

States. Demonstration projects conducted under Medicaid waivers have permitted self-directed care for patients with long-term care needs, improving quality of life.⁵ Most such U.S. models, however, have been limited to the hiring and supervising of personal assistants for a specified number of hours per week. Whereas in England direct cash payment is possible, U.S. officials have been reluctant to relinquish such control to patients.

Medicaid waivers have been used to broaden the home- and community-based services offered, and some of these services appear similar to those purchased with personal health budgets in England. But service specifications and providers are tightly controlled in these Medicaid initiatives. For example, beneficiaries may be offered set hours for personal care, home-delivered meals, and standardized equipment. The English experience suggests that if offered a personal health budget, some people choose to focus resources on items such as custom-designed wheelchairs, even though they are left with less money for other services.

Adoption of more ambitious models that shift public funds to

individual control would probably face political scrutiny in the United States, as it has in England. Yet the emergence of capitated health plans as nongovernmental intermediaries managing the finances and care of Medicaid and dually eligible (Medicare and Medicaid) beneficiaries may facilitate this approach, since such plans' spending patterns may draw less public attention than those of government agencies.

Under the Affordable Care Act, 13 states are conducting demonstration projects in which health plans are responsible for managing overall expenditures for dually eligible patients. These plans can offer flexible benefits outside traditional health care and are providing some such as home modifications, appliances, and cell phones as part of a case-management approach for populations with complex needs. These plans could provide even greater flexibility and patient control. Plans could use service history to assess a patient's expenses for home- and community-based services and then allow the patient to work with a case manager to develop a budget addressing personal needs and health goals.

As the U.S. system strives to

redesign care for high-cost patients, we believe that greater consideration should be given to self-directed care, informed by lessons from international models. The evidence from England suggests that patients themselves can help to design higher-value care.

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Vitamin D Deficiency — Is There Really a Pandemic?

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In recent years, numerous clinical research articles have concluded that large proportions of North American and global populations are “deficient” in vitamin D.¹⁻³ Most of the evidence cited focuses on one of two observations: that many people have serum concentrations of vitamin D (i.e., 25-hydroxyvitamin D

[25(OH)D]) below 20 ng per milliliter (50 nmol per liter), which the Institute of Medicine (IOM) estimated in 2011 was the appropriate level⁴; or that supplementation with 600 to 800 IU per day — the IOM Recommended Dietary Allowance (RDA) for adults — or more fails to achieve serum concentrations above 20 ng per milliliter

in some study participants. Such conclusions, however, are based on misinterpretation and misapplication of the IOM reference values for vitamin D. Because such misunderstandings can have adverse implications for patient care, including unnecessary vitamin D screening and supplementation as well as escalating health care costs

due to overscreening and overtreatment, it's important to clarify the meaning of IOM reference values for vitamin D as they relate to both population health and clinical practice.

To understand the concept of nutrient “deficiency” or “inadequacy,” one needs to know how the IOM nutrient reference values are defined and what they reflect. The IOM develops these reference values, referred to as Dietary Reference Intakes (DRIs), for an array of nutrients. Central to the DRI concept is the biologic reality that the need for any nutrient varies from person to person, generally in a normal distribution across the population. These reference values include an Estimated Average Requirement (EAR) for the nutrient, which is the median of the distribution of human requirements.⁴ The EAR reflects the most likely requirement for the population, whereas a second DRI reference value, the RDA, reflects the estimated requirement for people at the highest end of the distribution. Practically everyone in the population (at least 97.5%, or within 2 SD of the median) will have a requirement below the RDA.

Because of vitamin D's established role in bone health (postulated nonskeletal benefits remain under study), the EAR is set at 400 IU per day for persons 1 to 70 years of age and 600 IU per day for persons older than 70 — intakes corresponding to a serum 25(OH)D level of 16 ng per milliliter (40 nmol per liter). The RDAs are 600 IU per day and 800 IU per day, respectively, corresponding to a serum 25(OH)D level of 20 ng per milliliter (50 nmol per liter). Note that the EAR and RDA assume minimal to no sun exposure. Although obesity and overweight are associated with lower circulating concentrations

of 25(OH)D, evidence on the relationship with bone health and any implications for modified dietary intake requirements for people with greater adiposity remain inconclusive.⁴ The graph in Panel A illustrates the reference-value distribution for intakes related to the DRI-linked serum 25(OH)D levels as established by the IOM.

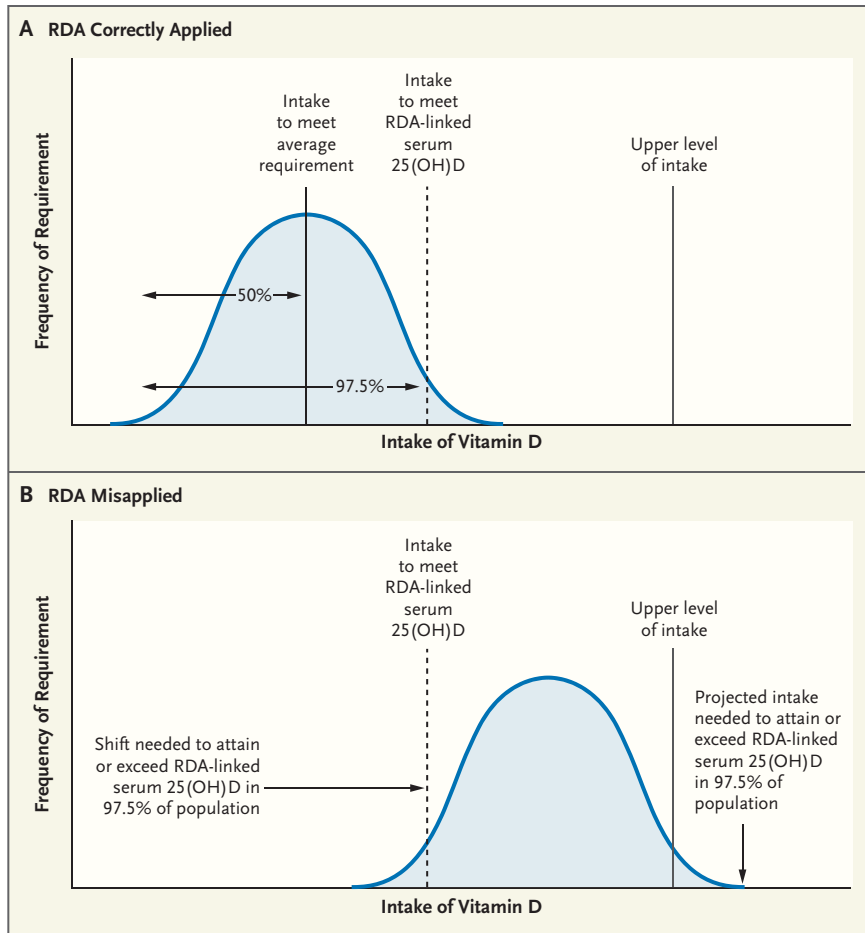
A common misconception is that the RDA functions as a “cut point” and that nearly the entire population must have a serum 25(OH)D level above 20 ng per milliliter to achieve good bone health. The reality is that the majority (about 97.5%) of the population has a requirement of 20 ng per milliliter or less. Moreover, by definition of an average requirement, approximately half the population has a requirement of 16 ng per milliliter (the EAR) or less. These concepts are depicted in the population reference-value distribution shown in Panel A, which highlights the relationship between the EAR and the RDA.

In creating its framework for reference values, the IOM anticipated the inherent variability in nutrient requirements and therefore established — and verified by statistical modeling⁴ — the goal of achieving population levels above the EAR, not the RDA. However, the literature is replete with misapplications of the RDA that treat it as a cut point. Many studies establish “inadequacy” using the RDA, though it is actually at the upper end of the spectrum of human need. Clearly, this approach misclassifies as “deficient” most people whose nutrient requirements are being met — thereby creating the appearance of a pandemic of deficiency.

Applying the correct method to data from the National Health and Nutrition Examination Survey (NHANES) for 2007 through 2010

reveals that 13% of Americans 1 to 70 years of age are “at risk” for vitamin D inadequacy. Less than 6% are deficient in vitamin D [serum 25(OH)D levels <12.5 ng per milliliter⁴]. The utility of measurement of parathyroid hormone (PTH) concentrations for identifying the optimal level of vitamin D remains controversial; the relationship between serum 25(OH)D and PTH is inconsistent, and no clear threshold defining “sufficiency” has been established.⁴ Vitamin D is a nutrient of concern, but these levels of deficiency do not constitute a pandemic.

Furthermore, using the RDA-associated serum concentrations of vitamin D to judge whether population groups have inadequate levels or to set intake goals for populations inflates the estimated prevalence of inadequacy and overestimates the needed intake. Indeed, ensuring that 97.5% of the population attains or exceeds vitamin D levels of 20 ng per milliliter would require shifting the entire population to a higher intake (see graph in Panel B). This misapplication of RDA-associated concentrations could cause harm to people whose intake is pushed above the Tolerable Upper Intake Level (UL, the level at which there may be adverse effects), which the IOM has established as 4000 IU daily with a resulting serum 25(OH)D concentration of approximately 50 ng per milliliter (125 nmol per liter). A modeling study by Taylor et al. suggested that shifting the distribution of serum 25(OH)D concentrations in adults 19 to 70 years of age upward so that the RDA-associated concentration of 20 ng per milliliter was achieved in nearly everyone (all but 2.5% of the population) would mean that levels in some people would exceed the UL.⁵



Distribution of Vitamin D Intake Requirements in a Healthy Population (Panel A) and the Upward Shift in Distribution Required to Attain the RDA-Linked Serum 25(OH)D Concentration in 97.5% of the Population (Panel B).

Correctly understood, the Estimated Average Requirement (EAR) is the intake that meets the needs of 50% of the population, and the Recommended Dietary Allowance (RDA) is the intake that meets the needs of 97.5% of the population (Panel A). If, instead, we strive to ensure that the RDA-linked serum 25(OH)D concentration is attained or exceeded in 97.5% of the population, some people will exceed the Tolerable Upper Intake Level (Panel B).

This problem highlights the concern that universal screening based on inappropriate cut points might lead to routine supplementation in generally healthy populations with adequate vitamin D levels. A preferable option would be to encourage patients and the public to choose foods containing, or fortified with, vitamin D — an approach that will be facilitated by new regulations requiring that vitamin D content be listed on nutrition labels.

Although our focus here is pro-

viding clarity about the use of nutrient reference values for estimating the prevalence of inadequacy in population groups, these values are also relevant to clinical settings in which patients are counseled individually. The two key clinical questions are whether to screen for vitamin D deficiency and what vitamin D intake to recommend for individual patients. For optimal decision making, the central issue is whether the patient is generally healthy and free of major risk factors for

vitamin D deficiency or whether he or she has a skeletal disorder or significant risk factors for vitamin D deficiency (such as osteoporosis, osteomalacia, malabsorption, use of medications [such as anticonvulsants] that can affect vitamin D metabolism, or institutionalization).⁴ For healthy patients, routine screening is not recommended by most medical organizations, and the pitfalls would be similar to those described above for population-based studies.

Although the average requirement can be used to estimate the probability that a patient's 25(OH)D level reflects an inadequate intake, practical counseling on vitamin D intake for healthy patients would use the RDA intake as a guidepost, given that it is impossible to know a given patient's actual requirement and the RDA will nearly always meet the needs of generally healthy people. For patients who are at high risk or who have a disorder related to calcium metabolism, targeted vitamin D assessment would be appropriate, and vitamin D supplementation at levels above the RDA may be necessary. Although clinical judgment and customized interventions can be used with individual patients, avoidance of overscreening and overprescribing of supplemental vitamin D remains important.

Drs. Manson, Brannon, and Rosen report being members of the Institute of Medicine Committee on Dietary Reference Intakes for Vitamin D and Calcium, 2009–2011; Dr. Taylor reports serving as IOM study director for the committee.

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Embodying the Three Rs in Fiji

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Ping! Another e-mail pops up, seeking my attention. “I’m writing to enquire about trainee positions in Fiji.” Familiar mixed emotions wash over me. I’d worked hard to get the Fiji emergency medicine training rotation accredited by the Australasian College for Emergency Medicine. I’d spoken at conferences and written articles to attract applicants. Having staff from emergency care systems in high-income countries working alongside local staff brought new skills to the team, built understanding and mutual respect, and added credibility to the program. So why this ambivalence?

Was it the effort of managing the expectations of people used to having everything at their fingertips? Of challenging their ideas of “giving back” and “making a difference”? Or of trying but failing to impress on them that 3 months in a country would open their eyes but accomplish little more? There was no shortage of local, smart, motivated young doctors — but there was so little I could do about the daily frustrations with bureaucracy and dysfunctional systems that prevented them from fulfilling their potential and caused many to seek employment opportunities elsewhere.

By introducing trainees from the promised land, would I risk accelerating the brain drain and training doctors for export? Our first cohort of Fiji-trained, master’s level emergency specialists will graduate at the end of the year and will face enormous challenges in establishing the specialty in their home country. Fijian doctors can be found worldwide, but particularly in Australia and New Zealand, where they are attracted by better pay and conditions and where resources are plentiful.¹

It is important to appropriately select and prepare visiting staff. Lack of cultural sensitivity and inappropriate ambitions and behaviors on the part of physicians trained elsewhere can cause substantial harm to patients, local staff, departments, and training programs. A new environment requires a significant period of adjustment and calibration. The first month should be spent watching and learning the demographics, epidemiology, illness behaviors, and “the way things are done around here.” Clinicians trained in countries with well-developed health systems often have little insight into how those systems facilitate their own clinical performance and protect their welfare. Actions taken without such in-

sight can undermine patients’ respect for local doctors by reinforcing the common notion that Western physicians are superior.²

If you’re a trainee seeking an exotic medical adventure here, you need to consider the kinds of cases you may encounter — and the qualities you will need in order to handle them well. Say you respond to a request to provide medical assistance: a truck illegally transporting cyanide has run off an embankment and is resting next to a river upstream of several villages. It’s dark out. There is no HAZMAT expertise, no standard operating procedure. No personal protective equipment is provided. Bystanders mingle with fire service personnel, taking photos with their mobile phones. There is no designated hot zone and no cyanide antidote.

Or a 30-year-old man presents to the emergency department with chest pain. You diagnose an inferior ST-segment elevation myocardial infarction. He is given aspirin — streptokinase has been out of stock for 3 months now, and other thrombolytics have been deemed unaffordable for the public system. He develops complete heart block and cardiogenic shock, which don’t respond to an adrenaline infusion. Central catheters