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Shapers of Our Future: (Re)Defining the Radiation Oncologist
The results of the 2019 ASTRO scope of practice study

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Leaders in Oncologic Care
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The authors detail the results of the 2019 ASTRO scope of practice study.

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A profile on the University of Michigan’s multidisciplinary spine oncology program.

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A firsthand account of a radiation oncologist in the role of cancer center director overseeing all aspects of cancer care.

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Maximizing the scope of practice by serving others through higher engagement and collaboration.

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Journals Highlights: Recently Published in ASTRO Journals
QUEEN ELIZABETH II referred to 1992 as “annis horribilis” — a horrible year. Three royal marriages collapsed, a fire destroyed part of Windsor Castle and scandal rocked the monarchy. 2020 certainly deserves that appellation — bitter political divisions, social unrest and an unrelenting pandemic. COVID-19 has consumed and depleted health care systems. Under such extreme circumstances, you might think there would be added protections to preserve access to vital services such as cancer care. If radiation oncology practices in the U.S. were hoping to catch a break, they got just the opposite — deep cuts in the Medicare Physician Fee Schedule and the Radiation Oncology Model. Thanks to valiant advocacy by ASTRO and the broader radiation oncology stakeholder community, Congress delayed the RO Model until January 1, 2022, and ameliorated the 5% anticipated overall reduction that would have taken effect this New Year’s Day.

That brings us to the theme for this issue of ASTROnews: The Scope of Practice of Radiation Oncology. While this loosely defines permitted functions by education, experience, certification and demonstrated competency, it is also a reflection of the role we play in patient care, and the say we have in that. What is our core skill set and how are we perceived by our patients and fellow professionals? In a recently published ASTRO survey, all respondents agreed that “radiation oncologists should be leaders in oncologic care.” However, practice rarely matched aspiration. Why is there such a mismatch? That’s something this issue examines, going into various aspects of our scope of practice. It also offers a fascinating look at how the scope of practice and roles vary across the world.

The challenge for us, in an ever-changing world, is this: We must imagine what the radiation oncologist of the future will do. There is no doubt there will be substantially more automation, augmented by artificial intelligence and robotic support in our process of care. We may play a decreasing role in target delineation, treatment planning steps, image guidance, online adaptations and supervision. Perhaps the scope of radiation therapists and dosimetrists will expand in these roles aided by automated tools, but every one of these changes could be contentious unless they are proven to not sacrifice quality patient care, are disconnected from whatever will be the reimbursement system of the future and not seen as threatening future job prospects. This could still generate heated disagreement. For instance, a recent JACR article said radiology extenders who read chest X-rays save attending radiologists more time during the day than radiology residents. The manuscript was withdrawn by the authors subsequent to publication.

Our training must evolve with the times to reflect education and knowledge in current and emerging areas of oncology for a more comprehensive picture of anticancer treatment options. The virtual ASTRO Annual Meeting featured discussions beyond the typical topics, such as cannabis in cancer care, radiopharmaceutical therapy (see page 33) and an engrossing session that included prescribing, managing and handling the side effects of the different second generation anti-androgens currently used in prostate cancer, which I found really useful. I am sure this type of exposure and training can help us expand the scope of services we offer, which won’t be without the attendant political hurdles and turf battles. Our roles, in addition to being experts in radiation, brachytherapy and radiopharmaceuticals therapy, could expand to wider multidisciplinary decision making, intensive counseling of patients before, during and after treatment and move us closer to our goal of becoming leaders in oncology care.

The end of the year brings hope on many fronts. John Dryden wrote the poem “Annis Mirabilis” or Year of Miracles to mark 1667, in truth a time of misery that saw the Great Fire of London among other tragedies. Dryden was trying to say that things could have been worse. If 2020 was horrible, can 2021 bring recovery, rejuvenation and healing? Yes, it can. Not just thanks to the wonder of science but also by people believing in themselves, thinking as a community and bridging their differences as we embark on a brand new year.

The ASTROnews editorial board joins me in wishing you all a happier 2021.
AS YOU READ THESE WORDS, it is likely that some of you, and perhaps your staff, will have already been vaccinated, that maybe there is finally light at the end of this long tunnel. The genetic sequencing, creation, testing and approval of multiple vaccines in the space of a year is unprecedented. The words of JFK echo across decades and speak more broadly to the entire human family: optimistic, creative, building greatly. A new phase has begun.

The theme of this issue of ASTROnews is the scope of practice. There are several thoughtful and elegantly written articles within that address the current state of affairs while casting an eye to the future. What lies ahead? Where are we going as a discipline? As a specialty society?

I spoke in some detail about these questions in my Presidential Address at the Annual Meeting in October and will not rehash those comments but rather expand on their meaning and try to add some context. Spoiler alert! I cannot foretell the future, but I can offer some observations based on the available data, my discussions with some of you and my own experience of being a radiation oncologist for nearly 30 years.

The practice of radiation oncology is different today than it was 30 years ago, but in some respects it hasn’t changed as much as we might think. We still see patients in consultation, develop therapy plans and follow our patients during and after treatment, but technology and the results of clinical trials have dramatically impacted the process of care. Like it or not, hypofractionation is a data-driven reality that will likely expand in the future. Yes, we all acknowledge that fewer fractions has negative economic ramifications for providers, but if you became a doctor simply to make money, you chose unwisely.

A thought: perhaps the radiation oncologist of the future needs to be more of a clinical oncologist than a radiation oncologist. Perhaps we need to take a more holistic approach to patient care rather than abnegating responsibility for overall patient management by deferring to our medical and surgical oncology colleagues. This would require a collective re-thinking of how radiation oncologists are trained and a gradual re-wiring of how we think and act. None of this will happen overnight, but the discussion has already begun and will continue until a clear path forward is identified and agreed upon. The times, they are a changin’.

There has been considerable hand-wringing re: workforce supply, often, unfortunately, in the unfiltered echo chamber of cyberspace. Although of little consolation, the specialty has been down this road before, on more than one occasion, and adjusted accordingly. We’re still here. ASTRO does not and cannot, as has been stated ad nauseam, control the number of training programs and residency positions. The Society has issued a carefully worded statement that urges training programs to be mindful of the potential future oversupply of radiation oncologists, without crossing the legal red line that suggests an attempt to control the marketplace. We also continue to engage SCAROP and ADROP to gauge their efforts on this critical issue.

All of this must be done with a conscious sensitivity for diversity, equity and inclusion as the Society and the specialty strive to improve the richness of our social fabric and improve health outcomes for all of our patients. Likewise, this process has already begun and will continue unabated.

Finally, ASTRO continues unceasing efforts to rectify the broken RO Model. Despite pushing the start date to January 1, 2022, the reality is that the model is fatally flawed and deserves a fresh look by the new administration and, perhaps, going back to the drawing board. If there was ever a time when your participation in ASTRO’s advocacy efforts was broadly needed, this is it!

There’s so much more to say. Please reach out to me directly (ndmd1974@gmail.com) with your questions and concerns. I serve you!
2020. WHAT A YEAR. Who could have imagined one year ago what our new normal would look like today? Despite the hurdles 2020 threw at all of us, I am so proud of the work the Society accomplished over the past year. Responding to the COVID-19 pandemic, with then-ASTRO President Thomas Eichler at the lead, ASTRO quickly produced many valuable resources for members who were, and still are, facing this public health emergency on the frontlines. From extensive FAQs, clinical guidance and webinars to expedited journal article publication and expert commentaries from those working directly with COVID patients, ASTRO utilized the expertise and experiences of our members around the world to quickly create and disseminate COVID-19 resources that remain available under the Daily Practice section of astro.org. In addition, we collaborated with a PPE supplier to make critical equipment available to members twice during the year. As the pandemic evolves, and hopefully soon dissipates, we will continue to provide resources, recommendations and guidance to support our members.

COVID-19 did not distract from ASTRO’s mission to advance the field of radiation oncology. Over the past few years, concern around the job market and size of residency programs has emerged. While ASTRO cannot control the number of training programs or applications accepted, ASTRO has been in active communication with SCAROP, ADROP and ARRO regarding the data needed to inform the discussion. In addition, the Board of Directors recently issued a statement on this topic. I am pleased to report that in a recent ARRO Graduating Resident Survey, which received a 94% response rate from the 2020 graduating class, 89% of respondents reported high satisfaction with their job offers. On average, graduating residents had a median of five interviews and received two job offers. And when asked how well their training prepared them for independent practice, 90% responded they were satisfied. ASTRO continues to work side-by-side with ARRO to ensure residents’ concerns are heard.

A large part of advancing the field is taking a hard look within to better understand how to improve recruitment and retention of Black and historically underrepresented minorities in candidates to residency programs. ASTRO is working to ensure that committees and councils provide opportunities for full engagement with all members, including those underrepresented in the field. As part of this effort, the Board approved the elevation of the Committee for Health Equity, Diversity and Inclusion (CHEDI) into a full ASTRO Council and with it, the associated two positions on the ASTRO Board. Ratification of this amendment to the ASTRO Bylaws will require a vote by membership later this year. The elevation of CHEDI to a full Council further demonstrates ASTRO’s commitment to health equity for our patients, a stronger culture of inclusive excellence in our field, and supports our vision for a radiation oncology workforce that better reflects our diverse patient population.

In August, the long-awaited RO Model was released, largely ignoring many ASTRO recommendations. However, with indomitable persistence, ASTRO successfully convinced CMS to delay implementation to January 2022. We continue
to push for changes to the RO Model to make value-based care work best for our members. ASTRO continues to fight burdensome prior authorization practices and is building bipartisan support in Congress to reform prior authorization practices.

And finally, I cannot reflect on 2020 without mentioning the Annual Meeting. This was my 18th meeting, and so far we’ve had a hurricane, superstorm Sandy and blazing fires outside Los Angeles. I was thinking locusts would be next; for some reason pandemic was never on my list! Transitioning from the in-person to an all-virtual Annual Meeting was an incredible undertaking. In a virtual environment, ASTRO was able to offer educational content and the latest science, providing members with more than 200 CME credit opportunities. We were able to retain 110 exhibitors, who offered impressive virtual booths and product demonstrations. While we were able to maintain much of what you expect from the ASTRO Annual Meeting’s science and content, we all missed the face-to-face networking and chance to catch up with friends from around the world. We hope to see everyone in Chicago in October and are working to make it a safe event for all.

Thank you for continuing to support ASTRO. This is a time when, with the many challenges we are all facing personally and professionally, you really take stock in what is important. I feel honored and blessed to lead ASTRO. I am so grateful to our leaders and Board who dedicate a great deal of time and energy to the Society and to you, our members, who volunteer countless hours to support the Society, all while treating patients. Thank you and best wishes for 2021! 🎉
A unique year! ASTRO members share their insights in the 2020 Membership Survey

BY TIM SANDERS, ASTRO SENIOR RESEARCH ANALYST

THE ASTRO MEMBERSHIP SURVEY IS AN ANNUAL LOOK INTO HOW MEMBERS FEEL about their membership and the Society's initiatives, programs and direction. We truly appreciate the engagement of our ASTRO members. 2020 was a different year due to the challenges of facing a pandemic, and the 2020 survey included several questions about how the COVID-19 pandemic affected members. This survey was fielded from May 26 to July 21, 2020, pushed back a few weeks from our normal timeframe to capture as much information about the pandemic as possible. The web-based survey was completed by 1,376 ASTRO members for a response rate of 16.1%. Many reasons (including the pandemic) can be attributed to the slight decrease (<2%) in response when compared to the 2019 Membership Survey.

Who responded?
Of the 1,376 members who completed the 2020 Membership Survey, 76% are located in the United States. Of all members who completed the survey, 70% are radiation oncologists. Engagement from members, both from the United States and radiation oncologists, increased 5% from the 2019 survey. Medical physicists (15%) and radiation oncology (RO) residents (9%) are the second and third most reported profession (Figure 1).

When we look across both our domestic and international respondents, half of all respondents practice at an academic setting, whereas only 39% practice in a private/community setting. When we look specifically at U.S. radiation oncologists, the academic/private practice split narrows, with 46% practicing at a private/community setting and 47% practicing in an academic setting. Across both domestic and international locations, the vast majority of respondents are hospital-based (88% international; 79% domestic).

Other demographic features of our respondents include:

- Slightly more than two-thirds of respondents are male.
- Respondents are experienced, averaging 17.8 years out of residency, spanning from less than one to 57 years.
- Domestically, respondents’ engagement is greater in more populated areas, yet all states, including the District of Columbia, are represented in 2020 (Figure 2).
- 95% of respondents practice in metro areas, with only 5% practicing in non-metro/rural areas, mirroring the ASTRO membership as a whole (96% to 4%).

![Figure 1: Respondent Demographics (Profession)](image)
**Figure 3: Challenges Faced by Respondents Regarding COVID-19**

More than half of all respondents found all but one of these aspects at least moderately challenging due to the pandemic. Sorted by “Very Challenging”

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Not challenging</th>
<th>Moderately challenging</th>
<th>Very challenging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to COVID-19 tests for self/staff (n=1179)</td>
<td>36%</td>
<td>40%</td>
<td>24%</td>
</tr>
<tr>
<td>Acquiring sufficient personal protective equipment (PPE) (n=1238)</td>
<td>33%</td>
<td>44%</td>
<td>23%</td>
</tr>
<tr>
<td>Scheduling of COVID-19+ patients (n=983)</td>
<td>31%</td>
<td>48%</td>
<td>21%</td>
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<tr>
<td>COVID-19 - Access to COVID-19 tests for patients (n=1169)</td>
<td>38%</td>
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<tr>
<td>Meeting payroll and expenses (n=927)</td>
<td>38%</td>
<td>43%</td>
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</tr>
<tr>
<td>Understanding how to bill and code for services provided (n=987)</td>
<td>36%</td>
<td>53%</td>
<td>11%</td>
</tr>
<tr>
<td>Disinfecting patient areas, equipment, etc. (n=1201)</td>
<td>45%</td>
<td>45%</td>
<td>11%</td>
</tr>
<tr>
<td>Maintaining adequate staffing levels to deliver needed radiation therapy (n=1192)</td>
<td>52%</td>
<td>37%</td>
<td>10%</td>
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<tr>
<td>Complying with regulatory requirements (n=1159)</td>
<td>45%</td>
<td>47%</td>
<td>8%</td>
</tr>
<tr>
<td>Accessing virtual education to acquire CME credits (n=1071)</td>
<td>64%</td>
<td>30%</td>
<td>7%</td>
</tr>
</tbody>
</table>

**COVID-19 and ASTRO members**

The COVID-19 pandemic has affected many aspects within the field of radiation oncology. ASTRO included questions in the survey about the challenges, location and geographic region, in addition to rurality. This representativeness gives us confidence that the survey results are reliable for ASTRO to use as we make decisions about future initiatives, programs and direction.
1. Scheduling COVID-19 positive patients.
2. Acquiring sufficient personal protective equipment (PPE).

ASTRO produced numerous resources as the pandemic hit that respondents found helpful. Respondents found ASTRO’s clinical guidance most helpful during the first few months of the pandemic. Other resources respondents found helpful were ASTRO’s COVID-19 information page on the ASTRO website, our advocacy, expedited journal article publication and our weekly ASTROgrams. The 2021 Membership Survey will take a deeper look at the far-reaching effects of the COVID-19 pandemic.

ASTRO also conducted a COVID-19 Practice Response Survey to understand and evaluate how radiation oncology practices were handling the pandemic. For more information, please see ASTRO’s COVID-19 Practice Response Survey (ASTRO Impact Survey) media resources at www.astro.org.

**Feelings about ASTRO**

Satisfaction among all respondents has remained steady and high over the last four years (Figure 4). Radiation oncology residents report the lowest rates of satisfaction with ASTRO membership.

Each year, we ask ASTRO members if they find participation in ASTRO a good use of their time. Over the last seven years, this number has ranged 85-90% (Figure 5). In 2020, 89% of our members reported that they thought participation in ASTRO was a good use of their time, up 4% from 2019. This high level of volunteer engagement allows ASTRO to build initiatives and programs for all our members. Residents reporting dissatisfaction with ASTRO still rated participation in ASTRO as a good use of time.

![Figure 4: Satisfaction with ASTRO Membership](image-url)

*Satisfaction with membership continues to stay high and consistent for all members with slight upticks for U.S. respondents*
Importance of the functions ASTRO provides
Knowing what members find important in their ASTRO membership is crucial to understanding the wants and needs of our members. Every other year, we ask our members to rate the importance of ASTRO’s core functions. These functions range from our advocacy, education and meetings to our journals, research and other programs. The most important function in 2020 among all respondents, both domestic and international, is to continue to publish scientific and practice journals, i.e., the Red Journal, PRO and Advances. U.S. radiation oncologists rate advocacy as the most important function, specifically, advocating on behalf of members for appropriate reimbursement.

Respondents’ primary reason for being a member of ASTRO
When members were asked about their primary reason for being a member of ASTRO, several common themes emerged. The most common theme was ASTRO’s education. This was followed by our journals, access and networking. Keeping up to date with field-related information and attending the Annual Meeting were also mentioned frequently (Figure 6). This, coupled with the functions mentioned earlier, give ASTRO a plethora of member services and benefits to build on moving forward.

Summary
ASTRO continues to use this feedback to inform and improve your membership experience and better the Society for the future. Thank you to everyone who took the time to complete the 2020 Membership Survey. The survey is sent out every summer, so don’t miss it in 2021! Your input is essential to making ASTRO work best for you.
Now that the 2020 ASTRO Annual Meeting has concluded, it’s time to reflect on some of the most exciting and noteworthy studies.

The CCTG SC.24/TROG 17.06 trial, a phase II/III trial that randomized patients with painful spinal metastases to 24 Gy in 2 fraction SBRT versus 20 Gy in 5 fraction CRT, demonstrated significant improvement in complete pain response favoring SBRT over CRT at three and six months. These findings are particularly noteworthy following RTOG 0631, which did not demonstrate improved pain response with single fraction SBRT to 16 or 18 Gy compared to single fraction EBRT to 8 Gy. As pain control is the primary objective of palliative radiation in this setting, the findings from SC.24 demonstrate that appropriately selected patients would likely benefit from 24 Gy in 2 fraction SBRT over CRT.

The most notable study presented from the gynecologic world was likely the PARCER trial, a phase III trial evaluating 3-D vs. IMRT for adjuvant radiation therapy for cervical cancer. This study demonstrated four-year grade 2+ late bowel toxicity of 19.2% in the IG-IMRT arm vs. 36.2% in the 3-D CRT arm (p=0.005). Complementing findings from the previously published TIME-C trial, which showed patient-reported significant improvements in acute GI morbidities, this study suggests a strong clinically meaningful benefit improvement in late GI effects with IG-IMRT in the post-operative gynecologic setting, making it a potential standard of care in this patient population.

The prostate cancer realm had several impactful studies as well. The FLAME trial was a multi-institutional phase III study, including 571 patients with intermediate- and high-risk prostate cancer, randomized to standard EBRT of 77 Gy in 35 fractions of 2.2 Gy to the whole prostate gland with or without simultaneous integrated boost (SIB) to 95 Gy to visible tumor on multiparametric MRI. OAR constraints were prioritized over SIB dose. At a median follow-up of 71 months in a patient cohort that was 84% high-risk, five-year bDFS was 93% in the SIB arm vs. 86% in the standard EBRT arm. Late grade 3+ GI and GU toxicity was similar in both arms. Given the impressive five-year bDFS with dose escalation in a predominantly high-risk cohort, SIB to gross intraprostatic tumor with some type of functional imaging may eventually represent an effective option.

A combined analysis of the prostate-only arms of RTOG 9413 and a similarly designed Canadian trial from Malone et al., which randomized patients to neoadjuvant/concurrent or concurrent/adjuvant ADT, challenged ideas regarding sequencing of ADT. With median follow up of 14.9 years and inclusion of 1,065 patients, adjuvant ADT was shown to be superior to neoadjuvant ADT in terms of BF (15-yr 33% vs. 43%, p=0.002), DM (15-yr: 12% vs. 18%, p=0.04), and PFS (15-yr: 36% vs. 29%, p=0.01), with similar overall survival and no increase in late GI or GU toxicity. This analysis may change sequencing of ADT with radiation therapy with higher use of adjuvant ADT in comparison to neoadjuvant approach.

Finally, additional supporting data for use of advanced imaging for prostate cancer emerged, with the EMPIRE-1 trial being the most significant. In this phase II/III trial, patients with biochemically recurrent prostate cancer were randomized to salvage RT with conventional imaging alone vs. fluciclovine (18F) PET/CT-guided XRT. The 165 patients enrolled had a median PSA of 0.34 ng/mL. Use of fluciclovine (18F) PET prior to salvage XRT resulted in 35.4% rate of decision changes. Use of conventional imaging alone resulted in significantly worse biochemical control (HR 2.04, 95% CI 1.06-3.93, p=0.033). This trial was the first of its kind to demonstrate improvement in treatment outcomes with addition of fluciclovine (18F) PET scan in prostate cancer prior to salvage XRT. Future studies are being done with more sensitive PSMA scan to see if PSMA can detect disease at an even lower PSA threshold.

Andrew Keller, MD, is a PGY-4 radiation oncology resident at UPMC Hillman Cancer Center in Pittsburgh.

Sushil Beriwal, MD, MBA, FASTRO, is a professor of radiation oncology at the University of Pittsburgh School of Medicine and residency program director at UPMC Hillman Cancer Center in Pittsburgh.
ASTRO’S CORPORATE MEMBERSHIP has elected the following companies to serve on the 2021 Corporate Advisory Council: GE Healthcare and Siemens Healthineers, both newly elected, and Standard Imaging and ViewRay, re-elected for another term. We are also pleased to announce that AstraZeneca will serve a second term. Having a pharmaceutical company on the Council is important, as it provides their unique industry perspective and contribution to the work of the Council.

The Council is a representative group of the Corporate Membership at-large, with a proportional mix of large and small companies from the Corporate Membership base. Seats on the Council are held by high-level decision makers within the corporations and represent a broad cross section of the industry. The Council allows for collaboration between ASTRO and its corporate members by focusing on issues and initiatives of mutual concern in radiation oncology. Priorities include increasing awareness of radiation therapy and advancing the science and practice of cancer treatment and patient care. In cooperation with ASTRO leadership, the Council convenes several times a year via conference call and meets in-person at ASTRO’s Annual Meeting.

All corporate members can nominate their company to serve on the Council. Nominations are accepted every fall with elections conducted during the winter. For more information about the Council and/or Corporate Membership, please contact Joanne DiCesare at joanne.dicesare@astro.org or 703-839-7398.

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<td>Blue Earth Diagnostics</td>
<td>Terri Wilson</td>
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<td>Elekta</td>
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<td>Lap Laser</td>
<td>Trent van Arkel</td>
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<td>Nanobiotix</td>
<td>Cathy Celestin, PharmD, MBA</td>
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<td>Varian</td>
<td>Chris Toth</td>
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<td>Nat Geissel</td>
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<td>IBA (Ion Beam Applications SA)</td>
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<td>Siemens Healthineers</td>
<td>Martin Tasler</td>
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Five companies elected to ASTRO’s Corporate Advisory Council
IN THIS AGE OF RAPIDLY GROWING MEDICAL KNOWLEDGE and technological capability, radiation oncologists (ROs) are critical drivers of scientific advances and high quality patient-centered cancer care. To help assess ROs’ perspective on their desired scope of practice to best meet the needs of today’s patients, ASTRO conducted a survey on U.S. ROs’ views on the ideal role of the RO, scope of practice and interest in service expansion.1

The online survey was distributed to 3,822 U.S. RO members of ASTRO during spring 2019. It generated 984 complete responses (26% response rate) for analysis.

Most respondents agreed that “ROs should be leaders in oncologic care,” with only 4% disagreeing. Regarding the ideal approach to patient care, the majority (82.5%) indicated that their ideal was “to provide an independent opinion on radiation therapy and other treatment options (ideal = comprehensive opinion),” while for 16.1% it was “to provide an independent opinion on radiation therapy but not outside of it (ideal = RT-only opinion)” and for 1.4% it was “to provide radiation therapy at the request of referring physicians (ideal = RT on request).”

Not surprisingly, few (18.2%) reported their actual practice matched their ideal approach completely. The vast majority of respondents reported that their individual actual practices were a mix of the three approaches: providing, on average, a “comprehensive opinion” (39.0%) of the time, a “RT-only opinion” (37.0%) of the time and “RT on request” (24.0%) of the time. Respondents most commonly practiced according to the approach they had identified as their ideal, but, on average, provided radiation on request (the least favored ideal scenario) a quarter of the time.

The top reasons for a mismatch between actual practice and ideal approach were concern that a potential disagreement with the referring physician about treatment would cause alienation and change in referral patterns (26.6%) and concern that the referring physician would not be receptive to an independent opinion (14.8%). These very real concerns that asserting independence would adversely affect the relationship with the referring physician reflect a common power dynamic in radiation oncology practice.

Power, as such, relates to who controls the patient flow. In the U.S., a new cancer patient’s first point of entry to the oncologic care path is often the surgeon, since surgery historically has been the first, and sometimes perceived to be the only, effective step in cancer treatment, in addition to the surgeon’s common role in performing a diagnostic biopsy. With dramatic shifts in treatment paradigms across many diseases, multimodiity therapy is often the norm, with modality sequencing a discussion point rather than a foregone conclusion. Nonetheless, the cancer patient’s first encounter is still commonly the surgeon, sometimes the medical oncologist and, less commonly, the RO. The RO, being downstream, therefore holds a weaker political position.2 In addition, cultural patterns of behavior may also undermine the RO’s influence.3

Surgeons, at the top of this hierarchy tend to speak confidently, while the status-disadvantaged may feel pressured, consciously or subconsciously, to acquiesce, even if they disagree, in order to avoid confrontation. To be sure, medicine has made huge strides in teamwork and professionalism, and such hierarchies are crumbling. Nonetheless, broader awareness of these potential undercurrents will benefit all stakeholders.

How can ROs improve their situation? One solution is to be the first point of oncology contact for the patient after a cancer diagnosis. In prostate cancer and head and neck cancer, for example, this would be entirely logical. Additionally, leadership in multidisciplinary clinics and conferences can also promote a strong, confident radiation oncology voice.

But ultimately the goal is not competition but collaboration among the specialties. A culture of mutual respect and partnership among medical, radiation and surgical oncologists would allow all disciplines to serve as co-leaders in cancer care and encourage ROs to practice with greater alignment with their ideal. Development of the social skills needed to navigate the interdisciplinary relationships is paramount. To this end, ASTRO presented the well-received “Leadership and Emotionally Intelligent Communication” masterclass at the 2020 Annual Meeting.

On the topic of practice scope, a majority of ROs provided management of radiation-related symptoms (99.3%), management of cancer-related symptoms (97.2%), narcotic analgesic prescriptions (92.3%), palliative care (87.9%), survivorship care (71.9%), end-of-life counseling (69.7%), administration of intravenous fluids (50%), management of systemic
treatment-related symptoms (52.8%) and cancer screening (52.8%). Between one-quarter to one-third of respondents provided cancer-related genetic counseling (33.4%), administered radiopharmaceuticals/theranostics (31.0%) or prescribed certain anti-cancer medications, hormonal or targeted systemic therapy (28.1%), for example. One in ten provided primary care services (10.9%) or medical marijuana prescriptions (10.0%).

Respondents with an interest in expanding practice scope (21.4%) were, on average, earlier in their career (average years in practice 13.3) than those who indicated no interest (average years in practice 17.2, p<0.001). The areas that held the most interest for expansion were medical marijuana prescribing, radiopharmaceuticals administration, and prescribing of certain anti-cancer medications. Coincidentally, <40% of all participants felt that they had the knowledge and of variables associated with job securement. Pract Radiat Oncol. 2017;7:425–432. doi.org/10.1016/j.prro.2017.04.017


References

Dr. Fung is a radiation oncologist at Beth Israel Deaconess Medical Center and immediate past chair of the ASTRO Workforce subcommittee. Dr. Ennis is vice chair for Network Integration and Quality Radiation Oncology at the Rutgers Cancer Institute of New Jersey.
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THE FORCES MOLDING CONTEMPORARY CANCER CARE ARE FORMIDABLE. Disruptive examples include the shift towards value-based care (e.g., CMS’s mandatory RO Model), therapeutic parsimony (e.g., observation in select patients with breast and prostate cancer; shorter fractionation schemes across disease sites) and telehealth catalyzed by COVID-19. Further, unprecedented advances in radiation dose-delivery precision (e.g., via SBRT, VMAT, IGRT, adaptive planning) for local/metastatic disease, integrating radiation with novel systemic/biologic agents and in the fields of imaging, genomics, machine learning and artificial intelligence, all expand the frontiers of our specialty. These forces bring the apprehension of change and optimism of opportunity.

Such an environment logically stimulates existential dialogue. Fung and colleagues recently surveyed ASTRO’s U.S. physicians on both what it means to be a radiation oncologist and what our role is in patient care. Their results reveal the current conceptions of our radiation oncology world and hint at its future.

A primary finding by Fung and colleagues is that while 83% of respondents feel the ideal approach to patient care is to provide “an independent opinion on radiation and other treatment options” (i.e., practicing holistic oncology), their actual practice fully matched this ideal in only 18.2% of respondents. For the rest, their actual practice did not always match the ideal, and 37% of the time they provided a clinical opinion only on the role of radiation therapy (i.e., practicing niche oncology), and 24% of the time they provided radiation “on request” (i.e., practicing as a technician). These findings raise two critical questions: Why is there a chasm between the majority’s ideal practice and actual practice? And how can we bridge the gap?

The first question is addressed in part by the survey results, with the most commonly stated reasons being concern that differences of clinical opinions would alienate the upstream physician and presumably result in fewer downstream patient referrals, the lifeblood of the specialist. To borrow from Edward Halperin, MD, in retelling a surgical chair’s characterization of radiation oncologists, these results portray us as “clinical catfish: the bottom-feeding garbage-eater at the end of the clinical referral chain.”

The second question strikes at our existential core and forces us to re-examine the role of radiation oncologists. We believe that bridging the gap between ideal and actual clinical practice requires a return to the foundational aspects of clinical medicine (as has been noted by others and for many years, including the late Morton Kligerman, MD). This is illustrated by the maxim often attributed to Samuel Hellman, MD, FASTRO: Be a good person, then a good doctor, then a good oncologist, then a good radiation oncologist, in that order.

Specifically, being considered integral members of the oncology care team requires dependable hard work and holistic care. One approach to actualizing this is with inpatient care. Our lack of an admitting inpatient service distinguishes U.S. radiation oncologists from many referring physicians. Whether we should desire admitting privileges is beyond the scope of this article, but fewer than 20% of radiation oncologists surveyed manage, or desire to manage, inpatients. At a minimum, it is essential that we be engaged participants with inpatient care to be considered an integral care team member. This includes seeing in-house consultations, and rounding on one’s admitted patients, in their

Continued on the following page
inpatient rooms rather than “insisting that the inpatient be brought to the radiation oncology clinic.”

A second related example is adapting a perspective that there is no such thing as an “inappropriate consult.” Rather, all consults represent a request for us to contribute to a patient’s oncologic management, including but not limited to issues related to radiation. Opinions on oncologic management and the role of radiation are not mutually exclusive, and both fall under the purview of a competent radiation oncologist, who has had at minimum four years of oncology-specific graduate medical education. In many ways, our training, which encompasses all disease sites, provides us with unique inter-disease perspectives that can provide meaningful, integrated management decisions.

A third example is in our approach to multidisciplinary tumor boards. We should be active participants (i.e., visible in the front row and speaking our data-based opinions) who regularly attend not only when there are cases that “need radiation input.” Our imaging-based practice provides us with a skillset for oncologic interpretations of diagnostic imaging, and our input can complement that of our diagnostic radiology colleagues. For example, radiation-induced normal tissue injury (e.g., manifesting as symptoms or imaging changes) can be misinterpreted as recurrent tumor. Often, we alone know where our beams have gone.

A fourth example is how we choose to approach supportive and palliative care. Following all patients, palliative and curative alike, can facilitate advance care planning, and ensures the opportunity to care for (and appreciate) the acute and chronic toxicities of our modality. Indeed, with short palliative courses, the acute effects often peak after radiation is completed. Being available to address these potential toxicities (e.g., via obtaining labs, giving intravenous fluids, prescriptions, or coordinating the necessary supportive services) sends an important message to our oncology colleagues. This is opposed to simply turfing them to the nearest emergency department at the first sign of distress. Of note, >50% of radiation oncologists surveyed reported providing these sorts of services.

Beyond the immediate effect of establishing oneself as an integral member of the care team, an inevitable consequence of these approaches is that radiation oncologists will be perceived as leaders in cancer care. Is this consequence desirable? The answer is a resounding yes: nearly all respondents (96%) felt that “radiation oncologists should be leaders in oncologic care.” It is thus plausible that working toward this can help close the gap between the ideal and actual clinical practice.

The definition of “leader” in this context is vague and personal: leadership roles exist on a spectrum from within the multidisciplinary care team to beyond the cancer center. Regardless, leadership training resources are increasingly available to the membership. Examples include the 2020 ASTRO Annual Meeting Master Class in Leadership and ASCO’s annual Leadership Development Program (in which many radiation oncologists have participated). The Cleveland Clinic Department of Radiation Oncology has integrated components into their standard curriculum. While there are relatively few radiation oncologists in the upper leadership echelons of academia, there are several, and thus there is ample precedent. The sky is the limit! Many radiation oncologists have shed the shackles of our name and taken on extraordinary roles beyond the cozy confines of the basement department. Perhaps the most visible contemporary examples are the two radiation oncologists currently serving as commissioner and deputy commissioner of the Food and Drug Administration, leading the regulatory side of the nation’s vaccine development and deployment during a once-in-a-century global pandemic.

Ultimately, how we respond to the formidable forces shaping contemporary cancer care is in our hands — whether we go the path of the bottom-feeder or of the fearless leader — and a return to the foundational aspects of clinical medicine may help show us the way.

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References
Radiation Oncology as the Multidisciplinary Team Leader

MULTIDISCIPLINARY CARE RESULTS IN SUPERIOR OUTCOMES when compared to single provider sequential care. The reason is multi-factorial due to improved patient convenience by seeing multiple specialists at once, which can also reduce financial toxicity of taking multiple days off from work or finding care for family members; accelerating treatment decisions from reducing sequential visits, patients are seen by all relevant specialties; it builds a respect between radiation oncology and the other specialists and keeps the focus centered on the patient. I believe that in an optimal care delivery system it would be patient and disease-type centered, rather than department centered.

Radiation oncology can and should serve as a key driver of multidisciplinary care. I was fortunate enough to have trained under Josh Yamada, MD, Brett Cox, MD, and Mark Bilsky, MD, at Memorial Sloan Kettering (MSKCC). Drs. Yamada and Cox are radiation oncologists and Dr. Bilsky is a neurosurgeon, and together they started a multidisciplinary clinic in spine oncology. During my faculty orientation at the University of Michigan, I was in line to get my ID badge, and right behind me was Nick Szerlip, MD, a neurosurgeon who serendipitously did his spine oncology fellowship at MSKCC. After a few months, we both realized there was not a true multidisciplinary spine oncology program at U-M (yet). Like 99% of centers in the United States, care delivery was segregated within the departments of radiation oncology and neurosurgery. We decided we needed to change this, and despite many naysayers that said it wouldn't work, we set out to prove them wrong.

In December 2015, we started the official University of Michigan Spine Oncology Program. It heavily leveraged radiation physics (Kelly Paradis, PhD, and Martha Matuszak, PhD), dosimetry (Paul Archer), advanced practice providers (Amyre Mitchell, NP), interventional radiology, and physical medicine and rehabilitation (PM&R). Our team established comprehensive workflows and triage for the multitude of complex spine cases and built a consensus framework for managing these patients (Spratt DE et al., Lancet Onc 2017). We were both very clear in our goal: to give the best patient care. That is how we would grow the program and grow each of our respective clinical services. It was not a turf war in any way, and from day one we committed to focusing on the patient. If the program succeeds, we succeed, and, more importantly, the patient wins. For this reason, our motto has always been that surgery for spine metastasis and cord compression is not oncologic. Almost 100% of the time, even after major spine surgeries, the cancer will recur. Surgery has real potential side effects that should be recognized. The goal of surgery, therefore, is to allow optimal high doses of radiotherapy delivered as SBRT to eradicate the disease, to stabilize the spine or provide rapid decompression. However, and very importantly, I also fully recognize what radiation can’t do: it can’t stabilize the spine, reduce mechanical pain, heal a fracture, rapidly relieve cord compression or give sufficiently high doses to tumors abutting the spinal cord without damaging the cord. We heavily rely on PM&R and interventional radiology for vertebroplasty, and these specialties are likely used more than either surgery or radiation to help our patients. We are patient centered, not department centered.

Is it possible for radiation oncology to have a driver’s seat in oncology? Absolutely. However, this takes work, time and leadership. Our spine multidisciplinary clinic began during one of my protected research days until it grew big enough to be a full-fledged program. My advice is to always focus on the patient and not on giving radiation therapy. They often may be one in the same, but at times they won't be. If referring providers know you will use your best judgement and avoid RT when appropriate, they will also listen to you when you recommend RT. Rather than trying to convince people with data, let them be part of the team and show them your results. Nothing is more powerful than a patient’s voice.

Daniel Spratt, MD, is a professor of radiation oncology, a Laurie Snow Endowed Professor and associate chair of clinical research at the University of Michigan.
RADIATION ONCOLOGISTS (ROS) ARE UNIQUE in the multidisciplinary field of oncology. We are highly trained clinicians, and, in many disease sites, we provide the primary treatment modality leading to long-term cures. We have the honor and privilege of taking care of people at a time in their lives that often can be extremely difficult for not only the patient but their entire family.

Our field has led improvements in survival in multiple malignancies, and with the advent of aggressive treatment of oligometastatic disease and the emergence of radiopharmaceuticals, we now are expanding our role in oncology.

My own expanded role in leading a cancer center began when after nearly three decades at Northwestern, I made the difficult decision to move to Loyola to become the chair of radiation oncology. The last seven years as chair have been the most exciting and fulfilling time in my career. I realize that if you recruit and retain talented faculty and give them mentorship and opportunity, growth of the department is inevitable. We have been able to find niches that have made our department unique, including advanced brachytherapy treatments, imaging research in physics, unique combinations of cytotoxic therapies and radiation, MRI-guided therapy, intraoperative radiation and the treatment of oligometastatic disease.

The Department of Radiation Oncology at Loyola is an integral part of Loyola’s Cardinal Bernardin Cancer Center (CBCC). The CBCC has a long history of innovation and research paving the way for new therapies in hematological malignancies, solid tumors and a culture of clinical research. The CBCC has also developed its own CAR-T program and explored dendritic cell vaccines in ovarian cancer among many other achievements. In 2018, Dr. Patrick Stiff, a remarkable individual and leader in the field of hematological malignancies and bone marrow transplantation, made the decision to step back from administration. I was approached for this role with a mandate to continue Patrick’s work and make CBCC even more competitive for an NCI Comprehensive Cancer Center grant.

When I reflected on this opportunity, I thought about the role of an RO in a cancer center that includes basic, translational and clinical researchers. ROs have markedly expanded our role in oncology; we interact with all manner of clinicians and scientists and as a specialty have a strong culture of innovation and research. Expanding our role to acting as cancer center directors is a natural evolution for our profession and, I believe, a benefit for oncology in general.

When I am asked to reflect on what skills I have acquired along the way that may have led to being asked to take on this wonderful opportunity, I think of various leadership positions I have held. These opportunities helped to develop the skills necessary to run a complex matrix of departments, clinicians and researchers. In particular, being the chair of the Gynecological Cancer Intergroup (GCIG) necessitated leading a large and diverse organization to advance gynecological research worldwide. Leading by consensus, getting leaders in a position for success and enacting strategic planning are all necessary skills for a cancer center director.

The last two years in the dual role of department chair and cancer center director have been personally challenging in terms of time management and priorities, as I have continued to carry a significant clinical load. Furthermore, my perspective has changed. As a department chair, I advocated primarily for the field of radiotherapy. As a cancer center director, I now have a duty to advocate for every aspect of oncology, with a focus on innovating along the entire spectrum of cancer control, research and treatment.

I would encourage young faculty interested in cancer center leadership to establish relationships with all levels of personnel involved in administration and research to develop an understanding of the whole spectrum of cancer. Most importantly, you must think big, understand our ultimate goal is to reduce or eliminate the burden of cancer and believe that you can be the difference.

It is incredibly fulfilling and exciting to be involved in every aspect of cancer care, with the ultimate goal of reducing, if not eliminating, the human burden of this terrible disease. My mother died of rectal cancer and I promised her I would do whatever I could to cure cancer. I think about that promise every day and, as a cancer center director, I can accomplish even more to try to make that promise a reality.

William Small Jr., MD, FASTRO is director of the Cardinal Bernardin Cancer Center and chair of radiation oncology at Loyola University Medical Center.
IN A RECENT SURVEY ON THE SCOPE OF PRACTICE OF U.S. RADIATION ONCOLOGISTS, nearly everyone agreed that “ROs should be leaders in oncologic care,” but only 18.2% felt actual practice matched this ideal.

As I reflected upon this and other questions, the concept of “How can I do this better?” came to mind. Is your scope of practice where you would like it to be? What can you do to change it?

As a practicing radiation oncologist in a community hospital setting, I believe our practice is an exception. We have striven and succeeded to be leaders in oncology care at our center. We all have our mentors. I have been fortunate enough to learn from stalwarts such as Eli Glatstein, Allen Lichter, Patricia Eifel, Herman Suit, Richard Evans, Carl Mansfield, Gilbert Fletcher and Jay Harris, to name a few — who helped shape my view of leadership in oncology. Our colleagues in medical and surgical oncology frequently look to us for co-managing patients, thanks not only to their great respect for our clinical acumen, knowledge and trust in our abilities, but also because of our excellent relationship with them.

We actively lead and participate in weekly tumor boards and multidisciplinary clinics. We hold positions of leadership in the Cancer Committee and lead the hospital’s Oncology Service-line. By sub-specializing in the care of prostate and head and neck cancer patients, our colleagues in urology and ENT, respectively, are more willing to refer patients to us, knowing that exceptional care close to home is in their patients’ best interest. It’s similar in breast, lung and gynecologic patients. Through expertise, teamwork and collaboration, we elevate the care of patients as we raise the scope of our practice to reach more people, who in turn benefit from this multidisciplinary care.

Here are some of the ways we have achieved this level of engagement:

**Clinical leadership:** In addition to active involvement in multidisciplinary tumor boards and clinics, get involved in your center’s cancer committee and site-specific program leadership committee. Offer to co-lead or serve on your hospital’s palliative care team.

**Patient access and visibility:** Having nurse navigators can help patients see all the specialists involved and ensure multidisciplinary participation, in addition to timely care and a better patient experience. Eliminate barriers to care, allow easier access to care for patients and referring physicians. Organize physician-led community outreach events, educational functions and disease-specific support groups. Look for unmet needs in the patient’s journey.

**Communication:** Improve rapid communication and availability among physicians, nurses and other key staff via secure texting and shared contacts. This includes primary care physicians who reach out directly with referrals.

**Continuous Quality Improvement (CQI):** The cornerstone of the practice has to be quality of care and constantly asking yourselves: How can we do this better?

**Initiate innovative programs:** This can be oncology specific — the precision medicine tumor board — or more general ones like the Schwartz Center Rounds.

Last, but not least, celebrate your department staff often.

I have been blessed to practice medicine in a culture where patients always come first. I am humbled daily by the trust of patients and referring physicians alike and challenged to do my part to preserve the unique culture of respect and caring that exists at my institution.

Relationships are everything. If we are to elevate our specialty within the increasingly value-based U.S. health care system to touch more patients’ lives, we have to continually find answers to the question: How can we do this better?

Stephen S. Nigh, MD, is the medical director of the Oncology Service-line, at Radiation Oncology Associates, Northwest Community Hospital, Arlington Heights, Illinois.
Indication
IMFINZI® (durvalumab) 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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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 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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UNPRECEDENTED 4 YEARS MEDIAN OVERALL SURVIVAL
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47.5 MONTHS WITH IMFINZI (95% CI, 38.4–52.6)1

VS 29.1 MONTHS WITH PLACEBO (95% CI, 22.1–35.1)1

Primary analysis at 2 years: Median OS not reached
vs 28.7 months for placebo (HR=0.68; P=0.0025)2†

Safety and tolerability

• Serious, potentially fatal risks were seen with IMFINZI; serious adverse reactions occurred in 29% of patients receiving IMFINZI and 23% receiving placebo3
• The most frequent serious adverse reactions (≥2%) with IMFINZI were pneumonitis or radiation pneumonitis (7%) and pneumonia (6%). Fatal pneumonitis was <2% and was similar across arms2
• The most common adverse reactions (≥20%) with IMFINZI were cough, fatigue, pneumonitis or radiation pneumonitis, upper respiratory tract infections, dyspnea, and rash2
• Discontinuation rates due to adverse events (regardless of causality) were 15% in patients receiving IMFINZI and 10% in patients receiving placebo3

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NSCLC=non-small cell lung cancer; CI=confidence interval; OS=overall survival; HR=hazard ratio; CRT=chemoradiotherapy; WHO=World Health Organization; PFS=progression-free survival; RECIST=Response Evaluation Criteria in Solid Tumors; BICR=blinded independent central review; NR=not reached.

Study Design: The PACIFIC study was a large, Phase III, randomized, double-blind, placebo-controlled, international study of 713 patients with unresectable Stage III NSCLC who had not progressed following concurrent, platinum-based CRT. Patients had completed at least 2 cycles of concurrent CRT within 42 days prior to initiation of the study drug and had a WHO performance status of 0 or 1. Randomization at enrollment was stratified according to age, sex, and smoking history. Patients were randomized 2:1 to receive 10 mg/kg IMFINZI or placebo every 2 weeks for up to 26 doses (12 months) or until unacceptable toxicity or confirmed disease progression. Coprimary endpoints were PFS (measured based on RECIST v1.1 criteria by BICR) and OS.2,3

*The post-hoc 4-year OS analysis was conducted at ~4 years after last patient was randomized and was not powered to show statistical significance. Reduction in the risk of death vs placebo was 29% (HR=0.71; 95% CI, 0.57-0.88). OS rates with IMFINZI vs placebo were: 83% (95% CI, 79.4-86.2) vs 75% (95% CI, 68.5-79.7) at 12 months, 66% (95% CI, 61.8-70.4) vs 55% (95% CI, 48.6-61.4) at 24 months, 57% (95% CI, 52.3-61.4) vs 44% (95% CI, 37.0-49.9) at 36 months, and 50% vs 36% at 48 months.1,4

†The primary 2-year OS analysis was conducted after 299 deaths for 42% maturity (61% of targeted events) with a median follow-up of 25.2 months. Reduction in the risk of death vs placebo was 32% (95% CI, 0.53-0.87). Median OS was NR with IMFINZI (95% CI, 34.7-NR) vs 28.7 months with placebo (95% CI, 22.9-NR).1,5

Please see additional Select Safety Information and Brief Summary of complete Prescribing Information on adjacent pages.
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.

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 2.0% (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 1.0% (19/1889) of patients receiving IMFINZI, including fatal (<0.1%) and Grade 3 (0.6%) adverse reactions.

Immune-Mediated Endocrinopaties
- **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 reactions. 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.
Immune-Mediated Endocrinopathies

Adverse reactions.

Mediated colitis occurred in 1.6% (31/1889) of patients in infectious workup to exclude alternative etiologies. Immune-of corticosteroid-refractory colitis, consider repeating IMFINZI can cause immune-mediated colitis that is in patients who received IMFINZI as a single agent or with receive definitive chemoradiation prior to IMFINZI were similar and 13.2% (31/234) in patients receiving placebo. Of the 79 pneumonitis (including radiation pneumonitis) in patients with (0.1%), and Grade 3-4 (0.4%) adverse reactions. In patients mediated pneumonitis was 2.0% (28/1414), including fatal received prior thoracic radiation. In patients who did not IMFINZI can cause immune-mediated pneumonitis. The improvement to Grade 1 or less, initiate corticosteroid taper and equivalent) until improvement to Grade 1 or less. Upon corticosteroid therapy (1 mg to 2 mg/kg/day prednisone or withhold or permanently speciality consultation as appropriate. Withhold or permanently suspected immune-mediated adverse reactions, initiate Immune-Mediated Dermatology Reactions

Exfoliative dermatitis, including Stevens Johnson Syndrome Adrenal Insufficiency:

Adrenal insufficiency, initiate symptomatic treatment, secondary adrenal insufficiency. For Grade 2 or higher include blindness can occur. If uveitis occurs in combination Type 1 Diabetes Mellitus, which can present with toxicity can occur. Some cases can be associated with Meningitis, encephalitis, myelitis and Cardiac/vascular:

Breastfeeding

Lactation

BREASTFEEDING MALES: Advise breastfeeding mothers to withhold IMFINZI from the infant for at least 3 months after the last dose of IMFINZI. breastfeed during treatment and for at least 3 months after the last dose.

Select Safety Information (continued)

• 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.

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.

DOSEAGE AND ADMINISTRATION
Recommended Dose
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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended IMFINZI dosage</th>
<th>Duration of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>Until disease progression, unacceptable toxicity, or a maximum of 12 months</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Severity</th>
<th>Dosage Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune-Mediated Adverse Reactions [see Warnings and Precautions (5.1) in the full Prescribing Information]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonitis</td>
<td>Grade 2</td>
<td>Withhold2</td>
</tr>
<tr>
<td></td>
<td>Grade 3 or 4</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td></td>
<td>Grade 5</td>
<td>Withhold2</td>
</tr>
<tr>
<td></td>
<td>Grade 4</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Colitis</td>
<td>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 the ULN</td>
<td>Withhold2</td>
</tr>
<tr>
<td></td>
<td>ALT or AST increases to more than 8 times ULN or total bilirubin increases to more than 3 times the ULN</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Hepatitis with no tumor involvement of the liver</td>
<td>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</td>
<td>Withhold2</td>
</tr>
<tr>
<td></td>
<td>AST or ALT is more than 3 and up to 5 times ULN at baseline and increases to more than 5 and up to 10 times ULN</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td></td>
<td>AST or ALT increases to more than 10 times ULN or total bilirubin increases to more than 3 times ULN</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Endocrinopathies</td>
<td>Grade 3 or 4</td>
<td>Withhold until clinically stable or permanently discontinue depending on severity</td>
</tr>
<tr>
<td>Nephritis with Renal Dysfunction</td>
<td>Grade 2 or 3 increased blood creatinine</td>
<td>Withhold2</td>
</tr>
<tr>
<td></td>
<td>Grade 4 increased blood creatinine</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Exudative Dermatologic Conditions</td>
<td>Suspected SJS, TEN, or DRESS</td>
<td>Withhold2</td>
</tr>
<tr>
<td></td>
<td>Confirmed SJS, TEN, or DRESS</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Myocarditis</td>
<td>Grade 2, 3, or 4</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Neurological Toxicities</td>
<td>Grade 2</td>
<td>Withhold2</td>
</tr>
<tr>
<td></td>
<td>Grade 3 or 4</td>
<td>Permanently discontinue</td>
</tr>
</tbody>
</table>

Other Adverse Reactions

| Infusion-related reactions [see Warnings and Precautions (3.2) in the full Prescribing Information] | Grade 1 or 2 | Interrupt or slow the rate of infusion |
| Grade 3 or 4 | Permanently discontinue |

Explanation:

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 Resumed 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 hepatic toxicity without 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.
- Remove 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-1 ligand (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 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 2.0% (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 12.3% (31/254) in patients receiving placebo. Of the 79 patients who received IMFINZI, 1.1% were fatal and 2.5% were Grade 3-4 adverse events. Events resolved in 33 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 chemoradiation 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 1.0% (19/1889) of patients receiving IMFINZI, including fatal (0.1%) and Grade 3 (0.8%) adverse reactions. Events resolved in 3 of 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 (0.1%) required use of mycophenolate with high-dose steroids.

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 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].

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].

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].

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].

Permanently discontinue IMFINZI based on the severity [see Dosage and Administration (2.2) in the full Prescribing Information]. For Grade 2 or 3 immune-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 (HVHD), 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 blocking antibody prior to or after an allogeneic HSCT.

Emirbo-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 maternal 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, 8.2) 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 191 patients with urothelial carcinoma and 779 patients with other solid tumors), and additional open-label, single-arm study 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 16% were exposed for 12 months or more. The data also reflects exposure to IMFINZI in combination with chemotherapy in 265 patients from the CAPSIN study (a randomized, open-label study in patients with SS-SCCL). In the CAPSIN 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 phase 3 randomized, double-blind, placebo-controlled study. A total of 742 patients received IMFINZI 10 mg/kg intravenously every 2 weeks. The study excluded patients who had diabetes 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 pneumonia or radiographic pneumonia 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 pneumonia or radiographic pneumonia (7%) and pneumonia (6%). Fatal pneumonitis or radiographic pneumonitis and fatal pneumonia occurred in 1% and 0.2% 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 5 summarizes the adverse reactions that occurred in at least 10% of patients treated with IMFINZI.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>IMFINZI</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 475</td>
<td>N = 234</td>
<td></td>
</tr>
<tr>
<td>All Grades (%)</td>
<td>All Grades (%)</td>
<td></td>
</tr>
<tr>
<td>Respiratory, Thoracic, and Mediastinal Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough/Pleural Fluid 40</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Pulmonary Radiation Pneumonitis 34</td>
<td>3.4</td>
<td></td>
</tr>
<tr>
<td>N = 19</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea 19</td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain* 10</td>
<td>6.0</td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Adverse Reactions Occurring in > 10% Patients in the PACIFIC Study
Complications of Allogeneic HSCT:

- Infusion-Related Reactions:
  - Hypersensitivity reactions (including anaphylaxis)
  - Hypertension
  - Palpitations

- Complications of Autologous HSCT:
  - Nausea
  - Vomiting
  - Diarrhea
  - Abdominal pain
  - Rheumatoid arthritis

Other Immune-Mediated Reactions:

- Dermatological Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of dermatomyositis, severe dermatitis, or worsening of pre-existing dermatological conditions.

- Endocrinopathies: Advise patients to contact their healthcare provider immediately for signs or symptoms of hypothyroidism, hyperthyroidism, adrenal insufficiency, type 1 diabetes mellitus, or hyperparathyroidism.

- Neurological Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of neuropathy, myelopathy, or peripheral neuropathy.

- Ocular Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of retinopathy, uveitis, keratitis, or myasthenia gravis.

- Renal Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of nephrotic syndrome, nephrotoxicity, or acute kidney injury.

- Cardiovascular Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of myocarditis, pericarditis, or myocardial infarction.

- Gastrointestinal Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of colitis, enterocolitis, or inflammatory bowel disease.

- Hematological Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of anemia, thrombocytopenia, or neutropenia.

- Other Immune-Mediated Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of systemic lupus erythematosus, polyarteritis nodosa, or other immune-mediated conditions.

Inclusion-Related Reactions:

- Patients with a known or suspected pregnancy should be informed of the potential risks to the fetus and should be advised to avoid pregnancy during treatment with IMFINZI.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of pregnancy-related complications, such as pre-eclampsia, preeclampsia, gestational diabetes, or other pregnancy-related conditions.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of miscarriage, premature labor, or other complications of pregnancy.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of postpartum hemorrhage, retained placenta, or other complications of delivery.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of neonatal complications, such as respiratory distress syndrome, congenital anomalies, or other complications of newborn care.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of neonatal death or other complications of neonatal care.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of congenital anomalies, such as congenital heart defects, neural tube defects, or other congenital anomalies.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of birth defects, such as cleft palate, cleft lip, or other birth defects.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of premature birth, stillbirth, or other complications of pregnancy.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal distress, such as oligohydramnios, polyhydramnios, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal anomalies, such as major congenital anomalies, multiple congenital anomalies, or other congenital anomalies.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal demise, stillbirth, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal infections, such as intrauterine infection, sepsis, or other complications of fetal infection.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal death, stillbirth, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal anomalies, such as neural tube defects, limb defects, or other congenital anomalies.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal distress, such as oligohydramnios, polyhydramnios, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal anomalies, such as congenital heart defects, neural tube defects, or other congenital anomalies.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal demise, stillbirth, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal infections, such as intrauterine infection, sepsis, or other complications of fetal infection.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal death, stillbirth, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal anomalies, such as neural tube defects, limb defects, or other congenital anomalies.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal distress, such as oligohydramnios, polyhydramnios, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal anomalies, such as congenital heart defects, neural tube defects, or other congenital anomalies.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal demise, stillbirth, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal infections, such as intrauterine infection, sepsis, or other complications of fetal infection.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal death, stillbirth, or other complications of fetal status.

- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal anomalies, such as neural tube defects, limb defects, or other congenital anomalies.

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- Advise patients to contact their healthcare provider immediately for signs or symptoms of fetal anomalies, such as neural tube defects, limb defects, or other congenital anomalies.
Regarding Residency: Perspectives from a Program Director

BY EMMA FIELDS, MD, PRESIDENT OF THE ASSOCIATION FOR DIRECTORS OF RADIATION ONCOLOGY PROGRAMS

THE ASTRO SCOPE OF PRACTICE SURVEY¹ SHOWED that radiation oncologists, particularly those earlier in their careers, were interested in expanding their scope of practice to include radiopharmaceuticals, palliative care, systemic therapies and running an inpatient service. From my perspective as a program director, there are certainly improvements to be made in the training of our residents to make them leaders in oncology. There is also a lot of work to be done to promote our specialty and continue to recruit excellent medical students to our programs. However, I am not convinced that the results of this survey will direct the future of residency training. For a start, not all of these areas are truly expansions of our scope. Additionally, I do not think that any or all of these expansions of scope would affect recruitment. More importantly, residency training should include learning about teamwork, emotional intelligence and leadership skills, so that wherever a trainee’s career takes them, they will be prepared.

In the survey, about a fifth of providers were interested in expanding their scope of practice. However, many RO providers already offer these services based on demand at their site and availability of providers who may more regularly supply those services. In my practice, and in the survey results, the major barrier to expanding scope is not education but political infeasibility. The use of radiopharmaceuticals is not new to RO, as residents are required by the ACGME to complete cases of unsealed sources for graduation. In accordance with the scope of practice survey, ACGME recently increased the number of cases required for graduation from six to eight, and ASTRO has released several training courses. Residents should certainly feel comfortable using radiopharmaceuticals, and this is a good expansion of practice, as these treatments fit well in many RO clinics.

However, I think providers have to be careful what they wish for with expansion of scope in some areas, such as running an inpatient service. Residency training is very compressed as is and includes apprentice-based clinical training, radiation biology, physics, clinical education, keeping up with evolving technology and performing research, etc. Even if it may seem like a good idea to have an inpatient service, this would generally be a deterrent to many trainees and faculty alike who have not practiced general medicine for years. From a training perspective, having an inpatient service would add a great deal of instruction time and resources. It would be the death of small programs and put average sized programs in jeopardy, as they would lack the faculty to devote to the increased teaching demand while maintaining a thriving practice. The benefit of radiation oncology, in addition to long and caring patient relationships, multidisciplinary care, use of technology, research and more, remains the favorable lifestyle of having outpatient clinic hours.

In my opinion, the major issue with attracting residents into our field is not our scope of practice. We are now in our third year of a downtrend in number of applications to radiation oncology programs. This is multi-factorial but largely related to bad publicity about our specialty on highly trafficked public forums for medical students.² Many of the potential RO applicants’ concerns are based on the job market, board passing rates and residency expansion, as highlighted in a paper by ARRO, published in the Red Journal.³ To combat this, we need to get into medical schools, both in the classroom and clinic, to increase exposure to RO and foster mentorship.⁴ Within our society, we should look at residency expansion and ensure we are training appropriate numbers of quality residents and not just adding bodies to help with clinical service.

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Should We Expand the Scope of Practice? A Resident’s Perspective
BY ELIZABETH B. JEANS, MED, MD, VICE-CHAIR, ASSOCIATION OF RESIDENTS IN RADIATION ONCOLOGY (ARRO)

IN THE ARTICLE BY FUNG ET AL., practicing radiation oncologists were queried about their interest in expanding their current scope of practice. The surveyed cohort comprised a wide variety of practicing radiation oncologists consisting of private practitioners and academicians trained over many decades and practicing across a variety of locations. Variability was seen in current practice patterns in regard to the delivery of radiopharmaceuticals/theranostics, anticancer therapies and additional patient care measures, including a dedicated inpatient service and the ability to prescribe medical marijuana. While the authors note the independence of radiation oncology from diagnostic radiology over several decades, they also note the continued need for radiation oncology to determine its place in being leaders in oncologic care, an important sentiment by nearly all survey respondents (>95%).

The inquiry into scope of practice highlights the interconnectedness in cancer care, which has substantially progressed over the past several years. As novel therapeutic strategies emerge, the role of a practicing radiation oncologist becomes more complex, as one must have a wide breadth of knowledge to provide adequate counseling and delivery of care to patients. Determining the interest in untangling the modern-day scope of practice for a practicing radiation oncologist is important; however, the ultimate decision to support the expansion of the current practice should be tempered by determining its importance in the educational milieu and the ability to effectively educate trainees.

A survey administered by the Association of Residents in Radiation Oncology (ARRO) in 2019 highlighted top concerns of trainees within the field of radiation oncology. Of greatest concern were board examinations and the current state of graduate medical education. Seventy-eight percent agreed that a lack of clarity in importance of educational topics, accompanied by lack of transparency in board examination, could be clarified by the development and maintenance of a comprehensive radiation oncology curriculum. A call was made for ASTRO to develop a subcommittee of graduate medical education to improve the educational practice and provide clarity and focus within resident training and assessment.

Similarly, an additional editorial published in 2020 by educational expert and practicing radiation oncologist Daniel Golden, MD, MHPE, highlighted that continued training and development of residents without a United States radiation oncology curriculum has left both educators and residents with a lack of focus in what content to teach. The lack of clarity provided by any stakeholder organization has led to a paradigm of “the tail wagging the dog,” a scenario in which residents and educators use examinations to determine importance of content.

Inherent to both these publications is the element that expansion of radiation oncology foci in the past several decades (clinical, radiation and cancer biology, and medical physics) without a correlative consensus on importance has set back trainees and educators. The breadth of knowledge required of trainees in the modern era is so vast that failure to develop a radiation oncology curriculum through deliberative educational curricular techniques has led to pages of accumulating topics provided to educators and trainees. The current process of training and assessing radiation oncology residents is faulted without a comprehensive top-down radiation oncology curriculum. Currently, the Radiation Oncology Educational Collaborative Study Group (ROECSG) has initiated a deliberative inquiry into a radiation oncology specific core curriculum.

Illustrated in the scope of practice survey, trainees in the modern era, represented by recent graduates, are excited to acquire new knowledge and further develop their skillsets to be a comprehensive resource for their patients. However, it is necessary to survey radiation oncology trainees to understand the current exposure of training that residents have in these areas of potential expansion. Failure to assess the current level of exposure as well as current content-specific resident education in these areas would further the education problem in residency learning and assessment. A clear understanding of the current exposure, the availability of programs to provide dedicated learning, and deliberative inquiry into how these topics would fit into a comprehensive radiation oncology curriculum is needed. It is crucial that the expanded training topics be weighed against the other important aspects of training prior to expanding the scope of practice.
As trainees, we aim to be at the forefront of practice and seek to find the void in treatment strategies, culminating in the development of further cancer-specific therapies. Our hope is to provide patients with the best care, and doing so requires the comprehension of multiple different subjects. However, with the current training paradigm, expanding any further into additional fields of practice would fail without an adequate educational development plan alongside a dedicated deliberative inquiry into how said topics fit into the greater radiation oncology curriculum.

Elizabeth B. Jeans, MEd, MD, is a radiation oncology resident at the Mayo Clinic Rochester, Minnesota, and serves on the Executive Committee of ARRO.

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Within residency programs, we must train our residents so that they are prepared to lead programs, develop new initiatives and feel confident taking on new challenges, no matter what our scope of practice entails. There is a hidden curriculum, in which residents learn by observing their mentors in the field. We need to be cognizant of this and ensure that we are modeling collegiality, leadership and good interprofessional dynamics. As stated in the discussion of the study, the goal should be to “promote a culture of meaningful multidisciplinary teamwork” and to “collaborate with mutual respect and ... share the common goal of consistently upholding the patient’s best interest.” Along these lines, the Radiation Oncology Education Collaborative Study Group (ROECSG) is developing a curricular framework with Entrustable Professional Activities to give trainees and faculty a standardized tool for resident assessment on the necessary skills for independent practice.

The scope of practice article opens with a quote from the 1975 ASTRO presidential address by Dr. del Regato motivating the newly minted therapeutic radiologists by saying, “No one is as deserving of the title of oncologist as you are,” while noting that many didn’t have their own departments or recognition as a distinct specialist. Dr. del Regato concluded the speech by saying, “You have come a long way, indeed! ... but it behooves you to anticipate new pitfalls that might be awaiting you.” Now, in 2020, we have certainly come a long way! While we may have more pitfalls ahead, by ensuring we promote ourselves accurately, provide mentorship at all stages along the path and recruit and train future leaders, I think we will have a thriving future.

Emma Fields, MD, is an associate professor and residency program director of radiation oncology at Virginia Commonwealth University in Richmond, Virginia, and serves as president of ADROP.

References

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THE SCOPE OF PRACTICE DESCRIBES THE PROCEDURES allowed by hospitals and clinics and are based on residency training, competency and experience. In the U.S., cancer care is provided by specialists in surgical, medical and radiation oncology. The practice of U.S. radiation oncologists is largely limited to independent opinion within the radiotherapy scope, including planning radiotherapy, supervision of radiation delivery, management of side effects from radiotherapy and post-radiotherapy follow-up.

A recent ASTRO scope of practice study showed that 82.5% of participating radiation oncologists felt that the ideal approach to patient care was to provide an independent opinion on radiation therapy and other treatment options. Over 16% (16.1) felt that an independent opinion on radiation therapy but not outside of it would be the ideal approach. However, the vast majority of radiation oncologists felt that they should be leaders in oncology care. In reality, actual practice fully matched the ideal approach in only 18.2% of respondents. Most radiation oncologists in the U.S. do not administer systemic therapy, admit inpatients or serve as a primary care physician. Only a minority of radiation oncologists in the U.S. administer radioactive isotopes for treatment, which is usually handled by a nuclear medicine physician.

Radiation oncology training varies across the globe, and in some countries, radiation oncologists are trained in administration of systemic therapy and they regularly manage inpatient admitted for oncology care. Furthermore, in some countries, radiation oncologists routinely administer radionuclide therapy.

BY SIMON S. LO, MB, CHB, FASTRO, AND SUSHIL BERIWAL, MD, MBA, FASTRO

Is it time for us to look at best practices for training across the globe and revisit radiation oncology training to increase scope of practice? The enhanced training may give radiation oncologists wider access and a role in management of cancers. The areas to explore would be the administration of concurrent chemotherapy, immunotherapy and targeted therapy with radiation therapy and being involved in decisions on and the administration of radionuclides. This may be important as the field of radiopharmaceuticals is advancing, such as the use of $^{177}$Lu-PSMA-based radioligand therapy for prostate cancer. These changes would require significant changes in residency structure but may be important for our role in oncology care in the future. To provide a broader perspective, this article will review the scope of practice of radiation in some countries across the globe.

Canada, United Kingdom (UK), Australia and New Zealand

Medical training in Canada bears the closest resemblance to that in the U.S. As such, medical schools in Canada are not regarded as foreign medical schools, as they are also accredited by the Association of American Medical Colleges (AAMC). Training in radiation oncology in Canada is under the governance of The Royal College of Physicians of Canada and is recognized by the American Board of Radiology for the purpose of board certification. Based on information obtained from radiation oncologists from major academic centers in Ontario and British Columbia, radiation oncologists admit their own inpatients.
also prescribe and manage iodine-131, radium-223, strontium-89, and lutetium-177 at some sites, although nuclear medicine does the ordering and administration of the isotopes. However, radiation oncologists only administer hormones, not chemotherapy, targeted therapy or immunotherapy.

In the UK, despite that The Royal College of Radiologists (RCR) governs the training, doctors who pass the fellowship examination and fulfill the post-fellowship requirements are called clinical oncologists, as both the training and examination cover both radiation and medical oncology. In other words, clinical oncologists admit their own inpatients and are responsible for making recommendations on and administering radiotherapy and hormonal therapy, chemotherapy, targeted therapy and immunotherapy. Furthermore, they also make recommendations on and are responsible for the administration of radioactive iodine in certain specialist centers.

In Australia and New Zealand, training and board certification in radiation oncology are governed by The Royal Australian and New Zealand College of Radiologists (RANZCR). Practice varies regionally, but radiation oncologists typically admit their inpatients. Australian radiation oncologists do not administer any systemic therapy. Radiopharmaceuticals are administered only in specialized centers that have rooms to give treatments.

In New Zealand, the majority of radiation oncologists prescribe androgen deprivation therapy for prostate cancer, and some prescribe abiraterone as well. For breast cancer, some of them prescribe hormonal therapy, and a majority of them also prescribe temozolomide for central nervous system tumors. They admit their inpatients to manage the side effects of treatment and for those needing inpatient radiotherapy. New Zealand radiation oncologists prescribe radioisotopes, including iodine-131, but this can overlap with the endocrinologist.

Continental Europe: Switzerland, Germany, The Netherlands, Italy, Denmark and Turkey

Training in radiation oncology in Switzerland includes radiation and medical oncology. As a result, radiation oncologists typically administer hormonal therapy, whereas the administration of chemotherapy, targeted therapy and immunotherapy is variable across centers. Whether radiation oncologists admit inpatients is institution dependent. They do not administer radiopharmaceuticals.

In Germany, radiation oncologists administer and supervise all systemic therapy, especially concurrent with radiotherapy, and they admit inpatients. They do not administer radiopharmaceuticals. Interestingly, some radiation oncologists assume the role of primary care doctors.

The scope of practice in the Netherlands is very similar to that in the U.S. in that radiation oncologists do not administer systemic therapy, admit inpatients (except for large centers with a large pulse dose rate practice and their own wards) or administer radiopharmaceuticals.

Radiation oncology training in Italy also includes medical oncology. Radiation oncologists typically administer hormones, whereas the administration of chemotherapy, targeted therapy and immunotherapy is variable across centers, generally limited to larger academic institutions and in the context of concurrent combinations. Inpatient radiation oncology service is again hospital dependent. Radiation oncologists are trained in administration of radiopharmaceuticals, but they are not always given by radiation oncologists.

Like in the UK, Danish oncologists are educated in both radiation and medical oncology, and medical license covers both medical and radiation oncology. A majority of oncologists practice both radiation and medical oncology, whereas a minority practice mainly radiation oncology, although they manage concurrent chemotherapy. Oncology centers in Denmark have their own hospital wards and can admit radiotherapy patients to their ward if needed. Radioisotopes are administered in collaboration with specialists in nuclear medicine. There are some differences across Denmark, but in general the oncologist prescribes and the nuclear medicine specialist handles the preparation and infusion. Generally, they serve as primary care doctors depending on the tumor type.

Radiation oncologists in Turkey have medical oncology/hematological oncology/internal medicine rotations for a total duration of one year in their five-year residency program and were exclusively prescribing chemotherapy previously in the era of limited number of medical oncologists. Currently, Turkish radiation oncologists have the license to administer chemotherapy in the setting of concurrent chemoradiotherapy as well as first line hormonal therapy (except second generation) when required. They also admit inpatients. Although they are given permission to administer radiopharmaceuticals, it is generally performed by nuclear medicine doctors. Interestingly, they also serve as primary care doctors.

Continued on the following page
**East Asia: Japan, Taiwan, Hong Kong and Singapore**

Japanese radiation oncologists provide medical oncology care in a limited capacity, in that they administer only chemotherapy, immunotherapy and targeted therapy for limited disease sites. They also admit their inpatients and administer radiopharmaceuticals to cancer patients. One unique aspect in the scope of practice in Japan is that most radiation oncologists also assume the role of medical physicists dealing with the technical aspects of radiotherapy, particularly dose planning and optimization.

In Taiwan, only a minority of radiation oncologists administer systemic therapy. Likewise, a minority of them admit inpatients or assume the role of primary care doctors, respectively. They do not administer radiopharmaceuticals.

Hong Kong is a former British colony and as a result, the practice of radiation oncology is influenced by the British system. In Hong Kong, radiation oncologists are clinical oncologists who pass the conjoint fellowship examination of Royal College of Radiologists and Hong Kong College of Radiologists, fulfill post-fellowship requirements and subsequently pass a final exit examination. As the training encompasses radiation and medical oncology, clinical oncologists in Hong Kong handle all non-surgical oncology care, including radiopharmaceuticals, as in the UK.

Although Singapore was also a British colony, the scope of practice is different from that in the UK. The training either follows the RCR or the RANZCR stream, depending on the site of training. Radiation oncologists (if certified by RANZCR) or clinical oncologists (if certified by RCR) do not administer any systemic therapy except hormones, and they do not admit inpatients or administer radiopharmaceuticals.

**Brazil**

In Brazil, radiation oncologists do not administer systemic therapy or radiopharmaceuticals. However, in some regions they are responsible for adverse effect management during combined radical treatment. The majority of radiation oncologists do not admit inpatients. There are also some radiation oncologists who serve as primary care doctors.

**India and Sub-Sahara Africa**

Apart from practicing radiation oncology, Indian radiation oncologists also administer systemic therapy and admit their own inpatients. However, they do not administer radiopharmaceuticals.

Similar to radiation oncologists in India, radiation oncologists in Sub-Sahara Africa administer systemic therapy and admit their own inpatients. However, they do not administer radiopharmaceuticals. They assume the role of primary care doctors for their patients.

It is enlightening to look at best practices and how they evolved across the globe with an eye to the future. Now is the time for us to pick up best training and practices from across the world and revisit our residency training structure. These changes will require significant but necessary changes in residency structure, but they may help us expand scope of practices and be leaders in oncology care.

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Radiopharmaceutical Therapy: A New Frontier for Radiation Oncologists

BY SUSAN KNOX, MD, PHD

RADIOPHARMACEUTICAL THERAPY (RPT) is a form of systemically targeted radiation delivered by radionuclides either unconjugated (e.g., Ra-223) or linked to carriers (e.g., peptides, antibodies or microspheres) that bind specifically to tumors or accumulate in tumors. Many are now approved, with others at various stages of development for the treatment of a variety of tumor types. Treatment of patients with metastatic castration resistant prostate cancer (mCRPC) with Lu-177 Prostate Specific Membrane Antigen (PSMA) agents is very promising, with Lu-177-PSMA-617 showing efficacy and tolerability in a phase II study. Results from a randomized phase III study of Lu-177-PSMA-617, VISION trial (NCT03511664) are eagerly anticipated and may result in FDA approval of this agent in the relatively near future. This will be an important new addition to the treatment armamentarium for mCRPC.

Radiation oncologists are well positioned to not only administer this therapy but to take a leadership role in the development of similar therapies. Involvement in a scientific role beyond just being authorized users of RPT could be transformative to our specialty. Radiation oncologists played an important role in the development of radioimmunotherapy, and some practices administer free radionuclide therapies such as I-131 and other forms of RPT. As a field, we have expertise in radiobiology, radiation effects on tumors and normal tissues, management of radiation-associated toxicities and dosimetry.

The growth of RPT requires an interdisciplinary approach and collaboration and is an opportunity for radiation oncologists to expand practice and further develop this important new service line. We are ideally suited to treat, follow and care for patients treated with RPT and have referral pathways to both oncologic specialists and supportive care providers.

Our understanding of individualized dosimetry and close collaboration with medical physics will facilitate optimization of the therapeutic index for RPTs, with delivery of targeted high dose radiation to tumors with maximal sparing of normal tissues. ASTRO and other organizations will be providing training to facilitate this expanded scope of practice for many radiation oncologists. This is a tremendous opportunity for our field and an exciting new therapy to be able to offer to our patients. We need to “get in the game.”

Susan Knox, MD, PhD, is associate professor of radiation oncology, emerita, at Stanford University.

Radiopharmaceuticals: Radiation Therapy Enters the Molecular Age

BY CHARLES A. KUNOS, MD, PHD

IN THE PERSONALIZED MEDICINE ERA, the National Cancer Institute (NCI) Division of Cancer Treatment and Diagnosis (DCTD) Cancer Therapy Evaluation Program (CTEP) has reconsidered its development strategies for radiopharmaceuticals. Over the past three years, this reconsideration promotes a shift away from external beam radiotherapy to a more modern use of targeted radiopharmaceuticals alone or in combination with biologically disruptive anticancer drugs. Issues that undercut the usual approaches to the development sequence are scarce patient, financial or professional resources; complex clinical trial objectives; and a belief that tolerable investigational agent toxicity brings about treatment efficacy. In an effort to overcome such barriers, the development sequence for targeted radiopharmaceuticals at NCI DCTD CTEP engages innovative phase 0 or 1 biomarker-driven trial designs recruiting smaller patient numbers, simpler...
safety and pharmacodynamic research objectives and biologically effective rather than maximally tolerated radiopharmaceutical exposures.

Radiation oncologists are firmly embedded in this radiopharmaceutical development initiative. Our specialty’s footprint on clinical trial infrastructure and trial implementation marks strides taken by NCI DCTD CTEP to study “radioactive drugs.” As infrastructure evolved, NCI DCTD CTEP brought in seven portfolio agents: radium-223 dichloride (Xofigo), lutetium-177 dotatate (Lutathera), tin-117m(4+) diethylenetriaminepentaacetic acid, and four thorium-227 radioimmunotherapy conjugates.1 As clinical trials roll out, NCI DCTD CTEP intends overarching goals of optimizing the therapeutic ratio of these agents alone or in combination and of testing efficacy in other disease indications. Only 2% of the clinical trial portfolio involves radiopharmaceuticals; however, it is projected over the next five years that up to 15% of the portfolio will engage radiopharmaceuticals as primary or maintenance therapy. 

References:

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Dosimetry for Radiopharmaceutical Therapy

BY ROBERT HOBBS, PHD

RADIOPHARMACEUTICAL THERAPY (RPT) IS FAST BECOMING A MAINSTREAM MODALITY with the development and approval of new emitters and conjugates. Currently, FDA-approved RPTs are administered with fixed activities or using mass-based dosing. However, RPT presents an advantage over chemotherapy, with the ability to image the drug using PET/CT or SPECT/CT. By administering a small pre-therapeutic activity of the therapeutic itself — or of a companion diagnostic agent (the theranostic paradigm) — and imaging over multiple time points, the pharmacokinetics specific to the individual patient are obtained, and the therapeutic administered activity may be adjusted to normal organ dosimetric tolerance limits, resulting in a more effective therapy. An early RPT targeting lymphoma, 131I-ibritumomab tiuxetan (Bexxar), implemented this approach using planar imaging and a whole body absorbed dose surrogate (75 cGy) for hematotoxicity. The administered activities for the threshold absorbed dose ranged from 50–150 mCi with a few patients able to receive upwards of 250 mCi. 1,2 This variability in pharmacokinetics is representative of RPTs and demonstrates the potential impact of rational dosimetric-based treatment planning. Recently, 90Y-therasphere therapy for HCC using tumor and normal organ dosimetric thresholds (minimum and maximum, respectively) rather than whole irradiated volume absorbed dose, showed a significant benefit in patients (26.6 vs. 10.7 months median survival).3

ASTRO, AAPM, SNMMI, IAEA, ICRU and NCI are all strong advocates for personalized dosimetry-based treatment planning, which is expected to become the norm in the near future with a demand for qualified physicians and medical physicists to oversee and apply these methodologies. The exceptions remain alpha-particle therapies, for which the dosimetric methodologies are more complex and not fully mature for widespread use. Radiation oncology has a long history of dosimetry-based treatment planning experience from EBRT, with tools, techniques, personnel and infrastructure readily adaptable to RPT, all necessary to implement such approaches with the precision, quality assurance and standardization to ensure safety and efficacy of treatments. Conversely, radiation oncologists typically lack experience specific to the field of RPT. Now is the time to embrace continuing RPT education and training and to support collaboration with colleagues from nuclear medicine to implement advanced dosimetric-based RPTs.  

References:

Robert Hobbs, PhD, is an associate professor of radiation oncology and molecular radiation sciences at Johns Hopkins Medicine.
From the ABR

SCOPE OF PRACTICE, CERTIFICATION ASSESSMENT AND AN UPDATE ON QUALIFYING EXAMS

A DISCUSSION OF THE SCOPE OF RADIATION ONCOLOGY PRACTICE, as considered by others in this edition of ASTROnews and related to the ASTRO survey and its analysis by Fung et al.,\(^1\) represents an important snapshot of the specialty. In addition to the survey, and of critical importance, is the difference between the legal and regulatory definition of “scope of practice,” as promulgated by various jurisdictional legislatures and medical regulatory bodies\(^2\) and an individual’s personal interest or practice focus. While licenses to practice medicine in most U.S. jurisdictions specify either Medicine or Medicine and Surgery, legislation or regulation in those jurisdictions defines what the individual can legally do in a more granular manner. Facilities may further define an individual’s practice role by institutional privileges. In the case of radiation oncology in the U.S., the legal scope of practice is further defined by regulations of the U.S. Nuclear Regulatory Commission (NRC) and individual Agreement States.\(^3\) In defining regulatory scope of practice, these jurisdictional entities invariably look to training requirements as specified by the Accreditation Council for Graduate Medical Education (ACGME) and the assessment instruments of the 24 American Board of Medical Specialties (ABMS) member boards. Interventions not included in ACGME training requirements or ABMS member board certification instruments will typically not be included in jurisdictional scope of practice regulations. In the case of radiation oncology, the ACGME Radiation Oncology Review Committee is careful to include all areas of the specialty, whether of significant interest or individual practice focus,\(^4\) and the ABR is careful to include all these areas in its initial certification and continuous certification assessment instruments.\(^5\)

The ABR recognizes that for continuous certification, its Online Longitudinal Assessment (OLA) instrument may include topics such as radiopharmaceutical management, pediatric cancer care or specific organ disease sites that may not be of relevance to some or many candidates or diplomates. However, to support the scope of practice interests of all, these must continue to be included in assessment. In the absence of subspecialty certification in specific radiation oncology modalities, the Board uses indications of “relevance” as noted by OLA responders in developing item frequency, but absolute elimination of these items is not within our interest as a specialty given these practice considerations.

Qualifying exams update

In summer 2020, the ABR radiation oncology trustees proposed a significant change in eligibility policy for the qualifying (computer-based) exams. The Board of Governors recently approved a change to the timing requirements for eligibility to sit for the qualifying exams. In medical physics for radiation oncology and radiation and cancer biology, trainees can now sit for the exam after completing 24 months of residency, reduced from 36 months. For the clinical oncology qualifying exam, timing has been reduced to 44 months in residency, from 48, with both needing approval from the program director. These changes were enacted to provide programs with greater flexibility in didactic programming and to allow residents greater flexibility in managing personal and professional time. Because of personal and program disruptions caused by the COVID-19 pandemic, the qualifying and certifying exams will each be administered twice in 2021. This semiannual administration is anticipated only for 2021. Dates of administration and additional details of the policy changes can be found at [www.theabr.org](http://www.theabr.org).

References

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October 1, 2020

**Radiation Fractionation Schedules Published During the COVID-19 Pandemic: A Systematic Review of the Quality of Evidence and Recommendations for Future Development**
Thomson et al.

Appearing in the Red Journal’s special issue dedicated to COVID-19, this article assessed aggregate changes in the quality of the evidence supporting hypofractionated RT schedules. Based on a systematic review of published recommendations related to dose fractionation during the pandemic, 20 expert panelists assigned to 14 disease groups named and graded the highest quality of evidence schedule(s) used routinely for each condition and graded all COVID-19 recommended schedules. Many publications recommended hypofractionated schedules across numerous major disease sites in the early days of the COVID-19 pandemic, which were supported by a lower quality of evidence than the highest quality, routinely used dose fractionation schedules.

November 1, 2020

**Cardiac Irradiation Predicts Activity Decline in Patients Receiving Concurrent Chemoradiation for Locally Advanced Lung Cancer**
Paul et al.

In this study, the authors explored dosimetric predictors of activity decline in a cohort of patients who underwent continuous activity monitoring during definitive concurrent chemoradiotherapy (CRT) for locally advanced lung cancer. Forty-six patients logged their steps from one week before treatment until two weeks after treatment. The extent of cardiac irradiation is associated with the rate of physical activity decline during CRT for lung cancer.

November 15, 2020

**Urethra-sparing Stereotactic Body Radiation Therapy for Prostate Cancer: Quality Assurance of a Randomized Phase 2 Trial**
Jaccard et al.

Between 2012 and 2015, 165 patients with prostate cancer from nine centers were randomized and treated with SBRT delivered either every other day or once a week; 36.25 Gy in 5 fractions were prescribed to the prostate with \( n = 92 \) or without \( n = 73 \) inclusion of the seminal vesicles (SV), and the urethra planning-risk volume received 32.5 Gy. Patients were treated either with volumetric modulated arc therapy (VMAT; \( n = 112 \)) or with intensity-modulated radiation therapy (IMRT; \( n = 53 \)). Deviations from protocol dose constraints, planning target volume (PTV) homogeneity index, PTV Dice similarity coefficient and number of monitor units for each treatment plan were retrospectively analyzed. Protocol deviations with potential impact on tumor control or toxicity occurred in 31% of patients in this prospective clinical trial. Protocol deviations were more frequent with IMRT.

HIGHLIGHTS FROM PRACTICAL RADIATION ONCOLOGY

**Practical Safety Considerations for Integration of Magnetic Resonance Imaging in Radiation Therapy**
Hu et al.

The authors of this article note that while there is strong interest in the integration of magnetic resonance (MR) imaging into radiation therapy (RT) treatment and that there are several notable benefits, there are also many challenges that have not been fully addressed. This article provides an overview of MR safety in the RT environment. Examples of issues considered include possible effects of the magnetic field on patients and equipment, patient check-in and screening procedures, and device and equipment safety considerations. A wide variety of equipment and devices are used in RT, and many are not clearly labeled for MR, safety, which in conjunction with a lack of staff familiarity with MR, can be a hazard. The authors suggest developing an MR safety program specific for RT, collaborating with the diagnostic imaging community.

*Continued on the following page*
Articles in Press

Radiation Therapy for Rectal Cancer: Executive Summary of an ASTRO Clinical Practice Guideline
Wo et al.
This ASTRO Clinical Practice Guideline reviews the evidence and provides recommendations for the use of neoadjuvant radiation therapy (RT) in the treatment of localized rectal cancer. The guideline addresses four key questions: What are the indications for neoadjuvant RT for operable rectal cancer? What are appropriate neoadjuvant regimens for operable rectal cancer when neoadjuvant therapy is indicated? What are the appropriate indications for consideration of a nonoperative (NOM) or LE approach after definitive/preoperative chemoradiation? And what are the appropriate treatment volumes, dose constraints and techniques for patients treated with RT? This guideline is discussed on a podcast hosted by Practical Radiation Oncology Senior Editor Michael Buckstein, MD, PhD, which is available on the ASTRO Journals podcast channel and at https://www.practicalradonc.org/content/podcast.

VMAT Grid Therapy: A Widely Applicable Planning Approach
Grams et al.
This article describes a volumetric modulated arc therapy (VMAT) approach to spatially fractionated radiation therapy (SFRT), also known as grid therapy. The authors suggest that a VMAT approach to grid therapy will help with two major drawbacks in conventional grid therapy: When considering organ sparing, assisted by gantry and couch angles as well as multileaf collimators, the depth of maximum dose may not be within the tumor itself; and because of the single static field, a significant portion of exit dose may be delivered beyond the target into normal tissue. The approach described in the article uses the software and general approach of standard VMAT planning and delivery, which would make it accessible to institutions already utilizing VMAT. The authors use preferentially located high-dose regions to better treat deep targets that may be surrounded by critical structures and suggest that their approach is accessible and can be readily implemented once the technique, patient selection and delivery processes are established.

Reirradiation of High-grade Gliomas: A Retrospective Analysis of 198 Patients Based on the Charité Data Set
Kaul et al.
This article explores the treatment of high-grade gliomas with reirradiation. Currently, there is no standard of care for the treatment of gliomas, treatment remains a challenge and a majority of patients experience relapse despite the use of multimodal treatment approaches. The authors conducted a retrospective analysis of patients who were treated with reirradiation for high-grade gliomas from January 1997 to February 2014. The study concluded that while reirradiation was well tolerated even in cases of early recurrence, fewer than 8% of patients developed grade 3 or greater toxicity, and prognosis remains dismal.

Patterns of Failure After Intensity-modulated Radiation Therapy in Head and Neck Squamous Cell Carcinoma of Unknown Primary: Implication of Elective Nodal and Mucosal Dose Coverage
Kamal et al.
Metastatic head and neck squamous cell carcinoma of unknown primary disease (HN-SCCUP) is uncommon. Due to very few randomized trials, there is a lack of consensus on the treatment of the disease. This article evaluates the dosimetric and geometric based distribution of mucosal and nodal recurrences after intensity-modulated radiation therapy (IMRT) using validated typology-indicative taxonomy among a large patient cohort. The study retrospectively analyzed patients treated with curative IMRT for HN-SCCUP. It showed that most patients who developed nodal recurrences did so in the irradiated tissue, specifically in the high-dose region (type A). Future research should focus on novel radiosensitizers, dose escalation of high-risk volumes and metabolic-directed tumor segmentation.

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