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Moderator: Dr. Olatokunbo Awodele and Dr. Juan Schaening-Perez
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Coordinator: Thank you for standing by. Your lines have been placed in a listen-only mode for today's presentation. The call is being recorded. If you have any objections, you may disconnect at this time. I will now turn the call over to your conference host, Dr. Ola Awodele. You may begin.

Olatokunbo Awodele: Thank you very much. Good afternoon, everyone. I hope everyone is well. My name is Dr. Olatokunbo Awodele. I'm one of the contractor medical directors with NGS, and I'm co-hosting today's multi-jurisdictional CAC meeting on superficial radiation therapy for the treatment of non-melanoma skin cancer alongside my colleague, Dr. Juan Schaening Perez. Thank you all for joining us today.

Juan Schaening Perez: Good afternoon, everyone. We appreciate your presence and participation. Just a quick reminder, this call is being recorded and transcribed to ensure we capture every detail of our discussion today. This is Dr. Schaening, and I will pass it now to Dr. Awodele.

Olatokunbo Awodele: Okay. So, as mentioned today, we also have representation from several Medicare administrative contractors. So, we have Noridian Healthcare Solutions, we have CGS Administrators, we have National Government

Services, as I said, that I represent. We have Palmetto GBA, and we have WPS Government Health Administrators.

I'm going to give a quick agenda for our meeting today. We have the welcoming remarks, which we just did. We're going to discuss evidence and key questions categorized into groups based on questions and led by contractor medical directors and subject-matter experts.

All of our subject-matter experts who have volunteered for today's CAC meeting, which we're very appreciative of, have been divided into three groups with each important specialty represented within that group and have been assigned questions that they should study, and be ready to discuss - come prepared, ready to discuss.

There's going to be a one-minute closing statement from each subject-matter expert at the end, and then concluding remarks to summarize our discussion. This is going to be a very tight meeting because we have a lot to discuss.

Juan Schaening Perez: So, thank you, Dr. Awodele. So, our esteemed subject-matter experts contributing today are Dr. Dole Baker, Dr. Bhisham Chera, Dr. Paul Chuba, Dr. George Hruza, Dr. Daniel Ladd, Dr. John Lukens, Dr. Joshua Mammen, Dr. William Posten, Dr. Donna Powell, Dr. Howard Rogers, Dr. Jacob Scott, and Medical Physicist Gerald White. Dr. Awodele?

Olatokunbo Awodele: Thank you. Thanks, Juan. So, even though everybody has been divided into groups and assigned questions, we are going to go at this in order of questions. So, I just wanted our group members to be aware that we're going to start with question one, the next question after question one is going to be question two, so it's not going to be the first group. So, we're going to be popping like that from group to group. So, let's get started. Let's begin.

The first one, you know, we have two minutes to respond to each of the questions, and the first question would be to the group that is Dr. Lukens, Dr. Hruza, Dr. Chera, and Dr. Scott. According to NCCN Guidelines, surgical excision with margins and/or Mohs is considered first-line therapy for patients with high-risk BCCA and high-risk and very high-risk SCCA. Is there sufficient evidence to support that superficial radiation therapy is equivalent for non-surgical candidates? Dr. Lukens, do you mind starting us off?

John Lukens: Yes. Hi. So, I assume that 1A here is referring to patients with high-risk basal cell and/or high-risk - very high-risk cutaneous squamous cell carcinoma. And in my opinion, for this patient population, there's not sufficient high-quality data to support the use of superficial radiation therapy for high-risk basal cells or squamous cell carcinoma, given the shallow depth penetration.

And in fact, I think one would expect lower rates of local control and/or higher rates of skin toxicity, because to get those at depth, you would need significantly higher dose at the surface. So, that's 1A. I don't know if I have two minutes for 1A, B, and C.

Olatokunbo Awodele: Yes, if you could keep going with...

John Lukens: Yes, sure. Okay. Is there - I mean, is that adding high-resolution ultrasound versus SRT alone, is there a benefit? And I don't think that there's sufficient literature to support that. The fact is that these cancers have been treated for a very long time, you know, both with external beam radiation and with superficial radiation therapy without the use of high-resolution ultrasound with very high rates of local control.

And in fact, most of the historic series, you know, using SRT, did not use

ultrasound guidance. And in fact, the 2019 consensus guideline, you know, for SRT did not recommend, you know, the use of ultrasound. They've said, "measuring non-melanoma skin cancer tumors" and identifying margins for SRT are similar to surgery, based on the fact that the number for SRT is only 1 millimeter.

Recently, proponents of IGSRT have conducted a meta-analysis comparing their results to historic data for basal cells and squamous cell carcinomas. This was published in 2022 in - sorry, Discovery Oncology, which has an impact factor of 1.1. They were comparing the meta-analysis looked at one cohort of patients, and then they took a second cohort of patients, which was actually the same cohort of patients from that first group, and they added some additional patients. They presented that combined group as a poster. It was never published. And then if you find those datasets and that was - that comprised the...

Olatokunbo Awodele: Hi. Disconnected.

John Lukens: I'm sorry.

Olatokunbo Awodele: You can go on, I think, just go ahead.

John Lukens: Okay. Sorry. So, they compared basically that single patient cohort to studies that were published in 1990 that included patients with recurrent node-positive squamous cell carcinoma. The follow-up in the IGSRT arm was very short relative to the follow-up in these studies, either, you know, using SRT or using external beam radiation. So - and furthermore, in the IGSRT study, a significant proportion of patients had pre-malignant lesions in situ, you know, squamous cell carcinoma.

So, I think these patient populations are really non-comparable, and therefore, I don't - oh, sorry. And the median follow-up for the IGSRT arm was only 1.3 years. It's not sufficiently long-term follow-up data to claim that the local control rates are superior. So, why don't we move on, just in the interest of time. I have more to say on that topic, but I just leave it there.

Olatokunbo Awodele: Yes. So...

John Lukens: Go ahead.

Olatokunbo Awodele: Okay. Can I just ask. I wanted to ask that Dr. Chera, what is your feeling about the couple that you've answered so far in terms of process 1A and B? Dr. Chara? Okay. All right. How about Dr. Hruza or Dr. Scott?

George Hruza: Yes. I can certainly comment. So, I agree, this is not at this time, lack of randomized controlled trials and use of SRT for MSC to consider to be equivalent to surgery. While not equivalent as cure rate may be lower and recurrence may be higher. SRT is a reasonable option for non-surgical candidates. Additionally, research is needed to determine if it is equivalent to surgery for non-surgical candidates.

The AADA, American Academy of Dermatology, withdrew from the ASRA guideline development in reference 10 and sent a letter to the editor about their concerns that was published in Forensic Radiation Oncology. That's for A. For B, again, there's a possibility of studies data to suggest that aiding HRUS assortative treatment products can improve on standard assortative treatment, because of the thickness, you really use pretty thin lesions, and so there's really no reason to assess whether a lesion is 3 millimeters or 4 millimeters or 5 millimeters thick, because you cover that whole area.

And SRT during a course of treatment has not been shown to offer an added therapeutic benefit at this time. And on three non-surgical candidates, from my perspective as a dermatologist and I had received training in SRT during my residency at NYU, I found very few patients that would be considered non-surgical candidates for non-rheumatoid cancer treatment.

From a dermatologist's perspective, there have been a lot of clinical treatments for cancer. There are very few patients. Traditional, physically and most surgically malignant destruction under local NPS are safe and well-prepared in all patient populations, including the elderly and very elderly, anxious patients, patients with anticoagulants, or with bleeding disorders or immunosuppressed. So, non-surgical candidates are patients unable to stay still for the duration of the procedure, which is done under local anesthesia, patients with tumors that are not resectable without resulting in severe functional deficits, tumors where a clear margin cannot be achieved over the margin at the conclusion of surgery are uncertain. Tumors with intensive METs or satellite METs. Some of these require more deep penetrative radiation than SRT can offer. Thank you.

Olatokunbo Awodele: Thank you, thank you very much. So, just real quick. I think, who was it that just finished speaking? Is that Dr. Chera or Dr...

George Hruza: Dr. Hruza

Olatokunbo Awodele: Dr. Hruza. Okay. Thank you. So, Dr. Chera, Dr. Scott, are either of you on? You know, you want to just chime in or add something.

Jacob Scott: I'm here. I think Dr. Chera is also on. I see him in video at least, but I think while he's working out the audio, I'll answer. So, hi, everyone. My name's Jacob Scott. I'm a board-certified radiation oncologist and established

NIH investigator at Cleveland Clinic, and I have a specific interest in new radiation technologies, outcomes, and personalized medicine.

I'm also just for everyone to know the president of a relatively new nonprofit called the Dermatology Association for Radiation Therapy, and I'd love to invite everyone who's interested in this call to join us So, we can learn more about this new technology together, and I think that's an important theme here is that this is a new technology that we are learning about in real time, and that sort of gets to the answer I want to give for this question, which is that. I think the existing guidelines, ASTRO, AAD and NCCN, are all a little bit outdated when it comes to the way we approach these. We're basically conflating SRT and IGSRT.

As everyone said, appropriately, IGSRT is new. There is less data and less follow-up than for other modalities, because it's only been around for seven years. That said, our association sponsored a bunch of studies for this year, and there's actually a bunch of papers that are missing from the bibliography, which I'm happy to share, which now show six-year follow-up for IGSRT, which is using the same SRT technology, but together with imaging.

Just like in radiation oncology over the decades, we've slowly started adding imaging and finding increased outcomes and better outcomes over the years. The same is true for what we're finding with this addition. Being able to measure the depth, being able to measure the changes has really made a big difference. And all of the improved outcomes that we are seeing in our literature now with up to 20,000 lesions and six years of follow-up are specifically about the combined modality.

And so I think comparing the SRT literature, which does have like a 9% recurrence rate. And probably should be second line to the different and new

modality of image guidance together with SRT is I think the most important thing. And it's also to note that today in practice, IGSRT is the community standard. Something like 90%-plus of all claims are for IGSRT instead of SRT, which is really falling out of favor, because of the lower rate spends than most, for example.

Olatokunbo Awodele: Okay.

Jacob Scott: For the last one here the non...

Olatokunbo Awodele: Okay. Real quick.

Jacob Scott: Oh no. I'm done. That's all.

Olatokunbo Awodele: Okay. You were going to say non-surgical. Okay. Well, thank you very much. I'm going to hand over to Dr. Schaening for the next question.

Juan Schaening Perez: Okay. Thank you. So, let's go to question number two, please. And question number two is, does the literature support that low-risk BCCCA and low-risk SCCA should be treated with non-surgical or alternative means or standard extension or Mohs? If so, what literature supports this approach? Could Dr. Posten start with this response?

William Posten: Yes. Sure. Thank you. So, I would say that the literature does support non-surgical or alternative treatments for low-risk basal cell carcinoma and squamous cell carcinoma, but typically is a secondary option when surgery's either contraindicated or declined. The NCCN guidelines, for instance, emphasize that while surgery, like standard excision or Mohs surgery, tends to offer the most effective and efficient path to cure,

Non-surgical treatments can be appropriate in cases where factors like function, cosmesis, or patient preference come into play. For low-risk basal cell, radiation therapy and topical therapies, like (Omicron) or 5-FU, are outlined as alternatives, particularly for superficial basal cells. Similarly, for low-risk squamous cell carcinoma, radiation is an option when patients decline surgery.

The AAD guidelines largely echo the NCCN guidelines, stating that surgery is the most effective treatment for both low-risk basal cell and squamous cell, but when surgery isn't feasible, they also allow for alternatives like cryosurgery or topical treatments for basal cell and radiation therapy for squamous cell, provided everyone involved is clear that the outcomes may be less certain. That said, both the NCCN and AAD flag that there's still insufficient long-term data on some non-surgical options to recommend them routinely.

For radiation options, both the NCCN and AAD guidelines recommend that these are secondary treatment options. And so, in short, literature does allow for non-surgical treatments for low-risk cases with the understanding that surgery remains the gold standard. And any alternative should be weighed carefully in terms of potential risks, benefits, and overall cure rate. I'd like to add, too, like where Dr. Scott had earlier said, you know, guidelines were made a while ago, and they are always changing. Thank you.

Juan Schaening Perez:Thank you. Appreciate your feedback. Dr. Rogers, your take on this question?

Howard Rogers: Yes, can you hear me?

Juan Schaening Perez:Perfectly.

Howard Rogers: All right. Okay. So, I'd say, you know, based on current evidence, surgery definitely remains the most effective and efficient treatment for skin cancer, and the majority of cases require one visit for treatment. However, NCCN and AAD guidelines acknowledge that non-excisional modalities may be used to treat low-risk non-melanoma skin cancer when such treatment is appropriate.

There are numerous non-excisional treatments. So, topical cream treatments like Fluorouracil have been proven safe and effective in select non-aggressive skin cancers. These therapies are self-administered and convenient to patients when one visit is typically required to ensure appropriate clinical response.

Non-excisional modalities like photodynamic
therapy, curettage destruction, intralesional chemotherapy have also been proven safe and effective. And these treatments typically are administered in a doctor's office and require one or two treatments. SRT, superficial radiation therapy, and EBT also appear to be effective in the treatment of select superficial skin cancers. However, compared to being treated in a single session, by other means, patients treated via SRT can expect to require multiple treatment sessions.

The most popular protocols invariably treat with 20 fractions of radiation for even the most minuscule in situ superficial skin cancers that could easily be treated in a single visit. Dermatology offices generally use a wide variety of treatment options for non-melanoma skin cancer, including topicals, destructions, excisions, BDT, and even Mohs surgery.

The choice is not just radiation or Mohs surgery, as some would have you believe. There's extensive research that multiple modalities can be used effectively and safely in treatment of lower skin cancer. I am concerned that

many derm practices that do IGSRT have almost entirely stopped doing simpler procedure, perhaps not based on the best interest of the patient. So, ensuring that patients receive not just an effective treatment, but an appropriate level of care for skin cancers is critical. Thank you.

Juan Schaening Perez: I appreciate your feedback. Dr. Chuba, could you please answer question number two?

Paul Chuba: Hi. I guess my first comment is I think that, if each person - if we have five people answering each question, and we have all these questions going to take like many hours to complete this session. So I don't mind like just supporting the other radiation oncologists for the time being.

Juan Schaening Perez: Okay. Thank you. I appreciate that, Dr. Chuba. But we will be asking questions for group of four. So, I think the allotted time of two hours will work if we could to the two-minute response. But I really appreciate your consideration about time. So, Dr. Mammen, your take.

Joshua Mammen: I'll also be brief read, and I won't reiterate what others have said. There is a variety of options that are reasonable to consider in addition to surgery, either by standard excision or by Mohs. Those options are typically not the primary option, and as others have mentioned, superficial radiation is an option, but it's typically used as a secondary option in situations where standard excision or Mohs is not an option.

There are no strong head-to-head comparisons of surgery showing equal efficacy with superficial radiation, though there are studies that attempt to use cross-study comparisons, and I have also performed a literature read that I can share showing some of those studies that show perhaps superiority or perhaps equivalence, but since those are not high-quality studies, I think the standard

remains surgical decision first with superficial radiation as a secondary option.

Juan Schaening Perez: Thank you. Dr. Awodele.

Olatokunbo Awodele: Thanks. Thank you. And in light of what Dr. Chuba said as well. I just wanted to kind of see if I could switch around the way I ask question three. So, this will be answered by Dr. Ladd, Powell, White, and Baker. And the main question is, is there sufficient evidence to treat any patient with non-melanoma skin cancers, including ones that are very small and easily treated in a single session by other means? And then it says, if yes, is this supported by current NCCN guidelines and AAD guidelines, Mohs guidelines, ASTRO guidelines?

And then we have second part, which is, is there an advantage to having a tissue diagnosis for complete margins being excised versus just visual follow-up for detecting recurrence? So, I would ask whoever wants to comment on that to jump in and start commenting. And if you want to do it as a discussion, let's try and do that. Dr. Ladd.

Daniel Ladd: Dr. Ladd. I'll go.

Olatokunbo Awodele: Yes. All right. Okay.

Daniel Ladd: Okay. I'm Dr. Daniel Ladd. I'm board certified dermatologist. I have 20 years of experience in general dermatology, 15 years of experience in Mohs surgery, four years of experience in superficial radiation therapy, two years of experience in electronic brachytherapy, and eight years of experience in image guided superficial radiation therapy.

And the fact that a lesion is very small, is not in and of itself a criteria for determining the appropriate treatment option. When choosing between alternatives, physicians must take into consideration the tumor size, location, and histopathological subtype. Special care should be taken when treating recurrent tumors.

In addition, adverse potential events, patient comorbidities, physician expertise, access to care, cosmetic concerns, and functional concerns also need to be considered. In summary, it is the treating dermatologist through their clinical judgment who should determine the best course of therapy on a case-by-case basis. So if yes, is this supported by current guidelines? Current guidelines for the treatment of NMSC advocate for Mohs surgery for all low-risk and high-risk basal cells, squamous cell and squamous cell carcinoma in situ.

These guidelines were all developed without reference to IGSRT studies produced since 2021. The evidence in the published studies on IGSRT is overwhelmingly conclusive in the safety and efficacy of IGSRT as a first-line treatment for low-risk and high-risk basal cells, squamous cell, and squamous cell carcinoma in situ. Therefore, based on the peer-reviewed literature, IGSRT is reasonable and necessary as first-line treatment for low-risk and high-risk basal, squamous, and squamous in situ.

In addition, IGSRT has become the overwhelming radiation treatment of choice, over all other forms of radiation therapy for early-stage non-melanoma skin cancer, making it the community standard of care. Is there an advantage to have a tissue diagnosis for complete margins being excised versus just visual follow-up for detecting recurrence?

The standard of care is to assure removal of all margins of the tumor. Moh’s

micrographic surgery and image-guided SRT provide visual confirmation during the treatment process, allowing for complete removal of the margins, resulting in statistically significant higher cure rates and all other forms of treatment for low-risk and high-risk basal cells, squamous cell, and squamous cell carcinoma in situ. Moh's has a 99% five-year recurrence-free survival for basal cells and 97% for squamous cells.

Image-guided SRT has over 99% five-year recurrence-free survival for basal cell and over 99% for squamous cells. The value of identification and capture of tumor margins by utilizing high-resolution and dermal ultrasound with each fraction has been proven in the peer-reviewed study by Stryker et al., published in 2024. Thank you.

Olatokunbo Awodele: Thank you, Dr. Ladd. Dr. Powell, Dr. Ladd, Dr. Baker, would you like to add to this?

Donna Powell: Hi. This is Dr. Powell. I'm the manager of the Radiation Therapy and Imaging Programs at the NCCN, and I've worked in the field of radiation oncology for 30 years as a radiation therapist, educator, and medical dosimetrist, and now I'm the manager of the Radiation Therapy and Imaging Programs and have been with NCCN for ten years.

In my name, NCCN facilitates the RT compendium, which is a streamlined resource for the clinicians and PET accessing radiation-related recommendations in the guidelines. In response to the question, I'm going to answer from an NCCN perspective, A - letter A. And based on ASTRO and NCCN guidelines, for patients who can't undergo or decline surgery, definitive RT is strongly recommended. And the ASTRO and NCCN guidelines indicate the strong support for the use of SRT in the treatment of low-risk disease for basal and squamous cell.

But it is the NCCN panel physician's role to determine the sufficiency and the quality of the (evidence). However, the NCCN guidelines are structured in a specific way. On an annual basis, the literature is gathered by the NCCN scientists, multidisciplinary panel members then gather and discuss the latest evidence-based literature and consensus on any given disease. And all panel members vote on a specific treatment modality.

Once the votes are cast, categories of evidence are then determined. Category of evidence is voted on by a multidisciplinary panel. All recommendations within the guideline are Category A, unless otherwise specified. The 2A represents at least 85% of the multidisciplinary panel that are in agreement.

And currently, that multidisciplinary panel for the non-melanoma skin cancer panel, it consists of multiple physicians who hold dual degrees across the spectrum of care, and they include 15 physicians with dermatology backgrounds, five radiation oncologists, three medical oncologists, multiple surgeons across specialties, pathology, radiology, hematology, internal medicine, and otolaryngology, as well as patient advocate, but all have an equal voice in the voting process for NCCN.

Once all the recommendations are approved, the recommendations go into the Radiation Therapy Compendium, and this becomes a streamlined resource for all recommendations for payers and clinicians. So, that basically, for me, is the evidence and the information for why NCCN recommendations are high-quality evidence because it is a multidisciplinary panel of physicians voting for this. Thank you.

Olatokunbo Awodele: Thank you, Dr. Powell. Dr. White? Dr. Baker?

Gerald White: This is Jerry White. I'll just - I'll try to be brief. I just - by the way of introduction, I'm a medical physicist. I probably - I did an envelope calculation, I've probably participated in more than 1,000 superficial radiation therapy treatments over the years. And so I'd say, first of all, in answer to the first question A, it is supported by - as we've already heard, supported by various guidelines for non-surgical candidates or patients who prefer not to have surgery. So, clearly, guidelines support the use of superficial radiation therapy and, you know, could be used after a joint decision by the patient and the physician.

The second part, B, is the advantage to have a tissue diagnosis for complete margins versus visual follow-up. I think those are two different things. I really didn't clearly understand the question. The first one has to do with what happens at the time of treatment and the other is a follow-up question. And I think the answer, both of them are appropriate and necessary depending on the choice of treatment.

The sufficient evidence question we've heard just a bit recently about previous publications. I have to say that the public - the literature is unconvincing on this. There's a number of publications about what's called IGSRT, and just - they don't talk about how the IGSRT is applied in terms of energy, in terms of dose, in terms of depth of being, not to mention other issues related to randomization, choice of patients, things like that. Just - the literature, although there are quite a number of papers published on this, it is most charitably described as unconvincing, I think.

And I'd just like to say one more thing quickly. I heard a comparison of IGSRT to Image-Guided Radiation Therapy, and those are two completely different processes. I've been involved with Image-Guided Radiation Therapy from its inception. The users of IGSRT have chosen a name that sounds like

Image-Guided Radiation Therapy, but it's a very, very different process. This is nothing - the procedure is different. And so the two procedures are homonyms and not synonyms. So, any comparison to IGRT is really inappropriate.

Juan Schaening Perez: Thank you.

Olatokunbo Awodele: Thank you very much. Yes, go ahead. Over to you.

Juan Schaening Perez: Let's go to question number four, please. So, question number four is, should the use of Image-Guided SRT follow other ASTRO guidelines for the safe delivery of Image-Guided Radiation Therapy? A, if ultrasound is being used prior to and not in conjunction with SRT, then is it really Image-Guided Radiation Therapy? Could Dr. Lukens, Hruza, Chera, Scott, address this question? Dr. Lukens, if you can.

John Lukens: So, I actually just wanted to echo what the medical physicist just said that. Image-Guided Radiation Therapy is a very specific - has a very specific meaning, basically refers to the use of either X-rays, CT scans, or MRI for visualization of tumors deeper within the body that cannot be visualized on the skin surface. For example, a lung cancer or tumor at the base of the skull, where you simply cannot safely treat these patients without image guidance prior to treatment.

But if IGSRT, which I agree is not the same thing. Yes, it should follow the same guidelines as far as safety. But I think what I wanted to focus on is this question, A, if the ultrasound is being used prior to as opposed to during delivery of the SRT, it really has to do with the timing. So, for patients who are treated with external beam radiation, the imaging is typically obtained with a patient in the treatment position immediately before treatment with

patient immobilization to minimize the time between the image and the treatment.

Otherwise, it would be considered a diagnostic study. So, if the ultrasound that's being used to guide the superficial radiation therapy is being done to, say, gauge the depth or the width of the tumor, and then the tumor is subsequently treated, that would be more of a diagnostic study, as opposed to image guidance in the true sense of the word, where it's used to ensure the alignment of the patient prior to treatment, sort of at the same time. Thank you.

Juan Schaening Perez: I appreciate your feedback. Dr. Hruza?

George Hruza: Yes. I agree I think the guidelines really are - really focused on larger deeper tumors and so yes, safety is important but they really - the aspects are not really fully aligned with what you would be doing when you do superficial treatment. I just want to talk a little bit about the dermatologists because the guidelines seem to talk about the dermatologists that only radiation oncologists and physicists should be doing.

So, I would say, not only dermatologists have extensive training and experience in managing normal skin cancer, but certain radiation devices have historically been used by dermatologists that have started to be used for over 100 years to treat skin cancer. So, I think dermatologists are very much comfortable with radiation therapy and also ultrasound, which we use in other techniques in dermatology. So, the image-guided, I think, I believe it's ultrasound. So, we should be very comfortable with that.

The other is that - it seems that the data doesn't suggest that Image-Guided really doesn't seem to play much of a role for SRT, because the thickness of the lesion is pretty obvious. I'm just struggling with why that would help you get better results. So, using it before treatment, I think, would be a good idea,

primarily to help in staging the tumor, so deciding if the patient is actually a good candidate for SRT, or if the tumor is thicker, then maybe they might need to go traditional radiation therapy. Thank you.

Juan Schaening Perez: Thank you. Dr. Chera.

Bhisham Chera: Yes. Thank you. I had connectivity problems earlier. I just want to reemphasize and kind of explain it in a little different way, but IGSRT is not image guidance as described by the CPT nomenclature. And the ASTRO guidelines do not have anything to do with IGSRT as image guidance. So, the key to a real image-guided system is that the imaging device is registered physically or optically to the treatment device, so that when you're looking at the image from your imaging device, you know where the image is in relation to the central way of the beam.

So, IGSRT physically cannot be an image-guided because it is not connected to the treatment device. And so, just again, the IGSRT, as described, is not image-guidance as described by the CPT nomenclature that we use in radiation oncology.

Juan Schaening Perez: Thank you. I appreciate it. Dr. Scott, your take on number four, please.

Jacob Scott: Yes. I'm going to pretty much agree with everything that's been said with a couple of small differences. So one, I think that, you know, the IGSRT and IGRT are clearly different things. That's true. There's the ones delivered in the Rad-Onc office for a deep-seated tumor and the other in outpatient derm. But I would say that the scope and the purpose is similar.

And further, on the newer machine, again, which has only existed for six or seven years. There is registration for the imaging and the delivery device. So,

there are a single device, but - and I think in the spirit of image guidance, IGSRT is, but I agree that when it comes to what we do and what ASTRO, in particular, and ACR consider IGRT, it's quite different.

I'd also say that whenever the guidelines were made, ASTRO, ACR, and ASTRO together, the guidelines were made. It was actually before any of the relevant literature on IGSRT was published. And again, I think to everyone's previous point, this is a new technology. We're learning about it in real time. Lots of things have been changing, and we're, you know - this is the same discussion I think we had 15 years ago in radiation oncology when we were arguing against daily cone beams.

And the point of you can see the lesion in, and you can - and you understand the depth like some of the others have said, I think is misguided in that if it didn't matter what the depth was, and you didn't care what the depth was like you do when you image. Why would you do Mohs? Otherwise, you would just take out a centimeter all around it and below it and be done.

But the whole point of treating these tumors with micrographic surgery is in order to be able to take as little extra tissue as possible. And that's the same reason that this image guidance for SRT is helpful, because you could treat much less of the normal tissue. Certainly, you could put a centimeter on the whole thing above and below and hit it with electrons. Certainly, you could do that with photons. Certainly, you could do that with a knife.

But in the case of most surgery, we don't, and the standard of care is to take as little extra tissue as possible. And I think that's the spirit of what's behind IGSRT as well, is to treat as little healthy tissue as possible while still maintaining excellent tumor cures. And really, in IGSRT, it's not just the ultrasound plus SRT, it's an entire procedure that's used both with adaptive,

you know, changing voltage, changing the energy, changing the TDF, maximizing efficiency and efficacy while minimizing toxicity, which I think is the same goal of therapy that we have for all of our patients, whatever the modality is.

And I think that the idea that we shouldn't have this as a choice when the efficacy's been shown, and I agree it's new, but 20,000 lesions and six years of follow-up is not trivial. I think that adding this to our armamentarium for the appropriate patient is the best thing we can do for our patients, who we took an oath to help in the best way we can.

And again, Just making sure we pay attention to the differences between the older literature with SRT and the newer literature with the combined modalities that also has multidisciplinary oversight and also well appropriate. We know evidence-based guidelines when it comes to fractionation schedules.

Another point to think about is that before - when SRT was more prevalent, fractionation schedules were all over the place. And in Rad-Onc, we do a really good job of making sure we're using the same fractionation schedules and reporting on them. And that's what's really come to the fore in IGSRT, and that's why I think the literature is bearing out significantly increased efficacy on par with micrographic surgery.

John Lukens: Could I just respond to that?

Olatokunbo Awodele: Sure.

John Lukens: So, the idea that you're going to spare a significant amount of normal tissue by using IGSRT as opposed to clinical judgment, I think, is overstated. If you look at the literature in terms of the depth as clinically assessed by a skilled

dermatologist versus the ultrasound. The difference was less than a millimeter. So, it's hard for me to see how that provides a meaningful benefit in terms of normal tissue sparing, especially if you're repeating ultrasound with each fraction, do you really expect it to change that much that it's going to spare the normal tissue? I think that's overselling it.

Jacob Scott: Well, there is a paper out just a few months ago that quantitatively looks at depth changes during therapy. I'm not sure if it may the bibliography, but it...

John Lukens: It doesn't matter clinically I think is the point.

Jacob Scott: Oh, well, then why would we do multiple stages for Mohs if we didn't care about sparing millimeters of tissue? I guess it's just a difference in opinion between the way an oncologist like me looks at it as - hey, all I want to do is cure, but when a dermatologist - and I'm not a dermatologist, so...

John Lukens: By the way, I'm a radiation oncologist and I treat skin cancer.

Jacob Scott: Okay, cool.

John Lukens: All right.

Juan Schaening Perez: Excellent discussion. Remember that we're going to give, at the end, time for comments. So, you can address any issues that you feel that must be clarified at the end. So, we will continue now with our schedule because we have very tight schedule here. So, Dr. Awodele.

Olatokunbo Awodele: Yes. Thank you, Dr. Schaening. And we do appreciate the robust discussion, that's kind of what we're here to do, so I really appreciate what just went on. So, moving on to the next question, which is kind of, you know, an extension of that previous question. In the absence of RCT or

comparative studies, are you confident that the addition of ultrasound guidance to SRT improves clinical outcomes? If yes, what literature supports your position? This question is to Dr. Posten, Rogers, Chuba, and Mammen.

William Posten: Yes, I can start, Dr. Posten. Just a little bit about my background, first of all. I'm a board-certified dermatologist and fellowship-trained Mohs surgeon, and my practice consists solely of skin cancer, and I've done a high volume of surgery, about 50,000 surgeries, and we do a fair amount of radiation as well. It's probably done about 4,000 to 5,000 treatments.

So, in answering this question, I would say, you know, the way it's phrased, in the absence of randomized clinical trials or direct comparative studies, it is challenging to confidently say that adding ultrasound guidance to superficial radiation therapy improves clinical outcomes. Available literature doesn't provide enough concrete evidence to support a definitive advantage. That being said, in my personal experience, I would say that ultrasound guidance helps with the clinical application of SRT.

The advantages it confers are the ability to monitor tumor response to radiation. It provides extra information to help make more informed decisions as to whether or not to change radiation parameters, and you're able to visualize that the radiation is creating an effect on tumor size.

Now, there may be a role for high-resolution ultrasound and tumor staging at the start of treatment, but you really need to do more research to clearly define the value in setting radiation fields or guiding treatment adjustments throughout therapy. There's that article by Yu et al., where they looked at the treatment of non-melanoma skin cancer with image-guided SRT.

And basically, they did a meta-analysis comparing superficial radiotherapy

and external beam radiotherapy with and without image guidance. But the study pooled data from different treatment regimens, patient cohorts, and follow-up periods, making direct comparisons difficult. Basically, so without randomized controlled trials or well-matched cohort comparisons, it's hard to confidently assert that high-resolution ultrasound enhances SRT outcomes. I think we definitely need more rigorous studies before we can draw any firm conclusions.

Olatokunbo Awodele: Thank you. Anyone else want to chime in?

Paul Chuba: Sure. This is Dr. Chuba. I'm sorry. I'll just say...

Howard Rogers: No, that's okay.

Paul Chuba: I support that previous comment. It seems to me that it's a diagnostic test just to see the depth of the tumor. You know, we were doing, by the way, superficial radiation therapy in the 1990s and before. And I don't really think it's that much different with a dedicated machine. That's all.

Olatokunbo Awodele: Dr. Rogers? Dr. Mammen?

Joshua Mammen: So, more research is clearly needed to prove any benefit of adding ultrasound to SRT. No matter how many times the words, you can't fly blind, are uttered by interested parties, it doesn't change the fact that high-quality studies comparing SRT to IGSRT are entirely lacking.

As mentioned by Dr. Posten, there was one meta-analysis from 2022 comparing SRT and IGSRT that concluded that IGSRT was statistically superior. But this report is plagued by flawed patient selection, improper methodology, and industry conflicts. In addition, the SRT studies all use

different protocols, fractions, energies, and margins than the IGSRT studies.

The IGSRT patient selection criteria are also clearly different than the SRT studies. So, with three variables changing, different patient populations, different radiation protocols, and the added ultrasound guidance, there's no way to understand how the addition of daily ultrasound affects the cure rates of SRT, if at all.

In addition, there's no evidence that small day-to-day differences in the ultrasound measurement of a tumor's depth is biologically relevant at all. There's no evidence that altering radiation delivery energy during a course of SRT based on subcentimeter ultrasound findings compares any advantage in terms of ethnic fear safety. There's no published or standardized protocol for assessing tumor depth by ultrasound, nor a correlation of ultrasound tumor depth with microscopic tumor invasion.

And the literature seems purposely vague in terms of how ultrasound is used to guide "adaptive therapy". So, there's no high - and there's no high quality studies comparing the use of different protocols, toll dosing on different radiation margins. So, in short, more scientific literature is needed to delineate any advantage for ultrasound for setting radiation field prior to therapy and to support ongoing usage of ultrasound during the course of therapy. Thank you.

Olatokunbo Awodele: Thank you. Dr. Lukens?

John Lukens: So, I'll just add, since I'm the last one, that I agree with what all the other panelists have mentioned, and that - I agree that without high-quality evidence that I have low confidence that ultrasound guidance really adds anything to SRT in terms of outcomes.

Olatokunbo Awodele: Thank you very much. So, over to you, Dr. Schaening.

Juan Schaening Perez: Thank you. So, let's address question number six, please. So, question number six is, is there potential risk for: A, recurrence. B, increased risk if needs surgical incision in future due to changes from irradiation. C, risk of new malignancies associated with irradiation in the future. D, challenges in detecting recovery after irradiation? And if yes, how many years of follow-up do research studies need to be certain, this is not causing inadvertent harm and should there be lower age limits to this technology given the lack of long-term data? So, Dr. Ladd, could you start addressing this question?

Daniel Ladd: Yes, sir. Image-Guided SRT is a superior alternative treatment for early-stage non-melanoma skin cancer for the following reasons. The chance of recurrence with Image-Guided SRT is less than 1% for low-risk and high-risk basal cell carcinoma, squamous cell carcinoma, and squamous cell carcinoma in situ, based on the previously cited published peer-reviewed studies.

Image-Guided leads to greater sparing of normal tissue, making it more likely that there will be less challenges for surgery if needed in the future. Image-Guided SRT leads to adaptive radiation treatment changes, sparing the surrounding normal tissues from excessive radiation exposure that can extremely rarely occur after the use of low-dose superficial radiotherapy.

Follow-up high-resolution dermal ultrasound imaging, as are other forms of dermatologic imaging of treating lesions, are very effective tools for recurrence monitoring and especially more effective than visualization alone. As far as the last one, theoretically, the development of latent basal cell carcinoma is possible. However, the literature does not describe any cases caused by SRT or Image-Guided SRT.

The literature does describe an increased risk of latent basal cell carcinoma in atomic bomb survivors. The incidence of basal cells among the population of atomic bomb survivors that received the highest dose was significantly elevated after 30 years. Age at exposure was also found to be a significant modifier of response among atomic bomb survivors. And there is an inverse relationship observed between age of exposure and the risk of developing basal cell carcinoma.

No apparent increased risk of basal cell carcinoma was observed for those aged 40 years or older at the time of detonation. So, one can assume that as long as adults under the age of 40 are not treated with Image-Guided SRT, the risk of latent basal cell carcinoma is minimal. Thank you.

Juan Schaening Perez: Thank you. Dr. Powell, your take on number six, please.

Donna Powell: Sure. Thank you. Well, in response to recurrence, there's always a risk of recurrence when radiation is used for any treatment. So, that's just a given. But there's always modern treatment planning techniques that can be used if surgery is needed, you know, in a previously irradiated field to mitigate any further risk.

And NCCN gives indefinite follow-up for radiation treatment as a recommendation. After radiation - I'm sorry, after radiation as a recommendation, and it allows for ongoing surveillance and detection and the modalities and timing used for follow-up are always left to treating physicians. So, the bottom line is this indefinite follow-up is what NCCN suggests after any radiation treatment. Thank you.

Juan Schaening Perez: Thank you. Dr. White, your take.

Gerald White: Yes. Thanks. In answer to the A, B, C, and D, the answer is yes to all of them for any definitive therapeutic procedure, including this. There is a potential risk for recurrence. There is a risk that if surgical intervention is needed in the future, it'll be more difficult for the irradiation.

There is a risk of secondary malignancies associated with radiation therapy that is well-known in radiation oncology. You don't need to look at atomic bomb survivors to come up with some sort of analysis of that. And challenges in affecting recurrence after radiation, I have to say that's not my field of expertise.

But I think that the answers to A, B, and C are minimal with radiation - superficial radiation therapy. Again, if applied, if used in appropriate clinical circumstances, and that's well described in the various guidance documents by ASTRO and AAD and NCCN. I think that the answer to these questions is clear and probably not illuminating on the particular questions under the - basic question we're discussing today.

And the last one, how many years of follow-up research is necessary? You know, clearly, many of the papers that have come out recently are one, two, or three years, and I've heard mention of a longer six, eight-year study, which is appropriate. But I particularly object to the - limit to this technology, given the lack of long-term data.

The long-term data refers to these Image-Guided superficial radiation therapy, and not superficial radiation therapy for cancer, which has 125 years of data. The institution where I practiced, we had case studies with images dating back to 1940 for superficial radiation therapy of skin cancers.

So, I think that the overall concept that this is something new really induces a

lot of unnecessary discussion. It's a red herring in all this superficial radiation therapy is well established. What is not well established is the process of every day applying an ultrasound probe to the patient and trying to assert that that makes some difference in the patient's management and the outcome.

And for that reason, long-term data would be great if someone thinks they can acquire it. But all the papers I've read so far, the weakness was not in the length of follow-up, the weakness was in the description of the patient selection, the processes, the techniques that were used. Years of follow-up is the least of their problems in those papers.

Juan Schaening Perez: Thank you for your feedback. Dr. Baker, your take on number six.

Dole Baker: Yes. Hi, I'd like to introduce myself. Dr. Dole Baker, I'm a board-certified otolaryngologist, head and neck surgeon, and a board-certified facial plastic surgeon with over 25 years of experience, taking care of patients with both head and neck cancer and skin cancer and reconstruction of such.

With regards to recurrence, yes, there is a risk of recurrence. Recurrence rates following surgical excision are uniformly lower than with superficial radiation therapy or other topical therapies. And I think that's also important with question three, where they asked about the importance of surgical margins. With small lesions, surgical margins that are negative, essentially assure almost cure and eliminate the need for further follow-up at times.

With regards to the increased risk from surgery in a radiated field, there's no question that there's significant risk and morbidity. In a previously irradiated field, I've had the opportunity and pleasure of operating in that such field many times. Makes it difficult to section, identification of anatomic landmarks, there's decreased tissue pliability, decreased viability of tissue,

increased necrosis, increased failure of any flaps or reconstruction, poor wound healing, you generally get a worse cosmetic result, and there's a significantly increased risk of infection.

There is a risk of new malignancies associated with irradiation. We've already discussed that. And there are challenges in detecting recurrences after irradiation. Radiation changes the patient's anatomy. There's significant edema. There's significant hardening. There's pigmentary changes, osteocalasias that make identification of recurrences extremely difficult, especially recurrences that are not on the skin, but on the deep margins, which is leads to the importance, really many of these with doing Moh's or surgical excision and obtaining negative margins.

Juan Schaening Perez: Thank you. Really appreciate your feedback. Let's move to number seven then, Dr. Awodele.

Olatokunbo Awodele: Thank you Dr. Schaening. So, this question is addressed to Ds. Lukens, Chera, and Scott. It says, for patients who are non-surgical candidates considered for alternative RT, should the appropriateness of RT be performed by a radiation oncologist according to NCCN and ASTRO guidelines? Do you feel this is required for superficial radiation therapy as well? Why or why not, depending on how you feel about that? Should dermatologist or other qualified healthcare professionals perform the radiation, dosing, sight blinding, image guidance, and other services associated with radiation therapy that are typically delegated to a radiation oncologist?

B, who interprets the images used for HRUS? Is it the radiation oncologist, the dermatologist, the radiation therapist, the ultrasound technician, ECC? What training requirements should be met and through what mechanisms before delivering this treatment? And, last but not least, can the fractionated

treatment be delivered by someone other than a radiation technologist, such as a trained medical assistant or other ancillary personnel delegated by the supervising physician, consistent with CMS guidelines for a post-incident to care? So, Dr. Lukens, Dr. Hruza, or Scott. I'll leave it to you who wants to answer first.

Juan Schaening Perez: Okay. We are going to go in order.

Olatokunbo Awodele: Yes, I'm just going to go in order. Dr. Lukens.

John Lukens: Okay. I'll try to keep it short and leave it for Dr. Chera as well. I think, do you feel that this is required for superficial radiation therapy as well? Why or why not? That's really the first question. Yes, radiation oncologists are trained in terms of the necessary dose, how to prescribe radiation, what margins, depths used, and the range of dose and fractionation schemes that are appropriate in order to balance the curate with quality of life, (Cosme), cysts based on patient age, performance status and priorities.

Also, we work closely with medical physicists who are qualified to commission radiation therapy units and perform the necessary quality assurance to ensure safe radiation dose delivery. It is not clear if these are incorporated into dermatology training and the rollout of these SRT or IGSRT units in the dermatology offices, it's not clear to what extent a medical physicist is involved.

We're still talking about ionizing radiation. The only reason that it falls below the threshold for being regulated by, you know, the SRT. But it is still ionizing radiation. It exposes staff to radiation, you know, other patients to radiation. And as far as what shielding is required and so on isn't really specified in any of the protocols as far as.

And I spoke to one of the physicists who is a nationally recognized expert in terms of quality assurance, and he spoke to a director at the IAEA, and they're actually going to come up with a new AAPM work force to address this problem specifically because it's so ill-defined as far as the medical physics requirement for the rollout of, you know, these SRT units. In the interest of time, maybe I'll just try to answer that one, and then I'll let the rest of the panelists talk. Thank you.

George Hruza: This is Dr Hruza.

Olatokunbo Awodele: Okay.

George Hruza: ...as a dermatologist that has done numerous radiation treatments in residencies with direct hands-on experience, I do agree that there is a variable level of dermatologist training in superficial radiation therapy. It is in all our textbooks, and many of the articles that have been published in peer-reviewed research that has been done by dermatologists.

So, and we mentioned that superficial irradiation therapy is different from traditional irradiation therapy and that's because of the depth of penetration of the treatment. Also, ultrasound is used routinely in dermatology practices for various other indications.

So, I believe that dermatologists should be allowed to continue offering superficial radiation therapy, along with the IGSRT as well, it is consistent. The key thing is that they, of course, if they have not had the training in residency because some of these treatments are new, there are avenues to obtain that additional training in CME programs such as the professional organizations such as the American Academy of Dermatology.

So, again, I do believe that dermatologists should be allowed to continue performing crucial radiation therapy consistent with their education, training, and individual competence in accordance with applicable federal and state law. Thank you.

Olatokunbo Awodele: Thank you. Does anyone else want to chime in? Thank you.

Bhisham Chera: Yes. Thanks. This is Bhisham Chera, radiation oncologist that treats skin cancer. I'm going to sort of repeat what everyone's already said. You know, you're absolutely right, in the NCCN Guidelines Skin - in the Skin Cancer Guidelines, it says that radiation should be given by a practicing radiation oncologist, and of course, in the ASHRAE Guidelines, and the ACR also says that. But it's kind of tricky, because you're right, dermatologists have been giving SRT treatments for many years, even before this ultrasound thing. But the training is very variable.

I've worked at three academic institutions and in one of the academic institutions I practiced at. The dermatologist didn't even think about radiation as being an option for patients. And so the training is very variable. And radiation is dangerous. And I understand that this is superficial radiotherapy. You know, the penetrates is not that deep, but there's all the risks that have been already explained to staff, to patients. And you can misuse superficial radiation therapy.

You know, we are radiating the same type more - same site more than once, will create a lot of complications. And you have to understand the dose volume. And normal tissue effects of radiotherapy to really be safe with it. And then there's all the quality control of the machines that physicists play a huge role in radiology with quality control, radiation oncology.

And I worry about in these SRT machines that are all over the place, you know, where's the physics involvement - physicist involvement to ensure quality control.

Olatokunbo Awodele: Thank you.

Jacob Scott: Thanks.

Olatokunbo Awodele: Any other...

Jacob Scott: Yes, I'm going to largely agree with what everyone said. I think that, you know, number one, like Mr. White said in the last question, SRT is not new. It has been given for over 100 years before radiation oncology even existed as a field.

And so, dermatologists have been using this as prime users for 100 years, and clearly they are the experts in these early-stage skin cancers, and this is a modality they've been using for a long, long time. I think it makes 100% that they should be allowed to continue to do that in particular.

And, you know, I also wanted to say something about the people or the folks that have been, I don't think, improperly - I don't think improperly, you know, talking about the earlier literature, the very early literature on IGSRT, and in particular some of the weaknesses and methodological issues and smaller sample sizes are exactly why we've sponsored the next series of studies from our society.

So, I think I'd love the folks that are carefully and thoughtfully reading the literature and bringing up real points to take a peek at the newer series, which

is 20 times as many lesions, much better methodological descriptions, including protocols and whatnot.

I just would love folks to take a peek at it. And I'd love feedback. We at the field would love everyone's feedback and continued discussions on all that. We're not going to learn to get better in a vacuum. And I think, you know, it's important to talk about safety here. I think there's probably hundreds of thousands of lesions that have now been treated by dermatologists in the office with these technologies that these are newer technologies, and not to mention SRT before that.

And when it comes to, you know, really oversight of this, it has always been left up to individual states. So, I also wear the hat of radiation safety chair here. And really, you know, each state sets its own standards for physician use of radiation devices, as well as the specific training requirements.

I mean, I agree, radiation is not safe by itself, right? If you're using it improperly, you can cause harm no matter what setting it's in, no matter what energy. Well, not no matter what energy, but you know what I mean. And I think that every state really has to approve any individual physician who wants to use it. IGSRT, SRT, MV, whatever it is, we all have to be authorized users, including electronic brachytherapy and internal radiations.

And no physician is allowed to use those without written approval of the individual state and licensure. These rules have existed for decades, and each state really does take charge of that. And I know, I think that that's still where that should remain. I love the idea of a specific AAPM panel to come out with guidelines specific to these modalities.

SRT clearly has been regulated in the same way for a long time, but now that

it's becoming much more of a community standard and a first-line choice for folks who have lesions and difficult to resect areas, it's sort of making a comeback with these newer efficacies that we're seeing.

I think it's great that we're going to address that at a larger and more national scale, but I think that it is, you know, it is just important to remember that SRT historically has been an IGSRT, which is the same part of the - there's a similarity in the therapeutic modality, but really the experts on skin cancer in dermatology offices should be the ones who are - well, not the only ones, but should be allowed to continue using this.

You know, it's also worth saying that there's more of these non-melanoma skin cancers treated every year than all tumors treated by RAD ONC, and so I think that, you know, relegate or keeping this in the derm - and the hands of the derm for the first-line therapies makes a ton of sense.

And the states, I think, and the oversight when it comes to safety should remain where it is, which is in the individual state medical boards. With that said, obviously, more research is wonderful, and more oversight from physics is great, and I think that's what I wanted to say here.

Olatokunbo Awodele: Thank you very much, Dr. Schaening.

Juan Schaening Perez: Okay. Let's go to question number 8, please. Are there standardized published protocols to define ultrasound findings and measurements for superficial skin lesions? A, if there are standards, do they take into account patients with irregular skin, irregular tumors, crusting, bleeding, ulceration, et cetera, as this can impact the death of the lesion? B, several of the studies specify limitation of the high-resolution ultrasound to 6 millimeters in depth. Do you agree with this finding? Why or why not?

Dr. Posten, could you start answering this question, please?

William Posten: Yes. Thank you. So, in terms of are there standardized published protocols, to my knowledge, there are not standardized published protocols that define ultrasound findings and measurements for superficial skin lesions. You know, do they take into account patients with irregular skin, irregular tumors, crusting, bleeding, et cetera?

The question is correct. I mean, in my belief is that these changes can impact the depth of the lesion. Typically, in clinical practice and in my practice, these types of changes preclude and disqualify the use of high-resolution ultrasound. And then in terms of several studies specify the limitation, I agree with this depth in my clinical experience, but my understanding is that this limitation really depends on the frequency of the ultrasound and the type of ultrasound being used.

The technology is rapidly changing. I know that we use a 22 megahertz ultrasound machine, and I understand that there's even differences among those. So, yes, in general, 6 millimeters sounds right, but this is a rapidly changing technology. Thank you.

Juan Schaening Perez:Thank you for your feedback. Dr. Rogers?

Howard Rogers: Yes. I agree there are no published or standard protocols for using ultrasound to determine the extent of lateral margins nor to measure the depth of the skin cancer. There's no published validation of ultrasound findings and correlation with microscopic tumor depth or the extent of lateral margins associated with delivery of SRT. There's no published validation of changes in ultrasound findings during a course of SRT therapy corresponding to specific biologic

changes in the tumor surrounding tissue.

There's no evidence that small day-to-day differences in ultrasound measurement of a tumor's depth is biologically relevant, or whether it's just an artifact of non-exact measurement by the ultrasound device itself. In terms of the irregular skin, you know, it has been repeatedly noted in the literature that factors such as irregular skin surface, irregular tumors, crusting, bleeding, and ulceration all affect the ability of ultrasound to detect the tumor and measure depth.

However, the published IGSRT studies list results from sites like ears that would, obviously, fall within these limitations, and the studies also don't mention any exclusion for bleeding, ulceration, crusting of the tumors within their results. In terms of the ultrasound depth, I agree with Dr. Posten, this depends on the frequency of the ultrasound.

The ultrasound devices of different frequencies can be used to focus resolution more deeply than 6 millimeters, but this would decrease the ability to visualize superficial structures. Recent studies in IGSRT confirm that the most common ultrasound in use today uses 22 megahertz, and recent studies state that ultrasounds in that frequency range are used for visualizing superficial skin depths of 0 to 6 millimeters. Thank you.

Juan Schaening Perez:Thank you. Dr. Chuba?

Paul Chuba: My comment is that I think, by all means, get an ultrasound, if you like, and that might help you to estimate the depth of invasion. But that shouldn't justify the use of billing for IGRT. And, basically, if you're concerned that the tumor's too deep, just use electron therapy.

Juan Schaening Perez: Thank you. I appreciate your feedback, Dr. Chuba. I am Dr. Mammen.

Jacob Scott: I agree with your earlier comments that there are no standardized protocols and standards that are widely accepted, so I think there's a lack of standardization in this area.

Juan Schaening Perez: Appreciate the feedback of you all, and let's move then to question number 9. Dr. Awodele?

Olatokunbo Awodele: Thank you. Thanks, Dr. Schaening. Now, this question here, looking at it, we've kind of touched on it a little bit so, but we'll separate it out and I'll be very interested in hearing people's responses. So, this question will be addressed by Dr. Ladd, Powell, White, and Baker.

And the question is simply, should there be limitations on the number of treatments or treatment sessions, use of image guidance, radiation planning procedures, and who can perform these procedures in terms of education and training. So, Dr. Ladd?

Daniel Ladd: Yes. Thank you. The use of high-resolution dermal ultrasound imaging is an integral part of image-guided SRT. And the course of treatment for image-guided SRT for which there is peer-reviewed published literature, demonstrating freedom from recurrence rates in excess of 99%, consists of the delivery of 20 sessions, inclusive of high-resolution dermal ultrasound imaging and radiation treatment at each session, which is standard within therapeutic radiation.

The imaging is performed by the radiation therapist, who also does the appropriate measurements of the tumor and field. Based on the measurements, established tables are utilized to determine the need for any alterations to the

radiation treatment plan.

The dermatologist will order, review the images and measurements, and must sign off on the treatment plan. In addition, a medical physicist reviews the dose calculations and treatment plan every five treatment sessions, and a radiation oncologist is available for consultation if needed.

At the end of the treatment cycle, a confirmatory image is performed to assure complete eradication of the tumor cells. It should be noted that image-guided SRT, unlike other forms of SRT, utilizes a multidisciplinary team approach. Image-guided SRT can be safely administered by a dermatologist working with a radiation therapist and supported by a medical physicist and radiation oncologist.

The radiation therapist receives education and training in the administration of radiotherapies and imaging techniques as a part of their educational and clinical rotation program. In residency programs, dermatologists receive education and training on the use of imaging and occasionally the use of SRT. But, unfortunately, since the rise of Mohs surgery, this form of training has been rare.

As with any therapeutic not taught in the formal education programs, the burden falls to other means. This is typically industry. The manufacturer of the IGSRT and other radiation therapy equipment has developed a formal education and training program that all dermatologists and radiation therapists must complete and pass prior to installation of the equipment.

In addition, management service organizations have their own education and training programs, including ongoing education that the dermatologist and radiation therapist must complete and pass prior to installation of the

equipment. More importantly, applicable state laws must be followed for the safe delivery of radiation therapy to the beneficiary, including any structural requirements where radiation therapy is delivered and any applicable supervision or training requirements for staff participating in the delivery of radiation services.

The state requires manufacturers to certify completion of the training prior to approval for installation and utilization. And finally, the radiation therapy services must be within the physician's scope of practice and consistent with any additional state regulations and guidelines. As far as the value of the imaging, Stryker, et al. did a study in which they identified that 92% of the time, the tumor does change in shape and size, and this is significant because the percentage step dose is changing as well.

So, as the tumor changes, the percentage step dose number is different. So we're making sure that we get enough radiation with each fraction to reach the bottom of the tumor. And because radiation gets weaker as it goes through the dermis, these measurements are significant and meaningful and lead to improvements in efficacy and reduction in toxicity. Thank you.

Olatokunbo Awodele: Thanks, Dr. Ladd. Dr. Powell?

Donna Powell: All right. The NCCN Guidelines currently do not recommend superficial radiation for treatment and, therefore, they don't document the number of treatments, treatment sessions, image guidance, or treatment planning. However, the guidelines do document the ranges of doses decided on by the panel for external beam.

The panel feels that the radiation oncologist and treating team should make the final decision on the fractionation of the treatment plan based on evidence

and consent reviews accepted by the panel. And great, we've seen the NCCN Guidelines, the panel that the radiation oncologist is a certified medical dosimetrist require extensive training, education, and national certification to be qualified to perform the treatment plan. Thank you.

Olatokunbo Awodele: Thank you. Mr. White? Dr. Baker?

Gerald White: Yes. Thank you. So, I think there - I'll just answer specifically as I can. I don't think there should be limitations on the number of treatments or treatment sessions. That's clinical decision, patient-specific, modality-specific, and so the answer to that first part is no. Use of image guidance. I've said previously that there is no image guidance done for these procedures based on the CPT description of image guidance.

We've heard some of the potential benefits of doing a diagnostic ultrasound to assess the depth of the tumor. I think the thought that there's a lack of serious evidence that doing that on a daily basis provides any value at all, and there is significant conceptual difficulty with that.

If you look at the depth dose for the various beam energies and the depth changes that are hypothesized to occur through these sequential ultrasound systems, it just doesn't add up that there's a significant difference that needs to be adjusted for on a daily basis.

I look forward to seeing some publications that would demonstrate that, but I haven't seen them yet. Radiation it. Who can perform these procedures as far as education and training? I note, as have others, that the residency standards requirements for dermatologists don't include training in radiation therapy. It might be a good thing if that occurred, but it doesn't exist now.

There has been some discussion of dermatologists having done these procedures for 100 years, and I can tell you that may be true, but the contemporary principles of radiation oncology were not applied by those dermatologists, and I can say that having worked with dermatologists over the last 40 years of my career, that the training is non-uniform.

And lastly, I'll say I did have the opportunity a number of years ago to review the training provided by the manufacturers of these systems, and I was, I think, to even suggest it has any equivalence at all to residency training is just incorrect. Thanks.

Olatokunbo Awodele: Thank you, sir. Any other comments on this question?

Dole Baker: Yes, I would. This is Dr. Baker.

Olatokunbo Awodele: Dr. Baker, you said.

Dole Baker: Yes. Absolutely yes. I think that there should be limitations. Given the resource heavy and high costs of superficial radiation therapy with or without image guidance, and the lack of demonstrable improved outcomes versus traditional treatment with Mohs or surgical excision, then limitations in guardrails should definitely be employed to be able to be competent stewards of Medicare and Medicare's resources.

And, additionally, I've yet to see any convincing evidence why image guidance needs to be utilized and paid for given the superficial and easily seen tumors that are easily treated with other modalities.

Olatokunbo Awodele: Thank you, sir. So, Dr. Schaening over to you.

Juan Schaening Perez: Okay. Thank you. Then let's move to question number 10. Key question number 10 says as follows. It has been foretold that the cosmesis is superior with either SRT or EBT treatments. How does the literature support that assertion to be the case?

Is this based upon subjective or objective evidence? Is there any comparison to traditional procedures in cost-message support by the leadership. What about the telangiectasias and skin changes that occur to irradiated skin short-term and long-term?

Okay. Dr. Lukens, could you start addressing this question, please?

John Lukens: Sure. So, there's very little data comparing cosmesis between primary modes or surgery versus superficial radiation therapy in the literature. The sparse data that does exist, again, published by the same author with a conflict of interest, it's a paper titled Enhancing Cosmesis While Achieving High Cure Rates for Early Non-Melanoma Skin Cancers published in 2021.

Their median follow-up for the SRT patients was 16 months, so, obviously not, that very short follow-up, not sufficient to account for late toxicity, fibrosis, et cetera. We all know what the long-term side effects of radiation are. They can be significant, so 16 months of follow-up is, obviously, not sufficient.

Furthermore, the cosmesis was graded by clinicians as good, very good, or excellent. So, this paper was published in a very low-impact journal once again, and that's about the best data that I could find to support any comparison between cosmesis and Mohs surgery, you know, for SRT. Thank you.

Juan Schaening Perez: Thank you. Dr. Hruza. Thank you.

George Hruza.: Dr. Hruza, sorry, I tend to agree. There was a study about 15 years ago, comparing SRT with surgical tumor section. We found that cosmetic outcome was better in the first two years after SRT than surgery. But the SRT lesions, the areas then looked worse when you were more than two years out, and progressively got worse over time.

I think the challenge is that these take many years to develop. And so, because of that, it's very difficult to do studies when you see patients 5 or 10 years later. So, what we have anecdotally, we see them in our office when those patients come back with recurrences, and we see the radiation changes when it's 5 years, 10 years later or we get secondary malignancies 15 or 20 years later.

That is the biggest problem. I think the other issue is that some of these treatments have been suggested, some of the EBT treatments were done with eight treatment sessions, and with such high doses, such large fractions, it's most certainly going to end up with a cosmetic outcome down the road.

So, certainly, if you do these treatments, you've got to go for at least 20 fractions to minimize damage to the skin. Thank you.

Juan Schaening Perez: Thank you. Dr. Chera, your take, please.

Bhisham Chera: Yes. I agree that there's not really good data comparing and the data is basically clinician-reported. That being said, in clinical practice, you know, it's very variable depending on who the most surgeon is and also what region you're treating with radiotherapy where it's located. And, you know, with proper multidisciplinary input and teamwork, you know, one modality

may be favored over the other for the possible improvement or perseverance of cosmesis in the opinion of the treating physician.

Juan Schaening Perez: Thank you. And Dr. Scott, your take on question number four.

Jacob Scott: Yes, I'd like to - oh, yes, sure. I'd like to echo, I think, what almost everyone said. I think, in particular, Dr. Chera, I really disagree with what you said. Like, you know, cosmesis isn't, we - most of the papers are like what we think about the cosmesis that the patient has, but really it should be about how the patient feels about their cosmesis, because that's their body.

And, you know, I think that it's difficult because cosmesis is subjective, largely, and if a patient's happy with what they have and we think it doesn't look great, is that good cosmesis or bad? And if the opposite is true, if we think it looks great, but they - you know, they've lost competency in their mouth and drooling, and they're unhappy, is that good?

I think it's just really hard to grade what cosmesis is. And I think the most important thing that Dr. Chera just said is, you know, it's lesion, the determination should really be made lesion-to-lesion-to-lesion with a multidisciplinary team and food for patients. And it depends on really, you know, what the goals of therapy are.

Obviously, curing a tumor is a goal, but also maintaining function. And so, depending on where the lesion is, who the patient is, I have an anecdote, which I shouldn't, you know, use in scientific discussions, but my mom just had a basal cell treated with IGSRT on her chin when she had previously had one on a different part of her face.

And, you know, I think having a choice is important, and, you know, she

wouldn't always choose the same thing, but she's happy with the cosmesis, and I think that the customer - sorry. Hot customer. The patient satisfaction survey studies that exist are super flawed, but they're kind of all we have.

You know, I think the good news is the objective published toxicity scoring based on RTOG criteria suggests that SRT and IGSRT have incredibly low, you know, less than 1% grade 3 and 4 toxicities per RTOG. But, like the other people have said, you know, these change over time, acute is different than chronic. And, you know, I think we do have long-term data on SRT, 100-year data, but not on the newer - there's no reason to expect to be different for IGSRT.

Juan Schaening Perez: Thank you for your feedback, Dr. Scott. And let's move to question number 11. Dr. Awodele?

Olatokunbo Awodele: So, this will be addressed by Dr. Posten, Rogers, Chuba, and Mammen, and the question is, what if complications develop during or between treatment sessions? Will a break in treatment, alter treatment planning, and potentially affect the outcome of the treatment? Dr. Posten?

William Posten: Yes. I guess I'll start. Yes. Thank you. So, the answer is yes. A complication such as erythema, ulceration, swelling, or pain triggers a break in treatment. Usually, the complication resolves with the break in treatment. A dosimetry calculation is usually performed to determine whether to change the prescription and/or treatment protocol. Assuming that the total number of breaks are less than 100 total days, this does not affect the total dose factor and does not affect the outcome of the treatment. Thank you.

Olatokunbo Awodele: Thank you.

Howard Rogers: Dr. Rogers. I don't have anything to add.

Olatokunbo Awodele: Okay. Thanks, Dr. Rogers. Dr. Chuba? Dr. Mammen? Okay. Here you go, Mammen. I'm sorry.

Paul Chuba: I'm going to add. I was...

Olatokunbo Awodele: Okay.

Paul Chuba: I was just going to briefly add that grade 3 and 4 toxicities are fairly rare. So, as mentioned, most of the toxicities are local wound-related issues, and grade 3 and 4 are well under 1%. And as mentioned earlier, short-duration delays from these toxicities are well-tolerated and have little effect on efficacy.

Olatokunbo Awodele: Okay. Thank you very much. Any other comments? No. Dr. Schaening, back to you.

Juan Schaening Perez: Okay. So, let's move to question number 12, please. So, question number 12 is, is there literature comparing cosmetic results of traditional excessions or most procedure to SRT or EBT, and does it support one being superior to the other? Let's start with Dr. Ladd, please.

Daniel Ladd: Great. Yes. Once again, the question does not recognize image-guided SRT as the separate and distinct treatment that it is. Image-guided SRT should be a first-line alternative for the treatment of low-risk and high-risk basal cell, squamous cell, and squamous cell carcinoma in situ, based on the safety and cure rates that are equal to or better than Mohs surgery.

In fact, it should be the treatment of choice for patients with comorbidity concerns, such as patients who are on blood-thinning medications, patients

with diabetes. It should be the treatment of choice for patients with functional concerns. For example, when a small non-melanoma skin cancer involves a delicate or highly functional structure like the nose, ears, lips, or eyelids.

And then there are patients that have a predisposition to the formation of keloids, especially patients of color or Asian descent. But I agree with Dr. Scott in his answer to question 10. Cosmesis is a subjective determination. More often the measurement is in patient satisfaction surveys.

Surveys of over 20,000 patients treated with image-guided SRT showed satisfaction scores of over 99% with satisfaction with the outcome and would refer to others. A review of the peer-reviewed literature illustrates virtually no side effects of the image-guided SRT treatments. You at all in the peer-reviewed study of 2021 reported grade 3 RTOG toxicity of 0.7%, that's 16 out of 2,177, and a grade 4 RTOG toxicity of 0.2%, which is 4 out of 21, 2,177. Thank you.

Juan Schaening Perez: Thank you. Dr. Powell, please, your take.

Donna Powell: Thank you. As stated before, it's the NCCN panel's position's role to determine the sufficiency and quality of the evidence in those procedures and surgery compared to external being. The panel members reviewed the evidence comparing the treatment modalities and procedures, and they vote on their superiority.

And the results of the vote at the time of the panel meeting are evidence that states multidisciplinary panel votes that indicate the preferred treatment method is indicated by categories of evidence. And most categories of evidence are stated as a 2A in our guideline, which means that 85, greater, that are equal to 85% of the panel agree with the recommendation.

So, while it's not 100%, the consensus is that it is an acceptable treatment. Thank you.

Juan Schaening Perez: Thank you. And Mr. White?

Gerald White: Yes. Thank you. I don't have any - I thought the answers to question 10 were, I don't have anything to add to that discussion. And I do think, though, that in describing potential benefits with respect to cosmesis for the IG part of IGSRT. It would be helpful to understand what the technical or theoretical underpinnings of that might be. What might the IG part contribute to improved cosmesis?

And I remain puzzled by that. And I haven't heard any convincing arguments that there is some theoretical possibility that the image guidance would enhance cosmesis as opposed to clinical judgment about prescription and prescription depth. But I would look forward to either an explanation of that or perhaps some well-structured publications that describe the benefit.

Juan Schaening Perez: Thank you, Mr. White. Dr. Baker, your take on number 12, please.

Dole Baker: Yes. There is not any literature directly comparing cosmetic results of traditional excisions to SRT, especially with regards to prospective blinded trials. There are for sure validated opportunities to evaluate cosmesis. It's been used in the facial plastic literature for years. And is independent analysis of the patient's own personal opinion. There was a study that was published in Cancer in 2019.

It was a meta-analysis of 58 studies and 21,000 patients, and it compared Mohs with external beam radiotherapy, standard surgical excision,

and brachytherapy, and they concluded that Mohs and brachytherapy had better cosmetic results. But they also noted that it was unclear whether this was because of treatment superiority or selection and reporting biases. And I'm aware of absolutely no studies that have demonstrated superiority of superficial radiation therapy for cosmesis over Mohs.

Juan Schaening Perez: And thank you for your feedback, Dr. Baker. Then let's move to question number 13. Dr. Awodele?

Olatokunbo Awodele: Thanks, Dr. Schaening.

Juan Schaening Perez: So, I'm just going to be addressed by Drs. Lukens, Hruza., Chera, and Scott. And the question is, what ancillary services / procedures / planning are required with a traditional surgical excision to most efficient to EBT and IGSRT? I guess comparing what's needed between the two - between all these modalities, you know, two, three, four, so. All right. Dr. Lukens, you want to say one.

John Lukens: Yes. Sure. So, not being a surgeon or a Mohs surgeon, I can't comment on A or B. I can just explain what we do in an external beam radiation. We do a treatment planning procedure, it's called a simulation, that's either CAT scan or a PET CT scan for complex deep tumors. We can do a clinical setup if it's an easily seen tumor on the skin, like a superficial skin cancer. We just do a clinical setup, we don't need to do a CAT scan and anything like that.

Then we do treatment planning in conjunction with a medical dosimetrist that for a skin cancer would be picking the electron energy, the size of the cutout that's used to shape the field, the prescription dose depth, i.e. prescribing to the 90% isotope line, and the quality assurance procedures for the linear accelerator, which is really standard in all radiation oncology, which includes

plan-specific quality assurance using a phantom to confirm dose delivered in patient.

And occasionally, we'll place a radiation dose monitor right on the skin to confirm the dose of what we were planning to give. Thanks.

Olatokunbo Awodele: Thanks. Dr. Hruza?

George Hruza: Yes. So, being a Mohs surgeon, I'll talk about those. So, for traditional surgical excisions, the decision to perform surgery and all planning is included in the global package. Post-surgery visits and handling most complications are included in the global package. And simple and immediate repair is included in the excision survey, but any other sort of repair is separately reported. Pathology is not included in the global package.

For Mohs, the decision from surgeon, all plans including in the package, and the defect repair is reported separately, and pathology is included in that. And I will leave the EBT and SRT to others.

Olatokunbo Awodele: Thank you. Dr. Chera? Dr. Scott?

Bhisham Chera: Yes. So, again, I'm a radiation oncologist and I'll give a perspective of using SRT without ultrasound because that's what I was trained to do when I was a resident. But the way that would work is, you know, these are patients that have very small, early stage, very thin tumors.

And so, we would do a clinical setup in the room with the SRT machine. It would be a medical physicist, a dosimetrist and a therapist there. We choose the appropriate cone size, and we would do the dose calculations by hand back then, and then verify them, double and triple check them.

And then we would, you know, the patient would see the first treatment. And with each daily treatment, as a physician, I would be called in to verify with the therapist that the cone was positioned in the exact area that we wanted to be treated.

We did not do adaptive. We did not have an ultrasound. We didn't think there was a benefit to that, and, you know, the outcomes are generally excellent. I think, in general, what I want to say is that, you know, SRT is a valuable treatment. We need to have patient access to it. We need to be able to deliver it in a valued way with cost consciousness as providers.

It is a useful technique, and I think what has been repeated a lot here is what's the value of the ultrasound. And I personally, you know, from a clinical standpoint, I don't see the value, but I know talking to other people, that they feel that there's value in doing this daily ultrasound and adaptive planning. But I do want to end by saying that I think SRT does have a place for the treatment of skin cancers.

Olatokunbo Awodele: Thank you, Dr. Chera.

Bhisham Chera: Thanks, Awodele.

Olatokunbo Awodele: Dr. Scott, if you'd like to add.

Jacob Scott: So, yes, please. So, I'm also a RAD ONC, so I'm not going to comment on A or B, and I guess we're all assuming that EBT here means electron and not electronic brachy. I'm not sure what the point was there, and what I'm going to focus on just for this, because no one else has really talked about it, is what is involved in an IGSRT treatment rather than any of the ones mentioned here.

And I think that's important maybe to answer a few of the questions people have been asking Dr. White and some others along the way during this conversation about, you know, what is the benefit of, you know, how could an ultrasound affect toxicity? How could an ultrasound affect efficacy and toxicity?

And I think that comes down to an entire sort of cancer center-like approach to the treatment, so standardization. We mentioned earlier, I think, I can't remember, I think it was Dr. Baker who mentioned that some of the higher doses per fraction could result in significantly different toxicity profiles compared to a more prolonged course.

And I think that one of the things that we've done as a society, well, in this - in the New Society of Dermatology Association of Radiation Therapy, is really try to standardize the approach. And we've actually published some on our Web site, mind you, the appropriate use criteria.

And I'm going to describe what that entails, and we'd love feedback on that. And I do think that it's the combination of the daily imaging, the assessment of the lesion, targeting, for sure, where you are. Instead of looking at a cone visually, you're now looking at it with a more - with a better scope, if you will, well, in terms of imaging.

And then further, there's a standardization to the process, oversight from medical physics and oncology, just like we have in the oncology clinic. So, I think, you know, really, a multidisciplinary team, including a licensed therapist, the treating physician, access to physics and oncology as well and then use the ultrasound to verify histology in depth, localization.

And then clinical treatment planning like Dr. Chera described, making sure the dose, that in depth are appropriate and creating of the lead shielding. And then the rationale for the daily treatment is just to make sure that those things haven't changed significantly.

And I think that the literature now supports that the use of the entire protocol together is providing better efficacy. What part of that protocol is exactly responsible for that change in efficacy, I think, as others have mentioned on this call, is not obvious, right?

A bunch of things have changed. We've gone from a kind of more wild west, you know, dealer's choice approach to fractionation and scheduling and targeting and dose fractionation to a now standardized protocol, or at least one that's recommended to be standardized.

And what we're finding is when we study that standardized regimen, which includes image guidance daily, the efficacy goes way up and the toxicity goes down. Is it exactly the ultrasound? I'm not sure. I don't think we can say that quite yet. But I do think that looking at the published studies, especially from this past year, which I think are of higher quality and massively improved on numbers and transparency, I don't think it's - I think it's undeniable that the results are better.

And they have now come from where SRP was once a reasonable thing to call second line because the efficacy was that much significantly lower than Mohs, we've now come to a point where there's, I think, at least, I think we can claim equipoise and bring that modality back to what should be considered a first-line alternative, or it's your choice depending on the patient and the team's choice when it comes to what's delivered.

And so, I do think that the standardization, fractionation, and then sort of thoughtful approach that the IGSRT protocols have, including daily imaging, but also including other things, is probably what's driving this change in efficacy. And I think if we don't consider it a package, we're not talking about the same thing.

Olatokunbo Awodele: Okay. Thank you, Dr. Scott. And I'm going to consider that your one-minute closing statement that you've just made. So, I'd like to thank everybody and now we're at the point where I want to invite each subject-matter expert to provide us just a one-minute closing statement summarizing what you consider is your key point or takeaway from today's discussion.

So, like I said earlier, I consider what Dr. Scott just said his one-minute, so I'll go to Dr. Baker, if you could just, you know, in one minute, summarize today for us.

Dole Baker: So, just to be clear, superficial radiation therapy with or without image-guided guidance is for lesions that are generally about less than 3 centimeters in size and less than 5 millimeters in depth, which is just over an inch and under a quarter of an inch very, very small lesions.

First line of gold standard treatment and has been a surgical excision of these lesions over the years, either standard or with Mohs, along with pathologic and histologic margins. It's very hard for me to fathom a patient who is not a surgical candidate for an excision of one of these lesions, this small under local, and it would be even harder for me to fathom that they could lie still for 20 treatments and transport back and forth for treatment of such lesions as opposed to one single setting.

There's no overwhelming evidence that the cosmesis is any better for

superficial radiation therapy. It's reserved mainly for patients with lesions in those areas that surgery would fundamentally compromise such as the eyelids or the canthus. Additionally, Medicare traditionally does not pay for cosmetic procedures.

Olatokunbo Awodele: Thank you, Dr. Baker.

Dole Baker: Thank you.

Olatokunbo Awodele: Sorry. And I just wanted to insert in here that we would certainly appreciate all these comments in writing as well. So, sorry, Dr. Chuba?

Juan Schaening Perez: want to thank everyone. Oh, sorry.

Paul Chuba: So, radiation oncologists depend generally on dermatologists for referral for radiation treatments. But most of our patients are already non-surgical. For many years, we've treated tumors around the eyes and the nose and the lips because of cosmesis with great success, and I provided an example in my email, comments.

I would like to point out that in Canada and Europe, radiation is far more prevalent in its use for these treatments. That's all.

Olatokunbo Awodele: Thank you. Thank you, sir. Dr. Hruza?

George Hruza: Yes. Thank you. So, SRT or IGSRT is an excellent option for patients that are non-surgical candidates. With primary treatment, SRT is less desirable due to uncertain cure rates, delayed sick quality, such as negative cosmetic outcomes and secondary malignancies.

There's also difficulty with treating SRT recurrences due to frequent multifocality of the tumor, along with more difficult reconstruction of radiated skin with high risk of necrosis, infection and difficulty healing. SRT should be used for all the patients due to the risk of secondary malignancies that have a 20 to 25 year lifetime. Thank you.

Olatokunbo Awodele: Thank you, Dr. Hruza. Dr. Ladd?

Daniel Ladd: Yes. Okay. So, a couple key points. Image-guided SRT is not SRT. It is a distinct treatment-encompassing high-resolution dermal ultrasound with each fraction of radiation delivered to the patient. This is the single factor leading to the freedom from recurrence rates that are superior to SRT and at least as good, if not better than Mohs surgery.

Also, image-guided SRT utilizes a multidisciplinary team consisting of the prescribing dermatologist, a radiation therapist, medical physicist, and radiation oncologists. Also, image-guided SRT is not IGRT. The guidelines pertaining to IGRT do not apply to image-guided SRT.

Guidelines developed by the NCCN, AED, and ASHRAE did not take into consideration any of the published studies on image-guided SRT. To reference them with respect to IGSRT would be misleading. IGSRT is the community standard of care for the radiologic treatment of early-stage NMSC.

There are eight peer-reviewed published studies on IGSRT issued since 2021. When taken into consideration collectively, the evidence is overwhelming with over 20,000 lesions showing five-year or more freedom from recurrence rates of over 99% regardless of segmentation by age, sex, histology, risk, and body location.

The standard treatment protocol used to obtain these success rates included high-resolution dermal ultrasound imaging with each of the 20 fractions. There is no published literature to substantiate the same clinical efficacy utilizing high-resolution dermal ultrasound less frequently or not at all. Any suggestion otherwise would be an unsubstantiated opinion.

Finally, the most important aspect, image-guided SRT should be a first-line alternative for the treatment of low-risk and high-risk basal cells, polymethyl and polymethyl carcinoma in situ based on the scientific evidence, validating safety and freedom from recurrence rates that are equal to or better than Mohs. Thank you.

Olatokunbo Awodele: Thank you. Dr. Chera?

Bhisham Chera: Yes. I want to thank everyone for sharing their perspective and I've learned a lot. Again, I think SRT has a role to play in skin cancer treatment. I think the issue is what is the value of the ultrasound in the use of correct CPT codes when billing for this is important and, you know, the importance of the multidisciplinary collaboration is important for managing skin cancers and so, you know, SRT has a role, but it's unclear to me about the ultrasound. Thank you.

Olatokunbo Awodele: Thank you, Dr. Lukens.

John Lukens: Yes. Thank you for letting me be part of the panel. So, if we take Mohs as sort of the gold standard, I think there's, and then we talked about some of the other modalities, I think that extra room name radiation is a good second line treatment option for patients who are non-surgical candidates or who have tumors, say large tumors on the nose where you don't want to do a partial or a total rhinectomy.

I agree, you know, SRT, probably a good option to remain for patients to have. I think the data supporting superiority of "image guidance" is still lacking sufficient follow-up and quality as evidenced by the quality of the publications.

I think it was Dr. Scott who has an interest in, you know, developing more rigorous protocols for treatment with IGSRT, and I look forward to the results of those standardized treatments, which will take probably about five years to get the clinical follow-up data on. Thank you.

Olatokunbo Awodele: Thank you. Dr. Mammen?

Joshua Mammen: Thank you, as well, for allowing me to participate in this panel. I agree with the other comments that SRT has a role to play in non-melanoma skin cancer, particularly in patients who are not candidates for surgical resection or opt not to have certain standard of care surgical resection.

For the image-guided version, IGSRT, the data, as others have pointed out, are still very early in terms of follow-up and quality, and certainly are not sufficient to recommend at this time.

Olatokunbo Awodele: Thank you. Dr. Posten.

William Posten: Yes. Thank you for having me on this panel. I just want to also say that I think that it's important for patients to have access to SRT therapy. I think it's important to allow dermatologists to continue to be able to use this in their offices.

In terms of IGSRT, I think that more research needs to be done, we need more

standardized protocols. And I agree with just following the AED and NCCN Guidelines for the usage of these therapies. Thank you.

Olatokunbo Awodele: Thank you, Dr. Posten. Dr. Powell?

Donna Powell: Hi. Thank you for letting me participate in this panel. NCCN's role is to facilitate the process of updating the guidelines based on physician agreement through voting. Each panel member across 33 member institutions, including the patient advocate, vote on the recommendations within the guidelines, ensuring a multidisciplinary, non-biased, interactive opinion for the recommendations that are within the guidelines.

All members of the committee are still in process. NCCN contains evidence-based, consensus-driven data. The consensus is multidisciplinary, and all members feel strongly that radiation oncologists should perform radiation treatment, dose-to-dose site plan, image guidance, and other services associated with radiation therapy. It does not feel as if they should be included in the guidance at this time.

The NCCN panel has decided the appropriateness of SRT treatment should be performed by radiation oncologists. Extensive screenings of physicists are essential to perform quality assurance. If form-appropriate radiation doses are delivered, extensively trained certified medical dosimetrists are essential to secure the radiation therapy under the radiation psychologist's guidance. Thank you.

Olatokunbo Awodele: Thank you, Dr. Powell. Dr. Rogers?

Howard Rogers: Hi. So, you know, I didn't introduce myself before, I'm a board-certified dermatologist and fellowship trained in micrographic hemorrhagic surgery

and cutaneous oncology. I've treated tens of thousands of skin cancers using the full gamut of surgical and non-surgical treatments, and I have no industry conflicts.

SRT and EBT, you know, may be effective in the treatment of select skin cancers, and I think that access is important. But these modalities are not out of panacea and not the best thing since sliced bread. Radiation, even SRT, is not benign and it carries potentially life-altering clinical risks.

Significant care needs to be taken to ensure that patients receive the appropriate level of care for their skin cancer. That being said, I am concerned about the current promotion of IGSRT. The value of the image guidance is based on highly flawed and conflicted literature that has been rushed through an inadequate review process.

This is true in the papers that report 1,000 patients and it's true in the patients - in the paper that reports 20,000 patients. IGSRT is aggressively marketed by industry interests that focus on vulnerable patients and impressionable dermatologists at a time when office revenues are contracting.

Careful attention needs to be paid to ensure that patients only receive services that are proven safe and effective, appropriate and medically necessary. Thank you.

Olatokunbo Awodele: Thank you, Dr. Rogers. Mr. White?

Gerald White: Thank you. I just summarize it. I think we're agreed that - many of us agreed that superficial radiation therapy is a well-established therapy for non-melanoma skin cancers. There are just guidelines on appropriate patient selection which should be taken into account by clinicians and patients as they

choose a therapy course.

The daily, an initial ultrasound might provide some useful information. Daily ultrasound is unwarranted. We talk about stratification in a great many studies, but the relevant stratification is daily ultrasound versus no daily ultrasound.

And there - to my knowledge, there's nothing that does a direct comparison, randomized controlled study with that sort of thing. But daily ultrasound is unwarranted and I believe should not be considered appropriate care for these patients.

Olatokunbo Awodele: Thank you very much, sir.

Juan Schaening Perez:Okay. So you can go, I think Dr. Scott.

Olatokunbo Awodele: And so...

Jacob Scott: Ma'am, I was unaware previously that I wouldn't be able to make a closing statement. Can I have just 30 seconds? I just have two things I wanted to say.

Olatokunbo Awodele: Okay. Sure.

Jacob Scott: Thank you. And I apologize. I just didn't realize that my last part was part of that. So, I just think it's...

Olatokunbo Awodele: Well, I decided that because you spoke about more than what the question had asked, so I just assumed that, okay, I'll let you finish talking so that, you know, and that will be part of your one minute, but that's fine, 30 seconds.

Jacob Scott: So, I apologize. Ma'am, so also, thank you very much for letting me be part of the panel. I think I've learned a ton as well. I think that, you know, all new technologies get pushed back when they first come, and there's lessons to change because we're all comfortable with the way that we do things. But I do think that what we're seeing and people are saying is that, you know, there is growing literature on this treatment, and if we kill this technology now, we'll never know the real answer.

I do think it's important that we continue to study it. And I do think that IGRT and IGSRT are different, and we should push to have codes specific for our IGSRT and not utilize the ASHRAE codes, but that doesn't mean we shouldn't have anything. So that's all I wanted to put out there.

Olatokunbo Awodele: All right. Thank you very much, sir. And I'd like to thank everyone on behalf of Noridian Healthcare Solutions, CGS Administrators, NGS which is National Government Services, Palmetto GBA, and WPS Government Health Administrators.

I would like to thank everyone for their valuable contributions and insights. And your expertise is crucial in helping us make informed decisions regarding the use of these technologies that we've discussed today. Thank you. Dr. Schaening, would you like to add anything to one-minute.

Juan Schaening Perez: Yes. Second your thoughts, you know, we appreciate everyone's participation and thoughtful discussion. With that, we conclude today's meeting. Thank you once again and have a great day. We appreciate your caring for our beneficiaries and the Medicare program. Have a beautiful day. Thank you, all.

Olatokunbo Awodele: Thank you.

Jacob Scott: Thank you.

Olatokunbo Awodele: You may now disconnect. Operator, can you...

Coordinator: Thank you, everyone.

END