IMPROVING LIVES. CURING TYPE 1 DIABETES.

200 Vesey St, 28th Floor
New York, NY 10281
t: 800 533 2873 f: 212 785 9595
jdrf.org

February 26, 2021

Centers for Disease Control and Prevention
Advisory Committee on Immunization Practices
Docket No. CDC–2021–0021
Submitted via regulations.gov

To Whom It May Concern:

Thank you for the opportunity to submit comments to the Advisory Committee on Immunization Practices. Your recommendations have the potential to reduce the risks of COVID-19 and save lives and we appreciate the opportunity to provide input on behalf of the 1.6 million Americans with type 1 diabetes (T1D).

JDRF is the leading global organization funding T1D research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications and we collaborate with a wide spectrum of partners to achieve this mission.

As we have previously indicated in letters dated December 18, 2020 and January 22, 2021, we urge the Committee to update the list of underlying medical conditions that increase risk of severe illness from COVID-19 to include T1D. While there was limited evidence when you made your initial vaccine prioritization recommendations, evidence in recent months clearly demonstrates the elevated risk from COVID-19 for those living with T1D[1,2,3] (for details, please see enclosed our January 22, 2021 letter). The evidence now available on T1D and COVID-19 risk is compelling and is leading local policymakers, such as those in Tennessee, New York and several other states, to elevate T1D to the same prioritization category as type 2 diabetes (T2D). As states and counties are determining order for vaccine access and distributing vaccine, there is a lack of clarity and consistency across the country on when people with T1D will be able to receive a vaccine. Clarity from the CDC that all types of diabetes pose an elevated risk is essential to allow state officials to focus on distributing vaccine and streamline the process for providers and people with T1D.

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[1] Gregory, J. M., Slaughter, J. C., Duffus, S. H., Smith, T. J., LeStourgeon, L. M., Jaser, S. S., McCoy, A. B., Luther, J. M., Giovannetti, E. R., Boeder, S., Pettus, J. H., & Moore, D. J. (2021). COVID-19 Severity Is Tripled in the Diabetes Community: A Prospective Analysis of the Pandemic's Impact in Type 1 and Type 2 Diabetes. *Diabetes Care*, *44*(2), 526–532. https://doi.org/10.2337/dc20-2260

[2]. Barron, E., Bakhai, C., Kar, P., Weaver, A., Bradley, D., Ismail, H., Knighton, P., Holman, N., Khunti, K., Sattar, N., Wareham, N. J., Young, B., & Valabhji, J. (2020). Associations of type 1 and type 2 diabetes with COVID-19-related mortality in England: a whole-population study. *The Lancet. Diabetes & Endocrinology*, *8*(10), 813–822. https://doi.org/10.1016/S2213-8587(20)30272-2

[3] McGurnaghan, S. J., Weir, A., Bishop, J., Kennedy, S., Blackbourn, L., McAllister, D. A., Hutchinson, S., Caparrotta, T. M., Mellor, J., Jeyam, A., O'Reilly, J. E., Wild, S. H., Hatam, S., Höhn, A., Colombo, M., Robertson, C., Lone, N., Murray, J., Butterly, E., Petrie, J., … Scottish Diabetes Research Network Epidemiology Group (2020). Risks of and risk factors for COVID-19 disease in people with diabetes: a cohort study of the total population of Scotland. *The Lancet. Diabetes & Endocrinology*, S2213-8587(20)30405-8. https://doi.org/10.1016/S2213-8587(20)30405-8

To demonstrate the confusion and inconsistencies being caused by the lack of clarity from CDC, we point to states such as Utah and Ohio that are imposing additional restrictions, such as HbA1C requirements or recent hospitalizations, on people with T1D as a condition of vaccine eligibility. States such as Michigan have identified people with diabetes as being prioritized but then call T2D a high risk condition and T1D a possible high risk condition. Other states, such as New Hampshire, are encouraging clinical judgement by health care providers, providing even less clarity for people with diabetes trying to determine when they will be eligible for vaccination.

We are very concerned that for people with T1D, this confusion could lead them to not seek vaccines when they are eligible or not understand when they will be eligible. Further, health care providers could also be confused and turn them down for a vaccine, increasing the risk of future vaccine hesitancy and the overall risks for people with T1D even more.

We strongly urge you to recognize the available data demonstrating the elevated risk of COVID-19 to those with T1D and include T1D and T2D in the highest priority comorbidity category. This will provide clarity to local policymakers, reduce the emerging confusion among current state policies and increase the number of high risk people getting vaccinated as soon as possible.

Once again, thank you for this commenting opportunity. If you have any additional questions, please contact Campbell Hutton, JDRF, Vice President, Regulatory and Health Policy, at chutton@jdrf.org or 202-309-2221.

JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

200 Vesey St, 28th Floor
New York, NY 10281
t: 800 533 2873 f: 212 785 9595
jdrf.org

January 22, 2021

Centers for Disease Control and Prevention
Advisory Committee on Immunization Practices
Docket No. CDC–2021–0002
Submitted via regulations.gov

To Whom It May Concern:

Thank you for the opportunity to submit comments to the Advisory Committee on Immunization Practices. Your recommendations have the potential to help save lives and reduce the risks of COVID-19 and we appreciate the ability to share our thoughts on behalf of the 1.6 million Americans with type 1 diabetes (T1D).

JDRF is the leading global organization funding T1D research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications and we collaborate with a wide spectrum of partners to achieve this mission.

We urge the committee to review and evaluate all of the available data on the risk of COVID-19 for people with T1D. As we have shared in our previous letter to the Committee dated December 18, 2020 in advance of your meeting on December 19, 2020 as well as a letter we recently submitted, along with many other diabetes stakeholder groups, to Dr. Redfield and Chairman Romero, these data, including new studies not yet considered by the Committee, show increased risk for people with both T1D and type 2 diabetes (T2D) with COVID-19 infection, with markedly increased odds ratios observed in T1D compared to T2D in all the reports cited below.

We are again highlighting data regarding the increased risk of serious illness from COVID-19 for people living with T1D. We are concerned that T1D is classified as a comorbid condition that "**might** be at an increased risk", and not one that "**is** at increased risk" for serious illness, like T2D. Data summarized below shows that people with T1D are at higher risk of hospitalization and mortality from COVID-19 compared to general population. Given this data we urge the Committee to update its guidelines to show COVID-19 holds a similar risk for people with T1D as it does for people with T2D. Based on the evidence, both T1D and T2D should be in the highest priority comorbidity category.

Data on Morbidity and Mortality in T1D

Data have shown that people with T1D are at higher morbidity and mortality risk than the general population, especially when hospitalized with COVID-19. A study[1] out of Scotland, released since the previous ACIP meeting, shows that the risk of serious outcomes among people with T1D and T2D were significantly higher than compared to a baseline population. The odds ratio was 2.396 for people with T1D and 1.369 for people with T2D to develop a fatal or critical-care complication from COVID-19, compared to the general population with COVID-19 in Scotland. The highest risk of worse outcomes was seen in people with diabetes complications, lower socio-economic status and smokers.

Other recent data, published in *Diabetes Care* in December 2020, show that people with diabetes, regardless of type, are more likely to have serious complications from COVID-19. This study shows that people who get COVID-19 and have diabetes, whether type 1 or type 2, have three to four times higher risk of severe illness and hospitalization. Per this study, hypertension, race, recent diabetic ketoacidosis, health insurance status, and less diabetes technology use were significantly associated with illness severity. Those at greatest risk are people with consistently elevated blood-sugar levels and those with a second comorbidity (such as obesity or heart, kidney, or lung disease)[2].

In August 2020, a study published in *Lancet Diabetes & Endocrinology* showed that COVID-19 hospital mortality was 3.3 times higher for people with T1D in the United Kingdom, and two times higher for people T2D compared to other people without diabetes hospitalized with COVID-19[3]. While there is some anecdotal evidence that higher mortality is tied to poor hospital care and not COVID-19 itself, keeping people with T1D out of the hospital at this time should be a goal. Doing so through vaccination will reduce overall risk of morbidity and mortality during this pandemic.

Burden of T1D on Health Care System

T1D is a condition with significant disease burden requiring moment to moment intense management and is dependent on appropriately titrated insulin dosing. Most hospital and emergency care facilities are neither trained nor have the opportunity during the current pandemic to get the necessary training to handle complex device-based diabetes management, which exacerbates the complications when an individual with T1D is admitted to the hospital due to COVID-19 infection.

Another factor that influences outcomes in COVID-19 for people with T1D is glucose control. People with and without diabetes who have high blood glucose levels – as an independent risk factor – upon admission for COVID-19 have higher mortality than those who did not[4] [5]. Most Americans with T1D have poor glucose control; only 21% of adults and 17% of people <18 years have an HbA1c at goal for their

[1] McGurnaghan, S. J., Weir, A., Bishop, J., Kennedy, S., Blackbourn, L., McAllister, D. A., Hutchinson, S., Caparrotta, T. M., Mellor, J., Jeyam, A., O'Reilly, J. E., Wild, S. H., Hatam, S., Höhn, A., Colombo, M., Robertson, C., Lone, N., Murray, J., Butterly, E., Petrie, J., … Scottish Diabetes Research Network Epidemiology Group (2020). Risks of and risk factors for COVID-19 disease in people with diabetes: a cohort study of the total population of Scotland. *The lancet. Diabetes & endocrinology*, S2213-8587(20)30405-8. https://doi.org/10.1016/S2213-8587(20)30405-8

[2] Gregory, J. M., Slaughter, J. C., Duffus, S. H., Smith, T. J., LeStourgeon, L. M., Jaser, S. S., McCoy, A. B., Luther, J. M., Giovannetti, E. R., Boeder, S., Pettus, J. H., & Moore, D. J. (2021). COVID-19 Severity Is Tripled in the Diabetes Community: A Prospective Analysis of the Pandemic's Impact in Type 1 and Type 2 Diabetes. *Diabetes care*, *44*(2), 526–532. https://doi.org/10.2337/dc20-2260

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[4] . Wang, S., Ma, P., Zhang, S., Song, S., Wang, Z., Ma, Y., Xu, J., Wu, F., Duan, L., Yin, Z., Luo, H., Xiong, N., Xu, M., Zeng, T., & Jin, Y. (2020). Fasting blood glucose at admission is an independent predictor for 28-day mortality in patients with COVID-19 without previous diagnosis of diabetes: a multi-centre retrospective study. *Diabetologia*, *63*(10), 2102–2111. https://doi.org/10.1007/s00125-020-05209-1

[5] Sardu C, D'Onofrio N, Balestrieri ML, et al. Hyperglycaemia on admission to hospital and COVID-19 (2020). *Diabetologia*.;1-2. doi:10.1007/s00125-020-05216-2

age group[6]. Of note, this data was derived from the minority of T1D patients who receive care from endocrinologists and large hospital systems, and not the majority of people with T1D who see primary care providers for diabetes care, making it highly likely that the overall status of glycemic control among people with T1D is worse than reported by this research. Consequently, the majority of people with T1D in the United States are at higher risk of mortality if they contract COVID-19 due to the fact that they likely have high blood glucose levels.

For these reasons, T1D as an underlying condition puts people at significantly higher risk of severe illness, hospitalization and death from COVID-19. We urge you to review the data and include both T1D and T2D in the highest priority comorbidity category.

Once again, thank you for this commenting opportunity. If you have any additional questions, please contact Campbell Hutton, JDRF, Vice President, Regulatory and Health Policy, at chutton@jdrf.org or 202-309-2221.

[6] Foster NC, Beck RW, Miller KM, et al. State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016-2018 [published correction appears in Diabetes Technol Ther. 2019 Apr;21(4):230]. *Diabetes Technol Ther*. 2019;21(2):66-72. doi:10.1089/dia.2018.0384.