implementing strategies to promote more judicious use of CT. Efforts by policy makers and medical-center leaders to realign incentives that promote the escalating use of CT remain a societal imperative.

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Invited Commentary

The use of surgical mesh for the surgical treatment of pelvic organ prolapse has increased over time. This increase has been accompanied by concerns about the effectiveness and safety of mesh. The FDA released a warning in 2011 about the risks associated with the use of mesh, including complications such as erosion, absorption, and infection. The prevalence of mesh use has decreased since 2011, but it remains relatively high in some regions.

Methods | We used data from the New York Statewide Planning and Research Cooperative System, which contains records of all surgical procedures done in the state. Patients undergoing surgical procedures for pelvic organ prolapse were included if they had the procedure between January 1, 2008, and December 31, 2013. The study included both mesh and nonmesh procedures.

Results | The annual number of repair procedures for pelvic organ prolapse decreased from 6960 in 2011 to 5757 in 2013. The use of mesh after the 2011 FDA warning declined from 30% (95% CI, 29%-31%) to 23% (95% CI, 22%-24%) in 2013, with the decrease being more pronounced in low-volume than in high-volume centers (from 25% [95% CI, 23%-27%] to 15% [95% CI, 13%-16%]) vs from 37% [95% CI, 35%-39%] to 34% [95% CI, 32%-36%]; P < .01). The decrease was also more dramatic in nonteaching than in teaching facilities (from 29% [95% CI, 27%-30%] to 20% [95% CI, 18%-21%] vs from 32% [95% CI, 31%-34%] to 27% [95% CI, 25%-29.0%]; P < .01).

Eighty-eight physicians performed at least 5 prolapse repair procedures annually during the 3-year period covered in the study and used mesh in the year 2011. In 2012, a total of 14 physicians, consisting of hospitals and outpatient surgical centers stopped using mesh, followed by another 8 in 2013 (Table). In terms of pelvic organ prolapse procedures performed, most of these institutions were low-volume facilities.

Discussion | We found that after the 2011 FDA warning, mesh use decreased from 30% in 2011 to 23% in 2013. In a prior analysis of data from the New York Statewide Planning and Research Cooperative System, we found that mesh use increased from 21% in 2008 to 30% in 2011. The FDA message in 2008 urged physicians to obtain specialized training for each technique in which mesh was used and to be aware of risks associated with the use of mesh. The FDA advised physicians to consider the indications for mesh use, the nature of the procedure, and the patient's overall health.

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nal repair of such prolapse for both physicians and patients. Although other explanations are possible, we believe that the stronger language in the 2011 FDA warning is at least partly related to the decline in mesh use and has implications for future risk-communications policy, suggesting that stronger regulatory warnings can influence physicians’ use of potentially unsafe medical devices.

We also found that most of the decline in the use of mesh in the post-2011 warning period occurred with low- to medium-volume centers of procedures involving its use and in nonacademic centers. The smaller decrease in academic and high-volume centers of procedures involving the use of mesh is interesting and might represent these centers’ treatment of disease of higher-grade severity or a higher comfort level with the use of mesh (based on experience) in the absence of strong recommendations from professional societies. The higher rate of decline in the use of mesh by low-volume and nonacademic providers may be related to a lower tolerance for litigation related to sizable awards and growing numbers of lawsuits in outpatient settings.

Our study is unique in including an entire state’s data and a recent period in the use of mesh. However, some variability in the use of mesh among states is possible and should be considered when generalizing to the US population. Another limitation of our study is its use of billing codes that are not specific to vaginally placed mesh. Although codes related to abdominally placed mesh were excluded, some misclassification may still have occurred.

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Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: All authors.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Sedrakyan, Mao.
Obtained funding: Sedrakyan.
Administrative, technical, or material support: Sedrakyan.
Study supervision: Sedrakyan.
Conflict of Interest Disclosures: None reported.
Funding/Support: The study was funded in part by grant 1U01FD004494-01 from the US National Institutes of Health and US Food and Drug Administration (Dr Sedrakyan).
Role of the Funder/Sponsor: The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.
Additional Information: Dr Chughtai is a senior investigator and Dr Mao is an analyst within the Weill Medical College of Cornell University Patient-Centered Comparative Effectiveness Program and the US Food and Drug Administration's Medical Device Epidemiology Network’s Science and Infrastructure Centre, of which Dr Sedrakyan is director.

Invited Commentary
The FDA and the Vaginal Mesh Controversy—Further Impetus to Change the 510(k) Pathway for Medical Device Approval
In this issue of JAMA Internal Medicine, Sedrakyan et al.1 evaluate changes in gynecologic practice in New York following the 2011 publication of a US Food and Drug Administration (FDA) Safety Communication on the use of transvaginally placed surgical mesh to repair pelvic organ prolapse (POP), which occurs when pelvic organs, such as the bladder or rectum, herniate to or beyond the vaginal walls. Prostate is present in 40% of women, but only 6% report symptoms such as a palpable vaginal bulge, impairment in urinary or bowel function, or decrements in sexual activity.2 Although POP in some women responds to conservative management with pelvic muscle exercises or a vaginal pessary, it is commonly corrected through surgery, with 200 000 inpatient surgical procedures performed annually in the United States. Traditionally, surgical repair of POP was performed by suturing injured or weakened connective tissue to support structures in the pelvic floor. However, this so-called native tissue repair has a high rate of failure, with 30% to 50% of women requiring reoperation.3 Surgical mesh for transvaginal placement, most commonly consisting of nonabsorbable polypropylene, was introduced in 2002 as an implantable device to improve the long-term efficacy of POP repairs by adding strength and support.

The FDA approved the use of transvaginal mesh through the 510(k) regulatory pathway for moderate-risk devices. The 510(k) process does not require device manufacturers to conduct clinical trials to gain FDA approval for marketing their products for use in surgical practice. Rather, the 510(k) application asks manufacturers of the device to demonstrate “substantial equivalence” of the structure and function of a new device to those of an existing, legally marketed device. The FDA approved vaginal mesh for POP on the basis of its substantial equivalence to mesh used for abdominal hernia repair—an entirely different surgery performed on tissues with characteristics disparate from those in POP repair.

Many physicians, researchers, and consumer advocates have criticized the 510(k) process and emphasized the dangers of approving a device for medical or surgical use with little clinical evidence of its safety and efficacy. In 2011, an Institute of Medicine report found the 510(k) pathway “flawed” and recommended supplanting it with an entirely new regulatory framework.4 The approval of surgical mesh through this pathway for the transvaginal repair of POP is an excellent case study of the adverse consequences of requiring only proof of substantial equivalence for the marketing of medical or surgical devices. Gynecologists began placing vaginal mesh without clinical studies of its safety or efficacy on the presumption that it was safe and probably more effective than native-tissue repair.

Gynecologists began reporting adverse events to the FDA soon after approval of the transvaginal mesh, including erosion into the vagina, severe vaginal pain, and dyspareunia. By 2008, the large number of reported adverse events with the transvaginal placement of mesh prompted the FDA to issue a Public Health Notification outlining the potential serious consequences of such placement. During the next 2 years, the rate of reported complications with the use of transvaginal mesh increased exponentially. In 2011, the FDA issued an Updated Safety Notification stating that serious adverse complications with transvaginal mesh are “not rare” and that “transvaginal POP repair with mesh may not be more effective than traditional non-mesh repair and may expose patients to greater risk.”5 In 2012, the FDA began requiring manufacturers of mesh to conduct postmarket clinical studies to assess its long-term safety and efficacy. In 2014, the FDA announced that it might reclassify mesh as a high-risk device, which would require evidence provided by clinical trials for future FDA approvals of its use.

Letters

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JAMA Internal Medicine February 2016 Volume 176, Number 2

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In the context of concerns about the safety of vaginal mesh, Sedrakyan et al report a 7% decrease in mesh use in surgery for transvaginal POP in the 2 years following the 2011 FDA safety communication. Although this decline may indicate the effect of FDA postmarket policies on surgical practice, the analysis by Sedrakyan et al also highlights the persistent high prevalence of use of vaginal mesh. In New York, 23% of surgical repair for vaginal POP includes mesh despite serious risks and the initiation of 49,000 federal lawsuits against manufacturers of mesh.

Why do a significant proportion of transvaginal surgical procedures for POP continue to use mesh? First, many pelvic surgeons have criticized the FDA safety warnings as inaccurate and misleading. Second, although the 2011 FDA safety warning recommends that surgeons recognize that “in most cases, POP can be treated successfully without mesh,” its language allows the continued use of mesh with consideration of the risks and benefits of this use. A strong FDA recommendation to avoid the transvaginal placement of mesh for the repair of POP would probably have had a more significant effect on surgical practice. In addition, guidelines issued by gynecologic professional societies have concurred with the FDA policy of allowing the use of transvaginal mesh in certain clinical situations, such as that of women at high risk for treatment failure, with an informed discussion of the risks and benefits of its surgical use.

The controversy over the transvaginal placement of mesh for the repair of POP provides an impetus to consider significant improvements in regulatory mechanisms for the approval of medical devices, particularly permanent implantable devices. Rather than relying on postmarket voluntary reporting to evaluate device safety, FDA regulations must require evidence provided by comparative clinical trials before an implantable device is introduced into surgical practice. The challenge facing the FDA is to construct regulatory policies that assure patient safety but do not stifle innovation and technologic advances that can improve human health.

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Conflict of Interest Disclosures: None reported.

Funding/Support: Dr Subak reported having received funding from Astellas Pharma US via contracts with the University of California, San Francisco, to conduct research unrelated to transvaginal mesh.

Role of the Funder/Sponsor: None.

COMMENT & RESPONSE

Spiritual Care Providers and Goals-of-Care Discussions

To the Editor—The study by Ernecoff et al1 reveals a number of insights into the nature of family conferences in the intensive care unit (ICU). We laud their assessment of the religious preferences of the physician in charge of the family conference; however, it may have been more revelatory to ask the participating physicians not merely the broad question of whether religion was important to them but how important religion was in dealing with their own major life challenges as Curlin et al2 did in their historic evaluation of physician religiosity. In that study, physicians were twice as likely (61% vs 29%) to cope with major life challenges without God. This finding may partly explain the low likelihood of physicians probing surrogates’ religious concerns discovered in the study by Ernecoff et al.

It was disheartening to find that only 2 of the 249 goals-of-care discussions involved a spiritual care provider. Although it is not standard in our institution to include our hospital chaplain in family meetings, our chaplain is very much involved in addressing the spiritual needs of dying patients in the ICU and often after the family meeting has taken place. By limiting assessment of religious and spiritual considerations to recordings of family conferences, the investigators could not explore the likely presence of these considerations outside the fixed framework of the family conference. The findings do, however, beg the issue as to whether chaplains should be automatic invitees to such meetings.

Another limitation of audio recordings used in the study is that they blinded the investigators to the nonverbal aspects of family conferences. For a study that involved evaluating physician responses to religious statements, the absence of an evaluation of nonverbal responses such as head nodding, eye contact, and social touch seems to be a major limitation that may account for the low response rate reported.3

The use of video recordings would have allowed for detailed...