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Exploring Drug Shortages in the U.S.: What Do We Need to Know?

Dr. Sands:
Drug shortages can create challenges in the treatment of patients and elicit fear and frustration among pharmacists and patients. So, what exactly is causing these shortages now? And what can we as healthcare professionals do about it?

Welcome to *Project Oncology* on ReachMD. I'm Dr. Jacob Sands. And joining me today to talk about drug shortages in the U.S. is Dr. Maya Leiva, a board-certified hematology and oncology clinical pharmacy specialist at Inova Schar Cancer Institute and Associate Professor of Pharmacy Practice at West Coast University.

Dr. Leiva, welcome to the program.

Dr. Leiva:
Thank you so much for having me.

Dr. Sands:
So, to start us off, can you give us a framework of the historical drug shortages in the U.S. and an overview of where we are now?

Dr. Leiva:
That's a great place to start. And, you know, as a pharmacist, I can say that having practiced now for more than 10 years, this has been a kind of frequent and beguiling issue for a long time. And, of course, we've seen a substantial increase in drug shortages that are actually affecting patients, and in some cases for prolonged periods of time. And, you know, this isn't necessarily specific to just oncology. I think at this point, you know, the general public is very familiar with the ones that have occurred and been highlighted during COVID, around hydroxychloroquine, dexamethasone, which is, unfortunately, a very common drug that we use in oncology in terms of both supportive care and also the backbone of a number of treatments for hematological and solid tumors. One other challenge with this is, again, is people were quite sick during the pandemic, and we had a lot more patients on ventilators. We were also seeing a lack of access to paralytic agents, drugs used for sedation—right?—antibiotics and then ultimately other drugs that were found to be very beneficial for COVID like tocilizumab.

But this is by no means a new problem, like I stated previously. In oncology, one of the first drug shortages that I dealt with that was really significant and severe and led to actual changes in practice was leucovorin. And leucovorin is, you know, a very important drug that we use in a number of GI malignancies along with 5-FU, or fluorouracil, and we had to, you know, decrease doses and do a whole lot of adjustments to therapy in the absence of data, because we just didn't have access to those drugs.

Dr. Sands:
So you've mentioned a few of effects, particularly within oncology. Are you able to flesh that out a little bit more? What are you seeing on oncology-related drugs beyond leucovorin, as you mentioned?

Dr. Leiva:
Yeah. So, most recently, we've had a number of other chemotherapy drugs: decitabine, which is used very frequently in, MDS treatment, and also some AML patients as well. We were dealing with actually a very prolonged shortage of dacarbazine, which is an essential drug in the ABVD regimen that's used for a very curable form of cancer—Hodgkin's lymphoma. And so, unfortunately, you know, again, with a lot of these shortages, we don't have a lot of warning. It can literally be you were able to order the drug the day before and then now you don't even have access to an allocation. So dacarbazine is one. You know, I mentioned Abraxane. Abraxane has also been a significant issue in terms of shortages. That one has fairly pretty much resolved at this point, but we actually had to investigate, you know, changing patients from Abraxane, for pancreatic cancer to other alternatives because we just didn't have access

to the drug.

Another thing I want to point out is, I had mentioned dexamethasone in the context of COVID and that being a very common drug—we also were having significant shortages in electrolytes, and even things as simple as fluids. If we can't put drugs in fluids, then, you know, we're going to have to potentially change the way we even administer some of these drugs.

Dr. Sands:
So, as a follow-up to that, you described a number of drugs that there have been shortages of. Are there solutions to those? Are there alternatives that are proven, or are teams being kind of stretched to come up with alternatives that aren't as considered a standard of care?

Dr. Leiva:
Yeah, that's a great question. And so I can tell you know, of course, anecdotally, as a clinician I deal with these all the time, and so I can tell you, you know, all the various pain points, but certainly, the literature that's been published within the last couple of years recognizes that a number of institutions across the country are, are also facing this pinch. And what's really difficult is, when it comes to oncology, we often don't have a lot of alternatives, and what I mean by that is, you know, we may not have data substantiating major therapeutic switches. Right? So, in the case of dacarbazine, for example, you know, we had to really entertain far more toxic regimens that, based on the evidence over the years, we know, yeah, they may be equally effective, but they might be far more toxic for patients, and so, often we're faced with an ethical quandary too. You know, how do we talk to patients, for example, about these shortages and get them to understand sort of what we're doing, to support them? How do we navigate restricting use or criteria for certain patients and prioritizing those patients? And then also trying to work with the pharmaceutical companies, you know, depending on who the supplier is to find out how we can, again, support the allocation of those drugs.

Again, it's kind of an evolving challenge. We know that it often results in treatment delays. You know, sometimes we have to strategically reduce doses, and then, again, in the literature, one of the recent publications, published by the Hematology/Oncology Pharmacists Association in 2021 reported that, 74 percent of respondents said that they had to do a number of different things, that essentially meant that the patient didn't necessarily get the, you know, optimal treatment.

Dr. Sands:
For those just tuning in, you're listening to *Project Oncology* on ReachMD. I'm Dr. Jacob Sands, and I'm speaking with Dr. Maya Leiva about drug shortages across the U.S.

So let's get into why the drug shortages are happening. Now, of course, one aspect of this that's affected so many of our lives at this point is the COVID-19 pandemic, but you've also mentioned other factors as well. So, what are some of the events happening across the globe that are impacting the availability of our oncology drugs?

Dr. Leiva:
Yeah. That's a great question. You know, the other thing that I want to point out is there are a lot of similarities with the current baby formula shortage, and unfortunately, again our drug shortages sort of mirror some of those challenges. Often there are raw material shortages. Also, climate change and associated disasters. So, for example, in 2017, when we had Hurricane Maria, a number of facilities in Puerto Rico that produced fluid supply for the United States and actually for a number of different countries in the world, they were shut down because of loss of power. You know, they were inundated with flooding. And so we, again, faced this substantial shortage in fluids and had to really change the way we practice in oncology, and, you know, a number of other specialties also had to adjust.

Unfortunately, we also see that there are supply chain bottlenecks and those are related to a variety of factors, including demand surges, which we saw, especially in COVID, and also conflict areas. Right? So, in areas where maybe they had been participating in the global supply chain and there are conflict zones, or other issues preventing the importation or exportation of medications, that can really kind of contribute to the issue.

Dr. Sands:
And from your vantage point, what are some changes that can happen at a pharmacy level that might help improve some of the access?

Dr. Leiva:
Absolutely. I think one of the things is trying to forecast. Right? So, even though none of us has a crystal ball. There are ways that we can kind of just generally monitor, storms recognizing kind of where we're getting supplies from and anticipating, especially as we're now approaching hurricane season, this is going to be very important.

And we also can use resources that are available, like the American Society of Health System Pharmacists, or ASHP. They actually

have a very helpful website that is updated daily anytime there is a shortage. And one of the things that's nice about the ASHP website is that they also provide any additional information around, when the shortage is anticipated to start, the potential duration as well, and then they provide a revolving list even of, of shortages that have resolved. And sometimes we find out about these things before we even get notification from the manufacturer.

And then there are other ways too. Making sure that you have or that systems have really good policies, procedures and protocols in place. How do we notify providers? How do we make decisions about treatment selection, right? So, how do we prioritize those patients? Do we have difficult discussions around prioritizing patients with curative intent or patients who for whom there are no other options at all?

And then also creating additional room for allocation storage. One of the things that happens sometimes is pharmacies in terms of drug store storage, especially for hazardous drugs, we have limited space, and so one thing that pharmacies can do is really anticipate where can we continue to purchase allocation of materials and keep those in the event that we're just not able to get enough supply. So that's part of it, real time inventory tracking.

So there are a number of things that we can do. It's just it does take an inordinate amount of energy, coordination and collaboration with the entire team and also patients to ensure that everyone gets what they need.

Dr. Sands:
Well, that is an amazing summary of things to do. It's actually really encouraging to hear that there's so much. On top of that, as we come to a close, Dr. Leiva, I'd like to give you a final option for any further takeaways that you'd recommend to our audience today.

Dr. Leiva:
Yeah. I would say, again, expect the unexpected. We're going to continue to see these drug shortages increase unless there is major action taken at a legislative level and at a manufacturing level to help prevent these breakdowns in supply chain. But at least we do have hope, right? And there are a number of ways that we can kind of collectively address this until we have real sustained solutions.

Dr. Sands:
With that insightful information in mind, I want to thank my guest, Dr. Maya Leiva, for sharing her perspective on the drug shortages seen across the country. Dr. Leiva, thank you for joining me today.

Dr. Leiva:
Thank you again for the time.

Dr. Sands:
I'm Dr. Jacob Sands. To access this and other episodes in our series, visit reachmd.com/projectoncology where you can be Part of the Knowledge. Thanks for listening.