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# Long-Term Safety of DMTs: What We Know and What We Need to Know

**Announcer:**
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**Dr. Freedman:**
Hello, everyone, this is CME on ReachMD, and I'm Dr. Mark Freedman from the University of Ottawa in Ottawa, Ontario, Canada. And with me is my colleague, Dr. Ahmed Obeidat.

So, Ahmed, you are well aware of some long-term data that's associated with many of the medications that we are using today, especially the high-efficacy DMTs. Can you talk a little bit about this data and how it's helped us, at least to maybe discuss the safety aspect?

**Dr. Obeidat:**
Yes. This is a great question, Mark. One of the things that I always kind of think about as a philosophic question is what is long term? What defines long term? Is it 5 years? Is it 10 years? Is it 15 years? Is it 20 years? Is it longer?

I always kind of think, the longer is the better, right? So the longer we have data, is the better kind of information that we do. And of course, this is limited by when the drug has been approved on the market, when the drug has been kind of used in multiple sclerosis, so that gives us the time that we can actually collect data on.

There are several sources for collecting long-term data. One of them is the main one. It kind of comes in after the clinical development programs for the drugs where we have this, what we call open-label, long-term extension, and we try to kind of get some information on safety from these studies. But these are sometimes very limited by attrition. People can leave these studies, and maybe sometimes the ones who leave are the ones who are not doing as well. So that's where the bias can happen.

So the other way of getting this, is just long-term cohort studies that people kind of follow over time in a real-world population, which I think that gives us a little bit more idea closer to what we're going to see in the clinic. And sometimes you look at kind of studies where they're looking at, as we know, sometimes looking at propensity score matching between drugs, trying to compare safety between drugs from real-world aspects.

But also, there is the FDA database and that is a voluntary reporting for people to send any of the adverse events to the FDA, and then people can analyze this data. But they have limitations because there's a lot of issues with kind of calculating risks from those types of databases. But at least it gives us an idea on any new safety signal, and that's one of the things that we always kind of think about is, can this medication – that what we saw in the clinical trial, is this what we're going to see in the real world? Or are we going to see new safety signals? And that's very important.

**Dr. Freedman:**
Now, at least one of these drugs has been around for a while. The newer higher-efficacy therapies, we're getting into maybe a decade's

worth of this follow-up. But at least one of these drugs, cladribine has been around since the ‘70s and started to go into clinical trials with MS probably early part of this century. And they’ve had probably one of the longest safety follow-ups of anybody who's been on this drug.

Can you speak to that? Because there was an issue initially, and the drug was not released in the United States and then came back, and mainly because of this long-term data that they've been able to collect.

**Dr. Obeidat:**
Yes. And I think this is a great point because this is a medication where there was an increased risk of malignancy, and that's one of the things in the actual US label, too, and other labels around the world, where there is an increased risk of malignancy, and that may be what hampered this drug from coming to market to the first place, when it was first presented. But what we know from long-term data – and that's where long-term data helped us, right? Because we know now that longer-term data is not showing a continued increased risk. And we know cancer risk is something that is cumulative over time, but what we're seeing, we're seeing that that signal maybe is still there, but it is not increasing over time. So something that provides reassurance, also, when we talk to our patients, that there is not that time-dependent component that could be a factor for adversity here.

So that’s one of the things that we kind of think about. But again, real-world data is very important. And for that particular medication actually, what we're seeing, we're seeing more and more cohorts from around the world publishing their own experience with the drug. And the message has been consistent, which is a good thing. The other group of medications that are very, very important is T cell-depleting therapy, and we are also collecting data on long-term safety, and we're seeing the same as the signal is kind of holding there, which is good.

**Dr. Freedman:**
Well, thanks for condensing all of that information for our audience, Ahmed. Our time is up. And thanks to all of you for listening.

**Dr. Obeidat:**
Thank you.

**Announcer:**
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