

Comparison of postal and non-postal post-vasectomy semen sample submission strategies on compliance and failures: an 11-year analysis of the audit database of the Association of Surgeons in Primary Care of the UK

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ABSTRACT

Background Vasectomy occlusive success is defined by the recommendation of ‘clearance’ to stop other contraception, and is elicited by post-vasectomy semen analysis (PVSA). We evaluated how the choice of either a postal or non-postal PVSA submission strategy was associated with compliance to PVSA and effectiveness of vasectomy.

Methods We studied vasectomies performed in the UK from 2008 to 2019, reported in annual audits by Association of Surgeons in Primary Care members. We calculated the difference between the two strategies for compliance with PVSA, and early and late vasectomy failure. We determined compliance by adding the numbers of men with early failure and those given clearance. We performed stratified analyses by the number of test guidance for clearance (one-test/two-test) and the study period (2008–2013/2014–2019).

Results Among 58 900 vasectomised men, 32 708 (56%) and 26 192 (44%) were advised submission by postal and non-postal strategies, respectively. Compliance with postal (79.5%) was significantly greater than with non-postal strategy (59.1%), the difference being 20.4% (95% CI 19.7% to 21.2%). In compliant patients, overall early failure detection was lower with postal (0.73%) than with non-postal (0.94%) strategy (−0.22%, 95% CI −0.41% to −0.04%), but this difference was neither clinically nor statistically significant with one-test guidance in 2014–2019. There was no difference in late failure rates.

Key messages

- Postal semen sample submission strategy after vasectomy results in better compliance and similar early failure and late failure rates compared with fresh sample non-postal strategy.
- When compliance is accounted for, postal strategy allows recommending cessation of other contraceptive methods (clearance) in one in five more men than a non-postal strategy.
- Postal semen sample submission strategy for post-vasectomy semen analysis warrants inclusion in future guidelines as a reliable and convenient option.

Conclusions Postal strategy significantly increased compliance to PVSA with similar failure detection rates. This resulted in more individuals receiving clearance or early failure because of the greater percentage of postal samples submitted. Postal strategy warrants inclusion in any future guidelines as a reliable and convenient option.

INTRODUCTION

Vasectomy is a compelling choice for couples requiring non-reversible contraception as it is safer, quicker, associated with less morbidity and more effective than female sterilisation.¹ Contraceptive efficacy, however, is not immediate

and post-vasectomy semen analysis (PVSA), usually undertaken around 12 weeks, is required to recommend 'clearance' to stop using other contraceptive methods.^{1–3}

In the UK, men who have had a vasectomy may use two strategies to submit their semen sample for PVSA. They may submit a fresh semen sample, produced either at the laboratory facility, or at home and delivered to the laboratory according to local protocol. Most UK and international guidelines recommend this approach, allowing assessment of sperm motility.^{1–6} However, the compliance of men when asked to provide a fresh sample for PVSA is generally poor, with only around two-thirds of men submitting one semen specimen.¹³ Many factors can compromise compliance with local laboratory testing, including lack of suitable appointments, embarrassment producing specimens on site, time restrictions, expense of transport, and loss of earnings.^{7–10} Alternatively, to avoid these inconveniences, men may use a postal strategy, whereby they produce a semen sample at home and send it through the post to a laboratory for analysis.

In 2016, the Association of Biomedical Andrologists (ABA), British Andrology Society (BAS) and British Association of Urological Surgeons (BAUS) advised against the use of postal PVSA, claiming sperm degradation.⁶ However, the American Urological Association (AUA)² and the most recent Royal College of Obstetricians and Gynaecologists (RCOG)¹ guidelines deem that postal semen sample submission is acceptable to decrease the inconveniences associated with submitting a fresh semen sample and potentially increases compliance. All the aforementioned organisations recommend that clearance be given if no sperm are seen in the postal semen sample. At first PVSA about 80% of vasectomised men will show no sperm, with only a minority required to produce additional postal or fresh samples.^{2,4} To our knowledge, no study has yet demonstrated an increase in compliance with a postal strategy.

The purpose of this study was to evaluate if the strategies for post-vasectomy semen sample submission (postal or non-postal) are associated with a difference in compliance to provide all required semen samples, and in early and late failure detection rates among men who have had a vasectomy.

METHODS

We conducted a retrospective cohort analysis using the vasectomy audit database of the Association of Surgeons in Primary Care (ASPC) from the UK over an 11-year period (2008–2019). The ASPC comprises doctors who perform surgical procedures in the community. It provides support, training and professional development to its members including an annual continuing professional development conference and an accredited audit programme.

Since 2008, the ASPC has collected data from members who performed vasectomies within the UK on an annual basis. The audit cycle covered 6 months in 2008, 12 months between 2009 and 2011, 15 months in 2012–2013, and 12 months thereafter. The surgeons were required to submit audit data by completing an electronic form 4 months after the last vasectomy performed until 2011, and 12 months since 2012, allowing sufficient time to assess the results. The most recent audit form (2020, collecting 2018–2019 data) and glossary are presented in online supplemental appendix 1.

DATA COLLECTION

The information on the following variables was extracted from the ASPC audit database for vasectomies performed during each yearly audit cycle: strategy used for submitting post-vasectomy semen sample (postal/non-postal), number of test guidance followed for giving clearance (one-test or two-test), clearance given to stop other contraception, clearance with rare non-motile sperm (RNMS or 'special clearance'), early failures and late failures. We excluded audit forms where data were missing for any of these variables. However, we did not exclude an audit form in which information on clearance given with RNMS was missing if it reported the total number of vasectomised men given clearance.

Online supplemental appendix 2 presents the guidelines endorsed by ASPC relating to the number of PVSA tests, their timings, and the criteria for vasectomy success and failure throughout the study period. Surgeons subscribed to a postal or non-postal semen sample submission strategy and to the use of one-test or two-test clearance guidance throughout each audit cycle. The chosen options were usually determined according to the surgeon's preference and local availability. However, the commissioners or local laboratory may have dictated these choices. The ASPC has been advocating a one-test clearance guidance to its members since 2008. Throughout the duration of the study, the ASPC recommended giving clearance with a PVSA showing no sperm or the presence of RNMS on a fresh specimen. The sperm concentration recommended threshold was <10 000 non-motile sperm/mL between 2008 and 2013^{11 12} and <1 000 000 non-motile sperm/mL from 2014 onwards.^{1 6 11 12} Throughout the study, the ASPC recommended to surgeons to report early failure (occlusive failure) as the inability to give clearance after 7 months post-operatively due to the presence of motile sperm in a fresh specimen (or rarely in a postal specimen) or large numbers of non-motile sperm. Online supplemental appendix 3 summarises the current clinical pathway suggested by the ASPC for semen sample submission and interpretation. The ASPC required reporting of late failure (contraceptive failure) when a pregnancy, apparently fathered by a

vasectomised man who was given clearance, occurred within the current or any previous audit cycle.

STATISTICAL ANALYSIS

We first calculated the number of vasectomies performed by surgeons who provided eligible audit forms and compared the proportion of vasectomised men whose surgeons reported using a postal and a non-postal semen sample submission strategy. We then calculated the absolute differences between these two groups according to the following outcomes: compliance, early failure and late failure. Compliance to all PVSA needed to establish the success or failure of vasectomy was calculated by adding the number of vasectomies with clearance given and those with early failure. We included all the late failures reported in an audit cycle year, whenever they occurred. The denominator for calculating compliance rates was the total number of vasectomies; for early and late failures, it was the number of vasectomies with compliance. Furthermore, we assessed the potential modifying and confounding effects of number of test guidance (one-test/two-test) and the year of audit (2008–2013/2014–2019) on these outcomes by stratified analysis. We dichotomised the years of audit based on the major changes issued in 2014 in the UK recommendations regarding PVSA.¹ Finally, using the data available, we compared clearance with RNMS between postal and non-postal strategies.

We tabulated descriptive data using Excel 2010. All differences are reported with their 95% CI calculated with the Wilson's procedure method without continuity correction.¹³

RESULTS

A total of 90 different surgeons (between 22 and 44 per year) provided audit data on 71 112 vasectomies during the 11-year study period. The number of vasectomies for which data were collected annually ranged from 2406 in 2008 to 8713 in 2018–2019. Among the 58 900 (83%) vasectomies eligible for analysis, the postal semen sample submission strategy was more commonly used (56%) than the fresh sample non-postal strategy (44%) (figure 1). Postal strategy was more common when surgeons subscribed to one-test guidance (31 227/52 707, 59%) than to two-test guidance (1481/6193, 24%). Postal strategy was also more common in recent years (2014–2019; 22 165/37 545, 59%) compared with earlier years of the study (2008–2013; 10 543/21 355, 49%).

Table 1 presents the PVSA outcomes in the studied vasectomies according to semen sample submission strategy stratified by number of test guidance and study period. Overall, the proportion of vasectomised men who fully complied with PVSA required was 20.4% higher (absolute difference) with the postal than with the non-postal strategy. Early and late failures reported were lower with the postal strategy; however, the

difference was statistically significant only for early failures.

The stratified analyses presented in table 1 show both modifying and confounding effects of number of test guidance and a modifying effect of study period on the difference in compliance between postal and non-postal strategies. However, large statistically significant differences in favour of postal strategy regarding compliance remained in all strata of number of test guidance and study period. This includes when limiting the analysis to reflect current practice, that is, vasectomies performed by surgeons using one-test guidance during the most recent years (17 655/22 011, 80.2% vs 8483/13 846, 61.3%; difference 18.9%, 95% CI 18% to 19.9%).

Both number of test guidance and study period modified the differences between postal and non-postal strategies regarding early failures (table 1). While surgeons less commonly reported early failures with postal strategy in all strata of number of test guidance and study period, the differences were smaller when they followed one-test guidance and during the more recent years of the study (2014–2019). Limiting the analysis to one-test guidance during the most recent years, the difference in favour of non-postal strategy was neither clinically nor statistically significant (152/17 655, 0.86% vs 79/8483, 0.93%; difference –0.07%, 95% CI –0.33% to 0.16%).

The differences between the semen sample submission strategies on late failures, in favour of non-postal strategy, were smaller when surgeons followed one-test guidance but during 2014–2019 surgeons using postal strategy reported a higher proportion of late failures (table 1). None of these differences regarding late failures was statistically significant.

Data on clearance given with RNMS were available in 87.2% (22 504/25 818) and 93.5% (14 337/15 329) of vasectomies performed by surgeons using postal and non-postal strategies, respectively. The proportion of patients cleared based on the presence of RNMS was significantly lower with postal (2.1%, 482/22 504) than with non-postal (5.4%, 767/14 337) strategy (–3.2%, 95% CI –3.6% to –2.8%).

DISCUSSION

Our study shows much higher compliance when a postal strategy for submitting post-vasectomy semen samples is used. Overall, with the postal strategy, one in five more men received confirmation of occlusive success of their vasectomy and were given clearance to stop using additional contraception. It also shows a small but significantly lower rate of early failures with postal strategy. However, this difference was neither clinically nor statistically significant with one-test clearance guidance in 2014–2019, reflecting the current guidelines and the practice of the vast majority of ASPC members.¹⁶ Late failure rates, as demonstrated

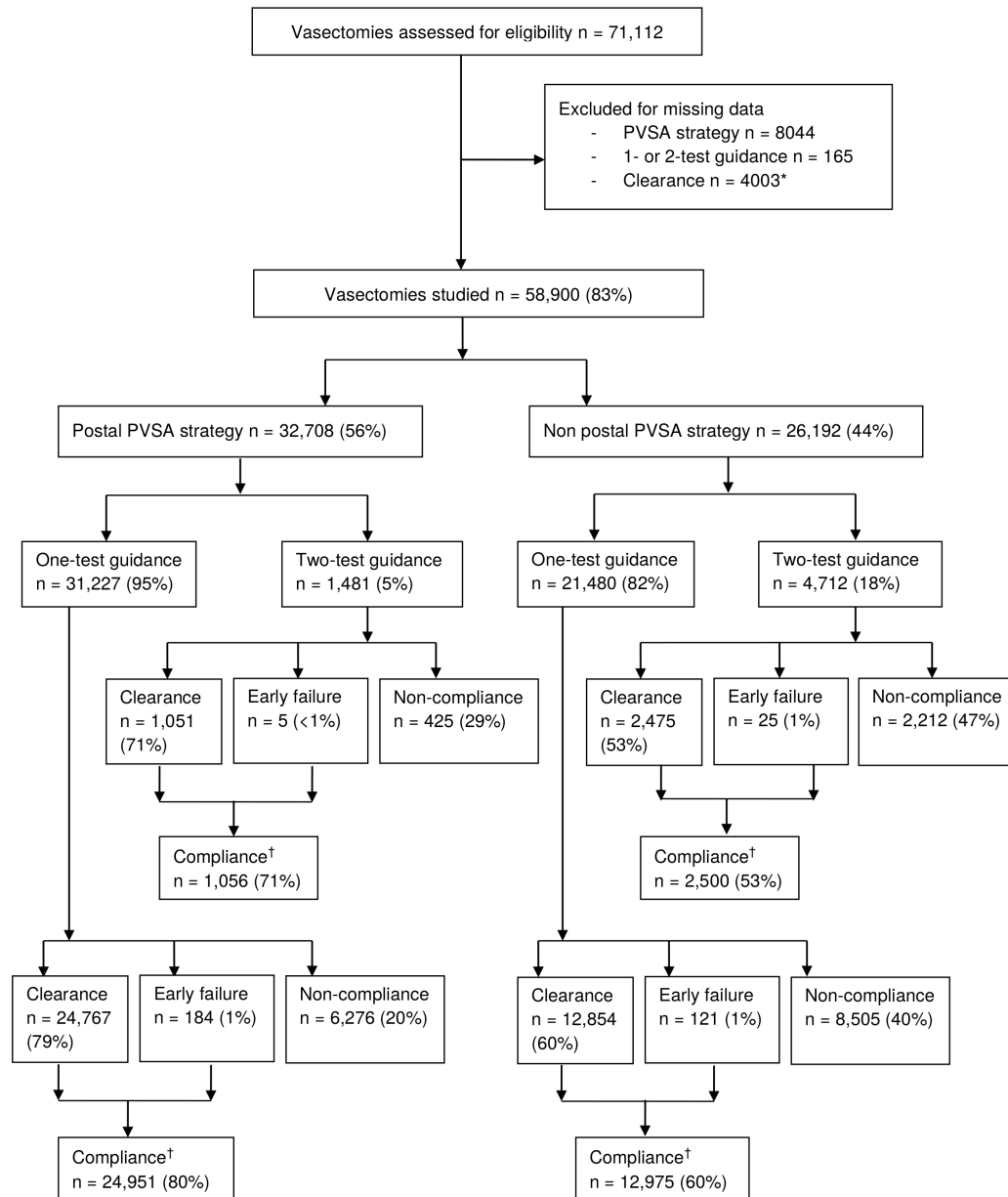


Figure 1 Study flow chart. *Vasectomies were not excluded from audit forms in which the number given clearance with rare non-motile sperm (special clearance) was missing if the total number of patients given clearance was reported. †Compliance calculated by adding the total number of vasectomised men with clearance given and those with early failure. PVSA, post-vasectomy semen analysis.

by pregnancy after confirmation of clearance, were also similar for the two strategies.

To the best of our knowledge, this is the first study showing higher compliance with postal compared with non-postal semen sample submission strategy. Nonetheless, Trussler *et al* recently reported an increased compliance (from 66% to 76%) with the use of a home-based post-vasectomy semen test eliminating many of the barriers associated with the submission of a fresh sample.¹⁴

Our results have major implications. Due to better compliance, surgeons can detect more early vasectomy failures with a postal strategy. Assuming a similar 1% early failure rate for both strategies, with 20% more men complying with a postal strategy, one more early

failure will be detected per 500 vasectomies (number-needed-to-be-tested). The ABA/BAS/BAUS 2016 guidelines for PVSA have questioned the validity of postal strategy regarding sperm degradation during transit, which could result in wrongly awarded clearance.⁶ Although a direct comparison of semen samples examined via both semen sample submission strategies could be undertaken to justify this statement, the similarity of both strategies on early and late failure rates in our study suggests that this concern should be refuted. Even if we conservatively repeat the calculation with the data reflecting the current one-test guidance practice in recent years (0.86% and 0.93% early failures with 80.2% and 61.3% compliance in postal and non-postal strategy, respectively), the higher

Table 1 Post-vasectomy semen analysis outcomes in 58 900 men vasectomised between 2008 and 2019 according to semen sample submission strategy (postal/non-postal) stratified by number of test guidance and study period

		PVSA outcomes					
		Compliance		Early failures*		Late failures*	
Parameter		n/N (%)	Difference % (95% CI)	n/N (%)	Difference % (95% CI)	n/N (%)	Difference % (95% CI)
Overall							
Postal		26 007/32 708 (79.5)	20.4 (19.7 to 21.2)	189/26 007 (0.73)	−0.22 (−0.41 to −0.04)	19/26 007 (0.07)	−0.02 (−0.09 to 0.03)
Non-postal		15 475/26 192 (59.1)	–	146/15 475 (0.94)	–	15/15 475 (0.10)	–
Number of test guidance							
Two-test	Postal	1056/1481 (71.3)	18.2 (15.5 to 20.9)	5/1056 (0.47)	−0.53 (−1.1 to 0.18)	1/1056 (0.09)	−0.07 (−0.33 to 0.39)
	Non-postal	2500/4712 (53.1)	–	25/2500 (1.00)	–	4/2500 (0.16)	–
One-test	Postal	24 951/31 227 (79.9)	19.5 (18.7 to 20.3)	184/24 951 (0.74)	−0.20 (−0.40 to −0.01)	18/24 951 (0.07)	−0.01 (−0.08 to 0.04)
	Non-postal	12 975/21 480 (60.4)	–	121/12 975 (0.93)	–	11/12 975 (0.08)	–
Study period							
2008–2013†	Postal	8247/10 543 (78.2)	22.0 (20.7 to 23.2)	36/8247 (0.44)	−0.47 (−0.76 to −0.20)	7/8247 (0.08)	−0.11 (−0.27 to 0.01)
	Non-postal	6082/10 812 (56.3)	–	55/6082 (0.90)	–	12/6082 (0.20)	–
2014–2019†	Postal	17 660/22 165 (79.7)	18.6 (17.7 to 19.5)	153/17 660 (0.87)	−0.10 (−0.36 to 0.13)	12/17 660 (0.07)	0.04 (−0.03 to 0.09)
	Non-postal	9393/15 380 (61.1)	–	91/9393 (0.97)	–	3/9393 (0.03)	–

*Failure rates are calculated with the number of compliant vasectomised men as the denominator.

†Year of vasectomy.

CI, confidence interval; PVSA, post-vasectomy semen analysis.

compliance of postal strategy still allows detection of one more failure in 833 vasectomies. Moreover, the non-statistically significant lower rate of failure with postal strategy may indicate that the surgeons using this strategy report fewer failures because they indeed have fewer failures.

The postal strategy requires examination of a fresh semen sample for RNMS clearance and when early failure is suspected. The proportion of men given clearance to stop contraception when RNMS are present was, unsurprisingly, significantly higher in the non-postal group, as this result can be obtained without additional testing on a fresh sample. This earlier clearance, however, occurred in only about 3% more men following the non-postal strategy. There is no evidence that the rate of late failure is higher when clearance in the presence of RNMS is given.^{1 2 4} Clearance could possibly be given without motility assessment with a postal strategy if the sperm concentration is low. A recent study on 5965 first PVSA done on fresh samples demonstrated that if the sperm concentration is below 10 000 sperm/mL and 100 000 sperm/mL, the probability of observing motile sperm is 0.7% and 0.9%, respectively.¹⁵

The main strengths of this study are its sample size and the fact that it spans over a decade, enabling stratification in relation to a major change of guidelines. Data collection continues through the ASPC, with annual review, and enables surgeons to compare

their data temporally and against other surgeons. The data reported appear to be valid. The compliance rate of about 60% for non-postal strategy, and the early (about 1%) and late failure (about 0.1%) rates reported for both postal and non-postal strategies are in line with evidence-based guidelines in the UK and North America.^{1 2}

This study has some limitations. We assessed the confounding and modifying effects of two major factors: number of test guidance and study period. However, many different surgeons submitted data over more than a decade. We cannot presume consistency between them for experience, technique, reminder systems, time schedule for testing, and clearance/failures criteria used. There may also be variation in the population demographic of the two strategies including socioeconomic status and access to local laboratory services. These factors could influence the differences observed between semen sample submission strategies for compliance and failures. We do not believe this would change our conclusions considering the scale of the difference in compliance.

The reduced length of time from last vasectomy performed to data collection in the early years of the study possibly led to underestimation of clearance and early failure. This situation was, however, similar in both study groups and limited to only 4 of the 11 years studied (2008–2011).

Notification and recording of late failures (contraceptive failures) are likely to be imprecise and underestimated.^{16–18} For instance, pregnancies may occur many years subsequent to vasectomy and the surgeon never informed. In addition, our data cannot confirm that the reported late failures from both strategies were indeed true late failures as proven by fresh PVSA or DNA testing.¹⁹ As the numbers of late failures are small, any misdiagnosis could greatly affect the figures. Nevertheless, the reported rate in our study, approximately 0.1%, may be more valid than the 0.05% usually quoted.¹²

CONCLUSIONS

The postal strategy of post-vasectomy semen sample submission is not only a less resource-intensive approach, but is clearly more acceptable to patients. The higher compliance of postal strategy confers overarching benefits to patients, their partners, and surgeons seeking confirmation of vasectomy success, without compromising efficacy to detect failures. These benefits are even more crucial in the current climate of COVID-19, when it is clearly preferable for men to post a semen sample than to attend a clinic.

Our study should reassure both surgeons and patients who presently use postal semen sample submission strategy. It may also inspire more surgeons, commissioners and laboratories to follow this approach. Future clinical practice guidelines should recommend submitting semen samples by post as a reliable option.

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REFERENCES

- 1 Faculty of Sexual and Reproductive Healthcare (FSRH). Male and female sterilisation (Clinical guidance), 2014. Available: <https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014/> [Accessed 16 Apr 2021].
- 2 Sharlip ID, Belker AM, Honig S, *et al.* Vasectomy: AUA guideline. *J Urol* 2012;188:2482–91.
- 3 Dohle GR, Diemer T, Kopa Z. European Association of Urology guidelines on vasectomy. *Actas Urológicas Españolas* 2012;36:276–81.
- 4 Griffin TT. *Post-vasectomy testing to confirm sterility: a systematic review (ASERNIP-S report; 39)*. North Adelaide: Australia: Royal Australasian College of Surgeons, Australian Safety and Efficacy Register of New Interventional Procedures (ASERNIP) - Surgical, 2003.
- 5 Zini A, Grantmyre J, Chan P. CUA guideline: vasectomy. *Can Urol Assoc J* 2016;10:274–8.
- 6 Hancock P, Woodward BJ, Muneer A, *et al.* 2016 laboratory guidelines for postvasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons. *J Clin Pathol* 2016;69:655–60.
- 7 Diederichs J, McMahon P, Tomas J, *et al.* Reasons for not completing postvasectomy semen analysis. *Can Fam Physician* 2019;65:e391–6.
- 8 Bradshaw A, Ballon-Landa E, Owusu R, *et al.* Poor compliance with postvasectomy semen testing: analysis of factors and barriers. *Urology* 2020;136:146–51.
- 9 Smucker DR, Mayhew HE, Nordlund DJ, *et al.* Postvasectomy semen analysis: why patients don't follow-up. *J Am Board Fam Pract* 1991;4:5–9.
- 10 Labrecque M, Hamel JF, Prévost JF. Pourquoi les vasectomisés ne se présentent-ils PAS au spermogramme post-opératoire? *Can Fam Physician* 1989;35:1781–5.
- 11 Royal College of Obstetricians & Gynaecologists. *Male and female sterilisation. National evidence-based clinical guideline number 4*. London, UK: RCOG Press, 2004.
- 12 Hancock P, McLaughlin E, British Andrology Society. British Andrology Society guidelines for the assessment of post vasectomy semen samples (2002). *J Clin Pathol* 2002;55:812–6.
- 13 Herbert R. Confidence interval calculator: PEDro physiotherapy evidence database, 2013. Available: <https://pedro.org.au/english/resources/confidence-interval-calculator/> [Accessed 16 Apr 2021].
- 14 Trussler J, Browne B, Merino M, *et al.* Post-vasectomy semen analysis compliance with use of a home-based test. *Can J Urol* 2020;27:10388–93.
- 15 McMartin C, Lehouillier P, Cloutier J, *et al.* Can a low sperm concentration without assessing motility confirm vasectomy success? A retrospective descriptive study. *J Urol* 2021;206:109–14.
- 16 Schwingl PJ, Guess HA. Safety and effectiveness of vasectomy. *Fertil Steril* 2000;73:923–36.
- 17 Deneux-Tharaux C, Kahn E, Nazerali H, *et al.* Pregnancy rates after vasectomy: a survey of US urologists. *Contraception* 2004;69:401–6.
- 18 Labrecque M, Dufresne C, Barone MA, *et al.* Vasectomy surgical techniques: a systematic review. *BMC Med* 2004;2:21.
- 19 Smith JC, Cranston D, O'Brien T, *et al.* Fatherhood without apparent spermatozoa after vasectomy. *Lancet* 1994;344:30.