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Racial disparities, FRAX, and the care of patients with osteoporosis

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A recent publication in a prestigious medical journal, released June 17, 2020, reviewed race-based adjustments in selected clinical algorithms and described their “potential dangers” [1]. The USA adaption of the fracture risk assessment tool, FRAX [2], was cited as an example of an algorithm with the potential “to perpetuate or even amplify race-based health inequities.” The concern was that Asian, Black, and Hispanic women are estimated to have a 10-year probability of major osteoporotic fracture that is one-half or less than White women, which might lead to a delay of treatment in non-Whites. The same day as the journal publication, a companion article appeared in the New York Times with the title “Many Medical Decision Tools Disadvantage Black Patients” [3]. Here, it was stated that the use of the FRAX USA calculator would result in Black women being less likely to be treated than “similar” White women, implying that women in need of treatment are being deprived of it because of their race. Considering the tremendous importance of addressing racial disparities in healthcare, the need for accurate information on which to base health policy and clinical decisions, and the many challenges in efforts to reduce the osteoporosis treatment gap, we offer the following thoughts on race and osteoporosis care.

We fully acknowledge that there are racial disparities in the care of osteoporosis. A study of women meeting the US Preventive Services Task Force recommendation for a screening bone mineral density (BMD) test [4] (women age 65 years and older and younger women at high fracture risk), found that Black women were 40% less likely than their White counterparts to have an incident screening dual-energy X-ray absorptiometry (DXA), with hazard ratio (95% confidence interval) = 0.60 (0.54–0.65) [5]. Black women are also less likely to have a DXA study after having a hip fracture [6]. Several studies have shown that Black women are less likely to be treated for osteoporosis than White women overall [7] and in the presence of fractures [8, 9]. There are also disparities in outcomes after an osteoporotic fracture, as shown in an analysis of 399,000 Black and White women with a major osteoporotic fracture (MOF) identified from Medicare claims data [10]. After adjusting for age, Black women had a significantly higher risk of death, disability, and

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destitution than Whites for most fracture types. These disparities must be fully recognized by the healthcare community, and aggressive efforts should be made to correct them.

The question raised by these new publications is whether these disparities could be due to racial discrimination imbedded in the FRAX algorithm. We think not. FRAX USA was designed and calibrated to estimate fracture risk based on easily obtainable variables that have been validated in large population-based studies [11]. In the USA, self-designated race (Asian, Black, non-Hispanic White, and Hispanic) is part of the algorithm because of robust data showing that fracture risk differs in these groups, even when BMD is the same [12, 13]. There are other countries with ethnicity-based stratifications due to the differences in fracture risk by ethnicity (e.g., FRAX China incudes China and Hong Kong, and FRAX Singapore includes Chinese, Malay, and Indian) [14]. The use of any FRAX calculator allows healthcare providers to stratify patients according to the level of fracture risk and use the information to direct treatment to those who will derive the greatest benefit. Unfortunately, there is currently a crisis in the care of osteoporosis [15], with most patients, even those with very high risk of fracture, often not being identified and not receiving effective treatment [16]. Closing the large osteoporosis treatment gap requires a commitment to identifying patients at high risk using clinical tools, such as BMD testing and FRAX, and treating them appropriately. At the same time, it would be inappropriate to recommend treatment to anyone, irrespective of race, when fracture risk is low and the expected benefit of treatment is likely to be low in proportion to potential risk of adverse effects.

We recognize FRAX USA has limitations with respect to race and ethnicity. First, “race” is a social construct. Although there are genetic differences within and between populations, race, as currently conceived, serves as a (good or bad) proxy for national origin, cultural practices, and a wide variety of social determinants of health. The algorithm requires self-designation into one of four race categories, thus does not account for individuals who are mixed race, and most importantly does not account for the social and genetic diversity within and among the four groups. With respect to bone health, there is evidence suggesting that BMD variation may be greater within ethnic groups than across them [17], so that limiting to one “race” group may bias the FRAX estimates. It is also not clear for immigrants or citizens of more than one country whether or when to use or consider FRAX USA or FRAX for the country of origin. Countries such as Canada and Brazil have populations as diverse as the USA, but nevertheless use non-race-adjusted FRAX.

Secondly, the FRAX USA algorithm was validated using data that may not reflect current fracture rates. In the Joint Official Positions Development Conference of the International Society for Clinical Densitometry and International Osteoporosis Foundation on FRAX, based on the data at the time, the authors concluded that “separate models are available because hip and MOF rates are lower” in non-White populations [18]. The most recent data utilized in their assessment was from 2005; given changes in the demographics in the USA older adult population, the previously made assumptions may no longer hold true. As more data become available, FRAX USA should be modified in ways that mitigate the known limitations and optimize its clinical utility.

Lastly, since the initial validation of the FRAX tool, there have been multiple studies identifying additional risk factors [19–21], as well as the underperformance of FRAX is certain subpopulations, primarily based on health conditions. This could be an area where the algorithm introduces racial bias. For example, the association between diabetes and fracture risk has become more appreciated from the physiological to the clinical level [22]. In the USA, the prevalence of type 2 diabetes is highest among Black and other communities of color [23, 24]. Without accounting for other conditions that increase fracture risk, particularly conditions that are more prevalent in the communities of color, the fracture risk calculation from FRAX may be biased lower than truth in populations of color.

Let us imagine two women, each age 65 years with femoral neck T-score = − 2.3 (using a standardized non-race adjusted young-adult White reference database) and a parent having a hip fracture. One is White and the other is Black. The FRAX USA calculator, with input of femoral neck BMD, estimates a 10-year probability of MOF that is 20% for the White woman and 9% for the Black woman. The risk of hip fracture is 2.3% for the White woman and 1.0% for the Black woman. The National Osteoporosis Foundation (NOF) Clinician's Guide recommends consideration of pharmacological therapy when FRAX thresholds are ≥ 20% for MOF and ≥ 3% for hip fracture [25]. In this example, pharmacological therapy would be indicated for the White woman but not the Black woman. Is this race-based discrimination that deprives the Black women of needed therapy? We submit that this is not the case. In fact, if the Black woman was indeed treated, there could potentially be more harm than good. Now, if the only difference between the two women was that the Black woman had type 2 diabetes, her fracture risks would increase to 13% and 1.4% for MOF and hip fracture, respectively. Although the addition of type 2 diabetes (using the rheumatoid arthritis surrogate) did not move the overall risk of the Black woman beyond the NOF treatment thresholds and the absolute risk is still small, it did increase her risk of hip fracture by 40%. What other factors are not being considered for either woman that could further add to their respective fracture risk? This is where communication between provider and patient is the key. Health care professionals must recognize that FRAX does not include all risk factors for fracture, and is not the only factor to be taken into account in making treatment decisions [26]. The entire health history must be considered. This is especially important for patients of color because of the high prevalence of health conditions and associated medications that negatively impact bone but are not included in FRAX.

Fracture risk algorithms and clinical practice guidelines are always imperfect, but good ones are useful. Despite the limitations of FRAX USA, it provides a quantitative estimation of fracture risk that is a component of well-established evidence-based clinical practice guidelines, such as those of the NOF [25], the Endocrine Society [27], and the American Association of Clinical Endocrinologists [28]. When considered alongside all other available clinical information, including patient preference, the treatment of osteoporosis can be directed to those most in need of it, for whom the expected benefits of treatment are likely to far outweigh the potential risks. It assists clinicians in their efforts to individualize treatment decisions and allocate limited healthcare resources in an equitable and cost-effective manner.

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