

## Availability of In-Office Laboratory Services and Use of Prostate Specific Antigen Testing

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### Abstract

**Introduction:** There are concerns that the availability of in-office ancillary services may lower thresholds for evaluation, leading to the overuse of testing without clear benefit. Motivated by this issue, we analyzed nationally representative survey data, and examined for associations between the availability of in-office laboratory services and the use of prostate specific antigen testing.

**Methods:** Using restricted data from the 2006-2008 NAMCS, we determined the prevalence of physician practices offering on-site laboratory services. We then characterized differences between practices with and without these capabilities as well as among the physicians working in them. Finally, we fitted multivariable logistic regression models to estimate the odds of prostate specific antigen testing given a man's mortality risk and the availability of in-office laboratory services at the practice where he received care.

**Results:** Approximately half of all primary care and urology practices offered in-office laboratory services. Practice characteristics associated with these capabilities included practice size ( $p < 0.001$ ) and breadth of specialization ( $p = 0.021$ ). Employed physicians were more likely to work in practices with in-office laboratory services than self-employed physicians ( $p < 0.001$ ). On multivariable regression the availability of on-site laboratory services was not associated with the use of prostate specific antigen testing (OR 0.86, 95% CI 0.62–1.20,  $p = 0.362$ ). In fact, the probability of prostate specific antigen testing among patients with the highest mortality risk was lower if they were seen at a practice with in-office laboratory services.

**Conclusions:** These findings provide some reassurance that in-office ancillaries do not lead to overuse of prostate specific antigen testing.

*Key Words:* prostate-specific antigen; ancillary services; hospital; jurisprudence; urology; physicians; primary care

### Abbreviations and Acronyms

IOAS = in-office ancillary services

NAMCS = National Ambulatory Medical Care Survey

PCP = primary care physician

PSA = prostate specific antigen

In response to the shifting health care landscape, more and more physician groups are adopting an integrated practice model to deliver one-stop shopping for their patients.<sup>1,2</sup> This

includes bringing laboratory and pathology services (which were traditionally outsourced) on site. Providing such services is allowed under the in-office ancillary services exception of the Stark law self-referral statute. The provision of such in-office ancillaries offers several possible advantages, including enhanced access and greater convenience for patients.<sup>3</sup> Moreover, physicians are able to obtain test results faster, leading to shorter diagnosis times and more rapid treatment.<sup>4</sup>

Despite these benefits, concerns have been raised that physician self-referral may lead to higher overall volume, potentially increasing health care costs.<sup>3,4</sup> Indeed a recent analysis of Medicare claims suggested that urologists who owned integrated pathology laboratories billed for more prostate biopsy specimens than urologists who used independent

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pathology providers.<sup>5</sup> While this work garnered substantial attention in the lay press, it was criticized for ignoring important secular trends.<sup>6</sup> Thus, the effects of in-office laboratory services on utilization need to be further clarified.

Therefore, we used nationally representative survey data to determine the prevalence of physician practices offering on-site laboratory services. We then characterized the organization of these practices and the physicians who work in them. Finally, we performed a visit level analysis to assess whether the availability of in-office laboratory services was associated with lower thresholds for PSA testing. The results of our study serve to inform the debate on the IOAS exception to the Stark law.

## Methods

### *Study Population*

For this study we used restricted data files from the 2006-2008 NAMCS via the National Center for Health Statistics Research Data Center. The NAMCS is an annual 3-stage probability sample of outpatient visits to randomly selected, nonfederal employed, office based physicians in the U.S.<sup>7</sup> It was necessary to use the restricted data files because they contain physician and practice characteristics obtained during a survey induction interview that are not included with the public use microdata files for confidentiality reasons.

Through information provided on the patient record form, we identified all outpatient visits made by men 40 years old or older. Unique specialty codes enabled us to differentiate between visits to a urologist and those to a PCP. As our analytic focus was on the use of PSA testing, we excluded visits related to benign prostatic hyperplasia, prostatitis and prostate cancer diagnoses using appropriate ICD-9-CM codes.

### *Identifying Practices with On-Site Laboratory Services*

Physicians were asked during their induction interview if they have the ability to provide certain types of on-site laboratory testing. Their responses to these questions allowed us to create a binary indicator for practices with in-office laboratory services. We then characterized physicians in these practices based on several factors (eg employment status), hypothesizing that some physicians may be more likely to work in them than others. We also described each practice by size, geographic region, breadth of specialization and urban/rural location.

### *Assessing the Risk of Mortality among Patients Eligible for PSA Testing*

To assess whether the threshold for PSA testing varied between practices with and without in-office laboratory services we used a modified version of the 10-year mortality index developed and validated by Cruz et al.<sup>8</sup> The original index is based on 12 items with varying points assigned to each item, the

majority of which are contained within the NAMCS. The developers of the index reported 10-year mortality rates ranging from 2.3% for participants with 0 points to 93% for participants with 14 or more points. The reported C-statistic for the index was 0.834 and there was no evidence of poor calibration (Hosmer-Lemeshow  $p = 0.38$ ). After accounting for the all-male sample, we constructed the 10-year mortality index by summing the assigned points for all available items. The index was then divided into the approximately equal size categories of 0 (lowest mortality risk), 1 to 2, 3 to 4, 5 to 6 and 7+ (highest mortality risk).

### *Statistical Analysis*

In all of our analyses we accounted for unequal probabilities of selection, clustering and stratification to correct standard errors for the complex sample design. The NAMCS samples physicians within practices and gives higher selection probabilities to those in smaller practices. Thus, to make the practice our unit of analysis we adjusted the physician sampling weight by the inverse of the number of physicians in a practice.<sup>9</sup> The resulting medical practice estimator allowed us to generate unbiased, nationally representative practice level estimates.

For our initial analytic step we calculated the proportion of primary care and urology practices with in-office laboratory services, testing for significant changes in this proportion over time. We then made bivariable comparisons between practices (and the physicians who worked in them) with and without these capabilities.

Next we calculated the distribution of patient visits to urologists and PCPs, stratified by the availability of on-site laboratory services, and determined the proportion at which PSA testing was ordered. We then performed logistic regression to examine for associations between PSA testing and availability of in-office laboratory services, adjusting for patient level (age, race, Medicaid eligibility and 10-year mortality risk using the index previously described), physician level (gender, age, specialty, professional degree, employment status) and practice level characteristics (size, breadth of specialization, geographic region, metropolitan status).

Finally, we calculated the adjusted probability of PSA testing being ordered during a visit stratified by availability of on-site laboratory services and a patient's 10-year mortality risk. This allowed us to determine whether the threshold for testing patients with shorter life expectancies was lower in practices with on-site capabilities.

For all analyses we used 2-sided significance testing with a type I error rate set at 0.05. The Health Sciences Institutional Review Board at the University of Michigan deemed that our study was exempt from its oversight.

## Results

Approximately half (52.4%) of all practices offered on-site laboratory services. This prevalence was stable during the study interval and did not vary between specialties (table 1).

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