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Postvasectomy Semen Analysis Compliance With Utilization of a Mail-In Semen Analysis Kit

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Full-length article available at https://doi.org/10.1097/JU.0000000000004185.

Study Need and Importance: Around half a million vasectomies are performed annually in the US. However, before a vasectomy can be used as a reliable method of contraception, per the AUA guidelines, a postvasectomy semen analysis (PVSA) must be done to ensure procedural success. Unfortunately, patient compliance with PVSA has historically been poor. We studied a cohort of patients from various practice settings who utilized an at-home mail-in kit to assess its impact on patient compliance with PVSA.

What We Found: In our cohort of over 16,000 patients, overall compliance with PVSA utilizing the mail-in kit at 16 weeks was 69%. When extending this observation to 40 weeks, compliance increased to 82%. Univariable logistic regression models demonstrated men receiving care in small urology practices had approximately 60% greater odds of compliance than those who received care in large practices (Figure).

Limitations: There are no direct comparisons of compliance to other current contemporary methods. We also do not have demographic data of the cohort, so compliance by demographics could not be assessed. As such, there may be hidden biases in the practices and patients who self-selected to use the mail-in kit.

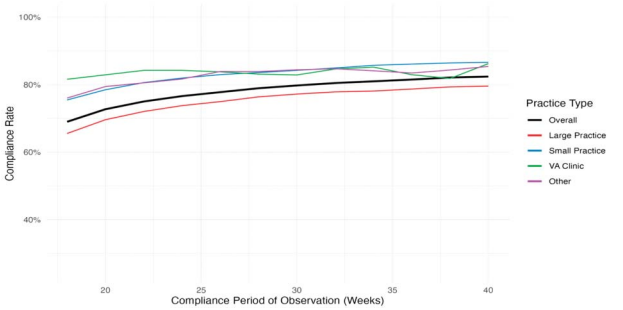

Figure. We tracked compliance over a variety of practice types starting from 18 weeks to 40 weeks. By 40 weeks, compliance around all practice types was around 82% with slight variation by practice setting. VA indicates Veterans Affairs.

Interpretation for Patient Care: PVSA is part of AUA guideline care and has been a historically frustrating test to obtain for both providers and patients. This is the largest cohort of American men studied in this area. Compliance rate at 40 weeks shows marked improvement over many other previous studies, suggesting that components of this platform, which may include more than the at-home collection aspect, are beneficial.

https://doi.org/10.1097/JU.0000000000004185
Vol. 212, 899-906, December 2024
Printed in U.S.A.

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www.auajournals.org/journal/juro

Postvasectomy Semen Analysis Compliance With Utilization of a Mail-In Semen Analysis Kit

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Purpose: The AUA recommends postvasectomy semen analysis (PVSA) to verify successful vasectomy. However there remains poor patient compliance. We sought to assess whether mail-in PVSA improves patient compliance across a wide range of practice types.

Materials and Methods: Prospective data were collected on all men who received a Fellow PVSA kit between April 2021 and August 2023 in a nationwide cohort. Date of kit activation, practice type, clinic zip code, and date of kit accession/processing at the lab were collected. Compliance rates for each practice area were reported. χ^2 tests of independence, logistic regression models, and multivariable logistic analysis were performed to assess the impact of relevant variables.

Results: Overall compliance across all practice areas was 69% following an 18-week period of observation (n = 16,105) and 82% (n = 6687) following a 40-week period. Compliance rates were highest and similar for small urology practices (<5 providers), including Veterans Affairs practices, ranging from 76% to 82% at 18 weeks to 85% to 87% at 40 weeks. Large urology practices had slightly lower compliance rates with 66% at 18 weeks to 80% at 40 weeks. The univariable logistic regression

Submitted February 3, 2024; accepted July 29, 2024; published August 2, 2024.

Recusal: Dr Suskind, associate editor (female urology) of *The Journal of Urology®*, was recused from the editorial and peer review processes due to affiliation with the University of California, San Francisco. Dr Leapman, reviewer board member of *The Journal of Urology®*, was recused from the editorial and peer review processes due to affiliation with Yale School of Medicine.

Funding/Support: None.

Conflict of Interest Disclosures: Dr Belarmino reported being a consultant at Fellow Health Inc. Dr Nolte reported being a data scientist at Fellow Health Inc. Dr Kenfield reported being a research consultant at Fellow Health Inc. Dr Civello reported being a data scientist at Fellow Health Inc. Dr Smith reported being chief medical officer at Fellow Health Inc. Dr Honig reported being an advisor with stock equity at Fellow Health Inc. Dr Lerner reported being principal investigator for a clinical trial supported by Janssen and being a consultant at Ambu and Boston Scientific. No other disclosures were reported.

Ethics Statement: This study was approved by WCG (IRB No. 20235680).

Author Contributions:

Conception and design: Gu, Lerner, Belarmino, Smith, Kenfield.
Data analysis and interpretation: Belarmino, Nolte, Civello.
Drafting manuscript: Gu, Belarmino, Lerner, Nolte.
Critical revision of the manuscript for scientific and factual content: Gu, Belarmino, Kenfield, Nolte, Smith, Honig, Mehta, Punjani, Lerner.
All authors reviewed and approved the final manuscript.

Data Availability: The datasets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

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Editor's Note: This article is the fifth of 5 published in this issue for which Category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 937 and 938.

https://doi.org/10.1097/JU.0000000000004185
Vol. 212, 899-906, December 2024
Printed in U.S.A.

model demonstrated that patients in small urology practices have a 63% greater odds of 26-week compliance, on average, compared to those who receive care in large urology practices (odds ratio 1.63, 95% CI 1.48-1.79).

Conclusions: Fellow's mail-in PVSA offers improved PVSA compliance over previously published data. Improved compliance is seen across all practice types. Despite these successes, there is significant room for improvement to achieve 100% compliance.

Key Words: semen analysis, vasectomy, patient compliance, male sterilization

AUA guidelines recommend that before using vasectomy as a sole contraceptive method, all patients should undergo a postvasectomy semen analysis (PVSA) to confirm success.[1] Although the exact timing of the PVSA has been debated, recommendations generally range from 8 to 16 weeks.[1] Unfortunately, patient compliance with PVSA has historically remained low, ranging from 35%[2,3] to 80%,[4] with a median of approximately 50%.[5-8] Multiple studies demonstrate this rate despite efforts to increase patient education around PVSA necessity.[6,9] Another study found less than 60% of couples use secondary contraception prior to having a PVSA, increasing the risk of unwanted pregnancies.[10]

There is a large body of evidence dedicated to investigating barriers to obtaining a PVSA and factors that influence compliance. The most common barriers patients cite include distance to the lab/inconvenience, time constraints/too busy, confidence in the procedure/surgeon, and forgetfulness.[9,11] That said, 92% of patients report increased likelihood of PVSA completion if able to utilize a home-based testing kit. In fact, one study found an inverse relationship between PVSA compliance and drive time to a lab site from the patient's home.[12] However, Punjani et al assessed compliance with at-home semen analysis tests in 364 men between 2007 and 2019 at a high-volume, single-surgeon center and revealed that, even with at-home testing, compliance rates remained low at 59%.[3] There are data to suggest that making a follow-up appointment for the patient increases compliance; however, this has not been consistently reproduced.[4,13] These low PVSA compliance rates result in increased stress and administrative burden on practices due to the efforts and resources needed to track patients and encourage testing. Furthermore, despite low vasectomy failure rates, patients can remain fertile, and low PVSA compliance may be associated with increased risk of pregnancy and possible litigation.[14]

In this study, the Fellow mail-in kit was utilized. Fellow's packaging is designed to be discrete, includes patient-friendly instructions, and has a simple collection process. In addition, Fellow provides reminders to patients to test starting 11 weeks post vasectomy, and will continue to remind patients to test until 6 months post vasectomy if a kit is not received at their lab. We sought to explore if a testing process that appears to address many of the patient-reported challenges impacts compliance across a wide range of practice types.

MATERIAL AND METHODS

Study Design and Patient Population

Data from a prospective cohort of men who utilized a Fellow mail-in PVSA kit between April 2021 and August 2023 were analyzed. Patients nationwide were included for review and analysis across a variety of clinical settings. For each compliance period of observation, patients were excluded if the full period had not yet elapsed (Figure 1). We also excluded direct-to-consumer (which largely eliminated academic institutions who rely on referral codes) and medical research kits. Patients obtained and activated their kit at the clinical practice. Activated users were then sent email reminders at specific time points to encourage completion and return of samples for analysis. This study was approved by WCG (IRB No. 20235680).

Key Exposure Variables

Each clinical practice was categorized as either a large urology practice (≥5 providers), small urology practice (≤4 providers), Veterans Affairs (VA) clinic, or grouped alongside all other settings combined (eg, wellness, hospital, acupuncture clinics). Direct-to-consumer and medical research sales were excluded.

Metropolitan status (metropolitan/nonmetropolitan) was determined by mapping each clinic zip code to its rural-urban commuting area code. These codes, provided by the United States Department of Agriculture Economic Research Service, classify US Census tracts on a 10-point scale as metropolitan (1-3), micropolitan (4-6), small town (7-9), or rural (10) based on measures of population density, levels of urbanization, and daily commuting patterns.[15] Clinics located in an area with a rural-urban commuting area code of 1 to 3 were classified as metropolitan, and the remaining clinics were classified as nonmetropolitan.

Clinic region was further classified by state as Midwest (Iowa, Illinois, Indiana, Kansas, Michigan, Missouri, Minnesota, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin), Northeast (Connecticut, Delaware, Maryland, Massachusetts, New Jersey, New York, Pennsylvania, Vermont, and Washington, District of Columbia), Southeast (Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia), Southwest (Arizona, New Mexico, Oklahoma, and Texas), or West (California, Colorado, Idaho, Montana, Nevada, Utah, Washington, and Wyoming). This was done to assess regional differences in compliance.

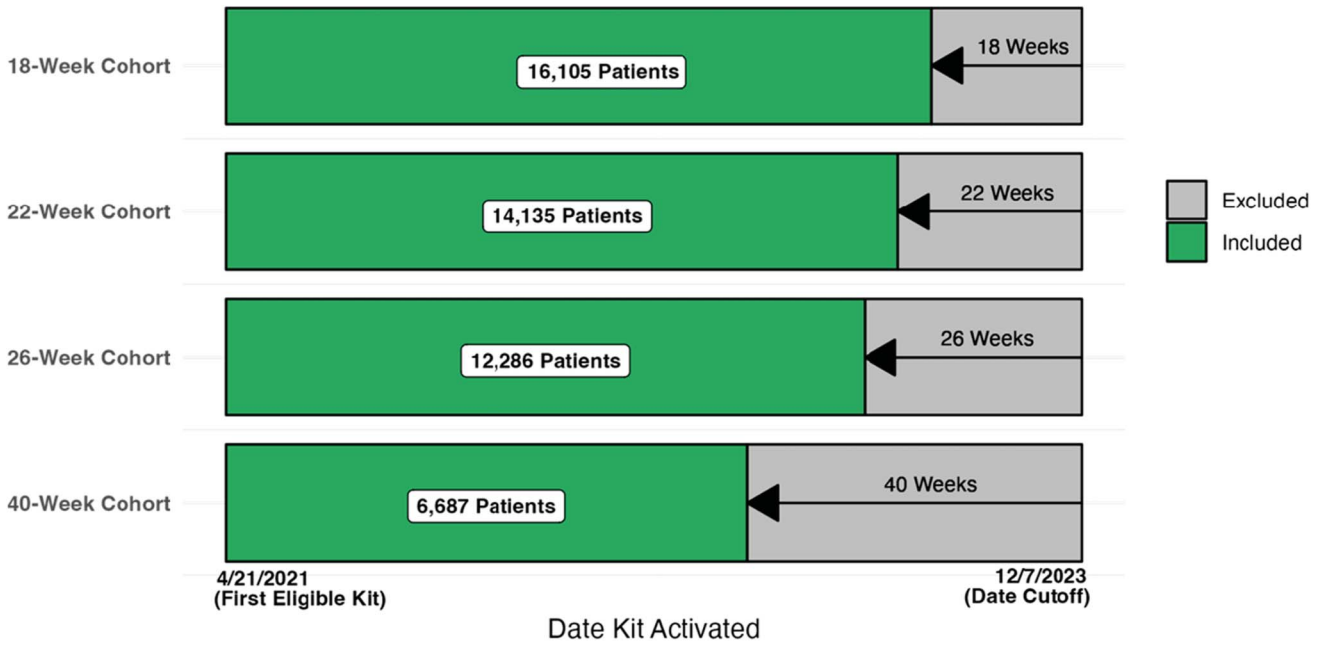

Figure 1. Schematic demonstrating the relationship between cohort size and period of observation. Since each patient must be observed for the entire period of observation, for example, 18 weeks, in order to reliably assess their compliance, recent patients who have not reached the end of the assessed window size must be excluded when calculating compliance rates. As a result, longer periods of observation result in smaller cohort sizes.

Outcome (Compliance) Definitions

Kit activation is the first step in a patient's journey with the Fellow PVSA system and is defined as the submission of basic contact information by the clinician or patient. The timing of kit activation varies among clinics but occurs most commonly on the date of vasectomy or at a vasectomy consult visit. Kit activation reflects the initial starting time for completing the PVSA. At all sites other than the VA, where kits are provided at no cost to patients, kit activation is the time at which the patient purchased the kit.

PVSA Compliance. Compliance is measured by dividing the number of accessioned kits, defined as the date of lab processing, by the number of activated kits. Compliance was reviewed at 18, 22, 26, and 40 weeks after kit activation.

Compliance Observation Time Points. The shortest window considered (18 weeks) was selected because it represents the upper limit of time encouraged by the AUA guidelines (16 weeks plus an additional 2 weeks for ground shipping, which can take up to 10 days). The 22- and 26-week periods were selected both to address limitations of kit activation as a proxy for vasectomy and to investigate compliance with longer permitted follow-up. An upper bound of 40 weeks was chosen as compliance appears to plateau by this time.

Statistical Analysis

After calculating compliance rates for each practice area, χ^2 tests of independence were used to evaluate whether compliance rates varied by practice type (small and large urology practices, VA, or other). Univariable and multivariable logistic regression models of practice type on compliance status were also considered. The initial multivariable logistic regression models were developed with exposure variables selected a priori including clinic region (Midwest, Northeast, Southeast, Southwest, West) and metropolitan status (metropolitan, nonmetropolitan). Statistical significance was set at $P < .05$ and all tests were 2-sided. All analyses were performed using the R Statistical Software (v4.3.2; R Core Team 2023).

RESULTS

A total of 31,721 kits were purchased and eligible for analysis. Kits sold to minors (<18 years old) were excluded (n = 4), as well as kits purchased directly via the Fellow website (n = 3941) or if the practice type was unknown (n = 20). If an individual ordered multiple kits, the first kit ordered was included and the rest were excluded (n = 636). Finally, for each compliance period of observation, patients were excluded if the full period had not yet elapsed (Figure 1). For the largest cohort, whose 18-week compliance was assessed, this final step excluded 11,015 patients, yielding a final sample size of 16,105 patients. Overall compliance across all practice areas was 69% for an 18-week compliance period of observation (n = 16,105) and 82% (n = 6687) for a 40-week compliance period of observation (Table 1). Compliance increased when extending observation periods, reflecting that when patients were permitted more time to return their kits, they were more often compliant. The most significant increases occurred as the compliance period of observation increased from 18 to 26 weeks and plateaued at approximately 40 weeks (Figure 2).

Table 1. *Postvasectomy Semen Analysis Compliance Across a Wide Range of Urology Practice Types in the United States Using χ^2 Analyses*

	18 wk			22 wk			26 wk			40 wk		
	Total patients, No.	Compliant patients, No.	Compliance rate (%)	Total patients, No.	Compliant patients, No.	Compliance rate (%)	Total patients, No.	Compliant patients, No.	Compliance rate (%)	Total patients, No.	Compliant patients, No.	Compliance rate (%)
Overall	16,105	11,110	69.0	14,135	10,600	75.0	12,286	9554	77.8	6687	5509	82.4
Subgroup analysis												
Practice type												
Large practice	10,555	6915	65.5	9273	6679	72.0	8018	6010	75.0	3974	3161	79.5
Small practice	5057	3816	75.5	4432	3572	80.6	3890	3227	83.0	2561	2218	86.6
VA clinic	76	62	81.6	76	64	84.2	74	62	83.8	29	25	86.2
Other	417	317	76.0	354	285	80.5	304	255	83.9	123	105	85.4
P value		< .001[a]			< .001[a]			< .001[a]			< .001[a]	
Region												
Midwest	4882	3289	67.4	4514	3300	73.1	4137	3154	76.2	2604	2115	81.2
Northeast	2042	1454	71.2	1833	1437	78.4	1643	1338	81.4	894	762	85.2
Southeast	4176	2706	64.8	3469	2484	71.6	2790	2098	75.2	1107	916	82.7
Southwest	1938	1371	70.7	1734	1301	75.0	1557	1198	76.9	918	726	79.1
West	3067	2290	74.7	2585	2078	80.4	2159	1766	81.8	1164	990	85.1
P value		< .001[a]			< .001[a]			< .001[a]			< .001[a]	
Metropolitan status												
Metropolitan	15,442	10,682	69.2	13,548	10,187	75.2	11,784	9194	78.0	6485	5353	82.5
Nonmetropolitan	529	347	65.6	472	338	71.6	414	304	73.4	199	156	78.4
P value		.09			.09			.03[a]			.16	

Abbreviations: VA, Veterans Affairs.
[a] Statistically significant *P* value < .05. Cohort total counts for the metropolitan status grouping variable sum to slightly less than the overall grouping because of missingness for this variable.

By practice type, compliance rates were highest and similar for small urology practices, VA practices, and all other settings, ranging from 76% to 82% at 18 weeks to 85% to 87% at 40 weeks (Table 1). Large urology practices had slightly lower compliance rates ranging from 66% at 18 weeks to 80% at 40 weeks. An association between compliance and practice type was evident at each observation period considered ($P < .05$, Table 1).

For the largest patient cohort (corresponding to an 18-week compliance observation period), the most patients using Fellow for PVSA were in the Midwest (n = 4882; 30%), followed by the Southeast (n = 4176; 26%), West (3067; 19%), Northeast (2042; 13%), and

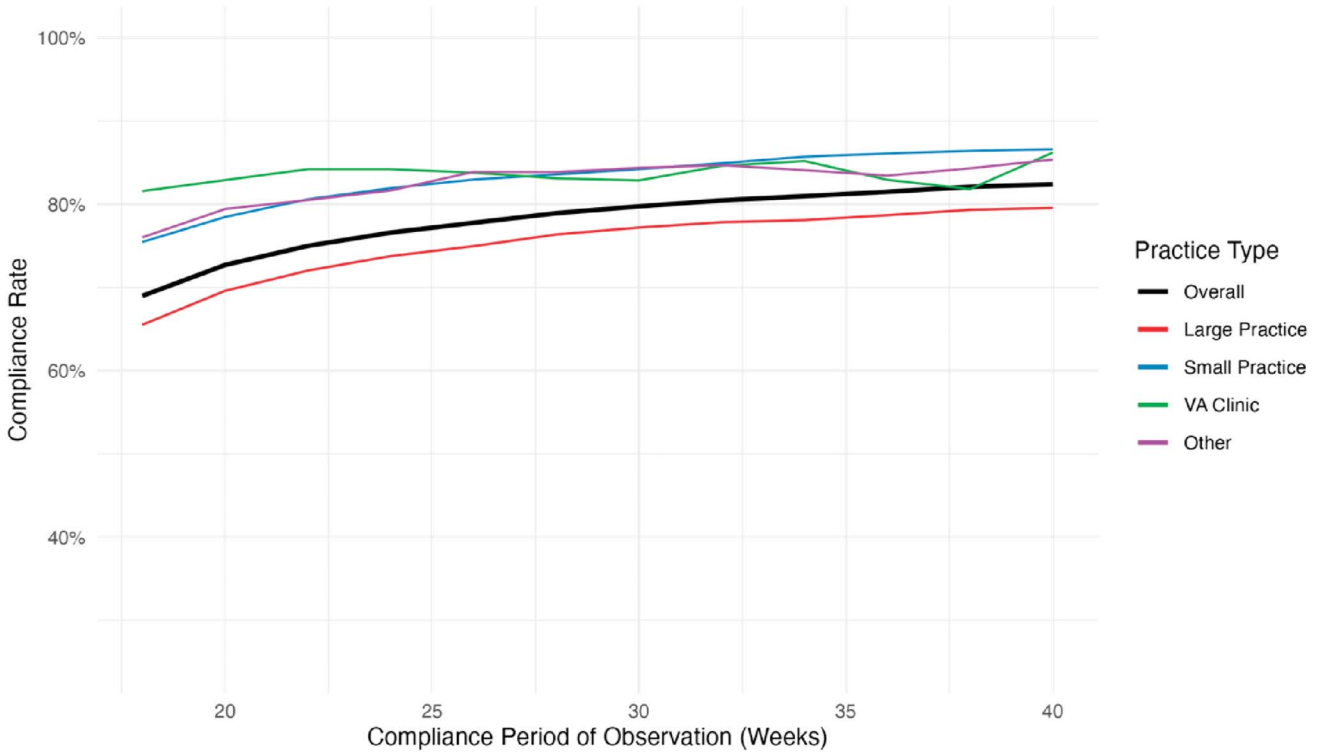

Figure 2. Fitted lines using captured compliance window data points demonstrating changes over time in compliance. VA indicates Veterans Affairs.

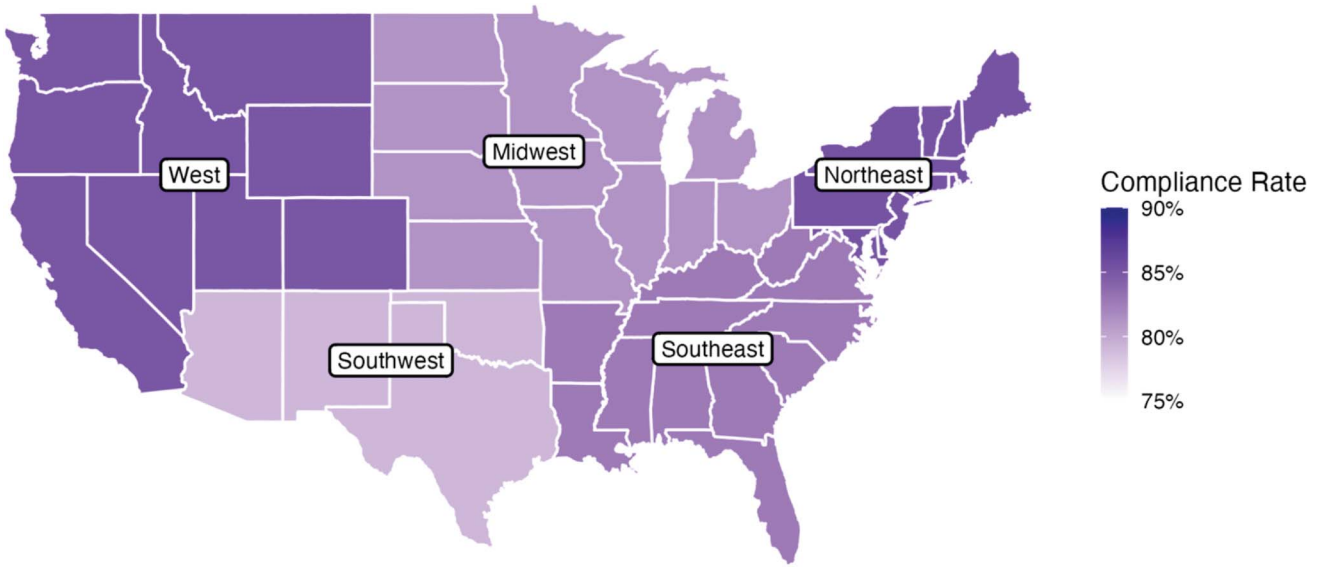

Figure 3. Forty-week compliance rate by region of the United States.

Southwest (1938; 12%). Compliance differed by region ($P < .05$) at each observation period and was consistently highest in the West and Northeast, with 40-week rates peaking at 85.1% and 85.2%, respectively, for those 2 regions (Figure 3). The vast majority of clinics (97%) were located in metropolitan areas with the remaining 3% in micropolitan, small town, and rural regions. PVSA compliance was significantly higher among metropolitan areas at the 26-week compliance window ($P < .05$) but was not statistically significant when assessing an 18-, 22-, or 40-week window.

The univariable logistic regression models demonstrated that no matter the period of observation, men receiving care in small urology practices had approximately 60% greater odds of compliance than those who received care in large practices (odds ratios [ORs] 1.62, 1.61, 1.63, and 1.66 for 18-, 22-, 26-, and 40-week periods, respectively; all $P < .05$). These differences persisted even after adjusting for clinic metropolitan status and region.

Similarly, those who received care in other nontraditional clinical settings were shown to have a greater odds of compliance as compared to large practice patients, with ORs ranging from 1.65 (22-week compliance) to 1.88 (26-week compliance) in the adjusted models (all $P < .05$).

Despite the fact that VA patients had higher compliance rates than those treated at large practices at each period of observation, the adjusted regression models suggested a statistically significant increase in the odds of compliance only at the 18-week period of observation (OR 2.03, 95% CI 1.17-3.79; Table 2).

DISCUSSION

Use of the Fellow mail-in PVSA kits was associated with an 82% compliance at 40 weeks of observation across all practice types in the United States. Additionally, even higher compliance rates among samples were demonstrated from small urology practices and the VA health care system with rates as high as 87%.

To our knowledge, this study represents the largest evaluated cohort for PVSA compliance with over 16,000 men evaluated for the shortest acceptable interval (18 weeks). The largest study previously reported included < 1000 men,[7] while a study with one of the highest reported compliance rates at

Table 2. *Multivariable Logistic Regression of the Relationship Between Practice Type and Compliance Adjusted for Locational Factors*

	Adjusted model							
	18 wk		22 wk		26 wk		40 wk	
Practice Type	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
LUGPA	1.00	REF	1.00	REF	1.00	REF	1.00	REF
Small practice	1.65	1.52, 1.79	1.60	1.46, 1.76	1.62	1.46, 1.81	1.77	1.50, 2.09
VA clinic	2.03	1.17, 3.79	1.75	0.97, 3.41	1.52	0.84, 2.97	1.55	0.59, 5.31
Other	1.75	1.38, 2.23	1.65	1.25, 2.21	1.88	1.36, 2.67	1.71	1.02, 3.07

Abbreviations: LUGPA, Large Urology Group Practice Association; OR, odds ratio; REF, reference; VA, Veterans Affairs.

80% only followed 193 men.[4] The latter study, published by Jacobsen et al, attributed their unusually high compliance to extensive patient communication regarding how to deliver a PVSA sample.[4] However, others have been less successful with this approach, reporting compliance rates ~50%.[6-8] While Dhar et al combined patient education and PVSA appointment scheduling to achieve their compliance rate of 84%,[13] Jacobsen et al did not find that scheduling appointments made any difference.[4]

While many patients may not find it necessary to complete testing, clinical practices feel postvasectomy testing is crucial as it proves sterility to reduce the risk for unwanted pregnancies and litigation, helps elucidate the rates of technical errors, and improves overall clinical practice. Practices can spend inordinate amounts of time and resources tracking patients down. Diederichs et al called a fraction of the 61% of patients (1193) who did not complete PVSA.[11] Out of the 454 calls made, they only reached 106 men, illustrating the excessive amount of work placed on clinic staff. Any process that outsources this effort represents significant cost savings to a practice. Interestingly, small urology practices had higher compliance. It has been shown that physicians and staff in smaller practices facilitate closer relationships with patients and are more accessible, achieving higher levels of patient satisfaction.[16] It is possible patients feel more loyalty and obligation to do what staff in those practices ask of them, improving compliance over large urology practices.

For the purposes of this study, one mail-in program was evaluated, Fellow, as it provided data on a national cohort. When considering reasons for improved compliance, at-home sample procurement may seem like a big contributor, but this has not been demonstrated in previous studies.[3] Other possible explanations include direct communication with reminders via email including text, graphics, and animations, a secure chat portal for customer support accessible via mobile devices, prepaid shipment labels, results provided directly to the patient, and increased patient comfort with telehealth services.

While not the focus of this paper, some discussion of cost is worth mentioning. It is possible that patient payment for the test has an impact on compliance rate and could be an impetus for completion; however, our results found similar compliance rates for VA patients who receive the kits for free. Additionally, there is the matter of additional patient cost with mail-in semen analysis, as PVSA is bundled into the vasectomy cost when performed by the same clinic. However, factors such as opportunity cost, appointment times, and driving distances required for in-person PVSA may ultimately outweigh the cost of mail-in. Additionally, when clinics don't have their own PVSA capabilities, they often outsource to external labs that then bill the patients.

There are additional differences with mail-in tests vs fresh samples that merit attention. With mail-in PVSA, patients can only be cleared if their results reveal azoospermia. This is due to the loss in motility that samples experience with the delay in processing from sample procurement to arrival at the lab when mailed. Fresh samples, however, can be cleared if there are fewer than 100,000 rare nonmotile sperm. As such, there may be patients who would have cleared a fresh sample but not a mail-in as it requires more strict criteria. To mitigate the cost of further testing, Fellow sends retest kits directly to the patient at no charge to support and encourage compliance with PVSA until sterility is proven. It is possible that this need to retest may decrease compliance. In this study, however, we only are looking at initial tests; subsequent tests were excluded.

Finally, our findings revealed that patients in metropolitan areas had statistically higher compliance rates at a 26-week window, but not at the 18-, 22-, or 40-week window. Our compliance rate is measured through kit activation that can occur at time of vasectomy or at the time of vasectomy scheduling, and this difference may be due to delays in procedure scheduling. To account for this, we reported compliance windows well beyond the recommended AUA guideline window.

Limitations of our study include utilizing activation as a proxy for actual vasectomy, which may be erroneous in some instances given that patients may activate their kits either at the time of consultation or vasectomy procedure, and some patients may not have proceeded to vasectomy despite kit activation. This would favor our results further away from the null rather than what is reported. Secondly, there was no direct comparison with other platforms. This group had direct communication with reminders via email containing text, graphics, and animations. This direct communication may be the major factor in compliance vs in-home testing. Finally, due to data limitations, compliance by demographic characteristics could not be evaluated. Despite these limitations, our study represents the largest analysis of consecutive American men observed prospectively for over 9 months and is the only nationwide PVSA study performed that also assesses compliance across region (metro vs nonmetro) and clinic types.

CONCLUSIONS

Mail-in PVSA utilizing the Fellow kit improved PVSA compliance over previously published data.

While the exact reason for improved compliance remains unknown, improvements in the collection process, the patient platform experience, patient messaging with encouragement, reminders, and instructions, and ease-of-use may be potential solutions to previously reported barriers.

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