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ASTRO news

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

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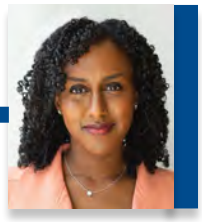
EDITOR'S*notes*

BY NAJEEB MOHIDEEN, MD, FASTRO
SENIOR EDITOR, *ASTRONEWS*

THE SUMMER EDITION OF *ASTRONEWS* TAKES A COMPREHENSIVE LOOK AT MENTORSHIP, with stories exploring The Art and Science of Mentorship (page 9) and programs run by societies and institutions, both existing and new — an absorbing read on a vital topic. We're launching a new feature called Beyond the Clinic — radiation oncologists taking on roles outside the discipline's confines. Australia's highly successful Targeting Cancer campaign, which raised awareness and effected change in health care policy, is the first in the series. We're also kicking off Guest Editorials, and I'm delighted to start with Editorial Board member Sewit Teckie reflecting on mentorship.

GUEST EDITOR

Sewit Teckie, MD



Thank you, Najeeb, for giving me the opportunity to write this guest editorial.

Mentorship has been incredibly meaningful in my education, training and now in my faculty career as a clinical researcher and associate professor of radiation medicine. You will see several formal definitions of mentorship in this issue, including in Dr. Erin Gillespie's and Dr. Daniel Golden's informative piece. Based on my own experiences, primarily as a mentee and now as a mentor to others, I would add the following: Mentorship requires believing in someone, providing them insight, advice, access and opportunities without expecting anything in return, and making oneself available to support one's mentee along their path.

I am the first person in my extended family to attend medical school. Mentorship is the critical piece that has helped me navigate a medical career. When preparing to write this editorial, I reflected on my experience as a mentee and the many remarkable people who have mentored me over the years. Beginning in medical school, Dr. Benjamin Ebert, then a junior faculty member and now chair of medical oncology at Dana-Farber Cancer Institute, mentored me in the Golub Lab at the Broad Institute of Harvard/MIT and later in the Ebert Lab at Dana-Farber. In the third year of medical school, Dr. Anthony D'Amico opened up the world of radiation oncology to me and countless other medical students. When I could not see myself fitting in to this rather male-dominated specialty, he showed me that my interests and skills were a great match for the field.

During residency at Memorial Sloan-Kettering, I was the fortunate mentee of Dr. Joachim Yahalom, a giant in the field of lymphoma. From Dr. Yahalom, I learned that one can leave a lasting academic legacy while having fun in the process. Dr. Nancy Lee mentored me on several research projects and gave me the confidence to become a head-and-neck radiation oncologist. Later in this issue, Dr. Sarah Donaldson and Jessica Frank write about the different types of mentors, including those who help their mentees understand personal success and work-life balance. During residency, Dr. Suzanne Wolden and Dr. Lee both showed me that one could be an excellent clinician, oncology leader, wife and mother. When I spent research year in the laboratory of medical oncologist Dr. Ping Chi, she provided patient, supportive mentorship as I learned an entirely new bench-side skill set.

The ASTRO network has also provided special mentorship relationships. I had the good fortune of being mentored by Dr. Michael Steinberg when he and I discovered a mutual interest for health economics. This mentorship led to co-authoring a review article for the Journal of Clinical Oncology — an experience I will never forget. Dr. Charles Thomas, chairman of OHSU Rad Onc, has also generously shared his time and access with me and many other radiation oncologists throughout the country.

In my current faculty role, I count several people within my institution as mentors, beginning with my chairman, Dr. Louis Potters. With his encouragement, I have joined several ASTRO and NRG committees, allowing me to sit "at the table" with leaders throughout oncology. Dr. Potters has also supported my interests in patient-facing health technology, a rather novel research area within radiation oncology. My research mentor is Dr. Michael Diefenbach, a behavioral health researcher with interests in oncology and digital health. His mentorship has helped me grow significantly as a researcher and collaborator.

Continued on page 4

CHAIR'S*update*

THOMAS EICHLER, MD, FASTRO
CHAIR, BOARD OF DIRECTORS

WHAT HAS **CHANGED**?

THE HEADLINE OF THE MAY 25, 2021, edition of the Richmond Times Dispatch was as sobering as it was thought-provoking: "After Unrest in Richmond, What Has Changed?" It was exactly one year after the murder of George Floyd, an unconscionable event that sparked a wave of social unrest across the country, including in the capital of the Confederacy, where time seems to have long stood still. But it wasn't just cities and regions that looked into the mirror. Individuals and organizations such as ASTRO took a long, hard look and frowned at what they saw. And so, the question: What has changed?

Here, the statuary on Monument Avenue that personified the Lost Cause has been largely removed, reminders of the past but disconnected from the present, their destination yet to be resolved. The sixty-foot-tall monument to Robert E. Lee, blanketed in a rainbow of graffiti and the flashpoint for local demonstrations, is the lone surviving figure whose fate will be determined by the state judicial system. The physical changes were swift and obvious. Reweaving the social fabric, on the other hand, will take more time, predicated on a genuine commitment to change.

What about ASTRO? What has changed? Like my adopted city, visible change came quickly. Then-Chair Ted DeWeese, MD, FASTRO, boldly proposed elevating the Committee for Health Equity, Diversity and Inclusion (CHEDI, under the Education Council) to full Council status, a major step toward fulfilling a stated core value in our Strategic Plan. On August 12, 2020, the ASTRO leadership team met with representatives from CHEDI, ARRO and their Equity and Inclusion Subcommittee, ADROP and SCAROP to begin mapping out a concrete game plan. By early September, a core group consisting of Education Chair Dr. Ben Movsas, Dr. Curt Deville, Dr. Iris Gibbs, Dr. Gita Suneja and CHEDI Chair Dr. Malika Siker, met virtually with the Board and presented a detailed proposal outlining five strategic goals of the nascent Council:

1. Leadership — Ensure the sustained inclusion of HEDI at the highest levels of the Society through the permanence of Board positions and Council representation;
2. Diversity — Develop and support a pipeline of diverse physicians and scientists that reflects the communities we serve;
3. Inclusion — Advance a culture of inclusive excellence in radiation oncology that values differences and seeks to eliminate bias;
4. Equity — Prioritize health equity in cancer care and delivery through Societal programming and policy;
5. Harmonization — Harmonize HEDI efforts across the Society and its related organizations to improve operational efficiency and cohesion, leverage resources and maximize impact.

Potential tactics and deliverables were also presented for consideration. At the time of my Presidential Address last October, I told you that I considered this proposal to be "an excellent roadmap to lead ASTRO and radiation oncology into a more diverse and inclusive environment and ultimately, to make our specialty look more like the patients we treat, following the lead of multiple specialty societies." I still believe that.

So, what *has* changed? Both the Board of Directors and ASTRO staff have since undergone anti-racism and implicit bias training facilitated by an outside consultant who also did an analysis of the Society's programs and procedures, resulting in specific recommendations for moving forward. Integrating HEDI principles across the existing Council structure has already begun and will likely accelerate after the 2021 Annual Meeting in Chicago this October. But like many other medical specialties, radiation oncology has a very obvious numbers problem: a discouraging lack of Black faculty, residents and applicants,[1] and until those numbers improve considerably, it will remain an uphill struggle to literally change the face of the specialty. That doesn't mean it can't be done, however. It will require a creative long-term recruitment strategy, patience and flexibility. It will mean expanding outreach to HBUCs, growing the successful ASTRO Minority Summer Fellowship program and nurturing the Aspiring Scientist and Physician Program at the Annual Meeting. Mentorship will be a visible

Continued on the following page

manifestation of that commitment. We need look no further than our colleagues at ASCO and the ACR who already have programs in place and are slowly seeing their numbers improve. Indeed, the ASCO plan published in the Journal of Clinical Oncology in 2017 stated very clearly: "The factors contributing to racial and ethnic disparities in cancer outcomes are complex and interrelated, but lack of access to high-quality care that is understanding and respectful of diverse traditions and cultures plays a significant role."[2] My friends, we don't need to reinvent the wheel, but our mindset needs to be no less focused than the sign that sat on Ronald Reagan's desk during his presidency: It CAN Be Done.

Indeed, it MUST be done.

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Continued from page 2

Not every mentorship relationship will last for years or decades: Most of mine have been between one and four years. Mentors will change over time as a mentee's interests evolve. I believe that this is only natural and should be welcomed. Furthermore, a trainee's interests may not be adequately addressed by the available mentors at their institution. Fortunately, we have the house of radiation oncology to look to, including ASTRO's new Mentor Match Program.

I would be remiss if I did not point out that the vast majority of my mentors did not look like me, share my background or even share my personal interests; I am an Eritrean-American immigrant Black woman and the first doctor in my family. What my mentors and I did share was a mutual interest in my future. I am incredibly grateful to all my mentors for believing in my potential and sharing their precious time with me.

In recent years, I have adjusted to becoming a mentor for others. I have the privilege of mentoring medical students and residents. I try to listen carefully to trainees' interests, ask how I can be helpful and suggest ways for them to meet their research or personal goals. I have learned that it is important to serve as an impartial, non-judgmental sounding board for trainees. I remember what it was like to be in their shoes: Sometimes you just want a more senior person to hear what you have to say and provide an uncritical perspective.

In summary, here are my takeaways from reflecting on my mentee and mentor journey:

1. Mentors are everywhere. Often, just speaking with others about your interest and asking the right questions can forge a powerful connection where you least expect it.
2. Mentorship requires trust, as mentioned by Donaldson and Frank in this issue. I would also add that mentorship requires open-mindedness and lack of judgment. Today's residents and medical students have more diverse research and career interests than existed in the past, and mentors should nurture those interests.
3. Mentors can benefit from formalized training. The role of a mentor is different from that of an academic advisor or clinical attending preceptor. Mentorship should be supported by institutions.
4. Mentorship is a fluid process that can last a finite period or continue over decades. There can be bursts of mentorship activity followed by lulls, or it can be a consistent relationship over time.
5. While mentors may seem very different from you on the surface (with regard to gender, race, ethnicity or location), a productive mentorship mostly requires shared interests. Look for shared interests that both parties care about and can work toward.

In historic first, U.S. president visits radiation oncology department

BY LIZ GARDNER, SENIOR MEDIA RELATIONS MANAGER

IN A FIRST FOR THE FIELD, U.S. President Joe Biden visited the radiation oncology department of The Ohio State University Comprehensive Cancer Center on March 23, 2021.

"This was the first visit by a sitting U.S. president for the sole purpose of showcasing a specific medical department — and he chose radiation oncology," said department Chair Arnab Chakravarti, MD, FASTRO. "The experience clearly illustrates the president's respect for the community of radiation oncologists."

Dr. Chakravarti welcomed the president on the 11th anniversary of the Affordable Care Act (ACA) to celebrate achievements in cancer care that were supported by a historic $100 million ACA grant to Ohio State's radiation oncology department. Dr. Chakravarti helped lead the effort to secure the competitive grant, the largest federal award in radiation oncology history.

Dr. Arnab Chakravarti, chair of Radiation Oncology at The Ohio State University Comprehensive Cancer Center, discusses radiation therapy with U.S. President Joe Biden during an official visit on March 23, 2021

The official visit was an opportunity for the president to learn more about radiation therapy modalities and how significantly the field has progressed in recent decades. He delivered a formal address from a linear accelerator vault, remarking that "the use of radiation is a very complex thing" and commending Dr. Chakravarti and "his colleagues around the country" for their work.

The visit had a dramatic impact on the department's patients, faculty and staff, said Dr. Chakravarti. "Our patients were very touched that the president would take the time to pay us a visit in person, and I think they took his comments to heart. They really felt that the president of the United States cares about them."

Because this was the first presidential visit to a radiation oncology department, there was limited precedent for how to stage it, but Dr. Chakravarti worked with advance teams from the White House to prepare the facility. "Security was incredibly tight," he said. "Several days before the visit, Secret Service arrived to implement all kinds of security measures." While he could not disclose specifics of the security detail, Dr. Chakravarti shared that armored cars and tanks surrounded the hospital during the visit.

Despite the heightened security, Dr. Chakravarti said he had extensive opportunities to discuss radiation oncology and patient care with the officials. "I had some very informative and memorable exchanges with President Biden and his key staffers before, during and after his visit," he said, also noting that he sensed genuine appreciation for the field during those conversations.

"The radiation oncology community truly has a supporter in the White House, and one with real insight into what we do on a daily basis. I can say with confidence that the president has tremendous respect for radiation oncology physicians, physicists, dosimetrists, therapists, nurses — he says we are heroes in his mind and his heart."

ROI-funded research effort to increase exposure of the field to med students

BY MALCOLM MATTES, MD

FOR MOST UNITED STATES MEDICAL STUDENTS, exposure to radiation oncology is not something that just happens. As a small specialty, without a lecture in most preclinical curricula, without required clerkship time during the clinical years, and even without an affiliated department or residency program at many medical schools, it is necessary for radiation oncologists to take active and creative approaches to educating students if we hope to inspire interest in the specialty or be more than a black box to the average physician.

Due to the inherent challenges many students face in finding small fields like ours in the first place, not to mention acquiring effective mentorship in it, radiation oncology has tended to attract the same types of students for the past several decades; predominantly white or Asian males with a scientific background. As such, radiation oncology has remained in the lower third of medical specialties in terms of the diversity of its workforce, with minimal improvement over time.[1-3]

Workforce diversity is important in all areas of medicine in order to help address the significant health disparities that impact underserved patient populations. If the radiation oncology community is going to play a meaningful role in facilitating equitable cancer care, starting to diversify our workforce is an important step in that direction. However, it is not going to happen because we talk about it, or because we write about it. It will happen because of the active and systematic steps we take to welcome students to explore our specialty.

My work aims to reverse the paradigm of general medical student education at most U.S. medical schools. Rather than wait for students to seek out radiation oncology, or for leaders in medical education to invite a radiation oncologist to speak to students about the specialty, I am bringing educational content and mentorship opportunities to them. Thus far, many medical school deans have been thrilled to have someone from an outside institution give an extracurricular talk introducing radiation oncology to their students. At schools lacking an affiliated radiation oncology department, this might be expected, but even at some schools with a radiation oncology department, there is great enthusiasm for outreach that goes beyond what is currently being offered. Many deans of diversity and inclusion are equally enthusiastic about promoting events in radiation oncology specifically for their local chapters of student groups like the Latino Medical Student Association (LMSA) or Student National Medical Association (SNMA), both of which have a high proportion of students who are underrepresented in medicine. Through this outreach, additional

Medical Student Presentations

A new slide presentation has been added to the Provider Resources section of ASTRO.org for use by radiation oncologists who are interested in promoting the specialty to students at medical schools. The presentation includes an introduction to radiation oncology, the radiation oncology job market and future prospects for the specialty. It also addresses the need for greater diversity in our workforce and general pathways for addressing health disparities in highly specialized fields like radiation oncology.

ASTRO.org also includes a section specifically for students interested in learning more about a career in radiation oncology. This section offers videos and resources for students, including two narrated slide presentations: An Introduction to Radiation Oncology and A Career in Radiation Oncology.

Radiation oncology remains an important component of multidisciplinary cancer care and an excellent career option for the right person. Our mission is to ensure all medical students are exposed to radiation oncology directly by radiation oncologists and support those who choose to pursue it.

opportunities have even been offered to me to serve on career panels at national meetings and to speak to premedical students in pipeline programs. The data collected from students who have attended such presentations has been overwhelmingly positive, and many students have reached out for further mentorship opportunities, which I have been able to help facilitate locally or nationally.

It is important to mention that I am white, and I say this to emphasize that anyone with an interest in advocating for students' education and career advancement can offer something similar to a diverse group of students at their home institution regardless of their own race or ethnicity. Ultimately, in coordination with other key stakeholders and colleagues in the ASTRO Committee on Health Equity, Diversity and Inclusion (CHEDI), the ARRO Equity and Inclusion Subcommittee (EISC), and the Society of Women in Radiation Oncology (SWRO), I hope to help build a robust infrastructure that incorporates the groundwork laid at individual institutions into a structured nationwide program to facilitate knowledge of radiation oncology and encourage students from all backgrounds to explore it further for themselves.

Learn more about Dr. Mattes' research, funded by the Radiation Oncology Institute, at www.ROInstitute.org/Mattes.

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In Memoriam

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

Heinz D. Boettcher, MD
Steinfeld, Germany

Jorge J. Rodriguez-Peral, MD
Sonora, Mexico

Dinko Plenkovich, PhD, MS, CMD
Broken Arrow, Oklahoma

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The Art and SCIENCE of Mentorship

BY ERIN F. GILLESPIE, MD, AND DANIEL W. GOLDEN, MD, MHPE

MENTORSHIP CAN FACILITATE CAREER SATISFACTION and advancement, with evidence suggesting that specific benefits may include enhanced productivity, accelerated promotion and higher compensation.[1] However, understanding what motivates individuals to seek and provide mentorship and what characteristics and actions underlie "good" mentorship can be more difficult to define and measure. A recent scoping review of the literature identified 14 publications on the state of mentorship and programmatic initiatives in radiation oncology.[2] Here we define mentorship, outline key components and frameworks to develop and sustain programmatic mentorship efforts, identify challenges that may be unique to radiation oncology and highlight opportunities and ongoing efforts.

It is first important to distinguish mentorship from similar concepts, such as teaching, apprenticeship, sponsorship and leadership. Although mentors often serve multiple roles, one should not discount their ability to mentor if they lack the ability to, for example, give mentees specific opportunities, which is more consistent with the "sponsor" role. Healy and Welchert define mentorship as "a dynamic, reciprocal relationship between an advanced career incumbent (mentor) and a beginner (protégé), aimed at promoting the development of both."[3] More modern definitions emphasize experience over career stage and recognize the value of mentorship at all levels, not just for beginners. For example, chief residents can provide critical mentorship to junior residents, despite being in the same general career stage. Residents and junior attendings can — and should — embrace their role as mentors for students, trainees and even colleagues. Peer mentorship is one of several examples of alternatives to the traditional mentor-mentee dyad (see Table 1, adapted from Marsiglio et al, *IJROBP* 2021).

Radiation oncology differs from many fields of medicine by primarily structuring residency training as an apprenticeship model. While this approach is effective at teaching clinical skills and can increase residents' access to senior faculty, it may reduce team based learning, independence and development of peer mentoring skills. Nonetheless, our literature review found themes that appear to transcend the specialty. Specifically, mentorship experiences and initiatives in radiation oncology commonly involve dyads, focus on resident or medical student mentees (but occasionally include attending physicians), and result in high levels of participant satisfaction.[2] Nonetheless, approximately 50% of radiation oncologists report not having a mentor, even in academic settings.[4,5] While this is not dissimilar from other medical specialties, it contrasts with the business world, where 75% of Forbes 500 companies provide employees access to formal mentorship programs.

Table 1: Types of mentorship

TYPE OF MENTORSHIP	DESCRIPTION
Dyad	A single senior mentor works with a single junior mentee.
Multiple dyad	Multiple senior mentors work with a single mentee on different topics.
Functional dyad	A single senior mentor works with the mentee on 1 topic.
Speed mentoring	Mentors and mentees meet for a brief 1-time event.
Distance mentoring	All mentee/mentor communication is made over a distance.
Team mentorship	Also called committee mentoring, in which multiple senior mentors work with a single mentee, no mentor is limited to a single topic, and there is interaction among the different mentors.
Peer mentorship	Peers of approximately the same rank fill both the mentee and mentor roles.
Facilitated peer mentorship	A senior mentor oversees peer mentorship.

Continued on the following page

Given the documented mentorship "gap" in radiation oncology, stakeholder groups are developing more robust opportunities to facilitate mentoring efforts. As we undertake these endeavors, it is important to learn from prior experience and incorporate evidence into program development. Kashiwagi et al conducted a systematic review of 18 mentorship programs among practicing physicians,[6] finding that once a program's primary objective is identified, the following components should be considered:

1. Participant pairings with mentee input (if assigning dyads).
2. Mentoring activities defined (i.e., regular meetings, peer mentoring sessions).
3. Goal setting and career planning worksheets.
4. Curricula/preparation (i.e., mentor readiness, professional skills development).
5. Steering committee (i.e., leadership support, accountability).
6. Program support (i.e., administrative meeting reminders, evaluations).

Once organizational objectives and structure are established, identifying the mentee's individual focus is critical. While early in one's career a single mentor may meet a trainee's needs in multiple domains (i.e., clinical, academic/professional and personal), as a trainee's interests and expertise differentiates, it becomes increasingly important to develop a network of mentors (Figure 1a and 1b). Mentors also ought to consider what guidance they are best suited to provide and open dialogue to ensure expectations are aligned. Ultimately, regardless of one's specific role, "Great mentors focus on the whole person, not just their career."[7]

Within the academic/professional domain of mentorship, it is important to support opportunities for mentorship outside research, where projects often facilitate mentor identification and development. Although limited, the literature suggests that clinical-track faculty struggle more to identify mentors. Therefore, physicians on non-research career paths may benefit most from formalized mentorship opportunities, regardless of practice setting.

While mentoring does require certain skills and level of commitment, mentoring can benefit mentors by increasing job satisfaction, improving teaching skills and increasing a sense of workplace camaraderie.[8]

Formal mentorship programs can increase faculty retention, making them potentially cost-effective for institutions.[9] Interacting with mentees can help mentors reflect on why they are in their selected profession, what the pros and cons of their current professional roles are and may help to revitalize intrinsic motivation, which is demonstrated to be protective against burnout.[10] There are an increasing number of opportunities to engage nationally or internationally with trainees and junior attendings to develop mentor-mentee relationships including ASTRO, SWRO, ARRO and others. Some of these initiatives are featured in this issue of *ASTROnews*.

Network of mentors

Figure 1a

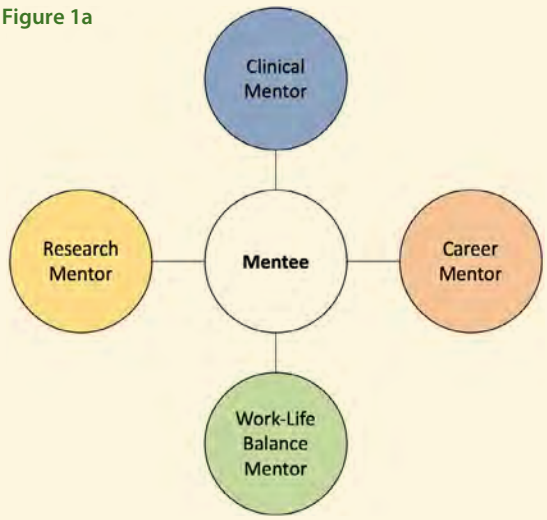
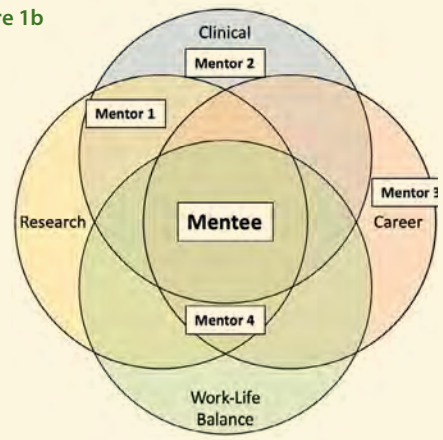


Figure 1b



Figures 1a and 1b illustrate the importance of developing a network of mentors as mentee's interests and expertise expand and grow throughout their career.

Can exemplary mentorship be learned? Fortunately, work from University of Wisconsin suggests that it can,[12] and mentor readiness assessments provide insight into the key characteristics and abilities of potential mentors. First, self-reflection on whether an individual has appropriate knowledge and expertise, along with the willingness to share (particularly the failures) and invest energy and effort to help others. Mentors need to model desirable behavior, since most behaviors are "caught not taught," and be active listeners that can give and receive feedback. One conceptual framework to consider when giving feedback is "radical candor,"[11] in which the mentor both "cares personally and challenges directly" when working with their mentee. Mentors often fall into the trap of "ruinous empathy" or unintentionally cross into "obnoxious aggression." Receiving feedback is often omitted in training exercises and yet likely contributes to the failure of most feedback opportunities, as law professor Sheila Heen emphasizes in her best-selling books called Difficult Conversations, written with Bruce Patton and Douglas Stone and Thanks for the Feedback, written with Douglas Stone. Providing short survey questions to guide feedback discussions, as are commonplace in workplace 360-degree evaluations, may help facilitate these potentially difficult conversations.

In conclusion, good mentorship can benefit both mentors and mentees by increasing career satisfaction and success and providing direction and meaning, all while supporting well-being and potentially limiting burnout. Although mentoring cannot be forced upon either mentees or mentors, mentoring skills can be learned, and generally those that have been mentored are the most likely to recognize the benefits and become mentors themselves. Mentorship initiatives are becoming increasingly prevalent in radiation oncology, and buy-in from institutional and clinic leadership will be important to sustain these programs. Champions of mentorship initiatives are encouraged to consider elements of successful communication and relationships (the art) while familiarizing themselves with the literature behind program development and evaluation (the science) to have the greatest chance of success and impact. And ongoing and planned efforts should be evaluated and disseminated in peer-review literature to further advance the art and science of mentorship in radiation oncology.

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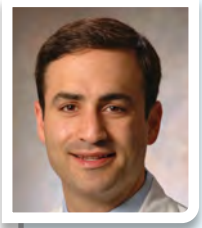

Daniel Golden, MD, MHPE, is an associate professor of Radiation and Cellular Oncology at The University of Chicago. He is the founder and chair of the Radiation Oncology Education Collaborative Study Group, roecsg.org. His research focuses on educational methods for medical students, RO residents and patients with cancer.

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Mentorship and Fellowship Programs

Mentor Match

ASTRO'S NEWEST MENTORSHIP PROGRAM, Mentor Match, launched this past April. This online networking and career development tool helps ASTRO members find, connect and share experiences with others. Located in the RO*hub*, ASTRO's online private member community forum, Mentor Match uses an automated process to facilitate matches between mentees and mentors based on search criteria. Any ASTRO member, Student through Emeritus, can enroll to be a mentor or mentee.

A mentor's expertise can contribute to furthering the career of someone new to the field by sharing leadership and management skills. Moreover, the experience can expose mentors to a variety of ways of thinking and practicing medicine that may be new or different to them.

Mentees can enhance their careers and connect with experienced leaders in the field, finding support during various stages of career development and using multiple mentors for guidance. Mentees, too, can be exposed to diverse perspectives.

Mentors can have multiple mentees. To participate, log in to the RO*hub* and select the Mentor Match tab in the top navigation bar to get started.

Journal Reviewer Training Programs

ASTRO JOURNALS OFFER TWO UNIQUE REVIEWER TRAINING PROGRAMS through which established scholars mentor early career researchers. In both programs, journal editors send trainees articles to review within the trainees' specialties and provide personalized feedback on the content and quality of reviews.

Applications for the Red Journal Resident Peer Reviewer Training Program (RePRT) are considered on a rolling basis. Applicants must be current residents, preferably in their third year of residency or earlier. In addition to receiving personalized feedback from editors, participants who complete six reviews within two years earn a certificate of recognition and their program directors are notified. At the Red Journal, associate editors are selected from the most engaged reviewers, so joining RePRT is an excellent way to initiate involvement with the journal. More information can be found at https://www.redjournal.org/content/review.

Similarly, *Practical Radiation Oncology*'s (*PRO*) Reviewer Apprentice Program offers emerging scholars an invaluable opportunity to routinely engage with a faculty mentor. Applications for *PRO*'s program open each fall, and selected participants are paired with a faculty mentor who guides them through the article review process. This program also lasts two years, and participants are asked to complete five reviews. The Reviewer Apprentice Program offers budding researchers the opportunity to learn about scholarly journals while connecting with a faculty mentor who will advise them throughout their time as a trainee. Additional information can be found at www.astro.org/News-and-Publications/Journals/PRO/Reviewer-Apprenticeship.

Continued on the following page

ASTRO-Industry Radiation Oncology Research Training Fellowships

PARTNERING WITH INDUSTRY LEADERS such as AstraZeneca and Varian, ASTRO offers fellowships that place early-career scientists in industry settings, offering the mentorship of leading scientists. This joint effort allows fellows to receive unique radiation oncology research training at the corporate sites while remaining affiliates of their home institutions.

At AstraZeneca, fellowship participants are provided real-world experience in late-stage clinical trial development that includes a focus on drug development challenges in late-stage drug-radiation combinations, drug sequences, immuno-oncology or epidermal growth factor receptor research.

The current fellow at AstraZeneca, Ryan Whitaker, MD, explains, "The development of this fellowship by ASTRO and AstraZeneca aligns with the shifting landscape of biologically adapted radiotherapy and radiation-drug combinations, and an expanding role in the multimodality management of complex cancer patients. It provides a unique opportunity to peer behind the curtain of how new medicines are taken from bench research to clinical development to patient care, while also developing new mentors outside of radiation oncology with diverse experience, backgrounds and expertise."

At Varian, the scope of mentored research includes, but is not limited to, radiobiology, immunotherapy, applications of artificial intelligence in radiation oncology and treatment planning.

"The ASTRO-Varian fellowship has been a wonderful opportunity to bridge clinical radiation oncology together with the core developers of the technology we use every day to treat patients," remarks Ricky Savjani, MD, the current ASTRO-Varian fellowship recipient. "This collaboration builds on having great mentors in the clinic (both physicians and medical physicists) as well as senior scientists and managers at Varian. Together, we are tackling challenging problems that will improve radiation treatment delivery for patients. I am very grateful for this unique experience."

Each fellowship provides up to $100,000 (USD) to fund the fellow's salary and benefits, and a fraction of the funds can be used for travel to the ASTRO Annual Meeting.

Leadership Pipeline Program

THE ASTRO LEADERSHIP PIPELINE PROGRAM (formerly known as the Pipeline Protégé Program) is a career development initiative aimed at increasing diversity among ASTRO leadership. The two-year program, which began in 2018, is currently underway with its second class of participants. The program is spearheaded by ASTRO's Committee on Health Equity, Diversity and Inclusion (CHEDI).

"I am honored to have been selected to participate in the ASTRO Leadership Pipeline Program. It has given me exposure to the tremendous work and mentorship ASTRO provides through its Science Committees," said Nana Yeboa, MD, assistant professor at MD Anderson Cancer Center and one of the four selected protégés in the 2020–2022 class of participants.

In the first year, participants learn about ASTRO's structure and start building their networks. Participants are asked to join an ASTRO committee and start working on a project, and they also receive mentorship from ASTRO leadership. In year two, participants will continue working on a committee project and partake in selecting the following year's cohort of protégés. At the end of the two years, participants will report on their committee projects and experience to the Board of Directors as well as submit an education session to the ASTRO Annual Meeting. Even though their participation window ends after two years, participants are encouraged to "pay it forward" and remain involved in ASTRO committees and task forces and be a leader in helping others better understand ASTRO's leadership structure and how to get involved.

As Dr. Yeboa shared, "My aspirations are to develop programs that equip students and future faculty to become educational and research leaders of their own."

Nana Yeboa, MD

Aspiring Scientists and Physicians Program

THE ASPIRING SCIENTISTS AND PHYSICIANS PROGRAM (ASPP) offers undergraduate and medical students who are underrepresented in medicine the opportunity to learn about the radiation oncology field. This free event comprises interactive panel discussions in which students meet radiation oncology faculty, residency program directors, medical physicists, residents and medical students sharing insights into their career journeys, and many opportunities for mentorship.

Former ASPP planning committee chair Kristina Woodhouse, MD, assistant professor in the Department of Radiation Oncology at The University of Texas MD Anderson Cancer Center, offers a perspective on the program.

"Over the past few years, I have watched ASTRO and its members make diversity, equity and inclusion an organizational priority through strategic programming, funding and content. Last October 2020, we hosted our 2nd annual virtual Aspiring Scientists and Physicians Program. As chair of ASPP's planning committee, I was so excited to have nearly 200 diverse undergraduate and graduate students register and more than 60 attend the virtual program to gain exposure to the field of radiation oncology," said Kristina Woodhouse, MD. "As a Black, female radiation oncologist, it was important for me to see talented physicians in the field who looked like me. And I hope to be that example for future generations of colleagues."

Interested students can learn more by contacting ASTRO staff at asp@astro.org.

Kristina Woodhouse, MD

Minority Summer Fellowship

THE ASTRO MINORITY SUMMER FELLOWSHIP (MSF) AWARD introduces medical students from backgrounds that are underrepresented in medicine to the discipline of radiation oncology early in their medical education. Since 2010, the fellowship has been awarded to more than 25 medical students in the United States.

Members of ASTRO's Committee on Health Equity, Diversity and Inclusion (CHEDI) are responsible for reviewing applications and selecting awardees. After selection, CHEDI members are assigned as liaisons to communicate with each awardee on a continual basis to provide informal mentorship, receive updates and keep the awardee connected to ASTRO.

In an effort to promote radiation oncology as a career choice, the fellowship provides medical students with an experience designed to expose them to clinical, basic and translational research questions in radiation oncology.

Recent awardee Alikem Miriam Agamah, attending school at Southern Illinois University School of Medicine shared, "I was drawn to the ASTRO Minority Summer Fellowship program, as I was curious to learn more about radiation oncology. I'm grateful for the opportunity I was provided to explore the field through research and clinical experience."

Participants are asked to partner with an ASTRO mentor, conduct research during the summer of their fellowship, and submit an abstract to the following year's ASTRO Annual Meeting. Participants are also asked to attend the Annual Meeting as it is an opportunity for further professional growth after the fellowship has ended. The MSF grant provides a $5,000 package, which includes a $3,000 stipend for the eight-week summer program, $1,000 for the completion of a final report and $1,000 toward the cost of attending the ASTRO Annual Meeting.

Continued on page 17

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APEx, ASTRO's practice accreditation program, establishes standards of performance that evaluate all aspects of radiation oncology practice. Practices accredited by APEx enjoy the prestige of being associated with ASTRO and the recognition that they are committed to delivering safe, high-quality patient care.

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Health Policy Fellowship

IN 2016, ASTRO'S CODE DEVELOPMENT AND VALUATION COMMITTEE began the Health Policy Fellowship to support ASTRO members interested in becoming ASTRO health policy leaders. A Health Policy fellow is exposed to ASTRO's health policy reimbursement and coding activities, including code development and valuation, coding guidance, payer engagement, and payment reform activities. The program is designed to help the fellow develop leadership skills to become the next generation of ASTRO health policy leaders and is open to board-certified radiation oncologists and medical physicists with five years of practice experience.

"I was an ASTRO Health Policy fellow in the inaugural class and highly recommend it to anyone looking to have an immersive experience into all aspects of radiation oncology payment, policy and valuation," said Amar Rewari, MD, MBA, chief of radiation oncology at Luminis Health in Annapolis, Maryland. "The fellowship has been instrumental in my professional development through leadership roles at ASTRO, new career opportunities and a national platform where I am empowered to help innovate and bring about meaningful change in code development and payment reform for the benefit of the radiation oncology community and stakeholders." Dr. Rewari is currently the chair of the Code Development and Valuation Committee and a RUC advisor to the AMA.

The Health Policy Fellowship application cycle opens in the fall of each year with the selected fellowship beginning January 1 the following year.

Amar Rewari, MD, MBA

Learn more about each of these unique programs, including when and how to apply, at www.astro.org.

Mentorship at Stanford's Department of Radiation Oncology

Focus on the residency program

BY: SARAH S. DONALDSON, MD, FASTRO, AND JESSICA FRANK

WHEN ASKED TO NAME AN INDIVIDUAL who has influenced one's academic journey, nearly all of us has someone special to mention, someone whom we consider our mentor. Mentoring is central in all our lives, yet we have been slow in medicine to embrace the power of mentoring for our professional wellness and academic success. In this issue of *ASTROnews*, the focus is on mentoring in radiation oncology; here, we specifically address mentoring for Stanford's trainees and include tips we have learned along the way.

The culture and policies at Stanford, which includes the School of Medicine and several hospital systems, emphasize mentoring of faculty, staff and trainees at doctoral, pre-doctoral and post-graduate levels. Individual departments customize their mentoring programs to fit their unique needs for support, direction and guidance. But how to do that well?

For the Department of Radiation Oncology, mentoring is core to our mission and goals. Since 2016, the department has had a structured mentoring program that is led by a mentoring director and is deeply embedded within the ACGME defined residency core curriculum. The program spans three divisions: Clinical Radiation Oncology, Radiation Physics and Cancer Biology, with locations at the central campus in Palo Alto and at each of the department's satellite outreach programs. The mentoring program is constantly evolving with continual reassessment of its value to faculty, residents and staff who serve as program mentors and mentees.

The structure

Faculty-resident mentoring pairs are formed each academic year and rotate annually. Additionally, the program utilizes focused mentors, who are faculty with skills in a specialized area, such as research, work-life balance and career development. So, by the end of four years of training, each resident will have partnered with four dedicated mentors and had additional access to focused mentors as well as peer mentors. The mentoring pairs meet quarterly. Mentees are asked to set goals while the mentors hold them responsible and accountable to meet their declared goals.

The program's education components include:

a. For mentors: Guidance, courses and curriculum on "how to be a mentor," including ways in which serving as a coach, advocate, big brother/big sister/best friend is key.

b. For mentees:

i. Training and learning to be assertive, take responsibility and meet their pre-determined goals in keeping the contract they have set with their mentor.

ii. Learning to ask for help if and when they perceive they might need it and to do so with trust that the partnership is held in confidence.

In addition to quarterly mentor-mentee meetings, the program's activities include monthly lunchtime mentoring meetings with invited speakers who address topics requested by the residents or determined by the mentoring director. Speakers are typically faculty and guests from other departments within Stanford University, as well as invited visiting professors. Residents also participate in all the departmental activities.

Faculty and residents throughout the department are equally committed to the program's success. Residents are encouraged to accompany faculty to our regional and national meetings, and the program has placed incentives within the schedule and rotations in order to encourage residents to submit abstracts, write manuscripts and apply for grants and resources appropriate for their level. We believe that these faculty-resident partnerships invite networking opportunities and add value to our future resident careers.

From this program, we learned that one cannot have too many mentors. We have also come to recognize that some pairs do not produce an instantly optimal relationship, and we have employed appropriate "exit" strategies as needed. The program, and its participants, have benefited from our ongoing evaluation by both mentors and mentees to obtain timely assessments of experience and support. Lastly, we learned that the support of the institution and of the department leadership is key to our success.

The Stanford mentoring program is a continuum. It cultivates our graduates as lifelong members of our departmental family, and this continually reminds us of those who helped us along our way so we can do the same for our own trainees.

KEYS TO SUCCESS:
Good communication is essential; It must be open, two-way, confidential and built upon trust.

DO:
- Listen, support and serve as a role model.
- Advise and guide in development of skills for advancement and promotion.
- Advocate and sponsor by leveraging resources and providing opportunities for progress.
- Find solutions without imposing them.
- Assist with networking that aligns with the trainee's desired career pathway.

DO NOT:
- Micromanage your mentee.
- Expect your mentee to follow all your advice.
- Force the mentor-mentee relationship if the partnership isn't working.
- Talk at your mentee. Instead, engage your mentee in dialogue.

REMEMBER: Mentoring is as easy as caring. Mentoring comes from within and is organic.

Sarah Donaldson, MD, FASTRO, is the Catharine and Howard Avery Professor at Stanford Medical School and director of the Stanford Radiation Oncology Mentoring Program. She is the inaugural recipient of the Women Who Conquer Cancer Mentorship award, a former ASTRO President, an ASTRO Gold Medal recipient and a member of the National Academies of Science, Engineering and Medicine.

Jessica Frank is the Education Program Manager for the Stanford Radiation Oncology Department and recipient of the Departmental Richard T. Hoppe Leadership award. She was also the recipient of the Award for Outstanding Contribution to Graduate Medical Education at Stanford Hospital and a recipient of the Golden Nugget Award, presented by the residents.

IMFINZI: THE FIRST AND ONLY APPROVED IMMUNOTHERAPY IN UNRESECTABLE STAGE III NSCLC FOLLOWING CRT[1]*

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NSCLC=non-small cell lung cancer; CRT=chemoradiotherapy; Q2W=once every 2 weeks; Q4W=once every 4 weeks.

*In patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemoradiotherapy.[1]

†Durvalumab (IMFINZI®) is recommended (Category 1) as consolidation immunotherapy for performance status 0 to 1 and no disease progression after 2 or more cycles of definitive concurrent CRT. The National Comprehensive Cancer Network® (NCCN®) makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way. For detailed recommendations, see the NCCN Guidelines® for NSCLC at NCCN.org.[2]

Indication

IMFINZI is indicated for the treatment of adult patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

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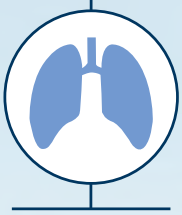
Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment or after discontinuation. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions.



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NSCLC

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Immune-Mediated Adverse Reactions (continued)

Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate. Withhold or permanently discontinue IMFINZI depending on severity. See Dosing and Administration for specific details. In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

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Immune-Mediated Pneumonitis

IMFINZI can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation. In patients who did not receive recent prior radiation, the incidence of immune-mediated pneumonitis was 2% (28/1414), including fatal (<0.1%), and Grade 3-4 (0.4%) adverse reactions. In patients who received recent prior radiation, the incidence of pneumonitis (including radiation pneumonitis) in patients with unresectable Stage III NSCLC following definitive chemoradiation within 42 days prior to initiation of IMFINZI in PACIFIC was 16.6% (79/475) in patients receiving IMFINZI and 13.2% (31/234) in patients receiving placebo. Of the 79 patients who received IMFINZI, 1.1% were fatal and 2.5% were Grade 3-4 adverse reactions. The frequency and severity of immune-mediated pneumonitis in patients who did not receive definitive chemoradiation prior to IMFINZI were similar in patients who received IMFINZI as a single agent or with ES-SCLC when in combination with chemotherapy.

Immune-Mediated Colitis

IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 1.6% (31/1889) of patients receiving IMFINZI, including Grade 4 (0.1%) and Grade 3 (0.3%) adverse reactions.

Immune-Mediated Hepatitis

IMFINZI can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 1% (19/1889) of patients receiving IMFINZI, including fatal (<0.1%) and Grade 3 (0.6%) adverse reactions.

Immune-Mediated Endocrinopathies

- ***Adrenal Insufficiency***: IMFINZI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Immune-mediated adrenal insufficiency occurred in 0.4% (7/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Hypophysitis***: IMFINZI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate symptomatic treatment including hormone replacement as clinically indicated. Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) of patients who received IMFINZI.
- ***Thyroid Disorders***: IMFINZI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement therapy for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated.
- ***Thyroiditis***: Immune-mediated thyroiditis occurred in 0.4% (7/1889) of patients receiving IMFINZI.
- ***Hyperthyroidism***: Immune-mediated hyperthyroidism occurred in 1.4% (27/1889) of patients receiving IMFINZI.
- ***Hypothyroidism***: Immune-mediated hypothyroidism occurred in 7.3% (137/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Type 1 Diabetes Mellitus, which can present with diabetic ketoacidosis***: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Grade 3 immune-mediated type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI.

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.3% (5/1889) of patients receiving IMFINZI, including Grade 3 (0.1%) adverse reactions.

Immune-Mediated Dermatology Reactions

IMFINZI can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), have occurred with PD-1/L-1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Immune-mediated rash or dermatitis occurred in 1.6% (30/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) adverse reactions.

Other Immune-Mediated Adverse Reactions

The following clinically significant, immune-mediated adverse reactions occurred at an incidence of less than 1% each in patients who received IMFINZI or were reported with the use of other PD-1/PD-L1 blocking antibodies.

- ***Cardiac/vascular***: Myocarditis, pericarditis, vasculitis.
- ***Nervous system***: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.
- ***Ocular***: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse

reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

- ***Gastrointestinal***: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis.
- ***Musculoskeletal and connective tissue disorders***: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic.
- ***Endocrine***: Hypoparathyroidism
- ***Other (hematologic/immune)***: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection.

Infusion-Related Reactions

IMFINZI can cause severe or life-threatening infusion-related reactions. Monitor for signs and symptoms of infusion-related reactions. Interrupt, slow the rate of, or permanently discontinue IMFINZI based on the severity. See Dosing and Administration for specific details. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses. Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, including Grade 3 (0.3%) adverse reactions.

Complications of Allogeneic HSCT after IMFINZI

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/L-1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/L-1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/L-1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IMFINZI and for at least 3 months after the last dose of IMFINZI.

Lactation

There is no information regarding the presence of IMFINZI in human milk; however, because of the potential for adverse reactions in breastfed infants from IMFINZI, advise women not to breastfeed during treatment and for at least 3 months after the last dose.

Adverse Reactions

- In patients with Stage III NSCLC in the PACIFIC study receiving IMFINZI (n=475), the most common adverse reactions (≥20%) were cough (40%), fatigue (34%), pneumonitis or radiation pneumonitis (34%), upper respiratory tract infections (26%), dyspnea (25%), and rash (23%). The most common Grade 3 or 4 adverse reactions (≥3%) were pneumonitis/radiation pneumonitis (3.4%) and pneumonia (7%)
- In patients with Stage III NSCLC in the PACIFIC study receiving IMFINZI (n=475), discontinuation due to adverse reactions occurred in 15% of patients in the IMFINZI arm. Serious adverse reactions occurred in 29% of patients receiving IMFINZI. The most frequent serious adverse reactions (≥2%) were pneumonitis or radiation pneumonitis (7%) and pneumonia (6%). Fatal pneumonitis or radiation pneumonitis and fatal pneumonia occurred in <2% of patients and were similar across arms

The safety and effectiveness of IMFINZI have not been established in pediatric patients.

Please see Brief Summary of complete Prescribing Information on adjacent pages.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

References: 1. IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2021. **2**. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.4.2021. ©National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Published March 3, 2021. Accessed March 5, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org.

AstraZeneca

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

IMFINZI® (durvalumab) injection, for intravenous use

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

INDICATIONS AND USAGE

Non-Small Cell Lung Cancer

IMFINZI is indicated for the treatment of adult patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

DOSAGE AND ADMINISTRATION

Recommended Dosage

The recommended dosages for IMFINZI as a single agent and IMFINZI in combination with chemotherapy are presented in Table 1 *[see Clinical Studies (14) in the full Prescribing Information]*.

IMFINZI is administered as an intravenous infusion over 60 minutes.

Table 1. Recommended Dosages of IMFINZI

Indication	Recommended IMFINZI dosage	Duration of Therapy
Unresectable stage III NSCLC	Patients with a body weight of 30 kg and more: 10 mg/kg every 2 weeks or 1500 mg every 4 weeks Patients with a body weight of less than 30 kg: 10 mg/kg every 2 weeks	Until disease progression, unacceptable toxicity, or a maximum of 12 months

Dosage Modifications for Adverse Reactions

No dose reduction for IMFINZI is recommended. In general, withhold IMFINZI for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue IMFINZI for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids.

Dosage modifications for IMFINZI for adverse reactions that require management different from these general guidelines are summarized in Table 2.

Table 2. Recommended Dosage Modifications for Adverse Reactions

Adverse Reaction	Severity[1]	Dosage Modification
Immune-Mediated Adverse Reactions *[see Warnings and Precautions (5.1) in the full Prescribing Information]*		
Pneumonitis	Grade 2	Withhold[2]
	Grade 3 or 4	Permanently discontinue
Colitis	Grade 2 or 3	Withhold[2]
	Grade 4	Permanently discontinue
Hepatitis with no tumor involvement of the liver	ALT or AST increases to more than 3 and up to 8 times the ULN or total bilirubin increases to more than 1.5 and up to 3 times ULN	Withhold[2]
	ALT or AST increases to more than 8 times ULN or total bilirubin increases to more than 3 times the ULN	Permanently discontinue
Hepatitis with tumor involvement of the liver[3]	AST or ALT is more than 1 and up to 3 times ULN at baseline and increases to more than 5 and up to 10 times ULN or AST or ALT is more than 3 and up to 5 times ULN at baseline and increases to more than 8 and up to 10 times ULN	Withhold[2]
	AST or ALT increases to more than 10 times ULN or Total bilirubin increases to more than 3 times ULN	Permanently discontinue
Endocrinopathies	Grade 3 or 4	Withhold until clinically stable or permanently discontinue depending on severity
Nephritis with Renal Dysfunction	Grade 2 or 3 increased blood creatinine	Withhold[2]
	Grade 4 increased blood creatinine	Permanently discontinue
Exfoliative Dermatologic Conditions	Suspected SJS, TEN, or DRESS	Withhold[2]
	Confirmed SJS, TEN, or DRESS	Permanently discontinue
Myocarditis	Grade 2, 3, or 4	Permanently discontinue
Neurological Toxicities	Grade 2	Withhold[2]
	Grade 3 or 4	Permanently discontinue
Other Adverse Reactions		
Infusion-related reactions *[see Warnings and Precautions (5.2) in the full Prescribing Information]*	Grade 1 or 2	Interrupt or slow the rate of infusion
	Grade 3 or 4	Permanently discontinue

ALT = alanine aminotransferase, AST = aspartate aminotransferase, DRESS = Drug Rash with Eosinophilia and Systemic Symptoms, SJS = Stevens Johnson Syndrome, TEN = toxic epidermal necrolysis, ULN = upper limit normal

[1] Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

[2] Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone 10 mg per day or less (or equivalent) within 12 weeks of initiating steroids.

[3] If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.

Preparation and Administration

Preparation

- Visually inspect drug product for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard the vial if the solution is cloudy, discolored, or visible particles are observed.
- Do not shake the vial.
- Withdraw the required volume from the vial(s) of IMFINZI and transfer into an intravenous bag containing 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Mix diluted solution by gentle inversion. Do not shake the solution. The final concentration of the diluted solution should be between 1 mg/mL and 15 mg/mL.
- Discard partially used or empty vials of IMFINZI.

Storage of Infusion Solution

- IMFINZI does not contain a preservative.
- Administer infusion solution immediately once prepared. If infusion solution is not administered immediately and needs to be stored, the total time from vial puncture to the start of the administration should not exceed:
  - 24 hours in a refrigerator at 2°C to 8°C (36°F to 46°F)
  - 8 hours at room temperature up to 25°C (77°F)
- Do not freeze.
- Do not shake.

Administration

- Administer infusion solution intravenously over 60 minutes through an intravenous line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter.
- Do not co-administer other drugs through the same infusion line.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Immune-Mediated Adverse Reactions

IMFINZI is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death-receptor 1 (PD-1) or the PD-ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment with a PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies.

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue IMFINZI depending on severity *[see Dosage and Administration (2.2) in the full Prescribing Information]*. In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies and dermatologic reactions) are discussed below.

Immune-Mediated Pneumonitis

IMFINZI can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

In Patients Who did Not Receive Recent Prior Radiation

In patients who received IMFINZI on clinical trials in which radiation therapy was generally not administered immediately prior to initiation of IMFINZI, the incidence of immune-mediated pneumonitis was 2% (28/1414), including fatal (<0.1%), and Grade 3-4 (0.4%) adverse reactions. Events resolved in 15 of the 28 patients and resulted in permanent discontinuation in 5 patients. Systemic corticosteroids were required in 17 patients (17/28) with pneumonitis who did not receive chemoradiation prior to initiation of IMFINZI.

In Patients Who Received Recent Prior Radiation

The incidence of pneumonitis (including radiation pneumonitis) in patients with unresectable Stage III NSCLC following definitive chemoradiation within 42 days prior to initiation of IMFINZI in PACIFIC was 16.6% (79/475) in patients receiving IMFINZI and 13.2% (31/234) in patients receiving placebo. Of the 79 patients who received IMFINZI, 1.1% were fatal and 2.5% were Grade 3-4 adverse reactions. Events resolved in 43 of the 79 patients and resulted in permanent discontinuation in 24 patients.

Systemic corticosteroids were required in 60 patients (60/79) with pneumonitis who had received chemo-radiation prior to initiation of IMFINZI, while 2 patients required use of infliximab with high-dose steroids.

The frequency and severity of immune-mediated pneumonitis in patients who did not receive definitive chemoradiation prior to IMFINZI were similar whether IMFINZI was given as a single agent in patients with various cancers in a pooled data set or in patients with ES-SCLC when given in combination with chemotherapy.

Immune-Mediated Colitis

IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 1.6% (31/1889) of patients receiving IMFINZI, including Grade 4 (0.1%) and Grade 3 (0.3%) adverse reactions. Events resolved in 23 of the 31 patients and resulted in permanent discontinuation in 8 patients. Systemic corticosteroids were required in all patients with immune-mediated colitis, while 2 patients (2/31) required other immunosuppressants (e.g., infliximab, mycophenolate).

Immune-Mediated Hepatitis

IMFINZI can cause immune-mediated hepatitis.

Immune-mediated hepatitis occurred in 1% (19/1889) of patients receiving IMFINZI, including fatal (<0.1%) and Grade 3 (0.6%) adverse reactions. Events resolved in 12 of the 19 patients and resulted in permanent discontinuation of IMFINZI in 4 patients. Systemic corticosteroids were required in all patients with immune-mediated hepatitis, while 1 patient (1/19) required use of mycophenolate with high-dose steroids.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency:

IMFINZI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold or permanently discontinue IMFINZI based on the severity *[see Dosage and Administration (2.2) in the full Prescribing Information]*.

Immune-mediated adrenal insufficiency occurred in 0.4% (7/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions. Adrenal insufficiency did not lead to permanent discontinuation of IMFINZI in any patients. Systemic corticosteroids were required in all patients with adrenal insufficiency; of these, the majority remained on systemic corticosteroids.

Hypophysitis:

IMFINZI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate symptomatic treatment including hormone replacement as clinically indicated. Withhold or permanently discontinue IMFINZI depending on severity *[see Dosage and Administration (2.2) in the full Prescribing Information]*.

Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) patients who received IMFINZI. Treatment with systemic corticosteroids was administered in this patient. The event did not lead to permanent discontinuation of IMFINZI.

Thyroid Disorders:

IMFINZI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement therapy for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or discontinue IMFINZI based on the severity *[see Dosage and Administration (2.2) in the full Prescribing Information]*.

Thyroiditis: Immune-mediated thyroiditis occurred in 0.4% (7/1889) of patients receiving IMFINZI. Events resolved in 3 of the 7 patients and none resulted in permanent discontinuation. Systemic corticosteroids were required in 3 patients (3/7) with immune-mediated thyroiditis, while 5 patients (5/7) required endocrine therapy.

Hyperthyroidism: Immune-mediated hyperthyroidism occurred in 1.4% (27/1889) of patients receiving IMFINZI. Events resolved in 20 of the 27 patients. Systemic corticosteroids were required in 9 patients (9/27) with immune-mediated hyperthyroidism, while 21 patients (21/27) required endocrine therapy.

Hypothyroidism: Immune-mediated hypothyroidism occurred in 7.3% (137/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions. Systemic corticosteroids were required in 10 patients (10/137) and the majority of patients (134/137) required long-term thyroid hormone replacement.

Type 1 Diabetes Mellitus, which can present with diabetic ketoacidosis: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue IMFINZI based on the severity *[see Dosage and Administration (2.2) in the full Prescribing Information]*.

Grade 3 immune-mediated type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI. This patient required long-term insulin therapy and IMFINZI was permanently discontinued.

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI can cause immune-mediated nephritis.

Immune-mediated nephritis occurred in 0.3% (5/1889) of patients receiving IMFINZI, including Grade 3 (0.1%) adverse reactions. Events resolved in 3 of the 5 patients and resulted in permanent discontinuation in 4 patients. Systemic corticosteroids were required in all patients with immune-mediated nephritis.

Immune-Mediated Dermatology Reactions

IMFINZI can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/L-1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue IMFINZI depending on severity *[see Dosage and Administration (2.2) in the full Prescribing Information]*.

Immune-mediated rash or dermatitis occurred in 1.6% (30/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) adverse reactions. Events resolved in 18 of the 30 patients and resulted in permanent discontinuation in 2 patients. Systemic corticosteroids were required in all patients with immune-mediated rash or dermatitis.

Other Immune-Mediated Adverse Reactions

The following clinically significant, immune-mediated adverse reactions occurred at an incidence of less than 1% each in patients who received IMFINZI or were reported with the use of other PD-1/PD-L1 blocking antibodies.

Cardiac/vascular: Myocarditis, pericarditis, vasculitis.

Nervous system: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.

Ocular: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis.

Musculoskeletal and connective tissue disorders: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic.

Endocrine: Hypoparathyroidism

Other (hematologic/immune): Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection.

Infusion-Related Reactions

IMFINZI can cause severe or life-threatening infusion-related reactions.

Monitor for signs and symptoms of infusion-related reactions. Interrupt, slow the rate of, or permanently discontinue IMFINZI based on the severity *[see Dosage and Administration (2.2) in the full Prescribing Information]*. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses.

Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, including Grade 3 (0.3%) adverse reactions.

Complications of Allogeneic HSCT after IMFINZI

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/L-1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/L-1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/L-1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of durvalumab to cynomolgus monkeys from the onset of organogenesis through delivery resulted in increased premature delivery, fetal loss and premature neonatal death. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IMFINZI and for at least 3 months after the last dose of IMFINZI *[see Use in Specific Populations (8.1, 8.3) in the full Prescribing Information]*.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling.

- Immune-Mediated Adverse Reactions *[see Warnings and Precautions (5.1) in the full Prescribing Information]*.
- Infusion-Related Reactions *[see Warnings and Precautions (5.2) in the full Prescribing Information]*.

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described in the Warnings and Precautions section reflect exposure to IMFINZI in 1889 patients from the PACIFIC study (a randomized, placebo-controlled study that enrolled 475 patients with Stage III NSCLC), Study 1108 (an open-label, single-arm, multicohort study that enrolled 970 patients with advanced solid tumors), and an additional open-label, single-arm trial that enrolled 444 patients with metastatic lung cancer, an indication for which durvalumab is not approved. In these trials, IMFINZI was administered at a dose of 10 mg/kg every 2 weeks. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more. The data also reflect exposure to IMFINZI in combination with chemotherapy in 265 patients from the CASPIAN study (a randomized, open-label study in patients with ES-SCLC). In the CASPIAN study, IMFINZI was administered at a dose of 1500 mg every 3 or 4 weeks.

The data described in this section reflect exposure to IMFINZI in patients with Stage III NSCLC enrolled in the PACIFIC study.

Non-Small Cell Lung Cancer

The safety of IMFINZI in patients with Stage III NSCLC who completed concurrent platinum-based chemoradiotherapy within 42 days prior to initiation of study drug was evaluated in the PACIFIC study, a multicenter, randomized, double-blind, placebo-controlled study. A total of 475 patients received IMFINZI 10 mg/kg intravenously every 2 weeks. The study excluded patients who had disease progression following chemoradiation, with active or prior autoimmune disease within 2 years of initiation of the study or with medical conditions that required systemic immunosuppression *[see Clinical Studies (14.2) in the full Prescribing Information]*.

The study population characteristics were: median age of 64 years (range: 23 to 90), 45% age 65 years or older, 70% male, 69% White, 27% Asian, 75% former smoker, 16% current smoker, and 51% had WHO performance status of 1. All patients received definitive radiotherapy as per protocol, of which 92% received a total radiation dose of 54 Gy to 66 Gy. The median duration of exposure to IMFINZI was 10 months (range: 0.2 to 12.6).

IMFINZI was discontinued due to adverse reactions in 15% of patients. The most common adverse reactions leading to IMFINZI discontinuation were pneumonitis or radiation pneumonitis in 6% of patients. Serious adverse reactions occurred in 29% of patients receiving IMFINZI. The most frequent serious adverse reactions reported in at least 2% of patients were pneumonitis or radiation pneumonitis (7%) and pneumonia (6%). Fatal pneumonitis or radiation pneumonitis and fatal pneumonia occurred in < 2% of patients and were similar across arms. The most common adverse reactions (occurring in ≥ 20% of patients) were cough, fatigue, pneumonitis or radiation pneumonitis, upper respiratory tract infections, dyspnea, and rash.

Table 3 summarizes the adverse reactions that occurred in at least 10% of patients treated with IMFINZI.

Table 3. Adverse Reactions Occurring in ≥ 10% Patients in the PACIFIC Study

	IMFINZI N = 475		Placebo[1] N = 234	
Adverse Reaction	**All Grades (%)**	**Grades 3-4 (%)**	**All Grades (%)**	**Grades 3-4 (%)**
Respiratory, Thoracic, and Mediastinal Disorders				
Cough/Productive Cough	40	0.6	30	0.4
Pneumonitis[2]/Radiation Pneumonitis	34	3.4	25	3
Dyspnea[3]	25	1.5	25	2.6
Gastrointestinal Disorders				
Diarrhea	18	0.6	19	1.3
Abdominal pain[4]	10	0.4	6	0.4

Table 3. Adverse Reactions Occurring in ≥ 10% Patients in the PACIFIC Study (cont'd)

	IMFINZI N = 475		Placebo[1] N = 234	
Adverse Reaction	**All Grades (%)**	**Grades 3-4 (%)**	**All Grades (%)**	**Grades 3-4 (%)**
Endocrine Disorders				
Hypothyroidism[5]	12	0.2	1.7	0
Skin and Subcutaneous Tissue Disorders				
Rash[6]	23	0.6	12	0
Pruritus[7]	12	0	6	0
General Disorders				
Fatigue[8]	34	0.8	32	1.3
Pyrexia	15	0.2	9	0
Infections				
Upper respiratory tract infections[9]	26	0.4	19	0
Pneumonia[10]	17	7	12	6

[1] The PACIFIC study was not designed to demonstrate statistically significant difference in adverse reaction rates for IMFINZI, as compared to placebo, for any specific adverse reaction listed in Table 3
[2] Includes acute interstitial pneumonitis, interstitial lung disease, pneumonitis, pulmonary fibrosis
[3] Includes dyspnea, and exertional dyspnea
[4] Includes abdominal pain, abdominal pain lower, abdominal pain upper, and flank pain
[5] Includes autoimmune hypothyroidism and hypothyroidism
[6] Includes rash erythematous, rash generalized, rash macular, rash maculopapular, rash papular, rash pruritic, rash pustular, erythema, eczema, rash, and dermatitis
[7] Includes pruritus generalized and pruritus
[8] Includes asthenia and fatigue
[9] Includes laryngitis, nasopharyngitis, peritonsillar abscess, pharyngitis, rhinitis, sinusitis, tonsillitis, tracheobronchitis, and upper respiratory tract infection
[10] Includes lung infection, pneumocystis jirovecii pneumonia, pneumonia, pneumonia adenoviral, pneumonia bacterial, pneumonia cytomegaloviral, pneumonia haemophilus, pneumonia klebsiella, pneumonia necrotising, pneumonia pneumococcal, and pneumonia streptococcal

Other adverse reactions occurring in less than 10% of patients treated with IMFINZI were dysphonia, dysuria, night sweats, peripheral edema, and increased susceptibility to infections.

Table 4 summarizes the laboratory abnormalities that occurred in at least 20% of patients treated with IMFINZI.

Table 4. Laboratory Abnormalities Worsening from Baseline Occurring in ≥ 20% of Patients in the PACIFIC Study

	IMFINZI		Placebo	
Laboratory Abnormality	**All Grades[1] (%)[2]**	**Grade 3 or 4 (%)**	**All Grades[1] (%)[2]**	**Grade 3 or 4 (%)**
Chemistry				
Hyperglycemia	52	8	51	8
Hypocalcemia	46	0.2	41	0
Increased ALT	39	2.3	22	0.4
Increased AST	36	2.8	21	0.4
Hyponatremia	33	3.6	30	3.1
Hyperkalemia	32	1.1	29	1.8
Increased GGT	24	3.4	22	1.7
Hematology				
Lymphopenia	43	17	39	18

[1] Graded according to NCI CTCAE version 4.0
[2] Each test incidence is based on the number of patients who had both baseline and at least one on-study laboratory measurement available: IMFINZI (range: 464 to 470) and placebo (range: 224 to 228)

Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to durvalumab to the incidence of antibodies to other products may be misleading.

Of 2280 patients who received IMFINZI 10 mg/kg every 2 weeks or 20 mg/kg every 4 weeks as a single-agent, 69 patients (3%) tested positive for treatment-emergent anti-drug antibodies (ADA) and 12 (0.5%) tested positive for neutralizing antibodies. The development of ADA against durvalumab appears to have no clinically relevant effect on its pharmacokinetics or safety.

Of 201 patients in the CASPIAN study who received IMFINZI 1500 mg every 3 weeks in combination with chemotherapy for four doses followed by IMFINZI 1500 mg every 4 weeks no patients tested positive for treatment-emergent ADA.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk summary

Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1) in the full Prescribing Information]*. There are no data on the use of IMFINZI in pregnant women.

In animal reproduction studies, administration of durvalumab to pregnant cynomolgus monkeys from the confirmation of pregnancy through delivery resulted in an increase in premature delivery, fetal loss, and premature neonatal death *(see Data)*. Human immunoglobulin G1 (IgG1) is known to cross the placental barrier; therefore, durvalumab has the potential to be transmitted from the mother to the developing fetus. Apprise pregnant women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

As reported in the literature, the PD-1/PD-L1 pathway plays a central role in preserving pregnancy by maintaining maternal immune tolerance to the fetus. In mouse allogeneic pregnancy models, disruption of PD-L1 signaling was shown to result in an increase in fetal loss. The effects of durvalumab on prenatal and postnatal development were evaluated in reproduction studies in cynomolgus monkeys. Durvalumab was administered from the confirmation of pregnancy through delivery at exposure levels approximately 6 to 20 times higher than those observed at the recommended clinical dose of 10 mg/kg (based on AUC). Administration of durvalumab resulted in premature delivery, fetal loss (abortion and stillbirth), and increase in neonatal deaths. Durvalumab was detected in infant serum on postpartum Day 1, indicating the presence of placental transfer of durvalumab. Based on its mechanism of action, fetal exposure to durvalumab may increase the risk of developing immune-mediated disorders or altering the normal immune response and immune-mediated disorders have been reported in PD-1 knockout mice.

Lactation

Risk Summary

There is no information regarding the presence of durvalumab in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG1 is excreted in human milk. Durvalumab was present in the milk of lactating cynomolgus monkeys and was associated with premature neonatal death *(see Data)*.

Because of the potential for adverse reactions in breastfed infants, advise women not to breastfeed during treatment with IMFINZI and for at least 3 months after the last dose.

Data

In lactating cynomolgus monkeys, durvalumab was present in breast milk at about 0.15% of maternal serum concentrations after administration of durvalumab from the confirmation of pregnancy through delivery at exposure levels approximately 6 to 20 times higher than those observed at the recommended clinical dose of 10 mg/kg (based on AUC). Administration of durvalumab resulted in premature neonatal death.

Females and Males of Reproductive Potential

Contraception

Females

Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1) in the full Prescribing Information]*. Advise females of reproductive potential to use effective contraception during treatment with IMFINZI and for at least 3 months following the last dose of IMFINZI.

Pediatric Use

The safety and effectiveness of IMFINZI have not been established in pediatric patients.

Geriatric Use

Of the 476 patients treated with IMFINZI in the PACIFIC study, 45% were 65 years or older, while 7.6% were 75 years or older. No overall differences in safety or effectiveness were observed between patients 65 years or older and younger patients. The PACIFIC study did not include sufficient numbers of patients aged 75 years and over to determine whether they respond differently from younger patients.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Immune-Mediated Adverse Reactions

Inform patients of the risk of immune-mediated adverse reactions that may require corticosteroid treatment and interruption or discontinuation of IMFINZI *[see Warnings and Precautions (5.1) in the full Prescribing Information]*, including:

- Pneumonitis: Advise patients to contact their healthcare provider immediately for any new or worsening cough, chest pain, or shortness of breath.
- Hepatitis: Advise patients to contact their healthcare provider immediately for jaundice, severe nausea or vomiting, pain on the right side of abdomen, lethargy, or easy bruising or bleeding.
- Colitis: Advise patients to contact their healthcare provider immediately for diarrhea, blood or mucus in stools, or severe abdominal pain.
- Endocrinopathies: Advise patients to contact their healthcare provider immediately for signs or symptoms of hypothyroidism, hyperthyroidism, adrenal insufficiency, type 1 diabetes mellitus, or hypophysitis.
- Nephritis: Advise patients to contact their healthcare provider immediately for signs or symptoms of nephritis.
- Dermatological Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of severe dermatological reactions.
- Other Immune-Mediated Adverse Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of aseptic meningitis, immune thrombocytopenia, myocarditis, hemolytic anemia, myositis, uveitis, keratitis, and myasthenia gravis.

Infusion-Related Reactions:

- Advise patients to contact their healthcare provider immediately for signs or symptoms of infusion-related reactions *[see Warnings and Precautions (5.2) in the full Prescribing Information]*.

Complications of Allogeneic HSCT:

- Advise patients of potential risk of post-transplant complications *[see Warnings and Precautions (5.3) in the full Prescribing Information]*.

Embryo-Fetal Toxicity:

- Advise females of reproductive potential that IMFINZI can cause harm to a fetus and to inform their healthcare provider of a known or suspected pregnancy *[see Warnings and Precautions (5.4) and Use in Specific Populations (8.1, 8.3) in the full Prescribing Information]*.
- Advise females of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose of IMFINZI *[see Use in Specific Populations (8.3) in the full Prescribing Information]*.

Lactation:

- Advise female patients not to breastfeed while taking IMFINZI and for at least 3 months after the last dose *[see Warnings and Precautions (5.4) and Use in Specific Populations (8.2) in the full Prescribing Information]*.

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MENTORSHIP PROGRAMS IN RADIATION ONCOLOGY

ARRO Mentorship Programs

BY AUSTIN J. SIM, MD, JD, IDALID "IVY" FRANCO, MD, MPH, AND JUSTIN D. ANDERSON, MD

AS AN ORGANIZATION REPRESENTING THE INTERESTS OF RESIDENTS, the Association of Residents in Radiation Oncology (ARRO) recognizes mentorship as a foundational tenet to ensure success in residency and beyond. A recent review by Marsiglio et al. highlighted successes of some initiatives, but large, multi-institutional collaborations were lacking.[1] Although ARRO currently doesn't have an overarching program, we have worked to improve formal and informal mentorship opportunities. Medical students are paired with enthusiastic residents and faculty based on specific needs, ranging from first- and second-year students interested in learning more about our field and getting involved in research projects, to third- and fourth-years seeking guidance through the residency application process.

More tailored approaches have also been a priority for ARRO subcommittees. Within the Global Health Subcommittee, Chair Justin Anderson, MD, and Co-chair Becky Lee, MD, MPH, have spearheaded Contour Connections. In coordination with Rayos Contra Cancer, this initiative pairs international residents with U.S. residents to review contours and discuss difficult cases on a regular basis. This program has garnered significant interest among residents in the ARRO Global Health Subcommittee in working with residents and other learners from around the globe.

Students and residents who identify as underrepresented in medicine have been even more underrepresented within radiation oncology.[2,3] Despite its relative youth, the Equity and Inclusion Subcommittee, formed in June 2020, has also been hard at work in the mentorship space. Avinash Chaurasia, MD, and Amanda Rivera, MD, have served as the architects of a new mentorship initiative. In contrast to many similarly situated programs, this initiative provides additional structure and more frequent formal interactions among mentors and mentees with specific interests in diversity, equity and inclusion. This initiative fills a previously unmet need for trainees in the space between the ASTRO Minority Summer Fellowship Award for medical students and the ASTRO Leadership Pipeline Program (formerly called the Pipeline Protégé Program) for early career faculty.

Although we currently offer a diverse array of mentorship opportunities, formal evaluation of initiatives and the recognized need for such programs within the field is still in its infancy. We are excited about new and emerging opportunities and remain optimistic for the future.

Austin J. Sim, MD, JD, is a PGY-5 chief resident in radiation oncology at Moffitt Cancer Center, Tampa Florida, and serves as the chair of the ARRO Executive Committee.

Idalid "Ivy" Franco, MD, MPH, is a PGY-5 chief resident at the Harvard Radiation Oncology Program, Boston Massachusetts, and serves on the ARRO Executive Committee and as the chair of the ARRO Equity and Inclusion Subcommittee.

Justin D. Anderson, MD, is a PGY-4 radiation oncology resident at the Mayo Clinic Arizona, Phoenix and serves on the ARRO Executive Committee and as the chair of the ARRO Global Health Subcommittee.

The authors would like to acknowledge the mentors and mentees throughout our programs for all their hard work and the ARRO Executive Committee for their editorial comments on this article.

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Continued on the following page

Society for Women in Radiation Oncology Mentorship Program

BY: CRYSTAL SELDON, MD, AND LINDSAY PUCKETT, MD

THE SOCIETY FOR WOMEN IN RADIATION ONCOLOGY (SWRO) was founded in 2017 with the aim of providing a platform and support for female radiation oncologists. In 2018, a dedicated mentorship program was initiated to fill an unmet need for female mentors. Over the next two years, more than 100 pairings were created among students, residents and junior and senior attendings based on commonalities such as geographic region and disease site interest.

In 2020, an IRB exempt, anonymous survey was administered to participants. This represented the initial evaluation of the first large scale mentorship program specifically among women in radiation oncology. Questions included topics related to professional characteristics, ethnicity, pairing and program satisfaction.

Amid the COVID-19 pandemic, overall survey response rate was low (22%). However, through detailed responses from open-ended questions, valuable information was gathered on participating in remote mentorship. Many (42.9%) reported that they found the virtual pairing to be a positive experience and wanted to continue with their pair. Interestingly, 23% of respondents noted a lack of compatibility with their pairing(s), which led to the dyad's dissolution or failure. Responses such as, "Did not really develop a relationship with mentee" and "Surprisingly, I felt my mentee and I were so different that we did not have much chemistry nor was it a fruitful experience" were given to questions evaluating the pairing. Responses suggested race and geographic location did not ultimately matter for the majority of respondents. Seemingly more crucial was chemistry in the pairing.

With more efficient telecommunication in recent times, one would assume that developing a relationship with a mentor would be easier than ever; however, this may not be the case. As many organizations move forward with virtual mentorship programs, developing a pairing process that goes beyond geography and ethnicity may yield a higher rate of successful pairings.

Crystal Seldon, MD, is a PGY-3 radiation oncology resident at the University of Miami. She is the current resident chair of the Mentorship Committee for SWRO.

Lindsay Puckett, MD, is an assistant professor at the Medical College of Wisconsin. She was one of the founders of SWRO and previously served as the SWRO Mentorship Committee faculty chair.

AAPM's Science Council Associates Mentorship Program

BY KRISTY BROCK, PHD, AND ERIC FORD, PHD

IN 2016, THE SCIENCE COUNCIL OF THE AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE (AAPM) created the Science Council Associates Mentorship Program, otherwise known as "SCAMP." The program is designed to recognize and cultivate outstanding researchers in medical physics at an early stage in their careers, with the goal of promoting a long-term commitment to science within AAPM. Eight SCAMP positions are filled each year, and the selected SCAMP mentees are paired with a mentor who is a senior investigator active within the research-related committees in AAPM. The program encourages the mentee to shadow the mentor to integrate the mentee into the scientific activities of the organization. The program also includes funding for two consecutive AAPM Annual Meetings to support the mentee's attendance.

SCAMP is open to current graduate students in medical physics as well as residents, post-doctoral fellows and early career faculty within five years of receiving their terminal degree. The program is very competitive, receiving significantly more highly qualified applications than the eight SCAMP positions available each year. The selection committee is composed of SCAMP mentees and mentors from the previous year. They evaluate the candidates based on demonstrated success in research, dedication to pursuing future research, engagement with AAPM as a researcher, their statement on diversity and a letter of support from their supervisor. The program has grown in visibility over the past five years and has been well-received by participants, with mentees attesting to it as a "career changing experience." The AAPM is committed to continuing to support this program and is considering an expansion of mentorship programs into areas outside of the Science Council.

Kristy Brock, PhD, is a professor in the Department of Imaging Physics and Department of Radiation Physics at the University of Texas MD Anderson Cancer Center and vice-chair of the AAPM Science Council Associates Mentorship Program committee.

Eric Ford, PhD, is a professor, director and vice chair of Medical Physics at the University of Washington and chair of the AAPM Science Council Associates Mentorship Program committee.

ABS 300 in 10 Update: Training the Next Gen of Brachytherapy Teams

BY DANIEL G. PETEREIT, MD, FASTRO; FIRAS MOURTADA, PHD; LISA SINGER, MD, PHD; AND IDALID FRANCO, MD, MPH;

THE AMERICAN BRACHYTHERAPY SOCIETY (ABS) first presented the 300 in 10 initiative in the spring 2019 *ASTROnews*. This new initiative, set in place as a natural progression of the ABS brachytherapy (BT) schools, is a 10-year strategy to address the declining trends in BT utilization via multifaceted approaches to train 30 competent BT teams per year over the next 10 years. Two years in, this initiative continues to build on the work of ABS "giants" who developed the schools and workshops, detailed by Beth Erickson, MD, FASTRO, last fall in the special issue on education in the Journal of Brachytherapy.[1] This strategic approach ensures formalized continuity despite changes in the ABS Board of Directors (BOD).

An editorial by 2019 Henschke Award recipient, Greg Merrick, MD,[2] details our 300 in 10 "road map," composed of six phases to establish BT competency: 1) a national BT curriculum; 2) simulation based medical education (SBME); 3) two-month fellowships at ABS certified centers; 4) competency evaluation by ABS certified experts; 5) ABS BT certification; and 6) maintenance of certification.[3] The program was developed to assist trainees who want to develop a BT practice but lack sufficient experience due to low institutional BT volume.[4]

Phases 1 and 2 are underway with ABS schools and workshops. Of the 130 teams trained in three prostate schools, nearly 80% implemented a prostate BT program within six months as described by Steven Frank, MD.[5] ABS developed two-month fellowships for PGY-4 and 5 residents at 20 BT centers. Although delayed due to the pandemic, these rotations will be offered for gynecologic and prostate cancer, using LDR and/or HDR BT, starting in fall 2021 or early 2022. To pilot the program, two residents rotated with Brian Moran, MD, at the Chicago Prostate Institute, and both implemented LDR prostate programs in their communities. While Jill Remick, MD, was not part of 300 in 10, her experience confirmed the validity of these two-month fellowships as she gained invaluable GYN BT training from Sushil Beriwal, MD, MBA, FASTRO, and has pursued a career in BT.[6]

NextGenBrachy, led by Lisa Singer, MD, PhD, and Idalid Franco, MD, MPH, highlights mentorship as a cornerstone of the 300 in 10 initiative. It was developed as a virtual mentorship program to allow for flexible communication and ongoing collaborations between experienced BT mentors and early-career mentees, with a strong focus to attract mentees from groups underrepresented in medicine, women,[7] those without access to mentors and those starting their own practice. This one-year program welcomed its first cohort at the 2020 ASTRO Annual Meeting with 17 mentees selected from sites throughout the U.S., at varying levels of expertise. Each was paired with one clinical, and if desired, one physics mentor. Mentee comfort and confidence was assessed via pre-program surveys. Future work will focus on increasing reach, serving as a catalyst to increase workforce diversity and BT utilization.[8,9]

While there has been significant progress in moving 300 in 10 forward, the pandemic has delayed several aspects due to travel and hospital restrictions. Fortunately, our industry partners have continued their support of 300 in 10 for which the ABS BOD is extremely grateful.

Daniel G. Petereit, MD, FASTRO, of Monument Health Cancer Care Institute in Rapid City, South Dakota, is the ABS chairman of the board.

Firas Mourtada, PhD, chief of clinical physics at the Helen F. Graham Cancer Center & Research Institute in Newark, Delaware, is the ABS president.

Lisa Singer, MD, PhD, of Brigham and Women's Hospital and Dana-Farber Cancer Institute, is an assistant professor at Harvard Medical School.

Idalid "Ivy" Franco, MD, MPH, is a PGY-5 chief resident at the Harvard Radiation Oncology Program.

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Evolving Paradigms in Medical Student Mentorship

BY ARIEL HIRSCH, MD, AND NICHOLAS DENUNZIO, MD, PHD

MEDICAL STUDENT MENTORSHIP HAS TRADITIONALLY BEEN AN IMPORTANT COMPONENT of radiation oncology programs, with many medical students identifying mentors to shadow in clinic, undertake research projects and obtain career guidance. In recent years, there has been significant interest in understanding how best to approach mentorship in this context and also growth in the creation of formalized mentorship initiatives (Barrett 2008, DeNunzio 2010, Hirsch 2015, Boyd 2019). These (largely) single-institution efforts have mainly examined traditional dyad-based approaches to foster awareness of and interest in radiation oncology and the pursuit of careers in the field. Now, in the wake of a global pandemic that has upended how we think about technologic and humanistic connectivity, there is no better time to think about the potential to expand medical student mentorship to connect future physicians with our field.

When the Oncology Education Initiative (OEI) was created at Boston University School of Medicine, the aim was to educate all medical students about radiation oncology. The OEI included dedicated didactics in both the core pre-clinical and clinical curricula such that every medical student was exposed to the field before graduation. Several current programs across the nation aim to create a formalized approach to educating medical students and residents interested in radiation oncology.

Given an increased reliance on telephone and video conferencing, some of which is certain to persist in a post-pandemic world, there are opportunities to connect students with mentors at other institutions and in geographic areas that are not germane to where they grew up or are attending medical school. Several virtual mentorships have been reported, including the RISE (Franco 2021) and ROVER (Pollum 2020) programs, among others, indicating that virtual mentorship is an excellent opportunity for medical students and trainees all over the world. This is not to say that mentorship should now be exclusively reliant on electronics, as it is difficult to replace the face-to-face impact of both the doctor-patient and mentor-mentee interaction. Furthermore, these approaches underscore that medical student mentorship may not be best realized in a vacuum, but rather is reliant on a departmental culture of support from trainees and attendings (especially those in leadership positions).

Introducing Medical Students to Radiation Oncology:

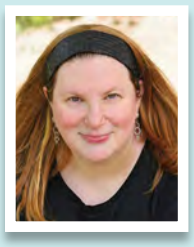
- Regardless of chosen specialty, medical students will encounter patients with cancer.
- The Oncology Education Initiative introduces all medical students to the basics of oncology and radiation oncology.
- Introductory topics in RO include treatment indications, field design and selection of dose and fractionation.
- Mentorship in RO can be extended to those specializing in other fields and is anticipated to benefit the profession.
- Mentorship initiatives are increasing in scope, now reaching across institutions and in different professional experiences.

By extension, peer mentorship in general has seldom been reported with regard to medical students. There may be an opportunity to formally connect students with recent graduates/residency matriculants who self-identify as interested in mentoring more junior trainees. Though this likely already happens informally at many institutions, a formalized program

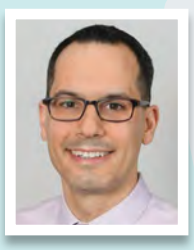
may benefit those at medical schools not associated with residency programs or well-structured advising. In our experience, we encourage peer mentorship between senior and junior medical students and find that research projects in particular can be enhanced with the input of a peer mentor, particularly when early-year medical students are nascent researchers.

What about students not intending to pursue radiation oncology training? Despite the tremendous strides already taken by the field to foster medical student awareness of and integration into the field, we should continue to augment mentorship for the benefit of those we will eventually refer to as colleagues, whether within the field, as part of the greater oncologic care team or the broader medical community. Benefits to the field include understanding the process and value of radiation therapy in the overall management of patients receiving oncologic care. In our experience, we have received excellent feedback from medical students — regardless of chosen specialty — not only for the radiation oncology didactics but for overall mentorship as well (Agarwal 2018, Huang 2021).

As described above, we have seen great efforts to engender stronger connectivity and engagement with our future colleagues through mentorship. Enhancing these efforts in radiation oncology has the potential to cultivate a more cohesive professional body starting at the very root of professional education as well as foster greater awareness and appreciation of the field in general. As we continue to address ongoing and new challenges that face our field, and as cancer care continues to evolve, ongoing and new mentorship initiatives will help inspire the next generation of radiation oncologists.



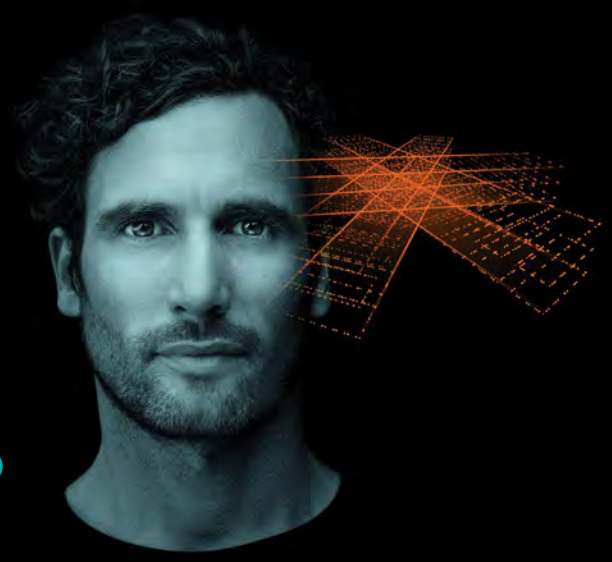
Ariel Hirsch, MD, is an associate professor and director of education of radiation oncology at Boston University School of Medicine and creator of the Oncology Education Initiative (OEI) and Radiation Oncology Mentorship Initiative (ROMI).



Nicholas DeNunzio, MD, PhD, has co-authored articles on medical student mentorship in radiation oncology and oncology curriculum development in medical schools. He is currently the director of proton therapy for the Hackensack Meridian Health Network.

RO-21-NAM-2214

Reduce organs-at-risk contouring time by 60% with AI



DirectORGANS with SOMATOM go.Sim from Siemens Healthineers

Alexander C Whitley, MD PhD FACRO
Medical Director, Central Alabama Radiation Oncology, Montgomery, Alabama

Introduction

The time to contour OAR contributes a significant amount of time in the entire radiation therapy process. In my experience, contouring contributes most of the time between simulations to initiation of radiation therapy. Contouring can range from 5-10 minutes to upwards of 60 minutes depending on the complexity of each case. Many centers schedule the start of radiation therapy based on contouring complexity. It is difficult to carve out the necessary time during clinic hours; thus, delays occur in completing contouring until after hours. This contributes to overall delays in radiotherapy initiation.

Decision

After careful review, we purchased two new Siemens Healthineers SOMATOM go.Sim CT simulators. As part of our review, we were enthused about DirectORGANS software, which utilizes an optimized reconstruction from the CT scanner and artificial intelligence (AI) to generate auto contours synchronous with CT simulation. All CT simulators utilize DirectORGANS auto contouring with adoption about 6 months ago.

Result

We have found the AI generated auto contours to be accurate in the over-whelming majority of cases, with minimal to no corrections. Time is the biggest benefit we have noticed thus far. With much of the contouring work completed prior to the radiation oncologist evaluating the CT simulation, there has been increased efficiency in completing the contouring task. Earlier completion of this work allows earlier initiation of the treatment planning, and subsequently patient treatment. We have found, because of decreased time needed, radiation oncologists are completing their contouring task throughout their clinic schedule in lieu of waiting for a larger block of time after clinic. We expect this will translate to earlier initiation of radiation therapy for patients from the time of consult and CT simulation. Traditionally we have a simulation start time of 5-7 business days, and I expect it will be decreased by 2-3 business days. With much of the contouring work completed prior to the radiation oncologist evaluating the CT simulation, there has been increased efficiency in completing the contouring task. We were able to cut down contouring time by 60%.

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The outcomes and statements provided by customers of Siemens Healthineers are unique to each customer's setting. Since there is no "typical" hospital and many variables exist (e.g., hospital size, case mix, and level of service/ technology adoption), there can be no guarantee that others will achieve the same results.

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BEYOND THE CLINIC

Beyond the Clinic is a new column focused on the newsmakers, entrepreneurs, inventors, government leaders and beyond — radiation oncologists that have melded their expertise in clinical practice with interests outside traditional work in medicine. Have a person you'd like to feature? Email suggestions to ASTROnews@astro.org.

TARGETING CANCER: RAISING AWARENESS TO EFFECT HEALTH CARE POLICY CHANGE

Lucinda Morris, MBBS

Shankar Siva, PhD, MBBS

Sandra Turner, PhD MBBS

Shankar Siva, PhD, MBBS, of Peter MacCallum Cancer Centre in Victoria, Australia, and member of the ASTRO Science Council, sat down with radiation oncologists and founding clinical leads of the Targeting Cancer Campaign within the Royal Australian New Zealand College of Radiologists (RANZCR), Faculty of Radiation Oncology Sandra Turner, PhD, MBBS, and Lucinda Morris, MBBS, to discuss Targeting Cancer, the education campaign to raise awareness about radiation oncology for patients and other health care professionals, as well as the group's recent accomplishments in effecting change in health care policy relating to prostate cancer.

**Responses have been edited for clarity and length. For the full interview and resources, visit www.astro.org/Summer21News.*

Dr. Siva: To start, can you please provide an overview of the Targeting Cancer program for the *ASTROnews* audience? How did this come about originally? What was the problem that was trying to be addressed?

Dr. Morris: Targeting Cancer is an international campaign, aimed at raising awareness and knowledge about radiation therapy in the general community, and also improving access for patients to radiation therapy worldwide. We launched in 2013 as an initiative of the RANZCR, Faculty of Radiation Oncology, when it was recognized that there was an area of need in terms of awareness and education around radiation therapy and the under-utilization of radiation therapy worldwide.

Our audience is the general public, patients and their caregivers, health care professionals, specifically GPs [general practitioners], and also medical students, as well as key stakeholders, including the government and industry. The key campaign messages are that radiation therapy could benefit one in two cancer patients, and that it is a highly safe, effective and cost-efficient cancer treatment that is delivered by a very highly trained, skilled team of professionals using sophisticated technology. And lastly, any patient that may benefit from radiation therapy should see a radiation oncologist.

Continued on the following page

Dr. Siva: You mentioned some of the key stakeholders as the public, the community practitioner, and briefly the government. Can you talk a bit more in detail about how you approach these three different groups? Who else are the key stakeholders for Targeting Cancer?
Dr. Morris: As I mentioned, one of our key audiences was general practitioners and the reason we identified them as a group was that we know in Australia and many countries in fact, GPs receive very little training or education around the basics of radiation therapy. GPs have many patients that will have a cancer diagnosis and will need to have radiation therapy. And, we also were aware that GPs and patients, both together, expect GPs to be advocates in their cancer care pathway.

So, we identified this and worked to develop a national GP education program in Australia. The program consisted of a face-to-face teaching program. We invited GPs to the radiation oncology department for a two-hour teaching session, usually held in the evening, and involved [a] one-hour case-based teaching session around two cases. The next component of the session was a walk-through tour of the department with a number of stations showcasing simulation treatment. And in some sessions, GPs could observe the patient actually having radiation therapy, so that GPs got a real sense of what their patients go through.

In total, there were around 60 sessions held across Australia and New Zealand. We surveyed GPs before and after the session in terms of their knowledge around the basics of radiation therapy, and we saw, not surprisingly, a huge increase from baseline knowledge to afterward having a really good understanding of the basics of radiation therapy and the likelihood of referring to a radiation oncologist. We also saw a spike in direct referrals from GPs in the community into radiation oncology departments.

I think that program is really one of the jewels in the crown of the Targeting [Cancer] campaign. Obviously, with COVID, there's been a hold on that style of teaching, but we look forward to reinvigorating that program in the future.

Dr. Siva: Let's pivot to the recent Medicare prostate cancer recommendations. You both have worked really closely with the Australian government, specifically around Medicare explanatory notes and recommendation for consultation, or at least all treatment options being canvassed with patients who have new diagnosis of prostate cancer. Can you explain in a bit more detail about this particular initiative?
Dr. Turner: After we'd built some momentum with Targeting Cancer, it was recommended that we pick some specific areas that we wanted to focus on as our next project. One of the biggest ones, and one being close to my heart, was around prostate cancer and men not receiving all the information they needed for informed decision making about treatment. Targeting Cancer provided lots of materials and content to help men understand their treatment options, but also outside the Targeting Cancer campaign, there was a body of work focused on moving the dial in the area of men knowing their radiation therapy options. Men and their families and GPs didn't know that radiation therapy could cure prostate cancer, so wherever possible, we got ourselves in places where we could get that message out.

The prostate cancer advocacy work took a multi-pronged approach. We launched a position statement from our College, which was very evidence based, and we put that out in the media. It was very controversial, because basically, it said that all men who were making a decision about active treatment for their prostate cancer should see a radiation oncologist. There was a lot of pushback from that. We did some TV and written media. We really pulled on patient experiences and had some really strong patient advocates that got involved with telling their story.

The Power of the Patient Voice

David Letts, a prostate cancer patient and professor of law at Australian National University, had been told by his urologist that he should have a radical prostatectomy. After seeking other opinions, he ultimately decided he wanted to have radiation therapy. As a lawyer, he felt strongly that informed consent required adequate discussion with all the relevant specialists who could provide expert advice about alternative treatments. He gladly shared his story in various news articles, including the the Daily Telegraph, and joined lobbying efforts. His efforts, and those of leaders within the RANZCR Faculty of Radiation Oncology, informed change in Australia's Medicare system for patients diagnosed with prostate cancer.

There was a bit of a movement building up in the media as well and in the community, which I'll say again was very controversial. It is fair to say that we were not always supported by our urological colleagues in our mission!

We also started collecting relevant data. There's now some really good New South Wales [NSW] and Victorian data showing the woeful rates of radiation oncologist referrals prior to radical prostatectomy. These data are a few years old now but show, for instance, that only 13% of men receiving a radical prostatectomy in NSW had talked to a radiation oncologist prior to their surgery. And we used every opportunity to lobby government. When we had roundtables or other meetings dealing with radiation therapy, particularly at a federal level, the discussions would include the specific situation of prostate cancer explaining how most men missed out on understanding all their treatment options.

The period we were getting active around the prostate cancer issue, four years ago now, coincided with the MBS [Medicare Benefits Schedule] review, in particular review of urological procedures. We decided to use this as another lever to help push urologists, GPs and the pubic in the direction of fully informed decision making. For the radical prostatectomy items, we pushed hard for including an explanatory note in the items stating that best evidence-based care was for men to talk to a radiation oncologist as well as urologist as part of informed decision making, prior to any active treatment starting. It was clearly not the whole answer but designed to push urologists and consumers to think about the idea of men seeing radiation oncologists.

There was a lot of pushback and many rounds of submissions. The committee chair was a urologist who was very against our proposal. So individually, we approached the other members on the committee who might support us: There were two general practitioners, one radiation oncologist who was obviously on board, and a couple of consumers and leaders of consumer bodies. We lobbied those people individually to help them understand what was at stake for men missing out on knowing their treatment options.

So, there was a lot of education of members on the committees and meeting requests to champion our cause with the ministers of Health and Veterans Affairs. The Chief Medical Officer (and advisor to the minister) was a renal physician and was quite supportive. A combination of all of those things, and raised awareness in the community from Targeting Cancer and other media, built to an acceptance that Medicare should recognize the role of radiation oncologists in providing information to men approaching active treatment for prostate cancer. And it became pretty hard in the end for the Minister *not* to agree to sign off on inclusion of the statement.

In September last year, the new Medicare schedule for urological items was implemented. Building on that, we worked with the Prostate Cancer Foundation Australia [PCFA], and our College and the urological society to release a joint media statement to promote the change. And we're still in the process of making sure that health professionals and the community know about it. There's a lot of work to do in making sure the recommendation is achieved across the board, but it's been a big step towards recognizing how prostate cancer treatment decision making should occur.

Learn more about these efforts in the full interview at www.astro.org/Summer21News.

Diane Kean, ASTRO communications manager and Dr. Shankar Siva (top, L to R) speak with Dr. Lucinda Morris and Dr. Sandra Turner (bottom, L to R) in early May 2021 to discuss the latest achievements in Australia's Medicare policies regarding prostate cancer as well as their efforts in educating patients through the Targeting Cancer campaign.

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BY PAUL E. WALLNER, DO, FASTRO, AND BRIAN J. DAVIS, MD, PHD

THE AMERICAN BOARD OF RADIOLOGY ROLE IN MENTORING AND CAREER DEVELOPMENT

THE MISSION STATEMENT OF THE AMERICAN BOARD OF RADIOLOGY (ABR) is "to certify that our diplomates demonstrate the requisite knowledge, skill and understanding of their disciplines to the benefit of patients."[1] This statement clearly defines the Board's role in the assessment of training and lifelong competence, but it provides no sense of the inherent responsibility to mentor candidates for initial certification and certified diplomates throughout the continuum of their careers so they can assume critical leadership roles in the disciplines represented by the Board.

ABR staff serve without specific job-related terms, but their roles and responsibilities are primarily to provide administrative and logistical support to volunteers who have the primary responsibility for policy development and exam creation and administration. All ABR volunteers, including those serving as governors, trustees or on one of numerous operational committees, have time-limited terms of service. The very nature of those term limitations provides an opportunity and, indeed, a necessity for constant volunteer recruitment and mentoring. Opportunities to serve as an ABR volunteer begin at the resident level,[2] with active participation on initial certification and continuous certification advisory committees. Radiation oncology (RO) residents who serve in those roles are nominated by the Association of Residents in Radiation Oncology (ARRO) and typically serve for two years. During their terms, they have an opportunity to learn the intricacies of exam development and administration from more senior volunteers and staff. These resident physicians are encouraged to maintain volunteer relationships with the Board following their graduation, and many have done so.

ABR RO diplomate volunteers are invited to serve on committees developing exam content. Volunteers may serve on one of the eight clinical category committees or two basic science committees, on the Online Longitudinal Assessment (OLA) item development committee, or on the ad hoc self-assessment module (SAM) review. SAM reviewers may begin to serve immediately after they receive initial certification. Qualifying (computer-based) exam item writers must be certified for at least two years, and certifying exam (oral) examiners must have attained initial certification a minimum of five years before this service. For these exam development and administration posts, the Board actively solicits early and mid-career diplomates. During their terms of service, these individuals are mentored by peers with more experience in exam development. Additionally, new oral examiners receive constant training from ABR staff and mentoring from their radiation oncology peers.

ABR volunteers are sought and encouraged to serve as mentors for others. Most ABR volunteers are actively involved in the training of medical students, residents and fellows. Many have received institutional and national awards for these activities.[3-8] The ABR will continue to recruit, mentor and nurture these talented, motivated and committed individuals.

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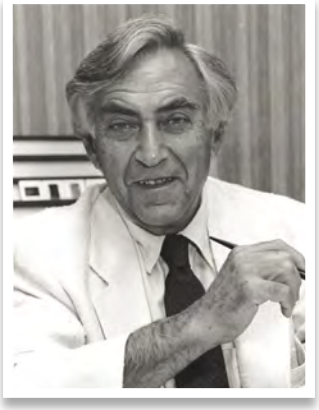
BY ERIC L. GRESSEN, MD

GIANTS OF RADIATION ONCOLOGY: *SIMON KRAMER, A MENTOR AND INNOVATOR, IN AND OUT OF THE CLINIC*



Simon Kramer, MD (1919-2002)

SIMON KRAMER, MD, WAS BORN IN 1919 IN ROMANIA during tumultuous times; he escaped with his immediate family to Poland and eventually to Great Britain, where he was educated. He was fluent in five languages: Romanian, French, German, Italian and English. He graduated from King's College and King's College Hospital Medical School of the University of London in 1943 and completed an internship at King's Hospital in London. During World War II, he joined the British Army Medical Corps and climbed to the rank of captain. After the war, as a ranking British officer in Palestine, he organized an ambulance service prior to the British pull-out. Dr. Kramer first trained in neurology before earning a diploma in radiology and radiation therapy in 1949. His radiation therapy and fellowship training was at the Meyerstein Institute of Radiotherapy, Middlesex Hospital, at the University of London. In 1954, he became director of radiation therapy at St. Boniface Hospital in Winnipeg, Manitoba, Canada, and in 1956, he was recruited to form a new radiation therapy division at Jefferson Medical College in Philadelphia, Pennsylvania, where he would remain for the rest of his career.

At Jefferson, Dr. Kramer established a residency program with his first resident, future department chair and ASTRO Gold Medalist Carl Mansfield, MD, ScD, FASTRO. More than 50 residents were trained by Dr. Kramer over the next two decades, many of whom became academic chairs. During his tenure at Jefferson, Dr. Kramer secured 21 major funding awards from the National Cancer Institute in areas as diverse as basic research, nuclear medicine, clinical studies and residency training. In collaboration with the Picker Medical Corporation, now Picker International, he developed and installed the first radiation therapy dose localizer (simulator) in the United States at Jefferson. In 1969, he was credited with developing the first independent academic radiation oncology program in the United States, which he combined with nuclear medicine.

Dr. Kramer understood the need for evidence-based medicine supported by multicenter clinical trials supported by a centralized research infrastructure. In 1968, he was awarded a grant from the NCI to create the Radiation Therapy Oncology Group (RTOG) and became its founding chair. In 1972, he created the Patterns of Care Study (PCS), a unique research initiative that involved surveying practices across the country regarding the methods they adopted for management of cancer. PCS helped to establish the highest standards of radiation oncology care in the world while subtly upgrading substandard practices and promoting greater conformity of quality in patient management. He chaired the subcommittee for the creation of the first of five "Blue Books," a series of documents setting the standard for radiation therapy practice. The first document, "A Prospect for Radiation Therapy in the United States," published in 1968, set the organizational structure for radiation oncology staffing of faculty and resources for decades.

Dr. Kramer was awarded gold medals by the Chicago Radiological Society, the Gilbert Fletcher Society, ASTRO and the ACR. In 1983, Jefferson awarded him the first distinguished professorship in any discipline. The date was memorialized by creation of an annual Simon Kramer lecture and symposium.

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

March 15, 2021

A Framework for Patient-Centered Pathways of Care for Radiopharmaceutical Therapy: An ASTRO Consensus Document

Buatti et al.

According to the authors, radiopharmaceutical therapy (RPT) is an area of projected growth and importance. There are several agents in clinical use, new agents in late-phase clinical trials and many others under testing and development. The paper argues that as RPT becomes more widely used in the care of a diverse spectrum of cancers, it is essential to develop a framework for patient-centered pathways of care. With equal input from radiation oncologists and nuclear medicine physicians, this consensus document expands on a patient-centered framework originally conceptualized by the ASTRO Working Group for patient-centered care.

April 1, 2021

Osteoradionecrosis: Exposing the Evidence Not the Bone

Frankart et al.

This review article explores the past 10 years of literature about osteoradionecrosis (ORN) for head and neck cancer (HNC). While ORN is relatively rare, it is a potentially morbid and often very costly side effect. The authors conclude that ORN of the jaw after radiation therapy for HNC represents a diagnostic and therapeutic challenge for which multidisciplinary collaboration is essential. The pathophysiology of ORN is multifactorial, and the etiology is not entirely understood. There are still no consensus predictive biomarkers or clinical risk factors; more research is necessary.

May 1, 2021

High Dose per Fraction, Hypofractionated Treatment Effects in the Clinic (HyTEC): An Overview

Grimm et al.

In this introduction to the HyTEC special issue, the authors explain that the goal of the initiative is to systematically pool published peer-reviewed clinical data to further refine dose, volume and outcome estimates for both normal tissue complication probability (NTCP) and tumor control probability (TCP) for SRS/SBRT. The historical context and general overview of HyTEC within this article frame the edition of the journal, and the authors explain their call for better data reporting. The HyTEC project was established within the Biological Effects Sub-Committee (BESC) of AAPM as the Working Group on Biological Effects of Hypofractionated Radiotherapy/SBRT.

HIGHLIGHTS FROM *PRACTICAL RADIATION ONCOLOGY*

March/April 2021

Consensus Statement on Proton Therapy in Mesothelioma

Zeng et al.

This article documents the findings of the Particle Therapy Cooperative Group (PTCOG) Thoracic Subcommittee task group's investigation into the use of proton therapy for malignant pleural mesothelioma. The authors suggest that radiation to the contralateral lung may be decreased by using proton therapy rather than photons, which can decrease the occurrence of life-threatening toxicity. The authors do caution that due to the complexities of delivering proton therapy for mesothelioma, treatment would preferably be delivered at high-volume centers with specialized expertise.

Continued on the following page

Phase 2 Clinical Trial of Stereotactic Body Radiation Therapy for Painful Nonspine Bone Metastases

Ito et al.

The authors of this study report the results of a multicenter single-arm trial evaluating palliative stereotactic body radiation therapy (SBRT) treatment for nonspine osseous lesions. The investigators treated 41 lesions in 38 patients, mostly presenting in the coxal bone. Over two-thirds of the treated lesions exhibited complete response (patient reported numerical pain rating score of zero) after six months. Twelve lesions showed partial response with an average reduction of 3.17. The authors do note that three patients who experienced severe limb edema associated with SBRT had a treatment history including surgery and suggest that this should be considered as a risk factor.

May/June 2021

Updating and Optimizing Anatomic Atlases for Elective Radiation of Para-Aortic Lymph Nodes in Cervical Cancer

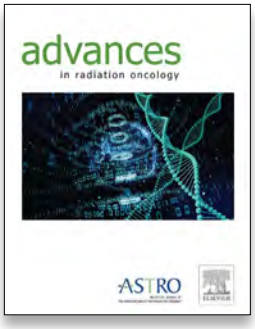
D'Cunha et al.

This report provides an update to the contouring atlases for para-aortic lymph nodes (PANs) for locally advanced cervical cancer. The authors provide mapping of 176 PANs and simulate contours based on guidelines from two previous studies to assess coverage. The authors designed a modified contouring guideline based on the prior studies and suggest that using the blended guideline may provide improved coverage in both the nodal center and anterior nodes.

ASTRO: The AUA-ASTRO-SUO Advanced Prostate Cancer Guidelines - a continued, but changing role for the radiation oncologist

Zietman

This editorial summarizes the key findings for radiation oncologists from the updated guidelines for the treatment of advanced prostate cancer. Radiation oncologists are encouraged to choose observation over intervention in the case of rising PSA without clinical evidence of disease and to consider systemic therapy for metastases appearing beyond the pelvis, based on the available evidence. This editorial also discusses the STAMPEDE and HORRAD trials as they pertain to the guideline.



HIGHLIGHTS FROM *ADVANCES IN RADIATION ONCOLOGY*

A Paradigm Shift in Radiation Oncology Training

Perni et al.

This article discusses the challenges in radiation oncology training as society and technology continue to change. Some inequalities and inefficiencies include gender-specific biases, obstacles faced by underrepresented minorities throughout their education, and ongoing stress related to COVID-19. The authors provided three recommendations that are essential to developing and maintaining diversity: using competency-based educational models that will streamline training and examination and decrease the economic burden; improve responsiveness to the needs of sexual and gender minorities, and racial/ethnic minorities, and disadvantaged groups; integrate technology to decrease barriers and increase efficiency.

Influence of Caregiver Presence During Physician Office Visits on Patients Undergoing Chemoradiation Therapy for Esophageal Cancer

Ho et al.

Previous studies show that being married is a protective factor for cancer patients; however, the role of other caregivers is understudied. This article explores the role of caregiver social support during physician office visits for patients with esophageal cancer undergoing chemoradiation therapy (CRT). The researchers hypothesized that marital status and social support will impact treatment tolerance and nutrition status in patients undergoing CRT. Patients diagnosed with nonmetastatic locally advanced esophageal cancer between January 1, 2005, and January 1, 2016, were included in the study. Using caregiver presence as a proxy for social support, patients were placed in one of two groups: frequent (present at ≥ 50% of visits) or infrequent (present at ≤ 50% of visits). The study found that patients with frequent caregiver presence had less weight loss, which may improve treatment tolerance and nutritional status; however, overall patient survival did not improve.

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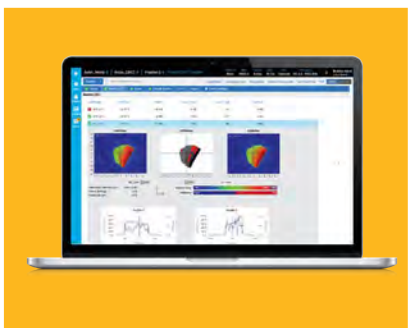

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