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Assisting Pulmonary Hypertension Patients and Families With Treatment Decisions

*To complement this issue's theme, "Living With Pulmonary Hypertension," a discussion on assisting patients with therapy decisions was led by guest editor **Glenna Traiger, RN, MSN**, Pulmonary Hypertension CNS, University of California, Los Angeles. The panelists included **Karen Frutiger, RN**, Clinical Nurse Coordinator, University of Rochester Pulmonary Arterial Hypertension Program, Rochester, NY; **Martha Kingman, Nurse Practitioner**, University of Texas South- western Medical Center, Dallas; and **Abby Poms, RRT**, Duke University Pulmonary Vascular Disease Program Manager, Duke University Medical Center, Durham,*

Ms Traiger: Now that we have 8 FDA-approved therapies for pulmonary arterial hypertension (PAH), patients and health care providers are faced with complex decisions about which therapy to start and when to add or change therapies. Multiple therapies and the change in donor lung allocation for transplant using the Lung Allocation Score (LAS) have affected how and when patients are referred for transplant evaluation. Unfortunately, many patients are not appropriate for transplant or will not live to receive a transplant. For those patients and families, end-of-life care decisions become central. First, let's address initial therapy for PAH. For a class II or early class III patient, how do you educate patients about their choices for therapy?

Ms Kingman: I tell patients we generally will start with oral therapy for early disease and that there are 2 categories from which to choose. I then explain the monitoring requirements of the endothelin receptor antagonists (ERAs) and side effects of all the oral therapy options. I also let them know that we typically start with one oral therapy, but if we don't see improvement within 3 months, we may need to add an oral therapy from the other category. Also, we're involved in a number of clinical trials here, so we will evaluate whether the patient may be a candidate for one of those; and if so, those options are discussed as well.

Ms Frutiger: We offer patients a follow-up visit in our office after their right heart catheterization, and we try to spend time educating patients about pulmonary hypertension (PH). At their new patient visits we provide patients with a *PHA Survival Guide* and information about how to get on the Web site for the Pulmonary Hypertension Association (PHA). After they've had a right heart catheterization, we try to integrate the interpretation of their testing into the trajectory of their clinical course. For instance, if a patient has had relatively stable symptoms over a long period of time, we're going to make different recommendations from those for the patient who has well-documented disease or progressive exercise intolerance over a very short time period. We try to recommend to patients that they involve family members in treatment decisions and we're very reluctant to offer aggressive therapy without family involvement. We find that a face-to-face meeting in the office with patients to discuss treatment options is very helpful.

Ms Poms: I agree with both Martha's and Karen's approach. NYHA class II or early class III patients are started on oral therapy if possible. We tend to be a bit more aggressive if a patient has symptomatically and functionally declined significantly over the previous few months. Other factors may affect treatment decisions such as insurance mandates which, unfortunately, sometimes do determine what therapy a patient might receive. I think there's really no right or wrong answer about which class of oral therapy to choose; some people prefer an ERA and others a phosphodiesterase type 5 (PDE-5) inhibitor. Patients with mild diastolic dysfunction and/or edema may be better served by initiating a PDE-5 inhibitor. And certainly other factors such as underlying liver and coronary disease will affect treatment decisions. Generally, there are good data to support the use of either class of drugs.

Ms Traiger: Abby, you brought up a good segue into my next question: What barriers do you and your patients face in making decisions about therapy? What role, for example, do insurance problems, lack of educational materials, or language barriers play when you're trying to advise patients?

Ms Poms: There certainly are outside forces that influence our decisions. I think we're all

experiencing those issues now with tiered medications, or preferred medications; for example, you may be able to get one ERA but not another. And there are barriers in terms of having to appeal insurance company decisions and obtain prior authorizations. We typically "go with the flow" if we don't have a compelling reason to use one class of medication over another. Other factors that affect treatment decisions include patient finances and insurance circumstances such as being underinsured, not insured, and the level of copays. For instance, we may choose a PDE-5 inhibitor over an ERA for a patient that does not have insurance coverage to get monthly lab tests done or will not comply with getting routine blood work. If it were only up to us, we would simply choose what we think would be best for a particular patient's circumstances.

Ms Frutiger: Fortunately, most of the time we don't have reimbursement barriers; but when we do experience them, they can certainly affect what you recommend to a patient. Dr White and I visited a local HMO office in our community this fall and spent an afternoon educating them about PH therapy options. We actually had to use leverage from community dissatisfaction with that particular insurance and the threat of negative publicity to get more options available to our PAH patients. The meeting did make a significant difference; and ironically, we had patients coming to our office with a letter from the insurer requesting that we switch them from one oral therapy to another based on the education that we had done in that office. Another barrier that we encounter with insurers is when a therapy is denied and the appeal is sent to an outside reviewer. Often the review panel is composed of non-PAH physicians who are not integrating current literature or the patient's clinical situation into their decision making. This has been a barrier to our patients' getting appropriate therapy and we believe that our patients would be best served by having appeals reviewed by physicians who focus their practice on PAH.

Ms Kingman: In Texas, we've had some similar issues. For instance, we have some insurance companies that use the "step" approach, where the insurance company will require that a PDE-5 inhibitor is used before an ERA. Most recently, inhaled treprostinil and tadalafil were not on the Medicare or Medicaid formularies at the time they were approved, so that was certainly a barrier-but that's getting resolved now.

Ms Poms: Martha, that made me think about the issue of what the copay actually is. That certainly plays a big role here for us in determining which oral therapy to choose. If a patient has a substantially lower copay for one class of medications over the other, we'll opt to choose the medication with the lower copay unless there's a compelling reason to do otherwise.

Ms Traiger: I think you've all brought up issues that point to how complex these decisions can be for patients and how important it is for the nurse, the respiratory therapist, or the other health care providers to help patients negotiate through these decisions. Physicians may not have time to sit and go through all of these issues with patients and their families. In the early years of treating PAH, only intravenous (IV) epoprostenol was available for the majority of patients who were not vasoreactive. With the advent of several oral therapies for PAH, do you find that patients with more severe functional disability are reluctant to go on prostacyclin therapy? And if so, what strategies have you found to be effective in helping patients accept prostacyclin therapy?

Ms Poms: I'm going to take a crack at that one, because it's a pet peeve of mine. I think there's a big difference with patient attitudes and acceptance of therapies outside of true PAH

centers where we do really make evidence-based decisions. At our institution we really don't have a problem trying to "convince" patients to go on IV therapy; there's such compelling long-term data available to share with them. For instance, epoprostenol is the only FDA-approved medication that has shown a mortality benefit. It all depends on how you present the data and the choices to the patient. We tend to be quite aggressive with very ill patients, letting them know how severe their disease is and what our goals are. We can then discuss the potential for transitioning off IV therapy if that is, in fact, a realistic goal for the patient. When you spend the necessary time to provide patients with an overview of the clinical data and, especially, the lack of data for using less intensive therapies, I think you can make a compelling argument for patients to accept IV therapy. In my opinion, inconvenience and/or risks associated with IV therapies are simply not good enough reasons to choose other therapies in very ill patients.

Ms Frutiger: I agree with Abby. I think this is all about patient education, and I think it's also about building a relationship of mutual trust. There have been some circumstances where we feel very certain that a patient needs to be on prostacyclin therapy, but we may use oral monotherapy as a bridge to getting there, so that we can continue to provide that patient with information, set some tangible goals in terms of exercise tolerance, and then return to reviewing those goals in the office. We will follow a patient very closely when we believe they should be on a prostacyclin therapy but are not yet ready to accept it. If they choose to go on an oral therapy, we'll repeat a right heart cath, 6-minute walk test, and an assessment of exercise tolerance. We encourage patients to keep the door open to prostacyclin therapy, to get more information about it, and we try to link them with patients that are already on prostacyclin therapy to help ease their fear and concern.

Ms Kingman: I actually show them their serial cath reports, cardiac MRI reports, echo reports, and their 6-minute walks. This allows them to visualize the trends, which has been a very convincing approach when talking with patients about the need to escalate therapy.

Ms Frutiger: I think the group of patients that really need to integrate and understand that hemodynamic data are those who are functional class II and are relatively well-compensated, but that are, nonetheless, very sick patients. They may not be that symptomatic, but their hemodynamics indicate that they need an aggressive treatment. Helping those patients understand their test results and giving them data about therapies are really helpful.

Ms Traiger: In your practice, what is the role of inhaled prostacyclin therapy? For example, is it used as a bridge to parenteral therapy for those who refuse parenteral therapy, or is it a "destination prostacyclin," meaning that they'll go on inhaled therapy and that would be the therapy on which they would remain?

Ms Poms: Certainly we use the inhaled therapies for all of those reasons. I think the group that's tough to deal with are those patients that start on an oral therapy and don't feel better but don't decline either. The patient perception may be, "I'm not getting any worse, so this medication's working for me." These patients may still have walk distances under 350 meters or so, echocardiograms showing enlarged hypocontractile right ventricles, and are symptomatically stable but not where we'd like them to be. Maybe they are not quite ready or willing to go on IV or subcutaneous (SQ) therapy, so we use inhaled therapies in these patients for a short period of time. After 3 to 6 months, if the patient is not improving, it's time to get serious and make sure that they understand the progressive nature of this disease. And, as Karen and Martha stated, provide the necessary education to show them all their

serial test results and make the case that it's time to go on an IV or SQ therapy. Inhaled therapy may also help us wean people off of IV or SQ therapy, and we've certainly done that successfully with a number of patients. It's important to point out that some patients will deteriorate and need to go back on IV or SQ therapy. Unfortunately, we don't have a good way of predicting who these patients might be. Overall, I think most patients with true WHO Group I PAH will continue to progress and eventually require IV or SQ therapy.

Ms Frutiger: I agree with Abby. If a patient needs a prostacyclin, we would prefer not to delay the best available therapy; and we believe that in most cases inhaled therapy is not the best available prostacyclin therapy. We have used inhaled therapy for patients that do not have a support system or the ability to handle complex pump-based therapy. We have offered it to some patients as a bridge, but that's a little unusual for us to do that. For functional class II patients who need a prostacyclin, a barrier to using inhaled therapy as a bridge to pump therapy is that some insurers justify denying inhaled prostacyclin therapy based on functional class alone.

Ms Kingman: In our practice, we do have some patients for whom inhaled therapy is a "destination prostacyclin." Those are the patients who have a concomitant lung disease such as severe interstitial lung disease (ILD) or chronic obstructive pulmonary disease (COPD) where we believe they have components of both PAH and ILD or COPD. We've found that if we use the inhaled prostacyclins, patients have less V/Q mismatching and desaturation issues compared with the IV therapies. This is a small percentage; for most patients we use inhaled therapy as a bridge until patients require IV therapy.

Ms Traiger: What advice do you all have for small centers or patients in remote areas that may not have easy access to other patients and clinics or support groups as they're trying to decide about prostacyclins and how to deal with that therapy?

Ms Frutiger: Refer them to a PAH center. I think that we, at our center, are really delighted to collaborate with other providers, and we have a number of patients that we may start on therapy, stabilize them, and then plan collaborative follow-up and communication between the local pulmonologist or cardiologist and our center. We may only see these patients once or twice a year as long as they are stable and work closely with local providers.

Ms Kingman: I certainly agree that patients should be referred to PAH centers. But if they are somewhere where they're not able to get to one, we will suggest they look at the PHA Web site where they can get online and chat with other patients who have PH and get some support that way. Also, there's the peer-to-peer network for patients on treprostinil, which connects similar patients for online communication.

Ms Poms: Peer-to-peer support services are very helpful. And with the advent of home health visits by skilled PH nurses that are available anywhere in the country, we can provide great education and follow-up in the home. We certainly do support the concept of a PH center playing a consultative and collaborative role for less-experienced providers. It's critical to establish the right diagnosis, get the most appropriate therapy started, and at least occasionally reassess the patient. We also try to connect patients by phone by asking those "go-to" patients in our practice who are willing to talk to people on the phone. I've talked to plenty of patients in outlying practices about how complex therapy is, and getting them to understand that, even though it's a few hundred miles away, it's worth a visit to get to a center.

Ms Traiger: Abby mentioned home health visits. Have any of you used what we call "pre-teach visits" by the specialty pharmacy (SP) nurses to teach patients in the home and show them the pump so they can see what they're getting into?

Ms Poms: Yes, that's exactly what I was referring to. We do this with every patient going on inhaled, IV, or SQ therapy, even if they live 10 minutes away. It's a great way to augment our clinic education.

Ms Frutiger: They're in their home, in their own environment, there's no white coat syndrome. The SP nurses can show them every pump and the supplies. They can spend that kind of time that many of us don't have to spend with the patients in the clinic. We do that automatically for every patient.

Ms Kingman: Additionally, the SP nurse can do an assessment of the home environment. In the doctor's office, you may not get a clear picture of the patient's home environment.

Ms Poms: For the SP nurse home visit, we order a home assessment, a demonstration of one or multiple therapies, and a pre-teach session.

Ms Frutiger: I think it's a great thing to do for patients that are considering, but have not committed yet, to pump-based therapy. Getting the SP nurse out there so that the patients can really get their hands on the pump and defuse their anxiety about using pump-based therapy is a great way to make a decision about therapy.

Ms Traiger: Pulmonary arterial hypertension is considered a progressive disease, and at some point many patients experience an unacceptable quality of life on maximal medical therapy. Some of these patients may be deemed acceptable candidates for lung or heart/lung transplantation. At what point are eligible patients referred for transplant?

Ms Kingman: In general, patients are eligible for transplant when they have failed maximum medical therapy. For us, and probably most centers, that means medication from all 3 pathways; in our practice, the prostacyclin would be Flolan. If the patient is still worsening and they're otherwise a candidate, we then refer for lung transplantation.

Ms Poms: One of the things that we focus on is talking with patients about overall lung transplant survival rates. If we have a patient whose probable survival rate appears to be less than the national survival rate for lung transplantation, we will initiate a serious discussion about their prognosis over the next 1 to 3 years and possibly refer them for transplant. It's a tough decision, because there is no longer an ability to waitlist for transplant, which allowed patients to build up time on the waiting list should they require a future transplant. Currently, once you refer a patient to a transplant program you are, in fact, saying, that they are ready to be transplanted as soon as a donor lung is offered.

Ms Frutiger: It's a very difficult window to nail down.

Ms Poms: Especially with the LAS that currently exists. It's an unfair system for our patients since some of the critical measures used in determining disease severity in PAH are not included in the LAS. The conundrum is whether you refer earlier, knowing that these patients are going to wait longer on the list compared to other patients before their scores allow them to receive a transplant.

Ms Traiger: What strategies have you found to be effective for patients who are reluctant to consider transplant?

Ms Poms: I think that's just such a personal decision. We give them as much factual information as we can, and connect them with PH patients that have undergone lung transplant so they get a better sense of what's involved. Certainly, for patients that are on multiple PH therapies and are oxygen dependent, quality-of-life issues are a key part of the discussion. If they're still hesitant, we don't push them.

Ms Traiger: What clinical markers are used to determine that the patient is ready for transplant? Do you have any particular testing that you do at your center?

Ms Poms: The patient's LAS will determine how quickly they get transplanted. There's a lot of work being done within the PH community to adapt the LAS to more accurately measure disease severity in PAH patients. For instance, pulmonary function tests are one of the best indicators of disease severity for most pulmonary patients, but with the exception of the DLCO, they are not helpful in defining how ill PH patients are. And these test results are one of the major components of the LAS. The LAS does not include right atrial pressure or cardiac index-data that we always focus on in PH. Once a patient is actively listed for transplant, there's not a lot we can do-other than work toward getting the system changed.

Ms Frutiger: As a nontransplant center, it's important for us to provide the transplant center with information and not hesitate to pick up the phone if the patient's deteriorating.

Ms Poms: Good point. Another option before transplant referral might be consideration of a clinical trial with a new type of therapy for PH. There's a lot to be considered; it has to be very individualized.

Ms Traiger: So things are different now from the way they were about 5 years ago in terms of referring patients for lung transplant?

Ms Poms: In the past we automatically referred anybody that went on an IV prostacyclin to transplant if they were a candidate. They could get evaluated, listed, and build up time on a waiting list until such time came that the patient was doing poorly with intractable right heart failure. At that point, the patient could be activated for transplant. That system certainly favored patients with PAH, and now the current system clearly does not, which is why it's so difficult to know when to commit to lung transplantation. I think that's the real critical decision.

Ms Frutiger: I think we tend to send patients for transplant referral earlier, rather than later, because we believe the patients benefit from being educated during the evaluation process. They benefit from getting the transplant team's expertise in regard to their own individual situation, and we want them to have a relationship with the transplant team before the time they actually get transplanted. So if they're failing maximal therapy, or we're going to put them on a third class of drugs, we send them for an evaluation concurrently.

Ms Poms: That's an excellent point. They should hear the statistics and what's involved from the experts. Sometimes you send patients for lung transplantation and when they find out what it's all about, they don't want to do it.

Ms Frutiger: We reassure our patients that a transplant evaluation is a learning process; an

introduction to transplant. For people who are very, very frightened at the prospect of transplant, we reassure them that they certainly can be evaluated and then make an educated decision regarding whether or not to go forward with transplant.

Ms Traiger: Pulmonary arterial hypertension is a chronic disease that is often accompanied by significant comorbid conditions. Pulmonary hypertension medications often cause significant side effects. What resources or strategies do you use to assist patients with depression, symptoms, and side effects?

Ms Frutiger: We have a nationally acclaimed palliative care team at the University of Rochester and we do not hesitate to refer our patients to the palliative care team for symptom management, for goal setting, and to involve another provider in their care. We've enjoyed a great relationship with those providers and they've made a significant difference in our patients' quality of life. So I would strongly advocate for a palliative care referral. If a community does not have a palliative care team, consider other providers, such as anesthesiologists who are interested in pain management. I wouldn't hesitate to refer a patient. Also, involving the primary care provider in management of mental health issues (depression, etc) has been very helpful.

Ms Poms: We are starting to work more and more with our palliative care team and consult them for any patient that goes on IV prostacyclin therapy. They can be extremely helpful, particularly with symptom management, some of which is related to non-PH issues. We tend to be more focused on the PH and make sure that our patients understand they need a really good internist, pulmonologist, or cardiologist in their home community with whom we can collaborate. Many patients have hypertension, diabetes, sleep apnea, and many other comorbid conditions. We just don't see the patients often enough to manage those disease states well.

Ms Kingman: I agree. Also many of these patients have depression as well. If we feel, after assessing them, that their depression is mild and they're in a safe situation, we will often prescribe an antidepressant. If they're not responding or worsening, we refer them to psychiatry for help with medications and counseling as well.

Ms Traiger: Unfortunately, sometimes when you say palliative care, patients, families, and even healthcare providers may be thinking hospice care. It's a challenge sometimes to educate all of those parties that palliative care is different from hospice care and it doesn't necessarily mean that end of life is near or that we're pulling back on therapy. So that's one of the challenges, to make sure that people understand the difference between palliative care and hospice care.

Ms Poms: I think that palliative care teams rue the day that anyone gave them that name. When we talk to patients about palliative care, we say, "these are the experts that can help you learn how to live well."

Ms Frutiger: Yes. And we really emphasize that we partner with palliative care, for example, to manage prostacyclin symptoms so that the patient's dose can be increased to manage their PAH while keeping their side effects under control.

Ms Traiger: At some point, many patients are faced with end-of-life decisions. What are the difficult issues that patients and families must deal with at end of life and how can health care

professionals facilitate end-of-life decisions?

Ms Frutiger: I think we should always keep in mind that the benefits of the therapies that we're providing should outweigh the downside. If a patient is clinically deteriorating and struggling with side effects from their medications, we should encourage and allow a discussion to take place about whether we're really doing more harm than good. That is certainly appropriate. I think there are some patients for whom the idea of withdrawing therapy at end of life is completely unacceptable and they are not comfortable discussing or considering that, and we would not press a patient on that issue. I think other patients really appreciate the option of being able to talk about stopping therapy and pursuing a comfort-oriented approach when the time is appropriate. So we try to meet patients where they are at and be open and supportive to their concerns.

Ms Poms: Based on my experience with patients, it's really a quality-of-life issue. The approach has to be very individualized. We all have those patients that are on IV therapy, maybe 1 or 2 oral therapies and oxygen, and they still have a decent quality of life. They are certainly end-stage but they have goals-to see a child graduate from high school or college or a wedding. Caretakers must be considered, as well, as it's often a huge burden emotionally and physically for them. And many patients live with the guilt of feeling like they're a burden to others. At Duke we case manage so we really get to know patients and families quite well and can individualize those discussions.

Ms Frutiger: At their request, we will meet with family members after a patient has died. That's been great for us and I think very helpful to family members to close the loop, get their questions answered, and feel like we've stayed involved right through the whole process.

Ms Traiger: At what point do you discuss advance directives with patients and their families?

Ms Kingman: When the patients come into the clinic for their office visit, the receptionist asks at every visit if they have an advance directive. If they don't have one, they're offered assistance to complete one. But I think that we often tend to wait too long, until the patients are clearly not doing well and things are not looking favorable, and that's when we start talking to them about advance directives. This includes what kind of things they want to have and not have done at the end of their life. Unfortunately, that sometimes takes place when they're in the hospital and they've become very sick, very quickly.

Ms Poms: We know with this disease state that people can do quite well for a long period of time, but when they fall off the cliff, they really fall fast.

Ms Frutiger: This is probably an area in which all of us can improve. With cancer patients and other chronic illnesses, advance directives are considered early in the course of the illness. Some of those real basic questions can be addressed early, and then, like Martha said, some of the more difficult decisions can be sorted out later.

Ms Traiger: One of our routine support group topics is advance directives. At the meeting we'll talk about advance directives and I will have advance directives for everybody to complete, including the caregivers and health care providers. So we present it as something that everybody should have, not only a patient with PH. We try to address end-of-life questions early, too. But sometimes it doesn't always happen early and we are faced with a difficult decision. Or sometimes patients deteriorate rather rapidly and then we're faced with

trying to do that counseling at a difficult time.

Ms Poms: Right. And you certainly want to do it at a point in time when the patient can be the one to direct the discussion and not have family members conflicted over what to do for the patient. Those are really difficult situations.

Ms Traiger: Thanks to all of you for taking time today to discuss how we can assist PH patients and families with treatment decisions. New developments in the science of PH will present continued opportunities and challenges in the future. The collaborative PH team is well-equipped to help patients and families navigate this complex maze of decisions.

"We encourage patients to keep the door open to prostacyclin therapy, to get more information about it."

-Karen Frutiger, RN

"For most patients we use inhaled therapy as a bridge until patients require IV therapy."

-Martha Kingman, RN

"Home health visits by skilled PH nurses ... can provide great education and follow-up in the home."

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