# Treatment and Management of Patients With Non-Small Cell Lung Cancer

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*The following is a lightly edited manuscript of a teleconference discussion on treating patients with non-small cell lung cancer in the VHA.*

## COMORBIDITIES

**Joshua M. Bauml, MD, Corporal Michael J. Crescenz VAMC, Philadelphia, PA.** One of the comorbidities that most commonly affects my patients is hearing loss—this is one of the most common causes of service-connected disability for veterans. Patients who have clinically significant hearing loss cannot receive cisplatin, which I frequently use in the adjuvant treatment of non-small cell lung cancer (NSCLC).

In addition, kidney dysfunction is quite common as a result of comorbid cardiovascular and hypertensive diseases. Kidney dysfunction can negatively impact our ability to administer both cisplatin and other systemic therapies.

**Millie Das, MD, Palo Alto Health Care System, CA.** Another major comorbidity for a lot of our veterans is COPD (chronic obstructive pulmonary disease). It doesn't complicate the chemotherapy choice, but it affects surgical candidacy for those patients who present with early stage disease. Many times if you obtain pulmonary function tests in patients with COPD, the tests are abnormal and can prohibit safe surgical resection. These are patients that I see in the clinic and refer for definitive radiation, usually SABR (stereotactic ablative radiotherapy)/SBRT (stereotactic body radiation therapy), at a local radiation facility that can offer specialized radiation treatment.

**Dr. Bauml.** The fact that the VA has so many patients who require stereotactic radiosurgery for their early stage lung cancer represents an opportunity. There is a newly opened study that is evaluating SBRT vs surgery for these early stage lung cancer patients within the VA system. That study model has previously failed in multiple health care settings, but the VA is uniquely suited to answer this question.

**Kelly A. Tammaro, PharmD, BCOP, Boston VA Healthcare System, MA.** I would add heart failure patients or patients who have cardiac comorbidities and fluid restrictions. These restrictions can affect hydration that is needed for cisplatin, for example, as well as final volumes used to mix other chemotherapeutic agents with narrow concentration maximums, such as etoposide.

**Julie Beck, RN, MSN, MPH, APRN-BC, VA Connecticut Healthcare System West Haven Campus.** As a lung cancer navigator, I find that psychosocial comorbidities are an impediment to getting patients to diagnosis and treatment. Patients will miss appointments because they don't have rides or will be reluctant to get imaging or other diagnostic testing because of anxiety or because it triggers PTSD (posttraumatic stress disorder) or because they are concerned about cost.

**Dr. Das.** I couldn't agree more.

**Dr. Bauml.** It's a great point.

**Ms. Beck.** You have to think outside the box with this patient population. We treat patients from as far away as Western Massachusetts. We have a dedicated oncology social worker who helps to arrange transportation. We have our CLC ( community living center), which is a rehabilitation and hospice unit but is also a resource for patients who live alone or far away and are getting an aggressive daily treatment regimen such as combined chemotherapy and radiation. We admit some patients to the CLC during their treatment to ensure that they get their treatment on time, maintain their nutritional status, and to provide emotional support. This is not an acute medical bed. Patients will sometimes go home on the weekend, but the support of the CLC increases the chance that they will get through their treatment safely.

Cancer care requires a lot of handholding. We often have to make multiple telephone calls to persuade our patients to get imaging or biopsies. Some of our patients require

admission following biopsy because they live alone and have no one to drive them home following the procedure.

**Dr. Tammaro.** Boston has a similar model. We have a social worker who is highly dedicated and is able address our patients needs immediately. We also have many patients with PTSD and other psychological comorbidities, and depending on the severity, may require admission for their treatment to avoid the overwhelming nature of the ambulatory setting. For those who have to travel long distances for treatment we the Huntington House, which is housing located next door to our ambulatory campus. This accommodation can be used by our patients and their caregivers. We also have long term care facilities and a hospice unit located at our Brockton facility.

**Ms. Beck.** In West Haven, we have both palliative care and health psychology providers embedded in our clinic. They assist with symptom management and issues related to coping with diagnosis, anxiety, sleep, pain, smoking cessation, and lifestyle changes. We have also been offering pet therapy through our social work team, which has been very helpful for many of our patients.

**Dr. Bauml.** Mental health issues also can affect the choice of the type of treatment. Patients who have severe claustrophobia associated with their PTSD may have difficulty undergoing radiation. This can impact their ability to comply with therapy, and we have to adjust the treatment accordingly. For instance, I have a patient who has a known brain metastasis that was treated with definitive intent, but this gentleman gets highly agitated doing a brain magnetic resonance image (MRI). Instead we have had to follow him with serial computed tomography (CAT) scans, which is suboptimal. We have discussed that, but the distress that it causes him is simply not worth it.

**Dr. Das.** In some instances, we have had to use IV sedation for some of our patients with severe claustrophobia just to be able to get them through a positron emission tomography (PET) scan as part of their staging workup. We discuss these types of challenging cases in a multidisciplinary setting in our thoracic tumor board in order to brainstorm and figure out a realistic plan with our radiology and anesthesia colleagues, with the goal of getting the patient through the necessary tests in order to establish a treatment recommendation.

Due to underlying mental health or other health issues, some of our patients may also have difficulty with breath holding or with following other necessary instructions during their radiation treatments. We sometimes have to get creative on an individual basis in order to help a patient get through the needed treatment.

We have a dedicated psychologist and social worker who are embedded in our clinics and work closely with the oncology providers to offer strategies that can help our patients comply and complete the recommended treatment plan.

## RURAL CARE

**Dr. Bauml.** One of the questions that comes up frequently when you have a patient who is remote is the type of treatment that you can administer. It's difficult to administer a weekly therapy if somebody's traveling 3 hours to see you every time. That can play into your decision making

## Discussion Participants

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**Julie R. Beck, RN, MSN, MPH, APRN-BC,** is an oncology nurse practitioner and cancer care coordinator at the VA Connecticut Healthcare System in West Haven. Ms. Beck is a clinical instructor at the Yale School of Nursing.

**Millie Das, MD,** is a clinical assistant professor at Stanford University and is chief of oncology at the VA Palo Alto Health Care System in California. Dr. Das also is the associate program director of the Oncology Fellowship at Stanford University.

**Kelly A. Tammaro, PharmD, BCOP,** is a clinical oncology pharmacist and the hematology/oncology clinical trials manager for the Boston VA Healthcare System in Massachusetts.

as you're choosing a chemotherapy. If there are equivalent treatment regimens and one involves visits every 3 weeks and one involves weekly visits, well, that will help sway your decision making after discussion with the patient.

We often have to balance things. For instance, when I give someone carboplatin and paclitaxel, my preference is to administer it weekly with 3 weeks on and 1 week off. However, if a patient tells me, "You know, I do not want to come in once a week," then I will discuss with them my concern for the increased adverse effects (AEs) with the every-3-week dosing. We will do it and then watch them closely. Of course, this gets even more complicated when you consider the fact that many of these patients have multiple medical comorbidities, so you'd like to administer the treatments in the least toxic way possible.

**The trend is to perform next-generation sequencing on all tumor specimens regardless of tumor type or histology, which can hopefully enable us to get to the bottom of what the driving genetic alteration is.**

**Ms. Beck.** We have overcome some of those challenges by partnering with the primary care doctors. We are very close to our primary care colleagues in Massachusetts. They will order labs for the patient the day before the patient's appointment, so if the patient has a long drive, we already have their lab work; and they are ready to go when they get here for their treatment. The nursing staff is very aware of who needs to get on a shuttle back to Massachusetts. For some patients, we will have them stay overnight before their treatment.

## PRECISION ONCOLOGY

**Dr. Tammaro.** In Boston, we have integrated Precision Oncology to be part of clinical practice, which we started with metastatic lung cancer patients. The VA Precision Oncology Program (POP) began at our healthcare center. We had to evaluate the genetic testing platforms, the accuracy of the results, and amount of tissue necessary for the laboratories. We have since succeeded in sending high-quality samples to the laboratories that generate accurate results. However, for your standard mutation panel for identifying therapy for first line treatment in lung cancer, we still use our local send out laboratory.

The POP has rolled out nationwide, and it is another clinical tool, especially for patients who have already failed multiple lines of therapy. When we send for a precision oncology consult, the "N of 1" report provides annotation. The report will generate a review of relevant literature and provide available abstracts or phase 1 or 2 trials that support a targeted therapy against potential point mutation for your patient.

The POP also has a research component, known as Re-POP. The goal is to open bucket trials that assess targeted therapy off label. Re-POP allows us to recontact these patients in the future to say, "You had your tissue sent through precision oncology, and you were diagnosed with a certain point mutation. Now we have a clinical trial that's available. Would you be interested?" The plan is to have those clinical trials open and available to our patients when we receive the results from precision oncology.

I have used POP for 2 metastatic prostate cancer patient who exhausted all lines of therapy in hopes to identify a potential *BCRA 1/2* mutation in order for us to use a PARP inhibitor. Unfortunately, neither harbored this mutation. Precision oncology does not perform immunohistochemistry, therefore identifying *HER-2* or PD-L1 status for example, would need to be done through your local laboratory. I have found POP to be helpful in identifying a patients potential therapeutic option after progression on first/second line therapy, by sending tissue to POP initially or at the time of relapse.

**Dr. Das.** In our clinical practice at the Palo Alto VA, we follow the National Comprehensive Cancer Network (NCCN) guidelines, and we routinely evaluate for the presence of an *EGFR* mutation and also for *ALK* and *ROS1* translocations in all lung cancer patients with nonsquamous histology. We send our molecular testing through Quest Diagnostics (Madison, NJ), and we usually get results back within a week or so.

For those patients who do not have any of those targetable gene alterations, we will go ahead and send for next-generation sequencing through POP, which allows testing of a much broader gene panel. Those results can take about a month or so to come back. I usually don't wait for these results in order to get someone started on treatment. For patients without *EGFR*, *ALK*, or *ROS1* found on initial testing, I will go ahead and start them on

IV systemic chemotherapy. It is often very useful when you do get the next-generation sequencing results back, since in almost all cases, a gene alteration can be detected and is provided in the accompanying report. In a large subset of lung cancer cases, a gene alteration is seen in *KRAS*, for which we still do not have an effective targeted therapy. Despite this, I still find it useful to obtain the results because we generally feel that the driving genetic alterations occur mutually exclusive of one another. When we do see *KRAS* reported from a patient's tumor specimen, we're not generally looking for other types of mutations, so I find it helpful to know what is the alteration that is driving the growth of a patient's tumor. The trend moving forward is to perform next-generation sequencing on all tumor specimens regardless of tumor type or histology, which can hopefully enable us to get to the bottom of what the driving genetic alteration is and to see if there are any targeted treatment approaches that can be offered to the patient.

In a few lung cancer cases, I have seen alterations in *HER2* and *BRAF* that have been detected and reported using a next-generation sequencing platform. Just recently the FDA approved the BRAF-directed therapies of dabrafenib and trametinib for patients with lung cancer who are found to have a *BRAF* V600E mutation. It is hoped that as the FDA continues to provide approvals for targeted drugs in patients with lung cancer, the VA formulary will be able to offer these therapies to our veteran patients with the ultimate goal of providing treatment that has increased efficacy and less toxicity compared to conventional IV chemotherapy.

One of my frustrations earlier on was when we did find these more rare targetable mutations, I would run into problems with the VA formulary in allowing me to prescribe certain targeted therapies. In many cases, if the drug was not FDA-approved for lung cancer, I was told that I couldn't use it and would have to go through the appeal process, which was quite onerous. Moving forward, we are seeing more and more data and trials with newer targeted agents in lung cancer, leading to new FDA approvals. With these approvals, I think it will be easier to be able to offer these targeted therapies to our patients.

**Dr. Bauml.** One of the issues that arises when we're discussing even the FDA-approved therapies, is that many of these targeted therapies are relatively rare, and they're especially rare amongst veterans. Now others have mentioned *BRAF* and *HER2*, and these do have some overexpression and mutations that occur among smokers. But the more common targetable genetic aberrations, *EGFR*, *ALK*, and *ROS1* are more common amongst never-smokers. Given the high prevalence of tobacco use among veterans, these changes are rare. The incidence of *ALK* translocation is 3% to 7%. The incidence amongst veterans is likely much lower than that, given the tobacco abuse—to the point that I actually had a patient who had an *ALK* translocation; and of course, I prescribed the patient crizotinib. This was prior to the ALEX Trial and alectinib data. I prescribed crizotinib and was told it wasn't on the formulary. Initially I was surprised, but when I said, "Well, look, when was the last time someone within our VA has prescribed crizotinib?" The answer was never.

This is the difficulty: As we enter this era of molecularly targetable therapy, the way we structure our formularies and the way that we review these data is going to have to change. This year at the American Society of Clinical Oncology (ASCO) meeting there were some very exciting lung cancer abstracts that evaluated adotrastuzumab emtansine, which is an antibody drug conjugate currently approved for the treatment of *HER2* overexpressing breast cancer. The abstracts showed response rates of up to 40% in lung cancer with the administration of this drug in *HER2*-mutated lung cancer. The HER2-amplified still had a response rate of 20%, which given the toxicity profile of this agent, is quite appealing. Being able to explore these early phase studies, as was described through the personalized medicine pathway, is, a great step forward for VA care.

**Dr. Tammaro.** The PBM in collaboration with the POP Advisory Board, are developing different levels of evidence to support the use of targeted medications identified to be potential therapy in those diagnosed with a point mutation. Even if a medication does not have an FDA approval, it has to have some evidence to support its use in a particular cancer. If you identify a point mutation or biomarker in a patient and provide evidence to supports its use within that particular disease state, the VA pharmacy could approve its use based off of that evidence. VA pharmacy would not require an actual FDA approval for that indication.

What the VISNs, PBM, and precision oncology are trying to do is determine the level of evidence that we have to support or approve

use of a targeted therapy. We are definitely moving forward and changing the horizon on how we actually treat our patients after they've gone through first-line therapy. We are trying to figure out where these point mutations come in, the line of the therapy, and how we actually treat these cancers. Pharmacy is making a step forward in conjunction with Michael Kelley, MD, the National Program Director for Oncology, Specialty Care Services, whose group is establishing those guidelines.

**Dr. Bauml.** I don't mean to downplay the difficulty of that process. This is a huge, difficult process. One only needs to look at the long line of failed trials looking at PI3 kinase inhibitors to show that just knowing that a mutation exists does not necessarily mean that a targeted therapy works in that space.

Drawing that line is really complicated, both within the VA and, indeed, outside of the VA. It's a really complicated process, and understanding the implications of different mutations is only going to get more complicated. Of course, now we have things like NTRK and even rarer genetic aberrations that are going to affect not only lung cancer, but also a wide range of malignancies.

## PROMISING RESEARCH

**Dr. Bauml.** The pathways that are emerging as clear driver mutations for which we have available therapies, at least within lung cancer, are MET exon 14, RET, and *NTRK*. I am also intrigued by the emerging data in the *HER2* space.

**Dr. Das.** The other therapy that has been getting a lot of press is immunotherapy, of course. And I've been seeing many really good responders to immunotherapy within the veteran population that I treat. It is felt that degree of PD-L1 expression correlates with responsiveness to the immune check point inhibitors that are being used in lung cancer, and we are tending to see higher rates of PD-L1 expression in patients who are prior or current smokers who have a higher overall tumor mutation burden.

I see patients both at Stanford and at the Palo Alto VA, and I have noticed that the patients that I have been treating at the VA tend to have higher levels of PD-L1 expression with better responses to the immunotherapy drugs, probably because most of the VA patients are former or current smokers. And, another interesting observation is that these veteran patients are, for whatever reason, having a lower incidence of some of the autoimmune AEs seen with these immune checkpoint inhibitors. I have been keeping an eye out for more data and information to support these observations I have had in my clinical practice and I specifically attended ASCO this year to learn more about what others have seen and studied with immune check point inhibition in lung cancer. We are learning now that PD-L1 is not a perfect marker for predicting response to the checkpoint inhibitors and the other immunotherapeutic agents, and there is a great deal of research going on to try to figure out what other biomarkers could be useful and which patients are most likely to benefit from these drugs.

I was excited to hear about the combination of nivolumab and ipilimumab that is being tested in both mesothelioma and in small-cell lung cancer where we really don't have as many treatment options as we have in non-small cell lung cancer. That data was quite exciting, and interestingly, there does not seem to be a correlation with PD-L1 expression and responsiveness to treatment with the immunotherapeutic agents in those histologic subtypes. The story is still unfolding, and we await additional data to help guide us in our treatment decisions.

**Dr. Tammaro.** Immunotherapy is the new fad in oncology. We have just scheduled our first patient for first-line therapy due to PD-L1 tumor proportion score is > 50%. Recently, at ASCO KEYNOTE-021 researchers looked at using pembrolizumab in combination with carboplatin plus pemetrexed chemotherapy for first-line metastatic non-squamous NSCLC. The research suggested that patients treated with pembrolizumab + chemotherapy continued to derive a higher overall response rate and progression free survival when compare with those on chemotherapy alone despite a low or no PD-L1 tumor expression.

It's very interesting that many clinical trials that we're evaluating are now using some type of checkpoint inhibitor up front with cytotoxic chemotherapy. If they are positive trials, this could change how patients are treated up front.

**Dr. Bauml.** There was some really interesting data that were presented at ASCO this year by Matthew Hellmann, MD, which evaluated the predictive nature of PD-L1 vs tumor mutation burden and other biomarkers, including gene expression profiling. In this particular abstract,

the PD-L1 and tumor mutation burden really do function as orthogonal biomarkers such that a patient who has high PD-L1 and high tumor mutation burden is the most likely to respond. Patients who are really low for both are unlikely to respond. We really need better biomarkers for immunotherapy, though. PD-L1 has a lot of limitations, namely, it is dynamic, so over time it changes. So I can do a biopsy at one point, then treat the patient and the PD-L1 may change.

More importantly, it's heterogeneous. There was this great paper by McLaughlin and colleagues in *JAMA Oncology* (2016) who described a patient who had a small tumor biopsy. They took a micrograph of the tumor and showed that one part of the micrograph was completely floridly PD-L1 positive. At another site of the same biopsy it was completely stone-cold negative, which is humbling when you think about the fact that we stick small needles into tumors and make clinical decisions on the basis of that.

The KEYNOTE-024 study evaluated pembrolizumab vs chemotherapy in high PD-L1 expressers. It's a very exciting study, but at the end of the day even in this highly select patient population, the response rate to immunotherapy was only about 50%, which is not the sort of biomarker-driven response that we're used to seeing with our EGFR inhibitors. That's really what we want to get to. More important even than that is being able to say the negative predictive value. One of the reasons that we're probably seeing more responses among veterans is that we know that patients who are veterans who have high tobacco exposure have a higher tumor mutation burden. I'm surprised to hear about the immune-related AEs, actually, because one of the things that was reported this year at ASCO was some data that showed that patients who have immune-related AEs are more likely to have a better outcome, which is an interesting biomarker of response.

**Dr. Das.** I heard that as well, and I found that to be really interesting. The patients that I've had on nivolumab for over a year are doing very well. These are stage IV patients who have essentially had complete responses to treatment and have not had any or have had very minor immune-related AEs to date.

Overall, these are a small numbers of patients, but I have been curious to see why that might be the case. Anecdotally, my colleagues and I who treat patients at Stanford have seen significantly higher rates of grades 3 and 4 pneumonitis and other autoimmune toxicities, such as myocarditis and enterocolitis, in those lung cancer patients who are light or never-smokers treated with immune checkpoint inhibitors.

**Dr. Bauml.** I really feel that PD-L1 as a biomarker has significant limitations. I certainly hope that in at least 2 or 3 years we're not going to be talking about PD-L1 anymore. I'm hopeful that we'll be able to use better predictive biomarkers, such as mutational burden and gene expression profiling. In the data in head and neck that was presented this year at ASCO, patients who were low for both gene expression profiling and mutational burden had a very low response (Haddad et al, ASCO 2017).

That's really what you want to be. You want to be able to say, "Here's a person who will not benefit from this therapy." From there you can identify, based upon these biomarkers, the combination that is going to be best for this person. Is it chemoimmunotherapy or combination immunotherapy with CTLA4, or another checkpoint blockade? That is really the way that we're going to be able to fine-tune this, because the toxicity is substantial for some treatments, like the nivolumab/ipilimumab combination. Using them in a biomarker-blind fashion is just scary to me, honestly.

## MANAGING ADVERSE REACTIONS

**Dr. Tammaro.** The increasing amount of oral chemotherapy has posed a significant challenge. As a clinical oncology pharmacist, it was difficult to grasp the most effective way to follow all these patients and ensure adherence, adverse drug event reporting/significance and adequate follow up. When patients are receiving IV chemotherapy, we know we will see them, we are assured compliance and are able to assess side effects in a timely manner. When we give oral chemotherapy, the tables are turned, where the responsibility is now on the patient. We are now depending on the patient to ensure they are taking the medication correctly and we may not see AEs if the patient misses an appointment or feels as though they are bothering the provider by calling.

In 2012, we started an oral oncology clinic here at the VA in Boston that I found to be extremely effective. When you're sending a patient home with an oral chemotherapy, you have to make sure that you are counseling them

correctly and encourage them to call at any time if they are experiencing any type of AE. One of the newest issues we have been seeing is bleeding with ibrutinib, especially in those patients on anticoagulation therapies.

A general strategy we employee for oral chemotherapy is to start at half dose and titrate slowly. This method has been effective in identifying AEs and preventing delays in therapy. We do this for the majority of oral chemotherapy. Patients are given a 2 week supply to start and then are reassessed on follow up for escalation to the target dose. We do not place refills on oral oncology prescriptions. They are instructed to call 10 days prior to running out if they are not scheduled to come in for an appointment. Having consistent dialogue with our patients allows us to assess for adherence, AEs, and tolerability. The other advantage to this clinic is ensuring our patients have someone to speak to at all times and answer all their questions. Direct lines of communication is what most of our patients are appreciative of when paying gratitude to the clinic.

**Ms. Beck.** We have an oral chemotherapy clinic staffed by dedicated oncology pharmacists. Patients meet with the pharmacist and have education prior to starting a new oral chemotherapy. They will then be followed by both the oncology provider and the pharmacist.

**Dr. Das.** One of the challenges we also face is with so many of our patients living so far away. When our patients do have AEs that require hospitalization, it can be very tricky to really get a sense for how they are being managed at the outside community (non-VA) facility. Sharing of electronic medical records can be a challenge in these cases, and I worry that the care teams at the more remote hospitals may not be as familiar with the newer cancer treatments and the toxicities associated with them, such as the autoimmune AEs associated with many of the immune checkpoint inhibitors.

I provide patients with pocket cards to keep in their wallets with my contact information and the name of the drug that they are getting because not all patients can remember or even pronounce the names of the drugs and may not be able to tell their local treating physician and care team what they are getting. I have been getting more frequent phone calls from emergency department physicians and hospitalists from the local communities where many of our veterans live, because they want guidance on how best to approach treatment for our patients when they show up with an AE related to their cancer treatment.

At times, the presenting symptoms may be vague or nonspecific, but for our patients being treated with immunotherapy, we always have to keep in mind the possibility of immune-related AEs because we know that prompt initiation of steroids is critical in these cases and can really help the patients feel better quickly.

**Dr. Tammaro.** You bring up a valid point. Our pharmacists meet with all the patients on checkpoint inhibitors. Specifically, when we started using ipilimumab it was uncharted territory for our team. We put together take home medication bag that included hydrocortisone cream, methylprednisolone dose pak, dipheydramine, and loperamide. This was utilized for all patients and specific attention was given to patients who lived far away from an emergency room. This bag system was accompanied by "what to do if I have this symptom" handout that outlined which medication to take depending on the severity of the AE. A direct line phone line to the oncology pharmacy also was supplied.

With the evolution to the PD-L1s and the anti-PD inhibitors, we haven't seen the same level of AEs. Patients go home with wallet cards that includes our staff contact numbers/pagers. The wallet card also serves as information to a treating provider if the patient presents outside the VA, to ensure they understand the severity of a potential autoimmune AE, such as diarrhea.

Another challenge is shared-care patients. We have patients coming from outside hospitals, and at times they want to use this pharmacy like a CVS, and it just doesn't operate that way. We want to collaborate with others. Most shared care patients present to our service for oral chemotherapy because the veteran just can't afford the copays. So, we will see the patient concurrently. They can still see their outside hospital physician as well, but they have to fax us the laboratory results and progress notes on a monthly basis (or longer depending on where they are in there therapy). Before we fill their medications, we talk to the patients, the same way we would treat a veteran who was getting their oral chemotherapy here. In addition, they need to be seen by the VA physician at least every 3 months. We want our veterans to feel comfortable with the cancer care and help them out as best as we can.