuring treatment machine capacity matches the need; and ensuring value for investment of existing infrastructure. The panel used data on cancer incidence, radiation utilization and machine throughput to support the recommendation to add 26 linear accelerators throughout Ontario by 2028 in order to continue providing province-wide access for the population.



PODCASTS

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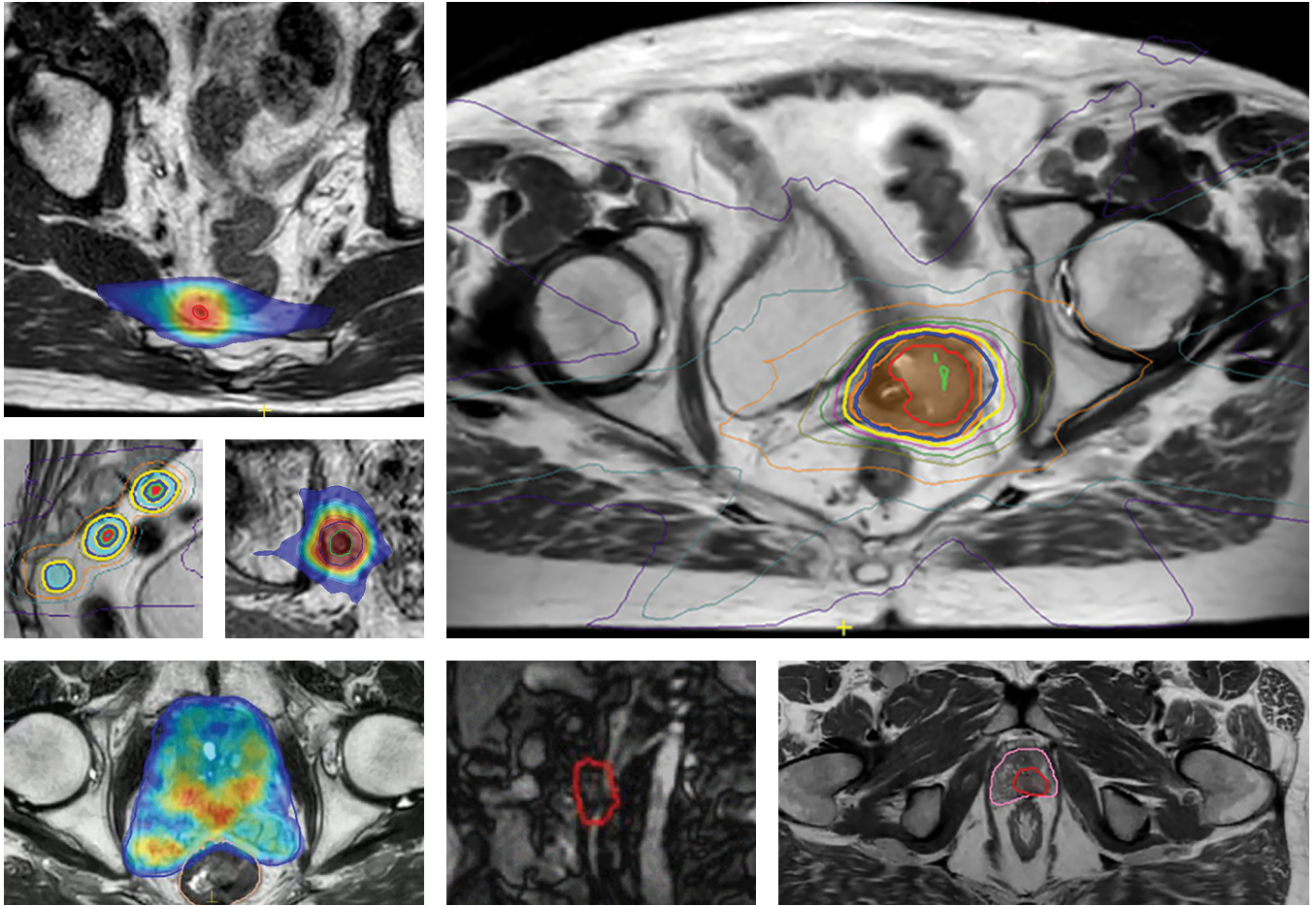
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