Study identifies barriers to physician adoption of federal Right to Try law

September 22 2020

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A new study published in the *Journal of the National Cancer Institute* is the first to examine the opinions and experiences of clinical oncologists working at a major medical center on the Federal Right to Try (RTT)

law.

Enacted in 2018, the Federal RTT law was created as a new and parallel pathway to the Food and Drug Administration's (FDA) Expanded Access Programs (EAPs). The federal RTT law permits patients to request experimental medicine outside of clinical trials for cancer patients and patients with other conditions, but differs from EAPs since it requires no FDA review or ethics approval from an Institutional Review Board.

The study team undertook 21 interviews with oncologists at Mayo Clinic locations in Florida, Minnesota and Arizona who had experience obtaining experimental medicines for patients outside of clinical trials via the FDA's EAPs. "We purposely chose oncologists with experience in clinical trials and EAPs because they were likely to know about RTT and may have had experience with RTT, " says the study's lead author, Zubin Master, Ph.D., a Biomedical Ethicist at Mayo Clinic. Dr. Master says oncology and hematology are two fields with some of the highest number of EAP requests.

EAPs are preapproval pathways that permit oncologists to request access to unapproved and experimental drugs from companies for their patients when the patient is ineligible to participate in a traditional clinical trial.

Dr. Master says that despite all of the study participants having some experience with EAPs, most had limited familiarity and experience with RTT. And several participants reported being confused about the provisions of the RTT law, including whether patients had a right to investigational drugs and whether a drug company had an obligation to provide them.

"The federal RTT law does not obligate pharmaceutical companies to provide experimental drugs to patients and patients do not have any

additional rights to access experimental drugs," says Dr. Master. "In this sense, RTT is similar to EAPs because in both cases, physicians have to request experimental drugs for patients, but companies do not have to provide them." Moreover, Dr. Master says "other studies have shown that FDA grants over 99 percent of EAP requests and gives physicians advice on dosage and monitoring."

After capturing the initial views of oncologists, the study team provided information about the federal RTT law to capture the opinions of participants. The study showed that the oncologists interviewed were interested in reducing their regulatory burden, but expressed concerns about RTT including:

- Concerns about patient safety, limited oversight, and an unclear mechanism for accessing experimental therapeutics
- No provision to collect data on patients who were given an investigational drug
- Potentially heightening patient expectations.

Dr. Master and his colleagues observed that only a handful of oncologists had experience discussing RTT with their patients and none of them obtained the drugs from companies. "Oncologists identified the need to have a nimbler regulatory framework for accessing drugs for patients outside of clinical trials, a desire for more education, and the need for administrative support on the preapproval process," said Dr. Master.

"Our study shows that oncologists at a major cancer center, most of whom were engaged in clinical research and all of whom had experience with EAPs, were less informed about RTT, says Dr. Master. The study concludes that oncologists need to be better informed about RTT and other preapproval pathways in order to provide the best care for oncology patients.

More information: Cambray Smith et al. "I think it's been met with a shrug:" Oncologists' views toward and experiences with Right-to-Try, *JNCI: Journal of the National Cancer Institute* (2020). DOI: 10.1093/jnci/djaa137

Provided by Mayo Clinic