

Although the study has limitations, it adds data to the ongoing debate regarding whether same-day discharge after elective PCI is safe and effective. The question is essential in this era of cost saving, bed availability concerns, and medicolegal issues; and we agree that the results should be confirmed by a more powerful, multicenter, randomized trial.

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In Reply: Dr Janus brings up several important issues regarding the practicalities of same-day discharge after PCI in the United States, such as fears over malpractice litigation and patient and family preferences. We agree that these are important issues to consider not only when attempting to explain patterns of care, but also when managing patients. Malpractice claims are often based on deviations from the standard of care, and we believe our study helps to define and defend the standard of care for low-risk patients undergoing PCI. While Janus laments the lack of real-world situations in studies such as ours, the CathPCI Registry is a contemporary registry of all patients undergoing PCI in clinical practice at the participating sites and thus does reflect real-world practice. What is missing from the data are patient preferences; however, we would argue that most patients who have social support would, if asked, prefer to recover at home rather than in the unfamiliar hospital setting.

Drs Hauville, Barbash, and Waksman raise concerns that our same-day discharge and overnight stay cohorts were not comparable. Specifically, those experiencing a minor post-procedure complication would be unlikely to be discharged on the same day, even if planned, and this might bias our results against the overnight stay group. While this concern is reasonable, a few comments are worthwhile. First, those with serious complications requiring long hospital stays were excluded. Second, while the rate of procedural complications was higher among those with overnight stays, the overall rates were both less than 1% so that these results were unlikely to bias our findings. Finally, the purpose of the study was to investigate whether an uncomplicated, elective patient could safely be sent home. Those with serious post-

procedure complications would not be candidates for same-day discharge, or be discharged after 23 hours.

Additionally, Hauville et al were concerned that we excluded patients who stayed longer than 23 hours because this may have underestimated the rate of in-hospital events in the control group. While they are correct that those going home after an overnight stay do have lower event rates than all-comer PCI cases, we specifically selected this group to be representative of a low-risk control group. Had we included all PCI cases as a control, our same-day results would have looked even more favorable.

Finally, there is concern about the generalizability of our findings. Our analysis involved more than 100 000 patients undergoing PCI using an ongoing contemporary database of PCI procedures in the United States. It is by far the largest study ever done comparing same-day discharge with overnight observation in elective PCI and used real-world data. We do agree, however, that ideally these observational results would be replicated in a large randomized trial. To date, there have already been 3 randomized trials¹⁻³ performed outside the United States, and their findings closely match those found in our large US-based observational analysis.

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Mandatory HPV Vaccination

To the Editor: Mr Gostin's Commentary questioned whether mandates for human papillomavirus (HPV) vaccination are effective enough to risk alienating the public.¹ Data in studies he cites address this matter. In the 2 places that have adopted mandates, Virginia and the District of Columbia, coverage remains modest. Compared with 49% of female adolescents nationwide, just 54% of those in Virginia and 58% of those in the District of Columbia had received 1 or more doses of HPV vaccine by 2010 according to medical records.² Existing mandates include generous opt-out provisions that, in the case of the District of Columbia, more than 40% of parents used to circumvent the policy.

Gostin suggested widespread educational campaigns and mandates without generous opt-outs as a last resort, but we think this focus on the public is likely misguided. Numerous surveys indicate that many people already agree with HPV vaccination mandates. Most recently, studies found that 47% to 59% of parents agreed with mandates that did not specify an opt-out provision.^{3,4} When opt-out provisions were included, agreement increased dramatically to 84% to 92%.^{3,4} Thus, the very thing that undermines the effectiveness of mandates, an opt-out clause, is what makes them palatable. Weakly effective interventions like education are neither likely to resolve this paradox nor substantially increase vaccine uptake.

By contrast, interventions that address the factors of health care systems such as cost and clinician recommendation show considerable promise. For example, voluntary provision of no-cost HPV vaccine is a strategy that 3 states, including South Dakota and Washington, currently use. With 69% of adolescent girls having received at least 1 dose, these 2 states have attained among the highest HPV vaccine initiation rates in the nation.² Evidence from abroad indicates that combining universal coverage with a school-based approach may be particularly effective; a voluntary, no-cost, school-based program in England, for example, has achieved vaccine initiation levels as high as 90%.⁵ Because the Affordable Care Act will provide nearly universal coverage for vaccination costs, such an approach may be increasingly feasible in the United States.

Gostin concluded, "Above all, health policy must be driven by science."¹ Although we are far from having conclusive evidence, an emergent literature indicates that cost and access are more important barriers to HPV vaccination than public opinion. Further study of voluntary, no-cost programs in schools to improve HPV vaccine uptake among adolescents in the United States is warranted.

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To the Editor: Mr Gostin,¹ in his Commentary, highlighted the unique issues and controversies surrounding the institution of a state vaccination law, or mandate, with regard to the HPV vaccine. The Commentary provided a much-needed focus on the undisputed safety and efficacy of the HPV vaccine in light of recent negative public attention.

We think, however, that it is important to clarify the author's statement that "research on the effectiveness of mandates is unavailable."¹ While specific evidence does not yet exist regarding the effectiveness of school mandates on HPV vaccination rates, it is clear that school mandates have uniformly increased state vaccination rates for other vaccines. In 1999, the Task Force on Community Preventive Services concluded, after a review of all available studies on the effectiveness of school-entry vaccination laws, that these laws are both effective at reducing disease rates and outbreaks as well as increasing overall vaccination coverage.² An updated Task Force review in 2009 similarly demonstrated the effectiveness of vaccination mandates and, as a result, the Centers for Disease Control and Prevention currently lists school mandates among the recommended interventions to increase vaccination rates.² States that currently have school mandates for adolescent hepatitis B vaccine have rates almost twice that of states without such mandates.³ Most recently, the 2007 school mandate at the middle school level in New York state for the combined tetanus, diphtheria and pertussis vaccine was found to be associated with a greater than 2-fold increase in tetanus, diphtheria and pertussis vaccination rates in 1 New York City cohort.⁴

Gostin states, "If voluntary vaccination proves unsuccessful, states should seriously consider compulsory vaccination laws without generous exemptions."¹ Nationally, HPV vaccination rates significantly lag behind those of other adolescent vaccines and differ by both race/ethnic group and poverty status.⁵ To date, traditional methods of increasing HPV vaccine uptake have been only marginally successful. School mandates for HPV vaccine, which reflect national vaccination recommendations of the Advisory Committee on Immunization Practices, have the potential to increase HPV vaccination levels among targeted, school-age populations.

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To the Editor: Mr Gostin made an important point in his Commentary on mandatory HPV vaccination: “Above all, health policy must be driven by science.”¹ However, the author’s recommendation that “if voluntary vaccination proves unsuccessful, states should seriously consider compulsory vaccination laws without generous exemptions” appears premature. As Gostin noted, clinical trial evidence has not demonstrated that HPV vaccines can actually prevent invasive cervical cancer, let alone cervical cancer deaths.^{2,3} Because HPV vaccines were specifically developed to protect against cervical cancer, we conclude that in the absence of long-term data, their true benefits remain speculative. The Food and Drug Administration acknowledges that “It is believed that prevention of cervical precancerous lesions is highly likely to result in the prevention of those cancers.”⁴

Clinical trials show that HPV vaccine efficacy against persistent HPV infection and precancerous lesions only lasts for 8.4 and 5 years for Cervarix and Gardasil, respectively.³ Antibodies to HPV-18 from Gardasil decrease rapidly, with 35% of women having no measurable antibody titers at 5 years.³ Thus, we currently do not know whether HPV vaccines will prevent future cases of cervical cancer cases or merely postpone them.

Given the demonstrable success of regular Papanicolaou screening in reducing the incidence of mortality from cervical cancer in the developed world (currently 1.4-2.3/100 000 women),⁵ it is unlikely that HPV vaccination (even if proven effective against cervical cancer) would reduce mortality rates beyond those already accomplished with routine Papanicolaou test screening.^{2,3}

There are still unresolved concerns regarding HPV vaccine safety. HPV vaccines can cause serious adverse events, including death and long-term disabling autoimmune conditions,^{2,3} but it is unclear how common such adverse events are. Nonetheless, for vaccines with unproven benefits designed to prevent a disease that is already preventable by Papanicolaou screening that carries no such risks, the risk to those vaccinated should be much lower, if not negligible. In that light, we agree with Gostin: “Political leaders [as well as the medical profession] have a moral responsibility to ensure their political advocacy is well informed and does not cause future harm to America’s youth.”¹

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datations and having conducted a histological analysis of brain samples from a Gardasil-suspected death case. Dr Shaw also reported being the founder of Neurodyn Corporation, a company that investigates early-state neurological disease mechanisms and biomarkers.

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In Reply: This collection of 3 letters in response to my Commentary vividly demonstrates the political and social divisiveness of HPV vaccination, which sets it apart from most childhood immunizations. Each letter is thoughtful, and yet all 3 letters come to distinctly different policy conclusions. Drs Gilkey and Brewer find that health system factors such as cost and enhanced access are more effective than mandates; Dr Berger and colleagues urge immediate state adoption of HPV mandates with limited opt-outs; and Drs Tomljenovic and Shaw reject HPV mandates as a flawed policy. Each letter expresses strong agreement with my view, “Above all, health policy must be driven by science,” and yet each draws different conclusions based on the available scientific evidence. How is this possible?

Gilkey and Brewer cite studies showing strong parental support for mandates—either with generous opt-outs (84%-92%) or without (47%-59%). But these polls have underlying flaws. First, the very reason for such high parental support for mandates with opt-outs is because such mandates can easily be circumvented. Moreover, the problem with mandates has never been the lack of majority public support. Rather, it is the vociferous, highly vocal minority that fuels controversy. I do, however, agree with their conclusion that system change is often the best public health strategy, so a voluntary, no-cost HPV vaccine program preferably in schools would be well worth pursuing.

Berger et al are correct in asserting that school mandates are highly effective for most childhood immunization programs. I have been an active supporter of mandatory vaccination when warranted.¹ However, given the recent history of sharp political controversy surrounding HPV vaccination and the evolving science, it may be best to seek system changes and informational campaigns in the near-term. For example, given the recent recommendation to vaccinate boys, would the mandate extend to this population?

Tomljenovic and Shaw raise their own doubts about the effectiveness of the HPV vaccine. They cite studies casting uncertainty about the vaccine’s protection against invasive cervical cancer, the potential short duration of the effects of the vaccine, and its safety record. Although I do not share their concerns about the public health benefits of HPV vaccination, the vaccine is relatively recent and politically di-

visive. On balance, I would implement immediate system changes relating to cost and clinician recommendations, as well as a public health information campaign. I would closely monitor uptake and if insufficient, move toward mandates with narrow, reasonable opt-outs.

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RESEARCH LETTER

Screening for Osteoporosis in Men Receiving Androgen Deprivation Therapy

To the Editor: Prostate cancer is the most common cancer in men.¹ One in 2 men with prostate cancer is expected to receive androgen deprivation therapy (ADT). Use of ADT is associated with accelerated bone loss and an increased risk of fractures.² To better characterize fracture risk and optimize bone health, a bone mineral density (BMD) test has been recommended prior to ADT initiation since 2006 in Canada³ and elsewhere.⁴ Low rates of BMD use have been reported by single centers.⁵ We examined the rate of BMD testing in men starting ADT in the province of Ontario, Canada, between 1995 and 2008.

Methods. We identified men aged 66 years or older who were starting ADT for prostate cancer, using linked administrative databases at the Institute for Clinical Evaluative Sciences in Ontario, Canada (population approximately 11 million) and the Ontario Cancer Registry as previously described.² These databases have been shown to be 85% to 99% complete and accurate. Men diagnosed between January 1, 1995, and December 31, 2008, and receiving at least 6 months of continuous medical ADT (luteinizing-hormone-releasing hormone agonists, antiandrogens, or both) or undergoing orchiectomy were included. The BMD tests used dual x-ray absorptiometry within 2 years of starting ADT and were captured using outpatient claims. Sociodemographic characteristics, comorbidity information (including prior diagnoses of osteoporosis and fragility fractures, ie, hip, spine, or wrist), and prior bisphosphonate use were obtained from inpatient and outpatient records using specific diagnostic, procedure, and claims codes as previously described.²

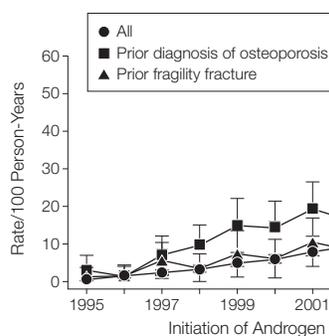
We examined whether a BMD test was performed over time using counts (per 100 person-years) and multivariable logistic regression using SAS version 9.2 (SAS Institute Inc). Level of significance was a *P* value of less than .05 and statistical tests were 2-sided. Study approval was obtained from the institutional research ethics board; individual patient consent was waived.

Results. We identified 33 036 men (mean age: 76.0 years; range: 66-100 years) with prostate cancer who initiated ADT

during the study period. A prior BMD test was performed in 1591 men (4.8%), 1332 (4.0%) had a prior diagnosis of osteoporosis, 1053 (3.2%) had a prior fragility fracture, and 808 (2.4%) were taking bisphosphonates at baseline.

The use of BMD tests within 2 years of starting ADT ranged from 0.5 per 100 person-years in 1995 to 18.0 per 100 person-years in 2008 (FIGURE). Even among ADT users at high risk of osteoporosis (prior fragility fractures) or fractures (prior diagnosis of osteoporosis), BMD test ordering remained low, never reaching 50% of patients (Figure). Predictors of greater BMD testing included younger age, not living in a rural area, later start year of ADT, prior osteoporosis, prior BMD test, prior bisphosphonate use, and having a regular primary care physician (all *P* < .01) (TABLE).

Figure. Rates of Bone Mineral Density Test Ordering After Starting Androgen Deprivation Therapy



Error bars indicate 95% CIs.

Table. Predictors of Bone Mineral Density (BMD) Test Ordering Within 24 Months of Initiating Androgen Deprivation Therapy (ADT)

	Odds Ratio (95% CI) ^a
Age range, y	
65-74	2.81 (2.41-3.27)
75-84	2.02 (1.73-2.36)
≥85	1 [Reference]
Living in rural area	0.57 (0.50-0.65)
Income quintile	
1 (lowest)	0.74 (0.65-0.84)
2	0.84 (0.75-0.95)
3	0.87 (0.77-0.98)
4	0.85 (0.76-0.96)
5 (highest)	1 [Reference]
Year of starting ADT (per year after 1995)	1.26 (1.25-1.27)
Prior diagnosis of osteoporosis, % ^b	1.48 (1.24-1.76)
Prior fragility fracture, % ^c	0.98 (0.79-1.22)
Prior BMD test, % ^b	2.53 (2.22-2.89)
Prior bisphosphonate use	1.56 (1.30-1.88)
Regular primary care physician	1.30 (1.20-1.40)

^aFrom the multivariable model, which was adjusted for all of the variables in this table. The odds ratios that are greater than 1 indicate a greater likelihood of undergoing a BMD test.

^bThe lookback period was 4.5 years.

^cThe lookback period was 7.75 years.