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Balancing the Scales: The Complementary Roles of RCTs and RWE in Modern Healthcare

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Dr. Gallagher:
Hello, I'm Dr. Christopher Gallagher, a Medical Oncologist and I'm going to be speaking today about Balancing the Scales: The Complementary Roles of Randomized Clinical Trials and Real-World Evidence in Modern Healthcare.

I'm going to start with what are the benefits of randomized controlled trials? It has served us as our gold standard. They're very highly reliable. We can study the safety and efficacy of a treatment under very well-defined controlled conditions in very select populations. This is the way we learn about unexpected adverse effects of the treatments. And we understand sort of how they're done and what the endpoints are. So, randomization, blinding, the intention-to-treat approaches, these will all limit sort of confounding factors that sort of allow us to look at the efficacy of a treatment between two specific interventions that we may be looking at in the trial. And the design points, whether it's progression-free survival, overall survival, response rate, all these endpoints are sort of understood by us in the scientific community. And the trial designs also do the best to protect the patients from harm while it's being conducted.

But what are the limitations? It's not representative of the general population in the real world. Patients can have performance statuses that wouldn't have been fit enough to participate in a trial. Minority populations are not always included in real-world – excuse me, in randomized clinical trials. Comorbidities, concurrent medications, and treatment of older. Older patients don't always participate. And the majority of our patients, many times are older, depending on the disease. Follow-up periods are often shorter. The patient populations are often smaller. And then clinical trials in general are very costly and slow to conduct and then to wait for results. But probably the most important limitation may be that once a trial has published, or presented, the standard-of-care arm that new treatment was compared to, may not actually reflect what our standard-of-care is at the time the trial is completed.

So, what are the benefits of real-world evidence? Well, there can be much more patient diversity. We can identify what real-world treatment patterns may look like. There's a much larger sample size, sometimes not always. And it can be much longer follow-ups, which may help us find sort of niche populations where either the treatment worked better or worse, and sort of inform us of sort of future study. They may uncover rare toxicities occasionally. And assessment of safety and tolerability in context with other comorbidities and concomitant medications. You know, we can see how people did in the real world with this evidence and kind of compare it to the patients who may be sitting in our clinic in front of us. And sometimes this external validation, we can look to see if the benefits of the intervention, you know, if it's a drug, are bigger or smaller than what we saw in randomized clinical trials.

So, looking at the limitations of real-world data, you know, how was the data collected? How was it used? Electronic health records can provide us lots of information. But a lot of the data is unstructured. It could be free text and natural language processing is trying to improve, but I think it has the way - a way to go. Insurance claims and registries are other sources of real-world data. And these huge data sets make it, you know, possible to look at lots of patients who may have received the treatment. But there can be a lot of lack of

data, inconsistent data. And sometimes even when the data was entered to the proximity of the disease, it's hard to make a lot of assessments. Real-world data, there's no randomization. There's no stratification based on performance status or comorbidities. But probably the biggest limitation is the data collection. There's no structured data necessarily. Imaging is not done at a certain time. There's no blinded, independent central review of imaging. There's no biomarker review. Understanding true adherence and dose reductions and dose interruptions, which is sometimes important information to understand when using a drug, is not always very understandable in real-world data. There's very inconsistent reporting of adverse events, especially in grades 1 to 3 that aren't necessarily going to be reported in this data. And we just know that the data can be very heterogeneous and there can be missing or inadequate data.

So why are they both needed? I think that there's a lot of complementary value in looking at real-world evidence in combination with randomized clinical trials. It can close gaps in knowledge and safety and efficacy. It can be hypothesis generating as far as what studies we may want to do next. But probably the most important part, it can aid in communication between the physician and the patient sitting in front of you to help them make decisions.

Okay that's the end. Thank you for listening.

Announcer:
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