Fwd: CSCs for Monoclonal Antibodies

Kevin Mcculley <kmcculley@utah.gov> Tue, Sep 21, 2021 at 5:53 PM
To: Michelle Hofmann <mhofmann@utah.gov>

Kevin M. McCulley
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---------- Forwarded message ---------
From: **Mark Shah** <Mark.Shah@imail.org>
Date: Tue, Sep 21, 2021 at 1:37 PM
Subject: Fwd: CSCs for Monoclonal Antibodies
To: Kevin Mcculley <kmcculley@utah.gov>
Cc: Brandon Webb <Brandon.Webb@imail.org>, Samuel Brown <Samuel.Brown@imail.org>

Hey Kevin,

Sharing with you an email thread below between Sam, Brandon, and myself with some folks from the U of U, regarding possible legal questions around our Mab guidance.

I thought you may want to share with Brittany and Krisanne and maybe a few others.

Let us know your thoughts on reaching out to the Maryland law professor.

Mark Shah, MD FACEP
Utah Emergency Physicians
Intermountain Disaster Preparedness
Utah Disaster Medical Assistance Team
Medical Advisor for Salt Lake, Summit, and Tooele Healthcare Coalition

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From: Brandon Webb <Brandon.Webb@imail.org>
Sent: Tuesday, September 21, 2021 1:04:17 PM
To: Samuel Brown <samuel.brown@imail.org>; Mark Shah <Mark.Shah@imail.org>
Subject: Re: CSCs for Monoclonal Antibodies

For sure. I'd prefer just using the "we're too busy trying to save lives during the surge " excuse.

My preference is to our heads down as much as possible.

Brandon Webb, MD
Associate Professor
Division of Infectious Diseases
Intermountain Healthcare

From: Samuel Brown <samuel.brown@imail.org>
Sent: Tuesday, September 21, 2021 1:00:41 PM
To: Brandon Webb <Brandon.Webb@imail.org>; Mark Shah <Mark.Shah@imail.org>
Subject: FW: CSCs for Monoclonal Antibodies

I'd probably clear the discussions with communications and legal before chatting with the Maryland person. We don't want them to write something that then becomes an exploded landmine.

What do you think?

From: Leslie Francis <francisl@law.utah.edu>
Date: Tuesday, September 21, 2021 at 12:58 PM
To: Brandon Webb <Brandon.Webb@imail.org>, Mark Shah <Mark.Shah@imail.org>, Samuel Brown <Samuel.Brown@imail.org>, Teneille Brown <Teneille.Brown@utah.edu>
Cc: Timothy Farrell <timothy.farrell@hsc.utah.edu>
Subject: Re: CSCs for Monoclonal Antibodies

This is so interesting. Thank you so very much for such a thoughtful and informative response.

I suspect that my colleague at the University of Maryland would very much like to talk with you. (We've written some stuff together, although aren't working actively together now). I want to be very careful of and respectful of your willingness to share any information. Would you be willing to speak directly with her? She's Diane Hoffmann, director of the law & health care program at Maryland, https://www.law.umaryland.edu/directory/profile.asp?id=064 I'm sure she'd be most grateful if you were willing.

Best, Leslie Francis

From: Brandon Webb <Brandon.Webb@imail.org>
Date: Tuesday, September 21, 2021 at 12:11 PM
To: Leslie Francis <francisl@law.utah.edu>, Mark Shah <Mark.Shah@imail.org>, Samuel Brown <Samuel.Brown@imail.org>, Teneille Brown <Teneille.Brown@utah.edu>
Cc: Timothy Farrell <timothy.farrell@hsc.utah.edu>
Subject: Re: CSCs for Monoclonal Antibodies

Hi Leslie and Teneille,

Thanks for the email. This has been a very interesting dilemma to have been involved with. Your questions (as well as those of your colleague in Maryland and elsewhere) are important, valid, and not surprising. I'm frankly surprised that this has not yet been subject to a legal challenge.

At the risk of coming across as "risk stratification apologists" rather than a group of clinicians anxious to do whatever we can to deliver effective treatments equitably to the patients who are most likely to benefit, let me try to provide some background. I hope you find some of this useful.

As you probably know, monoclonal antibody therapy has been in use since late November 2020 and from day one has always been limited in terms of capacity to administer. The risk score concept was adopted by the CSC committee in Nov 2020 to address the problem of resource scarcity with the three aims of: 1) optimizing clinical benefit (target treatment to the patients for whom the evidence suggests the treatment will have greatest efficacy, 2) equity (ensure that prioritization does not disadvantage patients who are at high probability of poor outcome from COVID from accessing treatment because of social determinants of health) and 3) adaptability (because of fluctuating drug supply and infusion capacity, and wildly fluctuating community transmission, we needed a prioritization schema that would create a dynamic, data-supported sliding scale eligibility criteria that could be flexed to match supply/capacity with demand). The overarching desire was to use clinical rationale for patient selection rather than "first-come, first-serve" or some type of lottery.

We recognized early on however that, for reasons we acknowledge we don't understand, individuals who identify with a community of color are at disproportionately high risk for hospitalization even after accounting for other factors. This has been observed in dozens of epidemiological studies. We identified the same trend in a cohort of more than 100,000 Utahns who tested positive for COVID and for whom we had detailed medical data. In our analysis, after statistically accounting for age, gender, symptoms, chronic medical conditions, and geography, persons of color remained 35-50% more likely to hospitalized.

We recognized that in general, gender and race/ethnicity are not included in risk classification for many reasons. However, we were concerned that, given the strong association of non-white race/ethnicity with hospitalization, and the clear benefit of monoclonal antibody treatment in *preventing* hospitalization, by omitting this characteristic from risk classification, persons of color at statistically equivalent risk

would be systematically deprioritized from access to effective therapy.

Because of these competing concerns, we wrote a letter to the Office of Civil Rights in November 2020, describing the dilemma and requesting they weigh in. In preparing this letter, we were interested to find that the National Quality Forum had addressed this issue in a 2014 document, suggesting that in certain situations when social determinants such as race or ethnicity are highly correlated with outcomes that could be prevented by more intensive treatment, omission of race or ethnicity in patient selection might actually perpetuate inequity in healthcare access and worsen outcomes disparity (National Quality Forum, Wash. D.C. 2014, "Risk adjustment for socioeconomic status or other sociodemographic factors").

We never received a response from OCR and at that point were so enmired in the winter surge of 2020 that we took the pragmatic approach and moved ahead, anticipating that at some point this would likely be subject to other review. It is worth noting that there have been several other risk prediction models in use around the country that also take into account race/ethnicity (Cleveland Clinic has an online tool and UC Irvine does as well). I don't know to what degree these have been adopted for use in allocation. The risk score has been very effective in it's designed aims. We actually have data that suggest that *despite* intentionally attempting to avoid deprioritizing communities of color through the risk score but also by conducting active outreach and establishing strategically-located treatment sites in geographic areas with lower SES, communities of color are still not receiving MAbs proportionate to their representation among COVID-test positives.

One final note that you may find interesting - the FDA emergency use authorization has always included age and medical conditions in the eligibility criteria. In a revision released in June, the language defining the "high-risk" population eligible for treatment included this statement: *Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors* [listed above]. *For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medicalconditions.html. Healthcare providers should consider the benefit-risk for an individual patient.vvvv* https://www.fda.gov/media/145611/download .

I hope that helps frame context a bit. I don't believe this approach has been reviewed legally, but not for lack of us requesting long ago.

Best,

BW

From: Leslie Francis <francisl@law.utah.edu>
Sent: Tuesday, September 21, 2021 10:01 AM
To: Mark Shah <Mark.Shah@imail.org>; Samuel Brown <Samuel.Brown@imail.org>; Teneille Brown <Teneille.Brown@utah.edu>
Cc: Timothy Farrell <timothy.farrell@hsc.utah.edu>; Brandon Webb <Brandon.Webb@imail.org>
Subject: Re: CSCs for Monoclonal Antibodies

I'm curious about whether this has ever been reviewed legally. There's been a fair amount of discussion about whether the use of characteristics such as race, sex, or age in making decisions about monoclonal antibodies is prohibited under federal anti-discrimination law, even if evidence based and (as you say) targeting high risk groups. The consensus among legal academics anyway seems to be that it does violate federal law.

A colleague of mine at the University of Maryland, who has been working on this issue, emailed me to ask about whether it was true that the Utah standards included race in any way. So it has come to national attention…. I told my colleague that I would find out whether these were actually the Utah standards. I will tell her that she did find the Utah standards, I guess—but I don't know what the result might be.

Any further thoughts most appreciated before I get back in touch with my colleague.

Best, Leslie Francis

From: Mark Shah <Mark.Shah@imail.org>
Date: Tuesday, September 21, 2021 at 9:48 AM
To: Samuel Brown <Samuel.Brown@imail.org>, Teneille Brown <Teneille.Brown@utah.edu>
Cc: Leslie Francis <francisl@law.utah.edu>, Timothy Farrell <timothy.farrell@hsc.utah.edu>, Brandon Webb <Brandon.Webb@imail.org>
Subject: RE: CSCs for Monoclonal Antibodies

Thanks Sam, and hello again Tim and Leslie, and hello Teneille,

Yes, the derivation of the risk score, and our ongoing adjustments are based on data derived largely within Intermountain on risk of hospitalization. We do now also include vaccination status, as vaccination is largely protective against hospitalization. I can see that your first email incorrectly thought that we were deprioritizing high risk groups. As you later noted, the opposite is true. Our goal all along is to target this limited resource to those most likely to benefit.

The lead on this data is Brandon Webb (cced). He has published and presented on this, including to HHS and the CDC, who has lauded our approach.

I have attached the most recent Mab guidance. The guidance explains all of this, and lays out the data for the derivation. I also attached two publications, discussing the risk score and also real world efficacy.

I hope this helps.

Mark Shah, MD FACEP
Utah Emergency Physicians
Intermountain Disaster Preparedness / Emergency Management
Utah Disaster Medical Assistance Team
Summit, Salt Lake, Tooele Coalition Clinical Advisor
Cell 801-633-6713

-----Original Message-----
From: Samuel Brown <samuel.brown@imail.org>
Sent: Tuesday, September 21, 2021 9:36 AM
To: Teneille Brown <Teneille.Brown@utah.edu>; Mark Shah <Mark.Shah@imail.org>
Cc: Leslie Francis <francisl@law.utah.edu>; Timothy Farrell <timothy.farrell@hsc.utah.edu>
Subject: Re: CSCs for Monoclonal Antibodies

Since these are such fraught topics easy to miscommunicate around, I'm referring you to Mark who chairs the committee.
The models were built on Utah data with a rigorous and non-biased approach. The risk factors were pretty darn clear in terms of maximizing benefit -- people of non-white race were at much higher risk of complications and thus much more likely to benefit from mabs.
There's a paper in Open Forum ID that reports on the rollout, although I don't think it engages the race/ethnicity issue from a legal perspective. First author is Brandon Webb.

On 9/21/21, 7:52 AM, "Teneille Brown" <Teneille.Brown@utah.edu> wrote:

External Sender: Be aware! Read with care!

Sorry — meant to be clear about the use of the listed risk factors to prioritize, not de-prioritize.

> On Sep 21, 2021, at 7:44 AM, Teneille Brown <Teneille.Brown@utah.edu> wrote:
>
> Hi Sam,
>
> Given the shortage nationally of monoclonal antibodies, I was reviewing Utah's CSC guidance and noticed you were listed as a member of the committee overseeing scarce meds like monoclonal antibodies.
>
> Any chance you might have some time to talk about the process for developing the risk scores? Specifically, do you recall the data used to de-prioritize older people, men, and people of "non-white race"? Tennessee includes vax status, such that those who are unvaccinated are prioritized over those who are not (presumably because the vaccinated should have antibodies?)
>
> The use of non-white race really set off alarm bells, not because of clinical risk necessarily, but anti-discrimination law.
>
> Any background you have and can share would be very welcome. Leslie, Tim and I have been working on the use of age in CSCs over the last year.
>
> -Teneille
>

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