

August 9, 2021

*Comments sent electronically via regulations.gov*

**Re: Food and Drug Administration (FDA) public workshop and request for comments: “Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions.”**

We write this letter on behalf of the National Council on Independent Living (NCIL), the nation’s longest-running national cross-disability, grassroots organization run by and for people with disabilities. NCIL represents thousands of individuals with disabilities and organizations including Centers for Independent Living (CILs), Statewide Independent Living Councils (SILCs), and other organizations that advocate for the human and civil rights of people with disabilities throughout the US.

As an organization working to represent the 61 million people with disabilities across the country, many who live with chronic pain, NCIL works to protect the rights of people with chronic pain. Our work in this area began as efforts to address the opioid crisis ramped up in the US, and we saw people with chronic pain left out of these efforts and harmed as a result.

We thank the U.S. Food and Drug Administration for inviting comments on the science underlying the MME (morphine milligram equivalent) measure.

We are particularly concerned about the gaps and limitations in data surrounding morphine milligram equivalents (MMEs), including, but not limited to, the significant variability in how they are calculated and the variability in metabolism based on genetic or other factors. MMEs have become an increasingly important metric used frequently to change or deny treatment,

despite the American Medical Association stating that “no entity should use MME (morphine milligram equivalents) as anything more than guidance.”

At the June 7-8 meeting “Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions,” the first discussion question summarized current uses of MME: as a tool for converting medication dosage, and as a risk predictor for broader populations.

We ask the FDA to emphasize the use of MME as a guide for clinicians treating individual patients, not as a population-wide risk predictor.

Given the consequences for patients, it is deeply problematic that the MME metric insufficiently accounts for variations in drug metabolization, both among medications and from genetic variability.[[1]](#footnote-1) [[2]](#footnote-2)

In addition, MMEs are calculated in the real world using flawed methods. As a result, recent research found that the same medication given at the same interval could be calculated as having an MME that falls below and above the 50-90 MME thresholds mentioned in the *CDC Guideline for Prescribing Opioids for Chronic Pain*.[[3]](#footnote-3)

Since the publication of the *CDC Guideline* in 2016, nearly every entity involved with opioid prescribing has equated dosage reduction with success, regardless of the health or functional status of the patients subjected to tapering.[[4]](#footnote-4) Recent observational studies paint a bleak picture of how opioid tapering is happening in the real world. Tapering often happens abruptly with negative health consequences, and may actually increase patients’ risk of overdose or suicide, in addition to destabilizing their lives.[[5]](#footnote-5) [[6]](#footnote-6) [[7]](#footnote-7) [[8]](#footnote-8) [[9]](#footnote-9) [[10]](#footnote-10) [[11]](#footnote-11) [[12]](#footnote-12)

National Committee on Quality Assurance (NCQA) quality metrics rate health plans by number of patients maintained on doses above 90 MME, “to align with CDC recommendations.”[[13]](#footnote-13) In 2020, this threshold was lowered to 90 MME from 120 MME, despite a letter from experts (including some involved in developing the *CDC Guideline*) protesting the use of dosage as a quality measure.[[14]](#footnote-14)

State Medicaid programs enforce dosage limits regardless of medical condition or disability. State legislatures, state agencies, pharmacies, pharmacy benefit managers, health systems, and insurance companies incentivize or require across-the-board dosage reduction, justified as “alignment with the Centers for Disease Control and Prevention’s (CDC) guidelines for opioid use.”[[15]](#footnote-15) [[16]](#footnote-16)

State and national metrics define “quality” as dosage reduction to 120, 90, or 50 MME,[[17]](#footnote-17) described as “full alignment to the CDC.” Individuals who were stable, functioning, and meeting life goals at higher dosage are “addressed” via nonconsensual taper. [[18]](#footnote-18)

As one pharmacy benefit manager announced: “the program has reduced prescriptions above the CDC recommended dose by 85%.... It has also decreased prescriptions for current chronic opioid users by 68%. Further, the average dose across all opioid prescriptions has been reduced by 14%.”[[19]](#footnote-19)

Whether the affected patients function better post-reduction – or even whether they are still alive – is rarely measured or even mentioned in such “quality improvement plans.”

MME metrics are also used by law enforcement as a basis for surveillance of physician prescribing practices, often without any consideration of the patient population a physician treats.[[20]](#footnote-20)

As the HHS Pain Management Best Practices Inter-Agency Task Force report points out, although risks increase with higher dosage, given the variability in underlying conditions and in how patients metabolize opioids, there is no clear cut off point. Nor is there evidence for 50 MME, 90 MME, or 120 MME as a particular inflection point for increased risk.[[21]](#footnote-21) Recent data from CMS (Centers for Medicare and Medicaid Services) shows that dosage-based safety measures fail to capture the majority of patients at risk for overdose, and wrongly flag patients who are not at risk.[[22]](#footnote-22) These results suggest that high dose itself does not directly cause overdose, but rather correlates with underlying factors that, if correctly identified, might inform a more useful safety measure.[[23]](#footnote-23)

. Reliance on the MME metric – Originally intended to ensure patient safety, reliance on the MME metric has proven detrimental to patients with multiple chronic conditions, patients with disabilities, and to patient-centered and individualized care. In light of these serious concerns about the scientific integrity, viability, and overall usefulness of the MME metric, we urge the FDA to remove this metric.

Thank you very much for your consideration of these concerns of the disability community.

Any questions or comments may be directed to Lindsay Baran at lindsay@ncil.org or Kate Nicholson at kate@katemnicholson.com, Co-Chairs of the Chronic Pain/Opioids Task Force for NCIL.

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