



April 23, 2020

Evy Engrav
Director of Diversity and Inclusion
Minnesota Department of Health
625 Robert St. North
St. Paul, MN 55164-0975

Dear Ms. Engrav,

On behalf of Cystic Fibrosis Research, Inc. (CFRI) and the Minnesota cystic fibrosis (CF) community we serve, I write to urge you to issue guidance in the refining of Minnesota's Health Crisis Standards of Care so as to protect the right of people with cystic fibrosis and other disabilities to receive equal treatment during the COVID-19 crisis, including mechanical ventilation if necessary.

In anticipation of healthcare staffing and resource shortages resulting from the COVID-19 pandemic, some prominent commentators have suggested guidelines for determining which patients should be offered intensive treatment, including rationing on the basis of pre-existing conditions.¹ In Italy, the primary professional organization for anesthesiologists and intensive care doctors has issued a set of guidelines for hospitals that includes setting a "ceiling of care," precluding mechanical ventilation for people with underlying conditions.²

These proposals raise serious concerns for people with cystic fibrosis. Currently, scant data exists on how COVID-19 manifests in patients with CF. We anticipate that, like people with other underlying respiratory conditions, people with CF are at increased risk of critical illness if infected with COVID-19. Increased rates of diabetes in adolescents and adults with CF also contribute to risk of complications. However, the best available evidence also suggests that the majority of people who contract COVID-19 survive even if they do have underlying respiratory conditions or diabetes.³ The Italian Cystic Fibrosis Research Foundation reports that the known Italian CF patients with COVID-19 are not experiencing severe symptoms.⁴

While survival rates are much poorer for any COVID-19 patient who progresses to requiring mechanical ventilation, the presence of cystic fibrosis must not be considered sufficient to establish futility or

¹ Ezekiel J. Emanuel, James Phillips, and Govind Persad, "Opinion | How the Coronavirus May Force Doctors to Decide Who Can Live and Who Dies," *The New York Times*, March 12, 2020, sec. Opinion, <https://www.nytimes.com/2020/03/12/opinion/coronavirus-hospital-shortage.html>.

² Marco Vergano et al., "IN CONDIZIONI ECCEZIONALI DI SQUILIBRIO TRA NECESSITÀ E RISORSE DISPONIBILI," March 6, 2020. <http://www.siaarti.it/SiteAssets/News/COVID19%20-%20documenti%20SIAARTI/SIAARTI%20-%20Covid19%20-%20Raccomandazioni%20di%20etica%20clinica.pdf>

³ The Novel Coronavirus Pneumonia Emergency Response Epidemiology Team, "The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19) — China, 2020," *China CDC Weekly*, 2020, 2(8): 113-122, <http://weekly.chinacdc.cn/en/article/id/e53946e2-c6c4-41e9-9a9b-fea8db1a8f51>.

⁴ Italian Cystic Fibrosis Research Foundation, "Epidemia Covid-19 e fibrosi cistica in Italia," March 12, 2020, <https://www.fibrosicisticaricerca.it/epidemia-covid-19-e-fibrosi-cistica-in-italia/>.

otherwise deny or give lower relative priority for access to care. Cystic fibrosis is a very heterogeneous condition. Though many practicing medical professionals were trained at a time when it was uncommon for people with CF to live beyond their teens, recent years have brought transformative advances in care. For example, a patient on Trikafta (a CFTR* modulator) whose most recent medical history prior to COVID-19 includes normal or near-normal pulmonary function testing and mild respiratory symptoms should not have treatment deemed futile based solely on a risk assessment reliant on historical or overgeneralized assumptions about CF.

Many of the current restrictions in state crisis plans can be traced back to exclusion criteria proposed in a model protocol by Christian et al in 2006 as part of the Ontario Health Plan for an Influenza Pandemic.⁵ The justification provided for these criteria is that they align with 1998 transplant eligibility guidelines, which “typically represent a baseline death rate [without transplantation] higher than 50% within the next 1 to 2 years.”

However, based on more recent data this prognosis is outdated. A 2017 retrospective cohort analysis by Ramos et al. of over 3,000 patients in the Cystic Fibrosis Foundation Patient Registry with FEV1 < 30% predicted found that median transplant-free survival was 6.6 years after reaching this benchmark.⁶ While the CF Foundation continues to recommend all patients with a stable FEV1 under 30% predicted be referred for transplant evaluation, they also note that “prolonged survival” is possible for patients in this category.⁷ The long-term impact of new CFTR modulators will not be known for some time, however, short term data reverses previous clinical assumptions for those with FEV1 <40%.⁸ The rationale that such patients should be excluded from consideration for mechanical ventilation on the basis of poor survival is clinically unjustifiable.

Any judgment of futility must be based on a more nuanced assessment of individual clinical history, not simply a diagnosis. In the absence of a futility determination, patients with CF should have the same chance to access care as any patient without an underlying condition.

Rationing on the basis of perceived quality of life prior to COVID-19 infection must also be prohibited. Even CF patients with severely limited pulmonary function value their lives and spend tremendous daily effort on extending their lifespan as long as possible. Providers’ subjective assessments of the value of life with CF must not override stated patient and family preferences. Similarly, CF patients should not be denied access to treatment simply on the basis that they are unlikely to return to their previous state of health. Cystic fibrosis is a progressive condition. People with CF and their families have come to terms with this fact and value survival even in the presence of severe impairment.

Finally, it may be expected that some patients with CF who develop pneumonia may require a ventilator for a longer period of time than would a young patient with no underlying conditions. Even so, allocation

⁵ Christian MD, Hawryluck L, Wax RS, Cook T, Lazar NM, Herridge MS. Development of a triage protocol for critical care during an influenza pandemic. *CMAJ*. 2006;175(11):1377-81.

⁶ Ramos KJ, Quon BS, Heltshe SL, Mayer-Hamblett N, Lease ED, Aitken ML. Heterogeneity in survival in adult patients with cystic fibrosis with FEV1 < 30% predicted in the United States. *Chest* 2017; 151(6):1320-8.

⁷ Ramos KJ, Smith PJ, McKone EF, Pilewski JM, Lucy A, Hempstead SE. Lung transplant referral for individuals with cystic fibrosis: Cystic Fibrosis Foundation consensus guidelines. *Journal of Cystic Fibrosis* 2019; 18(3):321-33.

*CFTR – Cystic Fibrosis Transmembrane Conductance Regulator

⁸ Middleton PJ, Mall, MA, Drevinek P, Lands, LC, McKone EF, Polineni D, et al. Elexacaftor-Tezacaftor-Ivacaftor for Cystic Fibrosis with a Single Phe508del Allele. *NEJM* 2019;381:1809-19

procedures should not be permitted to maximize efficiency at the expense of non-discrimination. When allocating scarce medical resources, such as ventilators, to patients anticipated to benefit from treatment, hospitals and other covered entities should not be permitted to deny or give lower relative priority to patients based on them requiring greater anticipated resource intensity than other patients or anticipated patients.

On a personal note, I entered the world of cystic fibrosis when my daughter was diagnosed with the disease in 1995. As the director of a national CF organization, I have developed strong ties with countless individuals with CF and their families. The COVID-19 pandemic has created extreme anxiety among our community, and the knowledge that policies are in place that could jeopardize the lives of those with CF should medical rationing be required is both horrifying and demoralizing.

While we understand that the COVID-19 pandemic may place unprecedented demands on healthcare systems, the lives of people with cystic fibrosis are not an acceptable sacrifice. We ask you to issue guidance clarifying that denial of treatment must be based on detailed clinical assessment and not merely the presence of a condition increasing the probability of a poor outcome. Patients with a reasonable probability of survival should not need to worry that their treatment will be inappropriately dismissed as futile.

I appreciate your immediate attention to this matter. Please do not hesitate to contact me at 650-665-7565 or svaeth@cfri.org if you have any questions or need additional information.

In health,



Siri Vaeth, M.S.W.
Executive Director
Cystic Fibrosis Research, Inc. (CFRI)



Protecting, Maintaining and Improving the Health of All Minnesotans

Friday, May 1, 2020

Siri Vaeth
Executive Director
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Palo Alto, CA 94303

Dear Ms. Vaeth,

Thank you for your letter advocating for the Minnesota cystic fibrosis (CF) community. Commissioner Malcolm has asked me to respond to your letter. For over fifteen years, the Minnesota Department of Health (MDH) has prepared for crisis standards of care situations and has conducted extensive ethical research in doing so.

Previous projects include the Minnesota Pandemic Ethics Project¹, which produced several publications including two detailed guidance documents addressing the ethics of allocating scarce resources during a severe influenza pandemic, and the development of the Minnesota Crisis Standards of Care Framework². Both of these projects focused on ethics and involved extensive community engagement. Just last year, we conducted a community engagement session with the Minnesota Department of Administration's System of Technology to Achieve Results (STAR) Advisory Council to engage the disability community with our planning efforts.

In light of the COVID-19 Pandemic, MDH is an active member of the Minnesota COVID Ethics Collaborative (MCEC)³, which is a multidisciplinary group consisting of bioethics, law, public health, medicine, nursing, disaster planning and spiritual professionals. This group has produced specific COVID-19 ethical guidance and is working with the Statewide Critical Care Workgroup to ensure any COVID-19 clinical guidance is in line with the ethical objectives we pride ourselves in keeping. MCEC, MDH, and the Minnesota Department of Human Rights have also been having open dialogue with the Minnesota Disability Law Center (MDLC) to ensure that we address the concerns of the disability community prior to any implementation of crisis standards of care.

To highlight a few of your concerns—namely exclusion criteria and judgments on quality of life—I would like to assure you that, in all of this work, Minnesota has *rejected* the use of exclusion criteria in our scarce resource and crisis standards of care guidance or recommendations. Additionally, our COVID-19 specific guidance, in line with previous guidance, states that “rationing decisions should not consider or be based upon:

¹ Minnesota Department of Health: Minnesota Pandemic Ethics Project, <https://www.health.state.mn.us/communities/ep/surge/crisis/panethics.html>

² Minnesota Department of Health: Crisis Standards of Care, <https://www.health.state.mn.us/communities/ep/surge/crisis/index.html>

³ Minnesota COVID Ethics Collaborative, <https://clinicalaffairs.umn.edu/resources/minnesota-covid-ethics-collaborative>

- Race, ethnicity, gender, gender identity, sexual orientation or preference, religion, citizenship or immigration status, or socioeconomic status;
- Ability to pay;
- Age as a criterion in and of itself (this does not limit consideration of a patient’s age in clinical prognostication of likelihood to survive to hospital discharge);
- **Disability status or comorbid condition(s) as a criterion in and of itself (this does not limit consideration of a patient’s physical condition in clinical prognostication of likelihood to survive to hospital discharge);**
- **Predictions about baseline life expectancy beyond the current episode of care (i.e., life expectancy if the patient were not facing the current crisis), unless the patient is imminently and irreversibly dying or terminally ill with life expectancy under 6 months (e.g., eligible for admission to hospice);**
- First-come, first-served;
- **Judgments that some people have greater “quality of life” than others;**
- Judgments that some people have greater “social value” than others.”⁴

Instead, prognostic information considered in allocation decisions should be based on individualized patient assessments and focused on each patient’s likelihood to survive to hospital discharge. Allocation decisions among patients should be based only on substantial differences in prognosis. Moreover, length of need for a resource can only be considered when that can be reliably predicted and when differences in length of need are substantial.

An important further protection is that “Patients who are chronically ventilator dependent outside of the critical care context will not have their ventilators withdrawn in order to extend supplies.”⁵ Additionally, the guidance reminds clinicians to avoid bias and stereotypes, and refrain from pressuring patients to make decisions to refuse or pursue treatment (e.g. intubation and mechanical ventilation). We recommend that allocation decisions be made by triage officers or teams, to allow treating clinicians to advocate for their patients. Triage officers or teams should incorporate protections against bias (e.g., anti-bias training, the inclusion of ethics and/or inclusion and equity personnel). In addition, we recommend that review processes be established to help ensure that decision-making is fair.

We hope, with the measures our state has put in place Minnesota will not be faced with the decision to allocate critical care resources such as ventilators. However, if we are forced to make those decisions, we are confident we will provide a consistent and ethical statewide approach.

Thank you again for your advocacy for the CF community.

Sincerely,



Deb Burns
 Interim Assistant Commissioner
 Minnesota Department of Health
 625 Robert Street North
 St. Paul, MN 55164-0975

⁴ MCEC, *Allocation of Ventilators & Related Scarce Critical Care Resources During the COVID-19 Crisis*.

⁵ Ibid.