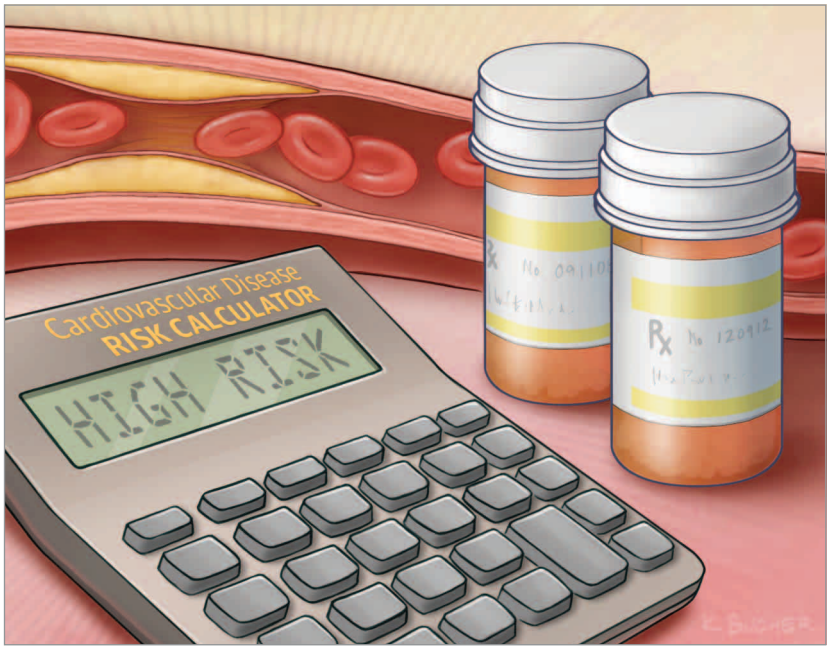

guidelines reaffirm the use of the pooled cohort equations for the US population, and state that they should be used as a "starting point, not as the final arbiter, for decision-making in primary prevention of ASCVD."

To address the uncertainties and to help provide more information to patients who are on the fence about statins, there's new advice for people with LDL-C levels of 70 mg/dL or higher and a 10-year ASCVD risk of 7.5% through 19.9%.

Among these intermediate-risk patients, "risk-enhancing" factors can tip the decision-making scales in favor of statins, according to Scott M. Grundy, MD, PhD, of the University of Texas Southwestern Medical Center, who chaired the guideline writing committee.

These factors include a family history of premature ASCVD, persistently elevated LDL-C levels or triglycerides, metabolic syndrome, chronic kidney disease, a history of preeclampsia or premature menopause, chronic inflammatory disorders, and high-risk ethnicities (like South Asian). If measured, apolipoprotein B, high-sensitivity C-reactive protein, ankle-brachial index, and lipoprotein(a) are additional risk factors to consider. "There are abundant epidemiologic data showing that risk-enhancing factors correlate significantly with ASCVD," Grundy said.

If there's still uncertainty about patients at intermediate risk, clinicians can also use coronary artery calcium (CAC) testing. Although no trial has been done to show that CAC testing improves selection of patients for treatment, "it's the best test for helping define risk beyond the standard risk factors," Greenland said.

A CAC score of 0 allows a delay of statin treatment except in cigarette smokers, patients with diabetes, and those with a family history of premature ASCVD. "Low levels of coronary calcium defer to clinical judgment, whereas high levels strongly support use of statin therapy," Grundy said.

Another new feature of the guidelines is that clinicians are now encouraged to have a comprehensive risk discussion with patients before initiating statin therapy, which should include a consideration of potential adverse effects and drug interactions, costs, and patient preferences and values. "The guideline places importance on a process of shared decision-making," said *JAMA* Deputy Editor Gregory Curfman, MD.

Meanwhile, a new AHA scientific statement released in December may help quell patient fears about statins. The report found that statin-related muscle aches and pains, the drugs' most common adverse effects, occur in no more than 1% of patients. The statement concluded that statins have a low risk of adverse effects and that, for most people, their benefits outweigh the risks. ■

Note: Source references are available online through embedded hyperlinks in the article text.

The JAMA Forum

Teaching Pelvic Examination Under Anesthesia Without Patient Consent

Eli Y. Adashi, MD, MS

"Every human being of adult years and sound mind has a right to determine what shall be done with his body." Justice Benjamin N. Cardozo, *Schloendorff v Society of New York Hospital*, (1914)

For many years, medical students working to master the art of the pelvic examination practiced the procedure on women under anesthesia. All too frequently, however, the right of the patient to decline participation in this educational endeavor was sidestepped; patient permission was rarely sought and explicit informed consent was similarly absent.

The topic periodically resurfaces in the media, online publications, and in journal articles, and though it is likely that the prevalence of unauthorized pelvic examinations by medical students has declined in recent years, the extent to which the practice still persists is unclear.

A lingering stain on the history of medical education, the age-old practice of unsanctioned pelvic examinations was hardly without consequences. Although rationalized as necessary for medical training, the practice all but suspended the ethical precept of respect for persons, upending expectations of patient privacy

and autonomy and undermining presumptions of professionalism, leaving notions of trust in tatters.

Viewed in hindsight, it is difficult to see how the conduct of unapproved pelvic examinations by medical students could have been rationalized, let alone condoned. What was once ethically acceptable is no longer, likely the result of a shifting of societal norms. Utilitarian ethical principles (judging the rightness of an action based on the most positive outcome) gave way to deontological principles (judging the rightness of an action based on a moral code). Focusing on benefits accrued to patients from medical student education no longer carried the day.

Unapproved pelvic examinations constituted but one expression of the medical paternalism of the day, along with nonconsented rectal examinations by medical students in male patients undergoing prostate surgery. Neither practice is compatible with the ethical and policy guidelines of the American Medical Association (AMA), which state that "patients' ... refusal of care by a trainee should be respected in keeping with ethics guidance."

Under Scrutiny

It was not until the late 1960s that the decades-old practice of unauthorized pelvic examinations came under some scrutiny. Position statements, regulatory edicts, and legislative initiatives, however, were slow to make their appearance.

In 1984, the Joint Committee on the Accreditation of Hospitals decreed that participation by patients in clinical training programs should be voluntary. The AMA Council on Ethical and Judicial Affairs followed suit in 2001 by recommending that in situations "where the patient will be temporarily incapacitated (e.g., anesthetized) and where student involvement is anticipated, involvement should be discussed before the procedure is undertaken whenever possible." The Association of American Medical Colleges, reversing its prior policy position, offered that "performing pelvic examinations on women under anesthesia, without their knowledge or approval ... is unethical and unacceptable." The Committee on Ethics of the American College of Obstetricians and Gynecologists (ACOG) resolved that "Pelvic examinations on an anesthetized woman ... performed solely for teaching purposes, should be performed only with her specific informed consent obtained before her surgery." State laws have been enacted (in California, Hawaii, Illinois, Iowa, Oregon, and Virginia) that define unauthorized pelvic examinations as a misdemeanor that could be grounds for loss of medical licensure.

Limited Educational Value

Apart and distinct from the considerations mentioned above, the educational value of pelvic examinations under anesthesia is limited at best. The deployment of paid nonpatient volunteers for the teaching of pelvic examination yields far greater educational returns, and this approach has been broadly embraced. In addition, the very utility of the traditional pelvic examination is being increasingly questioned. One such challenge is driven by the ever-improving quality of vaginal ultrasound probes, which provide far greater insight into pelvic pathology.

In yet another recent development, the US Preventive Services Task Force concluded in 2017 that "current evidence is insufficient to assess the balance of benefits and harms of performing screening pelvic examinations in asymptomatic, nonpregnant adult women." ACOG published a similar position statement in 2018. Taken together, these developments strip away any residual educational rationale for the continued deployment of pelvic examinations under anesthesia.

Relevant contemporary data are sorely lacking to shed light on the extent to which the practice of unauthorized pelvic examinations by medical students has been rooted out. Vanquishing the vestiges of a bygone era may well require additional regulatory and statutory initiatives.

Entities that could help guide the way forward include the Liaison Committee on Medical Education, the sponsors of which (the Association of American Medical Colleges [AAMC] and the AMA) have staked out their position. Policy initiatives from the American Hospital Association and the Federation of American Hospitals, as well as additional legislative initiatives at the state level, would also help. A concerted effort on these fronts might finally bring to a close a painful era, rife with ethical compromise—and not a moment too soon. ■

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