



June 25, 2018

### **Joint Statement from the American Diabetes Association and JDRF:**

On June 25, Dr. Denise Faustman presented data at the ADA's 78th Scientific Sessions, and the information presented was published in a medical literature article in *npj Vaccines*, a Nature Partner Journal. The findings in the June 21 article reported a follow-up study of people with established type 1 diabetes (T1D) treated with the bacillus Calmette-Guérin (BCG) vaccine, which evaluated the impact of the intervention and provided a hypothesis to support the notion that BCG vaccination could be beneficial for people with T1D.

While this work has attracted attention, the study only followed a very small number of patients—nine people at the five-year time point, and three people at the eight-year time point—and must be interpreted with caution.

Overall, the findings prompt thought-provoking questions but not definitive answers, and do not provide enough clinical evidence to support any recommended change in therapy at this time. Specific limitations that should be considered include:

- All study participants continued to use standard insulin therapy throughout the trial; it's not a situation whereby the treatment changed their standard of care (all vaccinated individuals remained on insulin therapy).
- The patients with reported positive outcomes achieved only moderately lower A1Cs, which, while marginally statistically significant, cannot be generalized to the millions of people living with T1D and is not established to be as a result of the vaccination.
- The article doesn't account for the natural variability in A1C levels over time, which is well known to occur in this population: they tend to improve in people with T1D as they age, particularly as they move out of their teens and early 20s. It's unclear what role that natural history may have played in these subjects.
- There is no detail on the standard of care in the BCG treated and control group. For example, was the care comparable between both study groups or were adjunctive therapies used?

JDRF and ADA do not currently fund Dr. Faustman's work. We will be monitoring the progress made by Dr. Faustman and want every researcher in our field to be successful. Both organizations employ rigorous, peer-review processes to make evidence-based funding decisions, and we will continue to focus our resources on projects that we believe give us the best opportunity to create a world without T1D—for ourselves and our loved ones—as fast as we can.