January 2004 By Lynne Peterson

SUMMARY

IMRT use is continuing to grow, and hospitals have added this capability to most if not all of their linear accelerators. • IMRT is being used for an average of 44% of patients. Medicare reimbursement cuts do not appear to be affecting IMRT use or orders. • IMRT systems are considered fairly comparable, and hospitals continue to be willing to mix and match accelerators and IMRT planning systems. • IGRT is the hot new radiation oncology product. It is considered both very important and very time consuming, and most new LINACs are expected to be equipped with IGRT. Doctors said it's too early to tell how Varian's Trilogy and Elekta's Synergy stack up.

Trends-in-Medicine has no financial connections with any pharmaceutical or medical device company. The information and opinions expressed have been compiled or arrived at from sources believed to be reliable and in good faith, but no liability is assumed for information contained in this newsletter. Copyright © 2004. This document may not be reproduced without written permission of the publisher.

Trends-in-Medicine

Stephen Snyder, Publisher 1879 Avenida Dracaena Jensen Beach, FL 34957 772-334-7409 Fax 772-334-0856 www.trends-in-medicine.com

IMRT AND IGRT UPDATE

A year ago, radiation oncologists, physicists and radiation oncology technicians said IMRT use was growing, and the trend was expected to continue. According to radiation oncology experts at 11 hospitals (not free standing centers) IMRT definitely has caught on, and there doesn't appear to be any softening of the market. A source said, "All LINACs have IMRT capability. IMRT use is here to stay. If the center down the block has IMRT, even if we were going to lose money on it, we're going to have to get it. That's just the way it works."

IMRT is a form of three-dimensional conformal radiation therapy (3D-CRT) that uses software to link treatment planning with the accelerator that delivers radiation therapy. Using IMRT, radiation oncologists can determine and deliver an optimal radiation dose for each cancer patient and each tumor. The radiation dose to the tumor is maximized, and the dose delivered to surrounding tissue is minimized.

Image-guided radiotherapy (IGRT) uses patient positioning devices and imaging tools to target tumors more precisely. IGRT combines a new form of scanning technology with IMRT, allowing physicians to optimize the accuracy and precision of the radiotherapy by adjusting the radiation beam based on the position of the target tumor and critical organs -- while the patient is in the treatment position. With IGRT, doctors can take tumor motion into account during radiation therapy planning and treatment. Because IGRT improves precision, it raises the possibility of shortening the duration of radiation therapy by reducing the number of treatment sessions for some forms of cancer.

Only a few of these sources use Varian software planning. The others use a variety of competitors including ADAC, CMS, Brainlab, and Nomos. A Virginia doctor said, "We have a Varian LINAC, but we use Nomos treatment planning." A Michigan doctor said, "We use a homegrown software system that's been developed and maintained by our physics group. We are one of a few small institutions that still do that." A New England doctor said, "We compared commercial planning systems, and ADAC's Pinnacle won over Varian's product. Varian came in second. If I didn't have a Varian LINAC, I'd see no compelling reason to buy Varian software." Another source said, "There's a whole industry that's grown up around add-ons to LINACs. Radionics, Brainlab and Nomos don't make LINACs, but they make good planning systems."

All but one hospital questioned currently has IMRT capability, and most have it available on all or nearly all their linear accelerators (LINACs). On average, sources have 3.1 linear accelerators (LINACs) at their hospitals, and 2.5 of these LINACs are equipped with IMRT. The one source with no IMRT plans to add it this year, but no source plans to add IMRT to any existing non-IMRT-ready LINACs this year. No sources are postponing any IMRT purchase decisions.

When purchasing a new LINAC, sources said the key factors in the selection process are price, technology, patient load, function, and online portal imaging. Four sources plan to purchase a new LINAC this year, and all said the new machines will be IMRT-equipped. A Colorado doctor said, "We are currently starting plans to have a fourth vault built at our new site, and it likely will be IMRT capable. But, to be honest, most LINACs today are IMRT capable. It's a matter of whether you have a compatible software planning system to do IMRT planning for the particular LINAC." A Pennsylvania doctor said, "We're getting another LINAC soon, and it will have IMRT capability like our other three LINACs...Most LINACs now are IMRT-ready."

IMRT and IGRT Systems Available in the U.S.

| Company | Linear Accelerator | IMRT | IGRT |
|---|-----------------------|-------------|----------------|
| Varian | Clinac | SmartBeam | Trilogy |
| Siemens | Primus | None | None |
| Nomos | None | Corvus | None |
| CMS (formerly Computerized Medical Systems) | None | Xio | In development |
| Royal Phillips Electronics' ADAC | None | Pinnacle | None |
| Tyco's Radionics | None | Xplan | None |
| MDS Nordion | None | TMS | None |
| Elekta (formerly Philips Medical Systems) | SL25 | PreciseBeam | Synergy |

Sources are using IMRT for an average of 44% of patients (range 5%-100%). A Michigan doctor said, "All four of our LINACs are capable of doing IMRT, but we only use it for 5% of patients. We're doing IMRT in investigational studies only. While we believe that IMRT is going to be very important in the future, we're limiting IMRT use for now to experimental situations because there are still some unanswered questions about it. We have an NIH grant to study IMRT in breast, head & neck, prostate and brain cancer." A Nebraska doctor said, "Two of our three LINACs are equipped with IMRT, and 75% of patients treated get therapy with IMRT." A Virginia doctor said, "A very low percent of our patients get IMRT because we have such a large patient load, that we don't have the time to do a lot of IMRT."

Cost and reimbursement are the primary barriers to further IMRT growth, sources agreed. A Colorado doctor said, "Reimbursement and treatment time are definite barriers. Treating patients using IMRT takes longer, and, therefore, fewer patients can be treated, especially in a system with limited resources. So, if reimbursement doesn't compensate for the increased treatment and planning time, it's really hard to justify IMRT – even though outcomes are *likely* to be better." Another doctor said, "Cost has been a barrier, but we decided to spend the money this year." A third said, "The only barriers to growth are cost and possibly reimbursement."

Only a few of these sources use Varian software planning. The others use a variety of competitors including ADAC, CMS, Brainlab, and Nomos. A Virginia doctor said, "We have a Varian LINAC, but we use Nomos treatment planning." A Michigan doctor said, "We use a homegrown software system that's been developed and maintained by our physics group. We are one of a few small institutions that still do that." A New England doctor said, "We compared commercial planning systems, and ADAC's Pinnacle won over Varian's product. Varian came in second. If I didn't have a Varian LINAC, I'd see no compelling reason to buy Varian software." Another source said, "There's a whole industry that's grown up around add-ons to LINACs. Radionics, Brainlab and Nomos don't make LINACs, but they make good planning systems."

Most of the planning systems are viewed as fairly comparable, though each has advantages and disadvantages -- its own bells and whistles. A Virginia doctor said, "They're all very competitive...I know CMS is constantly changing software, especially the GUI to make it more friendly." A Colorado doctor said, "Compared to Brainlab, CMS (Xio is comparable. Of course, Brainlab has some limitation in terms of maximal field size. I don't like the contouring feature in Brainlab either (you can't derive subtration volumes automatically). A Washington DC doctor said, "ADAC is superior in our opinion." A Massachusetts doctor said, "ADAC's Pinnacle has a strong scripting language, which allows my in-house programmers to get into the guts of the dose engine of the planning kernel. It's very robust and flexible. Varian is not like that."

IGRT is considered both very important and very timeconsuming. A doctor said, "IGRT is now possible. Everyone has talked about it for years and years. At every big show you go to, they show it. Now it is a reality. It's the future for right now." A Colorado doctor said, "IGRT is the future, but probably the distant future if reimbursement doesn't keep up with advancing technology. It's one stop for radiation planning, verification and treatment. We don't have IGRT (in the true sense of the term) at present, but hopefully our new machines will be IGRT-equipped." An Ohio doctor said, "IGRT is important for some tumors - those with organ motion." A third source said, "IGRT adds a lot more time physician time and machine time." A Washington DC doctor said, "IGRT adds 5-30 minutes." A Virginia doctor said, "Image guidance should ideally take less than five minutes per case. Future units need to be able to verify positioning and delivery." A New England doctor said, "IGRT isn't for a lot of diseases. There are a lot more man-hours involved. Last year all the studies came out and showcased these imageguided LINACs, but LINAC has CT capabilities, and we've had that for years. Last year, it was sort of a marketing kind of assault. None of my machines has IGRT, as defined by what people showcased this year at ASTRO (American Society for Therapeutic Radiology and Oncology)."

Sources were not able to directly compare Elekta's Synergy and Varian's Trilogy systems. One source said, "I can't tell how they compare yet." Another doctor said, "There is no good basis to evaluate these systems. IMRT developed with different treatment planning software companies and LINAC vendors. As IMRT becomes the standard of care, single module software/hardware purchases will become increasingly popular, and they may add to safety, as there is less transfer of data (with an integrated system)." A third doctor said, "Synergy is more of a planning tool...It's decent but not good tunnel graphics in 2D. It sounds attractive, and it's something we'll look at. I don't know anything about Trilogy."

Tomotherapy and CT/LINAC are considered interesting, but they are not viewed as serious threats to either IMRT or IGRT. One source said, "I think tomotherapy is hard to beat." Another doctor said, "Tomotherapy may be the best way to do IMRT and IGRT." A third source said, "Future units will need to be able to verify treatment positioning and treatment delivery. Precise isodose lines are of no use without precision in target positioning." A Michigan doctor said, "I don't know whether tomotherapy is better than IMRT, but it certainly has a catchy name and people are interested in it. My boss looked at tomotherapy for our department, and he decided he'd wait a while and see if, perhaps, other units might meet our needs better. He thought the table patients lie on wasn't well designed." A New England doctor said, "Tomotherapy has been around a long time, and periodically you hear these scare stories that it's coming to the forefront. I think that I, like others, will wait for other people with cash to burn to test it. It's a great idea, but can it ever be real time? I wonder about a technology that's been around as long as tomotherapy has been but has never seen the light of day. It's been around 20 years in the development stage. What does that say about it?" Another doctor said, "I've seen it, and in concept it could be a powerful addition. Once they get the cone working in a rapid fashion and in a user-friendly environment, it'll be powerful."

In October 2003, the Centers for Medicare and Medicaid Services (CMS) announced it would cut reimbursement for outpatient IMRT in 2004 by 27% (from \$400 to \$294), but hospital reimbursement for associated IMRT costs fell <1% from \$1,462 to \$1,456. IMRT reimbursement for free-standing, non-hospital facilities, which perform about a third of IMRT procedures, fell 5% to \$631, far less than 38% cut originally proposed. Payments to free-standing facilities for associated IMRT procedures, including the planning of the radiation treatment, also fell 5% to \$2,148 from \$2,264.

Sources do not think the cuts will put a damper on IMRT use. A Colorado doctor said, "Obviously, I don't like this. It will eventually come down to institutions refusing to treat CMS patients. Time will tell how this will affect us." An Ohio doctor said, "We haven't analyzed this yet. It does not appear to be a favorable development." A Pennsylvania doctor said, "It will probably hurt centers." A Virginia doctor said, "These changes were inevitable, especially since there is a much higher percentage of cases being treated with IMRT than what

Medicare expected. Obviously, the diminished revenue will require a more streamlined planning/treatment system to maintain profitability." A Michigan doctor said, "I would say that radiation oncologists are really good at figuring out how to do what needs to be done and get paid adequately for it. IMRT is here to stay." Another source said, "The original reimbursement for IMRT was probably higher than it should have been, so the reduction is bringing it more in line to what it should have been all along. I don't think the reduction will be disastrous for Varian. I don't think a reduction in reimbursement is going to make a big difference." A Massachusetts doctor said, "The problem with academic medicine is that we're not going to slow down because of reimbursements. That's part of the reason we're in such a poor financial situation. Will we stop using IMRT? No."

Varian offers good pricing, even if a hospital buys from multiple vendors and does not use exclusively Varian equipment/systems, sources agreed. A Michigan doctor who uses Varian accelerators but home-grown planning software said, "We have a very good relationship with Varian, so I think that they price their equipment competitively. They are interested in keeping us as satisfied customers."

However, a Massachusetts doctor (with nine LINACS, six of which are Varians) believes Varian is losing market share. He explained, "I bought two LINACs from Seimens, but I was in the market for one. First, I went to Varian, and Varian was so high priced, complacent, and unwilling to work with the customer – me – that I bought two Siemens instead. Over the last five years, Varian has gotten so phenomenally complacent. We told them they were acting like jerks. Varian has the best, the most stable, machine on the market. It is literally the Ford of the industry. It usually doesn't break down, but given that it is a great product, they managed through arrogance and complacency to drive the product to dust. Now, they are starting to see market share even out for just that reason. All the other vendors -- across the board - are much friendlier and offer better discounts...Varian definitely is losing market share." A Virginia doctor agreed, "Varian does have the No. 1 share, but I know Elekta is trying very hard and maybe has overtaken Siemens...Varian prices have all become very competitive. They are all after each other...Pricing is not going down if you add in the image part. If you buy a straight LINAC, the price is staying the same. With inflation, that means it's going down, but it depends on how much you load on. All the companies have sales forces that are very attentive. "

•